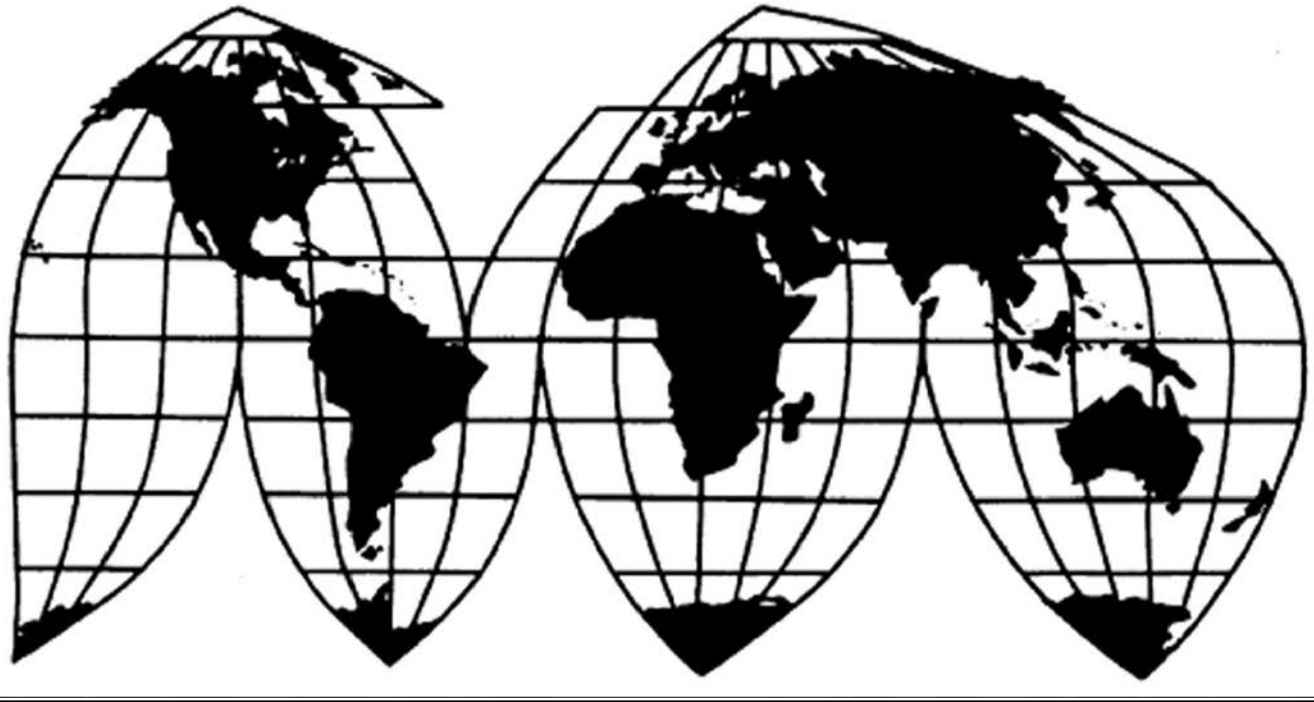
In the Matter of

CERTAIN DIGITAL MODELS, DIGITAL DATA, AND TREATMENT PLANS FOR USE IN MAKING INCREMENTAL DENTAL POSITIONING ADJUSTMENT APPLIANCES

337-TA-833

Publication 4555 **November 2017**

U.S. International Trade Commission



Washington, DC 20436

U.S. International Trade Commission

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Washington, DC 20436

U.S. International Trade Commission

Washington, DC 20436
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UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN DIGITAL MODELS, DIGITAL DATA, AND TREATMENT PLANS FOR USE IN MAKING INCREMENTAL DENTAL POSITIONING ADJUSTMENT APPLIANCES, THE APPLIANCES MADE THEREFROM, AND METHODS OF MAKING THE SAME**	**Investigation No. 337-TA-833**

RESCISSION OF CEASE AND DESIST ORDERS; TERMINATION OF INVESTIGATION

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to rescind the cease and desist orders issued in this investigation and to terminate the investigation with a finding of no violation of Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 ("Section 337").

FOR FURTHER INFORMATION CONTACT: Sidney A. Rosenzweig, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 708-2532. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-2000. General information concerning the Commission may also be obtained by accessing its Internet server (*https://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: This investigation was instituted on April 5, 2012, based upon a complaint filed on behalf of Align Technology, Inc., of San Jose, California ("Align"), on March 1, 2012, as corrected on March 22, 2012. 77 *Fed. Reg.* 20648 (April 5, 2012). The complaint alleged violations of Section 337 in the sale for importation, importation, or sale within the United States after importation of certain digital models, digital data, and

treatment plans for use in making incremental dental positioning adjustment appliances, the appliances made therefrom, and methods of making the same by reason of infringement of certain claims of U.S. Patent No. 6,217,325 ("the '325 patent"); U.S. Patent No. 6,471,511 ("the '511 patent"); U.S. Patent No. 6,626,666 ("the '666 patent"); U.S. Patent No. 6,705,863 ("the '863 patent"); U.S. Patent No. 6,722,880 ("the '880 patent"); U.S. Patent No. 7,134,874 ("the '874 patent"); and U.S. Patent No. 8,070,487 (the '487 patent"). The notice of institution named as respondents ClearCorrect Pakistan (Private), Ltd. of Lahore, Pakistan ("CCPK") and ClearCorrect Operating, LLC of Houston, Texas ("CCUS") (collectively, "the Respondents"). A Commission investigative attorney ("IA") participated in the investigation.

On May 6, 2013, the presiding administrative law judge ("ALJ") issued his final initial determination ("ID"), finding a violation of Section 337 with respect to the '325 patent, the '880 patent, the '487 patent, the '511 patent, the '863 patent, and the '874 patent. He found no violation as to the '666 patent. The ALJ recommended the issuance of cease and desist orders directed to the Respondents.

After receiving briefing from the parties and the public, on April 3, 2014, the Commission issued notice of its determination to affirm-in-part, modify-in-part, and reverse-in-part the final ID and to find a violation of Section 337. 79 *Fed. Reg.* 19640-41 (Apr. 9, 2014). The Commission found a violation of Section 337 with respect to (i) claims 1 and 4-8 of the '863 patent; (ii) claims 1, 3, 7, and 9 of the '666 patent; (iii) claims 1, 3, and 5 of the '487 patent; (iv) claims 21, 30, 31 and 32 of the '325 patent; and (v) claim 1 of the '880 patent. On the same day, the Commission issued an opinion, with a dissenting opinion from Commissioner Johanson, and also issued cease and desist orders directed to CCUS and CCPK. The Commission terminated the investigation.

On May 2, 2014, the Respondents filed a motion to stay the cease and desist orders pending appeal. On May 14, 2014, Complainant Align and the IA filed responses in opposition. On June 2, 2014, the Commission issued a notice and order granting the motion.

ClearCorrect and Align each took appeals of the Commission's determination to the U.S. Court of Appeals for the Federal Circuit. In ClearCorrect's appeal, the Federal Circuit reversed the Commission's decision that the electronic transmission of the digital models could constitute an imported "article" within the meaning of 19 U.S.C. § 1337, and remanded the case to the Commission. *ClearCorrect Operating, LLC v. ITC*, 810 F.3d 1283 (Fed. Cir. 2015), *reh'g en banc denied*, 819 F.3d 1334 (2016). No petition for *certiorari* was filed with the Supreme Court.

In Align's appeal, the Federal Circuit vacated and remanded the case to the Commission "for further proceedings in light of" the *ClearCorrect* decision. *Align Tech., Inc. v. ITC*, 622 F. App'x 910 (Fed. Cir. 2015).

In view of the foregoing final decisions of the Federal Circuit, the Commission has determined to rescind the cease and desist orders issued in this investigation. The investigation is terminated with a finding of no violation of section 337.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 C.F.R. Part 210).

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: September 23, 2016

CERTAIN DIGITAL MODELS, DIGITAL DATA, AND TREATMENT PLANS FOR USE, IN MAKING INCREMENTAL DENTAL POSITIONING ADJUSTMENT APPLIANCES, THE APPLIANCES MADE THEREFROM, AND METHODS OF MAKING THE SAME

337-TA-833

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **COMMISSION NOTICE** has been served by hand upon the Commission Investigative Attorney, Vu Bui, Esq., and the following parties as indicated, on **September 23, 2016.**

Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street, SW
Washington, DC 20436

On Behalf of Complainant:

Scott M. Flicker, Esq.
PAUL HASTINGS LLP
875 15th Street, NW
Washington, DC 20005

( ) Via Hand Delivery
( ) Via Express Delivery
(√) Via First Class Mail
( ) Other: _____

On Behalf of ClearCorrect Operating, LLC:

Gary M. Hnath, Esq.
MAYER BROWN LLP
1999 K Street, NW
Washington, DC 20006

( ) Via Hand Delivery
( ) Via Express Delivery
(√) Via First Class Mail
( ) Other: _____

On Behalf of ClearCorrect Pakistan (Private), Ltd.:

Lei Mei, Esq.
MEI & MARK LLP
818 18th Street NW, Suite 410
Washington, DC 20006

( ) Via Hand Delivery
( ) Via Express Delivery
(√) Via First Class Mail
( ) Other: _____

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN DIGITAL MODELS, DIGITAL DATA, AND TREATMENT PLANS FOR USE IN MAKING INCREMENTAL DENTAL POSITIONING ADJUSTMENT APPLIANCES, THE APPLIANCES MADE THEREFROM, AND METHODS OF MAKING THE SAME**	**Investigation No. 337-TA-833**

NOTICE OF COMMISSION GRANT OF MOTION TO STAY CEASE AND DESIST ORDERS PENDING APPEAL

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has issued an order and opinion granting Respondents' motion for a stay of the cease and desist orders pending appeal of the above-captioned investigation under Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 ("Section 337").

FOR FURTHER INFORMATION CONTACT: Sidney A. Rosenzweig, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 708-2532. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-2000. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: This investigation was instituted on April 5, 2012, based upon a complaint filed on behalf of Align Technology, Inc., of San Jose, California ("Align"), on March 1, 2012, as corrected on March 22, 2012. 77 *Fed. Reg.* 20648 (April 5, 2012). The complaint alleged violations of Section 337 in the sale for importation, importation, or sale within the United States after importation of certain digital models, digital data, and

treatment plans for use in making incremental dental positioning adjustment appliances, the appliances made therefrom, and methods of making the same by reason of infringement of certain claims of U.S. Patent No. 6,217,325 ("the '325 patent"); U.S. Patent No. 6,471,511 ("the '511 patent"); U.S. Patent No. 6,626,666 ("the '666 patent"); U.S. Patent No. 6,705,863 ("the '863 patent"); U.S. Patent No. 6,722,880 ("the '880 patent"); U.S. Patent No. 7,134,874 ("the '874 patent"); and U.S. Patent No. 8,070,487 (the '487 patent"). The notice of institution named as respondents ClearCorrect Pakistan (Private), Ltd. of Lahore, Pakistan ("CCPK") and ClearCorrect Operating, LLC of Houston, Texas ("CCUS") (collectively, "the Respondents"). A Commission investigative attorney ("IA") participated in the investigation.

On May 6, 2013, the presiding administrative law judge ("ALJ") issued the final initial determination ("ID"), finding a violation of Section 337 with respect to the '325 patent, the '880 patent, the '487 patent, the '511 patent, the '863 patent, and the '874 patent. He found no violation as to the '666 patent. The ALJ recommended the issuance of cease and desist orders directed to the Respondents.

On May 20, 2013, each of the parties filed a petition for review. On May 28, 2013, each of the parties filed a response thereto. On June 7, 2013, the Commission issued notice of its determination to extend the deadline for determining whether to review the final ID to July 25, 2013. On July 25, 2013, the Commission issued notice of its determination to review the final ID in its entirety and to solicit briefing on the issues on review and on remedy, the public interest, and bonding. 78 *Fed. Reg.* 46611 (August 1, 2013).

After receiving briefing from the parties and the public, on April 3, 2014, the Commission issued notice of its determination to affirm-in-part, modify-in-part, and reverse-in-part the final ID and to find a violation of Section 337. 79 *Fed. Reg.* 19640-41 (Apr. 9, 2014). The Commission found a violation of Section 337 with respect to (i) claims 1 and 4-8 of the '863 patent; (ii) claims 1, 3, 7, and 9 of the '666 patent; (iii) claims 1, 3, and 5 of the '487 patent; (iv) claims 21, 30, 31 and 32 of the '325 patent; and (v) claim 1 of the '880 patent. On the same day, the Commission issued an opinion, with a dissenting opinion from Commissioner Johanson, and the Commission issued cease and desist orders directed to CCUS and CCPK. The Commission terminated the investigation.

On May 2, 2014, the Respondents filed a motion to stay the cease and desist orders pending appeal. On May 14, 2014, Complainant Align and the IA filed responses in opposition.

Upon consideration of the motion and the responses, the cease and desist orders, and the relevant portions of the record, the Commission has granted the motion for a stay of the cease and desist orders pending appeal of this investigation.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 C.F.R. Part 210).

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: June 2, 2014

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN DIGITAL MODELS, DIGITAL DATA, AND TREATMENT PLANS FOR USE IN MAKING INCREMENTAL DENTAL POSITIONING ADJUSTMENT APPLIANCES, THE APPLIANCES MADE THEREFROM, AND METHODS OF MAKING THE SAME**	**Investigation No. 337-TA-833**

COMMISSION ORDER

This investigation was instituted on April 5, 2012, based upon a complaint filed on behalf of Align Technology, Inc. ("Align") of San Jose, California on March 1, 2012, and a corrected complaint filed on March 22, 2012. 77 *Fed. Reg.* 20648-49 (April 5, 2012). The complaint, as corrected, alleged violations of section 337 of the Tariff Act of 1930, as amended, (19 U.S.C. § 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain digital models, digital data, and treatment plans for use in making incremental dental positioning appliances, and the appliances made therefrom, by reason of infringement of U.S. Patent No. 6,217,325 ("the '325 patent"), U.S. Patent No. 6,722,880 ("the '880 patent"), U.S. Patent No. 8,070,487 ("the '487 patent"), U.S. Patent No. 6,471,511 ("the '511 patent"), U.S. Patent No. 6,626,666 ("the '666 patent"), U.S. Patent No. 6,705,863 ("the '863 patent") and U.S. Patent No. 7,134,874 ("the '874 patent"). The notice of investigation named as respondents ClearCorrect Operating, LLC ("ClearCorrect USA" or "CCUS") and ClearCorrect Pakistan (Private), Ltd ("ClearCorrect Pakistan" or "CCPK").

On January 14, 2013, the ALJ issued Order No. 20, denying CCUS's and CCPK's motion for summary determination that certain asserted claims were not infringed and that claim 1 of the '880 patent was invalid, and finding that CCUS and CCPK waived any estoppel defense, including defenses based on implied license or patent exhaustion.

On May 6, 2013, the ALJ issued his final initial determination ("final ID"), finding a violation of Section 337 with respect to the '325 patent, the '880 patent, the '487 patent, the '511 patent, the '863 patent, and the '874 patent. The ALJ found no violation as to the '666 patent. The ALJ recommended the issuance of cease and desist orders directed to CCUS and CCPK.

On May 20, 2013, each of the parties filed a petition for review. On May 28, 2013, each of the parties filed a response thereto.

On June 5, 2013, Align filed a statement on the public interest. On June 13, 2013, the Respondents filed a statement on the public interest.

On June 7, 2013, the Commission issued notice of its determination to extend the deadline for determining whether to review the final ID to July 25, 2013, and to extend the target date to September 24, 2013.

On July 25, 2013, the Commission issued notice of its determination to review the final ID in its entirety and to solicit briefing on the issues on review and on remedy, the public interest, and bonding. 78 *Fed. Reg.* 46611-12 (August 1, 2013). On August 8, 2013, each of the parties filed written submissions. On August 15, 2013, each filed reply submissions.

On September 24, 2013, the Commission issued notice of its determination to extend the target date to November 1, 2013. Due to the federal government shutdown

and the Commission Notice tolling all deadlines by the length of the shutdown, the target date became November 18, 2013. On November 18, 2013, the Commission issued notice of its determination to extend the target date to January 17, 2014.

On December 31, 2013, the Respondents filed a notice of supplemental authority. On January 10, 2014, Align filed a reply thereto.

On January 17, 2014, the Commission issued a notice extending the target date to March 21, 2014, and soliciting further briefing from the public and the parties. 79 *Fed. Reg.* 4174-75 (January 24, 2014).

On February 3, 2014, the Commission received written submissions from each of the parties and from Motion Picture Association of America ("MPAA"), Google Inc. ("Google"), and Andrew Katz (Mr. Katz).[1] On February 10, 2014, the Commission received reply submissions from each of the parties and from MPAA, the Association of American Publishers ("the AAP"), and Nokia Corporation ("Nokia").

On March 21, 2014, the Commission issued notice of its determination to extend the target date to April 3, 2014.

On April 3, 2014, the Commission issued notice of its determination to affirm-in-part, modify-in-part, and reverse-in-part the final ID and to find a violation of Section 337. 79 *Fed. Reg.* 19640-41 (Apr. 9, 2014). The Commission found a violation of Section 337 with respect to (i) claims 1 and 4-8 of the '863 patent; (ii) claims 1, 3, 7, and 9 of the '666 patent; (iii) claims 1, 3, and 5 of the '487 patent; (iv) claims 21, 30, 31 and 32 of the '325 patent; and (v) claim 1 of the '880 patent. On the same day, the Commission issued an opinion, with a dissenting opinion from Commissioner Johanson,

[1] Mr. Katz is an attorney of the law firm Belles Katz LLC in Horsham, Pennsylvania.

and the Commission issued cease and desist orders directed to CCUS and CCPK. The Commission terminated the investigation.

On May 2, 2014, the Respondents filed a motion to stay the cease and desist orders pending appeal. On May 14, 2014, Complainant Align and the IA filed responses in opposition.

The Commission, having examined the motion and responses, the cease and desist orders, and the relevant portions of the record, hereby ORDERS THAT --

1. The motion for a stay pending appeal is hereby GRANTED. The stay is effective upon the Respondents' filing an appeal of the Commission's April 3, 2014, determination, and will continue in effect through the issuance of a mandate by the U.S. Court of Appeals for the Federal Circuit.

2. The Secretary shall:

(a) serve a copy of this order upon each party to the investigation; and

(b) publish notice of this order.

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: June 2, 2014

CERTAIN DIGITAL MODELS, DIGITAL DATA, AND TREATMENT PLANS FOR USE, IN MAKING INCREMENTAL DENTAL POSITIONING ADJUSTMENT APPLIANCES, THE APPLIANCES MADE THEREFROM, AND METHODS OF MAKING THE SAME

337-TA-833

CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **NOTICE** has been served by hand upon the Commission Investigative Attorney, Vu Bui, Esq., and the following parties as indicated, on **June 2, 2014.**

Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street, SW
Washington, DC 20436

On Behalf of Complainant:

Scott M. Flicker, Esq.
PAUL HASTINGS LLP
875 15th Street, NW
Washington, DC 20005

( ) Via Hand Delivery
(√) Via Express Delivery
( ) Via First Class Mail
( ) Other: _____

On Behalf of Clearcorrect Operating, LLC:

Gary M. Hnath, Esq.
MAYER BROWN LLP
1999 K Street, NW
Washington, DC 20006

( ) Via Hand Delivery
(√) Via Express Delivery
( ) Via First Class Mail
( ) Other: _____

On Behalf of Clearcorrect Pakistan (Private), Ltd.:

Lei Mei, Esq.
MEI & MARK LLP
818 18th Street NW, Suite 410
Washington, DC 20006

( ) Via Hand Delivery
(√) Via Express Delivery
( ) Via First Class Mail
( ) Other: _____

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN DIGITAL MODELS, DIGITAL DATA, AND TREATMENT PLANS FOR USE IN MAKING INCREMENTAL DENTAL POSITIONING ADJUSTMENT APPLIANCES, THE APPLIANCES MADE THEREFROM, AND METHODS OF MAKING THE SAME**	**Investigation No. 337-TA-833**

NOTICE OF COMMISSION DETERMINATION TO AFFIRM-IN-PART, MODIFY-IN-PART, AND REVERSE-IN-PART THE FINAL INITIAL DETERMINATION AND TO FIND A VIOLATION OF SECTION 337; ISSUANCE OF CEASE AND DESIST ORDERS; TERMINATION OF INVESTIGATION

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to affirm-in-part, modify-in-part, and reverse-in-part the final initial determination ("final ID" or "ID"), and to find a violation of Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 ("Section 337") in the above-captioned investigation. The Commission has issued cease and desist orders.

FOR FURTHER INFORMATION CONTACT: James A. Worth, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-3065. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-2000. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: This investigation was instituted on April 5, 2012, based upon a complaint filed on behalf of Align Technology, Inc., of San Jose, California ("Align"), on March 1, 2012, as corrected on March 22, 2012. 77 *Fed. Reg.* 20648 (April 5,

2012). The complaint alleged violations of Section 337 in the sale for importation, importation, or sale within the United States after importation of certain digital models, digital data, and treatment plans for use in making incremental dental positioning adjustment appliances, the appliances made therefrom, and methods of making the same by reason of infringement of certain claims of U.S. Patent No. 6,217,325 ("the '325 patent"); U.S. Patent No. 6,471,511 ("the '511 patent"); U.S. Patent No. 6,626,666 ("the '666 patent"); U.S. Patent No. 6,705,863 ("the '863 patent"); U.S. Patent No. 6,722,880 ("the '880 patent"); U.S. Patent No. 7,134,874 ("the '874 patent"); and U.S. Patent No. 8,070,487 (the '487 patent"). The notice of institution named as respondents ClearCorrect Pakistan (Private), Ltd. of Lahore, Pakistan ("CCPK") and ClearCorrect Operating, LLC of Houston, Texas ("CCUS") (collectively, "the Respondents").

On May 6, 2013, the presiding administrative law judge ("ALJ") issued the final ID, finding a violation of Section 337 with respect to the '325 patent, the '880 patent, the '487 patent, the '511 patent, '863 patent, and the '874 patent. He found no violation as to the '666 patent. The ALJ recommended the issuance of cease and desist orders directed to the Respondents.

On May 20, 2013, each of the parties filed a petition for review. On May 28, 2013, each of the parties filed a response thereto.

On June 5, 2013, Align filed a statement on the public interest. On June 13, 2013, the Respondents filed a statement on the public interest.

On June 16, 2013, the Commission issued notice of its determination to extend the deadline for determining whether to review the final ID to July 25, 2013.

On July 25, 2013, the Commission issued notice of its determination to review the final ID in its entirety and to solicit briefing on the issues on review and on remedy, the public interest, and bonding. 78 *Fed. Reg.* 46611 (August 1, 2013). On August 8, 2013, each of the parties filed written submissions. On August 15, 2013, each filed reply submissions.

On September 24, 2013, the Commission issued notice of its determination to extend the target date to November 1, 2013.

On November 18, 2013, the Commission issued notice of its determination to extend the target date to January 17, 2014.

On January 17, 2014, the Commission determined to extend the target date for completion of the above-captioned investigation to March 21, 2014, and to solicit additional briefing from the parties and the public.

On March 21, 2014, the Commission issued notice of its determination to extend the target date for completion of the investigation to April 3, 2014.

After considering the ID and the relevant portions of the record, and the submissions of the parties and the public, the Commission has determined to affirm-in-part, modify-in-part, and reverse-in-part the final ID and to find a violation of Section 337. The Commission has issued its opinion setting forth the reasons for its determination. Commissioner Johanson dissents and has filed a dissenting opinion.

Specifically, the Commission affirms the ALJ's conclusion that the accused products are "articles" within the meaning of Section 337(a)(1)(B) and that the mode of bringing the accused products into the United States constitutes importation of the accused products into the United States pursuant to Section 337(a)(1)(B). The Commission has determined to find a violation with respect to (i) claims 1 and 4-8 of the '863 patent; (ii) claims 1, 3, 7, and 9 of the '666 patent; (iii) claims 1, 3, and 5 of the '487 patent; (iv) claims 21, 30, 31 and 32 of the '325 patent; and (v) claim 1 of the '880 patent. The Commission has issued cease and desist orders directed to CCUS and CCPK, with an exemption for activities related to treatment of existing patients in the United States. The investigation is hereby terminated.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 C.F.R. Part 210).

By order of the Commission.

Lisa R. Barton
Acting Secretary to the Commission

Issued: April 3, 2014

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of

CERTAIN DIGITAL MODELS, DIGITAL DATA, AND TREATMENT PLANS FOR USE IN MAKING INCREMENTAL DENTAL POSITIONING ADJUSTMENT APPLIANCES, THE APPLIANCES MADE THEREFROM, AND METHODS OF MAKING THE SAME

Investigation No. 337-TA-833

CEASE AND DESIST ORDER

IT IS HEREBY ORDERED THAT ClearCorrect Operating, LLC, 15151 Sommermeyer Street, Houston, Texas, 77041-5332, cease and desist from conducting any of the following activities in the United States: (1) importing (including through electronic transmission); (2) marketing, selling, distributing, and transferring (including through electronic transmission, except for exportation); (3) advertising in the United States; and (4) soliciting U.S. agents or distributors for digital models, digital data, and treatment plans for use in making incremental dental positioning adjustment appliances or the appliances made therefrom covered by one or more of (i) claims 1 and 4-8 of U.S. Patent No. 6,705,863 ("the '863 patent"); (ii) claims 1, 3, 7, and 9 of U.S. Patent No. 6,626,666 ("the '666 patent"); (iii) claims 1, 3, and 5 of U.S. Patent No. 8,070,487 ("the '487 patent"); (iv) claims 21, 30, 31 and 32 of U.S. Patent No. 6,217,325 ("the '325 patent"); and (v) claim 1 of U.S. Patent No. 6,722,880 ("the '880 patent") in violation of Section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337).

I.
Definitions

As used in this order:

(A) "Commission" shall mean the United States International Trade Commission.

(B) "Complainant" shall mean Align Technology, Inc. of San Jose, California.

(C) "Respondent" shall mean ClearCorrect Operating, LLC, 15151 Sommermeyer Street, Houston, Texas, 77041-5332.

(D) "Person" shall mean an individual, or any non-governmental partnership, firm, association, corporation, or other legal or business entity other than Respondent or its majority-owned or controlled subsidiaries, successors, or assigns.

(E) "United States" shall mean the fifty States, the District of Columbia, and Puerto Rico.

(F) The terms "import" and "importation" refer to importation for entry for consumption under the Customs laws of the United States; the terms also refer to the electronic transmission of covered products in whatever form, into the United States.

(G) The term "covered products" shall mean digital models, digital data, and treatment plans for use in making incremental dental positioning adjustment appliances and the appliances made therefrom covered by one or more of (i) claims 1 and 4-8 of the '863 patent; (ii) claims 1, 3, 7, and 9 of the '666 patent; (iii) claims 1, 3, and 5 of the '487 patent; (iv) claims 21, 30, 31 and 32 of the '325 patent; and (v) claim 1 of the '880 patent. Covered products shall not include

articles for which a provision of law or license avoids liability for the infringement of the claims listed above.

(H) The term "covered process" shall mean the use of methods of making digital models, digital data, and treatment plans, for use in making incremental dental positioning adjustment appliances, that infringe claims of (i) claims 1 and 4-8 of the '863 patent; (ii) claims 1, 3, 7, and 9 of the '666 patent; (iii) claims 1, 3, and 5 of the '487 patent; (iv) claims 21, 30, 31 and 32 of the '325 patent; and (v) Group I: claim 1 of the '880 patent.

(I) The phrase "products made using imported covered products" shall include any appliances (including without limitation, initial, intermediate and/or final) made by a covered process using the digital models, digital data, or treatment plans imported by Respondents.

II.
Applicability

The provisions of this Cease and Desist Order shall apply to Respondent and to any of its principals, stockholders, officers, directors, employees, agents, licensees, distributors, controlled (whether by stock ownership or otherwise) and majority-owned business entities, successors, and assigns, and to each of them, insofar as they are engaging in conduct prohibited by section III, *infra*, for, with, or otherwise on behalf of, Respondent.

III.
Conduct Prohibited

The following conduct of Respondent in the United States is prohibited by this Order. For the remaining term of the relevant '666 patent, '863 patent, '487 patent, '325 patent, or '880 patent, or Respondent shall not:

(A) import (including through electronic transmission or otherwise) or sell for importation into the United States covered products; or use, duplicate, transfer (except for exportation), in the United States imported covered products or any products made using imported covered products;

(B) market, distribute, sell, or otherwise transfer (including through electronic transmission) in the United States (except for exportation) imported covered products or any products made using covered products;

(C) advertise imported covered products or any products made using imported covered products;

(D) solicit U.S. agents, distributors, or purchasers for imported covered products or any products made using imported covered products; or

(E) aid or abet other entities in the importation, sale for importation, sale after importation, transfer, or distribution of covered products or any products made using imported covered products.

IV.
Conduct Permitted

Notwithstanding any other provision of this Order, specific conduct otherwise prohibited by the terms of this Order shall be permitted if, in a written instrument, the owner of the '666 patent, '863 patent,'487 patent, '325 patent, and '880 patent licenses or authorizes such specific

conduct, or such specific conduct is related to the importation or sale of covered products by or for the United States.

This order does not apply to activity related to treatment of patients who have begun treatment or signed a contract for treatment with covered products or any products made using imported covered products on or before April 10, 2014. Also exempted from this order are activities related to the repair, replacement, or refurbishment of covered products that were imported prior to April 10, 2014.

V.
Reporting

For purposes of this requirement, the reporting periods shall commence on July 1 of each year and shall end on the subsequent June 30. The first report required under this section shall cover the period from the date of issuance of this order through June 30, 2014. This reporting requirement shall continue in force until such time as Respondent has truthfully reported, in two consecutive timely filed reports, that it has no transfers of covered products or any products made using imported covered products in the United States.

Within thirty (30) days of the last day of the reporting period, Respondent shall report to the Commission: (a) the quantity in units and the value in dollars of covered products that it has (i) imported and/or (ii) sold in the United States after importation during the reporting period, and the number of patients receiving treatment or replacement products, and (b) the quantity in units and value in dollars of reported covered products that remain in inventory in the United States at the end of the reporting period. Respondent shall also include a certification that the imported products are for patients who were receiving treatment or who had signed a contract for treatment before April 10, 2014, and that replacement products are for products that were

previously imported before April 10, 2014. When filing written submissions, Respondent must file the original document electronically on or before the deadlines stated above and submit eight (8) true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.4(f)). Submissions should refer to the investigation number ("Inv. No. 337-TA-833") in a prominent place on the cover pages and/or the first page. (*See* Handbook for Electronic Filing Procedures, http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf). Persons with questions regarding filing should contact the Secretary (202-205-2000). If Respondent desires to submit a document to the Commission in confidence, it must file the original and a public version of the original with the Office of the Secretary and must serve a copy of the confidential version on Complainants' counsel.[1]

Any failure to make the required report or the filing of any false or inaccurate report shall constitute a violation of this Order, and the submission of a false or inaccurate report may be referred to the U.S. Department of Justice as a possible criminal violation of 18 U.S.C. § 1001.

VI.
Record-Keeping and Inspection

(A) For the purpose of securing compliance with this Order, Respondent shall retain any and all records relating to the sale, offer for sale, marketing, or distribution in the United States of covered products and any products made using imported covered products, made and received in the usual and ordinary course of business,

[1] Complainants must file a letter with the Secretary identifying the attorney to receive reports and bond information associated with this Order. The designated attorney must be on the protective order entered in the investigation.

whether in detail or in summary form, for a period of three (3) years from the close of the fiscal year to which they pertain.

(B) For the purposes of determining or securing compliance with this Order and for no other purpose, subject to any privilege recognized by the federal courts of the United States, and upon reasonable written notice by the Commission or its staff, duly authorized representatives of the Commission shall be permitted access and the right to inspect and copy, in Respondent's principal offices during office hours, and in the presence of counsel or other representatives if Respondent so chooses, all books, ledgers, accounts, correspondence, memoranda, and other records and documents, in detail and in summary form, that must be retained under subparagraph VI(A) of this Order.

VII.
Service of Cease and Desist Order

Respondent is ordered and directed to:

(A) Serve, within fifteen days after the effective date of this Order, a copy of this Order upon each of its respective officers, directors, managing agents, agents, and employees who have any responsibility for the importation, marketing, distribution, or sale of imported covered products and any products made using imported covered products in the United States;

(B) Serve, within fifteen days after the succession of any persons referred to in subparagraph VII(A) of this order, a copy of the Order upon each successor; and

(C) Maintain such records as will show the name, title, and address of each person upon whom the Order has been served, as described in subparagraphs VII(A) and VII(B) of this order, together with the date on which service was made.

The obligations set forth in subparagraphs VII(B) and VII(C) shall remain in effect until the expiration dates of the '666 patent, '863 patent,'487 patent, '325 patent, and '880 patent.

VIII.
Confidentiality

Any request for confidential treatment of information obtained by the Commission pursuant to section VI of this order should be made in accordance with section 201.6 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 201.6). For all reports for which confidential treatment is sought, Respondent must provide a public version of such report with confidential information redacted.

IX.
Enforcement

Violation of this order may result in any of the actions specified in section 210.75 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.75), including an action for civil penalties under section 337(f) of the Tariff Act of 1930 (19 U.S.C. § 1337(f)), as well as any other action that the Commission deems appropriate. In determining whether Respondent is in violation of this order, the Commission may infer facts adverse to Respondent if it fails to provide adequate or timely information.

X.
Modification

The Commission may amend this order on its own motion or in accordance with the procedure described in section 210.76 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.76).

XI.
Bonding

The conduct prohibited by section III of this order may be continued during the sixty-day period in which this Order is under review by the United States Trade Representative, as delegated by the President (70 *Fed. Reg.* 43,251 (Jul. 21, 2005)), without Respondent posting a bond.

By order of the Commission.

Lisa R. Barton
Acting Secretary to the Commission

Issued: April 3, 2014

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN DIGITAL MODELS, DIGITAL DATA, AND TREATMENT PLANS FOR USE IN MAKING INCREMENTAL DENTAL POSITIONING ADJUSTMENT APPLIANCES, THE APPLIANCES MADE THEREFROM, AND METHODS OF MAKING THE SAME**	**Investigation No. 337-TA-833**

CEASE AND DESIST ORDER

IT IS HEREBY ORDERED THAT ClearCorrect Pakistan (Private), Ltd., Azia Cottage, 9-Kanal Park, Gulberg II, Lahore, Pakistan, cease and desist from conducting any of the following activities in the United States: (1) importing (including through electronic transmission); (2) marketing, selling, distributing, and transferring (including through electronic transmission, except for exportation); (3) advertising in the United States; and (4) soliciting U.S. agents or distributors for digital models, digital data, and treatment plans for use in making incremental dental positioning adjustment appliances or the appliances made therefrom covered by one or more of (i) claims 1 and 4-8 of U.S. Patent No. 6,705,863 ("the '863 patent"); (ii) claims 1, 3, 7, and 9 of U.S. Patent No. 6,626,666 ("the '666 patent"); (iii) claims 1, 3, and 5 of U.S. Patent No. 8,070,487 ("the '487 patent"); (iv) claims 21, 30, 31 and 32 of U.S. Patent No. 6,217,325 ("the '325 patent"); and (v) claim 1 of U.S. Patent No. 6,722,880 ("the '880 patent") in violation of Section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337).

I.
Definitions

As used in this order:

(A) "Commission" shall mean the United States International Trade Commission.

(B) "Complainant" shall mean Align Technology, Inc. of San Jose, California.

(C) "Respondent" shall mean ClearCorrect Pakistan (Private), Ltd., Azia Cottage, 9-Kanal Park, Gulberg II, Lahore, Pakistan.

(D) "Person" shall mean an individual, or any non-governmental partnership, firm, association, corporation, or other legal or business entity other than Respondent or its majority-owned or controlled subsidiaries, successors, or assigns.

(E) "United States" shall mean the fifty States, the District of Columbia, and Puerto Rico.

(F) The terms "import" and "importation" refer to importation for entry for consumption under the Customs laws of the United States; the terms also refer to the electronic transmission of covered products in whatever form, into the United States.

(G) The term "covered products" shall mean digital models, digital data, and treatment plans for use in making incremental dental positioning adjustment appliances and the appliances made therefrom covered by one or more of (i) claims 1 and 4-8 of the '863 patent; (ii) claims 1, 3, 7, and 9 of the '666 patent; (iii) claims 1, 3, and 5 of the '487 patent; (iv) claims 21, 30, 31 and 32 of the '325 patent; and (v) claim 1 of the '880 patent. Covered products shall not include

articles for which a provision of law or license avoids liability for the infringement of the claims listed above.

(H) The term "covered process" shall mean the use of methods of making digital models, digital data, and treatment plans, for use in making incremental dental positioning adjustment appliances, that infringe claims of (i) claims 1 and 4-8 of the '863 patent; (ii) claims 1, 3, 7, and 9 of the '666 patent; (iii) claims 1, 3, and 5 of the '487 patent; (iv) claims 21, 30, 31 and 32 of the '325 patent; and (v) Group I: claim 1 of the '880 patent.

(I) The phrase "products made using imported covered products" shall include any appliances (including without limitation, initial, intermediate and/or final) made by a covered process using the digital models, digital data, or treatment plans imported by Respondents.

II.
Applicability

The provisions of this Cease and Desist Order shall apply to Respondent and to any of its principals, stockholders, officers, directors, employees, agents, licensees, distributors, controlled (whether by stock ownership or otherwise) and majority-owned business entities, successors, and assigns, and to each of them, insofar as they are engaging in conduct prohibited by section III, *infra*, for, with, or otherwise on behalf of, Respondent.

III.
Conduct Prohibited

The following conduct of Respondent in the United States is prohibited by this Order. For the remaining term of the relevant '666 patent, '863 patent, '487 patent, '325 patent, or '880 patent, or Respondent shall not:

(A) import (including through electronic transmission or otherwise) or sell for importation into the United States covered products; or use, duplicate, transfer (except for exportation), in the United States imported covered products or any products made using imported covered products;

(B) market, distribute, sell, or otherwise transfer (including through electronic transmission) in the United States (except for exportation) imported covered products or any products made using covered products;

(C) advertise imported covered products or any products made using imported covered products;

(D) solicit U.S. agents, distributors, or purchasers for imported covered products or any products made using imported covered products; or

(E) aid or abet other entities in the importation, sale for importation, sale after importation, transfer, or distribution of covered products or any products made using imported covered products.

IV.
Conduct Permitted

Notwithstanding any other provision of this Order, specific conduct otherwise prohibited by the terms of this Order shall be permitted if, in a written instrument, the owner of the '666

patent, '863 patent,'487 patent, '325 patent, and '880 patent licenses or authorizes such specific conduct, or such specific conduct is related to the importation or sale of covered products by or for the United States.

This order does not apply to activity related to treatment of patients who have begun treatment or signed a contract for treatment with covered products or any products made using imported covered products on or before April 10, 2014. Also exempted from this order are activities related to the repair, replacement, or refurbishment of covered products that were imported prior to April 10, 2014.

V.
Reporting

For purposes of this requirement, the reporting periods shall commence on July 1 of each year and shall end on the subsequent June 30. The first report required under this section shall cover the period from the date of issuance of this order through June 30, 2014. This reporting requirement shall continue in force until such time as Respondent has truthfully reported, in two consecutive timely filed reports, that it has no transfers of covered products or any products made using imported covered products in the United States.

Within thirty (30) days of the last day of the reporting period, Respondent shall report to the Commission: (a) the quantity in units and the value in dollars of covered products that it has (i) imported and/or (ii) sold in the United States after importation during the reporting period, and the number of patients receiving treatment or replacement products, and (b) the quantity in units and value in dollars of reported covered products that remain in inventory in the United States at the end of the reporting period. Respondent shall also include a certification that the

imported products are for patients who were receiving treatment or who had signed a contract for treatment before April 10, 2014, and that replacement products are for products that were previously imported before April 10, 2014. When filing written submissions, Respondent must file the original document electronically on or before the deadlines stated above and submit eight (8) true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.4(f)). Submissions should refer to the investigation number ("Inv. No. 337-TA-833") in a prominent place on the cover pages and/or the first page. (*See* Handbook for Electronic Filing Procedures, http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf). Persons with questions regarding filing should contact the Secretary (202-205-2000). If Respondent desires to submit a document to the Commission in confidence, it must file the original and a public version of the original with the Office of the Secretary and must serve a copy of the confidential version on Complainants' counsel.[1]

Any failure to make the required report or the filing of any false or inaccurate report shall constitute a violation of this Order, and the submission of a false or inaccurate report may be referred to the U.S. Department of Justice as a possible criminal violation of 18 U.S.C. § 1001.

VI.
Record-Keeping and Inspection

(A) For the purpose of securing compliance with this Order, Respondent shall retain any and all records relating to the sale, offer for sale, marketing, or distribution in

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[1] Complainants must file a letter with the Secretary identifying the attorney to receive reports and bond information associated with this Order. The designated attorney must be on the protective order entered in the investigation.

the United States of covered products and any products made using imported covered products, made and received in the usual and ordinary course of business, whether in detail or in summary form, for a period of three (3) years from the close of the fiscal year to which they pertain.

(B) For the purposes of determining or securing compliance with this Order and for no other purpose, subject to any privilege recognized by the federal courts of the United States, and upon reasonable written notice by the Commission or its staff, duly authorized representatives of the Commission shall be permitted access and the right to inspect and copy, in Respondent's principal offices during office hours, and in the presence of counsel or other representatives if Respondent so chooses, all books, ledgers, accounts, correspondence, memoranda, and other records and documents, in detail and in summary form, that must be retained under subparagraph VI(A) of this Order.

VII.
Service of Cease and Desist Order

Respondent is ordered and directed to:

(A) Serve, within fifteen days after the effective date of this Order, a copy of this Order upon each of its respective officers, directors, managing agents, agents, and employees who have any responsibility for the importation, marketing, distribution, or sale of imported covered products and any products made using imported covered products in the United States;

(B) Serve, within fifteen days after the succession of any persons referred to in subparagraph VII(A) of this order, a copy of the Order upon each successor; and

(C) Maintain such records as will show the name, title, and address of each person upon whom the Order has been served, as described in subparagraphs VII(A) and VII(B) of this order, together with the date on which service was made.

The obligations set forth in subparagraphs VII(B) and VII(C) shall remain in effect until the expiration dates of the '666 patent, '863 patent,'487 patent, '325 patent, and '880 patent.

VIII.
Confidentiality

Any request for confidential treatment of information obtained by the Commission pursuant to section VI of this order should be made in accordance with section 201.6 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 201.6). For all reports for which confidential treatment is sought, Respondent must provide a public version of such report with confidential information redacted.

IX.
Enforcement

Violation of this order may result in any of the actions specified in section 210.75 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.75), including an action for civil penalties under section 337(f) of the Tariff Act of 1930 (19 U.S.C. § 1337(f)), as well as any other action that the Commission deems appropriate. In determining whether Respondent is in violation of this order, the Commission may infer facts adverse to Respondent if it fails to provide adequate or timely information.

X.
Modification

The Commission may amend this order on its own motion or in accordance with the procedure described in section 210.76 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.76).

XI.
Bonding

The conduct prohibited by section III of this order may be continued during the sixty-day period in which this Order is under review by the United States Trade Representative, as delegated by the President (70 *Fed. Reg.* 43,251 (Jul. 21, 2005)), without Respondent posting a bond.

By order of the Commission.

Lisa R. Barton
Acting Secretary to the Commission

Issued: April 3, 2014

CERTAIN DIGITAL MODELS, DIGITAL DATA, AND TREATMENT PLANS FOR USE, IN MAKING INCREMENTAL DENTAL POSITIONING ADJUSTMENT APPLIANCES, THE APPLIANCES MADE THEREFROM, AND METHODS OF MAKING THE SAME

337-TA-833

CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **NOTICE** has been served by hand upon the Commission Investigative Attorney, Vu Bui, Esq., and the following parties as indicated, on **April 3, 2014.**

Lisa R. Barton, Acting Secretary
U.S. International Trade Commission
500 E Street, SW
Washington, DC 20436

On Behalf of Complainant:

Scott M. Flicker, Esq.
PAUL HASTINGS LLP
875 15th Street, NW
Washington, DC 20005

( ) Via Hand Delivery
(√) Via Express Delivery
( ) Via First Class Mail
( ) Other: _____

On Behalf of Clearcorrect Operating, LLC:

Gary M. Hnath, Esq.
MAYER BROWN LLP
1999 K Street, NW
Washington, DC 20006

( ) Via Hand Delivery
(√) Via Express Delivery
( ) Via First Class Mail
( ) Other: _____

On Behalf of Clearcorrect Pakistan (Private), Ltd.:

Lei Mei, Esq.
MEI & MARK LLP
818 18th Street NW, Suite 410
Washington, DC 20006

( ) Via Hand Delivery
(√) Via Express Delivery
( ) Via First Class Mail
( ) Other: _____

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN DIGITAL MODELS, DIGITAL DATA, AND TREATMENT PLANS FOR USE IN MAKING INCREMENTAL DENTAL APPLICANCES, THE APPLIANCES MADE THEREFROM, AND METHODS OF MAKING SAME**	**Investigation No. 337-TA-833**

NOTICE OF COMMISSION DETERMINATION TO REVIEW THE FINAL INITIAL DETERMINATION OF THE ADMINISTRATIVE LAW JUDGE; SCHEDULE FOR FILING WRITTEN SUBMISSIONS ON REVIEW

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review the final initial determination ("final ID" or "ID") in the above-captioned investigation.

FOR FURTHER INFORMATION CONTACT: James A. Worth, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-3065. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-2000. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: This investigation was instituted on April 5, 2012, based upon a complaint filed on behalf of Align Technology, Inc., of San Jose, California ("Align"), on March 1, 2012, as corrected on March 22, 2012. 77 *Fed. Reg.* 20648 (April 5, 2012). The complaint alleged violations of Section 337 of the Tariff Act of 1930, 19 U.S.C. § 1337 ("Section 337") in the sale for importation, importation, or sale within the United States after importation of certain digital models, digital data, and treatment plans for use in making incremental dental appliances, the appliances made therefrom, and methods of making the same by reason of infringement of certain claims of U.S. Patent No. 6,217,325 ("the '325 patent"); U.S. Patent No. 6,471,511 ("the '511 patent"); U.S. Patent No. 6,626,666; U.S. Patent No. 6,705,863 ("the '863 patent"); U.S. Patent No. 6,722,880 ("the '880 patent"); U.S. Patent No.

7,134,874 ("the '874 patent"); and U.S. Patent No. 8,070,487 (the '487 patent"). The notice of institution named as respondents ClearCorrect Pakistan (Private), Ltd. of Lahore, Pakistan and ClearCorrect Operating, LLC of Houston, Texas (collectively, "the Respondents").

On May 6, 2013, the administrative law review issued the final ID, finding a violation of Section 337 with respect to the '325 patent, the '880 patent, the '487 patent, the '511 patent, '863 patent, and the '874 patent. The ALJ recommended the issuance of cease and desist orders.

On May 20, 2013, Align, the Respondents, and the Commission investigative attorney each filed a petition for review. On May 28, 2013, each of the parties filed a response thereto. On June 5, 2013, Align filed a statement on the public interest. On June 13, 2013, the Respondents filed a statement on the public interest.

After considering the ID and the relevant portions of the record, the Commission has determined to review the ID in its entirety.

The parties should brief their positions on the issues under review with reference to the applicable law and the evidentiary record. In connection with its review, the Commission is particularly interested in responses to the following questions:

> **Question 1:** Does the language and legislative history of Section 337 provide a basis for interpreting "articles" to cover electronic transmissions? Does the Commission's remedial cease and desist order in *Certain Hardware Logic Emulation Systems and Components Thereof*, Inv. No. 337-TA-383 (1998), which prohibited the electronic transmission of data, necessarily mean that electronic transmission is importation for purposes of violation within the meaning of Section 337(a)(1)(B)?
>
> **Question 2:** Is the use of a computer to perform an operation (such as interpolation), which was previously performed in an analog manner, the type of advance which does not render the asserted patent claims nonobvious over the prior art on the facts of this case? Please answer with regard to the factual record in this investigation.

In connection with the final disposition of this investigation, the Commission may (1) issue an order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) issue one or more cease and desist orders that could result in a respondent being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, *see Certain Devices for Connecting Computers via Telephone Lines*, Inv. No. 337-TA-360, USITC Pub. No. 2843, Comm'n Op. at 9 (December 1994).

If the Commission contemplates some form of remedy, it must consider the effects of that remedy upon the public interest. The factors the Commission will consider include the effect that an exclusion order and/or cease and desist orders would have on (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the United States Trade Representative, as delegated by the President, has 60 days to approve or disapprove the Commission's action. *See* Presidential Memorandum of July 21, 2005, 70 *Fed. Reg.* 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

WRITTEN SUBMISSIONS: The parties to the investigation are requested to file written submissions on the issues identified in this notice. Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such submissions should address the recommended determination by the ALJ on remedy and bonding. Complainant and the Commission investigative attorney are also requested to submit proposed remedial orders for the Commission's consideration. Complainant is also requested to state the date that the patents expire and the HTSUS subheadings under which the accused products are imported. The written submissions and proposed remedial orders must be filed no later than close of business on August 8, 2013. Reply submissions must be filed no later than the close of business on August 15, 2013. The written submissions must be no longer than 20 pages and the reply submissions must be no longer than 10 pages. No further submissions on these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must do so in accordance with Commission rule 210.4(f), 19 C.F.R. § 210.4(f), which requires electronic filing. The original document and 8 true copies thereof must also be filed on or before the deadlines stated above with the Office of the Secretary. Any person desiring to submit a document to the Commission in confidence must request confidential treatment unless the information has already been granted such treatment during the proceedings. All such requests should be directed to the Secretary of the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 C.F.R. § 210.6. Documents for which confidential treatment by the Commission is sought will be treated accordingly. All non-confidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 C.F.R. Part 210).

By order of the Commission.

Lisa R. Barton
Acting Secretary to the Commission

Issued: July 25, 2013

CERTAIN DIGITAL MODELS, DIGITAL DATA, AND TREATMENT PLANS FOR USE, IN MAKING INCREMENTAL DENTAL POSITIONING ADJUSTMENT APPLIANCES, THE APPLIANCES MADE THEREFROM, AND METHODS OF MAKING THE SAME

337-TA-833

CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **NOTICE** has been served by hand upon the Commission Investigative Attorney, Vu Bui, Esq., and the following parties as indicated, on **July 25, 2013**

Lisa R. Barton, Acting Secretary
U.S. International Trade Commission
500 E Street, SW
Washington, DC 20436

On Behalf of Complainant:

Scott M. Flicker, Esq.
PAUL HASTINGS LLP
875 15th Street, NW
Washington, DC 20005

( ) Via Hand Delivery
( ) Via Express Delivery
(✓) Via First Class Mail
( ) Other: _____

On Behalf of Clearcorrect Operating, LLC:

Gary M. Hnath
MAYER BROWN LLP
1999 K Street, NW
Washington, DC 20006

( ) Via Hand Delivery
( ) Via Express Delivery
(✓) Via First Class Mail
( ) Other: _____

On Behalf of Clearcorrect Pakistan (Private), Ltd.:

Lei Mei
MEI & MARK LLP
818 18th Street NW, Suite 410
Washington, DC 20006

( ) Via Hand Delivery
( ) Via Express Delivery
(✓) Via First Class Mail
( ) Other: _____

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN DIGITAL MODELS, DIGITAL DATA, AND TREATMENT PLANS FOR USE IN MAKING INCREMENTAL DENTAL POSITIONING ADJUSTMENT APPLIANCES, THE APPLIANCES MADE THEREFROM, AND METHODS OF MAKING THE SAME**	**Investigation No. 337-TA-833**

COMMISSION OPINION ON MOTION TO CLARIFY OR MODIFY CEASE AND DESIST ORDERS

I. Introduction

On April 3, 2014, the Commission issued a final determination finding ClearCorrect Operating, LLC, of Houston, Texas ("CCUS"), and ClearCorrect Pakistan (Private), Ltd. ("CCPK") (collectively, "ClearCorrect"), in violation of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain digital models, digital data, and treatment plans for use in making incremental dental positioning adjustment appliances.[1] The Commission's determination rested on findings of infringement with respect to five patents owned by complainant Align

[1] While Commissioner Johanson concurs that the Commission's cease and desist orders proscribe activities involving imported covered products and not wholly domestic conduct, he is of the view that no violation occurred and, accordingly, no remedy should have issued. Thus, he does not join this opinion.

Technology, Inc. ("Align") of San Jose, California. As a remedy for the violation of section 337, the Commission issued cease and desist orders directed to CCUS and CCPK.

On April 16, 2014, ClearCorrect filed a motion to correct or clarify the cease and desist orders. Resp'ts' Mot. to Correct or Clarify Cease and Desist Orders (April 16, 2014) ("Mot."). On April 28, 2014, Align filed a response. Compl'nt Align Tech., Inc.'s Opp'n to Resp'ts' Mot. to Correct or Clarify Cease and Desist Orders (April 28, 2014) ("Opp."). The Commission investigative attorney did not file a response.

When viewed as a whole, the orders in question do not purport to proscribe "wholly domestic conduct," as questioned by ClearCorrect. Accordingly, the Commission has determined that ClearCorrect's motion need only be granted to the extent it is necessary to emphasize that point.

II. DISCUSSION

A. ClearCorrect's Motion

ClearCorrect requests clarification of two parts of the April 3, 2014, cease and desist orders.[2] First, ClearCorrect seeks clarification of the preamble of the orders. Mot. at 1. The preamble language identified by ClearCorrect is as follows:

> **IT IS HEREBY ORDERED THAT** ClearCorrect . . . cease and desist from conducting any of the following activities in the United States: (1) importing (including through electronic transmission); (2) marketing, selling, distributing, and transferring (including through electronic transmission, except for exportation); (3) advertising in the United States; and (4) soliciting U.S. agents or distributors for digital models, digital data, and treatment plans for use in making incremental dental positioning adjustment appliances or the appliances made therefrom covered by one or more of (i) claims 1 and 4-8 of U.S. Patent No. 6,705,863 ("the '863 patent"); (ii) claims 1, 3, 7, and 9 of U.S. Patent No. 6,626,666 ("the '666 patent"); (iii) claims 1, 3, and 5 of U.S. Patent No. 8,070,487 ("the '487

[2] The cease and desist orders against CCUS and CCPK are identical in all respects material to ClearCorrect's motion.

> patent"); (iv) claims 21, 30, 31 and 32 of U.S. Patent No. 6,217,325 ("the '325 patent"); and (v) claim 1 of U.S. Patent No. 6,722,880 ("the '880 patent") in violation of Section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337).

Cease and Desist Orders at 1 (underlining added).

ClearCorrect argues that while subsection (1) of the preamble prohibits "importing" digital data for use in making dental appliances, later subsections could be construed to prohibit some unspecified conduct that is allegedly "wholly domestic." For example, ClearCorrect contends that subsection (3) of the preamble prohibits "advertising within the United States of products made exclusively within the United States from processes that occur only in the United States." Mot. at 2.

Second, ClearCorrect seeks clarification of certain prohibitions enumerated in Section III(B) of the orders. Mot. at 3. Section III(B) states that ClearCorrect shall not:

> market, distribute, sell or otherwise transfer (including through electronic transmission) in the United States (except for exportation) imported covered products or any products made using covered products.

Cease and Desist Orders at Sec. III(B) (underlining added). ClearCorrect believes the Commission intended the word "imported" to be included in the final clause so that the provision would read "imported covered products or any products made using ***imported*** covered products." Mot. at 3. Unless "covered products" is modified to mean "***imported*** covered products," ClearCorrect contends, the provision could be read to prohibit the marketing, distribution, or sale of any domestic products made by using wholly domestic covered products. *Id.*[3]

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[3] In Section I(G), the orders define "covered products" as follows:

> The term "covered products" shall mean digital models, digital data, and treatment plans for use in making incremental dental positioning adjustment

B. Analysis

ClearCorrect's motion purports to question whether the cease and desist orders cover activities *not* related in any way to imported covered products. But the motion also substantially answers the question. As ClearCorrect admits, with the possible exception of the two passages cited above, "all of the prohibited conduct [in the cease and desist orders] is tied to activities involving the use of 'imported covered products.'" Mot. 2. We affirm that the conduct prohibited by the cease and desist orders, including the language in the preamble and Section III(B), involves imported covered products.

The opening paragraph of section 337 sets the context for the orders at issue here:

> (a) *Unlawful activities; covered industries; definitions*
>
> (1) Subject to paragraph (2), the following are unlawful, and when found by the Commission to exist shall be dealt with, in addition to any other provision of law, as provided in this section:
>
> ...
>
> (B) The importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that—
>
> (i) infringe a valid and enforceable United States patent . . .; or
>
> (ii) are made [or] processed . . . by means of, a process covered by the claims of a valid and enforceable United States patent.

19 U.S.C. § 1337(a)(1)(B). The activities that "shall be dealt with" by the Commission are "the importation into the United States, the sale for importation, or the sale within the United States after importation" of articles that infringe a patent or are made or processed

---

> appliances and the appliances made therefrom covered by one or more of (i) claims 1 and 4-8 of the '863 patent; (ii) claims 1, 3, 7, and 9 of the '666 patent; (iii) claims 1, 3, and 5 of the '487 patent; (iv) claims 21, 30, 31 and 32 of the '325 patent; and (v) claim 1 of the '880 patent. Covered products shall not include articles for which a provision of law or license avoids liability for the infringement of the claims listed above.

Cease and Desist Orders at Sec. I(G).

using a patented process. The Commission's cease and desist orders in this investigation are to remedy ClearCorrect's acts "involved" in violations of the statute, *see* 19 U.S.C. § 1337(f), and all violations of section 337 are tied to importation, *see id.* at § 1337(a)(1)(B). Thus, even if the orders were unclear on their face (as ClearCorrect incorrectly argues), the acts prohibited by the orders still would implicitly involve the imported covered products as contemplated in the statute.[4] Every passage of the cease and desist orders need not use the "imported" modifier when proscribing activities relating to covered articles.

In opposing ClearCorrect's motion, Align asserts that the Commission has issued remedial orders in past investigations that were directed to "wholly domestic conduct." Opp. at 4-5. Align's argument rests on language from our past opinions taken out of the context of the facts of those cases. All of the opinions cited by Align dealt with imported goods. In the cited decisions, the Commission restricted advertising, distribution, or conversion of goods that had already been imported into the United States. *See, e.g., Certain Baseband Processor Chips and Chipsets, Transmitter and Receiver (Radio) Chips, Power Control Chips, and Products Containing Same, Including Cellular Telephone Handsets*, Inv. No. 337-TA-543, Comm'n Op. on Remedy, the Public Interest, and Bonding, 2011 WL 6121182, *65 (Oct. 2011) ("The ALJ also found that 'Qualcomm has a commercially significant inventory of imported product in the United States and . . . a cease and desist order against Qualcomm's importations and sales, and also barring

[4] The Commission's remedial orders must be interpreted in the context of the statutory scheme enacted by Congress. *See FTC v. Ruberoid Co.*, 343 U.S. 470, 475-76 (1952) (interpreting a remedial order to contain provisos "necessarily implicit in every order issued under the authority of the [relevant] Act, just as if the order set them out in extenso").

Qualcomm from converting the imported chips to infringing articles and marketing such infringing chips is appropriate.'"). Similarly, when the Commission prohibited the domestic sale of tractors that had infringing trademarks affixed in the United States, the tractors in question had been imported. *Certain Agricultural Tractors Under 50 Power Take-off Horsepower*, Inv. No. 337-TA-380, Comm'n Determination, 1999 WL 631001, *20 (Aug. 18, 1999).

We caution that ClearCorrect should not construe our opinion today to provide a safe harbor for a specific course of conduct. ClearCorrect's motion did not ask whether a particular course of conduct is beyond the scope of the cease and desist orders; consequently, this opinion takes no position as to whether any hypothetical conduct that ClearCorrect might characterize as "wholly domestic" falls within or outside the scope of the orders. Rather, ClearCorrect sought clarification about how the orders should be interpreted with respect to the Commission's statutory authority. ClearCorrect may avail itself of the Commission's post-order procedures to obtain a ruling from the Commission concerning whether a proposed course of conduct would violate the cease and desist orders. *See, e.g.*, 19 C.F.R. § 210.79.

III. CONCLUSION

In sum, the Commission reiterates that the cease and desist orders issued in this investigation proscribe only activities involving imported covered products. Because the Commission finds that the orders are clear, when read in whole and in context, no modification of the orders is necessary.

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: September 16, 2014

CERTAIN DIGITAL MODELS, DIGITAL DATA, AND TREATMENT PLANS FOR USE, IN MAKING INCREMENTAL DENTAL POSITIONING ADJUSTMENT APPLIANCES, THE APPLIANCES MADE THEREFROM, AND METHODS OF MAKING THE SAME

Inv. No. 337-TA-833

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **COMMISSION OPINION** has been served by hand upon the Commission Investigative Attorney, **Vu Bui, Esq.**, and the following parties as indicated, on **September 16, 2014.**

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PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN DIGITAL MODELS, DIGITAL DATA, AND TREATMENT PLANS FOR USE IN MAKING INCREMENTAL DENTAL POSITIONING ADJUSTMENT APPLIANCES, THE APPLIANCES MADE THEREFROM, AND METHODS OF MAKING THE SAME**	**Investigation No. 337-TA-833**

COMMISSION OPINION

I. BACKGROUND

This investigation was instituted on April 5, 2012, based upon a complaint filed on behalf of Align Technology, Inc. ("Align") of San Jose, California on March 1, 2012, and a corrected complaint filed on March 22, 2012. 77 *Fed. Reg.* 20648-49 (April 5, 2012). The complaint, as corrected, alleged violations of section 337 of the Tariff Act of 1930, as amended, (19 U.S.C. § 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain digital models, digital data, and treatment plans for use in making incremental dental appliances by reason of infringement of U.S. Patent No. 6,217,325 ("the '325 patent"), U.S. Patent No. 6,722,880 ("the '880 patent"), U.S. Patent No. 8,070,487 ("the '487 patent"), U.S. Patent No. 6,471,511 ("the '511 patent"), U.S. Patent No. 6,626,666 ("the '666 patent"), U.S. Patent No. 6,705,863 ("the '863 patent") and U.S. Patent No. 7,134,874 ("the '874 patent"). The notice of investigation named as respondents ClearCorrect Operating, LLC

("CCUS") and ClearCorrect Pakistan (Private), Ltd ("CCPK," and collectively "ClearCorrect").

On May 6, 2013, the ALJ issued his final initial determination ("final ID"), finding a violation of Section 337 with respect to the '325 patent, the '880 patent, the '487 patent, the '511 patent, the '863 patent, and the '874 patent. The ALJ found no violation as to the '666 patent. The ALJ recommended the issuance of cease and desist orders directed to CCUS and CCPK. On April 3, 2014, the Commission issued notice of its determination to affirm-in-part, modify-in-part, and reverse-in-part the final ID and to find a violation of Section 337. 79 *Fed. Reg.* 19640-41. The Commission found a violation of Section 337 with respect to (i) claims 1 and 4-8 of the '863 patent; (ii) claims 1, 3, 7, and 9 of the '666 patent; (iii) claims 1, 3, and 5 of the '487 patent; (iv) claims 21, 30, 31 and 32 of the '325 patent; and (v) claim 1 of the '880 patent. On the same day, the Commission issued an opinion ("Comm'n Op."), with a dissenting opinion from Commissioner Johanson, and the Commission issued cease and desist orders directed to CCUS and CCPK.[1] The Commission terminated the investigation.

On May 2, 2014, ClearCorrect filed a motion to stay the cease and desist orders pending appeal pursuant to the Commission's authority under section 10(d) of the Administrative Procedure Act, 5 U.S.C. § 705.[2] ClearCorrect argues that the issue of whether electronic transmissions are "articles" within the meaning of section 337 is a difficult question. It also argues that the orders would cause irreparable harm to ClearCorrect in the form of lay-offs, disruption of operations, and impaired relationship

[1] Commissioner Johanson is of the view that no violation occurred and, accordingly, no remedy should have issued. He concludes that the record demonstrates that a stay is appropriate. He concurs with the outcome to stay the remedy but does not join the Commission opinion.

[2] Resp'ts' Mot. to Stay Cease and Desist Orders (May 2, 2014) ("ClearCorrect Mot.").

with vendors, and that potential harm to Align is insignificant because Align and ClearCorrect do not share customers. ClearCorrect also argues that the public interest favors a stay because doctors have no adequate substitute for ClearCorrect's appliances and doctors will be forced to buy new expensive equipment. *Id.* at 1-2.

On May 14, 2014, Align and the Commission investigative attorney filed responses in opposition.[3] Align argues that ClearCorrect cannot demonstrate that this issue presents an admittedly difficult question because the Commission's careful and deliberate construction of Section 337 is both correct and entitled to deference on appeal. Align Opp'n 2-6. In particular, Align argues that no "difficult" question would be presented to the Federal Circuit on review because the Commission's interpretation is entitled to deference. *Id.* at 3-4. Align asserts that ClearCorrect cannot demonstrate that ClearCorrect faces "irreparable injury" absent a stay, and that ClearCorrect alleges only harm to CCPK and not to CCUS, ClearCorrect's U.S. operations. *Id.* at 6. Align asserts that it would suffer harm if a stay is granted. *Id.* at 11.

Like Align, the IA asserts that ClearCorrect has failed to satisfy the test for a stay. IA Opp'n 4-8. The IA states that "granting a stay pending appeal would not promote the public interest, which generally favors the protection of intellectual property rights." *Id.* at 10.

[3] Compl't Align Technology, Inc.'s Opp'n to Resp'ts' Mot. to Stay Cease and Desist Orders (May 14, 2014) ("Align Opp'n"); Resp. of the Office of Unfair Import Investigations to Resp'ts' Mot. to Stay Cease and Desist Orders (May 14, 2014) ("IA Opp'n").

II. LEGAL STANDARD

Section 10(d) of the Administrative Procedure Act provides an agency with the authority to "postpone the effective date of action taken by it, pending judicial review" if the "agency finds that justice so requires." 5 U.S.C. § 705. The standard for a stay at the agency level has been construed to be "the same as the standard for a stay at the judicial level: each is governed by the four-part preliminary injunction test." *Sierra Club v. Jackson*, 833 F. Supp. 2d 11, 30 (D.D.C. 2012). The Federal Circuit has set forth the four-part test (in connection with a judicial stay) as follows:

> (1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether the issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies.

Standard Havens Prods., Inc. v. Gencor Indus., Inc., 897 F.2d 511, 512 (Fed. Cir. 1990) (quotation omitted). The Federal Circuit applies the test flexibly: each factor "need not be given equal weight," *id.*, and a sliding scale applies whereby the second through fourth factors (collectively, the equities or harms) can compensate for a weaker showing under the first factor, *id.* at 512. Of special note is the recognition that in cases since *Standard Havens*, the Federal Circuit has repeatedly explained that to "prevail, a movant must establish a likelihood of success on the merits or, failing that, must demonstrate that is has a substantial case on the merits and that the harm factors militate in its favor." *Spansion, Inc. v. ITC*, 2009 WL 2876448, at *1 (Sept. 8, 2009); *accord, e.g., General Protecht Grp., Inc. v. Leviton Mfg. Co.*, 407 Fed. App'x 450 (Fed. Cir. Jan. 18, 2011); *Turner Constr. Co. v. United States*, 410 Fed. Appx. 319 (Dec. 8, 2010); *see Hilton v. Braunskill*, 481 U.S. 770, 778 (1987).

Thus, the threshold for a stay at the agency level need not be whether the movant has demonstrated a likelihood of success. The Commission has recognized the futility of a likelihood-of-success test in this context. *Certain Agricultural Tractors Under 50 Power Take-Off Horsepower*, Inv. No. 337-TA-380 ("*Agricultural Tractors*"), Comm'n Op. Denying Resp'ts' Pet. for Reconsideration and Mot. for Relief Pending Appeal 10 (Apr. 25, 1997); *see also Washington Metro. Area Transit Comm. v. Holiday Tours, Inc.*, 559 F.2d 841, 844 (D.C. Cir. 1977) ("Prior recourse to the initial decisionmaker would hardly be required as a general matter if it could properly grant interim relief only on a prediction that it has rendered an erroneous decision."). Accordingly, a stay may be appropriate when the agency has "ruled on an admittedly difficult legal question and when the equities of the case suggest that the status quo should be maintained." *Id.* at 844-45; *see also Agricultural Tractors*, Comm'n Op. at 10. The Commission has repeatedly recited and applied this "admittedly difficult question" test in previous investigations in which stays were sought pending appeal.[4] The parties agree that this is the test to be applied by the Commission here. ClearCorrect Mot. 4; Align Opp'n 2; IA Opp'n 4.

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[4] *See Agricultural Tractors*, Comm'n Op. at 10; *Certain EPROM, EEPROM, Flash Memory, and Flash Microcontroller Semiconductor Devices, and Products Containing Same*, Inv. No. 337-TA-395, Comm'n Op., 2001 WL 242553, at *80 (July 9, 1998); *Certain Baseband Processor Chips & Chipsets, Transmitter & Receiver (Radio) Chips, Power Control Chips & Products Containing Same, Including Cellular Telephone Handsets*, Inv. No. 337-TA-543 ("*Baseband Processors*"), Comm'n Op. Denying Mots. for Stay 5-6 (June 21, 2007); *Certain High-Brightness Light Emitting Diodes, and Products Containing Same*, Inv. No. 337-TA-556, Comm'n Op., 2008 WL 2556199, at *4-*5; *Certain Semiconductor Chips with Minimized Chip Packages*, Inv. No. 337-TA-605, Comm'n Op., 2009 WL 2350644, at *2-*4 (July 29, 2009); *Certain Digital Television Products and Certain Products Containing Same and Methods of Using Same*, Inv. No. 337-TA-617, Comm'n Op., 2009 WL 2598777, at *2-*3.

III. ANALYSIS

Based on the foregoing, ClearCorrect may obtain a stay if it presents an "admittedly difficult question," and demonstrates that the harm factors militate in its favor. We conclude that ClearCorrect has met this test.[5]

A. An "Admittedly Difficult Question"

We recognized the difficulty of the legal question in this investigation in our April 3, 2014, opinion on violation and remedy. Comm'n Op. 36 ("We acknowledge that the construction of the term 'articles' is a difficult question in part because the term 'articles' is not expressly defined in the statute."). The Commission's extensive legal analysis—which the Commission continues to hold to be entirely correct—demonstrates the difficulty of the issue. Align argues that no "difficult" question would be presented to the U.S. Court of Appeals for the Federal Circuit on appeal because the Commission's interpretation is entitled to deference. *Id.* at 3-4 (citing *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 844 (1984)). We agree with Align that the difficulty of the question presented counsels in favor of judicial deference to an agency's interpretation of its organic statute. Yet, the existence of that deference does not, in and of itself, obviate the fact that the question ruled upon by the Commission was a difficult one.[6]

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[5] Commissioner Broadbent finds that ClearCorrect's motion should be denied because it has failed to satisfy its burden to demonstrate that a stay of the Commission's remedial orders is warranted under the governing legal standard applied by the Commission and as articulated by the Federal Circuit in *Standard Havens Prods. Inc. v. Gencor Indus., Inc.*, 897 F.2d 511 (Fed. Cir. 1990).

[6] We take note of Commissioner Johanson's dissent and the extensive public comments on both sides of the issue as further evidence that the legal question was difficult.

B. The Harms Factors

Having established that this investigation presents a difficult legal question, we turn to an analysis of the harm factors. We first focus on the balance of hardships, *i.e.*, the second and third factors in the *Standard Havens* recitation. As discussed in our April 3, 2014, opinion on violation and remedy, ClearCorrect is organized into U.S.-based and Pakastani operations.[7]

ClearCorrect argues that absent a stay, CCPK will face "immediate and irreparable ruin." Resp'ts Mot. 5. ClearCorrect states that CCPK has 115 employees, of whom 85 are computer technicians. *Id.* at 6. ClearCorrect also states that CCUS is CCPK's only customer and that CCPK has no prospect of any other customers. *Id.* ClearCorrect asserts that even though CCPK is permitted to work on CCUS's existing patients under the Commission's remedial orders, this work will decline rapidly as existing patients finish their treatment. ClearCorrect argues that if the orders take effect, CCPK will almost certainly have to discontinue its operations completely or drastically reduce its workforce within a short time. *Id.* ClearCorrect concludes that if the orders are not stayed, CCPK will almost certainly be ruined even if it wins its appeal. *Id.* ClearCorrect argues that the risk to Align is low because ClearCorrect and Align serve different customer bases. ClearCorrect Mot. 10-11.

[7] CCUS creates an initial digital data set by scanning a model of a patient's dental impressions. Comm'n Op. 18. CCUS uploads the digital scan to a server for CCPK to access. *Id.* CCPK uses modeling software to create proposed (*i.e.*, post-treatment) tooth positions, *id.* at 18, and sends that model to CCUS, which in turn seeks the treating dentist's approval, *id.* at 19. Upon such approval, CCPK interpolates changes in the tooth positions, creating a digital data set corresponding to each dental realignment device. *Id.* at 20. Such data sets are transmitted by CCPK to CCUS, which uses a 3D printer to fabricate a 3D model of each data set. *Id.* Aligners for patients are thermoformed over the 3D models. *Id.*

Align notes that ClearCorrect focuses substantially on harm to CCPK as opposed to CCUS. Align discounts the harm caused to CCPK, contending that CCPK could try to turn its attention to other markets besides the United States. Align Opp. 10. Align and the IA both note that ClearCorrect may have contingencies in place to try to serve U.S. customers even while the Commission's remedial orders are in place. Align Opp'n 7-8; IA Opp'n 6-7.

Align argues that the harm caused to ClearCorrect by the Commission's remedial orders fall short of the harm caused to Align by a stay. Align treats the dental repositioning market at issue as substantially a two-supplier marketplace, and argues that ClearCorrect's sales are sales lost by Align. Align Opp'n 12. Align further argues that damages are not capable of being calculated for several reasons. It asserts that it "would suffer price erosion due to ClearCorrect's conduct." *Id.* at 16. It also argues that it is harmed based on dentists' misrepresentations that they prescribe Invisalign products when in reality they use ClearCorrect. *Id.* at 18-20.

On balance, we find that the balance of hardships tilts in favor of ClearCorrect. We note that Align has a pending district court action against ClearCorrect that has been stayed pursuant to 28 U.S.C. § 1659(a). *Align Tech., Inc. v. ClearCorrect, Inc.*, No. 4:2011cv00695 (filed Feb. 28, 2011) (S.D. Tex.). That action provides a forum for Align to attempt recovery of damages for past infringement, not only for the period of the stay, but also for infringement during the pendency of Commission proceedings.[8]

[8] Commission relief is "in addition to" relief provided by the district courts. 19 U.S.C. § 1337(a)(1). Accordingly, the mere availability of a district court proceeding is not enough to tilt the harms factors in favor of a stay.

Align has contended that monetary recovery is impossible due to price erosion. Align Opp. 16. But Align never argues that it has responded to ClearCorrect by changing its pricing (to compete with the infringer) or that it intends to do so. Consequently, Align has provided no argument about any likely price erosion.[9] Align also argues that it suffers reputational harm from ClearCorrect's presence in the marketplace. Yet, Align's showing, Align Opp. 18-20, is anecdotal, and the harms that it alleges are founded, if anything, on theories of unfair competition (as under the Lanham Act) as opposed to the patent infringement it has alleged before the Commission.

The fourth factor in *Standard Havens*, and the last of the harms factors, is the public interest. We assessed the statutory public interest factors in the underlying investigation, and concluded they did not point to denial of relief (although we did tailor the orders in light of the public interest factors).[10] We recognize that the public interest factor in the stay analysis is broader than the statutory analysis under section 337. We also recognize, as Align and the IA argue, IA Opp'n 8-9, Align Opp'n 20-22, that there is a public interest in the enforcement of valid patents. *See, e.g., Celsis in Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 931-32 (Fed. Cir. 2012). However, the legal issue presented here may have particularly significant impact on the legal strategies pursued in future investigations, which will benefit from the guidance provided by the court. On

[9] Similarly, Align's contention that "over 60% of ClearCorrect cases would have otherwise been Align's cases but for ClearCorrect's participation in the market," Pepe. Decl. ¶ 8, is unsubstantiated and not explained. *See also* Align Opp'n 14-15.

[10] Comm'n Op. 148-52.

balance, we do not find that the public interest arguments raised in the briefings on stay weigh heavily in either direction.[11]

IV. CONCLUSION

Because we have recognized an admittedly difficult question (though certainly not a likelihood of success on the merits) and have weighed the harms as favoring a stay, we grant ClearCorrect's motion. We do not make this decision to stay the effect of our orders lightly. While the Federal Circuit has stayed the effect of our orders on occasion, *see, e.g.*, *Dynatec Int'l, Inc. v. ITC*, No. 99-1504, 1999 U.S. App. LEXIS 38842, at *2 (Fed. Cir. Sept. 24, 1999); *Broadcom Corp. v. ITC*, No. 2007-1164, Order at 6 (Fed. Cir. Sept. 12, 2007), we have not in the past, when requested to stay the effect of a remedial order, found that the facts so warranted.[12]

This determination, however, should not be viewed as a sharp departure from prior determinations denying stays. In considering stay motions, the Commission is always mindful of the effects that its orders can have on the parties, consumers, and competition in the marketplace generally, and our analysis here comports with that general practice.[13] Our historical experience demonstrates that the circumstances of most

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[11] The parties contest the relative benefits of their dental repositioning devices. ClearCorrect Mot. 7-10; Align Opp'n 15-16. We find the parties' arguments, and the evidence before us, insufficient to point in favor of either party.

[12] Commissioner Pinkert, along with then-Commissioner Pearson, dissented from the denial of a stay in *Certain Baseband Processor Chips & Chipsets, Transmitter & Receiver (Radio) Chips, Power Control Chips & Products Containing Same, Including Cellular Telephone Handsets*, Inv. No. 337-TA-543, Comm'n Op. Denying Mots. for Stay 6 n.2 (June 21, 2007), which is the Commission determination at issue in the *Broadcom* appeal cited in the text.

[13] Similarly, we have tailored our remedial orders to accommodate public interest considerations where appropriate. For example, in *Certain Personal Data and Mobile Communications Devices and Related Software*, Inv. No. 337-TA-710 ("*Personal Data Devices*"), we delayed the implementation of our exclusion order to a vulnerable customer of the respondent, to transition to other products. *Personal Data Devices*, Comm'n Op. 79-83. In the present investigation, we tailored the cease and desist orders to accommodate existing ClearCorrect customers in order to mitigate harm to U.S. consumers.

investigations do not justify a delay in effectuating statutory remedies against adjudged infringers. In those cases, the Commission's mandate to enforce valid and infringed U.S. intellectual property rights overshadows other contentions. However, given the nature of the legal question presented here, we find that a stay is appropriate. *Holiday Tours*, 559 F.2d at 844-45 ("What is fairly contemplated is that tribunals may properly stay their own orders when they have ruled on an admittedly difficult legal question and when the equities of the case suggest that the status quo should be maintained.").

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: June 11, 2014

CERTAIN DIGITAL MODELS, DIGITAL DATA, AND TREATMENT PLANS FOR USE, IN MAKING INCREMENTAL DENTAL POSITIONING ADJUSTMENT APPLIANCES, THE APPLIANCES MADE THEREFROM, AND METHODS OF MAKING THE SAME

337-TA-833

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **COMMISSION OPINION** has been served by hand upon the Commission Investigative Attorney, Vu Bui, Esq., and the following parties as indicated, on **June 11, 2014.**

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PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN DIGITAL MODELS, DIGITAL DATA, AND TREATMENT PLANS FOR USE IN MAKING INCREMENTAL DENTAL POSITIONING ADJUSTMENT APPLIANCES, THE APPLIANCES MADE THEREFROM, AND METHODS OF MAKING THE SAME**	**Investigation No. 337-TA-833**

COMMISSION OPINION

PUBLIC VERSION

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On May 6, 2013, the presiding administrative law judge ("ALJ") (Judge Rogers) issued his final initial determination ("ID") in this investigation, finding a violation of Section 337.

Having considered the ID, the submissions of the parties and the public, and the relevant portions of the record, the Commission has determined to affirm-in-part, modify-in-part, and reverse-in-part the final ID. The Commission has determined that the Respondents have violated Section 337 in the importation, sale for importation, or sale after importation of digital models, digital data, and treatment plans for use in making incremental dental appliances. Commissioner Johanson dissents.[1] The Commission has determined to adopt the ALJ's findings that are consistent with the Commission's opinion as set forth below.

I. BACKGROUND

A. Procedural History

This investigation was instituted on April 5, 2012, based upon a complaint filed on behalf of Align Technology, Inc. ("Align") of San Jose, California on March 1, 2012, and a corrected complaint filed on March 22, 2012. 77 *Fed. Reg.* 20648-49 (April 5, 2012). The complaint, as corrected, alleged violations of section 337 of the Tariff Act of 1930, as amended, (19 U.S.C. § 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain digital models, digital data, and treatment plans for use in making incremental dental appliances by reason of infringement of U.S. Patent No. 6,217,325 ("the '325 patent"), U.S. Patent

[1] Commissioner Johanson has filed a dissenting opinion, post.

No. 6,722,880 ("the '880 patent"), U.S. Patent No. 8,070,487 ("the '487 patent"), U.S. Patent No. 6,471,511 ("the '511 patent"), U.S. Patent No. 6,626,666 ("the '666 patent"), U.S. Patent No. 6,705,863 ("the '863 patent") and U.S. Patent No. 7,134,874 ("the '874 patent"). The notice of investigation named as respondents ClearCorrect Operating, LLC ("ClearCorrect USA" or "CCUS") and ClearCorrect Pakistan (Private), Ltd ("ClearCorrect Pakistan" or "CCPK"). A Commission investigative attorney ("IA") participated in this investigation.

On January 14, 2013, the ALJ issued Order No. 20, denying CCUS's and CCPK's motion for summary determination that certain asserted claims were not infringed and that claim 1 of the '880 patent was invalid, and finding that CCUS and CCPK waived any estoppel defense, including defenses based on implied license or patent exhaustion.

On May 6, 2013, the ALJ issued the final ID, finding a violation of Section 337 with respect to the '325 patent, the '880 patent, the '487 patent, the '511 patent, '863 patent, and the '874 patent. The ALJ found no violation as to the '666 patent. The ALJ recommended the issuance of cease and desist orders directed to CCUS and CCPK to prohibit the importation of digital data sets.

On May 20, 2013, each of the parties filed a petition for review. On May 28, 2013, each of the parties filed a response thereto.

On June 5, 2013, Align filed a statement on the public interest. On June 13, 2013, the Respondents filed a statement on the public interest.

On June 7, 2013, the Commission issued notice of its determination to extend the deadline for determining whether to review the final ID to July 25, 2013, and to extend the target date to September 24, 2013.

On July 25, 2013, the Commission issued notice of its determination to review the final ID in its entirety and to solicit briefing on the issues on review and on remedy, the public interest, and bonding. 78 *Fed. Reg.* 46611-12 (August 1, 2013). On August 8, 2013, each of the parties filed written submissions. On August 15, 2013, each filed reply submissions.

On September 24, 2013, the Commission issued notice of its determination to extend the target date to November 1, 2013. Due to the federal government shutdown and the Commission Notice tolling all deadlines by the length of the shutdown, the target date became November 18, 2013. On November 18, 2013, the Commission issued notice of its determination to extend the target date to January 17, 2014.

On December 31, 2013, the Respondents filed a notice of supplemental authority. On January 10, 2014, Align filed a reply thereto.

On January 17, 2014, the Commission issued a notice extending the target date to March 21, 2014, and soliciting further briefing from the public and the parties. 79 *Fed. Reg.* 4174-74 (January 24, 2014).

On February 3, 2014, the Commission received written submissions from each of the parties and from Motion Picture Association of America ("MPAA"), Google Inc. ("Google"), and Andrew Katz (Mr. Katz).[2] On February 10, 2014, the Commission received reply submissions from each of the parties and from MPAA, the Association of American Publishers ("the AAP"), and Nokia Corporation ("Nokia").

On March 21, 2004, the Commission issued notice of its determination to extend the target date to April 3, 2014.

[2] Mr. Katz is an attorney of the law firm Belles Katz LLC in Horsham, Pennsylvania.

B. Related Cases

On February 15, 2006, the Commission instituted an original investigation captioned *Certain Incremental Dental Positioning Adjustment Appliances and Methods of Producing Same*, Inv. No. 337-TA-562 ("the 562 investigation"), based on a complaint also filed by Align. 71 *Fed. Reg.* 7995-96 (February 15, 2006). Briefly, the complaint alleged that the OrthoClear Respondents[3] violated Section 337 when they imported and sold aligners in the United States which had been manufactured in Pakistan. The orthodontic aligners at issue were accused of infringing the '880 and '511 patents asserted in this investigation, among numerous others. *Id.*

On October 27, 2006, the presiding ALJ issued an Initial Determination granting Align's and OrthoClear's joint motion to terminate the investigation based on a consent order. The Commission determined not to review the ID. Notice (November 13, 2006).

The consent order provides in relevant part:

> 1. The incremental dental positioning adjustment appliances manufactured by or for OrthoClear referenced in the complaint and any other articles manufactured in violation of the patents or trade secrets described therein (the "Articles") are hereby prohibited from importation into the United States until the expiration of the last to expire of the following patents: (i) U.S. Patent No. 6,685,469 ("the '469 patent"); (ii) U.S. Patent No. 6,394,801 ("the '801 patent"); (iii) U.S. Patent No. 6,398,548 ("the '548 patent"); (iv) U.S. Patent No. 6,722,880 ("the '880 patent"); (v) U.S. Patent No. 6,629,840 ("the '840 patent"); (vi) U.S. Patent No. 6,699,037 ("the '037 patent"); (vii) U.S. Patent No. 6,318,994 ("the '994 patent"); (viii) U.S. Patent No. 6,729,876 ("the '876 patent"); (ix) U.S. Patent No. 6,602,070 ("the '070 patent"); (x) U.S. Patent No. 6,471,511 ("the '511 patent"); and (xi) U.S. Patent No. 6,227,850 ("the '850 patent") (collectively "the Patents-In-Suit"), except under license of the patent owner or as provided by law.

[3] The Commission's notice of investigation named OrthoClear, Inc. of San Francisco, California; OrthoClear Holdings, Inc. of Tortola, British Virgin Islands; and OrthoClear Pakistan Pvt, Ltd. of Lahore, Pakistan (collectively, "OrthoClear") as respondents.

> 2. Upon entry of this Consent Order, OrthoClear shall not sell for importation, import into the United States, or sell in the United States after importation the Articles, or knowingly aid, abet, encourage, participate in, or induce the sale for importation into the United States or sale in the United States after importation of the Articles.
>
> 3. This Consent Order shall be applicable and binding upon OrthoClear, its officers, directors, agents, servants, employees, successors and assigns, and all persons, firms, or corporations acting or claiming to act on its behalf or under its direction or authority.

On March 1, 2012, Align filed a complaint for an enforcement proceeding under Commission Rule 210.75, 19 C.F.R. § 210.75, which was instituted on April 25, 2012 ("the 562 Enforcement Proceeding"). Align based its complaint on alleged violations of the consent order by ClearCorrect USA of Houston, Texas ("CCUS"); ClearCorrect Pakistan (Private), Ltd. ("CCPK") of Lahore, Pakistan; and Mudassar Rathore, Waqas Wahab, Nadeem Arif, and Asim Waheed (collectively, "Enforcement Respondents"). 77 Fed. Reg. 25747 (May 1, 2012).

In the complaint for enforcement, Align alleged that the Enforcement Respondents violated the consent order when they sold for importation, imported, or sold after importation digital data sets, including digital models of a patient's teeth, digital data and/or treatment paths transmitted (electronically) to the United States, and subsequently manufactured aligners in the United States using those imported digital data sets. According to Align, the Enforcement Respondents' use of certain processes, systems, and techniques infringe at least claim 1 of the '511 patent and claims 1 and 3 of the '880 patent. Enforcement Complaint ¶ 90, 94-95.

Align further alleged that both CCUS and CCPK are "successor[s], assign[s], or agent[s]" of the original OrthoClear respondents. *Id.* ¶ 24, 31.[4] The complaint also alleges that the named individuals are former employees or a director of OrthoClear Enforcement Complaint ¶¶ 34, 38, 42, 46. ClearCorrect Pakistan admits that the individuals are former employees of OrthoClear and further admits that Mudassar Rathore is the CEO of CCPK, Waqas Wahab and Nadeem Arif are directors of orthodontics for CCPK, and that Asim Waheed is a manager of quality control at CCPK. Response of CCUS to Enforcement Complaint ¶¶ 34-35, 38-39, 42-43, 46-47.

On November 28, 2012, the ALJ issued Order No. 57, finding that the accused digital data sets are "articles manufactured" within the meaning of paragraph 1 of the consent order. On January 4, 2013, the Commission issued notice of its determination to review and reverse the ID and to terminate the proceeding with a finding of no violation of the consent order. 78 Fed. Reg. 2282-83 (January 10, 2013). In its opinion, the Commission held that, since the consent order at issue contained no express provision for electronic transmissions, the consent order did not cover electronic transmissions under Commission precedent and thus there was no violation of the consent order. *Certain Incremental Dental Positioning Adjustment Appliances and Methods of Producing Same*, Comm'n Op. (January 23, 2013). Align has appealed the Commission's determination from the 562 Enforcement Proceeding to the U.S. Court of Appeals for the Federal Circuit. Case Nos. 2013-1240, -1363. That appeal is currently pending.

[4] ClearCorrect USA and ClearCorrect Pakistan have denied these allegations. Response of CCUS to Enforcement Complaint ¶ 24; Response of CCPK to Enforcement Complaint ¶ 31.

C. The Patents

Align asserts seven U.S. patents that all claim priority to provisional application No. 60/050,342 filed on June 20, 1997. As with the specifications of all the patents in suit, each patent is directed towards a system for repositioning teeth comprising a plurality of individual appliances (aligners) which are configured to be placed successively on the patient's teeth and to incrementally reposition the teeth from an initial tooth arrangement to a final tooth arrangement.[5] *See, e.g.*, '880 Patent Abstract.[6] While the seven asserted patents all share a common inventive concept of using digital data sets to construct the individual appliances, a description of each asserted patent is set forth below.

1. The '325 Patent

The '325 patent,[7] entitled "Method and System For Incrementally Moving Teeth," issued on April 17, 2001, based on Application No. 09/298,268, filed by Muhammad Chishti, Apostolos Lerios, Brian Freyburger, Kelsey Wirth, and Richard Ridgley on April 23, 1999. ID at 2-3. The '325 patent is a divisional of non-asserted U.S. Patent No. 5,975,893 filed Oct. 8, 1997. The '325 patent was the subject of an ex parte reexamination based on a request received on July 27, 2005, that added limitations to original claims 1 and 18-21 and added new claims 27-39. *Id.* A reexamination certificate issued on January 15, 2008. *Id.*

[5] The asserted patents note that "the appliances can be braces, polymeric shells, or other forms of orthodontic appliances." '511 patent Abstract.
[6] The asserted patents have different specifications, but are from the same family.
[7] JX-3.

Align has asserted claims 1-3, 11, 13-14, 21, 30-35, and 38-39. Claims 1, 11, 21, 31, 35 and 38 are independent claims. Certain claims of the '325 patent are directed to a method for fabricating a plurality of dental incremental position adjustment appliances using digital data sets representing an initial tooth arrangement, a final tooth arrangement, and a series of intermediate digital data sets representing the tooth arrangements progressing from the initial to the final arrangement. '325 patent, col. 16, lines 19-34. Claim 1 recites:

> 1. A method for facilitating a tooth repositioning dental treatment, including producing a plurality of digital sets representing a plurality of tooth arrangements, said method comprising:
>
> providing an intial digital data set representing an initial tooth arrangement;
>
> presenting a visual image based on the initial data set;
>
> manipulating the visual image to reposition individual teeth in the visual image;
>
> producing a final digital data set representing the final tooth arrangement with repositioned teeth as observed in the image;
>
> producing a plurality of intermediate digital data sets representing a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement; and
>
> fabricating a plurality of successive tooth repositioning appliances, at least some of which are related to at least some of the produced digital data sets.

Id. Ex Parte Rexam Cert. at col. 1, lines 29-48.

2. The '880 Patent

The '880 patent,[8] entitled "Method and System for Incrementally Moving Teeth," issued on April 20, 2004, based on Application No. 10/047,077, filed by Muhammad Chishti and Kelsey Wirth on January 14, 2002. ID at 3. The '880 patent arises from an

[8] JX-2.

application which is a continuation-in-part of a related, non-asserted patent. Align has asserted claims 1 and 3; claim 1 is an independent claim.

Similar in manner to the '325 patent, claim 1 of the '880 patent is directed to a method for fabricating dental adjustment appliances using digital data sets. The asserted claims of the '880 patent expressly define the "dental adjustment appliances" as comprising "polymeric shells having cavities shaped to receive and resiliently reposition teeth." '880 patent, col. 22, lines 12-29. Claim 1 recites:

> 1. A method for making a predetermined series of dental incremental position adjustment appliances, said method comprising:
>
> a) obtaining a digital data set representing an initial tooth arrangement;
>
> b) obtaining a repositioned tooth arrangement based on the initial tooth arrangement;
>
> c) obtaining a series of successive digital data sets representing a series of successive tooth arrangements; and
>
> d) fabricating a predetermined series of dental incremental position adjustment appliances based on the series of successive digital data sets, wherein said appliances comprise polymeric shells having cavities shaped to receive and resiliently reposition teeth, and said appliances correspond to the series of successive tooth arrangements progressing from the initial to the repositioned tooth arrangement.

Id. Dependent claim 3 teaches that the digital data set is obtained by defining boundaries of the individual teeth and moving at least some of the tooth boundaries relative to other teeth in an image. *Id.* col. 22, lines 33-41. Claim 3 recites:

> 3. A method as in claim 1, wherein the step of obtaining a digital data set representing a repositioned tooth arrangement comprises:
>
> defining boundaries about at least some of the individual teeth; and
>
> moving at least some of the tooth boundaries relative to the other teeth in an image based on the digital data set to produce the repositioned data set.

Id.

3. The '487 Patent

The '487 patent,[9] entitled "System and Method for Positioning Teeth," issued on December 6, 2011, based on Application No. 11/981,680, filed by Muhammad Chishti and Andrew Beers on October 31, 2007. ID at 3. Align has asserted claims 1, 3, 5 and 7-9, of which claims 1 and 7 are independent.

The asserted claims are directed to a method of planning dental treatment by producing digital data sets. The '487 patent teaches the concept of an "orthodontic treatment plan." '487 patent, col. 11, lines 26-35. Claim 1 recites:

> 1. A method of planning orthodontic treatment of a patient comprising use of incremental tooth repositioning appliances, the method comprising:
> receiving an initial digital data set representing an initial arrangement of the patient's teeth;
> producing a final digital data set representing the patient's teeth in a desired or prescribed arrangement;
> producing a plurality of intermediate digital data sets representing intermediate arrangements of the patient's teeth, wherein at least some of the intermediate tooth arrangements represent different orthodontic treatment stages as the patient's teeth are moved from the initial arrangement toward the final arrangement.

Id., col. 10, line 61 to col. 11, line 6. In addition, claim 7 provides that the "treatment plan resid[es] on a computer readable media." *Id.*, col. 11, lines 28-29. Claim 7 recites:

> 7. An orthodontic treatment plan for repositioning a patient's teeth using incremental tooth repositioning appliances, the treatment plan residing on a computer readable storage media and comprising a plurality of intermediate digital data sets representing intermediate arrangements of the patient's teeth, wherein at least some of the intermediate tooth arrangements represent different orthodontic treatment stages as the patient's teeth are moved from an initial arrangement toward a final arrangement representing the patient's teeth in a desired or prescribed arrangement.

[9] JX-7.

Id., col. 11, lines 26-35. Although the '487 patent introduces the limitation of "orthodontic treatment plan," the underlying structure of the claim remains directed to development of digital data sets. *Id.*

4. The '511 Patent

The '511 patent,[10] entitled "Defining Tooth-Moving Appliances Computationally," issued on October 29 2002, based on Application No. 09/169,034, filed by Muhammad Chishti, Elena I. Pavlovskaia, Gregory P. Bala and Brian Freyburger on October 8, 1998. ID at 4. The '511 patent arises from an application which is a continuation-in-part of a non-asserted patent. The sole asserted claim is claim 1.

The '511 patent is directed towards methods for segmenting an orthodontic treatment plan, as referred previously in the '487 patent, into clinically appropriate sub-steps for repositioning the teeth of a patient. '511 patent, Abstract. The limitations presented in claim 1 of the '511 patent are distinguished from the claims of other asserted patents because claim 1 further provides for "calculating a segmentation of the aggregate tooth paths…so that each tooth's motion stays within threshold limits of linear and rotational translation." *Id.*, col. 11, lines 9-12. Claim 1 recites:

> 1. A computer-implemented method for segmenting an orthodontic treatment path into segments, comprising:
>
> for each tooth in a set of teeth, receiving a tooth path for the motion of the tooth from an initial position to a final position;
>
> calculating a segmentation of the aggregate tooth paths into a plurality of treatment segments so that each tooth's motion within a segment stays within threshold limits of linear and rotational translation; and
>
> generating a plurality of appliances, at least one or more appliances for each treatment segment, wherein the appliances comprise polymeric shells having cavities and wherein the cavities of

[10] JX-1.

> successive shells have different geometries shaped to receive and resiliently reposition the teeth from one arrangement to a successive arrangement.

Id., col. 11, lines 4-19.

5. The '666 Patent

The '666 patent,[11] entitled "Method and System for Incrementally Moving Teeth," issued on September 30, 2003, based on Application No. 09/757,044, filed by Muhammad Chishti, Apostolos Lerior, Brian Freyburger, Kelsey Wirth and Richard Ridgley on January 8, 2001. ID at 4-5. Align has asserted claims 1, 3, 7 and 9; claims 1 and 7 are independent claims.

The claims of the '666 patent are directed to a method of producing a "plurality of digital data sets." '666 patent, col. 15, lines 27-48. Similar to the manner of claims for the '880 patent, the '666 patent produces digital data sets by "moving at least some of the tooth boundaries relative to the other teeth in the visual image to produce a final data set." *Id.* at col. 15, lines 38-40. Claim 1 recites:

> 1. A method for producing a plurality of digital data sets representing a series of discrete tooth arrangements progressing from an initial to a final arrangement, said method comprising:
>
> providing a computer system;
>
> providing to the computer system an initial digital data set representing an initial tooth arrangement;
>
> defining boundaries about at least some of the individual teeth on a visual image provided by the computer system based on the initial data set;
>
> moving at least some of the tooth boundaries relative to the other teeth in the visual image to produce a final data set; and
>
> producing using the computer system a plurality of successive digital data sets based on both of the previously provided initial and final digital data sets, wherein said plurality of successive digital data sets represents a series of successive tooth

[11] JX-4.

> arrangements progressing from the initial tooth arrangement to the final tooth arrangement.

Id., col. 15, lines 27-47. Additionally, claim 7 of the '666 patent introduces the limitation of "interpolating positional differences between the teeth in the initial and final data sets." *Id.* at col. 16, lines 7-13. Claim 7 recites:

> 7. A method for producing a plurality of digital data sets representing a series of discrete tooth arrangements progressing from an initial to a final arrangement, said method comprising:
>
> providing a computer system;
>
> providing to the computer system digital data set representing an initial tooth arrangement;
>
> providing to the computer system a digital data set representing a final tooth arrangement;
>
> interpolating positional differences between the teeth in the initial and final data sets using the computer system to produce a plurality of successive digital data sets, wherein said plurality of successive digital data sets represents a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement.

Id., col. 15, line 64 to col. 16, line 13.

6. The '863 Patent

The '863 patent,[12] entitled "Attachment Devices and Methods for a Dental Appliance," issued on March 16, 2004, based on Application No. 10/040,269, filed by Loc X. Phan, Muhammad Z. Chishti and Ross J. Miller on October 29, 2001. ID at 5. The '863 patent was the subject of an ex parte reexamination based on a request received on June 23, 2005. *Id.* The '863 patent is a continuation-in-part of a non-asserted U.S. patent 6,309,215 filed Dec. 3, 1999.

Align has asserted claims 1 and 4-8; claim 1 is an independent claim. Claim 1 of the '863 patent was subject to ex parte reexamination and is directed towards a method

[12] JX-5.

for producing digital models of dental appliances. '863 patent, Ex Parte Reexam Cert. col. 1, lines 57-col. 2, line 4. The asserted claims disclose a method of "producing a plurality of modified digital models of the dentition, wherein the modified models represent successive treatment stages of an orthodontic treatment." *Id.* Claim 1 recites:

> A method for producing digital models of dental positioning appliances, said method comprising:
>
> providing a digital model of a patient's dentition;
>
> producing a plurality of modified digital models of the dentition, wherein the modified models represent successive treatment stages of an orthodontic treatment and wherein each modified model or a product of such model is to be used in fabrication of a distinct successive incremental dental positioning appliance associated with the respective treatment stage of that modified model;
>
> providing a digital model of at least one attachment device; and
>
> positioning the digital model of the attachment device on at least some of the plurality of modified digital models.

Id.

7. The '874 Patent

The '874 patent,[13] entitled "Computer Automated Development of an Orthodontic Treatment Plan and Appliance," issued on November 14, 2006, based on Application No. 10/718,779, filed by Muhammad Chishti, Brian Freyburger, Kelsey Wirth, Andrew Beers, Huafeng Wen, Phillips Alexander Benton, Timothy N. Jones, and Ross J. Miller on November 20, 2003. ID at 5-6.

Align has asserted claims 1, 2, 38-39, 41, and 62; claim 1 is an independent claim. Claim 1 of the '874 patent is directed to a method for "creating a treatment plan to reposition a patient's teeth from a set of initial tooth positions to a set of final tooth

[13] JX-6.

positions" in a manner similar to the other asserted patents. '874 patent, col. 32, lines 37-56. Claim 1 recites:

> 1. A computer-implemented method for use in creating a treatment plan to reposition a patient's teeth from a set of initial tooth positions to a set of final tooth positions, the method comprising:
>
> receiving an initial digital data set representing the teeth at the initial positions, wherein receiving the initial digital data set comprises receiving data obtained by scanning the patient's teeth or a physical model thereof;
>
> generating a set of intermediate positions toward which the teeth will move while moving from the initial positions toward the final positions; and
>
> generating a plurality of successive appliances having cavities and wherein the cavities of successive appliances have different geometries shaped to receive and reposition teeth from the initial positions toward the final positions,
>
> wherein the plurality of successive appliances is generated at a stage of treatment prior to the patient wearing any appliance of said plurality so as to reposition the teeth.

Id.. In contrast to the other patents in suit, the asserted claims of the '874 patent have a limitation of generating a plurality of appliances "prior to patient wearing any appliance." '874 patent, col. 32, lines 53-56.

D. The Groups of Asserted Claims

The asserted claims across the seven patents-in-suit share characteristics and limitations. Complainant Align placed them into four groups for the purpose of analyzing the threshold issues of violation, *e.g.*, whether there is an imported "article," and whether the territorial requirements of violation have been met. Align's Response to Respondents' Petition for Review ("Align Pet.") at 4-5. Some claims are in more than one group. There was no objection raised to the use of these groupings.[14]

[14] *See* Respondents' Response to the Notice of the Commission's Determination to Review the Final Initial Determination of the Administrative Law Judge ("Resps. Sub."); Response of the Office of Unfair Import Investigations to the Commission's Request for Written Submissions on Issues Under Review ("IA Sub.");

1. Group I

The Group I claims (Claims 21 and 30 of the '325 patent and claim 1 of the '880 patent) are directed to a method of forming dental appliances starting with a digital data set.

2. Group II

The Group II claims (Claims 31 and 32 of the '325 patent; claims 1 and 4-8 of the '863 patent; claims 1, 3, 7 and 9 of the '666 patent; and claims 1, 3 and 5 of the '487 patent) are directed to methods of producing digital data sets.

3. Group III

The Group III claims (Claims 7-9 of the '487 patent) are directed to a treatment plan (*i.e.*, a series of digital data sets) on a storage medium.

4. Group IV

The Group IV claims (Claims 1, 2, 3, 11, 13, 14, 21, 30, 31, 32, 33, 34, 35, 38, 39 of the '325 patent; claims 1 and 3 of the '880 patent; claims 1 of the '511 patent; and claims 1, 2, 38, 39, 41, and 62 of the '874 patent) are directed to methods of producing dental appliances.

E. The Accused Products and Processes

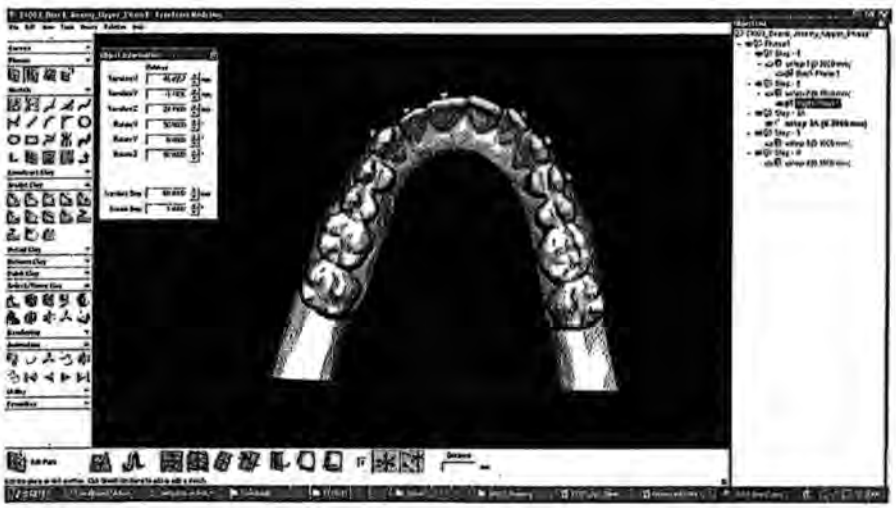
1. Accused Products

Align accuses digital data sets made by CCUS and CCPK and the customized sequential dental positioning appliances made therefrom for the purpose of orthodontic treatment.

Respondents' Reply To The OUII & Align's Response To Notice Of The Commission's Determination To Review The Final Initial Determination Of The ALJ and Exhibits ("Resps. Reply Sub."); Response of the Office of Unfair Import Investigations to Written Submissions on the Issues Under Review and on Remedy, the Public Interest, and Bonding ("IA Reply Sub.").

The ALJ found the accused products to be digital models, digital data, and treatment plans, expressed as digital data sets, which are virtual three-dimensional models of the desired position of patients' teeth at various stages of orthodontic treatment. The models are initially created based on impressions of patients' teeth. The models are manipulated in Pakistan by CCPK, as set forth below, and transmitted to CCUS. ID at 21-22. The digital models, digital data, and treatment plans are electronically transmitted by uploading them (a CCPK technician in Pakistan electronically transmits the digital data to CCUS's server for CCUS use in the United States). ID at 21-22; Tr. at 316-17; CX-1150C at Qs. 92-145; Tr. at 168:14-170:11, 170:18-173:24, and 177:2-193:6; Tr. at 312:20-322:12; Tr. at 442:5-443:10. The digital models are subsequently used to print 3-D physical models of a patient's teeth. *Id.* The aligners, *i.e.*, the incremental dental positioning adjustment appliances, are formed over the physical models of the teeth. *Id.*

Below is an image of a computer model of the teeth.



CX-90C at 54.

Below is a picture of a physical model of teeth.

CX-875C. CCUS forms aligners by thermoplastic molding over a physical model of the teeth. Tr. at 318:4-7.

2. Accused Processes

As set forth below, the ALJ found the process implemented by CCPK and CCUS to produce the digital data sets and subsequent dental positioning adjustment appliances to constitute the "accused process." CCUS performs certain steps in the United States and CCPK performs certain steps in Pakistan. *See* ID at 472-73.

a. Scanning stone models into a digital model: Employees of CCUS and CCPK testified that CCUS creates digital data sets by scanning stone models of a patient's dental impressions, which represent the patient's initial tooth arrangement. ID at 472 (citing Tr. at 171:8-11; 314:19-315:18).

b. and c. Transmission of initial digital data sets (from Texas to Pakistan) and software conversion: CCUS uploads the 3D digital scan to a server for CCPK to access. ID at 698. CCPK imports the scan data into FreeForm, which is a 3D modeling software program, to prepare the initial digital data set. *Id.*

d. Sectioning: Mr. Pumphrey, an employee of CCUS, testified that CCPK sections the initial digital data sets representing the initial position of teeth for the upper and lower jaws into 16 separate teeth. Tr. at 330:11-331:5. The ALJ found that this sectioning, depicted in CX-889C, shows that the sectioning defines boundaries about the individual teeth. ID at 484 (citing Tr. at 330:13-331:5; CX-889C).

e. [[

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f. [[

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g. Transmission of treatment setup to professional for approval: Mr. Arif testified that a copy of the "treatment setup" is transmitted to CCUS, which then sends the "treatment setup" to the dentist for approval. ID at 689; Tr. at 172:10-172:14; 335:1-

13; 335:19-336:2. Transmission occurs when CCPK uploads the setup to the CCUS server. Tr. at 316:4-8.

h. Stepping process (interpolation and festooning): If the dentist in the United States approves the planned model of the final position, CCPK proceeds to the "stepping process," which consists of creating steps, or intermediate tooth positions, that move the teeth from their initial position to the final position. Tr. at 172:15-173:13. The ALJ found that the CCPK technicians use the "Generate Steps" function of the FreeForm software to generate a set of stepped locations for a tooth between two tooth positions. ID at 495 (citing Tr. at 336:11-337:9; *see also* CX-1150C at Q. 198). The ALJ found that the text in the FreeForm software regarding the "Generate Steps" function states that "[s]teps will be generated automatically by interpolating between the positions of the corresponding pieces in the starting and ending folders." *Id.* (citing CX-107C at 5:33). The operator also cleans up the models of the teeth through a process known as "festooning" after the computer has performed the interpolation. Tr. at 339:23-341:5.

i. and j. Uploading of digital data sets [[

]]: CCPK electronically transmits the digital data sets to CCUS by uploading them onto the CCUS server. Tr. at 316:12-22; 341:14-17. [[

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II. STANDARD FOR DETERMINATION ON REVIEW

Once the Commission has determined to review the decision of the ALJ, the agency has all of the powers which it would have in making the initial decision except as it may limit the issues on notice or by rule. 5 U.S.C. § 557(b); *Certain Acid-Washed Garments and Accessories*, Inv. No. 337-TA-324, Comm'n Op. at 4-5 (Aug. 6, 1992). Commission Rule 210.45(c) implements 5 U.S.C. § 557(b). In other words, once the Commission decides to review the decision of the ALJ, the Commission may conduct a review of the findings of fact and conclusions of law presented by the record under a *de novo* standard.

III. DISCUSSION

A. "Importation . . . of Articles"

There is a threshold issue that relates to all of the patent claims asserted, *i.e.*, whether Respondents' electronic transmissions of digital data sets constitute "importation of . . . articles" within the meaning of Section 337.

In their petition for review, Respondents argue that the digital data sets representing the initial, intermediate, and final positions of patients' teeth are not "articles" within the meaning of Section 337(a)(1)(B), and therefore cannot be the basis of any unfair act under the statute. Resp. Pet. at 66-67. Moreover, Respondents contend that because the accused data sets are brought into the United States by CCPK by uploading them to CCUS's server in Houston, Texas, this mode of bringing the accused products into the United States is not an importation into the United States as anticipated by Section 337(a)(1)(B). *Id.* at 67. Align and the IA oppose Respondents' position,

arguing that the ALJ correctly found that the language of the statute and its legislative history indicate that the term "articles" includes within its meaning the accused products.

The Commission affirms the ALJ's finding that the accused products are "articles" within the meaning of Section 337(a)(1)(B) and that the mode of bringing the accused products into the United States constitutes importation of the accused products into the United States pursuant to Section 337(a)(1)(B).

1. The ID

The ALJ found that the accused digital data sets are "articles" within the scope of the Commission's "jurisdiction," although he acknowledged that the issue is not necessarily jurisdictional and that he was only treating the issue as one of jurisdiction because the parties had raised the issue in that manner. ID at 17 and n.1 (discussing *Certain Drill Bits and Products Containing Same*, Inv. No. 337-TA-844, Comm'n Notice (August 22, 2012) (not adopting statement in ID that issue was jurisdictional)). The ALJ found that *Hardware Logic* is directly on point. *Id.* at 18 (discussing *Certain Hardware Logic*, Inv. No. 337-TA-383). The ALJ noted that in *Hardware Logic*, the Commission rejected the argument that software is not an "article" and that remedial orders could not reach energy, which is intangible. *Id.* (citing *Hardware Logic*, Comm'n Op. at 18, fn. 84 (Dec. 1994)). The ALJ observed that the Commission issued a cease and desist order in *Hardware Logic* that prohibited, *inter alia*, "the importation (including via electronic transmission), sale, offer for sale, lease, loan, other transfer, duplication, or distribution (including electronic distribution) of imported software and other components that contributorily infringe the patents in issue." *Id.* (citing *Hardware Logic* Comm'n Op. at 21).

The ALJ stated that this understanding of *Hardware Logic* is confirmed by the Commission's Opinion in Investigation No. 337-TA-562 (Enforcement), where the Commission cited *Hardware Logic* to hold that "it has jurisdiction and authority to reach digital data electronically transmitted to a recipient in the United States," before finding that the consent order did not expressly prohibit electronic transmissions. *Id.* at 7.

The ALJ rejected Respondents' argument that the Federal Circuit opinion in *Bayer AG v. Housey Pharmaceuticals, Inc.*, 340 F.3d 1367 (Fed. Cir. 2003), stated that Section 337 does not cover information because the court in *Bayer AG* was addressing the issue of whether or not 35 U.S.C. § 271(g) applied to claims directed to methods of use rather than methods of manufacture.[15] *Id.* at 19 (discussing *Bayer*, 340 F.3d at 1371). The ALJ concluded that any discussion in *Bayer* regarding the scope of 19 U.S.C. § 1337 was dicta and is not controlling, and that in any case, the Federal Circuit acknowledged that the scope of 19 U.S.C. § 1337 may be broader than 271(g). *Id.*

The ALJ also rejected Respondents' argument that the Federal Circuit stated in *Nuijten* that an "article" must be tangible because that case addressed the specific question of whether certain claims directed to a "signal" were invalid as being directed to non-statutory subject matter under 35 U.S.C. § 101. *Id.* at 20 (citing *In re Nuijten*, 500 F.3d 1346, 1348 (Fed. Cir. 2007)).

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[15] The Federal Circuit in *Bayer* stated:

> We recognize that section 1337 covers both articles that were "made" and articles that were "produced, processed, or mined." While this language in section 1337 perhaps suggests a broader scope for section 1337 than for section 271(g), nothing in section 1337 suggests coverage of information, in addition to articles, under section 271(g).

Bayer AG, 340 F.3d at 1374 n.9.

2. Arguments[16]

Respondents argue that neither the plain language of Section 337 nor its legislative history provide a basis for interpreting intangible, electronic transmissions as "articles." Resps. Submission at 2. Respondents assert that the Federal Circuit has already concluded that the legislative history and language of Section 337 limit "articles" to tangible items. Respondents assert that the Court concluded that "product" in § 271(g) is the same as "articles" described in Section 337. *Id.* at 2-3 (quoting *Bayer*, 340 F.3d at 1373).

Respondents argue that it is clear from the debate that led to the enactment of the Tariff Act of 1930 that members of both houses equated "articles" with tangible items, often using the term "articles" synonymously with "goods," "merchandise," and "commodities." *Id.* Respondents state that Section 337 has been amended a dozen times, but none of these amendments suggest any Congressional intent to change its long-standing interpretation of "articles" from something tangible. *Id.* at 6-7. Respondents argue that, in other legislation, Congress explicitly exempted telecommunications from tariff duties and concludes that this is express evidence of Congress's intent not to regulate the entry of digital information through telecommunications transmission. *Id.*

Respondents argue that the Commission's order in *Hardware Logic* does not hold that electronic transmission is an "importation" or that digital data is an "article." *Id.* at 10. Respondents assert that the "software" component described in the Recommended Determination ("RD") was stored on a cartridge tape and was imported only one time, on

[16] The Commission fully considered the submissions of the parties and of the public third-party submitters. The full submissions are available on the Commission website at https://edis.usitc.gov.

August 2, 1996. *Id.* (citing RD at 6, 202). Respondents assert that "nowhere in the RD or cease and desist order did the Commission hold that the possible electronic transmission of that software was an importation of an article under the statute. Nor did it hold that the electronic data itself was an 'article.'" *Id.*

Respondents argue that the Commission's ability to protect domestic patents and copyrights would not be "eviscerated" if "articles" doesn't include electronic transmissions because patent and copyright holders will have remedies elsewhere, and the Federal Circuit rejected a similar argument in *Bayer* when it construed the scope of § 271(g). *Id.* at 2

Respondents note Align's proposed definition of "articles" as "units of commerce," and argue that there is no evidence that the electronic transmissions are sold as "units of commerce." Resps. Add. Sub. at 6. Respondents state that "[i]t is clear that CCUS paid CCPK for its services rendered in total and was not paid for "units." *Id.*

Respondents contest Align's reliance on two district court decisions, *CNET* and *Ormco*. *Id.* at 3. Respondents assert that *CNET* is simply the denial of defendant's motion for summary judgment, involved § 271(g), and is distinguishable on its facts because in *CNET* the electronic catalog is bought and sold while in the instant case there is no record evidence that the computer files are bought and sold. *Id.* at 3-4. Respondents assert that *Ormco*'s holding that no product was required to be sold under § 271(g) is undercut by the Federal Circuit's holding that such a sold product is required under § 271(c) in *PharmaStem Therapeutics, Inc. v. ViaCell*, 491 F.3d 1342, 1357-58 (Fed. Cir. 2007)).

Align argues that electronic transmission of data constitutes "importation" of "articles" under Section 337. Align Sub. at 1. Align suggests that the text, legislative history, and overall purpose of Section 337 support the conclusion that the term "articles" encompasses any identifiable unit of commercial value, including electronically transmitted data. *Id.* at 1-2. Align asserts that the Commission has interpreted "importation" of "articles" accordingly in *Hardware Logic* and in *Certain Incremental Dental Positioning Adjustment Appliances and Methods of Producing Same*, Inv. No. 337-TA-562. *Id.* at 2. Align quotes the Commission Opinion in the latter case that "it has jurisdiction and authority to reach digital data that are electronically transmitted to a recipient in the United States," and states that this is a conclusion equally applicable to determinations of violation and subsequent remedy. *Id.*

Align cites dictionary definitions to support its position. *Id* at 3. Align further contends that the broad meaning of the term "articles" is set by Section 337 itself, and that its title ("Unfair practices in import trade") and its terms reflect a concern regarding commercial practices. *Id.* Complainant argues that the accompanying terms "sale for importation," "importation," and "sale after importation," indicate that Congress meant all units of commercial value - - items that can be bought, sold, or otherwise transferred. Align concludes that this is consistent with other courts' findings that digital data is an "article of commerce." *Id.* at 4. Align argues that Congress intended "article" to encompass anything that infringes, and that limiting "articles" to physical objects would arbitrarily exclude a broad range of infringing products and severely limit the ability of this agency to perform its intended function. *Id.* at 4-5. Align states that a remedial

statute should be "construed broadly to effectuate its purposes," and suggests that Section 337 is such a remedial statute. *Id.* at 7.

Align asserts that "[e]xempting electronically transmitted data from Section 337(a)(1)(B) would eviscerate the Commission's ability to protect the domestic recording, entertainment, publishing, and software industries from copyright infringement by downloadable books, movies, television programs, software, and music." *Id.* at 7. Align also suggests that new three-dimensional printers could allow importers to switch from the importation of physical products to the electronic transmission of designs for these products. *Id.*

Align notes that, in issuing a cease and desist order in *Hardware Logic*, the Commission relied on the legislative history of Section 337 and the statutory mandate to ensure adequate protection of U.S. intellectual property rights, and found that coverage of electronic transmissions was necessary in order to make the order fully effective. *Id.* at 10.

Align argues that its view is supported by the conclusions of other courts and agencies. *Id.* at 11. Align points to a statement by the Supreme Court that "[i]f there be actual bringing in [to the United States] it is importation ***regardless of the mode in which it is effected.***" *Id.* at 8 (quoting *Cunard S.S. Co. v. Mellon*, 262 U.S. 100, 122 (1923) (emphasis in brief)). Align points to a Customs ruling that "the transmission of software modules and products to the United States from a foreign country via the Internet is an importation of merchandise into the customs territory of the United States in that the software modules and products are brought into the United States from a foreign country." *Id.* at 11-12 (quoting Customs Ruling HQ 114459 (Sept. 17, 1998)). Align

similarly points to a series of Court of International Trade ("CIT") decisions interpreting Section 222 of the Trade Act of 1974, 19 U.S.C. § 2272, in which the CIT refused to read a tangibility requirement into the statute. *Id.* at 12 (citing, *inter alia, Computer Scis. Corp v. Sec'y of Labor.*, 414 F. Supp.2d at 1340-41 (CIT 2006)). Align argues that the Trade Act of 1974 was an outgrowth of the Tariff Act of 1930 and that when Congress uses the same language in two statutes having the same purposes, it is appropriate to presume that Congress intended the text to have the same meaning in both statutes. *Id.* at 12-13 (citing *Smith v. City of Jackson*, 544 U.S. 228, 233 (2005)).

Align distinguishes *Bayer*, stating that the product in *Bayer* was "information in the abstract," specifically, "the knowledge that a substance possesses a particular quality," which is not the result of practicing a patented process. *Id.* at 3. Align states that in *CNET*, the court found that an electronic catalogue, maintained as a data file and downloaded, is a product under section 271(g). *Id.*

The IA also argues that "articles" includes electronic transmissions. The IA highlights a statement from the Commission Opinion on Remedy in *Hardware Logic*, and argues that this statement would be accorded deference by the Federal Circuit under *Chevron*: "We do not think the legislative history of Section 337 precludes coverage of electronically transmitted software; in fact, we believe that it supports the conclusion that such coverage is proper." IA Reply Sub. at 4 (quoting *Hardware Logic*, Commission Opinion on Remedy, the Public Interest, and Bonding at 28 (April 1, 1998); citing *Chevron U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837, 843 (1984)). The IA argues that *Hardware Logic* necessarily supports the conclusion that electronic transmission of data is importation for purposes of violation, and that this was confirmed

recently by *Dental Appliances*, Inv. No. 337-TA-562 (Enforcement). *Id.;* IA Add. Reply Sub. at 4.

The IA further agrees with the MPAA that the Commission's practice of exercising jurisdiction over electronically imported articles is mandated by Supreme Court precedent, specifically *Cunard* and *Canton Railroad*, because importation occurs regardless of the mode an article is brought into the country. IA Add. Reply Sub. at 2-3. The IA counters Google and Katz's reliance on *Nuitjen, Bayer, NTP, Microsoft,* and *Suprema*, arguing that *Nuitjen* is directed to an issue of patentability under § 101, *Bayer* and *NTP* were directed to the scope of § 271(g), *Microsoft* was directed to the scope of § 271(f) , and *Suprema* was directed to the scope of § 271(b) not § 271(c). *Id.* (discussing *Suprema, Inc. v. ITC*, 742 F.3d 1350 (Fed. Cir. 2013); *In re Nuitjen*, 500 F.3d 1346, 1353 (Fed. Cir. 2007); *Bayer AG v. Housey Pharmaceuticals, Inc.*, 340 F.3d 1367, 1372 (Fed. Cir. 2003); *NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282 (Fed. Cir. 2005); *Microsoft Corp. v. AT&T Corp.*, 550 U.S. 437 (2007)).

Third-Party Submitter Motion Picture Association of America, Inc. ("MPAA") states that physical media are being replaced by electronic, downloadable formats. MPAA Sub. at 2. The MPAA asserts that infringement is also shifting to downloadable formats, leading to a loss of $58 billion annually, including 373,000 jobs, $16 billion in lost employee earnings, and $3 billion in tax revenue. *Id.*

The MPAA states that the legislative history of Section 337 demonstrates that Congress intended for the Commission to have very broad jurisdiction over unfair acts in international trade. *Id.* at 11. The MPAA argues that the Commission has a longstanding

practice, affirmed by the Federal Circuit, of taking a flexible approach to its jurisdiction and authority, reflecting the "realities of the marketplace." *Id.* at 11-12.

The MPAA argues that the Federal Circuit's decisions in *Suprema* and *Bayer* were related to narrow patent issues and do not bear on whether imported electronic transmissions can constitute "articles" for purposes of Section 337. *Id.* at 13.

The MPAA asserts that the remedy provisions of Section 337 do not dictate that "articles" be limited to physical objects because Section 337 also gives the Commission authority to issue cease and desist orders, and that cease and desist orders need not be limited to the situation where they aid enforcement of exclusion orders or are issued in lieu of exclusion orders. *Id.* at 3-4.

The MPAA draws a different conclusion than Google about the absence of a specific discussion of electronic transmissions in the legislative history, stating that "the technological state of affairs at the time the statute was drafted does not lock in historical amber the meaning of a general term such as the word 'articles.'" *Id.* The MPAA instead cites *Diamond v. Chakrabarty* for the proposition that a statute is not to be confined to the particular applications contemplated by the legislators, and argues that statutory silence cannot be interpreted as lack of coverage. *Id.* at 5-6 (citing *Diamond v. Chakrabarty*, 447 U.S. 303, 315-16 (1980)).

The MPAA argues that the Commission's established practice regarding its authority over electronic articles is consistent with U.S. government policy. *Id.* at 8.

Third-Party Submitter Andrew Katz asserts that Federal Circuit case law strongly suggests that electronic transmissions are not articles under either Section 337(a)(1)(B)(i) or (ii) because they are intangible. Katz Sub. at 2.

Mr. Katz states that the article in § 271(a) is the "patented invention" and that a patented invention is one within the statutory classes of patentable subject matter in 35 U.S.C. § 101. *Id.* at 3. Mr. Katz reasons that electronic transmissions cannot be patentable inventions under *In re Nuitjen*, 500 F.3d 1346, 1353 (Fed. Cir. 2007), and therefore cannot be directly infringing articles under Section 337(a)(1)(B)(i). *Id.* at 2, 11. Mr. Katz further asserts that the case law, including *Microsoft*, suggests that an article for purposes of § 271(c) must also be a tangible product. *Id.* at 4.

Mr. Katz submits that the Commission should be guided by § 271 in deciding the meaning of "article" for purposes of Section 337 because the Federal Circuit in *Suprema* indicated that the infringement provisions of Section 337 must be interpreted to be consistent with, and limited by, the court's jurisprudence under 35 U.S.C. § 271. *Id.*

Mr. Katz argues that the Commission's opinion in *Hardware Logic* has been displaced by the Federal Circuit's decisions in *Suprema* and *Bayer* and the Supreme Court's decision in *Microsoft*. *Id.* at 12-13.

Third-Party Submitter Google submits that, as a matter of law and policy, the Commission is not an appropriate forum for software patent litigation if the accused products are non-tangible electronic transmissions into the United States. Google Sub. at 2.

Google submits that the Commission has recognized the limits of its jurisdiction and remedial powers when it observed that it is a creature of statute and that its authority must be found in its enabling statute. *Id.* at 2. Google argues that the *Electronic Devices* investigation stands for the proposition that Section 337 does not apply to all instances of infringement of a U.S. patent, even with a nexus to importation, because infringement

must apply to the "articles as imported." *Id.* at 2-3 (citing *Electronic Devices*, Comm'n Op. at 14, 19).

Google points out that the Commission recently reinforced the "finding of actual 'articles protected' even with respect to licensing-based domestic industries." *Id.* at 6 (citing *Certain Computers and Computer Peripheral Devices, and Components Thereof*, and Products Containing Same, Inv. No. 337-TA-841, Comm'n Op. at 32 (Jan. 9, 2014) ("There is an 'articles' requirement for subparagraph (C), in addition to (A) and (B).") Google further argues that exclusion orders under Section 337(d)(1) and seizure and forfeiture orders, under Section 337(i), cannot apply to electronic transmissions. *Id.* at 6.

Google argues that *Hardware Logic* did not consider the full legislative history and was incorrectly decided. *Id.* at 7.

Google further argues that "it would fly in the face of Section 337" to issue cease and desist orders directed at electronic transmissions when cease and desist orders were intended to aid the enforcement of exclusion orders. *Id.* at 14. Google states that regulation of electronic transmissions by the Commission should be left for Congress to decide. *Id.*

Third-Party Submitter Association of American Publishers ("AAP") submitted a reply submission, endorsing the comments submitted by the MPAA and taking the position that "electronic transmissions" are "articles" within the meaning of Section 337. AAP Reply Sub. at 1. The AAP submits that this topic is of critical concern to the U.S. publishing industry, which produces and trades millions of eBooks around the world annually. *Id.* The AAP states that today, software, books, movies, music, and games are increasingly transmitted to consumers in machine-readable form by electronic means

such as eBooks, mp3s, etc. *Id.* The AAP argues that the need for the Commission to provide a remedy for eBooks is greater than the need to provide a remedy for physical books. *Id.*

The AAP argues that Congress has consistently intended "the primary purpose of section 337 . . . to be a trade statute to prevent unfair practice through importation of goods." *Id.* at 2 (quoting Google Sub. at 4). The AAP suggests that Congress has left the term "articles" undefined in order to ensure that the language of Section 337 remains broad enough to prevent all types of unfair practice. *Id.* at 2-3.

The AAP argues that trade includes digital trade, which includes products and services delivered via the internet. *Id.* at 3. In reaching this understanding, the AAP relies on the Commission's definition of digital trade in its report "Digital Trade in the U.S. and Global Economies, Part 1." *Id.* at 3.

Third-Party Submitter Nokia argues that *Bayer* does not establish that electronic transmissions are not articles under Section 337. Nokia argues that the court's discussion of Section 337 was dicta, that it relates to Section 337(a)(1)(B)(ii) rather than Section 337(a)(1)(B)(i), and that electronic transmission of software that can be read and combined by a device is much more than intangible information. Nokia Sub. at 8.

Nokia argues that electronic transmissions are within the Commission's remedial authority, and that the Commission has broad discretion in selecting the form, scope, and extent of the remedy. *Id.* at 8-9. Nokia argues that if a violator attempts to circumvent an exclusion order, then Section 337(f) authorizes the Commission to order the violator to cease and desist. *Id.* at 9.

3. Analysis

In this investigation, Align's infringement claims concern respondents' digital datasets and treatment plans representing the initial, intermediate, and final positions of patients' teeth for use in fabricating dental appliances for orthodontic treatment of individual patients.[17] The Commission therefore must determine whether the phrase "importation ... of articles" as used in Section 337(a)(1)(B) encompasses these digital data sets that are electronically transmitted into the United States.

The Commission affirms the ALJ's conclusion that the accused products are "articles" within the meaning of Section 337(a)(1)(B) and that the mode of bringing the accused products into the United States constitutes importation of the accused products into the United States pursuant to Section 337(a)(1)(B).

The parties' arguments revolve around the specific authority conferred upon the Commission to investigate and determine whether a violation of Section 337 has occurred by the importation or sale of infringing articles in the United States pursuant to Section 337(a)(1)(B). The language of Section 337(a)(1)(B)(i) and (ii) at issue here provides:

> (a) *Unlawful activities; covered industries; definitions*
>
> (1) Subject to paragraph (2), the following are unlawful, and when found by the Commission to exist shall be dealt with, in addition to any other provision of law, as provided in this section:
>
> ...
>
> (B) The importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that--
>
> (i) infringe a valid and enforceable United States patent or a valid and enforceable United States copyright registered under Title 17; or

[17] Align disputes that the accused products are intangible, noting that the digital data sets at issue here are physical articles whether they are stored on a physical medium, *i.e.*, a physical server or hard drive, or transmitted in between storage media. Align Sub. at 1 n.2. Further, Align argues that the act of importation into the United States from Pakistan is not complete until the entire treatment plan is saved on a U.S.-based server. Align Sub. on Issues Under Review at 7 n.9.

> (ii) are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent.

The phrase "importation . . . of articles" appears in the introductory text of Section 337(a)(1)(B) and applies to both Section 337(a)(1)(B)(i) and (ii), which define a violation by reason of articles that infringe a valid and enforceable U.S. patent or that are "made, produced, processed or mined under, or by means of" a valid and enforceable process patent. The same language is used in defining a violation of Section 337 by reference to infringement of a valid and enforceable registered U.S. copyright, a valid and enforceable registered U.S. trademark, and a vessel design protected by chapter 13 of Title 17. *See* 19 U.S.C. § 1337(a)(1)(B), (C), and (E).[18] The Commission sought briefing from the parties and the public in order to address respondents' arguments concerning whether the statutory term "importation ... of articles" may encompass the respondents' digital data sets that are electronically transmitted into the United States.[19] 78 *Fed. Reg.* 46611 (Aug. 1, 2013); 79 *Fed. Reg.* 4174 (Jan. 24, 2014).

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[18] Section 337(a)(1)(D), which relates to a registered semiconductor mask work, does not use the term "article." 19 U.S.C. § 1337(a)(1)(D).

[19] Commenters dispute whether the Commission decided this issue in *Hardware Logic* and whether it held that electronic transmissions are "articles" within the meaning of Section 337 for purposes of violation in *Hardware Logic* and subsequent determinations. In *Hardware Logic*, the products at issue were hardware logic emulation systems consisting of reconfigurable logic devices and interconnect resources that were programmed primarily via software to emulate an integrated circuit design. *Certain Hardware Logic Systems and Components Thereof* ("*Hardware Logic*"), Inv. No. 337-TA-383, Initial Determination, 1997 WL 665006 at *8 (July 31, 1997). The ALJ found that software contributorily infringed certain asserted claims, including method claims. *Id.* at *92-*98. *See also* Comm'n Op. at 27. In so ruling, the ALJ found that the software components were electronically transmitted to the United States in some instances. *Id.* at * 95. With regard to importation, the ALJ found that the importation requirement was met by undisputed evidence of respondents' importation of logic boards and components such as software, and that even if he were to accept respondents' argument regarding electronic transmission of software, respondents had also imported software on a cartridge tape on at least one occasion. ID at 6. In the RD, the ALJ, referring to the Commission's broad remedial authority to fashion a remedy once it finds a violation, found that "there is a direct nexus between respondents' importation, via electronic transmission or otherwise, and infringement of the patents in issue," and recommended an exclusion order and cease and desist order prohibiting infringing imports, including electronic transmissions. RD at 197. Noting that "the Commission has the

We acknowledge that the construction of the term "articles" is a difficult question in part because the term "articles" is not expressly defined in the statute. The term "articles" in connection with unfairly traded imports originated in the 1922 Tariff Act and was re-enacted in the Tariff Act of 1930 at a time when internet downloads were not in existence. We have carefully examined the arguments of the parties and the third-party submitters on this issue. On balance, the Commission concludes that the statutory construction of "articles" that hews most closely to the language of the statute and implements the avowed Congressional purpose of Section 337 encompasses within its scope the electronic transmission of the digital data sets at issue in this investigation.

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legal authority to cover electronic importations," the Commission issued a cease and desist order including electronically transmitted software within its scope. *Hardware Logic*, Comm'n Op. on Remedy, the Public Interest, and Bonding, 1998 WL 307240 at *1 (March 1998). The Commission also issued an exclusion order, but declined to extend the scope to cover electronic transmissions deferring to Customs' enforcement position. *Id.* at *11, *15.

In *Certain Systems for Detecting and Removing Viruses or Worms, Components Thereof, and Products Containing Same*, Inv. No. 337-TA-510, respondent Fortinet's accused products were an encased combination of hardware and software. Final ID at 57 (May 9, 2005). The parties stipulated that at least certain hardware components were imported and either included the software or had the software installed in the United States after electronic transmission of the software to Fortinet's U.S. facility. The Commission determined not to review the ALJ's finding of violation. Notice, 70 *Fed. Reg.* 40731 (July 14, 2005). Consistent with *Hardware Logic*, the Commission included electronic transmissions in the cease and desist order but not the exclusion order. Comm'n Op. at 4-5 (August 23, 2005).

In *Certain Set Top Boxes and Components Thereof*, Inv. No. 337-TA-454, the accused products were hardware devices with software. The ALJ recommended an exclusion order covering software, RD at 306 (June 21, 2002), but the Commission determined not to review the ALJ's finding of no violation and therefore did not reach the issue of remedy. Notice, 67 *Fed. Reg.* 56856 (Sept. 5, 2002). The RD is a recommendation and has no legal effect itself. *See Key v. Sullivan*, 925 F.2d 1056 (7th Cir. 1991).

In *Certain Machine Vision Software, Mach. Vision Systems*, Inv. No. 337-TA-680, the ALJ found importation based on electronic transmission of software. Both the final ID and the Commission found no violation of Section 337. *See* ID at 96; Commission Notice, 75 *Fed. Reg.* 71146 (Nov. 22, 2010) (modifying the ID and finding no violation of Section 337 based on invalidity under 35 U.S.C. § 101). The ALJ noted in the ID that it was not disputed that the importation requirement may be satisfied by electronic transmission based on *Hardware Logic*, ID at 8 and n.2. The only importation issue in the final ID was with regard to Resolution Technology and Visics. They argued that they obtained their products from MVTec in the United States. But MVTec had been found to import in Order No. 60, so Resolution Technology and Visics were found to "sell after importation." It is unclear from Order No. 60 (and thus unclear from the ID) whether the ALJ relied on electronic transmission for importation.

Most recently in the related proceeding, *Certain Incremental Dental Positioning Adjustment Appliances and Methods of Producing Same*, Inv. No. 337-TA-562 (Enforcement), Public Comm'n Op. (Feb. 19, 2013), the Commission held that the scope of its cease and desist orders and consent orders can cover electronic transmissions when explicitly recited in those orders. That proceeding did not address whether electronic transmissions of digital data are articles in the context of violation.

The statute was drafted with broad language that encompasses imports that infringe the major forms of intellectual property rights – patent, trademark, and copyright – as well as other forms of unfair acts and methods of competition. Moreover, each time the statute has been amended, the legislative history has stated that the legislative purpose is to prevent every type of unfair act in connection with imported articles (assuming, starting with the Trade Act of 1974, consistency with the public interest) and to strengthen protection of intellectual property rights. To faithfully carry out the clear purpose of the statute in accordance with Congress's intent, the Commission concludes that "articles" cannot be limited in the manner argued by the respondents.

Our analysis begins with the language of the statute. *Perrin v. United States*, 444 U.S. 37, 42 (1979). The term "articles" in connection with unfair acts relating to imports first appeared in Section 316 of the 1922 Tariff Act, which was the predecessor to Section 337 of the Tariff Act of 1930. The 1922 Act provided remedies against unfair methods of competition and unfair acts in connection with articles imported or sold in the United States. This provision was re-enacted with some modifications in 1930. With each subsequent amendment, the term "articles" was retained in the statutory provisions circumscribing unfair acts in connection with importation.

"Articles" is not explicitly defined within Section 337. Notably, there are no statutory words of limitation used in conjunction with "articles" in Section 337 that would restrict the category, type, or form of imports that are covered by the scope of "articles" subject to Section 337. The fact that Congress did not place express restrictions limiting the scope of "articles" to any particular type or form is instructive as to the meaning of this term. *See generally* 2A Singer, Sutherland Statutory Construction

§ 47.38 (7th ed. 2007) ("In construing a statute, it is always safer not to add or to subtract from the language of the statute unless imperatively required to make it a rational statute."); *62 Cases of Jam v. United States,* 340 U.S. 593, 596 (1951) (in statutory construction, the court's role "is … to ascertain – neither to add nor to subtract, neither to delete nor to distort"). Likewise, the statutory language at issue here does not encompass some infringing importations while excluding others. *See United States v. Simpson,* 252 U.S. 465, 466-67 (1920) (refusing to confine the meaning of "transported" to be limited to transportation for hire or by public carriers and thereby exclude transportation by automobile).

Consistent with these authorities, the Commission, having examined the identical statutory language at issue here, has previously refused to impose limitations upon the term "articles" that were not mandated by this statutory language. *See Certain Sputtered Carbon Coated Computer Disks and Products Containing Same, Including Disk Drives,* Inv. No. 337-TA-350, USITC Pub. 2701, Comm'n Op. at 4-10 (Nov. 1993) (rejecting respondents' proposed construction of "articles" as restricted to "articles of foreign manufacture" because the statutory term "articles" contained no such restriction). In so doing, the Commission stated that "it is not appropriate for the Commission to insert into the statute jurisdictional limitations not placed there by Congress." *Id.* at 5. Thus, the Commission finds that the statutory language does not circumscribe the category of items that fall within the scope of articles. It appears to broadly cover infringing imports, without express limitation as to form or type of said articles.

To further ascertain the Congressionally intended scope of "articles," it is helpful to look to contemporaneous dictionaries to understand the plain and ordinary meaning of

"article" at the time of enactment. *See FDIC v. Meyer*, 510 U.S. 471, 476 (1994) (looking to dictionary definition); *Hibbs v. Winn*, 542 U.S. 88, 117 (2004) (contemporaneous dictionary is the relevant dictionary).

Contemporaneous definitions of "article" embrace a generic meaning that is synonymous with a particular item or thing, such as a unit of merchandise.[20] A 1924 edition of Webster's, which uses the 1909 edition's typesetting, defines "article," in pertinent part, as "Something considered by itself and as apart from other things of the same kind or from the whole of which it forms a part; also, a thing of a particular class or kind; as, an article of merchandise; salt is a necessary article." Harris, WEBSTER'S NEW INTERNATIONAL DICTIONARY OF THE ENGLISH LANGUAGE at 131, G. & C. Merriam Co. (1924).[21] Thus, the term "article" was understood at the time of the enactment of the Tariff Act to carry the meaning of an identifiable unit, item, or thing, with examples indicating that such articles may be traded in commerce or used by consumers.

Another common definition of the term "article" is a piece of writing included with others in a newspaper, magazine, or other publication. *See, e.g.*, Funk, NEW STANDARD DICTIONARY OF THE ENGLISH LANGUAGE, Funk & Wagnalls Co. at 162 (1929)

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[20] Some definitions of "article," in addition to stating a broader generic meaning, also set forth a more granular meaning of a material thing. For example, a 1929 edition of Funk and Wagnalls defines "article," in pertinent part, as: "A particular object or substance; a material thing or class of things; as, an article of food." Funk, NEW STANDARD DICTIONARY OF THE ENGLISH LANGUAGE, Funk & Wagnalls Co. at 162 (1929). The Federal Circuit, interpreting 35 U.S.C. § 271(g), noted one definition of "article" in Webster's Third New International Dictionary (a more recent edition of Webster's). "Article" is there defined as "one of a class of material things . . . pieces of goods; COMMODITY." *Bayer AG v. Housey Pharmaceuticals, Inc.*, 340 F.3d 1367, 1372 n.4 (Fed. Cir. 2003). Thus, while an "article" was understood to include something material, as shown in the text above, the term was also understood to embrace a broader meaning that describes something that is traded in commerce.

[21] More recent context relevant definitions of "articles" are in accord. *See, e.g.*, WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY (2002) ("5: a material thing"; ... "6a: a thing of a particular class or kind as distinct from a thing of another class of kind"); RANDOM HOUSE WEBSTER'S UNABRIDGED DICTIONARY (2nd Edition 2001) ("2. An individual object, member, or portion of a class; an item or particular; an article of food; articles of clothing; ... 4. An item for sale; commodity").

(providing an alternate definition of "article" as "A brief composition, as in a serial publication; an essay; a paper; as, an *article* in the morning daily."); Harris, WEBSTER'S NEW INTERNATIONAL DICTIONARY OF THE ENGLISH LANGUAGE at 131, G. & C. Merriam Co. (1924) (also defining "article" as "A literary composition forming an independent portion of a magazine, newspaper, or cyclopedia, etc."). Courts have long recognized various unfair competition causes of action for misappropriation when such literary works (articles) are electronically transmitted, including when the gravamen of the cause of action is the mere data contained within a broader arrangement of literary work.. *See, e.g., International News Service v Associated Press*, 248 US 215, 234 (1918) (misappropriation of "fresh" news within "news articles") (citing *Board of Trade v. Christie Grain & Stock,* 198 US 236 (1905) (wrongful appropriation of price quotes), and *National Tel. News Co. v. Western Union Tel. Co.,* 119 F. 294 (7th Cir. 1902) (injurious appropriation of news sent by telegraph before printing on ticker tape)).

The meaning of "articles" must also be interpreted in the context in which it appears in the statute. *Dolan v. United States Postal Service*, 546 U.S. 481, 486 (2006). In the statutory provisions defining a violation of Section 337, 19 U.S.C. §§ 1337(a)(1)(A), (B), (C), and (E), "articles" appears in conjunction with the terms "importation" and "sale," indicating that articles subject to the statute are imported items that are bought and sold in commerce. Pertinent to the present inquiry, both the Supreme Court and appellate courts have held that digital files are "articles of commerce." *Reno v. Condon* 528 U.S. 141, 148 (2000) ("Because drivers' information is, in this context, an article of commerce, its sale or release into the interstate stream of business is sufficient to support congressional regulation."); *Senne v. Vill. Of Palatine,* 695 F.3d 617, 620 (7th

Cir. 2012) ("Notably, *Reno* does not appear to rely on the *sale* of any information. Instead, it identifies the information that the state possesses and 'release[s]' into interstate commerce as 'an article of commerce.'") (emphasis in original). Further, with respect to importation, the Supreme Court explained in *Cunard S.S. Co. v. Mellon*, 262 U.S. 100, 122 (1923) that importation "consists in bringing an article into a country from the outside. If there be an actual bringing in it is importation regardless of the mode by which it is effected." *See also Canton Railroad Co. v. Rogan*, 340 U.S. 511, 515 (1951) ("to import means to bring into the country"). Accordingly, based on the juxtaposition of the term "articles" in relation to "importation" and "sale" in the violation provisions of Section 337, 19 U.S.C. §§ 1337(a)(1)(A), (B), (C), and (E), the Commission finds that the intended meaning of "articles" encompasses such items as are bought and sold in commerce and that are imported into the United States, regardless of the mode of importation. This meaning is consistent with the title of Section 337, "Unfair Practices in Import Trade," which further indicates that "articles" are involved in "import trade." *See Federal Trade Commission v. Mandel Bros. Inc.*, 359 U.S. 385, 388-89 (1959) (title of a statute is "a useful aid in resolving an ambiguity").

Moreover, in defining a Section 337 violation in connection with statutory intellectual property rights (as in the present investigation), the term "articles" appears in the phrase "articles that infringe" a patent, a registered trademark, and a registered copyright. 19 U.S.C. §§ 1337(a)(1)(B) and (C). Similarly, with respect to protected vessel hull designs, a violation is defined by an "article," the importation or sale of which "constitutes infringement of the exclusive rights in a design protected under chapter 13 of Title 17." 19 U.S.C. § 1337(a)(1)(E). The Supreme Court has found that digital

distribution of copyrighted songs and movies can infringe a U.S. copyright. *See, e.g., MGM Studios, Inc. v. Grokster, Ltd.*, 545 U.S. 913 (2005). Similarly, the use of trademarks on websites, or in internet domain names, can infringe a U.S. trademark under the Lanham Act or the Anticybersquatting Consumer Protection Act. *E.g., Voice of the Arab World, Inc. v. MDTV Medical News Now, Inc.*, 645 F.3d 26, 36 (1st Cir. 2011); *Coca-Cola Co. v. Purdy*, 382 F.3d 774, 778 (8th Cir. 2004). Thus, based on the statutory phrase "articles that infringe" with respect to statutory intellectual property rights in 19 U.S.C. §§ 1337(a)(1)(B), (C), and (E), the Commission finds that the meaning of "articles" is intended to encompass imported items of commerce as to which a finding of infringement of a patent, trademark, copyright or protected hull design may be sustained (provided that all other requirements of the statute are met).

Similarly, in defining a violation under Section 337(a)(1)(A) in connection with other "unfair methods of competition and unfair acts," the phrase "importation of articles" appears with the description that the "articles" at issue in the subparagraph are "other than articles provided for in subparagraphs (B), (C), (D), and (E)." 19 U.S.C. § 1337(a)(1)(A). *See TianRui Group Co. Ltd. v. ITC*, 661 F.3d 1322, 1331 (Fed. Cir. 2011) (citing S.Rep. No. 67–595, pt. 1, at 3 (1922) ("The provision relating to unfair methods of competition is broad enough to prevent every type and form of unfair practice and is, therefore, a more adequate protection to American industry than any antidumping statute the country ever had."). As an example, the Commission has held that trade secret misappropriation in the context of the importation of articles can constitute an unfair act under Section 337(a)(1)(A). *See, e.g., Rubber Resins and Processes for Manufacturing Same*, Inv. No. 337-TA-849, Comm'n Op. (Jan. 15, 2014). Based on the use of the broad

phrase "unfair methods of competition and unfair acts" in connection with "articles" in defining a violation of Section 337(a)(1)(A), the Commission finds that this subparagraph of the statute further suggests a broad meaning of "articles" that embraces imported items without limitations as to form or type of the articles.

Additional guidance as to the intended meaning of "articles" may be gleaned from the understanding of legislators considering the bill at the time of enactment. *See, e.g., Mastro Plastics Corp. v. National Labor Relations Bd.* 350 U.S. 270, 287-88 (1956) (discussing legislative reports and debates). The House and Senate Reports of the 1922 and 1930 Acts and Congressional debate refer to articles as synonymous with goods, commodities, and merchandise. *See* S. Rep. 67-595 at 3 (1922); H. R. Rep. 71-7 at 3 (1929); 71 Cong. Rec. S. 3872, 4640 (1929). The meanings of these terms, according to BLACK'S LAW DICTIONARY (2nd ed. 1910) in use at that time, indicate that the term "articles" broadly covers items that are bought and sold in commerce. *Id.* ("1. an item acquired through contract or purchase."). These definitions do not provide any particular limitations as to specific categories of articles, or specific forms or types of articles that would fall outside the ambit of Section 337's proscriptions. Indeed, these definitions of goods, merchandise, and commodities would encompass within their meaning various types and forms of products that are bought and sold in commerce.[22] These commercial terms have retained their expansive meanings even as the fundamental nature of international commerce has evolved over the many decades since Section 337 was

[22] Even if, as respondents contend, legislators in 1930 had contemplated goods, merchandise, and commodities to be the types of products traded at that time, the Supreme Court "frequently has observed that "a statute is not to be confined to the 'particular application[s] . . . contemplated by the legislators.'" *Diamond v. Chakrabarty,* 447 U.S. 303, 315-16 (1980) (quoting *United States v. Barr,* 324 U.S. 83, 90 (1945). *Accord Browder v. United States,* 312 U.S. 335, 339 (1941); *Puerto Rico v. Shell Co.,* 302 U.S. 253, 257 (1937)).

originally enacted. We note recent developments that show the acceptance of digital goods traded in commerce as falling within international trade. Senators Baucus and Hatch and Congressman Camp have introduced Trade Promotion Authority bills that instruct the Administration to seek increased protections for digital trade in future trade agreements. S.1900, 113th Congress, introduced January 9, 2014; H.R.3830, 113th Congress, introduced January 9, 2014. Moreover, Congress has requested that the Commission study the impact of digital trade under Section 332, another part of Title 19.[23] *See* Digital Trade In the U.S. and Global Economies, Part I, Inv. No. 332-531, USITC Pub. 4415 (July 2013) (recognizing trade in digital products as U.S. and global commercial activity).[24] Commenters have cited a number of industry and academic papers that have treated digital goods as articles of commerce.[25] Accordingly, the commercial terms that were used in the legislative history synonymously with "articles" suggest that Congress intended the statute expansively to embrace "articles" that may be traded in commerce, regardless of form or type.

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[23] Following receipt of a request dated December 13, 2012 from the Senate Committee on Finance under section 332(g) of the Tariff Act of 1930 (19 U.S.C. §1332(g)), the U.S. International Trade Commission instituted investigation Nos. 332-531 and 332-540, Digital Trade in the U.S. and Global Economies, Parts I and II.

[24] In its Digital Trade Report, the Commission requested public comments on how to describe digital trade in the context of the broader economy. The Commission adopted the following definition of digital trade: "Defined in this report as the delivery of products and services over either fixed line or wireless digital networks. This definition includes U.S. domestic commercial activity as well as international trade. It excludes commerce in most physical goods, such as goods ordered online and physical goods that have a digital counterpart such as books and software, music, and movies sold on CDs or DVDs." Digital Trade In the U.S. and Global Economies, Part I, Inv. No. 332-531, USITC Pub. 4415, at xii (July 2013).

[25] *See, e.g.,* MPAA Reply Sub. at 10 (citing recent publications including: Joshua Meltzer, "Supporting the Internet as a Platform for International Trade," Brookings Institution, Global Economy & Development Working Paper 69 (Feb 2014); Powering the Digital Economy: A Trade Agenda to Drive Growth," Business Software Alliance (2014); Edward Gesser, The Internet and the Next Generation's Global Economy," Progressive Economy (Jan. 30, 2014); Drs. William Kerr and Chad Moutray, "Economic Impact of Global Software Theft on U.S. Manufacturing Competitiveness and Innovation," National Association of Manufacturers and National Alliance for Jobs and Innovation (2014).

Importantly, the Commission must construe the term "articles" in such a manner as to faithfully implement the express purpose for which Congress enacted the statute. The central purpose of Section 337, since the enactment of the original statute in 1922, has been to prevent every type of unfair act or practice in import trade that harms U.S. industries. *See, e.g.,* S. Rep. 67-595, at 3 (1922) ("The provision relating to unfair methods of competition is broad enough to prevent every type and form of unfair practice and is, therefore, a more adequate protection to American industry than any antidumping statute the country ever had."); *see also* H. R. Rep. 100-40 at 155 (1987).

The Commission's reviewing courts have instructed that the terms of the statute must be construed to effectuate this central purpose of Section 337. The Court of Customs and Patent Appeals explained that Congress intended for a broad interpretation of the statutory terms of Section 337:

> The statute here under consideration provides broadly for action by the Tariff Commission in cases involving 'unfair methods of competition and unfair acts in the importation of articles', but does not define those terms nor set up a definite standard. As was noted in our decision in *In re Northern Pigment Co.*, 71 F.2d 447, 22 C.C.P.A., Customs, 166, T.D. 47124, the quoted language is broad and inclusive and should not be held to be limited to acts coming within the technical definition of unfair methods of competition as applied in some decisions. The importation of articles may involve questions which differ materially from any arising in purely domestic competition, and it is evident from the language used that Congress intended to allow wide discretion in determining what practices are to be regarded as unfair.

In re von Clemm, 229 F.2d 441 (CCPA 1955). Similar guidance was provided by the Federal Circuit in *TianRui* in which the Court stated that "Congress intended a similarly broad and flexible meaning when it used the same language [as the Federal Trade Commission Act] to prohibit 'unfair methods of competition' in importation." *TianRui*

Group Co. Ltd. v. ITC, 661 F.3d 1322, 1331 (Fed. Cir. 2011). Pertinent to the issue of "articles," the *Tian Rui* Court noted that "Congress contemplated that, in exercising its new authority over unfair competition, the Commission would consider conduct abroad in determining whether *imports that were the products of, or otherwise related to, that conduct* were unfairly competing in the domestic market." *Id.* at 1332. In accordance with our reviewing Court's instructions and to ensure that we properly implement Congressional intent, the Commission reviews the pertinent legislative history of Section 337 below.

The legislative history emphasizes the central purpose of preventing every type of unfair act or practice in connection with imported articles (assuming, starting with the Trade Act of 1974, consistency with the public interest), and endeavors to strengthen the reach of Section 337 to provide effective relief to U.S. industries that are harmed by imported articles. As the Court of Customs and Patent Appeals noted in *Frischer & Co. v. Bakelite Corp.*, "the purpose of the law is to give to industries in the United States, not only the benefit of favorable laws and conditions to be found in this country, but also to protect such industries from being unfairly deprived of the advantage of the same and permit them to grow and develop." 39 F.2d 247, 259 (C.C.P.A. 1930). *See also In re Orion Co.*, 71 F.2d 458 (CCPA 1934) ("these various provisions were intended to shelter, protect, and conserve the industries of the United States, as well as to provide revenues.").

The legislative history of the 1930 Act demonstrates Congress's continuing concern with protection of U.S. industries from unfairly traded imported articles. *See, e.g.*, H.R. Rep. 71-7 at 166 (1929); S. Rep. 71-37, at 68 (1929). This legislative history

also evinces Congress's recognition that innovation would yield many new types and forms of articles that would be traded in commerce in the future. For example, a Congressional Report accompanying the Tariff Act of 1930 recognizes that many new goods and manufacturing processes had been invented and brought to the U.S. market since the 1922 Act, and anticipates that many new goods and processes would come in the future. H. R. Rep. 71-7 at 3-4. It was also noted that U.S. industries needed protection from competition, particularly unfair competition, so that they could come forward with these new goods and processes. *See id.* at 4, 166. This forward-looking recognition in the legislative history that innovation would bring new goods to the U.S. market, and that U.S. industries needed protection against unfairly traded goods to foster such innovation, indicates that the term "articles" should be construed flexibly to fit new technologies. *See Diamond v. Chakrabarty,* 447 U.S. 303, 316 (1980) ("Congress employed broad general language in drafting § 101 precisely because such inventions are often unforeseeable."); *WGN Continental Broadcasting Co. v. United Video, Inc.*, 693 F.2d 622, 627 (7th Cir. 1982) (Congress intended definitions to be interpreted flexibly so that as new technologies appeared, Congress wouldn't have to update the statute periodically).

Likewise, the Trade Act of 1974 strengthened the statute to protect against unfairly traded imports by providing additional remedies for a violation, namely cease and desist orders, and by providing authority to the Commission itself to administer the statute and issue remedies. In so doing, the legislative history echoes the concerns of previous Congresses that Section 337 should provide strong protections against unfair

acts in connection with imported articles. *See, e.g.*, H.R. Rep. 93-571 at 77-79 (1973); S. Rep. 93-1298 at 193-200 (1974).

By the mid-1980s, Congress recognized the growing problems that infringing imports posed for U.S. intellectual property rights owners. The Omnibus Trade and Competitiveness Act of 1988 further strengthened Section 337 with respect to the protection of intellectual property rights and expressed the will of Congress to encompass within its scope infringing imports:

> Any sale in the United States of a product covered by an intellectual property right is a sale that rightfully belongs to the holder or licensees of that property. The importation of ***any infringing merchandise*** derogates from the statutory right, diminishes the value of the intellectual property, and thus indirectly harms the public interest.

S. Rep. 100-71 at 128-29 (1987) (emphasis added); H.R. Rep. 100-40 at 156 (1987) (same).

In further amending Section 337 in the Uruguay Round Agreements Act of 1994, Congress continued to emphasize the focus of Section 337 as authorizing the Commission "to exclude goods from the United States and enjoin activities with respect to imports that are found to infringe U.S. intellectual property right or are otherwise found to violate that statute." H.R. Rep. 100-826 at 140. The 1994 Act made certain procedural changes to remove the time limits on Commission proceedings and to stay simultaneously filed parallel district court litigation. H.R. Rep. 100-826 at 140 (1994); S. Rep. 103-412 at 118 (1994). The 1994 amendments made no change in the substance of the unfair acts or scope of the articles that are subject to a finding of a statutory violation.

Respondents urge the Commission to find that the term "articles" cannot be construed to include within its meaning the subject digital data sets that are electronically

transmitted into the United States, relying principally upon the Federal Circuit's decision in *Bayer AG v. Housey Pharmaceuticals, Inc.*, 340 F.3d 1367, 1372 (Fed. Cir. 2003). Resp. Sub, at 2-4. *Bayer*, however, is of limited relevance to the proper construction of the statutory term "articles," and does not mandate a different conclusion. At issue in *Bayer* was a patented method for screening substances to ascertain whether the substance inhibits or activates a particular protein. *Id.* at 1369. The practice of the patent there resulted in "information in the abstract," specifically, "the knowledge that a substance possesses a particular quality." *Id.* at 1371-72, 1376. Housey alleged that Bayer was liable as an infringer under 35 U.S.C. § 271(g), *not* 19 U.S.C. § 1337 (a)(1)(B), when it imported this "knowledge" or "information" obtained from performing the Housey patented methods. In finding that § 271(g) did not cover this type of abstract research data or information, the Federal Circuit held that the statutory term "made" in § 271(g) means "manufactured." According to the Court, the production of the information at issue was not within the scope of "manufacture."

In its analysis, the Federal Circuit examined the 1988 legislative history of 35 U.S.C. § 271(g) and Section 337(a)(1)(B)(ii). In so doing, the Court did not purport to ascertain the parameters of the Commission's Section 337 jurisdiction, but rather was construing 35 U.S.C. § 271(g). Indeed, the Court noted in a footnote that Section 337 may have a broader scope than 35 U.S.C. § 271(g), although it observed, without analysis, that Section 337 does not indicate that § 271(g) covers the type of "information" about the inhibitive or activating characteristics of a substance obtained through the practice of the process patent that was at issue in that case. *Id.* at 1374 n.9 ("We recognize that section 1337 covers both articles that were 'made' and articles that were

'produced, processed, or mined.' While this language in section 1337 perhaps suggests a broader scope for section 1337 than for section 271(g), nothing in section 1337 suggests coverage of information, in addition to articles, under section 271(g)."). As is clear from the Court's recitation of the specific "information" pertaining to the patent at issue in that case, that "information" obtained through the practice of the patent at issue in *Bayer* was whether a substance was an inhibitor or an activator of a protein. Thus, *Bayer* provides little, if any, guidance concerning the articles at issue here. In contrast to *Bayer,* the articles at issue here comprise infringing digital data sets that are models of an individual patient's teeth, as well as the aligners made therefrom, that result in incremental movements of those teeth through successive orthodontic treatments.

Comments of third party submitters present practical considerations that echo the concern of legislators in enacting Section 337 in order to protect U.S. industries against unfairly traded imports. The Motion Picture Association of America ("MPAA") and the Association of American Publishers ("AAP") describe the transition by IP-based industries to digital distribution (including industries producing motion pictures, software, books, music and games). MPAA Sub. at 2; AAP Sub. at 2. Both groups describe the problems of infringement by illegal download and streaming, and the importance of Section 337 to IP-based industries.[26] They point out that protecting the copyrights of U.S. companies from the importation of these infringing articles that are electronically transmitted by foreign sources is consistent with the intent of Congress and the longstanding purpose of Section 337. MPAA Sub. at 10-13; AAP Sub. at 3.

[26] MPAA estimates the cost of such infringement to the U.S. economy at $58 billion annually, including more than 373,000 jobs, $16 billion in lost employee earnings, and $3 billion in federal, state, and local tax revenue. MPAA Sub. at 2-3. MPAA cites numerous Congressional and industry studies that have estimated losses to the U.S. economy due to such IP infringement. *Id.* at 2-4.

MPAA also points out that construing "articles" in Section 337 to cover electronic transmissions is consistent with established practices of U.S. Customs and Border Protection ("CBP") and the Department of Labor ("DOL"). MPAA notes that CBP, which is charged with interpreting and administering the Harmonized Tariff Schedule of the United States ("HTSUS"), has ruled that the transmission of software modules and products into the United States via the internet constitutes an importation of foreign merchandise into the United States. MPAA Sub. at 8 (citing HQ 114459, 1998 US CUSTOM HQ LEXIS 640 (Sept. 17, 1988)). Similarly, MPAA notes that DOL, which administers trade adjustment assistance to U.S. workers displaced by imported products under the Trade Adjustment Assistance Act,[27] has ruled as a matter of policy that "[s]oftware and similar intangible goods that would have been considered articles ... if embodied in a physical medium will now be considered to be articles regardless of their method of transfer. *Id.* (citing 71 Fed. Reg. 18355, 18357 (Apr. 11, 2006)).[28] We more broadly observe that MPAA's submission shows that U.S. federal agencies charged with responsibilities over international trade agree that digital merchandise are articles of international commerce.

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[27] The Trade Adjustment Assistance Act ("TAA") was part of the Trade Expansion Act of 1962, Pub. L. 87-794, 76 Stat. 883.

[28] MPAA also cites a 2006 CIT decision finding that electronic transmissions of software were "articles produced" within the meaning of the TAA. MPAA Sub. at 8-9 (citing *Former Emps. of Computer Scis. Corp. v. Secretary of Labor*, 414 F. Supp.2d 1334 (Ct. Int'l Trade 2006); *Former Emps. Of Merrill Corp. v. United States*, 483 F. Supp. 2d 1256, 1257-68 (Ct. Int'l Trade 2007)). We note, for completeness, a Federal Circuit decision in *Woodrum v. United States*, 737 F.2d 1575 (Fed. Cir. 1984), "affirm[ing] on the basis of [the CIT] opinion," 564 F.Supp. 826, 829 (CIT 1983). In the CIT opinion, the CIT construed the TAA language "articles produced" such that "production under section 222(3) requires the manufacture or creation of something tangible" and therefore affirmed the Labor Secretary's denial of TAA benefits to mechanics employed by an independent automobile dealership who service and prepare vehicles for retail sale because they "have not transformed articles into new and different articles." 564 F.Supp. 2d at 829. Similarly, in *Nagy v. Donovan*, 571 F. Supp. 1261, 1264 (Ct. Int'l Trade1983), the CIT held that employees who provide automotive services do not engage in production of a new and different article.

Third party Google notes that Commission exclusion orders (and seizure and forfeiture orders) enforced by U.S. Customs and Border Protection relate only to physical goods passing through U.S. ports of entry, and thus would not remediate violations involving electronically transmitted articles. *See* Google Sub. at 6-7. Exclusion orders, however, are not the exclusive remedy for violations of Section 337.[29] The statute provides for highly effective remedies in the form of cease and desist orders under Section 337(f), to prevent further electronic shipments of infringing goods. 19 U.S.C. § 1337(f)(1). Under Section 337(f), cease and desist orders may be issued "[i]n addition to, or in lieu of" an exclusion order. The Commission vigorously enforces violations of cease and desist orders, and under the statute, may impose civil penalties for violations of up to $100,000 per day. 19 U.S.C. § 1337(f)(2). Moreover, the Commission's cease and desist orders typically require the posting of a bond with the Office of the Secretary to cover continued prohibited conduct during the Presidential review period "in an amount determined by the Commission to be sufficient to protect the complainant from any injury." 19 U.S.C. § 1337(j)(3). Thus, the fact that Customs enforces exclusion orders issued by the Commission by excluding from entry physical goods passing through U.S. ports does not limit our understanding of the scope of "articles." It should be noted that

[29] It is a feature, not a flaw, for a set of remedy provisions to include some subsections that apply only in some settings; and agencies are given deference on their choices about which statutory remedy to apply so they can appropriately address the particular facts of each case . *See Butz v. Glover Livestock Commission Company, Inc.*, 411 US 182, 188 (1973) (agencies must carefully weigh their selection of authorized remedy based on the evidence and the statutory scheme); *Mourning v. Family Publications Service, Inc.*, 411 US 356, 371-72 ("We have consistently held that where reasonable minds may differ as to which of several remedial measures should be chosen, courts should defer to the informed experience and judgment of the agency to whom Congress delegated appropriate authority.")This helps to ensure that at least some remedy is available for a violation. *See* S. Rep. 93-1298 at 198 (1974) (explaining the provision for cease and desist orders in the new amendment to Section 337) ("It is clear to your committee that the existing statute, which provides no remedy other than exclusion from entry, is so extreme or inappropriate in some cases that it is likely to result in the Commission not finding a violation of this section, thus reducing the effectiveness of section 337 for the purposes intended.").

in this investigation, complainant Align requests only cease and desist orders, as discussed more fully in Part IV below.

Third parties Nokia, the AAP, and the MPAA caution that "articles" should not be construed in such a way that infringers could avoid liability under Section 337, thereby denying an avenue of relief to IP-based industries in the United States. AAP Sub. at 2; MPAA Sub. at 6; Nokia Reply Sub. at 9. For example, an infringer could shift from importing its infringing software on a disk to importing the very same software by electronic transmission. They note that "it would be anomalous for the Commission to be able to stop the transfer of a CD-ROM or diskette containing the respondents' software but not be able to stop the transfer of the very same software when transmitted in machine readable form by electronic means." MPAA Sub. at 6; AAP Sub. at 2. The Commission concurs. "It has been called a golden rule of statutory interpretation that, when one of several possible interpretations produces an unreasonable result, that is a reason for rejecting that interpretation in favor of another which would produce a reasonable result." 2A Singer, Sutherland Statutory Construction § 45.12 (7th ed. 2007). The Commission concludes, in the context of this case, that an interpretation of "articles" that allows the Commission to reach the imported physical aligners at issue in Investigation No. 337-TA-562, but does not include the infringing digital data sets from which the aligners are produced, simply because they are in digital form, is unreasonable and inconsistent with the purpose of the statute.

Finally, a few commentators argue that principles of patent law preclude a finding that electronic data transmissions constitute "articles" under Section 337. Google Sub. at 10-13; Katz Sub. at 3, 8 (citing *In re Nuitjen*, 500 F.3d 1346, 1353 (Fed. Cir. 2007)).

They argue that because an electronic transmission is not patent eligible subject matter under 35 U.S.C. § 101, section 337 should not be construed to include electronic transmissions. The Commission disagrees with this view. First, the question we are deciding – whether the "importation . . . of articles" includes digital data sets that are electronically transmitted into the United States – goes to the importation requirement, not patent eligibility *per se*.[30] Second, the argument overlooks the fact that in defining a Section 337 violation in connection with statutory intellectual property rights the term "articles" appears in the phrase "articles that infringe" a patent, a registered trademark, and a registered copyright. Thus, the commenters fail to take into account that the phrase "articles that infringe" is not simply limited to patents, but also applies to trademarks and copyrights, as well as other unfair acts and methods of competition in connection with importation and sale of articles.[31] Third, section 337 is a trade statute that is part of Title 19. As we observe above, there is a consensus among government agencies charged with responsibilities over international trade that digital merchandise are articles of

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[30] In this investigation, respondents did not raise any § 101 arguments concerning the asserted patents. Furthermore, any such arguments are more properly addressed regarding validity, not importation, and the Commission may not invalidate a patent claim *sua sponte, i.e.*, where invalidity has not been asserted by the respondent as a defense to infringement of a properly asserted claim. *See generally, Lannom Mfg. Co. v. United States Int'l Trade Comm'n*, 799 F.2d 1572, (Fed.Cir.1986). We also note that the commenters may not be correct in their suggestion that the patent claims at issue would be invalid under § 101. In cases such as this one, where the digital data sets cause a physical arrangement (here, where to place the mechanical braces used to align human teeth), the Federal Circuit has determined that §101 would be satisfied, *see In re Alappat*, 33 F.3d 1540 (Fed. Cir. 1994) (*en banc*) (digital data produced a "useful, concrete, and tangible result" in the form of a smooth curve displayed on the screen). Similarly, in cases such as this one where the digital data sets correspond to a "useful, concrete, and tangible" thing (here, the relative locations of the human teeth), the Federal Circuit has determined that § 101 is satisfied, *see also Arrhythmia Research Technology Inc. v. Corazonix Corp.*, 958 F.2d 1053 (Fed.Cir.1992) (digital data set corresponded to electrical signals in a human heart).

[31] We note, in the sections that follow, that we find that the subject imports are processed by means of patented processes and are materials for use in practicing patented processes. Here, we are solely construing the statutory term "importation … of articles" in the violation provisions of Section 337.

international commerce. Accordingly, we reject these arguments presented by Google and Katz.

In sum, our task is to determine whether the phrase "importation … of articles" encompasses this modern form of international commerce, or should be understood as limited to the kinds of international transactions in existence when the statute was first enacted. Having carefully reviewed the plain language of the statute, its legislative history and purpose, pertinent case law, and the arguments of the parties and public commenters, we conclude that the statutory phrase "importation … of articles" should be construed to include electronic transmission of digital data because the digital data sets at issue in this investigation are true articles of international commerce that are imported into the United States and their inclusion within the purview of section 337 would effectuate the central purpose of the statute.

B. Claim Construction

1. One of Ordinary Skill in the Art

The ALJ found that one of ordinary skill in the art at the time of the invention of the asserted claims of each of the patents at issue in this investigation was an individual with expertise in digital modeling and analysis and a working knowledge of orthodontic principles. ID at 28.

Align argues that it showed that one of ordinary skill in the art at the time of the inventions for each of the asserted patents would include a practicing orthodontist. Align Pet. at 33.

The issue does not affect the outcome of the investigation. However, the issue is undisputed and the Commission agrees with Align that practicing orthodontists are also persons of ordinary skill in the art.

2. "a predetermined series of dental incremental position adjustment appliances"/"predetermined series of dental incremental position adjustment appliances" (the '880 patent)

The term "a predetermined series of dental incremental position adjustment appliances"/"predetermined series of dental incremental position adjustment appliances" appears in asserted claim 1.

The parties dispute the meaning of "predetermined series" and whether or not the phrase "predetermined series" includes all appliances to be used in treatment (not just a subset) and whether or not all of those appliances must be fabricated before any treatment begins. ID at 52. The ALJ found that the claims and the specification do not support Respondents' argument that the "repositioned tooth arrangement" would have to be further limited to mean the final tooth arrangement at the ***end of treatment***. ID at 54. The ALJ explained that the specification teaches that target intermediate tooth arrangements ("key frames") are defined and intermediate digital data sets are generated between the target intermediate tooth arrangements, rather than just between the initial and final tooth arrangements. *Id.* (citing JX-0002 at 6:56-67).

The ALJ found that claim 1 requires a method that comprises four steps that are performed in order. *Id.* at 52. The ALJ reasoned that, although method claims are not ordinarily construed to require a particular order of steps, here the claims require they be performed in the order written. *Id.* (discussing *Interactive Gift Exp., Inc. v. Compuserve*

Inc., 256 F.3d 1323, 1342 (Fed. Cir. 2001)). The ALJ explained that each subsequent step in claim 1 necessarily requires the previous step to have been executed.

Align argues that the ALJ should not have construed claim 1 of the '880 patent to require that the steps be performed in an ordered process. Align Pet. at 25. Align argues that one need not obtain a "repositioned tooth arrangement" before obtaining the "series of successive digital data sets." *Id.* Align argues that the Respondents waived any such construction, and that the ALJ further erred in finding that the fourth claim element builds on the third claim element. *Id.* (citing JX-0002 at 22:26–28).

The Respondents did not comment on this claim construction in their petition or response, or in their briefing on review.

We agree with the ALJ that each step of claim 1 of the '880 patent assumes the prior completion of the previous step.[32] For example, step b is "based on the initial tooth arrangement" of step a. The digital data sets of step c are based on the tooth arrangements of step b. The dental appliances of step d are based on the digital data sets of step c. We therefore affirm the ALJ's claim construction of these terms, and adopt the ALJ's reasoning, as set forth in the ID at 51-58, including his construction that the predetermined series can be constructed prior to an intermediate aligner and need not be prior to the fabrication of all aligners. See ID at 54-55 (discussing how repositioned tooth arrangements include intermediate tooth arrangements and not just final tooth arrangements).

[32] The ALJ was not precluded from deciding that the correct claim construction is one that was not argued. *See Exxon Chemical Patents Inc. v. Lubrizol Corp.*, 64 F.3d 1553, 1558 (Fed. Cir. 1995) (Court did not adopt the construction proposed by either party).

3. "treatment plan" (the '487 patent and the '874 patent)

The term "treatment plan" appears in asserted claims 7, 8 and 9 of the '487 patent and claim 1 of the '874 patent.

The ALJ found that Respondents waived the right to offer a construction for the term "treatment plan." ID at 68 (citing Second Revised Joint Claim Construction Chart ("SRJCCC") at 8 ("No construction proposed.")). The ALJ found that the plain language of claim 7 of the '487 patent defines a "treatment plan" as "two or more successive digital data sets representing arrangements of a patient's teeth progressing from an initial tooth arrangement toward a final tooth arrangement." ID at 68-69. The ALJ found that claim 7 is not limited to final arrangements that are prescribed. Id. at 70. The ALJ relied on the plain language of claim 7, which provides that the "treatment plan" comprises "a plurality of intermediate digital data sets." *Id.* at 68-69 (citing '487 patent, col. 11, lines 26-35.) The ALJ explained that claim 7 continues to explain that the intermediate digital data sets "represent[] intermediate arrangements of the patient's teeth," and the final data set "represent[s] the patient's teeth in a desired or prescribed arrangement." *Id.* at 69 (citing '487 patent, col. 11, lines 26-35). The ALJ continued that the specification supports this understanding of beginning, middle, and final tooth arrangements. Id. at 69-70 (citing '487 patent, col. 8, lines 38-47).

The Respondents argue that the plain and ordinary meaning of "treatment plan" is the course of treatment devised by the treating dentist or orthodontist, not by a dental lab like CCUS. Resp. Pet. at 63. The Respondents highlight that Align's expert, Dr. Valley, relied on the provisional application for priority, which states: "[u]sing treatment planner software, the orthodontist then creates a series of intermediate treatment states." *Id.*

(referring to CX-1247C at Q. 115; CX-1252-007). The Respondents further point to the testimony of Mr. Jarrett Pumphrey, a witness for CCUS, and Dr. Willis Pumphrey, an orthodontist, who stated that dental labs like ClearCorrect do not prepare treatment plans. *Id.* (citing Tr. 415:4-11; Tr. 350:15-351:13). Respondents also note that Dr. Pumphrey stated that treatment by the physician is a matter of law and industry standard. Tr. 415:12-14.

Align argues that the ALJ misconstrued the claim term "treatment plan" in claim 1 of the '874 patent and claim 7 of the '487 patent. Align Pet. at 23. Specifically, Align states that the ALJ improperly imposed a requirement that the "treatment plan" include "successive digital data sets." Align argues that there is no requirement that an "initial tooth arrangement" be present in the "treatment plan," but that the ALJ's construction is ambiguous in that regard. *Id.* Align also argues that Respondents' proposed construction is based on a single embodiment described in a provisional application to which the '487 Patent claims priority, and that this limitation cannot be imported into the claim. Align Resp. to Resps. at 47 (citing *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996)). Align further argues that Respondents ignore the ***other*** embodiments described in the specification - - that either an "orthodontist or other operator" may perform the steps of treatment planning. *Id.* (quoting CX-1252 at 13).

The Commission has determined to affirm the ALJ's construction of "treatment plan," and adopt the ALJ's reasoning, as set forth in the ID at 68-74 and 102-104. By the terms of claim 7, it is the "final arrangement representing the patient's teeth" which is "desired or prescribed." '487 patent, col. 11, line 34; see also col. 1, lines 37-41

(Background of the Invention); col. 11, lines 26-35. There is no requirement that the "intermediate digital data sets" are themselves prescribed by the dentist. Rather, the purpose of the invention is to allow a computer to calculate these intermediate positions based on the patient's initial and the prescribed final position. *See* Figure 3 (flow chart); col. 5, lines 56-61.

4. "computer-implemented method" (the '511 patent and the '874 patent)

The term "computer-implemented method" appears in the preamble to asserted claim 1 of the '511 patent and claim 1 of the '874 patent.

The ALJ found that "computer-implemented method" means "a method accomplished using a computer." The ALJ found the preamble to be limiting.

Align argues that the ALJ erred in finding that the claim term "computer-implemented" should be read into each element of claim 1 of the '511 patent and claim 1 of the '874 patent, *i.e.*, Align argues that the preamble does not place a restriction on each claim element to be computer-implemented. Align Pet. at 26. Align argues that Respondents waived such an argument, and that even where a court finds a preamble limiting, the limitation is not necessarily read into each element of the claim. *Id.* at 26 (citing *MercExchange, LLC v. eBay, Inc.*, 401 F.3d 1323 (Fed. Cir. 2005), *vacated on other grounds sub. nom. eBay Inc. v. MercExchange, LLC*, 547 U.S. 388 (2006)). Align points, *inter alia*, to the specification of the '511 patent, which teaches that generating the appliances may be done manually. *Id.* at 26-27 (citing '511 patent at 5:1-6).

The Respondents did not comment on this claim construction in their petition, response, or briefing on review.

The Commission has determined to affirm the ALJ's construction of "computer-implemented method" in claim 1 of the '511 patent and claim 1 of the '874 patent, and adopt the ALJ's reasoning, as set forth in the ID at 77-81 and 93-97. The ALJ is correct that the preamble is limiting in this case because it provides structure, *i.e.*, it explains that the computer will be performing the calculations. *See, e.g., Catalina Mktg. Int'l v. Coolsavings.com*, 289 F.3d 801, 808 (Fed. Cir. 2002) (one of the types of preamble that is limiting is a preamble that provides necessary structure). While we agree with the ALJ that the claims do not preclude human supervision or intervention as a supplement to computer computation, the both patents teach that the interpolations are performed by a computer. *See, e.g.*, '874 patent (Abstract) (A computer is used to create a plan . . . "); '511 patent, col. 1, line 23-24 (Background of the Invention) ("The present invention relates to computational orthodontics"). Further, a computer may be used to provide the original digital data set for interpolation, *see* '511 patent, col. 5, line 44 – col. 6, line 5, and to manufacture ("generate") the appliance from the digital data sets through an automated process. *See* '511 patent, col. 5, lines 1-5; '874 patent, col. 30, lines 9-13. The patent's specification and claims plainly contemplate the use of a computer for each step. See also '511 patent, col. 3, line 64 - col. 4, line 4 (discussing digital models of initial and final data sets); '874 patent, col. 11, lines 49-61. Similarly, the aligners are fabricated using models of the teeth based on the computer program. *See, e.g.*, '511 patent, col. 5, line 1-5 (discussing using automated processes and electronic information for manufacturing); '874 patent, col. 19, line 30-59 (discussing using data sets and application software for manufacturing).

5. "distinct successive incremental dental positioning appliance"/"successive incremental dental positioning appliance" (the '863 patent)

The term "distinct successive incremental dental positioning appliance" appears in asserted claim 1.

The ALJ found that "distinct successive incremental dental positioning appliance"/"successive incremental dental positioning appliance" means "a single, separate appliance to be used during a particular interval for repositioning teeth."

The ALJ found that the claim language only requires that two or more digital models be produced. ID at 87-88 (citing *Apple Inc. v. Samsung Electronics Co., Ltd.*, 695 F.3d 1370, 1379 (Fed. Cir. 2012); *August Technology Corp. v. Camtek, Ltd.*, 655 F.3d 1278 (Fed. Cir. 2011)). The ALJ found that use of the term "successive" in conjunction with the terms "distinct" and "incremental" does not require fabrication of "a series." The ALJ further found that the specification and prosecution history of the '863 patent describe replacing attachment devices mid-treatment or placing new attachment devices throughout treatment, JX-005 at 7:61-64; CX-1251 at 212, and teaches away from fabricating all of the dental appliances prior to the outset of treatment. ID at 88-89.[33]

There are two issues on review: whether there is more than one dental appliance and whether dental appliances are all fabricated before the beginning of treatment. Align argues that the ALJ misconstrued the claim term "distinct successive incremental dental positioning appliance" in claim 1 of the '863 patent. Align further argues that the ALJ was correct to reject late-proposed limiting constructions by the Respondents but

[33] ID at 89 (citing '863 patent, col. 7, lines 61-64; CX-1251 at 212). The ALJ found that Respondents had waived any proposed claim construction of this term because they relied on plain meaning in the SRJCCC. The ALJ further granted Align's first motion in limine and excluded that portion of Question 120 of Dr. Mah's testimony upon which Respondents rely to support their waived argument on construction.

disagrees with the ALJ's construction to the extent it disassociates the appliance from the series of which it is a part.

The Respondents do not discuss Align's contingent petition for review in their response or briefing on review. Resps. Resp. at 9.

The IA argues that the ALJ correctly construed the disputed claim terms and suggests that Align's disagreement with the ALJ's claim constructions has no bearing on the current dispute.

Although the claim construction has no bearing on the resolution of the current dispute, the Commission reverses the ALJ's construction and concludes that claim 1 requires a series of dental appliances. Although the specification mentions "one or more attachment devices," the '863 patent, col. 3, lines 14-15, the claims recite a "plurality" of modified digital models in the claims, each to be used to fabricate "successive" appliances. '863 patent, Ex Parte Reexam. Certificate, col. 1, line 60, 64-65. We note, however, that nothing requires the entire series to be manufactured before treatment begins. *See* '863 patent, col. 7, lines 61-64.

6. "providing" (the '325 patent)

The term "providing" appears in all of the asserted claims of the '325 patent. This claim construction issue arises from the ALJ's infringement analysis. The Respondents argue that the ALJ's infringement analysis indicates an inconsistent use of the term "providing" by the ALJ. The Respondents argue that while, for most asserted claims in this investigation, the ALJ found that CCPK provided information to CCUS or that CCUS provided information to CCPK, with respect to claim 31 of the '325 patent the ALJ found that CCPK "provides" the initial digital data set internally to itself. Resps.

Pet. at 61-62 (citing ID at 475, 512).[34] The Respondents argue that the ALJ apparently realized that his application of the term "providing" is tortured because he stated in the ID that "Mr. Beers [the witness] clearly did not intend to say that CCUS provided digital models to itself, and such a statement was clearly in error," ID at 435, in explaining that the witness meant to say CCPK instead of CCUS. *Id.*

Align argues that the ALJ applied a consistent interpretation of the term "providing" across the claims. Align Resp. to Resps. at 44. Align argues that in the context of the asserted claims and intrinsic evidence, the ALJ interpreted the term "providing" to broadly cover both transmitting to an external entity or uploading into a computer or machine. *Id.* (discussing ID at 475). Align argues that the ALJ found CCPK provides the digital data set to the FreeForm software, not to itself. *Id.* (discussing ID at 475, 512). Align further argues that Respondents' argument regarding the meaning of "providing" is waived because they failed to identify the term "providing," and their newly-advanced limiting construction in any of the *Joint Claim Construction Charts* ("*JCCC*"). *Id.*

The IA argues that the Respondents' arguments with respect to the claim term "providing" should be rejected because, as admitted by ClearCorrect, the parties did not ask that the term be construed beyond its plain and ordinary meaning. IA Resp. at 22. The IA further argues that the Respondents cite no support for their proposed limitation and the claim language does not recite any restriction as to whom or to what the "providing" is directed. *Id.*

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[34] The Respondents argue that the ALJ made the same inconsistent use when he held that CCUS "provides" the modified digital data sets it actually receives from CCPK. *Id.* (citing ID at 502). The Commission does not view this usage of providing as inconsistent.

While Respondents challenge the ALJ's use of "providing" in his infringement analysis, the issue is really one of claim construction. Even where the term "providing" is used only once in a patent claim (as in claim 1 of the '325 patent), the ALJ found that both CCUS and CCPK both provide data. ID at 475. The required "providing" of data may occur by the transmission of data from CCUS to CCPK, from CCUS to CCPK, from CCUS to a computer, or from CCPK to a computer. In claim 1, with respect to one occurrence of the term "providing," the ALJ found that both CCUS and CCPK satisfied the same claim term. The ALJ found that CCUS provides the initial data set to CCPK and also that CCPK provides the initial data set to a computer (by uploading the data). ID at 436, 475. Regarding the first element of claim 11, the ALJ found that CCUS provides an initial data set to CCPK and CCPK provides an initial data set to a computer; regarding the second element of claim 11, the ALJ found that CCPK provides the final data set to CCUS and CCUS provides the data set to a treatment professional. ID at 490. Regarding claim 21, the ALJ found that CCUS provides a digital data set to a computer and also that CCPK provides a data set to CCUS. ID at 502-03. The ALJ found the first through sixth elements of claim 31 to be identical to claim 1, and found that CCPK transmits the intermediate data sets to CCUS (and found an admission that CCUS imports them into a computer). ID at 512-13. The ALJ found that CCUS and CCPK both practice the first and second elements of claim 35 and claim 38. See ID at 522, 527-28.

In our view, the ALJ used the term "providing" in accordance with its plain and ordinary meaning of conveying or giving, including by "electronically transmitting." This is consistent with the meaning of "providing" within the specification. *See, e.g.*, '325 patent, col. 5, lines 36-41 ("Conveniently, the initial digital data set may be *provided*

by conventional techniques, including digitizing X-ray images, images produced by computer-aided tomography (CAT scans), images produced by magnetic resonance imaging (MRI), and the 40 like.")(emphasis added). It does not matter if the electronic transmission was to a computer owned by another individual or to a computer owned by the same individual. The patent claims do not make a distinction as to who receives the transmission. The plain language of the claims simply requires "providing." The Commission therefore affirms the ALJ's construction of "providing" with this clarification.

7. The Standard for Claim Construction As to Claims 1 and 33 of the '325 patent, Claim 2 of the '511 patent, and Claim 2 of the '874 patent

The ALJ provided the "broadest, reasonable" construction with respect to claims 1 and 33 of the '325 patent, claim 2 of the '511 patent, and claim 1 of the '874 patent. The ALJ relied on *Genentech, Inc. v. Chiron Corporation*, 112 F.3d 495, 499 (Fed. Cir. 1997), for the "broadest reasonable construction" standard. *See* ID at 81 n.9; 97 n.12 and 9. This is, however, the standard for an interference (or reexamination) at the PTO, s*ee Genentech*, 112 F.3d at 496-96, and is not the appropriate standard for claim construction in the context of an infringement analysis in district court or at the Commission, *i.e.*, claim terms are interpreted as they would be understood by a person of ordinary skill in the art in light of their ordinary meaning, the intrinsic evidence of the specification and the prosecution history, and certain extrinsic evidence. *See, e.g., Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-17 (Fed. Cir. 2005) (*en banc*). Nevertheless, the Commission agrees with the ALJ's ultimate claim construction of these four claims. As set forth below, the ALJ correctly interpreted the claims in light of the specification and other

intrinsic evidence. Thus, we have concluded that the ALJ's incorrect statement of the standard is harmless error, as his claim construction is consistent with an application of the correct standard for claim construction.

With respect to claims 1 and 33 of the '325 patent, the ALJ's claim construction of "at the outset of treatment" was correct because the ALJ properly rejected a prosecution history disclaimer argument which was based on claim language that is not present in claims 1 and 33 of the '325 patent. ID at 39.

With respect to claim 2 of the '511 patent, the ALJ correctly construed "a method accomplished using a computer," finding that the specification contemplates direct interaction with the computer by a clinician who may reset the final position(s) of teeth and specify constraints to be applied to segmented paths. ID at 80 (citing JX-001, 4:36-50).

With respect to claim 1 of the '874 patent, the ALJ correctly construed "a method accomplished using a computer," finding that the specification allows user modification: "some embodiments allow the user to modify the underlying digital data set by repositioning a tooth in the 3D graphical representation"; "[d]eveloping an orthodontic treatment plan for a patient involves manipulating the IDDS [Initial Digital Data Set] at a computer or workstation having a suitable graphical user interface (GUI) and software appropriate for viewing and modifying the images"; and Figure 3 of the '874 patent illustrates a representative technique for user-assisted manipulation of the IDDS to produce the FDDS [final digital data set] on the computer. ID at 95-96 (citing JX-006, 3:51-53, 10:12-15, 12:4-6, 12:11-44, 12:53-62).

8. Waiver of Other Arguments

With the exception of the claim terms "providing" and "treatment plan," the Respondents do not make specific arguments in their petition for review regarding claim construction or infringement, but rather attempt to stand on and incorporate by reference their contentions about claim construction and infringement from their post-hearing brief and post-hearing reply brief before the ALJ, and as summarized by the ALJ in his ID. Resp. Pet. at 64-65. We find these arguments to be waived under Commission rule and practice. *See* 19 C.F.R. § 210.43(b)[35]; *see also Finnigan Corp. v. ITC*, 180 F.3d 1354, 1362 (Fed. Cir. 1999) ("A party seeking review in this court of a determination by the Commission must 'specifically assert' the error made by the ALJ in its petition for review to the Commission.").

The Respondents argue that incorporation by reference is reasonable because the ALJ's ID is 814 pages long and his analysis of claim construction and infringement spans approximately 421 pages. Nevertheless, the Respondents did not make any motion for an extension of the 100 page limit to the petition for review. Instead, the Respondents submitted a petition for review of 72 pages, with the argument for incorporation by reference. Moreover, to the extent that most of the claim terms and elements of the claimed processes are common to multiple claims and multiple patents, the Respondents could have made arguments directed to most of the elements of the claimed processes without the repetition found in the ALJ's ID.

[35] The Commission stated in its recent rulemaking that it "believe[d] . . . .incorporation by reference to be inconsistent with the existing rule [*i.e.*, the former version of the rule]." 76 *Fed. Reg.* 23474, 23479 (April 19, 2013). Thus, the Commission considered the recent rule to be a clarification, and a prohibition on any attempt at an end-run around the existing rule, rather than a new rule.

C. Infringement

As set forth herein, the Commission has adopted the ALJ's finding that the CCUS and CCPK accused products satisfy the claim limitations as construed. The Commission herein analyzes whether infringement has been demonstrated in light of the requirements of Section 337 for each of the four asserted groups of claims. There is also an issue with respect to the Group I claims as to whether the elements of 35 U.S.C. § 271(c) are satisfied.

1. Group I Claims (Claims 21 and 30 of the '325 patent; Claim 1 of the '880 patent)[36]

a. Direct Infringement

The Group I claims are directed to methods of manufacturing dental appliances starting with a digital data set. Prior to the accused manufacturing activity related to these claims, CCPK manipulates the digital models, thereby generating intermediate and final digital data sets in Pakistan, and electronically transmits them to CCUS in the United States. ID at 472-73. Then, as relevant to these claims, CCUS uses the generated data sets to prepare molds of the patient's teeth which are in turn used to make the physical dental appliances in the United States. ID at 473 (citing Tr. at 172:15-173:8; 316:12-318:11; CX-1150C at 200-11).

As to the '325 patent, the ALJ found that CCUS independently practices each and every limitation of asserted claim 21 in the United States, and that CCPK and CCUS act

[36] Align includes these claims in both Group I and Group IV. Align includes the claims in Group I because the ALJ found that CCUS practices the claims entirely in the United States when it "provides" the data to the fabrication machine. The ALJ also found that CCPK acts in concert with CCUS, which would place the claims in Group IV, because CCPK "provides" the data to CCUS. As noted in our claim construction section, we understand "provide" to include conveying by an electronic transfer. Therefore, these claims can be analyzed with CCUS as the sole infringer when it electronically transfers the data to the computer and also with CCPK as a joint infringer when it electronically transfers the data set to CCUS.

in concert to practice claim 21 of the '325 patent when the digital data sets created by CCPK are used by CCUS to fabricate aligners ("dental appliances"). ID at 502-503. Similarly, the ALJ found that CCUS independently, and CCUS and CCPK acting in concert, practice dependent claim 30 of the '325 patent. ID at 505.

As to the '880 patent, the ALJ found that CCUS independently practices each and every limitation of claim 1 and that the concerted efforts of CCUS and CCPK practice each and every limitation of claim 1 when the digital data sets created by CCPK are used by CCUS to fabricate aligners. ID at 571-72.

The only claim construction issue which was the subject of a petition for review is construction of "predetermined digital data sets" for claim 1 of the '880 patent. The Commission has determined to affirm the ALJ's claim construction, and therefore agrees with the ALJ that the claim elements are met. There is no dispute that, under this claim construction, there is direct infringement of the Group I claims entirely in the United States by CCUS.[37] However, since the direct infringement of the method claims occurs entirely within the United States, it does not itself constitute a violation of Section 337. *See* 19 U.S.C. § 1337(a)(1)(B); *Certain Electronic Devices*, Inv. No. 337-TA-724, 2012 WL 3246515, Comm'n Op. at *8–9 (Dec. 2011). We therefore examine in the next section whether there is indirect infringement by the digital data sets.

b. Indirect Infringement

i. The ID

[37] Joint infringement with CCPK is addressed in the section on Group IV claims, *infra*. (The ALJ found that the Group I claims are satisfied in two ways. The ALJ found that CCUS independently satisfies the Group I claims and that CCPK acts in concert with CCUS to satisfy the claims). ID at 571-72.

The ALJ found that CCPK contributorily infringes claims 21 and 30 of the '325 patent by sending the digital data sets into the United States to CCUS. ID at 549. Similarly, the ALJ found that CCPK contributorily infringes claim 1 of the '880 patent, but did not find induced infringement of claim 1 of the '880 patent because Align did not prove specific intent. ID at 589-90.

ii. Parties' Arguments

The Respondents first argue that the ALJ applied the wrong intent standard for contributory infringement. Resp. Pet. at 55. Respondents rely on *DSU Medical Corp. v. JMS Co.*, 471 F.3d 1293, 1305 (Fed. Cir. 2006) (*en banc*), and *Global-Tech Appliances v. SEB SA*, 131 S. Ct. 2060, 2068 (2011) for the proposition that inducement requires knowledge that the induced acts constitute patent infringement. *Id.* The Respondents further note that the Supreme Court in *Global-Tech* adopted a willful blindness test for inducement. Resp. Pet. at 55-56 (citing *Global-Tech*, 131 S. Ct. at 2070). The Respondents argue that the intent required to show contributory infringement is at least as high, if not higher, than the standard for induced infringement. Resp. Pet. at 56 (citing *Global-Tech*, 131 S. Ct. at 2067-68; *Aguirre v. Powerchute Sports*, LLC, 2011 WL 3359554 (W.D. Texas 2011); *Bose Corp. v. SDI Technologies Imation Corp.*, 2012 WL 2862057 (D. Mass. 2012)).

The Respondents argue that with respect to the '325 and the '880 patents, the ALJ found only that the Respondents were aware of the patents, but did not satisfy the willful blindness standard for liability. Resp. Pet. at 57. Respondents argue that the ALJ's

finding that there was no intent to induce direct infringement should apply equally to Align's claims of contributory infringement. *Id.*

Respondents also argue that the ALJ improperly excluded evidence disproving any intent to infringe. *Id.* at 58. Respondents argue that, whether or not Align's covenant not to sue resulted in exhaustion of the patents-in-suit and liberated any acts from the possibility of infringement, Respondents' good faith belief in this defense bars a finding of culpable mens rea required for indirect infringement. *Id.*

In addition, Respondents argue that the files need only be "*suitable*" for a non-infringing use to avoid liability, meaning the ALJ erred in finding the files must *actually* be used for the non-infringing purpose. *Id.* (citing Robert L. Harmon, HARMON ON PATENTS: BLACK LETTER LAW AND COMMENTARY pp. 193-95 (2007)(citing *Sony Corp. of Am. v. Universal City Studios, Inc.*, 464 U.S. 417 (1984); *Metro-Goldwyn-Mayer Studios Inc. v. Grokster Ltd.*, 545 U.S. 913 (2005)). Respondents state that the record provides examples of non-infringing uses for the digital data sets in medical research, patient evaluation, and treatment planning. *Id.* at 11-12.

Further, the Respondents argue that digital data is not "a material" or "apparatus" used in a patented process within the meaning of the statute for contributory infringement, 35 U.S.C. § 271(c). *Id.* at 60; Resps. Add. Sub. Reply at 14. The Respondents point to the text of the statute, which requires that a person supply "a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process." 35 U.S.C. 271(c). The Respondents argue that the imported digital data is neither an "apparatus" nor "a material" used in a patented process, but is rather intangible information, which,

according to Respondents, does not meet the requirements of the statute. Resps. Post-Hrg. Reply Br. at 26; Resps. Pet. at 60.

Respondents cite Black's Law Dictionary (9th ed. 2009) which defines "material" as "[o]f or relating to matter; physical . . ." Resps. Add. Sub. at 8. Respondents further argue that *Bayer*'s analysis [of § 271(g)] uses the term "material" in discussing the meaning of manufacturing. *Id.* at 9 (citing 340 F.3d at 1372). Respondents note that the Supreme Court in *Microsoft* did not consider software to be a "component" under § 271(f). *Id.* at 10 (citing 550 U.S. at 451). Respondents also rely on *Veritas Operating Corp. v. Microsoft Corp.*, 562 F. Supp.2d 1141, 1275 (W.D. Wash. 2008), which held that electronically published software could not be "a material or apparatus." *Id.* at 13-14. Respondents argue that Align's citation to *Lucent Tech.*, where the Federal Circuit rejected Microsoft's argument as being without sufficient analysis, is also without sufficient analysis. Resps. Add. Reply Sub. at 14-15 (citing *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.Supp.2d 1016, 1039 (S.D. Cal. 2008)). Respondents note that the three district court cases Align relies on, Align Add. Sub. at 32, were about the use of software rather than electronic transmissions of data. *Id.* at 15. Respondents assert that the alleged "products" are not software. *Id.* at 13 (citing *Eolas Techs. Inc. v. Microsoft Corp.* 399 F.3d 1325 (Fed. Cir. 2005)), but rather that the data here identifies teeth locations. *Id.* (citing ID at 19).

Align argues that the ALJ correctly found contributory infringement by CCPK. Align Resp. to Resps. at 36. Align argues that the ALJ properly applied the "*Spansion*" test for contributory infringement with respect to the asserted claims of the '325 patent, the '880 patent, the '511 patent, and the '874 patent. *Id.* at 36 and n.22 (citing ID at 546–

551, 588-89, 638-39, 758-59; *Certain Elec. Devices With Image Processing Systems, Components Thereof, and Associated Software*, Inv. No. 337-TA-724, Comm'n Op. (Dec. 21, 2011) at n.9 (citing *Spansion, Inc. v. Int'l Trade Comm'n*, 629 F.3d 1331, 1353 (Fed. Cir. 2010)).

Align further asserts that the ALJ "correctly applied the correct" knowledge standard for contributory infringement. *Id.* at 37. Align notes Respondents' reliance on *DSU Med. Corp.* and *Global-Tech* for their argument that contributory infringement has a greater intent requirement than that applied by the ALJ. *Id.* Align counters that *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1303 (Fed. Cir. 2006), held that contributory infringement has only a "minimal intent requirement," and that *Global-Tech Appliances, Inc. v. SEB S.A.*, only addressed the intent requirement for § 271(c) in the context of explaining that knowledge of the ***existence of the patent*** is required for indirect infringement under both §§ 271(c) and (b). *Id.* (citing 131 S. Ct. 2060, 2067–68 (2011)). Align concludes that the "willful blindness" test for inducement does not apply to contributory infringement. Align contests Respondents' further reliance on two district court cases, *Aguirre* and *Bose*, for the proposition that contributory infringement requires "knowledge of the infringement" because the Federal Circuit in *Spansion*, rejected this standard and found the intent requirement for contributory infringement satisfied by presumption where there are no substantial noninfringing uses. *Id.* and n.23 (citing *Spansion*, 629 F.3d at 1355; *Metro-Goldwyn-Mayer Studios, Inc. v. Grokster, Ltd.*, 545 U.S. 913, 932 (2005) ("[o]ne who makes and sells articles which are only adapted to be used in a patented combination will be presumed to intend the natural consequences of

his acts; he will be presumed to intend that they shall be used in the combination of the patent")).

Align disagrees with Respondents' contention that the imported digital data sets have substantial noninfringing uses, actually or hypothetically. *Id.* Align asserts that Respondents' "testimony" is directed to the vague category of "three-dimensional files"—not the specific digital data sets at issue here. Align further asserts that Respondents misconstrue the standard for showing non-infringing uses. Align argues that under Federal Circuit case law, "non-infringing uses are substantial when they are not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental." *Id.* (citing *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1327 (Fed. Cir. 2009)). Align further notes that when assessing whether a use is substantial, the fact-finder may consider "the use's frequency, … the use's practicality, the invention's intended purpose, and the intended market." *Id.* (citing *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 851 (Fed. Cir. 2010)). Align argues that the ALJ was justified in rejecting the argument that a hypothetical use was substantial. *Id.* at 40-41 and n.27 (citing *Mentor H/S, Inc. v. Med. Device Alliance, Inc.*, 244 F.3d 1365, 1379–80 (Fed. Cir. 2001) (finding sufficient evidence of contributory infringement and agreeing that the jury was free to disregard the defendant's allegation that its device had a wide range of applications to surgical procedures other than liposuction where the record did not contain any evidence of any "actual uses of the device other than ultrasonic liposuction")). Align argues that Respondents have provided no particular evidence of any particular non-infringing use of the digital data sets, other than conclusory and speculative testimony, let alone evidence of a substantial non-infringing use. Align finally argues that not only is it conjecture that

there are noninfringing uses, but the evidence confirms the opposite—neither CCUS nor CCPK uses the digital files for any purpose besides making aligners (Tr. at 320:24–321:2, 442:24–443:10; CX-1160C.4 at 645:15–646:4), and the digital data sets themselves are useful only to one particular patient (Tr. at 320:20–23, 443:3–6; CX-1160C.4 at 646:1–4). *Id.* at 42.

Align argues that the ALJ correctly found that digital data can contributorily infringe, *i.e.*, constitute an "apparatus" or "material" used in a patented process within the meaning of the patent statute, 35 U.S.C. §271(c). *Id.* at 42. Align argues Respondents have waived any challenge to the ALJ's conclusion as to contributory infringement by failing to raise it in a timely fashion.[38] [39] Align further argues that Respondents are mistaken on the merits because various district courts have found that digital data can contribute to infringement (within the meaning of the patent statute). *Id.* at 42-43 (citing *T5 Labs (Del.) LLC v. Gaikai Inc.*, 2013 U.S. Dist. LEXIS 49710 (D. Del. Apr. 5, 2013) (finding sufficient pleadings that allege a 'cloud'-based gaming application and service contributorily infringes); *Walker Digital, LLC v. Facebook, Inc.*, 852 F.Supp.2d 559, 566 (D. Del. 2012) (finding that pleadings of "software" that contributorily infringe were facially plausible); *Oracle Corp. v. Parallel Networks, LLC*, 778 F.Supp.2d 527, 544 (D. Del. 2011) (finding that specialized computer software could plausibly contributorily infringe); *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F. Supp. 2d 1016, 1039 (S.D. Cal.

[38] Align overlooks the fact that this issue was raised by Respondents in their Post-Hearing Reply Brief. *See infra.*

[39] We note that this is different from the issue of whether the electronic transmission of digital data constitutes importation of an "article" within the meaning of the Commission's statute, 19 U.S.C. §1337(a)(1)(B).

2008) (declining to limit 271(c) to exclude software), *aff'd in part, vacated in part & remanded*, 580 F.3d 1301 (Fed. Cir. 2009)).

Align counters Respondents' argument that "digital data itself does not infringe the patents at issue" because it is not "a material or component of the aligner," and states that Respondents appear to be taking the position that a contributorily infringing article must be able to be identified in the end infringing product. Align argues that Respondents cite no precedent for such a position, that it is wrong, and that the ALJ correctly found that "the digital data sets created by CCPK are a material part of the process of creating the aligners" because the asserted claims make clear that once the digital data set(s) is (are) created, the only step remaining is to manufacture the aligners based on the digital data set(s). *Id.* at 43 (quoting ID at 547).

Align argues that the term "a material" in the phrase "a material or apparatus for use in practicing a patented process" in 35 U.S.C. § 271(c) may include electronic transmissions. Align Add. Sub. at 31. Align states that files placed by CCPK on CCUS's server do not differ in any meaningful way from digital files resident on CD-ROM and shipped by conventional means into the United States. *Id.* (citing *CNET Networks, Inc. v. Etilize, Inc.*, 528 F. Supp.2d 985, 994 (N.D. Cal. 2007)).

Align argues that the Federal Circuit held in *Lucent Technologies, Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1321 (Fed. Cir. 2009), that forms of data can be a "a material or apparatus," and rejected Microsoft's reliance on *Microsoft v. AT&T* for the contrary position. *Id.* at 32. Align asserts that other courts have regularly found that digital data can contributorily infringe. *Id.* (citing *T5 Labs. (Del.) LLC v. Gaikai Inc.*, 2013 U.S. Dist. LEXIS 49710 (D. Del. Apr. 5, 2013); *Walker Digital, LLC v. Facebook,*

Inc., 852 F. Supp.2d 559, 566 (D. Del. 2012); *Oracle Corp. v. Parallel Networks, LLC*, 778 F. Supp.2d 527, 544 (D. Del. 2011)).

The IA argues that the digital data sets have no substantial non-infringing uses. IA Resp. at 15 (citing CX-1160C (J. Pumphrey) at 174:20–175:4, 645:15–646:4; CX-1162C (Rathore) at 97:1–:14). The IA counters the Respondents' argument that the data sets have uses for "treatment planning and record keeping," on the theory that record keeping is not a "use," but something done in the ordinary course of medical and dental treatment. IA Resp. at 16.

The IA submits that the term "a material" in the phrase "a material or apparatus for use in practicing a patented process" in 35 U.S.C. § 271(c) includes electronic transmissions. The IA argues that the plain and ordinary meaning of the term "material" does not limit "material" to any specific type. *Id.* at 11. Further, the IA is not aware of any Federal Circuit opinion or Commission determination excluding electronic transmissions from being a material for use in practicing a patented process. The IA states that the Federal Circuit has affirmed district court determinations regarding contributory infringement based on the selling or offering for sale of software. *Id.* at 11-12 (citing *i4i Ltd. v. Microsoft Corp.*, 598 F.3d 831, 850-51 (Fed. Cir. 2010); *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1320-21 (Fed. Cir. 2009)). The IA notes that there is a district court decision in which "electronically published" software was determined not to be "material" for use in a patented process, *Veritas Operating Corp. v. Microsoft*, 562 F. Supp.2d 1141, 1275 (W.D. Wash. 2008), but argues that the rationale of this case concerned the application of § 271(f) and *Microsoft v. AT&T*, and not § 271(c). *Id.* at 11 n.4.

The IA agrees with Complainant that the term "material" in § 271(c) includes electronic transmissions. IA Add. Sub. Reply at 9 (citing *Lucent Techs., Inc.*, 580 F.3d at 1321). The IA argues that Respondents and Katz' reliance on dictionary definitions to the contrary is misplaced because the term "material" is not properly limited to a physical article, and even if it is, the digital data sets are representative of physical articles. *Id.* at 9-10 (also citing *Lucent*).

Third-Party Submitter Andrew Katz argues that the term "material" in the phrase "a material or apparatus for use in practicing a patented process" in 35 U.S.C. § 271(c) does not include electronic transmission, Katz Sub. at 16, relying primarily on dictionary definitions of "material." *Id.* at 16-17. Mr. Katz further asserts that the analysis of components in *Microsoft*, a case decided under § 271(f), is analogous to the analysis of components under § 271(c), and that *Microsoft* held that electronically transmitted software was not a component under § 271(f). *Id.* at 17-18.

Third-Party Submitter Nokia argues that both Supreme Court and Federal Circuit precedent establish that electronic transmissions can qualify as infringing "components" or "materials or apparatus" under 35 U.S.C. § 271(c), as well as be the subject of certain induced infringement claims under 35 U.S.C. § 271(b), and thus also constitute articles within the meaning of Section 337. Nokia Reply Sub. at 1. Nokia asserts that the third party arguments with respect to *Suprema* are beyond the scope of the questions posed by the Commission, and in any event mischaracterize *Suprema* because *Suprema* reaffirmed that contributory infringement is a valid basis for a violation of Section 337. *Id.*.at 2.

Nokia further argues that electronic transmission of software can be a "component" or a "material or apparatus" under § 271(c). Nokia Reply Sub. at 3. Nokia

argues that the Federal Circuit has never squarely held that electronically transmitted software is a "material or apparatus" but its rulings strongly support that notion in holding that software may be a "material or apparatus." *Id.* at 3-4 (citing *i4i*, 598 F.3d at 850-51 and *Lucent*, 580 F.3d at 1320). Nokia further argues that *Microsoft v. AT&T* supports the notion that electronically transmitted software is a "material or apparatus" because the Court differentiated between "software in the abstract" and a "tangible" copy of software, as on a CD-ROM. *Id.* at 5 (citing 550 U.S. at 448). Nokia quotes the Supreme Court's statement that "[u]ntil it is expressed as a computer-readable 'copy,' e.g., on a CD-ROM, Windows software—indeed any software detached from an activating medium—remains uncombinable." *Id.* at 5-6 (citing 550 U.S. at 449). Nokia concludes that the "key inquiry in *Microsoft*" is whether software was available in a form in which it was combinable to form the patented invention. *Id.* at 6.

iii. Analysis

Contributory infringement is set forth at 35 U.S.C. § 271(c), which provides as follows:

> (c) Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

See 35 U.S.C. § 271(c).

Specifically with respect to Section 337 investigations, the Federal Circuit has held that "to prevail on contributory infringement in a Section 337 case, the complainant

must show inter alia: (1) there is an act of direct infringement in violation of Section 337; (2) the accused device has no substantial non-infringing uses; and (3) the accused infringer imported, sold for importation, or sold after importation within the United States, the accused components that contributed to another's direct infringement." *Spansion, Inc. v. Int'l Trade Comm'n*, 629 F.3d 1331, 1353 (Fed. Cir. 2010).

With respect to the intent element of Section 271(c), the contributory infringement statute requires that the infringer knows that the patented component is specially adapted for infringement and that there are no substantial noninfringing uses. *See* 35 U.S.C. § 271(c). Recent cases have explained that the intent requirement for contributory infringement is knowledge of the patent. *Spansion,* 629 F.3d at 1353. The Court has explained that this is based on a presumption that the intent requirement is satisfied where there are no substantial noninfringing uses for the component. *Id.*

The ALJ found that Respondents had knowledge of the '325 and '880 patents. ID at 549, 589. We affirm this finding. The ALJ also noted Respondents' admission that "digital data sets and treatment plans are not bought and sold. ***They are essentially instructions for making physical aligners. They have no separate commercial value.***" ID at 548 (emphasis in ID). This statement is evidence of no substantial non-infringing uses and may also be evidence that Respondents acted "knowing the same to be specially adapted for their infringing use." *See* 35 U.S.C. § 271(c).[40] We affirm the ALJ's finding of no substantial non-infringing use. ID at 548. Therefore, we find that CCPK possessed the requisite intent for contributory infringement.

[40] The Respondents argue, as a defense, that they believed in good faith that they had an implied license to practice the patents in suit. However, this defense rises and falls with the implied license defense, which we determined is waived. We therefore conclude that Respondents possessed the requisite intent for contributory infringement.

Next we address whether the digital data sets are "a material or apparatus" within the meaning of § 271(c). To begin we determine that Respondents' argument that digital data is not an "apparatus" or "a material" was not waived because there was no requirement for Respondents to assert a defense before their brief in reply to Align's opening post-hearing brief. *Cf.* Ground Rules 8.2 and 11.1. The burden is on Align to establish all elements of its allegation of contributory infringement, and the defense here is not an affirmative defense, but rather a statement that complainant has failed to make out the elements of its case.

Align does not argue that an electronically transmitted data set can be an "apparatus." Rather, Align contends that the accused digital data sets are either a material or component within the meaning of Section 271(c).

We consider whether the term "a material" connotes something tangible which might pertain to whether the digital data at issue here are encompassed within the meaning of this statutory term. In assessing the meaning of this term, we first look to contemporaneous dictionary definitions. The word "material" has long had a widely accepted definition as an input into a more finished work. For example, Webster's defines material to include "[d]ata of any sort, such as notes, documents, sketches, etc., which may be worked up into a more finished form; as *materials* for a biography; hence, facts, perceptions; ideas, etc., viewed as data for a further operation; as the raw *material* of experience." *Id.*[41] This common meaning of the term "material" is reflected in a plurality of dictionary definitions. *See, e.g.*, FUNK & WAGNALLS NEW STANDARD

[41] *Accord* Webster's New Collegiate Dictionary (1979) (defining "material" as "data that can be worked into a more finished form.").

DICTIONARY OF THE ENGLISH LANGUAGE (1940) ("Collected facts, impressions, or ideas or notes containing them, and sketches, etc., that may be used in completing a literary or an artistic production; as *material*, for a sermon"); THE WINSTON DICTIONARY: COLLEGE ED. (1942) ("data, as notes and sketches, for further elaboration; as material for a speech; that which may be worked up into other forms or for other purposes");[42] THE NEW CENTURY DICTIONARY OF THE ENGLISH LANGUAGE. (1952) ("Material (n): the substance or substances of which a thing is made or composed; any constituent element of a thing; often, anything serving as crude or raw matter for working upon or developing (as, "the materials of seditions," Bacon's "Essays," Of Seditions and Troubles; the materials of a history or drama); also, a textile fabric; also, pl., articles of any kind requisite for making or doing something (as, writing-materials)).[43]

Furthermore, in law, as well as in many of the humanities and social sciences, it has long been very common for the content of some text or statement to be referred to as the "material" that was being conveyed. For example, it would be well within ordinary usage for a speech writer looking for famous quotes to refer to them as source "material;" and it likewise would be well within ordinary usage for someone who attends a lecture to use the word "material" when referring to the content of the lecture rather than to any physical props, visual aids, instruments, or costumes. Indeed, the Supreme Court in *International News Service v Associated Press*, 248 US 215 (1918), used the word "material" several times in its opinion referring to the misappropriation of the content

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[42] *Accord* NEW OXFORD AMERICAN DICTIONARY (3rd ed. 2010) (defining "material" as "facts, information, or ideas for use in creating a book or other work . . .").

[43] *Accord* WEBSTER'S NEW COLLEGIATE DICTIONARY (1979) (defining "material" to be "the elements, constituents, or substances of which something is composed.").

contained in fresh news transmitted electronically. 248 US 239 ("defendant…admits that it is taking material that has been acquired by complainant…"). Such intangible materials have also been the linchpin of well know contributory infringement cases for well over 100 years. *See, e.g., Kalem Co. v. Harper Brothers*, 222 U.S. 55 (1911) (contributory infringement of copyright in the book Ben Hur) (Holmes, J.); *Gershwin Pub. Corp. v. Columbia Artists Management*, 443 F.2d 1159 (2nd Cir. 1971) (contributory infringement of copyrights in music); *Screen Gems-Columbia Music v. Mark-Fi Records*, 327 F.Supp. 788 (SDNY 1971) (same).

Other definitions of "a material" do relate to physical matter. *See, e.g.*, BLACK'S LAW DICTIONARY (4th ed. 1951) (defining "materials" as "the substance or matter of which anything is made").[44] *See also* WEBSTER'S NEW INTERNATIONAL DICTIONARY OF THE ENGLISH LANGUAGE (2d. ed. 1948) (defining "material" as "the substance, or substances, or the parts, goods, stock, or the like, of which anything is composed or may be made . . . material things."[45] *See also* THE NEW CENTURY DICTIONARY OF THE ENGLISH LANGUAGE. (1952) ("Material (n): the substance or substances of which a thing is made or composed; any constituent element of a thing; often, anything serving as crude or raw matter for working upon or developing (as, "the materials of seditions," Bacon's "Essays," Of Seditions and Troubles; the materials of a history or drama); also, a textile fabric; also, pl., articles of any kind requisite for making or doing something (as, writing-materials)). But none of these definitions that relate to physical matter suggest they

[44] Contemporary editions are in accord. *See, e.g.*, BLACK'S LAW DICTIONARY (9th ed. 2009), (defining "material" as "[o]f or relating to matter; physical . . .").
[45] *Accord* Webster's New Collegiate Dictionary (1979) (defining "material" to be "the elements, constituents, or substances of which something is composed.").

would preclude the other definitions discussed earlier that do not relate to physical matter.

There is no controlling case law construing "a material" in § 271(c) in this factual context, but there are a number of court decisions that are instructive. There are two Federal Circuit cases which involve an allegation that the provision of software satisfied the requirement for contributory infringement, but it does not appear in either case that the involved software was electronically transmitted. Both cases were presented to the Court on review of jury verdicts finding contributory infringement. The first case is *Lucent Technologies, Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1321 (Fed. Cir. 2009). In that case, Lucent argued that Microsoft's software product, a calendar "date-picker" tool, contributorily infringed a method for displaying information in fields covered by its '356 patent. Microsoft argued that the "material or apparatus" was the entire Outlook software package, which had substantial non-infringing uses. The Court rejected this argument because the specific feature, the date-picker tool, was suitable only for the infringing use covered by the method claims and that inclusion within the larger Outlook program did not change the date-picker's ability to infringe. *Id.* at 1321. In so ruling, the Court observed that "if, instead of selling Outlook with the date-picker, Microsoft had offered the date-picker for sale ***as a separate download*** to be used with Outlook, there would be little dispute that Microsoft was contributing to infringement of the Day patent." *Id.* at 1320 (emphasis added). Thus, the Court appeared to suggest that electronic transmissions of software would fall within at least one of the statutory categories of "a material or apparatus" and thereby provide a basis for contributory infringement.

Microsoft also argued on appeal that its software product was not a "material or apparatus" under 35 U.S.C. § 271(c), based on the Supreme Court's decision in another case involving Microsoft, *Microsoft Corp. v. AT&T Corp.*, 550 U.S. 437 (2007). In *Microsoft*, the Supreme Court held that the export of a "golden disk" of software did not constitute export of a "component" under a different provision of the patent statute, 35 U.S.C. § 271(f). The *Lucent* Court, noting that Microsoft relied on *Microsoft* "without further analysis," held that the Supreme Court in *Microsoft* did not address the issue of what constituted a material or apparatus for purposes of 35 U.S.C. § 271(c), and *Lucent* did not comment on the issue further.[46]

In the lower court, the issue was framed in terms of "component" rather than "a material or apparatus," with Microsoft relying on the Supreme Court's decision in *Microsoft*. The lower court rejected that argument because the Supreme Court did not purport to reach 35 U.S.C. § 271(c). The lower court also noted that "The dispute over the '356 patent involves method claims and commercial sales of software copies, not apparatus claims and foreign distribution of software 'in the abstract.'" *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.Supp.2d 1016, 1039 (S.D. Cal. 2008) (citing *Microsoft*, 127 S. Ct. at 1727, as "distinguishing the abstract software code at issue from computer-readable copies, such as those 'inserted into a CD–ROM drive or downloaded from the Internet'"). Thus, it appears that the district court distinguished the computer readable Outlook software copies in the *Lucent* dispute as substantively distinct from software "in the abstract" that was involved in the *Microsoft* case. As noted above, the Supreme

[46] *See also Arris Group, Inc. v. British Telecommunications PLC*, 639 F.3d 1368 (Fed. Cir. 2011) (citing *Lucent* and finding an Article III case or controversy exists arising from allegations of contributory infringement).

Court's analysis in *Microsoft* indicates that for Section 271(f), software cannot be a component of a patented invention until it is in a form that can be installed or executed on a computer, *i.e.,* on a CD or downloaded from the internet. 550 U.S. at 449, 451, but is not dispositive of the meaning of "a material or apparatus" under § 271(c) as it was decided under § 271(f), and turned on the particular text and legislative history of that subsection of Section 271, which are different than those for subsection c.

The other Federal Circuit case is *i4i Ltd. Partnership v. Microsoft Corp.*, 598 F.3d 831 (Fed. Cir. 2010). In that case, i4i's '449 patent claimed an improved method for editing documents containing mark-up languages like XML. i4i sued Microsoft for infringement by making, using, selling, offering to sell, and/or importing Word products capable of processing or editing Custom XML. A jury found Microsoft guilty of willful infringement. i4i presented three theories of liability: direct, contributory, and induced infringement. The jury returned a general verdict which did not require separate findings on the different theories. On appeal, Microsoft argued the trial judge erred in his contributory infringement instructions because he used the term "component" rather than "material or apparatus." The Federal Circuit rejected that argument, stating that the difference in language did not make a difference in that case, noting that the parties' used the terms interchangeably and their argument had not turned on whether Word's XML editor was a "component" rather than a "method or apparatus." The Court concluded that "there was sufficient evidence before the jury for it to conclude that the relevant 'material or apparatus' was the custom XML editor, not all of Word." *Id.* at 849.

In *Ricoh Co., Ltd. v. Quanta Computer, Inc.*, 550 F.3d 1325 (Fed. Cir. 2008), the Court held that the sale of software containing instructions to perform a patented method

does not infringe a patented method under 35 U.S.C. § 271(a). The Court compared the situation to *Microsoft v. ATT*, which it cited for the proposition that "software is not a component of a patented device within the meaning of 35 U.S.C. § 271(f) until it is reduced to a machine-readable copy." *Id.* at 1335 (citing *Microsoft*, 127 S. Ct. at 1753-55).

Further, there is one district court case which held that electronic copies of software did not constitute "a material or apparatus," based on *Microsoft v. AT&T*. *See Veritas Operating Corp. v. Microsoft Corp.*, 562 F.Supp.2d 1141, 1275 (W.D.Wash. 2008). On the other hand, as Align notes, a California district court held that an electronic catalog was a physical "product" within the meaning of Section 271(g) finding *Microsoft v. AT&T* instructive on this point:

> In *Microsoft*, the issue before the court was whether software is a combinable "component" for purposes of section 271(f). [127 S.Ct.] at 1755. The court stated that software "abstracted from a tangible copy" is simply abstract information. *Id.* Only when expressed and stored as machine-readable object code, e.g. burned on a CD–ROM or written to a server hard drive such that it is capable of being downloaded from the internet, does software become an actual, physical component amenable to combination. *Id.* at 1756. The court held that "a copy of Windows [software], not Windows in the abstract, qualifies as a 'component' under § 271(f)." *Id.*

CNET Networks, Inc. v. Etilize, Inc., 528 F. Supp.2d 985, 994 (N.D. Cal. 2007).

Thus, the *Lucent* and *i4i* cases involve contributory infringement of software in a combinable form, which provide some indication as to whether digital data sets that are at issue here may be considered to contributorily infringe under Section 271(c). The Supreme Court's decision in *Microsoft* is instructive that software cannot be a "component" under § 271(f) unless it is in a form that can be read by and combined with

a computer regardless of whether it is "delivered by CD-ROM or some other means capable of interfacing with the computer," 550 US at 451, but is not dispositive of the meaning of "a material or apparatus" under § 271(c) as it was decided under § 271(f).

In addition, the Commission has previously found contributory infringement with respect to software that meets certain method steps in *Hardware Logic*. Inv. No. 337-TA-383, 1997 WL 665006, ID at *94. The Commission determined not to review the ID and thereby found a violation of Section 337. Notice (Oct. 2, 1997). The involved software was imported both on a CD and via electronic transmission. *Id.* at * 95. However, the issue of whether the software was a "material or apparatus" under Section 271(c) was not raised in that investigation.

In view of the guidance from these courts and these definitions, we affirm the ALJ's finding of contributory infringement of the Group I claims because electronic transmissions of digital data qualify as "a material or apparatus" within the meaning of 35 U.S.C. § 271(c).[47]

[47] This conclusion applies to all contributory infringement allegations in this investigation.

2. Group II Claims (Claims 31 and 32 of the '325 patent[48]; Claims 1 and 4-8 of the '863 patent; Claims 1, 3, 7, and 9 of the '666 patent; Claims 1, 3, and 5 of the '487 patent)

The Group II claims are directed to methods of generating digital data sets. The digital data sets at issue here are generated by CCPK in Pakistan prior to their electronic transmission to the United States. *See* ID at 472-73. Specifically, CCPK provides the initial data set it obtains from CCUS to the CCPK computer platform and manipulates the data set into final and intermediate positions. It is alleged that CCPK's process of generating final and intermediate data sets in Pakistan practices the Group II claims, and the subsequent transmission of the generated data sets to CCUS constitutes a violation under Section 337(a)(1)(B)(ii). That provision concerns violations related to the importation of artices "made, produced, processed, or mined" using a process covered by a U.S. Patent.

a. The ID

For the '325 patent, the ALJ found that CCPK independently practices claims 31 and 32. ID at 512-13, 514-15. As to the '863 patent, the ALJ found that CCPK practices claim 1. ID at 694-97. The ALJ further found that CCPK practices dependent claims 4-8 in Pakistan by producing the digital data sets. ID at 709, 714, 722, 725, 729. As to the '666 patent, the ALJ found that CCPK practices claims 1, 3, 7, and 9. ID at 655, 659,

[48] Align includes these claims in both Group II and Group IV. Align includes the claims in Group II because the ALJ found that CCPK independently infringes when it produces the digital data sets abroad and provides them to CCUS. ID at 512-13. The ALJ also found that CCUS provides the data sets to a computer, which would place the claims in Group IV. *Id.* (The ALJ did not make a factual finding that CCPK and CCUS therefore infringe in concert but that appears to be the implication.) As noted in our claim construction section, we understand "provide" to include conveying by electronic transfer. Therefore, these claims can be analyzed with CCUS as the sole infringer when it electronically transfers the data to the computer and also with CCPK as a joint infringer when it electronically transfers the data set to CCUS.

666, 669. As to the '487 patent, the ALJ found that CCPK practices claims 1, 3, and 5. ID at 607, 609, 612.

The ALJ found the Respondents imported digital data sets that were made in Pakistan using the entire process of the Group II claims. Based on this, he concluded that Respondents violated 19 U.S.C. § 1337(a)(1)(B)(ii). *See* ID at 550, 624, 670, 732. We affirm, adopting the ALJ's analysis finding that the claim limitations are met. We analyze the other requirements of Section 337 as follows.

b. Parties' Arguments

The Respondents have argued that the requirements of Section 337(a)(1)(B)(ii) are not met, *i.e.*, that there is no article that is "made, produced, processed, or mined" within the meaning of the statute as part of their arguments that there is no "article." Respondents point out that the Federal Circuit used the term "processes" as part of its analysis in *Bayer* that held that a physical product is required under Section 337 or § 271(g). Resps. Add. Sub. at 7.

Align argues that the plain meaning of "processed" must include "data processing on a computer." Align Add. Sub. at 17. Align reports the following dictionary definitions of the verb "process," *inter alia*,: "to prepare by or subject to a special process or method" (WEBSTER'S NEW WORLD DICTIONARY (1988)(where the noun "process" means a particular method of doing something, generally involving a number of steps or operations); "to treat or prepare by some particular process, as in manufacturing" (RANDOM HOUSE DICTIONARY (1987) (where the noun "process" means "a systematic series of actions directed to some end"). Align states that none of these definitions is limited to processes that use physical items. *Id.* at 18. Align continues that contemporary

dictionary definitions and dictionary definitions contemporaneous with the enactment of [the process patent provision of] Section 337(a) in 1940 are similar. *Id.* at 18-19.

Align suggests that "processed" and "process" in subsection (ii) [of Section 337(a)(1)(B)] must be given the same meaning, and must be coextensive with any patented process. *Id.* at 20. Align argues that the close proximity of these terms in the statute provides a strong indication that they should be accorded the same meaning, and the meaning of either should inform the other. *Id.* at 20 (citing *Hall v. United States*, 132 S. Ct. 1882, 1891 (2012); *Brown v. Gardner*, 513 U.S. 115, 118 (1994)). Align concludes that "process" refers to any process that is claimed in a valid and enforceable U.S. patent, and that "processed" refers to the use of any patented process. *Id.* at 20.

Align further reasons that because "articles" may be digital data, subsection (ii) must contemplate processes that create digital data. *Id.* at 21. Align argues that a statutory term must be read in its context and with a view to its place in the overall statutory scheme. *Id.* at 21 (citing *Bettcher Indus., Inc. v. Bunzl USA, Inc.*, 661 F.3d 629, 644 (Fed. Cir. 2011) (citing *Davis v. Mich. Dep't of Treasury*, 489 U.S. 803, 809 (1989)); *King v. St. Vincent's Hosp.*, 502 U.S. 215, 221 (1991)); see also *id.* at 22 (citing cases for the proposition that terms in related provisions have similar interpretations).

Align asserts that the term "process" as used in Title 35 includes data processing, and that is informative here. *Id.* at 22. Align argues that the Supreme Court in *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972), interpreted the term "process," which is defined in 35 U.S.C. § 100(b), to mean "a mode of treatment of certain materials to produce a given result. It is an act or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing." *Id.* at 23 (quoting *Gottschalk*

(quoting *Cochrane v. Deener*, 94 U.S. 780, 788 (1876)).[49] Align urges that data processing satisfies this definition because it is "an act" or "a series of acts." *Id.* Align argues that "process" in § 271(c) and (g) also includes data processing. *Id.* at 24-24. With respect to § 271(g), Align relies on *CNET*, 528 F. Supp.2d at 993, which distinguishes *Bayer*, and explains that a data file is a product of a patented process where practicing each step of the method leads directly to the creation of the [data file]. *Id.* at 25.

Align argues that precedent confirms a broad reading of subsection (ii). *Id.* at 26. Align remarks that the Federal Circuit has referred to Section 337 as conferring rights on "process patent holders" and not on a subset thereof. *Id.* (citing *Kinik Co. v. ITC*, 362 F.3d 1359, 1362-63 (2004); *Zoltek Corp. v. United States*, 672 F.3d 1309, 1322 (Fed. Cir. 2012)). Align relates that the Commission's references to the process patent provision are in accord. *Id.* at 26 (citing *Certain Methods of Making Carbonated Candy Products*, Inv. No. 337-TA-292, Notice of Termination (March 8, 1990); *Certain Plastic Encapsulated Integrated Circuits*, Inv. No. 337-TA-315, 1992 ITC LEXIS 738, n.138 (Nov. 1992)).

Align asserts that the legislative history of Section 337 dictates that "processed" include the practice of all types of patented process claims, although Align maintains that there is no need to consult the legislative history because of the plain meaning of the term. *Id.* at 27 (*Darby v. Cisneros*, 509 U.S. 137, 147 (1993)). Align relates how the process patent amendment to Section 337 was intended to overrule the CCPA's decision

[49] We note that the Court in *Gottschalk* ultimately decided not to resolve whether computer programs were patentable, instead leaving the question to Congress. 409 U.S. at 72-73.

in *In re Amtorg*, 75 F.2d 826 (CCPA 1935), and how a Congressional proponent of the legislation explained that it would include "all of the products and articles and the importation of articles produced on which there is a patent." 86 Cong. Rec. H3783 (daily ed. Apr. 1, 1940) (statement of Rep. Wolcott). *Id.* at 29. Align argues that the legislative language was directed to the practice of any process covered by a valid and enforceable U.S. patent, and was not meant to otherwise limit the scope of the provision. *Id.* at 30.

The IA submits that the term "processed" in Section 337(a)(1)(B)(ii) includes data processing by a computer. IA Add. Sub. at 9. The IA argues that neither the plain language nor the legislative history of the statute supports limiting the term "processed" to any specific type of processing, much less excluding data processed by a computer. *Id.*

The IA further argues that the plain language of the statute distinguishes articles that are "processed" from three other types of articles (i.e., articles that are "made," articles that are "produced," and articles that are "mined.") *Id.* The IA argues that the plain and ordinary meaning of "processed" includes "data processing," and that a claim for a process may include data processing by a computer. *Id.*

The IA asserts that the legislative history also supports interpreting the term processed in this manner, and that nothing in the legislative history supports a limiting construction. *Id.* at 10 (citing *Amgen v. ITC*, 902 F.2d 1532 (Fed. Cir. 1990)).

The IA agrees with Complainant that "processed" in Section 337(a)(1)(B)(ii) includes data processing in view of *Gottshalk v. Benson*, 409 U.S. 63, 70 (1972), discussing the term "process" in the patent context, and *Zoltek Corp. v. United States*, 672 F.3d 1309, 1322 (Fed. Cir. 2012), discussing the process patent provision of Section 337. IA Add. Sub. Reply at 8. The IA asserts that Katz's reliance on *Bayer* and *NTP* for

the meaning of "processed" in Section 337 is misplaced because those cases interpret § 271(g) rather than Section 337. *Id.* at 8-9.

Mr. Katz argues that the term "processed" in Section 337(a)(1)(B)(ii) does not include data processing by a computer. *Id.* at 15. Mr. Katz reasons that "processed" cannot include data processing by a computer where data is the only product because data, information, and electronic transmissions do not qualify as articles under *Bayer* and *NTP*. *Id.* at 16. Mr. Katz argues that the court in Bayer held that § 271(g) was "concerned solely with physical goods that had undergone manufacture" and "for a product to have been 'made by a process patented in the United States' it must have been a physical article that was 'manufactured' and that the production of information is not covered." *Id.* at 16 (quoting *Bayer*, 340 F.3d at 1373; also citing *NTP*, 418 F.3d at 1323-24).

c. Analysis

Section 337(a)(1)(B)(ii) provides as follows:

> *(a) Unlawful activities; covered industries; definitions*
> (1) Subject to paragraph (2), the following are unlawful, and when found by the Commission to exist shall be dealt with, in addition to any other provision of law, as provided in this section:
> ...
> (B) The importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that--
> ...
> (ii) are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent.

19 U.S.C. § 1337.

We assess whether data processing results in something "processed" within the meaning of the statute.

The four statutory terms in the list of Section 337(a)(1)(B)(ii), "made, produced, processed, or mined," represent four different kinds of methods by which goods are created. "Made" is the past participle of "to make" which means "to produce by a combination of parts, or by giving a certain form to a portion of matter; to construct, frame, fashion, bring into existence."[50] SHORTER OXFORD ENGLISH DICTIONARY (1933). Something that is "made" thus has the meaning of having been assembled or shaped. "Produced" is the past participle of "to produce" meaning "to compose or bring out (a work of literature); to work up from raw material (material objects)." *Id.* Something that is "produced" is therefore composed or worked. "Processed," the term in question, is the past participle of "to process" which means "2. to treat by a special process; e.g., to reproduce (a drawing, etc.) by a mechanical or photographic process." *Id.* The noun form of "process," in turn, means "6. A continuous and regular action or succession of actions taking place or carried out in a definite manner. . . b. A particular method of operation in any manufacture. . ." *Id.*[51][52] These definitions support the conclusion that

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[50] The Federal Circuit in *Bayer* found "made" in § 271(g) to mean "manufactured." *See Bayer*, 340 F.3d at 1372.

[51] Other contemporaneous dictionaries are in accord. *See* WEBSTER'S NEW INTERNATIONAL DICTIONARY OF THE ENGLISH LANGUAGE (2d. ed. 1937) ("2.To subject to some special process or treatment. . . b. To subject (esp. raw material) to a process of manufacture, development, preparation for the market, etc.; to convert into marketable form . . . c. To make usable, marketable, or the like . . . d. To produce or copy by photomechanical methods; to develop, fix, wash, and dry, or otherwise treat"); FUNK & WAGNALLS NEW STANDARD DICTIONARY OF THE ENGLISH LANGUAGE (1938) ("2.To produce, as illustrations, by a process, especially by photoengraving: used chiefly in the past participle. 3. To treat by a process; specif. to heat, by steam or otherwise, so as to cook or sterilize").

[52] Modern, contemporary definitions are in accord. In fact, the Sixth Edition (2007) of the SHORTER OXFORD ENGLISH DICTIONARY has an example relating to data as a specific case of the generic definition: "Subject to or treat by a process or in a processor; spec. (a) reproduce . . . (b) preserve . . . (c) operate on (data) using a computer; (d) puree or liquidize (food) in a food processor....")

"processed" is the result of treatment or change through a fixed series of actions. "Mined" refers to extraction from the earth. *Id.*

Thus, the term "processed" refers to something that has been subjected to a treatment or change according to a series of actions, in contradistinction to "made" which generally refers to something assembled from parts and in contradistinction to "produced" which generally refers to something that is "composed" (if it is a literary composition) or "worked" (if it is a material object). These are all ways that something may be the result of a patented process. Thus it appears that by using the phrase "made, produced, processed, or mined under, or by means of a process covered by the claims of a valid and enforceable United States patent," Congress was trying to comprehensively cover all ways in which a method patent can be infringed.

The legislative history is consistent with this understanding of the statute. Section 337(a)(1)(B)(ii) is the reenactment of former Section 337a. Congress explicitly gave the Commission this jurisdiction in 1940 to overturn the CCPA's decision in *In re Amtorg*, 75 F.2d 826 (CCPA 1935), where the Court held that the importation of a phosphate rock mined abroad by a process that was patented in the United States did not constitute an unfair trade practice. The legislative report states that "Since the Amtorg decision owners of American process patents are helpless to prevent the infringement abroad of their patent rights. This bill will give to them the same rights which the owners of product patents have." S. Rep. 76-1903 at 4 (1940) (no emphasis in original). Moreover, the language of the amendment and this legislative history indicate that the legislation was not limited to the mining of phosphate rock at issue in *Amtorg*, but rather was intended to cover the full range of activity that may be covered by a patented process - -

"made, produced, processed, [and] mined." This is in keeping with prior Commission cases under the Tariff Act of 1922 and 1930.[53] Indeed, one Congressman explained that Section 337a would include "all of the products and articles and the importation of articles produced on which there is a patent." 86 Cong. Rec. H3783 (daily ed. Apr. 1, 1940) (statement of Rep. Wolcott). *Id.* at 29.

Commission cases are in accord with the understanding that "processed" means treated. For example, in *Sucralose*, without differentiating between "made, produced,

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[53] Section 337a was intended to overrule *In re Amtorg*, 75 F.2d 826, 22 CCPA 558 (1935), and to re-instate two prior CCPA decisions, *Frischer & Co. v. Bakelite Corporation*, 39 F.2d 247 (CCPA 1930) and *Northern Pigment Co.*, 71 F.2d 447, 22 CCPA 166 (1934).

In *Synthetic Phenolic Resin, Form C, and Articles Made Wholly or in Part Thereof* the Commission, under the Tariff Act of 1922, found unfair methods of competition in the importation of synthetic phenolic resin, Form C, and articles made wholly or in part thereof made abroad using patented processes. U.S. Tariff Commission, Report No. 3, at 15 (1930). One of the patents covered a method for making synthetic phenolic resin, Form C, and another covered a method of fusing synthetic phenolic resin material, Form C, together including material of different colors. In each case, the direct result of the patented process was a material which could then be used to make various articles, such as the imported products. The Commission recommended that the President issue an exclusion order, based in part on the recited process claims. The Court of Customs and Patent Appeals subsequently affirmed the Commission. *Frischer & Co. v. Bakelite Corporation*, 39 F.2d 247 (CCPA 1930), cert. denied sub nom. *Frischer & Co. v. Tariff Commission & Bakelite Corporation*, 282 U.S. 852 (1930).

In *Oxides of Iron Suitable for Pigment Purposes*, Inv. No.337-4 (Tariff Commission 1934)), the Commission, under the original Section 337 of the Tariff Act of 1930, found unfair methods of competition in the importation of iron oxide pigment made from iron ore using patented processes. The Commission recommended issuance of an exclusion order covering the subject imports: a yellow pigment directly produced by the patented process and a red pigment which was a dehydrated form of the yellow pigment. The Court of Customs and Patent Appeals subsequently affirmed the Commission in *In re Northern Pigment Co.*, 71 F.2d 447, 22 CCPA 166 (1934).

The Commission followed *Iron Oxides* in *Phosphate Rock*, Inv. No. 337-3. Tariff Commission 17th Annual Report at 41 (1933) and 18th Annual Report at 41 (1934). In that investigation, the Commission found unfair methods of competition based on the importation of phosphate rock or apatite which had been processed (concentrated) by a method covered by the claims of two patents. The imported phosphate rock appears to have been the direct product of the patented process. The Court of Customs and Patent Appeals subsequently reversed the Commission's determination in *Phosphate Rock* in *In re Amtorg*, 75 F.2d 826, 22 CCPA 558 (1935), thereby also overruling *Northern Pigment* and *Frischer*

After conducting hearings on the impact of *In re Amtorg* in 1938, Congress passed former section 337a (former 19 U.S.C. § 1337a) to overrule that decision, providing:

> The importation for use, sale, or exchange of a product made, produced, processed, or mined under or by means of a process covered by the claims of any unexpired valid United States letters patent, shall have the same status for purposes of section 1337 of this title as the importation of any product or article covered by the claims of any unexpired valid United States letters patent.

54 Stat. 724 (July 2, 1940). This statute was intended to overrule the CCPA's decision in *In re Amtorg*.

[or] processed," the Commission found that the chemical treatment or transformation of sucrose to sucralose by the substitution of chlorine atoms for hydroxyl groups satisfied the requirements of Section 337(a)(1)(B)(ii). Similarly, data processing can infringe a method claim in the United States under 35 U.S.C. § 271(a). *See, e.g., SiRF Technology, Inc. v. ITC*, 601 F.3d 1319, 1329 (Fed. Cir. 2010) (a method of receiving global positioning system (GPS) satellite signals). Further, a claim for a process may include data processing by a computer where the claim is not directed to a purely abstract idea. *See Bilski v. Kappos*, 130 S. Ct. 3218, 3228-29, 3231 (2010) (discussing business method patents). Accordingly, the Commission agrees with Align and the IA that the plain meaning of "processed" includes data processing on a computer. This is the plain meaning in modern parlance, and is consistent with the historical meaning of "process" as a mode of treatment, as explained below.

As we explained in detail above, the *Bayer* case, relied on by Respondents, interpreted the meaning of 35 U.S.C. § 271(g). The meaning of Section 337 was not directly before the Court in *Bayer*. To the extent it commented on Section 337(a)(1)(B)(ii), it addressed the term "made" which appears in § 271(g). Consistent with this definition, the Court in *Bayer* found "made" in § 271(g) to mean "manufactured." It did not address the meaning of "processed" in Section 337. *Bayer*, 340 F.3d at 1372. As *Bayer* states, the language of Section 337 indicates that it has a broader scope than § 271(g). *Id.* at 1374 n.9. *Bayer*, in construing the term "made," concluded that information in that case was not "made." *Id.* at 1371. However, while § 271(g) may be limited to products that are "made," Section 337 may be broader in scope because it also covers articles that are "processed" and "mined" (and perhaps also

"produced" depending on the sense of the word). Further, even to the extent that the process patent jurisdiction of Section 337 is similar to that of § 271(g), the obtaining of the information in *Bayer* is different than the "process[ing]" of the digital data sets representative of teeth here. In *Bayer*, the information was obtained by applying substances to cell lines in order to determine whether the agent is an inhibitor or an activator. *Id.* at 1369. That was simple information because the agent was either an inhibitor or an activator. However, here the digital data sets are more complex, are directly representative of teeth, and are "processed" or treated through a series of interpolations, in a manner analogous to physical manipulation of a mold of teeth. Indeed, Respondents have argued in defense to violation that the claimed processes are anticipated or rendered obvious by physical analogs from the 1940s. *See, e.g.*, Resps. Sub. at 12. While we do not find that the prior art taught the same interpolation technique, we find that the art of processing of the digital data is analogous to the art of processing of plaster casts of teeth which had been physically manipulated since at least the 1940's in the treatment of patients. *See* U.S. Patent No. 2,467,432. The digital data set of teeth is treated or manipulated in the same manner as a plaster cast of teeth.

We therefore conclude that digital data are "articles" that are "processed" within the meaning of Section 337(a)(1)(B)(ii). Because CCPK practices the method of the Group II claims, CCUS and CCPK satisfy the elements of Section 337(a)(1)(B)(ii) in the sale for importation, importation, and sale after importation of the subject digital data sets and treatment plans.

3. Group III Claims (Claims 7-9 of the '487 patent)

The Group III claims are directed to treatment plans (*i.e.*, a series of digital data sets) on a storage medium.

a. Direct Infringement

i. The ID

The ALJ found that the intermediate digital data sets produced by CCPK meet each and every limitation of claim 7 when they are stored on CCPK or CCUS computers, servers, or other forms of "computer readable storage media." ID at 616. However, the ALJ proceeded to analyse the activity with respect to the requirements of Section 337: "This does not, however, end the inquiry. The Commission has explained that "section 337(a)(1)(B)(i) covers imported articles that directly or indirectly infringe when it refers to 'articles that -- infringe.' ***We also interpret the phrase 'articles that – infringe' to reference the status of the articles at the time of importation.*** Thus, infringement, direct or indirect, must be based on the articles as imported to satisfy the requirements of section 337." ID at 619 (quoting *Certain Electronic Devices With Image Processing Systems, Components Thereof, And Associated Software*, Inv. No. 337-TA-724, Comm'n Op. (Dec. 21, 2011) (emphasis in ID))." The ALJ found that at the time of importation, the accused digital data sets do not meet each and every limitation of claim 1 and thus do not directly infringe that claim because they are electronically transmitted and thus do not reside on "storage media," as required by the claims, at the time of importation. ID at 619. Because the ALJ found no direct infringement of claim 7 at the time of importation, he found no direct infringement of dependent claims 8 and 9. ID at 620, 622.

ii. Parties' Arguments

Align argues that Respondents waived their noninfringement arguments because these arguments did not appear in their pre-hearing brief, but appeared for the first time in their post-hearing brief. Align Pet. at 7. Align argues that the ALJ therefore abused his discretion in finding no infringement. *Id.*

Align also argues that there is a sale for importation, *i.e.*, CCPK sells its data sets to CCUS, and that at the time this sale occurs, the data sets are residing on CCPK's storage medium. *Id.* at 8-9. Align further argues that the act of importation includes the act of putting the electronically transmitted data on a storage medium. *Id.* at 9. Align further asserts that the policy underlying the 724 decision is not implicated here because this a not situation where, as there, an imported article arrives in a non-infringing state and is later transformed into an infringing article by some separate post-importation step such that it would not be fair to say that the product infringes "as imported." *Id.* at 10.

The Respondents respond that neither the workstation nor the computer is imported. Resps. Resp. at 3. The Respondents argue that it does not matter whether there is a sale for importation or sale after importation because the law, as embodied by the 724 decision, requires infringement at the time of importation. *Id.* at 4.

The IA argues that Respondents waived their non-infringement arguments because they were not included in the pre-hearing brief. IA Resp. at 4. However, to the extent that the arguments were not waived before the ALJ, the IA agrees with Respondents. *Id.* at 4-6.

iii. Analysis

The Commission affirms and adopts the ALJ's finding that there is no direct infringement of the Group III claims at the time of importation, as set forth in the ID at

617-623. In raising certain non-infringement arguments for the first time in their post-hearing brief, Respondents did fail to comply with ALJ's Ground Rule 8.2, which requires that all arguments appear in the pre-hearing brief. Although the ALJ would have been entitled to find waiver based thereon, his decision not to do so is generally reviewed for abuse of discretion and for whether it is contrary to law. *Cf.* 19 C.F.R. §210.43 (standard for petition for review). The ALJ in his management of the case considers the interests of justice, prejudice to the parties, and whether a finding of violation of Section 337 would be contrary to law. Here, the ALJ chose not to find waiver of the *Electronic Devices* (724) argument (*i.e.*, that there is no direct infringement at the time of importation) and we find no abuse of discretion in his finding. See ID at 619 (finding elements not met). Furthermore, while Align argues prejudice, there is no reason why Align could not have asserted indirect infringement of the Group III claims in the complaint and before the ALJ, which Align failed to do.

Therefore, we affirm the ALJ's finding of no direct infringement of the Group III claims.

b. Contributory Infringement

The ALJ did not address the issue of contributory infringement of the Group III claims. *See* ID at 616-19; Align Pet. at 11.

Align acknowledges that it did not argue contributory infringement before the ALJ. In its petition for review, Align raises contributory infringement for the first time and asks to be excused from waiver: Align argues that "Respondents' failure to timely raise the 'computer-readable storage media' argument prejudiced Align; if Align had known that Respondents disputed the 'computer readable storage media' limitation,

Align would have developed and asserted a contributory infringement theory." Align Pet. at 11.

Respondents counter that Align never alleged contributory infringement and thereby waived the argument. Resps. Resp. at 4. Respondents argue that even if Align did not waive the argument, "the ALJ's findings on induced infringement are fatal to any finding of contributory infringement." *Id.* at 5.[54]

Align had full opportunity to assert indirect infringement of the Group III claims in the complaint and before the ALJ. The Commission has not in the past allowed parties to assert new theories of infringement after the taking of evidence, when the ALJ has certified the record and rendered a final initial determination on violation. *See* 19 C.F.R. § 210.14(c) (amendment of pleadings may be granted when theory asserted during the taking of evidence). Even in the 724 investigation when the Commission found that there was no importation of an article that directly infringes, the Commission did not allow the parties to assert new theories of indirect infringement. *Certain Electronic Devices With Image Processing Systems, Components Thereof, and Associated Software*, Inv. No. 337-TA-724, Pub. 4374 (February 2013). The Commission has therefore determined to consider Align's new theory of indirect infringement of the Group III claims to be waived.

[54] The ALJ found that there was no induced infringement with respect to claims 1 and 3 of the '880 patent because Align failed to show that CCPK possessed the requirement intent. ID at 589. Claim 1 of the '880 patent is in Group I and claim 3 of the '880 patent is in Groups I and IV. Respondents argue elsewhere that there is the same intent requirement for contributory infringement as for induced infringement, an argument we reject. Resps. Pet. at 56 ("The intent required to show contributory infringement is at least as high, if not higher, than the standard for induced infringement.") (citing *Global-Tech Appliances v. SEB SA*, 131 S. Ct. 2060, 2067-68 (2011)). Align did not petition for review with respect to inducement, nor did it raise the issue in either of its briefs on review.

4. Group IV Claims (Claims 1- 3, 11, 13-14, 21, 30-35, 38-39 of the '325 patent; Claims 1 and 3 of the '880 patent; Claim 1 of the '511 patent; and Claims 1, 2, 38-39, 41, and 62 of the '874 patent)

The Group IV claims are directed to methods of producing dental appliances starting with the images of the patient's teeth which are exported to Pakistan, manipulated abroad, and then imported. The final digital data sets are imported and the dental appliances are constructed by CCUS in the United States after importation.

a. Direct Infringement (Combining Foreign and Domestic Conduct and the Applicability of Section 271(g))

i. The ID

The ALJ found that CCPK and CCUS act in concert to practice the Group IV claims (although the ALJ found that claims 21 and 30 of the '325 patent and claim 1 of the '880 patent are also practiced independently by CCUS and claims 31 and 32 of the '325 patent are also practiced independently by CCPK).[55]

As to the '325 patent, the ALJ found that CCPK and CCUS jointly practice every limitation of claims 1, 11, 21, 30, 33, 34, 35, and 38. ID at 477, 490-91, 503, 505, 517, 518, 523, 529.[56] As noted above, the ALJ found that CCUS also independently practices

[55] Claims 21 and 30 of the '325 patent and claim 1 of the '880 patent fall in Group IV if practiced by CCUS and CCPK together and fall in Group I if practiced independently by CCUS. Similarly, claims 31 and 32 of the '325 patent fall in Group IV if practiced by CCUS and CCPK together and fall in Group II if practiced independently by CCPK.

[56] The ALJ stated that CCUS practices dependent claim 2, ID at 478, but since he found that claim 1, from which claim 2 depends, was practiced by the concerted efforts of CCUS and CCPK, it appears that he meant to state that CCUS practices the additional limitation of claim 2 and that CCUS and CCPK together practice claim 2. Similarly, the ALJ found that CCUS practices dependent claim 39, where the practice should be joint. ID at 530. The ALJ appears to have made an analogous misstatement for certain claims with respect to CCPK, finding that CCPK practices dependent claim 3. ID at 484. It appears that he meant to state that CCPK practices the additional limitation of claim 3 but that CCUS and CCPK together practice claim 3. Similarly, the ALJ found that claim 13 is "substantively identical" to claim 3, ID at 492, and that CCPK practices claim 14, 31, 32. ID at 496, 513, 515. It appears that he meant to state that claim 31 is also jointly practiced and that claims 14 and 32 are jointly practiced based on the practice of the independent claims.

claims 21 and 30 of the '325 patent. ID at 502-03, 504-05. As to the '880 patent, the ALJ found that CCPK and CCUS practice every limitation of claims 1 and 3. ID at 571-72, 577. The ALJ found that CCUS also independently practices claim 1 of the '880 patent. ID at 571. As to the '511 patent, the ALJ found that CCPK and CCUS practice every limitation of claim 1. ID at 638. As to the '874 patent, the ALJ found that CCPK and CCUS practice every limitation of claims 1, 2, 38, 39, 41, and 62. ID at 747, 748, 750-01, 753, 755-56, 758. The ALJ found that CCUS also independently practices claim 62 of the '874 patent. ID at 758.[57]

With respect to the Group IV claims, the ALJ found a violation under 19 U.S.C. § 1337(a)(1)(B)(ii), *see* ID at 550-51,592-93, 639, 758-59. He also found a violation under 35 U.S.C. § 271(g), apparently holding that infringement under 35 U.S.C. § 271(g) can serve as a predicate for a violation under 19 U.S.C. § 1337(a)(1)(B)(i), notwithstanding *Kinik v. ITC*, 362 F.3d 1359, 1363 (Fed. Cir. 2004) (defenses of § 271(g) do not apply to Section 337(a)(1)(B)(ii)). *See* ID at 432. For those claims which were jointly infringed (by CCPK's acts abroad and CCUS's acts in the United States), the ALJ held that foreign and domestic conduct may be combined by using 35 U.S.C. § 271(g) as a basis for direct infringement (with some claimed method steps performed prior to importation) and that this direct infringement could serve as a predicate for contributory infringement.

The ALJ suggested that infringement under section 271 of the Patent Act is limited to acts within the United States but that Section 337 is different because "[t]he purpose of section 337 from its inception was to provide relief to United States industry

[57] The ALJ found that CCPK practices the additional elements of dependent claims 2, 28, 39, and 41. Thus, by implication, CCUS and CCPK jointly practice these claims because they jointly practice claim 1 from which they depend.

from unfair acts, including infringement of United States patents by goods manufactured abroad." ID at 429-430 (citing *Lannom Mfg. Co., Inc. v. U.S.I.T.C.*, 799 F.2d 1572, 1580 (Fed. Cir. 1986)). The ALJ stated that: "The Commission made clear, however, that a violation of section 337 does not depend upon a violation of section 271, ..." *Id.* at 430 (citing *Certain Hardware Logic Emulation Systems*, Inv. No. 337-TA-383, Comm'n Op. (March 1998)). The ALJ rejected the IA's argument that infringement must occur pursuant to 35 U.S.C. § 271(a) and cannot be premised on 35 U.S.C. § 271(g). *Id.* The ALJ found that "*NTP v. RIM* is not controlling on this point." *Id.* The ALJ stated that "I reaffirm my finding that the parties' arguments regarding the territorial limitations found in *NTP v. RIM* to apply to 35 U.S.C. § 271 are irrelevant to whether or not Respondents violate 19 U.S.C. § 1337(a)(1)(B)(i) or (ii)." *Id.* at 431.

The ALJ found that there is no requirement that the direct infringement occur prior to importation, and articles that contributorily infringe prior to importation may be the subject of Commission remedial orders. *Id.* The ALJ stated that "infringe" also includes 35 U.S.C. § 271(g). ID at 432-34. The ALJ held that while the defenses of 35 U.S.C. § 271(g) do not apply to investigations under Section 337(a)(1)(B)(ii), 35 U.S.C. § 271(g) may still as a basis for violation under Section 337(a)(1)(B)(i). ID at 434.

ii. Parties' Arguments

The Respondents argue that the ALJ improperly combined foreign and domestic conduct to find infringement of method claims. Resp. Pet. at 11.[58] The Respondents

[58] The Respondents argue (in a footnote) that it does not appear that the ALJ relied on 271(g) to find infringement, and that 271(g) cannot be a basis for a finding of infringement under Section 337. Resp. Pet. at 10 n.1 *(citing Kinik Co. v. Int'l Trade Comm'n*, 362 F.3d 1359 (Fed. Cir. 2004) (holding that the defenses under §271(g) do not apply in Section 337 proceedings)). However, the ALJ held that § 271(g) was a basis for a finding of infringement (which Align argues allows the ALJ to combine foreign and

quote the Federal Circuit in *NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1318 (Fed. Cir. 2005):

> We therefore hold that a process cannot be used 'within' the United States as required by section 271(a) unless each of the steps is performed within this country.

Id. Respondents further quote *Research in Motion* that, "if a private party practiced even one step of a patented process outside the United States, it avoided infringement liability . . ." *Id.* (citing *Zoltek Corp. v. United States*, 51 Fed. Cl. 829, 836 (2002)). Respondents therefore conclude that there can be no infringement under § 271(a) if *any part* of a step is performed outside of the U.S. *Id.*

Respondents state that there would be no infringement finding absent the ALJ's errors of law. *Id.* (citing ID at 477, 491, 503, 505, 518, 527, 571, 577 and 747). The Respondents argue that even in the limited instances in which the ALJ found that one Respondent practiced all claim limitations, he still relied on combined conduct to find infringement. For example, Respondents acknowledge that the ALJ found that CCUS performed all of the limitations of two independent claims—claim 21 of the '325 patent and claim 1 of the '880 patent—but argue that the ALJ expressly noted that CCUS and CCPK "act in concert to practice claim 21 of the '325 patent." *Id.* (discussing ID at 503; 566-71).

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domestic conduct), ID at 434. Respondents may be basing their statement on the fact that the ALJ also held that contributory infringement may occur through the combination of foreign and domestic conduct. *See* ID at 434 and n.31. The Respondents further assert that, if 271(g) did apply in Section 337 investigations, it would not apply in a case of "divided infringement" where part of the process is performed in the United States. *Id.* (citing *Asahi Glass Co., Ltd. v. Guardian Indus. Corp.*, 813 F.Supp.2d 602, 613-14 (D. Del. 2011)).

Conversely, the Respondents acknowledge that the ALJ found that CCPK itself practices each claim limitation of claim 31 of the '325 patent, claim 1 of the '863 patent, claim 1 of the 487 patent, and claims 1 and 7 of the '666 patent, but argue that the ALJ improperly combined CCPK's conduct with that of CCUS. Respondents state that throughout his ID, the ALJ consistently found that CCUS performed the step of providing data sets when it sent the initial data sets to CCPK or otherwise provided the initial scan to it, discussing ID at 475, 498-90, 530, but the Respondents assert that Align argued that when the data set is received in both the United States and Pakistan, Align alleges a joint process that does not occur entirely within Pakistan or the United States.

The Respondents argue that the ALJ erred when he impermissibly combined the Respondents' independent conduct to find "concerted" infringement. The Respondents refer to *Akamai Tech., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301, 1307 (Fed. Cir. 2012) (*en banc*), and argue that liability for induced infringement requires direct infringement by a single actor.

The Respondents state that the ALJ combined the Respondents' acts to find direct infringement, citing the Respondents' "concerted efforts" or acts "in concert" as support for his infringement conclusions. *See* Resp. Pet. at 9 (referring to ID at 477, 491, 503, 571, and 747 for "concerted efforts" findings and ID at 505, 518, 522, 527 and 577 for "in concert" findings. The Respondents further argue that the ALJ accepted and approved the testimony of Align's lone infringement expert, Andrew Beers, who likewise relied on combined acts to opine about infringement. *Id.* (citing Tr. 541:14 to 555:9 for his testimony about the independent claims of the '325, '880, '487, '863 and '666 patents and 583:21 to 586:13 for his testimony about the '511 and '874 patents; ID at 434-35).

Align argues that the ALJ did not "improperly combine foreign and domestic conduct" to find infringement. Align notes that Respondents cite *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1317 (Fed. Cir. 2005) for the proposition that, to find infringement of a process claim under 35 U.S.C. § 271(a), all of the claimed steps must be performed in the United States. Align Resp. to Resps. at 7. However, Align counters that this proposition does not apply to other parts of 35 U.S.C. § 271 such as § 271(g). *Id.* at 8.

Align states that the ITC has instructed that "infringe" includes "all forms of infringement," which would include § 271(g) claims. *Id.* (citing *Certain GPS Chips, Assoc. Software and Sys. and Prods. Containing Same*, Inv. No. 337-TA-596, 2010 ITC LEXIS 582, at *81 (Mar. 2010)). Align argues that while it is true that the court has found that the defenses of § 271(g) do not apply in the context of a violation under 337(a)(1)(B)(ii), this finding is inapplicable to Align's present assertions. *Id.* (discussing ID at 432–34). Align argues that both 35 U.S.C. § 271(a) and 35 U.S.C. § 271(g) infringement is "direct infringement" for purposes of Section 337(a)(1)(B)(i). Align Resp. to IA at 5-6. Align states the Federal Circuit has repeatedly confirmed that infringement under 35 U.S.C. 271(g) is a form of direct infringement. *Id.* at 5. Align cites district court precedent for the proposition that infringement under § 271(g) may serve as a basis for indirect infringement under 271(b) or (c). *Id.*

Align argues that the IA has conceded that the holding of *Kinik* is limited to the [non]application of the § 271(g) defenses to Title 19. Align Resps. to IA Pet. at 9.

Align further argues that the Federal Circuit recently confirmed in *Akamai* that the process steps of the asserted claims do not have to be performed by a single entity for §

271(g) infringement. *Id.* (citing *Akamai*, 692 F.3d at 1306). Align asserts that no one advances a theory involving multi-actor performance of method steps under 35 U.S.C. § 271(a). *Id.* at 4.

With respect to the Group IV claims, Align argues that Respondents violate 337(a)(1)(B)(i) when they import, sell for importation, or sell after importation, digital data sets made by CCPK according to the steps of various claims, and CCUS then creates aligners based on the digital data. *Id.* at 5. Align argues that these are the imported digital data sets that contributorily infringe under 35 U.S.C. § 271(c), and the ultimate sale, offer for sale, or use of the manufactured aligners by CCUS is a direct infringement under 35 U.S.C. § 271(g). *Id.* at 5-6. Align argues that Respondents' arguments are again irrelevant, as the asserted basis is § 271(***g***), not § 271(***a***).[59] *Id.*

The IA argues against the ALJ's legal conclusion that claims under 35 U.S.C. § 271(g) are cognizable as direct infringement before the Commission, and any infringement determinations based thereon. The IA notes that in *Kinik*, the Federal Circuit "affirm[ed] the Commission's ruling that the defenses established in § 271(g) are not available in § 1337(a)(1)(B)(ii) actions." 362 F.3d at 1363. The IA submits that *Kinik*'s holding regarding section 271(g)'s defenses indicates that section 271(g) infringement claims are also not cognizable as direct infringement before the Commission. Furthermore, the IA argues that Congress enacted 35 U.S.C. § 271(g)'s process patent provisions at the same time, and within the same act, in which it incorporated the Commission's separate process patent authority into 19 U.S.C. 1337(a)(1)(B)(ii), and argues that had Congress intended to incorporate the process patent

[59] *See also* Align's Response to Staff's *Petition*, Issues A and B.

standards of 35 U.S.C. § 271(g) into the Commission's authority regarding process patents, it could have done so explicitly. *Id.* (citing *See Abrasive Products*, Inv. 337-TA-449, Comm'n Op. Affirming ALJ Order No. 40 at 3); *Amgen, Inc. v. Int'l Trade Comm'n*, 565 F.3d 846, 851 (Fed. Cir. 2009) ("In *Kinik* . . . this court explained that § 271(g) provided a new right and remedy in the district court, but held that the Tariff Remedy of exclusion based on practice of a patented process was unchanged."). The IA states that OUII is not aware of any post-*Kinik* Commission opinions that have adopted an infringement theory based on § 271(g). The IA states that in *Certain Rubber Antidegradants, Components Thereof, and Products Containing Same*, Inv. No. 337-TA-533, the ALJ's Final ID discussed the legal standards for infringement, referring in passing to §§ 271(a) and 271(g), ID at 93–94 (Feb. 17, 2006), but the Commission re-characterized the infringement determination as one that should be assessed pursuant to Section 337(a)(1)(B)(ii). *Rubber Antidegradants*, Inv. 337-TA-533, Comm'n Op. at 2, 9 n.2 (Jul. 24, 2006), vacated on other grounds, 511 F.3d 1132 (Fed. Cir. 2007).[60]

The IA states that CCUS and CCPK are not independent entities, because, according to the IA, the overwhelming evidence does not support ClearCorrect's contention. IA Resp. at 16. Nevertheless, the IA agrees with the Respondents that the ALJ erred in his finding to the extent that the ID combined foreign and domestic conduct to find infringement of method claims under either 35 U.S.C. § 271(a) or § 271(g). IA Resp. at 16 n.3 (citing IA Pet. 4–10).

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[60] The IA notes that, according to the Complainant, infringement of the following claims was based on 35 U.S.C. § 271(g): claims 1, 2, 3, 11, 13, 14, 30, 33, 34, 35, 38, and 39 of U.S. Patent No. 6,217,325; claim 3 of U.S. Patent No. 6,722,880; claim 1 of U.S. Patent No. 6,471,511; and claims 1, 2, 38, 39, 41, and 62 of U.S. Patent No. 7,134,874.

iii. Analysis

The ALJ found a violation with respect to the Group IV claims under Section 337(a)(1)(B)(ii) and Align argues that the ALJ also found violation under 35 U.S.C. § 271(g). The pertinent questions are whether there is violation under Section 337(a)(1)(B)(ii), whether 35 U.S.C. § 271(g) is applicable to Section 337 as an alternative theory propounded by Align, and if so, whether § 271(g) would cover the Group IV claims.

First, we find that the ALJ erred in finding a violation of Section 337(a)(1)(B)(ii) with respect to the Group IV claims because the imported digital data sets are not the end product of the Group IV claims, which disclose methods for fabricating dental appliances. Therefore, because the Group IV claims are directed to fabricating dental appliances, the last claim step is not performed prior to importation as required by Section 337(a)(1)(B)(ii).

Second, we find that Align is mistaken when it argues that infringement under 35 U.S.C. § 271(g) can form the basis for a finding of violation of Section 337(a)(1)(B)(i). Align argues that 35 U.S.C. § 271(g) is included in the term "infringe" in Section 337(a)(1)(B)(i). It is a well-established canon of statutory construction that a specific provision governs over a general provision. *RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. ——, ——, 132 S. Ct. 2065, 2068 (2012) (quoting *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 384, 112 S. Ct. 2031, 119 L.Ed.2d 157 (1992)). The existence of Section 337(a)(1)(B)(ii), which specifically defines violations of Section 337 based on the importation of articles produced by a patented process, persuades us that violations of Section 337 based on process of manufacture

claims should not be addressed under Section 337(a)(1)(B)(i) read in conjunction with § 271(g). Section 337(a)(1)(B)(ii) is a special provision which governs over the general provision of Section 337(a)(1)(B)(i). Therefore, violation premised on the importation (or sale after importation) of articles produced by a patented process should be analyzed under Section 337(a)(1)(B)(ii) rather than Section 337(a)(1)(B)(i). *See id.*

The Court in *Kinik Co. v. ITC*, explained that the Process Patent Amendments which created Section 271(g) were not intended to change existing remedies at the Commission. 362 F.3d 1359, 1362-63 (Fed. Cir. 2004) (holding that the statutory defenses to infringement under 35 U.S.C. 271(g) were not available as defenses to Section 337(a)(1)(B)(ii) at the Commission) ("However, § 9006(c) of the Process Patent Amendments Act, supra, states the intent to preserve all existing remedies, as elaborated in the Senate Report.") Indeed, the Federal Circuit in *Kinik* stated that "It was explained [in the legislative history] that § 271(g) was intended to provide 'patent owners the new right to sue for damages and seek an injunction in Federal district court.'" 362 F.3d 1359, 1362 (Fed. Cir. 2004) (quoting S. Rep. No. 100–83 at 27 (1987). Thus, § 271(g) was intended to serve as a supplement in district courts analogous to the practice at the Commission, and the re-eenactment of Section 337a as Section 337(a)(1)(B)(ii) was intended to govern practice at the Commission regarding process patents. Further, the Court in *Kinik* did not apply the defenses of § 271(g) to Section 337(a)(1)(B)(ii). If § 271(g) applied, then the defenses would apply. They do not.

Because § 271(g) does not apply to Section 337, we need not address the indirect infringement allegations regarding Group IV claims.[61] In conclusion, we find no violation with respect to the Group IV claims.

D. Invalidity

The only claims which the Respondents specifically cite for anticipation and obviousness, as exemplary claims to represent the entire ID, are claims 1, 37, and 38 of the '325 patent. Resps. Pet. at 48 n.80 ("The ALJ made this finding throughout the *ID.* For example, he applied this finding in claims 1, 37, & 38 of the '325 Patent.").[62] Since Respondents failed to make a specific case for any of the other claims, the Commission has determined that they have waived any similar arguments with respect to those claims.[63]

[61] Parenthetically, we note that even if § 271(g) applied to the Commission, it is our view that § 271(g) only applies to imported products made abroad by patented processes. We have not been briefed with any case, and we have not found any case, in which the Federal Circuit has applied § 271(g) to conduct that is entirely domestic (*i.e.*, with no importation).

[62] Claim 37 of the '325 patent was not asserted in this investigation.

[63] Although the Respondents do not make separate arguments for each of the asserted claims, the Respondents appear to argue that each of the 40 asserted claims is anticipated or obvious, and adopt, for the purposes of their invalidity analysis, a uniform characterization of the asserted claims as involving a five-step process for making aligners: (1) a digital representation of the patient's existing teeth arrangement is created; (2) the representation is digitally modified to allow each individual tooth to be manipulated; (3) 3D graphics software is used to move the virtual teeth to the desired (final) position; (4) virtual intermediate tooth arrangements are created (by interpolation between the initial and final positions); and (5) physical molds are created to form aligners. Resps. Pet. at 39. We note that some of the claims are directed to digital data sets, but the Respondents argue invalidity in generic terms (*i.e.*, not differentiating the asserted claims), arguing with respect to what they characterize as the patentee's method (above) for manufacturing dental appliances.

1. Prior art at issue

a. U.S. Patent No. RE35,169 ("Lemchen")

Lemchen, entitled "Method for Determining Orthodontic Bracket Placement," discloses a method for determining orthodonic bracket placement on a malocclused[64] tooth to correct the malocclusion by repositioning of the tooth to a "finish" position. Lemchen was originally filed on January 24, 1989, and is prior art to all patents-in-suit. Lemchen's disclosed method includes the steps of: (1) generating digital information which defines the shape and location of the malocclused tooth in the patient's jaw, from which digital information a mathematical model of the tooth and jaw is generated; (2) calculating the "finish" position of the malocclused tooth or teeth from the digitized information, with respect to their positions in the model; (3) calculating the correct placement of a bracket from the digitized information; (4) modifying the bracket in view of the patient's physical deviations from the statistical averages; and (5) forming an archwire (force-producing attachment) for the brackets. Also, the method may be used on one or more teeth in the same dental arch, as well as for both dental arches with respect to malocclusion between them. CX-945 (Lemchen), Abstract, 2:48-4:16.

Further, the method may generate the digital information in a variety of ways, including electromechanically, using laser scanning, sonic ranging, digital video scanning, or magnetically. *Id.* The method may also use computer-aided design ("CAD") techniques to generate the mathematical model, and the repositioning may be done mathematically by appropriate software programs which may be derived by conventional means for the particular method of treatment elected by the orthodontist.

[64] Malocclusion is faulty contact between upper and lower teeth when the jaw is closed.

Id. Also, Lemchen specifically refers to Figs. 1 and 3 of U.S. Patent No. 2,467,432 ("Kesling") as prior art examples, respectively, of a physical embodiment of the mathematical model and a manual step of physically removing duplicated teeth from a model and repositioning them in a new model in the finish position. *Id.* at 3:7-15, 25-40.

b. U.S. Patent No. 2,467,432 ("Kesling")

Kesling, entitled "Method of Making Orthodontic Appliances and of Positioning Teeth," discloses a method for providing removable tooth positioning appliances (*i.e.*, aligners) which are adapted to be used to maintain or bring the teeth of the user into a predetermined ideal or desirable position without the necessity for the use of metallic bands, wires, or any other prior art appliance. Kesling was originally filed July 23, 1943, and is prior art to all patents-in-suit. The disclosed method includes the steps of: (1) generating a physical model, *e.g.*, a cast, of the teeth to be repositioned; (2) removing the teeth to be repositioned from the model; (3) resetting the teeth in their desired positions; (4) generating a new model of the repositioned teeth; and (5) using the new model, generating a tray for taking an impression of the repositioned teeth which is used to form the removable tooth positioning appliance to be worn by the user. CX-944 (Kesling), 1:1-8, 2:43-4:70. Fig. 1 of Kesling illustrates a plaster model of an upper and lower jaw and shows the condition of the patient's teeth prior to the beginning of treatment. *Id.* at Fig. 1, 2:7-9. Fig. 3 illustrates a similar plaster cast and shows the teeth after they have been dissected from the cast, and reset upon the same base to show the ideal position in which they are finally to be positioned. *Id.* at Fig. 3, 2:15-21.

c. U.S. Patent No. 6,471,511 ("the '511 patent")

The '511 patent, entitled "Defining Tooth-Moving Appliances Computationally," is asserted by Align in this investigation and discloses a method and corresponding apparatus for segmenting an orthodontic treatment path, *i.e.*, repositioning of trouble teeth to a "finish" position, into clinically appropriate substeps to perform correct repositioning using tooth-moving appliances. The '511 patent was originally filed June 20, 1997. The disclosed method includes the steps of: (1) acquiring a mold of the patient's teeth and tissue using a variety of methods including direct contact scanning and imaging that provides information about the structure of the teeth, jaw, gums, and other orthodontically relevant tissue; (2) deriving a digital data set from the mold and the orthodontic information that represents the initial arrangement of the patient's teeth and other tissues; (3) processing the digital data set to segment extraneous elements, *e.g.*, individual tooth crowns, hidden surfaces, and root structures, from each other; (4) calculating the desired final position of the teeth, *i.e.*, the end result of orthodontic treatment, using a clinical prescription such that the final position and surface geometry of each tooth can be specified; (5) using the beginning and finish teeth positions, defining a tooth path for the motion of each tooth which is optimized so that the teeth are moved in the quickest fashion with the least amount of duplicative back-and-forth tooth movement to bring the teeth to their desired final positions; (6) segmenting the tooth paths so that each tooth's position within a segment stays within threshold limits of linear and rotational translation; and (7) using the segmented tooth paths and associated tooth position data to calculate and make clinically acceptable appliance configurations (or successive changes in appliance configuration) that will move the teeth on the defined

treatment path in steps specified by the path segments. Also, the method discloses that the appliances can be braces, polymeric shells, or other forms of orthodontic appliance. JX-1 ("the ''511 patent"), Abstract, Fig. 1, 3:22-4:67.

2. Anticipation

Respondents contend that Lemchen incorporates Kesling and anticipates the asserted claims of the '325 patent.

a. Relevant Law

A patent is presumed valid, and a party challenging validity has the burden of proving invalidity by clear and convincing evidence. *See* 35 U.S.C. § 282; *Iron Grip Barbell Co., v. USA Sports, Inc.*, 392 F.3d 1317, 1320 (Fed. Cir. 2004). A patent claim is invalid as anticipated if "the invention was known or used by others, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent,[.]" 35 U.S.C. § 102(a). Anticipation requires that a single prior art reference discloses each and every limitation of the claimed invention. *Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1379-80 (Fed. Cir. 2003). The Federal Circuit has held that "[m]aterial not explicitly contained in the single, prior art document may still be considered for purposes of anticipation if that material is incorporated by reference into the document." *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000) (*citing Ultradent Prods., Inc. v. Life-Like Cosmetics, Inc.*, 127 F.3d 1065, 1069 (Fed. Cir. 1997)).

b. Does Lemchen Incorporate Kesling In Whole or In Part?

A threshold issue is whether Kesling is fully incorporated by reference into

Lemchen.[65] At the hearing, respondents contended that asserted claims 1-3, 11, 13-14, 21, 30-35, and 38-39 of the '325 patent, where claim 1 is representative, are anticipated by Lemchen, which they purported fully incorporates Kesling by reference. ID at 108, 148-68. The two passages in Lemchen incorporating Kesling read:

> Thus, in many applications of the preferred embodiment, a complete "model", as that term is used in the dental art to refer to a full replication of the upper and lower dental arches and associated jaw structure, will be mathematically generated. A physical embodiment of such a model is shown, for example, in FIG. 1 of [Kesling].

Id. at 145 (citing Lemchen, 3:10-15).

> In the prior art, a similar step was accomplished manually in order to account for individual tooth morphology by physically removing duplicated teeth from a model and repositioning them in a new model in the finish position. See, for example, FIG. 3 in the above referenced [Kesling].

Id. (citing Lemchen, 3:35-40).

However, the IA and Align argued that Kesling was not fully incorporated by reference into Lemchen by these passages. *Id.* at 128-38, 139-42.

Reviewing the relevant precedent, the ALJ found that "[t]o incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents." ID at 142 (citing *Advanced Display*, 212 F.3d at 1282 (citing *In Re Seversky*, 474 F.2d 671, 674 (C.C.P.A. 1973)). The ALJ noted, however, that the Federal Circuit and its predecessor have limited incorporation to the portions of the external reference that are specifically identified in the incorporation language of the host

[65] Also at issue is whether the ALJ properly limited the evidentiary use of certain expert reports from the *Ormco* litigation. *See infra*.

document. *Id.* at 143-44 (citing *Zenon Environmental, Inc. v. U.S. Filter Corp.*, 506 F.3d 1370, 1379 (Fed. Cir. 2007); *In re Saunders*, 444 F.2d 599, 600 (C.C.P.A. 1971).

Applying the relevant case law, the ALJ found that the incorporation language of Lemchen identifies with detailed particularity what specific material it incorporates from Kesling and clearly indicates where the material is found, *i.e.*, Figs. 1 and 3 of Kesling. *Id.* Accordingly, the ALJ concluded that Lemchen does not incorporate Kesling beyond Figs. 1 and 3 of Kesling. *Id.* Further, even assuming *arguendo* that Lemchen incorporates fully by reference Kesling, the ALJ still found no anticipation because each and every limitation of claim 1 of the '325 patent is not disclosed by Lemchen and Kesling. *Id.* at 146.

Respondents contend that the ALJ clearly erred on the threshold issue of whether Lemchen fully incorporates Kesling. Respondents' Pet. at 36-38. They argue that language in a patent such as "[*r*]*eference is made to*" can be sufficient to indicate to one of ordinary skill in the art that the referenced material is *fully incorporated* [into] the host document." *Id.* at 36 (citing *Callaway Golf Co. v. Acushnet Co.*, 576 F.3d 1331, 1346 (Fed. Cir. 2009) (emphasis added)). They argue that Lemchen uses similar language and makes clear that it is referring to the "methods of treatment" in the prior art, and not just the figures in stating: "In the prior art, a similar step was accomplished manually in order to account for individual tooth morphology by physically removing duplicated teeth from a model and repositioning them in a new model I the finish position." *Id.* (citing Lemchen, 3:35-40). They further argue that it is important to consider the entirety of the incorporated document to properly understand its teachings, particularly because Kesling is small and only contains one page of figures and approximately 3.5 pages of text. *Id.* at

38 (citing *In re Hughes*, 550 F.2d 1273, 1275-76 (C.C.P.A. 1977)). They submit that Figs. 1 and 3 of Kesling are substantively discussed repeatedly througout the first two pages of the reference, and are essentially omitted only from the claim section and the listing of the prior art. *Id.*

Align points out that Lemchen only briefly refers to two *figures* from Kesling. Align's Resp. at 21 (emphasis added). Align argues that these references to Figs. 1 and 3 of Kesling are used only as examples of *models*, and that Lemchen does not state that the *entire* disclosure of Kesling or any of its *particular* methods are incorporated. *Id.* (emphasis added). Complainant submits that Lemchen's use of the language "in the above referenced [Kesling]" is merely citing Lemchen's prior reference to Fig. 1 of Kesling. *Id.* Align also contends that Lemchen's use of the language "methods of treatment" merely refers to different methods of treating a patient with brackets and archwires – not the removable appliance disclosed by Kesling. *Id.* (emphasis added).

The Commission has determined to affirm the ALJ's finding that Lemchen does not incorporate Kesling in its entirety, as set forth in the ID at 142-48. Incorporation by reference requires the host document to "identify with detailed particularity what specific material it incorporates and clearly indicate where the material is found in the various documents." *See Advanced Display Sys.*, 212 F.3d at 1282. Lemchen specifically discloses that the "physical embodiment of such a [digital] model is shown, for example, in FIG. 1 of [Kesling]." This passage thus refers to a model of a patient's jaw structure in Kesling that is found solely in Fig. 1 of Kesling, thereby obviating any need to view other portions of Kesling to understand the incorporated subject matter. Further, Lemchen specifically discloses that this physical model is shown, "for example, [in] FIG. 3 in the

above-referenced [Kesling]." *Id.* at 3:39-40. Again, based on this specific language of Lemchen, this refers to a model of a patient's jaw structure, this time with the teeth repositioned in the finish position, that is found solely in Fig. 3 of Kesling.

The patents in the precedent cited by Respondents used different language than the patent here which clearly indicates what subject matter is incorporated and where it can be found. In both *Callaway Golf* and *Hughes*, the material to be incorporated was designated more broadly. *See Callaway Golf*, 576 F.3d at 1346; *Hughes*, 550 F.2d at 1275-76. Further, in *Mobile Devices* the incorporation by reference language was not in dispute. *See Certain Mobile Devices, Associated Software, and Components Thereof* ("*Mobile Devices*"), Inv. No. 337-TA-744, Final ID, 2011 WL 6916539, at *103-04 (Dec. 20, 2011).

c. Comparison of Exemplary Claimed Process to Prior Art

The ALJ found that Lemchen describes "generating digital information" regarding the initial "malocclused teeth," and then determines their respective "finish positions." ID at 146-47. The ALJ found that Lemchen discloses calculating positions on the teeth for bracket placement, and completes movement of the teeth with traditional brackets and archwires, not polymeric shell, *i.e.*, removable, appliances. *Id.* (citing CX-495 at 1-2, CX-1247C at Q. 186). However, he found that Align's expert (Dr. Valley) credibly testified that Lemchen does not disclose, teach, or suggest calculating positions-in-between. *Id.* (citing CX-945 at 1-3, CX-1247C at QQ. 184-85). As a result, the ALJ found that Lemchen does not disclose "producing a plurality of intermediate digital data sets representing a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement," as required by exemplary claim 1 of

the '325 patent. *Id.* Based on the foregoing, the ALJ found that Lemchen does not disclose "fabricating a plurality of sucessive tooth repositioning appliances, at least some of which are related to at least some of the produced digital data sets," as required by claim 1 of the '325 patent. *Id.* at 147.

The ALJ further found that the incorporation of Figs. 1 and 3 of Kesling, as well as its full incorporation, into Lemchen does not disclose these limitations of claim 1. *Id.* He noted that Kesling was originally filed in 1943 and issued in 1949, before the concept of digital data existed. *Id.* Also, he found that Dr. Valley testified credibly that Kesling "does not disclose, teach, or suggest, or even remotely contemplate" the use of computers or digital technology. *Id.* (citing CX-1247C at QQ. 141-42, 564-71, 574-77). He also found that Kesling describes making tooth arrangements by (1) using a plaster mold of teeth, (2) separating the plaster teeth with a saw, and (3) reassembling the plaster teeth in wax into their assumed positions. *Id.* at 148 (citing CX-944 at 3).

In addition, the ALJ found that Dr. Valley testified credibly that Kesling only contemplated a reactive process, performed one step at a time, where appliances beyond a first appliance may be created by repeating the disclosed process for making the first appliance. *Id.* (citing CX-1247C at QQ. 144-45, CX-944 at 5). He further found that Kesling does not expressly or inherently disclose, or teach or suggest, fabricating a dental appliance based on a digital data set. *Id.* Rather, he found that Kesling discloses manually making an appliance using tools, supplies, and materials, including by, *inter alia*, (1) articulating the plaster cast; (2) taking an impression of the teeth of the plaster

cast; and (3) making a mold filled with the appliance material. *Id.* (citing CX-944 at 3-4, CX-1247C at Q. 146).[66]

Based on the foregoing, the ALJ concluded that respondents failed to meet their burden to prove by clear and convincing evidence that Lemchen anticipates independent claims 1, 11, 21, 31, 33, 35, and 38 of the '325 patent. *Id.* at 148. Based on his non-anticipation finding with respect to these asserted independent claims, he also found that asserted dependent claims 2-3, 13-14, 30, 32-34, and 39 are not anticipated by Lemchen. *Id.* at 148-171.

The Respondents argue that, once it is correctly found that Lemchen fully incorporates Kesling by reference as respondents argue, Lemchen anticipates the asserted claims of the '325 patent. Resps. Pet. at 39-48. Specifically, Respondents submit that Kesling teaches the following: (1) creating a model of the teeth in their existing position (citing Kesling, 2:7-9); (2) methods for modifying the initial model to allow the teeth to be individually manipulated (citing Kesling, 3:30-49); (3) methods for moving the modeled teeth to the desired location (citing Kesling, 3:49-64); (4) creating intermediate tooth arrangement models between the existing tooth arrangement model and the desired arrangement (citing Kesling, 2:50-3:1); and (5) a plurality of successive or intermediate

[66] The ALJ observed that, in previous litigation, the Federal Circuit found that the asserted claims of certain Align patents describing systems and methods for incrementally repositioning teeth, U.S. Patent Nos. 6,554,611 ("the '611 patent") and 6,398,548 ("the '548 patent"), are rendered invalid in view of prior art showing use of such systems and methods by orthodontists. *Ormco Corp. v. Align Technology, Inc.*, 463 F.3d 1299, 1302 (Fed. Cir. 2006). Respondents asserted *Ormco*'s findings, especially Dr. Diane Rekow's (expert for Align in the litigation) expert reports from that litigation from Dr. Diane Rekow (Align's expert in that litigation), as proof of the knowledge of one of ordinary skill in the art and invalidity of the patents at issue here. *Id.* at 187 (also at 201, 219-20, 380, 397). However, the ALJ ruled that respondents' evidentiary exhibits (RX-102C and RX-103C) that contained the expert reports from *Ormco*, which included reports on the issue of the asserted combination of Lemchen and Kesling, were limited in evidentiary use to show only that Align took an inconsistent position in *Ormco*. *Id.* at 187 (also at 201, 219-20, 380, 397); *see also* Tr. at 20-21 (granting-in-part Align's motion in limine to exclude the reports as hearsay).

tooth positions and the fabrication of a series of appliances based on the intermediate tooth positions as recited by claim 1 of the '325 patent.

Align submits that the ALJ correctly concluded that, even assuming *arguendo* that Lemchen fully incorporates Kesling, this combination does not render any of the asserted claims obvious because it still does not disclose all elements of the claims. Align Resp. to Resps. at 23-29. Align submits that, contrary to respondents' contention, the claimed feature of determining intermediate digital data sets representing a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement is completely absent from Kesling and Lemchen. *Id.* at 24-25 (citing CX-1247C at QQ. 137-62; CX-1254C, ¶ 62-65 at 21-23, ¶67 at 24-25, Tr. at 790-93). Specifically, Align contends that Kesling does not disclose, *inter alia*, the following claimed features: (1) digital data sets or models of a dentition; (2) intermediate or successive tooth arrangements based on initial and final positions; (3) fabricating a dental appliance, or controlling a fabricating machine, based on a digital data set; or (4) numerous other elements. *Id.* at 25. Rather, Align contends, Kesling only discloses a *reactive* process, done *one step at a time*, where subsequent appliances are created by repeating the process for making the first. *Id.* at 24 (emphasis added).

The Commission affirms the ALJ's finding and adopts the ALJ's reasoning, as set forth in the ID at 142-48 and 168-69, that Lemchen does not anticipate claim 1 or 38 of the '325 patent.[67] Lemchen does not teach interpolation or how to create successive appliances. ID at 149 (citing CX-945 at 1-3, CX-1247C at QQ. 184-85). Further, we

[67] Further, although Respondents have not petitioned with specificity with respect to other claims, the Commission adopts the ALJ's findings in the ID that Respondents have not proven that the remaining claims of the patents in suit are anticipated by Lemchen, whether or not it incorporates Kesling.

agree with Align that Lemchen does not discuss defining or moving tooth boundaries. We agree with the ALJ that this combination, even assuming *arguendo* that Kesling is fully incorporated into Lemchen, still fails to disclose the claimed feature of mathematical interpolation.

3. Obviousness

a. Relevant Law

Under 35 U.S.C. § 103(a), a patent is valid unless "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." See 35 U.S.C. § 103(a). Once claims have been properly construed, "[t]he second step in an obviousness inquiry is to determine whether the claimed invention would have been obvious as a legal matter, based on underlying factual inquiries including: (1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between the claimed invention and the prior art; and (4) secondary considerations of non-obviousness" (also known as "objective evidence"). *See Smiths Indus. Med. Sys., Inc. v. Vital Signs, Inc.*, 183 F.3d 1347, 1354 (Fed. Cir. 1999) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966)).

The Supreme Court rejected a "rigid approach" to prove obviousness, that requires an express "teaching, suggestion, or motivation to combine references," in favor of a non-formalistic approach that considers other factors, *e.g.*, demands of the market and the technical community, interrelated teachings of multiple patents, background knowledge of one skilled in the art, inferences and creative steps one skilled in the art would employ, etc. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007). All of these

factors may be considered by the court to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. *Id.* at 417-21.

b. Combination of Lemchen and Kesling for all Asserted Claims

The ALJ found that Lemchen combined with Kesling would not render obvious any asserted claim of the '325 patent. ID at 181-223. Focusing on the motivation to combine references, the ALJ found that the mention of Kesling in Lemchen would be adequate to cause a person of ordinary skill in the art to consider both references in combination. *Id.* at 182. However, the ALJ found that Kesling "does not disclose, or teach or suggest, or even remotely contemplate" the use of computers or digital technology, and Kesling does not expressly or inherently disclose, or teach or suggest, fabricating a dental appliance based on a digital data set. *Id.*

The Respondents submit that the only difference between Kesling and the claimed subject matter of the asserted patents is the use of digital data. Resps. Pet. at 41. They submit that the mere application of modern electronics to existing subject matter is commonplace and obvious to one skilled in the art. *Id.* (citing *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007) ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results."); *Western Union Co. v. MoneyGram Payment Sys., Inc.*, 626 F.3d 1361, 1370 ("Our conclusion of obviousness was based in part on the reasoning that applying modern electronics to older mechanical devices has been commonplace in recent years."); *Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1161 (Fed. Cir. 2007) (the

Court rejecting arguments that such incorporation, *i.e.*, applying modern electronics to a prior art mechanical device, would have been beyond the ability of a person of ordinary skill in the art)).

Respondents argue that the record in this investigation demonstrates that the asserted claims are for digitally performing operations, such as interpolation, which were previously performed in an analog manner and therefore are invalid as obvious. Resps. Sub. at 12. Respondents assert that the technology at issue is easy to understand, and that the fact that analog methods were performed to accomplish the same steps to make aligners cannot be meaningfully disputed. *Id.* at 12. Respondents point to the *Ormco* litigation in which the Federal Circuit held claims of other of Align's patents to be invalid, and argue that "[t]hese holdings, discussed in greater detail in Respondents' petition for review, conclusively demonstrate that analog and digital methods of designing and manufacturing aligners predated Align's asserted claims." *Id.* at 13 (citing *Ormco Corp. v. Align Tech., Inc.*, 498 F.3d 1307, 1313-18 (Fed. Cir. 2007)). Respondents discuss the Kesling analog system, *Id.* at 13-14, and cite the expert report from the *Ormco* litigation for the proposition that the only difference between Kesling and the claimed subject matter is the use of digital technology. *Id.* at 14 (RX-103C at 2). Respondents argue that Lemchen taught the use of 3D graphics to move the virtual teeth to the desired position. *Id.* at 15 (citing CX-945 at 2:66-3:6). Respondents argue that each individual step of the claimed methods was known and performed both manually and digitally prior to the claimed invention. *Id.* at 17-19 (citing RX-103C at 2). Respondents argue that Dr. Rekow's expert report in the *Ormco* litigation and Dr. Mah's testimony set forth the motivation to combine. *Id.* (citing RX-103C at 2; RX-113 Q.95).

Align asserts that its inventions are not simply computerized versions of prior art systems. Align Sub. at 14. Align states that Respondents never submitted any evidence that the asserted claims merely recite manual methods using modern electronics. *Id.* at 14-15. Align argues that one significant difference between Align's asserted claims and the prior art is Align's inventive concept of determining intermediate or successive states based on the initial and desired final states. *Id.* at 15. Align continues that Dr. Valley, Align's expert, explained why this is fundamentally different from the prior art. *Id.* at 16 (citing, CX-1247C at Q.141, 144-45, 183-85, 293-95, 304-06, 335-38, 410, 412, 414-15, 418-22, 440-41, 443-44; CX-1254C ¶¶ 65, 82, 126, 149-50, 194; Tr. at 791:21-793:5, 794:3-795:17).

Align argues that Kesling describes a reactive process, done one step at a time based on the position of the teeth, and repeated, and that Kesling's method is not based on the initial and final positions. *Id.* at 16 (citing ID at 147; CX-1247C at Q.144-45; CX-1254C at ¶ 65; Tr. at 790:9-791:20). Align argues that Respondents do not dispute this and that Dr. Rekow testified in the *Ormco* litigation only that Kesling moved the teeth by incremental amounts. *Id.* at 16-17 (citing RX-103C at 13).[68] Align asserts that the prior art fails to disclose other limitations of other claims either in digital or physical form, *e.g.*, "interpolation," which is recited in claim 14 of the '325 patent, claim 8 of the '863 patent, and claims 3, 7, and 9 of the '666 patent.

Align contends that the authority relied on by Respondents is readily distinguishable. *Id.* at 18. Align argues that *Leapfrog Enters. v. Fisher-Price, Inc.*, 485

[68] Regarding the *Ormco* expert reports, Align submits that the ALJ was correct to limit respondents' use of these reports. Align Resp. to Pet. at 30-31. Align submits that only relevant, reliable, and material evidence is admissible in Commission proceedings. *Id.* (citing 19 C.F.R. § 210.37(b)).

F.3d 1157 (Fed. Cir. 2007), is distinguishable because Align's invention is not merely an old system with new parts. Align argues that *Western Union Co. v. MoneyGram Payment Sys.*, 626 F.3d 1361 (Fed. Cir. 2010), is distinguishable because Align's inventions are not merely an upgrade to an old or existing system. Align argues that Respondents have no support (except citation to Dr. Rekow's report in the *Ormco* litigation) for their claim that Lemchen taught intermediate tooth arrangements and that applying digital technology to prior art was obvious to one of ordinary skill in the art. *Id.* at 8.

The IA argues that the testimony provided by Respondents' expert Dr. Mah is merely conclusory and does not make up for the deficiency with respect to the claimed knowledge of one of ordinary skill or the alleged motivation to apply any digitial technology. IA Sub. at 8 (citing RX-113C at QQ.114-121).

The IA asserts that the use of digital data is not the only difference between Kesling's teachings and the subject matter of the asserted claims. *Id.* at 9. The IA states that the ALJ found that Kesling contemplated a reactive process, and that Lemchen does not dislcose or teach calculating positions in between. *Id.* (citing ID at 146-47).

The Commission affirms the ALJ's findings, and adopts the ALJ's reasoning, as set forth in the ID at 180-82 and 203-206, that Respondents have not proven that claim 1 or claim 38 of the '325 patent is obvious.[69] Kesling and Lemchen do not teach the interpolation of digital data sets, and Respondents have not cited any substantive evidence of record to support the defense that the asserted claims are an obvious

[69] Further, although Respondents have not petitioned with specificity with respect to other claims, the Commission explicitly adopts the ALJ's findings in the ID that Respondents have not proven that the remaining claims of the patents in suit are anticipated or rendered obvious by Lemchen, whether or not it incorporates Kesling.

application of digital technology. Respondents point only to the expert report of Dr. Rekow, Align's expert, from the *Ormco* litigation, which the ALJ held could only be used for impeachment purposes in this investigation, and the testimony of Dr. Mah, which the ALJ found to be conclusory and unsupported. Therefore, Respondents have not met their burden of proof.

c. Combination of the '511 Patent and Knowledge of One of Ordinary Skill in the Art (for the asserted claims of the '863 patent)

At issue is whether respondents waived their arguments with respect to, *inter alia*, the combination of the asserted '511 patent and knowledge of one of ordinary skill in the art.[70] The ALJ found that Respondents failed to set forth any specific combination and thus waived their argument. ID at 349-50. However, the ALJ made the finding in the

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[70] In a contingent petition for review, Align asserts that the ALJ erred in finding that the'863 patent is not entitled to a priority date of December 4, 1998, based on claiming priority to the '881 provisional application, and notes that this issue was not disputed at the hearing. Align's Pet. at 40-41. Align submits that the ALJ's factual finding was incorrect because the '881 provisional application incorporates by reference the '080 patent application, which incorporates the '342 provisonal application. *Id.* (citing CX-1253 at 4, '893 patent). Accordingly, Align asserts that the '881 provisional application does incorporate by reference the disclosure of the '342 provisonal appliction to provide sufficient support for asserted claims 1 and 4-8 of the '863 patent, and therefore the '863 patent is entitled to a priority date of Dececember 4, 1998. *Id.* (citing CX-1247C at QQ. 91-97; CX-1254C at 13). Align thus contends that ALJ's findings on this issue should be reversed.

The IA agrees with Align and submits that the ALJ does not adequately explain why a claim to a Dec. 4, 1998, priority date requires the incorporation by reference of an application filed on Jun. 20, 1997, thereby warranting review by the Commission on this issue. IA's Pet. at 7-8.

Respondents disagree with Align and submit that Align did not meet its burden for establishing an earlier priority date for the '863 patent than its filing date on the face of the patent. Respondents' Pet. at 18 (citing *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1305-06 (Fed. Cir. 2008) (patentee has the burden to establishing an earlier priority date than on the face of the patent to overcome a prima facie case of invalidity)).

We agree with Align and the IA that the relevant priority date for the '863 patent is Dec. 4, 1998, because it has an adequate disclosure based on the incorporation by reference of the '342 provisional application. Nevertheless, the ALJ's determination of the priority date was harmless error in view of the ALJ's finding that the '511 patent is prior art to the '863 patent regardless of whether the '863 patent may claim priority to Dec. 4, 1998. *See* ID at 355.

alternative that, if Respondents did not waive this combination, the combination would render the asserted claims of the '863 patent obvious. ID at 350.

At the hearing, Respondents contended that the asserted claims 1 and 4-8 of the '863 patent are obvious in view of various combinations of prior art including the asserted '511 patent and the knowledge of one of ordinary skill in the art. *Id.* at 344-45. The ALJ noted that respondents do mention "knowledge of one of ordinary skill in the art" in their pre-hearing brief (section 3.5.2.2), but found that the invalidity arguments in their brief amount to a general discussion of eleven separate references with no element-by-element discussion of how those eleven references would be combined to render the asserted claims of the asserted patents obvious. *Id.* at 349 (also at 180); *see also* sections 4.1.2.2, 5.5.2.2, 6.5.2.2, 7.5.2.2, and 8.5.3.2 of Respondents' Pre-Hearing Br. (RPHB). He found rather that Respondents' pre-hearing brief only included a general reference to a "claim chart" that they would produce at the hearing. *Id.* The ALJ found that this general reference to a future claim chart is inadequate notice to Align regarding the specific prior art to be addressed and the manner in which the prior art discloses each and every element of an asserted claim. *Id.* (citing RPHG at 60-67). Accordingly, the ALJ granted Align's motion in limine number 6 and excluded the claim charts that were not specifically cited in respondents' pre-hearing brief as required by his Ground Rule 8.2.[71] *Id.* (citing Tr. at 18-20).

In addition, although he noted that respondents discussed these eleven different prior art references in their pre-hearing brief at section 3.5.2.2, the ALJ found that they

[71] ALJ's Ground 8.2 states that "[a]ny contentions not set forth in detail as required herein shall be deemed abandoned or withdrawn, except for contentions of which a party is not aware and could not be aware in the exercise of reasonable diligence at the time of filing the pre-trial brief." *See* Order No. 2 (Apr. 2, 2012).

failed to identify any specific combinations of prior art references other than Lemchen, Kesling, and the knowledge of one of ordinary skill in the art. *Id.* (citing RPHB at 49). Having identified only these specific combinations, the ALJ found that any other combinations were waived including the combination of the asserted '511 patent and the knowledge of one of ordinary skill in the art. *Id.* at 350.

Respondents contend that their excluded claim chart was disclosed to Align as part of respondents' discovery responses and it was an exhibit to respondents' invalidity expert report. Resps. Pet. at 54. They also argue that their pre-hearing brief provided their contentions that all asserted claims were obvious and discussed the prior art in particular detail, including identifying where the disclosed subject matter was located in the prior art references. *Id.* (citing RPHB at 48-67, 97-106, 127-36, 146-54, 174-83, 205-17, 240-48). They further submit that under *Certain Mobile Devices, Associated Software, and Components Thereof* ("*Mobile Devices*"), Inv. No. 337-TA-744, Final ID, 2011 WL 6916539, at *103-04 (Dec. 20, 2011), their detailed disclosure complies with the ground rules and does not waive their invalidity defenses.

Complainant contends that the ALJ correctly found waiver because respondents failed to disclose this argument in their pre-hearing brief in violation of his Ground Rule 8.2. *Id.* at 30 (citing ID at 349-50).

The Commission affirms and adopts the waiver, exclusion, and limitation determinatons made by the ALJ set forth in the ID at 349-50. Invalidity is an affirmative defense. 35 U.S.C. § 282. Respondents' pre-hearing briefing on invalidity states only the following with respect to the '511 patent:

8.5.3 Obviousness under 35 U.S.C. § 103(a)

> The Respondents['] contentions concerning obviousness described above are incorporated here. During the hearing, the Respondents intend to introduce a chart prepared by Dr. Mah that shows where each element of each asserted claim is found in the prior art reference.

* * *

8.5.3.2 The following prior art references in combination with the knowledge of one of ordinary skill in the art, and with other prior art where specifically referenced.

* * *

8.5.3.2.13 U.S. Patent No. 6,471,511 (Chishti)

> Align claims a priority date of December 4, 1998 [for the '863 patent]. This priority date makes the other asserted patents prior art as to the '863 [patent]. Each of the other asserted patents discloses the following: 1) methods for producing digital models used to generate orthodontic appliances; 2) methods for providing a digital model of a patient's dentition; 3) methods for producing a plurality of digital dentition models that represent successive orthodontic treatment stages from initial to final that are used to fabricate appliances; 4) presenting a visual image of the digital model; 5) manipulating the visual image to reposition the teeth; and 6) defining boundaries around individual teeth. These patents also disclose the use of attachment devices. One skilled in the art would also understand the use of attachment devices in light of these references.

RPHB at 205, 214.

The ALJ's Ground Rule 8.2 states, with respect to pre-hearing briefs, that "[a]ny contentions not set forth in detail as required herein shall be deemed abandoned or withdrawn[.]" *See* Order No. 2. The Commission agrees with the ALJ that Respondents' general, broad reference to the prior art as disclosing the claimed features, along with a claim chart to be purportedly presented later at the hearing does not serve to satisfy this rule. Align had no notice prior to the hearing of what arguments were to be made with respect to the asserted prior art such as: (1) where exactly in the prior art are the claim

features disclosed; (2) what evidence would be presented; and (3) what motivation to combine such knowledge and the prior art would be presented that would lead to the claimed invention. The Commission thus affirms the ALJ's determination that Respondents' argument with respect to the '511 patent was waived and to exclude the claim chart at issue.

E. Estoppel Defense (Including Defense of Implied License or Patent Exhaustion)

Respondents argue in their petition for review that Align is estopped from asserting the patents-in-suit against them by reason of Align's withdrawal of a prior lawsuit in Texas in which Align asserted United States Patent No. 6,554,611 (the '611 Patent) and Align's issuance of a statement, which Respondents regard as a covenant not to sue (the so-called "Texas Covenant") at the time that Align withdrew its Texas lawsuit.

The ALJ, in Order No. 20, found that the Respondents had waived their right to assert a defense of estoppel or patent exhaustion because it was not previously raised in their response to the original complaint, and, assuming arguendo that the defenses were not waived, that there was no implied license of the patents-in-suit. Order. No. 20 at 23. The ALJ found that the instant situation is distinguished from the patent exhaustion cases relied on by Respondents, *TransCore* and *Leviton*, because Respondents have not established that the '880 patent and '511 patents are necessary to practice the '611 patent. *Id.* at 25 (citing *TransCore LP v. Electronic Transaction Consultants Corp,* 563 F.3d 1271, 1279 (Fed. Cir. 2009); *General Protecht Group, Inc. v. Leviton Manufacturing Co.*, 651 F.3d 1355, 1361 (Fed. Cir. 2011)). The ALJ further found that *Leviton* was not

applicable with respect to the Texas Covenant because the asserted patents are not continuations of the '611 patent. *Id.*

The Respondents argue that the ALJ erred in his finding because the Respondents pleaded the affirmative defense of estoppel as their "Fourth Affirmative Defense" in their response to the Complaint. Resp. Pet. at 31. Respondents' Fourth Affirmative Defense stated:

> Because of proceedings in the U.S. Patent and Trademark Office during the prosecution of the application that resulted in U.S. Patent Nos. 6,685,469, 6,394,801, 6,398,548, 6,722,880, 6,629,840, 6,699,037, 6,318,994, 6,729,876, 6,602,070, 6,471,511 or 6,227,850--as shown by the prosecution histories--Align is estopped from construing the claims of these patents in a way that would cause any valid claim thereof to cover or include any products that are or have been manufactured, used, sold, offered for sale, or imported by ClearCorrect, or any process used by ClearCorrect to manufacture its products.[72]

The Respondents argue that the Fourth Affirmative Defense does not relate to prosecution estoppel, as noted by the ALJ, because the Respondents had pleaded prosecution history estoppel as a separate defense. Resp. Pet. at 32. The Respondents further argue that they could not have waived their affirmative defense of estoppel because Align was on notice of the defense based on Align's interrogatories that sought the basis of the estoppel defense. *Id.*

Align argues that the Fourth Affirmative Defense referred to by the Respondents was unrelated to the alleged defense of implied license or patent exhaustion. Align Resp. to Pet. at 10. Rather, Align argues that this affirmative defense refers exclusively to prosecution histories and claim construction. *Id.*

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[72] Response of ClearCorrect Operating, LLC to Complaint under Section 337 of the Tariff Act of 1930, as amended; Inv. 337-TA-833 (CX-1021).

Align contends that neither *TransCore* nor *Leviton* are applicable here because unlike in *TransCore* and *Leviton,* Align never asserted the '611 patent against Respondents nor did they receive consideration in exchange for the agreement. *Id.* at 17. Align argues that to establish patent exhaustion, an accused infringer must show that the product sold substantially embodies the patented invention, and that Respondents cannot establish that its products embody the '611 patent claims or that there was an authorized sale. Align Resp. to Resps. at 18-19.

The Commission has determined to affirm and adopt the ALJ's finding that the Respondents had waived their right to assert implied license and patent exhaustion because they were not asserted in their response to Align's complaint. ID at 1-2; Order No. 20. The Commission requires that the affirmative defenses be pleaded with as much specificity as possible in the response to the complaint. 19 C.F.R. § 210.13(b) The Fourth Affirmative Defense upon which the Respondents base their defense of estoppel with respect to implied license and patent exhaustion is instead solely directed to Align's prosecution of the patents-in-suit before the USPTO and does not even reference the '611 patent upon which its defense is based.

Aside from waiver, the Commission has determined to affirm the ALJ's findings in Order No. 20 that the facts of the current case differ from those in *TransCore* and *Leviton* because in the Texas action, Align withdrew its complaint without a settlement agreement and Respondents provided no consideration. Order No. 20 at 25. Further, although the patents at issue are derived from a common provisional application, the resulting claims are not necessarily exhausted by operation of the '611 patent at issue in the withdrawn Texas suit.

F. Domestic Industry - - Economic Prong

The ALJ found that Respondents waived the right to contest domestic industry and found that Align established the economic prong of the domestic industry requirement. ID at 766-67. He concluded that Align made a significant investment in plant and equipment and significant employment of labor and capital in the United States. Specifically, the ALJ found that Align spends money on rent for a research facility and hires employees who perform research and development. *Id.* at 767. The evidence shows that Align employs over [[

]], and has paid approximately [[

]] ID at 767 (citing CX-1237C at Q 32). Align has a corporate headquarters in San Jose, California, [[ ]] CX-1237C, QQ.25-52. Align [[ ]] for its San Jose facility, [[

]] ID at 766 (citing CX-1237C at Q. 27.).

Respondents argue that the ALJ erred in not allowing them to cross-examine Align's witness. Respondents' Pet. at 69. We affirm and adopt the ALJ's findings that Respondents waived this issue before the ALJ by stipulating that it would not contest domestic industry (either prong), and that Align has established that it met the economic prong of the domestic industry requirement.[73] ID at 766-67; Tr. at 46-48, 72-79, 619-624.

G. Domestic Industry - - Technical Prong

As stated above, the ALJ found that Respondents waived the right to contest domestic industry. He found that Align's Invisalign system satisfied representative

[73] We clarify that the economic prong was proven under 19 U.S.C. § 1337(a)(3)(A) and (B).

claims of all the asserted patents except the '666 patent based on Dr. Kuo's Witness Statement. ID at 771-795.[74]

1. The '487 Patent

The Respondents petitioned for review of the ALJ's finding that Align satisfied the technical prong of the domestic industry requirement based on their claim construction argument that a "treatment plan" (in claim 7) can be made only by a clinician. Resps. Pet. at 68. Because we affirm the ALJ's claim construction, we affirm the ALJ's finding that the technical prong is satisfied for the '487 patent.

2. The '863 Patent

Respondents argued in their petition that Align does not make digital models of actual dental appliances, and only makes digital models of teeth. Resps. Pet. at 68. Align responds that this argument was waived because it was not presented in a claim construction chart in a timely fashion, that the ALJ correctly held that the preamble of claim 1 is not limiting, and that Align's digital models of the teeth should be considered negative models of the aligners. Align Resp. to Pet. at 52-53. We find that Respondents waived any technical prong argument for this patent. Tr. at 46-48, 72-79, 619-624.

3. The '666 Patent

Pursuant to the claim chart set forth in the ID at 784-85, the ALJ found that Align had not made a *prima facie* showing that it practiced claim 7 of the '666 patent. ID at 787-88. The ALJ found that Dr. Kuo's witness statement did not provide any evidence

[74] The Commission adopts the ALJ's finding that the technical prong is satisfied for those patents for which there is no petition for review.

that Align's process includes the step of "interpolating positional differences between the initial and final position of teeth." ID at 788.

Align contends that the ALJ's exclusion of factual evidence as "impermissible expert testimony" caused the ALJ to improperly rule that Align had failed to establish the technical prong of the domestic industry requirement with respect to the '666 patent. Align. Pet. at 13. Align argues that had the ALJ retained the factual testimony regarding Align's process, while striking only Dr. Kuo's conclusion, the evidence would have supported that Align's process includes "the step of interpolating positional differences between the initial and final position of teeth." *Id.* The Complainant cites the Commission's prior holding in *Certain Video Graphics Display Controllers & Prods. Containing Same*, Inv. No. 337-TA-412, Order No. 53 (Jan. 20, 1999) and a district court holding in *LaSalle Bank Nat'l Ass'n v. Nomura Asset Capital Corp.*, 2004 U.S. Dist. LEXIS 18599 (S.D.N.Y. Sept. 13, 2004) as support for the proposition that a witness's factual testimony should remain admissible even where the court determines that opinion testimony should be excluded. Align. Pet. at 16.

The IA submits that the ALJ erred in its finding that although Dr. Kuo's witness statement does not recite the exact words from the allegedly missing limitation, "his statement describes the step in sufficient detail to make a *prima facie* showing that Align practices claim 7 of the '666 patent." IA Pet. at 11. Specifically, the IA argues that the computer software, as described in Dr. Kuo's statement, "interpolates positional differences between the initial and final position of teeth" when computer software is used by Align technicians to "generate a plan wherein a tooth path is determined for motion of each tooth from an initial position to a final position." *Id.* at 11.

The IA further argues that the ID's finding with respect to the '666 patent contradicts the finding that Align met its burden to make a *prima facie* showing that it practiced claim 1 of the '511 patent. IA Pet. at 12. The IA argues that the testimony that supported finding that Align practiced claim limitation "calculating a segmentation of the aggregate tooth paths" of the '511 patent should also satisfy the *prima facie* showing that Align practices the "step of interpolating positional differences between the initial and final position of teeth." *Id.*

The Respondents argue that Dr. Kuo's Witness Statement was the only evidence Align cites for its practice of the fourth element of claim 7 describing "interpolating positional differences" between teeth in different positions. Resps. Resp. at 5. The Respondents contend that the ALJ properly excluded Dr. Kuo's improper opinion testimony because he was never disclosed as an expert. *Id.* As such, the Respondents argue that since the relevant part of the statement was excluded, no other evidence supports the practice of "interpolation" limitation.

Respondents further disagree with the IA's comparison of the contested limitation to the '511 patent as flawed because "interpolate" is understood to mean, "To estimate a value of (a function or series) between two known values." Resps. Resp. at 7 (citing THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE 915 (4th ed. 2000)). The Respondents argue that Align offered no evidence that its technicians estimate values when they "generate tooth paths" or "calculate a segmentation of tooth paths." *Id.*

The sole limitation that the ALJ found was not satisfied was the step of "interpolating positional differences between the initial and final position of teeth" of claim 7 of the '666 patent. ID at 788. We agree that the ALJ did not abuse his discretion

with respect to excluding Dr. Kuo's concluding opinion. *See* ID at 188. However, the IA is correct to point out that the ALJ relied on Dr. Kuo's Witness Statement (and only on his Witness Statement) as evidence in finding that Align satisfied the technical prong with respect to the '511 patent. ID at 784 (citing CX-1235, Qs. 20-23). The IA is therefore correct that this same evidence (from the Witness Statement as opposed to the trial testimony) may be relied on to satisfy the technical prong with respect to the '666 patent. In our view, this same statement is equally applicable to the limitation at issue in the '666 patent. CX-1235, Q. 22 [[

]] Therefore, Align has put forth sufficient evidence to show that it practices claim 7 the '666 patent. We therefore reverse the ALJ's finding that Align has not satisfied the technical prong of the domestic industry requirement with respect to the '666 patent.

4. The '325 patent, the '880 patent, the '511 patent, and the '874 patent

The ALJ found that Align established the technical prong of the domestic industry requirement with respect to the '325 patent, the '880 patent, the '511 patent, and the '874 patent for the reasons set forth in the claim charts of the ID at 771-72, 776-77, 782, 793. None of the parties petitioned for review of satisfaction of the technical prong with respect to these patents, and we adopt the ALJ's findings with respect thereto.

IV. REMEDY, THE PUBLIC INTEREST, AND BONDING

A. Remedy

1. The Recommended Determination

The ALJ did not recommend the issuance of an exclusion order. Recommended Determination ("RD") at 797. Instead, the ALJ recommended the issuance of a cease and desist order against CCPK and CCUS that prohibits importation (electronically or otherwise) into the United States of certain digital models, digital data, and treatment plans (for use in making dental appliances), citing Inv. No. 337-TA-383, *Certain Hardware Logic Emulation Systems and Components Thereof*, Comm'n Op. at 28 (March 1998). RD at 802. The ALJ found the presence of a "rolling" inventory in the United States because CCUS imports digital data sets on a daily basis and pays on average $3000/day based on a monthly payment of approximately $85,000 to CCPK. *Id.* at 803.

The ALJ observed that the Commission has granted cease and desist orders directed to electronic transmission of software in previous investigations. *Id.* at 803 (citing *Hardware Logic*). The ALJ also observed that the Commission has issued a cease and desist order against a foreign entity, Kinik Co. of Taipei, Taiwan, in *Certain Abrasive Products*, Inv. No. 337-TA-449, Comm'n Op. (May 9, 2002).

2. Parties' Arguments

Align does not seek an exclusion order, and argues that the Commission should adopt the ALJ's recommendation for issuance of a cease and desist order.[75] Align Sub. at 20; Align Reply Sub. at 10. Align proposes that the language of any such order should encompass the principals and managing employees of both Respondents. Align Sub. at 20. Align argues that the Commission should issue a cease and desist order against CCPK because CCUS is at least the second company with which personnel of CCPK have worked, and an order against CCPK would better enable Align to file an enforcement action should CCPK continue its infringing conduct. Align Reply Sub. at 10.

Respondents argue that typically the complainant must prove commercially significant inventories of infringing products in the United States to justify a cease and desist order. Resps. Sub. at 19 (citing *Certain Cigarettes & Packaging Thereof*, USITC Pub. 3366, Inv. No. 337-TA-424 (Nov. 2000)). Respondents state that here there are no "inventories" of digital information at issue. *Id.* Respondents argue that the evidence does not show significant inventories of the orthodontic appliances either. *Id.*

Further, Respondents discuss the possible types of electronic communications (including telephone calls) and argue that "any cease and desist order should therefore be written narrowly to avoid excessive peripheral litigation about what transmissions and activities are prohibited." *Id.* at 20; Respondents Reply Sub. at 10. Respondents agree

[75] Align argued to the ALJ that the imposition of a "commercially significant inventory" requirement for issuing a cease and desist order would leave no practical mechanism to prevent importation in the absence of an exclusion order. Align Post-Hrg. Reply Br. at 94. Align cited the Commission Opinion in *Hardware Logic* for the notion that the purpose of issuing a cease and desist order that includes electronic transmissions is to prevent relief from being meaningless. *Id.* Align argued that the Commission has previously issued a cease and desist order against a foreign respondent in an analogous situation where that respondent's domestic distributor maintained a commercially significant inventory in the U.S. *Id.* at 96 (citing *Certain Toner Cartridges*, Inv. No. 337-TA-740, Comm'n Op. at 7-8 (Oct. 5, 2011) (citing *Certain Abrasive Products*, Inv. No. 337-TA-449, Comm'n Op. at 7-8 (May 2, 2002))).

with the IA that any cease and desist order should not include CCPK. Respondents Reply Sub. at 10.

The IA agrees with the ALJ's recommendation that the issuance of an exclusion order is not appropriate in this case. IA Sub. at 10. The IA states that the Commission has previously considered and rejected requests that exclusion orders cover electronic transmissions. *Id.* (citing *Hardware Logic*, Comm'n Op. at 19-20).

The IA agrees with the ALJ's recommendation to issue a cease and desist order to CCUS. *Id.* at 11. The IA asserts that the ALJ correctly determined that CCUS has a commercially significant inventory in the United States. *Id.* at 11 (citing *Certain Semiconductor Chips with Minimized Chip Package Size and Products Containing Same*, Inv. No. 337-TA-605, Comm'n Op. at 73 (June 3, 2009)). The IA states that the ALJ determined that CCUS pays CCPK approximately $3000.00 per day, based on a monthly payment of $85,000.00, and that this rolling daily inventory of $3000.00 worth of digital data sets is sufficient to find that CCUS has a commercially significant inventory in the United States.

The IA disagrees with the ALJ's recommendation that a cease and desist order should be directed to CCPK because, as a matter of prudence, the Commission does not issue cease and desist orders to foreign companies that do not have a domestic inventory because it would not have an effective means of enforcing such an order. *Id.* at 12. The IA cites Commission precedent for the proposition that it is Commission practice to issue cease and desist orders only to domestic respondents, particularly in light of the difficulty of enforcing such orders against foreign entities, that cease and desist orders may ultimately be enforced by the Commission in U.S. district courts, and that it is

inappropriate to issue one unless a party in the United States can be compelled to do some act or refrain from doing some act. *Id.* (citing *Certain Flash Memory Circuits and Products Containing Same*, Inv. No. 337-TA-382, Comm'n Op. at 25 (July 1997); *Certain Wear Components and Products Containing Same*, Inv. No. 337-TA-644, Comm'n Op. at 22-23 (Nov. 24, 2009)); IA Reply Sub. at 10.

3. Analysis

The appropriate remedy in this case (and the only remedy requested) would be cease and desist orders directed to CCUS and CCPK.

As noted by the IA, the Commission typically imposes cease and desist orders against Respondents with domestic inventories because the ultimate mechanism for dealing with noncompliance is in district courts.[76] *See* 19 U.S.C. § 1337(f)(2). The ALJ found that CCUS had a "rolling" inventory of digital data sets that make up particular phases of patients' treatment provided by CCPK to CCUS on a daily basis, which are then used by CCUS to manufacture aligners. ID/RD at 803. Although Respondents dispute whether these digital data sets may constitute inventory, the Commission nonetheless has authority to issue a cease and desist order for any violation found because the presence of a U.S. inventory is not a statutory requirement.

The Commission has issued cease and desist orders against a foreign respondent in several investigations. In *Abrasive Products*, the Commission issued a cease and desist order against Kinik Co. of Taipei, Taiwan, because the U.S. distributor, Rodel,

[76] If a person violates a cease and desist order, the Commission, in an enforcement proceeding, may replace the cease and desist order with an exclusion order, 19 U.S.C. § 1337(f)(1), or impose a penalty "of not more than the greater of $100,000 or twice the domestic value of the articles entered or sold on such day in violation of the order." 19 U.S.C. § 1337(f)(2). The Commission may also bring a civil action in the U.S. District Court for the District of Columbia for a mandatory injunction. *Id.*

Inc., was not a respondent. *Abrasive Products Made Using a Process for Making Powder Preforms and Products Containing Same*, Inv. No. 337-TA-449, Comm'n Op. at 7-8 (May 9, 2000). The Commission intended to thereby bind the domestic distributor through an order directed against the foreign respondent. *Id.* The Commission also issued cease and desist orders against foreign respondents in *Certain Toner Cartridges and Components Thereof*, Inv. No. 337-TA-740. In that investigation, the Commission explained that Ninestar Tech was the same company as Ziprint, both domestic companies, and that Ninestar Tech was a subsidiary of Ninestar Image Int'l., of China, which shared a headquarters with Ninestar, also of China. In *Lighting Control Devices*, the Commission issued a cease and desist order against a foreign respondent, where a domestic reseller held the foreign manufacturers' inventories for resale in the United States, Inv. No. 337-TA-776, Comm'n Op. at 26-27 (Nov. 8, 2012).

Here, unlike *Abrasive Products*, there is a domestic respondent, CCUS. With regard to the business relationships between respondents in connection with the infringing imports, which was considered in *Toner Cartridges*, Respondents contend that CCPK is independent of CCUS. The ALJ's findings, however, show that CCPK and CCUS engage in concerted activities to produce aligners for distribution in the United States through CCPK's production of digital data sets and treatment plans that are transmitted to CCUS as set forth in the detailed findings of the ALJ in the ID.

The Commission has therefore determined that the issuance of a cease and desist order would be the appropriate remedy for the violation of Section 337 if the issuance of such an order is not precluded by the public interest factors. We consider the public interest factors in the following section.

B. The Public Interest

1. Parties' Arguments

Respondents argue that a cease and desist order would harm the public welfare. Resps. Public Interest Sub. at 2. Respondents state that in 2010, Align declared that any doctor who did not buy at least ten cases a year from Align and take the continuing education Align dictated would be stricken from Align's customer rolls and would not be sold any clear aligners. *Id.* Respondents state that Align's misconduct was addressed generally in the class action suit Case No. 3:10-cv-2010, *Leiszler v. Align Technology, Inc.*, in the United States District Court for the Northern District of California, which Align settled two years ago. *Id.* Respondents state that Dr. Willis Pumphrey founded ClearCorrect because he could not buy aligners from Align after it bought OrthoClear's assets. *Id.*

Respondents state that Align received a letter from the FDA during 2010 advising that Align had failed to disclose reports of important side effects to patients using its Invisalign system, including allergic reactions to the product. *Id.* (citing the FDA letter at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm234578.htm). *Id.* at 4. Respondents further state that Align concedes in its SEC filings that its manufacturing operations are located outside the United States. *Id.*

Align argues that cease and desist orders would not be adverse to the public interest, discussing each of the public interest factors. Align Public Interest Sub.at 2-5. Align argues that Respondents rely on vague and unauthenticated statements of doctors, that the record is closed, and that Respondents' public interest statement was untimely. Align Reply Sub. at 10.

The IA states that Respondents do not assert any concerns that would contradict Align's assertion that the teeth positioning systems at issue are elective and not part of an essential life-saving device. IA Sub. at 12-13. The IA notes that Align attests that it has adequate capacity to service patients who want clear removable teeth positioning appliances, and that conventional braces still constitute 90% of the treatments for malocclusion. *Id.* at 13 (citing Align's Public Interest Comments at 5). As to competitive conditions in the United States economy, the IA asserts that Respondents' exit from the market would not diminish competition in the overall U.S. orthodontic market because providers and consumers would continue to have choices in the overall orthodontic market. *Id.* at 12-13. The IA notes that Align's technology makes up 10% of the orthodontic market, and that Respondents make up 10% of that market share or 1% of the overall orthodontic market. *Id.* at 12. As to the production of like or directly competitive articles in the United States, the IA notes Align's assertion that it can replace the articles covered by the cease and desist order. *Id.* at 14 (citing Align's Public Interest Comments at 4). As to United States consumers, the IA is of the view that a cease and desist order would not harm United States consumers, and that the fact that some consumers may have to pay a higher price does not outweigh the protection of intellectual property. *Id.* (citing *Certain Telecommunications Chips*, Inv. No. 337-TA-337, Comm'n Op. at 40-41 (August 1993)).

2. Analysis

After considering the record and the parties' arguments, the Commission finds that the evidence pertaining to the statutory public interest factors does not indicate that

cease and desist orders should not be issued. However, the Commission determines to include an exemption in the cease and desist orders for existing ClearCorrect patients.

Respondents' arguments with respect to effects on public health and welfare warrant analysis both with respect to that factor and potential impact on U.S. consumers.[77] The record indicates that Align is fully capable of providing its products to all doctors seeking incremental orthodontic appliances for their patients. There is no indication that Align continues to refuse to sell to dentists after settling the class action. Indeed, Respondents note that this issue was addressed in the settlement of that litigation. Also, conventional braces account for the large majority of orthodontic treatments in the United States. As for Align's citation for failure to report side effects in 2010, the record does not reflect any continuing failure to provide such reports to the FDA or that the use of Align's products for orthodontic treatment may adversely impact patients' health. Therefore, the effects of the orders on the public health and welfare and on U.S. consumers do not indicate that the orders should not issue.

The potential effects of the orders on U.S. consumers (and possibly public health and welfare), however, warrant an exemption for activities related to treatment of patients who have already begun treatment with ClearCorrect's aligners. As the Commission has recognized in certain investigations relating to cellular telephones, *see, e.g.*, *Personal Data and Mobile Communications Devices and Related*, Inv. No. 337-TA-710 (Exclusion Order), the Commission may balance the public interest to accommodate the needs of

[77] Respondents submitted letters from dentists on their behalf, in support of the Commission not issuing a remedial order. Resps. Sub., Attachment 13. These letters request that the dentists be allowed to continue to give their patients the option of ClearCorrect aligners. The Commission has considered these letters in considering the effect on U.S. consumers. As set forth herein, the Commission has determined that Align's system and traditional braces are both acceptable alternatives to ClearCorrect's aligners.

U.S. consumers who require repair and replacement of existing devices. Given the ongoing nature of orthodontic treatment, we do not place a time limit on these exemptions. However, certifications and compliance reporting requirements apply to all such continuing treatments throughout the duration of treatment for existing patients. Thus, the Commission exempts repair and replacement of existing appliances from the scope of the cease and desist orders, and activities relating to treatment of patients who have already contracted for treatment with ClearCorrect as of April 10, 2014. (The one-week grace period from issuance of this order is intended to allow time for the cease and desist orders to be communicated to orthodontists and dentists.) This exemption is subject to reporting to the Commission and to a certification requirement.

As to competitive conditions in the United States economy, the record reflects that Align is able to manufacture sufficient dental appliances to meet U.S. demand for this specific type of aligner for orthodontic treatment. Moreover, the record reflects that traditional dental appliances are the predominant choice for the treatment of malocclusions and there is no indication of any adverse impacts of the cease and desist orders on these traditional appliance treatments.

As to the production of like or directly competitive articles, the record indicates that the predominant mode of orthodontic treatment in the United States is traditional braces. The record provides no indication that the orders will have any adverse effect on production of orthodontic appliances in the United States.

The Commission has therefore determined that there would be no adverse effect on the public health and welfare, competitive conditions in the U.S. economy, the

production of like or directly competitive articles in the Unites States, or U.S. consumers such that the orders (with the exemption discussed above) should not be issued.

C. Bonding

The ALJ did not recommend the issuance of a bond during the period of presidential review. RD at 810.

Align states that it "does not seek review" of the ALJ's finding that no bond is appropriate. *Id.* The IA notes that Align has not requested any bond before the Commission. IA Reply Sub. at 9.

As there is no request for a bond, the Commission has determined not to require a bond during the Presidential review period.

V. CONCLUSION

For the foregoing reasons, the Commission has determined to affirm-in-part, modify-in-part, and reverse-in-part the ID of the ALJ and to issue a cease and desist order against CCUS and CCPK.

By order of the Commission.

Lisa R. Barton
Acting Secretary to the Commission

Issued: April 9, 2014

DISSENTING VIEWS OF COMMISSIONER DAVID S. JOHANSON

It is a question of first impression whether the electronic transmission of digital data into the United States constitutes importation of an "article" within the meaning of Section 337(a)(1)(B) of the Tariff Act of 1930. The Commission majority broadly interprets the statute to allow it to exercise jurisdiction and find a violation by treating electronic transmission of data as an "article." As this interpretation does not address Congress's delegation of authority to the Commission, ignores Section 337's remedial scheme, and contradicts the federal courts' interpretation of "articles," I respectfully dissent.[1]

1. The Commerce Clause of the United States Constitution empowers Congress to "regulate commerce with foreign nations" and to "lay and collect taxes, duties, imposts, and excises." U.S. Const. Art. I, § 8, cl. 1-3. Under that authority, Congress has passed into law numerous federal statutes, including the Tariff Act of 1930, as amended. Section 337 was originally enacted as Section 316 of the Tariff Act of 1922, one of the so-called "flexible tariff" provisions of that Act. As a trade act, Section 337 is not meant to remedy every unfair act in every context, but rather is directed to remedy those acts in the context of the statutory framework established by Congress for importation into the customs territory of the United States.[2] Thus, Section 337 is not the international extension of our patent, copyright, and

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[1] Align bears the burden of proof under the Administrative Procedure Act to show that electronic transmissions are "articles" within the meaning of Section 337. 5 U.S.C. § 556(d) ("Except as otherwise provided by statute, the proponent of a rule or order has the burden of proof."). Specifically, Align has the burden of showing Congress intended to cover digital transmissions under Section 337. Align has failed to meet that burden.

[2]As discussed below, Align and the majority assert Section 337 is a remedial statute and should be broadly construed. But the legislative history makes clear that the only part of Section 337 that should be broadly construed is "unfair methods of competition and unfair acts" in Section 337(a)(1)(A), not the portion of the statute at issue here. *See, e.g.*, Report, S. Rep. 67-595 at 3 (1922), 62 Cong. Rec. 5879 (1922). Indeed, the "unfair competition" part of the statute was

trademark laws, but has restrictions that stem from the fact that it is, first and foremost, a trade law. *See, e.g., Schaper Mfg. Co. v. ITC*, 717 F.2d 1368, 1373 (Fed. Cir. 1983) (rejecting broader construction of the domestic industry requirement); *Corning Glass Works v. ITC*, 799 F.2d 1559, 1566 (Fed. Cir. 1986) (rejecting broader construction of the injury requirement); *Kyocera Wireless Corp. v. ITC*, 545 F.3d 1340, 1355 (Fed. Cir. 2008). Indeed, the statute provides that the remedies it permits are in addition to other provisions of law. 19 U.S.C. 1337(a)(1). Thus, Section 337 provides a customs remedy in addition to the remedies that can be obtained from the courts. Align is currently seeking relief from the courts.[3]

Section 337's requirements—and in particular, what it means to be an imported "article"—therefore must be informed by Congress's understanding of the scope of the enacted United States trade laws. The ITC is a creature of statute and must find authority for its actions in its enabling statute. *See Vastfame Camera, Ltd. v. ITC*, 386 F.3d 1108, 1112 (Fed. Cir. 2004). It therefore is simply incorrect to say that the Commission has broad authority except as expressly limited by Congress. Absent clear indications to the contrary, it makes little sense to interpret Section 337 in a way that differs from the interpretation of other trade statutes. Besides lying closer to Congress's intent, a consideration of the trade laws in unison reduces the

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never at issue here as this case was brought under the specific patent provisions of Section 337(a)(1)(B). I further note that denominating a statute as "remedial" does not permit an agency or tribunal to add to a statute. *Fortin v. Marshall*, 608 F.2d 525, 529 (1st Cir. 1979) (citing *United Shoe Workers of America, AFL-CIO v. Bedell*, 506 F.2d 174, 187 (D.C. Cir. 1974); *U.S. EEOC v. AIC Security Investigations, Ltd.*, 55 F.3d 1276, 1282 (7th Cir. 1995) ("A liberal construction does not mean one that flies in the face of the structure of the statute."). It is argued that the term "that infringe" which follows "articles" in Section 337(a)(1)(B)(i) modifies "articles" so that the term covers electronic transmissions. However, a modifier narrows its subject; it does not broaden it.

[3] The parties are involved in a civil action in the Southern District of Texas, which has been stayed during the Commission investigation. *Align Technology, Inc. v. ClearCorrect, Inc., ClearCorrect Operating, LLC, and ClearCorrect Holdings, LLC*, No. 4:11-cv-00695 (Jury Demanded), Order (May 10, 2012).

possibility of inconsistent or contradictory treatment of different imports. Therefore, to understand Section 337, it is important to consider, for example, the Harmonized Tariff Schedule of the United States (HTSUS). Indeed, Section 337 specifically references the HTSUS. *See* 19 U.S.C. § 1337(m) (defining the United States to mean the customs territory of the United States as defined in general note 2 of the HTSUS).[4]

Under the HTSUS, tangible items are subject to tariff[5] as has always been the case with the customs laws of the United States. This comports with the plain understanding of the term in the context of the statute; namely, "articles" are physical things.[6] *See Dolan v. United States*

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[4] The Commission routinely requires the complainant to provide the applicable HTS number for the articles subject to a Section 337 investigation.

[5] The dutiable lists or schedules of the Tariff Act of 1930, set forth in Title I, were replaced in 1963 by the Tariff Schedule of the United States, (the "TSUS"), Pub. L. 87-456. The legislative history of the TSUS includes the Tariff Classification Study Submitting Report, which accompanied the proposed revisions to the tariff laws. In that Report, the Commission wrote "General headnote 5 sets forth certain intangibles which, under various established customs practices, are not regarded as articles subject to treatment under the tariff schedules." *Id.* at 18. In this connection, the original TSUS explicitly excepted electricity from the scope of the tariff schedules. General headnote 5(c). The TSUS was in turn replaced by the Harmonized Tariff Schedule of the United States ("HTSUS"), pursuant to the Omnibus Trade and Competitiveness Act of 1988, Pub. L. 100-418 § 1206, 102 Stat. 1151, codified at 19 U.S.C. § 3006. The HTSUS includes a heading for electrical energy but provides that electrical energy shall enter duty free and is not subject to entry under Section 484 of the Tariff Act of 1930; rather, the HTSUS provides that electrical energy is subject to entry under regulations to be prescribed by the Secretary of the Treasury. *Compare* HTSUS 2716 *with* HTSUS General Headnote 3(e)(iii) and Headnote 6(b) to Chapter 27. While the amendments subsequent to 1930 to the tariff schedules may or may not be relevant to the interpretation of Section 337, it is clear that the original tariff schedules only included tangible items and that the HTSUS excludes telecommunications transmissions and business data as intangibles (and even excludes electric energy from the entry requirements of Section 484 of the Tariff Act of 1930).

[6] When looking to the plain meaning of "article" based on a reliance on certain dictionary definitions from 1922 to 1930 at the time of the enactment of Section 337 as the Supreme Court requires us to do, it must not be viewed in the abstract. Rather, one should look to the statute when read in the context of other trade laws to determine which definition fits within that context. *Dolan v. United States*, 546 U.S. at 486. Under that analysis "article" means a tangible good. Numerous definitions were submitted to support a "plain meaning" construction of the

Postal Service, 546 U.S. 481, 486 (2006) ("The definition of words in isolation, however, is not necessarily controlling in statutory construction. A word in a statute may or may not extend to the outer limits of its definitional possibilities. Interpretation of a word or phrase depends upon reading the whole statutory text, considering the purpose and context of the statute, and consulting any precedents or authorities that inform the analysis."). In fact, the only clear reference to Customs' authority to regulate electronic transmission of digital data strongly suggests Congress did *not* intend for Section 337 to remedy electronic transmissions. Congress explicitly exempted electronic transmissions as a good from the tariff schedule. *See* HTSUS General Headnote 3(e)("For the purposes of general note 1 – (ii) telecommunication transmissions ... are not goods subject to the provisions of the Tariff schedule."). Thus, Congress has specifically limited Customs' authority to regulate or lay and collect taxes, and/or duties on electronic transmissions. *Id.* There is nothing in the legislative history of Section 337 to suggest that the Commission's authority exceeds Customs' in this regard.

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term "article," and the majority of such definitions suggest some tangible quality (or are at best ambiguous): (1) "Something considered by itself and as apart from other things of the same kind or from the whole of which it forms a part; also, a thing of a particular class or kind; as, an *article* of merchandise; salt is a necessary article" (Harris, Webster's New International Dictionary of the English Language at 131, G. & C. Merriam Co. (1924)); (2) "A particular object or substance; a material thing or class of things; as, an *article* of food" (Funk, New Standard Dictionary of the English Language, Funk & Wagnalls Co. at 162 (1929)); (3) "a particular thing; item" (Webster's New International Dictionary, 2d. Edition (1927)); (4) "a particular thing" (Funk & Wagnall's Concise Standard Dictionary of the English Language, 2d. Edition (1929) and Fowler, H. W., Concise Oxford dictionary of Current English, 2d. Edition (1929)); (5) "a particular object or substance; a material thing or class of things" (Funk & Wagnall's College Standard Dictionary of the English Language, 1st edition (1929)). Relatedly, the Federal Circuit relied on a definition of "article" in Webster's Third New International Dictionary (a more recent edition of Webster's) in interpreting 35 U.S.C. § 271(g), which was enacted in 1988. "Article" is there defined as "one of a class of *material things . . . piece of goods*; COMMODITY." *Bayer AG v. Housey Pharmaceuticals, Inc.*, 340 F.3d 1367, 1372 n.4 (Fed. Cir. 2003) (emphasis added by Federal Circuit).

Other related trade laws also have been limited to tangible goods. For example, under the previous countervailing duty law, Section 303 of the Tariff Act of 1930 (now repealed), the term "merchandise" was limited to tangible items. *See Preliminary Affirmative Countervailing Duty Determination: Certain Computer Aided Software Engineering Products from Singapore*, International Trade Administration, Department of Commerce (Commerce), 55 *Fed. Reg.* 1596 (January 17, 1990). In that case, Commerce rejected the argument that the imported software should be analyzed exclusively in terms of its (intangible) intellectual property and be considered merchandise under Section 303. Commerce concluded that it is the tangible medium, and not the intangible software, which can give the imported goods their characteristics as merchandise under Section 303. There, software on a tangible medium was an article or "merchandise," but electronic transmission of software would not have been. Section 303 was, like Section 337, part of Title III of the Tariff Act of 1930. It specifically referenced an "article or merchandise." The use of the terms article and merchandise interchangeably suggests they should be afforded the same meaning, and both appear in the same provision of the Tariff Act of 1930. Again, there is no indication in the legislative history that Congress intended to construe "article" differently in Section 337 as compared to the rest of Title 19. In sum, there is nothing in related trade acts to suggest inclusion of anything other than tangible articles.

2. There are additional indications within Section 337 itself that support an interpretation of "articles" that does not include electronic transmissions. Congress created Section 337 to remedy unfair practices in the importation of goods and provided specific remedies—central of which is exclusion from entry. The statute's references to "entry"[7] are

[7] Citations to interpretations of terms in unrelated statutes or cases that generally concern the term "importation" and "articles of commerce" untied to Section 337 offer little guidance. *See*

found in eight of the fourteen subsections of Section 337 and provide various remedies directed toward articles specifically: exclusion from entry and seizure and forfeiture orders. *See* 19 U.S.C. § 1337(d), (e), (i), (j) (*e.g.*, "articles concerned" be excluded from entry; "attempted entry"; and "denial of entry"). This focus on how "articles" obtain "entry" into the United States is no accident. The concern with entry reflects Congress's explicit choice to attack the problem of articles that violate Section 337 through established Customs entry procedures (*i.e.*, Section 484 of the Tariff Act of 1930 (19 U.S.C. § 1484) and associated Customs regulations 19 U.S.C. § 1484(c)(1) (Entry).[8] It is this remedial scheme that was adopted in Section 337.

That scheme contemplates only tangibles as "articles." Electronic transmissions do not arrive at ports of entry, are incapable of being held in Customs custody, cannot be presented to Customs, and therefore can never be refused or denied entry. An exclusion order directed against electronic transmissions could not only have no effect within the context of Section 337—it simply would make no sense as it would not be enforced. Moreover, to define "articles" as including electronic transmissions would render much of Section 337 meaningless because the definition cannot be applied to all or part of eight of the fourteen subsections of Section 337. *See United States v. Ron Pair Enterprises, Inc.* 489 U.S. 235, 242 n.5 (1989) (a definition should be

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Cedar Rapids Community School Dist. V. Garret F. ex rel. Charlene F., 526 U.S. 66, 78 n.10 (1999).

[8] The procedure may be briefly described as follows: Once merchandise arrives at a port of entry, it is regarded as imported and comes under Customs' custody. In order to obtain release from Customs' custody into the "United States," *i.e.*, the customs territory of the United States, the importer must "make entry," *i.e.*, present certain documentation to Customs so that Customs may determine whether the merchandise may be admitted into the customs territory of the United States and, if admissible, what duties, if any, are applicable. It is a hallmark of this process that both the merchandise and entry documentation are presented to Customs before Customs may permit the merchandise to enter the customs territory of the United States. 19 U.S.C. § 1484(c)(1) (Entry); *see, generally, Ernesto F. Rodriguez, Inc. v. United States,* 65 Cust. Ct. 163, C.D. 4072 (1970); *United States v. Mussman & Shafer,* 40 C.C.P.A. 108 (1953); *Wilcon v. United States*, 13 Cust. Ct. 96, C.D. 876 (1944).

consistent with and give effect to the entire statute). For example, Section 337(i) discusses "attempted entry" of the article. It makes little sense to say electronic data is the subject of "attempted entry"—it was either transmitted or it was not. This provision only reasonably applies to attempts to import physical goods. Congress has chosen not to regulate electronic transmissions or other forms of data[9] through Custom's entry procedures. An interpretation of "article" that captures that which Congress expressly denied Customs from regulating would be entirely inconsistent with the remedial scheme of Section 337 established by Congress.

In addition, the term "article" should be construed to have the same meaning throughout the statute, regardless of the remedy. *See Sullivan v. Stroop*, 496 U.S. 478, 484 (1990) ("The substantial relation between the two programs presents a classic case for application of the 'normal rule of statutory construction that "identical words used in different parts of the same act are intended to have the same meaning'.'") (citations omitted). It would be improper to define "article" differently depending on whether one is referring to an exclusion order or a cease and desist order. Indeed, to define "article" in such a way that a separate regime is created for electronic transmissions consisting of only select portions of Section 337 would run afoul of the remedial framework established by Congress. For example, cease and desist orders may be issued "in lieu of" exclusion orders. The legislative history makes clear that cease and desist orders were added to provide a less draconian remedy than exclusion orders, and our reviewing court has referred to cease and desist orders as a "softer remedy" than exclusion orders. *Textron, Inc. v. USITC*, 753 F.2d 1019, 1029 (Fed. Cir. 1985); *see* S. Rep. 93-1298 at 198 (1974). This is laid out by the language of the statute, which provides that cease and desist orders can be

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[9] HTSUS General Headnote 3(e)(ii) and (iii) (emphasis added) (2012). For the purposes of general note 1 the following are also exempt: (ii) telecommunication transmissions…(iii) records, diagrams and **other data** with regard to any business, engineering or exploration operation whether on paper, cards, photographs, blueprints, tapes or **other media.**

replaced with exclusion orders. If "articles" were defined to include electronic transmissions, such replacement would not be possible. Indeed, that provision demonstrates that the definition of "articles" for Section 337(f) must be the same as the rest of the statute; otherwise the provision for replacement would be rendered a nullity and read out of the statute.[10] Due to the nature of electronic data transmissions, for example, an exclusion order's requirement that goods be "permitted entry" if a respondent posts a bond makes little sense when such transmissions cannot be subject to the Customs entry and other port requirements. If issuing an exclusion order against electronic data is incompatible with this scheme then, according to the express statements of the statute, cease and desist orders solely based upon electronic transmissions should not issue either.

3. The federal courts also have provided significant guidance on the meaning of the term "article" that strongly suggests that it should not include intangibles for the purposes of the importation requirement.

In *Bayer v. Housey*, the Federal Circuit analyzed Section 337, stating that Section 337 does not cover intangibles.[11] 340 F.3d at 1374. In *Bayer*, the question before the Federal Circuit

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[10] Critically, this does *not* prevent the Commission from including electronic transmissions within the scope of a cease and desist order, as in *Hardware Logic*, in order to prevent circumvention of its remedial orders after it has already found a violation of Section 337. This possibility is based on the Commission's broad remedial authority. It does not depend on whether electronic transmissions are "articles."

[11] Multiple courts are in accord. For example, in interpreting the term "article" in a previous Tariff Act, the Supreme Court held that it "applied to almost every separate substance or material, whether as a member of a class, or as a particular substance or commodity." *Junge v. Hedden*, 146 U.S. 233, 238 (1892). The Court of Customs and Patent Appeals (the "C.C.P.A."), the predecessor to the Federal Circuit, explained that the term "articles" is used hundreds of times in most tariff statutes, with narrower or broader meanings, but that in providing a dutiable list in Title I of the Tariff Act of 1930, it means, in a broad sense, "any provided-for substance, material or thing of whatever kind or character." *United States v. Eimer & Amend*, 28 CCPA 10, 12 (1940). Thus, according to the C.C.P.A., the dutiable schedule of the Tariff Act of 1930

was whether the term "a product which is made by a [patented] process" in 35 U.S.C. § 271(g) includes information as a result of that process. The court held that it does not. To arrive at that conclusion, the court looked to Section 337 as section 271(g) "was designed to provide new remedies to supplement existing remedies from the International Trade Commission ("ITC") under 19 U.S.C. § 1337 (2000)." [12] *Id.* at 1373. Indeed, in expanding infringement to include section 271(g), Congress "recognized the availability of redress from the ITC, but noted that the remedies available thereunder were insufficient to fully protect the owners of process patents." *Id.* at 1374. The court stated that the "legislative history suggests that section 271(g) was intended to address the same 'articles' as were addressed by section 1337, but to add additional rights against importers of such 'articles.'" *Id.* at 1374. It then stated:

> We recognize that section 1337 covers both articles that were "made" and articles that were "produced, processed, or mined." While this language in section 1337 perhaps suggests a broader scope for section 1337 than for section 271(g), nothing in section 1337 suggests coverage of information, in addition to articles, under section 271(g).

Id. at 1374 n.9. While the Federal Circuit decision concerned section 271(g), that decision was based on the court's understanding that Section 337 does not cover intangible information. Indeed, in the absence of that understanding, there would be little or no basis for the Court's holding regarding section 271(g), thereby indicating that this discussion should not be discounted as dicta.

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represents the broadest possible sense of the term "article." As noted above, the schedule lists tangible goods.

[12] The court specifically noted Section 337(a)(1)(B)(ii) (referring to "articles that – are made, produced, processed or mined under . . ."), but also referred to Section 337(a)(1)(A) (referring to "unfair acts in the importation of articles"). *Id.* at 1373-74. The court had previously noted that the term "article" refers to "one of a class of material things . . . piece of goods: commodity." *Id.* at 1372 n.4.

The Federal Circuit further clarified that the creation of electronic data cannot be considered to be "manufactured" or a "product" under section 271(g) in *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1323-24 (Fed. Cir. 2005). In that case, the plaintiff argued that, while *Bayer* might address electronic data in the abstract, the defendant's intangible e-mail packets were actually "manufactured" and "imported" due to the specific packaging of the data by the defendant. *Id.* The court disagreed, holding that "transmission of information … does not entail the manufacturing of a physical product," so section 271(g) did not apply. Similarly, the complainant in this case cannot escape the requirements of Section 337 through the argument that the respondent's data is packaged in any specific format and so is "manufactured."

The Federal Circuit also has suggested that "articles" are limited to "tangible articles" in interpreting the portion of Section 337 dealing with the domestic industry requirement. Under Section 337(a)(3), "an industry in the United States shall be considered to exist if there is in the United States, with respect to the articles protected by the patent," certain investments. The court interpreted this language in several cases this year. In *Interdigital Communications, LLC v. International Trade Commission*, 707 F.3d 1295 (Fed. Cir. 2013) (opinion on denial of rehearing), the court extensively examined the legislative history of Section 337(a)(3).[13] The court held that the domestic industry requirement is met by goods manufactured outside the United States as long as there is substantial investment in licensing in the United States. *See id.*

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[13] The court restated this point in *Motiva* holding that licensing programs only meet the need that there be "articles protected by the patent" when those programs "encourage adoption and development of articles that incorporated… patented technology." *Motiva, LLC v. International Trade Commission*, 716 F.3d 596, 600 (Fed. Cir. 2013). In *Motiva*, the Federal Circuit relied not only on *Interdigital* but also on *John Mezzalingua Assocs. v. Int'l Trade Comm'n*, 660 F.3d 1322 (Fed. Cir. 2011) in which it noted that the "Commission is fundamentally a trade forum, not an intellectual property forum" and holding that "litigation expenses directed at preventing instead of encouraging *manufacture of articles* incorporating patented technology does not satisfy the domestic industry requirement of Section 337." *Id.* at 600 (emphasis added).

at 1303-04. But the court also held that licensing activity only meets the domestic industry requirement if there are "articles protected by the patent." *Id.* at 1300-04. The court held that the legislative history made clear "that a sufficiently substantial domestic industry will need to license its technology *to a manufacturer somewhere*; they do not say that the manufacturer must be domestic." *Id.* at 1303 n.4 (emphasis added). This suggests that the "articles protected by the patent" are physical articles manufactured somewhere. Recently, in *Microsoft Corp. v. Int'l Trade Comm.*, 731 F.3d 1354, 1362 (Fed. Cir. 2013)(emphasis added), the court noted that "[a] company seeking section 337 protection must therefore provide evidence that its substantial domestic investment … relates to an *actual article* that practices the patent, regardless of whether or not that article is *manufactured* domestically or abroad."

In sum, the Federal Circuit has indicated an "article protected by the patent" under Section 337(a)(3) is a physical good—and specifically a good that can practice the patent. Indeed, it is difficult to see how abstract data can be said to be "practicing the patent." The key point is that the word "article" appears both in the domestic industry requirement of Section 337(a)(3) and in the importation requirement of Section 337(a)(1)(b). Accordingly, the same word found in adjoining statutory sections should be given the same meaning. *See Taniguchi v. Kan Pac. Saipan, Ltd.*, 132 S. Ct. 1997, 2004-05 (2012) ("[I]t is a 'normal rule of statutory construction' that 'identical words used in different parts of the same act are intended to have the same meaning'."). It is contrary to canons of statutory construction to construe the "articles" being "protected" one way and the "articles" causing the harm another way.

Nor do prior decisions of this Commission compel a different interpretation of "articles."[14] For example, in *Hardware Logic*,[15,16] the Commission determined to include electronic transmission of the respondents' infringing software in a cease and desist order (but not an exclusion order). *Id.* at *11. Importantly, the allegedly infringing import was not an electronic transmission in that investigation, but rather a (tangible) emulation device system, which included software. It was argued that some systems were imported without software. It was also argued that some of the software was imported on a disk or electronically transmitted into the United States. As to the software imported as part of an infringing emulation system and on a disk, which clearly could be imported or excluded by Customs from importation, the

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[14] Most recently, in the related proceeding, *Certain Incremental Dental Positioning Adjustment Appliances and Methods of Producing Same*, Inv. No. 337-TA-562 (Enforcement), Public Comm'n Op. (Feb. 19, 2013), the Commission reaffirmed the holding of *Hardware Logic* that the Commission may craft its cease and desist orders and consent orders to prohibit the importation of electronic transmissions after a determination of violation. As the Commission noted in its submission to the Federal Circuit on appeal, the 562 investigation did not address whether an electronic transmission of digital data is an article in the context of violation. On page 7 of its opinion in *Certain Incremental Dental Positioning Adjustment Appliances and Methods of Producing Same*, Inv. No. 337-TA-562 (Enforcement), the Commission stated "[T]he Commission has held that it has jurisdiction and authority to reach digital data that are electronically transmitted to a recipient in the United States," *Id.* (citing *Certain Hardware Logic Systems and Components Thereof ("Hardware Logic")*, Inv. No. 337-TA-383). The citation includes the following parenthetical as to the holding in *Hardware Logic*: "(stating that the Commission has the legal authority to issue a remedial order that covers electronic importations, and issuing a cease and desist order that covered electronic importation)." Thus, *Dental Appliances* confirms that the Commission's broad authority to fashion a remedy (covering acts which might not themselves be a violation of the statute) can justify a cease and desist order addressing electronic transmissions in an appropriate case.

[15] *Certain Hardware Logic Emulation Systems and Components Thereof*, Inv. No. 337-TA-383, Commission Determination (U.S.I.T.C. 1998), 1998 WL 307240.

[16] Similarly, in *Certain Systems for Detecting and Removing Viruses or Worms, Components Thereof, and Products Containing Same*, Inv. No. 337-TA-510, the accused products were hardware with versions of source code. Final ID at 57 (May 9, 2005). In *Viruses*, the Commission stated that it was following *Hardware Logic*, and prohibiting electronic transmissions in the cease and desist order but not in the exclusion order. Comm'n Op. at 4-5 (Aug. 23, 2005).

Commission entered an exclusion order covering those emulation systems found in violation. *See id.* at *7-9. But the Commission was concerned that its remedy could be circumvented if it did not preclude transmission of the software running those emulation systems. *Id.* at *15.

To avoid circumvention of its orders of a Section 337 violation—based on importation of physical articles—the Commission recognized that its remedial authority to issue cease and desist orders could cover electronic transmissions of data. *Id.* at *16. Put another way, the Commission's remedy may go beyond merely stopping the actual violation that triggered the Commission's jurisdiction and also include "reasonably related" acts that would result in circumvention of the Commission's order. *See FTC v. Mandel Bros.*, 359 U.S. 385, 392-93 (1958) (permitting FTC to prohibit like and related acts of misbranding with amended wording of cease and desist order).[17] But the fact that the Commission has broad remedial power does not expand the Commission's ability to change activity that is not a violation of Section 337 into one that is. To the extent that others have interpreted the Commission as holding otherwise, those interpretations stretch that decision too far.[18]

4. While the majority carefully provides a thoughtful analysis of the statute and law to come to a contrary conclusion, I must respectfully disagree.

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[17] The language of Section 337 closely resembles the language of the FTC Act, 15 U.S.C. § 45.

[18] One such interpretation is found in *Former Employees of Computer Sciences Corp. v. United States Secretary of Labor*, 414 F. Supp. 2d 1334 (C.I.T. 2006), but *cf. Woodrum v. U.S.*, 737 F.2d 1575 (Fed Cir. 1984) (Federal Circuit affirmed the CIT's determination that the term "article," under section 222(3) of the Trade Act of 1974, does not cover activity that fails to create or manufacture a tangible commodity, or transforming an existing product into a new and different article). This decision concerns whether former employees ought to receive certain benefits under 19 U.S.C. § 2272(a)(2)(A) ("Trade Adjustment Assistance"). In interpreting that statute the CIT characterized our decision in *Hardware Logic*, as holding that "software [is] an article of importation regardless of its mode of importation." *Id.* at 1342. This 2006 decision is not binding on the Commission but is instead binding on the Department of Labor and appears inconsistent with other authority.

The majority states that its "task is to determine whether the phrase 'importation ... of articles' encompasses this modern form of international commerce, or should be understood as limited to the kinds of international transactions in existence when the statute was first enacted" (at 54). To be sure, it is appropriate to apply a statute to new technology when that technology falls within the words of the statute. No one would argue that Section 337 is frozen to cover only items that existed in 1930. But we are also bound by the words of statute, and we should examine new technologies in light of the statute and regulations as written. The Supreme Court's decision in *Fortnigthly Corp. v United Artists Television, Inc.*, 392 U.S. 390 (1968), highlights this principle.

In *Fortnightly*, the owners of copyrighted motion pictures brought suit against community antenna television systems that acted as large antennas to receive television broadcasts for communities that had trouble picking up the broadcasts using standard household receivers. *See id.* at 391. The Supreme Court acknowledged that it "must read the statutory language of 60 years ago in the light of drastic technological change." *Id.* at 396. But the Court did not divorce such a reading from the language of the statute and held that those transmissions could not be understood to violate the enumerated rights listed in the Copyright Act. *See id.* 400-01. In doing so, the Court rejected the argument that it "accommodate various competing considerations of copyright, communications, and antitrust policy," stating "[w]e decline the invitation. That job is for Congress. We take the Copyright Act of 1909 as we find it." *Id.* at 401.[19] In this instance, extending the term "article" in Section 337 to cover electronic

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[19] Congress subsequently took up that job in enacting the Copyright Act of 1976 to cover such situations. *See WGN Continental Broadcasting Co. v. United Video, Inc.*, 693 F.2d 622, 624 (7th Cir. 1982).

transmissions of digital data would be an over extension of the statute. *See Kyocera Wireless Corp. v. Int'l Trade Comm'n*, 545 F.3d 1355 ("The ITC is a creature of statute, and must find authority for its actions in its enabling statute.").

Moreover, based on its goals of preventing every type and form of unfair practice, the majority finds that electronic transmissions must be covered under Section 337 by holding that "the meaning of 'articles' extends to all imported items of commerce as to which a finding of infringement by a patent, trademark, copyright or protected hull design may be sustained (provided that all other requirements of the statute are met)." Op. at 42. But defining "article" in Section 337 in terms of what infringes raises the question of what the definition of "article" is.[20] This definition does not account for the numerous cases in which infringement is clearly demonstrated, but no violation of Section 337 is found based on additional statutory requirements contained in Section 337, *e.g.*, 1337(a)(2), (3). If there can be acts of infringement that do not yield a violation of Section 337, then one should avoid treating infringement and Section 337 as coextensive.

Indeed, the "other requirements of the statute" *also* use the term "article"; it does not appear only in the phrase "articles that infringe" in Section 337(a)(1)(B). It is also found in the phrases "exclusion of articles from entry," § 337(d), "articles ... be seized," § 337(i), "previously attempted to import the article," § 337(i)(1)(A), and "consignee of any article," § 337(i)(4). As explained above, those phrases lack clear meaning if "article" includes electronic transmissions. Thus, any interpretation focused solely on the phrase "articles that infringe" without consideration of those other uses of the word in this trade statute is improper.

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[20] *See* n. 2 supra.

Finally, an alternative definition of "article" that "encompasses such items as are bought and sold in commerce and that are imported into the United States, regardless of the mode of importation," (Op. at 41) appears overly broad. In fact, there are things that are not "articles" under anyone's definition, which "could be bought and sold"— for example a service.

Ultimately, I am sympathetic to protecting against all manner of unfair trade actions. The Commission, however, is bound by statute, and I am reluctant to broaden the definition of "article" as suggested by Align and the majority without an act of Congress.

5. In sum, the plain language of the statute, its interplay with other trade statutes, the lack of guidance in the statute's legislative history, and the statute's prior judicial interpretation all lead to the same place: Congress did not delegate to the Commission the authority to remedy importation of "articles" based only on electronic data transmitted into the United States. Under the facts in this investigation, the activities of the respondents may be unfair business practices and may even deserve a remedy in some other forum. But it is not clear that electronic transmissions of data are "articles" under Section 337, and absent such clarity the Commission should defer to Congress and should err on not assuming new powers. So far, Congress has not taken this step. *See Schaper Mfg. Co. v. International Trade Comm'n*, 717 F.2d at 1373 ("If, as appellants suggest, present-day 'economic realities' call for a broader definition to protect American interests (apparently including many of today's importers) it is for Congress, not the courts or the Commission, to legislate that policy."). For these reasons, I respectfully dissent and hold that due to a lack of importation of "articles" within the meaning of Section 337 there can be no violation of Section 337 in this investigation, and, therefore, do not join the remainder of the Commission's opinion.

CERTAIN DIGITAL MODELS, DIGITAL DATA, AND TREATMENT PLANS FOR USE, IN MAKING INCREMENTAL DENTAL POSITIONING ADJUSTMENT APPLIANCES, THE APPLIANCES MADE THEREFROM, AND METHODS OF MAKING THE SAME

337-TA-833

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **COMMISSION OPINION** has been served by hand upon the Commission Investigative Attorney, Vu Bui, Esq., and the following parties as indicated, on **April 10, 2014.**

Lisa R. Barton, Acting Secretary
U.S. International Trade Commission
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PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of **CERTAIN DIGITAL MODELS, DIGITAL DATA, AND TREATMENT PLANS FOR USE, IN MAKING INCREMENTAL DENTAL POSITIONING ADJUSTMENT APPLIANCES MADE THEREFROM, AND METHODS OF MAKING THE SAME**	**Inv. No. 337-TA-833**

INITIAL DETERMINATION ON VIOLATION OF SECTION 337 AND RECOMMENDED DETERMINATION ON REMEDY AND BOND

Administrative Law Judge Robert K. Rogers, Jr.

(May 6, 2013)

Appearances:

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TABLE OF CONTENTS

Pursuant to the Notice of Investigation and Rule 210.42 of the Rules of Practice and Procedure of the United States International Trade Commission, this is the Administrative Law Judge's Final Initial Determination in the matter of Certain Digital Models, Digital Data, And Treatment Plans For Use, In Making Incremental Dental Positioning Adjustment Appliances Made Therefrom, And Methods Of Making The Same, investigation No. 337-TA-833.

The Administrative Law Judge hereby determines that a violation of Section 337 of the Tariff Act of 1930, as amended, has been found in in the sale for importation and the importation into the United States of certain digital models, digital data sets, and treatment plans, and the sale of incremental dental positioning adjustment appliances made using the digital models, digital data sets, and treatment plans after importation thereof, in connection with U.S. Patent Nos. 6,217,325, 6,471,511, 6,705,863, 6,722,880, 7,134,874, and 8,070,487. Furthermore, the Administrative Law Judge hereby determines that a domestic industry in the United States exists that practices U.S. Patent Nos. 6,217,325, 6,471,511, 6,705,863, 6,722,880, 7,134,874, and 8,070,487.

The following abbreviations may be used in this Initial Determination:

CPX	Complainant's physical exhibit
CDX	Complainant's demonstrative exhibit
CX	Complainant's exhibit
CIB	Complainant's initial post-hearing brief
CRB	Complainant's reply post-hearing brief
RPX	Respondents' physical exhibit
RDX	Respondents' demonstrative exhibit
RX	Respondents' exhibit
RIB	Respondents' initial post-hearing brief
RRB	Respondents' reply post-hearing brief
SIB	Commission Investigative Staff's initial post-hearing brief
SRB	Commission Investigative Staff's reply post-hearing brief
Dep.	Deposition
SRJCCC	Second Revised Joint Claim Construction Chart
JSCI	Joint Stipulation of Contested Issues
JX	Joint Exhibit
Tr. at	Transcript
CPHB	Complainant's pre-hearing brief
RPHB	Respondents' pre-hearing brief
SPHB	Commission Investigative Staff's pre-hearing brief

I. BACKGROUND

A. Procedural History

On March 30, 2012, the Commission issued a Notice of Investigation in this matter to determine:

> [W]hether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain digital models, digital data, and treatment plans for use in making incremental dental positioning adjustment appliances, the appliances made therefrom, and methods of making the same that infringe one or more of claims 1-3, 11, 13, 14, 21, 30-35, 38, and 39 of [U.S. Patent No. 6,217,325]; claim 1 of [U.S. Patent No. 6,471,511]; claims 1, 3, 7, and 9 of [U.S. Patent No. 6,626,666]; claims 1 and 4-8 of [U.S. Patent No. 6,705,863]; claims 1 and 3 of [U.S. Patent No. 6,722,880]; claims 1, 2, 38, 39, 41, and 62 of [U.S. Patent No. 7,134,874]; and claims 1, 3, 5, and 7-9 of [U.S. Patent No. 8,070,487], and whether an industry in the United States exists as required by subsection (a)(2) of section 337.

(*See* Notice of Investigation) The investigation was instituted upon publication of the Notice of Investigation in the *Federal Register* on April 5, 2012. *See* 77 Fed. Reg. 20648-49; 19 CFR § 210.10(b).

The complainant is Align Technology, Inc. ("Align") 2560 Orchard Parkway, San Jose, CA 95131. The respondents are ClearCorrect Pakistan (Private), Ltd. ("CCPK"), Azia Cottage, 9–Kanal Park, Gulberg II, Lahore, Pakistan and ClearCorrect Operating, LLC ("CCUS"), 15151 Sommermeyer Street, Houston, TX 77041–5332. The Commission Investigative Staff of the Office of Unfair Import Investigations ("Staff") is also a party in this investigation.

On January 2, 2013, I issued Order No. 17, an order that granted Align's motion to strike CCUS's and CCPK's ninth affirmative defense directed to inequitable conduct.

On January 14, 2013, I issued Order No. 20, an order that denied CCUS's and CCPK's motion for summary determination and found that CCUS and CCPK waived any estoppel

defense, including defenses based on implied license or patent exhaustion.

On February 4, 2013, I granted-in-part CCUS's and CCPK's Motion In Limine No. 4, finding that while Align can argue the doctrine of equivalents, they waived the right to rely on any evidence to show the doctrine of equivalents. (Tr. at 42:3-17)

An evidentiary hearing in this investigation was held on February 4-6, 2013.

B. The Private Parties

1. Align Technology, Inc.

Align is a corporation organized and existing under the laws of the state of Delaware with its principal place of business in San Jose, California. (Corrected Complaint at ¶ 16)

2. ClearCorrect Operating, LLC.

CCUS is a corporation organized and existing under the laws of the state of Texas with its principal place of business in Houston, Texas. (CCUS Response to Corrected Complaint at ¶ 17)

3. ClearCorrect Pakistan (Private), Ltd.

CCPK is a corporation organized and existing under the laws of Pakistan with its principal place of business in Lahore, Pakistan. (CCPK Response to Corrected Complaint at ¶ 18)

C. Overview Of The Patents At Issue

U.S. Patent No. 6,217,325 ("the '325 patent") is entitled "Method and System for Incrementally Moving Teeth." (JX-003) It lists Muhammad Chishti, Apostolos Lerlos, Brian Freburger, Kelsey Wirth, and Richard Ridgley as the inventors. (*Id.*) It was filed on April 23, 1999 and issued on April 17, 2001 and is subject to a terminal disclaimer. (*Id.*) The '325 patent was the subject of an ex parte reexamination based on a request received on July 27, 2005. (*Id.*)

A reexamination certificate issued on January 15, 2008. (*Id.*) The Abstract of the '325 patent states:

> A system for repositioning teeth comprises a plurality of individual appliances. The appliances are configured to be placed successively on the patient's teeth and to incrementally reposition the teeth from an initial tooth arrangement, through a plurality of intermediate tooth arrangements, and to a final tooth arrangement. The system of appliances is usually configured at the outset of treatment so that the patient may progress through treatment without the need to have the treating professional perform each successive step in the procedure.

(JX-003 at Abstract)

U.S. Patent No. 6,722,880 ("the '880 patent") is entitled "Method and System for Incrementally Moving Teeth." (JX-002) It lists Muhammad Chishti and Kelsey Worth as the inventors. (*Id.*) It was filed on January 14, 2002 and issued April 20, 2004 and is subject to a terminal disclaimer. (*Id.*) The Abstract of the '880 patent states:

> A system for repositioning teeth comprises a plurality of individual appliances. The appliances are configured to be placed successively on the patient's teeth and to incrementally reposition the teeth from an initial tooth arrangement, through a plurality of intermediate tooth arrangements, and to a final tooth arrangement. The system of appliances is usually configured at the outset of treatment so that the patient may progress through treatment without the need to have the treating professional perform each successive step in the procedure.

(JX-002 at Abstract)

U.S. Patent No. 8,070,487 ("the '487 patent") is entitled "System and Method for Positioning Teeth." (JX-007) It lists Muhammad Chishti and Andrew Beers as the inventors. (*Id.*) It was filed on October 31, 2007 and issued December 6, 2011 and is subject to a terminal disclaimer. (*Id.*) The Abstract of the '487 patent states:

> Methods and apparatus fit a set of upper and lower teeth in a masticatory system by generating a computer representation of the masticatory system and computing an occlusion based on interactions in the computer

representation of the masticatory system.

(JX-007 at Abstract)

U.S. Patent No. 6,471,511 ("the '511 patent") is entitled "Defining Tooth-Moving Appliances Computationally." (JX-001) It lists Muhammad Chishti, Elena I. Pavlovskaia, Gregory P. Bala, and Brian Freyburger as the inventors. (*Id.*) It was filed on October 8, 1998 and issued October 29, 2002, and is subject to a terminal disclaimer. (*Id.*) The Abstract of the '511 patent states:

> Methods and corresponding apparatus for segmenting an orthodontic treatment path into clinically appropriate substeps for repositioning the teeth of a patient. The methods include providing a digital finite element model of the shape and material of each of a sequence of appliances to be applied to a patient; providing a digital finite element model of the teeth and related mouth tissue of the patient; computing the actual effect of the appliances on the teeth by analyzing the finite elements models computationally; and evaluating the effect against clinical constraints. The appliances can be braces, polymeric shells, or other forms of orthodontic appliance. Implementations can include comparing the actual effect of the appliances with an intended effect of the appliances; and identifying an appliance as an unsatisfactory appliance if the actual effect of the appliance is more than a threshold different from the intended effect of the appliance and modifying a model of the unsatisfactory appliance according to the results of the comparison. The model and resulting appliance can be modified by modifying the shape of the unsatisfactory appliance, by adding a dimple, by adding material to cause an overcorrection of tooth position, by adding a ridge of material to increase stiffness, by adding a rim of material along a gumline to increase stiffness, by removing material to reduce stiffness, or by redefining the shape to be a shape defined by the complement of the difference between the intended effect and the actual effect of the unsatisfactory appliance.

(JX-001 at Abstract)

U.S. Patent No. 6,626,666 ("the '666 patent") is entitled "Method and System for Incrementally Moving Teeth." (JX-004) It lists Muhammad Chishti, Apostolos Lerios, Brian Freyburger, Kelsey Wirth, and Richard Ridgley as the inventors. (*Id.*) It was filed on January 8,

2001 and issued on September 30, 2003 and is subject to a terminal disclaimer. (*Id.*) The Abstract of the '666 patent states:

> A system for repositioning teeth comprises a plurality of individual appliances. The appliances are configured to be placed successively on the patient's teeth and to incrementally reposition the teeth from an initial tooth arrangement, through a plurality of intermediate tooth arrangements, and to a final tooth arrangement. The system of appliances is usually configured at the outset of treatment so that the patient may progress through treatment without the need to have the treating professional perform each successive step in the procedure.

(JX-004 at Abstract)

U.S. Patent No. 6,705,863 ("the '863 patent") is entitled "Attachment Devices and Methods for a Dental Appliance." (JX-005) It lists Loc Phan, Muhammad Chishti, and Ross Miller as the inventors. (*Id.*) It was filed on October 29, 2001 and issued on March 16, 2004 and is subject to a terminal disclaimer. (*Id.*) The '863 patent was the subject of an ex parte reexamination based on a request received on June 23, 2005. (*Id.*) A reexamination certificate issued on January 8, 2008. (*Id.*) The Abstract of the '863 patent states:

> The present invention provides improved systems and methods for removably attaching a dental positioning appliance to the dental features of a patient during orthodontic treatment. These appliances function by applying force to specific surfaces of the teeth or dental features to cause directed movement. The application of force is improved by the use of one or more attachment devices which may be positioned on the teeth or dental features to provide the appropriate physical features. Specific design and location of these attachment devices may provide newly achievable and/or more effective repositioning forces, anchoring ability and appliance retention. The systems and methods of the present invention provide the design, production and use of such attachment devices with removable dental positioning appliances in orthodontic treatment.

(JX-005 at Abstract)

U.S. Patent No. 7,134,874 ("the '874 patent") is entitled "Computer Automated Development of an Orthodontic Treatment Plan and Appliance." (JX-006) It lists Muhammad

Chishti, Brian Freyburger, Kelsey Wirth, Andrew Beers, Huafeng Wen, Phillips Benton, Timothy Jones, and Ross Miller as the inventors. (*Id.*) It was filed on November 20, 2003 and issued November 14, 2006. (*Id.*) The Abstract of the '874 patent states:

> A computer is used to create a plan for repositioning an orthodontic patient's teeth. The computer receives an initial digital data set representing the patient's teeth at their initial positions and a final digital data set representing the teeth at their final positions. The computer then uses the data sets to generate treatment paths along which the teeth will move from the initial positions to the final positions.

(JX-006 at Abstract)

D. Products At Issue

Align accuses digital data sets made by CCUS and CCPK and customized sequential aligners made by CCUS, and the processes used to make those data sets and aligners, of infringing claims 1, 2, 3, 11, 13, 14, 21, 30, 31, 32, 33, 34, 35, 38, and 39 of the '325 patent, claims 1 and 3 of the '880 patent, claims 1, 3, 5, 7, 8, and 9 of the '487 patent, claim 1 of the '511 patent, claims 1, 3, 7, and 9 of the '666 patent, claims 1, 4, 5, 6, 7, and 8 of the '863 patent, and claims 1, 2, 38, 39, 41, and 62 of the '874 patent. (*See* CIB at 4-5)

II. JURISDICTION

A. Subject Matter Jurisdiction

Align's Position: Align says that while Respondents do not dispute they import the digital data, they dispute whether the digital data is an "article" under 19 U.S.C. § 1337. Align asserts that "Article" is a Commission term of art, the precedent of which holds that "data" is an "article." Align says that when used in any context before the Commission, "articles" should include all types of "data," including the Respondents' "digital data sets." Align says that the Commission has recently confirmed, in a related investigation, that "it has jurisdiction and authority to reach digital data that are electronically transmitted to a recipient in the United

States." (Citing *Certain Incremental Dental Positioning Adjustment Appliances*, Inv. No. 337-TA-562, Comm'n Op. at 7 (Jan. 23, 2013))

Align contends that Congress selected the broad word "articles" to enable the Commission to serve its high purpose of protecting domestic industry from foreign infringement and other unfair trade practices. (Citing *Certain Devices for Connecting Computers*, Inv. No. 337-TA-360, USITC Pub. 2843, Comm'n Op. at 9 (Dec. 1994) (quoting Senate Committee report that predecessor to section 337 "'is broad enough to prevent every type and form of unfair practice' with respect to imports," and declaring that "[n]othing since then indicates any Congressional intent to narrow this remedial authority")) Align says that while perhaps most imported articles are tangible goods, there is nothing in the unqualified word "articles" that inherently narrows the scope of section 337. Align continues that Congress intended to vest the Commission with plenary powers to protect domestic industries from infringing articles of all kinds, irrespective of medium or shifting technologies of production or distribution.

Align says that the Commission has held that "[t]he scope of section 337 is broad enough to prevent every type and form of unfair practice, including the transmission of infringing software by electronic means, electronic transmission of software and/or data that induces an infringing use of an imported product, and the servicing of imported products that induce infringement." *(Citing Certain Set Top Boxes*, Inv. No. 337-TA-454, USITC Pub. 3564, Final I.D. at 304-05 (Nov. 8, 2002) (citing *Certain Hardware Logic*, Inv. No. 337-TA-383, USITC Pub. 3089, Comm'n Op. at 25-29 (Mar. 1998))) Align continues that the Commission has specifically held that software and data, such as the digital data sets here, is an "article." For example, Align says that in *Certain Hardware Logic* respondents argued "that software cannot be fairly defined as one of the 'articles' encompassed by section 337(a)(1)(B)." (Citing *Certain*

Hardware, Inv. No. 337-TA-383, Final I.D. at 292 (July 31, 1997)) Align continues that Judge Luckern disagreed, in a section titled "Software Is An 'Article' That May Be Excluded," and finding that "any exclusion order should cover . . . software." (Citing *id.* at 292, 295.) Align says that Judge Luckern observed that there was:

> a direct nexus between respondents importation [of software], via electronic transmission or otherwise, and infringement of the patents in issue. It is undisputed that the software necessary to operate the accused Meta systems is created in France and transmitted to the United States . . . Accordingly, the administrative law judge finds that a cease and desist order directed to Meta software is necessary to prevent respondents' continued violation of section 337.

(Citing *Id.* at 197)

Align argues that the same situation is present here. Align says that the data created by CCPK and imported into the U.S. is essential to CCUS's fabrication of appliances. (Citing Tr. at 320:2-9, 320:20-321:15, 443:3-6) Align says that CCUS could not make its appliances without this data, and no other customer would purchase this data, as it cannot be used for any purpose other than making customized dental appliances. (Citing Tr. at 320:2-9, 320:20-321:15, 442:24-443:10, 443:25-444:3; CX-1162C.3 at 97:1-14)

Align disagrees with Respondents' legal arguments as to the scope of "articles" in their Prehearing Brief. First, Align says that Respondents argue that *Bayer AG v. Housey Pharms., Inc.*, 340 F.3d 1367, 1372-78 (Fed. Cir. 2003), somehow limits the scope of "article" in 19 U.S.C. § 1337. Align argues that *Bayer* addressed the scope of 35 U.S.C. § 271(g) – not 19 U.S.C. § 1337. Align says that the Commission has not limited the scope of "article" in 19 U.S.C. § 1337(B) in a fashion similar to *Bayer* and has, in fact, expressly held that the word "article" may include data and that precedent controls, not *Bayer*.

Align says that Respondents argue that the definition of "article" should be dictated by case law interpreting the meaning of "manufacture" under 35 U.S.C. § 101. Align contends that this argument is neither logically nor legally correct. Align says that 35 U.S.C. § 101 sets the scope of allowable subject matter for patenting as, "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title." Align continues that both cases cited by Respondents, *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), and *In re Nuijten*, 500 F.3d 1346 (Fed. Cir. 2007), are directed toward defining, *inter alia*, the scope of the noun "manufacture" in 35 U.S.C. § 101, not "articles" as used before the Commission, and are therefore not on point.

Align says that Respondents admit that, since June of 2009, digital data from CCPK has been sent to CCUS in the U.S. for the purpose of making the physical models used to fabricate aligners for sale to U.S. providers. (Citing Tr. at 320:2-9, 320:12-15, 364:20-365:12, 442:19-23) Align says that CCPK receives payment from CCUS for that digital data. (Citing Tr. at 320:2-9, 364:20-365:12, 373:24-374:4; CX-1160C.2 at 278:2-9, 294:2-7, 296:3-7; CX-1160C.3 at 422:25-423:8) As a result, Align concludes that it is beyond dispute that CCPK sold or offered to sell the digital data in the U.S., and that these digital data sets were brought into the U.S. { } (Citing Tr. at 316:4-22, 320:12-15, 442:19-23; CX-1160C.1 at 97:22-98:2; CX-1160C.3 at 472:3-17) Align adds that these digital data sets are then used by CCUS to fabricate the infringing aligners that it sells in the U.S. Align concludes that in sum, Respondents have jointly or individually imported into the U.S., sold for importation into the U.S., and/or sold in the U.S. after importation the accused digital data sets.

Align says that Respondents do not address any of the precedent cited by Align and Staff, and instead cite to inapposite cases analyzing different statutes (35 U.S.C. § 271(g) and 35 U.S.C. § 101) in an attempt to graft additional restrictions onto the scope of "articles" in § 337. (Citing RIB at 5 (citing *Bayer AG v. Housey Pharm., Inc.*, 340 F.3d 1367, 1375 (Fed. Cir. 2003); Diamond v. Chakrabarty, 447 U.S. 303, 308 (1980); In re Nuijten, 500 F.3d 1346, 1356 (Fed. Cir. 2007))) Align says that Respondents' arguments are not proper. (Citing *Exxon Mobil Corp. v. Allapattah Servs.*, 545 U.S. 546, 568 (2005) ("[T]he authoritative statement is the statutory text, not the legislative history or any other extrinsic material. Extrinsic materials have a role in statutory interpretation only to the extent they shed a reliable light on the enacting Legislature's understanding of otherwise ambiguous terms.")) Align continues that even if the cases were relevant in view of the controlling precedent cited by Align and Staff (they are not), Respondents misconstrue them.

Align contends that it has introduced extensive, undisputed evidence that Respondents import, sell for importation, or sell after importation the digital data sets. Align says that the evidence shows that: (i) CCPK sold or offered to sell the relevant digital data sets to CCUS { } (ii) these digital data sets were brought into the U.S. { } (Citing Tr. at 316:4-22, 320:12-15, 442:19-23; CX-1160C.1 at 97:22-98:2; CX-1160C.3 at 472:3-17); (iii) this activity was designed and implemented by CCUS (Citing Tr. at 460:18-461:2, 472:9-19); and (iv) CCUS provides CCPK with process instructions on how to prepare the digital data sets CCUS uses to prepare its clear aligners (Citing Tr. at 321:21-322:8, 445:7-11, 472:9-13; *see also* CX-1151C.1 at 115:25-116:20, 117:3-118:22, 198:5-11, 199:1-9, 299:24-300:9) Align concludes, that either CCPK or CCUS, or both jointly, are importing the digital data. Align adds that CCPK also sells the digital

data to CCUS after its importation into the U.S. or sells the digital data to CCUS for importation into the U.S., depending on the alternative acts of importation. Align says that Respondents introduced no evidence to the contrary; rather, they relied on the argument that the digital data sets cannot be "imported" because they are not "articles" under § 337. (Citing RIB at 5)

> Align says that Respondents raise a brand-new argument in their *PostHearing Brief* that:
>
> claims 7-9 of the '487 patent are directed to "treatment plans" contained on a "removable storage medium." Align has offered no proof that any of the Respondents sell for importation, import, or sell after importation treatment plans contained on a computer readable storage media. Tr. at 552:20-555:9.

(Citing RIB at 5) Align says that this argument fails because it was not raised in Respondents' Prehearing Brief (Citing RPHB at 6-7) and is therefore waived. (Citing GR 8.2)

Respondents' Position: Respondents argue that the Commission has neither subject matter jurisdiction nor *in rem* jurisdiction because the allegedly imported digital data sets are not "articles" within the meaning of the statute and are not "imported." Respondents continue that Respondents have not been involved in any acts that would constitute the sale for importation, importation, or sale after importation of the CCPK data sets.

Respondents say that the Federal Circuit has construed the term "article" according to its plain, common meaning as requiring tangibility. Respondents continue that the Federal Circuit defined both "manufactured" and "articles" in *Bayer AG v. Housey Pharm., Inc.*, 340 F.3d 1367, 1375 (Fed. Cir. 2003). According to Respondents, the Federal Circuit rejected the argument that intangible information is "manufactured" when it held "[t]hus, the production of information is not within the scope of processes of 'manufacture,'" (Citing *Id.* at 1372) Respondents say that the Federal Circuit next considered whether reading the term "manufactured" in conjunction with "articles" changed the meaning and, in so doing, drew from amendments to the ITC's enabling legislation concerning the importation of "articles" in concluding that the terms "manufactured"

and "articles" "failed to reach intangible information." (Citing *id.* at 1374-75) Respondents continue that the Federal Circuit, in interpreting the Supreme Court's decision in *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980) (citation omitted), acknowledged the tangibility requirement of the term "article." (Citing *In re Nuijten*, 500 F.3d 1346, 1356 (Fed. Cir. 2007))

Respondents conclude that their digital data sets are not "articles," nor are they "imported" in any common usage of that term. Respondents add that claims 7-9 of the '487 patent are directed to "treatment plans" contained on a "computer readable storage medium." Respondents say that Align has offered no proof that any of the Respondents sell for importation, import, or sell after importation treatment plans contained on a computer readable storage media. (Citing Tr. at 552:20-555:9) Respondents conclude that, as to those claims, Align fails to meet its burden of proof relating to the importation requirement of the statute.

Respondents' do not agree that *Bayer AG v. Housey Pharms., Inc.*, 340 F.3d 1367, 1372-78 (Fed. Cir. 2003) is irrelevant because that case addresses the scope of §271(g), not Section 337. Respondents say that while the primary issue addressed in *Bayer* was the scope of §271(g), the Federal Circuit stated its understanding of the term "articles" as used in Section 337. Respondents continue that the Federal Circuit considered how to interpret language in §271(g) referring to "a product which is made by a process patented in the United States" and "a product which is made by a patented process." Respondents contend that the issue was whether this language encompassed the production of information.

Respondents say that the Federal Circuit, in resolving this question, considered the fact that §271(g) "was not enacted on an entirely blank slate. Rather, it was designed to provide new remedies to supplement existing remedies available from the International Trade Commission ("ITC") under 19 U.S.C. §1337 (2000)." (Citing *id.* at 1373) Respondents continue that

Congress recognized that the remedies available under Section 337 "were insufficient to fully protect the owners of process patents. ... Thus, the legislative history suggests that §271(g) was intended to address the same 'articles' as were addressed by section 1337, but to add additional rights against importers of such 'articles.'" (Citing *id.* at 1374) Respondents note that the Federal Circuit concluded that 271(g) does not cover intangible information, only tangible products. Respondents argue that the Federal Circuit specifically noted that "nothing in §1337 suggests coverage of information, in addition to articles, under section §271(g)." (Citing *id.* at 1374 n.9) Respondents conclude, as a result, that the Federal Circuit in *Bayer* expressly held that information is not an "article" and recognized that information is not included within the scope of Section 337. Respondents say that the Commission did not have the benefit of the *Bayer* decision (decided in 2003) when it decided *Hardware Logic Emulation Systems* (decided in 1998) and the Federal Circuit's decision in *Bayer* is controlling here.

Respondents add that Align fails to meet its burden of proving the importation requirement as claims 7-9 of the '487 patent, directed to treatment plans on computer readable storage media. Respondents say that this is a jurisdictional issue. Respondents say that Mr. Beers testified that "I have analyzed this element and conclude that {

} (Citing CX-1150C, Q. 252; Tr. at 554:7-23) {

} (Citing Tr. at 554:24-555:9)

Staff's Position: Staff asserts that the Commission has both subject matter jurisdiction and *in rem* jurisdiction over the digital data sets that are created in Pakistan and that are imported into the United States. Staff says that Section 337(a)(1)(B) prohibits "the importation into the

United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that – (i) infringe a valid and enforceable United States patent . . .; or (ii) are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent." (Citing 19 U.S.C. §1337(a)(1)(B)) Staff continues that pursuant to this statutory authority, the Commission has issued, on multiple occasions, remedial orders covering electronically transmitted data. (Citing *Certain Systems for Detecting and Removing Computer Viruses or Worms, Components Thereof* ("*Computer Viruses*"), Inv. No. 337-TA-510, Comm'n Determination at 16 (August 2007) (holding that a cease and desist order covering electronically transmitted data is appropriate where the failure to cover such would result in the circumvention of the cease and desist order); *Certain Set Top Boxes and Components Thereof*, Inv. No. 337-TA-454, Final Initial Determination at 304-314 (November 8, 2002) (noting that Section 337 is broad enough to prevent the electronic transmission of software and/or data that induces infringing use of an imported product) *Certain Hardware Logic Emulation Systems and Components Thereof* ("*Hardware Logic*"), Inv. No. 337-TA-383, Comm'n Opinion at 25-29 (March 1998) (issuing permanent cease and desist order prohibiting importation of electronically transmitted software))

Staff avers that one important policy rationale behind these decisions was that the failure to cover electronically transmitted data would allow for an obvious method of circumvention such that cease and desist orders would be rendered meaningless. Staff says that, for example, in *Hardware Logic*, the respondents imported software via the Internet and argued that the Commission did not have the power to regulate such electronic transmission. Staff continues that the Commission disagreed, stating that:

> It is well settled that the scope of section 337 is "broad enough to prevent every type and form of unfair practice." Software is useful only if it is reduced to an

> electronic form. Consequently, in applying the cease and desist order to respondents' software when it is transferred in an electronic form . . ., we are simply preventing the transfer of the infringing software in the very from in which it is executed by the computer.
> ***
> Indeed, a cease and desist order that did not prohibit electronic transmission would be meaningless as to the software since respondents would be free simply to transmit the software electronically to a U.S. customer, who would then copy it onto a diskette or other tangible medium for use with an infringing emulation system. As the ALJ noted, the Commission clearly could and should reach software if it were sought to be transferred on a CD-ROM or diskette. We agree ... that it would be anomalous for the Commission to be able to stop the transfer of a CD-ROM or diskette containing respondents' software, but not be able to stop the same software when transmitted in machine readable form by electronic means.

(Citing *Hardware Logic*, Inv. No. 337-TA-383, Comm'n Opinion at 56-57 (March 1998)) Staff argues that recognizing the duty to prevent its remedial orders from being circumvented, the Commission issued a permanent cease and desist order covering both software in a tangible medium; and software transmitted in an electronic form. Staff says that the Commission interpreted the term articles from section 337(a)(1)(B) to encompass both tangible and intangible subject matter.

Staff says that in *Computer Viruses*, the parties disagreed about the proper scope of the cease and desist order. Staff continues that the respondent argued that electronic transmissions of its software should not be prohibited under the cease and desist order although the software continued to include infringing modules. Staff says that the Commission disagreed and noted that without a prohibition against the electronic submission of the software (including the infringing module), the respondent could simply instruct its customers to electronically download the anti-virus module from the Internet, thereby circumscribing cease and desist orders. Staff concludes that the Commission then issued a cease and desist order covering electronically transmitted software. (Citing *Computer Viruses*, Inv. No. 337-TA-510, Comm'n Determination at 16)

Staff contends that in all of the above mentioned investigations, the term "articles" was consistently understood to include software and data whether in a tangible medium or in an electronic format. Staff asserts that any argument advanced by Respondents that the Commission does not have subject matter jurisdiction or *in rem* jurisdiction because the accused digital data sets are not "articles" within the meaning of the statute, should be rejected.

Staff argues that the evidence demonstrates that Respondents have been involved in the importation, sale for importation, or sale after importation of the accused digital data sets. Staff says that the evidence demonstrates that digital data sets are sent from CCPK in Pakistan to CCUS in the United States for purposes of manufacturing a model for fabricating an aligner for sale to a provider or a patient. (Citing Tr. at 171:4-172:19, 192:3-193:19, 206:16-208:9, 315:19-318:11, 341:2-21, and 442:5-23).

Staff contends that, with respect to digital data sets, the Commission has confirmed that "it has jurisdiction and authority to reach digital data that are electronically transmitted to a recipient in the United States." (Citing *Certain Incremental Dental Positioning Adjustment Appliances and Methods of Producing the Same*, Inv. No. 337-TA-562 (Enforcement Proceeding), Comm'n Opinion at 7 (Jan. 23, 2013))

Staff says that Respondents' argument that the digital data sets at issue are not imported should be rejected because the evidence demonstrates that the digital data sets at issue are sent from CCPK in Pakistan to CCUS in the United States for purposes of manufacturing models for fabricating aligners. (Citing Tr. at 171:4-172:19, 192:3-193:19, 206:16-208:9, 315:19-318:11, 341:2-21, and 442:5-23) Staff says that Respondents actually admit as much in their brief when reciting their summary of {

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A. I believe that's fair, yes.

(Citing RIB at 4)

Analysis and Conclusions: The complaint alleges that CCUS and CCPK have violated Subsection 337(a)(1)(B) by the importation and/or sale of products that infringe the asserted patents or are produced by methods that infringe the asserted patents.

I find that the accused digital datasets are "articles" within the scope of the Commission's jurisdiction.[1] *Hardware Logic* is directly on point. In that case Respondents contended, assuming *arguendo* that the Commission has authority to prohibit the importation of articles that do not literally infringe[2], the prohibition of importation of respondents' software would restrict the importation of "things that are not 'articles' and that do not induce infringement, under 35 U.S.C. §§ 271(b)." According to respondents in that case, the legislative history of section 337 demonstrates that an article must be "tangible merchandise." *Hardware Logic, Commission*

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[1] In *Certain Drill Bits and Products Containing Same*, in reviewing an initial determination terminating the investigation on jurisdictional grounds, the Commission indicated that "[o]n review, the Commission affirms the ALJ's grant of summary determination of no importation but does not adopt any statements in the ID to the effect that the determination is on jurisdictional grounds." Inv. No. 337-TA-844, Comm'n Notice (August 22, 2012). As a result, I am treating this issue as one of jurisdiction solely because the parties raised this issue as one of jurisdiction.

[2] In *Hardware Logic* respondents also argued that an exclusion order should be limited to articles that directly infringe, and should not extend to components that indirectly infringe, including software. *Hardware Logic* at 4. Respondents raised the possibility that their software would be transmitted electronically into the United States and argued that the Commission does not have jurisdiction to exclude such transmissions. (*Id.* at 5) Respondents contended that software, either in source code or object code form, should not be covered by the Commission's remedial orders. Respondents said that their software, when it exists in the form of source code, cannot contributorily infringe the claims at issue, because source code is not executable by the accused emulation systems. Respondents reasoned that coverage of source code is, therefore, beyond the Commission's remedial jurisdiction. *Id.* at 8, 9.

Opinion on Remedy The Public Interest and Bonding at 9, 10. In addition, respondents argued that the importation by electronic transmission of their infringing software should not be covered by the Commission's remedial orders, because such transmissions are "energy, which is not tangible." *Hardware Logic* at 10.

The Commission rejected the respondents' arguments, finding *inter alia*, that remedial orders must reach software whether imported in the form of source code or otherwise. In a footnote, the Commission discussed this finding in more depth, saying:

> As discussed above, source code cannot be run by a computer unless and until it is transformed into object code. However, as the ALJ found and as respondents conceded, source code is typically considered the primary software medium. The substance – the intellectual property – of software is most clearly embodied in the programer's (sic) source code. Object code is merely a form of the software that the computer can "read." Indeed, respondents ... have only alleged that there is "no legal authority which provides that something that can 'easily and automatically' be transformed to produce a component constitutes or is equivalent to that 'component'." In effect, if source code could not be considered a component of a patented invention, then no software could ever be considered such a component. Yet it is clear that software can be a "component" of a patented invention. Indeed, respondents' software falls within the realm of patentable subject matter.

Hardware Logic at 18, fn. 84 (internal citations omitted). The Commission issued a cease and desist order in *Hardware Logic* that prohibited, *inter alia*, "the importation (including via electronic transmission), sale, offer for sale, lease, loan, other transfer, duplication, or distribution (including electronic distribution) of imported software and other components that contributorily infringe the patents in issue." *Hardware Logic* at 21.

This understanding of *Hardware Logic* is confirmed by the Commission's Opinion in Investigation No. 337-TA-562, which was an enforcement action that addressed the same data sets that are at issue in this investigation. *See Certain Incremental Dental Positioning Adjustment Appliances and Methods of Producing Same*, Inv. No. 337-TA-562, Public Comm'n

Op. (February 19, 2013). The Commission ultimately determined that the same digital data sets at issue in this investigation were not within the scope of a consent order in that enforcement action "because the subject consent order did not contain an express provision prohibiting the electronic transmission of data." *Id.* at 1. The Commission, however, confirmed that it had jurisdiction and cited *Hardware Logic* to hold that "it has jurisdiction and authority to reach digital data electronically transmitted to a recipient in the United States." *Id.* at 7.

In this investigation, the asserted claims are method claims that describe processes for using software to generate digital data sets for dental appliances for straightening teeth and generating dental appliances, and apparatus claims directed to the digital data sets and dental appliances. This is undisputed. {

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Respondents aver at that point, { } and CCPK sends the computer files (i.e., the digital datasets) to CCUS. The remaining steps needed to create the aligners are completed in Houston, Texas by CCUS using the digital datasets provided by CCPK.

Respondents' reliance on *Bayer AG v. Housey Pharmaceuticals, Inc.*, 340 F.3d 1367 (Fed. Cir. 2003) is misplaced. *Bayer AG* specifically addressed the issue of whether or not 35 U.S.C. § 271(g) applied to claims directed to methods of use rather than methods of manufacture. *Id.* at 1371. As a result, any discussion regarding the scope of 19 U.S.C. § 1337 was dicta and is not controlling. *See id.* Moreover, the Federal Circuit acknowledged that the scope of 19 U.S.C. § 1337 may be broader than 271(g):

> We recognize that section 1337 covers both articles that were "made" and articles that were "produced, processed, or mined." While this language in

> section 1337 perhaps suggests a broader scope for section 1337 than for section 271(g), nothing in section 1337 suggests coverage of information, in addition to articles, under section 271(g).

Id. at n.9. As a result, I find that Bayer does not limit the jurisdictional scope of 19 U.S.C. § 1337.

Respondents' reliance upon *Nuijten* is also wide of the mark. In Nuijten, the sole subject of the claim was a "signal" that had been encoded in a particular manner. The process of embedding additional data into the "signal," called watermarking, was patented. The watermarking was accomplished by a technique by which an original signal (such as a digital audio file) was manipulated to embed within it additional data. *Nuijten*, 500 F.3d at 1353, 1354, 1356, 1357.

Nuijten is distinguishable from the facts before me. *Nuijten* addressed the specific question of whether certain claims directed to a "signal" were invalid as being directed to non-statutory subject matter under 35 U.S.C. § 101. *Nuijten* 500 F.3d at 1348. Here, the issue is not whether or not the asserted claims are valid, because validity under 35 U.S.C. § 101 has not been raised as a defense. Rather, the question is whether or not digital data sets are "articles." The Court in *Nuijten* did not find that software is not an article of manufacture. *Nuijten* is, therefore, inapposite.

I find that the digital datasets produced by CCPK {

} are clearly articles over which the Commission has jurisdiction and authority. Thus, I find that the Commission has subject matter jurisdiction over this investigation under Section 337 of the Tariff Act of 1930. *See Amgen, Inc. v. United States Int'l Trade Comm'n*, 902 F.2d 1532, 1536 (Fed. Cir. 1990).

B. Personal Jurisdiction

CCUS and CCPK each responded to the complaint and notice of investigation, participated in the investigation, made an appearance at the hearing, and submitted joint post-hearing briefs. Thus, I find that CCUS and CCPK submitted to the personal jurisdiction of the Commission. *See Certain Miniature Hacksaws*, Inv. No. 337-TA-237, Initial Determination, 1986 WL 379287 (October 15, 1986).

C. In Rem Jurisdiction

The Commission has *in rem* jurisdiction over the digital models, digital data, and treatment plans for use in making incremental dental positioning adjustment appliances, and the appliances made therefrom, because the digital data sets have been imported into the United States. *See Sealed Air Corp. v. United States Int'l Trade Comm'n*, 645 F.2d 976, 985 (C.C.P.A. 1981). Mr. Pumphrey admitted that digital data sets prepared by CCPK are sent from CCPK in Pakistan to CCUS in the United States and are used by CCUS to manufacture clear aligners. (Tr. at 341:14-21) Moreover, in its prehearing brief, Respondents admitted that CCPK creates the digital data sets in Pakistan, sends the digital data sets to CCUS, which then uses the digital data sets to prepare aligners:

> The accused 'products' are computer files that are created in Pakistan as part of the service provided by CCPPL to ClearCorrect. ClearCorrect subsequently uses the computer files to print 3-D physical models of a patient's dentition.

(RPHB at 6-7)

Respondents' arguments regarding claims 7-9 of the '487 patent are unpersuasive. First, these arguments were waived because they were not raised in Respondents' prehearing brief. (*See* RPHB at 5-7) Second, there is no question that the digital models, digital data, and treatment plans for use in making incremental dental positioning adjustment appliances are

imported. The evidence shows that the data is imported by being transmitted electronically.[3]

As a result, I find that the Commission has *in rem* jurisdiction over the digital models, digital data, and treatment plans for use in making incremental dental positioning adjustment appliances, and the appliances made therefrom, because the digital models, digital data sets, and treatment plans for use in making incremental dental positioning adjustment appliances have been imported into the United States.

III. CLAIM CONSTRUCTION

A. Applicable Law

"An infringement analysis entails two steps. The first step is determining the meaning and scope of the patent claims asserted to be infringed. The second step is comparing the properly construed claims to the device accused of infringing." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996) (citation omitted). Claim construction "is a matter of law exclusively for the court." *Id.* at 970-71. "The construction of claims is simply a way of elaborating the normally terse claim language in order to understand and explain, but not to change, the scope of the claims." *Embrex, Inc. v. Serv. Eng'g Corp.*, 216 F.3d 1343, 1347 (Fed. Cir. 2000). "[O]nly those [claim] terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy." *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

Claim construction focuses on the intrinsic evidence, which consists of the claims themselves, the specification, and the prosecution history. *See generally Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*). The Federal Circuit in *Phillips* explained that in

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[3] The separate question of whether or not the imported digital data sets infringe claims 7, 8, and 9 of the '487 patent is addressed in Sections V.D.4-6, *infra*.

construing terms, courts must analyze each of these components to determine the "ordinary and customary meaning of a claim term," which is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Id.* at 1313.

"It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" *Id.* at 1312 (citations omitted). "Quite apart from the written description and the prosecution history, the claims themselves provide substantial guidance as to the meaning of particular claim terms." *Id.* at 1314. For example, "the context in which a term is used in the asserted claim can be highly instructive," and "[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment as to the meaning of a claim term." *Id.*

"[T]he specification 'is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.'" *Id.* (citation omitted). "The longstanding difficulty is the contrasting nature of the axioms that (a) a claim must be read in view of the specification and (b) a court may not read a limitation into a claim from the specification." *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1117 (Fed. Cir. 2004). The Federal Circuit has explained that there are certain instances when the specification may limit the meaning of the claim language:

> [O]ur cases recognize that the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs. In other cases, the specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor. In that instance as well, the inventor has dictated the correct claim scope, and the inventor's intention, as expressed in the specification, is regarded as dispositive.

Phillips, 415 F.3d at 1316.

In addition to the claims and the specification, the prosecution history should be

examined if in evidence. "The prosecution history…consists of the complete record of the proceedings before the PTO and includes the prior art cited during the examination of the patent. Like the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent." *Id.* at 1317 (citation omitted). "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.*

If the intrinsic evidence does not establish the meaning of a claim, then extrinsic evidence may be considered. Extrinsic evidence consists of all evidence external to the patent and the prosecution history, including dictionaries, inventor testimony, expert testimony and learned treatises. *Id.* at 1317. Extrinsic evidence is generally viewed "as less reliable than the patent and its prosecution history in determining how to read claim terms[.]" *Id.* at 1318. "The court may receive extrinsic evidence to educate itself about the invention and the relevant technology, but the court may not use extrinsic evidence to arrive at a claim construction that is clearly at odds with the construction mandated by the intrinsic evidence." *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 977 (Fed. Cir. 1999).

"Unless the steps of a method actually recite an order, the steps are not ordinarily construed to require one. However, such a result can ensue when the method steps implicitly require that they be performed in the order written." *Interactive Gift Exp., Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1342 (Fed. Cir. 2001) (citing *Loral Fairchild Corp. v. Sony Corp.*, 181 F.3d 1313, 1322 (Fed.Cir.1999)) (internal citations omitted). This determination requires a two-part test to decide whether or not the steps of a method claim that do not otherwise recite an order must be performed in the order in which they are written. *Altiris, Inc. v. Symantec Corp.*, 318

F.3d 1363, 1369-1370 (Fed. Cir. 2003) (citing *Interactive Gift* 256 F.3d at 1342-43).

First, I must look to the claim language to determine if logic or grammar requires they be performed in the order written. *Id.* (citing *Interactive Gift* 256 F.3d at 1343). In *Loral Fairchild Corp. v. Sony Electronics Corp.*, the Federal Circuit held that the claim language required the steps be performed in their written order because the second step required the alignment of a second structure with a first structure that was formed by the first step. 181 F.3d 1313, 1321 (Fed.Cir.1999); *see also Altiris, Inc. v. Symantec Corp.*, 318 F.3d at 1370. If the first part of the test is not met, I must look to the rest of the specification to determine whether or not it directly or implicitly requires the steps be performed in the order written. *Altiris, Inc. v. Symantec Corp.*, 318 F.3d at 1370 (citing *Interactive Gift* 256 F.3d at 1343). If the second part of the test also is not met, the sequence in which such steps are written is not a requirement. *Altiris, Inc. v. Symantec Corp.*, 318 F.3d at 1370.

B. The '325 Patent

1. Level of Ordinary Skill in the Art

Align's position: Align asserts that one of ordinary skill in the art at the time of the invention of the asserted claims of all of the patents-in-suit was a practicing orthodontist, or an individual with expertise in digital modeling and analysis and a substantive knowledge of orthodontics. (Citing CX-1247C, Qs. 120-121; CX-1254C at 14-15) Align says that this is confirmed by: (i) the "well-settled understanding that inventors are typically persons skilled in the field of the invention" (Citing *Phillips*, 415 F.3d at 1313) because the inventors of the asserted patents fall within the latter category (Citing Tr. at 598:20-608:19); and (ii) the systems discussed in the specification of the asserted patents. (Citing JX-0001 at 1:24-30, 2:40-58; JX-0002 at 1:19-2:22, 5:31-7:46, 11:8-20:3, Figs. 2-3, 8A, 8D; JX-0003 at 1:12-2:23; 5:28-51; JX-

0004 at 1:17-2:63, 5:31-54; JX-0005 at 1:31-36, 6:54-7:5; JX-0006 at 1:29-2:26, 3:7-4:42; JX-0007 at 1:22-24, 3:3-9)

Align says that because Respondents advance only attorney argument in support of their definition and do not cite to a single fact or opinion supporting their attorney argument, their definition should be rejected.

Respondents' Position: Respondents assert that the applicable level of ordinary skill in the art is that of an experienced orthodontist who has access to an individual, such as an engineer, who has training in developing computer-aided design and computer-aided manufacturing programs (CAD/CAM). Respondents say that the '325 Patent and other patents at issue are directed to orthodontic appliances and methods for making those appliances. Respondents continue that orthodontists prescribe the type of appliance to be used and are involved in the design of those orthodontic appliances. Respondents say that the patents attest, that typically, orthodontists prescribe the type of appliance to be used and are involved in the design of those orthodontic appliances. Respondents say that a person of ordinary skill is presumed to have complete knowledge of all pertinent prior art.

Respondents agree that a practicing orthodontist is one of ordinary skill in the art to the extent that "practicing" means experienced. Respondents disagree with Align's alternative definition "individual with expertise in digital modeling and analysis and a substantive knowledge of orthodontics." Respondents say that this definition does not delineate what constitutes "substantive knowledge of orthodontics" or how that knowledge is to be measured. Respondents continue that under Align's measure it is clear that Mr. Beers does not qualify as one of ordinary skill. Respondents allege that Mr. Beers has provided no showing of "substantive knowledge of orthodontics" and testified that his only source of knowledge of

orthodontics was on the job training with Align during the time that he worked there approximately ten years ago. (Citing Tr. at. 510:12-511-10; Tr. at 511:25-512:11)

Staff's Position: Staff says that Complainant's technical expert Dr. Maureen Valley testified that a person of ordinary skill is "a practicing orthodontist, or an individual with expertise in digital modeling and analysis and substantive knowledge of orthodontics." (Citing CX-1247C (Valley) at Q. 121) Staff continues that Respondents' technical expert Dr. James Mah testified that a person of ordinary skill is "an experienced orthodontist who has access to an individual, such as an engineer, who has training in developing computer-aided design and computer-aided manufacturing programs (CAD/CAM)." (Citing RX-0129C (Mah) at Q. 23)

Staff contends that the difference in the proposed levels of ordinary skill does not impact the opinions of these technical experts or the positions of the private parties or Staff. Staff says that none of the private parties has identified differences between the two hypothetical persons of ordinary skill in the art that would affect claim construction (or infringement/invalidity). Staff continues that the technical experts testified that their opinions would not change if the other's proposed level of ordinary skill was determined to be proper. (Citing CX-1247C (Valley) at Q. 125-127; RX-0129C (Mah) at Q. 24; Tr. at 597:4-18; CX-1198C at 3) Staff says that the parties and the technical experts agree that the same level of ordinary skill in the art applies to all of the patents at issue herein.

Staff reasons that based on the educational background and professional experience of the inventors of the patents at issue, and the opinions provided by Complainant's technical experts, whose opinions appear to the Staff to be more consistent with the disclosures of the subject matter at issue, Staff submits that the more appropriate level of ordinary skill in the art is that proposed by Complainant and Complainant's technical experts. Staff continues that Mr. Beers,

who is one of the named inventors of the '487 patent and '874 patent, testified that the majority of the inventors of the patents at issue are not orthodontists; rather, they are computer scientists who had access to orthodontists while working at Align (which is a qualification generally reflected in Complainant's proposed level of ordinary skill in the art). (Citing Tr. at 598:17-607:22)

Analysis and Conclusions: I find that one of ordinary skill in the art at the time of the invention of the asserted claims of all of the patents at issue in this investigation was an individual with expertise in digital modeling and analysis and a working knowledge of orthodontic principles.

Focusing on the '325 patent, I note that it is directed to a method and system for incrementally moving teeth. (JX-0003 at Title) Although the '325 patent discusses orthodontic principles (*see, e.g.*, JX-0003 at 1:13-2:5) and contemplates a treating professional (i.e., an orthodontist) providing a prescription that identifies final tooth positions (JX-0003 at 6:4-14), the '325 patent does not delve into the intricacies of the practice of orthodontics. (*See* JX-0003 at 6:4-14) Rather, the focus of the '325 patent is the methods used to generate the digital data sets for treatment, including the intermediate digital data sets representing tooth positions between the initial position and the final position. (*See, e.g.*, JX-0003 at 6:15-40) The '325 patent discusses, in detail, the manipulation of digital data to prepare the initial data set (JX-0003 at 11:1-12:22), generate the final tooth arrangement, and generate the intermediate digital data sets. (JX-0003 at 12:30-65; *see also* JX-0003 at 13:59-14:25) Because of the level of complexity and detail including regarding the manipulation of digital data, I find that one of ordinary skill in the art would have expertise in digital modeling and analysis.

Although a person of ordinary skill in the art would not need to be an orthodontist, the

'325 patent notes that software that operates in accordance with the invention is designed to operate at a sophistication commensurate with the operator's training level, including "providing feedback regarding permissible and forbidden manipulations of the teeth." (JX-0003 at 14:26-36) As a result, I find that a person of ordinary skill in the art would need to have a working knowledge of orthodontic principles to implement software that provides such feedback.

As explained in Sections III.C.1, III.D.1, III.E.1, IV.F.1, IV.F.1, and III.G.1 *infra*, all of the patents at issue have very similar focus and details, and the parties have agreed that the person of ordinary skill in the art is the same for each of the patents at issue. Based upon the similarities between the patents and the agreement of the parties, I find that a person of ordinary skill in the art is the same for each of the patents at issue.

2. "Fabricating a plurality of successive tooth repositioning appliances"

The term "fabricating a plurality of successive tooth repositioning appliances" appears in asserted claims 1 and 33.

Align's position: Align says that this term should be given its plain and ordinary meaning. Align continues that to the extent construction is required, this term should be construed to mean "fabricating more than one of a series of appliances to be worn for incrementally positioning teeth."

Align asserts that if this term is construed, it should be construed simply to have its plain and ordinary meaning. Align contends that because the words in the phrase are easily understandable and there is no explicit definition or disclaimer of the scope of the disputed phrase in the '325 patent, construction is not needed. (Citing *CCS Fitness*, 288 F.3d at 1366-67)

Align disagrees with Respondents' "all aligners" argument, because it seeks to add an improper "temporal requirement" that the appliances must be "fabricated prior to the outset of

treatment." Align says that Respondents cite to no evidence that supports their construction. Align continues that Respondents cite to a portion of the '325 patent specification says that aligners must be designed before they can be fabricated. Align asserts that the cited portion does not mention treatment and Respondents' position is therefore logically incoherent. Align says that no portion of the '325 patent requires that appliances be fabricated prior to the outset of treatment.

Align says that the intrinsic record does not require that any part of the claimed process occur prior to the outset of treatment. (Citing JX-0003 at 1:29-48, 2:2:54-57) Align contends that Claim 1 simply requires that "a plurality of successive tooth repositioning appliances" be fabricated, and that they be related to at least some of the previously produced digital data sets. (Citing JX-0003 at 1:29-48) Align adds that the specification requires only that the appliances be "fabricated based on at least some of the digital data sets." (Citing JX-0003 at 6:53-61) Align reasons that as long as at least two appliances are fabricated, which relate to at least two of the previously produced digital data sets, the claim is satisfied. Align says that the only "temporal" requirement of the claim is that the digital data sets be determined prior to fabricating appliances.

Align also disagrees with Respondents' argument that Align is estopped from seeking a construction that covers sets of appliances "fabricated after the outset of treatment" citing the prosecution history of the '874 patent for support. Align contends that Respondents confuse the concept of (i) a single "set" of appliances (one upper and one lower) used in one treatment stage with (ii) a series of appliances for use in successive treatment stages. Align continues that during the prosecution of the '874 patent, it distinguished prior art that "teaches a manual method for making one set of appliances (one upper jaw appliance and one lower jaw appliance) . . . ."

(Citing JX-0016 at 274) Align says that its statement that the prior art "teaches making one set of appliances at a time" in the prosecution history refers to one upper appliance and one lower appliance corresponding to a single treatment stage. Align adds that Respondents have also failed to explain how the prosecution of the '874 patent can affect the asserted claims of the other patents at issue herein. Align argues that Respondents' argument is incorrect because the statements were made ***after*** the '325 patent issued in a different application chain.

Align says that "[i]n the absence of an incorporation into the intrinsic evidence, [the Federal Circuit's] precedent takes a narrow view on when a related patent or its prosecution history is available to construe the claims of a patent at issue[.]" (Citing *Goldenberg v. Cytogen, Inc.*, 373 F.3d 1158, 1167 (Fed. Cir. 2004); *see also Georgia-Pacific Corp. v. United States Gypsum Co.*, 195 F.3d 1322, 1333 (Fed. Cir. 1999) (For a patentee "to be bound by the statement made to the PTO in connection with a later prosecution of a different patent, the statement would have to be one that the examiner relied upon in allowing the claims in the patent at issue."); and *Mannesmann Demag Corp. v. Engineered Metal Prods. Co.*, 793 F.2d 1279, 1284-85 (Fed. Cir. 1986) ("In cases where a patentee's amendments were not required in response to an examiner's rejection or critical to the allowance of the claims, no estoppel has been found.")) Align continues that Respondents have not shown how these narrow exceptions would apply. Align contends that the fact that Align's other asserted claims do not recite "generating a plurality of sets of appliances at the outset of treatment" (the limitation advocated by Respondents) confirms that prosecution history estoppel cannot apply to the other claims. (Citing *Al-Site Corp. v. VSI Int'l, Inc.*, 174 F.3d 1308, 1322-23 (Fed. Cir. 1999))

Align contends that Respondents' characterization of Align's argument is wrong, because during prosecution of the '874 patent, Align distinguished a pending claim that recited

"generating a plurality of sets of appliances at the outset of treatment" from the prior art by arguing that the prior art "simply teaches a manual method for making one set of appliances (one upper jaw appliance and one lower jaw appliance) using a manually manipulated wax setup." (Citing JX-0016 at 274) Align asserts that Respondents seek to muddy the waters by arguing that "one set" (*i.e.*, one lower and one upper) actually means "one series" (*i.e.* two or more successive treatment stages). Align argues that there is no support for such an interpretation other than argument by Respondents' attorney, and Align did not limit its claims in the manner suggested by Respondents.

Respondents' Position: Respondents assert that this term should be construed to mean "the appliances are fabricated prior to the outset of treatment."

Respondents say that the specification of the '325 Patent provides:

> In still another aspect, methods according to the present invention provide for fabricating a plurality of dental incremental position adjustment appliances. Said methods comprise providing an initial digital data set, a final digital data set, and producing a plurality of successive digital data sets representing the target successive tooth arrangements, generally as just described. The dental appliances are then fabricated based on at least some of the digital data sets representing the successive tooth arrangements.

(Citing JX-3 at 6:53-61) Respondents contend that this has a temporal requirement, "the dental appliances are then fabricated," and requires that the "digital data sets," including an "initial," "final," and a "plurality of successive," be "provided" prior to fabrication. Respondents reason that this requires "a plurality of successive tooth repositioning appliances" to be fabricated prior to the outset of treatment, otherwise the treatment could not begin. Respondents say that there is no teaching in the patent of multiple pluralities of successive tooth repositioning appliances. Accordingly, the Respondents contend that this phrase should be construed to mean that the appliances are fabricated prior to the outset of treatment.

Respondents assert that Align is estopped from seeking a claim construction that covers sets of appliances that are fabricated after the outset of treatment. Respondents say that during the prosecution of the '874 patent Align overcame rejection by distinguishing prior art and disavowing the scope of its claims. (Citing JX-0016 at 274) Respondents continue that Align argued that its modified claim of "generating a plurality of sets of appliances at the outset of treatment" was not disclosed in the prior art. (Citing JX-0016 at 299-300) Respondents conclude that Align is therefore estopped from arguing a different interpretation for the '874 patents, as well as the other patents asserted here. (Citing *NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1293 (Fed. Cir. 2005) (citing *Microsoft Corp. v. Multi-Tech. Sys., Inc.*, 357 F.3d 1340, 1350 (Fed. Cir. 2004) (holding that statements made in prosecution of one patent are relevant to the scope of all sibling patents) & *Laitram Corp. v. Morehouse Indus., Inc.*, 143 F.3d 1456, 1460 & n. 2 (Fed. Cir. 1998) (noting that it was proper to consider the prosecution histories of two related re-examination patents originating from the same patent, to determine the meaning of a term used in both patents))) Respondents contend that it is well settled that a patentee's disavowal of scope of claimed subject matter applies to related patents.

Staff's Position: Staff contends that this term should be construed to mean "producing more than one of a series of dental appliances for repositioning teeth that are made according to data sets."

Staff contends that the parties' claim construction dispute encompasses two issues. Staff says that the parties disagree over whether there is a temporal requirement, *i.e.*, whether the appliances (i) must be fabricated prior to the outset of treatment, as proposed by Respondents, or (ii) need not be fabricated prior to the outset of treatment, as proposed by Complainant. Staff contends that there is no temporal requirement requiring the appliances to be fabricated prior to

the outset of treatment. Staff says that Respondents improperly seek to rewrite the claims by inserting the phrase "prior to the outset of treatment" into the claims.

Staff continues that in addition to rewriting the claims, Respondents seek to limit the claims to a disclosure in the specification that states, *inter alia*, that "[s]aid methods comprise providing an initial digital data set, a final digital data set, and producing a plurality of successive digital data sets....The dental appliances are then fabricated based on at least some of the digital data sets representing the successive tooth arrangements." (Citing JX-0003 at 6:53-61) Staff disagrees with Respondents' proposed reading of this disclosure, noting that the specification discloses, *inter alia*, "[t]he system of appliances is *usually* configured at the outset of treatment so that the patient may progress through treatment without the need to have the treating professional perform each successive step in the procedure." (Citing JX-0003 at Abstract (emphasis added by Staff)) Staff continues that the specification also discloses that "the systems *may* be planned and all individual appliances fabricated at the outset of treatment." (Citing JX-003 at 3:53-56)

Staff says that the parties also disagree about whether or not the plurality of tooth repositioning appliances (i) must include all the appliances in the patient's treatment, as proposed by Respondents, or (ii) need not include all the appliances in the patient's treatment, as proposed by Complainants. Staff notes that Respondents are precluded from presenting any arguments in this regard because Dr. Mah was precluded from offering testimony that "fabricating a plurality of successive tooth repositioning appliances" requires all the appliances in the patient's treatment. (Citing RX-0129C, Q. 51)

Staff contends that the plurality of tooth repositioning appliances need not include all the appliances in the patient's treatment. Staff says that Respondents rely on the same disclosure of

the specification to support their argument. Staff continues that for at least the reasons stated above, the specification does not support construing "fabricating a plurality of successive tooth repositioning appliances" restrictively as proposed by Respondents.

Staff disagrees with Respondents' contention that Complainant is estopped based on statements made during prosecution of the related '874 patent. Staff says that under the circumstances here, arguments made with respect to the "outset of treatment" limitation do not affect the proper construction of a different term. (Citing *Al-Site Corp. v. VSI Int'l, Inc.*, 174 F.3d 1308, 1322-23 (Fed. Cir. 1999))

Construction to be applied: "fabricating two or more dental appliances to be used successively to adjust the position of teeth"

The plain language of claim 1 teaches:

> A method for facilitating a tooth repositioning dental treatment, including producing a plurality of digital sets representing a plurality of tooth arrangements, said method comprising:
>
> providing an initial digital data set representing an initial tooth arrangement;
>
> presenting a visual image based on the initial data set;
>
> manipulating the visual image to reposition individual teeth in the visual image;
>
> producing a final digital data set representing the final tooth arrangement with repositioned teeth as observed in the image;
>
> producing a plurality of intermediate digital data sets representing a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement; and
>
> ***fabricating a plurality of successive tooth repositioning appliances***, at least some of which are related to at least some of the produced digital data sets.

(JX-0003-027 at 1:29-48 (emphasis added)) Similarly, claim 33 requires:

> A method as in claim 31, further comprising ***fabricating a plurality of successive tooth repositioning appliances*** based on at least a plurality of said produced digital data sets provided to the fabrication operation.

(JX-0003-027 at 2:54-57 (emphasis added)) At its essence, the dispute between the parties is whether or not "fabricating a plurality of successive tooth repositioning appliances" requires that all appliances to be used in treatment be fabricated before any treatment is begun. I find nothing in the intrinsic record to support Respondents' restrictive construction.

The plain language of the asserted claims does not require that all appliances to be used in treatment be fabricated before treatment begins. Element five of claim 1 requires, *inter alia*, producing a plurality of intermediate digital data sets that represent tooth arrangements that progress "from the original tooth arrangement to the final tooth arrangement." Element six requires fabricating a plurality of successive tooth repositioning appliances, at least some of which are related to at least "some" of the produced digital data sets. Thus, the plain language of element six only requires fabricating appliances that are related to "some" of the digital data sets, but not necessarily ***all*** intermediate data sets. Requiring that all appliances to be used in treatment be fabricated before any treatment begins would directly conflict with the language of the claim. Claim 33 includes similar language, requiring only that appliances be fabricated "based on ***at least a plurality*** of said produced digital data sets provided to the fabrication operation." It does not provide a limitation that the appliances be fabricated based upon ***all*** produced digital data sets.

In my view the specification does not assign a special meaning to this phrase that deviates from the plain and ordinary meaning reflected in the claim. There is a "heavy presumption in favor of the ordinary meaning of claim language." *Johnson Worldwide Assocs. v. Zebco Corp.*, 175 F.3d 985, 989 (Fed.Cir.1999); cf. *Markman*, 52 F.3d at 980 ("[A]ny special

definition given to a word must be clearly defined in the specification."). Although the written description may aid in the proper construction of a claim term, limitations, examples, or embodiments appearing only there may not be read into the claim. *Comark Communications, Inc. v. Harris Corp.*, 156 F.3d 1182, 1186-1187 (Fed. Cir. 1998). The Federal Circuit has explained that:

> We do not import limitations into claims from examples or embodiments appearing only in a patent's written description, even when a specification describes very specific embodiments of the invention or even describes only a single embodiment, unless the specification makes clear that "the patentee ... intends for the claims and the embodiments in the specification to be strictly coextensive."

JVW Enters., Inc. v. Interact Accessories, Inc., 424 F.3d 1324, 1335 (Fed. Cir. 2005) (quoting *Phillips*, 415 F.3d at 1323). To put it another way, the Federal Circuit has stated that "[g]enerally, a claim is not limited to the embodiments described in the specification unless the patentee has demonstrated a 'clear intention' to limit the claim's scope with 'words or expressions of manifest exclusion or restriction.'" *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 843 (Fed. Cir. 2010) (quoting *Liebel-Flarshiem Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)).

Here, the specification indicates that the production of all tooth repositioning appliances before treatment begins is one embodiment. The Abstract of the '325 patent explains that "[t]he system of appliances is ***usually*** configured at the outset of treatment so that the patient may progress through treatment without the need to have the treating professional perform each successive step in the procedure." (JX-003 at Abstract (emphasis added)) Elsewhere, the '325 patent explains that "[a]s will be described in more detail below in connection with the methods of the present invention, the systems ***may*** be planned and all individual appliances fabricated at the outset of treatment, and the appliances may thus be provided to the patient as a single

package or system." (JX-003 at 3:49-55 (emphasis added)) The '325 patent also states that "[a]fter production, the plurality of appliances which comprise the system of the present invention are ***preferably*** supplied to the treating professional all at one time." (JX-003 at 15:1-3 (emphasis added)) These portions of the specification describe a single embodiment, and they do not demonstrate the inventor's clear intent to provide a limitation beyond the clear meaning of the term "fabricating a plurality of successive tooth repositioning appliances."

Not only does the specification indicate that production of all tooth repositioning appliances before treatment begins is but one embodiment, it actually describes changes being made to the treatment plan after treatment is underway. The specification explains that one of the benefits of the treatment system taught by the '325 patent is that "[u]nlike braces, the patient need not visit the treating professional every time an adjustment in the treatment is made." (JX-003 at 3:57-59) The specification continues, "[w]hile patients will usually want to visit their treating professionals periodically to assure that treatment is going according to the ***original*** plan, eliminating the need to visit the treating professional each time an adjustment is to be made allows the treatment to be carried out in many more, but smaller, successive steps while still reducing the time spent by the treating professional with the individual patient." (JX-003 at 3:59-66 (emphasis added)) Thus, the specification acknowledges that treatment might not actually progress according to the "original" plan, and in so doing tacitly acknowledges that the treatment plan may need to be modified after treatment has begun. This acknowledgement is further evidence that the inventors did not clearly intend to provide a limitation beyond the clear meaning of the term "fabricating a plurality of successive tooth repositioning appliances."

Respondents' prosecution history estoppel arguments miss the mark. Respondents rely on arguments Align made during prosecution of the '874 patent to assert that the claims of the

'325 patent should be interpreted to require that all appliances to be used in treatment be fabricated before any treatment begins. The arguments on which Respondents rely, however, were based on claim language that is not present in claims 1 and 33 of the '325 patent.

During prosecution of the '874 patent, Align argued that certain prior art references did not disclose "generating, **at the outset of treatment**, a plurality of sets of appliances." (JX-0016 at 258, 273 (emphasis in original)) Specifically, Align said that "Martz simply teaches a manual method for making one set of appliances (one upper jaw appliance and one lower jaw appliance) using a manually manipulated wax setup. If additional sets of appliances were made using the Martz method, they would be made after treatment had commenced ('as time goes on') and would be made one set at a time from separate wax setup models." (JX-0016 at 274) The claims at issue in the prosecution of the '874 patent explicitly included the language "at the outset of treatment." (JX-0016 at 258) In contrast, claims 1 and 33 of the '325 patent do not include the phrase "at the outset of treatment." (JX-0003-027 at 1:29-48, 2:54-57) Because claims 1 and 33 do not include the phrase "at the outset of treatment," arguments made during prosecution of the '874 patent regarding the phrase "at the outset of treatment" are not relevant to determining the scope of the claims of the '325 patent.

In a case with similar facts, the Federal Circuit rejected an argument that the scope of a claim term should be limited by statements made during later prosecution of a related patent. In reaching this conclusion, the Federal Circuit noted that for the patentee "to be bound by the statement made to the PTO in connection with a later prosecution of a different patent, the statement would have to be one that the examiner relied upon in allowing the claims in the patent at issue." *Georgia-Pacific Corp. v. U.S. Gypsum Co.*, 195 F.3d 1322, 1332-1333 (Fed. Cir. 1999) Similarly, the Federal Circuit has rejected arguments that infringement under the doctrine

of equivalents was foreclosed based on prosecution history estoppel where the arguments at issue were made in a related patent that included different claim language. *Al-Site Corp. v. VSI Intern., Inc.*, 174 F.3d 1308, 1322-1323 (Fed. Cir. 1999). In rejecting the defendant's argument, the Federal Circuit explained that "[t]he specific limitations added to gain allowance of the '532 patent are not included in and are therefore not relevant to determining the scope of the claims of the later issued patents." Here, as noted *supra*, claims 1 and 33 do not include the language at issue during prosecution of the '874 patent. As a result, I find Respondents' arguments unpersuasive.

In order to give the asserted claims their broadest, reasonable interpretation, I conclude that, while the process clearly requires fabricating two or more dental appliances to be used successively to adjust the position of teeth, it does not require that all of the dental appliances used in treatment be fabricated prior to the outset of treatment. I, therefore, reject the narrower interpretation offered by Respondents.

I find that examination of the extrinsic evidence offered by the parties is unnecessary because the intrinsic evidence is sufficient to understand the meaning of the terms construed in this section. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996) ("In most situations, an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term. In such circumstances, it is improper to rely on extrinsic evidence.")

Based upon all of the foregoing, I find that the proper construction for the term "fabricating a plurality of successive tooth repositioning appliances," as used in asserted claims 1 and 33, is "fabricating two or more dental appliances to be used successively to adjust the position of teeth."

C. The '880 Patent

1. Level of Ordinary Skill in the Art

Analysis and Conclusions: In section III.B.1, *supra*, I found that one of ordinary skill in the art at the time of the invention of the asserted claims of Align's asserted patents was an individual with expertise in digital modeling and analysis and a working knowledge of orthodontic principles. The parties agree that the person of ordinary skill in the art is the same for all asserted patents. Based upon the similarities between the teachings of the '325 patent and the '880 patent, and the agreement of the parties that one of ordinary skill in the art is the same for the '325 patent and the '880 patent, I find that one of ordinary skill in the art at the time of the invention of the asserted claims of the '880 patent has the same knowledge and expertise as one of ordinary skill in the art for the '325 patent.

Similar to the '325 patent, the '880 patent is directed to a method and system for incrementally moving teeth. (JX-0002 at Abstract) The '880 patent discusses orthodontic principles (*see, e.g.*, JX-0002 at 1:19-2:4) and contemplates a treating professional (i.e., an orthodontist) providing a prescription that identifies final tooth positions (JX-0002 at 6:15-17); but the '880 patent does not delve into the intricacies of the practice of orthodontics. (*See* JX-0002 at 6:15-17) Like the '325 patent, the focus of the '880 patent is the methods used to generate the digital data sets for treatment, including the intermediate digital data sets representing tooth positions between the initial position and the final position. (*See, e.g.*, JX-0002 at 6:27-55) The '880 patent discusses, in detail, the manipulation of digital data to prepare the initial data set (JX-0002 at 11:1-14:59), generate the final tooth arrangement, and generate the intermediate digital data sets. (JX-0002 at 14:60-15:55; *see also* JX-0002 at 16:19-44) The '880 patent also notes that software that operates in accordance with the invention is designed to

operate at a level of sophistication commensurate with the operator's training level, including "providing feedback regarding permissible and forbidden manipulations of the teeth." (JX-0003 at 19:60-20:3)

2. "a predetermined series of dental incremental position adjustment appliances"/"predetermined series of dental incremental position adjustment appliances"

The term "a predetermined series of dental incremental position adjustment appliances"/"predetermined series of dental incremental position adjustment appliances" appears in asserted claim 1.

Align's position: Align contends that this term should be assigned its plain and ordinary meaning, and to the extent a construction is required, Align submits that the term should be construed to mean "a plurality of consecutively worn appliances for incrementally positioning teeth, wherein the geometries of each of the plurality of appliances are determined prior to the fabrication of any of the plurality of appliances."

Align contends that this phrase should be construed under its plain and ordinary meaning. Align says that no other definition is necessary, as the words in the phrase (*e.g.*, "predetermined" and "series") are easily understandable, and there is no explicit definition of "predetermined series ..." or disclaimer of the scope of this phrase in the '880 patent. (Citing *CCS Fitness*, 288 F.3d at 1366-67)

Align asserts that the claim construction advanced in Respondents' Prehearing Brief is markedly different from the construction proposed by Respondents in the SRJCCC. Align says that Respondents now assert that the construction must be that "all of the appliances in the series or system of appliances are fabricated prior to the outset of treatment." Align continues that Dr. Mah takes a similar position. (Citing RX-0129C, Qs. 136-137, 139) Align contends that the

belated introduction of this new construction is improper because it was not disclosed in the SRJCCC. (Citing Tr. at 8:4-9:4)

Align contends that nothing in the intrinsic record requires, or even suggests, that a "series" must be every single aligner used in a patient's treatment. Align says that "series" is used, *inter alia*, to describe a batch of successive aligners. (Citing JX-0002, 3:1-8) Align continues that this batch of successive aligners could be any subseries of the entire series of aligners (e.g., the first four, middle six, last three). (Citing CX-1150C, Q. 262) Align says that claim 1 specifies the opposite of Respondents' construction, as it states that the "predetermined series" corresponds to a series "progressing from the initial to the repositioned tooth arrangement." Align continues that a repositioned tooth arrangement does not have to be the final tooth arrangement, and no part of the specification leads to a different conclusion.

Align contends that no portion of the intrinsic record requires that the appliances be "fabricated prior to the outset of treatment." Align says that a review of claim 1 shows that the word "predetermined" refers only to the dental appliances themselves, not to when any treatment begins. Align continues that treatment is not mentioned at all in claim 1. Align concludes, as a result, that the tooth arrangements of the particular appliances need only be determined before their fabrication, and no portion of the specification states otherwise.

Align asserts that respondents' argument that Align cannot seek a construction that covers sets of appliances "fabricated after the outset of treatment" and cites its earlier discussion of the issue.[4] Align says that this argument is improper here because the statements were made after the '880 patent issued and were made in a different application chain.

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[4] Align's arguments are fully discussed in section III.B.2, *supra*.

Align says that Respondents' arguments ignore the language of the claims and cite to exemplary embodiments in the specification; but do not point out where the specification expressly limits "series." Align continues that there is no such limiting language, and it is improper to limit the claims to exemplary embodiments; rather, the instance of "series" Respondents cite is merely an exemplary discussion that a "system" uses a "series" of aligners – not a requirement that a "series" be any particular length, or that a "series" be all aligners from a to z.

Respondents' Position: In the Second Joint Claim Construction Chart, Respondents asserted that this term should be construed to mean "the appliances are fabricated prior to the outset of treatment." In their post-hearing brief, Respondents contend that this term means that all of the appliances in the series or system of appliances are fabricated prior to the outset of treatment. Respondents say that the limitation of a "predetermined series of dental incremental position adjustment appliances" appears in the preamble and in element "d." Respondents continue that the intrinsic evidence demonstrates that the combination of words used to create this phrase refers to all of the appliances designed to reposition teeth from the initial to the final tooth arrangement collectively and demonstrates that the appliances are fabricated prior to the outset of treatment. Respondents contend that the word "series" is key.

Respondents contend that the intrinsic evidence conclusively demonstrates that the claimed "series" makes up the "system" of all appliances. Respondents say that the '880 Patent specification states:

> The present invention provides improved methods and systems for repositioning teeth from an initial tooth arrangement to a final tooth arrangement. Repositioning is accomplished with a system comprising a series of appliances configured to receive the teeth in a cavity and incrementally reposition individual teeth . . . .

(Citing JX-0002 at 2:66-3:4) Based on this statement, Respondents conclude that each "system" comprises "a series." Respondents reason that a single "series of appliances" makes up the "system" that repositions teeth from the initial tooth arrangement to the final tooth arrangement. Respondents say that this definition is consistently repeated throughout the specification. (Citing JX-0002 at 3:37–48) Respondents say that while a series could have as few as three steps, or in excess of forty steps, each series must reposition teeth from the initial to the final arrangement. Respondents continue that the specification teaches that each "system," which comprises the claimed "series," includes all appliances necessary to complete the treatment. Citing JX-0002 at 4:21–25)

Respondents contend that the intrinsic evidence also demonstrates that "predetermined" means determined "at the outset" of treatment. Respondents say that the term "predetermined" is only used once in the specification in connection with the appliances, which confirms that "predetermined" means "determined at the outset." (Citing JX-0002 at 4:63–5:1) Respondents say that the specification demonstrates that the appliances are fabricated prior to the outset of treatment. (Citing JX-0002 at 20:35–37) Respondents contend that under the "system" described in the specification, all appliances are fabricated prior to the outset of treatment. Respondents reason that, otherwise, it would be impossible to use the preferred method of delivery, which is supplying the appliances "all at one time" to the treating professional. Respondents say that the specification consistently uses the phrase "outset of treatment" in connection with fabrication. (Citing JX-0002 at 3:53–56)

Respondents contend that Align is estopped from seeking a claim construction that covers sets of appliances that are fabricated after the outset of treatment. Respondents say that during the prosecution of a related patent, Align distinguished prior art by disclaiming "making one set

of appliances at a time" during the course of treatment. Respondents continue that Align claims that the '880 Patent and the '874 Patent arise from the same application and share many common terms. Respondents say that the Federal Circuit has held that courts must interpret the claims consistently across all asserted patents. (Citing *NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1293 (Fed. Cir. 2005) (citing *Microsoft Corp. v. Multi-Tech. Sys., Inc.*, 357 F.3d 1340, 1350 (Fed. Cir. 2004); *Laitram Corp. v. Morehouse Indus., Inc.*, 143 F.3d 1456, 1460 & n. 2 (Fed. Cir. 1998))) Respondents continue that Align successfully argued "that a patentee can make a disavowal of scope as to the general nature of an invention that in turn limits all claims even though specific claim language is not being interpreted." (Citing *Ormco Corp. v. Align Tech., Inc.*, 498 F.3d 1307, 1312 (Fed. Cir. 2007)("*Ormco II*")) Respondents aver that the Federal Circuit agreed with Align and held that "[w]hen the application of prosecution disclaimer involves statements from prosecution of a familial patent relating to the same subject matter as the claim language at issue in the patent being construed, those statements in the familial application are relevant in construing the claims at issue. (Citing *id.* at 1314)

Respondents say that during the prosecution of what became the '874 Patent, the examiner rejected Align's proposed claims directed to a method for making a series of appliances. Respondents continue that the examiner noted that U.S. Patent No. 4,793,803 taught methods for generating a plurality of appliances having geometries to reposition teeth and U.S. Patent No. 5,454,717 taught using a computer to receive initial scanned data and calculating desired tooth positions to design and manufacture appliances and concluded that Align's claimed invention was obvious in light of the described prior art because "[w]hile Martz does not show forming the appliances at the outset of treatment, it is held obvious as indicated above." Respondents say that in response, Align argued that the prior art "simply teaches making one set

of appliances at a time" and its modified claim of "generating a plurality of sets of appliances at the outset of treatment" was not disclosed in the prior art. Respondents say that Align ultimately prevailed and the claims issued in the '874 Patent. Respondents continue that the issued claim required:

> A computer-implemented method for use in creating a treatment plan to reposition a patient's teeth from a set of initial tooth positions to a set of final tooth positions, the method comprising:
>
> ***
>
> and generating a plurality of successive appliances having cavities and wherein the cavities of successive appliances have different geometries shaped to receive and reposition teeth from the initial positions toward the final positions,
>
> wherein the plurality of successive appliances is generated at a stage of treatment prior to the patient wearing any appliance of said plurality so as to reposition the teeth.

Respondents reason that because Align successfully argued this language overcame the prior art that disclosed "making one set of appliances at a time," Align disavowed claims to "making one set of appliances at a time" during the prosecution of the '874 Patent and is therefore estopped from seeking to claim a scope in the '880 Patent that was surrendered to obtain the '874 Patent.

Respondents assert that extrinsic evidence confirms that "a predetermined series of dental incremental position adjustment appliances" means that all of the appliances that comprise a system are fabricated prior to the outset of treatment. Respondents say that expert testimony confirms that the phrase at issue refers to all appliances and requires that the appliances are fabricated at the outset of treatment. Respondents say that Align relies upon its former longtime employee with a computer science background to opine as to whether orthodontists or dentists

would understand that this limitation has been met. Respondents contend that he is not qualified as an expert. Respondents continue that even if he were qualified, Align's expert cannot now provide any opinion as to the construction of this phrase because he failed to disclose any such opinion in his expert report. Respondents assert that Dr. Mah, their expert who is an orthodontist, has provided his expert opinion that CCUS's products do not meet the claimed limitation.

Respondents assert that Align alleges that its products practice claim 1 of the '880 patent. Respondents say that Align's exclusive method is to design, fabricate, and deliver all of the aligners that comprise its system prior to the outset of treatment. Respondents say that Align's contentions corroborate Respondents' proposed construction that "a predetermined series of dental incremental position adjustment appliances" means that all of the appliances that comprise a system are fabricated prior to the outset of treatment.

Staff's Position: Staff contends that this term should be construed to mean "Dental appliances that are fabricated according to data sets which are determined at the outset."

Staff contends that the dispute over the proper meaning of "predetermined series of dental incremental position adjustment appliances" encompasses two issues. Staff says that the parties disagree over whether or not a "series" must include all the appliances used in the patient's treatment, as proposed by Respondents, or (ii) need not include all the appliances and may simply include a plurality of consecutively worn appliances, as proposed by Complainant.

Staff contends that because I excluded Dr. Mah's opinion that a "predetermined series of dental incremental position adjustment appliances" would refer to a *system* of appliances, *i.e.*, all of the appliances in the patient's treatment (Citing RX-019C at Q. 136), Respondents are precluded from presenting any arguments in this regard. Staff says because it is not clear that

Respondents will abandon their argument of non-infringement based on their proposed claim construction requiring a system of appliances, it addresses whether the claimed "series" must include all of the appliances in the patient's treatment.

Staff contends that that the term "series" does not necessarily require that the "series" constitute all the appliances used for a patient's treatment. Staff says that claim 1, element (d), recites a "series of dental incremental position adjustment appliances" for tooth arrangements "progressing from the initial to the *repositioned*" arrangement," indicating that the "series" can constitute a subset of the entire treatment series, *i.e.,* the subset between the initial and any repositioned tooth arrangement. (Citing JX-0002 at 22:12-29) Staff continues that the specification also includes language indicating that the entire treatment set of appliances is not necessarily designed or fabricated before treatment begins. (Citing JX-0002 at Abstract ("The system of appliances is *usually* configured at the outset of treatment so that the patient may progress through treatment without the need to have the treating professional perform each successive step in the procedure"); 3:53-56 ("the systems *may* be planned and all individual appliances fabricated at the outset of treatment")) Staff says that in view of the intrinsic evidence that does not require that the "series" constitute all appliances used for a patient's treatment, Staff agrees with Complainant that the claimed "series" may simply constitute a "plurality of consecutively worn" appliances that does not necessarily comprise an entire treatment series. Staff explains that the constructions proposed by the Staff and Complainant do not differ substantively and Staff does not object to Complainant's proposed construction in this respect. Staff says that if Respondents rely on any testimony from their experts, that testimony is extrinsic evidence, and any testimony that is merely conclusory or that contradicts the intrinsic

evidence should be disregarded. (Citing *Phillips*, 415 F.3d at 1318; *Network Commerce, Inc. v. Microsoft Corp.*, 422 F.3d 1353, 1361 (Fed. Cir. 2005))

Staff says that the parties also disagree over the meaning of the word "predetermined," including what needs to be "predetermined" and when it needs to be predetermined. Staff contends that the word "predetermined," as used in Claim 1 of the '880 patent, refers to appliances fabricated based on *digital data sets*, where the series of digital data sets is *determined* "at the outset" (*i.e.*, before fabrication). Staff says that the constructions proposed the Staff and Complainant are also similar; but the Staff's proposed construction further clarifies that the series of appliances must be based on predetermined digital data sets. Staff continues that the proposed construction of "predetermined" as referring to digital data sets finds support in the plain language of claim 1 of the '880 patent, which refers to appliances "based on the series of successive digital data sets." Staff says that the plain language of claim 1 of the '880 patent also supports construing "predetermined" as requiring the digital data sets to be determined before the *fabrication* of the appliances. (Citing JX-0002 at 22:12-29)

Staff disagrees with Respondents argument that the entire predetermined series must be fabricated before the treatment begins. Staff says that although the specification states that it is preferable to supply all appliances at the outset of treatment, it is not required. (Citing JX-0002 at 20:35-37 ("the plurality of appliances which comprise the system of the present invention are *preferably supplied* to the treating professional all at one time") (emphasis added); 3:53-56 ("the systems *may* be planned and all individual appliances fabricated at the outset of treatment") (emphasis added)) Staff continues that nothing in the claim language itself refers to "treatment" (as opposed to fabrication) as the critical time marker.

Staff also disagrees with Respondents' contention that Complainant is estopped "from seeking to claim a scope in the '880 Patent that was surrendered to obtain the '874 Patent" based on statements made during prosecution of the related '874 patent. Staff says that the statements at issue were made after the '880 patent issued and, moreover concern a limitation in the '874 patent --"outset of treatment" – not present in the '880 patent (among other differences in language between the patent claims). Staff submits that arguments made with respect to the "outset of treatment" limitation do not affect the proper construction of a different term -- "predetermined series" – at issue in the '880 patent. (Citing *AI-Site Corp. v. VSI Int'l, Inc.*, 174 F.3d 1308, 1322-23 (Fed. Cir. 1999) ("the specific limitations added to gain allowance of the '532 patent are not included and are therefore not relevant to determining the scope of the claims of the later issued patents"))

Staff says that unlike Respondents' proposed construction, Staff's proposed construction (similar to Complainant's proposed construction) adheres to the claim language and does not seek to improperly import limitations from the specification.

Construction to be Applied: "Two or more dental appliances to be used successively to adjust the position of teeth between an initial tooth arrangement and a repositioned tooth arrangement, the digital data sets on which they are based having been created before any of said two or more dental appliances in the series are fabricated "

The plain language of claim 1 requires a method for making a predetermined series of dental appliances. Specifically, claim 1 requires:

> A method for making ***a predetermined series of dental incremental position adjustment appliances***, said method comprising:
>
> a) obtaining a digital data set representing an initial tooth arrangement;

b) obtaining a repositioned tooth arrangement based on the initial tooth arrangement;

c) obtaining a series of successive digital data sets representing a series of successive tooth arrangements; and

d) fabricating ***a predetermined series of dental incremental position adjustment appliances*** based on the series of successive digital data sets, wherein said appliances comprise polymeric shells having cavities shaped to receive and resiliently reposition teeth, and said appliances correspond to the series of successive tooth arrangements progressing from the initial to the repositioned tooth arrangement.

(JX-0002 at 22:12-29 (emphasis added)) The parties dispute the meaning of "predetermined series" and whether or not the phrase "predetermined series" includes all appliances to be used in treatment (not just a subset) and whether or not all of those appliances must be fabricated before any treatment begins.

I note that the construction proposed by Respondents in their post-hearing briefing, requiring that all of the appliances in the series or system of appliances are fabricated prior to the outset of treatment, differs substantively from the construction Respondents identified in the Second Revised Joint Claim Construction Chart ("the appliances are fabricated prior to the outset of treatment"). One important difference between Respondents' two proposed constructions is the addition of the argument that "all" of the appliances in the series are fabricated, not just that "the appliances" are fabricated. Because Respondents failed to disclose this construction in the Second Revised Joint Claim Construction Chart, Respondents have waived the right to argue this construction should be adopted. Assuming *arguendo* that Respondents had not waived this argument, I find nothing in the intrinsic record to support their proposed construction.

Claim 1 requires a method that comprises four steps that are performed in order. Although method claims are not ordinarily construed to require a particular order of steps, here the claims require they be performed in the order written. *Interactive Gift Exp., Inc.* 256 F.3d at

1342. Like the claims in *Loral Fairchild Corp.*, each subsequent step in the asserted claim is directed to further processing on what was produced in the previous step. 181 F.3d at 1321. The first step of claim 1 requires "obtaining a digital data set representing an initial tooth arrangement." (JX-0002 at 22:15-16.) The second element of claim 1 refers back to the "initial tooth arrangement" and requires "obtaining a repositioned tooth arrangement based on the ***initial tooth arrangement***." (*Id.* at 22:17-18 (emphasis added)) The third element of claim 1 requires "obtaining a series of successive digital data sets representing a series of successive tooth arrangements." (*Id.* at 19-20) Although the third element does not itself refer to the repositioned tooth arrangement "obtained" in the second element, the fourth element explains that the "series of successive tooth arrangements" disclosed in element three "progress[] from the ***initial to the repositioned tooth arrangement***." (*Id.* at 22:26-28 (emphasis added)) The fourth element requires "fabricating a predetermined series of dental incremental position adjustment appliances based on the series of ***successive digital data sets***." (*Id.* at 22:21-23 (emphasis added)) Because each subsequent step in claim 1 necessarily requires the previous step to have been executed, I find that the claim 1 requires the steps be performed in the order written.

With the foregoing in mind, the plain language of claim 1 provides substantial guidance for the meaning of "a predetermined series of dental incremental position adjustment appliances." Step number four explains that the "predetermined series of dental incremental position adjustment appliance*s* [plural]" are "based on the series of successive digital data sets," which step number three says represent "a series of successive tooth arrangements." Step number four continues to explain that the predetermined series "correspond[s] to the series of successive tooth arrangements progressing from the initial to the repositioned tooth arrangement." The necessary implication of the plain language of the claim is that the

"repositioned tooth arrangement" is not merely any "successive tooth arrangement"; rather, the "repositioned tooth arrangement" is the tooth arrangement at the end of a defined ***series*** of successive tooth arrangements. For Respondents' construction to be correct, however, the "repositioned tooth arrangement" would have to be further limited to mean the final tooth arrangement at the end of ***treatment***. The claims and the specification do not support this interpretation.

First, claim 1 uses the term "repositioned tooth arrangement," and claim 7, which depends from claim 1, uses the term "final tooth arrangement."[5] (JX-0002 at 22:50-53) This differing language raises the issue of the doctrine of claim differentiation, which originates in "the common sense notion that different words or phrases used in separate claims are presumed to indicate that the claims have different meanings and scope." *Karlin Tech. Inc. v. Surgical Dynamics, Inc.*, 177 F.3d 968, 971-72 (Fed.Cir.1999). Claim differentiation "create[s] a presumption that each claim in a patent has a different scope." *Comark Communications, Inc. v. Harris Corp.*, 156 F.3d 1182, 1187 (Fed. Cir. 1998). "In the most specific sense, 'claim differentiation' refers to the presumption that an independent claim should not be construed as requiring a limitation added by a dependent claim." *Curtiss-Wright Flow Control Corp. v. Velan, Inc.*, 438 F.3d 1374, 1380 (Fed. Cir. 2006).

The Federal Circuit has stated that the "presumption is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim." *SunRace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir.

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[5] Claim 7 is directed to an embodiment in which intermediate target tooth arrangements between the initial position and the final position are identified and a series of appliances is produced between those intermediate target tooth arrangements.

2003); *see also Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 910 (Fed. Cir. 2004) ("[W]here the limitation that is sought to be 'read into' an independent claim already appears in a dependent claim, the doctrine of claim differentiation is at its strongest.") Here, claim 7 uses the term "final tooth arrangement" while claim 1, from which claim 7 depends, uses the term "repositioned tooth arrangement." Respondents have offered no evidence to rebut the presumption that the term "repositioned tooth arrangement" has a different meaning from the term "final tooth arrangement." In fact, Respondents failed to address the issue of claim differentiation at all. (*See* RIB at 76-82.)

The specification does not support Respondents' restrictive construction. In fact, one embodiment taught in the specification contemplates multiple series of repositioning appliances between the initial and final tooth arrangements. More specifically, the specification teaches that target intermediate tooth arrangements ("key frames") are defined and intermediate digital data sets are generated between the target intermediate tooth arrangements, rather than just between the initial and final tooth arrangements. (JX-0002 at 6:56-67) Thus, the specification contemplates multiple series of appliances being generated, each series repositioning teeth between two target intermediate tooth arrangements, which are combined to progress from the initial tooth arrangement to the final tooth arrangement. (*See id.*) Under Respondents' construction, the target intermediate tooth arrangement would not qualify as a "repositioned tooth arrangement." Each of the independent claims requires a "repositioned tooth arrangement." (JX-0002 at 22:17-18, 23:15-16) Therefore, Respondents' construction would exclude this embodiment from all of the claims of the '880 patent, which the Federal Circuit has described as being rarely correct. *Verizon Servs., Corp. v. Vonage Holdings Corp.*, 503 F.3d 1295, 1305 (Fed. Cir. 2007); *MBO Labs., Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323, 1333

(Fed. Cir. 2007). Based upon all of the foregoing, I find that the "predetermined series of dental incremental position adjustment appliances" need not necessarily include all appliances between the initial arrangement and the final arrangement as Respondents contend.

Respondents' prosecution history estoppel argument again misses the mark. Respondents rely on arguments that Align made during prosecution of the '874 patent to assert that the claims of the '880 patent should be interpreted to require that all appliances to be used in treatment be fabricated before treatment begins. The arguments upon which Respondents rely, however, were based on claim language that is not present in claim 1 of the '880 patent. Like the claims of the '325 patent discussed in Section III.B.2, *supra*, claim 1 of the '880 patent does not include the phrase "at the outset of treatment." (*See* JX-0002 at 22:22-29) For the reasons explained in in Section III.B.2, *supra*, which I reaffirm here, because claim 1 does not include the limiting phrase "at the outset of treatment," arguments made during prosecution of the '874 patent regarding that limiting phrase are not relevant to determining the scope of the claims of the '880 patent.

The facts here can be distinguished from *Ormco II*, cited by Respondents to argue that statements made during prosecution of the '874 patent can limit the scope of the claims of the '880 patent. (RIB at 80-82) In *Ormco II*, the district court had interpreted certain claims of ***Ormco's*** patents (not Align's patents) to require automatic determination of "finish tooth positions." On appeal, the Federal Circuit noted that the Ormco patents' common specification made clear that the inventors' primary basis for distinguishing their invention from the prior art was its high level of automation. The Federal Circuit specifically noted a statement that "[i]n reality, the treatment of patients is in many cases more of an art than a science, with results ranging from poor to excellent, and generally variable" and a statement that that the prior art had

encountered difficulties in "the task of developing an automated system that includes reliable and efficient decision making algorithms and techniques for automatically determining an ideal finish position of the teeth." *Id.* at 1313 (Emphasis added by Federal Circuit).

The Federal Circuit also found that the specification did not suggest or even allow for human adjustment of the computer-calculated "finish tooth position." Moreover, the Federal Circuit noted that during prosecution of a patent related to the Ormco patents-in-suit, the patentee had distinguished a certain prior art reference by emphasizing its reliance on an operator for the decision making process and made a statement that the "present invention of applicants is directed toward the most complete and fully automated method for orthodontic appliance design and manufacture made." Based on the disclosure of the specification and the arguments made during prosecution in the related patent regarding the "present invention," the Federal Circuit held that certain of the claims at issue were properly limited to require automatic determination of "finish tooth positions." *Ormco II*, 498 F.3d at 1314-1316.

As noted *supra*, and in contrast with *Ormco II*, the specification of the '880 patent merely indicates that fabrication of all of the appliances prior to the outset of treatment is one preferred embodiment. The claims of the '874 patent included the phrase "at the outset of treatment" that was used to distinguish those claims from the prior art. Moreover, unlike the patentees in *Ormco II*, the applicants for the '874 patent did not make broad statements regarding what was required by the "present invention" during prosecution. (JX-0016 at 272-275) As a result, I find that *Ormco II* is inapposite.

I find that examination of the extrinsic evidence offered by the parties is unnecessary because the intrinsic evidence is sufficient to understand the meaning of the terms construed in this section. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996) ("In

most situations, an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term. In such circumstances, it is improper to rely on extrinsic evidence.")

Based upon all of the foregoing, I find that the proper construction for the term "predetermined series of dental incremental position adjustment appliances," as used in asserted claim 1, is "two or more dental appliances to be used successively to adjust the position of teeth between an initial tooth arrangement and a repositioned tooth arrangement, the digital data sets on which they are based having been created before any of said two or more dental appliances in the series are fabricated."

D. The '487 Patent

1. Level of Ordinary Skill in the Art

Analysis and Conclusions: In section III.B.1, *supra*, I found that one of ordinary skill in the art at the time of the invention of the asserted claims of Align's asserted patents was an individual with expertise in digital modeling and analysis and a working knowledge of orthodontic principles. The parties agree that the person of ordinary skill in the art is the same for all patents in suit. Based upon the similarities between the teachings of the '325 patent and the '487 patent, and the agreement of the parties that one of ordinary skill in the art is the same for the '325 patent and the '487 patent, I find that one of ordinary skill in the art at the time of the invention of the asserted claims of the '487 patent has the same knowledge and expertise as one of ordinary skill in the art for the '325 patent.

Like the '325 patent, the '487 patent discusses orthodontic principles (*see, e.g.*, JX-0007 at 1:20-42) and contemplates a treating professional (i.e., an orthodontist) providing a prescription that identifies final tooth positions. (JX-0007 at 3:3-8, 5:35-38). The '487 patent does not, however, delve into the intricacies of the practice of orthodontics. (*See id.*) As in the

'325 patent, the focus of the '487 patent is upon the methods used to generate digital data sets for treatment, including intermediate digital data sets representing tooth positions between the initial position and the final position. (*See, e.g.*, JX-0007 at 3:45-8:31) The '487 patent discusses, in detail, the manipulation of digital data to prepare the initial data set, generate the final tooth arrangement, and generate the intermediate digital data sets. (JX-0007 at 5:19-8:31) Based on the similarities between the disclosures of the '325 patent and the '487 patent, I find nothing in the record to indicate that one of ordinary skill in the art at the time of the invention of the asserted claims of the '487 patent is different than one of ordinary skill in the art for the '325 patent.

2. "treatment plan"

The term "treatment plan" appears in asserted claims 7, 8 and 9.

Align's position: Align asserts that this term should be construed as "a strategy formulated to reposition a patient's teeth." Align contends that Staff's proposed construction, which is generally consistent with Align's, improperly requires that the patient be an orthodontic patient. Align says that there is no requirement in the intrinsic record that the patient be an Orthodontist's patient; rather, the patient can be a dental patient or the patient of any other practitioner licensed to prescribe dental treatment using incremental repositioning dental appliances.

Align avers that Respondents argue they do not infringe claims of the '487 patent because the phrase "treatment plan" should be construed to require that an orthodontist or clinician formulate the treatment plan. (Citing RPHB at 119-120, 220-21, 226, 233) Align says that Respondents stated "No Construction Proposed" in the SRJCCC for this phrase, and cannot, therefore, advance this new construction now. (Citing Tr. at 8:4-16) Align continues that neither

Respondents nor Dr. Mah cite to any supporting intrinsic evidence. Align contends that such a construction is nonsensical in view of the intrinsic record. Align says that the "treatment plans" of the asserted claims refer to "intermediate digital data sets" that represent "intermediate arrangements of the patient's teeth." Align continues that neither the '487 or '874 patents disclose, much less require, that an orthodontist plan out the treatment or prepare the digital models used to create the aligners; rather, they teach that most of the treatment planning is done by a technician interacting with a computer and following established protocols. (Citing JX-0006 at 10:12–15; JX-0007 at 5:29-32; JX-0003 at 12:33-38; CX-1150C at Q. 242, 251, 316) Align says that Respondents ignore the intrinsic evidence (as they must), and instead piece together their new construction based on unsupported statements from Dr. Mah along with an irrelevant argument regarding unauthorized practice of dentistry. (Citing RPHB at 107) Align contends that such extrinsic evidence is of little value in view of the clear intrinsic record. (Citing *Advanced Fiber Techs. Trust v. J&L Fiber Servs.*, 674 F.3d 1365, 1375 (Fed. Cir. 2012))

Align contends that despite electing not to provide a definition for *"treatment plan"* in the *SRJCCC*, Respondents again seek to now construe it to require that an orthodontist or clinician formulate the treatment plan in their post-hearing brief. (Citing RIB at 87-91) Align says that Staff agrees that this construction is unsupported. (Citing SIB at 72) Align says that in their post-hearing briefing, Respondents assert they do not infringe claims of at least the '487 and '874 Patents because "[t]he plain and ordinary meaning of 'treatment plan' is the course of treatment devised by the treating dentist or orthodontist." (Citing RIB at 91) Align asserts that because Respondents stated "No Construction Proposed" in the SRJCCC for this phrase, they cannot advance this new construction now. (Citing Tr. at 8:4-9:4) Align says that Respondents' new construction has already been excluded. (Citing *See, e.g.*, RX-0129C at Q. 32) Align

continues that Staff agrees that Respondents' new construction is precluded. (Citing SIB at 72, 109)

Align contends that Respondents also did not cite to any supporting intrinsic evidence in their Prehearing Brief (citing RPHB at 107, 220-21), and thus should not be heard to cite to Align's provisional application (CX-1252) now. Waiver notwithstanding, Align contends that Respondents' construction such a construction is nonsensical in view of the intrinsic record. Align says that Claim 7 of the '487 Patent recites:

> 7. An orthodontic treatment plan for repositioning a patient's teeth using incremental tooth repositioning appliances, the treatment plan residing on a computer readable storage media and comprising a plurality of intermediate digital data sets representing intermediate arrangements of the patient's teeth, wherein ...

(Citing JX-0007 at 11:26-35) Align continues that the recited "treatment plan" includes "a plurality of intermediate digital data sets" that represent "intermediate arrangements of the patient's teeth." (Citing *id.*) Align reasons that it is clear that the recited "treatment plans" are simply the product of the claimed process. Align continues that Claim 1 of the '874 patent is similar. (Citing JX-0006 at 32:37-56) Align says that Staff agrees. (Citing SIB at 73, 109)

Align says that "intermediate digital data sets" are also the product of exemplary embodiments of the processes taught by the '487 and '874 Patents. (Citing JX-0007 at 5:57-61; JX-0006 at 10:12-15, 19:9-11, 27:36-50) Align continues that the'487 and '874 patents teach that treatment planning is done on a computer by a user (*e.g.*, a "treatment plan designer") following established protocols. (Citing JX-0006 at 12:4-8) Align says that neither the '487 nor '874 patents disclose, much less require, that the user be an orthodontist; rather, the '874 Patent specifically provides for a system where a clinician can review the treatment plan that has already been prepared *via* a "viewer application," as cited above. (Citing JX-0006 at 27:36-50)

Align asserts that the provision of this "viewer application" would make no sense if the orthodontist was operating the system.

Align contends that Respondents' citation to Align's provisional application 60/050,342 (CX-1252) is irrelevant. Align says that while it does indicate in some instances that an orthodontist may utilize the disclosed system, it does not teach that only an orthodontist may use it. Align continues that the claims of the '487 or '874 patents also do not preclude an orthodontist from creating the "treatment plan"—they are just not limited to such a situation. Align says that the provisional application also states that an "operator" may use the disclosed system. (Citing CX-1252 at 9:13, 20, 24, 10:23, 28)

Align asserts that despite Respondents' citation to my instruction that I was "going to be focusing on treatment plan as it is used in the patent," Respondents argue that extrinsic evidence should dictate the meaning of "treatment plan," citing testimony from Jarrett Pumphrey and Willis Pumphrey, excluded Mah testimony (Citing RIB at 88 ("The evidence presented at the hearing shows..."); RX-0129C at Q. 32 (Excluded)), and an out-of-context quote from Dr. Valley. Align continues that Respondents fail to cite to their own documents which specify that they—not their orthodontists—prepare "treatment plans." (Citing CX-0055 ("ClearCorrect maps out a complete treatment plan . . ."); CX-0090C at 28 ("a [DPS] sheet is used to make a treatment plan. . . ."); CX-078 at 64-68 (Treatment plan paperwork shipped with each phase)) Align concludes that to the extent extrinsic evidence is relevant it cuts against Respondents' position.

Respondents' Position: In the Second Revised Joint Claim Construction Chart, Respondents did not propose a construction for this term. In their post-hearing briefing, Respondents contend that the plain and ordinary meaning of "treatment plan" is the course of treatment devised by the treating dentist or orthodontist.

Respondents say that the claims of the '487 patent involve the phrases "planning orthodontic treatment" and "orthodontic treatment plan." Respondents continue that the parties have differing views concerning these phrases. Respondents say that one of Align's expert witnesses, Dr. Valley, testified there are "many ways of defining treatment plan." (Citing Tr. at 804:14-15) Respondents continue that Align's other expert witness, Mr. Beers, testified that treatment plan was a "tough" phrase to define. Respondents say that I offered a more pragmatic approach, stating the phrase would be defined by its use in the patent: "Because you seem to be going all over the lot, several of you have tried this, but I am telling you that I am going to be focusing on treatment plan as it is used in the patent" (Citing Tr. at 704:24-705:3) and "I've also already told you I think the patent is what's important and the use of the term in the patent is what's important." (Citing Tr. at 805:5-6)

Respondents contend that the plain and ordinary meaning of this phrase should apply. Respondents say Align's expert has testified that a treatment plan is a document prepared by a Clinician, and not a dental lab such as CCUS or Align, for use in treating patients. Respondents continue that the evidence presented at the hearing shows that to one skilled in the art, a "treatment plan" is a systematic approach to correction or improvement of malocclusion which takes into account the patient's chief complaint and preferences, a clinical problem list, complicating factors, prognosis, clinical experience, and the Clinician's judgment relating to this items. Respondents say that one skilled in the art would understand that a treatment plan means a comprehensive plan and timing for management of the malocclusion which may include, but is not limited to, detailed biomechanical treatments with various orthodontic appliances, adjunctive therapies such as surgery, restorations or other dental care, re-evaluation, retention, referrals to other health professionals, and observation as indicated.

Respondents say that Align attempts to establish the 1997 priority date for the '487 patent through Dr. Valley's witness statement. (Citing CX-1247C at Q. 115) Respondents continue that Dr. Valley testifies that the '487 patent does indeed claim priority to the earlier application. (Citing *id.*) Respondents say that the provisional application contains an express statement of how the treating orthodontist prepares the treatment plan. Respondents continue that in the "summary of the invention," the application states "[u]sing treatment planner software, the orthodontist then creates a series of intermediate treatment states." (Citing CX-1252-007) Respondents say that the "detailed description of the invention" likewise describes how the orthodontist partitions a digital model of the patient's teeth, manipulates the model to create a "goal state" of the patient's teeth, and then creates "intermediate states" that correspond "to progressive stages of teeth movement between the initial and goal states." (Citing CX-1252-008) Respondents contend that while the '487 patent is itself silent about who prepares the treatment plan, the original application from which it was derived expressed that the orthodontist prepares all the planning for the orthodontic treatment.

Respondents assert that the disclosures in Align's provisional application are consistent with the other evidence presented at the hearing. Respondents say that Jarrett Pumphrey testified that the treating doctor prepares the treatment plan and dental labs like CCUS do not. (Citing Tr. at 350:15-351:13) Respondents continue that Dr. Willis Pumphrey testified that neither OrthoClear, Align, nor CCUS prepare treatment plans:

> Because the doctor that produces the treatment plan, to treat the person that treats the patient is me. OrthoClear, Align, and ClearCorrect, they are dental labs. They don't treat patients, you know. At least we don't at ClearCorrect. We definitely don't treat patents.

(Citing Tr. at 415:4-11) Respondents say that Dr. Pumphrey added that treatment by the physician is a matter of law and industry standard. (Citing Tr. at 415:12-14) Respondents

contend that for almost a century, virtually all states have prohibited corporations from practicing health care professions that require state licensure, such as medicine and dentistry. Respondents say that all states generally outlaw any interference by unlicensed people or entities with dentists' independent clinical judgment and patient care and courts repeatedly uphold the state laws. (Citing *Semler v. Oregon State Bd. of Dental Examiners*, 294 U.S. 608, 611 (1935) ("That the state may regulate the practice of dentistry, prescribing the qualifications that are reasonably necessary, and to that end may require licenses and establish supervision by an administrative board, is not open to dispute... We have held that the state may deny to corporations the right to practice, insisting upon the personal obligation of individuals"))

Respondents contend that there are two primary reasons why business corporations cannot practice medicine or dentistry. Respondents say that only people can obtain the medical licenses needed to practice. Respondents continue that permitting business corporations to practice medicine or dentistry would threaten physicians' bonds with patients and risk care motivated by profit rather than purely medical decision-making.

Respondents aver that California, the state in which Align Technology, Inc. is headquartered, has typical statutes outlawing the corporate practice of medicine. (Citing CAL BUS. & PROF. CODE § 1625.1(a)) Respondents say that unlicensed practice is, in some circumstances, a criminal offense. (Citing *id.* at § 1701.1) Respondents contend that California courts recognize that "[i]t is an established doctrine that a corporation may not engage in the practice of such professions as law, medicine or dentistry." (Citing *Cal. Physicians Serv. v. Aoki Diabetes Research Inst.* 163 Cal. App. 4th 1506, 1514 (Cal. App. 2008, rev. denied) (quotation omitted)) Respondents say that as described in CAL BUS. & PROF. CODE § 2400 "Corporations and other artificial legal entities shall have no professional rights, privileges, or

powers." Respondents continue that the evidence Align itself submitted demonstrates how Align frequently counsels investors about how Align is subject to various state laws concerning dentistry. (Citing CX-1201-013 ("As a participant in the health care industry we [Align] are subject to extensive and frequently changing regulation under many other laws administered by governmental entities at the federal, state and local levels, some of which are, and others of which may be, applicable to our business."))

Respondents contend that the plain and ordinary meaning of "treatment plan" is the course of treatment devised by the treating dentist or orthodontist. Respondents say that this meaning is consistent with the provisional patent application to which the '487 patent claims priority, the witness testimony, applicable state law, and Align's own representations about its compliance with state law. Respondents continue that Align attempts to expand the plain and ordinary meaning of the phrase by suggesting that a treatment plan can be prepared by anyone. Respondents conclude that Align's broad interpretation is inconsistent with its provisional application, the witness testimony and state law.

Respondents assert that the CCPK operators do not "create treatment plans."

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Respondents assert that Align effectively offers nothing to contradict the plain and ordinary meaning of "treatment plan." Respondents say that One of Align's expert witness, Dr.

Valley, testified there are "many ways of defining treatment plan." (Citing Tr. at 804:14-15) Respondents continue that Align's other expert witness, Mr. Beers, testified that treatment plan was a "tough" phrase to define. (Citing Tr. at 551:21) Respondents aver that Align offers only three of CCUS's documents that state the phrase "treatment plan" to support Align's request for a modification of "treatment plan's" plain and ordinary meaning. (Citing CIB at 39) Respondents say that these items were addressed at the hearing and Align has no response to the witness testimony explaining:

> You know, I would say that for the documents that we send to doctors, if we have labeled them treatment plan, it is just so they can kind of think with how that's supposed to fit into their treatment plan. It is not actually a plan of treatment similar to anything like what a doctor would plan.

(Citing Tr. at 351:19-25)

Staff's Position: Staff asserts that this term should be construed to mean "a strategy formulated for repositioning an orthodontic patient's teeth." Staff asserts that because Respondents originally proposed no construction for "treatment plan" and I excluded Dr. Mah's opinion that a "treatment plan" is only planned by a Clinician (citing RX-0129C, Q. 162), Respondents are precluded from arguing this as a proposed construction. Staff adds that its proposed construction, which does not materially differ from Align's proposed construction, is consistent with the plain language of the claims and disclosures in the specification. Staff says that claim 1 recites in pertinent part: "A method of *planning orthodontic treatment of a patient.*" (Citing JX-0007 at 10:61-63 (emphasis added)) Staff continues that the specification discloses, "[t]he present invention is related generally to the *field of orthodontics*, and more particularly to a system and method for gradually repositioning teeth." Staff says that any arguments to the contrary by Respondents should be rejected.

Construction to be applied: "two or more successive digital data sets representing arrangements of a patient's teeth progressing from an initial tooth arrangement toward a final tooth arrangement"

The plain language of claim 7 requires an "orthodontic treatment plan" and provides details regarding what is required by that orthodontic treatment plan. Specifically, claim 7 requires:

> An orthodontic ***treatment plan*** for repositioning a patient's teeth using incremental tooth repositioning appliances,
>
> the ***treatment plan*** residing on a computer readable storage media and comprising a plurality of intermediate digital data sets representing intermediate arrangements of the patient's teeth,
>
> wherein at least some of the intermediate tooth arrangements represent different orthodontic treatment stages as the patient's teeth are moved from an initial arrangement toward a final arrangement representing the patient's teeth in a desired or prescribed arrangement.

(JX-0007 at 11:26-35 (emphasis added))

Respondents have waived the right to offer a construction for the term "treatment plan." Respondents did not propose a construction for "treatment plan" in the Second Revised Joint Claim Construction Chart. (SRJCCC at 8 ("No construction proposed.")) In their post-hearing briefing, however, Respondents contend that the plain and ordinary meaning of "treatment plan" is "the course of treatment devised by the treating dentist or orthodontist." (RIB at 87-91) Because Respondents failed to disclose this construction in the Second Revised Joint Claim Construction Chart, Respondents have waived the right to argue that this construction should be adopted. Assuming *arguendo* that Respondents had not waived this argument, I find nothing in the intrinsic record to support their construction.

The plain language of claim 7 provides clear guidance for the meaning of "treatment

plan." Claim 7 first identifies the purpose of the "treatment plan," saying it is "for repositioning a patient's teeth using incremental tooth repositioning appliances." Claim 7 continues to provide that the treatment plan "resides on a computer readable storage media" and comprises "a plurality of intermediate digital data sets." (JX-0007 at 11:26-35) Thus, the plain language of claim 7 explains that the "treatment plan" for repositioning a patient's teeth includes a plurality of digital data sets that can be stored on computer readable storage media.

Claim 7 continues to explain that the intermediate digital data sets "represent[] intermediate arrangements of the patient's teeth." Claim 7 also explains that the "intermediate arrangements" represent "different orthodontic treatment stages as the patient's teeth are moved from an initial arrangement toward a final arrangement." Claim 7 says that the final arrangement "represent[s] the patient's teeth in a desired or prescribed arrangement." (JX-0007 at 11:26-35) Thus, the plain language of claim 7 provides that the "treatment plan" represents tooth arrangements from an initial arrangement toward a final arrangement. Based on the foregoing, it is clear that the plain language of claim 7 defines a "treatment plan" as "two or more successive digital data sets representing arrangements of a patient's teeth progressing from an initial tooth arrangement toward a final tooth arrangement."

This meaning finds support in the use of the term "treatment plan" in the specification for the '487 patent. The term "treatment plan" appears in the specification twice and only within a single paragraph. The specification provides:

> Next, the digital model is segmented into one model for each tooth (step 344). Each tooth is then matched against a model associated with a prior scan developed at the beginning of the ***treatment plan*** (step 346). The matching process is based on matching corresponding points between the current scan and the prior scan of the teeth. In most cases, the teeth segmented from the current scan retain the shapes determined at the beginning of the ***treatment plan***, and the matching process is easy because the models should be similar to each other.

(JX-0007 at 8:38-47 (emphasis added)) The portion of the specification from which this quote is taken discusses an optional process whereby mid-treatment information—*i.e.*, a scan of the patient's teeth taken in the middle of the treatment—is incorporated into the final positioning process. (JX-0007 at 8:32-37) Thus, the quoted portion of the specification explains that a scan is developed at the "beginning of the treatment plan," and the shape of the teeth from that scan are matched to the shape of the teeth from a scan taken in the middle of the treatment. This is consistent with the meaning of the term "treatment plan" that is evident in claim 7—the treatment plan includes digital data sets representing tooth arrangements progressing from an initial tooth arrangement (e.g., a scan developed at the beginning of the treatment plan) toward a final tooth arrangement.

Limiting the definition of "treatment plan" to "the course of treatment devised by the treating dentist or orthodontist" as proposed by Respondents in post-hearing briefing would conflict with the language of claim 7 and the specification. First, claim 7 already addresses the role of the "treating dentist or orthodontist," disclosing that the final arrangement of the patient's teeth can be based on a prescription. Specifically, claim 7 says that the final arrangement "represent[s] the patient's teeth in a ***desired or prescribed*** arrangement." (JX-0007 at 11:34-35 (emphasis added)) Thus, claim 7 is not limited to final arrangements that are prescribed; rather, claim 7 also contemplates final arrangements that are "desired."

Limiting the definition of "treatment plan" as proposed by Respondents would also conflict with the specification. The specification distinguishes between actions of a "user" to generate the treatment plan and the actions of the "treating professional." Specifically, the specification says that:

FIG. 3 shows a process 200 for producing the incremental position

> adjustment appliances for subsequent use by a patient to reposition the patient's teeth. As a first step, an initial digital data set (IDDS) representing an initial tooth arrangement is obtained (step 202). The IDDS may be obtained in a variety of ways. For example, the patient's teeth may be scanned or imaged using X-rays, three dimensional X-rays, computer-aided tomographic images or data sets, or magnetic resonance images, among others. The teeth data may be generated by a destructive scanner, as described in the incorporated-by-reference U.S. application Ser. No. 09/169,276, filed Oct. 8, 1998.
>
> The IDDS is then manipulated using a computer having a suitable graphical user interface (GUI) and software appropriate for viewing and modifying the images. More specific aspects of this process will be described in detail below.
>
> Individual tooth and other components may be segmented or isolated in the model to permit their individual repositioning or removal from the digital model. After segmenting or isolating the components, ***the user will often reposition the tooth in the model by following a prescription or other written specification provided by the treating professional. Alternatively, the user may reposition one or more teeth based on a visual appearance or based on rules and algorithms programmed into the computer.*** Once the user is satisfied, the final teeth arrangement is incorporated into a final digital data set (FDDS) (step 204). The FDDS is used to generate appliances that move the teeth in a specified sequence.

(JX-0007 at 5:17-44 (emphasis added)) Clearly the specification allows that a "user" may operate the software to generate the final digital data set, while the role of the "treating professional" is to provide a prescription or other written specification. The specification does not require that the "treating professional" necessarily operates the software to generate the final digital data set. Moreover, this portion of the specification teaches that instead of relying on a prescription from the treating professional, the user can "alternatively" reposition the teeth based on a visual appearance or rules or algorithms programmed into the computer. This is further evidence that the inventors did not intend to provide a limitation beyond the clear meaning of the term "treatment plan."

Respondents' arguments based on U.S. Provisional Application No. 60/050342 were not

raised in their pre-hearing brief (*see* RPHB at 107), and have been waived. Nevertheless, even if these arguments had not been waived, they are incorrect. Although the provisional application does teach that an orthodontist can operate the software to generate final digital data sets and intermediate digital data sets, this is merely one embodiment. The provisional application also contemplates users other than orthodontists operating the software, saying that: "[t]he orthodontist or ***other operator*** may further simplify the identification process by marking the physical replica prior to scanning." (CX-1252 at CX1252-13 (emphasis added)) The provisional application states that "[t]he current version of treatment planning software functions to automatically calculate, for each state, a physically realizable (i.e. collision-free) movement path. However, it also permits the orthodontist or ***other operator*** to guide the computer in several ways." (*Id.* at CX1252-017 (emphasis added))

The provisional application actually contemplates users without orthodontic training operating the software:

> The above-described component identification and component manipulation software is designed to operate at a sophistication commensurate with the operator's training level. For example, ***the component manipulation software can assist a computer operator, lacking orthodontic training***, by providing feedback regarding permissible and forbidden manipulations of the teeth. On the other hand, an orthodontist, having greater skill in intraoral physiology and teeth-moving dynamics, can simply use the component identification and manipulation software as a tool and disable or otherwise ignore the advice.

(*Id.* at CX1252-015 (emphasis added)) Clearly the provisional application teaches not only an embodiment in which an orthodontist operates the software; but it includes one in which a user "lacking orthodontic training" operates the software. I find nothing in the provisional application to evidence a clear intention of the inventors to limit the meaning of "treatment plan" to the embodiment in which the orthodontist operates the software. *See i4i Ltd. P'ship v. Microsoft*

Corp., 598 F.3d 831, 843 (Fed. Cir. 2010) (quoting *Liebel-Flarshiem Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)).

Respondents' argument that California law requires that a "treatment plan" be created by a dentist or orthodontist lacks any relevance to this issue. As noted above, limiting the claims as proposed by Respondents would conflict with the plain language of the claims and the specification. The Federal Circuit has explained that extrinsic evidence shall not be used to arrive at a claim construction that is clearly at odds with the construction mandated by the intrinsic evidence. *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 977 (Fed. Cir. 1999). Reference to California law on the unlicensed practice of dentistry epitomizes this principle. The claim makes clear that a "treatment plan" is the object of the claim and what is obtained by practicing the claim (*i.e.* the successive digital data sets that represent arrangements of a patient's teeth from an initial arrangement toward a final arrangement). There is nothing in the claims or specification that suggests abandoning the guidance of the claims themselves and looking to a legal definition related to the practice of the profession contemplated in California law.

I also find that Align's proposed construction is incorrect. The Federal Circuit has explained that "claims are construed as an aid to the decision-maker, by restating the claims in non-technical terms." *Abbott Laboratories v. Sandoz, Inc.*, 544 F.3d 1341, 1360 (Fed. Cir. 2008)(citing *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477 (Fed.Cir.1998)). Here, Align's construction essentially replaces the word "treatment plan" with "strategy." This fails to provide any more context or clarification for understanding claim 7 than the original claim language, and Align cites no support from the claims or specification for its proposed construction. (CIB at 89-90) Defining treatment plan merely as a "strategy formulated . . ." also would conflict with the language of the claim, which requires that the "treatment plan" include

digital data sets. (JX-0007 at 11:29-31) The ordinary meaning of a "strategy" would not necessarily include the creation of digital data sets. Moreover, as noted above, the claims make clear that a "treatment plan" is the object of the claim and what is obtained by practicing the claim (*i.e.* the successive digital data sets that represent arrangements of a patient's teeth from an initial arrangement toward a final arrangement).

I find that examination of the extrinsic evidence offered by the parties is unnecessary because the intrinsic evidence is sufficient to understand the meaning of the terms construed in this section. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996) ("In most situations, an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term. In such circumstances, it is improper to rely on extrinsic evidence.")

Based upon all of the foregoing, I find that the proper construction for the term "treatment plan," as used in asserted claim 7, is "two or more successive digital data sets representing arrangements of a patient's teeth progressing from an initial tooth arrangement toward a final tooth arrangement."

E. The '511 Patent

1. Level of Ordinary Skill in the Art

In section III.B.1, *supra*, I found that one of ordinary skill in the art at the time of the invention of the asserted claims of Align's asserted patents was an individual with expertise in digital modeling and analysis and a working knowledge of orthodontic principles. The parties agree that the person of ordinary skill in the art is the same for all patents in suit. Based upon the similarities between the teachings of the '325 patent and the '511 patent, and the agreement of the parties that one of ordinary skill in the art is the same for the '325 patent and the '511 patent, I find that one of ordinary skill in the art at the time of the invention of the asserted claims of the

'511 patent has the same knowledge and expertise as one of ordinary skill in the art for the '325 patent.

The '511 patent is directed at a computer implemented method of defining tooth-moving appliances, which is the same field as that of the '325 patent. (JX-001, 1:23-24) The '511 patent discusses orthodontic principles. (*see, e.g.* JX-001, 3:23-30) and contemplates a treating professional (i.e., an orthodontist) providing a prescription that identifies final tooth positions (JX-001, 3:59-62); but the '511 patent focuses on the methods used to computationally generate a planned path for repositioning a patient's teeth from an initial to a final position and for segmenting that path into a plurality of treatment segments. (JX-001, 1:32-67, 2:34-39) The invention of the '511 patent then generates a plurality of appliances that will be used to reposition the patient's teeth in successive arrangements. (JX-001, 2:1-12) The '511 patent describes a system that can be used to augment a computational or manual process using a designer (human or automated) to finely tune the performance of the aligners and to facilitate direct aligner manufacturing under numerical control. (JX-001, 2:45-57, 11:4-19)

2. "computer-implemented method"

The term "computer-implemented method" appears in the preamble to asserted claim 1.

Align's position: Align contends that the proper construction for this term is "A method implemented wholly or in part using a computer."

Align asserts that this phrase needs no construction because the terms are easily understandable words with ordinary meanings, and there is no explicit definition of "computer-implemented method" or disclaimer of the scope of this phrase in the '511 patent. (Citing *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366-67 (Fed. Cir. 2002)) Nevertheless, Align says it has provided a clarifying construction of this term that is proper in view of the '511

patent's description of user interaction with the described methods and systems. (Citing JX-001, at 4:36-50) Align argues that Respondents have improperly advanced a ***new*** construction for this phrase in their *Prehearing Brief* that is markedly different from that they proposed in the *SRJCCC*, which also now seeks to expand the limitation to every element. Align reasons that Respondents' new construction has been waived, and as a result Align does not address it, other than to note that it is similarly unsupported.

Respondents' Position: In the SRJCCC, Respondents contended that the proper construction for this term is "a computer automated creation process in which each step is a computer program module for execution on one or more conventional digital computers, and where the data comprises signals corresponding to physical objects or activities external to the computer system, and the process causes a physical transformation of the signals which represent the physical objects or activities."

In their initial Post-Hearing Brief, Respondents assert that a person with ordinary skill in the art would understand a "computer-implemented method" to require "an automated process carried out by computer programs." Respondents assert that the context of the '511 Patent makes this clear. Respondents say, for example, the "detailed description" of the invention states: "The computational steps of the process are advantageously implemented as computer program modules for execution on one or more conventional digital computers." (Citing JX-001, at 3:35-38) Respondents continue that the summary states, that the "apparatus of the invention can be implemented as a system, or it can be implemented as a computer program product, tangibly stored on a computer-readable medium, having instructions operable to cause a computer to perform the steps of the method of the invention." Respondents add that there are no teachings in the patent that suggest anything other than an automated process carried out by

computer programs. Respondents conclude that this limitation does not mean a manual method carried out with the assistance of a computer; but rather requires that each step be computationally implemented on a computer. The Respondents contend that this phrase should be construed to mean: a computer automated creation process in which each step is a computer program module for execution on one or more conventional digital computers.

Staff's Position: Staff is of the view that the term should be given its "Plain and ordinary meaning."[6]

Staff contends that the term "computer-implemented method" requires no construction. Staff disagrees with Respondents' proposed construction, which requires the process to be a "computer automated creation process in which each step is a computer program module." Staff says that the patent specification contemplates user intervention, thus conflicting with Respondents' requirement of a "computer automated" process. (Citing JX-001 at 4:36-39) Staff adds that Respondents have not cited any support for the language "and where the data comprises signals corresponding to physical objects or activities external to the computer system, and the process causes a physical transformation of the signals which represent the physical objects or activities."

The Staff also disagrees with Complainant's proposed construction to the extent it allows a "computer implemented method" to cover methods that use computers in a tangential manner.

Construction to be Applied: "a method accomplished using a computer"

The plain language of asserted claim 1 teaches:

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[6] Staff's assertion of "plain and ordinary meaning," without further elaboration, does not rise to the level of a proposed construction. *See, e.g., O2 Micro Int'l Ltd. v. Beyond Innovation Technology Co., Ltd.*, 521 F.3d 1351, 1360 (Fed. Cir. 2008); *Maytag Corp. v. Electrolux Home Prods., Inc.*, 411 F. Supp. 2d 1008, 1037 (N.D. Iowa 2006); *Certain Semiconductor Integrated Circuits and Products Containing Same*, Inv. No. 337-TA-665, Order No. 19 (April 8, 2009).

> A computer-implemented method for segmenting an orthodontic treatment path into segments, comprising:
>
> for each tooth in a set of teeth, receiving a tooth path for the motion of the tooth from an initial position to a final position;
>
> calculating a segmentation of the aggregate tooth paths into a plurality of treatment segments so that each tooth's motion within a segment stays within threshold limits of linear and rotational translation; and
>
> generating a plurality of appliances, at least one or more appliances for each treatment segment, wherein the appliances comprise polymeric shells having cavities and wherein the cavities of successive shells have different geometries shaped to receive and resiliently reposition the teeth from one arrangement to a successive arrangement.

(JX-001, 11:4-19) Taken in context, the language of the claim is clear that the method for segmenting an orthodontic treatment into segments is to be accomplished using a computer. The claim further teaches the foregoing three elements as "comprising" the method. "Comprising" is a term of art which, when used in claim language, means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim. *Genentech, Inc. v. Chiron Corporation*, 112 F.3d 495, 501 (Fed. Cir. 1997) (*Genentech*) (citing *In re Baxter*, 656 F.2d 679, 686 (CCPA 1981)). Thus, a method that satisfies asserted claim 1 must contain the listed elements; but it may contain additional, unnamed elements.

The parties agree that asserted claim 1 requires the use of a computer to accomplish the method. Respondents, however, urge a specific and very narrow construction that is neither taught nor suggested by the language of asserted claim 1[7]. In addition, Respondents offer only two brief references from the patent to support their position. For the reasons set forth, *infra*, I find that the two references offered by Respondents, when considered in context, do not support

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[7] While Respondents, in their post-hearing brief, have omitted some of the restrictive language they included in their proposed construction in the SRJCCC, it is clear from their argument that they continue to take the position that the use of the computer requires a wholly automated process carried out by computer programs and that the limitation does not allow for an interactive method carried out with the assistance of a computer.

their position.

The patent specification is informative. The Detailed Description, referring to Figure 1, states "[t]he process 100 includes the methods, and is suitable for the apparatus, of the present invention, as will be described. The computational steps of the process are advantageously implemented as computer program modules for execution on one or more conventional digital computers." (JX-001, 3:36-39) The specification describes acquiring data in the form of "a mold or scan of a patient's teeth or mouth tissue," and says the step "generally involves taking casts of the patient's teeth and gums, and may also involve taking wax bites, direct contact scanning, x-ray imaging, tomographic imaging, sonographic imaging, and other techniques ..." It concludes "[f]rom the data so obtained, a digital data set is derived that represents the initial ... arrangement of the patient's teeth and other tissues." (JX-001, 3:39-50)

The specification provides that the final position of the teeth "can be received from a clinician in the form of a prescription, can be calculated from basic orthodontic principles, or can be extrapolated computationally from a clinical prescription." (JX-001, 3:59-63) The Detailed Description goes on to describe that with a specification of final positions and a digital representation of the teeth, the final position and surface geometry of each tooth can be specified to form a complete model of the teeth at the desired end of treatment. It concludes that the result of this step is a set of digital data structures that represents an orthodontically correct repositioning of the modeled teeth. (JX-001, 3:64-4:6)

Finally, the specification describes that having both a beginning and final position for each tooth, the process defines a tooth path for the motion of each tooth, and the tooth paths are segmented. The segments are calculated so that each tooth's motion with a segment stays within threshold limits of linear and rotational translation. (JX-001, 4:7-18)

While the description of Figure 1 in the specification clearly describes use of a computer to accomplish this method, it also describes:

> At various stages of the process, and in particular after the segmented paths have been defined, the process can, and generally will, interact with a clinician responsible for the treatment of the patient (step 160). Clinician interaction can be implemented using a client process programmed to receive tooth positions and models, as well as path information from a server computer or process in which other steps of process 100 are implemented. The client process is advantageously programmed to allow the clinician to display an animation of the positions and paths and to allow the clinician to reset the final positions of one or more of the teeth and to specify constraints to be applied to the segmented paths. If the clinician makes any such changes, the subprocess of defining segmented paths (step 150) is performed again.

(JX-001, 4:36-50) Thus, the specification anticipates direct interaction with the computer by a clinician who may reset the final position(s) of teeth and specify constraints to be applied to segmented paths.

The Detailed Description then provides that the segmented tooth paths and associated tooth position data are used to calculate clinically acceptable appliance configurations that will move the teeth on the defined treatment path in the steps specified by the path segments. Nevertheless, even at this stage, the specification allows for interactions and "even iterative interactions" with the clinician (step 160). (JX-001, 4:51-56, 4:63-65)

The process ends at the manufacturing step, "in which appliances defined by the process are manufactured, or electronic or printed information is produced that can be used by a manual or automated process to define appliance configurations or changes to appliance configurations[8]." (JX-001, 5:1-6) Clearly, the specification contemplates human intervention and interaction with the computer during the segmentation process as well as the manufacturing

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[8] Further references to human interaction in the manufacturing stage can be found at JX-001, 8:66-9:14.

process. Respondents have not identified any language in claim 1 that justifies excluding these disclosed embodiments.

Additionally, limiting claim 1 to preclude human intervention and interaction would conflict with claim 6, which depends from claim 1. Claim 6 requires "[t]he method of claim 1, further comprising: displaying the segmentation to a user; and receiving input from the user changing the segmentation." (JX-001 at 11:40-42.) Because claim 6 explicitly contemplates user interaction with the "computer implemented method" of claim 1, construing claim 1 to preclude user intervention would directly conflict with the user intervention contemplated in claim 6.

In order to give the asserted claim its broadest, reasonable interpretation[9], I conclude that, while the process clearly requires the use of one or more computers to accomplish the method of asserted claim 1, it also allows for additional elements such as interaction – even iterative interaction – by a clinician or other person. I, therefore, reject the narrower interpretation offered by Respondents.

Based upon all of the foregoing, I find that the proper construction for the term "computer implemented method" as used in asserted claim 1, is "a method accomplished using a computer."

F. The '863 Patent

1. Level of Ordinary Skill in the Art

Align's position: Align says that a person of ordinary skill in the field of the invention of the asserted claims is the same for all of the patents at issue.

Respondents' Position: Respondents say that, because the subject matter is the same,

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[9] See *Genentech, supra*, at 499.

the applicable level of ordinary skill in the art is the same for all of the patents at issue.

Staff's Position: Staff says that, because the parties and the technical experts agree that the same level of ordinary skill in the art applies to all of the patents at issue, the Staff's discussion of the applicable level of ordinary skill in the art regarding the '325 patent also applies to the '863 patent.

Analysis and Conclusions: In section III.B.1, *supra*, I found that one of ordinary skill in the art at the time of the invention of the asserted claims of Align's asserted patents was an individual with expertise in digital modeling and analysis and a working knowledge of orthodontic principles. The parties agree that the person of ordinary skill in the art is the same for all patents in suit. Based upon the similarities between the teachings of the '325 patent and the '863 patent, and the agreement of the parties that one of ordinary skill in the art is the same for the '325 patent and the '863 patent, I find that one of ordinary skill in the art at the time of the invention of the asserted claims of the '863 patent has the same knowledge and expertise as one of ordinary skill in the art for the '325 patent.

Similar to the '325 patent, the focus of the claims of the '863 patent is the method used to generate the digital models of dental positioning appliances used for orthodontic treatment. (*See, e.g.*, JX-0005 at R1:57-2:4; JX-005 at 13:65-14:60) The '863 patent incorporates by reference U.S. Patent No. 5,975,893 ("the '893 patent").[10] (JX-0005 at 2:20-25) The incorporated '893 patent discusses, in detail, the manipulation of digital data to prepare the initial data set, generate the final tooth arrangement, and generate the intermediate digital data sets. (*See, e.g.*, '893 patent at 6:50-56) As in the '325 patent, the '863 patent describes fabricating a plurality of

[10] The '863 patent, which was filed on October 29, 2001, is a continuation-in-part of U.S. Patent No. 6,398,548 ("the '548 patent"), which was filed December 17, 1999. The '548 patent, in turn, is a continuation-in-part of the '893 patent, which was filed on October 8, 1997. Both the '863 patent and '893 patent claim priority to the same provisional application 60/050,342, which was filed on June 20, 1997. *See* JX-0005 at 1:6-28.

dental incremental position adjustment appliances based on the digital data sets. (*See, e.g.*, '893 patent at 6:56-62) The '863 patent teaches providing a digital model of an attachment device, and positioning the digital model of the attachment device on the digital model of the dental positioning appliance. (*See, e.g.*, JX-0005 at R2:1-4 and 12:46-60)

Similar to the '325 patent, the '863 patent contemplates a treating professional (an orthodontist) providing a prescription that identifies final tooth positions (*see, e.g.*, '893 patent at 6:1-11), but does not delve into the intricacies of the practice of orthodontics. For example, the '863 patent states that it would be possible to provide software which could interpret a prescription from a treating professional in order to generate digital data representing a final tooth arrangement. (*Id.*) Based on the similarities between the '325 patent and the '863 patent, I find that one of ordinary skill in the art at the time of the invention of the asserted claims of the '863 patent is the same as one of ordinary skill in the art for the '325 patent.

2. "distinct successive incremental dental positional appliance"/"successive incremental dental positional appliance"

The term "distinct successive incremental dental positional appliance"/"successive incremental dental positional appliance" appears in asserted claim 1.

Align's position: Align asserts that this term should be construed as "one of a series of appliances to be worn for incrementally positioning teeth." Align contends that the '863 patent describes how the repeating use of "successive appliances comprising new configurations eventually move the teeth through a series of intermediate configurations to a final desired configuration." (Citing JX-0005 at 2:10-20) Align argues that its construction follows this description and clarifies the term by construing it to mean "one of a series."

Align contends that Respondents are wrong in their argument that Align cannot seek a construction that covers sets of appliances "fabricated after the outset of treatment," citing the

prosecution history of the '874 patent. (Citing RPHB at 217) Align contends that Respondents confuse the concept of (i) a single "set" of appliances (one upper and one lower) used at one treatment stage with (ii) a series of appliances for successive treatment stages. Align asserts that, during the prosecution of the '874 patent, Align distinguished prior art that "teaches a manual method for making one set of appliances (one upper jaw appliance and one lower jaw appliance) ..." (Citing JX-0016 at 274) Align says that its statement that the prior art "teaches making one set of appliances at a time" refers to one upper appliance and one lower appliance corresponding to a single treatment stage. Align argues that Respondents have also not explained how the prosecution of the '874 patent can affect the asserted claims of the other patents. Align continues that Respondents arguments are further improper for the '863 patent because the statements to which Respondents refer were made after the '863 patent issued.

Respondents' Position: Respondents contend that the plain and ordinary meaning of this phrase should apply, and that there is no basis to conclude that any meaning other than the plain and ordinary meaning should apply. In the infringement section of its post-hearing brief, however, Respondents assert that one skilled in the art would understand the second element of claim 1 would require that all of the "plurality" of "modified digital models" progress successively from the initial tooth arrangement to the final tooth arrangement and be produced prior to active treatment. (RIB at 120)

Staff's Position: Staff asserts that this term should be construed to mean "one of a series of dental appliances for repositioning teeth." Staff contends that, because Respondents contend that the plain and ordinary meaning should apply, they have effectively taken the position that no construction of this claim term is necessary. (Citing Order No. 9) Staff notes that, nonetheless, Respondents argue that one of ordinary skill in the art would understand that the claim element

reciting these claim terms would require that all of the "plurality of modified digital models" progress successively from the initial tooth arrangement to the final tooth arrangement. (Citing RPHB at 186-187) Staff asserts that Respondents' arguments appear to be based on Dr. Mah's opinions, which the ALJ has excluded. (Citing RX-0129C at Questions 118 and 120) As such, Staff is of the view that Respondents are precluded from presenting those arguments.

Staff contends that, even if permitted, Respondents' new claim construction appears to conflict with the plain language of the claim, which recites in pertinent part, "a plurality of modified digital models, wherein the modified models represent successive *treatment stages of an orthodontic treatment*." (Citing JX-0005 at 1:57-67 (emphasis added by Staff)) Staff argues that Respondents' proposed construction requires that all of the "plurality" of "modified digital models" progress from the initial tooth arrangement to the final tooth arrangement, i.e. a phase-based process would not fall within the scope of the claim. (Citing RIB at 187) Staff asserts that the claim clearly recites "stages" of an orthodontic treatment, wherein the modified models represent successive stages of orthodontic treatment, as opposed to the overall orthodontic treatment. As such, Staff is of the view that, if considered, Respondents' claim construction should be rejected.

Construction to be Applied: "a single, separate appliance to be used during a particular interval for repositioning teeth"

The plain language of claim 1 discloses a method for producing digital models of dental positioning appliances, and provides details regarding what is required by that method. Specifically, claim 1 requires, in pertinent part:

> A method for producing digital models of dental positioning appliances, said method comprising:
>
> providing a digital model of a patient's dentition;

> producing a plurality of modified digital models of the dentition, wherein the modified models represent successive treatment stages of an orthodontic treatment and wherein each modified model or a product of such model is to be used in fabrication of a ***distinct successive incremental dental positioning appliance*** associated with the respective treatment stage of that modified model;
>
> ...

(JX-0005 at R1:55-2:4[11] (emphasis added)) The parties dispute the meaning of "successive" and whether or not the phrase "successive" includes *all* successive appliances to be used in treatment.

Respondents offered "plain and ordinary meaning" as a construction for the term "distinct successive incremental dental positional appliance" in both the Second Revised Joint Claim Construction Chart and its post-hearing brief, and offered no construction beyond that comment. (SRJCCC at 8; RIB at 119) Assertion of "plain and ordinary meaning," without further elaboration, does not rise to the level of a proposed construction. *See, e.g., O2 Micro Int'l Ltd. v. Beyond Innovation Technology Co., Ltd.*, 521 F.3d 1351, 1360 (Fed. Cir. 2008); *Maytag Corp. v. Electrolux Home Prods., Inc.*, 411 F. Supp. 2d 1008, 1037 (N.D. Iowa 2006); *Certain Semiconductor Integrated Circuits and Products Containing Same*, Inv. No. 337-TA-665, Order No. 19 (April 8, 2009)." In Order No. 9, in the instant investigation, I stated that a party, who offered "plain and ordinary meaning" as a construction in the SRJCCC, would be precluded from offering another construction at a later point in the investigation.

Nevertheless, in the non-infringement section of its post-hearing brief, when referring to the limitation of the second element of asserted claim 1, Respondents argue that they do not infringe this limitation because, "[b]ased on the context of the patent and related prosecution history, one skilled in the art would understand that this limitation would require that ***all*** of the 'plurality' of 'modified digital models' progress successively from the initial tooth arrangement

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[11] *See* Ex Parte Reexamination Certificate ("the Reexamination Certificate") appended to the '863 patent. The designation "R" will be used to refer to the Reexamination Certificate.

to the final tooth arrangement and be produced ***prior*** to active treatment." (RIB at 120 (emphasis added)) Respondents continue that "[a] final tooth arrangement can only be a projection at the treatment stage prior to active treatment." (Citing RX-0129C, Q. 120) Respondents also argue that "this means that the Clinician does not determine the successive tooth arrangements that are required until after treatment has begun." (RIB at 120)

Because Respondents failed to previously disclose any construction for this term, Respondents have waived the right to propose any construction for this term anywhere in its post-hearing briefing. Respondents have attempted to overcome the waiver of that right by offering a backdoor construction for this term in the non-infringement section of their post-hearing brief. In ruling on Align's first motion *in limine*, I excluded that portion of Question 120 of Dr. Mah's testimony, upon which Respondents rely to support their waived argument on construction. Respondents' disingenuous attempt to recover their waived argument is rejected.

Nevertheless, assuming *arguendo* that Respondents had not waived their argument that the limitation of the second element of asserted claim 1 means that "all of the plurality of modified digital models progress successively from the initial tooth arrangement to the final tooth arrangement and be produced prior to active treatment," I find that nothing in the intrinsic record even hints at such a restrictive construction.

The claims themselves conflict with Respondents' construction, and provide substantial guidance regarding the meaning of the term "distinct successive incremental dental positioning appliance." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005). The first limitation of the second element of claim 1 recites, in pertinent part, "producing a ***plurality*** of … digital models." This language only requires that two or more digital models be produced. *See Apple v. Samsung Electronics Co., Ltd.*, 695 F.3d 1370, 1379 (Fed. Cir. 2012); *see also August*

Technology Corp. v. Camtek, Ltd., 655 F.3d 1278 (Fed. Cir. 2011). The remainder of claim 1 does not change this meaning. In pertinent part, the second limitation of the second element recites that, "the ... models represent successive treatment stages." The third limitation of the second element then recites that "***each*** modified ***model*** ... is to be used in fabrication of ***a*** distinct successive incremental dental positioning appliance associated with ***the respective*** treatment ***stage of that*** modified ***model***." (JX-0005 at R1:63-67 (emphasis added)) Nothing in these limitations in any way requires a specific *total* of models required to be produced before the fabrication of dental positioning appliances. Rather, they explain the one-to-one *ratio* that one digital model (representing a single "treatment stage") is used to fabricate one dental appliance. This arises from the use of the word "each" to clarify that a single model is used to fabricate "a distinct" (i.e. single and separate) dental appliance associated with a particular treatment stage.

Although, the Federal Circuit has stated that "an indefinite article 'a' or 'an' in patent parlance carries the meaning of 'one or more' in open-ended claims containing the transitional phrase 'comprising,'" there is an exception when the patentee evinces a clear intent to limit the article 'a' to receive a singular interpretation. *KJC Corp. v. Kinetic Concepts, Inc.*, 223 F.3d 1351, 1356 (Fed. Cir. 2010). As noted above, claim 1 clearly and specifically requires that one digital model be used to fabricate a single dental positioning appliance associated with a particular treatment interval. Based upon all of the foregoing, I find that the language of the second element provides a limitation on the article "a" such that it refers to a single, separate dental appliance as opposed to the normal use of the article to represent one or more dental appliances.

In addition, the specification and prosecution history of the '863 patent describe replacing

attachment devices mid-treatment or placing new attachment devices throughout treatment. (JX-005 at 7:61-64; CX-1251 at 212) This description, which is not limited to a preferred embodiment, teaches away from Respondents' restrictive construction of fabricating all of the dental appliances prior to the outset of treatment, and is not inconsistent with the view that claim 1 requires that one digital model and corresponding appliance be used during one particular treatment stage.

Found nowhere in claim 1is the additional temporal requirement of "a series" of dental positioning appliances, as Align's and Staff's constructions introduce. Rather, this limitation is added by claim 57, which depends from claim 1. Specifically, claim 57 recites, "[a] method as in claim 1, further comprising providing the produced plurality of modified digital models for use in fabricating ***a series*** of successive dental positioning appliances." (JX-0005 at R6:15-18 (emphasis added))

The doctrine of claim differentiation is applicable here. The doctrine of claim differentiation, stems from "the common sense notion that different words or phrases used in separate claims are presumed to indicate that the claims have different meanings and scope." *Seachange Int'l, Inc. v. C-COR Inc.*, 413 F.3d 1361, 1368-69 (Fed. Cir. 2005). There is a presumption that an independent claim should not be construed as requiring a limitation added by a dependent claim, and the presumption is "especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim." *SunRace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003).

The only meaningful difference between claim 57 and claim 1 is the use of the term "a series." Claim 57 recites producing a plurality of modified digital models for use in fabricating "***a series***" of successive dental positioning "***appliances***" (plural), while claim 1 recites producing

a plurality of modified digital models, wherein "***each modified model***" is used to fabricate a "***a distinct***" successive incremental dental positioning "***appliance***" (singular). Claim 1 does not describe fabricating *a series* of dental repositioning appliances after the production of a plurality of digital models.

Use of the term "successive" in conjunction with the terms "distinct" and "incremental" in claim 1 does not change the meaning of the plain language of the claim to require "a series." Claim 1 associates "a distinct successive incremental dental appliance" with a corresponding treatment stage, which as discussed above, is a single interval in orthodontic treatment that uses a single fabricated dental repositioning appliance derived from a single digital model. If one assumes that claim 1 requires using one digital model to produce "one of a series" of dental appliances, then either claim 57 would be rendered superfluous or it would render that portion of claim 1 superfluous. *InterDigital Communications, LLC v. Int'l Trade Comm'n*, 690 F.3d 1318, 1324-25 (Fed. Cir. 2012); *Aristocrat Technologies Australia Pty Ltd. v. Int'l Game Technology and IGT*, 709 F.3d 1348, 1355-56 (Fed. Cir. 2013). Either result is incorrect.

Respondents' prosecution history estoppel arguments, once again, are ill-considered. Respondents rely on arguments that Align made during prosecution of the '874 patent to assert that the claims of the '863 patent should be interpreted to require that all appliances to be used in treatment be fabricated before treatment begins. The arguments ascribed to Align by Respondents were based on claim language that is not present in asserted claim 1 of the '863 patent. Like the claims of the '325 patent discussed in Section III.B.2, *supra*, claim 1 of the '863 patent does not include the phrase "at the outset of treatment." (*See* JX-0005 at R1:57-67) For the reasons explained in in Section III.B.2, *supra*, which I reaffirm here, because claim 1 does not include the phrase "at the outset of treatment," arguments made during prosecution of the

'874 patent regarding the phrase "at the outset of treatment" are not relevant to determining the scope of the claims of the '863 patent.

Based upon all the foregoing, I find that the proper construction for the term "distinct successive incremental dental positional appliance" as used in asserted claim 1 is "a single, separate appliance to be used during a particular interval for repositioning teeth."

G. The '874 Patent

1. Level of Ordinary Skill in the Art

In section III.B.1, *supra*, I found that one of ordinary skill in the art at the time of the invention of the asserted claims of Align's asserted patents was an individual with expertise in digital modeling and analysis and a working knowledge of orthodontic principles. The parties agree that the person of ordinary skill in the art is the same for all patents in suit. Based upon the similarities between the teachings of the '325 patent and the '874 patent, and the agreement of the parties that one of ordinary skill in the art is the same for the '325 patent and the '874 patent, I find that one of ordinary skill in the art at the time of the invention of the asserted claims of the '874 patent has the same knowledge and expertise as one of ordinary skill in the art for the '325 patent.

Similar to the '325 patent, the '874 patent is directed to a method to use a computer to create a plan for repositioning an orthodontic patient's teeth. (JX-006, Abstract, and 1:29-31) The '874 patent discusses orthodontic principles (*see, e.g.*, JX-006, 1:32-2:25) and contemplates involvement by a clinician (JX-006, 16:19-33, 22:26-28, 30:40-54) and a prescription by an orthodontist. (JX-006, 17:17-20) Similar to the '325 patent, the focus of the '874 patent is a computer implemented method and related program for use in creating a treatment plan to reposition a patient's teeth from a set of initial tooth positions to a set of final tooth positions.

(*See, e.g.*, JX-006, 32:37-39, 37:18-22) The '874 patent discusses, in detail, the manipulation of digital data to prepare the treatment plan. (JX-006, 10:12-32:14)

2. "computer-implemented method"

The term "computer-implemented method" appears in asserted claim 1.

Align's position: Align contends that the proper construction for this term is "A method implemented wholly or in part using a computer."

Align refers to its argument regarding this same term as it appears in the '511 patent. (See section III.E.3, *supra*)

Respondents' Position: The Respondents refer to their argument regarding this phrase in relation to the '511 patent and contend that this phrase should construed to mean the same as it does in the '511 Patent.

Staff's Position: Staff notes that the term "computer-implemented method" also appears in the '511 patent, and the parties agree that the term should be construed consistently between the patents. Staff contends that this term requires no construction. Staff adds that, rather than provide clarity, the constructions proposed by the private parties introduce confusion into the analysis. Thus, Staff disagrees with Complainant's proposed construction to the extent it allows a "computer implemented method" to cover methods that use computers in a tangential manner. Staff also disagrees with Respondents' proposed construction, which requires the process to be a "computer automated creation process in which each step is a computer program module." Staff reiterates that this requirement is inconsistent with the intrinsic evidence. Staff contends that Respondents' proposed addition of the language "and where the data comprises signals corresponding to physical objects or activities external to the computer system, and the process

causes a physical transformation of the signals which represent the physical objects or activities" is also unsupported.

Staff argues that, where, as here, the terms are ordinary, simple English words, they mean what they say absent an indication that their use has been altered. (Citing *Philips*, 415 F.3d at 1313) Staff asserts that there is no indication, and the private parties have pointed to nothing suggesting that, the use of the terms has been altered beyond their plain and ordinary meaning. Staff concludes that there is nothing in the patent specification or prosecution history that shows that the patentees clearly assigned any specialized meaning to or otherwise narrowed the meaning of "computer-implemented method."

Staff is of the view that the term "computer-implemented method" requires no construction beyond its plain and ordinary meaning.

Construction to be Applied: "a method accomplished using a computer"

The plain language of asserted claim 1 teaches a computer implemented method for segmenting an orthodontic treatment path into segments, when it states:

> A computer-implemented method for use in creating a treatment plan to reposition a patient's teeth from a set of initial tooth positions to a set of final tooth positions, the method comprising:
>
> receiving an initial digital data set representing the teeth at the initial positions, wherein receiving the initial data set comprises receiving data obtained by scanning the patient's teeth or a physical model thereof;
>
> generating a set of intermediate positions toward which the teeth will move while moving from the initial positions toward the final positions; and
>
> generating a plurality of successive appliances having cavities and wherein the cavities of successive appliances have different geometries shaped to receive and reposition teeth from the initial positions toward the final positions,

> wherein the plurality of successive appliances is generated at a stage of treatment prior to the patient wearing any appliance of said plurality so as to reposition the teeth.

(JX-006, 32:37-56) Taken in context, the language of the claim is clear that the method for creating a treatment plan is to be accomplished using a computer. The claim teaches use of an initial digital data set that represents the teeth in their initial positions and the data produced by scanning the patient's teeth or a physical model of the teeth. In the second and third elements, the claim calls for "generating" a set of intermediate positions for movement of the teeth while moving toward final positions and then "generating" successive appliances to accomplish the repositioning of the teeth from the initial positions to the final positions. These three elements clearly intend for the treatment plan to be accomplished using a computer. As in the '511 patent, asserted claim 1 of the '874 patent uses the term "comprising" in its preamble. "Comprising" is a term of art which, when used in claim language, means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim. *Genentech, Inc. v. Chiron Corporation*, 112 F.3d 495, 501 (Fed. Cir. 1997) (*Genentech*) (citing *In re Baxter*, 656 F.2d 679, 686 (CCPA 1981)). Thus, a method that satisfies asserted claim 1 must contain the listed elements; but it may contain additional, unnamed elements.

The parties agree that asserted claim 1 requires the use of a computer to accomplish the method, and they each refer to or reiterate their arguments in section III.E.3, supra, related to the '511 patent to support their proposed construction to be applied to this term in the '874 patent.

The patent specification is informative. In the Background of the Invention, the inventor notes that the invention "relates generally to the field of orthodontics and, more particularly, to computer automated development of an orthodontic treatment plan and appliance." (JX-006,

1:29-31) In the Summary of the Invention, the inventor makes clear that there are multiple ways in which a computer may be used in this context. The inventor states:

> In one aspect, the invention relates to the computer-automated creation of a plan for repositioning an orthodontic patient's teeth. A computer receives an initial digital data set representing the patient's teeth at their initial positions and a final digital data set representing the teeth at their final positions. The computer uses the data sets to generate treatment paths along which the teeth will move from the initial positions to the final positions.
>
> In some implementations, the initial data set includes data obtained by scanning a physical model of the patient's teeth, such as by scanning a positive impression or a negative impression of the patient's teeth with a laser scanner or a destructive scanner...

(JX-006, 3:7-19) The inventor continues:

> In other embodiments, the computer applies a set of rules to detect collisions that will occur as the patient's teeth move along the treatment paths... The computer also can be used to detect improper bite occlusions that will occur as the patient's teeth move along the treatment paths. Other embodiments allow the computer to render a three-dimensional (3D) graphical representation of the teeth at any selected treatment step. The computer also can be used to animate the graphical representation of the teeth to provide a visual display of the movement of the teeth along the treatment paths.

(JX-006, 3:34-47)

Respondents' proposed construction, which requires the process to be a "computer automated creation process in which each step is a computer program module," improperly narrows the scope of the claim. While it is clear that the computer implemented method includes some automated features, as discussed, *supra*, the Summary of the Invention and the Detailed Description of the Invention both allow for some user interaction beyond mere automation. For example, the specification notes "some embodiments allow the user to modify the underlying digital data set by repositioning a tooth in the 3D graphical representation." (JX-006, 3:51-53) Other examples include, "[d]eveloping an orthodontic treatment plan for a patient involves

manipulating the IDDS [Initial Digital Data Set] at a computer or workstation having a suitable graphical user interface (GUI) and software appropriate for viewing and modifying the images." (JX-006, 10:12-15) Figure 3 of the '874 patent illustrates a representative technique for user-assisted manipulation of the IDDS to produce the FDDS [final digital data set] on the computer. (JX-006, 12:4-6) The specification clearly contemplates a combination of automated processes along with user input and interaction to create the treatment paths for a patient's teeth. (*See, e.g.*, JX-006, 12:11-44; 12:53-62

The specification describes segmenting the teeth in a 3D model and details the methods for both human-assisted segmentation (*e.g.* using tools such as a "saw" (JX-006, 13:3-23) and an "eraser" (JX-006, 13:36-51)) and automated segmentation, in which the includes a subsystem that performs automatic or semi-automatic segmentation of the 3D dentition model into models of individual teeth (JX-006, 14:20-25). Other examples of automatic and human-assisted features abound in the specification. (JX-006, 14:39-22:4, 22:41-23:31) Clearly the '874 patent does not limit a computer implemented method to a fully automatic scenario; it includes interactive uses as well.

Additionally, limiting claim 1 to preclude human intervention and interaction would conflict with claims 32, 37, 45, 46, 47, 51, 53, 72 and 76, all of which depend from claim 1. For example, dependent claim 45, which depends from claim 1 via dependent claim 42, comprises receiving an instruction from a human user to modify the graphical representation of the teeth and modifying the graphical representation in response to the instruction. Dependent claim 46 depends from claim 45 and teaches modifying the selected data set in response to instruction from the user. Claim 53, which depends from claim 42, teaches "further comprising receiving an input signal from a 3D input device controlled by a human user and using the input signal to alter the

orientation of the teeth in graphical representation." Finally, claim 72, which depends from claim 1 via dependent claim 71, comprises displaying at least two different sets of intermediate treatment positions to a user and allowing the user to select one of the sets for use in treating the patient's teeth. Clearly, the use of the term "computer-implemented method" in independent claim 1 does not limit itself to a fully automated system. (JX-006, 35:17-20, 35:21-23, 35:45-48, and 36:50-53)

In order to give the asserted claim its broadest, reasonable interpretation[12], I conclude that, while the process clearly requires the use of one or more computers to accomplish the method of asserted claim 1, it also allows for interaction with a human user. I, therefore, reject the narrower interpretation offered by Respondents.

Based upon all of the foregoing, I find that the proper construction for the term "computer implemented method" as used in asserted claim 1, is "a method accomplished using a computer."

3. "treatment plan"

The term "treatment plan" appears in asserted claim 1.

Align's position: Align says that this term is discussed in CIB Sections IV.D and VII.A.1 in the discussion of the '487 patent. Align argues that its construction is proper for the reasons advanced in those sections.

In its argument regarding the '487 patent, Align contends that this term should be construed as "a strategy formulated to reposition a patient's teeth." Align says that Staff's proposed construction, which is generally consistent with Align's, improperly requires that the patient be an orthodontic patient. Align asserts that there is no requirement in the intrinsic record that the patient be an Orthodontist's patient; rather, the patient can be a dental patient or the

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[12] See *Genentech, supra*, at 499.

patient of any other practitioner licensed to prescribe dental treatment using incremental repositioning dental appliances.

Align notes that, in their non-infringement argument, Respondents attempt to offer a new construction for this term which would require that an orthodontist or clinician formulate the treatment plan. Align asserts that Respondents cannot advance their new construction, because it has been excluded. (Citing Tr. at 8:4-9:4; and RX-0129C at Q. 32) Align says that Respondents stated "No Construction Proposed" in the SRJCCC for this phrase, and cannot, therefore, advance a new construction now. (Citing Tr. at 8:4-16)

Align contends that Respondents also did not cite to any supporting intrinsic evidence in their Prehearing Brief (citing RIB at 107, 220-21), and thus should not be heard to cite to Align's provisional application (CX-1252) now. Waiver notwithstanding, Align contends that Respondents' construction is nonsensical in view of the intrinsic record. Align recites the relevant portion of claim 7 of the '487 Patent and notes that the term "treatment plan" includes "a plurality of intermediate digital data sets" that represent "intermediate arrangements of the patient's teeth." (Citing JX-0006, 32:37-56) Align reasons that it is clear that the recited "treatment plans" are simply the product of the claimed process. Align adds that Claim 1 of the '874 patent is similar. (Citing JX-007, 11:26-35)

Align continues that neither the '487 or '874 patents disclose, much less require, that an orthodontist plan out the treatment or prepare the digital models used to create the aligners; rather, they teach that most of the treatment planning is done by a technician interacting with a computer and following established protocols. (Citing JX-006, 10:12–15; JX-007, 5:29-32; JX-003, 12:33-38; and CX-1150C, Qs. 242, 251, 316) Align says that Respondents ignore the intrinsic evidence and piece together a new construction based on unsupported statements from

Respondents' expert Dr. Mah along with an irrelevant argument regarding unauthorized practice of dentistry. (Citing RIB at 107) Align contends that such extrinsic evidence is of little value in view of the clear intrinsic record. (Citing *Advanced Fiber Techs. Trust v. J&L Fiber Servs.*, 674 F.3d 1365, 1375 (Fed. Cir. 2012))

Align asserts that "intermediate digital data sets" are also the product of exemplary embodiments of the processes taught by the '487 and '874 Patents. (Citing JX-007, 5:57-61; JX-006, 10:12-15, 19:9-11, 27:36-50) Align continues that the'487 and '874 patents teach that treatment planning is done on a computer by a user (*e.g.*, a "treatment plan designer") following established protocols. (Citing JX-006, 12:4-8) Align says that neither the '487 nor '874 patents disclose, much less require, that the user be an orthodontist; rather, the '874 Patent specifically provides for a system where a clinician can review the treatment plan that has already been prepared *via* a "viewer application," as cited above. (Citing JX-006, 27:36-50) Align asserts that the provision of this "viewer application" would make no sense if the orthodontist was operating the system.

Align contends that Respondents' citation to Align's provisional application 60/050,342 (CX-1252) is irrelevant. Align says that while it does indicate in some instances that an orthodontist may utilize the disclosed system, it does not teach that only an orthodontist may use it. Align continues that the claims of the '487 or '874 patents also do not preclude an orthodontist from creating the "treatment plan"—they are just not limited to such a situation. Align says that the provisional application also states that an "operator" may use the disclosed system. (Citing CX-1252 at 9:13, 20, 24, 10:23, 28)

Align asserts that despite my instruction that I would "be focusing on treatment plan as it is used in the patent," Respondents argue that extrinsic evidence should dictate the meaning of

"treatment plan," citing testimony from Jarrett Pumphrey and Willis Pumphrey, the excluded testimony of Dr. Mah. (Citing RIB at 88; and RX-129C at Q. 32 (Excluded)), and "an out-of-context quote from Dr. Valley." Align adds Respondents fail to cite to their own documents which specify that they—not their orthodontists—prepare "treatment plans." (Citing CX-055 ("ClearCorrect maps out a complete treatment plan . . ."); CX-090C at 28 ("a [DPS] sheet is used to make a treatment plan. . . ."); and CX-078 at 64-68 (Treatment plan paperwork shipped with each phase))

Respondents' Position: The Respondents contend that this phrase should be construed to mean the same thing as it does in the '487 Patent. Accordingly, that discussion, supra, is incorporated here.

Discussing construction for the '487 patent, Respondents contend that the plain and ordinary meaning of "treatment plan" should apply. Respondents rely heavily on extrinsic evidence in their argument, reciting testimony of witnesses such as Dr. Valley, Mr. Beers, and Jarrett Pumphrey. Respondents argue that California law precludes the creation of a treatment plan, because it would amount to the unlawful practice of dentistry pursuant to Section 1625.1(a) of the California Business and Professions Code.

Respondents also say that I offered a "pragmatic approach", stating the phrase would be defined by its use in the patent. (Citing Tr. at 704:24-705:3, and 805:5-6)

Respondents argue that one skilled in the art would understand that a treatment plan means a comprehensive plan and timing for management of the malocclusion which may include, but is not limited to, detailed biomechanical treatments with various orthodontic appliances, adjunctive therapies such as surgery, restorations or other dental care, re-evaluation, retention, referrals to other health professionals, and observation as indicated.

Respondents now contend that the plain and ordinary meaning of "treatment plan" is "the course of treatment devised by the treating dentist or orthodontist." Respondents say that this meaning is consistent with the provisional patent application to which the '487 patent claims priority, the witness testimony, applicable state law, and Align's own representations about its compliance with state law. Respondents continue that Align attempts to expand the plain and ordinary meaning of the phrase by suggesting that a treatment plan can be prepared by anyone. Respondents conclude that Align's broad interpretation is inconsistent with its provisional application, the witness testimony and state law.

Respondents assert that Align effectively offers nothing to contradict the plain and ordinary meaning of "treatment plan." Respondents aver that Align offers only three of CCUS's documents that state the phrase "treatment plan" to support Align's request for a modification of "treatment plan's" plain and ordinary meaning. (Citing CIB at 39) Respondents say that these items were addressed at the hearing and Align has no response to the witness testimony explaining:

> You know, I would say that for the documents that we send to doctors, if we have labeled them treatment plan, it is just so they can kind of think with how that's supposed to fit into their treatment plan. It is not actually a plan of treatment similar to anything like what a doctor would plan.

(Citing Tr. at 351:19-25)

Staff's Position: Staff asserts that this term should be construed to mean "a strategy formulated for repositioning an orthodontic patient's teeth." Staff asserts that because Respondents originally proposed no construction for "treatment plan" and I excluded Dr. Mah's opinion that a "treatment plan" is only planned by a Clinician (citing RX-0129C, Q. 162), Respondents are precluded from arguing this as a proposed construction. Staff adds that its proposed construction, which does not materially differ from Align's proposed construction, is

consistent with the plain language of the claims and disclosures in the specification. Staff says that claim 1 recites in pertinent part: "A method of *planning orthodontic treatment of a patient*." (Citing JX-0007 at 10:61-63 (emphasis added)) Staff continues that the specification discloses, "[t]he present invention is related generally to the *field of orthodontics*, and more particularly to a system and method for gradually repositioning teeth." Staff says that any arguments to the contrary by Respondents should be rejected.

Construction to be Applied: "two or more successive digital data sets representing arrangements of a patient's teeth progressing from an initial tooth arrangement toward a final tooth arrangement."

Respondents did not propose a construction for "treatment plan" in the SRJCCC. In their post-hearing briefing, however, Respondents contend that the plain and ordinary meaning of "treatment plan" is "is the course of treatment devised by the treating dentist or orthodontist." (RIB at 138, and 87-91) I have repeatedly and consistently held that assertion of "plain and ordinary meaning," without further elaboration, does not rise to the level of a proposed construction. *See, e.g., O2 Micro Int'l Ltd. v. Beyond Innovation Technology Co., Ltd.*, 521 F.3d 1351, 1360 (Fed. Cir. 2008); *Maytag Corp. v. Electrolux Home Prods., Inc.*, 411 F. Supp. 2d 1008, 1037 (N.D. Iowa 2006); *Certain Semiconductor Integrated Circuits and Products Containing Same*, Inv. No. 337-TA-665, Order No. 19 (April 8, 2009)." In Order No. 9, in the instant investigation, I stated that a party, who offered "plain and ordinary meaning" as a construction in the SRJCCC, would be precluded form offering another construction at a later point in the investigation. Because Respondents failed to disclose this construction in the SRJCCC, Respondents have waived the right to argue that this construction should be adopted.

Because Respondents failed to previously disclose any construction for this term,

Respondents have waived the right to propose any construction for this term anywhere in its post-hearing briefing. Respondents have attempted to overcome the waiver of that right by offering a backdoor construction for this term in the non-infringement section of their post-hearing brief. In ruling on Align's first motion *in limine*, I excluded that portion of Question 120 of Dr. Mah's testimony, upon which Respondents rely to support their waived argument on construction. Respondents' disingenuous attempt to recover their waived argument is rejected.

Nevertheless, assuming *arguendo* that Respondents had not waived their argument, I find nothing in the intrinsic record to support their proposed construction.

The parties all agree that the construction for "treatment plan" should be the same in the '874 patent as it is in the '487 patent. Align and Staff agree with each other that the construction for this term should be a strategy formulated to reposition a patient's teeth. Align and Staff only disagree on whether or not the word patient should be modified by the descriptor "orthodontic," a point that I find not material here.

Asserted claim 1 describes a computer-implemented method for use in creating a treatment plan to reposition a patient's teeth from a set initial tooth positions to a set of final tooth positions. The method entails first receiving an initial data set obtained by scanning the patient's teeth or a physical model thereof. Then the method teaches generating a set of intermediate positions toward which the teeth will move while moving from the initial positions toward the final positions. Finally, the method requires generating a plurality of successive appliances to receive and reposition teeth from the initial positions toward the final positions.

As in the '487 patent, asserted claim 1 of the '874 patent begins, in the first element, with the receipt of "an initial digital data set" representing the teeth at their initial positions. The second element of claim 1 teaches "generating a set of intermediate positions" toward which the

teeth will move, and the third element requires "generating a plurality of successive appliances ... to receive and reposition teeth."

The specification offers additional enlightenment, when it describes, "[d]eveloping an orthodontic treatment plan for a patient involves manipulating the IDDS [Initial Digital Data Set] at a computer or workstation having a suitable graphical user interface (GUI) and software appropriate for viewing and modifying the images." (JX-006, 10:12-15) Figure 3 of the '874 patent illustrates a representative technique for user-assisted manipulation of the IDDS to produce the FDDS [final digital data set] on the computer. (JX-006, 12:4-6) The specification clearly contemplates a combination of automated processes along with user input and interaction to create the treatment paths for a patient's teeth, which are represented by digital data sets. (*See, e.g.*, JX-006, 12:11-44; 12:53-62) Additionally, dependent claim 46, which depends from claim 1 via claims 45 and 42, teaches modifying the selected data set in response to instruction from the user. (JX-006, 35:21-23)

Based upon the foregoing, I find that the term "treatment plan" shall be construed in accordance with its plain and ordinary meaning to be, "two or more successive digital data sets representing arrangements of a patient's teeth progressing from an initial tooth arrangement toward a final tooth arrangement."

I find that examination of the extrinsic evidence offered by the parties is unnecessary because the intrinsic evidence is sufficient to understand the meaning of the terms construed in this section. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996) ("In most situations, an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term. In such circumstances, it is improper to rely on extrinsic evidence.")

IV. INVALIDITY AND OTHER DEFENSES

A. Applicable Law

It is the respondent's burden to prove invalidity, and the burden of proof never shifts to the patentee to prove validity. *Scanner Techs. Corp. v. ICOS Vision Sys. Corp. N.V.*, 528 F.3d 1365, 1380 (Fed. Cir. 2008). "Under the patent statutes, a patent enjoys a presumption of validity, *see* 35 U.S.C. § 282, which can be overcome only through facts supported by clear and convincing evidence[.]" *SRAM Corp. v. AD-II Eng'g, Inc.*, 465 F.3d 1351, 1357 (Fed. Cir. 2006). The clear and convincing standard was recently reaffirmed by the Supreme Court. *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S.Ct. 2238 (2011) (upholding the Federal Circuit's interpretation of 35 U.S.C. § 282).

The clear and convincing evidence standard placed on the party asserting the invalidity defense requires a level of proof beyond the preponderance of the evidence. Although not susceptible to precise definition, "clear and convincing" evidence has been described as evidence which produces in the mind of the trier of fact "an abiding conviction that the truth of a factual contention is 'highly probable.'" *Price v. Symsek*, 988 F.2d 1187, 1191 (Fed. Cir. 1993) (citing *Buildex, Inc. v. Kason Indus., Inc.*, 849 F.2d 1461, 1463 (Fed.Cir.1988)).

"When no prior art other than that which was considered by the PTO examiner is relied on by the attacker, he has the added burden of overcoming the deference that is due to a qualified government agency presumed to have properly done its job[.]" *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359 (Fed. Cir. 1984). Therefore, the challenger's "burden is especially difficult when the prior art was before the PTO examiner during prosecution of the application." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1467 (Fed.Cir.1990).

1. Anticipation

"A patent is invalid for anticipation if a single prior art reference discloses each and every limitation of the claimed invention. Moreover, a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference." *Schering Corp. v. Geneva Pharm., Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003) (citations omitted).

2. Obviousness

Section 103 of the Patent Act states:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

35 U.S.C. § 103(a) (2008).

"Obviousness is a question of law based on underlying questions of fact." *Scanner Techs. Corp. v. ICOS Vision Sys. Corp. N.V.*, 528 F.3d 1365, 1379 (Fed. Cir. 2008). The underlying factual determinations include: "(1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between the claimed invention and the prior art, and (4) objective indicia of non-obviousness." *Id.* (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966)). These factual determinations are often referred to as the "*Graham* factors."

The critical inquiry in determining the differences between the claimed invention and the prior art is whether there is a reason to combine the prior art references. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417-418 (2007). In *KSR*, the Supreme Court rejected the Federal Circuit's rigid application of the teaching-suggestion-motivation test. The Court stated that "it can be

important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *Id.* at 418. The Court described a more flexible analysis:

> Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue...As our precedents make clear, however, the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.

Id.

Since *KSR* was decided, the Federal Circuit has announced that, where a patent challenger contends that a patent is invalid for obviousness based on a combination of prior art references, "the burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make the composition or device, . . . and would have had a reasonable expectation of success in doing so." *PharmaStem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007).

In addition to demonstrating that a reason exists to combine prior art references, the challenger must demonstrate that the combination of prior art references discloses all of the limitations of the claims. *Hearing Components, Inc. v. Shure Inc.*, 600 F.3d 1357, 1373-1374 (Fed. Cir. 2010) (upholding finding of non-obviousness based on the fact that there was substantial evidence that the asserted combination of references failed to disclose a claim limitation); *Velander v. Garner*, 348 F.3d 1359, 1363 (Fed. Cir. 2003) (explaining that a requirement for a finding of obviousness is that "all the elements of an invention are found in a combination of prior art references").

B. The '325 Patent

1. Anticipation

a. Claim 1

Asserted claim 1 teaches:

> A method for facilitating a tooth repositioning dental treatment, including producing a plurality of digital sets representing a plurality of tooth arrangements, said method comprising:
>
> providing an initial digital data set representing an initial tooth arrangement;
>
> presenting a visual image based on the initial data set;
>
> manipulating the visual image to reposition individual teeth in the visual image;
>
> producing a final digital data set representing the final tooth arrangement with repositioned teeth as observed in the image;
>
> producing a plurality of intermediate digital data sets representing a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement; and
>
> fabricating a plurality of successive tooth repositioning appliances, at least some of which are related to at least some of the produced digital data sets.

(JX-0003 at R1:29-48)

Respondents' Position: Respondents state in their brief that, to avoid repetition they have identified 10 corresponding categories of disclosures made by U.S. Patent No. RE 35,169 ("Lemchen") and, as incorporated, U.S. Patent No. 2,467,432 ("Kesling"). Respondents say that the categories are used to identify common disclosures applicable to claims with similar subject matter. For ease of reference, categories 1, 3, 4, 5, 7, 9, and 10 are identified in section IV.B, *infra*, addressing anticipation of Claim 1 of the '325 patent. Category 2 is identified in section IV.F, *infra*, addressing Claim 1 of the '666 patent. Category 6 is identified in section IV.H,

infra, addressing Claim 38 of the '874 patent. Category 8 is identified in section IV.G, *infra*, addressing Claim 1 of the '863 patent.

Respondents argue that each of the asserted claims of the '325 patent is anticipated by U.S. Patent No. RE 35,169 ("Lemchen") and, as incorporated, U.S. Patent No. 2,467,432 ("Kesling") under 35 U.S.C. § 102. Respondents say that their arguments regarding invalidity for each of the asserted patents, both anticipation and obviousness, apply whether the Court adopts Align's, Respondents' or the Staff's claim constructions.

Respondents assert that when a document is "incorporated by reference" into a host document, such as a patent, the referenced document becomes effectively part of the host document as if it were explicitly contained therein. (Citing *Telemac Cellular Corp. v. Topp Telecom Inc.*, 247 F.3d 1316, 1328 (Fed. Cir. 2001)) Respondents say that material not explicitly contained in the single, prior art document may still be considered for purposes of anticipation if that material is incorporated by reference into the document. Respondents continue that incorporation by reference is accomplished by citing such material in a manner that makes clear that the material is effectively part of the host document. (Citing Robert L. Harmon et al., Patents and the Federal Circuit 125-26 (10th ed. 2011))

Respondents contend that Kesling is incorporated by reference into Lemchen. Respondents say that Kesling is specifically identified. Respondents aver that the referenced figures cannot be understood in isolation. Respondents say that the referenced figures require the context of Kesling's disclosures to be understood. Respondents conclude that Kesling disclosures are necessarily incorporated into Lemchen, because they are necessary to understand the manual three dimensional modeling that Lemchen teaches digitally. (Citing RX-0113C at Q. 45 & 47)

Respondents argue that Dr. Lemchen expressly incorporated the disclosures of Kesling to explain that the digital three-dimensional model that they disclosed was the same as the manual 3-D model created by Dr. Kesling in Kesling. (Citing CX-0945 at 3:43 – 46) Respondents say that Align's present expert, Dr. Valley, disagrees with Align's former expert, Dr. Rekow on this issue. Respondents say that one skilled in the art would understand that this statement necessarily incorporates the entire disclosure of Kesling because Figure 1 in isolation does not explain the significance of the displayed model; rather, it is only in the context of the entire disclosure that the significance of the model displayed in Figure 1 as a representation of the patient's teeth prior to treatment is understood.

Respondents contend that Dr. Lemchen also expressly incorporated the disclosure of Kesling to explain their three dimensional modeling methodology. (Citing CX-0945 at 3:36 – 40) Respondents say that the inventors stated that FIG. 3 was one example of a repositioned tooth arrangement. Respondents argue that one skilled in the art would understand that this same method would apply equally to the intermediate or successive tooth arrangements that are described in Kesling. Respondents continue that this is because the methodology is the exact same for all successive tooth arrangements from the initial position to the final position. Respondents add that intermediate or successive tooth arrangements are inherent in tooth modeling because one cannot model tooth movement accurately without including the intermediate steps. Respondents say that one skilled in the art would understand that this statement necessarily incorporates the entire disclosure of Kesling because Figure 3 in isolation does not explain the significance of the displayed model. Respondents continue that it is only in the context of the entire disclosure that the significance of the model displayed in Figure 3 as a

representation of the patient's teeth as a modified tooth arrangement is understood. (Citing RX-0113C at Q. 47-48)

According to Respondents, Dr. Lemchen and Dr. Andreiko expressly stated that the three-dimensional modeling methods that they invented, using software, "may be derived by conventional means for the particular method of treatment elected by the orthodontist." (Citing CX-0945 at 3:25 – 26) Respondents continue that inventors similarly stated in their detailed description that there "are a number of methods of treatment commonly used by the orthodontist." (Citing CX-0945 at 3:43 – 46) Respondents reason that Lemchen expressly recognizes that its methods may be used with different types of orthodontic treatment. Respondents contend that one skilled in the art would understand that other treatment methods, such as the aligner treatment method disclosed in Kesling could be used with the digital methods disclosed in Lemchen. (Citing RX-0113C at Q. 49) Respondents say that one skilled in the art would understand that the methods of Kesling were not limited to brackets (which are custom fabricated in the disclosed methods to conform to the surface of the teeth) and arch wires; rather, the incorporation of the disclosures of Kesling and the other statements concerning other treatment methods makes it clear that the methodology of Lemchen applies beyond brackets and archwires. (Citing RX-0113C at Q. 49)

Respondents aver that Kesling's disclosures are limited to methods for making aligners based on a series of 3-D tooth models. Respondents say that one skilled in the art would understand the incorporation of Kesling to mean that the methods of Lemchen would apply to aligners, the appliance expressly described in Kesling. Respondents continue that one skilled in the art would understand that the modeling of teeth movement is the same, regardless of the type of appliance used. (Citing RX-0113C at Q. 51)

Respondents argue that each and every step of the claimed processes is described or embodied, either expressly or inherently, in Lemchen. Respondents say that the evidence establishes that there are no differences between the claimed invention and Lemchen, as viewed by one skilled in the art. Respondents say that there is no evidence in the prosecution histories that the PTO considered that Lemchen incorporated Kesling, despite Align's contentions in the *Ormco II* litigation. Respondents assert that it is well settled that the scope of patent claims does not change between an infringement analysis and an invalidity analysis and Align cannot now contend that the scope of the asserted claims is less for the invalidity analysis.

Respondents contend that claim 1 of the '325 Patent is broadly directed to the fabrication of "tooth repositioning appliances." Respondents say that under its plain language, this claim is not limited to removable appliances and no party has requested the construction of this phrase and its plain meaning applies here. Respondents say that Align has suggested that there is a distinction between removable and fixed appliances; but this is an improper attempt to apply an undisclosed claim construction and this argument should be rejected here.

Respondents argue that the subject matter of the preamble of claim 1 is disclosed in the prior art reference. Respondents say Kesling expressly discloses a plurality of tooth arrangements, the use and fabrication of a series of dental appliances, and using a machine to fabricate a series of dental appliances by producing a positive model of a tooth arrangement. (Citing RX-0113C at Q. 49)

According to Respondents, Lemchen discloses a digital method for three dimensional modeling of teeth movement that was the same as the manual method disclosed in Kesling. (Citing RX-0113C at Q. 39-40) Respondents say that this digital modeling includes intermediate or successive tooth arrangements. (Citing RX-0113C at Q. 41) Respondents continue that

Lemchen discloses methods for the fabrication of multiple custom appliances based on the three dimensional modeling. (Citing RX-0113C at Q. 42) Respondents say that Lemchen also discloses using positive models generated from digital data. (Citing RX-0113C at Q. 42-43)

Respondents aver that Align previously recognized that "[c]apitalizing on work of the dental CAD/CAM systems, Lemchen describes approaches [that] acquire data, automatically determine . . . ideal position for an individual patient, design . . . configuration to conform to the orthodontic treatment to be undertaken for an individual patient, and use numerically controlled systems to shape . . . that design." (Citing RX-0102C at 6) Respondents say that Align contended in that litigation that "the idea of fabricating custom appliances," for orthodontic treatment "was not new in 1990." (Citing RX-0102C at 7)

Respondents assert that Lemchen discloses the first element of claim 1. (Citing CX-0945 at 2:54 – 63) Respondents say that Dr. Lemchen specifically discloses that his method generates "accurate digital information" defining the teeth locations. (Citing CX-0945 at 2:55 –57) Respondents continue that Dr. Lemchen expressly incorporated the disclosures of Kesling to explain that the digital three-dimensional model of an initial tooth arrangement that they disclosed was the same as the manual three-dimensional model of an initial tooth arrangement disclosed in Kesling. (Citing CX-0945 at 3:43 – 46) Respondents say that Align previously recognized that Lemchen developed a digital representation of the physical model of an initial tooth arrangement described by Kesling. (Citing RX-103C at 16) Respondents identify these disclosures as "disclosure category 1."

Respondents argue that Lemchen also discloses the second element of claim 1 by disclosing the use of commercially available computer-aided design software to create visual images of digital three-dimensional models. (Citing CX-0945 at 2:66 – 3:6) Respondents say

that Align previously recognized that the CAD system described by Lemchen presented visual images based on the initial data set and successfully argued to the Federal Circuit that one skilled in the art would understand that Lemchen disclosed visual images based on the initial data set. (Citing *Ormco II* at 498 F.3d 1315) Respondents identify these disclosures as "disclosure category 2."

Respondents contend that Lemchen discloses the third element of claim 1 by expressly noting that the invention "may be utilized with some or all of the teeth in a given dental arch . . . ." (Citing CX-0945 at 5:21 – 24) Respondents say that Align previously recognized that the CAD system described by Lemchen presented visual images based on the initial data set that are manipulated to reposition individual teeth. (Citing RX-103C at 16) Respondents continue that Align successfully argued to the Federal Circuit that one skilled in the art would understand that Lemchen discloses manipulating visual images to reposition individual teeth in the visual image. (Citing *Ormco II* at 498 F.3d 1315) Respondents identify these disclosures as "disclosure category 4."

According to Respondents, Kesling discloses the fourth element of claim 1 by disclosing modeling a final tooth arrangement. (Citing CX-0944 at 2:50 – 3:1) Respondents say that Align previously contended that Kesling disclosed producing a final tooth arrangement through full 3-D modeling. (Citing RX-103C at 12-13) Respondents continue that Dr. Lemchen expressly incorporated the disclosure of Kesling to explain the final tooth arrangement in the disclosed three dimensional modeling methodology. (Citing CX-0945 at 3:36 – 40) Respondents aver that Align previously recognized that Lemchen disclosed producing a final digital data set representing the final tooth arrangement with repositioned teeth as observed in the image.

(Citing RX-103C at 16; *Ormco II* at 498 F.3d 1315) Respondents identify these disclosures as "disclosure category 5."

Respondents contend that Kesling discloses the fifth element of claim 1 by disclosing the manufacture and use of a plurality of appliances, each appliance in the series representing intermediate or successive tooth positions. (Citing CX-0944 at 2:50 – 3:1) Respondents say that Kesling describes the necessity of making a plurality of appliances as obvious. (Citing CX-0944 at 2:50 – 3:1) Respondents say that in a previous litigation, Dr. Rekow, on behalf of Align, recognized that Kesling broadly disclosed a three dimensional method for modeling tooth movement that included successive tooth arrangements that proceeded from the initial to the final. (Citing RX-103C at 12-13)

Respondents say that Lemchen discloses that the "repositioning is done mathematically by appropriate software programs which may be derived by conventional means . . . ." (Citing CX-0945 at 2:66–3:6) Respondents assert that one skilled in the art would understand this to mean that the tooth path between the initial and final positions would be determined and then the tooth positions for each segment representing the successive stages of treatment would be determined by interpolation or a method for calculating movements of incremental equal sizes. (Citing RX-0113C at Q. 59) Respondents say that it is uncontroverted that interpolation is a conventional mathematical means for determining positional differences. (Citing RX-0113C at Q. 59)

Respondents aver that Dr. Rekow, on behalf of Align, also recognized that Lemchen incorporated Kesling and broadly disclosed a digital three dimensional method for modeling tooth movement. (Citing RX-103C at 16) Respondents contend that this demonstrates that one skilled in the art would understand that Lemchen incorporates Kesling and discloses three

dimensional modeling of teeth movement digitally through a series of incremental or intermediate steps from an initial position to the desired position. Respondents say that Align previously successfully argued to the Federal Circuit that Lemchen disclosed an incremental approach to calculating desired tooth positions. (Citing *Ormco II* at 498 F.3d 1315) Respondents identify these disclosures as "disclosure category 7."

Respondents assert that Kesling discloses the sixth element of claim 1 by disclosing "tooth positioning appliances" that were "adapted to . . . bring the teeth of a user of such an appliance into a pre-determined ideal or desirable position without the necessity for the use of metallic bands, wires or any of the other appliances of the prior art." (Citing CX-0944 at 1:1-6) Respondents say that figure 7 shows that a "tooth positioning appliance," similar to an aligner, was disclosed. (Citing CX-0944 at Fig. 7) Respondents continue that Kesling teaches that each aligner in the series is made by molding a polymeric material over positive models of intermediate or successive tooth arrangements.

Respondents say that Kesling discloses that a cast of the teeth in their initial position is created using traditional methods (citing CX-0944 at 2:43 – 49) and then each individual tooth is manually sectioned out by an operator using a scroll saw. (Citing CX-0944 at 3:30 – 43) Respondents continue that next, the operator manually moves each now individually sectioned out tooth to a new position in the base, securing the tooth with wax or another suitable material. (Citing CX-0944 at 3:30 – 60) Respondents say that a positive model of the teeth in their new position is made. (Citing CX-0944 at 3:61 – 64 & Figure 3) Respondents continue that the aligners are then fabricated by using a mechanical device to mold a polymeric material over the positive model of the intermediate tooth arrangements. CX-0944 at 3:65 – 4:70. Respondents reason that the incorporated disclosures of Kesling demonstrate methods for producing a series

of polymeric shell dental appliances that are a negative of a positive model of modified tooth arrangements. Respondents conclude, as a result, that Kesling expressly discloses intermediate or successive models representing tooth positions, the use and fabrication of a series of dental appliances, and using a machine to fabricate a series of dental appliances by producing a positive model of a tooth arrangement.

Respondents say that Dr. Lemchen discloses methods that include controlling a fabrication machine. (CX-0945 at 5:4 –8) Respondents continue that the inventors also describe the use of a "laboratory model of the tooth . . . ." Respondents add that the inventors expressly noted that while they referred to a single tooth, their invention "may be utilized with some or all of the teeth in a given arch . . . ." (Citing CX-0945 at 5:21 – 24) Respondents assert that these statements expressly disclose the controlling of a fabrication machine to produce a positive model of a modified tooth arrangement based on the digital information generated.

Respondents contend that Align previously argued that the references cited by Lemchen, including the Rekow reference, disclosed using CAD/CAM systems to control fabrication machines to produce positive models of teeth. (Citing RX-103C at 17 – 26) Respondents identify these disclosures as "disclosure category 10."

Respondents assert that the transfer of digital data was disclosed in Lemchen. Respondents say that Dr. Lemchen disclosed the transfer of digital information between a practitioner and a dental lab, and the use of that digital information by the dental lab in its manufacturing process, "where the digitized information is utilized in the process of providing the practitioner with the required dental appliances for the correction of the malocclusion." (Citing CX-0945 at 5:15 –20) Respondents identify these disclosures as "disclosure category 9."

Respondents disagree with Align's argument that Respondents have waived their invalidity defenses. Respondents say that contrary to Align's assertions, Respondents' Pre-Hearing Brief provided Respondents' contentions that all asserted claims were obvious and discussed the prior art in particular detail, identifying where the disclosed subject matter was located in the prior art references. (Citing RPHB at 48-67, 97-106, 127-136, 146-154, 174-183, 205-217, & 240-248) Respondents say that in *Certain Mobile Devices*, Inv. No. 337-TA-744, Final I.D., 2011 WL 6916539, at *103-04 (Dec. 20, 2011), the Respondent's failed to discuss certain of the prior art at all, but the ALJ addressed the defenses on the merits and did not hold the defenses waived. *Id.* Respondents assert that Align has long known that the Respondents have asserted the combination of Lemchen and Kesling with the knowledge of one of ordinary skill and there is no waiver.

Respondents also disagree with Align's arguments that *Ormco Corp. v. Align Tech., Inc.* is irrelevant. (Citing *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1302 (Fed. Cir. 2006) ("*Ormco I*")) Respondents say that clinicians have long used series of removable tooth positioning devices, such as the aligners at issue here, to treat patients. Respondents say that in *Ormco I*, the Federal Circuit considered several of Align's patent claims to series of orthodontic aligners. (*Ormco I. at* 463 F.3d 1302) Respondents continue that the Federal Circuit considered the systems claimed in United States Patent No. 6,554,611 (the '611 Patent) and United States Patent No. 6,398,548 (the '548 Patent), the asserted claims of which the Federal Circuit found invalid as obvious based on the past use of such series of aligners by orthodontists. (Citing *id.*) Respondents argue that the findings in the *Ormco I* case are relevant here because it is also indisputable that methods for making such aligners existed in the prior art. Respondents say that if the apparatus existed before Align's patents, there can be no question but that methods for

making the apparatus existed before Align's patents. Respondents say that the series of prior art appliances that were addressed by the Federal Circuit were obviously fabricated by a method for making such a series.

Respondents say that Align's argument appears to be based solely on the fact that in *Ormco I,* Align was a defendant accused of infringing Ormco's patent claims directed to methods for fabricating aligners. Respondents say that Align does not dispute that the subject matter of a series of appliances that was at issue in *Ormco I* is the same subject matter at issue here. Respondents assert that Align's methods for making these series of aligners were at issue in *Ormco I.* Respondents continue that Align's methods were held to infringe claims asserted by Ormco and the scope of the disclosures of the prior art does not change based on who is the defendant. Respondents say that the Federal Circuit's findings in *Ormco I* related to series of aligners and methods for manufacturing those aligners are relevant here.

Respondents say that the question in this investigation is whether the prior art disclosed digital methods to manufacture such series of aligners or, alternatively, whether such methods would have been obvious to one skilled in the art, which is the same issue that was addressed in *Ormco I.* Respondents say that it is instructive, by way of example, to compare the elements of the asserted claim 1 of the '880 Patent to the elements of the invalidated system claims to show how closely related the claims asserted here are to the apparatus claims invalidated in the *Ormco I* litigation:

Claim 1 of the '880 Patent (JX-0002)	Invalidated Claim 1 of the '611 Patent (the sequence of elements 2 and 3 has been switched)
A method for making a predetermined series of dental incremental position adjustment appliances, said method comprising:	A system for repositioning teeth from an initial tooth arrangement to a final tooth arrangement, said system comprising a plurality of dental incremental position adjustment appliances including:

a) obtaining a digital data set representing an initial tooth arrangement;	a first appliance having a geometry selected to reposition the teeth from the initial tooth arrangement to a first intermediate arrangement;
b) obtaining a repositioned tooth arrangement based on the initial tooth arrangement;	a final appliance having a geometry selected to progressively reposition the teeth from the last intermediate arrangement to the final tooth arrangement;
c) obtaining a series of successive digital data sets representing a series of successive tooth arrangements; and	one or more intermediate appliances having geometries selected to progressively reposition the teeth from the first intermediate arrangements to successive intermediate arrangement;
d) fabricating a predetermined series of dental incremental position adjustment appliances based on the series of successive digital data sets, wherein said appliances comprise polymeric shells having cavities shaped to receive and resiliently reposition teeth, and said appliances correspond to the series of successive tooth arrangements progressing from the initial to the repositioned tooth arrangement.	and instructions which set forth that the patient is to wear the individual appliances in a predetermined order which will progressively move the patient's teeth toward the final arrangement, a package, said package containing said first appliance, said one more [sic] intermediate appliances and said final appliance, wherein the appliances are provided in a single package to the patient.

(Citing *Ormco I* 463 F.3d at 1302) Respondents assert that invalidated claims 1 and claim 11 of the '548 Patent are similar. (Citing *id.* at 1303) Respondents say that this comparison demonstrates how closely related the subject matter is between the invalidated apparatus claims and the asserted method claims.

Respondents assert that it is also apparent from the foregoing chart that Align is simply claiming the application of modern electronics (the use of "digital data") to the subject matter of the orthodontic appliances that existed in the prior art. Respondents say that is improper under well settled precedent. Respondents continue that the application of modern electronics to orthodontic appliances pre-dates the asserted claims in the prior art by several years.

Respondents disagree with Align's incorporation by reference arguments. Respondents say that the standard for determining incorporation is straightforward: "the host document must

identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents." (Citing *Callaway Golf Co. v. Acushnet Co.*, 576 F.3d 1331, 1346 (Fed. Cir. 2009)) Respondents continue that the Federal Circuit has taken a practical approach in determining whether a host document incorporates a reference. (Citing *id.*) Respondents assert that when the statements in the Lemchen reference are considered light of the Federal Circuit's standard for determining incorporation, it is clear that the Lemchen reference incorporates the entire Kesling patent.

Respondents say that the first reference to the Kesling patent provides:

> The mathematical model may be as detailed as the particular circumstances require, dependent only upon the quantity of digitized information generated in the prior step. Thus, in many applications of the preferred embodiment, a complete "model", as that term is used in the dental art to refer to a full replication of the upper and lower dental arches and associated jaw structure, will be mathematically generated. A physical embodiment of such a model is shown, for example, in FIG. 1 of U.S. Pat. No. 2,467,432.

(Citing CX-0945 at 3:6 – 15) Respondents continue that Dr. Lemchen also stated:

> There are a number of **methods of treatment commonly used by the orthodontist**. Each method takes different factors into account with varying degrees of emphasis. As utilized in the present invention, the orthodontist provides a description of the desired results, which is prescribed for reaching the finish position of each individual tooth relative to adjacent teeth, opposing teeth, supporting bony foundations and soft tissue, and the entire cranial-facial complex. Utilizing standard statistical tooth position data, the repositioning of the teeth is calculated to provide a mathematical model of the finish position. **In the prior art, a similar step was accomplished manually in order to account for individual tooth morphology by physically removing duplicated teeth from a model and repositioning them in a new model in the finish position.** See, for example, FIG. 3 **in the above referenced U.S. Pat. No. 2,467,432.**

(Citing CX-0945 at 3:25–40 (emphasis added)) Respondents conclude that the only reasonable conclusion is that Lemchen intended to incorporate the entire Kesling reference.

Respondents say that Lemchen uses language "in the above referenced U.S. Pat. No. 2,467,432" that is very similar to the language that the Federal Circuit has held incorporates the entire reference ("reference is made to"). Respondents continue that Lemchen makes it clear that he is referring to the "methods of treatment" in the prior art, and not just the figures in abstract: "In the prior art, a similar step was accomplished manually in order to account for individual tooth morphology by physically removing duplicated teeth from a model and repositioning them in a new model in the finish position." Respondents argue that this statement expressly describes the methods disclosed by Kesling and is not limited to the abstract figures.

Respondents say that Courts have held that it is important to consider the entirety of the incorporated document to properly understand its teachings:

> The reason for requiring the consideration of the whole reference, . . . is that . . . when 'all of the disclosures in a reference' are considered, the overall suggestion to emerge from the prior art reference may be contrary to that which might appear from an isolated portion of the reference."

(Citing *In re Hughes*, 550 F.2d 1273, 1275-76 (CCPA 1977)) Respondents reason that this rule prevents a party from misrepresenting the substance of a prior art reference by limiting the amount of incorporation. Respondents argue that this is precisely what Align is attempting to do.

Respondents say that this rule especially makes sense in light of the Kesling reference. Respondents say that the Kesling reference is small, it contains one page of figures and approximately three and one half pages of text. (Citing CX-0945) Respondents say that figures 1 and 3 are substantively discussed repeatedly throughout the first two pages, essentially omitted only from the claim section and the listing of prior art. (Citing CX-0945) Respondents say that Align's attempt to carve up the portions of Kesling that are incorporated is directly contrary to the settled law that seeks to avoid misunderstanding the teachings of the prior art. Respondents conclude that I should find that the Lemchen reference has incorporated the Kesling patent.

Respondents argue that Align's reliance upon an overruled Initial Determination shows the fallacy of their argument. Respondents say that the Commission overruled my finding in the cited Initial Determination that a referenced document was not incorporated, holding: "when considering incorporation by reference, the proper focus is on material and content rather than semantics and typographical errors." (Citing *Certain MEMS Devices*, Inv. 337-TA-700, Commission Determination, 2011 WL 7592771, at *16-18 (USITC November 2011)) Respondents say that I should reject Align's argument here.

Respondents say that Align has described the method for making aligners as a process with essentially five steps:

> Aligners are generally made in a five-step process: (1) a digital representation of a patient's existing tooth arrangement is created; (2) the representation is digitally modified to allow the virtual teeth to be individually manipulated; (3) 3D graphics software is used to move the virtual teeth to the desired position; (4) virtual intermediate tooth arrangement models are created between the existing tooth arrangement and the desired arrangement; and (5) physical molds are created from these digital representations in order to form aligners.

Respondents argue that this description highlights the inconsistency between Align's infringement contentions and its invalidity contentions. According to Respondents, to find infringement, Align is forced to characterize the Respondents' methods one way; but to avoid invalidity, Align argues that there are differences between its claims and the prior art and characterizes its claims differently. Respondents assert that there is no difference between the five steps identified by Align and the methods disclosed in Lemchen and in the incorporated Kesling.

Respondents disagree with Align's current position that Kesling did not disclose "intermediate or successive tooth arrangements based on initial and final positions." Respondents say that the evidence relied upon by Align for this assertion is Dr. Valley.

Respondents say that As Dr. Rekow explained, contrary to Align's contentions here, the incremental movements are based on obtaining the desired final position. Respondents say that Dr. Valley conceded that Dr. Rekow was "much more of an expert than I am in this area." (Citing Tr. at 760:19-761:1) Respondents argue that Align is improperly attempting to create a new, undisclosed claim construction to avoid the prior art disclosures.

Respondents say that the only difference between Kesling's teachings and the claimed subject matter, is the use of digital data. Respondents continue that It is not surprising that Dr. Kesling did not disclose digital methods, because he patented his invention in the 1940s. Respondents say that as Dr. Rekow opined in the *Ormco II* case that:

> The evolution of computers in the 1970s and 1980s enticed many inventors to explore dental and orthodontic applications using and manipulating digital data. Ideas that were explored, as seen below were demonstrated, included opportunities where manual manipulations were automated. The time consuming manipulation of plaster casts to model orthodontic treatment options was replaced by systems that modeled multiple combinations of tooth movement, permitting the clinician to choose the most ideal. Labor-intensive design and fabrication of dental restorations was replaced by computer-aided design and manufacturing systems to speed delivery . . . .

(Citing RX-103C at 2)

Respondents say that in its litigation with *Ormco*, Align recognized that Lemchen had developed a digital method based on the Kesling physical method. Respondents continue that Dr. Rekow recognized that Lemchen incorporated Kesling and broadly disclosed a digital three dimensional method for modeling tooth movement. (Citing RX-103C at 16) Respondents argue that Lemchen's disclosures confirm that Dr. Rekow's opinion is correct.

Respondents assert that Lemchen's disclosures demonstrate that there is no difference between the five steps identified by Align and the methods disclosed in Lemchen and in the incorporated Kesling. Respondents say that Lemchen taught creating a digital representation of a

patient's existing tooth arrangement. (Citing CX-0945 at 2:54 – 63) Respondents continue that Lemchen taught digitally modifying the model to allow the virtual teeth to be individually manipulated and taught that the use of commercially available computer-aided design software to create digital three-dimensional models was well known in the art. (Citing CX-0945 at 2:66–3:6) Respondents say that Lemchen describes scanning and modeling the movement of each individual tooth, and expressly noted that the invention "may be utilized with some or all of the teeth in a given dental arch . . . ." (Citing CX-0945 at 5:21 – 24) Respondents continue that Dr. Rekow confirms this in her description of Lemchen's teachings: "To accomplish these operations mathematically, individual teeth had to be segmented from digital data representing a plurality of teeth." (Citing RX-103C at 16) Respondents say that Lemchen taught the use of 3D graphics software to move the virtual teeth to the desired position. Respondents continue that Lemchen taught the use of conventional CAD software create 3D models to move the teeth to their desired position. (Citing CX-0945 at 2:66 – 3:6) Respondents continue that Dr. Rekow confirms this in her description of Lemchen's teachings. (Citing RX-103C at 16) Respondents say that The Federal Circuit noted the following characterization of Lemchen:

> The Lemchen patent relies, to produce the calculations, on the conventional calculation techniques employed in generalized CAD software. This in turn relies on a user interactive interface by which an operator contributes human decision making powers to manipulate images until the operator is satisfied that finish tooth position criteria have been met . . . .

(Citing *Ormco II* at 498 F.3d 1315)

Respondents contend that Lemchen taught creating virtual intermediate tooth arrangement models between the existing tooth arrangement and the desired arrangement. Respondents say that Lemchen disclosed that his method "produces appropriate force magnitudes at various stages of treatment to move the tooth to its ideal position." (Citing CX-

0945 at 2:37-38) Respondents continue that the uncontroverted testimony establishes that one skilled in the art would understand that the "various stages of treatment" refers the successive stages of treatment typical in orthodontic treatment. (Citing RX-0113C at Q. 57) Respondents say that Dr. Rekow confirms that "Full three-dimensional modeling in orthodontic treatment planning was described by Lemchen" and that this "model is the mathematical representation of the physical model described by Kesling in 1949." (Citing RX-103C at 16)

Respondents argue that it is undeniable that Kesling taught intermediate successive tooth arrangements as part of the disclosed 3D modeling method. (Citing CX-0944 at 2:50 – 3:1) Respondents say that the modeling of teeth movement is the same regardless of the type of appliance that is to be used. (Citing RX-0113C at Q. 25) Respondents contend that Lemchen taught that creating physical molds from digital models to make appliances. Respondents say that Lemchen taught methods that include controlling a fabrication machine:

> the present method may be utilized in conjunction with computer-aided design and computer-aided manufacturer (CAD/CAM), as described in the Rekow article referred to above, to provide a machined or cast base conforming to the tooth morphology . . . .

(Citing CX-0945 at 5:4–8) Respondents continue that Lemchen also describes the use of a "laboratory model of the tooth" in the disclosed methods for fabricating an appliance. (Citing CX-0945 at 4:63–67) Respondents reason that this physical tooth model is to be fabricated by the disclosed methods. Respondents add that, as described above, the inventors expressly noted that while they referred to a single tooth, their invention "may be utilized with some or all of the teeth in a given arch . . . ." (Citing CX-0945 at 5:21–24) Respondents argue that these statements expressly disclose the controlling of a fabrication machine to produce a positive model of a modified tooth arrangement based on the digital information generated, and Dr. Rekow confirms that references cited in the Lemchen article expressly address using CAD/CAM

to fabricate positive models of modified tooth arrangements based on digital data. (Citing RX-103C at 17-26)

Respondents argue that Align identifies additional subject matter that it now contends that Lemchen/Kesling incorporated reference does not disclose. Respondents say that Kesling discloses polymeric shell appliances. (Citing CX-0944 at 2:38 – 42 & Figure 7) Respondents continue that Lemchen disclosed the use of polymeric shell appliances as part of the referenced "indirect" method of bracket application. (Citing CX-0945 at 4:6 –12) Respondents add that Lemchen discloses the subject matter of threshold limits. (Citing CX-0945 at 2:37 – 38 & RX-0113C at Q. 58) Respondents say that Lemchen also discloses substantially accurate shapes of a patient's teeth:

> The first step of the method of the present invention is the generation of accurate digital information defining the shape and location of the malocclused tooth with respect to the patient's jaw.

(Citing CX-0945 at 2:54 – 63) Respondents continue that Lemchen discloses the use of attachment devices in his digital three-dimensional modeling: "The structural adhesive is initially a moldable putty which easily takes on the contour of the dental surface to which the appliance will be fixed . . . . (Citing CX-0945 at 4:56–60) Respondents add that Lemchen discloses the use of brackets which are devices that attach appliances to teeth. (Citing CX-0945 at 3:55 – 4:2)

Respondents disagree with Align's argument that this combination was disclosed to the PTO. Respondents say that there is no evidence in the prosecution history that Align ever disclosed that the Kesling teachings were combined with the Lemchen reference. Respondents continue that there is no evidence in the prosecution history that the PTO ever considered the

combination of these references. Respondents reason, as a result, that the PTO was never informed of this incorporated reference that is the key to the invalidity analysis.

Align's Position: Align asserts that Respondents' invalidity case relies on a cursory, 25-page statement of Dr. Mah that fails to undertake the most basic analyses, such as comparing the asserted claims on an element-by-element basis with the prior art or providing specific citations to the alleged disclosures of the prior art he identifies, rendering it, as noted by the presiding ALJ, "conclusory." (Citing Tr. at 643:24-644:6, 649:8-14) Align says that Respondents' Prehearing Brief provides no more specificity. (Citing RPHB at 48-67, 97-106, 127-136, 146-154, 174-183, 205-217, 240-248) Align continues that Respondents' failure to introduce an element-by-element comparison of the prior art with Align's asserted claims is ***fatal*** to their invalidity defenses. (Citing *Certain Mobile Devices*, Inv. No. 337-TA-744, Final I.D., 2011 WL 6916539, at *103-04, *103 n.33 (Dec. 20, 2011)) Align says that neither Respondents nor their expert have explained how the prior art meets, *inter alia*, any of the constructions for the disputed claim terms. Align asserts that Respondents cannot legitimately contend that any of Align's claims are invalid.

Align says that Respondents contend that ***all*** of the asserted claims are anticipated by U.S. Patent No. RE 35,169 ("Lemchen"), including "as incorporated" U.S. Patent No. 2,467,432 ("Kesling"). Align asserts that Respondents' anticipation defense fails as a matter of law because it relies on the flawed assumption that Lemchen incorporates the full disclosures of Kesling. Align continues that even if Kesling is somehow deemed to be fully incorporated in Lemchen, Lemchen/Kesling still fails to anticipate any of Align's asserted claims because it does not disclose all elements of ***any*** of those asserted claims.

Align argues that *Ormco I* is irrelevant to the validity of the patents-in-suit because it addressed different patents, claims, limitations, and prior art. Align says that Dr. Rekow's reports from *Ormco I* (Citing RX-0102C; RX-0103C) are only available to possibly show "prior inconsistent positions" (Citing Tr. at 20:5-21:21) and Respondents cannot, therefore, use them to bolster their invalidity theories. Align continues that even if they could, the Rekow reports do not support Respondents' invalidity theories. (Citing CX-1247C at Q. 274, 622-627; CX-1254C ¶ 274 at 97; Tr. at 801:6-802:13)

Align asserts that as depicted in CDX-0288 and shown on the face of the patents (and reexam certificates), almost every reference cited by Respondents was ***already*** considered by the USPTO, and determined to ***not*** preclude issuance of the claims. (Citing JX-0001 at 2; JX-0002 at 2; JX-0003 at 1-2, 21-26; JX-0004 at 1-2; JX-0005 at 1-2, 26-31; JX-0006 at 1-4; JX-0007 at 1-5; CX-1250 at 257) Align continues that the USPTO has repeatedly approved the claims over Lemchen and Kesling.

Align says that Kesling (CX-0944) generally discloses tooth positioning appliances made manually using tools and equipment available in the 1940s (*e.g.*, plaster and wax). (Citing CX-1247C at Q. 142-143; CX-1254C ¶ 63 at 21-22) Align says that its inventive concept of determining intermediate states based on the initial and final states is absent from Kesling. (Citing CX-1247C at Q. 144-145; CX-1254C ¶ 65 at 23) Align continues that Kesling only disclosed a reactive process, done one step at a time, where subsequent appliances are created by repeating the process for making the first. (Citing CX-1247C at Q. 144-145; CX-1254C ¶ 65 at 23; Tr. at 790:9-791:20) According to Align, Kesling makes one appliance at a time. Kesling does not disclose a proactive method of determining intermediate tooth positions at the outset

based on both the initial and final positions. (Citing CX-1247C at Q. 144-145; CX-1254C ¶ 65 at 23)

Align asserts that Kesling does not disclose, *inter alia*: (i) digital data sets or models of a dentition (citing CX-1247C at Q. 141-143; CX-1254C ¶¶ 62-63 at 21-22); (ii) intermediate or successive tooth arrangements based on initial and final positions (citing CX-1247C at Q. 141, 144-145; CX-1254C ¶ 65 at 23; Tr. at 791:21-793:5); (iii) fabricating a dental appliance, or controlling a fabrication machine, based on a digital data set (citing CX-1247C at Q. 141, 146-147; CX-1254C ¶ 67 at 24-25); or (iv) numerous other elements (citing CX-1247C at Q. 137-162; CX-1258 at 2-8).

Align asserts that Lemchen (CX-0945) discloses a method for determining orthodontic bracket placement. (Citing CX-0945 at 1:55-2:8) Align says that Lemchen is directed to a single fixed appliance used for the duration of a patient's treatment, not a removable appliance. (Citing *id.*; CX-1247C at Q. 190-191; CX-1254C ¶¶ 90-91 at 32-33; CX-1264 at 5) Align continues that Lemchen's disclosure is limited to the idea of treating a patient with the single set of brackets. (Citing CX-1247C at Q. 190-191; CX-1254C ¶¶ 90-91 at 32-33) Based on this, Align contends that the concept of intermediate digital data sets or tooth arrangements is, therefore, absent from, and irrelevant to, Lemchen. (Citing CX-1247C at Q. 183-185; CX-1254C ¶ 82 at 29-30) Align avers that Lemchen teaches away from the use of intermediate arrangements. (Citing CX-1247C at Q. 225-227; CX-1254C ¶ 97 at 34-35)

Align concludes that Lemchen does not disclose, *inter alia*: (i) intermediate or successive digital data sets or tooth arrangements (citing CX-1247C at Q. 183-185; CX-1254C ¶ 82 at 29-30); (ii) polymeric shell appliances (citing CX-1247C at Q. 183, 186-189; CX-1254C ¶¶ 85-86 at 31-32; CX-1264 at 5); (iii) positive models of modified tooth arrangements based on digital data

sets (citing CX-1247C at Q. 183, 186-189, 207, 209-214; CX-1254C ¶ 87 at 32; CX-1264); (iv) multiple removable appliances or fabricating intermediate or successive appliances based on digital data sets (citing CX-1247C at Q. 183, 190-191; CX-1254C ¶¶ 90-91 at 32-33); (v) threshold limits (citing CX-1247C at Q. 233-235; CX-1254C ¶ 105 at 39-40); (vi) interpolation or movements of equal sizes (citing CX-1247C at Q. 236-238; CX-1254C ¶ 106 at 40); (vii) substantially accurate shapes of a patient's teeth in a modified arrangement (citing CX-1247C at Q. 239-240; CX-1254C ¶ 108 at 41); (viii) attachment devices (citing CX-1247C at Q. 241-243; CX-1254C ¶ 109 at 41-42); or (ix) numerous other elements of the asserted claims (citing CX-1247C at Q. 275-277; CX-1258 at 9-15).

Align disagrees with Respondents' claim that Lemchen incorporates the entire disclosure of Kesling. Align asserts that to incorporate by reference, the host document "must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents." (Citing *Advanced Display Sys.*, 212 F.3d at 1282.) Align says that a "mere reference to another [patent] is not an incorporation of anything therein." (Citing *In re De Seversky*, 474 F.2d 671, 674 (C.C.P.A. 1973)) Align continues that I have previously held that incorporation of a disclosed patent was limited to the express reference, and did not incorporate all disclosures contained within the patent. (Citing *Certain Digital Imaging Devices*, Inv. No. 337-TA-717, I.D., 2010 WL 5646142, at *53 (USITC May 12, 2011) (Rogers, J.))

Align asserts that Lemchen only briefly refers to two figures from Kesling. (Citing CX-0945 at 3:14-15, 3:35-40) Align says that these are references to FIGS. 1 and 3 as examples of ***models***, nothing else. Align continues that Lemchen does not say that the ***entire*** disclosure of Kesling, or any of its particular methods, is incorporated. Align says that Dr. Valley agrees that

Lemchen cites these FIGS as examples of what models look like and does not otherwise address Kesling or the relationship between the FIGS. (Citing CX-1247C at Q. 249, 251-258; CX-1254C ¶¶ 112-117 at 42-46) Align adds that Kesling FIGS. 1 and 3 do not disclose the claim elements that are absent from Lemchen. (Citing CX-1247C at Q. 257-258; CX-1254C ¶¶ 112-117 at 42-46)

Align says that Dr. Mah contends, "[i]t is only in the context of the entire disclosure [of Kesling] that the significance of the model displayed as Figure 1 [or Figure 3] as a representation of the patient's teeth prior to treatment [or as a modified tooth arrangement] is understood." (Citing RX-0113C at Q. 47-48) Align disagrees and asserts that one of ordinary skill in the art would have understood the concept of a representation of teeth based on FIGS. 1 and 3 without needing to review Kesling's entire disclosure. (Citing CX-1247C at Q. 264-265; CX-1254C ¶ 117 at 45-46; Tr. at 786:24-787:17, 788:11-789:8, 796:13-798:6) Align explains that plaster tooth arrangements were commonly known and used. (Citing CX-1247C at Q. 264-265; CX-1254C ¶ 117 at 45-46)

Align alternatively argues that even if Lemchen fully incorporated Kesling, Lemchen/Kesling still would not disclose all elements of any of the asserted claims. (Citing CX-1247C at Q. 568-569; CX-1254C ¶ 274 at 97)

Align disagrees with Respondents' '325 patent invalidity positions as wholly unsupported and insufficient to meet their high burden. Align says that Respondents have no particular evidence to support their invalidity case because no claim charts explaining where each claimed element is shown in the cited references are in evidence. (Citing Tr. at 19:11-20:4, 651:14-653:25) Align continues that the prior art also fails to disclose all elements of any of the asserted claims of the '325 patent, individually or under any combination, as explained above. (Citing

CX-1247C at Q. 606, 610; CX-1258) Align adds that none of the prior art discloses, *inter alia*, "a plurality of digital data sets" or "controlling a fabrication machine based on the digital data set to produce a positive model of the modified tooth arrangement." (Citing *id.*)

Align disagrees with Respondents' argument that all of the asserted claims of the '325 patent are anticipated by Lemchen and "as incorporated," Kesling and asserts that Respondents' argument is unsupported, because no claim charts (or other explanatory vehicle) showing this assertion in detail are in evidence. Align contends that Respondents' argument relies on accepting that Lemchen incorporates the entire disclosure of Kesling, which is wrong for the reasons described above. Alternatively, Align asserts that even assuming incorporation, Lemchen/Kesling would still fail to disclose all elements of the asserted claims.
Align argues that because Respondents did not introduce evidence that even attempts an element-by-element comparison of the prior art with Align's asserted claims, their arguments fail. (Citing *Certain Mobile Devices*, Inv. No. 337-TA-744, Final I.D., 2011 WL 6916539, at *103-04, *103 n.33 (Dec. 20, 2011)) Align asserts that neither Respondents nor Dr. Mah explained how the elements of Align's claims read on the prior art in view of their ever-changing claim constructions or, for that matter, Align's or Staff's proposed constructions; rather, Respondents simply state in a conclusory footnote, "[t]he Respondents' arguments regarding invalidity for each of the asserted patents, both anticipation and obviousness, apply whether the Court adopts Align's, Respondents' or the Staff's claim constructions." (Citing RIB at 39 n.3) Align says that Respondents' failure to address claim construction is likewise fatal to their invalidity defenses.

Align says that the USPTO considered Lemchen and Kesling during the prosecution of the '874 and '487 patents and the reexaminations of the '863 and '325 patents. (Citing JX-0006

at 1-2; JX-0007 at 1-2; JX-0005 at 26-27; JX-0003 at 21, 22.) Align asserts that Respondents' anticipation defense fails as a matter of law because it relies on the assumption that Lemchen incorporates the full disclosures of Kesling, which is wrong. Align says that the majority of Kesling is completely unrelated to FIG. 1 or FIG. 3. Align says that this illustrates that Respondents' mantra that reading such portions of Kesling is somehow necessary to understand "the significance of" FIGS. 1 and 3 is incorrect.

Align says that Lemchen's disclosure is limited to the idea of treating a patient with a single set of brackets. (Citing CX-1247C at Q. 190-191; CX-1254C ¶¶ 90-91 at 32-33) Align disagrees and says that the "methods of treatment" in Lemchen refer to different methods of treating a patient with brackets and archwires – not aligners. (Citing CX-1247C at Q. 215-219; CX-1254C ¶ 98 at 35-36; Tr. at 798:7-799:25) Align disagrees with Respondents' argument that "modeling of teeth movement is the same, regardless of the type of appliance used." (Citing CX-1247C at Q. 221-222; CX-1254C ¶ 99 at 37) Align explains that the anchorage needs and, therefore, the biomechanics of tooth movement, vary depending on the type of appliance used. (Citing CX-1247C at Q. 221-222; CX-1254C ¶ 99 at 37)

Align says that Respondents' "element-by-element" analysis should be wholly rejected under GR 8.2 because it was not disclosed in Respondents' Align continues that the "disclosure categories" consist of mischaracterizations of Lemchen and Kesling that are largely unsupported by anything other than attorney argument. Align adds that the disclosure categories do not address numerous elements of the asserted claims. Align argues that Respondents' methodology is flawed by failing to apply their disclosure categories consistently with the methodology used by Align's expert.

Align says that Respondents fail to establish that Lemchen discloses presenting a visual image based on a data set; rather, the portion of Lemchen cited by Respondents merely discusses CAD generally and does not indicate that a visual image is presented in Lemchen's method. Align continues that Respondents quote *Ormco II* at 498 F.3d 1312, claiming that "Align successfully argued . . . that one skilled in the art would understand that Lemchen disclosed visual images based on the initial data set[.]" Align disagrees, explaining that *Ormco II* does not contain ***Align's*** characterizations of Lemchen.

Align disagrees with Respondents' identification of "disclosures relating to manipulation of the image to reposition teeth." Align says that Respondents fail to establish that Lemchen discloses manipulating an image to reposition teeth because they do not cite to any portion of Lemchen supposedly disclosing manipulating an image to reposition teeth. Rather, Align says that Respondents rely on Dr. Rekow's report (RX-103C), which refers to teeth being "***digitally*** manipulated," but not manipulated ***visually*** in an image. (Citing *Id.* at 46) Align continues that Lemchen merely discusses "the ***calculation*** of the 'finish' position," not ***visual manipulation*** of teeth. (Citing CX-0945 at 3:16-18; Tr. at 765:21-766:18)

Align also disagrees with Respondents' identification of "disclosures relating to the final digital data set." Align says that Respondents cite the Rekow report (RX-103C) and contend that Align has now taken a contrary position regarding the disclosures of Kesling. Align says that Respondents fail to substantiate their contention that Lemchen discloses "producing a final digital data set representing the final tooth arrangement with repositioned teeth as observed in the image." Align says that Respondents do not cite any portion of Lemchen or explain where this is allegedly disclosed; rather Respondents rely on the Rekow report (RX-103C), which merely

indicates that, in Lemchen, finish positions of teeth are ***calculated***, not observed in an image. (Citing *Id.*; Tr. at 765:21-766:18)

Align disagrees with Respondents' identification of "disclosures relating to generating the intermediate tooth arrangements or digital models." Align says that Respondents claim that Kesling "discloses the manufacture and use of a plurality of appliances, each appliance in the series representing intermediate or successive tooth positions." Align says that its inventive concept of determining intermediate states based on both the initial and final states is absent from Kesling. (Citing CX-1247C at Q. 144-145; CX-1254C ¶ 65 at 23) Align explains that Kesling only disclosed a ***reactive*** process, done ***one step at a time***, where subsequent appliances are created by repeating the process for making the first appliance. (Citing *Id.*; Tr. at 790:9-791:20) Align says that Kesling makes one appliance at a time and does not disclose a ***proactive*** method of determining intermediate tooth positions at the outset based on both the initial and final tooth positions. (Citing CX-1247C at Q. 144-145; CX-1254C ¶ 65 at 23) Align says that the Rekow Report merely describes Kesling's wax setups (Citing RX-103C at 12-13), and does not contradict Dr. Valley's explanation of Kesling's ***reactive*** process, described above.
Align asserts that one of ordinary skill in the art would understand Lemchen as simply indicating that repositioning teeth into the finish position may involve using software. (Citing CX-1247C at Q. 236-238; CX-1254C at ¶ 106 at 40) Align contends that Lemchen does not disclose the concepts of treatment segments, interpolation, or equal-sized translational movements between tooth positions. (Citing CX-1247C at Q. 236-238; CX-1254C at ¶ 106 at 40)

Align disagrees with Respondents' claim that the Rekow Report "demonstrates that one skilled in the art would understand that [Lemchen] incorporates [Kesling] and discloses three dimensional modeling of teeth movement digitally through a series of incremental or

intermediate steps from an initial position to the desired position." (Citing RIB at 50) Align contends that the concept of intermediate digital data sets or tooth arrangements is absent from, and irrelevant to, Lemchen. (Citing CX-1247C at Q. 183-185; CX-1254C ¶ 82 at 29-30) Rather, Align says that Lemchen is limited to the idea of treating a patient with a single set of brackets (citing CX-1247C at Q. 190-191; CX-1254C ¶¶ 90-91 at 32-33) and teaches ***away*** from using intermediate arrangements (citing CX-1247C at Q. 225-227; CX-1254C ¶ 97 at 34-35). Align continues that the Rekow Report does not indicate that Lemchen discloses intermediate steps or incorporates Kesling.

Align says that throughout their PostHearing Brief, Respondents rely on Disclosure Category 7 for Align's claim elements relating to, *e.g.*, intermediate digital data sets and successive digital data sets. (Citing RIB at 58, 86) Align disagrees, saying that nowhere in Disclosure Category 7 do Respondents actually contend that the prior art discloses intermediate or successive digital data sets. (Citing RIB at 49-51) Align says that the prior art does not disclose these elements. (Citing CX-1247C at Q. 141-145, 183-185; CX-1254C ¶¶ 62-63, 65, 82 at 21-23, 29-30; Tr. at 791:21-793:5)

Align says that Respondents identify purported disclosures "relating to digital models of attachment devices." Align says that Respondents mischaracterize Lemchen. Align explains that Lemchen does not disclose attachment devices or digital models thereof. (Citing CX-1247C at Q. 241-243; CX-1254C ¶ 109 at 41-42)

Align says that Respondents identify purported "disclosures relating to the transferring of digital data sets." Align says that the portion of Lemchen relied on by Respondents merely indicates that digitized information is "utilized," not transferred.

Align says that Respondents identify purported "disclosures relating to the fabrication of the appliances." Align contends that Respondents mischaracterize the disclosures of Kesling and Lemchen. Align says that Respondents contend that Kesling discloses making an appliance "by molding a polymeric material over positive models." (Citing RIB at 51) Align disagrees, saying that Kesling discloses making an appliance by filling a cast with rubber, not molding it over a positive model. (Citing Tr. at 789:9-790:8) Align says that Respondents contend that Kesling discloses "using a machine to fabricate a series of dental appliances by producing a positive model of a tooth arrangement." (Citing RIB at 52) Align again disagrees, saying that Kesling discloses using dental materials, tools, and an articulating device, not a fabrication machine. (Citing CX-0944 at 3:65-4:70, Fig. 4; CX-1247C at Q. 153; CX-1254C ¶ 72 at 26) Align says that Respondents contend that Lemchen discloses "the controlling of a fabrication machine to produce a positive model of a modified tooth arrangement based on the digital information generated." (Citing RIB at 52) Align continues that Respondents cite to disparate portions of Lemchen that do not combine the concepts of fabrication, positive models, and digital data sets. (Citing CX-1247C at Q. 209-210; CX-1254C ¶ 109 at 41-42) Align adds that Respondents inexplicably cite to the Rekow Report's discussion of other "references cited by Lemchen." (Citing RIB at 52) Align says that these other alleged references are not in evidence and, thus, cannot support Respondents' invalidity defense.

Align asserts that Respondents fail to point to any portion of the prior art that they contend discloses, *e.g.*, "presenting a visual image based on the initial data set" ('325 claims 1, 31); "manipulating the visual image to reposition individual teeth in the visual image" ('325 patent claim 1); "producing a final digital data set representing the final tooth arrangement with repositioned teeth as observed in the image" ('325 patent claims 1, 31); "intermediate digital data

sets" ('325 patent claims 1, 31); "fabricating a plurality of successive tooth repositioning appliances, at least some of which are related to at least some of the produced digital data sets" ('325 patent claim 1); "defining boundaries about at least some of the individual teeth" ('325 patent claims 3, 13); "successive digital data sets" ('325 patent claims 11, 35); "fabricating appliances based on at least some of the produced digital data sets" ('325 patent claim 11); "determining positional differences . . . and interpolating said differences" ('325 patent claim 14); digital data sets representing "substantially accurate shapes of the patient's actual teeth" ('325 patent claims 30, 32, 35); "fabricating a plurality of successive tooth repositioning appliances based on at least a plurality of said produced digital data sets provided to the fabrication operation" ('325 patent claim 33); "the appliances are fabricated based on individual ones of at least a corresponding plurality of the produced digital data sets" ('325 patent claim 39). (Citing RIB at 45-61) Align says that Respondents' theory relies on their "disclosure categories," which advance new and unsupported mischaracterizations of Lemchen and Kesling, and fail to fairly address the elements of the asserted claims. Align continues that Respondents also misapply their "disclosure categories" with respect to at least claims 11, 31, and 38 of the '325 patent. Align adds that the USPTO considered Lemchen and Kesling during the reexamination of the '325 patent, further demonstrating that the asserted claims are not anticipated. (Citing JX-0003 at 21, 22)

Staff's Position: Staff argues that the evidence does not demonstrate clearly and convincingly that any of the Asserted Claims of the '325 patent (or any of the other Asserted Patents) is anticipated by U.S. Patent No. 35,169 (Lemchen) (CX-0945) and, "as incorporated," U.S. Patent No. 2,467,432 (Kesling) (CX-0944).

Staff asserts that Lemchen does not incorporate the entirety of Kesling. Staff says that

Lemchen includes two references to Kesling, specifically, (i) Lemchen refers to Figure 1 of Kesling to explain the representation of the digitized mathematical model of Lemchen; and (ii) Lemchen refers to Figure 3 of Kesling to disclose the method of moving teeth in a digitized mathematical model to a "finish" position. (Citing CX-1247C at Q. 252-256; CX-0945 at 2:66-3:16 and 3:32-40; CX-0944 at FIG. 1 and FIG. 3) Staff continues that the evidence does not further demonstrate that Lemchen incorporates the concepts or teachings from Kesling beyond these figures. (Citing CX-1247C at Q. 259-274; CX-0945; CX-0944) Staff adds that the evidence does not demonstrate that Lemchen necessarily incorporates the entirety of Kesling. (Citing CX-1247C at Q. 259-274; CX-0945; CX-0944)

Staff contends that even if it was determined that Lemchen necessarily incorporates the entirety of Kesling, the evidence does not show clearly and convincingly that any Asserted Claim of the '325 patent (or any of the other patents in suit) is anticipated by Lemchen and, "as incorporated," Kesling. (Citing CX-1247C at Q. 561-571; CX-1258 at 1-14) Staff says that Lemchen does not disclose, teach, or suggest, inter alia, (i) intermediate or successive digital data sets or (ii) intermediate or successive tooth arrangements. (Citing CX-1247C at Q. 178-186; CX-1258 at 8-14) Staff continues that Kesling docs not disclose, teach, or suggest, inter alia, (i) intermediate or successive digital data sets; (ii) the use or fabrication of a series of dental appliances or (iii) controlling a fabrication machine or producing a positive model of a tooth arrangement from a digital data set. (Citing CX-1247C at Q. 136-163; CX-1258 at 1-7)

Staff says that Respondents' technical expert Dr. Mah provides only conclusory testimony about the subject matter of the prior art and the '325 patent (and the other patents in suit); but does not provide a detailed discussion of how and where Lemchen and, "as incorporated," Kesling disclose, teach, or suggest each and every element of the Asserted Claims

of the '325 patent (or any of the other patents in suit). (Citing RX-0113C at Q. 100-111) Staff says that Dr. Mah apparently prepared a claim chart setting forth more details about how and where Lemchen and, "as incorporated," Kesling disclose, teach, or suggest each and every element of the Asserted Claims of the patents in suit, but the ALJ has excluded that claim chart (Citing Tr. at 18:13-19:25 (excluding RX-0124 and RX-0113C at Q. 110)) According to Staff, the record contains no evidence explaining clearly and convincingly how and where Lemchen and, "as incorporated," Kesling disclose, teach, or suggest each and every element of the Asserted Claims.

Staff says that the PTO considered both Lemchen and Kesling during: (i) prosecution of the '487 patent, (ii) prosecution of the '874 patent, (iii) reexamination of the '325 patent, and (iv) reexamination of the '863 patent, and the PTO still approved all of the asserted claims of the patents in suit. (Citing CX-1247C at Q. 135 and 177; JX-0003; JX-0005; JX-0006; JX-0007)

Staff concludes that there is a lack of evidence demonstrating clearly and convincingly that any of the Asserted Claims of the '325 patent (or the other patents in suit) are anticipated by Lemchen and, "as incorporated," Kesling.

Staff agrees with Complainants' argument that Respondents have failed to meet their burden of proving that all of the asserted claims of the patents in suit are anticipated or rendered obvious because Respondents have failed to provide, *inter alia*, an element-by-element comparison of the prior art with the asserted claims of the patents in suit. Staff says that Respondents, in their Post-Hearing Brief, attempt to make up for shortcomings by comparing, on an element-by-element basis, their prior art references with the Asserted Claims of the '325 patent. Staff says that because Respondents admittedly did not perform this comparison in their Pre-Hearing Brief, Respondents should not be permitted to do so now. (Citing G.R. 8.2) Staff

continues that Even if Respondents' comparison of their prior art references with the Asserted Claims of the '325 patent is permitted, that comparison consists of primarily attorney argument, which is no substitute for evidence. Staff avers that in their comparison, Respondents cite to Dr. Mah's testimony to support their allegations of anticipation and obviousness, but that testimony is merely conclusory, as it too references a claim chart, purporting to show how and where the prior art discloses each element of each asserted claim, that has been excluded by the ALJ. Staff continues that Respondents' allegations of obviousness also include Nahoum (RX-0096), but Respondents further fail to show how one of ordinary skill in the art would have been motivated to combine Nahoum in any manner. Staff concludes, as a result, that there is a lack of evidence explaining clearly and convincingly how the prior art discloses, teaches, or suggests each element of the Asserted Claims of the '325 patent.

Analysis and Conclusions: After thorough review of the evidence and arguments presented, I find that the Lemchen reference only incorporates by reference Figures 1 and 3 of Kesling.

In *Advanced Display Systems*, the Federal Circuit treated the issue of a rejection for anticipation in which the single reference "expressly incorporates a particular part" of another reference. *Advanced Display Systems, Inc. v. Kent State University*, 212 F.3d 1272 (Fed. Cir. 2000). The court said, at page 1282, "[m]aterial not explicitly contained in the single, prior art document may still be considered for purposes of anticipation if that material is incorporated by reference into the document." (Citing *Ultradent Prods., Inc. v. Life-Like Cosmetics, Inc.*, 127 F.3d 1065, 1069, 44 USPQ2d 1336, 1339-40 (Fed. Cir. 1997)) The court went on to explain, "[t]o incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is

found in the various documents." (Citing *In re Seversky*, 474 F.2d 671, 674, 177 USPQ 144, 146 (C.C.P.A. 1973); *see also In re Saunders*, 444 F.2d 599 (C.C.P.A. 1971))

Whether material has been incorporated by reference into a host document, and the extent to which it has been incorporated, is a question of law. (*Cook Biotech Inc. v. Acell, Inc.*, 460 F.3d 1365, 1376 (Fed. Cir. 2006)) In making that determination, "the standard of one reasonably skilled in the art should be used to determine whether the host document describes the material to be incorporated by reference with sufficient particularity." *Advanced Display Systems*, 212 F.3d at 1283.

Incorporation by reference and anticipation are separate inquiries. While incorporation by reference is a question of law, anticipation is a question of fact. The Federal Circuit has held "if incorporation by reference comes into play in an anticipation determination, the court's role is to determine what material in addition to the host document constitutes the single reference. The factfinder's role, in turn, is to determine whether that single reference describes the claimed invention." *Id.*

The first issue, therefore, is what, if anything, was specifically identified and incorporated by reference in Lemchen. In *Zenon Environmental*, the court considered the scope of incorporation by reference in a patent that said,

> The vertical skein is not the subject matter of this invention and any prior art vertical skein may be used. Further details relating to the construction and deployment of a most preferred skein are found in the parent U.S. Pat. No. 5,639,373, and in Ser. No. 08/690,045, the relevant disclosures of each of which are included by reference thereto as if fully set forth herein.

Zenon Environmental, Inc. v. United States Filter Corporation, 506 F.3d 1370, 1379 (Fed. Cir. 2007). The Federal Circuit panel disagreed with the trial court's finding that the foregoing

language incorporated by reference the entire disclosures of the referenced patents. The court stated:

> The plain language expressly limits the incorporation to only relevant disclosures of the patents, indicating that the disclosures are not being incorporated in their entirety. Moreover, the plain language indicates that the subject matter that is being incorporated by reference pertains to the details relating to the construction and deployment of a vertical skein. Thus, we must look, as one reasonably skilled in the art would, to the grandparent patents to determine what the patentees meant by details relating to the construction and deployment of a vertical skein.

Id.

In *Saunders*, the court reviewed a patent denial issued by the Patent Office Board of Appeals, based upon the theories of anticipation and obviousness. The subject matter of the patent was a family of methods for preparing cellular polyurethane foam by what the court characterized as a "one shot" technique. (*Saunders*, 444 F.2d at 600) In connection with the anticipation issue, the court examined incorporating language that said,

> The above-described siloxane-oxyalkylene block copolymers can be prepared in accordance with the procedures described and claimed in the copending application of D. L. Bailey and F. M. O'Conner, Serial No. 417,935, filed December 14, 1953.

Id. at 603.

The court found that the incorporation by reference was limited to the specific method of making surfactants of this general type in which the oxyalkylene chains were composed entirely of one type of oxyalkylene, and would not expressly indicate that other compounds which the Bailey reference also taught how to make could also be employed as surfactants in the applicant's process. *Id.*

Applying the foregoing principles to the case at bar, I examine the reference in Lemchen, which states:

> Thus, in many applications of the preferred embodiment, a complete "model", at the term is used in the dental art to refer to a full replication of the upper and lower dental arches and associated jaw structure, will be mathematically generated. A physical embodiment of such a model is shown, for example, in FIG. 1 of U.S. Pat. No. 2,467,432.

(CX-945, 3:10-15) I note that this quote from Lemchen, similar to the language in *Saunders*, does not specifically indicate that Kesling is incorporated by reference. Rather, the allusion in Lemchen to Figure 1 in Kesling is used as an example in the prior art of a physical model representing the replication of the upper and lower dental arches and associated jaw structure of a patient, which the invention of Lemchen would generate mathematically using digitized information in a computer. (CX-944, Figure 1)

Similarly, Lemchen's nod to Figure 3 in Kesling represents an example in the prior art of a manually created model of a patient's teeth in the finish position, and which Lemchen teaches could be generated mathematically by its invention. Lemchen *states:*

> In the prior art, a similar step was accomplished manually in order to account for individual tooth morphology by physically removing duplicated teeth from a model and repositioning them in a new model in a finish position. See, for example, FIG. 3 in the above referenced U.S. Pat. No. 2,467,432.

(CX-945, 3:35-40; and CX-944, Figure 3)

Following the rationale of *Advanced Display Systems* and *Saunders*[13], supra, I find that the foregoing language from Lemchen identifies with detailed particularity what specific material it incorporates from Kesling and clearly indicates where that material is found, to wit: Figures 1 and 3 of Kesling. As in *Saunders*, however, I find that the reference in Lemchen does not extend beyond Figures 1 and 3 of Kesling.

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[13] Neither Lemchen nor *Saunders* contains an expression that the relevant language is "incorporated by reference." This does not appear to be required as long as the context indicates such an intent. Inasmuch as, the court in *Saunders* inferred such an intent, I draw the same inference in Lemchen, the language of which is similar to that of *Saunders*.

Even assuming that Lemchen incorporated the entirety of Kesling, each and every limitation of the asserted claims is not disclosed. First, I note that both Lemchen and Kesling were considered by the United States Patent and Trademark Office during the re-examination of the '325 patent. (JX-003 at 21-22 (Re-Exam References Cited)) As a result, Respondents must "overcome[e] the deference that is due to a qualified government agency presumed to have properly done its job" to show that the claims of the '325 patent are invalid.[14] *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359 (Fed. Cir. 1984). Respondents, however, have failed to meet the burden to prove by clear and convincing evidence that each and every limitation of the asserted claims is disclosed expressly or inherently in the cited references.

Lemchen describes "generating digital information" regarding the initial "malocclused teeth," and then determining their respective "finish positions." As Dr. Valley testified credibly, Lemchen does not disclose, or teach or suggest, calculating positions-in-between. (CX-945, 1:55-2:1; 2:54-57; 3:16-24; CX-1247C at Q. 184-185) As a result, I find that Lemchen does not disclose "producing a plurality of intermediate digital data sets representing a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement," as required by exemplary claim 1.

Lemchen discloses calculating position on the teeth for bracket placement, and completes moving teeth with traditional brackets and archwires, not polymeric shell appliances. (CX-945, 1:55-57; 1:63-2:8; CX-1247C at Q. 186) According to the credible testimony of Dr. Valley, this is different from fabricating brackets or other appliances, and Lemchen's disclosure is limited to the idea of treating a patient with a single set of brackets, i.e. one bracket per tooth to be used

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[14] Lemchen and Kesling were also considered by the United States Patent and Trademark Office during the re-examination of the '863 patent (JX-005 at 26-27 (Re-Exam References Cited)) and during prosecution of the '874 patent (JX-006 at 1-2 (References Cited)) and the '487 patent (JX-007 at 1-2). The same heightened burden applies for those patents as well.

over the entirely of the treatment. (CX-945, 1:56-62; 3:55-63; CX-1247C at Q. 190) As a result, I also find that Lemchen does not disclose "fabricating a plurality of successive tooth repositioning appliances, at least some of which are related to at least some of the produced digital data sets," as required by exemplary claim 1.

I note, too, that the incorporation of Figures 1 and 3 of Kesling into Lemchen provides no greater insight into the teachings of the asserted claims. As described, *supra*, Figure 1 only describes a physical model of a mathematically generated model of a patient's teeth, and Figure 3 demonstrates a method of physically moving portions of a model representing the patient's teeth into a "finish position."

In addition, assuming *arguendo* that one were to find that Lemchen incorporates all of Kesling by reference, the result would not change. Kesling was originally filed in 1943, and the patent issued in 1949, before the concept of digital data existed. As Dr. Valley testified credibly, Kesling "does not disclose, or teach or suggest, or even remotely contemplate" the use of computers or digital technology. (CX-1247C, Qs. 141-142, 564-571, 574-577; CDX-145) Kesling describes making tooth arrangements by (i) using a plaster mold of teeth, (ii) dissecting the plaster teeth with a saw, and (iii) reassembling the plaster teeth in wax into their assumed positions. (CX-944, 3:13-22; 3:30-43; 3:61-64)

Dr. Valley also testified credibly that Kesling only contemplated a reactive process, performed one step at a time, where appliances beyond a first appliance may be created by repeating the disclosed process for making the first appliance. (CX-1247C, Qs. 144-145; CX-944, 5:22-32) Kesling does not expressly or inherently disclose, or teach or suggest, fabricating a dental appliance based on a digital data set. Rather, Kesling discloses manually making an appliance using tools, supplies, and materials, including, inter alia, (i) articulating the plaster

cast; (ii) taking an impression of the teeth of the plaster cast, and (iii) making a mold filled with the appliance material. (CX-944, 3:65-4:58; CX-1247C at Q. 146)

Based upon all of the foregoing, I find that Respondents have failed to meet their burden to prove by clear and convincing evidence that Lemchen anticipates claims 1, 11, 21, 31, 33, 35, and 38 of the '325 patent. Because Respondents have failed to meet their burden to prove by clear and convincing evidence that the asserted independent claims are anticipated by Lemchen, I find that the asserted dependent claims (claims 2, 3, 13, 14, 30, 32, 33, 34 and 39) also are not anticipated by Lemchen.

b. Claim 2

Claim 2 recites:

> A method as in claim 1, wherein the step of providing a digital data set representing an initial tooth arrangement comprises scanning a three-dimensional model of a patient's teeth.

(JX-003 at 15:33-36)

Respondents' Position: Respondents argue that Lemchen discloses the subject matter of claim 2 by disclosing that a digital data set representing an initial tooth arrangement is generated by scanning a model of the patient's teeth. (Citing CX-0945 at 2:54 – 63)

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of claim 1.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 1 to be anticipated and invalid, I could still find that claim 2 is valid. Since, however, I have found claim 1 to be valid and ***not*** anticipated by Lemchen, claim 2 is necessarily valid, because it depends from claim 1 and necessarily contains all of the elements of claim 1.

See In re Fritch, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 1 is anticipated by Lemchen, I would find that Respondents have failed to show by clear and convincing evidence that claim 2 of the '325 patent is anticipated by Lemchen with the incorporation of Kesling.

Lemchen discloses "generating digital information" regarding the initial "malocclused teeth." (CX-945, 1:55-61; 3:16-24). Lemchen specifically discloses

> The first step of the method of the present invention is the generation of accurate digital information defining the shape and location of the malocclused tooth with respect to the patient's jaw. This information may be generated in a number of ways, such as electromechanically, by laser scanning, sonic ranging, digital video scanning, or magnetically.

(CX-945, 2:54-60) Lemchen does not, however, reveal generating the initial data regarding malocclused teeth from a physical model of the patient's teeth as shown in Kesling. Rather it uses Kesling to illustrate what a model of the upper and lower dental arches looks like. Lemchen actually teaches away from using a physical model such as that in Kesling, when Lemchen states:

> Utilizing standard statistical tooth position data, the repositioning of the teeth is calculated to provide a mathematical model of the finish position. In the prior art, a similar step was accomplished manually in order to account for individual tooth morphology by physically removing duplicated teeth from a model and repositioning them in a new model in the finish position. See, for example, FIG. 3 in the above referenced U.S. Pat. No. 2,467,432. However, this procedure did not take into account the individual finish position desired related to the cranial-facial base.
>
> In the present method, this repositioning is done mathematically by appropriate software programs which may be derived by conventional means for the particular method of treatment elected by the orthodontist. An "ideal" finish position is not based upon statistical averages and takes into account the variation and physical characteristics of the individual patient. Therefore, it is preferable that, the program be utilized to provide a customized finish position for the particular patient, so as to make the finish position ideal for the patient, rather than attempting to have the patient duplicate the statistically average position.

(CX-945, 3:32-53) The foregoing discussion teaches away from use of the physical model. Rather, it forwards an approach that uses scanning of the patient's actual teeth to take into account the individual finish position related to the cranial-facial base. Lemchen endorses taking into account "the variation and physical characteristics of the individual patient." Thus, Lemchen with the incorporation of Kesling, does not reveal "data obtained by scanning a physical model of the patient's teeth."

c. Claim 3

Claim 3 recites:

> A method as in claim 2, wherein the manipulating step comprises:
>
> defining boundaries about at least some of the individual teeth; and
>
> moving at least some of the tooth boundaries relative to the other teeth in an image based on the digital data set.

(JX-003 at 15:37-43)

Respondents' Position: Respondents say that Lemchen also discloses the subject matter of claim 3. Respondents continue that Align successfully argued to the Federal Circuit that one skilled in the art would understand that Lemchen disclosed manipulating visual images to reposition individual teeth in the visual image. (Citing *Ormco II* at 498 F.3d 1315)

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of claim 1.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined both claim 1 and claim 2 to be anticipated and invalid, I could still find that claim 3 is valid. Since, however, I have found claims 1 and 2 to be valid and ***not*** anticipated Lemchen,

claim 3 is necessarily valid, because it depends from claim 1 via claim 2 and necessarily contains all of the elements of claims 1 and 2. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that claims 1 and 2 are anticipated by Lemchen, I would find that Respondents have shown by clear and convincing evidence that claim 3 of the '325 patent is anticipated by Lemchen with the incorporation of Kesling.

Claim 1 teaches "manipulating the visual image to reposition individual teeth in the visual image." (JX-003 at R1:29-48) Assuming, *arguendo*, that Lemchen disclosed this limitation, because this limitation discusses moving "individual" teeth, Lemchen would necessarily disclose defining boundaries around those teeth in order to move those teeth in the image. As a result, I find that if claims 1 and 2 were anticipated by Lemchen, claim 3 would be anticipated by Lemchen.

d. Claim 11

Asserted claim 11 teaches:

> A method for fabricating a plurality of denial incremental position adjustment appliances, said method comprising:
>
> providing an initial digital data set representing an initial tooth arrangement;
>
> providing a final digital data set representing a final tooth arrangement;
>
> producing a plurality of successive digital data sets based on both of the previously provided initial and final digital data sets, wherein said plurality of digital data sets represent a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement; and
>
> fabricating appliances based on at least some of the produced digital data sets.

(JX-003 at 16:19-34)

Respondents' Position: Respondents contend that, like claim 1, the preamble and first and second elements of claim 11 are disclosed by Lemchen and Kesling. Respondents assert that the third element of claim 11 is disclosed by Kesling because the Kesling reference discloses the manufacture and use of a plurality of appliances, each appliance in the series representing intermediate or successive tooth positions. (Citing CX-0944 at 2:50 – 3:1) Respondents say that the Kesling reference describes the necessity of making a plurality of appliances as obvious. (Citing CX-0944 at 2:50 – 3:1) Respondents say that, as described above, Lemchen discloses a digital method of performing the manual method disclosed in Kesling.

Respondents assert that Lemchen and Kesling disclose the fourth element of claim 11. Respondents say Lemchen discloses methods that include controlling an appliance fabrication machine (Citing CX-0945 at 5:4 –8) Respondents say that Lemchen also describes the use of a "laboratory model of the tooth . . . " and note that while they referred to a single tooth, their invention "may be utilized with some or all of the teeth in a given arch . . . ." (Citing CX-0945 at 5:21 – 24) Respondents assert that these statements expressly disclose the controlling of a fabrication machine to produce a positive model of a modified tooth arrangement based on the digital information generated in order to produce appliances.

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of claim 1.

Analysis and Conclusions: In section IV.B.1, *supra*, I find that the Lemchen reference only incorporates by reference Figures 1 and 3 of Kesling. I also find that because Lemchen only describes "generating digital information" regarding the initial "malocclused teeth," and then determining their respective "finish positions," Lemchen does not disclose "producing a plurality of intermediate digital data sets representing a series of successive tooth arrangements

progressing from the initial tooth arrangement to the final tooth arrangement," as required by claim 1. Additionally, I find that Lemchen discloses calculating position on the teeth for bracket placement, and completes moving teeth with traditional brackets and archwires, not polymeric shell appliances, and Lemchen's disclosure is limited to the idea of treating a patient with a single set of brackets, i.e. one bracket per tooth to be used over the entirely of the treatment. As a result, I find that Lemchen does not disclose "fabricating a plurality of successive tooth repositioning appliances, at least some of which are related to at least some of the produced digital data sets," as required by claim 1. I further found that the incorporation of Figures 1 and 3 of Kesling into Lemchen provides no greater insight into the teachings of the asserted claims, and assuming *arguendo* that one were to find that Lemchen incorporates all of Kesling by reference, the result would not change.

Similar to claim 1, Claim 11 requires, *inter alia*,

> producing a plurality of successive digital data sets based on both of the previously provided initial and final digital data sets, wherein said plurality of digital data sets represent a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement; and
>
> fabricating appliances based on at least some of the produced digital data sets.

(JX-003 at 16:27-34) As a result, and based on the findings discussed above, I find that Respondents have failed to prove by clear and convincing evidence that Lemchen discloses explicitly or inherently each and every limitation of claim 11.

e. Claim 13

Dependent claim 13 recites:

> A method as in claim 11, wherein the step of providing a digital data set representing a final tooth arrangement comprises:

defining boundaries about at least some of the individual teeth; and

moving at least some of the tooth boundaries relative to the other teeth in an image based on the digital data set to produce the final data set.

(JX-003 at 16:39-46)

Respondents' Position: Respondents argue that, as discussed above, Lemchen and Kesling disclose the subject matter of claim 13.

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of claim 1.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 11 to be anticipated and invalid, I could still find that claim 13 is valid. Since, however, I have found claim 11 to be valid and ***not*** anticipated by Lemchen, claim 13 is necessarily valid, because it depends from claim 11 and necessarily contains all of the elements of claim 11. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming *arguendo* that one were to find that independent claim 11 is anticipated by Lemchen, I would find that Respondents have not shown by clear and convincing evidence that claim 13 of the '325 patent is anticipated by Lemchen with the incorporation of Kesling. Claim 11 merely teaches "providing a final digital data set representing a final tooth arrangement." (JX-003 at 16:24-25) Unlike claim 1, claim 11 does not teach manipulating a visual image to move "individual" teeth. Although Lemchen teaches generating a digital data set representing teeth in their "final" position (*see* CX-945 at 1:55-2:1; 2:54-57; 3:16-24), Lemchen does not disclose the specific details of how this would be accomplished (*see* CX-945 at 3:44-54). Thus, I find that Lemchen with the incorporation of Kesling, does not reveal the subject matter of claim 13.

f. Claim 14

Dependent claim 14 recites:

> A method as in claim 11, wherein the step of producing a plurality of successive digital data sets comprises determining positional differences between the initial data set and the final data set and interpolating said differences.

(JX-003 at 16:47-50)

Respondents' Position: Respondents argue that, as discussed above, Lemchen and Kesling disclose the subject matter of claim 14.

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of claim 1.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 11 to be anticipated and invalid, I could still find that claim 14 is valid. Since, however, I have found claim 11 to be valid and ***not*** anticipated by Lemchen, claim 14 is necessarily valid, because it depends from claim 11 and necessarily contains all of the elements of claim 11. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 11 is anticipated by Lemchen, I would find that Respondents have not shown by clear and convincing evidence that claim 14 of the '325 patent is anticipated by Lemchen with the incorporation of Kesling. Although Lemchen teaches generating a digital data set representing teeth in their "final" position (*see* CX-945 at 1:55-2:1; 2:54-57; 3:16-24), Lemchen does not disclose the specific details of how this would be accomplished, and does not discuss interpolating differences between an initial position and a final position (*see* CX-945 at 3:44-54). Thus, I find that Lemchen with the incorporation of Kesling, does not reveal the subject matter of claim 14.

g. Claim 21

Claim 21 teaches:

> A method for fabricating a polymeric shell dental appliance for moving a patient's teeth, said method comprising:
>
> providing a digital data set representing a modified tooth arrangement for a patient, wherein the modified tooth arrangement comprises a repositioned tooth arrangement for a plurality of the patient's teeth;
>
> controlling a fabrication machine based on the digital data set to produce a positive model of the modified tooth arrangement; and
>
> producing the polymeric shell dental appliance as a negative of the positive model, wherein the polymeric shell appliance covers a plurality of teeth in an upper or lower jaw of the patient, and wherein the polymeric shell appliance is configured to move at least some of the patient 's teeth substantially to the modified tooth arrangement.

(JX-003 at R1:65-R2:14)

Respondents' Position: According to Respondents, Claim 21 of the '325 Patent is noteworthy, because it claims a method for fabricating a single appliance. Respondents say that because the prior art taught methods for fabricating polymeric appliances that formed a shell over the individual teeth using digitally modified teeth arrangements, this independent claim is anticipated by Lemchen and, as incorporated, Kesling for the reasons discussed above. Respondents say that Lemchen and Kesling disclose the third element of claim 21 because Kesling discloses a method for producing aligners by using a mechanical device to mold a polymeric material over the positive model of the intermediate tooth arrangements. (Citing CX-0944 at 3:65 – 4:70) Respondents reason that the incorporated disclosures of Kesling demonstrate methods for producing a series of polymeric shell dental appliances that are a negative of a positive model of modified tooth arrangements. Respondents say that Lemchen discloses methods that include controlling a fabrication machine. (Citing CX-0945 at 5:4 –8)

Respondents continue that Lemchen also describes the use of a "laboratory model of the tooth . . ." and as notes that while it referred to a single tooth, the invention "may be utilized with some or all of the teeth in a given arch . . . ." (Citing CX-0945 at 5:21 – 24) Respondents conclude that these statements expressly disclose the controlling of a fabrication machine to produce a positive model of a modified tooth arrangement based on the digital information generated.

Respondents assert that claim 21 does not include any limitation relating to a series of appliances. Respondents say that Lemchen discloses generating a repositioned tooth arrangement, such as a desired final tooth arrangement. (Citing CX-0945 at 2:54 – 63) Respondents continue that Lemchen discloses references that teach controlling a fabrication machine to make positive models of teeth. (Citing CX-0945 at 5:4 –8) Respondents say that Kesling discloses making a polymeric shell appliance as a negative of the positive models created using the disclosed methods. (Citing CX-0944 at 3:65 – 4:70) Respondents argue that these facts demonstrate that the Lemchen/Kesling reference anticipates this claim because there is no material difference between the claim and the prior art.

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of claim 1.

Analysis and Conclusions: Asserted claim 21 requires, *inter alia*:

> providing a digital data set representing a modified tooth arrangement for a patient, wherein the modified tooth arrangement comprises a repositioned tooth arrangement for a plurality of the patient's teeth;
>
> controlling a fabrication machine based on the digital data set to produce a positive model of the modified tooth arrangement;
>
> producing the polymeric shell dental appliance as a negative of the positive model . . . .

(JX-0003 at R2:1-9) As noted above regarding claim 1 in section IV.B.1.a, *supra*, Lemchen is limited to the idea of treating a patient with a single set of brackets, not with polymeric shell appliances. As a result, I find that Lemchen does not disclose the above quoted limitations of claim 21.

h. Claim 30

Claim 30 depends from claim 21 and teaches:

> A method as in claim 21, wherein the digital data set represents substantially accurate shapes of the patient's actual teeth in the modified tooth arrangement.

(JX-003 at R2:24-26)

Respondents' Position: Respondents argue that Lemchen discloses the subject matter of Claim 30. Respondents say that Lemchen specifically discloses that his method generates "accurate digital information" defining the teeth locations. (Citing CX-0945 at 2:55 –57)

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of claim 1.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 21 to be anticipated and invalid, I could still find that claim 30 is valid. Since, however, I have found claim 21 to be valid and ***not*** anticipated by Lemchen, claim 30 is necessarily valid, because it depends from claim 21 and necessarily contains all of the elements of claim 21. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 21 is anticipated by Lemchen, I would find that Respondents have shown by clear and convincing evidence that claim 30 of the '325 patent is anticipated by Lemchen with the incorporation of Kesling.

Lemchen discloses generating digital information that defines the shape and location of a malocclused tooth and determining the desired position of that tooth after treatment. (CX-945 at 1:56-62) Lemchen explains that the digital information defining the shape and location of the malocclused tooth is "accurate." (CX-945 at 2: 54-57) Thus, I find that Lemchen with the incorporation of Kesling, reveals that "the digital data set represents substantially accurate shapes of the patient's actual teeth in the modified tooth arrangement."

i. Claim 31

Claim 31 teaches:

> A method for facilitating a tooth repositioning dental treatment of a patient by use of a series of successive tooth positioning appliances, including producing a plurality of digital data sets representing a plurality of tooth arrangements and providing a plurality of the digital data sets to a fabrication operation for fabricating the treatment, said method comprising:
>
> providing an initial digital data set representing an initial tooth arrangement;
>
> presenting a visual image based on the initial data set;
>
> manipulating the visual image to reposition individual teeth in the visual image;
>
> producing a final digital data set representing the final tooth arrangement with repositioned teeth as observed in the image;
>
> producing a plurality of intermediate digital data sets representing a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement;
>
> and providing a plurality of the produced intermediate digital data sets to a fabrication operation to facilitate the tooth repositioning dental treatment of the patient with a series of successive tooth repositioning appliances.

(JX-003 at R2:27-50)

Respondents' Position: Respondents contend that Lemchen anticipates Claim 31 of the '325 Patent. Respondents say that the subject matter of the preamble and claim elements 1-5 of claim 31 are disclosed in the prior art as explained above. Respondents assert that claim element 6 is disclosed by Lemchen. Respondents say that Lemchen discloses the transfer of digital information between a practitioner and a dental lab, and the use of that digital information by the dental lab in its manufacturing process, "where the digitized information is utilized in the process of providing the practitioner with the required dental appliances for the correction of the malocclusion." (Citing CX-0945 at 5:15–20)

Respondents assert that claim 31 is directed to the fabrication of a series of successive tooth repositioning appliances and is not limited to aligners or removable appliances. Respondents say that Dr. Rekow opined that Lemchen taught "[f]ull three-dimensional modeling in orthodontic treatment planning . . . ." (Citing RX-0103C at 16) Respondents continue that Dr. Rekow opined that Lemchen taught a digital method of the physical method taught by Kesling. (Citing RX-0103C at 16.) Respondents argue that it is clear that Lemchen disclosed the transfer of digital information between a practitioner and a dental lab, and the use of that digital information by the dental lab in its manufacturing process, "where the digitized information is utilized in the process of providing the practitioner with the required dental appliances for the correction of the malocclusion." (Citing CX-0945 at 5:15 –20) Respondent argue that these facts demonstrate that the Lemchen/Kesling reference anticipates this claim because there is no material difference between the claim and the prior art.

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of claim 1.

Analysis and Conclusions: In section IV.B.1.a, *supra*, I find that the Lemchen reference only incorporates by reference Figures 1 and 3 of Kesling. I also find that because Lemchen only describes "generating digital information" regarding the initial "malocclused teeth," and then determining their respective "finish positions," Lemchen does not disclose "producing a plurality of intermediate digital data sets representing a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement," as required by claim 1. Additionally, I find that Lemchen discloses calculating position on the teeth for bracket placement, and completes moving teeth with traditional brackets and archwires, not polymeric shell appliances, and Lemchen's disclosure is limited to the idea of treating a patient with a single set of brackets, i.e. one bracket per tooth to be used over the entirely of the treatment. As a result, I find that Lemchen does not disclose "fabricating a plurality of successive tooth repositioning appliances, at least some of which are related to at least some of the produced digital data sets," as required by claim 1. I further found that the incorporation of Figures 1 and 3 of Kesling into Lemchen provides no greater insight into the teachings of the asserted claims, and assuming *arguendo* that one were to find that Lemchen incorporates all of Kesling by reference, the result would not change.

> Similar to claim 1, Claim 31 requires, *inter alia*,
>
> producing a plurality of intermediate digital data sets representing a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement[.]

(JX-003 at R2:43-46) As a result, and based on the findings discussed above, I find that Respondents have failed to prove by clear and convincing evidence that Lemchen discloses explicitly or inherently each and every limitation of claim 31.

j. Claim 32

Claim 32 depends from claim 31 and teaches:

> A method as in claim 31, wherein the produced digital data sets represent substantially accurate shapes of the patient's actual teeth.

(JX-003 at R2:51-53)

Respondents' Position: Respondents say that, as discussed above, Lemchen and Kesling disclose the subject matter of claim 32. Respondents allege that claim 32 is anticipated by Lemchen/Kesling because Lemchen specifically discloses that his method generates "accurate digital information" defining the teeth locations. (Citing CX-0945 at 2:55 –57) Respondents continue that these facts demonstrate that the Lemchen/Kesling reference anticipates this claim because there is no material difference between the claim and the prior art.

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of claim 1.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 31 to be anticipated and invalid, I could still find that claim 32 is valid. Since, however, I have found claim 31 to be valid and ***not*** anticipated by Lemchen, claim 32 is necessarily valid, because it depends from claim 31 and necessarily contains all of the elements of claim 31. *See In re Fritch,* 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 31 is anticipated by Lemchen, I would find that Respondents have shown by clear and convincing evidence that claim 32 of the '325 patent is anticipated by Lemchen with the incorporation of Kesling. Lemchen discloses generating digital information that defines the shape and location of a malocclused tooth and determining the desired position of that tooth after treatment. (CX-945 at

1:56-62) Lemchen explains that the digital information defining the shape and location of the malocclused tooth is "accurate." (CX-945 at 2: 54-57) Thus, I find that Lemchen with the incorporation of Kesling, reveals that "the produced digital data sets represent substantially accurate shapes of the patient's actual teeth."

k. Claim 33

Claim 33 depends from claim 31 and teaches:

> A method as in claim 31, further comprising fabricating a plurality of successive tooth repositioning appliances based on at least a plurality of said produced digital data sets provided to the fabrication operation.

(JX-003 at R2:54-57)

Respondents' Position: Respondents say that, as discussed above, Lemchen and Kesling disclose the subject matter of claim 33.

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of claim 1.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 31 to be anticipated and invalid, I could still find that claim 33 is valid. Since, however, I have found claim 31 to be valid and ***not*** anticipated by Lemchen, claim 33 is necessarily valid, because it depends from claim 31 and necessarily contains all of the elements of claim 31. *See In re Fritch,* 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 31 is anticipated by Lemchen, I would find that Respondents have not shown by clear and convincing evidence that claim 33 of the '325 patent is anticipated by Lemchen with the incorporation of Kesling.

In section IV.B.1.a, *supra*, I find that the Lemchen reference only incorporates by reference Figures 1 and 3 of Kesling. I also find that because Lemchen only describes "generating digital information" regarding the initial "malocclused teeth," and then determining their respective "finish positions," Lemchen does not disclose "producing a plurality of intermediate digital data sets representing a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement," as required by claim 1. Additionally, I find that Lemchen discloses calculating position on the teeth for bracket placement, and completes moving teeth with traditional brackets and archwires, not polymeric shell appliances, and Lemchen's disclosure is limited to the idea of treating a patient with a single set of brackets, i.e. one bracket per tooth to be used over the entirely of the treatment. As a result, I find that Lemchen does not disclose "fabricating a plurality of successive tooth repositioning appliances, at least some of which are related to at least some of the produced digital data sets," as required by claim 1. I further found that the incorporation of Figures 1 and 3 of Kesling into Lemchen provides no greater insight into the teachings of the asserted claims, and assuming *arguendo* that one were to find that Lemchen incorporates all of Kesling by reference, the result would not change.

Similar to claim 1, Claim 33 requires, *inter alia*,

> fabricating a plurality of successive tooth repositioning appliances based on at least a plurality of said produced digital data sets provided to the fabrication operation.

(JX-003 at R2:54-57) As a result, and based on the findings discussed above, I find that Respondents have failed to prove by clear and convincing evidence that Lemchen discloses explicitly or inherently each and every limitation of claim 33.

l. Claim 34

Claim 34 teaches:

> A method as in claim 33, wherein fabricating the successive tooth repositioning appliances comprises fabricating polymeric shell appliances.

(JX-003 at R2:58-60)

Respondents' Position: Respondents contend that Lemchen and Kesling disclose the subject matter of claim 34. Respondents aver that this claim element is similar to the element in Claim 21 of the '325 patent. Respondents say that Kesling teaches a method for producing aligners by using a mechanical device to mold a polymeric material over the positive model of the intermediate tooth arrangements. (Citing CX-0944 at 3:65 – 4:70) Respondents continue that Lemchen discloses methods that include controlling a fabrication machine. (Citing CX-0945 at 5:4 –8)

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of claim 1.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined both claims 31 and 33 to be anticipated and invalid, I could still find that claim 34 is valid. Since, however, I have found claims 31 and 33 to be valid and ***not*** anticipated by Lemchen, claim 34 is necessarily valid, because it depends from claim 31 via claim 33 and necessarily contains all of the elements of claims 31 and 33. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that claims 31 and 33 are anticipated by Lemchen, I would find that Respondents have not shown by clear and convincing evidence that claim 34 of the '325 patent is anticipated by Lemchen with the incorporation of Kesling. As

noted above regarding claim 1, Lemchen is limited to the idea of treating a patient with a single set of brackets, not with plural polymeric shell appliances. As a result, I find that Lemchen does not disclose the limitations of claim 34.

m. Claim 35

Claim 35 teaches:

> A method for fabricating a plurality of successive dental incremental position adjustment appliances, said method comprising:
>
> providing an initial digital data set representing an initial tooth arrangement;
>
> providing a final digital data set representing the final tooth arrangement;
>
> producing a plurality of successive digital data sets based on both of the previously provided initial and final digital data sets, wherein said plurality of digital data sets represent a series successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement;
>
> controlling a fabrication machine based on the successive digital data sets to produce successive positive models of the successive tooth arrangements; and
>
> producing the successive dental appliances as negatives of the positive models.

(JX-002 at R2:61-R3:11)

Respondents' Position: Respondents assert that Lemchen anticipates Claim 35 of the '325 Patent. Respondents say that the subject matter of the preamble and all claim elements are disclosed in the prior art as explained above.

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of claim 1.

Analysis and Conclusions: in section IV.B.1, *supra*, I find that the Lemchen reference only incorporates by reference Figures 1 and 3 of Kesling. I also find that because Lemchen

only describes "generating digital information" regarding the initial "malocclused teeth," and then determining their respective "finish positions," Lemchen does not disclose "producing a plurality of intermediate digital data sets representing a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement," as required by claim 1. Additionally, I find that Lemchen discloses calculating position on the teeth for bracket placement, and completes moving teeth with traditional brackets and archwires, not polymeric shell appliances, and Lemchen's disclosure is limited to the idea of treating a patient with a single set of brackets, i.e. one bracket per tooth to be used over the entirely of the treatment. As a result, I find that Lemchen does not disclose "fabricating a plurality of successive tooth repositioning appliances, at least some of which are related to at least some of the produced digital data sets," as required by claim 1. I further found that the incorporation of Figures 1 and 3 of Kesling into Lemchen provides no greater insight into the teachings of the asserted claims, and assuming *arguendo* that one were to find that Lemchen incorporates all of Kesling by reference, the result would not change.

Similar to claim 1, Claim 35 requires, *inter alia*,

> producing a plurality of successive digital data sets based on both of the previously provided initial and final digital data sets, wherein said plurality of digital data sets represent a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement;
>
> controlling a fabrication machine based on the successive digital data sets to produce successive positive models of the successive tooth arrangements; and
>
> producing the successive dental appliances as negatives of the positive models.

(JX-003 at R3:1-11) As a result, and based on the findings discussed above, I find that Respondents have failed to prove by clear and convincing evidence that Lemchen discloses explicitly or inherently each and every limitation of claim 35.

n. Claim 38

Claim 38 teaches:

> A method for fabricating a plurality of successive, polymeric shell, dental incremental position adjustment appliances for repositioning at least some of a patient's teeth, said method comprising:
>
> providing an initial digital data set representing substantially accurate shapes of the patient's actual teeth in an initial tooth arrangement;
>
> providing a final digital data set representing substantially accurate shapes of the patient's actual teeth in a final tooth arrangement;
>
> producing a plurality of successive digital data sets based on both of the previously provided initial and final digital data sets, wherein said plurality of digital datasets represents substantially accurate shapes of the patient's actual teeth in a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement;
>
> and fabricating a plurality of successive, polymeric shell, dental incremental position adjustment appliances based on at least some of the produced digital data sets.

(JX-003 at R3:21-R4:19)

Respondents' Position: Respondents contend that Lemchen anticipates also Claim 38 of the '325 Patent. Respondents say that the subject matter of the preamble and claim elements 1-4 of claim 38 are disclosed in the prior art as explained above.

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of claim 1.

Analysis and Conclusions: In section IV.B.1, *supra*, I find that the Lemchen reference only incorporates by reference Figures 1 and 3 of Kesling. I also find that because Lemchen

only describes "generating digital information" regarding the initial "malocclused teeth," and then determining their respective "finish positions," Lemchen does not disclose "producing a plurality of intermediate digital data sets representing a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement," as required by claim 1. Additionally, I find that Lemchen discloses calculating position on the teeth for bracket placement, and completes moving teeth with traditional brackets and archwires, not polymeric shell appliances, and Lemchen's disclosure is limited to the idea of treating a patient with a single set of brackets, i.e. one bracket per tooth to be used over the entirely of the treatment. As a result, I find that Lemchen does not disclose "fabricating a plurality of successive tooth repositioning appliances, at least some of which are related to at least some of the produced digital data sets," as required by claim 1. I further found that the incorporation of Figures 1 and 3 of Kesling into Lemchen provides no greater insight into the teachings of the asserted claims, and assuming *arguendo* that one were to find that Lemchen incorporates all of Kesling by reference, the result would not change.

Similar to claim 1, Claim 38 requires, *inter alia*,

> producing a plurality of successive digital data sets based on both of the previously provided initial and final digital data sets, wherein said plurality of digital data sets represents substantially accurate shapes of the patient's actual teeth in a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement; and
>
> fabricating a plurality of successive, polymeric shell, dental incremental position adjustment appliances based on at least some of the produced digital data sets.

(JX-003 at R4:8-19) As a result, and based on the findings discussed above, I find that Respondents have failed to prove by clear and convincing evidence that Lemchen discloses explicitly or inherently each and every limitation of claim 38.

o. Claim 39

Claim 39 depends from claim 38 and teaches:

> A method as in claim 38, wherein the appliances are fabricated based on individual ones of at least a corresponding plurality of the produced digital data sets.

(JX-003 at R4:20-22)

Respondents' Position: Respondents continue that the subject matter of claim 39 is disclosed by Lemchen and Kesling as explained above.

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of claim 1.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 38 to be anticipated and invalid, I could still find that claim 39 is valid. Since, however, I have found claim 38 to be valid and ***not*** anticipated by Lemchen, claim 39 is necessarily valid, because it depends from claim 38 and necessarily contains all of the elements of claim 38. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that claim 38 is anticipated by Lemchen, I would find that Respondents have shown by clear and convincing evidence that claim 39 of the '325 patent is anticipated by Lemchen with the incorporation of Kesling.

Claim 38 teaches "fabricating a plurality of successive, polymeric shell, dental incremental position adjustment appliances based on at least some of the produced digital data sets." (JX-002 at R4:16-19) Assuming, *arguendo*, that Lemchen disclosed this limitation, because this limitation discusses fabricating appliances based on the produced digital data sets, Lemchen would necessarily disclose fabricated based on individual ones of at least a

corresponding plurality of the produced digital data sets. As a result, I find that if claim 38 were anticipated by Lemchen, claim 39 would be anticipated by Lemchen.

2. Obviousness

a. Claim 1

Respondents' Position: Respondents assert that Align's expert in a previous litigation, Dr. Rekow, stated that:

> The evolution of computers in the 1970s and 1980s enticed many inventors to explore dental and orthodontic applications using and manipulating digital data. Ideas that were explored, as seen below were demonstrated, included opportunities where manual manipulations were automated. The time consuming manipulation of plaster casts to model orthodontic treatment options was replaced by systems that modeled multiple combinations of tooth movement, permitting the clinician to choose the most ideal. Labor-intensive design and fabrication of dental restorations was replaced by computer-aided design and manufacturing systems to speed delivery . . . .

RX-103C at 2. Respondents contend that the related nature of the subject matters and the problems addressed made the combination obvious. Respondents continue that this is especially true given the internal references between Lemchen and Kesling. Respondents assert that Dr. Rekow also stated that the Lemchen reference and the Kesling reference were combined based on her analysis of the references in the Lemchen patent. Respondents say that Dr. Rekow's report states that Lemchen's methods for digital 3-D modeling was a representation of Kesling's physical 3-D modeling. (Citing RX-103C at 16) Respondents argue that each asserted claim is obvious in light of the identified prior art references with the knowledge of one of ordinary skill.

Respondents assert that the preamble of claim 1 is obvious in light of the prior art references. Respondents say Align previously recognized that:

> Capitalizing on work of the dental CAD/CAM systems, Lemchen describes approaches [that] acquire data, automatically determine . . . ideal position for an individual patient, design . . . configuration to conform to

> the orthodontic treatment to be undertaken for an individual patient, and use numerically controlled systems to shape . . . that design.

(Citing RX-0102C at 6) Respondents continue that Align contended in that litigation that "the idea of fabricating custom appliances," for orthodontic treatment "was not new in 1990." (Citing RX-0102C at 7) Respondents say that this evidence shows the knowledge of one skilled in the art. Respondents say that combined with the disclosures of the prior art identified in the anticipation section addressing the preamble to Claim 1 of the '325 patent, the preamble is obvious.

Respondents say that Lemchen discloses that the "repositioning is done mathematically by appropriate software programs which may be derived by conventional means . . . ." (Citing CX-0945 at 2:66 – 3:6) Respondents assert that one skilled in the art would understand this to mean that the tooth path between the initial and final positions would be determined and then the tooth positions for each segment representing the successive stages of treatment would be determined by interpolation or a method for calculating movements of incremental equal sizes. (Citing RX-0113C at Q. 59) Respondents say that it is uncontroverted that interpolation is a conventional mathematical means for determining positional differences. (Citing RX-0113C at Q. 59)

Respondents say that Dr. Lemchen also expressly incorporated the disclosure of Kesling to explain his 3-D modeling methodology. (Citing CX-0945 at 3:36 – 40) Respondents conclude that Lemchen stated that FIG. 3 was one example of a repositioned tooth arrangement. Respondents say that one skilled in the art would understand that this same method would apply equally to the intermediate or successive tooth arrangements that are described in Kesling. (Citing RX-0113C at Q. 48) Respondents aver that the methodology is the same for all successive tooth arrangements from the initial position to the final position. (Citing RX-0113C

at Q. 48) Respondents add that intermediate or successive tooth arrangements are inherent in tooth modeling. (Citing RX-0113C at Q. 48) Respondents explain that one cannot model tooth movement accurately without including the intermediate steps. (Citing RX-0113C at Q. 48)

Respondents say that the figures in Kesling demonstrate that a "tooth positioning appliance," similar to an aligner, was disclosed. (Citing CX-0944 at Fig. 7) Respondents continue that Kesling expressly discloses: intermediate or successive models representing tooth positions, the use and fabrication of a series of dental appliances, using a machine to fabricate a series of dental appliances by producing a positive model of a tooth arrangement. (Citing RX-0113C at Q. 33)

Respondents assert that Dr. Lemchen discloses methods that include controlling a fabrication machine. (Citing CX-0945 at 5:4–8) Respondents say that the inventors also describe the use of a "laboratory model of the tooth ..." and as described above, the inventors expressly noted that while they referred to a single tooth, their invention "may be utilized with some or all of the teeth in a given arch . . . ." (Citing CX-0945 at 5:21 – 24) Respondents contend that these statements expressly disclose the controlling of a fabrication machine to produce a positive model of a modified tooth arrangement based on the digital information generated. (Citing RX-0113C at Q. 43)

Respondents assert that Nahoum also taught methods for fabricating series of successive aligners in the 1960s. Respondents say that Dr. Nahoum taught methods for fabricating a series of aligners by vacuum forming thermoplastics over positive models. (Citing RX-0096) Respondents continue that one skilled in the art would understand, in light of this reference, the following subject matter: an initial tooth arrangement; a projected final tooth arrangement;

intermediate or successive tooth positions; the use or fabrication of a series of dental appliances; and producing a positive model of a tooth arrangement. (Citing RX-0113C at Q. 88-89)

Respondents assert that Dr. Lemchen expressly stated that the three-dimensional modeling methods, using software, "may be derived by conventional means for the particular method of treatment elected by the orthodontist." (Citing CX-0945 at 3:25 – 26) Respondents say that Lemchen similarly stated in the detailed description that there "are a number of methods of treatment commonly used by the orthodontist." (Citing CX-0945 at 3:43 – 46) Respondents conclude that Lemchen expressly recognizes that its methods may be used with different types of orthodontic treatment and one skilled in the art would understand that other treatment methods, such as the aligner treatment method disclosed in Kesling could be used with the digital methods disclosed in Lemchen. (Citing RX-0113C at Q. 49)

Respondents argue that one skilled in the art would understand that the methods of Kesling were not limited to brackets (which are custom fabricated in the disclosed methods to conform to the surface of the teeth) and arch wires. (Citing RX-0113C at Q. 49) Rather, Respondents assert that the incorporation of the disclosures of Kesling and the other statements concerning other treatment methods makes it clear that methodology disclosed in Lemchen applies beyond brackets and archwires. (Citing RX-0113C at Q. 49) Respondents say that Kesling disclosures are limited to methods for making polymeric shell appliances based on a series of three-dimensional tooth models. (Citing RX-0113C at Q. 49) Respondents contend that one skilled in the art would understand the incorporation of Kesling to mean that the methods of Lemchen would apply to polymeric shell appliances, the orthodontic appliance expressly described in Kesling. (Citing RX-0113C at Q. 49) Respondents conclude that one

skilled in the art would also understand that the modeling of teeth movement is the same, regardless of the type of orthodontic appliance used. (Citing RX-0113C at Q. 51)

Respondents say that Dr. Lemchen also disclosed the transfer of digital information between a practitioner and a dental lab, and the use of that digital information by the dental lab in its manufacturing process, "where the digitized information is utilized in the process of providing the practitioner with the required dental appliances for the correction of the malocclusion." (Citing CX-0945 at 5:15 –20) Respondents assert that these disclosures render the claim obvious.

Align's Position: Align asserts that Respondents' *Prehearing Brief* raises obviousness, but does not identify which claims are allegedly obvious. Align concludes that any obviousness contentions are waived. Respondents say that a *prima facie* showing requires clear and convincing evidence that: a particular combination of prior art discloses all elements of a claim; and one of ordinary skill in the art would have some reason to make the combination. Align argues that Respondents' evidence fails on both requirements for every asserted claim.

Align says that Respondents generally refer to a combination of Lemchen, Kesling, and "the knowledge of one of ordinary skill in the art." Align argues that this combination fails to disclose all elements of any of the asserted claims. Align says that Respondents' Prehearing Brief did not identify any other combinations with particularity; rather, Respondents simply presented a "jumble of references," which the presiding ALJ recognized is insufficient to identify a combination. (Citing Tr. at 652:8-13) Align concludes that any other combinations are waived. Align asserts that none of the prior art, in ***any*** combination, discloses all elements of any of the asserted claims.

Align contends that there is no evidence that one of ordinary skill in the art at the time of the inventions would have been motivated to combine ***any*** of the identified references in ***any*** manner. Align says that Respondents refused, throughout this Investigation, to identify particular motivations to combine and I limited Respondents to motivations purportedly identified by the Rekow reports of November 10, 2008 (RX-0103C) and May 18, 2004 (RX-0102C) (the use of which was also limited to "showing that prior inconsistent positions were taken by Align in previous litigation"). (Citing Tr. at 16:19-17:23; 20:5-21:21) Align continues that these reports provide no motivation to combine the prior art asserted here, and I noted that Respondents face an "uphill struggle" to identify any motivation to combine specific references within these reports. (Citing Tr. at 16:19-17:23)

Align argues that the evidence shows that one of ordinary skill in the art would ***not*** have been motivated to combine prior art directed to removable appliances (*e.g.*, Kesling) with prior art directed to fixed appliances (*e.g.*, Lemchen) because the knowledge and understanding of the capabilities of these different types of appliances was vastly different. (Citing CX-1247C at Q. 165-166, 280-281, 318-319, 349-350, 427-428, 452-453, 577; CX-1254C ¶ 77 at 27-28, ¶ 121 at 47)

Align disagrees with Respondents' argument that all of the asserted claims of the '325 patent are obvious in view of the combination of: (i) Lemchen; (ii) Kesling; and (iii) "the knowledge of one of ordinary skill in the art." Align says that Respondents' argument fails because this particular combination was disclosed for the first time in the *JSCI*, as explained in Align's *Motion in Limine No. 4*, and is therefore improperly raised now. Align continues that the argument is unsupported because no claim charts showing this assertion in detail are in evidence. Align adds that these references, in any combination, fail to disclose all the elements of any

asserted claim, as discussed above. Align continues that one of ordinary skill in the art at the time of the invention would not have been motivated to combine a reference directed to fixed appliances made of brackets and wires (Lemchen) with a reference directed to removable appliances (Kesling). Align says that secondary considerations support a finding of non-obviousness.

Align asserts that Respondents waived any obviousness defense under GR 8.2 because their *Prehearing Brief* did not specify, *inter alia*, which asserted claims they contend are obvious. (Citing RPHB at 48-67, 98-106, 128-136, 146-154, 175-183, 205-217, 240-248) Align says that the record is devoid of evidence supporting obviousness.

Align asserts that Respondents fail to even identify what combination of prior art they rely on for each asserted claim; rather, consistent with their practice throughout the Investigation, Respondents simply present a jumble of prior art references and occasionally a conclusory statement such as, "[t]his claim is thus obvious" or "[t]his independent claim is obvious in light of the identified prior art with the knowledge of one of ordinary skill in the art." Align says that Respondents also fail to contend that certain claims are obvious at all, including for example, for claim 14 of the '325 patent, where Respondents simply state:

> Mr. Beers identifies common evidence that he contends covers this limitation as Evidence Category 7. CX-1150C at Q. 198. Respondents incorporate Disclosure Category 7 with the knowledge of one of ordinary skill as described addressing Claim 1 of the '325.

(Citing RIB at 68)

Align says that Respondents only cursorily address motivation for their obviousness positions, citing 2 pages from RX-103C that fail to discuss any motivation. (Citing RIB at 62) Align says that this position is also waived under GR 8.2 because it was not specified in Respondents' *Prehearing Brief*. Align continues that Respondents do not assert that there was a

motivation to combine any specific prior art other than Lemchen and Kesling. Align adds that Respondents fail to rebut the evidence showing that one of ordinary skill in the art would not have combined Lemchen and Kesling. (Citing CX-1247C at Q. 165-166, 280-281, 318-319, 349-350, 427-428, 452-453, 577; CX-1254C ¶ 77 at 27-28, ¶ 121 at 47.)

Align says that Respondents improperly rely on the Federal Circuit's decision in *Ormco I*, which addressed different patents and unrelated claims. (Citing *In re Dillon*, 892 F.2d 1554, 1565 (Fed. Cir. 1989)) Align continues that Respondents improperly rely on *Ormco I*'s discussion of prior art devices made by Dr. Truax that are not in evidence here.

Align asserts that the *Ormco II* opinion only provides Ormco inventors' characterizations of Lemchen, in the form of statements made during the prosecution of an Ormco patent. (Citing *Ormco II*, 498 F.3d at 1314-15) Align explains that the Federal Circuit does not adopt these characterizations of Lemchen, but merely references them in the context of construing Ormco's patent claims.

Align says that Respondents improperly rely on Dr. Rekow's Reports from the *Ormco* litigation because Respondents failed to show that prior statements ***by Dr. Rekow***, an independent expert, are attributable to Align. Align says that I ruled that the Rekow Reports "will not be accepted as expert testimony" here. (Citing Tr. at 20:5-21:21) Align concludes that Respondents cannot use the Reports to bolster their invalidity theories. Alternatively, Align says that the Reports do not support Respondents' contentions regarding the prior art. Align says that the cited portions of RX-0102C simply confirm that Lemchen is directed to a fixed appliance that includes brackets. (Citing RX-0102C at 7-8)

Align says that Respondents reference Nahoum in regards to claim 1 of the '325 patent (Citing RIB at 64-65) Align contends that any obviousness combination involving Nahoum has been waived because it was not disclosed in Respondents' PreHearing Brief.

Staff's Position: Staff says that in view of my ruling precluding Respondents from relying on any claim charts disclosing combinations of prior art that allegedly render the Asserted Claims of the '325 patent (or any Asserted Patent) invalid for obviousness (citing Tr. at 19:11-25), the record is devoid of any evidence showing clearly and convincingly how and where any combination of prior art discloses each and every element of the Asserted Claims of the '325 patent (and the other patents in suit).

Staff contends that even if Respondents were to argue that the combination of Lemchen with Kesling (and the knowledge of one of ordinary skill) renders the Asserted Claims of the '325 patent (and the other patents in suit) invalid for obviousness, Respondents cannot meet their burden of clear and convincing evidence. Staff says that, like the testimony alleging anticipation, the testimony alleging obviousness provided by Dr. Mah is merely conclusory. (Citing RX-0113C at Q. 114-121) Staff concludes, as a result, that Dr. Mah's testimony does not cure the lack of any claim charts (or other evidence) explaining clearly and convincingly how and where the combination of Lemchen with Kesling (and the knowledge of one of ordinary skill) disclose, teach, or suggest each and every element of the asserted claims of the '325 patent (or any of the other patents in suit). Staff says that, in sum, there is a lack of evidence demonstrating clearly and convincingly that any of the asserted claims of the '325 patent (or the other patents in suit) are rendered invalid for obviousness by the combination of Lemchen with Kesling (and the knowledge of one of ordinary skill).

Analysis and Conclusions: Respondents have asserted two separate combinations in post-hearing briefing—Lemchen, Kesling, and the knowledge of one of ordinary skill in the art and Lemchen, Kesling, Nahoum, and the knowledge of one of ordinary skill in the art.

I note that while Respondents do mention "knowledge of one of ordinary skill in the art" in RPHB, section 3.5.2.2, their references in that pre-hearing brief amount to a general discussion of eleven separate references with no element by element discussion of how those eleven references would combine to render the asserted claims of the '325 patent obvious. There is only a general reference to a "claim chart" that Respondents say they will produce at the hearing. This is inadequate to provide notice to Align regarding the specific prior art to be addressed and the manner in which the prior art discloses each and every element of an asserted claim. (RPHB at 60-67) As a result, at the hearing I granted Align's motion *in limine* number 6, and excluded the claim charts that were not specifically cited in Respondents' prehearing brief as required by Ground Rule 8.2. (Tr. 18:13-20:4)

Although Respondents discussed eleven different prior art references in RPHB section 3.5.2.2, Respondents failed to identify any specification combinations of prior art references other than Lemchen, Kesling, and the knowledge of one of ordinary skill in the art. (RPHB at 49). Ground Rule 8.2 states "[a]ny contentions not set forth in detail as required herein shall be deemed abandoned or withdrawn, except for contentions of which a party is not aware and could not be aware in the exercise of reasonable diligence at the time of filing the pre-trial brief." Because Respondents did not identify any specific combinations other than Lemchen, Kesling, and the knowledge of one of ordinary skill in the art, any other combinations, including Nahoum with Lemchen, Kesling, and the knowledge of one of ordinary skill in the art, were waived.

In order to prevail on their argument that claim 1 of the'325 patent is invalid as obvious,

Respondents must first demonstrate that the combination of Lemchen, either alone or in combination with Kesling discloses all of the limitations of the claim 1. (*Hearing Components, Inc. v. Shure Inc.*, 600 F.3d 1357, 1373-1374 (Fed. Cir. 2010); and *Velander v. Garner*, 348 F.3d 1359, 1363 (Fed. Cir. 2003))

Equally important is the requirement that the Respondents establish by clear and convincing evidence that a person of ordinary skill in the art would have had reason to combine the various asserted prior art references to attempt to produce the invention and would have had a reasonable expectation of success in doing so. (See *PharmaStem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007))

Assuming, *arguendo*, that Respondents had properly disclosed their arguments based on the combination of Lemchen, Kesling, Nahoum, and the knowledge of one or ordinary skill in the art in their pre-hearing brief, there is nothing in the evidence submitted by Respondents to support a finding that a PHOSITA would be motivated by anything in Lemchen, Kesling or Nahoum to follow the methods in the '325 patent. In section IV.B.1, *supra*, I noted that even if I had found that Lemchen incorporated the ***entirety*** of Kesling by reference, those two references taken together would still not disclose each and every element of the claim 1 of the '325 patent. Based upon that finding, it follows that Lemchen combined with Kesling would not render obvious asserted claim 1 of the '325 patent.

Respondents' evidence regarding the knowledge of one of ordinary skill in the art would not fill the gaps in Lemchen and Kesling. Respondents' evidence is limited to expert reports of a former expert for Align (RX-102C and RX-103C) and the opening witness statement of Dr. Mah. At the prehearing conference, I ruled that that Dr. Rekow's expert reports (RX-102C and RX-103C) could be used solely to show that Align took an inconsistent position in the prior

litigation. (Tr. at 20:24-21:7) Here, Respondents are improperly attempting to rely on the expert reports to show the knowledge of one of ordinary skill in the art. The testimony of Dr. Mah is not helpful on this subject because he expresses a series of conclusory opinions without citing to evidentiary support. (*See, e.g.*, RX-113C, Qs. 100, 113-121)

Focusing on the motivation to combine references, I find that the mention of Kesling in Lemchen would be adequate to cause a PHOSITA to consider both references in combination. Respondents do not, however, provide any basis for combining Nahoum with the Lemchen and Kesling references.

Notwithstanding the foregoing, examining Nahoum in combination with Lemchen and Kesling, I find that Nahoum does not provide the elements missing from the Lemchen and Kesling references. Lemchen does not in any way disclose, or hint at, designing or fabricating intermediate or successive tooth repositioning appliances based on digital data sets. Lemchen's disclosure is limited to the idea of treating a patient with a single set of brackets, i.e. one bracket per tooth to be used over the entirely of the treatment.

Kesling "does not disclose, or teach or suggest, or even remotely contemplate" the use of computers or digital technology. Kesling describes making tooth arrangements by (i) using a plaster mold of teeth, (ii) dissecting the plaster teeth with a saw, and (iii) reassembling the plaster teeth in wax into their assumed positions. (CX-944, 3:13-22; 3:30-43; 3:61-64)

Kesling does not expressly or inherently disclose, or teach or suggest, fabricating a dental appliance based on a digital data set. Rather, Kesling discloses manually making an appliance using tools, supplies, and materials, including, inter alia, (i) articulating the plaster cast; (ii) taking an impression of the teeth of the plaster cast, and (iii) making a mold filled with the appliance material. (CX-944, 3:65-4:58)

The Nahoum reference is an article reprinted from the New York State Dental Journal, Vol. 20, No. 9, pp. 385-390 (November, 1964). It describes a method for constructing dental appliances by vacuum forming thermoplastics using plaster model(s) of a patient's teeth. Nahoum says that the appliance can be fabricated to move teeth. The Nahoum method contemplates a plaster model of a patient's teeth, cutting the teeth from the model with a saw or fissure burr, repositioning the teeth into the model using wax, and vacuum forming the appliance over the altered model. (RX-096, ALGN0001447) Nahoum includes a description of making an adjustment in two or more phases in which partial and progressive adjustments are made in each appliance. (RX-096, ALGN0001448) Nahoum does not in any way disclose use of computers or digital data to assist in fabricating a dental appliance.

Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of asserted claim 1 of the '325 patent are present in Lemchen, either alone or in combination with Kesling, and Nahoum, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine the those references to create the method claimed in the invention of the '325 patent.

b. Claim 2

Respondents' Position: Respondents assert that dependent claim 2 is obvious in light of the identified prior art discussed above and the knowledge of one of ordinary skill in the art. Respondents say that the disclosures of Lemchen demonstrate that a digital data set representing an initial tooth arrangement is generated by scanning a model of the patient's teeth (Citing CX-0945 at 2:54 – 63)

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of claim 1.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 1 to be rendered obvious by the asserted prior art and invalid, I could still find that claim 2 is valid. Since, however, I have found claim 1 to be valid and ***not*** rendered obvious by Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, claim 2 is necessarily valid, because it depends from claim 1 and necessarily contains all of the elements of claim 1. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 1 is rendered obvious by by Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, I would find that Respondents have failed to show by clear and convincing evidence that claim 2 of the '325 patent is rendered obvious by that combination.

In section IV.B.1.b, *supra*, I found that Lemchen does not reveal generating the initial data regarding malocclused teeth from a physical model of the patient's teeth as shown in Kesling. In the interest of brevity, I will not repeat the discussion in section IV.B.1.b in its entirety; but I reaffirm that finding and the rationale for it.

Nahoum and the knowledge of one of ordinary skill in the art do not fill these gaps. Nahoum does not in any way disclose use of computers or digital data to assist in fabricating a dental appliance. Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of asserted claim 2 of the '325 patent are present in Lemchen combined with Kesling, Nahoum, and the knowledge of one of ordinary skill in the art, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine those references to create the method claimed in asserted claim 2 of the '325 patent.

c. Claim 3

Respondents' Position: Respondents assert that dependent claim 3 is obvious in light of the identified prior art discussed above and the knowledge of one of ordinary skill in the art. Respondents say that Align successfully argued to the Federal Circuit that one skilled in the art would understand that Lemchen disclosed manipulating visual images to reposition individual teeth in the visual image. (Citing *Ormco II at* 498 F.3d 1315)

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of claim 1.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claims 1 and 2 to be rendered obvious by the asserted prior art and invalid, I could still find that claim 3 is valid. Since, however, I have found claims 1 and 2 to be valid and ***not*** rendered obvious by Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, claim 3 is necessarily valid, because it depends from claim 1 via claim 2 and necessarily contains all of the elements of claims 1 and 2. *See In re Fritch,* 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that claims 1 and 2 are rendered obvious by Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, I would find that Respondents have shown by clear and convincing evidence that claim 3 of the '325 patent is rendered obvious by that combination.

In section IV.B.1.c, *supra*, I found that if Lemchen anticipated claims 1 and 2, it would also anticipate claim 3. As a result, assuming arguendo that claims 1 and 2 are obvious over Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, I would find that

claim 3 is obvious based on the rationale discussed in section IV.B.1.c.

d. Claim 11

Respondents' Position: Respondents assert that claim 11 is obvious in light of the identified prior art discussed above and the knowledge of one of ordinary skill in the art. Respondents say that the subject matter of the preamble is disclosed in the prior art, as explained regarding claim 1. Respondents say that Kesling discloses the manufacture and use of a plurality of appliances, each appliance in the series representing intermediate or successive tooth positions. (Citing CX-0944 at 2:50–3:1) Respondents continue that Kesling describes the necessity of making a plurality of appliances as "obviously" necessary. (Citing CX-0944 at 2:50–3:1) Respondents add that Lemchen discloses methods that include controlling an appliance fabrication machine. (Citing CX-0945 at 5:4–8) Respondents continue that the inventors also describe the use of a "laboratory model of the tooth . . ." and as described above, the inventors expressly noted that while they referred to a single tooth, their invention "may be utilized with some or all of the teeth in a given arch . . . ." (Citing CX-0945 at 5:21–24) Respondents conclude that these statements expressly disclose the controlling of a fabrication machine to produce a positive model of a modified tooth arrangement based on the digital information generated in order to produce appliances and claim 11 is thus obvious.

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of claim 1.

Analysis and Conclusions: In Section IV.B.2.a, *supra*, I find that Respondents' prehearing brief does not provide notice to Align regarding the specific prior art to be addressed and the manner in which the prior art discloses each and every element of an asserted claim and although Respondents discussed eleven different prior art references in RPHB section 3.5.2.2,

Respondents failed to identify any specification combinations of prior art references other than Lemchen, Kesling, and the knowledge of one of ordinary skill in the art and any other combinations, including Nahoum with Lemchen, Kesling, and the knowledge of one of ordinary skill in the art, were waived.

Assuming, *arguendo*, that Respondents had properly disclosed their arguments based on the combination of Lemchen, Kesling, Nahoum, and the knowledge of one or ordinary skill in the art in their pre-hearing brief, there is nothing in the evidence submitted by Respondents to support a finding that a PHOSITA would be motivated by anything in Lemchen, Kesling or Nahoum to follow the methods in the '325 patent. In section IV.B.1, *supra*, I noted that even if I had found that Lemchen incorporated the ***entirety*** of Kesling by reference, those two references taken together would still not disclose each and every element of the claim 11 of the '325 patent. Based upon that finding, it follows that Lemchen combined with Kesling would not render obvious asserted claim 11 of the '325 patent.

Respondents' evidence regarding the knowledge of one of ordinary skill in the art would not fill the gaps in Lemchen and Kesling. Respondents' evidence is limited to expert reports of a former expert for Align (RX-102C and RX-103C) and the opening witness statement of Dr. Mah. At the prehearing conference, I ruled that that Dr. Rekow's expert reports (RX-102C and RX-103C) could be used solely to show that Align took an inconsistent position in the prior litigation. (Tr. at 20:24-21:7) Here, Respondents are improperly attempting to rely on the expert reports to show the knowledge of one of ordinary skill in the art. The testimony of Dr. Mah is not helpful on this subject because he expresses a series of conclusory opinions without citing to evidentiary support. (*See, e.g.*, RX-113C, Qs. 100, 113-121)

Focusing on the motivation to combine references, I find that the mention of Kesling in

Lemchen would be adequate to cause a PHOSITA to consider both references in combination. Respondents do not, however, provide any basis for combining Nahoum with the Lemchen and Kesling references.

In Section IV.B.1.a, *supra*, I find that Lemchen does not disclose, or teach or suggest, calculating positions-in-between an initial data set and a final data set. In Section IV.B.2.a, *supra*, I find that Lemchen does not in any way disclose, or hint at, designing or fabricating intermediate or successive tooth repositioning appliances based on digital data sets. Lemchen's disclosure is limited to the idea of treating a patient with a single set of brackets, i.e. one bracket per tooth to be used over the entirely of the treatment. In Section IV.B.1.a, *supra*, I find that Kesling contemplated a reactive process, performed one step at a time, where appliances beyond a first appliance may be created by repeating the disclosed process for making the first appliance. In Section IV.B.2.a, *supra*, I also find that Kesling "does not disclose, or teach or suggest, or even remotely contemplate" the use of computers or digital technology and does not expressly or inherently disclose, or teach or suggest, fabricating a dental appliance based on a digital data set. Additionally, in Section IV.B.2.a, *supra*, I find that Nahoum does not in any way disclose use of computers or digital data to assist in fabricating a dental appliance. I reaffirm and incorporate these findings and rationales here.

Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of asserted claim 11 of the '325 patent are present in Lemchen, either alone or in combination with Kesling, and Nahoum, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine the those references to create the method claimed in the invention of the '325 patent.

e. **Claim 13**

Respondents' Position: Respondents assert that the subject matter of claim 13 is obvious for the reasons discussed above.

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of claim 1.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 11 to be rendered obvious by the asserted prior art and invalid, I could still find that claim 13 is valid. Since, however, I have found claim 11 to be valid and ***not*** rendered obvious by Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, claim 13 is necessarily valid, because it depends from claim 11 and necessarily contains all of the elements of claim 11. *See In re Fritch,* 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 11 is rendered obvious by Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, I would find that Respondents have failed to show by clear and convincing evidence that claim 13 of the '325 patent is rendered obvious by that combination.

In section IV.B.1.e, *supra*, I found that although Lemchen teaches generating a digital data set representing teeth in their "final" position (*see* CX-945 at 1:55-2:1; 2:54-57; 3:16-24), Lemchen does not disclose the specific details of how this would be accomplished (*see* CX-945 at 3:44-54). In the interest of brevity, I will not repeat the discussion in section IV.B.1.e in its entirety; but I reaffirm that finding and the rationale for it.

Nahoum and the knowledge of one of ordinary skill in the art do not fill these gaps. Nahoum does not in any way disclose use of computers or digital data to assist in fabricating a

dental appliance. Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of asserted claim 13 of the '325 patent are present in Lemchen combined with Kesling, Nahoum, and the knowledge of one of ordinary skill in the art, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine those references to create the method claimed in asserted claim 13 of the '325 patent.

f. Claim 14

Respondents' Position: Respondents assert that the subject matter of claim 14 is obvious for the reasons discussed above.

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of claim 1.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 11 to be rendered obvious by the asserted prior art and invalid, I could still find that claim 14 is valid. Since, however, I have found claim 11 to be valid and ***not*** rendered obvious by Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, claim 14 is necessarily valid, because it depends from claim 11 and necessarily contains all of the elements of claim 11. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 11 is rendered obvious by Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, I would find that Respondents have failed to show by clear and convincing evidence that claim 14 of the '325 patent is rendered obvious by that combination.

In section IV.B.1.f, *supra*) Although Lemchen teaches generating a digital data set

representing teeth in their "final" position (*see* CX-945 at 1:55-2:1; 2:54-57; 3:16-24), Lemchen does not disclose the specific details of how this would be accomplished, and does not discuss interpolating differences between an initial position and a final position (*see* CX-945 at 3:44-54). In the interest of brevity, I will not repeat the discussion in section IV.B.1.f in its entirety; but I reaffirm that finding and the rationale for it.

Nahoum and the knowledge of one of ordinary skill in the art do not fill these gaps. Nahoum does not in any way disclose use of computers or digital data to assist in fabricating a dental appliance. Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of asserted claim 14 of the '325 patent are present in Lemchen combined with Kesling, Nahoum, and the knowledge of one of ordinary skill in the art, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine those references to create the method claimed in asserted claim 14 of the '325 patent.

g. Claim 21

Respondents' Position: Respondents assert that claim 21 is noteworthy because it claims a method for fabricating a single appliance. Respondents continue that, as explained above regarding claim 1, because the prior art taught methods for fabricating polymeric appliances that formed a shell over the individual teeth using digitally modified teeth arrangements, this independent claim is obvious in light of the prior art references with the knowledge of one of ordinary. Respondents say that Kesling teaches a method for producing aligners by using a mechanical device to mold a polymeric material over the positive model of the intermediate tooth arrangements. (Citing CX-0944 at 3:65 – 4:70) Respondents continue that the incorporated disclosures of Kesling demonstrate methods for producing a series of

polymeric shell dental appliances that are a negative of a positive model of modified tooth arrangements. Respondents add that Lemchen discloses methods that include controlling a fabrication machine to provide a "machined" base conforming to tooth morphology. (Citing CX-0945 at 5:4–8) Respondents say that this and similar statements identified above expressly disclose the controlling of a fabrication machine to produce a positive model of a modified tooth arrangement based on digital data.

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of claim 1.

Analysis and Conclusions: In Section IV.B.2.a, *supra*, I find that Respondents' prehearing brief does not provide notice to Align regarding the specific prior art to be addressed and the manner in which the prior art discloses each and every element of an asserted claim and although Respondents discussed eleven different prior art references in RPHB section 3.5.2.2, Respondents failed to identify any specification combinations of prior art references other than Lemchen, Kesling, and the knowledge of one of ordinary skill in the art and any other combinations, including Nahoum with Lemchen, Kesling, and the knowledge of one of ordinary skill in the art, were waived.

Assuming, *arguendo*, that Respondents had properly disclosed their arguments based on the combination of Lemchen, Kesling, Nahoum, and the knowledge of one or ordinary skill in the art in their pre-hearing brief, there is nothing in the evidence submitted by Respondents to support a finding that a PHOSITA would be motivated by anything in Lemchen, Kesling or Nahoum to follow the methods in the '325 patent. In section IV.B.1, *supra*, I noted that even if I had found that Lemchen incorporated the ***entirety*** of Kesling by reference, those two references taken together would still not disclose each and every element of the claim 21 of the '325 patent. Based upon

that finding, it follows that Lemchen combined with Kesling would not render obvious asserted claim 21 of the '325 patent.

Respondents' evidence regarding the knowledge of one of ordinary skill in the art would not fill the gaps in Lemchen and Kesling. Respondents' evidence is limited to expert reports of a former expert for Align (RX-102C and RX-103C) and the opening witness statement of Dr. Mah. At the prehearing conference, I ruled that that Dr. Rekow's expert reports (RX-102C and RX-103C) could be used solely to show that Align took an inconsistent position in the prior litigation. (Tr. at 20:24-21:7) Here, Respondents are improperly attempting to rely on the expert reports to show the knowledge of one of ordinary skill in the art. The testimony of Dr. Mah is not helpful on this subject because he expresses a series of conclusory opinions without citing to evidentiary support. (*See, e.g.*, RX-113C, Qs. 100, 113-121)

Focusing on the motivation to combine references, I find that the mention of Kesling in Lemchen would be adequate to cause a PHOSITA to consider both references in combination. Respondents do not, however, provide any basis for combining Nahoum with the Lemchen and Kesling references.

Notwithstanding the foregoing, examining Nahoum in combination with Lemchen and Kesling, I find that Nahoum does not provide the elements missing from the Lemchen and Kesling references. In Section IV.B.2.a, *supra*, I find that Lemchen does not in any way disclose, or hint at, designing or fabricating intermediate or successive tooth repositioning appliances based on digital data sets. I also find that Kesling "does not disclose, or teach or suggest, or even remotely contemplate" the use of computers or digital technology and does not expressly or inherently disclose, or teach or suggest, fabricating a dental appliance based on a digital data set. Additionally, I find that Nahoum does not in any way disclose use of computers

or digital data to assist in fabricating a dental appliance. I reaffirm and incorporate these findings and rationales here.

Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of asserted claim 21 of the '325 patent are present in Lemchen, either alone or in combination with Kesling, and Nahoum, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine the those references to create the method claimed in the invention of the '325 patent.

h. Claim 30

Respondents' Position: Respondents assert that the subject matter of claim 30 is obvious for the reasons discussed above.

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of claim 1.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 21 to be rendered obvious by the asserted prior art and invalid, I could still find that claim 30 is valid. Since, however, I have found claim 21 to be valid and ***not*** rendered obvious by Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, claim 30 is necessarily valid, because it depends from claim 21 and necessarily contains all of the elements of claim 21. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 21 is rendered obvious by Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, I would find that Respondents have shown by clear and convincing evidence that claim 30 of the '325 patent is rendered obvious by that combination.

In section IV.B.1.h, *supra*, I found that if Lemchen anticipated claim 21, it would also anticipate claim 30. As a result, assuming *arguendo* that claim 21 is obvious over Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, I would find that claim 30 is obvious based on the rationale discussed in section IV.B.1.h.

i. Claim 31

Respondents' Position: Respondents assert that claim 31 is obvious in light of the identified prior art with the knowledge of one of ordinary skill in the art as explained regarding claim 1.

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of claim 1.

Analysis and Conclusions: In Section IV.B.2.a, *supra*, I find that Respondents' prehearing brief does not provide notice to Align regarding the specific prior art to be addressed and the manner in which the prior art discloses each and every element of an asserted claim and although Respondents discussed eleven different prior art references in RPHB section 3.5.2.2, Respondents failed to identify any specification combinations of prior art references other than Lemchen, Kesling, and the knowledge of one of ordinary skill in the art and any other combinations, including Nahoum with Lemchen, Kesling, and the knowledge of one of ordinary skill in the art, were waived.

Assuming, *arguendo*, that Respondents had properly disclosed their arguments based on the combination of Lemchen, Kesling, Nahoum, and the knowledge of one or ordinary skill in the art in their pre-hearing brief, there is nothing in the evidence submitted by Respondents to support a finding that a PHOSITA would be motivated by anything in Lemchen, Kesling or Nahoum to follow the methods in the '325 patent. In section IV.B.1, *supra*, I noted that even if I had found that

Lemchen incorporated the ***entirety*** of Kesling by reference, those two references taken together would still not disclose each and every element of the claim 31 of the '325 patent. Based upon that finding, it follows that Lemchen combined with Kesling would not render obvious asserted claim 31 of the '325 patent.

Respondents' evidence regarding the knowledge of one of ordinary skill in the art would not fill the gaps in Lemchen and Kesling. Respondents' evidence is limited to expert reports of a former expert for Align (RX-102C and RX-103C) and the opening witness statement of Dr. Mah. At the prehearing conference, I ruled that that Dr. Rekow's expert reports (RX-102C and RX-103C) could be used solely to show that Align took an inconsistent position in the prior litigation. (Tr. at 20:24-21:7) Here, Respondents are improperly attempting to rely on the expert reports to show the knowledge of one of ordinary skill in the art. The testimony of Dr. Mah is not helpful on this subject because he expresses a series of conclusory opinions without citing to evidentiary support. (*See, e.g.*, RX-113C, Qs. 100, 113-121)

Focusing on the motivation to combine references, I find that the mention of Kesling in Lemchen would be adequate to cause a PHOSITA to consider both references in combination. Respondents do not, however, provide any basis for combining Nahoum with the Lemchen and Kesling references.

Notwithstanding the foregoing, examining Nahoum in combination with Lemchen and Kesling, I find that Nahoum does not provide the elements missing from the Lemchen and Kesling references. In Section IV.B.1.a, *supra*, I find that Lemchen does not disclose, or teach or suggest, calculating positions-in-between an initial data set and a final data set. In Section IV.B.2.a, *supra*, I find that Lemchen does not in any way disclose, or hint at, designing or fabricating intermediate or successive tooth repositioning appliances based on digital data sets.

Lemchen's disclosure is limited to the idea of treating a patient with a single set of brackets, i.e. one bracket per tooth to be used over the entirely of the treatment. In Section IV.B.1.a, *supra*, I find that Kesling contemplated a reactive process, performed one step at a time, where appliances beyond a first appliance may be created by repeating the disclosed process for making the first appliance. In Section IV.B.2.a, *supra*, I also find that Kesling "does not disclose, or teach or suggest, or even remotely contemplate" the use of computers or digital technology and does not expressly or inherently disclose, or teach or suggest, fabricating a dental appliance based on a digital data set. Additionally, in Section IV.B.2.a, *supra*, I find that Nahoum does not in any way disclose use of computers or digital data to assist in fabricating a dental appliance. I reaffirm and incorporate these findings and rationales here.

Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of asserted claim 31 of the '325 patent are present in Lemchen, either alone or in combination with Kesling, and Nahoum, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine the those references to create the method claimed in the invention of the '325 patent.

j. Claim 32

Respondents' Position: Respondents assert that the subject matter of claim 32 is obvious for the reasons discussed above.

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of claim 1.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 31 to be rendered obvious by the asserted prior art and invalid, I could still find

that claim 32 is valid. Since, however, I have found claim 31 to be valid and ***not*** rendered obvious by Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, claim 32 is necessarily valid, because it depends from claim 31 and necessarily contains all of the elements of claim 31. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 31 is rendered obvious by Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, I would find that Respondents have shown by clear and convincing evidence that claim 32 of the '325 patent is rendered obvious by that combination.

In section IV.B.1.j, *supra*, I found that if Lemchen anticipated claim 31, it would also anticipate claim 32. As a result, assuming *arguendo* that claim 31 is obvious over Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, I would find that claim 32 is obvious based on the rationale discussed in section IV.B.1.j.

k. Claim 33

Respondents' Position: Respondents assert that the subject matter of claim 33 is obvious for the reasons discussed above.

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of claim 1.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 31 to be rendered obvious by the asserted prior art and invalid, I could still find that claim 33 is valid. Since, however, I have found claim 31 to be valid and ***not*** rendered obvious by Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, claim 33 is necessarily valid, because it depends from claim 31 and necessarily contains all of

the elements of claim 31. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 31 is rendered obvious by Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, I would find that Respondents have failed to show by clear and convincing evidence that claim 33 of the '325 patent is rendered obvious by that combination.

Claim 33 requires, *inter alia*,

> fabricating a plurality of successive tooth repositioning appliances based on at least a plurality of said produced digital data sets provided to the fabrication operation.

(JX-003 at R2:54-57) Examining Nahoum in combination with Lemchen and Kesling, Lemchen does not in any way disclose, or hint at, designing or fabricating intermediate or successive tooth repositioning appliances based on digital data sets. Kesling does not expressly or inherently disclose, or teach or suggest, fabricating a dental appliance based on a digital data set. Nahoum does not in any way disclose use of computers or digital data to assist in fabricating a dental appliance.

Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of asserted claim 33 of the '325 patent are present in Lemchen, either alone or in combination with Kesling, Nahoum, and the knowledge of a person of ordinary skill in the art, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine the those references to create the method claimed in the invention of the '325 patent.

l. Claim 34

Respondents' Position: Respondents assert that the subject matter of claim 34 is obvious for the reasons discussed above.

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of claim 1.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claims 31 and 33 to be rendered obvious by the asserted prior art and invalid, I could still find that claim 34 is valid. Since, however, I have found claims 31 and 33 to be valid and ***not*** rendered obvious by Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, claim 34 is necessarily valid, because it depends from claim 31 via claim 33 and necessarily contains all of the elements of claims 31 and 33. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that claims 31 and 33 are rendered obvious by Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, I would find that Respondents have failed to show by clear and convincing evidence that claim 34 of the '325 patent is rendered obvious by that combination. In Section IV.B.1.a, *supra*, I find that Lemchen is limited to the idea of treating a patient with a single set of brackets, not with plural polymeric shell appliances. Nahoum and the knowledge of one of ordinary skill in the art do not fill these gaps. Nahoum does not in any way disclose use of computers or digital data to assist in fabricating a dental appliance, as required by claims 34.

Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of asserted claim 34 of the '325 patent are

present in Lemchen combined with Kesling, Nahoum, and the knowledge of one of ordinary skill in the art, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine those references to create the method claimed in asserted claim 34 of the '325 patent.

m. Claim 35

Respondents' Position: Respondents assert that the subject matter of claim 35 is obvious for the reasons discussed above.

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of claim 1.

Analysis and Conclusions: In Section IV.B.2.a, *supra*, I find that Respondents' prehearing brief does not provide notice to Align regarding the specific prior art to be addressed and the manner in which the prior art discloses each and every element of an asserted claim and although Respondents discussed eleven different prior art references in RPHB section 3.5.2.2, Respondents failed to identify any specification combinations of prior art references other than Lemchen, Kesling, and the knowledge of one of ordinary skill in the art and any other combinations, including Nahoum with Lemchen, Kesling, and the knowledge of one of ordinary skill in the art, were waived.

Assuming, *arguendo*, that Respondents had properly disclosed their arguments based on the combination of Lemchen, Kesling, Nahoum, and the knowledge of one or ordinary skill in the art in their pre-hearing brief, there is nothing in the evidence submitted by Respondents to support a finding that a PHOSITA would be motivated by anything in Lemchen, Kesling or Nahoum to follow the methods in the '325 patent. In section IV.B.1, *supra*, I noted that even if I had found that Lemchen incorporated the ***entirety*** of Kesling by reference, those two references taken together

would still not disclose each and every element of the claim 35 of the '325 patent. Based upon that finding, it follows that Lemchen combined with Kesling would not render obvious asserted claim 35 of the '325 patent.

Respondents' evidence regarding the knowledge of one of ordinary skill in the art would not fill the gaps in Lemchen and Kesling. Respondents' evidence is limited to expert reports of a former expert for Align (RX-102C and RX-103C) and the opening witness statement of Dr. Mah. At the prehearing conference, I ruled that that Dr. Rekow's expert reports (RX-102C and RX-103C) could be used solely to show that Align took an inconsistent position in the prior litigation. (Tr. at 20:24-21:7) Here, Respondents are improperly attempting to rely on the expert reports to show the knowledge of one of ordinary skill in the art. The testimony of Dr. Mah is not helpful on this subject because he expresses a series of conclusory opinions without citing to evidentiary support. (*See, e.g.*, RX-113C, Qs. 100, 113-121)

Focusing on the motivation to combine references, I find that the mention of Kesling in Lemchen would be adequate to cause a PHOSITA to consider both references in combination. Respondents do not, however, provide any basis for combining Nahoum with the Lemchen and Kesling references.

Notwithstanding the foregoing, examining Nahoum in combination with Lemchen and Kesling, I find that Nahoum does not provide the elements missing from the Lemchen and Kesling references. In Section IV.B.1.a, *supra*, I find that Lemchen does not disclose, or teach or suggest, calculating positions-in-between an initial data set and a final data set. In Section IV.B.2.a, *supra*, I find that Lemchen does not in any way disclose, or hint at, designing or fabricating intermediate or successive tooth repositioning appliances based on digital data sets. Lemchen's disclosure is limited to the idea of treating a patient with a single set of brackets, i.e.

one bracket per tooth to be used over the entirely of the treatment. In Section IV.B.1.a, *supra*, I find that Kesling contemplated a reactive process, performed one step at a time, where appliances beyond a first appliance may be created by repeating the disclosed process for making the first appliance. In Section IV.B.2.a, *supra*, I also find that Kesling "does not disclose, or teach or suggest, or even remotely contemplate" the use of computers or digital technology and does not expressly or inherently disclose, or teach or suggest, fabricating a dental appliance based on a digital data set. Additionally, in Section IV.B.2.a, *supra*, I find that Nahoum does not in any way disclose use of computers or digital data to assist in fabricating a dental appliance. I reaffirm and incorporate these findings and rationales here.

Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of asserted claim 35 of the '325 patent are present in Lemchen, either alone or in combination with Kesling, and Nahoum, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine the those references to create the method claimed in the invention of the '325 patent.

n. Claim 38

Respondents' Position: Respondents assert that the subject matter of claim 38 is obvious for the reasons discussed above.

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of claim 1.

Analysis and Conclusions: In Section IV.B.2.a, *supra*, I find that Respondents' prehearing brief does not provide notice to Align regarding the specific prior art to be addressed and the manner in which the prior art discloses each and every element of an asserted claim and although Respondents discussed eleven different prior art references in RPHB section 3.5.2.2,

Respondents failed to identify any specification combinations of prior art references other than Lemchen, Kesling, and the knowledge of one of ordinary skill in the art and any other combinations, including Nahoum with Lemchen, Kesling, and the knowledge of one of ordinary skill in the art, were waived.

Assuming, *arguendo*, that Respondents had properly disclosed their arguments based on the combination of Lemchen, Kesling, Nahoum, and the knowledge of one or ordinary skill in the art in their pre-hearing brief, there is nothing in the evidence submitted by Respondents to support a finding that a PHOSITA would be motivated by anything in Lemchen, Kesling or Nahoum to follow the methods in the '325 patent. In section IV.B.1, *supra*, I noted that even if I had found that Lemchen incorporated the ***entirety*** of Kesling by reference, those two references taken together would still not disclose each and every element of the claim 38 of the '325 patent. Based upon that finding, it follows that Lemchen combined with Kesling would not render obvious asserted claim 38 of the '325 patent.

Respondents' evidence regarding the knowledge of one of ordinary skill in the art would not fill the gaps in Lemchen and Kesling. Respondents' evidence is limited to expert reports of a former expert for Align (RX-102C and RX-103C) and the opening witness statement of Dr. Mah. At the prehearing conference, I ruled that that Dr. Rekow's expert reports (RX-102C and RX-103C) could be used solely to show that Align took an inconsistent position in the prior litigation. (Tr. at 20:24-21:7) Here, Respondents are improperly attempting to rely on the expert reports to show the knowledge of one of ordinary skill in the art. The testimony of Dr. Mah is not helpful on this subject because he expresses a series of conclusory opinions without citing to evidentiary support. (*See, e.g.*, RX-113C, Qs. 100, 113-121)

Focusing on the motivation to combine references, I find that the mention of Kesling in

Lemchen would be adequate to cause a PHOSITA to consider both references in combination. Respondents do not, however, provide any basis for combining Nahoum with the Lemchen and Kesling references.

Notwithstanding the foregoing, examining Nahoum in combination with Lemchen and Kesling, I find that Nahoum does not provide the elements missing from the Lemchen and Kesling references. In Section IV.B.1.a, *supra*, I find that Lemchen does not disclose, or teach or suggest, calculating positions-in-between an initial data set and a final data set. In Section IV.B.2.a, *supra*, I find that Lemchen does not in any way disclose, or hint at, designing or fabricating intermediate or successive tooth repositioning appliances based on digital data sets. Lemchen's disclosure is limited to the idea of treating a patient with a single set of brackets, i.e. one bracket per tooth to be used over the entirely of the treatment. In Section IV.B.1.a, *supra*, I find that Kesling contemplated a reactive process, performed one step at a time, where appliances beyond a first appliance may be created by repeating the disclosed process for making the first appliance. In Section IV.B.2.a, *supra*, I also find that Kesling "does not disclose, or teach or suggest, or even remotely contemplate" the use of computers or digital technology and does not expressly or inherently disclose, or teach or suggest, fabricating a dental appliance based on a digital data set. Additionally, in Section IV.B.2.a, *supra*, I find that Nahoum does not in any way disclose use of computers or digital data to assist in fabricating a dental appliance. I reaffirm and incorporate these findings and rationales here.

Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of asserted claim 38 of the '325 patent are present in Lemchen, either alone or in combination with Kesling, and Nahoum, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine the

those references to create the method claimed in the invention of the '325 patent.

o. Claim 39

Respondents' Position: Respondents assert that the subject matter of claim 39 is obvious for the reasons discussed above.

Align's Position: Align treats all claims above in its discussion of claim 1.

Staff's Position: Staff treats all claims above in its discussion of claim 1.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 38 to be rendered obvious by the asserted prior art and invalid, I could still find that claim 39 is valid. Since, however, I have found claim 38 to be valid and ***not*** rendered obvious by Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, claim 39 is necessarily valid, because it depends from claim 38 and necessarily contains all of the elements of claim 38. *See In re Fritch,* 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 38 is rendered obvious by Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, I would find that Respondents have shown by clear and convincing evidence that claim 39 of the '325 patent is rendered obvious by that combination.

In section IV.B.1.o, *supra*, I found that if Lemchen anticipated claim 38, it would also anticipate claim 39. As a result, assuming *arguendo* that claim 38 is obvious over Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, I would find that claim 39 is obvious based on the rationale discussed in section IV.B.1.o.

3. Secondary Consideration of Non-Obviousness

Respondents' Position: Respondents assert that Align's reliance on secondary considerations of non-obviousness is not persuasive. Respondents say that there is no doubt that Align has been a commercial success. Respondents continue that Dr. Valley, Align's expert, did not consider the factors noted by the Federal Circuit in *Ormco I*. Respondents say that Dr. Valley does not appear to attribute any of Align's commercial success to: (1) resolving aesthetic concerns associated with braces, (2) eliminating abrasive discomfort associated with wires and braces, (3) reduced pain of treatment, or (4) better ease of brushing and flossing because the appliances were removable. Respondents say that Align contended in *Ormco I* that these accomplishments were critically important to its commercial success, they are apparently of no moment now.

Respondents assert that Dr. Valley's conclusions on Align's computerized design and manufacturing demand close scrutiny. Respondents say that Dr. Valley testifies that Align's commercial success is directly connected the use of computers to: (1) fabricate aligners which "facilitate major tooth movements over multiple treatment stages," (2) create a powerful communication tool between the clinician and patient, and (3) create three-dimensional visualizations that allow clinicians to quickly determine the feasibility of a treatment plan. (Citing CX-1247C at Q. 497) Respondents argue that Dr. Valley's first contention was effectively rejected by the Federal Circuit in *Ormco I*. Respondents say that the Federal Circuit's opinion describes in detail how an orthodontist named Dr. Lloyd Truax, in prior art, fabricated multiple orthodontic appliances to treat patients in multiple stages. (Citing *Ormco I* at 1307-09) Respondents reason that Align's fabrication of multiple appliances that facilitate tooth movements over multiple stages cannot be used to avoid obviousness here because that concept

was disclosed in the prior art. (Citing *J.T. Eaton & Co. v. Atlantic Paste & Glue Co.*, 106 F.3d 1563, 1571 (Fed. Cir. 1997) ("[T]he asserted commercial success of the product must be due to the merits of the claimed invention beyond what was readily available in the prior art."))

Respondents argue that Dr. Valley's remaining two contentions likewise fail. Respondents assert that The Federal Circuit noted in *Ormco I* that "commercial success" of the patent holder is not relevant if that success is due to an unclaimed feature. (Citing *Ormco I* at 1312) Respondents say that the patent claims at issue here claim digital modeling of treatment for the fabrication of appliances. Respondents continue that nowhere do the patents at issue in this investigation claim a communication tool between the clinician and patient or three-dimensional visualizations that allow clinicians to determine the feasibility of their treatment plans. Respondents contend that the features Dr. Valley describes are not claimed and cannot support any conclusion of "commercial success" that cuts against obviousness.

Respondents assert that Align has itself presented substantial evidence that weighs against Dr. Valley's testimony. Respondents say that Align's 10-K filing for the period ending December 31, 2003 is typical. (Citing CX-1266) Respondents aver that Align has a complete section describing the "Benefits of Invisalign." (Citing CX-1266-007) Respondents continue that the section describes the aesthetic and comfort factors addressed in *Ormco I*. Respondents say that nowhere in the section does Align claim computer modeling or the use of intermediate data sets as a benefit. Respondents continue that the same is true for Align's section on "Competition." (Citing CX-1266-0014) Respondents say that Align describes the "principal competitive factors for orthodontic appliances" as: (1) aesthetic appeal of the treatment method; (2) comfort associated with the treatment method; (3) oral hygiene; (4) effectiveness of treatment; (5) ease of use; and (6) dental professional's chair time. (Citing CX-1266-014)

Respondents aver that Align made no mention of computer modeling or digital data sets. According to Respondents, these were the factors Align considered critical three years before the Federal Circuit rejected them as "secondary considerations" in *Ormco I*. Respondents argue that only now does Align assert that the digital files are Align's alleged reasons for its "commercial success."

Respondents assert that Dr. Valley also opines that "Align's invisalign products met a long felt need for an aesthetic, removable alternative to fixed appliances." (Citing CX-1247C at Q. 501) Respondents say that one typical article she cites was entitled "Invisible Orthodontics" and, as Dr. Valley notes, indicates that an invisible appliance is the "holy grail" of orthodontics. (Citing CX-1272 and CX1247C at Q. 510) Respondents say that the article's theme is described in the first paragraph: "One of the attributes of a perfect appliance is its aesthetics; an invisible appliance is the holy grail of orthodontics. The reasons are obvious. Who would not want to be able to have his teeth straightened if it could be done without metal braces?" (Citing CX-1272)

Respondents argue that these arguments, particularly addressing the aesthetics of an invisible appliance, are precisely the arguments Align made in *Ormco I*. Respondents say that the Federal Circuit specifically considered Align's argument that its product offered the same aesthetic, comfort and hygienic properties that Dr. Valley lauds here. (Citing *Ormco I*, 463 F.3d at 1311-13) Respondents continue that the arguments were not enough to overcome obviousness and were expressly rejected when the Federal Circuit held "Nor has Align submitted probative evidence that claimed and novel features met a long felt but unresolved need." (Citing *Ormco I*, 463 F.3d at 1313) Respondents say that Align offers no reason why the result should be different in this case.

Respondents contend that the Federal Circuit held in *Ormco I* that evidence of any "secondary consideration" is significant only if there is a nexus with the claimed invention. (Citing *Ormco I*, 463 F.3d at 1311-12) Respondents say that Align's arguments about initial skepticism and subsequent industry praise are flawed because neither the skepticism, nor the praise, it cites are directed to the "digital data sets" that are the subject of this investigation and the patent claims at issue here. Respondents add that both the skepticism and praise are directed to the use of the removable orthodontic appliances to treat complicated cases. Respondents say that this skepticism could therefore apply equally to the multiple appliances referenced in Kesling from the 1940s or Dr. Nahoum's article from the 1960s.

Respondents say that Align attempts to prove the initial skepticism through Dr. Valley's witness statement and several articles she cites. (Citing CX-1247C at Q. 521-531) Respondents disagree, saying that nowhere does Align or Dr. Valley suggest that any skepticism was directed toward Align's ability to create computer models or "digital data sets" concerning the projected treatment; rather, most of the cited articles appear to accept the digital modeling as proficient and only challenge the use of removable appliances for complex orthodontic cases. Respondents say that this skepticism goes to the apparatus itself—the removable appliances called aligners—and not to any particular method of making that appliance. Respondents continue that the patent claims here do not claim any such apparatus. Respondents say that because the skepticism Align and Dr. Valley cite is directed to the use of appliance instead of the methods for making it, that skepticism cannot support the claims.

Respondents add that the same is true for Align's arguments concerning industry praise. Respondents say that Dr. Valley testified about the number of dentists who are trained to use the Invisialign product, but there is no link to the subject of the patent claims at issue here. (Citing

CX-1247C at Q.537-543) Respondents conclude, as a result, that Dr. Valley's opinions on "industry praise" fail to establish a viable "secondary consideration."

Respondents assert that Align failed to establish the "secondary consideration" of copying. Respondents say that the evidence demonstrates that Align itself copied the relevant prior art. Respondents continue that the evidence disproves that either OrthoClear or CCUS copied Align; rather, the evidence Align tendered at the hearing indicates that Align actually copied Ormco's intellectual property. Respondents say that the 10-K filings Align offered describe Ormco's successful pursuit of patent infringement against Align. Respondents aver that Ormco initially sued Align during 2000. (Citing CX-1266-018) Respondents say that on February 25, 2009, the presiding federal district court granted judgment in Ormco's favor, finding that Align infringed Ormco's patented technology. (Citing CX-1204-042) Respondents continue that on August 16, 2009, Align settled by paying Ormco a settlement valued at $76.7 million. (Citing CX-1201-048)

Respondents argue that the evidence also disproves that Align's intellectual property was copied by OrthoClear or CCUS. Respondents say that Dr. Nadeem Arif, a former employee of both Align and OrthoClear and current employee of CCPK, testified that OrthoClear's process involved sectioning a physical model of a patient's teeth, placing them on pins, and inserting the pins into a base plate to re-locate the teeth during projected treatment. (Citing Tr. at 214:4 to Tr. 216:9) Respondents say that none of Align's claims address such a process. Respondents continue that Dr. Pumphrey testified that all of the appliances for the Invisalign product were fabricated and delivered to the doctor before the patient's treatment began. (Citing Tr. at 406:8-16) Respondents say that OrthoClear used a system in which it fabricated only two appliances at a time, which was more efficient for doctors. (Citing Tr. at 407:10-408:12)

Respondents argue that Dr. Valley does not form an opinion that either OrthoClear or CCUS actually copied Align; rather she instead makes a series of statements such as she "has been informed there is evidence" that suggests similarities between the companies' products or that she "has been informed" that OrthoClear used similar software. (Citing CX-1247C at Q. 546-547) Respondents assert that Dr. Valley's hedged and equivocal statements are not evidence of copying.

Respondents assert that the prior art demonstrates that long before Align, orthodontists had applied digital methods to earlier mechanical methods of modeling the movement of teeth to create digital data that represented successive tooth positions. Respondents say that the prior art also teaches the use and fabrication of series of appliances and shows controlling a fabrication machine to make positive models of tooth arrangement. Respondents say that Align contended likewise in prior litigation. Respondents alternatively contend that the asserted claims are simply the application of modern digital methods to long existing mechanical methods, and because the application of modern digital methods was previously disclosed in the prior art, the asserted claims are invalid as obvious.

Align's position: Align asserts that even if a proper obviousness analysis had been advanced, the asserted claims of Align's patents are nonobvious based on secondary considerations. Align says that such evidence is tied to Align's commercial embodiment of the asserted claims, the Invisalign products. (Citing *See* CX-1254C ¶ 219 at 79-80; CX-1247C at Q. 487-488) Align continues that sales and market share provides strong evidence of commercial success. (Citing *See Tec Air, Inc. v. Denso Mfg. Mich., Inc.*, 192 F.3d 1353, 1360-61 (Fed. Cir. 1999)) Align asserts that revenues from sales of Invisalign products have increased since its commercial introduction and the volume of cases shipped has tripled between 2004 and 2011.

(Citing CX-1254C ¶¶ 221-222 at 80-81; CX-1247C at Q. 489-492, 498-99; CX-1265 at 37; CX-1266 at 46; CX-1267 at 47; CX-1204 at 53-54; CX-1201 at 43-44) Align says that in 2009, Invisalign had 87.2% of the clear aligner market by volume and 95.26% by revenue. (Citing CX-1254C ¶¶ 223-224 at 81-82; CX-1247C at Q. 493-494; CX-1268 at 17-18; CX-1259) Align says that Dr. Valley confirmed that Align's commercial success is directly connected to the claims. (Citing Tr. at 803:22-804:16, 805:8-19; CX-1254C ¶¶ 225-230 at 77-79; CX-1247C at Q. 495-497)

Align asserts that a long-felt need resolved by an invention is evidence of non-obviousness. (Citing *Star Sci.*, 655 F.3d at 1376) Align says that Invisalign met a long-felt need for aesthetic, removable appliances that: (i) serve as an alternative to fixed appliances; and (ii) can treat moderate to severe malocclusions over multiple treatment stages. (Citing CX-1254C ¶¶ 231-239 at 84-87; CX-1247C at Q. 500-511, 519-20; CX-1269C at 15, 29-30; CX-1288 at 2-8; CX-1271 at 1, 5; CX-1272) Align continues that removable aesthetic orthodontic appliances with these capabilities did not exist before Invisalign. (Citing CX-1254C ¶¶ 240-244 at 87-89; CX-1247C at Q. 512-515; CX-1273 at 1; CX-1274 at 5; CX-1275 at 8) Align says that satisfaction of this long-felt need is tied to the claims. (Citing CX-1254C ¶¶ 245-246 at 89; CX-1247C at Q. 516-518)

Align asserts that Evidence of the skepticism and disbelief of an invention supports nonobviousness. (Citing *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1350 (Fed. Cir. 2007)) Align says that Considerable skepticism existed in the orthodontic community regarding Invisalign. (Citing CX-1254C ¶¶ 247-253 at 90-92; CX-1247C at Q. 521-529, 530-31; CX-1277C at 22-23) Align explains that there was doubt as to whether Invisalign would work in

"more complex cases" or was merely a "marketing gimmick." (Citing CX-1254C ¶¶ 247-253 at 90-92; CX-1247C at Q. 521-529; CX-1269C at 30; CX-1274 at 4; CX-1278 at 2; CX-1260)

Align asserts that industry praise of an invention supports nonobviousness. (Citing *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling U.S., Inc.*, 699 F.3d 1340 (Fed. Cir. 2012)) Align says that in 2002, Align won the Canon Communications LLC Medical Design Excellence Award. (Citing CX-1254C ¶ 256 at 92; CX-1247C at Q. 534-535; CX-1279) Align continues that in 2004, Align received the Frost and Sullivan Technology Leadership of the Year Award for Invisalign's role in creating an "entirely new concept for a well-established product technology[.]" (Citing CX-1254C ¶ 257 at 92-93; CX-1247C at Q. 534, 536; CX-1280 at 1-3) Align avers that virtually all U.S. orthodontists have undergone Invisalign training and Invisalign is taught in most dental schools. (Citing CX-1254C ¶ 258 at 93; CX-1247C at Q. 537-538; CX-1281 at 5; CX-1282 at 3) Align continues that Invisalign has been recognized repeatedly as a "game-changer" in the field of orthodontics due to its ability "to treat extraordinarily difficult malocclusions to a high standard of care without the need for fixed appliances or dentoalveolar surgery." (Citing CX-1254C ¶¶ 258-260 at 93-94; CX-1247C at Q. 539-543; CX-1283 at 6; CX-1284 at 1-2)

Align contends that copying also provides compelling evidence of non-obviousness. *See Akamai Techs. v. Cable & Wireless Internet Servs.*, 344 F.3d 1186, 1196 (Fed. Cir. 2003). Align argues that OrthoClear misappropriated Align's IP and used modified versions of Align's software. (Citing CX-1254C ¶¶ 262-264 at 94-95; CX-1247C at Q. 544-546, 549-50; CX-1267 at 33-34) Align says that Respondents copied Invisalign and Align's software. (Citing Tr. at 314:4-318:11, 319:22-320:9; CX-1254C ¶¶ 265-271 at 95-96; CX-1247C at Q. 544, 547; CX-1151C.1 at 127:22-133:1; CX-0116C; CX-1241C) Align continues that Respondents' copying is directly

tied to the claims. (Citing Tr. at 415:15-416:7; CX-1254C ¶¶ 270-271 at 96; CX-1247C at Q. 548)

Align asserts that Respondents' wrongly assert that Align's method of creating visual images of tooth arrangements is not recited in the asserted claims. Align says that its claims specifically recite a method for creating visual images based on digital data sets representing substantially accurate shapes of a patient's actual teeth. (Citing JX-0003 at 27 (2:27-53)) Respondents say that as Dr. Valley opined that these images may be used as a diagnostic tool between the clinician and the patient and support the commercial success of Align's inventions. (Respondents say that CX-1254C at ¶¶ 228-230, at 83-84; CX-1247C at Q. 496-497) Align disagrees with Respondents' reliance on a single 10-K to claim that Align never acknowledged either "computer modeling" or the use of "digital data sets" as being commercially beneficial. Align says that this 10-K actually discusses the benefits of being able to (i) "visualize treatment," (ii) determine a "likely outcome," and (iii) produce highly customized aligners in volume. (Citing CX-1266 at 7, 11)

Align disagrees with Respondents' argument that Invisalign satisfied a long-felt need solely because of its aesthetic appeal. Align says that Invisalign met a long-felt need for a removable appliance with the ability to treat moderate to severe malocclusions over multiple treatment stages without the disadvantages of fixed appliances, of which only one was poor aesthetics. (Citing CIB at 46; CX-1247C at Q. 501-502, 516-518.) Align says that Respondents rely solely on CX-1272 for the proposition that aesthetics is the "holy grail" of orthodontics. (Citing RIB at 73) Align says that the article further discusses the disadvantages of existing manual methods for creating existing removable appliances that were limited to "cases requiring small changes" as well as "[a]dvances in computer programs" that would allow for a series of

models to be created from start to final position to facilitate tooth movements. (Citing CX-1272 at 1-2)

Align disagrees with Respondents' argument that the evidence concerning the initial skepticism and later industry praise is insufficiently related to the asserted claims. Align says that skepticism existed in the orthodontic community regarding Align's computerized system. (Citing CX-1278 at 2) Align continues that the industry later recognized and praised Invisalign's ability to facilitate major tooth movements, including Align's system for fabricating aligners. (Citing CX-1280 at 1-2; CX-1275 at 9)

Align asserts that Respondents fail to rebut the evidence showing that OrthoClear and the Respondents copied Align's inventions. Align says that Respondents ignore their own copying and address only Align's allegations regarding OrthoClear, and limit their arguments only to a small portion of OrthoClear's entire process to improperly assert that none of OrthoClear's processes and/or products were copied from Align. Align continues that Respondents also argue that Dr. Valley did not form an opinion as to whether OrthoClear or CCUS copied Align. Align disagrees, explaining that Dr. Valley specifically testified that: (i) there was "evidence that both [Respondents and OrthoClear] have sold products that embody the inventions disclosed in Align's patents[,]"; (ii) she considered this evidence; and (iii) it supported her conclusions regarding the nonobviousness of the asserted Align patent claims. (Citing CX-1247C at Q. 148-152)

Staff's Position: Staff says that the issue of secondary considerations need not even be reached, because Respondents have failed to provide, as a preliminary matter, any evidence of any motivation to combine any of the prior art references in any particular manner.

Analysis and Conclusions: I have found that Respondents have failed to prove by clear and convincing evidence that any of the asserted claims of the '325 patent are rendered obvious by the prior art. It is, therefore, unnecessary for me to consider Align's contentions regarding secondary considerations. Nevertheless, assuming *arguendo* that the Commission finds that one or more claims of the '325 patent are rendered obvious by the prior art asserted by Respondents, I would find that Align has not adduced evidence of secondary considerations that would overcome a clear and convincing showing of obviousness. Because Align's arguments on secondary considerations of non-obviousness addressed all patents generally (and did not directly address any specific patents) (CIB at 45-47, CRB at 47-49), this analysis applies also for the asserted claims of the '880, '487, '511, '666, '863, and '874 patents.

Secondary considerations may include evidence of copying, long felt but unsolved need, failure of others, commercial success, unexpected results created by the claimed invention, unexpected properties of the claimed invention, licenses showing industry respect for the invention, and skepticism of skilled artisans before the invention. *In re Rouffet*, 149 F.3d 1350, 1355 (Fed. Cir. 1998). Reviewing the evidence of secondary considerations is an important step in the obviousness analysis. As explained by the Federal Circuit:

> It is jurisprudentially inappropriate to disregard any relevant evidence on any issue in any case, patent cases included. Thus evidence rising out of the so-called "secondary considerations" must always when present be considered en route to a determination of obviousness. Indeed, evidence of secondary considerations may often be the most probative and cogent evidence in the record. It may often establish that an invention appearing to have been obvious in light of the prior art was not. It is to be considered as part of all the evidence, not just when the decisionmaker remains in doubt after reviewing the art.

Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1538-39 (Fed. Cir. 1983) (citations omitted).

Even when evidence of secondary considerations is present, it cannot overcome a strong *prima facie* showing of obviousness. *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010); *Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007).

In *Ormco I*, the Federal Circuit rejected Align's attempt to show commercial success as a secondary consideration to overcome obviousness, concluding "that the evidence does not show that the commercial success ***was the result of claimed and novel features.***" 463 F.3d at 1312-13 (emphasis added). In that case, the Court explained that evidence of commercial success, or other secondary considerations,[15] is only significant if there is a nexus between the claimed invention and the commercial success. *Id. at 1312* (citing *J.T. Eaton & Co. v. Atlantic Paste & Glue Co.*, 106 F.3d 1563 (Fed.Cir.1997)). The Court also pointed out that the presumption that commercial success is due to the patented invention applies "if the marketed product embodies the claimed features, and is coextensive with them." *Id.* at 1312 (Citing *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1130 (Fed.Cir.2000).) The court noted that where the commercial success is due to an unclaimed feature of the device, the commercial success is irrelevant. *Id.* at 1312 (Citing *Brown & Williamson*, 229 F.3d at 1130; *Ecolochem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1361, 1377 (Fed.Cir.2000); *J.T. Eaton*, 106 F.3d at 1571). So too, if the feature that creates the commercial success was known in the prior art, the success is not pertinent. *Id.* at 1312 (Citing *J.T. Eaton*, 106 F.3d at 1571; *Richdel, Inc. v. Sunspool Corp.*, 714 F.2d 1573, 1580 (Fed.Cir.1983).)

I have found in Section VI.C, *infra*, that Align has proven that it practices claim 21 of the '325 patent, claim 1 of the '880 patent, claim 3 of the '487 patent, claim 1 of the '511 patent,

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[15] The Federal Circuit included in its reasoning that the assertion of meeting "a long-felt but unresolved need" and the "failure of others" must also arise from "claimed and novel features." (*Ormco I* at 1313)

claim 7 of the '863 patent, and claim 1 of the '874 patent. Although Align provides evidence that it has been commercially successful in selling its clear aligners, the evidence cited by Align links the commercial success of Align to the demand for an aesthetic alternative to traditional brackets and the ability to treat "moderate and severe occlusions." (CX-1247C at Q. 497) Specifically, Dr. Valley testifies that:

> Prior to invisalign's introduction, there was a strong consumer demand in the adult orthodontics market for an aesthetic alternative to traditional brackets and wires that could perform major tooth movements over multiple treatment stages. The invisalign products met this demand.

(CX-1247C at Q. 497) Dr. Valley continues that:

> The commercial success of the invisalign products is therefore directly connected to Align's novel method of fabricating aligners by generating intermediate or successive digital data sets based on an initial digital data set and final digital data set. ***Using these digital data sets, Align is able to automatically fabricate unique and highly specific aligners that can facilitate major tooth movements over multiple treatment stages***. This is contrasted with other removable appliances that were capable of only minor tooth movements using a manual method of creating individual appliances. Align's novel method of correcting moderate and severe malocclusions undoubtedly contributed to Invisalign's commercial success.

(*Id.* (emphasis added)) Other than Dr. Valley's conclusory statement that the use of "digital data sets" allows Align to "automatically fabricate unique and highly specific aligners," Dr. Valley does not tie the ability to treat "moderate and severe malocclusions" to the inventions claimed in the claims upon which Align relies to support its domestic industry argument for any of the patents in suit. Respondents' evidence regarding the knowledge of one of ordinary skill in the art would not fill the gaps in Lemchen and Kesling. Respondents' evidence is limited to expert reports of a former expert for Align (RX-102C and RX-103C) and the opening witness statement of Dr. Mah. At the prehearing conference, I ruled that that Dr. Rekow's expert reports (RX-102C and RX-103C) could be used solely to show that Align took an inconsistent position in the

prior litigation. (Tr. at 20:24-21:7) Here, Respondents are improperly attempting to rely on the expert reports to show the knowledge of one of ordinary skill in the art. The testimony of Dr. Mah is not helpful on this subject because he expresses a series of conclusory opinions without citing to evidentiary support. (*See, e.g.*, RX-113C, Qs. 100, 113-121)

Similarly, Align fails to tie the long-felt need to the claimed inventions. Dr. Valley testified that:

> Align's invisalign products met a long felt need for an aesthetic, removable alternative to fixed appliances.

(CX-1247C at Q. 501) Dr. Valley continued that:

> Removable orthodontic appliances that existed at the time were limited by the small amount of tooth movements possible through their use. This prevented them from being a viable alternative for patients with moderate and severe malocclusions. In such systems, individual appliances had to be crafted by hand, either by the clinician or a lab technician. If a large movement over several treatment stages was required, it was necessary for an operator to manually divide this movement into small, precise stages, a process that was prone to human error and inaccuracies.

(CX01247C at Q. 512) Dr. Valley also testified that:

> Align's solution to the limitations of other removable appliances is directly connected to elements and features recited in the asserted patent claims. The asserted claims recite a new treatment modality of using computer assisted technology to scan models of a patient's teeth in order to produce digital data sets projecting stages of tooth movements from an initial to final arrangement and all successive arrangements in between. The digital data sets are then used to efficiently fabricate a series of polymeric shell appliances. The use of a computerized system solved the problem of having a human operator attempt to manually divide a larger tooth movement into small, precise movements.

(CX-1247C at Q. 518) Although Dr. Valley says that the claims recite a "new treatment modality," she fails to tie this "new treatment modality" to the specific limitations of the claims upon which Align relies to support its domestic industry argument for any of the patents in suit

or to explain which features of the claims actually "solved the problem of having a human operator attempt to manually divide a larger tooth movement into small, precise movements." (*Id.*)

Align also failed to show that skepticism and disbelief was directed to the claimed inventions rather than removable aligners in general. Dr. Valley testified that:

> From personal experience, the leading reasons orthodontists did not use Invisalign included skepticism that it was capable of more than simple cases, skepticism because it looked too simple and skepticism that anything other than fixed appliances were capable of controlling tooth movements.

(CX-1247C at Q. 523) Dr. Valley continued that:

> Align found that while orthodontists believed the invisalign system could work in easier to treat patients, there was skepticism as to whether it would work in more complex cases. The focus group studies likewise found that general practitioners were hesitant to adopt this new type of treatment approach quickly.

(CX-1247C at Q. 526) Other than this skepticism regarding Invisalign products generally, Dr. Valley did not provide any evidence that tied this skepticism to the invention addressed by the claims relied upon for purposes of domestic industry for any of the patents in suit. (*See id.*) Dr. Valley also failed to show that awards given to Align were directed to the claimed invention rather than Align's removable aligners in general or the ability of Align to treat complex cases with clear aligners. (CX-1247C at 534). As I found above, Align has not tied the ability to treat complex cases with clear aligners to the inventions claimed in the claims relied upon for purposes of domestic industry for any of the patents in suit.

Regarding evidence of copying, although Align has averred that there is evidence of process similarities and evidence of former OrthoClear employees working for Respondents, Align has not introduced evidence showing actual copying. (*See* CIB at 47) Notably, one of the

exhibits cited by Align, CX-116C, actually suggests that what the former employees of Align and OrthoClear learned from Align and OrthoClear "may conflict" with what Respondents do. (CX-116C) Such a conflict weighs against a finding of actual copying.[16] As a result, I find that Align has failed to introduce sufficient evidence to show actual copying by Respondents. Based upon all of the foregoing, and assuming *arguendo* that the Commission finds that one or more claims of patents in suit are rendered obvious by the prior art asserted by Respondents, I would find that Align has not adduced evidence of secondary considerations that would overcome a clear and convincing showing of obviousness for any of the patents in suit.

C. The '880 Patent

1. Anticipation

a. Claim 1

Asserted claim 1 teaches:

> A method for making a predetermined series of dental incremental position adjustment appliances, said method comprising:
>
> a) obtaining a digital data set representing an initial tooth arrangement;
>
> b) obtaining a repositioned tooth arrangement based on the initial tooth arrangement;
>
> c) obtaining a series of successive digital data sets representing a series of successive tooth arrangements; and
>
> d) fabricating a predetermined series of dental incremental position adjustment appliances based on the series of successive digital data sets, wherein said appliances comprise polymeric shells having cavities shaped to receive and resiliently reposition teeth, and said appliances correspond to the series of successive tooth arrangements progressing from the initial to the repositioned tooth arrangement.

(JX-0002 at 22:12-29)

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[16] This does not, however, weigh against a finding of infringement.

Respondents' Position: Respondents assert that while Align argues that the preamble is not an element of the claimed invention, the subject matter of the preamble is disclosed in the prior art reference. Respondents incorporate by reference the section addressing the anticipation of the preamble of Claim 1 of the '325. Respondents also incorporate by reference Disclosure Categories 1, 5, 7, 9, and 10 here. Respondents argue that the first element of claim 1 is similar to several elements in the asserted claims. Respondents incorporate by reference Disclosure Category 1. Respondents assert that the second element of claim 1 is similar to several elements in the asserted claims. Respondents incorporate by reference Disclosure Categories 5, 7, and 9. Respondents contend that the third element of claim 1 is similar to several elements in the asserted claims. Respondents incorporate by reference Disclosure Categories 7 and 9. Respondents assert that the fourth element of claim 1 is similar to several elements in the asserted claims. Respondents incorporate by reference Disclosure Category 10.

Respondents say that claim 1 teaches: 1) obtaining a digital initial tooth arrangement; 2) obtaining a repositioned tooth arrangement; 3) obtaining a series of successive digital tooth arrangements; and 4) fabricating polymeric shell appliances that correspond to the successive tooth arrangements. Respondents argue that the novelty of claim 1 is flatly contradicted by the Lemchen/Kesling reference, and Dr. Rekow's opinions confirm this, when she opined that Lemchen taught "[f]ull three-dimensional modeling in orthodontic treatment planning . . . ." (Citing RX-0103C at 16) Respondents continue that Dr. Rekow opines that Lemchen taught a digital method of the physical method taught by Kesling. (Citing RX-0103C at 16) Respondents add that Kesling taught fabrication of a series of polymeric shell appliances made using the corresponding physical models. (Citing CX-0944 at 2:43 – 4:70) Respondents conclude, as a result, that that the Lemchen/Kesling reference anticipates this claim because there is no material

difference between the claim and the prior art.

Align's Position: Align argues that Respondents' '880 invalidity positions are unsupported and insufficient to meet their high burden for invalidity. Align says that Respondents have no particular evidence to support their invalidity case, as no claim charts explaining where each claimed element is shown in the cited references is in evidence - because they were not included with Respondents' Prehearing Brief. (Citing Tr. at 19:11-20:4; 651:14-653:25) Align continues that the prior art references simply fail to disclose all elements of either of the asserted claims of the '880 patent, individually or under any combination. (Citing CX-1247C at Q. 606, 610; CX-1258) Align says that the failings of the prior art are explained in CIB Section IV.F.4. Align asserts that elements of the asserted claims of the '880 are missing from each prior art reference are illustrated in CDX-0156—CDX-0157. Align says, for example, none of the prior art discloses, *inter alia*, "fabricating a predetermined series of dental incremental position adjustment appliances based on the series of successive digital data sets."

Align says that Respondents contend that all of the asserted claims of the '880 patent are anticipated by Lemchen and "as incorporated," Kesling. Align argues that this argument is unsupported, because no claim charts (or other explanatory vehicle) showing this assertion in detail are in evidence. Moreover, Respondents' argument is wrong. Align says that this argument relies on accepting that Lemchen incorporates the entire disclosure of Kesling, which is wrong for the reasons described in CIB Section IV.F.4.c. Align continues that even assuming incorporation, Lemchen/Kesling would still fail to disclose all elements of either claim 1 or 3. (Citing CIB Section IV.F.4.c)

Align asserts that Respondents fail to point to any portion of the prior art that they contend discloses, *e.g.*, "successive digital data sets" ('880 claim 1) or "fabricating a

predetermined series of dental incremental position adjustment appliances" ('880 claim 1). (Citing RIB at 86-87)

Align argues that Respondents failed to make a *prima facie* showing of anticipation. (Citing CRB Section IV.H; Tr. at 19:11-20:4, 651:14-653:25) Align says that Respondents rely on the flawed theory that Lemchen incorporates the entire disclosure of Kesling. (Citing CRB Section IV.H.1; CIB at 49-51) Align says that even assuming incorporation, Lemchen/Kesling fails to disclose all elements of any asserted claim. (Citing CIB at 48-51; CX-1247C at Q. 568-569; CX-1254C ¶ 274 at 97; CDX-0156—CDX-0157) Align continues that Respondents' theory relies on their "disclosure categories," which advance new and unsupported mischaracterizations of Lemchen and Kesling, and fail to fairly address the elements of the asserted claims. (Citing CRB Section IV.H.4) Align says that Respondents also misapply their "disclosure categories" with respect to claims 1 and 3 of the '880 patent. (Citing *id.*)

Staff's Position: Staff says that given that Respondents' arguments and Dr. Mah's testimony alleging anticipation of the Asserted Claims of the '325 patent are also made with respect to the Asserted Claims of the '880 patent, the Staff's discussion of anticipation in SIB Section IV.E.1 applies equally for the '880 patent.

Staff asserts that Respondents have failed to demonstrate clearly and convincingly that any Asserted Claim of the '880 patent is invalid because Respondents have failed to provide an element-by-element comparison of the prior art with the Asserted Claims of the '880 patent. Staff says that in their Pre-Hearing Brief, Respondents represented that they would introduce a claim chart showing "where each element of each asserted claim is found in the prior art." (Citing RPHB at 47) Staff says that I excluded that claim chart. (Citing Tr. at 18:13-19:25) Staff says that in their Post-Hearing Brief, Respondents attempt to make up this shortcoming by

comparing, on an element-by-element basis, their prior art references with the Asserted Claims of the '880 patent. Staff says that because Respondents admittedly did not perform this comparison in their Pre-Hearing Brief, Respondents should not be permitted to do so now. (Citing G.R. 8.2)

Staff argues that even if Respondents' comparison of their prior art references with the Asserted Claims of the '880 patent is permitted, that comparison consists of primarily attorney argument, which is no substitute for evidence. Staff says that in their comparison, Respondents cite to Dr. Mah's testimony to support their allegations of anticipation and obviousness, but that testimony is merely conclusory, as it too references a claim chart, purporting to show how and where the prior art discloses each element of each asserted claim, that has been excluded.

Staff concludes, as a result, that there is a lack of evidence explaining clearly and convincingly how the prior art discloses, teaches, or suggests each and every element of the Asserted Claims of the '880 patent.

Analysis and Conclusions: In Section IV.B.1, *supra*, I found that Lemchen only incorporates by reference Figures 1 and 3 of Kesling. I incorporate and reaffirm those findings here. Even assuming that Lemchen incorporated the entirety of Kesling, the combination does not disclose each and every limitation of the asserted claims.

In Section IV.B.1.a, *supra*, I find that Lemchen does not disclose, or teach or suggest, calculating positions-in-between an initial data set and a final data set. I incorporate and reaffirm that finding and rationale here. As a result, I find that Lemchen does not disclose "obtaining a series of successive digital data sets representing a series of successive tooth arrangements," as required by claim 1.

In Section IV.B.1.a, *supra*, I also find that Lemchen's disclosure is limited to the idea of treating a patient with a single set of brackets, i.e. one bracket per tooth to be used over the entirely of the treatment. I incorporate and reaffirm that finding and rationale here. As a result, I also find that Lemchen does not disclose "fabricating a predetermined series of dental incremental position adjustment appliances based on the series of successive digital data sets, wherein said appliances comprise polymeric shells having cavities shaped to receive and resiliently reposition teeth, and said appliances correspond to the series of successive tooth arrangements progressing from the initial to the repositioned tooth arrangement" as required by claim 1.

I note, too, that the incorporation of Figures 1 and 3 of Kesling into Lemchen provides no greater insight into the teachings of the asserted claims. In Section IV.B.1.a, *supra*, I find that Figure 1 only describes a physical model of a mathematically generated model of a patient's teeth, and Figure 3 demonstrates a method of physically moving portions of a model representing the patient's teeth into a "finish position." I incorporate and reaffirm that finding and rationale here.

In addition, assuming *arguendo* that one were to find that Lemchen incorporates all of Kesling by reference, the result would not change. In Section IV.B.1.a, supra I find that Kesling "does not disclose, or teach or suggest, or even remotely contemplate" the use of computers or digital technology and contemplated a reactive process, performed one step at a time, where appliances beyond a first appliance may be created by repeating the disclosed process for making the first appliance. I incorporate and reaffirm that finding and rationale here.

Assuming, arguendo, that Kesling disclosed "digital data sets," because Kesling discloses a reactive process performed one step at a time, Kesling does not disclose "***fabricating two or***

more dental appliances to be used successively to adjust the position of teeth between an initial tooth arrangement and a repositioned tooth arrangement, ***the digital data sets on which they are based having been created before any of said two or more dental appliances in the series are fabricated***," as required by the construction for "fabricating a predetermined series of dental incremental position adjustment appliances" found in Section III.B.2, *supra*.

In Section IV.B.1.a, supra, I find that Kesling also does not expressly or inherently disclose, or teach or suggest, fabricating a dental appliance based on a digital data set. I incorporate and reaffirm that finding and rationale here.

Based upon all of the foregoing, I find that Respondents have failed to meet their burden to prove by clear and convincing evidence that Lemchen anticipates claim 1 of the '880 patent.

b. Claim 3

Claim 3 depends from claim 1 and teaches:

> A method as in claim 1, wherein the step of obtaining a digital data set representing a repositioned tooth arrangement comprises:
>
> defining boundaries about at least some of the individual teeth; and
>
> moving at least some of the tooth boundaries relative to the other teeth in an image based on the digital data set to produce the repositioned data set.

(JX-002 at 22:33-41)

Respondents' Position: Respondents assert that dependent claim 3 is anticipated by Lemchen and, as incorporated, Kesling. Respondents incorporate by reference Disclosure Category 4.

Align's Position: Align addressed all asserted claims at once, as discussed above regarding claim 1. Align additionally asserts that Respondents fail to point to any portion of the

prior art that they contend discloses "defining boundaries about at least some of the individual teeth" ('880 claim 3). (Citing RIB at 86-87)

Staff's Position: Staff's position is stated above regarding claim 1.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 1 to be anticipated and invalid, I could still find that claim 3 is valid. Since, however, I have found claim 1 to be valid and ***not*** anticipated by Lemchen, claim 3 is necessarily valid, because it depends from claim 1 and necessarily contains all of the elements of claim 1. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 1 is anticipated by Lemchen, I would find that Respondents have failed to show by clear and convincing evidence that claim 3 of the '880 patent is anticipated by Lemchen with the incorporation of Kesling. Although Lemchen teaches generating a digital data set representing teeth in their "final" position (*see* CX-945 at 1:55-2:1; 2:54-57; 3:16-24), Lemchen does not disclose the specific details of how this would be accomplished (*see* CX-945 at 3:44-54). Thus, I find that Lemchen with the incorporation of Kesling, does not reveal the subject matter of claim 3.

2. Obviousness

a. Claim 1

Respondents' position: Respondents assert that claim 1 is obvious. Respondents incorporate by reference the section of RIB addressing the preamble of Claim 1 of the '325. Respondents also incorporate by reference Disclosure Categories 1, 5, 7, 9, and 10 together with the knowledge of one of ordinary skill. Respondents argue that these disclosures demonstrate that the claim was obvious.

Align's Position: Align says that Respondents argue that all of the asserted claims of the '880 patent are obvious in view of the combination of: (i) Lemchen; (ii) Kesling; and (iii) "the knowledge of one of ordinary skill in the art." Align argues that Respondents' argument fails for a myriad of reasons. Align says that this particular combination was disclosed for the first time in the *JSCI*, as explained in Align's *Motion in Limine No. 4*, and is therefore improperly raised now. Align continues that the argument is unsupported because no claim charts showing this assertion in detail are in evidence. Align argues that Respondents' argument is also wrong because these references, in any combination, fail to disclose all the elements of claims 1 or 3, as discussed in CIB Sec. IV.F.4. Align continues that one of ordinary skill in the art at the time of the invention would not have been motivated to combine a reference directed to fixed appliances made of brackets and wires (Lemchen) with a reference directed to removable appliances (Kesling). (Citing CIB Section IV.F.2.b) Align contends that secondary considerations support a finding of non-obviousness. (Citing CIB Section IV.F.2.c)

Align says Respondents identified several other combinations in the RJSCI. Align contends that none were properly raised in Respondents' Prehearing Brief, and have been waived, for the reasons discussed above in CIB Section IV.F.2. Align argues alternatively that as explained in Sec. IV.F.2.a, IV.F.4, and illustrated in CDX-0156—CDX-0157, no combination of the prior art discloses all elements of the asserted claims of the '880 patent.

Align argues that any obviousness contentions or combinations have been waived. (Citing CRB Section IV.H.2) Align alternatively argues that none of the asserted claims are obvious. Align says that Respondents failed to make a *prima facie* showing of obviousness. (Citing CRB Section IV.H; Tr. at 19:11-20:4, 651:14-653:25) Align continues that any combination of prior art other than Lemchen and Kesling was waived. (Citing CRB Sec.

IV.H.2.a) Align says that the combination of Lemchen and Kesling cannot render any of the asserted claims obvious; it does not disclose all elements of any of the asserted claims. (Citing CIB at 48-51; CX-1247C at Q. 568-569; CX-1254C ¶ 274 at 97; CDX-0156—CDX-0157) *Align* continues that Respondents' obviousness theory relies on their "disclosure categories," which advance new and unsupported mischaracterizations of Lemchen and Kesling, and fail to fairly address the elements of the asserted claims. (Citing Sec. IV.H.4) Align says that Respondents also misapply their "disclosure categories" with respect to claims 1 and 3 of the '880 patent. (Citing *id.*) Align continues that none of the prior art discloses all elements of any of the asserted claims, in ***any*** combination. (Citing CIB at 47-52; CX-1247C at Q. 606, 610; CX-1258; CDX-0156—CDX-0157) Align says that there is no evidence of a motivation to combine the prior art. (Citing CRB Section IV.H.2.b) Align concludes that, secondary considerations show nonobviousness. (Citing CRB Section IV.H.2.c; CIB at 45-47)

Staff's Position: Staff says that given that Respondents' arguments and Dr. Mah's testimony alleging obviousness of the Asserted Claims of the '325 patent are also made with respect to the Asserted Claims of the '880 patent, the Staff's discussion of obviousness in SIB Section IV.E.2, applies equally for the '880 patent.

Analysis and Conclusions: Respondents have failed to provide clear and convincing evidence that asserted claim 1 of the '880 patent is obvious. Respondents have asserted two separate combinations in post-hearing briefing—Lemchen, Kesling, and the knowledge of one of ordinary skill in the art and Lemchen, Kesling, Nahoum, and the knowledge of one of ordinary skill in the art.

I note that while Respondents do mention "knowledge of one of ordinary skill in the art" in RPHB, section 4.1.2.2, their references in that pre-hearing brief amount to a general

discussion of eleven separate references with no element by element discussion of how those eleven references would combine to render the asserted claims of the '880 patent obvious. There is only a general reference to a "claim chart" that Respondents say they will produce at the hearing. This is inadequate to provide notice to Align regarding the specific prior art to be addressed and the manner in which the prior art discloses each and every element of an asserted claim. (RPHB at 99-106) As a result, at the hearing I granted Align's motion *in limine* number 6, and excluded the claim charts that were not specifically cited in Respondents' prehearing brief as required by Ground Rule 8.2. (Tr. 18:13-20:4)

Although Respondents discussed eleven different prior art references in RPHB section 4.1.2.2, Respondents failed to identify any specific combinations of prior art references other than Lemchen, Kesling, and the knowledge of one of ordinary skill in the art. (RPHB at 49). Ground Rule 8.2 states "[a]ny contentions not set forth in detail as required herein shall be deemed abandoned or withdrawn, except for contentions of which a party is not aware and could not be aware in the exercise of reasonable diligence at the time of filing the pre-trial brief." Because Respondents did not identify any specific combinations other than Lemchen, Kesling, and the knowledge of one of ordinary skill in the art, any other combinations, including Nahoum with Lemchen, Kesling, and the knowledge of one of ordinary skill in the art, were waived.

In order to prevail on their claim that the asserted claims of the '880 patent are invalid as obvious, Respondents must first demonstrate that the combination of Lemchen, either alone or in combination with Kesling discloses all of the limitations of the asserted claims. (*Hearing Components, Inc. v. Shure Inc.*, 600 F.3d 1357, 1373-1374 (Fed. Cir. 2010); and *Velander v. Garner*, 348 F.3d 1359, 1363 (Fed. Cir. 2003))

Equally important is the requirement that the Respondents establish by clear and

convincing evidence that a person of ordinary skill in the art would have had reason to combine the various asserted prior art references to attempt to produce the invention and would have had a reasonable expectation of success in doing so. (See *PharmaStem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007))

Assuming, *arguendo*, that Respondents had properly disclosed their arguments based on the combination of Lemchen, Kesling, Nahoum, and the knowledge of one or ordinary skill in the art in their pre-hearing brief, there is nothing in the evidence submitted by Respondents to support a finding that a PHOSITA would be motivated by anything in Lemchen, Kesling or Nahoum to follow the methods in the '880 patent. In section IV.C.1, *supra*, I noted that even if I had found that Lemchen incorporated the ***entirety*** of Kesling by reference, those two references taken together would still not disclose each and every element of the asserted claims of the '880 patent. Based upon that finding, it follows that Lemchen combined with Kesling would not render obvious the asserted claims of the '880 patent.

Respondents' evidence regarding the knowledge of one of ordinary skill in the art does not fill the gaps in Lemchen and Kesling. Respondents' evidence is limited to expert reports of a former expert for Align (RX-102C and RX-103C) and the opening witness statement of Dr. Mah. At the prehearing conference, I ruled that that Dr. Rekow's expert reports (RX-102C and RX-103C) could be used solely to show that Align took an inconsistent position in the prior litigation. (Tr. at 20:24-21:7) Here, Respondents are improperly attempting to rely on the expert reports to show the knowledge of one of ordinary skill in the art. The testimony of Dr. Mah is not helpful on this subject because he expresses a series of conclusory opinions without citing to evidentiary support. (*See, e.g.*, RX-113C, Qs. 104, 113-121)

Focusing on the motivation to combine references, in Section IV.B.2, *supra*, I find that it

was obvious to combine Lemchen and Kesling. I incorporate that finding and reaffirm it here. Respondents do not, however, provide any basis for combining Nahoum with the Lemchen and Kesling references.

Notwithstanding the foregoing, examining Nahoum in combination with Lemchen and Kesling, I find that Nahoum does not provide the elements missing from the Lemchen and Kesling references. In Section IV.B.1.a, *supra*, I find that Lemchen does not disclose, or teach or suggest, calculating positions-in-between an initial data set and a final data set. In Section IV.B.2.a, *supra*, I find that Lemchen does not in any way disclose, or hint at, designing or fabricating intermediate or successive tooth repositioning appliances based on digital data sets. Lemchen's disclosure is limited to the idea of treating a patient with a single set of brackets, i.e. one bracket per tooth to be used over the entirely of the treatment. In Section IV.B.1.a, *supra*, I find that Kesling contemplated a reactive process, performed one step at a time, where appliances beyond a first appliance may be created by repeating the disclosed process for making the first appliance. In Section IV.B.2.a, *supra*, I also find that Kesling "does not disclose, or teach or suggest, or even remotely contemplate" the use of computers or digital technology and does not expressly or inherently disclose, or teach or suggest, fabricating a dental appliance based on a digital data set. Additionally, in Section IV.B.2.a, *supra*, I find that Nahoum does not in any way disclose use of computers or digital data to assist in fabricating a dental appliance. I reaffirm and incorporate these findings and rationales here.

Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of the asserted claims of the '880 patent are present in Lemchen, either alone or in combination with Kesling, and Nahoum, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine the

those references to create the method claimed in the invention of the '880 patent.

b. Claim 3

Respondents' Position: Respondents contend that claim 3 is obvious. Respondents incorporate Disclosure Category 4 together with the knowledge of one of ordinary skill addressed in the '325 section. Respondents argue that these disclosures demonstrate that the claim was obvious.

Align's Position: Align addressed all asserted claims at once, as discussed above regarding claim 1.

Staff's Position: Staff's position is stated above regarding claim 1.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 1 to be rendered obvious by the asserted prior art and invalid, I could still find that claim 3 is valid. Since, however, I have found claim 1 to be valid and ***not*** rendered obvious by Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, claim 3 is necessarily valid, because it depends from claim 1 and necessarily contains all of the elements of claim 1. *See In re Fritch,* 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 1 is rendered obvious by Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, I would find that Respondents have failed to show by clear and convincing evidence that claim 3 of the '880 patent is rendered obvious by that combination.

In section IV.C.1.b, *supra*, I found that although Lemchen teaches generating a digital data set representing teeth in their "final" position (*see* CX-945 at 1:55-2:1; 2:54-57; 3:16-24), Lemchen does not disclose the specific details of how this would be accomplished (*see* CX-945

at 3:44-54). In the interest of brevity, I will not repeat the discussion in section IV.C.1.b in its entirety; but I reaffirm that finding and the rationale for it.

Nahoum and the knowledge of one of ordinary skill in the art do not fill these gaps. In Section IV.B.2.a, *supra*, I find that Nahoum does not in any way disclose use of computers or digital data to assist in fabricating a dental appliance. Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of asserted claim 3 of the '880 patent are present in Lemchen combined with Kesling, Nahoum, and the knowledge of one of ordinary skill in the art, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine those references to create the method claimed in asserted claim 3 of the '880 patent.

D. The '487 Patent

1. Anticipation

a. Claim 1

Claim 1 teaches:

> A method of planning orthodontic treatment of a patient comprising use of incremental tooth repositioning appliances, the method comprising:
>
> receiving an initial digital data set representing an initial arrangement of the patient's teeth;
>
> producing a final digital data set representing the patient's teeth in a desired or prescribed arrangement;
>
> producing a plurality of intermediate digital data sets representing intermediate arrangements of the patient's teeth, wherein at least some of the intermediate tooth arrangements represent different orthodontic treatment stages as the patient's teeth are moved from the initial arrangement toward the final arrangement.

(JX-007 at 10:61-11:6)

Respondents' Position: Respondents say that while Align argues that the preamble is not an element of the claimed invention, the subject matter is disclosed in the prior art. Respondents incorporate the section addressing the preamble of Claim 1 of the '325 Patent. Respondents say that Align previously recognized that Lemchen developed a full digital three dimensional modeling for planning orthodontic treatment:

> Full three-dimensional modeling in **orthodontic treatment planning** was described by Lemchen . . . . . This model is the mathematical representation of the physical model described by Kesling in 1949. . . . This digital/mathematical model was used for the **planning orthodontic treatment**.

(Citing RX-103C at 16 (emphasis added)) Respondents incorporate Disclosure Categories 1, 5, and 7.

Respondents incorporate Disclosure Category 1, and argue it discloses the first limitation of claim 1. Respondents incorporate Disclosure Categories 4 and 5, contending that they disclosing the second limitation of claim 1. Respondents assert that Disclosure Category 7 discloses the third limitation of claim 1.

Respondents argue that claim 1 is broadly directed to a method for "planning orthodontic treatment of a patient" and contains no limitations as to the appliance to be used. Respondents say that Lemchen anticipates this claim. Respondents continue that it is beyond dispute that Kesling's three-dimensional modeling method taught initial, final and intermediate tooth arrangements. (Citing CX-0944 at 2:50–3:1) Respondents says that these facts demonstrate that Lemchen anticipates this claim because there is no material difference between the claim and the prior art.

Align's Position: Align contends that Respondents' invalidity positions are wholly unsupported and totally insufficient to meet their high burden for an invalidity finding. Align says that Respondents have no particular evidence to support their invalidity case, as no claim

charts explaining where each claimed element is shown in the cited references is in evidence - because they were not included with Respondents' Prehearing Brief. (Citing Tr. at 19:11-20:4; 651:14-653:25) Align continues that the prior art references simply fail to disclose all elements of any of the asserted claims of the '487 patent, individually or under any combination. (Citing CX-1247C at Q. 606, 610; CX-1258) Align adds that the failings of the prior art are explained in CIB Sec. IV.F.4. Align says that elements of the asserted claims of the '487 are missing from each prior art reference are illustrated in CDX-0164—CDX-0169. Align argues that none of the prior art discloses, *inter alia*, "a plurality of intermediate digital data sets representing intermediate arrangements of the patient's teeth."

Align says that Respondents contend that all of the asserted claims of the '487 patent are anticipated by Lemchen and "as incorporated," Kesling. Align disagrees, saying that this argument is unsupported, because no claim charts (or other explanatory vehicle) showing this assertion in detail are in evidence. Alternatively Align asserts that this argument relies on accepting that Lemchen incorporates the entire disclosure of Kesling, which is wrong for the reasons described in CIB Sec. IV.F.4.c. Align continues, saying that even assuming incorporation, Lemchen/Kesling would still fail to disclose all elements of the asserted claims. Align says that both Lemchen and Kesling were considered by the USPTO during the prosecution of the '487 patent, further confirming that the claims of the '487 patent are valid over Lemchen and Kesling.

Align says that Respondents fail to point to any portion of the prior art that they contend discloses, *e.g.*, "intermediate digital data sets" (claim 1) or "orthodontic treatment plan for repositioning a patient's teeth using incremental tooth repositioning appliances" (claim 7). Align says that Respondents contend that all of the asserted claims are anticipated by Lemchen and "as

incorporated," Kesling. Align says that Respondents failed to make a *prima facie* showing of anticipation. (Citing CRB Section IV.H; Tr. at 19:11-20:4, 651:14-653:25) Align continues that Respondents rely on the flawed theory that Lemchen incorporates the entire disclosure of Kesling. (Citing CRB Section IV.H.1) Align says that even assuming incorporation, Lemchen/Kesling fails to disclose all elements of any asserted claim. (Citing CX-1247C at Q. 568-569; CX-1254C ¶ 274 at 97; CDX-0164—CDX-0169) Align continues that Respondents' theory relies on their "disclosure categories," which advance new and unsupported mischaracterizations of Lemchen and Kesling, and fail to fairly address the elements of the asserted claims. (Citing CRB Section IV.H.4.) Respondents also misapply their "disclosure categories" with respect to at least claim 3 of the '487 patent. (Citing *id.*) Respondents say that the USPTO considered Lemchen and Kesling during the prosecution of the '487 patent, further demonstrating that the asserted claims are not anticipated. (Citing JX-0007 at 1-2)

Staff's Position: Staff contends that because Respondents' arguments and Dr. Mah's testimony alleging anticipation of the Asserted Claims of the '325 patent are also made with respect to the Asserted Claims of the '487 patent, the Staff's discussion of anticipation in SIB Section IV.E.1, *infra*, applies equally here.

Staff says that Respondents have failed to demonstrate clearly and convincingly that any asserted claim of the '487 patent is invalid because Respondents have failed to provide an element-by-element comparison of the prior art with the asserted claims of the '487 patent. Staff continues that in their Pre-Hearing Brief, Respondents represented that they would introduce a claim chart showing "where each element of each asserted claim is found in the prior art." (Citing RPHB at 47) Staff says that I excluded that claim chart. (Citing Tr. at 18:13-19:25) Staff says that Respondents attempt to make up this shortcoming in their post-hearing brief by

comparing, on an element-by-element basis, their prior art references with the Asserted Claims of the '487 patent. Staff says that because Respondents admittedly did not make perform this comparison in their Pre-Hearing Brief, Respondents should not be permitted to do so now. (Citing Ground Rule 8.2)

Staff argues that even if Respondents' comparison of their prior art references with the Asserted Claims of the '487 patent is permitted, that comparison consists of primarily attorney argument, which is no substitute for evidence. Staff says that Respondents cite to Dr. Mah's testimony to support their allegations of anticipation and obviousness, but that testimony is merely conclusory, as it too references a claim chart, purporting to show how and where the prior art discloses each element of each asserted claim, that has been excluded by the ALJ.

Analysis and Conclusions: In Section IV.B.1, *supra*, I found that Lemchen only incorporates by reference Figures 1 and 3 of Kesling. I incorporate and reaffirm those findings and rationale here. As noted in Section IV.B.1, *supra*, Lemchen and Kesling were considered by the United States Patent and Trademark Office during prosecution of the '487 patent (JX-007 at 1-2), and Respondents face a heighted burden to establish invalidity based on Lemchen and Kesling. Respondents, however, have failed even to meet the ordinary burden to prove by clear and convincing evidence that each and every limitation of the asserted claims is disclosed expressly or inherently.

In Section IV.B.1.a, *supra*, I find that Lemchen does not disclose, or teach or suggest, calculating positions-in-between an initial data set and a final data set. I incorporate and reaffirm that finding and rationale here. As a result, I find that Lemchen does not disclose "producing a plurality of intermediate digital data sets representing intermediate arrangements of the patient's teeth," as required by claim 1.

I note, too, that the incorporation of Figures 1 and 3 of Kesling into Lemchen provides no greater insight into the teachings of the asserted claims. In Section IV.B.1.a, *supra*, I find that Figure 1 only describes a physical model of a mathematically generated model of a patient's teeth, and Figure 3 demonstrates a method of physically moving portions of a model representing the patient's teeth into a "finish position." I incorporate and reaffirm that finding and rationale here.

In addition, assuming *arguendo* that one were to find that Lemchen incorporates all of Kesling by reference, the result would not change. In Section IV.B.1.a, supra I find that Kesling "does not disclose, or teach or suggest, or even remotely contemplate" the use of computers or digital technology and contemplated a reactive process, performed one step at a time, where appliances beyond a first appliance may be created by repeating the disclosed process for making the first appliance. I incorporate and reaffirm that finding and rationale here.

Assuming, arguendo, that Kesling disclosed "digital data sets," because Kesling discloses a reactive process performed one step at a time, Kesling does not disclose "producing a plurality of intermediate digital data sets representing intermediate arrangements of the patient's teeth, wherein at least some of the intermediate tooth arrangements represent different orthodontic treatment stages as the patient's teeth are moved from the initial arrangement toward the final arrangement," as required by claim 1.

Based upon all of the foregoing, I find that Respondents have failed to meet their burden to prove by clear and convincing evidence that Lemchen anticipates claim 1 of the '487 patent.

b. Claim 3

Dependent claim 3 recites:

> The method of claim 1, wherein the intermediate digital data sets for different orthodontic treatment stages are configured for facilitating

fabrication of shell appliances for a corresponding treatment stage.

(JX-007 at 11:10-13)

Respondents' Position: Respondents argue that Lemchen discloses the subject matter of claim 3 and incorporate Disclosure Categories 7 and 9.

Respondents assert that claim 3 is broadly directed to a method for "planning orthodontic treatment of a patient." Respondents say that claim 3's added limitation as to a shell appliance is not meaningful in the validity analysis because the models of dentition, virtual or physical, are necessarily configured as positive models of teeth arrangements which facilitates the fabrication of the shell appliances. Respondents say that this fact demonstrates that Lemchen reference anticipates this claim because there is no material difference between the claim and the prior art.

Align's Position: Align addressed all asserted claims at once, as discussed above regarding claim 1.

Staff's Position: Staff's position is stated above regarding claim 1.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 1 to be anticipated and invalid, I could still find that claim 3 is valid. Since, however, I have found claim 1 to be valid and ***not*** anticipated by Lemchen, claim 3 is necessarily valid, because it depends from claim 1 and necessarily contains all of the elements of claim 1. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 1 is anticipated by Lemchen, I would find that Respondents have failed to show by clear and convincing evidence that claim 3 of the '487 patent is anticipated by Lemchen with the incorporation of Kesling.

In Section IV.B.1.a, *supra*, I find that Lemchen is limited to the idea of treating a patient

with a single set of brackets, not with plural polymeric shell appliances. I incorporate and reaffirm that finding and rationale here. As a result, I find that Lemchen does not disclose the above quoted limitations of claim 3.

c. Claim 5

Claim 5 teaches:

> The method of claim 1, further comprising providing a plurality of the intermediate digital data sets to a fabrication operation for fabrication of a series of successive tooth repositioning appliances.

(JX-007 at 11:19-22)

Respondents' Position: The Respondents incorporate Disclosure Category 9. Respondents contend that Disclosure Category 9 discloses the subject matter of claim 5.

Respondents say that dependent claim 9 is broadly directed to a method for "planning orthodontic treatment of a patient." Respondents say that the claim's additional limitation of providing digital data of tooth arrangements to a fabrication operation is also anticipates by Lemchen reference. According to Respondents, Kesling taught fabrication of a series of aligners. (Citing CX-0944 at 2:50–3:1) Respondents say that Lemchen disclosed the transfer of digital information between a practitioner and a dental lab, and the use of that digital information by the dental lab in its manufacturing process, "where the digitized information is utilized in the process of providing the practitioner with the required dental appliances for the correction of the malocclusion." (Citing CX-0945 at 5:15–20) Respondents argue that this demonstrates that the Lemchen anticipates this claim because there is no material difference between the claim and the prior art.

Align's Position: Align addressed all asserted claims at once, as discussed above regarding claim 1.

Staff's Position: Staff's position is stated above regarding claim 1.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 1 to be anticipated and invalid, I could still find that claim 5 is valid. Since, however, I have found claim 1 to be valid and ***not*** anticipated by Lemchen, claim 5 is necessarily valid, because it depends from claim 1 and necessarily contains all of the elements of claim 1. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 1 is anticipated by Lemchen, I would find that Respondents have failed to show by clear and convincing evidence that claim 5 of the '487 patent is anticipated by Lemchen with the incorporation of Kesling. In Section IV.B.1.a, I find that Lemchen is limited to the idea of treating a patient with a single set of brackets, not with plural appliances. I incorporate and reaffirm that finding and rationale here. As a result, I find that Lemchen does not disclose the above quoted limitations of claim 5.

d. Claim 7

Claim 7 teaches:

> An orthodontic treatment plan for repositioning a patient's teeth using incremental tooth repositioning appliances, the treatment plan residing on a computer readable storage media and comprising a plurality of intermediate digital data sets representing intermediate arrangements of the patient's teeth,
>
> wherein at least some of the intermediate tooth arrangements represent different orthodontic treatment stages as the patient's teeth are moved from an initial arrangement toward a final arrangement representing the patient's teeth in a desired or prescribed arrangement.

(JX-007 at 11:26-35)

Respondents' Position: Respondents assert that while Align argues that the preamble is not an element of the claimed invention, the subject matter is disclosed in the prior art.

Respondents incorporate the section addressing the preamble of Claim 1 of the '325. Respondents say that Align previously recognized that Lemchen developed a full digital three dimensional modeling for planning orthodontic treatment. (Citing RX-103C at 16.) Respondents incorporate Disclosure Categories 1, 5, and 7.

Respondents assert that Disclosure Category 2 discloses "the treatment plan residing on a computer readable storage media and comprising a plurality of intermediate digital data sets representing intermediate arrangements of the patient's teeth."

Respondents contend that Disclosure Categories 7 and 10 disclose "wherein at least some of the intermediate tooth arrangements represent different orthodontic treatment stages as the patient's teeth are moved from an initial arrangement toward a final arrangement representing the patient's teeth in a desired or prescribed arrangement."

This independent claim is broadly directed to an "orthodontic treatment plan." This claim relates broadly to incremental tooth repositioning appliance and is not limited to aligners. Respondents have identified evidence that demonstrates the invalidity of this claim in the Respondents' Post-Hearing Brief. That evidence is incorporated here.

Respondents argue that claim 7 requires: 1) a treatment plan residing on a computer readable storage media; 2) a plurality of intermediate digital tooth arrangements representing different orthodontic treatment stages. Respondents say that Lemchen clearly anticipates this claim. Respondents continue that contrary to Align's position here, Dr. Rekow's opinions confirm this:

> Full three-dimensional modeling in **orthodontic treatment planning** was described by Lemchen . . . . . This model is the mathematical representation of the physical model described by Kesling in 1949. . . . This digital/mathematical model was used for the **planning orthodontic treatment.**

(Citing RX-103C at 16 (emphasis added)) Respondents add that it is beyond dispute that Kesling's three-dimensional modeling method taught initial, final and intermediate tooth arrangements. (Citing CX-0944 at 2:50–3:1) Respondents contend that these facts demonstrate that Lemchen anticipates this claim because there is no material difference between the claim and the prior art.

Align's Position: Align addressed all asserted claims at once, as discussed above regarding claim 1.

Staff's Position: Staff's position is stated above regarding claim 1.

Analysis and Conclusions: In Section IV.B.1, *supra*, I found that Lemchen only incorporates by reference Figures 1 and 3 of Kesling. I incorporate and reaffirm those findings a rationale here. Even assuming that Lemchen incorporated the entirety of Kesling, each and every limitation of the asserted claims is not disclosed.

In Section IV.B.1.a, *supra*, I find that Lemchen does not disclose, or teach or suggest, calculating positions-in-between an initial data set and a final data set. I incorporate and reaffirm that finding and rationale here. As a result, I find that Lemchen does not disclose "a plurality of intermediate digital data sets representing intermediate arrangements of the patient's teeth," as required by claim 7.

I note, too, that the incorporation of Figures 1 and 3 of Kesling into Lemchen provides no greater insight into the teachings of the asserted claims. In Section IV.B.1.a, *supra*, I find that Figure 1 only describes a physical model of a mathematically generated model of a patient's teeth, and Figure 3 demonstrates a method of physically moving portions of a model representing the patient's teeth into a "finish position." I incorporate and reaffirm that finding and rationale here.

In addition, assuming *arguendo* that one were to find that Lemchen incorporates all of Kesling by reference, the result would not change. In Section IV.B.1.a, supra I find that Kesling "does not disclose, or teach or suggest, or even remotely contemplate" the use of computers or digital technology and contemplated a reactive process, performed one step at a time, where appliances beyond a first appliance may be created by repeating the disclosed process for making the first appliance. I incorporate and reaffirm that finding and rationale here.

Assuming, arguendo, that Kesling disclosed "digital data sets," because Kesling discloses a reactive process performed one step at a time, Kesling does not disclose "a plurality of intermediate digital data sets representing intermediate arrangements of the patient's teeth," or "a treatment plan," which as construed in Section III.D.2, *supra*, requires "two or more successive digital data sets representing arrangements of a patient's teeth progressing from an initial tooth arrangement toward a final tooth arrangement," as required by claim 7.

Based upon all of the foregoing, I find that Respondents have failed to meet their burden to prove by clear and convincing evidence that Lemchen anticipates claim 7 of the '487 patent.

e. Claim 8

Claim 8 teaches:

> The orthodontic treatment plan of claim 7, wherein the intermediate digital data sets for different orthodontic treatment stages are configured for facilitating fabrication of shell appliances for a corresponding treatment stage.

(JX-007 at 11:36-39)

Respondents' Position: Respondents argue that Disclosure Category 10 discloses the subject matter of claim 8.

Respondents assert that claim 8 is also broadly directed to an "orthodontic treatment plan." Respondents say that claim 8's added limitation of a shell appliance is not meaningful in

the validity analysis because the models of dentition, virtual or physical, are necessarily configured as positive models of teeth arrangements which facilitates the fabrication of the shell appliances. Respondents contend that this fact demonstrates that Lemchen anticipates this claim because there is no material difference between the claim and the prior art.

Align's Position: Align addressed all asserted claims at once, as discussed above regarding claim 1.

Staff's Position: Staff's position is stated above regarding claim 1.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 7 to be anticipated and invalid, I could still find that claim 8 is valid. Since, however, I have found claim 7 to be valid and ***not*** anticipated by Lemchen, claim 8 is necessarily valid, because it depends from claim 7 and necessarily contains all of the elements of claim 8. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 7 is anticipated by Lemchen, I would find that Respondents have failed to show by clear and convincing evidence that claim 8 of the '487 patent is anticipated by Lemchen with the incorporation of Kesling.

In Section IV.B.1.a, I find that Lemchen is limited to the idea of treating a patient with a single set of brackets, not with plural polymeric shell appliances. I incorporate and reaffirm that finding and rational here. As a result, I find that Lemchen does not disclose the above quoted limitations of claim 8.

f. Claim 9

Claim 9 teaches:

> The orthodontic treatment plan of claim 8, wherein the shell appliances comprise a plurality of successive appliances having teeth receiving

> cavities, and wherein cavities of at least two successive appliances have different geometries shaped to receive and reposition the patient's teeth.

(JX-007 at 11:40-44)

Respondents' Position: Respondents incorporate Disclosure Category 10 and assert that it discloses the subject matter of claim 9.

Respondents argue that dependent claim 9 is also broadly directed to an "orthodontic treatment plan." Respondents say that claim 9's added limitation of successive appliances with teeth receiving cavities does not change the validity analysis because the appliances taught by Kesling have teeth receiving cavities. (Citing CX-0944 at Figure 7) Respondents conclude that Lemchen anticipates this claim because there is no material difference between the claim and the prior art.

Align's Position: Align addressed all asserted claims at once, as discussed above regarding claim 1.

Staff's Position: Staff's position is stated above regarding claim 1.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claims 7 and 8 to be anticipated and invalid, I could still find that claim 9 is valid. Since, however, I have found claims 7 and 8 to be valid and ***not*** anticipated by Lemchen, claim 9 is necessarily valid, because it depends from claim 7 via claim 8 and necessarily contains all of the elements of claims 7 and 8. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that claims 7 and 8 are anticipated by Lemchen, I would find that Respondents have shown by clear and convincing evidence that claim 9 of the '487 patent is anticipated by Lemchen with the incorporation of Kesling.

Claim 8 teaches "the intermediate digital data sets for different orthodontic treatment

stages are configured for facilitating fabrication of shell appliances for a corresponding treatment stage." (JX-007 at 11:36-39) In order to reposition teeth, the successive shell appliances disclosed in claim 8 necessarily will have different shapes. As a result, I find that if Lemchen were found to anticipate claim 8, Lemchen also it would also anticipate claim 9.

2. Obviousness

a. Claim 1

Respondents' Position: Respondents incorporate the section of RIB addressing the preamble of Claim 1 of the '325. Respondents say that, contrary to its position here, Align previously recognized that Lemchen developed a full digital three dimensional modeling for planning orthodontic treatment. (Citing RX-103C at 16) Respondents argue that this demonstrates that there is no difference between the Lemchen reference and this claimed invention. Respondents incorporate Disclosure Categories 1, 4, 5, and 7 together with the knowledge of one of ordinary skill. Respondents say that these disclosures show that the claimed invention was obvious.

Respondents assert that claim 1 is further rendered obvious in light of U.S. Patent No. 8,338,198 ("Wu") and the knowledge of one of ordinary skill. Respondents say that Wu describes a method of planning orthodontic treatment, simulating that treatment and the design of the orthodontic appliances to facilitate that treatment. (Citing RX-0095 at 4:14-20) Respondents continue that Wu describes the creation of a 3-D initial digital set by scanning an impression of the patient's dental arch. (Citing RX-0095 at 5:41-50) Respondents add that Wu describes segmentation of the 3-D digital model of the patient's dental arch, the relocation of the teeth in simulated, digitized orthodontic treatment, and use of the digitized simulation to demonstrate treatment outcomes and gain approval for the treatment. (Citing RX-0095 at 5:41-50; at 7:29-34;

at 8:55-58, at 7:2-3) Respondents argue that these disclosures show that the claimed invention was obvious.

Align's Position: Align says that Respondents argue that all of the asserted claims of the '487 patent are obvious in view of the combination of: (i) Lemchen; (ii) Kesling; and (iii) "the knowledge of one of ordinary skill in the art." Align argues that this particular combination was disclosed for the first time in the *JSCI*, as explained in Align's Motion in Limine No. 4, and is therefore improperly raised now. Align continues that the argument is unsupported because no claim charts showing this assertion in detail are in evidence. Align adds that Respondents' argument is wrong because these references, in any combination, fail to disclose all the elements of the asserted claims, as discussed in CIB Sections IV.F.2.a, IV.F.4. Align contends that one of ordinary skill in the art at the time of the invention would not have been motivated to combine a reference directed to fixed appliances made of brackets and wires (Lemchen) with a reference directed to removable appliances (Kesling). (Citing CIB Sec. IV.F.2.b) Align continues that Lemchen and Kesling were considered by the USPTO during the prosecution of the '487 patent, further confirming that the asserted claims of the '487 patent are valid over these references. Align adds that secondary considerations support a finding of non-obviousness. CITING CIB Sec. IV.F.2.c)

Align says that Respondents identified several other combinations in the RJSCI. None were properly raised in Respondents' Prehearing Brief, and have been waived, for the reasons discussed in CIB Sec. IV.F.2. Align continues that, as explained in CIB Sections IV.F.2.a, IV.F.4, and illustrated in CDX-0164—CDX-0169, no combination of the prior art discloses all elements of the asserted claims of the '487 patent. Align says that Respondents contend that asserted claims 1, 3, 5, 7 and 8 of the '487 patent are "further rendered obvious in light of Wu

and the knowledge of one of ordinary skill in the art." Align says that any obviousness combination involving Wu has been waived because it was not disclosed in Respondents' Prehearing Brief. Align continues that Wu cannot render any of the claims obvious under any combination.

Align argues that Wu does not disclose, *inter alia*: (i) a plurality of digital data sets representing a plurality of tooth arrangements (Citing CX-1247C at Q. 410, 412, 414-415, 418-422; CX-1254C ¶ 185 at 69); (ii) intermediate digital data sets or tooth arrangements (Citing CX-1247C at Q. 410, 412, 414-415, 418-422); or (iii) numerous other elements of Align's claims (Citing CX-1247C at Q. 410, 412, 414-415, 418-422; CX-1258 at 37-42).

Staff's Position: Staff says that because Respondents' arguments and Dr. Mah's testimony alleging obviousness of the Asserted Claims of the '325 patent are also made with respect to the Asserted Claims of the '487 patent, the Staff's discussion of obviousness in SIB Section IV.E.2, *infra*, applies equally here.

Staff says that Respondents have failed to demonstrate clearly and convincingly that any asserted claim of the '487 patent is invalid because Respondents have failed to provide an element-by-element comparison of the prior art with the asserted claims of the '487 patent. Staff continues that in their Pre-Hearing Brief, Respondents represented that they would introduce a claim chart showing "where each element of each asserted claim is found in the prior art." (Citing RPHB at 47) Staff says that I excluded that claim chart. (Citing Tr. at 18:13-19:25) Staff says that Respondents attempt to make up this shortcoming in their post-hearing brief by comparing, on an element-by-element basis, their prior art references with the Asserted Claims of the '487 patent. Staff says that because Respondents admittedly did not make perform this

comparison in their Pre-Hearing Brief, Respondents should not be permitted to do so now. (Citing Ground Rule 8.2)

Staff argues that even if Respondents' comparison of their prior art references with the Asserted Claims of the '487 patent is permitted, that comparison consists of primarily attorney argument, which is no substitute for evidence. Staff says that Respondents cite to Dr. Mah's testimony to support their allegations of anticipation and obviousness, but that testimony is merely conclusory, as it too references a claim chart, purporting to show how and where the prior art discloses each element of each asserted claim, that has been excluded by the ALJ. Staff adds that Respondents' allegations of obviousness also include Wu (RX-0095), but Respondents fail to show how one of ordinary skill would have been motivated to combine Wu in any manner.

Analysis and Conclusions: Respondents have failed to provide clear and convincing evidence that asserted claim 1 of the '487 patent is obvious. Respondents have asserted three[17] separate combinations in post-hearing briefing—Lemchen, Kesling, and the knowledge of one of ordinary skill in the art, Nahoum, Lemchen, Kesling, Wu, and the knowledge of one of ordinary skill in the art.

I note that while Respondents do mention "knowledge of one of ordinary skill in the art" in RPHB, section 5.5.2.2, their references in that pre-hearing brief amount to a general discussion of eleven separate references with no element by element discussion of how those eleven references would combine to render the asserted claims of the '487 patent obvious. There is only a general reference to a "claim chart" that Respondents say they will produce at the

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[17] It is not clear from Respondents' briefing whether Wu and the knowledge of one of ordinary skill in the art is a separate combination, or an additional reference to be combined with Lemchen, Kesling, and Nahoum. I have assumed, *arguendo*, that Wu is to be combined with Lemchen, Kesling, and Nahoum. Because Wu does not fill the gaps in Lemchen, Kesling, Nahoum, and the knowledge of one of ordinary skill in the art, Wu also would not individually render claim 1 obvious.

hearing. This is inadequate to provide notice to Align regarding the specific prior art to be addressed and the manner in which the prior art discloses each and every element of an asserted claim. (RPHB at 128-136) As a result, at the hearing I granted Align's motion *in limine* number 6, and excluded the claim charts that were not specifically cited in Respondents' prehearing brief as required by Ground Rule 8.2. (Tr. 18:13-20:4)

Although Respondents discussed eleven different prior art references in RPHB section 5.2.2.2, Respondents failed to identify any specification combinations of prior art references other than Lemchen, Kesling, and the knowledge of one of ordinary skill in the art. (RPHB at 128) Because Respondents did not identify any specific combinations other than Lemchen, Kesling, and the knowledge of one of ordinary skill in the art, any other combinations, including Nahoum with Lemchen, Kesling, Wu, and the knowledge of one of ordinary skill in the art, were waived.

Assuming, *arguendo*, that Respondents had properly disclosed their arguments based on the combination of Lemchen, Kesling, Nahoum, Wu and the knowledge of one or ordinary skill in the art in their pre-hearing brief, there is nothing in the evidence submitted by Respondents to support a finding that a PHOSITA would be motivated by anything in Lemchen, Kesling, Nahoum, or Wu to follow the methods in the '487 patent. In section IV.D.1, *supra*, I noted that even if I had found that Lemchen incorporated the ***entirety*** of Kesling by reference, those two references taken together would still not disclose each and every element of the asserted claims of the '487 patent. Based upon that finding, it follows that Lemchen combined with Kesling would not render obvious the asserted claims of the '487 patent.

Respondents' evidence regarding the knowledge of one of ordinary skill in the art would not fill the gaps in Lemchen and Kesling. Respondents' evidence is limited to expert reports of a

former expert for Align (RX-102C and RX-103C) and the opening witness statement of Dr. Mah. At the prehearing conference, I ruled that that Dr. Rekow's expert reports (RX-102C and RX-103C) could be used solely to show that Align took an inconsistent position in the prior litigation. (Tr. at 20:24-21:7) Here, Respondents are improperly attempting to rely on the expert reports to show the knowledge of one of ordinary skill in the art. The testimony of Dr. Mah is not helpful on this subject because he expresses a series of conclusory opinions without citing to evidentiary support. (*See, e.g.*, RX-113C, Qs. 106, 113-121)

Focusing on the motivation to combine references, in Section IV.B.2, *supra*, I find that it was obvious to combine Lemchen and Kesling. I incorporate that finding and rationale and reaffirm it here. Respondents do not, however, provide any basis for combining Nahoum and Wu with the Lemchen and Kesling references.

Notwithstanding the foregoing, examining Nahoum and Wu in combination with Lemchen and Kesling, I find that Nahoum and Wu do not provide the elements missing from the Lemchen and Kesling references. Lemchen does not in any way disclose, or hint at, designing or fabricating intermediate or successive tooth repositioning appliances based on digital data sets. In Section IV.B.1.a, *supra*, I find that Lemchen does not disclose, or teach or suggest, calculating positions-in-between an initial data set and a final data set and Lemchen is limited to the idea of treating a patient with a single set of brackets, i.e. one bracket per tooth to be used over the entirely of the treatment. In Section IV.B.1.a, supra I find that Kesling "does not disclose, or teach or suggest, or even remotely contemplate" the use of computers or digital technology and contemplated a reactive process, performed one step at a time, where appliances beyond a first appliance may be created by repeating the disclosed process for making the first appliance. In Section IV.B.2.a, *supra*, I find that Nahoum does not in any way disclose use of computers or

digital data to assist in fabricating a dental appliance. I incorporate and reaffirm these findings and rationales here.

Wu does not disclose, or teach or suggest, or even remotely contemplate "producing a plurality of intermediate digital data sets representing intermediate arrangements of the patient's teeth," as required by claim 1. Rather, Wu is directed to a method for generating a three dimensional model of the teeth and dental arch of a patient. (RX-095 at 1:4-6) Although Wu discloses scanning a dental arch to create a digital model (*Id.* at 5:41-50) and enabling a user to "move any or all other teeth independently to simulate potential treatment options," (*Id.* at 7:29-35), Wu does not disclose producing plural intermediate digital data sets between these two models. (*See* RX-095) Respondents do not identify where this element is disclosed in Wu

Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of asserted claim of the '487 patent are present in Lemchen, either alone or in combination with Kesling, Nahoum, and Wu, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine the those references to create the method claimed in the invention of the '487 patent.

b. Claim 3

Respondents' Position: Respondents assert that claim 3 is obvious in light of the prior art references and the knowledge of one of ordinary skill. Respondents incorporate the disclosures identified as Disclosure Categories 7 and 9 here together with the knowledge of one of ordinary skill as described in the section of RIB addressing the '325 Patent.

Respondents say that this claim is further rendered obvious in light of Wu and the knowledge of one of ordinary skill. Respondents say that Wu describes the use of 3-D, digital modeling for the design of orthodontic appliances to facilitate orthodontic treatment and

describes traditional CAD/CAM dental applications including the CEREC system of digital prototyping used for fabricating positive models of teeth. (Citing RX-0095 at 1:47-52; at 3:7-17) Respondents contend that these disclosures demonstrate that the claimed invention was obvious.

Align's Position: Align addressed all asserted claims at once, as discussed above regarding claim 1.

Staff's Position: Staff's position is stated above regarding claim 1.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 1 to be rendered obvious by the asserted prior art and invalid, I could still find that claim 3 is valid. Since, however, I have found claim 1 to be valid and ***not*** rendered obvious by Lemchen, combined with Kesling, Nahoum, Wu, and the knowledge of a PHOSITA, claim 3 is necessarily valid, because it depends from claim 1 and necessarily contains all of the elements of claim 1. *See In re Fritch,* 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 1 is rendered obvious by Lemchen, combined with Kesling, Nahoum, Wu, and the knowledge of a PHOSITA, I would find that Respondents have failed to show by clear and convincing evidence that claim 3 of the '487 patent is rendered obvious by that combination. In Section IV.B.1.a, *supra*, I find that Lemchen is limited to the idea of treating a patient with a single set of brackets, not with plural polymeric shell appliances. In Section IV.B.2.a, *supra*, I find that Nahoum does not in any way disclose use of computers or digital data to assist in fabricating a dental appliance. In Section IV.D.2.a, *supra*, I find that Wu does not disclose producing plural intermediate digital data sets between the initial and final data sets. I incorporate and reaffirm these findings and rationales here.

Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of asserted claim 3 of the '487 patent are present in Lemchen combined with Kesling, Nahoum, Wu and the knowledge of one of ordinary skill in the art, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine those references to create the method claimed in asserted claim 3 of the '487 patent.

c. Claim 5

Respondents' Position: Respondents contend that dependent claim 5 is obvious in light of the prior art references and the knowledge of one of ordinary skill. Mr. Beers identifies common evidence that he contends covers this claim as Evidence Category 9. CX-1150C at Q. 249. Respondents incorporate Disclosure Categories 9 and 10 together with the knowledge of one of ordinary skill as described in the section addressing the '325.

Respondents argue that this claim is further rendered obvious in light of Wu and the knowledge of one of ordinary skill in the art. Respondents contend that Wu describes the use of 3-D, digital modeling for the design of orthodontic appliances to facilitate orthodontic treatment and describes traditional CAD/CAM dental applications including the CEREC system of digital prototyping used for fabricating positive models of teeth. (Citing RX-0095 at 1:47-52; at 3:7-17) These disclosures demonstrate that the claimed invention was obvious.

Align's Position: Align addressed all asserted claims at once, as discussed above regarding claim 1.

Staff's Position: Staff's position is stated above regarding claim 1.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I

determined claim 1 to be rendered obvious by the asserted prior art and invalid, I could still find that claim 5 is valid. Since, however, I have found claim 1 to be valid and ***not*** rendered obvious by Lemchen, combined with Kesling, Nahoum, Wu, and the knowledge of a PHOSITA, claim 5 is necessarily valid, because it depends from claim 1 and necessarily contains all of the elements of claim 1. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 1 is rendered obvious by Lemchen, combined with Kesling, Nahoum, Wu, and the knowledge of a PHOSITA, I would find that Respondents have failed to show by clear and convincing evidence that claim 5 of the '487 patent is rendered obvious by that combination. In Section IV.B.1.a, *supra*, I find that Lemchen is limited to the idea of treating a patient with a single set of brackets, not with plural polymeric shell appliances. In Section IV.B.2.a, *supra*, I find that Nahoum does not in any way disclose use of computers or digital data to assist in fabricating a dental appliance. In Section IV.D.2.a, *supra*, I find that Wu does not disclose producing plural intermediate digital data sets between the initial and final data sets. I incorporate and reaffirm these findings and rationales here.

Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of asserted claim 5 of the '487 patent are present in Lemchen combined with Kesling, Nahoum, Wu and the knowledge of one of ordinary skill in the art, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine those references to create the method claimed in asserted claim 5 of the '487 patent.

d. Claim 7

Respondents' Position: Respondents incorporate the section of RIB addressing the preamble of Claim 1 of the '325 Patent. Respondent say that Align previously recognized that Lemchen developed a full digital three dimensional modeling for planning orthodontic treatment. (Citing RX-103C at 16) Respondents argue that this demonstrates that there is no difference between Lemchen and this claimed invention.

Respondents incorporate Disclosure Categories 1, 2, 5, 7, and 10 here together with the knowledge of one of ordinary skill in the art.

Respondents argue that claim 7 is further rendered obvious in light of Wu and the knowledge of one of ordinary skill in the art. Respondents say that Wu describes the creation of an orthodontic treatment plan and the use of 3-D, digital modeling for the design of orthodontic appliances to facilitate orthodontic treatment. (Citing RX-0095 at 1:47-52) Respondents continue that Wu describes the creation of an orthodontic treatment plan, simulated orthodontic treatment, and storage on a computer readable storage media. (Citing RX-0095 at 5:41-50, 6:60-61, 7:29-34, 8:55-58, and 7:2-3) Respondents contend that these disclosures demonstrate that the claimed invention was obvious.

Align's Position: Align addressed all asserted claims at once, as discussed above regarding claim 1.

Staff's Position: Staff's position is stated above regarding claim 1.

Analysis and Conclusions: Respondents have failed to provide clear and convincing evidence that asserted claim 7 of the '487 patent is obvious. Respondents have asserted three separate combinations in post-hearing briefing—Lemchen, Kesling, and the knowledge of one of

ordinary skill in the art, Nahoum, Lemchen, Kesling, and the knowledge of one of ordinary skill in the art and Wu and the knowledge of one of ordinary skill in the art.

Similar to claim 1, discussed *supra*, I note that while Respondents do mention "knowledge of one of ordinary skill in the art" in RPHB, section 5.5.2.2, their references in that pre-hearing brief amount to a general discussion of eleven separate references with no element by element discussion of how those eleven references would combine to render the asserted claims of the '487 patent obvious. There is only a general reference to a "claim chart" that Respondents say they will produce at the hearing. This is inadequate to provide notice to Align regarding the specific prior art to be addressed and the manner in which the prior art discloses each and every element of an asserted claim. (RPHB at 128-136) As a result, at the hearing I granted Align's motion *in limine* number 6, and excluded the claim charts that were not specifically cited in Respondents' prehearing brief as required by Ground Rule 8.2. (Tr. 18:13-20:4)

Although Respondents discussed eleven different prior art references in RPHB section 5.2.2.2, Respondents failed to identify any specification combinations of prior art references other than Lemchen, Kesling, and the knowledge of one of ordinary skill in the art. (RPHB at 128) Ground Rule 8.2 states "[a]ny contentions not set forth in detail as required herein shall be deemed abandoned or withdrawn, except for contentions of which a party is not aware and could not be aware in the exercise of reasonable diligence at the time of filing the pre-trial brief." Because Respondents did not identify any specific combinations other than Lemchen, Kesling, and the knowledge of one of ordinary skill in the art, any other combinations, including Nahoum with Lemchen, Kesling, and the knowledge of one of ordinary skill in the art, and Wu and the knowledge of one of ordinary skill in the art, were waived.

Assuming, *arguendo*, that Respondents had properly disclosed their arguments based on the combination of Lemchen, Kesling, Nahoum, and the knowledge of one or ordinary skill in the art in their pre-hearing brief, there is nothing in the evidence submitted by Respondents to support a finding that a PHOSITA would be motivated by anything in Lemchen, Kesling or Nahoum to create "a plurality of intermediate digital data sets representing intermediate arrangements of the patient's teeth," or "a treatment plan," which as construed in Section III.D.2, *supra*, requires "two or more successive digital data sets representing arrangements of a patient's teeth progressing from an initial tooth arrangement toward a final tooth arrangement." In section IV.D.1, *supra*, I noted that even if I had found that Lemchen incorporated the ***entirety*** of Kesling by reference, those two references taken together would still not disclose each and every element of claim 7 of the '487 patent. Based upon that finding, it follows that Lemchen combined with Kesling would not render obvious claim 7 of the '487 patent.

Respondents' evidence regarding the knowledge of one of ordinary skill in the art would not fill the gaps in Lemchen and Kesling. Respondents' evidence is limited to expert reports of a former expert for Align (RX-102C and RX-103C) and the opening witness statement of Dr. Mah. At the prehearing conference, I ruled that that Dr. Rekow's expert reports (RX-102C and RX-103C) could be used solely to show that Align took an inconsistent position in the prior litigation. (Tr. at 20:24-21:7) Here, Respondents are improperly attempting to rely on the expert reports to show the knowledge of one of ordinary skill in the art. The testimony of Dr. Mah is not helpful on this subject because he expresses a series of conclusory opinions without citing to evidentiary support. (*See, e.g.*, RX-113C, Qs. 106, 113-121)

Focusing on the motivation to combine references, in Section IV.B.2, *supra*, I find that it was obvious to combine Lemchen and Kesling. I incorporate that finding and reaffirm it here.

Respondents do not, however, provide any basis for combining Nahoum with the Lemchen and Kesling references.

Notwithstanding the foregoing, examining Nahoum in combination with Lemchen and Kesling, I find that Nahoum does not provide the elements missing from the Lemchen and Kesling references. In Section IV.B.1.a, *supra*, I find that Lemchen does not disclose, or teach or suggest, calculating positions-in-between an initial data set and a final data set. In Section IV.B.2.a, *supra*, I find that Lemchen does not in any way disclose, or hint at, designing or fabricating intermediate or successive tooth repositioning appliances based on digital data sets. Lemchen's disclosure is limited to the idea of treating a patient with a single set of brackets, i.e. one bracket per tooth to be used over the entirely of the treatment. In Section IV.B.1.a, *supra*, I find that Kesling contemplated a reactive process, performed one step at a time, where appliances beyond a first appliance may be created by repeating the disclosed process for making the first appliance. In Section IV.B.2.a, *supra*, I also find that Kesling "does not disclose, or teach or suggest, or even remotely contemplate" the use of computers or digital technology and does not expressly or inherently disclose, or teach or suggest, fabricating a dental appliance based on a digital data set. Additionally, in Section IV.B.2.a, *supra*, I find that Nahoum does not in any way disclose use of computers or digital data to assist in fabricating a dental appliance. I reaffirm and incorporate these findings and rationales here.

Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of asserted claim 7 of the '487 patent are present in Lemchen, either alone or in combination with Kesling, and Nahoum, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine the those references to create the treatment plan claimed in claim 7 of the '487 patent.

Assuming, *arguendo*, that Respondents had properly disclosed their arguments based on the combination of Wu and the knowledge of one or ordinary skill in the art in their pre-hearing brief, there is nothing in the evidence submitted by Respondents to support a finding that a PHOSITA would be motivated by anything in Wu to produce the treatment plan of the '487 patent.

Wu does not disclose, or teach or suggest, or even remotely contemplate "a plurality of intermediate digital data sets representing intermediate arrangements of the patient's teeth," or "a treatment plan," as required by claim 7. Rather, Wu is directed to a method for generating a three dimensional model of the teeth and dental arch of a patient. (RX-095 at 1:4-6) Although Wu discloses scanning a dental arch to create a digital model (*Id.* at 5:41-50) and enabling a user to "move any or all other teeth independently to simulate potential treatment options," (*Id.* at 7:29-35), Wu does not disclose producing plural intermediate digital data sets between these two models. (*See* RX-095) Respondents do not identify where this element is disclosed in Wu.

Respondents also do not argue that this element would be obvious to one of ordinary skill in the art. The testimony of Dr. Mah is not helpful on this subject because he expresses a series of conclusory opinions without citing to evidentiary support. (*See, e.g.*, RX-113C, Qs. 86, 118)

Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of claim 7 of the '487 patent is present in Wu, either alone or in combination with the knowledge of one of ordinary skill in the art at the time of the invention.

e. Claim 8

Respondents' Position: Respondents argue that dependent claim 8 is obvious in light of the prior art references with the knowledge of one of ordinary skill in the art. Respondents

incorporate Disclosure Category 10 together with the knowledge of one of ordinary skill as described in this brief addressing the '325 patent.

Respondents say that claim 8 is further rendered obvious in light of Wu and the knowledge of one of ordinary skill. Respondents continue that Wu describes the use of 3-D, digital modeling for the design of orthodontic appliances to facilitate orthodontic treatment and describes traditional CAD/CAM dental applications including the CEREC system of digital prototyping used for fabricating positive models of teeth. (Citing RX-0095 at 1:47-52; at 3:7-17) Respondents conclude that these disclosures demonstrate that the claimed invention was obvious.

Align's Position: Align addressed all asserted claims at once, as discussed above regarding claim 1.

Staff's Position: Staff's position is stated above regarding claim 1.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 7 to be rendered obvious by the asserted prior art and invalid, I could still find that claim 8 is valid. Since, however, I have found claim 7 to be valid and ***not*** rendered obvious by Lemchen, combined with Kesling, Nahoum, Wu, and the knowledge of a PHOSITA, claim 8 is necessarily valid, because it depends from claim 7 and necessarily contains all of the elements of claim 7. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 7 is rendered obvious by Lemchen, combined with Kesling, Nahoum, Wu, and the knowledge of a PHOSITA, I would find that Respondents have failed to show by clear and convincing evidence that claim 8 of the '487 patent is rendered obvious by that combination. In Section IV.B.1.a, *supra*, I find that Lemchen is limited to the idea of treating a patient with a single set of brackets, not with plural

polymeric shell appliances. In Section IV.B.2.a, *supra*, I find that Nahoum does not in any way disclose use of computers or digital data to assist in fabricating a dental appliance. In Section IV.D.2.a, *supra*, I find that Wu does not disclose producing plural intermediate digital data sets between the initial and final data sets. I incorporate and reaffirm these findings and rationales here.

Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that "the intermediate digital data sets for different orthodontic treatment stages are configured for facilitating fabrication of shell appliances for a corresponding treatment stage" (as required by claim 8 of the '487 patent) is disclosed by Lemchen combined with Kesling, Nahoum, Wu and the knowledge of one of ordinary skill in the art, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine those references to create the method claimed in asserted claim 8 of the '487 patent.

f. Claim 9

Respondents' Position: Respondents argue that dependent claim 9 is obvious in light of the prior art references with the knowledge of one of ordinary skill. Respondents incorporate Disclosure Category 10 together with the knowledge of one of ordinary skill as described in this brief addressing the '325. Respondents conclude that these disclosures demonstrate that the claimed invention was obvious.

Align's Position: Align addressed all asserted claims at once, as discussed above regarding claim 1.

Staff's Position: Staff's position is stated above regarding claim 1.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I

determined claims 7 and 8 to be rendered obvious by the asserted prior art and invalid, I could still find that claim 9 is valid. Since, however, I have found claims 7 and 8 to be valid and ***not*** rendered obvious by Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, claim 9 is necessarily valid, because it depends from claim 7 via claim 8 and necessarily contains all of the elements of claims 7 and 8. *See In re Fritch,* 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that claims 7 and 8 are rendered obvious by Lemchen, combined with Kesling, Nahoum, Wu, and the knowledge of a PHOSITA, I would find that Respondents have shown by clear and convincing evidence that claim 9 of the '487 patent is rendered obvious by that combination.

In section IV.D.1.f, *supra*, I found that if Lemchen anticipated claims 7 and 8, it would also anticipate claim 9. As a result, assuming *arguendo* that claims 7 and 8 are obvious over Lemchen combined with Kesling, Nahoum, Wu, and the knowledge of a PHOSITA, I would find that claim 9 is obvious based on the rationale discussed in section IV.D.1.f.

E. The '511 Patent

1. Anticipation

Respondents' Position:

The preamble of asserted claim 1 of the '511 patent reads:

> A computer-implemented method for segmenting an orthodontic treatment path into segments, comprising:

(JX-001, 11:4-5)

Addressing the preamble, Respondents incorporate the portion of their brief discussed in section IV.B, *supra*, addressing the anticipation of the preamble of Claim 1 of the '325 patent. Respondents say that while Align argues that the preamble is not an element of the claimed

invention, the subject matter of the preamble is disclosed in the prior art reference. Respondents note that in 1943, Dr. Kesling filed an application that resulted in U.S. Patent No. 2,467,432. (the '432 patent or "Kesling")(Citing CX-944) Respondents assert that Kesling expressly discloses: (1) a plurality of tooth arrangements; (2) the use and fabrication of a series of dental appliances; and (3) using a machine to fabricate a series of dental appliances by producing a positive model of a tooth arrangement. (Citing RX-113C, Q. 49)

Respondents say that in 1989, Dr. Lemchen applied for what ultimately became U.S. Patent No. "Re. 35,169" (the '169 patent or "Lemchen") (Citing CX-945) Respondents assert that Dr. Lemchen disclosed a digital method for three dimensional modeling of teeth movement that was the same as the manual method disclosed in Kesling. (Citing RX-113C, Qs. 39-40) Respondents claim that this digital modeling includes intermediate or successive tooth arrangements. (Citing RX-113C, Q. 41) Respondents say that Lemchen disclosed methods for the fabrication of multiple custom appliances based on the three dimensional modeling. (Citing RX-113C, Q. 42) Respondents conclude that Lemchen disclosed using positive models generated from digital data. (Citing RX-113C, Qs. 42-43)

Respondents say that contrary to its position in this investigation, Align previously recognized that "Capitalizing on work of the dental CAD/CAM systems, Lemchen describes approaches [that] acquire data, automatically determine . . . ideal position for an individual patient, design . . . configuration to conform to the orthodontic treatment to be undertaken for an individual patient, and use numerically controlled systems to shape . . . that design." (Citing RX-102C at 6) Respondents state that, Align contended in that litigation that "the idea of fabricating custom appliances," for orthodontic treatment "was not new in 1990." (Citing RX-102C at 7)

The first element of asserted claim 1 teaches:

> for each tooth in a set of teeth, receiving a tooth path for the motion of the tooth from an initial position to a final position;

(JX-001, 11:6-8)

Regarding this element, Respondents incorporate their Disclosure Category 7, in which they represent that Lemchen discloses that "repositioning is done mathematically by appropriate software programs which may be derived by conventional means . . . ." (Citing CX-945, 2:66-3:6) Respondents contend that one skilled in the art would understand this to mean that the tooth path between the initial and final positions would be determined and then the tooth positions for each segment representing the successive stages of treatment would be determined by interpolation or a method for calculating movements of incremental equal sizes. Respondents assert that it is uncontroverted that interpolation is a conventional mathematical means for determining positional differences. (Citing RX-113C, Q. 59)

Respondents allege that Dr. Rekow, on behalf of Align, also recognized that Lemchen incorporated Kesling and broadly disclosed a digital three dimensional method for modeling tooth movement, quoting:

> **Full three-dimensional modeling in orthodontic treatment planning was described by Lemchen** *[59 Lemchen, ALN005891-895; 60 Lemchen, ALN005821-829]*. The first step in this process was acquisition of digital data defining the shape and location of the malocclused tooth or teeth respect to the patient's jaw. A variety of techniques, including those described by Rekow *[89 Rekow, ALN128301-305]* were capable of capturing the required data. The required data, in most applications, were a complete 3D model of the upper and lower dental arches and associated jaw structure *[59 Lemchen, ALN005893, col 3, lines 13-19]*. This model is the mathematical representation of the physical model described by Kesling in 1949. *[*Kesling, *'432 patent, ALN125695-699]* This digital/mathematical model was used for the planning orthodontic treatment.

(Citing "RX-103C at 16" (bracketed information is in the original, bold added by Respondents) Respondents argue that this demonstrates that one skilled in the art would understand that Lemchen incorporates Kesling and discloses three dimensional modeling of teeth movement

digitally through a series of incremental or intermediate steps from an initial position to the desired position.

The second element of asserted claim 1, requires:

> calculating a segmentation of the aggregate tooth paths into a plurality of treatment segments so that each tooth's motion within a segment stays within threshold limits of linear and rotational translation; and

(JX-001, 11:9-12)

Turning to the second element of asserted claim 1, Respondents incorporate their Disclosure Categories 6 and 7, in which they state that the Kesling reference discloses the manufacture and use of a plurality of appliances, each appliance in the series representing intermediate or successive tooth positions, quoting:

> the present tooth positioning appliances may be used for changing the position of teeth from the [initial position] to that of [the pre-determined ideal or desirable position] by using a multiplicity or a **plurality** of different steps and making intermediate tooth positioning devices, which are to move the teeth only a fraction of the way toward their final position.

(Citing CX-944, 2:50-3:1 (emphasis added by Respondents) Respondents aver that the Kesling reference describes the necessity of making a plurality of appliances as "obvious" and quote:

> While I have illustrated an appliance and described the technique for producing only the last or final change to the desired ideal position, it will also be evident that this appliance and technique may be employed in a **plurality** of steps for moving the teeth step by step from any extreme position to the desired and final position; but in such cases it will obviously be necessary to make a number of different appliances, each representing one step of attainment toward the final positioning of the teeth.

(Citing CX-944, 5:22-32) (emphasis added by Respondents)

Respondents assert that Lemchen discloses that the "repositioning is done mathematically by appropriate software programs which may be derived by conventional means . . . ." (Citing CX-945, 2:66-3:6) Respondents contend that one skilled in the art would understand this to

mean that the tooth path between the initial and final positions would be determined and then the tooth positions for each segment representing the successive stages of treatment would be determined by interpolation or a method for calculating movements of incremental equal sizes. Respondents allege that it is uncontroverted that interpolation is a conventional mathematical means for determining positional differences. (Citing RX-113C, Q. 59)

Respondents reiterate the quote from Dr. Rekow, quoted *supra*, and their contention that Align used the quote to support the position that Lemchen incorporated Kesling and broadly disclosed a digital three dimensional method for modeling tooth movement. (Citing "RX-103C at 16") Respondents reiterate that this demonstrates that one skilled in the art would understand that Lemchen incorporates Kesling and discloses three dimensional modeling of teeth movement digitally through a series of incremental or intermediate steps from an initial position to the desired position.

Respondents argue that Lemchen discloses that his method "produces appropriate force magnitudes at various stages of treatment to move the tooth to its ideal position." (Citing CX-945, 2:37-38) Respondents posit that one skilled in the art would understand that the "various stages of treatment" would refer the successive stages of treatment typical in orthodontic treatment. (Citing RX-113C, Q. 57) Respondents add that one skilled in the art would also understand that "appropriate force magnitudes" would mean that any threshold limits on movement would not be exceeded, because the only way that movement could exceed a threshold limit is by the application of inappropriate or excessive force on the tooth. Respondents conclude that one skilled in the art would also understand that "appropriate force magnitudes" would mean at least the minimum force necessary to move the teeth toward the

successive stage of treatment; otherwise the treatment would be ineffective. (Citing RX-113C, Q. 58)

The third element of asserted claim 1, states:

> generating a plurality of appliances, at least one or more appliances for each treatment segment, wherein the appliances comprise polymeric shells having cavities and wherein the cavities of successive shells have different geometries shaped to receive and resiliently reposition the teeth from one arrangement to a successive arrangement.

(IX-001, 11:13-19)

Finally, concerning the third element, Respondents incorporate their Disclosure Category 10 and allege that the Kesling reference disclosed "tooth positioning appliances" that were "adapted to . . . bring the teeth of a user of such an appliance into a pre-determined ideal or desirable position without the necessity for the use of metallic bands, wires or any of the other appliances of the prior art." (Citing CX-944, 1:1-6) Respondents add that Figure 7 shows that a "tooth positioning appliance," similar to an aligner, was disclosed. (Citing CX-944, Fig. 7)

Respondents continue that Kesling teaches that each aligner in the series is made by molding a polymeric material over positive models of intermediate or successive tooth arrangements. First a cast of the teeth in their initial position is created using traditional methods. (Citing CX-944, 2:43-49) Then, each individual tooth is manually sectioned out by an operator using a scroll saw. (Citing CX-944, 3:30-43) Next, the operator manually moves each now individually sectioned out tooth to a new position in the base, securing the tooth with wax or another suitable material. (Citing CX-944, 3:30-60) Then, a positive model of the teeth in their new position is made. (Citing CX-944, 3:61-64 and Figure 3) Respondents continue, the aligners are then fabricated by using a mechanical device to mold a polymeric material over the positive model of the intermediate tooth arrangements. (Citing CX-944, 3:65-4:70)

Respondents assert that Lemchen discloses methods that include controlling a fabrication machine:

> The present method may be utilized in conjunction with computer-aided design and computer-aided manufacturer (CAD/CAM), as described in the Rekow article referred to above, to provide a machined or cast base conforming to the tooth morphology . . . .

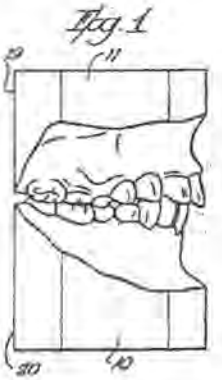
(Citing CX-945, 5:4-8) Respondents aver that the inventors also describe the use of a "laboratory model of the tooth . . . ." And as described above, the inventors expressly noted that while they referred to a single tooth, their invention "may be utilized with some or all of the teeth in a given arch . . . ." (Citing CX-945, 5:21-24) Respondents allege that these statements expressly disclose the controlling of a fabrication machine to produce a positive model of a modified tooth arrangement based on the digital information generated.

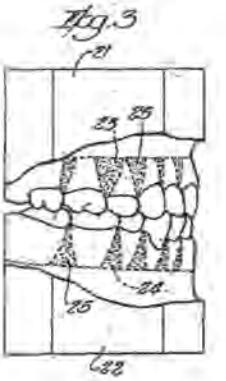
Respondents allege that contrary to its position in this investigation, Align previously argued that the references cited by Lemchen, including the Rekow reference, disclosed using CAD/CAM systems to control fabrication machines to produce positive models of teeth. (Citing "RX-103C at 17-26")

Align's Position: Align says that Respondents contend that ***all*** of the asserted claims are anticipated by Lemchen, including "as incorporated" Kesling. (Citing RPHB at 44, 98, 127, 146, 175, 205 and 240) Align argues that Respondents' anticipation defense fails as a matter of law because it relies on the flawed assumption that Lemchen incorporates the full disclosures of Kesling, which Align contends is wrong as a matter of law. Align states that, to incorporate by reference, the host document "must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents." (Citing *Advanced Display Sys., Inc. v. Kent State Univ.*,212 F.3d 1272, 1282 (Fed. Cir. 2000)) Align argues that "mere reference to another [patent] is not an incorporation of anything therein."

(Citing *In re De Seversky*, 474 F.2d 671, 674 (C.C.P.A. 1973); *Certain Digital Imaging Devices*, Inv. No. 337-TA-717, I.D., 2010 WL 5646142, at *53 (USITC May 12, 2011) (Rogers, J.))

Align asserts that Lemchen only briefly refers to two figures from Kesling. (Citing CX-945, 3:14-15 ("[a] physical embodiment of such a model is shown, for example, in FIG. 1 of U.S. Pat. No. 2,467,432"); *id.* at 3:35-40) and includes Figures 1 and 3 in its brief for reference.





Align quotes the text of Lemchen, "[i]n order to account for individual tooth morphology by physically removing duplicated teeth from a model and repositioning them in a new model in the finish position. *See*, for example, FIG. 3 in the above referenced U.S. Pat. No. 2,467,432"). Align contends that these are references to FIGS. 1 and 3 as examples of models, nothing else. Align avers that Lemchen does not say that the entire disclosure of Kesling, or any of its particular methods, is incorporated. Align alleges that Dr. Valley agrees that Lemchen cites the figures as examples of what models look like and does not otherwise address Kesling or the relationship between the figures. Align adds that Kesling FIGS. 1 and 3 do not disclose the claim elements that are absent from Lemchen. (Citing CX-1247C, Qs. 249, 251-258; and CX-1254C ¶¶ 112-117 at 42-46)

Align says that contrary to the express description found in the words of Lemchen that cite to Kesling's FIGS. 1 and 3 as examples of models, Dr. Mah contends, "[i]t is only in the context of the entire disclosure [of Kesling] that the significance of the model displayed as

Figure 1 [or Figure 3] as a representation of the patient's teeth prior to treatment [or as a modified tooth arrangement] is understood." (Citing RX-113C, Qs. 47-48) Align says these contentions lack merit, and observes that one of ordinary skill in the art would have understood the concept of a representation of teeth based on FIGS. 1 and 3 without needing to review Kesling's entire disclosure. Concluding, plaster tooth arrangements were commonly known and used. (Citing CX-1247C, Qs. 264-265; CX-1254C ¶ 117 at 45-46; and Tr. at 786:24-787:17, 788:11-789:8, 796:13-798:6)

In its reply brief, Align adds that the majority of Kesling is completely unrelated to FIG. 1 or FIG. 3, and notes, for example, Kesling discusses the design of an impression tray:

> The proportions of this tray are made with a view to making it the pattern for the tooth positioning appliance, which will later be worn in the mouth; and therefore it is desirable to dispense with any unnecessary bulk in the design of the tray. The tray 30 is preferably made of a suitable relatively stiff material which is initially plastic and which is moldable so that the tray may be molded to correspond substantially to the arch of the teeth of the patient without having more than a few sizes of trays.

(Citing CX-944, 4:24-35) Align continues that Kesling also contemplates the patient using its rubber appliance while sleeping:

> The tooth positioning appliance of Fig. 7 may be worn at night by the patient, and while he is sleeping; and it is found that in a short time the patient will become accustomed to wearing the appliance, which also prevents mouth breathing, due to the fact that the mouth is closed on the appliance during sleep. Breathing through the nose is then a matter of necessity, and the present appliance may also be used to prevent undesirable breathing noises during sleeping.

Id. at 5:4-13. Align asserts that Kesling further compares the tooth positioning device to "unsightly" 1940s braces:

> The present device may be kept more sanitary than devices which are relatively permanently attached to the teeth, as the present device may be cleaned before and after every using. It has been found that where the present invention is employed, the unsightly metal wires and bands of the conventional tooth positioning devices of the prior art may be removed from the teeth of the patient

> much sooner, and the present device usually produces a finished job in from four to six months.

Id. at 5:67-6:2. Align argues that these sections of Kesling, among others, have nothing to do with the plaster models of FIGS. 1 and 3, which Align says illustrates the fallacy of Respondents' mantra that reading such portions of Kesling is somehow necessary to understand "the significance of" FIGS. 1 and 3. (Citing RIB at 40)

Align adds that Respondents claim that Lemchen "applies beyond brackets and archwires." *Id.* at 41. Align says that Respondents are wrong, and Lemchen's disclosure is limited to the idea of treating a patient with a single set of brackets. (Citing CX-1247C, Qs. 190-191; and CX-1254C ¶¶ 90-91 at 32-33) Align states that here, Respondents rely on language from Lemchen regarding "methods of treatment." (Citing RIB at 40-41) Align argues that, "methods of treatment" in Lemchen refer to different methods of treating a patient with brackets and archwires – not aligners. (Citing CX-1247C, Qs. 215-219; CX-1254C ¶ 98 at 35-36; and Tr. at 798:7-799:25. Align says that Respondents also allege that "modeling of teeth movement is the same, regardless of the type of appliance used." (Citing RIB at 41) Align says once again, Respondents are wrong. (Citing CX-1247C, Qs. 221-222; and CX-1254C ¶ 99 at 37) Align counters that the anchorage needs and, therefore, the biomechanics of tooth movement, vary depending on the type of appliance used. (Citing CX-1247C, Qs. 221-222; and CX-1254C ¶ 99 at 37)

Align goes on to argue that, even if Kesling is somehow deemed to be fully incorporated in Lemchen, then Lemchen/Kesling still fails to anticipate any of Align's asserted claims because it does not disclose all elements of any of those asserted claims.

Focusing on asserted claim 1 of the '511 patent, Align contends that Respondents' invalidity positions are unsupported and insufficient to meet their high burden for invalidity.

Align argues that Respondents have no particular evidence to support their invalidity case, as no claim charts explaining where each claimed element is shown in the cited references are in evidence, because they were not included with Respondents' Prehearing Brief. (Citing Tr. at 19:11-25; 651:14-653:25)

Align adds that elements of asserted claim 1of the '511 patent are missing from each prior art reference as illustrated in CDX-0145. Align avers, for example, none of the prior art discloses, *inter alia*, "calculating a segmentation of the aggregate tooth paths into a plurality of treatment segments."

Align argues that Dr. Valley provided a full analysis of each reference in both her expert report (CX-1254C) and witness statement (CX-1247C). Align contends that based on her analysis, Dr. Valley opined that specific elements of each claim are not disclosed by the prior art. (Citing CX-1258) Align refers to CDX-130 and CDX-0169 to illustrate the missing claim elements for each prior art reference based upon Dr. Valley's testimony.

Moreover, as depicted in CDX-0288 and shown on the face of the patents (and reexam certificates), Lemchen was considered by the USPTO and determined not to preclude issuance of the claims. (Citing JX-001 at 2)

Focusing on substance, Align avers that Lemchen discloses a method for determining orthodontic bracket placement and is directed to a single fixed appliance used for the duration of a patient's treatment, rather than a removable appliance. Align says that Lemchen's disclosure is limited to the idea of treating a patient with the single set of brackets. (Citing CX-945, 1:55-2:8; CX-1247C, Qs. 190-191; CX-1254C ¶¶ 90-91 at 32-33; and CX-1264 at 5) Align contends that the concept of intermediate digital data sets or tooth arrangements is, therefore, absent from, and irrelevant to, Lemchen. (Citing CX-1247C, Qs. 183-185; and CX-1254C ¶ 82 at 29-30)

Align adds that, in fact, Lemchen teaches away from the use of intermediate arrangements. (Citing CX-1247C, Qs. 225-227; and CX-1254C ¶ 97 at 34-35)

Align argues that Lemchen does not disclose, *inter alia*: (1) intermediate or successive digital data sets or tooth arrangements (Citing CX-1247C, Qs. 183-185; and CX-1254C ¶ 82 at 29-30); (2) polymeric shell appliances (Citing CX-1247C, Qs. 183, 186-189; CX-1254C ¶¶ 85-86 at 31-32; and CX-1264 at 5); (3) positive models of modified tooth arrangements based on digital data sets (Citing CX-1247C, Qs. 183, 186-189, 207, 209-214; CX-1254C ¶ 87 at 32; and CX-1264); (4) multiple removable appliances or fabricating intermediate or successive appliances based on digital data sets (Citing CX-1247C, Qs. 183, 190-191; and CX-1254C ¶¶ 90-91 at 32-33); (5) threshold limits (Citing CX-1247C, Qs. 233-235; and CX-1254C ¶ 105 at 39-40); (6) interpolation or movements of equal sizes (Citing CX-1247C, Qs. 236-238; and CX-1254C ¶ 106 at 40); (7) substantially accurate shapes of a patient's teeth in a modified arrangement (Citing CX-1247C, Qs. 239-240; and CX-1254C ¶ 108 at 41); (8) attachment devices (Citing CX-1247C, Qs. 241-243; and CX-1254C ¶ 109 at 41-42); or (9) "numerous other elements of the asserted claims." (Citing CX-1247C, Qs. 275-277; and CX-1258 at 9-15)

Align turns to Kesling, in the event that one were to find Kesling incorporated by reference into Lemchen, and argues that Kesling generally discloses tooth positioning appliances made manually using tools and equipment available in the 1940s (*e.g.*, plaster and wax). Align asserts that its inventive concept of determining intermediate states based on the initial and final states is absent from Kesling. Align says, rather, Kesling only disclosed a reactive process, done one step at a time, where subsequent appliances are created by repeating the process for making the first. Align avers that Kesling makes one appliance at a time, and it does not disclose a proactive method of determining intermediate tooth positions at the outset based on both the

initial and final positions. (Citing CX-1247C, Qs. 142-145; CX-1254C ¶¶ 63 at 21-22, 65 at 23; and Tr. at 790:9-791:20)

Align contends that Kesling does not disclose, *inter alia*: (1) digital data sets or models of a dentition (2) intermediate or successive tooth arrangements based on initial and final positions (3) fabricating a dental appliance, or controlling a fabrication machine, based on a digital data set (Citing CX-1247C, Qs. 141-147; CX-1254C ¶¶ 62-63 at 21-22, 65 at 23, 67 at 24-25; and Tr. At 791:21-793:5); or (4) "numerous other elements" (Citing CX-1247C, Qs. 137-162; and CX-1258 at 2-8)

Align concludes that based upon the evidence cited, supra, even if Lemchen is found to have incorporated Kesling by reference the two references taken together as one would still fail to disclose all elements of asserted claim 1 of the '511 patent. (Citing CX-1247C, Qs. 568-569; and CX-1254C ¶ 274 at 97)

In its reply brief, Align says that neither Respondents nor Dr. Mah explained how the elements of Align's claims read on the prior art in view of their "ever-changing claim constructions" or Align's or Staff's proposed constructions. Align asserts that Respondents simply state in a conclusory footnote, "[t]he Respondents' arguments regarding invalidity for each of the asserted patents, both anticipation and obviousness, apply whether the Court adopts Align's, Respondents' or the Staff's claim constructions." (Citing RIB at 39 n.3) Align argues that Respondents' failure to address claim construction is fatal to their invalidity defenses. (Citing *Certain Digital Photo Frames & Image Display Devices*, Inv. No. 337-TA-807, Order No. 44 at 11 n. 1 (Aug. 2, 2012) (Rogers, J.); *Nano-Second Tech. Co. v. Dynaflex Int'l*, 2011 U.S. Dist. LEXIS 111836, at *5 (C.D. Cal. Sept. 28, 2011))

Align contends that Respondents fail to point to any portion of the prior art that they contend discloses, *e.g.*, "a computer-implemented method for segmenting an orthodontic treatment path into segments," "receiving a tooth path," or "calculating a segmentation of the aggregate tooth paths into a plurality of treatment segments." (Citing RIB at 108-109)

Align adds that Respondents' theory relies on their "disclosure categories," which advance new and unsupported mischaracterizations of Lemchen and Kesling, and fail to fairly address the elements of the asserted claims. Align refers to Section IV.H.4 of its Reply brief.

In Section IV.H.4 of its reply brief, Align argues that Respondents have manufactured 10 "disclosure categories" that set forth their contentions regarding Lemchen and Kesling. Align contends that despite the fact that Respondents failed to present an element-by-element invalidity analysis of the asserted claims at the hearing, Respondents now purport to apply these disclosure categories to each asserted claim, for both anticipation and obviousness. (Citing RIB at 42-70, 85-87, 97-103, 108-109, 115-118, 127-135, 144-148) Align argues that Respondents' disclosure categories do not support either defense.

Align argues that this "new purported element-by-element" analysis should be wholly rejected under GR 8.2 because it was not disclosed in Respondents' *PreHearing Brief*. (Citing RPHB at 44-67, 98-106, 127-36, 146-54, 174-83, 205-17, 240-48) Align contends, too, that the "disclosure categories" consist of mischaracterizations of Lemchen and Kesling that are largely unsupported by anything other than attorney argument. Align continues that the disclosure categories do not address numerous elements of the asserted claims. Finally, Align says that Respondents' methodology is flawed, because Respondents fail to apply their disclosure categories consistently with the methodology used by Align's expert.

While Align addresses all of Respondents' disclosure categories in its reply brief, only 6,

7 and 10 are relevant to the asserted claim of the '511 patent.

Addressing Respondents' disclosure category 6, Align says that Respondents identify purported "disclosures relating to restraints on movement ..." (Citing RIB at 145-146) Align asserts that Respondents contend that Lemchen discloses threshold limits on tooth movement, relying on Dr. Mah's "flawed interpretation" of Lemchen's reference to "appropriate force magnitudes." *Id.* (*Citing* CX-0945, 2:37-38; and RX-133C, Qs. 57-58) Align counters that a PHOSITA would understand this portion of Lemchen as merely describing the function of an archwire and the forces to effect treatment, not an indication that Lemchen contemplated or determined any threshold limits of linear or translational rotation. (Citing CX-1247C, Qs. 233-235; and CX-1254C ¶ 105 at 39-40)

Next, Align says that Respondents identify purported "disclosures relating to generating the intermediate tooth arrangements or digital models as Disclosure Category 7." (Citing RIB at 49-51)

Align says that Respondents claim that Kesling "discloses the manufacture and use of a plurality of appliances, each appliance in the series representing intermediate or successive tooth positions." (*Id.* at 49) Align says that its inventive concept of determining intermediate states based on both the initial and final states is absent from Kesling. (Citing CX-1247C, Qs. 144-145; and CX-1254C ¶ 65 at 23) Align contends that Kesling only disclosed a reactive process, done one step at a time, where subsequent appliances are created by repeating the process for making the first appliance. (*Id.*; Tr. at 790:9-791:20) Align emphasizes that Kesling makes one appliance at a time and does not disclose a proactive method of determining intermediate tooth positions at the outset based on both the initial and final tooth positions. (Citing CX-1247C, Qs. 144-145; CX-1254C ¶ 65 at 23).

Align states that Respondents claim that Dr. Rekow "recognized that [Kesling] broadly disclosed a three dimensional method for modeling tooth movement that included successive tooth arrangements that proceeded from the initial to the final[.]" (Citing RIB at 49 (*citing* RX-103C)) Align avers that the Rekow Report merely describes Kesling's wax setups (Citing RX-103C at 12-13), and does not contradict Dr. Valley's explanation of Kesling's reactive process, described above.

Align notes that Respondents cite Lemchen at 2:66-3:6, claiming that "[o]ne skilled in the art would understand this to mean that the tooth path between the initial and final positions would be determined and then the tooth positions for each segment representing the successive stages of treatment would be determined by interpolation or a method for calculating movements of incremental equal sizes." (Citing RIB at 49-50) Align demurs, saying that a PHOSITA would understand Lemchen as simply indicating that repositioning teeth into the finish position may involve using software. Align contends that Lemchen does not disclose the concepts of treatment segments, interpolation, or equal-sized translational movements between tooth positions. (Citing CX-1247C, Qs. 236-238; and CX-1254C at ¶ 106 at 40)

Align says that Respondents claim the Rekow Report "demonstrates that one skilled in the art would understand that [Lemchen] incorporates [Kesling] and discloses three dimensional modeling of teeth movement digitally through a series of incremental or intermediate steps from an initial position to the desired position." (Citing RIB at 50 (citing RX-103C)) Align counters that Lemchen does not incorporate Kesling. (Referring to CIB Sec. IV.H.1) Align continues, the concept of intermediate digital data sets or tooth arrangements is absent from, and irrelevant to, Lemchen. (Citing CX-1247C, Qs. 183-185; and CX-1254C ¶ 82 at 29-30) Align argues that Lemchen is limited to the idea of treating a patient with a single set of brackets and teaches ***away***

from using intermediate arrangements (Citing CX-1247C, Qs. 190-191, 225-227; and CX-1254C ¶¶ 90-91 at 32-33, 97 at 34-35) Finally, Align contends that the Rekow Report plainly does not indicate that Lemchen discloses intermediate steps or incorporates Kesling. (Citing RIB at 50 (quoting RX-103C at 16))

Align notes that Respondents also cite *Ormco II*, claiming that "Align previously successfully argued to the Federal Circuit that Lemchen disclosed an incremental approach to calculating desired tooth positions[.]" (Citing RIB at 50-51) Align contends that that *Ormco II* does not contain Align's characterizations of Lemchen. (Citing CIB Sec. IV.H.3) Align adds that the statement by Ormco inventors solely discusses "finish positions of the teeth," not any incremental approach or intermediate steps. (*Id.*)

Align states that throughout their *PostHearing Brief*, Respondents rely on Disclosure Category 7 for Align's claim elements relating to, *e.g.*, intermediate digital data sets and successive digital data sets. (Citing for example, RIB at 58, 86) Align counters that nowhere in Disclosure Category 7 do Respondents actually contend that the prior art discloses intermediate or successive digital data sets. (Citing *id.* at 49-51) Align alleges that the prior art does not disclose these elements. (Citing CX-1247C, Qs. 141-145, 183-185; CX-1254C ¶¶ 62-63, 65, 82 at 21-23, 29-30; and Tr. at 791:21-793:5.

Align turns to Disclosure Category 10, and says that in that category Respondents identify purported "disclosures relating to the fabrication of the appliances … " (Citing RIB at 51-52) Align alleges that Respondents mischaracterize the disclosures of Kesling and Lemchen. Align says that Respondents contend that Kesling discloses making an appliance "by molding a polymeric material over positive models." (*Id.* at 51) Align aver that Kesling discloses making

an appliance by filling a cast with rubber, not molding it over a positive model. (Citing Tr. at 789:9-790:8)

Align notes that Respondents contend that Kesling discloses "using a machine to fabricate a series of dental appliances by producing a positive model of a tooth arrangement." (Citing RIB at 52) Align contends that Kesling discloses using dental materials, tools, and an articulating device, not a fabrication machine. (Citing CX-944, 3:65-4:70, Fig. 4; CX-1247C, Q. 153; and CX-1254C ¶ 72 at 26)

Align says Respondents contend that Lemchen discloses "the controlling of a fabrication machine to produce a positive model of a modified tooth arrangement based on the digital information generated." (Citing RIB at 52) Align cites Dr. Valley's testimony to say that Respondents cite to disparate portions of Lemchen that do not combine the concepts of fabrication, positive models, and digital data sets. (Citing CX-1247C, Qs. 209-210; and CX-1254C ¶ 109 at 41-42)

Staff's Position: Staff refers to SIB section IV.E.1, which they say applies equally here, because Respondents' arguments and Dr. Mah's testimony alleging anticipation of the Asserted Claims of the '325 patent are also made with respect to the Asserted Claim of the '511 patent.

In their reply brief, Staff expresses the view that Respondents have failed to demonstrate clearly and convincingly that the Asserted Claim of the '511 patent is invalid because Respondents have failed to provide an element-by-element comparison of the prior art with the Asserted Claim of the '511 patent. Staff says that in their Pre-Hearing Brief, Respondents represented that they would introduce a claim chart showing "where each element of each asserted claim is found in the prior art." (Citing RPHB at 47) Staff notes that the claim chart has been excluded. (Citing Tr. at 18:13-19:25) Staff asserts that in their Post-Hearing Brief,

Respondents attempt to make up this shortcoming by comparing, on an element-by-element basis, their prior art references with the Asserted Claims of the '325 patent. Staff argues that, because Respondents admittedly did not perform this comparison in their Pre-Hearing Brief, Respondents should not be permitted to do so now. (Citing G.R. 8.2)

Staff adds, even if Respondents' comparison of their prior art references with the Asserted Claim of the '511 patent is permitted, that comparison consists of primarily attorney argument, which is no substitute for evidence. Staff says, in their comparison, Respondents cite to Dr. Mah's testimony to support their allegations of anticipation and obviousness; but that testimony is merely conclusory, because it references a claim chart that has been excluded by the ALJ.

Staff concludes that there is a lack of evidence explaining clearly and convincingly how the prior art discloses, teaches, or suggests each and every element of the Asserted Claim of the '511 patent.

Analysis and Conclusions: In section IV.B.1, I found that the Lemchen reference only incorporates by reference Figures 1 and 3 of Kesling. In the interest of brevity, I will not repeat that discussion here; but I reaffirm that finding and the rationale for it.

I also find that Respondents have failed to carry their burden to prove by clear and convincing evidence that Lemchen, including those portions of Kesling that are incorporated by reference into Lemchen, anticipates each and every element of asserted claim 1 of the '511 patent.

The plain language of asserted claim 1 teaches:

> A computer-implemented method for segmenting an orthodontic treatment path into segments, comprising:
>
> for each tooth in a set of teeth, receiving a tooth path for the motion of the

tooth from an initial position to a final position;

calculating a segmentation of the aggregate tooth paths into a plurality of treatment segments so that each tooth's motion within a segment stays within threshold limits of linear and rotational translation; and

generating a plurality of appliances, at least one or more appliances for each treatment segment, wherein the appliances comprise polymeric shells having cavities and wherein the cavities of successive shells have different geometries shaped to receive and resiliently reposition the teeth from one arrangement to a successive arrangement.

(JX-001, 11:4-19)

In Section IV.B.1.a, *supra*, I find that Lemchen does not disclose, or teach or suggest, calculating positions-in-between an initial data set and a final data set. I incorporate and reaffirm that finding and rationale here. Lemchen does not, then, reveal the requirement of "a segmentation of the aggregate tooth paths into a plurality of treatment segments" taught in the second element of asserted claim 1 of the '511 patent.

Lemchen does not, in any way, address polymeric shell appliances, which are taught in the third element of asserted claim 1 of the '511 patent. Lemchen does not in any way disclose, or hint at, multiple removable appliances or fabricating intermediate or successive tooth repositioning appliances based on digital data sets. Rather, Lemchen discloses calculating position on the teeth for bracket placement, and completes moving teeth with traditional brackets and archwires, not polymeric shell appliances. (CX-945, 1:55-57; 1:63-2:8; CX-1247C at Q. 186) According to the credible testimony of Dr. Valley, this is different from fabricating brackets or other appliances, and Lemchen's disclosure is limited to the idea of treating a patient with a single set of brackets, i.e. one bracket per tooth to be used over the entirely of the treatment. (CX-945, 1:56-62; 3:55-63; CX-1247C at Q. 190)

I note, too, that the incorporation of Figures 1 and 3 of Kesling into Lemchen provides no greater insight into the teachings of asserted claim 1. In Section IV.B.1.a, *supra*, I find that Figure 1 only describes a physical model of a mathematically generated model of a patient's teeth, and Figure 3 demonstrates a method of physically moving portions of a model representing the patient's teeth into a "finish position." I incorporate and reaffirm that finding and rationale here.

In addition, assuming *arguendo* that one were to find that Lemchen incorporates all of Kesling by reference, the result would not change. In Section IV.B.1.a, supra I find that Kesling "does not disclose, or teach or suggest, or even remotely contemplate" the use of computers or digital technology and contemplated a reactive process, performed one step at a time, where appliances beyond a first appliance may be created by repeating the disclosed process for making the first appliance. In Section IV.B.1.a, supra, I find that Kesling also does not expressly or inherently disclose, or teach or suggest, fabricating a dental appliance based on a digital data set. I incorporate and reaffirm these findings and rationales here.

Based upon all of the foregoing, I find that Respondents have failed to meet their burden to prove by clear and convincing evidence that Lemchen anticipates asserted claim 1 of the '511 patent.

2. Obviousness

Respondents' Position: Respondents incorporate RIB section 3.5.2.1 addressing the preamble of Claim 1 of the '325 patent. Respondents also incorporate Disclosure Categories 6, 7, and 10 together with knowledge of one of ordinary skill as described in the section addressing claim 1 of the '325 patent.

Respondents' sole reference to "Nahoum" is that "Nahoum also taught methods for fabricating series of successive aligners in the 1960s. Respondents aver that Dr. Nahoum taught methods for fabricating a series of aligners by vacuum forming thermoplastics over positive models. (Citing RX-096) Respondents say that a PHOSITA would understand, in light of this reference, the following subject matter: 1) an initial tooth arrangement; 2) a projected final tooth arrangement; 3) intermediate or successive tooth positions, 4) the use or fabrication of a series of dental appliances, and 5) producing a positive model of a tooth arrangement." (Citing RX-113C, Qs. 88-89)

Align's Position: Align argues that this particular combination (i.e. Lemchen, Kesling and the knowledge of a PHOSITA) was disclosed for the first time in the *JSCI*, and is therefore improperly raised now.

Align asserts, too, that the argument is unsupported because no claim charts showing this assertion in detail are in evidence. Align continues that Respondents' the references fail to disclose all the elements of claim 1. (Citing CIB Sec. IV.F.2.a) Align adds that a PHOSITA at the time of the invention would not have been motivated to combine a reference directed to fixed appliances made of brackets and wires (Lemchen) with a reference directed to removable appliances (Kesling). (Citing CIB Sec. IV.F.2.b) Finally, Align contends that secondary considerations support a finding of non-obviousness. (Citing CIB Sec. IV.F.2.c)

In its reply brief, Align reiterates that any obviousness contentions other than Lemchen combined with Kesling have been waived. (Citing CIB Sec. IV.H.2) Align adds that there is no evidence of a motivation to combine the prior art. (Citing CIB Sec. IV.H.2.b)

In the cited CIB section IV.H.2, Align argues that Respondents waived any obviousness defense under GR 8.2 because their *PreHearing Brief* did not specify, *inter alia*, which asserted

claims they contend are obvious. (Citing RPHB at 48-67, 146-154 and 240-248) (discussion of various prior art references generally), 98-106, 128-136, 146-154, 175-183, 205-217, 240-248 (874). Align contends that the record is devoid of evidence supporting a *prima facie* showing of clear and convincing evidence that: (i) a particular combination of prior art discloses all elements of a claim; and (ii) one of ordinary skill in the art would have some reason to make the combination. (Citing CIB at 30-31)

Align says that Respondents' *PreHearing Brief* generally refers to a combination of Lemchen, Kesling, and "the knowledge of one of ordinary skill in the art." (Citing RPHB at 49, 98, 128, 147, 175, 205, 240) Align contends that this combination fails to disclose all elements of any of the asserted claims. (Citing CIB at 48-51; CX-1247C at Q. 568-569; CX-1254C ¶ 274 at 97; CDX-0130-CDX-0169)

Align argues that Respondents' *PostHearing Brief* again fails to set forth any coherent obviousness contentions. (Citing RIB at 61-70, 86-87, 100-103, 109, 117-118, 130-135, 146-148. Align asserts that Respondents moved backwards from the *RJSCI* and fail to even identify what combination of prior art they rely on for each asserted claim. *Id.* Align says rather, Respondents simply present a jumble of prior art references and occasionally a conclusory statement such as, "[t]his claim is thus obvious" or "[t]his independent claim is obvious in light of the identified prior art with the knowledge of one of ordinary skill in the art." *Id.* at 68-69.

Align states that I limited Respondents to motivations purportedly identified by the Rekow Reports (Citing RX-102C; RX-103C),[18] noting that Respondents faced an "uphill struggle" to identify any motivation to combine specific references. (Citing Tr. at 16:9-17:23)

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[18] Align says that beyond this restriction, Respondents' use of the Rekow Reports is even further limited to "showing that prior inconsistent positions were taken by Align in previous litigation." Tr. at 20:5-21:21.

Align says that Respondents only cursorily address motivation for their obviousness positions, citing 2 pages from RX-103C that fail to discuss any motivation. (Citing RIB at 62)[19] Align asserts that this position is also waived under GR 8.2, because it was not specified in Respondents' *PreHearing Brief*. (Citing RPHB at 49) Align adds that Respondents do not assert that there was a motivation to combine any specific prior art other than Lemchen and Kesling. (Citing RPHB at 62) Finally, Align argues that Respondents fail to rebut the evidence showing that one of ordinary skill in the art would not have combined Lemchen and Kesling. (Citing CX-1247C, Qs. 165-166, 280-281, 318-319, 349-350, 427-428, 452-453, 577; and CX-1254C ¶ 77 at 27-28, ¶ 121 at 47)

Staff's Position: Staff says that given that Respondents' arguments and Dr. Mah's testimony alleging obviousness of the Asserted Claims of the '325 patent are also made with respect to the Asserted Claim of the '511 patent, the Staff's discussion of obviousness in SIB Section IV.E.2 applies equally here.

Staff is of the view that Respondents have failed to demonstrate clearly and convincingly that asserted claim 1 of the '511 patent is invalid, because Respondents have failed to provide an element-by-element comparison of the prior art with the Asserted Claim of the '511 patent. Staff says that, in their Pre-Hearing Brief, Respondents represented that they would introduce a claim chart showing "where each element of each asserted claim is found in the prior art." (Citing RPHB at 47) Staff notes that I excluded that claim chart. (Citing Tr. at 18:13-19:25) Staff asserts that, in their Post-Hearing Brief, Respondents attempt to make up this shortcoming by comparing, on an element-by-element basis, their prior art references with the Asserted Claims

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[19] Align contends that Respondents are wrong in saying that Dr. Rekow stated that *Lemchen* and *Kesling* "were combined." (Citing RIB at 62) Align adds that the statement would not provide a motivation to combine Lemchen and Kesling.

of the '325 patent. Staff argues that, because Respondents admittedly did not make this comparison in their Pre-Hearing Brief, Respondents should not be permitted to do so now. (Citing G.R. 8.2)

Staff contends that, even if Respondents' comparison of their prior art references with the Asserted Claim of the '511 patent is permitted, that comparison consists of primarily attorney argument, which is no substitute for evidence. Staff says, in their comparison, Respondents cite to Dr. Mah's testimony to support their allegations of anticipation and obviousness; but that testimony is merely conclusory, as it too references an excluded claim chart, purporting to show how and where the prior art discloses each element of each asserted claim.

Staff concludes that there is a lack of evidence explaining clearly and convincingly how the prior art discloses, teaches, or suggests each and every element of the Asserted Claim of the '511 patent.

Analysis and Conclusions: While Respondents do mention "knowledge of one of ordinary skill in the art" in RPHB, section 6.5.2.2, their references in that pre-hearing brief amount to a general discussion of eleven separate references with no element by element discussion of how those eleven references would combine to render asserted claim 1 of the '511 patent obvious.[20] There is only a general reference to a "claim chart" that Respondents say they will produce at the hearing. Respondents' prehearing brief does not list any specific combination as rendering the asserted claims obvious. More specifically, the prehearing brief is devoid of a discussion of Lemchen, Kesling, Nahoum, and the knowledge of one of ordinary skill in the art. This is inadequate to provide notice to Align regarding the specific prior art to be addressed and

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[20] I note that, while Align is correct that the Respondents also fail to identify the claim(s) addressed by the prior art, there is only one asserted claim in the '511 patent. Despite the fact that Respondents refer to each of the asserted claims (plural) in this section of their prehearing brief, I will infer that their reference was to the only claim asserted.

the manner in which the prior art discloses each and every element of an asserted claim as required by Ground Rule 8.2. (RPHB at 147-154) As a result, at the hearing I granted Align's motion *in limine* number 6, and excluded the claim charts that were not specifically cited in Respondents' prehearing brief. (Tr. 18:13-20:4) I find here that Respondents have waived the right to assert the combination of Lemchen, Kesling, Nahoum and the knowledge of a PHOSITA at the time of the invention.

Nevertheless, assuming *arguendo* that one were to find that the combination at issue here was not waived, then I would find that the Respondents have failed to meet their burden to prove by clear and convincing evidence that the combination of Lemchen, Kesling, Nahoum and the knowledge of a PHOSITA at the time of the invention renders asserted claim 1 obvious.

In order to prevail on their argument that asserted claim 1 of the'511 patent is invalid as obvious, Respondents must first demonstrate that the combination of Lemchen, either alone or in combination with Kesling, and Nahoum discloses all of the limitations of asserted claim 1. (*Hearing Components, Inc. v. Shure Inc.*, 600 F.3d 1357, 1373-1374 (Fed. Cir. 2010); and *Velander v. Garner*, 348 F.3d 1359, 1363 (Fed. Cir. 2003))

Equally important is the requirement that the Respondents establish by clear and convincing evidence that a person of ordinary skill in the art would have had reason to combine the various asserted prior art references to attempt to produce the invention and would have had a reasonable expectation of success in doing so. (See *PharmaStem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007))

There is nothing in the evidence submitted by Respondents to support a finding that a PHOSITA would be motivated by anything in Lemchen, Kesling or Nahoum to follow the method in the '511 patent which specifically requires, *inter alia*, that the dental appliances be fabricated using

digital data sets. In section IV.E.1, *supra*, I noted that even if I had found that Lemchen incorporated the ***entirety*** of Kesling by reference, those two references taken together would still not disclose each and every element of asserted claim 1 of the '511 patent. Based upon that finding, it follows that Lemchen combined with Kesling would not render obvious asserted claim 1 of the '511 patent.

Focusing on the motivation to combine references, I find that the mention of Kesling in Lemchen would be adequate to cause a PHOSITA to consider both references in combination. Respondents do not, however, provide any basis for combining Nahoum with the Lemchen and Kesling references.

Notwithstanding the foregoing, examining Nahoum in combination with Lemchen and Kesling, I find that Nahoum does not provide the elements missing from the Lemchen and Kesling references.

Lemchen does not in any way disclose, or hint at, multiple removable appliances or fabricating intermediate or successive tooth repositioning appliances based on digital data sets. Lemchen's disclosure is limited to the idea of treating a patient with a single set of brackets, i.e. one bracket per tooth to be used over the entirely of the treatment.

In Section IV.B.1.a, *supra*, I find that Lemchen does not disclose, or teach or suggest, calculating positions-in-between an initial data set and a final data set. In Section IV.B.2.a, *supra*, I find that Lemchen does not in any way disclose, or hint at, designing or fabricating intermediate or successive tooth repositioning appliances based on digital data sets. Lemchen's disclosure is limited to the idea of treating a patient with a single set of brackets, i.e. one bracket per tooth to be used over the entirely of the treatment. In Section IV.B.1.a, *supra*, I find that Kesling contemplated a reactive process, performed one step at a time, where appliances beyond

a first appliance may be created by repeating the disclosed process for making the first appliance. In Section IV.B.2.a, *supra*, I also find that Kesling "does not disclose, or teach or suggest, or even remotely contemplate" the use of computers or digital technology and does not expressly or inherently disclose, or teach or suggest, fabricating a dental appliance based on a digital data set. Additionally, in Section IV.B.2.a, *supra*, I find that Nahoum does not in any way disclose use of computers or digital data to assist in fabricating a dental appliance. I reaffirm and incorporate these findings and rationales here..

Dr. Mah's testimony on this subject is not helpful, because he expresses a series of conclusory opinions without citing to evidentiary support. (RX-113C, Qs. 101, 113-121)

Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of asserted claim 1 of the '511 patent are present in Lemchen, either alone or in combination with Kesling, and Nahoum, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine the those references to create the method claimed in the invention of the '511 patent.

F. The '666 Patent

1. Level of Ordinary Skill in the Art

Align's position: Align says that a person of ordinary skill in the field of the invention of the asserted claims is the same for all of the patents at issue.

Respondents' Position: Respondents say that, because the subject matter is the same, the applicable level of ordinary skill in the art is the same for all of the patents at issue.

Staff's Position: Staff says that, because the parties and the technical experts agree that the same level of ordinary skill in the art applies to all of the patents at issue, the Staff's discussion of the applicable level of ordinary skill in the art regarding the '325 patent also

applies to the '666 patent.

Analysis and Conclusions: In section III.B.1, *supra*, I found that one of ordinary skill in the art at the time of the invention of the asserted claims of Align's asserted patents was an individual with expertise in digital modeling and analysis and a working knowledge of orthodontic principles. The parties agree that the person of ordinary skill in the art is the same for all asserted patents at issue in this investigation. Based upon the similarities between the teachings of the '325 patent and the '666 patent, and the agreement of the parties that one of ordinary skill in the art is the same for the '325 patent and the '666 patent, I find that one of ordinary skill in the art at the time of the invention of the asserted claims of the '666 patent has the same knowledge and expertise as one of ordinary skill in the art for the '325 patent.

Like the '325 patent, the '666 patent discusses orthodontic principles (*see, e.g.*, JX-0004 at 1:22-2:9) and contemplates a treating professional (i.e., an orthodontist) providing a prescription that identifies final tooth positions. (JX-0004 at 6:7-17). The '666 patent does not, however, delve into the intricacies of the practice of orthodontics. (*See id.*) As in the '325 patent, the focus of the '666 patent is upon the methods used to generate digital data sets for treatment, including intermediate digital data sets representing tooth positions between the initial position and the final position. (*See, e.g.*, JX-0004 at 5:31-6:55, 9:20-13:4, 14:3-43) The '666 patent discusses, in detail, the manipulation of digital data to prepare the initial data set, generate the final tooth arrangement, and generate the intermediate digital data sets. (*Id.*) Based on the similarities between the disclosures of the '325 patent and the '666 patent, I find nothing in the record to indicate that one of ordinary skill in the art at the time of the invention of the asserted claims of the '666 patent is different than one of ordinary skill in the art for the '325 patent.

2. Anticipation

a. Claim 1

Claim 1 teaches:

> A method for producing a plurality of digital data sets representing a series of discrete tooth arrangements progressing from an initial to a final arrangement, said method comprising:
>
> providing a computer system;
>
> providing to the computer system an initial digital data set representing an initial tooth arrangement;
>
> defining boundaries about at least some of the individual teeth on a visual image provided by the computer system based on the initial data set;
>
> moving at least some of the tooth boundaries relative to the other teeth in the visual image to produce a final data set; and
>
> producing using the computer system a plurality of successive digital data sets based on both of the previously provided initial and final digital data sets, wherein said plurality of successive digital data sets represents a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement.

(JX-004 at 15:27-47)

Respondents' Position: Respondents assert that while Align argues that the preamble is not an element of the claimed invention, the subject matter of the preamble is disclosed in the prior art reference. Respondents incorporate the section addressing the anticipation of the preamble of Claim 1 of the '325. Respondents incorporate Disclosure Categories 1, 2, 4, and 7. Respondents assert that Lemchen discloses "providing a computer system." Respondents say that Lemchen discloses the use of conventional CAD/CAM software on computers. (Citing CX-0945 at 2:66 – 3:6) Respondents identify these disclosures in this section relating to providing a computer as Disclosure Category 2.

Respondents argue that Lemchen discloses the second element of claim 1 and incorporate Disclosure Categories 1 and 2. Respondents continue that Lemchen discloses the third element of claim 1 and incorporate Disclosure Category 4. Respondents say that Lemchen discloses the fourth element of claim 1 and incorporate Disclosure Categories 4 and 5. Respondents contend that Lemchen discloses the fifth element of claim 1 and incorporate Disclosure Category 7.

Respondents argue that claim 1 is broadly directed to a method for producing digital teeth arrangements. Respondents continue that claim 1 claims: 1) providing a computer; 2) providing a digital initial tooth arrangement; 3) defining boundaries around individual teeth; 4) moving the tooth boundaries to produce a final data set; and 3) producing a plurality of intermediate digital tooth arrangements based on progressing from the initial to the final. Respondents argue that Lemchen anticipates this claim. Respondents continue that contrary to Align's position here, Dr. Rekow's opinions confirm this:

> Full three-dimensional modeling in **orthodontic treatment planning** was described by Lemchen . . . . . This model is the mathematical representation of the physical model described by Kesling in 1949. . . . This digital/mathematical model was used for the **planning orthodontic treatment**.

(Citing RX-103C at 16 (Emphasis added)) Respondents say that it is beyond dispute that Kesling's three-dimensional modeling method taught initial, final and intermediate tooth arrangements that were based on the initial and the final and progressed from the initial to the final. (Citing CX-0944 at 2:50–3:1) Respondents argue that these facts demonstrate that Lemchen anticipates this claim because there is no material difference between the claim and the prior art.

Align's Position: Align asserts that Respondents' invalidity positions are wholly unsupported and totally insufficient to meet their high burden for an invalidity finding. Align says that Respondents have no particular evidence to support their invalidity case, as no claim

charts explaining where each claimed element is shown in the cited references is in evidence - because they were not included with Respondents' Prehearing Brief. (Citing Tr. at 19:11-20:4; 651:14-653:25) Align continues that the prior art references simply fail to disclose all elements of either of the asserted claims of the '666 patent, individually or under any combination. (Citing CX-1247C at Q. 606, 610; CX-1258) Align says that the failings of the prior art are explained in CIB Section IV.F.4. Align says that the elements of the asserted claims of the '666 missing from each prior art reference are illustrated in CDX-0146—CDX-0149. Align explains that for example, none of the prior art discloses, inter alia, "a plurality of successive digital data sets" or "tooth arrangements based on the initial and final digital data sets."

Align says that Respondents contend that all of the asserted claims of the '666 patent are anticipated by Lemchen and "as incorporated," Kesling. Align argues that this argument is unsupported, because no claim charts (or other explanatory vehicle) showing this assertion in detail are in evidence. Alternatively, Align says that this argument relies on accepting that Lemchen incorporates the entire disclosure of Kesling, which is wrong for the reasons described in CIB Section IV.F.4.c. Align continues that even assuming incorporation, Lemchen would still fail to disclose all elements of any of the asserted claims of the '666 patent.

Align argues that Respondents' invalidity defenses are unsupported. Align says that Respondents also fail to point to any portion of the prior art that they contend discloses "defining boundaries about at least some of the individual teeth" ('666 claim 1); "successive digital data sets" ('666 claims 1, 7); "determining positional differences ... and interpolating said differences" ('666 claim 3); or "interpolating positional differences" ('666 claim 7). (Citing RIB at 115-118) Align adds that Respondents also address the wrong claim in attempting to address the validity of claim 9 of the '666 patent. *(Citing* RIB at 117; JX-0004 at 16:18-27)

Align says that Respondents contend that all of the asserted claims are anticipated by Lemchen and "as incorporated," Kesling. Align disagrees, saying that Respondents failed to make a prima facie showing of anticipation. (Citing Tr. at 19:11-20:4, 651:14-653:25) Align continues that Respondents rely on the flawed theory that Lemchen incorporates the entire disclosure of Kesling. Align adds that, even assuming incorporation, Lemchen/Kesling fails to disclose all elements of any asserted claim. (Citing CX-1247C at Q. 568-569; CX-1254C ¶ 274 at 97; CDX-0146—CDX-0149) Align continues that Respondents' theory relies on their "disclosure categories," which advance new and unsupported mischaracterizations of Lemchen and Kesling, and fail to fairly address the elements of the asserted claims and Respondents also misapply their "disclosure categories" with respect to at least claim 7 of the '666 patent.

Staff's Position: Staff says that given that Respondents' arguments and Dr. Mah's testimony alleging anticipation of the Asserted Claims of the '325 patent are also made with respect to the Asserted Claims of the '666 patent, the Staff's discussion of anticipation in SIB Section IV.E.1 applies equally here.

Staff argues that Respondents have failed to demonstrate clearly and convincingly that any Asserted Claim of the '666 patent is invalid because Respondents have failed to provide an element-by-element comparison of the prior art with the Asserted Claims of the '666 patent. Staff says that in their Pre-Hearing Brief, Respondents represented that they would introduce a claim chart showing "where each element of each asserted claim is found in the prior art." Staff says I excluded that claim chart, however. (Citing Tr. at 18:13-19:25) Staff continues that Respondents attempt to make up this shortcoming by comparing, on an element-by-element basis, their prior art references with the Asserted Claims of the '666 patent. Staff says that

because Respondents admittedly did not perform this comparison in their Pre-Hearing Brief, Respondents should not be permitted to do so now. (Citing Ground Rule 8.2)

Staff asserts that even if Respondents' comparison of their prior art references with the Asserted Claims of the '666 patent is permitted, that comparison consists of primarily attorney argument, which is no substitute for evidence. Staff says that Respondents cite to Dr. Mah's testimony to support their allegations of anticipation, but that testimony is merely conclusory, as it too references a claim chart, purporting to show how and where the prior art discloses each element of each asserted claim, that has been excluded by the ALJ.

Analysis and Conclusions: In Section IV.B.1, *supra*, I found that Lemchen only incorporates by reference Figures 1 and 3 of Kesling. I incorporate and reaffirm those findings here. Even assuming that Lemchen incorporated the entirety of Kesling, each and every limitation of the asserted claims is not disclosed.

In Section IV.B.1.a, *supra*, I find that Lemchen does not disclose, or teach or suggest, calculating positions-in-between an initial data set and a final data set. I incorporate and reaffirm that finding and rationale here. As a result, I find that Lemchen does not disclose "producing using the computer system a plurality of successive digital data sets based on both of the previously provided initial and final digital data sets," as required by claim 1.

In Section IV.B.1.a, *supra*, I also find that Lemchen's disclosure is limited to the idea of treating a patient with a single set of brackets, i.e. one bracket per tooth to be used over the entirely of the treatment. I incorporate and reaffirm that finding and rationale here. As a result, I also find that Lemchen does not disclose "wherein said plurality of ***successive*** digital data sets represents a series of ***successive*** tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement" as required by claim 1.

I note, too, that the incorporation of Figures 1 and 3 of Kesling into Lemchen provides no greater insight into the teachings of the asserted claims. In Section IV.B.1.a, *supra*, I find that Figure 1 only describes a physical model of a mathematically generated model of a patient's teeth, and Figure 3 demonstrates a method of physically moving portions of a model representing the patient's teeth into a "finish position." I incorporate and reaffirm that finding and rationale here.

In addition, assuming *arguendo* that one were to find that Lemchen incorporates all of Kesling by reference, the result would not change. Although Respondents argue that Kesling teaches a plurality of steps and making "intermediate tooth positioning devices," In Section IV.B.1.a, supra I find that Kesling "does not disclose, or teach or suggest, or even remotely contemplate" the use of computers or digital technology and contemplated a reactive process, performed one step at a time, where appliances beyond a first appliance may be created by repeating the disclosed process for making the first appliance. I incorporate and reaffirm that finding and rationale here.

Assuming, arguendo, that Kesling disclosed "digital data sets," because Kesling discloses a reactive process performed one step at a time, Kesling does not disclose "wherein said plurality of successive digital data sets represents a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement," as required by claim 1.

Based upon all of the foregoing, I find that Lemchen does not anticipate claim 1.

b. Claim 3

Claim 3 teaches:

> A method as in claim 1, wherein the step of producing a plurality of successive digital data sets comprises determining positional differences between the initial data set and the final data set and interpolating said differences.

(JX-004 at 15:52-55)

Respondents Position: Respondents argue that Lemchen discloses the subject matter of claim 3, and incorporate Disclosure Category 7.

Respondents argue that dependent claim 3 is also broadly directed to a method for producing digital teeth arrangements. Respondents say that this claim's added limitation directed to interpolation as a means for determining positional differences dos not change the invalidity analysis. Respondents aver that Lemchen taught that the repositioning of the tooth positions was determined by conventional means using software. (Citing CX-0945 at 3:42-47) Respondents say that it is undisputed that interpolation is a common mathematical means. (Citing RX-0113C at Q. 59) Respondents continue that the Federal Circuit also noted the following characterization of Lemchen:

> The Lemchen patent relies, to produce the calculations, on the conventional calculation techniques employed in generalized CAD software. This in turn relies on a user interactive interface by which an operator contributes human decision making powers to manipulate images until the operator is satisfied that finish tooth position criteria have been met . . . .

(Citing *Ormco II at* 498 F.3d 1315) Respondents contend that this demonstrates that Lemchen anticipates this claim because there is no material difference between the claim and the prior art.

Align's Position: Align's position is stated above regarding claim 1.

Staff's Position: Staff's position is stated above regarding claim 1.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 1 to be anticipated and invalid, I could still find that claim 3 is valid. Since, however, I have found claim 1 to be valid and ***not*** anticipated by Lemchen, claim 3 is necessarily valid, because it depends from claim 1 and necessarily contains all of the elements of claim 1.

See In re Fritch, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 1 is anticipated by Lemchen, I would find that Respondents have failed to show by clear and convincing evidence that claim 3 of the '666 patent is anticipated by Lemchen with the incorporation of Kesling.

Lemchen discloses "repositioning is done mathematically by appropriate software programs which may be derived by conventional means for the particular method of treatment elected by the orthodontist." (CX-945 at 3:44-46) Although Respondents say that interpolation is a common mathematical means, I find nothing in Lemchen actually disclosing interpolation, and Respondents identify no evidence that Lemchen actually disclosed interpolation. Thus, Lemchen with the incorporation of Kesling, does not reveal "determining positional differences between the initial data set and the final data set and interpolating said differences."

c. Claim 7

Claim 7 teaches:

> A method for producing a plurality of digital data sets representing a series of discrete tooth arrangements progressing from an initial to a final arrangement, said method comprising:
>
> providing a computer system;
>
> providing to the computer system digital data set representing an initial tooth arrangement;
>
> providing to the computer system a digital data set representing a final tooth arrangement;
>
> interpolating positional differences between the teeth in the initial and final data sets using the computer system to produce a plurality of successive digital data sets, wherein said plurality of successive digital data sets represents a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement.

(JX-004 at 15:64-16:13)

Respondents' Position: Respondents assert that while Align argues that the preamble of claim 7 is not an element of the claimed invention, the subject matter of the preamble is disclosed in the prior art reference. Respondents incorporate the section of this brief addressing the anticipation of the preamble of Claim 1 of the '325 Patent. Respondents incorporate Disclosure Categories 1, 2, 5, and 7.

Citing Disclosure Category 2, Respondents argue that Lemchen discloses the first element of claim 7. Respondents continue that Lemchen discloses the second element of claim 7 and incorporate Disclosure Categories 1 and 2. Respondents say that Lemchen discloses the third element of claim 7 and cite Disclosure Categories 5 and 7 for support. Respondents continue that Lemchen discloses the fourth element of claim 7 based on Disclosure Category 7.

Respondents assert that independent claim 7 is broadly directed to a method for producing digital teeth arrangements. Respondents say claim 7 contains no limitations as to the appliance to be used or the fabrication of an appliance. Respondents say that as described in the sections addressing Claims 1 and 5 of the '666 Patent, Lemchen anticipates this claim because there is no material difference between the claim and the prior art.

Align's Position: Align's position is stated above regarding claim 1.

Staff's Position: Staff's position is stated above regarding claim 1.

Analysis and Conclusions: Similar to claim 1, discussed *supra*, claim 7 requires "said plurality of successive digital data sets represents a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement." Similar to claim 3, discussed *supra*, claim 7 also requires "interpolating positional differences between the teeth in the initial and final data sets using the computer system to produce a plurality of successive

digital data sets." For the reasons discussed regarding claims 1 and 3, which I incorporate and reaffirm here, Lemchen does not disclose these elements and does not anticipate claim 7.

d. Claim 9

Claim 9 teaches:

> A method as in claim 7, wherein the step of providing a digital data set representing a final tooth arrangement comprises:
>
> defining boundaries about at least some of the individual teeth on a visual image provided by the computer system;
>
> and moving at least some of the tooth boundaries relative to the other teeth in the visual image to produce the final data set.

(JX-004 at 16:18-27)

Respondents' Position: Respondents argue that Lemchen discloses the subject matter of claim 9, citing Disclosure Categories 1, 4, 5.

Respondents say that the added limitation of claim 9 of using the minimum amount of transformation to require the minimum amount of movement does not affect the invalidity analysis. Respondents argue that Lemchen teaches that his method "produces appropriate force magnitudes to at various treatment stages of treatment to move the tooth to its ideal position." (Citing CX-0945 at 2:37-38) Respondents continue that the uncontroverted evidence establishes that the appropriate force magnitude means the minimum force necessary to move the teeth toward the successive stage of treatment. (Citing RX-0113C at Q. 58) Respondents contend that Lemchen anticipates this claim because there is no material difference between the claim and the prior art.

Align's Position: Align's position is stated above regarding claim 1.

Staff's Position: Staff's position is stated above regarding claim 1.

Analysis and Conclusions: First, I note that Respondents' arguments do not address the

subject matter of claim 9. While Respondents' arguments are addressed to "minimum amount of transformation," claim 9 actually teaches:

> A method as in claim 7, wherein the step of providing a digital data set representing a final tooth arrangement comprises:
>
> defining boundaries about at least some of the individual teeth on a visual image provided by the computer system;
>
> and moving at least some of the tooth boundaries relative to the other teeth in the visual image to produce the final data set.

(JX-004 at 16:18-27) As a result, Respondents have failed to set forth any argument that claim 9 is anticipated.

Moreover, a patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 7 to be anticipated and invalid, I could still find that claim 9 is valid. Since, however, I have found claim 7 to be valid and ***not*** anticipated by Lemchen, claim 9 is necessarily valid, because it depends from claim 7 and necessarily contains all of the elements of claim 7. *See In re Fritch.* 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 7 is anticipated by Lemchen, I would find that Respondents have failed to show by clear and convincing evidence that claim 9 of the '666 patent is anticipated by Lemchen with the incorporation of Kesling. Claim 7 merely teaches "providing to the computer system a digital data set representing a final tooth arrangement." (JX-003 at 16:24-25) Even if this were disclosed by Lemchen, although Lemchen teaches generating a digital data set representing teeth in their "final" position (*see* CX-945 at 1:55-2:1; 2:54-57; 3:16-24), Lemchen does not disclose the specific details of how this would be accomplished (*see* CX-945 at 3:44-54). Thus, I find that Lemchen with the incorporation of Kesling, does not reveal the subject matter of claim 9.

3. Obviousness

a. Claim 1

Respondents' Position: Respondents say that while Align argues that the preamble is not an element of the claimed invention, the subject matter of the preamble is obvious in light of Lemchen, Kesling, and the knowledge of one of ordinary skill in the art. Respondents incorporate the section of their brief addressing the anticipation of the preamble of Claim 1 of the '325 Patent here together with knowledge of one of ordinary skill in the art. Respondents assert that Disclosure Categories 1, 2, 4, 5, and 7 here together with knowledge of one of ordinary skill in the art show that the claimed invention was obvious.

Align's Position: Align says that Respondents argue that all of the asserted claims of the '666 patent are obvious in view of the combination of: (i) Lemchen; (ii) Kesling; and (iii) "the knowledge of one of ordinary skill in the art." Align says that this particular combination was disclosed for the first time in the JSCI, as explained in Align's Motion in Limine No. 4, and is therefore improperly raised now. Align continues that the argument is unsupported because no claim charts showing this assertion in detail are in evidence. Align argues that these references, in any combination, fail to disclose all the elements of any asserted claims, as discussed above. Align says that one of ordinary skill in the art at the time of the invention would not have been motivated to combine a reference directed to fixed appliances made of brackets and wires (Lemchen) with a reference directed to removable appliances (Kesling). (Citing CIB Section IV.F.2.b) Align adds that secondary considerations support a finding of non-obviousness. (Citing CIB Section IV.F.2.c)

Align says that Respondents identified several other combinations in the RJSCI, but none were properly raised in Respondents' Prehearing Brief, and have been waived, for the reasons

discussed in CIB Section IV.F.2. Align contends that as explained in CIB Sections IV.F.2.a. IV.F.4, and illustrated in CDX-0146—CDX-0149, no combination of the prior art discloses all elements of the asserted claims of the '666 patent.

Align asserts that all obviousness contentions or combinations have been waived. Alternatively, Align says that none of the asserted claims are obvious because Respondents failed to make a *prima facie* showing of obviousness. (Citing Tr. at 19:11-20:4, 651:14-653:25) Align continues that any combination of prior art other than Lemchen and Kesling was waived. Align says that the combination of Lemchen and Kesling cannot render any of the asserted claims obvious; it does not disclose all elements of any of the asserted claims. (Citing CX-1247C at Q. 568-569; CX-1254C ¶ 274 at 97; CDX-0146—CDX-0149) Align continues that Respondents' obviousness theory relies on their "disclosure categories," which advance new and unsupported mischaracterizations of Lemchen and Kesling, and fail to fairly address the elements of the asserted claims. Align argues that Respondents also misapply their "disclosure categories" with respect to at least claim 7 of the '666 patent. Align contends that none of the prior art discloses all elements of any of the asserted claims, in any combination. (Citing CX-1247C at Q. 606, 610; CX-1258; CDX-0146—CDX-0149) Align adds that there is no evidence of a motivation to combine the prior art and secondary considerations show non-obviousness. Align notes that Respondents have not even contended that at least claim 3 of the '666 patent is obvious.

Staff's Position: Staff says that given that Respondents' arguments and Dr. Mah's testimony alleging obviousness of the Asserted Claims of the '325 patent are also made with respect to the Asserted Claims of the '666 patent, the Staff's discussion of obviousness in SIB Section IV.E.2 applies equally here.

Staff argues that Respondents have failed to demonstrate clearly and convincingly that any Asserted Claim of the '666 patent is invalid because Respondents have failed to provide an element-by-element comparison of the prior art with the Asserted Claims of the '666 patent. Staff says that in their Pre-Hearing Brief, Respondents represented that they would introduce a claim chart showing "where each element of each asserted claim is found in the prior art." Staff says I excluded that claim chart, however. (Citing Tr. at 18:13-19:25) Staff continues that Respondents attempt to make up this shortcoming by comparing, on an element-by-element basis, their prior art references with the Asserted Claims of the '666 patent. Staff says that because Respondents admittedly did not perform this comparison in their Pre-Hearing Brief, Respondents should not be permitted to do so now. (Citing Ground Rule 8.2)

Staff asserts that even if Respondents' comparison of their prior art references with the Asserted Claims of the '666 patent is permitted, that comparison consists of primarily attorney argument, which is no substitute for evidence. Staff says that Respondents cite to Dr. Mah's testimony to support their allegations of anticipation and obviousness, but that testimony is merely conclusory, as it too references a claim chart, purporting to show how and where the prior art discloses each element of each asserted claim, that has been excluded by the ALJ.

Analysis and Conclusions: Respondents have failed to provide clear and convincing evidence that asserted claim 1 of the '666 patent is obvious. Respondents appear to have asserted two separate combinations in post-hearing briefing—Lemchen, Kesling, and the knowledge of one of ordinary skill in the art and Lemchen, Kesling, Nahoum, and the knowledge of one of ordinary skill in the art.

I note that while Respondents do mention "knowledge of one of ordinary skill in the art" in RPHB, section 7.5.2.2, their references in that pre-hearing brief amount to a general

discussion of eleven separate references with no element by element discussion of how those eleven references would combine to render the asserted claims of the '666 patent obvious. There is only a general reference to a "claim chart" that Respondents say they will produce at the hearing. This is inadequate to provide notice to Align regarding the specific prior art to be addressed and the manner in which the prior art discloses each and every element of an asserted claim. (RPHB at 176-183) As a result, at the hearing I granted Align's motion *in limine* number 6, and excluded the claim charts that were not specifically cited in Respondents' prehearing brief as required by Ground Rule 8.2. (Tr. 18:13-20:4)

Although Respondents discussed eleven different prior art references in RPHB section 7.5.2.2, Respondents failed to identify any specification combinations of prior art references other than Lemchen, Kesling, and the knowledge of one of ordinary skill in the art. (RPHB at 175). Ground Rule 8.2 states "[a]ny contentions not set forth in detail as required herein shall be deemed abandoned or withdrawn, except for contentions of which a party is not aware and could not be aware in the exercise of reasonable diligence at the time of filing the pre-trial brief." Because Respondents did not identify any specific combinations other than Lemchen, Kesling, and the knowledge of one of ordinary skill in the art, any other combinations, including Nahoum with Lemchen, Kesling, and the knowledge of one of ordinary skill in the art, were waived.

In order to prevail on their claim that the asserted claims of the '666 patent are invalid as obvious, Respondents must first demonstrate that the combination of Lemchen, either alone or in combination with Kesling discloses all of the limitations of the asserted claims. (*Hearing Components, Inc. v. Shure Inc.*, 600 F.3d 1357, 1373-1374 (Fed. Cir. 2010); and *Velander v. Garner*, 348 F.3d 1359, 1363 (Fed. Cir. 2003))

Equally important is the requirement that the Respondents establish by clear and

convincing evidence that a person of ordinary skill in the art would have had reason to combine the various asserted prior art references to attempt to produce the invention and would have had a reasonable expectation of success in doing so. (See *PharmaStem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007))

Assuming, *arguendo*, that Respondents had properly disclosed their arguments based on the combination of Lemchen, Kesling, Nahoum, and the knowledge of one or ordinary skill in the art in their pre-hearing brief, there is nothing in the evidence submitted by Respondents to support a finding that a PHOSITA would be motivated by anything in Lemchen, Kesling or Nahoum to follow the methods in the '666 patent. In section IV.F.2, *supra*, I noted that even if I had found that Lemchen incorporated the ***entirety*** of Kesling by reference, those two references taken together would still not disclose each and every element of the asserted claims of the '666 patent. Based upon that finding, it follows that Lemchen combined with Kesling would not render obvious the asserted claims of the '666 patent.

Respondents' evidence regarding the knowledge of one of ordinary skill in the art would not fill the gaps in Lemchen and Kesling. Respondents' evidence is limited to expert reports of a former expert for Align (RX-102C and RX-103C) and the opening witness statement of Dr. Mah. At the prehearing conference, I ruled that that Dr. Rekow's expert reports (RX-102C and RX-103C) could be used solely to show that Align took an inconsistent position in the prior litigation. (Tr. at 20:24-21:7) Here, Respondents are improperly attempting to rely on the expert reports to show the knowledge of one of ordinary skill in the art. The testimony of Dr. Mah is not helpful on this subject because he expresses a series of conclusory opinions without citing to evidentiary support. (*See, e.g.*, RX-113C, Qs. 102, 113-121)

Focusing on the motivation to combine references, in Section IV.B.2, *supra*, I find that it

was obvious to combine Lemchen and Kesling. I incorporate that finding and reaffirm it here. Respondents do not, however, provide any basis for combining Nahoum with the Lemchen and Kesling references.

Notwithstanding the foregoing, examining Nahoum in combination with Lemchen and Kesling, I find that Nahoum does not provide the elements missing from the Lemchen and Kesling references. In Section IV.B.1.a, *supra*, I find that Lemchen does not disclose, or teach or suggest, calculating positions-in-between an initial data set and a final data set. In Section IV.B.2.a, *supra*, I find that Lemchen does not in any way disclose, or hint at, designing or fabricating intermediate or successive tooth repositioning appliances based on digital data sets. Lemchen's disclosure is limited to the idea of treating a patient with a single set of brackets, i.e. one bracket per tooth to be used over the entirely of the treatment. In Section IV.B.1.a, *supra*, I find that Kesling contemplated a reactive process, performed one step at a time, where appliances beyond a first appliance may be created by repeating the disclosed process for making the first appliance. In Section IV.B.2.a, *supra*, I also find that Kesling "does not disclose, or teach or suggest, or even remotely contemplate" the use of computers or digital technology and does not expressly or inherently disclose, or teach or suggest, fabricating a dental appliance based on a digital data set. Additionally, in Section IV.B.2.a, *supra*, I find that Nahoum does not in any way disclose use of computers or digital data to assist in fabricating a dental appliance. I reaffirm and incorporate these findings and rationales here.

Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of asserted claim 1 of the '666 patent are present in Lemchen, either alone or in combination with Kesling, and Nahoum, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine the

those references to create the method claimed in the invention of the '666 patent.

b. Claim 3

Respondents' Position: Respondents assert that claim 3 is obvious based on Disclosure Category 7 together with the knowledge of one of ordinary skill.

Align's Position: Align's position is stated above regarding claim 1.

Staff's Position: Staff's position is stated above regarding claim 1.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 1 to be rendered obvious by the asserted prior art and invalid, I could still find that claim 3 is valid. Since, however, I have found claim 1 to be valid and ***not*** rendered obvious by Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, claim 3 is necessarily valid, because it depends from claim 1 and necessarily contains all of the elements of claim 1. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 1 is rendered obvious by Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, I would find that Respondents have failed to show by clear and convincing evidence that claim 3 of the '666 patent is rendered obvious by that combination.

In section IV.F.1.b, *supra*, I found that although Lemchen discloses "repositioning is done mathematically by appropriate software programs which may be derived by conventional means for the particular method of treatment elected by the orthodontist" (CX-945 at 3:44-46); but I find nothing in in Lemchen actually disclosing interpolation. In the interest of brevity, I will not repeat the discussion in section IV.F.1.b in its entirety; but I reaffirm that finding and the rationale for it. Other than a conclusory statement from their expert that "interpolation is a

conventional mathematical means for determining positional differences," (RX-113C at Q.59) Respondents cite no evidence that interpolation would be obvious to one of ordinary skill in the art. In Section IV.B.2.a, *supra*, I find that Nahoum does not in any way disclose use of computers or digital data to assist in fabricating a dental appliance. As a result, I find that Nahoum necessarily does not disclose interpolating the differences between the initial data set and the final data set.

Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that interpolating the differences between the initial data set and the final data set is disclosed in Lemchen combined with Kesling, Nahoum, and the knowledge of one of ordinary skill in the art, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine those references to create the method claimed in asserted claim 3 of the '666 patent.

c. Claim 7

Respondents' Position: Respondents say that while Align argues that the preamble is not an element of the claimed invention, the subject matter of the preamble is obvious in light of the prior art reference with the knowledge of one of ordinary skill in the art. Respondents incorporate the section of their brief addressing anticipation of the preamble of Claim 1 of the '325 Patent together with knowledge of one of ordinary skill. Respondents argue that Disclosure Categories 1, 2, 5, and 7 together with knowledge of one of ordinary skill as described in the section addressing claim 1 of the '325 patent show that the claimed invention was obvious.

Align's Position: Align's position is stated above regarding claim 1.

Staff's Position: Staff's position is stated above regarding claim 1.

Analysis and Conclusions: Claim 7 teaches:

> A method for producing a plurality of digital data sets representing a series of discrete tooth arrangements progressing from an initial to a final arrangement, said method comprising:
>
> providing a computer system;
>
> providing to the computer system digital data set representing an initial tooth arrangement;
>
> providing to the computer system a digital data set representing a final tooth arrangement;
>
> interpolating positional differences between the teeth in the initial and final data sets using the computer system to produce a plurality of successive digital data sets, wherein said plurality of successive digital data sets represents a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement.

(JX-004 at 15:64-16:13) Similar to claims 1 and 3, discussed *supra*, claim 7 requires "interpolating positional differences between the teeth in the initial and final data sets using the computer system to produce a plurality of successive digital data sets" and explains that "said plurality of successive digital data sets represents a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement." For the reasons discussed regarding claims 1 and 3, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of asserted claim 7 of the '666 patent are present in Lemchen, either alone or in combination with Kesling, and Nahoum, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine the those references to create the method claimed in the invention of the '666 patent.

d. Claim 9

Respondents' Position: Respondents assert that claim 9 is obvious based on Disclosure Categories 1, 4, and 5 together with knowledge of one of ordinary skill in the art as described in

the section addressing claim 1 of the '325. These disclosures show that the claimed invention was obvious.

Align's Position: Align's position is stated above regarding claim 1.

Staff's Position: Staff's position is stated above regarding claim 1.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 7 to be rendered obvious by the asserted prior art and invalid, I could still find that claim 9 is valid. Since, however, I have found claim 7 to be valid and ***not*** rendered obvious by Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, claim 9 is necessarily valid, because it depends from claim 7 and necessarily contains all of the elements of claim 7. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 7 is rendered obvious by Lemchen, combined with Kesling, Nahoum, and the knowledge of a PHOSITA, I would find that Respondents have failed to show by clear and convincing evidence that claim 9 of the '666 patent is rendered obvious by that combination.

In section IV.F.1.d, *supra*, I found that although Lemchen teaches generating a digital data set representing teeth in their "final" position (*see* CX-945 at 1:55-2:1; 2:54-57; 3:16-24), Lemchen does not disclose the specific details of how this would be accomplished (*see* CX-945 at 3:44-54). In Section IV.B.2.a, *supra*, I find that Nahoum does not in any way disclose use of computers or digital data to assist in fabricating a dental appliance. In the interest of brevity, I will not repeat the discussion in section IV.F.1.d and IV.B.2.a in their entirety; but I reaffirm those finding and the rationales for them.

Based upon the evidence before me, I find that Respondents have failed to show by clear

and convincing evidence that all of the limitations of asserted claim 9 of the '666 patent are present in Lemchen combined with Kesling, Nahoum, and the knowledge of one of ordinary skill in the art, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine those references to create the method claimed in asserted claim 9 of the '325 patent.

G. The '863 Patent

1. Anticipation

a. Asserted Claim 1

Asserted claim 1 teaches:

> A method for producing digital models of dental positioning appliances, said method comprising:
>
> providing a digital model of a patient's dentition;
>
> producing a plurality of modified digital models of the dentition, wherein the modified models represent successive treatment stages of an orthodontic treatment and wherein each modified model or a product of such model is to be used in fabrication of a distinct successive incremental dental positioning appliance associated with the respective treatment stage of that modified model;
>
> providing a digital model of at least one attachment device; and
>
> positioning the digital model of the attachment device on at least some of the plurality of modified digital models.

(JX-005 at R1:57-67)

Respondents' position: Respondents assert that their arguments regarding anticipation for the '863 patent apply whether the Court adopts Align's, Respondents' or the Staff's claim constructions. Respondents also argue that the scope of the patent claims does not change between an infringement analysis and an invalidity analysis. Referring to Mr. Beers, Align's infringement expert, Respondents note that he identified categories of evidence that covers

common elements of the asserted claims. (Citing CX-1150C at Q. 91) Respondents assert that, because evidence of the subject matter for each category exists in the prior art, the asserted claims were anticipated. Respondents aver that categories 1, 3, 4, 5, 7, 9, and 10 are identified in the section addressing claim 1 of the '325 patent, category 2 is identified in the section addressing claim 1 of the '666 patent, and category 8 is identified in the section addressing claim 1 of the '863 patent.

Respondents incorporate Disclosure Categories 1, 7, and 8 for the preamble of claim 1, discussed *infra*. Respondents assert that while Align argues that the preamble is not an element of the claimed invention, the subject matter of the preamble is disclosed in the prior art references. Respondents incorporate by reference the section addressing the anticipation of the preamble of claim 1 of the '325 patent.

Regarding anticipation of the preamble of claim 1 of the '325 patent, Respondents argue that each of the asserted claims is anticipated by U.S. Patent No. RE 35,169 ("Lemchen") and, as incorporated U.S. Patent No. 2,467,432 ("Kesling") under 35 U.S.C. § 102(a). Respondents submit that the use of aligners in orthodontics is long standing. Respondents state that, in 1943, Dr. Kesling filed an application that resulted in U.S. Patent No. 2,467,432 ("Kesling"). (Citing CX-0944) Respondents assert that Kesling expressly discloses: (1) a plurality of tooth arrangements; (2) the use and fabrication of a series of dental appliances; and (3) using a machine to fabricate a series of dental appliances by producing a positive model of a tooth arrangement. (Citing RX-0113C at Q. 49)

Respondents also say that, in 1989, Dr. Lemchen applied for what ultimately became U.S. Patent No. Re. 35,169 ("Lemchen"). (Citing CX-0945) Respondents assert that he disclosed a digital method for three dimensional modeling of teeth movement that was the same

as the manual method disclosed in the '432 Patent. (Citing RX-0113C at Q. 39-40) Respondents argue that this digital modeling includes intermediate or successive tooth arrangements. (Citing RX-0113C at Q. 41) Respondents contend that Lemchen disclosed methods for the fabrication of multiple custom appliances based on the three dimensional modeling. (Citing RX-0113C at Q. 42) Respondents also contend that Lemchen disclosed using positive models generated from digital data. (Citing RX-0113C at Q. 42-43)

Respondents continue that, contrary to its position in this investigation, Align previously recognized that "Capitalizing on work of the dental CAD/CAM systems, Lemchen describes approaches [that] acquire data, automatically determine . . . ideal position for an individual patient, design . . . configuration to conform to the orthodontic treatment to be undertaken for an individual patient, and use numerically controlled systems to shape . . . that design." (Citing RX-0102C at 6) Accordingly, Respondents say that Align contended in that litigation that "the idea of fabricating custom appliances," for orthodontic treatment "was not new in 1990." (Citing RX-0102C at 7)

Regarding the first element, Respondents incorporate Disclosure Category 1, in which they represent that Lemchen discloses that an initial digital data set representing an initial tooth arrangement is generated, quoting:

> The first step of the method of the present invention is the generation of accurate digital information defining the shape and location of the malocclused tooth with respect to the patient's jaw. This information may be generated in a number of ways, such as electromechanically, by laser scanning, sonic ranging, digital video scanning or magnetically. Various devices which may be so utilized are described in Rekow, Computer Aided Design And Manufacture In Dentistry: A Review Of The State Of The Art, 58 The Journal of Prosthetic Dentistry 512 (1987).

(Citing CX-945, 2:54–63) Respondents assert that Dr. Lemchen specifically discloses that his method generates "accurate digital information" defining the teeth locations. (Citing CX-0945, 2:55-57)

Respondents state that Lemchen expressly incorporated the disclosures of Kesling to explain that the digital three-dimensional model of an initial tooth arrangement that they disclosed was the same as the manual three-dimensional model of an initial tooth arrangement revealed in Kesling, quoting Lemchen:

> in many applications of the preferred embodiment, a complete "model", as that term is used in the dental art to refer to a full replication of the upper and lower dental arches and associated jaw structure, will be mathematically generated. A physical embodiment of such a model is shown, for example, in FIG. 1 of U.S. Pat. No. 2,467,432.

(Citing CX-945, 3:43–46)

Respondents say that contrary to its position here, Align previously recognized that Lemchen developed a digital representation of the physical model of an initial tooth arrangement described by Kesling, quoting:

> Full three-dimensional modeling in orthodontic treatment planning was described by Lemchen *[59 Lemchen, ALN005891-895; 60 Lemchen, ALN005821-829]*. The first step in this process was acquisition of digital data defining the shape and location of the malocclused tooth or teeth [sic] respect to the patient's jaw. A variety of techniques, including those described by Rekow *[89 Rekow, ALN128301-305]* were capable of capturing the required data. The required data, in most applications, were a complete 3D model of the upper and lower dental arches and associated jaw structure *[59 Lemchen, ALN005893, col 3, lines 13-19]*. This model is the mathematical representation of the physical model described by Kesling in 1949. *[Kesling, '432 patent, ALN125695-699]* This digital/mathematical model was used for the planning orthodontic treatment.

(Citing RX-103C at 16)(bracketed information in the original)

Concerning the second element, Respondents incorporate Disclosure Category 7, in which they represent that Kesling discloses the manufacture and use of a plurality of appliances, each appliance in the series representing intermediate or successive tooth positions. (Citing CX-944, 2:50-3:1) Respondents say that Kesling describes the necessity of making a plurality of appliances as obvious. (Citing CX-0944, 2:50-3:1) Respondents say that in a previous litigation, Dr. Rekow, on behalf of Align, recognized that Kesling broadly disclosed a three dimensional method for modeling tooth movement that included successive tooth arrangements that proceeded from the initial to the final. (Citing RX-103C at 12-13)

Respondents say that Lemchen discloses that the "repositioning is done mathematically by appropriate software programs which may be derived by conventional means . . . ." (Citing CX-945, 2:66-3:6) Respondents assert that one skilled in the art would understand this to mean that the tooth path between the initial and final positions would be determined and then the tooth positions for each segment representing the successive stages of treatment would be determined by interpolation or a method for calculating movements of incremental equal sizes. (Citing RX-113C, Q. 59) Respondents say that it is uncontroverted that interpolation is a conventional mathematical means for determining positional differences. (Citing RX-113C, Q. 59)

Respondents aver that Dr. Rekow, on behalf of Align, also recognized that Lemchen incorporated Kesling and broadly disclosed a digital three dimensional method for modeling tooth movement. (Citing RX-103C at 16) Respondents contend that this demonstrates that one skilled in the art would understand that Lemchen incorporates Kesling and discloses three dimensional modeling of teeth movement digitally through a series of incremental or intermediate steps from an initial position to the desired position. Respondents say that Align

previously successfully argued to the Federal Circuit that Lemchen disclosed an incremental approach to calculating desired tooth positions. (Citing *Ormco II*)

Turning to the third and fourth elements, Respondents assert that Lemchen discloses the use of attachment devices in his digital three-dimensional modeling, including brackets. (Citing CX-945, 3:55-4:2) Respondents contend that Lemchen also discloses the method of "indirect" bonding, a method of creating polymeric shell appliances to place the attachment devices. (Citing CX-945, 3:64-4:12) Respondents identify these disclosures as Disclosure Category 8.

Align's position: Regarding the priority date for claim 1 of the '863 patent, Align contends that it claims the benefit of Prov. App. Nos. 60/050,342 and 60/110,881. (Citing CX-1252; CX-1253; JX-005) As shown below, Align asserts that claim 1 of the '863 patent is entitled to a priority date of December 4, 1998. (Citing CX-1247C, Q. 97; *Star Sci.*, 655 F.3d at 1371)

'863 Claim Element	Dec. 4, 1998 Priority Date
1. A method for producing digital models of dental positioning appliances, said method comprising:	CX-1252 at 3:25-28, 4:30-5:23, 5:5-16, 8:1-7, 8:10-28, 10:1-8, 12:20-14:26, 14:29-16:6, 16:9-11, Figs. 1, 5, 6
providing a digital model of a patient's dentition;	CX-1252 at 3:25-28, 4:30-5:23, 8:1-7, 10:1-8, Figs. 1, 5.
producing a plurality of modified digital models of the dentition, wherein the modified models represent successive treatment stages of an orthodontic treatment and wherein each modified model or a product of such model is to be used in fabrication of a distinct successive incremental dental positioning appliance associated with the respective treatment stage of that modified model;	CX-1252 at 5:5-16, 8:10-28, 12:20-14:26, 14:29-16:6, 16:9-11, Figs. 1, 5, 6.
providing a digital model of at least one attachment device; and	CX-1253 at 3:9-21, 3:30-32, 4:26-5:2, Figs. 4A-C, 5.
positioning the digital model of the attachment device on at least some of the plurality of modified digital models.	CX-1253 at 3:9-21, 3:30-32, 4:26-5:2, Figs. 4A-C, 5.

Regarding the prior art and asserted claims, Align contends that Respondents' '863 patent invalidity positions are wholly unsupported and totally insufficient to meet their high burden for an invalidity finding. Align says that Respondents contend that all of the asserted claims of the '863 patent are anticipated by Lemchen and "as incorporated," Kesling. Align submits that this argument is unsupported, because no claim charts (or other explanation) showing this assertion in detail are in evidence. (Citing Tr. at 19:11-20:4; 651:14-653:25) First, Align asserts that this argument relies on accepting that Lemchen incorporates the entire disclosure of Kesling, which is wrong. (Citing CIB Sec. IV.F.4.c) Second, Align argues that, even assuming incorporation, Lemchen/Kesling would still fail to disclose all elements of any of the asserted claims of the '863 patent. For example, Align contends that none of the prior art discloses, *inter alia*, "providing a digital model of at least one attachment device" or "positioning the digital model of the attachment device on at least some of the plurality of modified digital models." (Citing *id.*; CX-1247C at Q. 606, 610; CX-1258) Third, Align contends that both Lemchen and Kesling were considered by the USPTO during the re-examination of the '863 patent, further confirming that the claims of the '863 patent are valid over Lemchen and Kesling. (Citing RPHB at 44, 98, 127, 146, 175, 205, 240; CIB Sec. IV.F.4; CX-1251)

Specifically, Align says Dr. Valley provided a full analysis of each reference in both her expert report (CX-1254C) and witness statement (CX-1247C), and based on her analysis, Dr. Valley opined that specific elements of each claim are not disclosed by the prior art. (Citing CX-1258) Align says the missing claim elements for each prior art reference are illustrated in CDX-130 through CDX-169.

Align says, as depicted in CDX-288 and shown on the face of the patents (and re-exam certificates), almost every reference cited by Respondents was already considered by the

USPTO, and determined to not preclude issuance of the claims. (Citing JX-001 at 2; JX-002 at 2; JX-003 at 1-2, 21-26; JX-004 at 1-2; JX-005 at 1-2, 26-31; JX-006 at 1-4; JX-007 at 1-5; and CX-1250 at 257) Align submits that the USPTO has repeatedly approved the claims over Lemchen and Kesling.

Align argues that Kesling generally discloses tooth positioning appliances made manually using tools and equipment available in the 1940s (*e.g.*, plaster and wax). (Citing CX-1247C, Qs. 142-143; CX-1254C ¶ 63 at 21-22) Align avers that its inventive concept of determining intermediate states based on the initial and final states is absent from Kesling. (Citing CX-1247C, Qs. 144-145; CX-1254C ¶ 65 at 23) Rather, Align submits that Kesling only disclosed a reactive process, done one step at a time, where subsequent appliances are created by repeating the process for making the first. (Citing CX-1247C, Qs. 144-145; CX-1254C ¶ 65 at 23; Tr. at 790:9-791:20) Align contends that Kesling makes one appliance at a time. Align asserts that Kesling does not disclose a proactive method of determining intermediate tooth positions at the outset based on both the initial and final positions. (Citing CX-1247C. Qs. 144-145; CX-1254C ¶ 65 at 23)

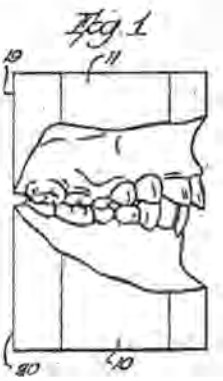
Align argues that Kesling does not disclose, *inter alia*: (i) digital data sets or models of a dentition (Citing CX-1247C, Qs. 141-143; CX-1254C ¶¶ 62-63 at 21-22); (ii) intermediate or successive tooth arrangements based on initial and final positions (Citing CX-1247C, Qs. 141, 144-145; CX-1254C ¶ 65 at 23; and Tr. at 791:21-793:5); (iii) fabricating a dental appliance, or controlling a fabrication machine, based on a digital data set (citing CX-1247C, Qs. 141, 146-147; CX-1254C ¶ 67 at 24-25); or (iv) numerous other elements (citing CX-1247C, Qs. 137-162; CX-1258 at 2-8).

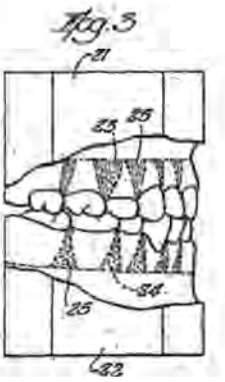
Align asserts that Lemchen discloses a method for determining orthodontic bracket placement. (Citing CX-945, 1:55-2:8) Align contends that Lemchen is directed to a single fixed appliance used for the duration of a patient's treatment, not a removable appliance. (Citing CX-1247C, Qs. 190-191; CX-1254C ¶¶ 90-91 at 32-33; CX-1264 at 5) Align submits that Lemchen's disclosure is limited to the idea of treating a patient with the single set of brackets. (Citing CX-1247C, Qs. 190-191; CX-1254C ¶¶ 90-91 at 32-33) Align avers that the concept of intermediate digital data sets or tooth arrangements is, therefore, absent from, and irrelevant to, Lemchen. (Citing CX-1247C, Qs. 183-185; CX-1254C ¶ 82 at 29-30) Align maintains that Lemchen teaches away from the use of intermediate arrangements. (Citing CX-1247C, Qs. 225-227; CX-1254C ¶ 97 at 34-35)

Align argues that Lemchen does not disclose, *inter alia*: (i) intermediate or successive digital data sets or tooth arrangements (citing CX-1247C, Qs. 183-185; CX-1254C ¶ 82 at 29-30); (ii) polymeric shell appliances (citing CX-1247C, Qs. 183, 186-189; CX-1254C ¶¶ 85-86 at 31-32; CX-1264 at 5); (iii) positive models of modified tooth arrangements based on digital data sets (citing CX-1247C, Qs. 183, 186-189, 207, 209-214; CX-1254C ¶ 87 at 32; CX-1264); (iv) multiple removable appliances or fabricating intermediate or successive appliances based on digital data sets (citing CX-1247C, Qs. 183, 190-191; CX-1254C ¶¶ 90-91 at 32-33); (v) threshold limits (citing CX-1247C, Qs. 233-235; CX-1254C ¶ 105 at 39-40); (vi) interpolation or movements of equal sizes (citing CX-1247C, Qs. 236-238; CX-1254C ¶ 106 at 40); (vii) substantially accurate shapes of a patient's teeth in a modified arrangement (citing CX-1247C, Qs. 239-240; CX-1254C ¶ 108 at 41); (viii) attachment devices (citing CX-1247C, Qs. 241-243; CX-1254C ¶ 109 at 41-42); or (ix) numerous other elements of the asserted claims (citing CX-1247C, Qs. 275-277; CX-1258 at 9-15).

Align contends that Respondents' claim that Lemchen incorporates the entire disclosure of Kesling is wrong as a matter of law. (Citing RPHB at 46-48) Align argues that, to incorporate by reference, the host document "must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents." (Citing *Advanced Display Sys.*, 212 F.3d at 1282 (A "mere reference to another [patent] is not an incorporation of anything therein."; *In re De Seversky*, 474 F.2d 671, 674 (C.C.P.A. 1973)) Align argues that I have previously held that incorporation of a disclosed patent was limited to the express reference, and did not incorporate all disclosures contained within the patent. (Citing *Certain Digital Imaging Devices*, Inv. No. 337-TA-717, I.D., 2010 WL 5646142, at *53 (USITC May 12, 2011) (Rogers, J.))

Align argues that Lemchen only briefly refers to two figures from Kesling. (Citing CX-945, 3:14-15 ("[a] physical embodiment of such a model is shown, for example, in FIG. 1 of U.S. Pat. No. 2,467,432"); *id.* at 3:35-40 ("[i]n the prior art, a similar step was accomplished manually in order to account





for individual tooth morphology by physically removing duplicated teeth from a model and repositioning them in a new model in the finish position. *See*, for example, FIG. 3 in the above referenced U.S. Pat. No. 2,467,432") Align contends that the references to FIGS. 1 and 3 are only examples of models. Align submits that Lemchen does not say that the entire disclosure of

Kesling, or any of its particular methods, is incorporated. Align says that Dr. Valley agrees that Lemchen cites these Figures as examples of what models look like and does not otherwise address Kesling or the relationship between the Figures. (Citing CX-1247C at Q. 249, 251-258; CX-1254C ¶¶ 112-117 at 42-46) Align also argues that, Figures 1 and 3 of Kesling do not disclose the claim elements that are absent from Lemchen. (Citing CX-1247C at Q. 257-258; CX-1254C ¶¶ 112-117 at 42-46)

Align asserts that, contrary to the express description found in the words of Lemchen that cite to Kesling's Figures 1 and 3 as examples of models, Dr. Mah contends, "[i]t is only in the context of the entire disclosure [of Kesling] that the significance of the model displayed as Figure 1 [or Figure 3] as a representation of the patient's teeth prior to treatment [or as a modified tooth arrangement] is understood." (Citing RX-0113C at Q. 47-48) Align argues that these contentions lack merit. Align contends that one of ordinary skill in the art would have understood the concept of a representation of teeth based on Figures 1 and 3 without needing to review Kesling's entire disclosure. (Citing CX-1247C at Q. 264-265; CX-1254C ¶ 117 at 45-46; Tr. at 786:24-787:17, 788:11-789:8, 796:13-798:6) Align submits that plaster tooth arrangements were commonly known and used. (Citing CX-1247C at Q. 264-265; CX-1254C ¶ 117 at 45-46) Align also submits that, even if Lemchen fully incorporated Kesling, Lemchen/Kesling still would not disclose all elements of any of the asserted claims. (Citing CX-1247C at Q. 568-569; CX-1254C ¶ 274 at 97)

Staff's position: Staff says that Respondents' arguments and Dr. Mah's testimony alleging anticipation of the asserted claims of the '325 patent are also made with respect to the asserted claims of the '863 patent. Staff's submits that their discussion of anticipation with respect to the '325 applies equally here. (Citing CIB Section IV.E.1)

In the Staff's view, the evidence does not demonstrate clearly and convincingly that any of the asserted claims of the '863 patent is anticipated by U.S. Patent No. 35,169 (Lemchen) (CX-0945) and, "as incorporated," U.S. Patent No. 2,467,432 (Kesling) (CX-0944). As a preliminary matter, the Staff is of the view that Lemchen does not incorporate the entirety of Kesling. Staff asserts that the evidence demonstrates that Lemchen includes two references to Kesling, specifically, (i) Lemchen refers to Figure 1 of Kesling to explain the representation of the digitized mathematical model of Lemchen; and (ii) Lemchen refers to Figure 3 of Kesling to disclose the method of moving teeth in a digitized mathematical model to a "finish" position. (Citing CX-1247C at Q. 252-256; CX-0945 at 2:66-3:16 and 3:32-40; CX-0944 at FIG. 1 and FIG. 3) Staff contends, however, that the evidence does not further demonstrate that Lemchen incorporates the concepts or teachings from Kesling beyond these figures. (Citing CX-1247C at Q. 259-274; CX-0945; CX-0944) Staff argues that the evidence does not demonstrate that Lemchen necessarily incorporates the entirety of Kesling. (Citing CX-1247C at Q. 259-274; CX-0945; CX-0944)

Staff argues that, even if it was determined that Lemchen necessarily incorporates the entirety of Kesling, the evidence does not show clearly and convincingly that any asserted claim of the '325 patent (or any of the other Asserted Patents) is anticipated by Lemchen and, "as incorporated," Kesling. (Citing CX-1247C at Q. 561-571; CX-1258 at 1-14) Staff asserts that Lemchen does not disclose, teach, or suggest, *inter alia*, (i) intermediate or successive digital data sets or (ii) intermediate or successive tooth arrangements. (Citing CX-1247C at Q. 178-186; CX-1258 at 8-14) Staff argues that Kesling does not disclose, teach, or suggest, *inter alia*, (i) intermediate or successive digital data sets; (ii) the use or fabrication of a series of dental

appliances or (iii) controlling a fabrication machine or producing a positive model of a tooth arrangement from a digital data set. (Citing CX-1247C at Q. 136-163; CX-1258 at 1-7)

Staff continues that Respondents' technical expert Dr. Mah provides only conclusory testimony about the subject matter of the prior art and the '863 patent rather than a detailed discussion of how and where Lemchen and, "as incorporated," Kesling disclose, teach, or suggest each and every element of the Asserted Claims of the '325 patent (or any of the other Asserted Patents). (Citing RX-0113C at Q. 100-111) Staff says that Dr. Mah apparently prepared a claim chart setting forth more details about how and where Lemchen and, "as incorporated," Kesling disclose, teach, or suggest each and every element of the asserted claims of the asserted patents, but I excluded that claim chart. (Citing Hearing Tr. at 18:13-19:25 (excluding RX-0124 and RX-0113C at Q. 110)) Staff submits that absent from the record is any evidence explaining clearly and convincingly how and where Lemchen and, "as incorporated," Kesling disclose, teach, or suggest each and every element of the asserted claims.

Staff also asserts that the PTO considered both Lemchen and Kesling during the reexamination of the '863 patent, and the PTO still approved all of the asserted claims of the '863 patent. (Citing CX-1247C at Q. 135 and 177)

In sum, Staff argues that there is a lack of evidence demonstrating clearly and convincingly that any of the asserted claims of the '863 patent are anticipated by Lemchen and, "as incorporated," Kesling.

Analysis and Conclusions: In Section IV.B.1.a, *supra*, I found that Lemchen incorporates by reference only Figures 1 and 3 of Kesling. I incorporate and reaffirm those findings here. Even assuming that Lemchen incorporated the entirety of Kesling, each and every limitation of the asserted claims is not disclosed.

First, I note that both Lemchen and Kesling were considered by the USPTO during the original prosecution and the re-examination of the '863 patent. (JX-005 at 1, 26-27 (Re-Exam References Cited)) As a result, Respondents must "overcome[e] the deference that is due to a qualified government agency presumed to have properly done its job" to show that the claims of the '325 patent are invalid. *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359 (Fed. Cir. 1984).

Respondents have failed even to meet their burden to prove by clear and convincing evidence that each and every limitation of the asserted claims is disclosed expressly or inherently in the cited references.

In Section IV.B.1.a, *supra*, I find that Lemchen does not disclose, or teach or suggest, calculating positions-in-between an initial data set and a final data set. In Section IV.B.2.a, *supra*, I find that Lemchen does not in any way disclose, or hint at, designing or fabricating intermediate or successive tooth repositioning appliances based on digital data sets. Lemchen's disclosure is limited to the idea of treating a patient with a single set of brackets, i.e. one bracket per tooth to be used over the entirely of the treatment. In Section IV.B.1.a, *supra*, I find that Kesling contemplated a reactive process, performed one step at a time, where appliances beyond a first appliance may be created by repeating the disclosed process for making the first appliance. In Section IV.B.2.a, *supra*, I also find that Kesling "does not disclose, or teach or suggest, or even remotely contemplate" the use of computers or digital technology and does not expressly or inherently disclose, or teach or suggest, fabricating a dental appliance based on a digital data set. I reaffirm and incorporate these findings and rationales here.

Based on the evidence before me, I find that Lemchen does not disclose "producing a plurality of modified digital models of the dentition, wherein the modified models represent

successive treatment stages of an orthodontic treatment," as required by claim 1. I also find that Lemchen does not disclose "wherein each modified model or a product of such model is to be used in fabrication of a distinct successive incremental dental positioning appliance associated with the respective treatment stage of that modified model," as required by claim 1.

Moreover, Lemchen discloses the use of a "machined or cast base" to assist in the positioning a bracket on a tooth. According to the unrebutted testimony of Dr. Valley, this is different from an "attachment device" within the meaning of the '863 patent. Dr. Valley provided the unrebutted testimony that the machined or cast base is simply a customization of the bracket. The machined or cast base is not an object that provides or secures repositioning force, anchoring ability, or retention force, and it is not used for the purpose of securing an orthodontic appliance. Also, the machined or cast base is not used with a removable positioning appliance. (CX-944, 5:3-14; CX-1247C at Q. 243)

Based upon all of the foregoing, I find that Respondents have failed to meet their burden to prove by clear and convincing evidence that Lemchen anticipates asserted claim 1 of the '863 patent.

b. Asserted Claim 4

Asserted claim 4 recites:

> A method as in claim 1, wherein producing a plurality of modified digital models of the dentition comprises:
>
> presenting a visual image based on the digital model of the patient's dentition;
>
> manipulating the visual image to reposition individual teeth in the visual image;
>
> producing a digital data set representing the final tooth arrangement with repositioned teeth as observed in the image; and

producing the plurality of modified digital models as a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement.

(JX-005 at 14:-4-16)

Respondents' position:

Regarding the preamble and first element, Respondents incorporate Disclosure Category 1, discussed *supra* with respect to the first element of claim 1. Regarding the second element, Respondents incorporate Disclosure Category 4, in which they contend that Lemchen expressly discloses that the invention "may be utilized with some or all of the teeth in a given dental arch . . ." (Citing CX-0945 at 5:21 – 24) Respondents say that Align previously recognized that the CAD system described by Lemchen presented visual images based on the initial data set that are manipulated to reposition individual teeth. (Citing RX-103C at 16) Respondents continue that Align successfully argued to the Federal Circuit that one skilled in the art would understand that Lemchen discloses manipulating visual images to reposition individual teeth in the visual image. (Citing *Ormco II*).

Regarding the third element, Respondents incorporate Disclosure Category 5, in which they assert that Kesling discloses modeling a final tooth arrangement. Respondents say that Align previously contended that Kesling disclosed producing a final tooth arrangement through full 3-D modeling. (Citing RX-103C at 12-13) Respondents continue that Dr. Lemchen expressly incorporated the disclosure of Kesling to explain the final tooth arrangement in the disclosed three dimensional modeling methodology. (Citing CX-0945 at 3:36 – 40) Respondents aver that Align previously recognized that Lemchen disclosed producing a final digital data set representing the final tooth arrangement with repositioned teeth as observed in the image (Citing RX-103C at 16; and *Ormco II*).

Regarding the fourth element, Respondents incorporate Disclosure Category 7, discussed *supra* with respect to the second element of claim 1.

Align's position: Regarding the priority date for claim 4 of the '863 patent, Align contends that it claims the benefit of Prov. App. Nos. 60/050,342 and 60/110,881. (Citing CX-1252; CX-1253; JX-0005) As shown below, Align asserts that claims 4 of the '863 patent is entitled to a priority date of December 4, 1998. (Citing CX-1247C at Q. 97; *Star Sci.*, 655 F.3d at 1371) Align provides no additional general argument beyond that which it forwarded in a general response to Respondents' invalidity argument in section IV.G.1.a, *supra*.

'863 Claim Element	Dec. 4, 1998 Priority Date
4. A method as in claim 1, wherein producing a plurality of modified digital models of the dentition comprises:	*See* claim 1, above
presenting a visual image based on the digital model of the patient's dentition;	CX-1252 at 9:24-25, 10:6-8, 11:25-28.
manipulating the visual image to reposition individual teeth in the visual image;	CX-1252 at 4:1-3, 10:23-11:9, 11:25-12:3, Fig. 1.
producing a digital data set representing the final tooth arrangement with repositioned teeth as observed in the image; and	CX-1252 at 4:1-3, 8:10-12:17, Fig. 1.
producing the plurality of modified digital models as a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement.	CX-1252 at 5:5-16, 8:10-28, 12:20-14:26, 14:29-16:6; 16:9-11, Fig. 1.

Staff's position: Staff refers to their argument in section IV.B.1.a, *supra*, and reasserts it.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 1 to be anticipated and invalid, I could still find that claim 4 is valid. Since, however, I have found claim 1 to be valid and ***not*** anticipated the Lemchen, claim 4 is necessarily valid, because it depends from claim 1 and necessarily contains all of the elements of claim 1. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming *arguendo* that one were to find that independent claim 1 is anticipated by

Lemchen and one were to find that Lemchen incorporates all of Kesling by reference, I would find that Respondents have failed to show by clear and convincing evidence that claim 4 of the '863 patent is anticipated by Lemchen with the incorporation of Kesling.

In Section IV.B.1.a, *supra*, I find that Lemchen does not disclose, or teach or suggest, calculating positions-in-between an initial data set and a final data set. In Section IV.B.2.a, *supra*, I find that Lemchen does not in any way disclose, or hint at, designing or fabricating intermediate or successive tooth repositioning appliances based on digital data sets. Lemchen's disclosure is limited to the idea of treating a patient with a single set of brackets, i.e. one bracket per tooth to be used over the entirely of the treatment. In Section IV.B.1.a, *supra*, I find that Kesling contemplated a reactive process, performed one step at a time, where appliances beyond a first appliance may be created by repeating the disclosed process for making the first appliance. In Section IV.B.2.a, *supra*, I also find that Kesling "does not disclose, or teach or suggest, or even remotely contemplate" the use of computers or digital technology and does not expressly or inherently disclose, or teach or suggest, fabricating a dental appliance based on a digital data set. I reaffirm and incorporate these findings and rationales here.

Based on the evidence before me, I find that Lemchen does not disclose "producing the plurality of modified digital models as a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement," as required by claim 4.

Based upon the foregoing, I find that in the unlikely event that one were to find that Lemchen discloses all of the elements of asserted claim 1, the Respondents have failed to demonstrate by clear and convincing evidence that Lemchen in any way discloses all of elements of claim 4.

c. Asserted Claim 5

Claim 5 states:

A method as in claim 4, wherein the manipulating step comprises:

defining boundaries about at least some of the individual teeth; and

moving at least some of the tooth boundaries relative to the other teeth in an image based on the digital data set.

(JX-005 at 14:18-23)

Respondents' position:

Respondents incorporate Disclosure Category 4, discussed *supra* with respect to the second element of claim 4.

Align's position: Regarding the priority date for claim 5 of the '863 patent, Align contends that it claims the benefit of Prov. App. Nos. 60/050,342 and 60/110,881. (Citing CX-1252; CX-1253; JX-0005) As shown below, Align asserts that claim 5 of the '863 patent is entitled to a priority date of December 4, 1998. (Citing CX-1247C at Q. 97; *Star Sci.*, 655 F.3d at 1371) Align provides no additional general argument beyond that which it forwarded in a general response to Respondents' invalidity argument in section IV.G.1.a, *supra*.

'863 Claim Element	Dec. 4, 1998 Priority Date
5. A method as in claim 4, wherein the manipulating step comprises:	*See* claim 4, above
defining boundaries about at least some of the individual teeth; and	CX-1252 at 9:16-28, 10:10-21, Fig. 1.
moving at least some of the tooth boundaries relative to the other teeth in an image based on the digital data set.	CX-1252 at 4:1-3, 10:23-11:9, 11:25-12:3, Fig. 1.

Staff's position: Staff refers to their argument in section IV.B.1.a, *supra*, and reasserts it.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claims 1 and 4 to be anticipated and invalid, I could still find that claim 5 is valid.

Since, however, I have found claims 1 and 4 to be valid and ***not*** anticipated by Lemchen, claim 5 is necessarily valid, because it depends from claim 1 via claim 4 and necessarily contains all of the elements of claims 1 and 4. *See In re Fritch,* 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming *arguendo* that one were to find that claims 1 and 4 are anticipated by Lemchen, I would find that Respondents have failed to show by clear and convincing evidence that claim 5 of the '863 patent is anticipated by Lemchen with the incorporation of Kesling.

Lemchen describes "generating digital information which defines the shape and location of each malocclused tooth in the patient's jaw," generating a mathematical model of the tooth and jaw, and then calculating the respective "finish positions" for each tooth. (CX-0945 at 1:55-62) Lemchen thus discloses defining boundaries about at least some of the individual teeth, which the first element of claim 5 requires. Lemchen, however, does not disclose moving at least some of the tooth boundaries relative to the other teeth in an image based on the digital data set as the second element of claim 5 requires. Although Lemchen teaches generating a digital data set representing teeth in their "final" position, Lemchen does not disclose the specific details of how to generate a "final" digital data set.

Kesling was originally filed in 1943, and the patent issued in 1949, before the concept of digital data existed. According to Dr. Valley's unrebutted testimony, Kesling "does not disclose, or teach or suggest, or even remotely contemplate" the use of computers or digital technology. (CX-1247C, Qs. 141-142, 564-571, 574-577; CDX-145) Kesling describes making tooth arrangements by (i) using a plaster mold of teeth, (ii) dissecting the plaster teeth with a saw, and (iii) reassembling the plaster teeth in wax into their assumed positions. (CX-944, 3:13-22; 3:30-43; 3:61-64) As a result, I find that Kesling does not disclose "moving at least some of the tooth

boundaries relative to the other teeth in an image based on the digital data set," as required by claim 5.

Based upon the foregoing, I find that in the unlikely event that one were to find that Lemchen discloses all of the elements of asserted claims 1 and 4, the Respondents have failed to demonstrate by clear and convincing evidence that Lemchen in any way discloses all of elements of claim 5.

d. Asserted claim 6

Claim 6 states:

> A method as in claim 1, wherein producing a plurality of modified digital models of the dentition comprises:
>
> providing a computer system having at least one processor and memory;
>
> providing to the computer system the digital model of the patient's dentition;
>
> providing to the computer system a digital model set representing a final tooth arrangement;
>
> producing using the computer system the plurality of models based on both of the previously provided initial and final digital data sets.

(JX-005 at 14:24-35)

Respondents' position: Regarding the preamble, first and second elements, Respondents incorporate Disclosure Category 2, in which they submit that Lemchen discloses the use of conventional CAD/CAM software on computers. (Citing CX-0945 at 2:66 – 3:6) Regarding the third element, Respondents incorporate Disclosure Categories 5 and 7, discussed *supra* with respect to the third and fourth elements of claim 4, respectively. Regarding the fourth element, Respondents incorporate Disclosure Category 7, discussed *supra* with respect to the second element of claim 1.

Align's position: Regarding the priority date for claim 6 of the '863 patent, Align contends that it claims the benefit of Prov. App. Nos. 60/050,342 and 60/110,881. (Citing CX-1252; CX-1253; JX-0005) As shown below, Align asserts that claim 6 of the '863 patent is entitled to a priority date of December 4, 1998. (Citing CX-1247C at Q. 97; *Star Sci.*, 655 F.3d at 1371) Align provides no additional general argument beyond that which it forwarded in a general response to Respondents' invalidity argument in section IV.G.1.a, *supra*.

'863 Claim Element	Dec. 4, 1998 Priority Date
6. A method as in claim 1, wherein producing a plurality of modified digital models of the dentition comprises:	*See* claim 1, above
providing a computer system having at least one processor and memory;	CX-1252 at 4:28-14:26, Fig. 1.
providing to the computer system the digital model of the patient's dentition;	CX-1252 at 3:25-28, 4:30-5:23, 8:1-7, 10:1-8, Fig. 1.
providing to the computer system a digital model set representing a final tooth arrangement;	CX-1252 at 4:1-3, 8:10-12:17, Fig. 1.
producing using the computer system the plurality of models based on both of the previously provided initial and final digital data sets.	CX-1252 at 5:5-16, 8:10-28, 12:20-14:26, 14:29-16:6; 16:9-11, Fig. 1.

Staff's position: Staff refers to their argument in section IV.B.1.a, *supra*, and reasserts it.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 1 to be anticipated and invalid, I could still find that claim 6 is valid. Since, however, I have found claim 1 to be valid and ***not*** anticipated the Lemchen, claim 6 is necessarily valid, because it depends from claim 1 and necessarily contains all of the elements of claim 1. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming *arguendo* that one were to find that independent claim 1 is anticipated by Lemchen, I would find that Respondents have failed to show by clear and convincing evidence that claim 6 of the '863 patent is anticipated by Lemchen with the incorporation of Kesling.

Lemchen describes "generating digital information" regarding the initial "malocclused teeth," and then determining their respective "finish positions." According to Dr. Valley's unrebutted testimony, Lemchen does not disclose, or teach or suggest, calculating positions-in-between. (CX-945, 1:55-2:1; 2:54-57; 3:16-24; CX-1247C at Q. 184-185) As a result, I find that Lemchen does not disclose "producing using the computer system the plurality of models based on both of the previously provided initial and final digital data sets," as required by claim 6.

In addition, assuming *arguendo* that one were to find that Lemchen incorporates all of Kesling by reference, the result would not change. Lemchen describes "generating digital information" regarding the initial "malocclused teeth." Kesling was originally filed in 1943, and the patent issued in 1949, before the concept of digital data existed. As Dr. Valley testified credibly, Kesling "does not disclose, or teach or suggest, or even remotely contemplate" the use of computers or digital technology. (CX-1247C, Qs. 141-142, 564-571, 574-577; CDX-145) Kesling describes making tooth arrangements by (i) using a plaster mold of teeth, (ii) dissecting the plaster teeth with a saw, and (iii) reassembling the plaster teeth in wax into their assumed positions. (CX-944, 3:13-22; 3:30-43; 3:61-64)

Based upon the foregoing, I find that in the unlikely event that one were to find that Lemchen discloses all of the elements of asserted claim 1, the Respondents have failed to demonstrate by clear and convincing evidence that Lemchen in any way discloses all of elements of claim 6.

e. Asserted Claim 7

Claim 7 states:

> A method as in claim 6, wherein the step of providing a digital model set representing a final tooth arrangement comprises:

defining boundaries about at least some of the individual teeth on a visual image provided by the computer system; and

moving at least some of the tooth boundaries relative to the other teeth in the visual image to produce the final data set.

(JX-005 at 14:36-44)

Respondents' position: Respondents incorporate Disclosure Category 4, discussed *supra* with respect to the second element of claim 4.

Align's position: Regarding the priority date for claim 7 of the '863 patent, Align contends that it claims the benefit of Prov. App. Nos. 60/050,342 and 60/110,881. (Citing CX-1252; CX-1253; JX-0005) As shown below, Align asserts that claim 7 of the '863 patent is entitled to a priority date of December 4, 1998. (Citing CX-1247C at Q. 97; *Star Sci.*, 655 F.3d at 1371) Align provides no additional general argument beyond that which it forwarded in a general response to Respondents' invalidity argument in section IV.G.1.a, *supra*.

'863 Claim Element	Dec. 4, 1998 Priority Date
7. A method as in claim 6, wherein the step of providing a digital model set representing a final tooth arrangement comprises:	*See* claim 6, above
defining boundaries about at least some of the individual teeth on a visual image provided by the computer system; and	CX-1252 at 9:16-28, 10:10-21, Fig. 1.
moving at least some of the tooth boundaries relative to the other teeth in the visual image to produce the final data set.	CX-1252 at 4:1-3, 10:23-11:9, 11:25-12:3, Fig. 1.

Staff's position: Staff refers to their argument in section IV.B.1.a, *supra*, and reasserts it.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claims 1 and 6 to be anticipated and invalid, I could still find that claim 7 is valid. Since, however, I have found claims 1 and 6 to be valid and ***not*** anticipated the Lemchen, claim 7 is necessarily valid, because it depends from claim 1 via claim 6 and necessarily contains all of

the elements of claims 1 and 6. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming *arguendo* that one were to find that independent claim 1 and dependent claim 6 are anticipated by Lemchen, I would find that Respondents have failed to show by clear and convincing evidence that claim 7 of the '863 patent is anticipated by Lemchen with the incorporation of Kesling.

Lemchen describes "generating digital information which defines the shape and location of each malocclused tooth in the patient's jaw," generating a mathematical model of the tooth and jaw, and then calculating the respective "finish positions" for each tooth. (CX-0945 at 1:55-62) Lemchen discloses that the generation of digital information may be accomplished through digital video scanning. (CX-0945 at 2:59) Lemchen, thus, discloses defining boundaries about at least some of the individual teeth on a visual image provided by the computer system, which the first element of claim 7 requires. Lemchen, however, does not disclose moving at least some of the tooth boundaries relative to the other teeth in the visual image to produce the final data set as the second element of claim 7 requires. Although Lemchen teaches generating a digital data set representing teeth in their "final" position, Lemchen does not disclose the specific details of how to generate a "final" digital data set.

Kesling was originally filed in 1943, and the patent issued in 1949, before the concept of digital data existed. According to Dr. Valley's unrebutted testimony, Kesling "does not disclose, or teach or suggest, or even remotely contemplate" the use of computers or digital technology. (CX-1247C, Qs. 141-142, 564-571, 574-577; CDX-145) Kesling describes making tooth arrangements by (i) using a plaster mold of teeth, (ii) dissecting the plaster teeth with a saw, and (iii) reassembling the plaster teeth in wax into their assumed positions. (CX-944, 3:13-22; 3:30-43; 3:61-64) As a result, I find that Kesling does not disclose "defining boundaries about at least

some of the individual teeth on a visual image provided by the computer system; and moving at least some of the tooth boundaries relative to the other teeth in the visual image to produce the final data set," as required by claim 7.

Based upon the foregoing, I find that in the unlikely event that one were to find that Lemchen discloses all of the elements of asserted claims 1 and 6, the Respondents have failed to demonstrate by clear and convincing evidence that Lemchen in any way discloses all of the elements of claim 7.

f. Asserted Claim 8

Asserted claim 8 recites:

> A method as in claim 6, wherein the step of producing the plurality of models comprises determining positional differences between the initial digital model and the final digital model and interpolating said differences.

(JX-005 at 14:45-48)

Respondents' position: Respondents incorporate Disclosure Category 7, discussed *supra* with respect to the second element of claim 1.

Align's position: Regarding the priority date for claim 8 of the '863 patent, Align contends that it claims the benefit of Prov. App. Nos. 60/050,342 and 60/110,881. (Citing CX-1252; CX-1253; JX-0005) As shown below, Align asserts that claim 8 of the '863 patent is entitled to a priority date of December 4, 1998. (Citing CX-1247C at Q. 97; *Star Sci.*, 655 F.3d at 1371) Align provides no additional general argument beyond that which it forwarded in a general response to Respondents' invalidity argument in section IV.G.1.a, *supra*.

'863 Claim Element	Dec. 4, 1998 Priority Date
8. A method as in claim 6, wherein the step of producing the plurality of models comprises determining positional differences between the initial digital model and the final digital model and interpolating said differences.	CX-1252 at 12:20-14:26

Staff's position: Staff refers to their argument in section IV.B.1.a, *supra*, and reasserts it.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claims 1 and claim 6 to be anticipated and invalid, I could still find that claim 8 is valid. Since, however, I have found claims 1 and 6 to be valid and ***not*** anticipated the Lemchen, claim 8 is necessarily valid, because it depends from claim 1 via claim 6 and necessarily contains all of the elements of claims 1 and 6. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming *arguendo* that one were to find that independent claim 1 is anticipated by Lemchen, I would find that Respondents have failed to show by clear and convincing evidence that claim 8 of the '863 patent is anticipated by Lemchen with the incorporation of Kesling.

Lemchen describes "generating digital information" regarding the initial "malocclused teeth," and then determining their respective "finish positions." As Dr. Valley testified credibly, Lemchen does not disclose, or teach or suggest, calculating positions-in-between. (CX-945, 1:55-2:1; 2:54-57; 3:16-24; CX-1247C at Q. 184-185) As a result, I find that Lemchen does not disclose "determining positional differences between the initial digital model and the final digital model and interpolating said differences," as required by claim 8.

I note, too, that the incorporation of Figures 1 and 3 of Kesling into Lemchen provides no greater insight into the teachings of the asserted claims. As described, *supra*, Figure 1 only describes a physical model of a mathematically generated model of a patient's teeth, and Figure 3 demonstrates a method of physically moving portions of a model representing the patient's teeth into a "finish position."

In addition, assuming *arguendo* that one were to find that Lemchen incorporates all of Kesling by reference, the result would not change. Kesling was originally filed in 1943, and the

patent issued in 1949, before the concept of digital data existed. According to Dr. Valley's unrebutted testimony, Kesling "does not disclose, or teach or suggest, or even remotely contemplate" the use of computers or digital technology. (CX-1247C, Qs. 141-142, 564-571, 574-577; CDX-145) Kesling describes making tooth arrangements by (i) using a plaster mold of teeth, (ii) dissecting the plaster teeth with a saw, and (iii) reassembling the plaster teeth in wax into their assumed positions. (CX-944, 3:13-22; 3:30-43; 3:61-64)

Based upon the foregoing, I find that in the unlikely event that one were to find that Lemchen discloses all of the elements of asserted claims 1 and 6, the Respondents have failed to demonstrate by clear and convincing evidence that Lemchen in any way discloses all of elements of claim 8.

2. Obviousness

a. Asserted claim 1

Respondents assert that their arguments regarding obviousness for the '863 patent apply whether the Court adopts Align's, Respondents', or the Staff's claim constructions. Respondents incorporate Disclosure Categories 1, 7, and 8, discussed *supra*, together with knowledge of one of ordinary skill addressed in claim 1 of the '325 patent. Respondents also incorporate the section addressing the preamble of claim 1 of the '325 patent together with knowledge of one of ordinary skill in the art. In that section, Respondents asserted two separate combinations in their post-hearing briefing— (1) Lemchen, Kesling, and the knowledge of one of ordinary skill in the art; and (2) Lemchen, Kesling, Nahoum, and the knowledge of one of ordinary skill in the art.

Respondents argue that claim 1 is further rendered obvious in light of U.S. Patent No. 4,793,803 ("Martz") and the knowledge of one of ordinary skill in the art. Respondents assert that Martz discloses a method of producing dental positioning appliances. (Citing CX-0941 at

5:4-14) Respondents contend that Martz also discloses a model of a patient's dentition. (Citing CX-0941 at 3:50-52, 3:65 – 4:5) Respondents also submit that Martz further discloses the production of a plurality of models of the dentition, wherein the modified models represent successive treatment stages of an orthodontic treatment and wherein each modified model or a product of such model is to be used in fabrication of a distinct successive incremental dental positioning appliance associated with the respective treatment stage of that modified model. (Citing CX-0941 at 3:65 -4:5; at 5: 4-14) Respondents claim that Martz also discloses the provision of attachment devices to the models of the patient's dentition. (Citing CX-0941 at 5: 33-45; at. 7:36-41) Respondents argue that these disclosures show that the claimed invention was obvious.

Respondents argue that claim 1 is also rendered obvious in light of the asserted '511 patent and the knowledge of one of ordinary skill in the art. Respondents assert that the '511 patent discloses the production of digital models of dental positioning appliances. (Citing JX-0001 at 6:10-17) Respondents contend that the '511 patent also discloses the provision of a digital model of a patient's dentition. (Citing JX-0001 at 3:40-50; 5:60-66) Respondents submit that the '511 patent also discloses the production of a plurality of models of the dentition, wherein the modified models represent successive treatment stages of an orthodontic treatment and wherein each modified model or a product of such model is to be used in fabrication of a distinct successive incremental dental positioning appliance associated with the respective treatment stage of that modified model. (Citing JX-0001 at 4:51-57; JX-0001 at 9:2-35; JX-0001 at flowcharts) Respondents submit that the '511 patent further discloses the provision of a digital model of an attachment device positioned on a modified digital model of the patient's dentition. (Citing JX-0001 at 8:47 - 50; JX-0001 at 9:2 – 11 & 9:25-28)

Align's position: Align says that Respondents argue that all of the asserted claims of the '863 patent are obvious in view of the combination of: (i) Lemchen; (ii) Kesling; and (iii) "the knowledge of one of ordinary skill in the art." Align argues that Respondents' arguments fail for a myriad of reasons. First, Align asserts that this particular combination was disclosed for the first time in the JSCI, as explained in Align's Motion in Limine No. 4, and is therefore improperly raised now. Second, Align contends that the argument is unsupported because no claim charts showing this assertion in detail are in evidence. Third, Align submits that these references, in any combination, fail to disclose all the elements of the asserted claims of the '863 patent. (Citing CIB Sec. IV.F.2.a, IV.F.4) Fourth, Align asserts that one of ordinary skill in the art at the time of the invention would not have been motivated to combine a reference directed to fixed appliances made of brackets and wires (Lemchen) with a reference directed to removable appliances (Kesling). (Citing CIB Sec. IV.F.2.b) Fifth, Align maintains that both Lemchen and Kesling were considered by the USPTO during the re-examination of the '863 patent, further confirming that the asserted claims of the '863 patent are valid over these references. (Citing Sec. IV.F.4) Sixth, Align argues that secondary considerations support a finding of non-obviousness. (Citing Sec. IV.F.2.c)

Align says that Respondents identified several other combinations in the JSCI. Align asserts that none were properly raised in Respondents' Prehearing Brief, and have been waived. (Citing CIB Sec. IV.F.2) Align asserts that, regardless, no combination of the prior art discloses all elements of the asserted claims of the '863 patent. (Citing CIB Secs. IV.F.2.a, IV.F.4; CDX-150-CDX-155) Align says that Respondents assert that other prior art renders Align's asserted claims obvious in the most general way. Align asserts, however, that Respondents have not disclosed any obviousness combination involving this art. Thus, Align argues that there are no

allegations, much less a *prima facie* case, for Align to address. Align says that Dr. Mah treats these additional prior art references in a particularly cursory manner. (Citing RX-0113C at Q. 81-82, 85-86) Align argues that each of these references fails to disclose numerous claim elements.

Align argues that U.S. Patent No. 4,793,803 ("Martz") (CX-0941) does not disclose, *inter alia*: (i) digital data sets or models (citing CX-1247C at Q. 331-333; CX-1254C ¶¶ 146-147 at 57-58); (ii) intermediate or successive tooth arrangements based on initial and final positions (citing CX-1247C at Q. 335-338; CX-1254C ¶¶ 149-150 at 58-60; Tr. at 794:3-795:17); or (iii) numerous other claim elements (citing CX-1247C at Q. 330, 344-346; CX-1258 at 22-28). In its reply brief, Align argues that any obviousness combination involving the Martz patent has been waived because it was not disclosed in Respondents' PreHearing Brief. Align also argues that the Martz patent cannot render any of the claims obvious under any combination. (Citing CIB at Sec. IV.F.4.d)

Align argues that its '325 patent, '511 patent, '666 patent, '880 patent, '874 patent and '487 patent do not render any claim of the '863 patent obvious. (Citing CDX-0122) First, Align asserts that Respondents have no element-by-element analysis supporting such a contention. Second, Align contends that the other patents do not qualify as prior art given that: (i) the '863 patent's priority date is December 4, 1998 and (ii) all were commonly assigned to Align when filed. (Citing JX-0011 at 14-15; JX-0016 at 57-60; JX-0017 at 28-29; JX-0014 at 3-5; 35 U.S.C. § 103(c)). In its reply brief, Align further argues that Respondents fail to specify any combination involving the '511 patent, and any such combination would be waived because it was not specifically identified in Respondents' PreHearing Brief. (Citing CIB Sec. IV.H.2.a)

Staff's position: Staff says that Respondents' arguments and Dr. Mah's testimony alleging obviousness of the asserted claims of the '325 patent are also made with respect to the

asserted claims of the '863 patent. Staff's submits that their discussion of obviousness with respect to the '325 patent applies equally here. (Citing SIB Section IV.E.2)

Staff asserts that, in view of my ruling precluding Respondents from relying on any claim charts disclosing combinations of prior art that allegedly render the asserted claims of the '325 patent (and the '863 patent) invalid for obviousness, the record is devoid of any evidence showing clearly and convincingly how and where any combination of prior art discloses each and every element of the asserted claims of the '325 patent (and the '863 patent). (Citing Hearing Tr. at 19:11-25)

Staff contends that, even if Respondents were to argue that the combination of Lemchen with Kesling (and the knowledge of one of ordinary skill) renders the asserted claims of the '325 patent (and the '863 patent) invalid for obviousness, Staff is of the view that Respondents cannot meet their burden of clear and convincing evidence. Staff avers that, like the testimony alleging anticipation, the testimony alleging obviousness provided by Dr. Mah is merely conclusory. (Citing RX-0113C at Q. 114-121) Thus, Staff submits that Dr. Mah's testimony does not cure the lack of any claim charts (or other evidence) explaining clearly and convincingly how and where the combination of Lemchen with Kesling (and the knowledge of one of ordinary skill) disclose, teach, or suggest each and every element of the asserted claims of the '325 patent (and the '863 patent).

In sum, Staff argues that there is a lack of evidence demonstrating clearly and convincingly that any of the asserted claims of the '325 patent (and the '863 patent) are rendered invalid for obviousness by the combination of Lemchen with Kesling (and the knowledge of one of ordinary skill).

Analysis and Conclusions: Respondents have failed to provide clear and convincing evidence that any of the asserted claims of the '863 patent are rendered obvious by the cited prior art. Respondents have asserted four separate combinations in post-hearing briefing: (1) Lemchen, Kesling, and the knowledge of one of ordinary skill in the art; (2) Lemchen, Kesling, Nahoum, and the knowledge of one of ordinary skill in the art; (3) Martz and the knowledge of one of ordinary skill in the art; and (4) the asserted '511 patent and the knowledge of one of ordinary skill in the art.

I note that while Respondents do mention "knowledge of one of ordinary skill in the art" in RPHB, section 3.5.2.2, their references in that pre-hearing brief amount to a general discussion of eleven separate references with no element by element discussion of how those eleven references would combine to render the asserted claims of the '325 patent obvious. There is only a general reference to a "claim chart" that Respondents say they will produce at the hearing. This is inadequate to provide notice to Align regarding the specific prior art to be addressed and the manner in which the prior art discloses each and every element of an asserted claim. (RPHB at 60-67) As a result, at the hearing I granted Align's motion *in limine* number 6, and excluded the claim charts that were not specifically cited in Respondents' prehearing brief as required by Ground Rule 8.2. (Tr. 18:13-20:4)

Although Respondents discussed eleven different prior art references in RPHB section 3.5.2.2, Respondents failed to identify any specification combinations of prior art references other than Lemchen, Kesling, and the knowledge of one of ordinary skill in the art. (RPHB at 49) Ground Rule 8.2 states "[a]ny contentions not set forth in detail as required herein shall be deemed abandoned or withdrawn, except for contentions of which a party is not aware and could not be aware in the exercise of reasonable diligence at the time of filing the pre-trial brief."

Because Respondents did not identify any specific combinations other than Lemchen, Kesling, and the knowledge of one of ordinary skill in the art, any other combinations were waived, including: (1) Nahoum with Lemchen, Kesling, and the knowledge of one of ordinary skill in the art; (2) Martz and the knowledge of one of ordinary skill in the art; and (3) the asserted '511 patent and the knowledge of one of ordinary skill in the art. Nevertheless, assuming *arguendo* that Respondents had not waived their right to assert those combinations, I would find that Respondents have not met their burden to show by clear and convincing evidence that the following combinations render the asserted claims obvious: (1) Nahoum with Lemchen, Kesling, and the knowledge of one of ordinary skill in the art; and (2) Martz and the knowledge of one of ordinary skill in the art. I find that the third combination of the '511 patent and the knowledge of one of ordinary skill in the art renders the asserted claims of the '863 patent obvious.

In order to prevail on their claim that the asserted claims of the'863 patent are invalid as obvious, Respondents must first demonstrate that the combination of Lemchen, either alone or in combination with Kesling and/or Nahoum discloses all of the limitations of the asserted claims. *Hearing Components, Inc. v. Shure Inc.*, 600 F.3d 1357, 1373-1374 (Fed. Cir. 2010); *Velander v. Garner*, 348 F.3d 1359, 1363 (Fed. Cir. 2003). Equally important is the requirement that the Respondents establish by clear and convincing evidence that a person of ordinary skill in the art would have had reason to combine the various asserted prior art references to attempt to produce the invention and would have had a reasonable expectation of success in doing so. *See PharmaStem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007).

Assuming, *arguendo*, that Respondents had properly disclosed their arguments based on the combination of Lemchen, Kesling, Nahoum, and the knowledge of one or ordinary skill in the art in

their pre-hearing brief, there is nothing in the evidence submitted by Respondents to support a finding that a PHOSITA would be motivated by anything in Lemchen, Kesling or Nahoum to follow the methods in the '863 patent. In section IV.G.1, *supra*, I noted that even if I had found that Lemchen incorporated the entirety of Kesling by reference, those two references taken together would still not disclose each and every element of the asserted claims of the '863 patent. Based upon that finding, it follows that Lemchen combined with Kesling would not render obvious the asserted claims of the '863 patent.

Respondents' evidence regarding the knowledge of one of ordinary skill in the art would not fill the gaps in Lemchen and Kesling and/or Nahoum. Respondents' evidence is limited to expert reports of a former expert for Align (RX-102C and RX-103C) and the opening witness statement of Dr. Mah. At the prehearing conference, I ruled that that Dr. Rekow's expert reports (RX-102C and RX-103C) could be used solely to show that Align took an inconsistent position in the prior litigation. (Tr. at 20:24-21:7) Here, Respondents are improperly attempting to rely on the expert reports to show the knowledge of one of ordinary skill in the art. The testimony of Dr. Mah is not helpful on this subject because he expresses a series of conclusory opinions without citing to evidentiary support. (*See, e.g.*, RX-113C, Qs. 103, 113-121)

Focusing on the motivation to combine references, I find that the mention of Kesling in Lemchen would be adequate to cause a PHOSITA to consider both references in combination. Respondents do not, however, provide any basis for combining Nahoum with the Lemchen and Kesling references.

Notwithstanding the foregoing, examining Nahoum in combination with Lemchen and Kesling, I find that Nahoum does not provide the elements missing from the Lemchen and Kesling references. I found in section IV.G.1.a that Lemchen does not in any way disclose, or

hint at, producing digital models that represent successive treatment stages and which are used to fabricate distinct successive incremental dental positioning appliances. I found that Lemchen only discloses calculating a finish position for the teeth, and that Lemchen's disclosure is limited to the idea of treating a patient with a single set of brackets, i.e. one bracket per tooth to be used over the entirely of the treatment.

I also found in section IV.G.1.a that Kesling does not disclose, teach, suggest, or even remotely contemplate the use of computers or digital technology. I found that Kesling describes making tooth arrangements by (i) using a plaster mold of teeth, (ii) dissecting the plaster teeth with a saw, and (iii) reassembling the plaster teeth in wax into their assumed positions. (CX-944, 3:13-22; 3:30-43; 3:61-64)

The Nahoum reference is an article reprinted from the New York State Dental Journal, Vol. 20, No. 9, pp. 385-390 (November, 1964). It describes a method for constructing dental appliances by vacuum forming thermoplastics using plaster model(s) of a patient's teeth. Nahoum says that the appliance can be fabricated to move teeth. The Nahoum method contemplates a plaster model of a patient's teeth, cutting the teeth from the model with a saw or fissure burr, repositioning the teeth into the model using wax, and vacuum forming the appliance over the altered model. Nahoum includes a description of making an adjustment in two or more phases in which partial and progressive adjustments are made in each appliance. Nahoum does not in any way disclose use of computers or digital data to assist in fabricating a dental appliance.

Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of asserted claim 1 of the '863 patent are present in Lemchen, either alone or in combination with Kesling, and Nahoum, and that a person

having ordinary skill in the art at the time of the invention would have had reason to combine the those references to create the method claimed in the invention of the '863 patent.

Turning to the combination of Martz with the knowledge of one of ordinary skill in the art, I find that Martz describes a method of forming dental positioners using plaster casts of teeth and wax setups of plaster teeth, similar to Kesling. (CX-0941 at 3:50-4:15) Specifically, Martz discloses that a dentist first makes plaster casts of the upper and lower teeth in their original positions and then makes duplicate plaster casts which are mounted in a device known as an "articulator." The articulator allows the casts to be moved and manipulated in a way which simulate the actual jaw movements of the patient. To prepare a positioner, a technician cuts apart the plaster casts with a saw. Plaster teeth are then arranged into desired positions and held in place by wax. (*Id.*) Similar to Kesling, Martz does not disclose, teach, suggest, or remotely contemplate the use of computers or digital technology. Therefore, Martz does not disclose a digital model of a patient's dentition, or a plurality of digital models where each digital model represents a successive orthodontic treatment stage.

I find, too, that Respondents' evidence regarding the knowledge of one of ordinary skill in the art would not fill the gaps in Martz. Here, Respondents simply make a conclusory statement that claim 1 is rendered obvious in light of Martz and the knowledge of one of ordinary skill in the art. Respondents do not cite to any evidence showing how the knowledge of one of ordinary skill in the art would fill in any claim elements that are allegedly not disclosed in Martz. Also, beyond simply providing citations, Respondents do not explain how the disclosure of Martz reads on any of the elements of the '863 patent.

Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of asserted claim 1 of the '863 patent are

disclosed or suggested by Martz in combination with the knowledge of a person of ordinary skill in the art at the time of the invention.

Finally, turning to the '511 patent, it was filed on October 8, 1998 and issued as a patented on October 29, 2002. The '863 patent was filed on October 29, 2001 and issued as a patent on March 16, 2004. Providing the chart below, Align argues that the '863 patent claims a priority date to December 4, 1998.

'863 Claim Element	Dec. 4, 1998 Priority Date
1. A method for producing digital models of dental positioning appliances, said method comprising:	CX-1252 at 3:25-28, 4:30-5:23, 5:5-16, 8:1-7, 8:10-28, 10:1-8, 12:20-14:26, 14:29-16:6, 16:9-11, Figs. 1, 5, 6
providing a digital model of a patient's dentition;	CX-1252 at 3:25-28, 4:30-5:23, 8:1-7, 10:1-8, Figs. 1, 5.
producing a plurality of modified digital models of the dentition, wherein the modified models represent successive treatment stages of an orthodontic treatment and wherein each modified model or a product of such model is to be used in fabrication of a distinct successive incremental dental positioning appliance associated with the respective treatment stage of that modified model;	CX-1252 at 5:5-16, 8:10-28, 12:20-14:26, 14:29-16:6, 16:9-11, Figs. 1, 5, 6.
providing a digital model of at least one attachment device; and	CX-1253 at 3:9-21, 3:30-32, 4:26-5:2, Figs. 4A-C, 5.
positioning the digital model of the attachment device on at least some of the plurality of modified digital models.	CX-1253 at 3:9-21, 3:30-32, 4:26-5:2, Figs. 4A-C, 5.

As a threshold matter, I find that Align has not demonstrated that all elements of claim 1 of the '511 patent are entitled to the asserted priority date. *PowerOasis. Inc. v. T-Mobile USA. Inc.*, 522 F.3d 1299, 1305 (Fed. Cir. 2008).

The '881 Provisional Application does not appear to incorporate by reference the '342 Provisional Application. It only states, "A full description of an exemplary repositioning appliance is described in co-pending U.S. application Serial No. 08/947,080, filed October 1997, which is herein incorporated by reference for all purposes." (CX-1253 at 4) U.S. application

Serial No. 08/947,080 eventually issued as U.S. Patent No. 5,975,893 ("the '893 patent"). Although the '893 patent claims the priority from the '342 Provisional Application, the '342 Provisional Application was not itself incorporated into the '881 Provisional Application. Thus, Align improperly cites to disclosure from the '342 Provisional Application to support the December 4, 1998 priority date for the preamble and first two elements of claim 1. Align has not shown that the '342 Provisional Application is actually incorporated into the '881 Provisional Application.

Moreover, even if the '863 patent does sufficiently claim a priority date to December 4, 1998, Align has still not shown that the '511 patent does not qualify as prior art under 35 U.S.C. § 102(a) which recites:

> A person shall be entitled to a patent unless—
>
> (a) ***The invention was known or used by others***, or patented or described in a printed publication in this or a foreign country, ***before the invention thereof by the applicant*** for patent

35 U.S.C. § 102(a) (emphasis added). The filing date of the '511 patent, October 8, 1998, is before December 4, 1998, the date to which Align attempts to claim priority. Also, the '511 patent and the '863 patent do not have identical inventive entities (although they do have Chishti as a common inventor). *In re Hubbell*, 709 F.3d 1140, 1143 (Fed. Cir. 2013). The inventors of the '511 patent include Chishti, Pavlovskaia, Bala, and Freyburger, while the inventors of the '863 patent include Phan, Chishti, and Miller. Because the '511 patent was known or used by "others" before Align's claimed December 4, 1998 priority date, I find that the '511 patent qualifies as prior art under § 102(a).

I turn to the issue of whether or not the substance of the '511 patent reads on the asserted claims of the '863 patent. The '511 patent is entitled "Defining Tooth-Moving Appliances

Computationally" and describes a computer-implemented method for segmenting an orthodontic treatment path in the process of repositioning teeth from an initial tooth arrangement to a final tooth arrangement, and fabricated appliances for the treatment segments. (JX-001 at 1:32-35; 11:4-20)

I find that the '511 patent discloses "providing a digital model of a patient's dentition" as required by the first element of claim 1. The '511 patent reveals producing a digital data set that represents the initial arrangement of the patient's teeth and other tissues. (JX-001 at 3:47-50)

The '511 discloses "producing a plurality of modified digital models of the dentition, wherein the modified models represent successive treatment stages of an orthodontic treatment," as taught by the second element of claim 1. The '511 patent reveals repositioning a patient's teeth from an initial tooth arrangement to a final tooth arrangement by making a series of incremental position adjustments. (JX-001 at 1:44-47) The '511 patent also reveals providing digital models of the shape and material of each of a sequence of appliances to be applied to a patient. (JX-001 at 2:4-7) The '511 patent discloses computationally defining aligner geometries and shapes. (JX-001 at 2:55-57; 2:65-67; Fig. 6) The '511 patent also discloses that the computational steps of the process are advantageously implemented as computer program ***modules*** for execution on one or more conventional digital computers. (JX-001 at 3:35-38) The '511 patent reveals defining tooth paths for each tooth, after having both a beginning position and a final position for each tooth. (JX-001 at 4:7-12) As discussed above, the '511 patent discloses that the clinican interaction can be implemented using a client process programmed to receive tooth positions ***and models***, as well as path information from a server computer or process in which other steps of the process are implemented. (JX-001 at 4:39-43)

The '511 patent also discloses "and wherein each modified model or a product of such model is to be used in fabrication of a distinct successive incremental dental positioning appliance associated with the respective treatmtne stage of that modified model" as taught by the second element. The '511 patent reveals manufacturing appliances defined by the process, having calculating appliance definitions. (JX-001 at 5:1-6) The '511 patent discusses manufacturing processes that rely of the generation of the models to produce repositioning appliances. (JX-001 at 9:43-47)

The '511 patent also reveals "providing a digital model of at least one attachment device" as recited in the third element of claim 1. The '511 patent discusses executing a module that calculates the configuration of a hardware attachment to the subject tooth, to which forces can be applied to achieve the required motion. (JX-001 at 8:47-54)

The '511 patent also discloses "positioning the digital model of the attachment device on at least some of the plurality of modified digital models" as taught by the fourth element. The '511 patent discusses interacting with a clinician to define attachments to be attached to a tooth. (JX-001 at 9:7-11) The '511 patent reveals that a model aligner is computationally manipulated to place it over the modeled teeth in a model jaw to create a composition model of an in-place aligner. (JX-001 at 6:18-20) The '511 patent discloses computing the forces required to deform the aligner to fit over the teeth, including any hardware attached to the teeth. (JX-001 at 6:20-25) The '511 patent also reveals modeling aligner deformation by applying enough force to its insides to make it large enough to fit over the teeth, placing the model aligner over the model tooth in the composite model. (JX-001 at 6:25-29)

Based upon the evidence before me, I find that all of the limitations of claim 1 of the '863 patent are present in the '511 patent in combination with the knowledge of a person of ordinary skill in the art at the time of the invention.

b. Asserted claim 4

Respondents' position: Respondents incorporate Disclosure Categories 1, 4, 5, and 7 together with the knowledge of one of ordinary skill in the art identified in the section addressing claim 1 of the '325 patent. Respondents argue that this claim is further rendered obvious in light of Martz and the knowledge of one of ordinary skill in the art. Respondents assert that Martz discloses the provision of a visual model of a patient's dentition. (Citing CX-0941 at 3:50-52, at 3:65 – 4:5) Respondents submit that Martz also discloses manipulating the model of the patient's dentition to reposition the individual teeth. (Citing CX-0941 at 3:65 – 4:5; at 5: 4-14) Respondents claim that Martz further discloses manipulating the model of the patient's dentition to reposition the individual teeth in a final position at the conclusion of orthodontic treatment. (Citing CX-0941 at 3:65 – 4:5; at 5:4-14) Respondents allege that Martz also discloses the creation of a series of tooth arrangements using the model of the patient's dentition progressing from the initial to the final tooth arrangement. (Citing CX-0941 at 3:65 – 4:5; at 5:4-14)

Respondents assert that claim 4 is also rendered obvious in light of the '511 patent and the knowledge of one of ordinary skill in the art. For example, Respondents argue that the '511 patent discloses presenting a visual image based on the digital model of the patient's dentition. (Citing JX-001 at 3:40-58) Respondents maintain that the '511 patent also discloses manipulating the visual image to reposition individual teeth in the visual image. (Citing JX-0001 at 3:58-4:9) Respondents contend that the '511 patent further discloses producing a digital data set representing the final tooth arrangement with repositioned teeth as observed in the image.

(Citing JX-0001 at 3:58 – 4:9) Respondents claim that the '511 patent also discloses producing the plurality of modified digital models as a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement. (Citing JX-0001 at 3:58 – 4:9; at 4:51-57; JX-0001 at 9:17-35) Respondents reason that these disclosures show that the claimed invention was obvious.

Align's position: Align provides no additional argument beyond that which it forwarded in a general response to Respondents' obviousness argument in section IV.G.2.a.

Staff's position: Staff refers to their argument in section IV.B.2.a, *supra*, and reasserts it.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 1 to be rendered obvious by the asserted prior art and invalid, I could still find that claim 4 is valid. Since, however, I have found claim 1 to be valid and ***not*** rendered obvious by Lemchen, combined with Kesling and the knowledge of a PHOSITA, claim 4 is necessarily valid, because it depends from claim 1 and necessarily contains all of the elements of claim 1. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 1 is rendered obvious by by Lemchen, combined with Kesling and the knowledge of a PHOSITA, I would find that Respondents have failed to show by clear and convincing evidence that claim 4 of the '863 patent is rendered obvious by that combination.

In section IV.G.1.b, *supra*, I found that Lemchen does not reveal producing the plurality of modified digital models as a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement because Lemchen does not disclose,

teach, or suggest calculating positions-in-between. I also found that Kesling does not disclose, teach, or suggest the use of computers or digital technology. In the interest of brevity, I will not repeat the discussion in section IV.G.1.b in its entirety; but I reaffirm that finding and the rationale for it. I found in section IV.G.2.a that Nahoum does not in any way disclose use of computers or digital data to assist in fabricating a dental appliance. Again, in the interest of brevity, I will not repeat the discussion in section IV.G.2.a in its entirety; but I reaffirm that finding and the rationale for it.

Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of asserted claim 4 of the '863 patent are present in Lemchen, either alone or in combination with Kesling, and Nahoum, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine the those references to create the method claimed in the invention of the '863 patent.

In section IV.G.2.a, *supra*, I found that that Martz does not disclose in any way the use of computers or digital data to assist in fabricating a dental appliance. As a result, I found that it does not disclose a digital model of a patient's dentition. I also found that the knowledge of one of ordinary skill in the art does not account for the deficiencies in Martz. Again, in the interest of brevity, I will not repeat the discussion in section IV.G.2.a in its entirety; but I reaffirm that finding and the rationale for it. Thus, without the disclosure of digital data, I find that Martz does not disclose presenting a visual image based on the digital model of the patient's dentition; or producing a digital data set representing the final tooth arrangement with repositioned teeth as observed in the image. Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of asserted claim 4 of the '863 patent are present in Martz either alone or in combination with the knowledge of one of

ordinary skill in the art at the time of the invention.

Turning to the '511 patent, I find that it discloses "presenting a visual image based on the digital model of the patient's dentition" and "manipulating a visual image to reposition individual teeth in the visual image" as taught in claim 4. The '511 patent also discloses interacting with a clinician after defining segmented paths. (JX-001 at 4:7-22; 4:36-39) The '511 patent reveals that the clinican interaction can be implemented using a client process programmed to receive tooth positions ***and models***, as well as path information from a server computer or process in which other steps of the process are implemented. (JX-001 at 4:39-43) The '511 patent also reveals that the client process is programmed to allow the clinican to display an animation of the positions and paths to allow the clinican to reset the positions of one or more of the teeth. (JX-001 at 4:43-45)

I find that the '511 patent discusses "producing a digital data set representing the final tooth arrangement with repositioned teeth as observed in the image" as required by the third element of claim 4. The '511 patent reveals specifying the final position and surface geometry of each tooth to form a complete model of the teeth at the desired end of treatment. (JX-001 at 3:64-4:1) The' 511 patent also reveals that the result of this step is a set of digital data structures that represents an orthodontically correct repositioning of the modeled teeth relative to presumed-stable tissue. (JX-001 at 4:2-5)

I also find that the '511 patent discloses "producing the plurality of modified digital models as a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement" as recited in the fourth element of claim 4. The '511 patent also discloses repositioning a patient's teeth from an initial tooth arrangement to a final tooth arrangement by making a series of incremental position adjustments. (JX-001 at 1:44-47)

The '511 patent also discloses providing digital models of the shape and material of each of a sequence of appliances to be applied to a patient. (JX-001 at 2:4-7) The '511 patent reveals computationally defining aligner geometries and shapes. (JX-001 at 2:55-57; 2:65-67; Fig. 6) The '511 patent discloses that the computational steps of the process are advantageously implemented as computer program ***modules*** for execution on one or more conventional digital computers. (JX-001 at 3:35-38) The '511 patent also discloses defining tooth paths for each tooth, after having both a beginning position and a final position for each tooth. (JX-001 at 4:7-12) As discussed above, the '511 patent reveals that the clinican interaction can be implemented using a client process programmed to receive tooth positions ***and models***, as well as path information from a server computer or process in which other steps of the process are implemented. (JX-001 at 4:39-43)

Based upon the evidence before me, I find that all of the limitations of asserted claim 4 of the '863 patent are present in the '511 patent either alone or in combination with the knowledge of one of ordinary skill in the art at the time of the invention.

c. Asserted claim 5

Respondents' position: Respondents incorporate Disclosure Category 4 together with the knowledge of one of ordinary skill identified in the section addressing claim 1 of the '325 patent. Respondents assert that claim 5 is further rendered obvious in light of Martz and the knowledge of one of ordinary skill in the art. Respondents argue that Martz discloses defining boundaries about some of the individual teeth by making cuts in the plaster model. (Citing CX-0941 at 3:65 – 4:5) Respondents aver that Martz also discloses moving the teeth relative to other teeth in the model of the patient's dentition. (Citing CX-0941 at. 3:65 – 4:5; at 5:4-14)

Respondents contend that claim 5 is also rendered obvious in light of the asserted '511 patent and the knowledge of one of ordinary skill in the art. Respondents maintain that the '511 patent discloses defining boundaries about at least some of the individual teeth by digitally separating tissue constituents and individual tooth crowns from the digitized initial tooth arrangement. (Citing JX-0001 at 3:50-57) Respondents submit that the '511 patent also discloses moving at least some of the tooth boundaries relative to the other teeth in an image based on the digital data set. (Citing JX-0001 at 3:58 – 4:9; 4:51-57; JX-0001 at 9:17-35)

Align's position: Align provides no additional argument beyond that which it forwarded in a general response to Respondents' obviousness argument in section IV.G.2.a.

Staff's position: Staff refers to their argument in section IV.B.2.a, *supra*, and reasserts it.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claims 1 and 4 to be rendered obvious by the asserted prior art and invalid, I could still find that claim 5 is valid. Since, however, I have found claims 1 and 4 to be valid and ***not*** rendered obvious by Lemchen, combined with Kesling and the knowledge of a PHOSITA, claim 5 is necessarily valid, because it depends from claim 1 via claim 4 and necessarily contains all of the elements of claims 1 and 4. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that claims 1 and 4 are both rendered obvious by Lemchen, combined with Kesling and the knowledge of a PHOSITA, I would find that Respondents have failed to show by clear and convincing evidence that claim 5 of the '863 patent is rendered obvious by that combination.

In section IV.G.1.c, *supra*, I found that Lemchen does not reveal moving at least some of

the tooth boundaries relative to the other teeth in an image. I found that, although Lemchen teaches generating a digital data set representing teeth in their final position, Lemchen does not disclose the specific details of how this would be accomplished. I also found that Kesling does not disclose, teach, or suggest the use of computers or digital technology. In the interest of brevity, I will not repeat the discussion in section IV.G.1.c in its entirety; but I reaffirm that finding and the rationale for it. I found in section IV.G.2.a that Nahoum does not in any way disclose use of computers or digital data to assist in fabricating a dental appliance. Again, in the interest of brevity, I will not repeat the discussion in section IV.G.2.a in its entirety; but I reaffirm that finding and the rationale for it.

Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of asserted claim 5 of the '863 patent are present in Lemchen, either alone or in combination with Kesling, and Nahoum, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine the those references to create the method claimed in the invention of the '863 patent.

In section IV.G.2.a, *supra*, I found that that Martz does not disclose in any way the use of computers or digital data to assist in fabricating a dental appliance. As a result, I found that it does not disclose digital models. I also found that the knowledge of one of ordinary skill in the art does not account for the deficiencies in Martz. Again, in the interest of brevity, I will not repeat the discussion in section IV.G.2.a in its entirety; but I reaffirm those findings and the rationales. Thus, without the disclosure of digital data, I find that Martz does not disclose moving at least some of the tooth boundaries relative to the other teeth in an image based on the digital data set. Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of asserted claim 5 of the '863 patent

are present in Martz either alone or in combination with the knowledge of one of ordinary skill in the art at the time of the invention.

I find that the '511 patent discloses "defining boundaries about at least some of the individual teeth" a required by the first element. The '511 patent also discloses creating an initial digital data set that represents the initial arrangement of the patient's teeth and other tissues. (JX-001 at 3:47-50) The '511 patent reveals segmenting tissue constituents from each other. (JX-001 at 3:53-54) The '511 patent also reveals that data structures that digitally represent individual tooth crowns are produced. (JX-001 at 3:56-57) The '511 patent then discloses defining a tooth path for the motion of each tooth, having both a beginning position and final position for each tooth. (JX-001 at 4:6-7)

I also find that the '511 patent discloses "moving at least some of the tooth boundaries relative to the other teeth in an image based on the digital data set" as required by the second element. The '511 patent reveals interacting with a clinician after defining segmented paths. (JX-001 at 4:7-22; 4:36-39) The '511 patent also reveals that the clinican interaction can be implemented using a client process programmed to receive tooth positions ***and models***, as well as path information from a server computer or process in which other steps of the process are implemented. (JX-001 at 4:39-43) The '511 patent discloses that the client process is programmed to allow the clinican to display an animation of the positions and paths to allow the clinican to reset the positions of one or more of the teeth. (JX-001 at 4:43-45)

Based upon the evidence before me, I find that all of the limitations of asserted claim 5 of the '863 patent are present in the '511 patent either alone or in combination with the knowledge of one of ordinary skill in the art at the time of the invention.

d. Asserted claim 6

Respondents' position: Respondents incorporate Disclosure Categories 2, 5, 7 together with the knowledge of one of ordinary skill identified in the section addressing claim 1 of the '325 patent. Respondents argue that claim 6 is further rendered obvious in light of Martz and the knowledge of one of ordinary skill in the art. Respondents contend that Martz discloses the production of a plurality of models of the patient's dentition. (Citing CX-0941 at 3:65 – 4:5; at 5:4-14) Respondents assert that Martz also discloses the creation of a series of tooth arrangements using the model of the patient's dentition progressing from the initial to the final tooth arrangement. (Citing CX-0941 at 3: 65 – 4:5; at 5:4-14) Respondents submit that Martz further discloses the creation of a series of tooth arrangements using the model of the patient's dentition progressing from the initial to the final tooth arrangement. (Citing CX-0941 at 3:65 – 4:5; at 5:4-14)

Respondents assert that this claim is also rendered obvious in light of the asserted '511 patent and the knowledge of one of ordinary skill in the art. Respondents aver that the '511 patent discloses producing modified digital models of the dentition by providing the described computer system with processor and memory and the digital model of the patient's dentition. (Citing JX-0001 at 3:40-50; at 5:60-66; JX-0001 at 10:19-52) Respondents claim that the '511 patent also discloses providing a digital model of the final tooth arrangement to the computer system. (Citing JX-0001 at 3:40 - 4:9; at 5:60-66; at 10:19-52; at 9:17-35) Respondents allege that the '511 patent further discloses producing using the computer system the plurality of models based on both of the previously provided initial and final digital data sets. (Citing JX-0001 at 3:58 – 4:9; 4:51-57; at 9:17-35)

Align's position: Align provides no additional argument beyond that which it forwarded in a general response to Respondents' obviousness argument in section IV.G.2.a.

Staff's position: Staff refers to their argument in section IV.B.2.a, *supra*, and reasserts it.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 1 to be rendered obvious by the asserted prior art and invalid, I could still find that claim 6 is valid. Since, however, I have found claim 1 to be valid and ***not*** rendered obvious by Lemchen, combined with Kesling and the knowledge of a PHOSITA, claim 6 is necessarily valid, because it depends from claim 1 and necessarily contains all of the elements of claim 1. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 1 is rendered obvious by by Lemchen, combined with Kesling and the knowledge of a PHOSITA, I would find that Respondents have failed to show by clear and convincing evidence that claim 6 of the '863 patent is rendered obvious by that combination.

In section IV.G.1.d, *supra*, I found that Lemchen does not reveal producing using the computer system the plurality of models based on both of the previously provided initial and final digital data sets because Lemchen does not disclose, teach, or suggest calculating positions-in-between. I also found that Kesling does not disclose, teach, or suggest the use of computers or digital technology. In the interest of brevity, I will not repeat the discussion in section IV.G.1.d in its entirety; but I reaffirm that finding and the rationale for it. I found in section IV.G.2.a that Nahoum does not in any way disclose use of computers or digital data to assist in fabricating a dental appliance. Again, in the interest of brevity, I will not repeat the discussion in section

IV.G.2.a in its entirety; but I reaffirm that finding and the rationale for it.

Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of asserted claim 6 of the '863 patent are present in Lemchen, either alone or in combination with Kesling, and Nahoum, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine the those references to create the method claimed in the invention of the '863 patent.

In section IV.G.2.a, *supra*, I found that that Martz does not disclose in any way the use of computers or digital data to assist in fabricating a dental appliance. I also found that Martz does not disclose providing a digital model of the patient's dentition. I also found that the knowledge of one of ordinary skill in the art does not account for the deficiencies in Martz. Again, in the interest of brevity, I will not repeat the discussion in section IV.G.2.a in its entirety; but I reaffirm that finding and the rationale for it. Thus, without the disclosure of digital data, I find that Martz does not disclose providing a computer system having at least one processor and memory, and providing to the computer system the digital model of the patient's dentition. Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of asserted claim 6 of the '863 patent are present in Martz either alone or in combination with the knowledge of one of ordinary skill in the art at the time of the invention.

Turning to the '511 patent, I find that it discloses "providing a computer system having at least one processor and memory," and "providing to the computer system the digital model of the patient's dentition" as recited in the first two elements of claim 6. The '511 patent also discloses that the computational steps of the process are implemented as computer-program modules for execution on one or more conventional digital computers. (JX-001 at 3:35-38) The '511 patent

also reveals producing an initial digital data set. (JX-001 at 3:50-54)

I also find that the' 511 patent discloses "providing to the computer system a digital model set representing a final tooth arrangement." The' 511 patent also discloses forming a complete model of the teeth at the desired end of treatment. (JX-001 at 3:67-4:1) The '511 patent reveals that the result of this step is a set of digital data structures that represents a repositioning of the modeled teeth. (JX-001 at 4:2-5)

I also find that the '511 patent reveals "producing using the computer system the plurality of models based on both of the previously provided initial and final digital data sets" as required by the fourth element of claim 6. The '511 patent discusses repositioning a patient's teeth from an initial tooth arrangement to a final tooth arrangement by making a series of incremental position adjustments. (JX-001 at 1:44-47) The '511 patent also discusses producing an initial digial data set. (JX-001 at 3:51-58). The '511 patent discloses producing a final digital data set. (JX-001 at 3:64-4:6)

The '511 patent also discusses providing digital models of the shape and material of each of a sequence of appliances to be applied to a patient. (JX-001 at 2:4-7) The '511 patent discloses computationally defining aligner geometries and shapes. (JX-001 at 2:55-57; 2:65-67; Fig. 6) The '511 patent also discloses that the computational steps of the process are advantageously implemented as computer program ***modules*** for execution on one or more conventional digital computers. (JX-001 at 3:35-38) The '511 patent also reveals defining tooth paths for each tooth, after having both a beginning position and a final position for each tooth. (JX-001 at 4:7-12) As discussed above, the '511 patent discloses that the clinican interaction can be implemented using a client process programmed to receive tooth positions ***and models***, as well as path information from a server computer or process in which other steps of the process

are implemented. (JX-001 at 4:39-43)

Based upon the evidence before me, I find that all of the limitations of asserted claim 6 of the '863 patent are present in the '511 patent either alone or in combination with the knowledge of one of ordinary skill in the art at the time of the invention

e. Asserted claim 7

Respondents' position: Respondents incorporate Disclosure Category 4 together with the knowledge of one of ordinary skill identified in the section addressing the '325 patent. Respondents assert that claim 7 is further rendered obvious in light of Martz and the knowledge of one of ordinary skill. Respondents contend that Martz discloses defining boundaries about some of the individual teeth by making cuts in the plaster model. (Citing CX-0941 at 3:65 – 4:5) Respondents argue that Martz also discloses moving the teeth relative to other teeth in the model of the patient's dentition. (Citing CX-0941 at 3:65 – 4:5; at 5:4-14)

Respondents submit that this claim is also obvious in light of the asserted '511 patent and the knowledge of one of ordinary skill. Respondents contend that the '511 patent discloses defining boundaries about at least some of the individual teeth by digitally separating tissue constituents and individual tooth crowns from the digitized initial tooth arrangement. (Citing JX-0001 at 3:50-57) Respondents maintain that the '511 patent also discloses moving at least some of the tooth boundaries relative to the other teeth in an image based on the digital data set. (Citing JX-0001 at 3:58 – 4:9; at 4:51-57; 9:17-35)

Align's position: Align provides no additional argument beyond that which it forwarded in a general response to Respondents' obviousness argument in section IV.G.2.a.

Staff's position: Staff refers to their argument in section IV.B.2.a, *supra*, and reasserts it.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claims 1 and 6 to be rendered obvious by the asserted prior art and invalid, I could still find that claim 7 is valid. Since, however, I have found claims 1 and 6 to be valid and ***not*** rendered obvious by Lemchen, combined with Kesling and the knowledge of a PHOSITA, claim 7 is necessarily valid, because it depends from claim 1 via claim 6 and necessarily contains all of the elements of claims 1 and 6. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 1 is rendered obvious by by Lemchen, combined with Kesling and the knowledge of a PHOSITA, I would find that Respondents have failed to show by clear and convincing evidence that claim 7 of the '863 patent is rendered obvious by that combination.

In section IV.G.1.e, *supra*, I found that Lemchen does not reveal moving at least some of the tooth boundaries relative to the other teeth in the visual image to produce the final data set. I also found that Kesling does not disclose, teach, or suggest the use of computers or digital technology. In the interest of brevity, I will not repeat the discussion in section IV.G.1.e in its entirety; but I reaffirm that finding and the rationale for it. I found in section IV.G.2.a that Nahoum does not in any way disclose use of computers or digital data to assist in fabricating a dental appliance. Again, in the interest of brevity, I will not repeat the discussion in section IV.G.2.a in its entirety; but I reaffirm that finding and the rationale for it.

Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of asserted claim 7 of the '863 patent are present in Lemchen, either alone or in combination with Kesling, and Nahoum, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine the

those references to create the method claimed in the invention of the '863 patent.

In section IV.G.2.a, *supra*, I found that that Martz does not disclose in any way the use of computers or digital data to assist in fabricating a dental appliance. I also found that the knowledge of one of ordinary skill in the art does not account for the deficiencies in Martz. Again, in the interest of brevity, I will not repeat the discussion in section IV.G.2.a in its entirety; but I reaffirm that finding and the rationale for it. Thus, without the disclosure of digital data, I find that Martz does not disclose "on a visual image provided by the computer system" or "in the visual image to produce the final data set." Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of asserted claim 7 of the '863 patent are present in Martz either alone or in combination with the knowledge of one of ordinary skill in the art at the time of the invention.

Turning to the '511 patent, I find that it discloses "defining boundaries about at least some of the individual teeth on a visual image provided by the computer system" as required by the first element. The '511 patent discloses that the computational stesp of the process are implemented as computer program moduels for execution on one or more conventional digital computers. (JX-001 at 3:35-39) The '511 patent also discloses creating an initial digital data set that represents the initial arrangement of the patient's teeth and other tissues. (JX-001 at 3:47-50) The '511 patent reveals segmenting tissue constituents from each other. (JX-001 at 3:53-54) The '511 patent also teaches that data structures that digitally represent individual tooth crowns are produced. (JX-001 at 3:56-57) The '511 patent then reveals defining a tooth path for the motion of each tooth, having both a beginning position and final position for each tooth. (JX-001 at 4:6-7) The '511 patent discloses interacting with a clinician after defining segmented paths. (JX-001 at 4:7-22; 4:36-39) The '511 patent also discloses that the clinican interaction

can be implemented using a client process programmed to receive tooth positions ***and models***, as well as path information from a server computer or process in which other steps of the process are implemented. (JX-001 at 4:39-43)

I also find that the '511 patent discloses "moving at least some of the tooth boundaries relative to the other teeth in the visual image to produce the final data set" as required by the second element. The '511 patent reveals that the client process is programmed to allow the clinican to display an animation of the positions and paths to allow the clinican to reset the positions of one or more of the teeth. (JX-001 at 4:43-45)

Based upon the evidence before me, I find that all of the limitations of asserted claim 7 of the '863 patent are present in the '511 patent either alone or in combination with the knowledge of one of ordinary skill in the art at the time of the invention.

f. Asserted claim 8

Respondents' position: Respondents incorporate Disclosure Category 7 together with the knowledge of one of ordinary skill identified in the section addressing the '325 patent. Respondents argue that claim 8 is further rendered obvious in light of Martz and the knowledge of one of ordinary skill. Respondents aver that Martz discloses the creation of a series of tooth arrangements using the model of the patient's dentition progressing from the initial to the final tooth arrangement. (Citing CX-0941 at 3:65 – 4:5; at 5:4-14) Respondents contend that this claim is also obvious in light of the asserted '511 patent and the knowledge of one of ordinary skill. Respondents submit that the '511 patent discloses determining positional differences between the initial and final digital models and interpolating those differences. (Citing JX-0001 at 4:7-67)

Align's position: Align provides no additional argument beyond that which it forwarded in a general response to Respondents' obviousness argument in section IV.G.2.a.

Staff's position: Staff refers to their argument in section IV.B.2.a, *supra*, and reasserts it.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claims 1 and 6 to be rendered obvious by the asserted prior art and invalid, I could still find that claim 8 is valid. Since, however, I have found claims 1 and 6 to be valid and ***not*** rendered obvious by Lemchen, combined with Kesling and the knowledge of a PHOSITA, claim 8 is necessarily valid, because it depends from claim 1 via claim 6 and necessarily contains all of the elements of claims 1 and 6. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 1 is rendered obvious by by Lemchen, combined with Kesling and the knowledge of a PHOSITA, I would find that Respondents have failed to show by clear and convincing evidence that claim 8 of the '863 patent is rendered obvious by that combination.

In section IV.G.1.f, *supra*, I found that Lemchen does not reveal determining positional differences between the initial digital model and the final digital model and interpolating said differences because Lemchen does not disclose calculating positions-in-between. I also found that Kesling does not disclose, teach, or suggest the use of computers or digital technology. In the interest of brevity, I will not repeat the discussion in section IV.G.1.f in its entirety; but I reaffirm that finding and the rationale for it. I found in section IV.G.2.a that Nahoum does not in any way disclose use of computers or digital data to assist in fabricating a dental appliance. Again, in the interest of brevity, I will not repeat the discussion in section IV.G.2.a in its entirety;

but I reaffirm that finding and the rationale for it.

Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of asserted claim 8 of the '863 patent are present in Lemchen, either alone or in combination with Kesling, and Nahoum, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine the those references to create the method claimed in the invention of the '863 patent.

In section IV.G.2.a, *supra*, I found that that Martz does not disclose in any way the use of computers or digital data to assist in fabricating a dental appliance. As a result, I found that it does not disclose a digital model of a patient's dentition or a plurality of digital models. I also found that the knowledge of one of ordinary skill in the art does not account for the deficiencies in Martz. Again, in the interest of brevity, I will not repeat the discussion in section IV.G.2.a in its entirety; but I reaffirm that finding and the rationale for it. Thus, without the disclosure of digital data, I find that Martz does not disclose an "initial digital model" or a "final digital model." Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of asserted claim 8 of the '863 patent are present in Martz either alone or in combination with the knowledge of one of ordinary skill in the art at the time of the invention.

Thus, I find that the '511 patent discloses "determining positional differences between the initial digital model and the final digital model and interpolating said differences" as taught in claim 8. The '511 patent reveals producing an intial digital data set. (JX-001 at 3:49-54) The '511 patent also reveals producing a final digital data set. (JX-001 at 4:64-4:6) The '511 patent discloses extrapolating computationally a desired position of the teeth using the initial data set. (JX-011 at 4:59-4:6) Based upon the evidence before me, I find that all of the limitations of

asserted claim 8 of the '863 patent are present in the '511 patent either alone or in combination with the knowledge of one of ordinary skill in the art at the time of the invention.

H. The '874 Patent

1. Anticipation

Lemchen and, as incorporated, Kesling under 35 U.S.C. § 102

a. Claim 1

Respondents' Position:

Asserted claim 1 reads:

> A computer-implemented method for use in creating a treatment plan to reposition a patient's teeth from a set of initial tooth positions to a set of final tooth positions, the method comprising:
>
> receiving an initial digital data set representing the teeth at the initial positions, wherein receiving the initial digital data set comprises receiving data obtained by scanning the patient's teeth or a physical model thereof;
>
> generating a set of intermediate positions toward which the teeth will move while moving from the initial positions toward the final positions; and
>
> generating a plurality of successive appliances having cavities and wherein the cavities of successive appliances have different geometries shaped to receive and reposition teeth from the initial positions toward the final positions,
>
> wherein the plurality of successive appliances is generated at a stage of treatment prior to the patient wearing any appliance of said plurality so as to reposition the teeth.

(JX-006, 32:37-56)

Respondents incorporate RIB section 3.5.1.1 addressing the anticipation of the preamble of Claim 1 of the '325 Patent.

In their preamble argument, Respondents contend that the subject matter of the preamble is disclosed in the prior art reference, and the use of aligners in orthodontics is long standing. Respondents assert that Kesling expressly discloses: (1) a plurality of tooth arrangements; (2) the use and fabrication of a series of dental appliances; and (3) using a machine to fabricate a series of dental appliances by producing a positive model of a tooth arrangement. (Citing RX-113C, Q. 49)

Respondents contend that Lemchen disclosed a digital method for three dimensional modeling of teeth movement that was the same as the manual method disclosed in Kesling. (Citing RX-113C, Qs. 39-40) Respondents say this digital modeling includes intermediate or successive tooth arrangements. (Citing RX-113C, Q. 41) Respondents argue that Lemchen disclosed methods for the fabrication of multiple custom appliances based on the three dimensional modeling. (Citing RX-113C, Q. 42) Respondents conclude that Lemchen disclosed using positive models generated from digital data. (Citing RX-113C, Qs. 42-43)

Respondents reiterate their argument that contrary to its position in this investigation, Align previously recognized that "Capitalizing on work of the dental CAD/CAM systems, Lemchen describes approaches [that] acquire data, automatically determine . . . ideal position for an individual patient, design . . . configuration to conform to the orthodontic treatment to be undertaken for an individual patient, and use numerically controlled systems to shape . . . that design." (Citing RX-102C at 6) Respondents argue that Align contended in that litigation that "the idea of fabricating custom appliances," for orthodontic treatment "was not new in 1990." (Citing RX-102C at 7)

Respondents also incorporate their disclosure categories 1, 7, and 10, and their discussion of treatment plans. Addressing the first element, Respondents incorporate their disclosure

category 1, which argues that Lemchen discloses that an initial digital data set representing an initial tooth arrangement is generated, quoting:

> The first step of the method of the present invention is the generation of accurate digital information defining the shape and location of the malocclused tooth with respect to the patient's jaw. This information may be generated in a number of ways, such as electromechanically, by laser scanning, sonic ranging, digital video scanning or magnetically. Various devices which may be so utilized are described in Rekow, Computer Aided Design And Manufacturer In Dentistry: A Review Of The State Of The Art, 58 The Journal of Prosthetic Dentistry 512 (1987).

(Citing CX-945, 2:54–63) Dr. Lemchen specifically discloses that his method generates "accurate digital information" defining the teeth locations. CX-0945 at 2:55 –57.

Respondents state that Lemchen expressly incorporated the disclosures of Kesling to explain that the digital three-dimensional model of an initial tooth arrangement that they disclosed was the same as the manual three-dimensional model of an initial tooth arrangement revealed in Kesling, quoting Lemchen:

> in many applications of the preferred embodiment, a complete "model", as that term is used in the dental art to refer to a full replication of the upper and lower dental arches and associated jaw structure, will be mathematically generated. A physical embodiment of such a model is shown, for example, in FIG. 1 of U.S. Pat. No. 2,467,432.

(Citing CX-945, 3:43–46)

Respondents say that contrary to its position here, Align previously recognized that Lemchen developed a digital representation of the physical model of an initial tooth arrangement described by Kesling, quoting:

> Full three-dimensional modeling in orthodontic treatment planning was described by Lemchen *[59 Lemchen, ALN005891-895; 60 Lemchen, ALN005821-829]*. The first step in this process was acquisition of digital data defining the shape and location of the malocclused tooth or teeth [sic] respect to the patient's jaw. A variety of techniques, including those described by Rekow *[89 Rekow, ALN128301-305]* were capable of capturing the required data. The required data, in most applications, were a

> complete 3D model of the upper and lower dental arches and associated jaw structure *[59 Lemchen, ALN005893, col 3, lines 13-19]*. This model is the mathematical representation of the physical model described by Kesling in 1949. *[Kesling, '432 patent, ALN125695-699]* This digital/mathematical model was used for the planning orthodontic treatment.

(Citing RX-103C at 16)(bracketed information in the original)

Regarding the second element, Respondents incorporate their disclosure category 7, arguing that Kesling also discloses the manufacture and use of a plurality of appliances, each appliance in the series representing intermediate or successive tooth positions, quoting:

> the present tooth positioning appliances may be used for changing the position of teeth from the [initial position] to that of [the pre-determined ideal or desirable position] by using a multiplicity or a **plurality** of different steps and making intermediate tooth positioning devices, which are to move the teeth only a fraction of the way toward their final position.

(Citing CX-944, 2:50–3:1)(emphasis added by Respondents) Respondents continue that Kesling describes the necessity of making a plurality of appliances as "obvious," quoting:

> While I have illustrated an appliance and described the technique for producing only the last or final change to the desired ideal position, it will also be evident that this appliance and technique may be employed in a **plurality** of steps for moving the teeth step by step from any extreme position to the desired and final position; but in such cases it will obviously be necessary to make a number of different appliances, each representing one step of attainment toward the final positioning of the teeth.

(Citing CX-944, 2:50–3:1)(emphasis added by Respondents)

Respondents assert that Align submitted expert reports in an earlier litigation where Align, as the defendant, sought to invalidate patent claims asserted by a competitor. Respondents say in that case, Dr. Rekow, on behalf of Align, recognized that Kesling broadly disclosed a three dimensional method for modeling tooth movement that included successive tooth arrangements that proceeded from the initial to the final. (Citing RX-103C at 12-13)

Respondents submit that Lemchen discloses that the "repositioning is done mathematically by appropriate software programs which may be derived by conventional means . . . ." (Citing CX-945, 2:66–3:6) Respondents argue that a PHOSITA would understand this to mean that the tooth path between the initial and final positions would be determined and then the tooth positions for each segment representing the successive stages of treatment would be determined by interpolation or a method for calculating movements of incremental equal sizes. (Citing RX-113C, Q. 59) Respondents allege that it is uncontroverted that interpolation is a conventional mathematical means for determining positional differences. (Citing RX-113C, Q. 59)

Respondents say that Dr. Rekow, on behalf of Align, also recognized that Lemchen incorporated Kesling and broadly disclosed a digital three dimensional method for modeling tooth movement, quoting:

> **Full three-dimensional modeling in orthodontic treatment planning was described by Lemchen** *[59 Lemchen, ALN005891-895; 60 Lemchen, ALN005821-829].* The first step in this process was acquisition of digital data defining the shape and location of the malocclused tooth or teeth respect to the patient's jaw. A variety of techniques, including those described by Rekow *[89 Rekow, ALN128301-305]* were capable of capturing the required data. The required data, in most applications, were a complete 3D model of the upper and lower dental arches and associated jaw structure *[59 Lemchen, ALN005893, col 3, lines 13-19].* This model is the mathematical representation of the physical model described by Kesling in 1949. *[Kesling, '432 patent, ALN125695-699]* This digital/mathematical model was used for the planning orthodontic treatment.

(Citing RX-103C at 16)[21](bracketed information in original)(bold added by Respondents) Respondents argue that this demonstrates that one skilled in the art would understand that Lemchen incorporates Kesling and discloses three dimensional modeling of teeth movement

[21] Citing RX-103C for this purpose violated my ruling on Align's Motion in Limine No. 6, and is rejected.

digitally through a series of incremental or intermediate steps from an initial position to the desired position.

Respondents reiterate that contrary to its position in this investigation, Align previously successfully argued to the Federal Circuit that Lemchen disclosed an incremental approach to calculating desired tooth positions:

> Using such a CAD [computer-aided design] program in a conventional manner, as Lemchen describes, ***an operator would manipulate*** **the tooth images to provide the desired occlusion**. This would presumably involve *some decision making* by the operator. As the operator manipulates the images, the computer, under the control of the conventional CAD program, would perform the calculations that would generate data of the tooth movements made by the operator and thus of the finish positions of the teeth.

(Citing *Ormco II at* 498 F.3d 1315 (italics in original)(bold added by Respondents))

Focusing on the third element, Respondents argue that neither Lemchen, nor the incorporated Kesling patent, contain any limit to the time when the disclosed appliances are generated and the appliances can be generated prior to the patient wearing any appliance in that reference.

The Respondents incorporate Disclosure Category 10 at this point, in which they argue that Kesling disclosed "tooth positioning appliances" that were "adapted to . . . bring the teeth of a user of such an appliance into a pre-determined ideal or desirable position without the necessity for the use of metallic bands, wires or any of the other appliances of the prior art." (Citing CX-944, 1:1-6) Respondents say Figure 7 shows that a "tooth positioning appliance," similar to an aligner, was disclosed. (Citing CX-944, Fig. 7)

Respondents add that Kesling teaches that each aligner in the series is made by molding a polymeric material over positive models of intermediate or successive tooth arrangements, and first a cast of the teeth in their initial position is created using traditional methods. (Citing CX-

944, 2:43–49) Respondents continue, then each individual tooth is manually sectioned out by an operator using a scroll saw. Respondents say next, the operator manually moves each now individually sectioned out tooth to a new position in the base, securing the tooth with wax or another suitable material, and then a positive model of the teeth in their new position is made. Respondents continue the aligners are then fabricated by using a mechanical device to mold a polymeric material over the positive model of the intermediate tooth arrangements. (Citing CX-0944 at 3:30–70, and Figure 3) Respondents reason that the incorporated disclosures of Kesling demonstrate methods for producing a series of polymeric shell dental appliances that are a negative of a positive model of modified tooth arrangements. Respondents conclude that Kesling expressly discloses: (1) intermediate or successive models representing tooth positions; (2) the use and fabrication of a series of dental appliances; and (3) using a machine to fabricate a series of dental appliances by producing a positive model of a tooth arrangement.

Respondents state that Lemchen discloses methods that include controlling a fabrication machine, quoting:

> The present method may be utilized in conjunction with computer-aided design and computer-aided manufacturer (CAD/CAM), as described in the Rekow article referred to above, to provide a machined or cast base conforming to the tooth morphology . . . .

(Citing CX-945, 5:4–8) Respondents add that the inventors describe the use of a "laboratory model of the tooth . . . ," and as described above, the inventors expressly noted that while they referred to a single tooth, their invention "may be utilized with some or all of the teeth in a given arch . . . ." (Citing CX-945, 5:21–24) Respondents contend that these statements expressly disclose the controlling of a fabrication machine to produce a positive model of a modified tooth arrangement based on the digital information generated.

Respondents assert that contrary to its position in this investigation, Align previously argued that the references cited by Lemchen, including the Rekow reference, disclosed using CAD/CAM systems to control fabrication machines to produce positive models of teeth. (Citing RX-103C at 17–26)

Regarding Respondents' allusion to treatment plans, I note that the discussion is set forth in full in sections III.D.2 and III.G.3. I see nothing relevant or material in that discussion that relates to an invalidity defense based upon anticipation. I, therefore, reject Respondents' argument as without merit.

Align's position: Align contends generally that the prior art simply fails to disclose all elements of any of the asserted claims of the '874 patent. (Citing CX-1247C, Qs. 606, 610; CX-1258; and CDX158-163) Align refers to CIB section IV.F.4. Align asserts, for example, that none of the prior art discloses, *inter alia*, a "plurality of successive appliances ... generated at a stage of treatment prior to the patient wearing any appliance of said plurality." Align argues that Respondents' '874 invalidity positions are wholly unsupported and totally insufficient to meet their high burden for an invalidity finding, and Respondents have no particular evidence to support their invalidity case, as no claim charts explaining where each claimed element is shown in the cited references is in evidence - because they were not included with Respondents' *Prehearing Brief*. (Citing Tr. at 19:11-20:4, 651:14-653:25)

In its reply brief, Align asserts that Respondents fail to point to any portion of the prior art that they contend discloses "scanning the patient's teeth or a physical model thereof" ('874 claim 1); "the plurality of successive appliances is generated at a stage of treatment prior to the patient wearing any appliance." (Citing RIB at 144-148)

Addressing anticipation in particular, Align says that Respondents contend that all of the asserted claims of the '874 patent are anticipated by *Lemchen* and "as incorporated," *Kesling*. Align says this argument is unsupported, because no claim charts (or other explanatory vehicle) showing this assertion in detail are in evidence. Align adds that Respondents' argument is wrong, because the argument relies on accepting that *Lemchen* incorporates the entire disclosure of *Kesling*, which is incorrect for the reasons described in CIB Sec. IV.F.4.c. Align concludes, even assuming incorporation, *Lemchen/Kesling* would still fail to disclose all elements of any of the asserted claims of the '874 patent. *Id.*; CIB at 48-51; CX-1247C at Qs. 568-569; CX-1254C ¶ 274 at 97; CDX-158—CDX-163. Align alleges that Respondents' theory relies on their "disclosure categories," which advance new and unsupported mischaracterizations of *Lemchen* and *Kesling*, and fail to fairly address the elements of the asserted claims. (Citing CIB Sec. IV.H.4) Finally, Align asserts that the USPTO considered *Lemchen* and *Kesling* during the prosecution of the '874 patent, further demonstrating that the asserted claims are not anticipated. (Citing JX-006 at 1-2)

Staff's Position: Staff takes the position that since Respondents' arguments and Dr. Mah's testimony alleging anticipation of the Asserted Claims of the '325 patent are also made with respect to the Asserted Claims of the '874 patent, the Staff's discussion of anticipation in SIB Section IV.E.1 applies equally here.

In their reply brief, Staff notes that in their Pre-Hearing Brief, Respondents represented that they would introduce a claim chart showing "where each element of each asserted claim is found in the prior art." (Citing RPHB at 47) Staff states that the ALJ excluded that claim chart. (Citing Tr. at 18:13-19:25) Staff says that in their Post-Hearing Brief, Respondents attempt to make up this shortcoming by comparing, on an element-by-element basis, their prior art

references with the Asserted Claims of the '874 patent. Staff argues that, because Respondents "admittedly" did not make this comparison in their Pre-Hearing Brief, Respondents should not be permitted to do so now. (Citing G.R. 8.2)

Staff continues even if Respondents' comparison of their prior art references with the Asserted Claims of the '874 patent is permitted, that comparison consists of primarily attorney argument, which is no substitute for evidence. Staff says in their comparison, Respondents cite to Dr. Mah's testimony to support their allegations of anticipation and obviousness; but that testimony is merely conclusory, as it too references an excluded claim chart, purporting to show how and where the prior art discloses each element of each asserted claim.

Staff reasons that there is a lack of clear and convincing evidence explaining how the prior art discloses, teaches, or suggests each and every element of the asserted claims of the '874 patent.

Analysis and Conclusions: In section IV.B.1, *supra*, I found that Lemchen only incorporates by reference Figures 1 and 3 of Kesling. In the interest of brevity, I will not repeat that discussion here; but I reaffirm that finding and its rationale.

In Section IV.B.1.a, *supra*, I find that Lemchen does not disclose, or teach or suggest, calculating positions-in-between an initial data set and a final data set. I incorporate and reaffirm that finding and rationale here. Lemchen does not, then, reveal the requirement of "generating a set of intermediate positions toward which the teeth will move while moving from the initial positions toward the final positions" taught in the second element of asserted claim 1 of the '874 patent.

Lemchen does not, in any way, address, disclose, or hint at, multiple removable appliances or generating successive appliances as required by element three of asserted claim 1.

Rather, Lemchen discloses calculating position on the teeth for bracket placement, and completes moving teeth with traditional brackets and archwires, not multiple appliances having cavities with different geometries shaped to receive and reposition teeth. (CX-945, 1:55-57; 1:63-2:8) According to the credible testimony of Dr. Valley, this requirement in asserted claim 1 is different from fabricating brackets or other appliances, and *Lemchen's* disclosure is limited to the idea of treating a patient with a single set of brackets, i.e. one bracket per tooth to be used over the entirely of the treatment. (CX-945, 1:56-62; 3:55-63.)

I note, too, that the incorporation of Figures 1 and 3 of Kesling into Lemchen provides no greater insight into the teachings of asserted claim 1. In Section IV.B.1.a, *supra*, I find that Figure 1 only describes a physical model of a mathematically generated model of a patient's teeth, and Figure 3 demonstrates a method of physically moving portions of a model representing the patient's teeth into a "finish position." I incorporate and reaffirm that finding and rationale here.

In addition, assuming *arguendo* that one were to find that Lemchen incorporates all of Kesling by reference, the result would not change.

In Section IV.B.1.a, *supra* I find that Kesling "does not disclose, or teach or suggest, or even remotely contemplate" the use of computers or digital technology and contemplated a reactive process, performed one step at a time, where appliances beyond a first appliance may be created by repeating the disclosed process for making the first appliance. In Section IV.B.1.a, supra, I find that Kesling also does not expressly or inherently disclose, or teach or suggest, fabricating a dental appliance based on a digital data set. I incorporate and reaffirm those findings and rationales here.

Based upon all of the foregoing, I find that Respondents have failed to meet their burden to prove by clear and convincing evidence that Lemchen anticipates asserted claim 1 of the '874 patent.

b. Claim 2

Asserted claim 2 depends from claim 1 and reads:

> The method of claim 1, wherein receiving the initial digital data set comprises receiving data obtained by scanning a physical model of the patient's teeth.

(JX-006, 32:57-59)

Respondents' Position: Respondents incorporate their disclosure category 1.

Align's Position: Align provides no additional general argument beyond that which it forwarded in a general response to Respondents' invalidity argument in section IV.H.1.a, *supra*. Align asserts that the limitation "scanning a physical model of the patient's teeth" is not disclosed by the prior art. (Citing RIB at 144-148)

Staff's Position: Staff refers to its argument in SIB section IV.E.1 as applicable here. In that argument, staff is of the view that Respondents' technical expert Dr. Mah provides only conclusory testimony about the subject matter of the prior art and the patents-in-suit rather than a detailed discussion of how and where Lemchen and, "as incorporated," Kesling disclose, teach, or suggest each and every element of the asserted claims. (Citing RX-113C, Qs. 100-111) Staff says that Dr. Mah apparently prepared a claim chart setting forth more details about how and where Lemchen and, "as incorporated," Kesling disclose, teach, or suggest each and every element of the Asserted Claims of the Asserted Patents; but the ALJ has excluded that claim chart. (Citing Tr. at 18:13-19:25 (excluding RX-124 and RX-113C at Q. 110)) Staff states that absent from the record is any evidence explaining clearly and convincingly how and where

Lemchen and, "as incorporated," Kesling disclose, teach, or suggest each and every element of the Asserted Claims.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 1 to be anticipated and invalid, I could still find that claim 2 is valid. Since, however, I have found claim 1 to be valid and ***not*** anticipated by Lemchen, claim 2 is necessarily valid, because it depends from claim 1 and necessarily contains all of the elements of claim 1. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 1 is anticipated by Lemchen, I would find that Respondents have failed to show by clear and convincing evidence that claim 2 of the '874 patent is anticipated by Lemchen with the incorporation of Kesling.

Lemchen discloses "generating digital information" regarding the initial "malocclused teeth." (CX-945, 1:55-61; 3:16-24). Lemchen specifically discloses

> The first step of the method of the present invention is the generation of accurate digital information defining the shape and location of the malocclused tooth with respect to the patient's jaw. This information may be generated in a number of ways, such as electromechanically, by laser scanning, sonic ranging, digital video scanning, or magnetically.

(CX-945, 2:54-60) Lemchen does not, however, reveal generating the initial data regarding malocclused teeth from a physical model of the patient's teeth as shown in Kesling. Rather it uses Kesling to illustrate what a model of the upper and lower dental arches looks like. Lemchen actually teaches away from using a physical model such as that in Kesling, when Lemchen states:

> Utilizing standard statistical tooth position data, the repositioning of the teeth is calculated to provide a mathematical model of the finish position. In the prior art, a similar step was accomplished manually in order to account for individual tooth morphology by physically removing

> duplicated teeth from a model and repositioning them in a new model in the finish position. See, for example, FIG. 3 in the above referenced U.S. Pat. No. 2,467,432. However, this procedure did not take into account the individual finish position desired related to the cranial-facial base.
>
> In the present method, this repositioning is done mathematically by appropriate software programs which may be derived by conventional means for the particular method of treatment elected by the orthodontist. An "ideal" finish position is not based upon statistical averages and takes into account the variation and physical characteristics of the individual patient. Therefore, it is preferable that, the program be utilized to provide a customized finish position for the particular patient, so as to make the finish position ideal for the patient, rather than attempting to have the patient duplicate the statistically average position.

(CX-945, 3:32-53) The foregoing discussion teaches away from use of the physical model. Rather, it forwards an approach that uses scanning of the patient's actual teeth to take into account the individual finish position related to the cranial-facial base. Lemchen endorses taking into account "the variation and physical characteristics of the individual patient." Thus, Lemchen with the incorporation of Kesling, does not reveal "data obtained by scanning a physical model of the patient's teeth[22]."

c. Asserted claim 38.

Asserted claim 38 depends from claim 1 and reads:

> The method of claim 1, wherein generating the set of intermediate positions includes receiving data indicating restraints on movement of the patient's teeth and applying the data to generate the intermediate positions.

(JX-006, 34:56-59)

Respondents' Position: Respondents argue that Lemchen discloses that his method "produces appropriate force magnitudes at various stages of treatment to move the tooth to its

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[22] It is not inconsistent that one could find claim 1 anticipated while claim 2 is not anticipated, because claim 1 allows data to be obtained by scanning the patient's teeth, which is an option foreclosed by the language of claim 2.

ideal position." (Citing CX-945, 2:37–38) Respondents contend that a PHOSITA would understand that the "various stages of treatment" would refer the successive stages of treatment typical in orthodontic treatment, and would understand that "appropriate force magnitudes" would mean that any threshold limits on movement would not be exceeded. Respondents reason this is because the only way that movement could exceed a threshold limit is by the application of inappropriate or excessive force on the tooth. Respondents add a PHOSITA would also understand that "appropriate force magnitudes" would mean at least the minimum force necessary to move the teeth toward the successive stage of treatment, otherwise the treatment would be ineffective[23]. (Citing RX-113C at Qs. 57, 58)

Align's Position: Align provides no additional general argument beyond that which it forwarded in a general response to Respondents' invalidity argument in section IV.H.1.a, *supra*. Align alleges that the limitation "receiving data indicating restraints on movement of the patient's teeth and applying the data to generate the intermediate positions" is not disclosed by the prior art references. (Citing RIB at 144-148)

Staff's Position: Staff refers to its argument in section IV.B.1.b, *supra*, and reasserts it.

Analysis and conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 1 to be anticipated by Lemchen, I could still find that claim 38 is valid. Since, however, I have found claim 1 to be valid and ***not*** anticipated by Lemchen, claim 38 is necessarily valid, because it depends from claim 1 and necessarily contains all of the elements of claim 1. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 1 is anticipated by

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[23] Respondents identify this argument as their disclosure category 6.

Lemchen, I would find that Respondents have failed to show by clear and convincing evidence that claim 38 of the '874 patent is anticipated by Lemchen.

Lemchen addresses "orthodontic bracket ***placement*** on a malocclused tooth to correct the malocclusion." (CX-945, Abstract (*see also* 1:63-2:8) (emphasis added) While Lemchen discusses "specific force vectors," it does so in the context of a system of bracket-adhesive ***placement*** and does not include disclosure of applying digital data to "generate … intermediate positions." (*See e.g.* CX-945, 4:35-38) A typical allusion in Lemchen states, "The preferred embodiment takes into account the relative resistance to movement of various teeth or groups of teeth. Bracket positions are customized to account for these forces." (CX-945, 5:35-38) As Lemchen makes clear, the concept of force magnitudes and directions of orthodontic forces, were used from the beginning of orthodontic treatment. (CX-945, 1:11-20) Asserted claim 38 of the '874 patent goes well beyond Lemchen when it teaches generating intermediate positions and including in the data "indicating restraints on movement of the patient's teeth and applying the data to generate the intermediate positions." There is no evidence to connect the disclosures of Lemchen to the teachings of asserted claim 38.

Based upon the foregoing, I find that in the unlikely event that one were to find that Lemchen discloses all of the elements of asserted claim 1, the Respondents have failed to demonstrate by clear and convincing evidence that Lemchen in any way discloses all of the limitations of the element in asserted claim 38.

d. Asserted claim 39.

Asserted claim 39 depends from claim 1 and reads:

> The method of claim 1, wherein generating the set of intermediate positions includes determining the minimum amount of transformation required to move each tooth from the initial

position toward the final position and creating the intermediate positions to require the minimum amount of movement.

(JX-006, 34:60-65)

Respondents' Position: Respondents incorporate their disclosure categories 6 and 7 which are discussed in section IV.H.1.a and c, *supra*.

Align's Position: Align provides no additional general argument beyond that which it forwarded in a general response to Respondents' invalidity argument in section IV.H.1.a and c, *supra*.

Align alleges that the limitation "determining the minimum amount of transformation required to move each tooth from the initial position toward the final position and creating the intermediate positions to require the minimum amount of movement" is not disclosed by any of the prior art. (Citing RIB at 144-148)

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 1 to be anticipated by Lemchen, I could still find that claim 39 is valid. Since, however, I have found claim 1 to be valid and ***not*** anticipated by Lemchen, claim 39 is necessarily valid, because it depends from claim 1 and necessarily contains all of the elements of claim 1. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 1 is anticipated by Lemchen, I would find that Respondents have failed to show by clear and convincing evidence that claim 39 of the '874 patent is anticipated by Lemchen.

The difference between dependent claim 38 and dependent claim 39 is the amount of movement of the patient's teeth that is contemplated. Dependent claim 38 focuses on data "indicating restraints on movement of the patient's teeth," and dependent claim 39, looks to

"determining the minimum amount of transformation required to move each tooth from the initial position toward the final position." (JX-006, 34:56-65)

My analysis of this issue in section IV.H.1, supra, is equally applicable to this discussion and is incorporated here by this reference.

Based upon the foregoing, I find that in the unlikely event that one were to find that Lemchen discloses all of the elements of asserted claim 1, the Respondents have failed to demonstrate by clear and convincing evidence that Lemchen in any way discloses all of the limitations of the element in asserted claim 39.

e. Asserted claim 41.

Asserted claim 41 depends from claim 1 and reads:

> The method of claim 1, wherein generating the set of intermediate positions includes generating intermediate positions for at least one tooth between which the tooth undergoes translational movements of equal sizes.

(JX-006, 35:4-7)

Respondents' Position: Respondents incorporate their disclosure categories 6 and 7, which are discussed in sections IV.H.1.a and c, *supra*.

Align's position: Align provides no argument beyond that which it forwarded in a general response to Respondents' invalidity argument in sections IV.H.1.a and c, *supra*.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 1 to be anticipated by Lemchen, I could still find that claim 41 is valid. Since, however, I have found claim 1 to be valid and ***not*** anticipated by Lemchen, claim 41 is necessarily valid, because it depends from claim 1 and necessarily contains all of the elements of claim 1. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 1 is anticipated by Lemchen, I would find that Respondents have failed to show by clear and convincing evidence that claim 41 of the '874 patent is anticipated by Lemchen.

As evidenced by the summary of Respondents' argument in section IV.H.1.c, supra, Respondents make no effort to demonstrate that Lemchen discloses generating intermediate positions for one tooth in which the tooth "undergoes translational movements of equal sizes." There is simply no mention of this limitation of dependent claim 41 in Respondents' argument.

Based upon the foregoing, I find that in the unlikely event that one were to find that Lemchen discloses all of the elements of asserted claim 1, the Respondents have failed to demonstrate by clear and convincing evidence that Lemchen in any way discloses all of the limitations of the element in asserted claim 41.

f. Asserted claim 62.

Asserted claim 62 depends from claim 1 and reads:

> The method of claim 1, further comprising delivering data identifying the intermediate treatment positions to an appliance fabrication system for use in fabricating at least one orthodontic appliance structured to move the patient's teeth toward the final position.
>
> (JX-006, 36:12-16)

Respondents' Position: Respondents incorporate their disclosure categories 9 and 10, discussed in section IV.H.1.f, *supra*.

Align's position: Align provides no additional general argument beyond that which it forwarded in a general response to Respondents' invalidity argument in sections IV.H.1.a and c, *supra*.

Align avers that the limitation "delivering data identifying the intermediate treatment positions to an appliance fabrication system..." is not disclosed by the prior art. (Citing RIB at 144-148)

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 1 to be anticipated by Lemchen, I could still find that claim 62 is valid. Since, however, I have found claim 1 to be valid and ***not*** anticipated by Lemchen, claim 62 is necessarily valid, because it depends from claim 1 and necessarily contains all of the elements of claim 1. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 1 is anticipated by Lemchen, I would find that Respondents have failed to show by clear and convincing evidence that claim 62 of the '874 patent is anticipated by Lemchen.

Respondents' argument relies in part upon the non-existent finding that Lemchen incorporates the entirety of Kesling by reference. Nevertheless, regardless of whether or not the entirety of Kesling is incorporated into Lemchen, I would find that Respondents have not demonstrated by clear and convincing evidence that Lemchen anticipates each and every limitation in the element of claim 62.

Respondents' candid assessment of Kesling is that it discloses manually sectioning out the teeth from the physical model and manually moving each now individually sectioned out tooth to a new position in the base, securing the tooth with wax or another suitable material. Kesling describes making tooth arrangements by (i) using a plaster mold of teeth, (ii) dissecting the plaster teeth with a saw, and (iii) reassembling the plaster teeth in wax into their assumed positions. (CX-944, 3:13-22; 3:30-43; 3:61-4:58)

As discussed, *supra*, Lemchen addresses "orthodontic bracket ***placement*** on a malocclused tooth to correct the malocclusion." (CX-945, Abstract (*see also* 1:63-2:8) (emphasis added) It does not address the creation of individual dental repositioning aligners. Asserted claim 62 of the '874 patent teaches delivering data identifying ... intermediate treatment positions to an appliance fabrication system for use in fabricating at least one orthodontic appliance structured to move the patient's teeth toward the final position. The data produced in the invention of Lemchen is used to assist in the creation and placement of brackets and arch wires. (CX-945, 3:61-4:39)

Based upon the foregoing, I find that in the unlikely event that one were to find that Lemchen discloses all of the elements of asserted claim 1, the Respondents have failed to demonstrate by clear and convincing evidence that Lemchen in any way discloses all of the limitations of the element in asserted claim 62.

2. Obviousness

Lemchen, Kesling, and the knowledge of one of ordinary skill in the art

a. Asserted Claim 1

Respondents' Position: Respondents incorporate the disclosures of the prior art identified in the anticipation section addressing this preamble to Claim 1 of the '874 patent together with knowledge of one of ordinary skill in the art as described in the section addressing claim 1 of the '325 patent. Respondents assert that neither Lemchen, nor the incorporated Kesling patent, limit the time when the disclosed appliances are generated and the appliances can be generated prior to the patient wearing any appliance.

First, Respondents address the issue of motivation to combine generally, and say that Align's expert, Dr. Rekow, stated that:

> The evolution of computers in the 1970s and 1980s enticed many inventors to explore dental and orthodontic applications using and manipulating digital data. Ideas that were explored, as seen below were demonstrated, included opportunities where manual manipulations were automated. The time consuming manipulation of plaster casts to model orthodontic treatment options was replaced by systems that modeled multiple combinations of tooth movement, permitting the clinician to choose the most ideal. Labor-intensive design and fabrication of dental restorations was replaced by computer-aided design and manufacturing systems to speed delivery . . . .

(Citing RX-103C at 2)[24] Respondents contend that the related nature of the subject matters and the problems addressed made the combination obvious. Respondents add that Dr. Rekow stated that the Lemchen reference and the Kesling reference were combined based on her analysis of the references in the Lemchen patent. Respondents assert that Dr. Rekow's report states that Lemchen's methods for digital 3-D modeling was a representation of Kesling's physical 3-D modeling. (Citing RX-103C at 16) Respondents conclude that these references with the knowledge of one of ordinary skill show that the asserted claims are obvious. Respondents then take the position that the topics in this section are common to the obviousness analysis for each claim and are incorporated therein to avoid repetition. In their view, each asserted claim is obvious in light of the identified prior art references with the knowledge of one of ordinary skill.

Respondents argue that Lemchen discloses that the "repositioning is done mathematically by appropriate software programs which may be derived by conventional means . . . ." (Citing CX-945, 2:66–3:6) Respondents contend that a PHOSITA would understand this to mean that the tooth path between the initial and final positions would be determined and then the tooth positions for each segment representing the successive stages of treatment would be determined by interpolation or a method for calculating movements of incremental equal sizes. Respondents

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[24] This use of the cited reference violates the limited scope contained in my ruling on Align's Motion in Limine No. 6, and is rejected.

allege that it is uncontroverted that interpolation is a conventional mathematical means for determining positional differences. (Citing RX-113C, Q. 59)

Respondents state that Lemchen also expressly incorporated the disclosure of Kesling to explain the inventor's 3-D modeling methodology, quoting:

> In the prior art, a similar step was accomplished manually in order to account for individual tooth morphology by physically removing duplicated teeth from a model and repositioning them in a new model in the finish position. See, for example, FIG. 3 in the above referenced U.S. Pat. No. 2,

(Citing CX-945, 3:36–40) Respondents reason that Lemchen stated that FIG. 3 was one example of a repositioned tooth arrangement, and a PHOSITA would understand that this same method would apply equally to the intermediate or successive tooth arrangements that are described in Kesling, because the methodology is the same for all successive tooth arrangements from the initial position to the final position. Respondents add that intermediate or successive tooth arrangements are inherent in tooth modeling, because one cannot model tooth movement accurately without including the intermediate steps. (Citing RX-113C, Q. 48)

Respondents argue that the figures in Kesling demonstrate that a "tooth positioning appliance," similar to an aligner, was disclosed. (Citing CX-944, Fig. 7) Respondents assert that Kesling expressly discloses: (1) intermediate or successive models representing tooth positions; (2) the use and fabrication of a series of dental appliances; and (3) using a machine to fabricate a series of dental appliances by producing a positive model of a tooth arrangement. (Citing RX-113C, Q. 33)

Respondents say that Lemchen discloses methods that include controlling a fabrication machine, quoting:

> The present method may be utilized in conjunction with computer-aided design and computer-aided manufacturer (CAD/CAM), as described in the

> Rekow article referred to above, to provide a machined or cast base conforming to the tooth morphology . . . .

(Citing CX-945, 5:4–8) Respondents add that Lemchen also describes the use of a "laboratory model of the tooth . . . ." and the inventors expressly noted that while they referred to a single tooth, their invention "may be utilized with some or all of the teeth in a given arch . . . ." (Citing CX-945, 5:21–24) Respondents contend that these statements expressly disclose the controlling of a fabrication machine to produce a positive model of a modified tooth arrangement based on the digital information generated. (Citing RX-113C, Q. 43)

Respondents say that Lemchen expressly stated that the three-dimensional modeling methods, using software, "may be derived by conventional means for the particular method of treatment elected by the orthodontist." (Citing CX-945, 3:25–26) Respondents continue that Lemchen similarly stated in the detailed description that there "are a number of methods of treatment commonly used by the orthodontist." (Citing CX-945, 3:43–46) Respondents reason that as a result Lemchen expressly recognizes that its methods may be used with different types of orthodontic treatment. Respondents conclude that a PHOSITA would understand that other treatment methods, such as the aligner treatment method disclosed in Kesling could be used with the digital methods disclosed in Lemchen. (Citing RX-113C, Q. 49)

Respondents says that a PHOSITA would understand that the methods of Kesling were not limited to brackets (which are custom fabricated in the disclosed methods to conform to the surface of the teeth) and arch wires. Respondents argue that the incorporation of the disclosures of Kesling and "the other statements concerning other treatment methods" makes it clear that the Lemchen methodology applies beyond brackets and archwires. Respondents say Kesling's disclosures are limited to methods for making polymeric shell appliances based on a series of three-dimensional tooth models, and a PHOSITA would understand the incorporation of Kesling

to mean that the methods of Lemchen would apply to polymeric shell appliances, the orthodontic appliance expressly described in Kesling. Respondents add that a PHOSITA would also understand that the modeling of teeth movement is the same, regardless of the type of orthodontic appliance used. (Citing RX-113C, Qs. 49, 51)

Respondents continue that Lemchen also disclosed the transfer of digital information between a practitioner and a dental lab, and the use of that digital information by the dental lab in its manufacturing process, "where the digitized information is utilized in the process of providing the practitioner with the required dental appliances for the correction of the malocclusion." (Citing CX-945, 5:15–20) Respondents argue that these disclosures render the claim obvious.

Respondents incorporate Disclosure Categories 1, 7, and 10, which are discussed in section IV.H.1.a, combined with the knowledge of one of ordinary skill in the art. Respondents also incorporate their discussion of treatment plans[25].

Align's Position: Align argues that the combination of Lemchen with Kesling, and "the knowledge of one of ordinary skill in the art" was disclosed for the first time in the *JSCI*, and is therefore improperly raised now and has been waived. Align continues that the argument is unsupported because no claim charts showing this assertion in detail are in evidence and the combination of Lemchen and Kesling fail to disclose all the elements of any of the asserted claims of the '874 patent, "as discussed above[26]". Align states that a PHOSITA at the time of the invention would not have been motivated to combine a reference directed to fixed appliances made of brackets and wires (Lemchen) with a reference directed to removable appliances

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[25] Inasmuch as, Respondents' argument about treatment plans adds nothing relevant or material to the issue of obviousness, I reject it as without merit and will not further discuss it.

[26] In its reply brief, Align cites to CIB at 48-51; CX-1247C, Qs. 568-569; CX-1254C ¶ 274 at 97; and CDX-158—163) to support this argument.

(Kesling). (Citing CIB Sec. IV.F.2.b) Align adds that secondary considerations support a finding of non-obviousness. (Citing CIB Sec. IV.F.2.c)

In its reply brief, Align argues that Respondents failed to make a *prima facie* showing of obviousness. (Citing CRB Sec. IV.H; and Tr. at 19:11-20:4, 651:14-653:25). Align adds that the USPTO considered Lemchen and Kesling during the prosecution of the '874 patent, further demonstrating that the asserted claims are not obvious. (Citing JX-006 at 1-2) Align says that Respondents' obviousness theory relies on their "disclosure categories," which advance new and unsupported mischaracterizations of Lemchen and Kesling, and fail to fairly address the elements of the asserted claims. (Citing CRB Sec. IV.H.4)

Staff's Position: Staff refers to its discussion of obviousness in SIB Section IV.E.2, and says it applies equally here.

Analysis and Conclusions: While Respondents do mention "knowledge of one of ordinary skill in the art" in RPHB, section 6.5.2.2, their references in that pre-hearing brief amount to a general discussion of eleven separate references with no element by element discussion of how those eleven references would combine to render any specific asserted claim of the '874 patent obvious.[27] There is only a general reference to a "claim chart" that Respondents say they will produce at the hearing. This is inadequate to provide notice to Align regarding the specific prior art to be addressed and the manner in which the prior art discloses each and every element of an asserted claim. (RPHB at 147-154) As a result, at the hearing I granted Align's motion *in limine* number 6, and excluded the claim charts that were not specifically cited in Respondents' prehearing brief as required by Ground Rule 8.2. (Tr. 18:13-20:4)

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[27] Align correctly argues that the Respondents also fail to identify the claim(s) addressed by the prior art.

In order to prevail on their claim that asserted claim 1 of the'874 patent is invalid as obvious, Respondents must first demonstrate that Lemchen, either alone or in combination with Kesling, and the knowledge of a PHOSITA discloses all of the limitations of asserted claim 1. (*Hearing Components, Inc. v. Shure Inc.*, 600 F.3d 1357, 1373-1374 (Fed. Cir. 2010); and *Velander v. Garner*, 348 F.3d 1359, 1363 (Fed. Cir. 2003))

Equally important is the requirement that the Respondents establish by clear and convincing evidence that a person of ordinary skill in the art would have had reason to combine the various asserted prior art references to attempt to produce the invention and would have had a reasonable expectation of success in doing so. (See *PharmaStem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007))

There is nothing in the evidence submitted by Respondents to support a finding that a PHOSITA would be motivated by anything in Lemchen or Kesling to follow the method in the '874 patent. In section IV.B.1, *supra*, I found that Lemchen only incorporates by reference Figures 1 and 3 of Kesling. In the interest of brevity, I will not repeat that discussion here; but I reaffirm that finding and its rationale.

In section IV.H.1.a, I found that Lemchen does not reveal the requirement of "generating a set of intermediate positions toward which the teeth will move while moving from the initial positions toward the final positions" taught in the second element of asserted claim 1and that Lemchen does not, in any way, address, disclose, or hint at, multiple removable appliances or generating successive appliances. In the interest of brevity, I will not repeat that discussion; but I reaffirm those findings and the rationale supporting them.

I note, too, that the incorporation of Figures 1 and 3 of Kesling into Lemchen provides no greater insight into the teachings of asserted claim 1. As described, *supra*, Figure 1 only

describes a physical model of a mathematically generated model of a patient's teeth, and Figure 3 demonstrates a method of physically moving portions of a model representing the patient's teeth into a "finish position."

Assuming arguendo that Lemchen incorporated the entirety of Kesling by reference, I found in section IV.H.1.a that those two references taken together would still not disclose each and every element of asserted claim 1 of the '874 reference. Notably, I found that Kesling only contemplated a reactive process, performed one step at a time, where appliances beyond a first appliance may be created by repeating the disclosed process for making the first appliance. (CX-1247C, Qs. 144-145; CX-944, 5:22-32) I concluded that Kesling does not expressly or inherently disclose, or teach or suggest, fabricating a dental appliance based on digital data. Rather, Kesling discloses manually making an appliance using tools, supplies, and materials, including, inter alia, (i) articulating the plaster cast; (ii) taking an impression of the teeth of the plaster cast, and (iii) making a mold filled with the appliance material. (CX-944, 3:65-4:58)

Consistent with the foregoing, I found that Lemchen's disclosure is limited to the idea of treating a patient with a single set of brackets, i.e. one bracket per tooth to be used over the entirely of the treatment. Based upon the foregoing findings, it follows that Lemchen combined with Kesling would not provide any impetus for a PHOSITA to combine the teachings of Lemchen and Kesling to produce the invention of asserted claim 1 of the '874 patent. I will not repeat my analysis in full in the interest of brevity; but that analysis and the conclusions reached are reaffirmed here.

While Respondents' expert, Dr. Mah, opines to the contrary, I find that his testimony was conclusory and unconvincing. (See RX-113C, Qs. 113-121)

Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of asserted claim 1 of the '874 patent are present in Lemchen combined with Kesling, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine the those references to create the method claimed in asserted claim 1of the '874 patent.

b. Asserted Claim 2

Respondents' Position: The Respondents incorporate the disclosures identified as their Disclosure Category 1 together with knowledge of one of ordinary skill in the art as described in RIB section 3.5.2.2 addressing claim 1 of the '325 patent.

Align's Position: Align provides no additional general argument beyond that which it forwarded in a general response to Respondents' obviousness argument in section IV.H.2.a, *supra*.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 1 to be rendered obvious by the asserted prior art and invalid, I could still find that claim 2 is valid. Since, however, I have found claim 1 to be valid and ***not*** rendered obvious by Lemchen, combined with Kesling and the knowledge of a PHOSITA, claim 2 is necessarily valid, because it depends from claim 1 and necessarily contains all of the elements of claim 1. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 1 is rendered obvious by Lemchen, combined with Kesling and the knowledge of a PHOSITA, I would find that Respondents have failed to show by clear and convincing evidence that claim 2 of the '874 patent is rendered obvious by that combination.

In section IV.H.1.b, *supra*, I found that Lemchen does not reveal generating the initial data regarding malocclused teeth from a physical model of the patient's teeth as shown in Kesling. In the interest of brevity, I will not repeat the discussion in section IV.H.1.b in its entirety; but I reaffirm that finding and the rationale for it.

Based upon the evidence before me, I find that Respondents have failed to show by clear and convincing evidence that all of the limitations of asserted claim 2 of the '874 patent are present in Lemchen combined with *Kesling*, and that a person having ordinary skill in the art at the time of the invention would have had reason to combine those references to create the method claimed in asserted claim 2 of the '874 patent.

c. Asserted Claim 38

Respondents' Position: Respondents incorporate Disclosure Category 6 combined with the knowledge of a PHOSITA.

Respondents argue that Lemchen discloses that his method "produces appropriate force magnitudes at various stages of treatment to move the tooth to its ideal position." (Citing CX-945, 2:37–38) Respondents contend that a PHOSITA would understand that the "various stages of treatment" would refer the successive stages of treatment typical in orthodontic treatment, and would understand that "appropriate force magnitudes" would mean that any threshold limits on movement would not be exceeded. Respondents reason this is because the only way that movement could exceed a threshold limit is by the application of inappropriate or excessive force on the tooth. Respondents add a PHOSITA would also understand that "appropriate force magnitudes" would mean at least the minimum force necessary to move the teeth toward the

successive stage of treatment, otherwise the treatment would be ineffective[28]. (Citing RX-113C at Qs. 57, 58)

Align's Position: Align provides no additional general argument beyond that which it forwarded in a general response to Respondents' obviousness argument in section IV.H.2.a, *supra*.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 1 to be rendered obvious by the asserted prior art and invalid, I could still find that claim 38 is valid. Since, however, I have found claim 1 to be valid and ***not*** rendered obvious by Lemchen, combined with Kesling and the knowledge of a PHOSITA, claim 38 is necessarily valid, because it depends from claim 1 and necessarily contains all of the elements of claim 1. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 1 is rendered obvious by Lemchen, combined with Kesling and the knowledge of a PHOSITA, I would find that Respondents have failed to show by clear and convincing evidence that claim 38 of the '874 patent is rendered obvious by that combination.

In section IV.H.1.c, *supra*, I fully discussed Respondents argument using their disclosure category 6. In the interest of brevity, I will not repeat that discussion here; but I reaffirm the findings and rationale in section IV.H.1.c.

A portion of Respondents' argument in section IV.H.1.c said that a PHOSITA would also understand that "appropriate force magnitudes" would mean at least the minimum force necessary to move the teeth toward the successive stage of treatment, otherwise the treatment

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[28] Respondents identify this argument as their disclosure category 6.

would be ineffective[29]. Respondents offered the testimony of their expert, Dr. Mah, to prove this point; but that brief testimony amounts to mere conclusory opinions without any supporting rationale demonstrated. It is unhelpful. (See RX-113C at Qs. 57, 58)

Based upon the foregoing, I find that in the unlikely event that one were to find that Lemchen discloses all of the elements of asserted claim 1, the Respondents have failed to demonstrate by clear and convincing evidence that Lemchen combined with Kesling and the knowledge of a PHOSITA, discloses each and every of the limitation of the element in asserted claim 38.

d. Asserted Claim 39

Respondents' Position: Respondents incorporate Disclosure Categories 6 and 7 and the knowledge of a PHOSITA, all of which are discussed in section IV.H.2.a and c, and the references to the record contained therein.

Align's Position: Align provides no additional general argument beyond that which it forwarded in a general response to Respondents' obviousness argument in section IV.H.2.a, *supra*.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 1 to be rendered obvious by the asserted prior art and invalid, I could still find that claim 39 is valid. Since, however, I have found claim 1 to be valid and ***not*** rendered obvious by Lemchen, combined with Kesling and the knowledge of a PHOSITA, claim 39 is necessarily valid, because it depends from claim 1 and necessarily contains all of the elements of claim 1. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

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[29] Respondents identify this argument as their disclosure category 6.

Assuming arguendo that one were to find that independent claim 1 is rendered obvious by Lemchen, combined with Kesling and the knowledge of a PHOSITA, I would find that Respondents have failed to show by clear and convincing evidence that claim 39 of the '874 patent is rendered obvious by that combination.

In the interest of brevity, by this reference I incorporate the discussion, findings and rationale in section IV.H.2.a and c.

Based upon the foregoing, I find that in the unlikely event that one were to find that Lemchen discloses all of the elements of asserted claim 1, the Respondents have failed to demonstrate by clear and convincing evidence that Lemchen combined with Kesling and the knowledge of a PHOSITA, discloses each and every of the limitation of the element in asserted claim 39.

e. Asserted Claim 41

Respondents' Position: Respondents incorporate Disclosure Categories 6 and 7, discussed in sections IV.H.2a and c, combined with the knowledge of a PHOSITA.

Align's Position: Align provides no additional general argument beyond that which it forwarded in a general response to Respondents' invalidity argument in section IV.H.2.a, *supra*.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 1 to be rendered obvious by the asserted prior art and invalid, I could still find that claim 41 is valid. Since, however, I have found claim 1 to be valid and ***not*** rendered obvious by Lemchen, combined with Kesling and the knowledge of a PHOSITA, claim 41 is necessarily valid, because it depends from claim 1 and necessarily contains all of the elements of claim 1. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 1 is rendered obvious by Lemchen, combined with Kesling and the knowledge of a PHOSITA, I would find that Respondents have failed to show by clear and convincing evidence that claim 41 of the '874 patent is rendered obvious by that combination.

In the interest of brevity, by this reference I incorporate the discussion, findings and rationale in sections IV.H.2.a and c, *supra*.

Based upon the foregoing, I find that in the unlikely event that one were to find that Lemchen discloses all of the elements of asserted claim 1, the Respondents have failed to demonstrate by clear and convincing evidence that Lemchen combined with Kesling and the knowledge of a PHOSITA, discloses each and every of the limitation of the element in asserted claim 41.

f. Asserted Claim 62

Respondents' Position: Respondents incorporate Disclosure Categories 9 and 10, discussed in section IV.H.1.f, *supra*, combined with the knowledge of a PHOSITA.

Arguing disclosure category 10, Respondents say Kesling disclosed "tooth positioning appliances" that were "adapted to . . . bring the teeth of a user of such an appliance into a pre-determined ideal or desirable position without the necessity for the use of metallic bands, wires or any of the other appliances of the prior art." (Citing CX-944, 1:1-6) Respondents say Figure 7 shows that a "tooth positioning appliance," similar to an aligner. was disclosed. (Citing CX-944, Fig. 7)

Respondents contend that Kesling further teaches that each aligner in the series is made by molding a polymeric material over positive models of intermediate or successive tooth arrangements. Respondents assert, first a cast of the teeth in their initial position is created using

traditional methods. (Citing CX-944, 2:43–49) Respondents admit that each individual tooth is manually sectioned out by an operator using a scroll saw, and the operator manually moves each now individually sectioned out tooth to a new position in the base, securing the tooth with wax or another suitable material. Respondents say a positive model of the teeth in their new position is made, and the aligners are fabricated by using a mechanical device to mold a polymeric material over the positive model of the intermediate tooth arrangements. (Citing CX-944, 3:30-4:70 and Figure 3) Respondents conclude that the incorporated disclosures of Kesling demonstrate methods for producing a series of polymeric shell dental appliances that are a negative of a positive model of modified tooth arrangements, and Kesling therefore discloses: (1) intermediate or successive models representing tooth positions; (2) the use and fabrication of a series of dental appliances; and (3) using a machine to fabricate a series of dental appliances by producing a positive model of a tooth arrangement.

Respondents contend that Lemchen discloses methods that include controlling a fabrication machine, quoting:

> The present method may be utilized in conjunction with computer-aided design and computer-aided manufacturer (CAD/CAM), as described in the Rekow article referred to above, to provide a machined or cast base conforming to the tooth morphology . . . .

(Citing CX-945, 5:4–8) Respondents assert that the inventors expressly noted that while they referred to a single tooth, their invention "may be utilized with some or all of the teeth in a given arch . . . ." (Citing CX-945, 5:21–24) Respondents argue that these statements expressly disclose the controlling of a fabrication machine to produce a positive model of a modified tooth arrangement based on the digital information generated.

Regarding their disclosure category 9, Respondents argue that Lemchen disclosed the transfer of digital information between a practitioner and a dental lab, and the use of that digital

information by the dental lab in its manufacturing process, "where the digitized information is utilized in the process of providing the practitioner with the required dental appliances for the correction of the malocclusion." (Citing CX-945, 5:15–20)

Align's Position: Align provides no additional general argument beyond that which it forwarded in a general response to Respondents' invalidity argument in section IV.H.2.a, *supra*.

Analysis and Conclusions: A patent is presumed to be valid, and each claim of a patent shall be presumed valid even though dependent on an invalid claim. 35 U.S.C. § 282. If I determined claim 1 to be rendered obvious by the asserted prior art and invalid, I could still find that claim 62 is valid. Since, however, I have found claim 1 to be valid and ***not*** rendered obvious by Lemchen, combined with Kesling and the knowledge of a PHOSITA, claim 62 is necessarily valid, because it depends from claim 1 and necessarily contains all of the elements of claim 1. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

Assuming arguendo that one were to find that independent claim 1 is rendered obvious by Lemchen, combined with Kesling and the knowledge of a PHOSITA, I would find that Respondents have failed to show by clear and convincing evidence that claim 62 of the '874 patent is rendered obvious by that combination.

In the interest of brevity, by this reference I incorporate the discussion, findings and rationale in sections IV.H.1.f and IV.H.2.a[30], *supra*.

Based upon the foregoing, I find that in the unlikely event that one were to find that Lemchen discloses all of the elements of asserted claim 1, the Respondents have failed to demonstrate by clear and convincing evidence that Lemchen combined with Kesling and the

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[30] Reference to this section is to that portion that discusses combining the Lemchen reference with Kesling and the knowledge of a PHOSITA.

knowledge of a PHOSITA, discloses each and every of the limitation of the element in asserted claim 62.

V. INFRINGEMENT

A. Applicable Law

A complainant must prove either literal infringement or infringement under the doctrine of equivalents. Infringement must be proven by a preponderance of the evidence. *SmithKline Diagnostics, Inc. v. Helena Labs. Corp.*, 859 F.2d 878, 889 (Fed. Cir. 1988). A preponderance of the evidence standard "requires proving that infringement was more likely than not to have occurred." *Warner-Lambert Co. v. Teva Pharm. USA, Inc.*, 418 F.3d 1326, 1341 n. 15 (Fed. Cir. 2005).

Literal infringement is a question of fact. *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323, 1332 (Fed. Cir. 2008). Literal infringement requires the patentee to prove that the accused device contains each and every limitation of the asserted claim(s). *Frank's Casing Crew & Rental Tools, Inc. v. Weatherford Int'l, Inc.*, 389 F.3d 1370, 1378 (Fed. Cir. 2004).

Contributory infringement requires the patentee to prove that: (1) there is an act of direct infringement in violation of section 337; (2) the accused device has no substantial non-infringing uses; (3) the component is a material part of the invention; and (4) the accused infringer imported, sold for importation, or sold after importation within the United States, the accused components that contributed to another's direct infringement. *Certain Electronic Devices With Image Processing Systems, Components Thereof, and Associated Software*, Inv. No. 337-TA-724; Comm'n Op. (Dec. 21, 2011) at n.9 (citing *Spansion, Inc. v. Int'l Trade Comm'n*, 629 F.3d 1331, 1353 (Fed. Cir. 2010)). In addition to the foregoing factors, the Federal Circuit has explained that the patentee must also demonstrate that the alleged infringer "knew that the

combination for which its components were especially made was both patented and infringing." *Golden Blount, Inc. v. Robert H. Peterson Co.*, 365 F.3d 1054, 1061 (Fed. Cir. 2004) (quoting *Preemption Devices, Inc. v. Minn. Mining & Mfg., Co.*, 803 F.2d 1170, 1174 (Fed. Cir. 1986)).

B. The '325 Patent

1. General Arguments

Align's Position: Align says that Respondents assert they "cannot jointly infringe" and that their conduct cannot be "combined" for purposes of showing infringement. Align disagrees, saying that the Federal Circuit in *Akamai* identified the specific factual situation in this Investigation (*i.e.*, where CCUS has induced CCPK to perform part of its process (*see* Section IV.C.)) as an example of when its new inducement standard would apply (*Akamai*, 692 F.3d. at 1309) and that the joint performance of the claimed process provided the requisite "direct" infringement. Align continues that CCUS exercises complete control over CCPK.

Align says that Respondents have long known about Align's patents and processes and have attempted to structure their relationship to disguise CCPK's role (Citing CX-0166C; CX-0305C) and in an effort to avoid infringement liability. Align continues that this structure is not arms-length (and was called a "sham" (Citing Order No. 63 at 42 (December 31, 2012) in Inv. 337-TA-562), and neither CCPK (Citing CX-1162C.1 at 194:5-14, 207:1-11; CX-1162C.2 at 302:17-303:12; 387:21-388:8) nor CCUS (Citing CX-1160C.3 at 461:4-462:8.; CX-0916C at 18-46) have maintained corporate formalities.

Align asserts that since its creation, {

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Align disagrees with Respondents' argument that Align cannot rely upon CCPK's "foreign conduct to argue infringement." Align says that infringement can include situations where process steps are performed both inside and outside the U.S. by multiple parties. (Citing 35 U.S.C. § 271(g), 35 U.S.C. § 271(b); and 19 U.S.C. § 1337(a)(1)(B)(ii))

Align also disagrees with Respondents' assertion that 35 U.S.C. § 271(g) claims cannot be advanced in the ITC. Align says that the ITC has instructed that the term "infringe" includes "all forms of infringement," which would include § 271(g) claims. (Citing *Certain GPS Chips*, 2010 ITC LEXIS 582, at *81) Align continues that while it is true that the ITC has found that the defenses of § 271(g) do not apply in the context of a violation under 337(a)(1)(B)(ii), this does not mean that Align cannot rely on § 271(g) to show infringement. (Citing *Certain Sucralose*, INV. No. 337-TA-604, Comm'n Op., 2009 ITC LEXIS 727, at *44 (Apr.28, 2009)) Align argues that it is asserting § 271(g) in connection with a violation under § 337(a)(1)(B)(i), not §337(a)(1)(B)(ii). (Citing *Certain Recombinant Erythropoietin*, Inv. No. 337-TA-281, 1989 ITC LEXIS 56, at *9) Align continues that while the Commission found that the defenses for § 271(g) are limited by their implementation language to actions under Title 35, the language defining infringement in § 271(g) is not so limited.

Align additionally disagrees with Respondents' argument that "transmission of information" is not covered by § 271(g). Align says that this argument is inapplicable to a majority of Align's asserted claims, because Align is asserting direct infringement under § 271(g) by CCUS's offering to sell, selling, or using aligners in the U.S. – not digital data. Align continues that for Align's remaining claims where the accused product is a digital data set, this argument is legally unsupported.

Align says that Respondents cite *Bayer*, which held that the scope of the phrase "a product which is made by a process patented in the United States," as used in 35 U.S.C. § 271(g), does not cover "research data or information obtained from using the patented methods," as somehow being on point. Align continues that the research information in *Bayer* was effectively an answer to a question or inquiry (*e.g.*, whether a substance is X or Y) – not a product, and thus not comparable to products such as the digital data sets here.

Align contends that other courts have found that digital data similar to the digital data sets imported by Respondents is a "product" under § 271(g). (Citing *CNET Networks, Inc. v. Etilize, Inc.*, 528 F. Supp. 2d 985, 995 (N.D. Cal. 2007)) Align says that In *CNET*, the court found that an imported electronic catalogue is a "product" under § 271(g), and distinguished *Bayer* by explaining that:

> [u]nlike Bayer, where the patented process was not used in the actual manufacture of the drug, the patented process in this case is directly used to manufacture the catalog. In other words, while practicing each step of the research method in Bayer did not lead to the creation of a drug, practicing each step of the method in this case leads directly to the creation of a catalog.

(Citing *id.* at 993) Align continues that the *CNET* court further noted that the creation of a product catalogue stored on computer readable media was no different from a product catalogue manufactured and assembled on paper bound with stitching, glue, or staples. (Citing *id.* at 994) Align contends that here, as in *CNET*, practicing each step of the asserted claims leads to the creation of the digital data sets. Align adds that like the electronic catalogue in *CNET*, the digital data is the digital version of a physical model. (Citing Tr. at 400:4-7; CX-0868C)

Align notes that the district court in Align's previous dispute with Ormco has already found that digital 3D models, similar to the digital data sets at issue here, are covered by § 271(g). (Citing *Ormco Corp. v. Align Tec. Inc.*, 8:03-cv-00016-CAS-AN, slip op. at 9 (C.D. Cal.

Aug. 3, 2009) ("Ormco III").) Align says that Respondents have ignored this holding notwithstanding that they often cite to the Ormco dispute.

Align says it is not clear that the defenses of § 271(g) would be available as a defense under § 337(a)(1)(B)(i). (Citing *Kinik Co. v. ITC*, 362 F.3d 1359, 1363 (Fed. Cir. 2004)) Align adds that even if the defenses of § 271(g) are available, they would be inapplicable to Align's infringement assertions. Align says that it is asserting direct infringement, under § 271(g), for example, by CCUS's sale, offer for sale, or use of aligners, and CCPK's sale, offer for sale, or importation of digital data sets. Align continues that in either case, the accused product has not been changed and has not become a trivial part of another product.

Align says that the intent of Congress when adopting the Process Patent Act Amendments Act of 1988, which enacted § 271(g), was to ***preserve*** the full extent of that jurisdiction. Align continues that 35 U.S.C. §§ 271(a), (b), and (c) are available in Commission actions, and Congress has not added specific language to 19 U.S.C. §1337 indicating that they may be so used. Align notes that 19 U.S.C. §1337(a)(1)(B)(i) simply uses the word "infringe" and there is nothing in the statutory language, the legislative history or any decision of the Commission or any court that would support a reading of that word to exclude any act of infringement as defined in § 271 of the Patent Act, including the acts defined under § 271(g).

Align says that a party may certainly infringe under § 271(g) where the process steps are performed both inside and outside the U.S. (Citing *Avery Dennison Corp. v. UCB Films PLC*, 1997 U.S. Dist. LEXIS 16535, at *6-8 (N.D. Ill. Oct. 17, 1997); *Zoltek Corp. v. United States*, 85 Fed. Cl. 409, 420 (Fed. Cl. 2009) (rev'd on other grounds by 672 F.3d 1309 (Fed. Cir 2012)) Align says that Respondents reliance on *Asahi Glass* is misplaced because the district court in that case merely declined to address § 271(g) where there was already a remedy under § 271(a).

(Citing *Asahi Glass Co. Ltd. v. Guardian Indus. Corp.*, 813 F. Supp. 2d 602, 613-14 (D. Del. 2011))

Align asserts that infringement under § 271(g) is not limited to "importation." Align says that one can also infringe under § 271(g) by offering to sell, selling, or using a product made by a process patented in the U.S. Align continues that infringement by these acts relates to the product as sold or used – not as it is imported. (Citing *Avery*, 1997 U.S. Dist. LEXIS 16535, at *7) Align continues that the court in *Avery* held that, where the first two steps of a three step process were performed outside the U.S. by the manufacturer and the third step was performed in the U.S. by the retailer, the entire three-step process could directly infringe under § 271(g), and that the manufacturer was a contributory infringer. (Citing *Id.* at *3-7)

Align asserts that *NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1323 (Fed. Cir. 2005) is not on point because it is directed to e-mail messages. Align says that the more applicable analysis is that in *CNET Networks, Inc. v. Etilize, Inc.*, 528 F. Supp. 2d 985, 995 (N.D. Cal. 2007). Align avers that Respondents attempt to distinguish their products from the electronic catalog in *CNET* by claiming that the digital data set is mere "information, not a copy of a physical object." Align disagrees, saying that Respondents have admitted that the digital data set is "a virtual three-dimensional model of the patient's teeth," (Citing Tr. at 315:10-18, 170:18-24, 171:8-11; 171:25-172:6) and are used to fabricate appliances. (Citing Tr. at 168:24-169:2, 320:6-321:2)

Respondents' Position: Respondents assert that Mr. Beers combines the conduct of the Respondents to reach his conclusion that there is direct infringement. Respondents say that this is improper as a matter of law in the context of a claim for direct infringement. (Citing *Akamai Tech., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301, 1307 (Fed. Cir. 2012) (permitting

combined conduct only for a claim of induced infringement)) Respondents continue that CCUS and CCPK cannot jointly infringe. Respondents say that Align has previously contended that CCPK improperly caused CCUS to infringe and now contends that CCUS caused CCPK to infringe. Respondents disagree, saying that the evidence presented at the hearing shows that CCUS and CCPK are two separate entities.

Respondents say that CCPK is not a subsidiary of CCUS. (Citing Tr. at 355:22-24) Respondents continue that CCUS has never owned any part of CCPK (Citing Tr. at 356:3-5) and there is no common ownership between the companies. (Citing Tr. at 356:9-11) Respondents say that they keep separate finances, have no common officers, directors or business departments, and do not have consolidated financial statements or tax returns. (Citing Tr. at 356:6-8, 356:12-24) Respondent say that CCUS did not cause the incorporation of CCPK and their daily operations are kept separate. (Citing Tr. at 358:1-3, 357:4-6)

{ } (Citing Tr. at 319:7-11) Respondents argue that this is no different than any contractor giving job specifications to a subcontractor. {

} (Citing Tr. at 359:2– 360:4)

Respondents argue that Align offered no evidence of the business formalities that have been ignored by Respondents. Respondents add that Mr. Rathore testified that CCPK is a Pakistani

corporation, and he has followed the instructions of his attorneys and CPAs to do whatever is required by the laws of Pakistan. (Citing Tr. at 446:5-15)

Respondents add that even if there were an overlap of ownership, the law is settled that absent a strong showing of one party exerting control over the other party or inducement, the conduct cannot be combined. (Citing *Akamai Tech., Inc.*, 692 F.3d at 1307-08) Respondents conclude that Align's claims of infringement should be denied for each theory based on joint infringement between CCUS and CCPK.

Respondents assert that the Federal Circuit has also held that "[u]nder section 271(a), the concept of 'use' of a patented method or process is fundamentally different from the use of a patented system or device." (Citing *NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1317 (Fed. Cir. 2005)) Respondents continue that the Federal Circuit held that "[w]e therefore hold that a process cannot be used 'within' the United States as required by section 271(a) unless each of the steps is performed within this country." (Citing *id.* at 1318) Respondents contend that the Federal Circuit has recognized the principle that "if a private party practiced even one step of a patented process outside the United States, it avoided infringement liability . . . ." (Citing *id.* (citing *Zoltek Corp. v. United States*, 51 Fed. Cl. 829, 836 (2002))) Respondents conclude that there can be no infringement under 271(a) if any part of a step is performed outside of the U.S.

Respondents argue that even if 271(g) did apply in Section 337 investigations, it would not apply in a case of "divided infringement" where part of the process is performed in the U.S. Respondents say that in *Asahi Glass Co., Ltd. v. Guardian Indus. Corp.*, 813 F.Supp.2d 602, 613-14 (D. Del. 2011), a federal court declined to apply § 271(g) to domestically-manufactured goods since § 271(a) covers those uses by providing the patentee with a cause of action against the domestic suppliers who use the process in the U.S.. Respondents contend that the plain

language of § 271(g) also requires importation of "a product which is made by a process patented in the United States." Respondents assert that if a part of the process is done in the U.S. after importation, there would be no product made by a patented process at the time of importation under § 271(g). Respondents conclude that Align's arguments of infringement should be denied as to any patent claims that are practiced, at least in part, both in the United States and in Pakistan.

Respondents agree with the Staff that 35 U.S.C. § 271(g) is not available as a basis for infringement under Section 337 and adopt the arguments in the Staff's Brief. Respondents say that the Federal Circuit held in *Kinik Co. v. International Trade Commission*, 362 F.3d 1359 (Fed. Cir. 2004) that the defenses under 271(g) do not apply in Section 337 proceedings. Respondents contend that it logically follows that 271(g) cannot be used affirmatively as a basis for relief under Section 337.

Respondents assert that Align's claims under 35 U.S.C. § 271(g) also fail a matter of law because 271(g) does not apply to the transmission of information, such as computer files, digital data sets and treatment plans as alleged by Align. Respondents say that the Federal Circuit has held "[w]e conclude that infringement under 35 U.S.C. § 271(g) is limited to physical goods that were manufactured and does not include information generated by a patented process." (Citing *Bayer AG v. Housey Pharm., Inc.* 340 F.3d 1367, 1368 (Fed. Cir. 2003)) Respondents continue that The Federal Circuit has reaffirmed this ruling, holding that the "transmission of information" is not covered by § 271(g). (Citing *NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1323 (Fed. Cir. 2005))

Respondents say that Align has suggested that the district court in *CNET Networks, Inc. v. Etilize, Inc.* 528 F.Supp.2d 985, 995 (N.D. Cal. 2007) overturned this long settled Federal

Circuit precedent. Respondents disagree, saying that the product in that case was an electronic copy of catalogs and the *CNET* Court found that there was no distinction between the electronic copy of the catalog and the physical catalog. Respondents contend that this holding stands in stark contrast to Align's allegations here. Respondents say that Align alleges that digital data, treatment plans, and computer files are generated as a result of its asserted claims. Respondents contend that data is information, not a copy of a physical object, and § 271(g) does not apply.

Respondents argue Align's claims under § 271(g) are precluded because there is a material change between the "product" alleged to be "imported" that supposedly contributes to infringement and the product ultimately sold, physical aligners. Respondents contend that while the Federal Circuit in *Kinik* held that the defenses of § 271(g) do not apply in Section 337 investigations, Respondents submit that if the substantive provisions of § 271(g) did apply, then the defenses would have to apply as well and would preclude a finding of infringement.

Respondents assert that Section 1337(a)(1)(B)(i) protects against only unfair acts involving "[t]he importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that "infringe a valid and enforceable United States patent ..." (Citing 19 U.S.C. § 1337(a)(1)(B)(i)) Respondents say that the Commission has explained that only infringement that occurs in the importation, sale after importation, or sale for importation can form the basis for a violation of Section 337. (Citing *Certain Electronic Devices With Image Processing Systems, Components Thereof, and Associated Software*, Inv. No. 337-TA-724, Comm'n Op. at 10 (Dec. 21, 2011)) Respondents argue that the articles must infringe at the time of importation and a violation cannot be based on purely domestic activity like testing of an infringing product. (Citing *id.* at 14)

Respondents assert that Section 1337(a)(1)(B)(i) does not apply to Align's method claims, which are the vast majority of the asserted claims (other than the three claims of the '487 patent directed to "treatment plans"). Respondents say that to the extent that Align argues that CCUS is inducing conduct by CCPK, Section 337(a)(1)(B)(i) does not apply because Align is essentially arguing an unfair act in the exportation of information or computer files from the U.S. to Pakistan. Respondents say that this is not an unfair act in the importation of articles into the United States, and would be outside of the Commission's jurisdiction.

Respondents argue that for method claims, a complainant must prove infringement at the time of importation in order to demonstrate a violation of Section 337. (Citing *Electronic Devices* at 17) Respondents say that the Commission noted in *Electronic Devices* that "[m]erely importing a device that may be used to perform a patented method does not constitute direct infringement of a claim to that method." (Citing *Id.* at 12) Respondents conclude that there can be no violation of Section 337(a)(1)(B)(ii) if part of the patented process is performed in the United States. Respondents add that there can be no violation of Section 337(a)(1)(B)(ii) at the time of importation for the asserted method claims that are directed to fabricating orthodontic appliances. Respondents say that it is undisputed that those appliances are not fabricated until after the digital information prepared in Pakistan is received in the United States and no dental appliances have been made, and thus no allegedly infringing product exists, that has been "made, produced, processed, or mined under, or by means of" a process patent at the time of "importation."

Respondents assert that Align relies in substantial part upon CCPK's foreign conduct to argue infringement, which is contrary to well settled law. Respondents say that there is a strong presumption against the extraterritorial application of United States patent law. (Citing *Cardiac*

Pacemakers, Inc. v. St. Jude Medical, Inc., 576 F.3d 1348, 1365 (Fed. Cir. 2009)) Respondents continue that the Federal Circuit has been especially clear on this point as it pertains to the direct infringement of method claims. (Citing *NTB, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1313 (Fed. Cir. 2005)) Respondents add that the Federal Circuit has also held that "[u]nder section 271(a), the concept of 'use' of a patented method or process is fundamentally different from the use of a patented system or device." (Citing *id.*) Respondent say that "if a private party practiced even one step of a patented process outside the United States, it avoided infringement liability . . . ." (Citing *id.*)

Respondents say that to the extent Align attempts to argue infringement under the doctrine of equivalents, it has not met its burden, and any such claim should be precluded based on Align's failure to provide adequate disclosures and support for any contention under the doctrine of equivalents. Respondents incorporate by reference the arguments made in their Motion in Limine concerning doctrine of equivalents. Respondent say that I held that Align may not offer any particularized evidence, including testimony, regarding infringement under the doctrine of equivalents. (Citing Tr. 41:8-14; 42:7-14.) Respondents further contend that where Align fails to establish infringement of any claim element, the evidence is insufficient to show infringement of that claim element under the doctrine of equivalents.

Respondents assert that Align's expert witness on infringement, Andrew Beers, was accepted as an expert only in "3D computer software and graphics and their use in orthodontics as software, including clear aligners" and was not accepted as an expert in orthodontics or as any type of dental professional. (Citing Tr. at 512:1-11) Respondents say that his expert report was obviously written by Align's lawyers, and Mr. Beers signed it without even reading it carefully. (Citing Tr. at 516:7-9, 518:11-16, 519:4-10, 520:7-15, 520:16-24, 521:2-9, 521:10-19)

Respondents continue that Mr. Beers testified that he "can't really talking [sic] about infringement;" rather, he offered "an analysis of all the elements in the claim and a comparison to what the Respondents do." (Citing Tr. at 531:1-7) Respondents say that his witness statement is replete with his conclusions about infringement (Citing CX-1150C at Q. 170, 173, 175, 177, 184, 185, 187, 188, 195, 197, 199, 212, 214, 216, 227, 238, 240, 246, 248, 250, 254, 255, 257, 258, 260, 261, 268, 269, 271, 279, 281, 288, 290, 296, 301, 303, 308, 311, 314, 321, 323, 325, 327, 329, 331, 338) Respondents conclude that Mr. Beers should not be viewed as providing independent, credible proof on any issue on which Align bears the burden and since he was Align's only expert witness on infringement, Align has not met its burden of proof on any claim, and Respondents should not to be found to have infringed any claim at issue in this case.

Staff's Position: Staff says that Section 337(a)(1)(B)(i) prohibits "the importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that – (i) *infringe* a valid and enforceable United States patent." (Citing 19 U.S.C. §1337(a)(1)(B)(i) (emphasis added)) Staff continues that the Commission has held that the word "infringe" in Section 337(a)(1)(B)(i) "derives its legal meaning from 35 U.S.C. § 271, the section of the Patent Act that defines patent infringement." (Citing *Certain Electronic Devices with Image Processing Systems, Components Thereof, and Associated Software*, Inv. 337-TA-724, Comm'n Opinion at 13-14 (December 21, 2011) ("*Electronic Devices*")) Staff explains that Section 271 defines infringement "to include direct infringement (35 U.S.C. § 271(a)) and the two varieties of indirect infringement, active inducement of infringement and contributory infringement (35 U.S.C. § 271(b), (c))." (Citing *id.*) Staff adds that the term "articles that -- infringe" in Section 337(a)(1)(B)(i) references "the status of the articles at the time of importation." *Id.* Staff says that indirect infringement can be found,

at the time of importation, if the imported articles induce infringement or contributorily infringe based on a subsequent (*i.e.*, post-importation) direct infringement of a method claim. (Citing *Electronic Devices*, Inv. No. 337-TA-724, Comm'n Opinion at 18-19)

The Staff disagrees with the finding in Order No. 20, and Staff says that the Commission has made clear that, for purposes of Section 337(a)(1)(B)(i), the meaning of "infringe" derives from Section 271. (Citing *Electronic Devices*, Inv. 337-TA-724, Comm'n Opinion at 13-14) Staff continues that the Commission has also rejected attempts that seek to interpret the word "infringe" more broadly than the statutory meaning. (Citing *id.* at 17-19) Staff reasons that activity which does not constitute "infringement" (either direct or indirect) under Section 271 does not constitute infringement under Section 337(a)(1)(B)(i).

Staff argues that direct infringement of a method claim, for purposes of Section 337(a)(1)(B)(i), must occur pursuant to 35 U.S.C. § 271(a) and cannot be premised on 35 U.S.C. § 271(g). (Citing *Certain DC-DC Controllers and Products Containing the Same*, Inv. 337-TA-698, Comm'n Opinion at 13 (January 4, 2013) ("*DC-DC Controllers*")) Staff concludes that where the steps of a method are not all performed within the United States, no direct infringement exists.

Staff says that Section 271(a) is commonly understood as the "direct infringement" statute, and requires that each step of a claimed method be performed within the United States. (Citing 35 U.S.C. § 271(a); *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S.Ct. 2060, 2065 (2011); *Akamai Technologies, Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301, 1309 (Fed. Cir. 2012) ("*Akamai*"); *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1318 (Fed. Cir. 2005) ("*NTP*"); *Electronic Devices*, Inv. 337-TA-724, Comm'n Opinion at 13. Staff continues that the Commission has acknowledged that section 271(a) applies to analysis of method claims in

Commission proceedings. (Citing *DC-DC Controllers, supra*; *Electronic Devices, supra*, at 17-18) Staff says that Section 271(g)'s status before the Commission was discussed in *Kinik Co. v. International Trade Commission*, 362 F.3d 1359 (Fed. Cir. 2004). Staff explains that in *Kinik*, the Federal Circuit affirmed the Commission's determination that the defenses to 35 U.S.C. §271(g), concerning the meaning of product "made by a patented process," do not apply in section 337(a)(1)(B)(ii) actions. (Citing 362 F.3d at 1363) Staff says that the Commission and the Federal Circuit noted that section 271(g)'s language expressly limited the application of these defenses "for purposes of this title" -- *i.e.*, to actions brought in district court pursuant to Title 35, not before the Commission pursuant to Title 19. (Citing *Certain Abrasive Products Made Using A Process For Powder Pre-Forms*, Inv. 337-TA-449, 2002 WL 31093607 at *2, Comm'n Opinion (July 26, 2002)("*Abrasive Products*"); *Kinik*, 362 F.3d at 1362) Staff continues that the Federal Circuit further acknowledged the legislative distinction between the different tribunals with regard to certain infringement issues. (Citing *Kinik*, 362 F.2d at 1363.)

Staff argues that *Kinik*'s holding regarding Section 271(g)'s defenses indicates that Section 271(g) infringement claims are also not cognizable as direct infringement before the Commission. Staff says that In light of *Kinik*, asserting 35 U.S.C. § 271(g) before the Commission would extend the word "infringe," as used in Section 337(a)(1)(B)(i), beyond the meaning of patent infringement under 35 U.S.C. § 271 by imposing one portion of section 271(g) without its concomitant limitations, and would therefore be improper.

Staff contends that Congress enacted 35 U.S.C. § 271(g)'s process patent provisions at the same time, and within the same act, as it incorporated the Commission's separate process patent authority into 19 U.S.C. 1337(a)(1)(B)(ii). (Citing *Abrasive Products*, Inv. 337-TA-449, 2002 WL 31093607 at *2, Comm'n Opinion) Staff argues that had Congress intended to

incorporate the process patent standards of 35 U.S.C. § 271(g) into the Commission's authority regarding process patents, it could have done so explicitly. (Citing *id.*) Staff concludes that the *Kinik* court indicated that the Commission assesses overseas violations of process patents pursuant to the pre-existing Tariff Act process patent provisions of 19 U.S.C. § 1337(a)(1)(B)(ii), and that the Section 271(g) exceptions do not apply to these (B)(ii) claims. (Citing *Amgen, Inc. v. International Trade Commission*, 565 F.3d 846, 851 (Fed. Cir. 2009))

Staff avers that it is not aware of any post-*Kinik* Commission opinions that have adopted an infringement theory based on 271(g). Rather, Staff says that in *Certain Rubber Antidegradants, Components Thereof, and Products Containing Same*, Inv. No. 337-TA-533, the ALJ's Final Initial and Recommended Determination discussed the legal standards for infringement, referring in passing to 271(a) and 271(g). (Citing *Id.*, 2006 WL 1196473 at *48) Staff continues that in the opinion reviewing that decision, the Commission re-characterized the infringement determination as one that should be assessed pursuant to Section 337(a)(1)(B)(ii). (Citing *Rubber Antidegradants*, Inv. 337-TA-533, Comm'n Opinion at 2, 9 n.2 (July 24, 2006) ("We understand the term 'infringe' in this investigation as referring to a violation of section 337(a)(1)(B)(ii).")) Staff reasons that the Commission's correction provides an additional indication that, under current precedent, allegations concerning overseas violations of process patents should be brought pursuant to 19 U.S.C. § 1337(a)(1)(B)(ii), not through 35 U.S.C. § 271(g). Staff concludes, as a result, that a finding of "direct infringement" pursuant to Section 337(a)(1)(B)(i) -- specifically, direct infringement to support a finding of induced or contributory infringement -- must meet 35 U.S.C. § 271(a) standards for infringement.

Staff says that Section 337(a)(1)(B)(ii) prohibits "the importation into the United States, the sale for importation, or the sale within the United States after importation by the owner,

importer, or consignee, of articles that are "made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable patent." (Citing 19 U.S.C. §1337(a)(1)(B)(ii)) Staff continues that the Commission has held that "infringement" can also be found pursuant to Section 337(a)(1)(B)(ii). (Citing *Rubber Antidegradants*, Comm'n Opinion at 2, 9 n.2)

Analysis and Conclusion: There are three key disputes between the parties that are relevant to all asserted patents. The first dispute is whether or not all steps of a method claim must be practiced in the same country to find a violation of Section 337. In Order No. 20, I found that they do not. Section 337 and Section 271 create separate causes of action in separate tribunals and use different language in creating those causes of action. Section 337 addresses unfair practices in import trade, and it provides, in pertinent part:

> (a) Unlawful activities; covered industries; definitions
>
> (1) Subject to paragraph (2), the following are unlawful, and when found by the Commission to exist shall be dealt with, in addition to any other provision of law, as provided in this section:
>
> ***
>
> (B) The importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that—
>
> (i)infringe a valid and enforceable United States patent ... or
> (ii) are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent.

19 C.F.R. §§ 1337(a)(1)(B)(i) and (ii). In contrast, Section 271 addresses acts within the United States and provides, in relevant part, that "[e]xcept as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent

therefor, infringes the patent." 35 U.S.C. § 271(a); *see NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1313 (Fed. Cir. 2005)(noting that "[t]he territorial reach of section 271 is limited" and holding that "a process cannot be used 'within' the United States as required by section 271(a) unless each of the steps is performed within this country.").

The Federal Circuit acknowledged the distinctions between the two statutory provisions, when it stated that "[t]he purpose of section 337 from its inception was to provide relief to United States industry from unfair acts, including infringement of United States patents by goods manufactured abroad." *Lannom Mfg. Co., Inc. v. U.S.I.T.C.*, 799 F.2d 1572, 1580 (Fed. Cir. 1986).

The Commission, too, has recognized the distinctions between Sections 337 and 271. The Commission has explained that the word "infringe" in section 337 derives its legal meaning from 35 U.S.C. § 271. *Certain Electronic Devices With Image Processing Systems, Components Thereof, and Associated Software*, Inv. No. 337-TA-724, Comm'n Op. (Dec. 21, 2011)("Certain Electronic Devices") The Commission made clear, however, that a violation of section 337 does not depend upon a violation of section 271, when it said:

> [W]e do not agree . . . that direct infringement must precede importation in order for the Commission's remedial orders to reach products, such as software, that contributorily infringe [Complainants][] patents.
>
> By its terms, section 337 is not limited to articles that directly infringe a valid and enforceable United States patent. As the ALJ noted, ***section 337 does not distinguish between direct, contributory, or induced infringement***, and the Commission has adopted the ALJ's finding that section 337 incorporates the indirect forms of infringement provided for in the patent statute.

Certain Hardware Logic Emulation Systems, Inv. No. 337-TA-383, Comm'n Op. (March 1998) (citations omitted)(emphasis added).

Staff cites *Certain DC-DC Controllers and Products Containing the Same*, Inv. 337-TA-698, Comm'n Opinion at 13 (January 4, 2013) ("*DC-DC Controllers*") to support its position that direct infringement of a method claim, for purposes of Section 337(a)(1)(B)(i), must occur pursuant to 35 U.S.C. § 271(a) and cannot be premised on 35 U.S.C. § 271(g). In the enforcement action related to a Consent Order issued previously in *DC-DC Controllers*, the Commission recited, "Direct infringement of a method claim can only be shown by performance of the patented method in the United States." (Citing *NTP v. RIM* and *Certain Electronic Devices*, *17)

NTP v. RIM is not controlling on this point. The Commission has made clear (and Staff concedes) that, while an act of direct infringement is a requirement to find contributory infringement, there is no requirement that the direct infringement occur prior to importation, and articles that contributorily infringe prior to importation may be the subject of Commission remedial orders. *Certain Hardware Logic Emulation Systems*, Inv. No. 337-TA-383, Comm'n Op. at 18-19 (March 1998). I reaffirm my finding that the parties' arguments regarding the territorial limitations found in *NTP v. RIM* to apply to 35 U.S.C. § 271 are irrelevant to whether or not Respondents violate 19 U.S.C. § 1337(a)(1)(B)(i) or (ii).

Electronic Devices, too, is not controlling. In that case it was argued that mere importation of an infringing device practiced a "method" covered by a patent. The Commission held that "the act of importation is not an act that practices the steps of the asserted method claim." The Commission went on to say that "[m]erely importing a device that may be used to perform a patented method does not constitute direct infringement of a claim to that method." *Electronic Devices*, at 17 (Citing, *inter alia*, *NTP v. RIM*) Nothing in *Electronic Devices* touches

on the specific facts of the case before me. Here, the scope of the investigation includes both 19 U.S.C. §§ 1337(a)(1)(B)(i) and (ii).

While I recognize that the word "infringe" in section 337 derives its legal meaning from 35 U.S.C. § 271, I do not concur with Staff that proof of a violation of direct infringement pursuant to 19 U.S.C. §§ 1337(a)(1)(B)(i) requires that all elements of 35 U.S.C. § 271(a) be met – including the requirement that the violation occur in the United States. In addition, I note that the case at bar is one that involves patents-in-suit that protect processes. Importation of articles that are made or produced pursuant to claimed processes are properly treated under 19 U.S.C. § 1337(a)(1)(B)(ii). Using Staff's logic regarding 35 U.S.C. § 271(a) consistently, one would reason that the latter claims would then refer back to 35 U.S.C. § 271(g).

I believe that Staff makes an incorrect logical leap when they argue that *Kinik*'s holding regarding Section 271(g)'s defenses indicates that Section 271(g) infringement claims are also not cognizable as direct infringement before the Commission. In fact, in *Kinik Company v. ITC*, 362 F.3d 1359 (Fed. Cir., 2004), the court noted at page 1361,

> The Commission held that the recently enacted defenses to infringement, when the issue is offshore practice of a patented process, do not apply to infringement actions before the International Trade Commission.

and at, page 1362,

> The Commission relied for its interpretation on the Process Patent Amendments Act of 1988, which states, in adding § 271(g) to Title 35, that "[t]he amendments made by this subtitle shall not deprive a patent owner of any remedies available ... under section 337 of the Tariff Act of 1930, or under any other provision of law." Pub. L. 100–418, § 9006(c). The Commission held that the new defenses under § 271(g) were not intended to be available in ITC actions, for to hold otherwise would deprive the patent owner of a remedy available under the Tariff Act. **The Commission pointed to the explicit statement that the existing scope of**

> **§ 337 actions would not be diminished**, and that § 271(g), in the clause introducing the new defenses to infringement by overseas practice, states that they are "for purposes of this title." Such clause would have been unnecessary unless it served to avert conflict between the Patent Act and the Tariff Act, for the contemporaneous record shows that such conflict was recognized. *See Duncan v. Walker*, 533 U.S. 167, 174, 121 S.Ct. 2120, 150 L.Ed.2d 251 (2001) (it is "a cardinal principle of statutory construction" that "a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant"). (emphasis added)

The court found,

> The purpose of § 271(g) was to authorize the district courts to adjudicate and impose liability for infringement based on the overseas practice of processes patented in the United States, upon importation of the products of those processes. **Previously, remedy was available only by exclusion action under the Tariff Act.**

(*Kinik*, at 1362)(emphasis added)

In upholding the Commission's ruling the court discussed this issue in detail, saying

> The Commission ruled that the enactment of § 271(g) preserved § 337(a) undiminished by the new defenses provided for § 271(g) actions in district court. To the extent that there is any uncertainty or ambiguity in the interpretation of § 337(a) and its successor § 1337(a)(1)(B)(ii), deference must be given to the view of the agency that is charged with its administration. *Chevron U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837, 843, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984). In *Amgen, Inc. v. United States Int'l Trade Comm'n*, 902 F.2d 1532, 1540 n. 13 (Fed.Cir.1990) **this court observed that no material changes were made in the text of § 1337(a)(1)(B)(ii) as reenacted in 1988, despite the concurrent enactment of § 271(g), reinforcing the intention to preserve the scope of former § 337a.** The *Amgen* court pointed out that § 271(g) expressly limited the new defenses to infringement "for purpose of this title." Although Kinik argues that it is anomalous to create a legislative distinction in the defenses available in different tribunals, before this enactment there was an even greater distinction, for overseas manufacture could not be reached at all in the district courts.

(*Kinik* at 1363)(emphasis added)

It is readily apparent from the foregoing discussion in *Kinik* that, contrary to Staff's argument, while the defenses of § 271(g) were found not to apply to exclusion cases before the Commission, that finding did not eliminate § 271(g) as a source to be used by the Commission in a manner similar to § 271(a).

Based upon all of the foregoing, I find that Respondents do not escape a violation of Section 337 as a matter of law merely because they practice some elements of the asserted method claims within the United States and other elements of the asserted method claims outside of the United States[31]. This is true for all patents-in-suit in this investigation.

The second dispute between the parties is based on Respondents' argument that the digital data sets cannot be found infringing because they are not "articles" within the scope of 19 U.S.C. § 1337. For the reasons discussed in Sections II.A and II.C, these arguments are unpersuasive.

The third general dispute between the parties is whether or not Align can meet its burden of proving infringement through the testimony of Mr. Beers. The essence of Respondents' argument is that because Mr. Beers (i) was accepted as an expert only in "3D computer software and graphics and their use in orthodontics as software, including clear aligners," (Tr. at 511:25-512:11) (ii) said that he "can't really talk[] about infringement," (Tr. at 531:1-7), and (iii) made

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[31] In *Akamai Technologies, Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301, 1309 (Fed. Cir. 2012) ("*Akamai*") the Federal Circuit held that in indirect infringement cases, the underlying "direct infringement" doesn't require that a single entity practice all the steps of a claim; rather, all of the claimed steps must be performed. While not directly relevant to the question of whether or not claims must be practiced entirely within the same country, it does establish that CCUS and CCPK cannot escape responsibility by asserting that they only performed some of the elements while the other party performed other elements.

mistakes in his witness statement regarding where "festooning" occurs (Tr. at 518:11-16), Mr. Beers cannot be relied upon to show infringement. This argument is without merit.

Mr. Beers was accepted as an expert in 3D computer software and graphics and their use in orthodontics as software, including clear aligners. (Tr. at 511:25-512:11) His expertise falls within the scope of one of ordinary skill in the art found in Sections III.B.2, III.C.2, III.D.2, III.E.2, III.F.2, III.F.2, and III.G.2, *supra*. Mr. Beers' testimony that he "can't really talk[] about infringement" was taken out of context and does not warrant preventing Mr. Beers from providing testimony on infringement. Immediately after the statement cited by Respondents, Mr. Beers explained that "I can do exactly what I presented, which was an analysis of all the elements in the claim and a comparison to what the Respondents do." (Tr. at 531:4-7)

Regarding the mistakes made by Mr. Beers in his witness statement about where "festooning" occurs, the errors clearly were typographical in nature based on the context of the witness statement. In response to Question 193, Mr. Beers stated that "[a]lthough ClearCorrect USA festoons and provides four digital models to ClearCorrect USA at a time, eventually, ClearCorrect Pakistan will have produced and provided the entire treatment plan, from initial to final tooth arrangement, to ClearCorrect USA." (CX-1150C at Q. 193) Mr. Beers clearly did not intend to say that CCUS provided digital models to itself, and such a statement was clearly in error. Mr. Beers explained the errors during cross-examination. (Tr. at 518:11-16) Based upon all of the foregoing, Respondents' argument based on Mr. Beers qualifications is without merit.

2. Claim 1

Asserted claim 1 teaches:

> A method for facilitating a tooth repositioning dental treatment, including producing a plurality of digital sets representing a plurality of tooth arrangements, said method comprising:

providing an initial digital data set representing an initial tooth arrangement;

presenting a visual image based on the initial data set;

manipulating the visual image to reposition individual teeth in the visual image;

producing a final digital data set representing the final tooth arrangement with repositioned teeth as observed in the image;

producing a plurality of intermediate digital data sets representing a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement; and

fabricating a plurality of successive tooth repositioning appliances, at least some of which are related to at least some of the produced digital data sets.

(JX-0003 at R1:29-48)

Align's position: Align contends that the asserted claims of the '325 Patent are process claims with straightforward language. Align avers that Respondents' processes infringe these claims, as explained in full in the direct testimony of Align's expert, Andrew Beers (Citing CX-1150C at Q. 149-240), along with his detailed "claim chart" comparison of the claim language with Respondents' process (Citing CX-1198C at 99-188).

Align asserts that CCUS's aligners are made according to each of the claimed steps in claim 1 by the joint CCUS/CCPK process, and are sold, offered for sale, and used in the U.S. (Citing Tr. at 312:20-314:3) Align continues that CCUS's aligners directly infringe under 35 U.S.C. § 271(g).

Turning to the claims, Align says that the preamble of claim 1 is not limiting, as it merely states the purpose of the claimed method. (Citing *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999)) Align continues that Respondents have not asserted the

contrary in their Prehearing Brief, and have therefore waived such a position. Align concludes, as a result, that an infringement analysis of the preamble is unnecessary.

Alternatively, Align asserts that if the preamble is limiting, Respondents practice the preamble by their joint method of designing, making and selling clear aligners, where {

} (Citing CX-1150C at Q. 201) Align continues that Respondents provide these aligners to patients to "facilitate" dental treatment. Align says that {

} Align adds that these physical models are positive representations of the patient's tooth arrangements at each step, based on the digital models. (Citing CX-0875C (single printed physical mold))

Align says that {

} Align says that the aligners are meant to be worn for period of three weeks, 22 hours a day, in proper sequence. (Citing Tr. at 342:7-15; CX-0074A at 26, 28; CX-078 at 25.) Align continues that the tooth arrangement of each subsequent aligner, or the geometry of the aligner, changes slightly in order

to progressively reposition the teeth. (Citing CX-078 at 25) Align adds that CCUS ships paperwork with the aligners that describes the "treatment plan" prepared for the dentist that includes the four steps of the phase. (Citing CX-078 at 64-68; CX-0069 (an example of this paperwork from a sample case)) Align refers to this evidence regarding Respondents' process as evidence category 10.

Align asserts that CCUS practices the first element of claim 1, which requires "providing an initial digital data set ...," {

}

Align says that {

} (Citing Tr. at 170:25-171:7, 315:19-23, 329:22-330:8; CX-1160C.3 at 472:3-13; CX-1164C.1 at 101:13-102:17; CX-1151C.1 at 211:22-214:13.) Align continues that {

} (Citing Tr. at 170:25-172:9, 206:21-207:3, 315:19-316:3, 329:22-330:8; CX-0090C at 3-4 ("Download the allocated case data . . ."); CX-1151C.1 at 212:1-11; CX-1160C.3 at 472:3-13) Next, Align says that {

} (Citing Tr. at 173:18-21, 178:23-179:3, 330:11-20, 474:11-21, 526:6-11; CX-0090C at 3-4; CX-1151C.1 at 198:12-199:9, 214:16-215:6; CX-1157C.1-3 at 48:13-49:15.)

Align contends that {

} Align avers that these models all represent a patient's initial tooth arrangement. (Citing Tr. at 219:24-220:5, 225:17-22; CX-0090C at 3-26; CX-1157C.1-3 at 47:25-62:22, 78:11-18) In the process, Align says that {

} (Citing Tr. at 171:25-172:6; CX-078 at 55; CX-0090C at 20-21 ("<Case#>-Before_Upper.Stl," "<Case#>-Before_Lower.Stl."); CX-1157C.1-3 at 78:11-18) Align continues that {

} (Citing Tr. at 172:10-14; CX-0090C at 20-26.)

Align says that next, {

} (Citing Tr. at 219:24-220:5, 257:3-8; CX-0092C) Align explains that the { } (Citing Tr. at 219:24-220:5, 225:17-22; CX-0110C at 2.) Align continues that {

} (Citing Tr. at 168:14-20, 316:12-22; CX-0110C at 2; CX-1160C.1 at 97:22-25; 98:15-99:12; CX-0110C at 2; CX-1151C.1 at 235:8-17)

Align says that next, {

} (Citing Tr. at 190:14-23, 191:4-7, CX-1157C.1-3 at 60:2-62:22). Align continues that {

}

Align avers that Respondents' protocols aim to produce "[d]igital files required to produce accurate thermoformable models which will result in aligners for patient cases from beginning to end of their clear aligner therapy treatment" (Citing CX-0110C at 2; Tr. at 180:18-181:3), and CCUS has verified the accuracy of the software used to create the 3D digital models of the patients' teeth, and therefore produce substantially accurate shapes of the teeth in their initial, intermediate and final positions. (Citing CX-0937C; Tr. at 247:14-248:5; see also CX-1164C.1 at 101:6-18) Align refers to this evidence regarding Respondents' process as evidence category 1.

Align asserts that CCUS alternatively practices this element when it {

} (Citing CX-1150C at Q. 204) Align asserts that CCPK also performs this element when it { } (Citing CX-1150C at Q. 204) Align continues that CCPK alternatively practices this element when it {

} (Citing CX-1150C at Q. 204.) Align avers that Respondents take no issue with Align's identification of CCUS's

infringing actions, but argue that there is no evidence that CCPK performs this limitation. Align says that Respondents did not contest infringement of this element in their interrogatory responses, and thus cannot argue non-infringement here.

Align asserts that CCPK practices the second element of claim 1, which requires "presenting a visual image ...," when it {

} (Citing CX-1150C at Q. 205) Align says that {

} (Citing CX-0090C at 6-8; CX-078 at 55; CX-0104C; CX-0105C; Tr. at 179:4-13; CX-1157C.1- 3 at 49:2–50:17; CX- 1151C.1 at 198:12–199:9, 298:7–311:7; CDX-0012C; CDX-0013C) Align continues that {

} (Citing Tr. at 173:18-21; CX-0889C; CX-0104C; CX-0105C; CX-0106C; CX-0107C; CX-0090C at 31-55; CX-1157C.3 at 50:23-80:13) Align refers to this evidence regarding Respondents' process as evidence category 3. Align adds that Respondents do not contest they infringe this element. (Citing RX-0129C at Q. 47)

Align asserts that CCPK practices the third element of claim 1, which requires "manipulating the visual image...," after it {

}

(Citing CX-1150C at Q. 206) Align says that {

} (Citing Tr. at 329:22-333:9;

CX-0090C at 8-19; CX-0104C; CX-0105C; CX-0106C; CX-1157C.1-3 at 49:14-67:4; CDX-0014C; CDX-0015C)

Align says that {

} (Citing Tr. at 329:22-331:12; CX-0090C at 8-16; CX-1157C.1-3 at 49:2-54:9, 56:23-59:19.) Align continues that {

} (Citing Tr. at 311:3-10, 323:12-19; CX-1157C.1-3 at 50:15-52:2 {

} 52:15-54:9, 56:23-59:19, and 70:13-20; CX-0104C; CX-1158C.1-3 at 99:3-100:18; CX-0090C at 8-16; CX-0864C.) Align avers that boundaries are defined around each tooth, and may necessarily include gum material below the crown. (Citing CX-0865C; CX-0104 at 2:30-4:50; CX-1157C.1-3 at 52:15-54:9, 56:23-59:19) Align says that "tooth" is used in the asserted patents, and in Respondents' documents, as inclusive of the tooth and such additional materials. (Citing JX-0002 at 12:51-56; CX-0090C at 8, 14)

Align says that {

} (Citing Tr. at 190:20-191:7; CX-1157C.1-3 at 55:6-56:22, 60:20-62:3; CX-0104C at 11:30-12:35; CX-0090C at 9; CX-1158C.1-3 at 53:20-22) Align continues that {

} (Citing Tr. at 171:16-172:9, 191:1-14, 325:7-14; CX-0889C; CX-1157C.1-3 at 61:14-69:3; CX-0104C; CX-0105C) Align avers that to move the teeth, {

} (Citing CX-1157C.1-3 at 60:20-63:4, 63:15-69:3, 72:22-77:14; CX-1158C.1-3 at 100:19-101:21; CX-0105C; CX-0106C) Align refers to this evidence regarding Respondents' process as evidence category 4.

Align asserts that CCPK practices the fourth element of claim 1, which requires "producing a final digital data set …," by {

} (Citing CX-1150C at Q. 207) Align says that {

} (Citing Tr. at 171:16-172:9, 191:8-14, 325:7-14, 333:3-9; CX-0889C; CX-1157C.1-3 at 60:20-63:4, 63:15-69:3, 72:22-77:14; CX-1158C.1-3 at 53:23-25, 100:19-101:21; CX-0106C) Align says that {

} (Citing Tr. at 171:16-172:9, 191:8-14, 209:21-24, 210:5-20; CX-1157C.1-3 at 68:22-69:3; 73:2-77:14, 78:9-79:4; CX-0090C at 20-26 ("<Case#>-After_Upper.Stl" and "<Case#>-After_Lower.Stl")) Align continues that {

} (Citing Tr. at 172:10-14, 335:19-336:7; CX-0090C at 17-25; CX-1157C.1-3 at 48:14-68:21, 78:11-79:4) Align says that once the treatment setup is approved, {

} Align refers to this evidence regarding Respondents' process as evidence category 5.

Align contends that CCPK practices the fifth element of claim 1, which requires "producing a plurality of intermediate digital data sets …," when it {

} (Citing CX-1150C at Q. 208) Align says that {

} (Citing CX-0090C at 28-49; CX-1158C.1-3 at 54:1-83:18; CX-0107C; see CDX-0020C-21C) Align avers that the tooth arrangement in each "step" (i.e., the resulting intermediate tooth arrangement) represents an aligner step in the patient's treatment.

Align says that before stepping/staging can begin, the {

}

(Citing CX-0090C at 27-49; CX-1158C.1-3 at 51:4-83:21, 98:2-99:2) Align continues that the {

} (Citing Tr. at 325:21-326:9, 333:12-19, 334:2-9; CX-1158C.1-3 at 54:1-62:21; CX-0981; CX-0090C at 28-36; CX-0900C.) Align continues that {

}

(Citing CX-0086C at 1; CX-0090C at 28-29; CX-1158C.1-3 at 56:14-62:21) Align says that the

{

} (Citing CX-0090C at 28-29; see CX-0086C; CX-1158C.1-3 at 56:14-62:21.)

Align explains that the results of this calculation provide the minimum number of steps required to take the tooth from its initial to final position. (Citing CX-0090C at 28-29.)

Next, Align says that the {

} (Citing CX-0090C at 32; CX-0086C at 2; CX-0110C) Align continues that {

} (Citing CX-0086C at 1; CX-1158C.1-3 at 58:22-59:9, 62:16-63:2) Align says that {

} (Citing CX-0086C at 1)

Align contends that the {

} (Citing CX-1158C.1-3 at 67:2-86:14; CX-0107C) Align says that {

} (Citing CX-1158C.1-3 at 72:5-75:13; CX-0107C at 5:30-7:15) Align continues that the {

} (Citing CX-090C at 44; CX-0107C at 5:33) According to Align, at this point, {

} (Citing CX-0107C at 5:30-

7:15; see CX-0087C at 1; CX-1158C.1-3 at 62:25–72:18 (e.g. 70:5-71:4); CX-1151C.1 at 316:18–319:2)

Align says that {

}

(Citing CX-0107C at 5:30-7:15) Align continues that that {

} (Citing CX-0107C; CX-0087C at 1; CX-1158C.1-3 at 62:25–72:18; CX-0981; CX-1151C.1 at 198:12–199:9, 237:10–238:10, 259:4–260:4, 305:23–316:7.)

Align says that {

} (Citing CX-0087C at 1-2; CX-0107C; CX-1158C.1-3 at 68:21-70:4) According to Align, {

} (Citing CX-0087C at 1-2; CX-0107C; CX-1158C.1-3 at 69:16-70:4.)

Align contends that together {

} (Citing CX-0107C; CX-0090C at 44-47; CX-0087 at 1-2; CX-1158C.1-3 at 62:25–72:18; CX-1151C.1 at 198:12–199:9, 237:10–238:10, 259:4–260:4, 316:18–319:2) Align says that {

} (Citing CX-1158C.1-3 at 83:16-85:21; CX-1151C.1 at 262:12-263:13)

Align says that {

} (Citing Tr. at 193:3-16, 194:4-6, 477:3-14, 516:1-6; CX-1158C.1-3 at 70:21-71:1, 102:18-103:20; CX-0107C at 5:55-6:45) Align says that {

} (Citing Tr. at 316:12-22)

Align contends that {

} (Citing CX-1150C at Q. 134, 198, 280, 287, 313; CX-0090C at 44-47; CX-0107C; CX-0087C at 1-2; CX-1158C.1-3 at 71:11-72:18)

{

} Align refers to this evidence regarding Respondents' process as evidence category 7.

Align asserts that CCUS practices the sixth element of claim 1, which requires "fabricating a plurality of successive tooth repositioning appliances ...," {

} Align refers to this evidence regarding Respondents' process as evidence category 9. Align continues that Respondents did not contest infringement of this element in their interrogatory responses and cannot argue non-infringement here.

Align disagrees with Respondents' "all data sets" non-infringement argument. Align says that Respondents assert they do not infringe claim 1[32] of the '325 patent because phrases such as "intermediate digital data sets" require that all data sets for a patient's treatment be "produced prior to active treatment." Align says that this construction was not identified in the SRJCCC. Align continues that Respondents cite to no supporting evidence for such a construction. Align contends that Respondents still infringe under this construction because

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[32] Align says that Respondents also raise this argument for claims 11, 14, 31, 33, 35, and 38.

{

}

Align also contends that Respondents' "manipulating a visual image" non-infringement argument is incorrect. Align says that Respondents assert they do not infringe claim 1[33] of the '325 patent because the phrase "manipulating a visual image" cannot include manipulation by entering coordinates. Align says that Respondents are wrong for three reasons. Align says that this is a claim construction argument not identified in the SRJCCC. Align continues that the intrinsic record shows the opposite of Respondents' position because the patent specifications describe an exemplary Graphical User Interface that provides a user with "instant and visual interaction with the digital model components," and is adapted for manipulating the image. (Citing JX-0003 at 13:64-14:11; CX-1150C at Q. 124-125). Align says that Dr. Mah admitted that by changing the coordinates of the teeth, the new visual image reflects those coordinates. (Citing RX-0129C at Q. 48) {

} (Citing CX-1157C.1 at 66:22-67:4; CX-1158C.1 at 100:25-101:21)

Align asserts that Respondents' "final tooth arrangement" non-infringement argument is incorrect. Align says that Respondents assert they do not infringe claim 1[34] of the '325 patent

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[33] Align says that Respondents also raise this argument for claim 31.
[34] Align says that Respondents also raise this argument for claims , 11, 21, 31, 35, and 38.

because the phrase "final tooth arrangement" in the claims "can only be a projection at the treatment stage prior to active treatment." Align continues that Respondents appear to argue that the "final tooth arrangement" projected by Respondents' process is not really a "final tooth arrangement" because the clinician has the ability to change the course of treatment, and thus, a "final tooth arrangement" can only be the patient's actual tooth positions at the end of his treatment. Align contends that this construction was not identified in the SRJCCC and neither Respondents nor Dr. Mah cite to any supporting evidence. Align continues that the "final tooth arrangement" contemplated by the patents is simply the planned "final" position of the teeth, which is preferably according to a clinician's prescription. (Citing JX-0003 at 10:36-43; JX-0004 at 6:7-17; CX-1150C at Q. 347) Align says that Respondents' construction necessarily excludes preferred embodiments of the specification, and should be rejected. Align continues that planning a final position of teeth is exactly what Respondents' process does by manipulating the image into a final position according to the clinician's prescription and receiving approval. Align says that even in the event of a "mid-course corrections," or change to the course of treatment, Respondents must start the entire process over again to obtain a new "final" tooth arrangement. (Citing CX-1150C at Q. 137)

Align says that claim 1 of the '325 Patent specifies the production of a "final digital data set representing the final tooth arrangement" as part of its method. (Citing JX-0003 at 27 (1:38-40)) Align avers that the method creates the planned final tooth arrangement, which is confirmed by the specification of the '325 patent, which provides:

> after the IDDS has been obtained, the digital information will be introduced to the computer or other workstation for manipulation. In the preferred approach, individual teeth and other components will be "cut" to permit their individual repositioning or removal from the digital data. After thus "freeing" the components, the user will often follow a prescription or other written specification provided by the treating professional. Alternatively, the user may reposition them

> based on the visual appearance or using rules and algorithms programmed into the computer. Once the user is satisfied with the final arrangement, the ***final tooth arrangement*** is incorporated into a final digital data set (FDDS).

(Citing JX-0003 at 10:31-43 (emphasis added by Align)) Align reasons that it is therefore clearly the operator that is setting the "final tooth arrangement" as part of the process. Similarly, with respect to the "treatment plan" (*see* Sec. IV.F.5) produced by the method, the '325 patent teaches that:

> After the teeth and other components have been placed or removed so that the ***final tooth arrangement*** has been produced, it is necessary to generate a treatment plan, as illustrated in FIG. 6. The treatment plan will ultimately produce the series of INTDDS's and FDDS as described previously. To produce these data sets, it is necessary to define or map the movement of selected individual teeth from the initial position to the final position over a series of successive steps.

JX-0003 at 12:30-38 (emphasis added). Align contends that this discusses a final tooth arrangement that is "produced" as part of the treatment plan – not one that is measured at the end of treatment.

Align asserts that Respondents' construction is contrary to the intrinsic record and excludes exemplary embodiments of the specification, and it should be rejected on that basis. (Citing *Vitronics Corp. v. Conceptronic*, 90 F.3d 1576, 1583 (Fed. Cir. 1996)) Align says that Mr. Beers agrees that Respondents' construction is incorrect. (Citing CX-1150C at Q. 347) Align continues that Respondents' reference to Dr. Valley's comment that the "final tooth arrangement" "may not actually be the final location of the patient's teeth" is consistent with the intrinsic record. (Citing RIB at 31)

Align says that planning a final position of teeth is exactly what Respondents' process does by manipulating the image into a final position according to the clinician's prescription, which was confirmed by Dr. Arif. (Citing Tr. at 171:16-172:9; CX-0090C at 21) Align continues that {

} (Citing CX-1150C at Q. 137; CX-0090C at 26)

Align asserts that Respondents' "all aligners" non-infringement argument is incorrect. Align says that Respondents assert they do not infringe claim 1[35] of the '325 patent because the phrase "plurality of successive tooth repositioning appliances" requires that "all" of the appliances or shells "be produced prior to active treatment." Align asserts that this is a claim construction argument not identified in the SRJCCC and neither Respondents nor Dr. Mah cite to any supporting evidence. Align says that Respondents fail to distinguish the claimed "appliances" from their "phase-based" approach because this phrase reads literally on either a single phase of four consecutive aligners (*e.g.*, "Phase 1") or a group of all the "phases" prepared by Respondents. (Citing CX-1150C) Align says that Respondents fail to explain why the claimed "appliances" do not read on their "phase-based" approach. Align continues that at least Respondents' "Phase 1" is fabricated prior to a patient's treatment and because there is no temporal requirement in the claims, it reads on Respondents' entire treatment system, regardless of the fact they are shipped in phases.

Align also contends that Respondents' "facilitating" non-infringement argument is incorrect. Align says that Respondents argue that they do not infringe claim 1[36] of the 325 patent because the phrase "method for facilitating a tooth repositioning dental treatment" in the claims "requires that a patient receive dental treatment," and they do not provide such "dental treatment." Align says that this construction was not identified in the SRJCCC and neither Respondents nor Dr. Mah (citing RX-0129C at Q. 45) cite to any supporting evidence. Align

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[35] Align says that Respondents also raise this argument for claims 11, 21, 34, 35, 38, and 39.
[36] Align says that Respondents also raise this argument for claims 11, and 31.

continues that all the preamble requires is "facilitating a tooth repositioning dental treatment" and providing aligners to a dentist facilitates treatment. (Citing CX-1150C at Q. 345) Align says that Respondents only "evidence" is extrinsic and is its own webinar book. (Citing CX-0084C). Align avers that this document was not identified in Respondents' PreHearing Brief, and is therefore improperly raised now. (Citing Ground Rule 8.2) Align contends that the document is irrelevant to claim construction because "facilitating" has an ordinary meaning that is not changed by the intrinsic record, and this meaning cannot be trumped by extrinsic evidence.

Align disagrees with Respondents' argument that CCUS's process is phase-based, meaning the Clinician does not determine all of the successive tooth arrangements that are required until after treatment has begun, based upon the patient's progress. Align avers that it appears Respondents are seeking to graft onto the claim a requirement that a "clinician" must determine the successive tooth arrangements and arguing that because a clinician might request changes be applied to phases occurring after phase 1, that the successive tooth arrangements originally determined by CCPK become somehow irrelevant. Align continues that Respondents' arguments regarding these elements were not identified in the PreHearing Brief and are therefore waived. (Citing Ground Rule 8.2) Align says that Respondents cite no supporting intrinsic evidence for any of their varying constructions and Respondents' effort to add a requirement that a clinician prepare the digital data sets is improper, for at least the reasons discussed with regard to their "treatment plan" argument.

Align says that {

} (Citing CX-1150C at Q. 130-136, 347, 352) Align explains that, in other words, while CCUS says it forms aligner sets only four at a time (a "phase"), {

}

Align asserts that even where a clinician alters the treatment plan after treatment has begun (which does not happen all the time), it must be done through a "mid-course correction," wherein the entire process begins again. (Citing CX-1150C at Q. 137) Align reasons that a "mid-course correction" includes preparing a new initial, a new final, and "stepping" the case all over again from the initial to the final. (Citing *id.*; Tr. at 205:21-206:15)

Respondents' Position: Respondents assert that the prevailing issue concerning the majority of the subject patent claims is the creation of computer files for the "intermediate" tooth arrangements. Respondents say that Align relies heavily upon {

}

Respondents contend that {

}

Respondents argue that Align's allegations are not accurate because {

}

Respondents also disagree with Align's argument that CCPK "treatment operator uses the DPS and FreeForm's "Generate Steps" function to stage all of the tooth movements and determine the intermediate tooth arrangements for each tooth that moves, one tooth at a time" and that CCPK "provides the final tooth arrangement, along with the initial tooth arrangement, to FreeForm's "Generate Steps" function to produce the intermediary steps between the initial and final tooth arrangements. Respondents assert that the {

} (Citing Tr. 332:2 to 333:9; 337:18 to 338:5; CX1158C.1 at 62:25 to 73:6)

Respondents say that in reality, {

}

Respondents assert that Align's allegations regarding how intermediate data sets are transferred from CCPK to CCUS is misleading. Respondents say that Align omits several critical details about the way the process is actually conducted, when the data files are actually made available to CCUS, and when those files can actually be used to make aligners. Respondents say that there is no dispute that {

}

Respondents assert that {

} Respondents add that only

{

}

{

}

{

}

Respondents also disagree with Align's allegations that the CCPK operators manipulate a visual image of a digital manual to cut and move teeth and to create treatment plans and that CCPK operators use a stylus and FreeForm's Create Planes cutting feature to define borders or boundaries around each of the patients individual, and then Sculpt tools to further define the boundaries of each tooth. Respondents argue that the {

} (Citing CX1157C.1 at 70:13-20)

Respondents assert that in offering an opinion on validity, Align's expert Dr. Valley stresses how Align makes all of its intermediate steps—with mathematical accuracy—before the

patient's treatment begins by interpolating between the initial and final tooth positions. Respondents say that {

} Respondents aver that Dr. Valley described the Kesling method as "step-by-step and step-by-step towards the attainment of what you are—the goals you're trying to reach." (Citing Tr. at 792:17-19). {

}

Respondents say that Align asserts that certain elements of claim 1 are performed only by CCPK, and certain elements only by CCUS. Respondents continue that claim 1 (along with several other claims at issue) includes the step of "providing an initial digital data set representing an initial tooth arrangement," or similar wording that Mr. Beers considers the same. (Citing JX-3 at 15:21-22) Respondents say that Mr. Beers alleged that CCUS practices this step in the United States. (Citing Tr. at 534:20-23; 536:5-17; 537:8-23; 538:6-539:6) Respondents continue that Align and Mr. Beers assert the claim's sixth element, concerning fabricating appliances, is also practiced by CCUS. (Citing CX-1150C at Q. 211; Tr. at 541:3-8) Respondents say that Align and Mr. Beers assert that the second, through fifth elements of the claim are practiced by CCPK. (Citing CX-1150C at Q. 205-208; RX-0129C at Q. 47-48; Tr. at 540:5-9, 540:14-541:1) Respondents say that under Align's theory, some of the claim elements are practiced in the United States and others in Pakistan, meaning the method claim is not

infringed. Respondents say that Dr. Mah testified that neither CCUS nor CCPK practice several of the claim elements. (Citing RX-0129C at Q. 47-50)

Respondents say that during reexamination before the patent office, the phrase "facilitating a tooth repositioning dental treatment" was added to the claim language to overcome a prior art reference. Respondents assert that this added limitation requires that a patient receive dental treatment. Respondents say that only a licensed clinician may provide dental treatment. Respondents argue that CCUS and CCPK do not provide dental treatment and cannot directly infringe the claim. (Citing CX-0084C; Tr. 349:21-351:6) Respondents continue CCUS does not infringe because it does not produce a plurality of "digital sets" or digital information that represents a "plurality of tooth arrangements." (Citing RX-0129C at Q. 45)

Respondents assert that there is no evidence that CCPK performs the element of "providing an initial digital data set representing an initial tooth arrangement." Respondents say that Mr. Beers states that both CCUS and CCPK perform this step. (Citing CX-1150C at Q. 204) Respondents argue that assuming that this step is performed by scanning "a 3D physical model of a patient's teeth taken from dental impressions" and subsequently sending that information to another party, there is no evidence that CCPK performs this limitation.

Respondents assert that there is no evidence that CCUS performs the element of "presenting a visual image based on the initial data set." Respondents say that Mr. Beers only identifies conduct by CCPK as meeting this limitation. (Citing CX-1150C at Q. 205) Respondents say that Mr. Beers does not identify any conduct by CCUS as meeting this limitation and there is no evidence that CCUS practices this claim limitation. (Citing RX-0129C at Q. 47)

Respondents assert that there is no evidence that CCPK or CCUS perform the element of "manipulating the visual image to reposition individual teeth in the visual image." Respondents argue that this limitation requires that a "visual image" actually be manipulated in order to reposition individual teeth. Respondents disagree with Mr. Beers' testimony that when new coordinates for a defined tooth position are entered numerically, the visual image is manipulated. Rather, Respondents say that when new coordinates are entered the new visual image reflects those coordinates; but this is not "manipulating the visual image". (Citing RX-0129C at Q. 54) Respondents say that Mr. Beers only asserts CCPK as meets this limitation. And there is no evidence that CCUS practices this claim limitation. (Citing RX-0129C at Q. 48; CX-1150C at Q. 206)

Respondents assert that there is no evidence that CCUS performs the element of "producing a final digital data set representing the final tooth arrangement with repositioned teeth as observed in the image." Respondents say that a "final" tooth arrangement can only be a projection at the treatment stage prior to active treatment, meaning the projection may not actually be the final location of the patient's teeth. (Citing Tr. at 778:5-23; RX-0129C at Q. 58) Respondents assert that Mr. Beers only identifies conduct by CCPK as meeting this limitation and there is no evidence that CCUS practices this claim limitation. (Citing CX-1150C at Q. 207; RX-0129C at Q. 49)

Respondents assert that there is no evidence that CCUS performs the element of "producing a plurality of intermediate digital data sets representing a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement." Respondents say that this limitation requires producing all of the "plurality" of "successive tooth arrangements" and "progressing" from the "initial tooth arrangement" to the "final tooth

arrangement". Respondents contend that, in contrast, CCUS's process is phase-based, meaning the Clinician does not determine all of the successive tooth arrangements that are required until after treatment has begun, based upon the patient's progress. (Citing Tr. at 416:8-17) Respondents argue that CCUS's phase-based system does not meet this limitation. (Citing RX-0129C at Q.50) Respondents add that Mr. Beers only identifies conduct by CCPK as meeting this limitation and there is no evidence that CCUS practices this claim limitation. (Citing CX-1150C at Q. 208)

Respondents assert that there is no evidence that CCPK practices the element of "fabricating a plurality of successive tooth repositioning appliances, at least some of which are related to at least some of the produced digital data sets." Respondents say that based on the context of the patent and the related prosecution history, one skilled in the art would understand that this limitation requires that all of the "plurality" of "successive tooth repositioning appliances" be produced prior to active treatment. Respondents continue that CCUS's phase-based system does not meet this limitation. Respondents add that Mr. Beers only identifies conduct by CCUS as meeting this limitation and there is no evidence that CCPK practices this claim limitation. (Citing CX-1150C at Q. 211)

Respondents say that Align now argues that CCUS infringes claim 1 of the '325 patent under 271(g). Respondents argue that these new theories were introduced by Align because Align's arguments that CCUS induces infringement were stricken as not properly raised.

Staff's Position: Staff says that Align asserts CCUS directly infringes claims 1, 2, 3, 11, 13, 14, 30, 33, 34, 35, 38, and 39 of the '325 Patent under 35 U.S.C. § 271(g) by offering to sell, selling, or using aligners in the United States that are made by the joint CCUS / CCPK process, and CCPK contributes to that infringement under 35 U.S.C. § 271(c) by creating the digital data.

Staff continues that Align also asserts that CCUS directly infringes claim 21 of the '325 patent under 35 U.S.C. § 271(a) by {

} Staff says that Align alleges that CCUS directly infringes claim 21 of the '325 patent under 35 U.S.C. § 271(g) by offering to sell, selling, or using aligners in the United States that are made by the joint CCUS / CCPK process, and CCPK contributes to that infringement under 35 U.S.C. 271(c) by creating the digital data. Staff says that Align also asserts that CCPK directly infringes claim 31-32 of the '325 patent under 35 U.S.C. § 271(g) by offering to sell or selling digital data sets, digital models, or treatment plans in the United States.

Staff asserts that when applying Staff's understanding of the legal standards of patent infringement to Align's infringement theories, the Staff is of the view that CCUS would not infringe the '325 patent under 35 U.S.C. § 271(g) (and, therefore, CCPK would not infringe the '325 patent under 35 U.S.C. § 271(c)). Staff continues that based on a proper claim construction, the evidence supports finding infringement of claim 12 of the '325 patent pursuant to Align's § 271(a) infringement theory under 19 U.S.C. § 1337(a)(1)(B)(i), and (ii) infringement of claims 31-32 of the '325 patent pursuant to Align's infringement theory under 19 U.S.C. § 1337(a)(1)(B)(ii). Staff says that based on Order No. 20 (as well as Order No. 58 of Inv. No. 337-TA-562 (Enforcement Proceeding)), it appears to the Staff that Align's § 271(g) infringement theories under 19 U.S.C. § 1337(a)(1)(B)(i) may be determined to be legally proper. Staff says that Applying my rulings regarding patent infringement and a proper claim construction, the Staff is of the view that the evidence supports finding infringement of each of the Asserted Claims of the '325 patent.

Staff argues that Align's interpretation of *Akamai* is incorrect. Staff says that territorial limitations for patent infringement were not at issue in *Akamai* and an interpretation eliminating these limitations would contradict the strong presumption against extraterritorial application of U.S. patent law by allowing inducement liability under 35 U.S.C. § 271(b) to rest upon activities with no connection to the United States. (Citing *Microsoft Corp. v. AT&T Corp.*, 550 U.S. 437, 454 (2007)) Rather, Staff says that the most reasonable interpretation is that, for purposes of inducement liability, *Akamai* eliminated the single-actor requirement of *BMC Resources*, but retained the other direct infringement requirements set forth in Section 271(a), including its territorial limitations. (Citing *Akamai*, 692 F.3d at 1315) Staff says the fact that *Akamai* also describes 35 U.S.C. § 271(a) in terms of an "all steps" requirement -- without referencing that provision's statutorily-required territorial limitations -- further confirms that the Federal Circuit assumed, without explicitly stating, such limitations. (Citing *See Akamai*, 692 F.3d at 1307)

Staff says that based on my rulings (Tr. at 36:10 and 42:3-17), Align is precluded from, *inter alia*, (i) presenting any argument that CCUS induces infringement of the '325 patent, and (ii) offering any evidence that CCUS or CCPK infringes the '325 patent under the doctrine of equivalents. Therefore, Align's allegations of infringement in this regard will not be addressed further below.

Staff asserts that under Align's § 271(g) infringement theory, the evidence supports finding infringement of claims 1, 2, 3, 11, 13, 14, 30, 33, 34, 35, 38, and 39 of the '325 patent. Staff says that applying my rulings, the evidence shows that CCUS directly infringes each of these claims by selling or using aligners in the United States that are made by the joint CCUS / CCPK process. Staff says that CCUS and CCPK work together and their coordinated activities culminate in the fabrication of aligners by CCUS based on digital data sets produced by CCPK.

Staff continues that the evidence shows that each element in these claims is performed by CCUS and/or CCPK.

Staff says that for claim 1 of the '325 patent; (i) the claim preamble, if limiting, is performed by CCUS and CCPK (Citing CX-1150C at Q. 200-201; CX-1198C at 99-101); (ii) the first claim element is performed by both CCUS and CCPK (Citing CX-1150C at Q. 202-204; CX-1198C at 102-104); (iii) the second claim element is performed by CCPK (Citing CX-1150C at Q. 205; CX-1198C at 104-106); (iv) the third claim element is performed by CCPK (Citing CX-1150C at Q. 206; CX-1198C at 106-107); (v) the fourth claim element is performed by CCPK (Citing CX-1150C at Q. 207; CX-1198C at 107-109); (vi) the fifth claim element is performed by CCPK (Citing CX-1150C at Q. 208; CX-1198C at 110-112); and (vii) the sixth claim element is performed by CCUS (Citing CX-1150C at Q.209-211; CX-1198C at 112-113).

Staff asserts that Respondents' non-infringement arguments for the '325 patent advance claim constructions that were not properly identified in the Second Revised Joint Claim Construction Chart (and, thus, are waived) and are not properly supported by any intrinsic (or extrinsic) evidence. Staff says that Respondents argue that they do not infringe independent claims 1, 11, and 31 of the '325 patent (or the claims depending therefrom) because the term "facilitating a tooth repositioning dental treatment" requires that a patient receive dental treatment, and Respondents do not provide dental treatment because only a licensed clinician may provide dental treatment. Staff contends that this argument should be rejected because this particular term was not properly identified in the Second Revised Joint Claim Construction Chart. Staff continues that even if raised properly, this argument should be rejected because the claim language plainly recites "facilitating" dental treatment, not providing dental treatment by a licensed clinician. Respondents rely on Dr. Mah's testimony that "facilitating" dental treatment

requires providing dental treatment by a licensed clinician. Staff says that Dr. Mah's testimony is merely conclusory and there is nothing in the intrinsic evidence that supports Respondents' (and Dr. Mah's) construction of "facilitating" dental treatment as providing dental treatment by a licensed clinician.

Staff says that Respondents argue that they do not infringe independent claims 1 and 31 of the '325 patent (or the claims depending therefrom) because the term "manipulating the visual image to reposition individual teeth in the visual image" requires that a visual image actually be manipulated. Staff argues that this argument should be rejected because this term was not properly identified in the Second Revised Joint Claim Construction Chart. Staff continues that even if raised properly, this argument should be rejected because Respondents (and Dr. Mah) do not identify any intrinsic evidence that would support a construction seeking to add such a limitation to the claims. Staff adds that this argument is based on testimony in Dr. Mah's Rebuttal Witness Statement that was excluded by the ALJ. (Citing RX-0129C at Q.48)

Staff says that Respondents also argue that they do not infringe any asserted independent claim (*i.e.*, claims 1, 11, 21, 31, 35, and 38) of the '325 patent (or any asserted claim depending therefrom) because the terms "a final tooth arrangement" and "a modified tooth arrangement" can only be a projection at the treatment stage prior to active treatment. Staff asserts that these arguments should be rejected because these claims phrases were not properly identified in the Second Revised Joint Claim Construction Chart. Staff continues that even if raised properly, these arguments should be rejected because Respondents (and Dr. Mah) do not identify any intrinsic evidence that would support a construction seeking to add such a limitation to the

claims and Dr. Mah's testimony in this respect is merely conclusory. (Citing RX-0129C at Q. 49)

Staff asserts that the evidence shows that Mr. Beer's testimony includes typographical errors, which is evident in the context of Mr. Beers' answers, which recite in pertinent part: "Although ClearCorrect USA [sic – ClearCorrect Pakistan] festoons and provides four digital models to Clearcorrect USA at a time, eventually Clearcorrect Pakistan will have produced and provided the entire treatment plan, from initial to final tooth arrangement, to ClearCorrect USA." (Citing CX-1150C at Q. 193, 223, 278, and 300; Tr. at 593:18-597:3) Staff continues that Respondents cannot credibly dispute that this testimony on festooning consists of typographical errors, particularly when none of the parties in this investigation dispute that festooning is performed by CCPK (not CCUS). (Citing Tr. at 593:18-594:9) Staff says that Respondents' attacks on Mr. Beers' credibility are not persuasive.

Staff says that Mr. Beers' testimony admitting that he is not a lawyer and, thus, not one who can talk about the legal principles of infringement, does not foreclose Mr. Beers' testimony regarding the asserted claims of the patents in suit and the CCUS / CCPK process.

Analysis and Conclusions: In addition to the three disputes that are applicable for all asserted patents discussed in Section V.B.1, *supra*, there is a dispute relevant to all of the asserted claims of the '325 patent that that centers on Respondents' argument that to be infringed all "successive tooth repositioning appliances" to be used in treatment of a particular patient must be fabricated before the patient wears any of the appliances. Fabricating all "successive tooth repositioning appliances" ***before*** treatment is not required by any of the asserted claims. As noted in Section III.B.2, I found nothing in the language of claim 1 that would require such a

restrictive reading. I also find nothing in asserted independent claims 11, 21, 31[37], and 38 that would require such a restrictive reading. Rather, these claims only require the fabrication of tooth repositioning appliances for "one," "some," or a "plurality" (not all) of the digital data sets. (JX-003 at R1:45-47, 16:33-34, R2:5-7, R2:47-50, R4:16-18) Although independent claim 35 requires that dental appliances be produced for all of the successive digital data sets progressing from the initial tooth arrangement to the final tooth arrangement (JX-0003 at R:3:1-11), unlike the claims at issue in the '874 patent, there is no requirement that this be done before the outset of treatment. (*See id.*) As a result, Respondents' non-infringement argument based on the timing of fabrication relative to treatment is not persuasive.

Respondents also assert, incorrectly, that because Respondents' process of producing aligners is phase based, they do not generate all of the digital data sets from the initial tooth arrangement to the final tooth arrangement before treatment begins. First, not all of the asserted claims require the production of all digital data sets from the initial tooth arrangement to the final tooth arrangement. Rather, claims 21 and 30 merely require providing a digital data set representing a modified tooth arrangement, not all digital data sets from the initial arrangement to the final arrangement. (JX-003 at R2:1-4, R2:24-26)

Second, none of the remaining asserted claims includes a requirement that all digital data sets be produced before the start of treatment. For example, asserted claim 1 teaches a method that comprises six steps. Step numbers four and five of Claim 1 say that a final digital data set representing the final tooth arrangement and a plurality of intermediate digital data sets is produced. Step number six of claim 1 says that a plurality of successive tooth repositioning

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[37] Claim 31 only requires that a plurality of the produced intermediate digital data sets be provided to a fabrication operation, not actual fabrication. (JX-0002 at R2:47-50)

appliances is fabricated. Step number six continues to say that at least some of the fabricated plurality of successive tooth repositioning appliances are "related" to at least some of the produced digital data sets. (JX-003 at R1:29-48) Because certain data sets are used for fabrication, the claims necessarily require that fabrication is conducted ***after*** the production of those specific digital data sets. There is no requirement, however, that ***all*** digital data sets that are used in treatment of a particular patient be produced before any fabrication. (*See id.*) The remaining asserted claims (claims 2, 3, 11, 13, 14, 31, 32, 33, 34, 35, 38, and 39) likewise have no such requirement. (*See* JX-0003 at R2:27-R3:11, R3:21-R4:22, 15:34-43, 16:19-34, 16:38-50) Rather, digital data sets progressing from the initial tooth arrangement to the final tooth arrangement must merely be produced at some point for asserted claims 1, 2, 3, 11, 13, 14, 31, 32, 33, 34, 35, 38, and 39 to be infringed.

The fact that a "mid-course correction" may occur during treatment under Respondents' process does not preclude a finding of infringement. Respondents admitted that a "mid-course correction," under which changes are made to the treatment of a patient after treatment has begun, is not made in every case. (Tr. at 224:11-13; *See also* Tr. at 213:9-21) As a result, even if "mid-course corrections" resulted in a course of treatment being stopped before all of the intermediate digital data sets between initial and final tooth arrangements were produced, it would only apply to a subset of all cases handled by Respondents. Also, Respondents admitted that when a "mid-course correction" does take place, the entire accused process is executed again, using new initial and new final tooth positions, between which intermediate data sets are generated. (Tr. at 195:7-196:4, 205:24-206:15, 224:14-21, 318:21-319:3) For any given patient for whom "mid-course corrections" are provided, there will necessarily be a final "mid-course correction" after which no additional "mid-course corrections" will take place in his treatment.

After this final "mid-course correction," Respondents will generate intermediate digital data sets between the new initial and new final tooth positions that will be used for all of the remaining treatment series. As a result, Respondents' arguments based on "mid-course corrections" are not persuasive.

Turning to claim 1, I find that the preamble of claim 1 is not a limitation. Respondents have not offered any explanation regarding why the preambles of claim 1, 11, 21, 31, 35, and 38 are limiting. (*See* RIB at 21, 24, 28, 30, 34, and 36) Thus, any argument that the preamble of claim 1 is a limitation has been waived. Assuming, *arguendo*, that Respondents had not waived this argument, I find that the preamble of claim 1 is not a limitation. Whether to treat a claim preamble as a limitation is a determination made after a review of the entire patent. *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002). In *Catalina*, the Federal Circuit stated:

> In general, a preamble limits the invention if it recites essential structure or steps, or if it is "necessary to give life, meaning, and vitality" to the claim. Conversely, a preamble is not limiting "where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention."

Id. (citations omitted). The court went on to explain that "a preamble generally is not limiting when the claim body describes a structurally complete invention such that deletion of the preamble phrase does not affect the structure or steps of the claimed invention." *Id.* at 809.

The invention at issue in *Catalina* was a system for distributing coupons to consumers through kiosks. The court had to determine whether the phrase "located at predesignated sites such as consumer stores" was a limitation when it appeared in the preamble. *Id.* at 807-808. The court found that the phrase was not a claim limitation. The court examined the specification and found that the location of the kiosks was not an essential feature of the invention. *Id.* at 810.

The applicants did not rely on the preamble to distinguish the invention from the prior art during prosecution. *Id.* Importantly, the court found that the claim was complete without the preamble:

> Moreover, deletion of the disputed phrase from the preamble of Claim 1 does not affect the structural definition or operation of the terminal itself. The claim body defines a structurally complete invention. The location of the terminals in stores merely gives an intended use for the claimed terminals.

Id. Like the preamble in *Catalina*, the preamble of claim 1 is not necessary to give life, meaning and vitality to the claim. The claim body of claim 1 itself defines a structurally complete invention, and the mere fact that the preamble explains that it is directed to a method for facilitating a tooth repositioning dental treatment is not needed to understand the body of the claim. The fact that the claim is directed to a method for facilitating a tooth repositioning dental treatment and uses plural data sets representing plural tooth positions is clear from the body of the claim, which includes a limitation of "fabricating a plurality of tooth repositioning appliances." (JX-0003 at R1:29-48)

Assuming, *arguendo*, that the preamble of claim 1 were a limitation, I find that Align has shown by a preponderance of the evidence that CCUS and CCPK both practice the preamble[38] and the first claim element of independent claim 1. Employees of CCUS and CCPK testified that CCUS creates digital data sets by scanning stone models of patient's dental impressions, which represent the patient's initial tooth arrangement. (Tr. at 171:8-11; 314:19-315:18) Mr. Jarrett Pumphrey, an employee of CCUS, explained that {

} (Tr. at 316:24-316:3).

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[38] Even assuming, *arguendo*, that the preambles are limiting, Respondents' accused process practices the preambles.

Documents created by CCUS in the ordinary course of business that were submitted to the Food and Drug Administration by CCUS to show CCUS's process state that the digital data sets representing the initial tooth arrangement are imported into FreeForm Modeling software, which is a 3D modeling program. (CX-078 at 55; Tr. at 248:9-249:3) The document continues that the software shows how the teeth will look before and after the prescribed treatment. (CX-078 at 55) Mr. Arif, an employee of CCPK, explained that {

} (RX-0129C at Qs. 48, 69)

Mr. Arif testified that {

} Align's expert, Mr. Beers, provided similar testimony regarding Respondents' process. (CX-1150C at 200-211)

I find that this testimony and documentary evidence demonstrate that, assuming *arguendo* the preamble of claim 1 is a limitation, CCUS and CCPK practice the preamble of

claim 1 by facilitating the repositioning treatment of a patient using a plurality of digital data sets representing a plurality of tooth arrangements.

Respondents' first argument is that they do not infringe independent claim 1[39] of the '325 patent because the phrase "facilitating a tooth repositioning dental treatment[40]" requires that a patient receive dental treatment, and Respondents do not provide dental treatment because only a licensed clinician may provide dental treatment. First, I find above that the preamble of claim 1 is not a limitation. I also find that Respondents have waived the right to offer a construction for the term "facilitating a tooth repositioning dental treatment." Respondents did not propose a construction for "facilitating a tooth repositioning dental treatment" in the Second Revised Joint Claim Construction Chart. (*See* SRJCCC)

Second, in Section III.D.2 I rejected a similar argument raised in construction of "treatment plan" for the '487 patent. Like the '487 patent, there is nothing in the claims or specification of the '325 patent that provides a clear intent to require that the "treatment" be conducted by a licensed clinician. Rather, the specification of the '325 patent distinguishes between the "treating professional" and the user operating software to generate the digital data sets, explaining that:

> [T]he user will often follow a prescription or other written specification provided by the treating professional. Alternatively, the user may reposition them based on the visual appearance or using rules and algorithms programmed into the computer. Once the user is satisfied with the final arrangement, the final tooth arrangement is incorporated into a final digital data set (FDDS).

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[39] Respondents raise the same argument for claims 11 and 31. My analysis and conclusions apply for those claims as well.

[40] This phrase appears in the preambles of claims 1 and 31, not 11 as Respondents' contend. Moreover, Respondents have not provided any explanation or argument regarding why the preambles of claims 1 and 31 are limiting. For purposes of addressing Respondents' arguments, I assume, *arguendo*, that the preambles of claims 1 and 31 are limitations.

(JX-003 at 10:37-43) As a result, I find Respondents' argument unpersuasive.

Turning to claim 1, the testimony and documentary evidence also demonstrate that CCUS and CCPK practice the first element of claim 1. Mr. Jarrett Pumphrey, an employee of CCUS, explained that { } Documents created by CCUS in the ordinary course of business that were submitted to the Food and Drug Administration by CCUS to show CCUS's process state that the digital data sets representing the initial tooth arrangement are imported into FreeForm Modeling software, which is a 3D modeling program. (CX-078 at 55; Tr. at 248:9-249:3) Based upon the foregoing, I find that CCUS practices the first element of claim 1 when it transmits the initial digital dataset to CCPK, and CCPK also practices the first element of claim 1 when it { }

The evidence also demonstrates that CCPK practices the second element of claim 1 in Pakistan. Documents created by CCUS in the ordinary course of business that were submitted to the Food and Drug Administration by CCUS to show CCUS's process state that { } Mr. Beers' testimony regarding the second element of claim 1 is unrebutted. (CX-1150C at Q. 205)

The admissions of Dr. Mah confirm that the third element of claim 1 is practiced by CCPK. Respondents argue that they do not infringe independent claim 1[41] of the '325 patent, because the phrase "manipulating the visual image to reposition individual teeth in the visual image" requires that a visual image actually be manipulated. Respondents' contention is incorrect. First, I find that Respondents have waived the right to offer a construction for the term "manipulating the visual image to reposition individual teeth in the visual image." Respondents did not propose a construction for that term in the SRJCCC. Moreover, the portion of Dr. Mah's testimony addressing this construction was excluded. (RX-0129C at Qs. 48, 69) Respondents cite no evidence that shows a clear intent to limit the meaning of "manipulate[]" as Respondents' propose. In addition, Dr. Mah admits that {

} (RX-0129C at Qs. 48, 69) I find Respondents' admitted processes are sufficient to practice this claim limitation.

Mr. Arif's testimony, regarding the creation of the "treatment setup," combined with the above-referenced CCUS process document, shows that CCPK practices the fourth element of claim 1 by producing a final digital data set representing the final tooth arrangement with repositioned teeth as observed in the image. (Tr. at 170:25-172:14; CX-078 at 55) Mr. Arif testified that {

} (Tr. at 172:15-173:8) These admissions by Mr. Arif's regarding the "stepping" process show that CCPK practices the fifth element of claim 1 by producing a plurality of intermediate digital data sets representing a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth

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[41] Respondents raise the same argument for claim 31. My conclusions apply equally for claim 31.

arrangement. Based upon all of the foregoing, I find that CCPK practices the second through fifth elements of claim 1.

Mr. Pumphrey testified that {

} I find that these admissions are sufficient to show that CCUS practices the sixth element of claim 1 by fabricating a plurality of successive tooth repositioning appliances, at least some of which are related to at least some of the produced digital data sets. Based upon all of the foregoing, I find that Align has shown by a preponderance of the evidence that the concerted efforts of CCUS and CCPK practice each and every limitation of claim 1 when the digital data sets created by CCPK are used by CCUS to fabricate aligners.

3. Claim 2

Claim 2 recites:

> A method as in claim 1, wherein the step of providing a digital data set representing an initial tooth arrangement comprises scanning a three-dimensional model of a patient's teeth.

(JX-003 at 15:33-36)

Align's position: Align asserts that CCUS practices claim 2, which requires "wherein the step of providing a digital data set representing an initial tooth arrangement comprises scanning a three dimensional model of a patient's teeth," by {

} (Citing CX-1150C at Q. 213-214) Align continues that Respondents assert no non-infringement argument as to claim 2 (Citing RX-0129C at Q. 52)

Respondents' Position: Respondents assert that they do not infringe dependent claim 2 because they do not infringe the independent claim. Respondents say that the claim cannot be infringed because Align contends that some elements are practiced by CCUS in the United States while others are practiced by CCPK in Pakistan. (Citing CX-1150C at Q. 213.) Respondents assert that Align does not contend that CCPK practices claim 2.

Staff's Position: Staff says that for claim 2 of the '325 patent, the additional claim element recited in claim 2 of the '325 patent, which depends from claim 1 of the '325 patent, is performed by CCUS. (Citing CX-1150C at Q. 213; CX-1198C at 113-115)

Analysis and Conclusions: If I had found that Align had failed to prove that Respondents infringe claim 1, it would follow that Align failed to prove infringement of claim 2, which depends from claim 1. *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n. 9 (Fed. Cir. 1989) ("One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim.")

Nevertheless, I have found that Respondents infringe asserted claim 1. I find that CCUS practices dependent claim 2 of the '325 patent. Asserted claim 2 depends from claim 1 and teaches: "a method as in claim 1, wherein the step of providing a digital data set representing an initial tooth arrangement comprises scanning a three-dimensional model of a patient's teeth." (JX-003 at 15:33-36) As noted above, Mr. Pumphrey admitted that {

} (Tr. at 314:19-315:18) Mr. Beers provided similar testimony. (CX-1150C at Q. 213) As a result, I find that Align has shown by a preponderance of the evidence that CCUS practices dependent claim 2 of the '325 patent.

4. Claim 3

Claim 3 recites:

> A method as in claim 2, wherein the manipulating step comprises:
>
> defining boundaries about at least some of the individual teeth; and
>
> moving at least some of the tooth boundaries relative to the other teeth in an image based on the digital data set.

(JX-003 at 15:37-43)

Align's position: Align asserts that the preamble of claim 3 is not limiting because it is a statement of dependency. Align continues that Respondents did not contest this point in their *Prehearing Brief* (RPHB at 17) and have therefore waived such a position. Align says that an infringement analysis is unnecessary. Align adds that, as explained above, either (or both of) CCUS and CCPK practice each of the elements of claims 1 and 2.

Align asserts that CCPK practices the first element of claim 3, which requires "defining boundaries …," when it { } (Citing CX-1150C at Q. 215-216) Align says that CCPK practices the second element of claim 3, which requires "moving at least some …," when it { } (Citing CX-1150C at Q. 215-216) Align avers that Respondents assert no non-infringement arguments for claim 3 other than a conclusory statement. (Citing RPHB at 17-18) Align concludes that Respondents infringe for the same reason as claims 1 and 2.

Align asserts that Respondents' "individual teeth" non-infringement argument is also incorrect. Align says that Respondents assert they do not infringe claims 3 and 13 of the '325 patent because the phrase "individual teeth" in the claims must be "a three-dimensional model

that resembled an actual tooth, and not a three-dimensional object that includes a tooth crown and sectioned gum material." Align says that this construction was not identified in the SRJCCC and Respondents cite to no supporting evidence. Align continues that "teeth" is generally used in the asserted patents inclusively for the tooth and surrounding gum material (citing JX-0002 at 12:51-56 and CX-1150C at Q. 123, 348) and Respondents themselves use "teeth" in such an inclusive manner. (Citing CX-1157C.1 at 54:1- 9; CX-0090C at 14)

Align asserts that Respondents would still infringe even if "tooth" only included a "tooth," and not any gum material. Align says that claim 1 of the '325 patent recites "manipulating the visual image to reposition individual teeth in the visual image." (Citing JX-0003 at 27 (R1:36-37)) Align contends that regardless of whether "tooth" were defined to mean: a tooth or a tooth plus surrounding gum material, the tooth itself would still be repositioned. Align adds that claim 3 of the '325 patent recites "defining boundaries about at least some of the individual teeth." JX-0003 at 15:40-41. Align contends that if one defined boundaries around the tooth that included the tooth itself or the tooth plus some gum material, the boundary would still be defined around the tooth.

Align says that Respondents use {

} of the

tooth as suggested by Respondents. Align reasons that although not visible in the image, the gum material merely covers the root structure, which is also being repositioned with the rest of the tooth object.

Align argues that "tooth" or "teeth" is not utilized in the '325 patent as being equivalent only to a tooth with a crown and root and no gum material as Respondents assert. Align says

that the '325 patent discusses obtaining an initial "digital data set representing an initial tooth arrangement" by scanning a plaster cast of the patient's teeth. (Citing JX-0003 at 9:17-42) Align continues that the results of such a scan – the "initial tooth arrangement" – would include gum material covering the root structure, but would not actually show the root structure. Align adds that this usage is consistent with Mr. Beers' opinion that people in this industry refer to the crown and gum objects defined by CCPK in Freeform as "individual teeth" (Citing CX-1150C at Q. 348) and Respondents' own documents. (Citing CX-1157C.1 at 54:1-9; CX-0090C at 14)

Align disagrees with Respondents' argument that they do not infringe claims 3 and 13 of the '325 patent because they "do not 'move' the 'tooth boundaries' 'relative to other teeth' in an 'image.'" Align says that Respondents do not provide any explanation as to why Respondents process of moving the teeth using FreeForm (as described in regards to their "manipulating the visual image" argument) does not satisfy these claims. Align continues that the record citation identified by Respondents is to testimony from Jarrett Pumphrey as to the use of Freeform to section and move teeth in Freeform. (Citing Tr. at 330:11-333:9) Align contends that this sectioning and moving is the claimed "moving," and therefore fails to support Respondents' argument. Align adds that to the extent that this argument is based on Respondents' "individual teeth" argument, it is incorrect for the reasons discussed above.

Respondents' Position: Respondents assert that they do not infringe claim 3 because they do not infringe the independent claim. Respondents say that the claim cannot be infringed because Align contends that some elements are practiced by CCUS in the United States while others are practiced by CCPK in Pakistan. (Citing CX-1150C at Q. 215) Respondents add that claim 3 recites "A method as in claim 2, wherein the manipulating step comprises: defining boundaries about at least some of the individual teeth" and the plain meaning of "individual

teeth" means a representation of a three-dimensional model that resembled an actual tooth, and not a three-dimensional object that includes a tooth crown and sectioned gum material. Respondents say that Dr. Valley testified an actual tooth includes the root. (Citing Tr. at 707:25-708:6) Respondents say that CCPK sections, and manipulates, only part of a tooth, and it therefore moves only parts of teeth. Respondents continue that this limitation is not met by the Respondents. Respondents say that Dr. Mah agrees. (Citing RX-0129C at Q. 54) Respondents add that Mr. Beers only asserts CCPK meets this additional limitation and there is no evidence that CCUS practices this limitation. (Citing CX-1150C at Q. 215)

Respondents assert that Claim 3 further recites "moving at least some of the tooth boundaries relative to the other teeth in an image based on the digital data set." Respondents argue that Respondents do not "move" the "tooth boundaries" "relative to other teeth" in an "image." (Citing CX-0889C; Tr. 330:11 to 333:9) Respondents say that Mr. Beers only identifies conduct by CCPK as meeting this limitation and there is no evidence that CCUS practices this claim limitation. (Citing CX-1150C at Q. 215)

Respondents say that Align now argues that CCUS infringes claim 3 of the '325 patent under 271(g). Respondents argue that these new theories were introduced by Align because Align's arguments that CCUS induces infringement were stricken as not properly raised.

Staff's Position: Staff says that for claim 3 of the '325 patent, the evidence shows that the additional claim elements recited in claim 3 of the '325 patent, which depends from claim 2 of the '325 patent, are performed by CCPK. (Citing CX-1150C at Q. 215; CX-1198C at 115-117)

Staff says that Respondents argue that they do not infringe claims 3 and 13 of the '325 patent because the term "defining boundaries about at least some of the individual teeth" requires

that the "individual teeth" be "a representation of a three-dimensional model that resembled an actual tooth, and not a three-dimensional object that includes a tooth crown and sectioned gum material." Staff asserts that this argument should be rejected because this particular term was not properly identified in the Second Revised Joint Claim Construction Chart. Staff continues that even if raised properly, this argument should be rejected because Respondents (and Dr. Mah) do not identify any intrinsic evidence that would support a construction seeking to add such a limitation to the claims. (Citing RX-0129C at Q. 53) Staff adds that this argument is based on testimony in Dr. Mah's Rebuttal Witness Statement that was excluded by the ALJ. (Citing RX-0129C at Q. 53)

Analysis and Conclusions: If I had found that Align had failed to prove that Respondents infringe claims 1 or 2, it would follow that Align failed to prove infringement of claim 3, which depends from claims 1 and 2. *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n. 9 (Fed. Cir. 1989) ("One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim.")

Nevertheless, I have found that Respondents infringe asserted claims 1 and 2. I find that CCPK practices dependent claim 3 of the '325 patent in Pakistan. Asserted claim 3 depends from claim 1 via claim 2.

Respondents' argument on claim 3 is to no avail.[42] First, I find that Respondents have waived the right to offer a construction for the term "defining boundaries about at least some of the individual teeth." Respondents did not propose a construction for that term in the SRJCCC. Moreover, the portion of Dr. Mah's testimony addressing this construction was excluded. (RX-

[42] Respondents raise the same argument for claim 13. My conclusions apply equally for claim 13.

0129C at Qs. 53, 60) Respondents cite no evidence that shows a clear intent to limit the meaning of this limitation as Respondents' propose. As a result, I reject this argument.

Treating the substance of the assertion, the evidence introduced at the hearing shows that Respondents' process includes a step of "defining boundaries about at least some of the individual teeth." Mr. Jarrett Pumphrey admitted that {

} All that is required is "defining boundaries about" individual teeth. (JX-0003 at 15:39-40, 16:42-43) Based on the foregoing testimony and supporting evidence, I find that Respondents meet this limitation.

Respondents also argue unpersuasively that they do not "mov[e] at least some of the tooth boundaries relative to the other teeth in an image based on the digital data set," as required by claim 3[43]. Mr. Jarrett Pumphrey admitted that {

} (Tr. at 332:20-333:9; CX-0889C) Based on this testimony, I find that CCPK practices claim 3.

[43] Respondents raise the same argument for claim 13. My conclusions apply equally for claim 13.

5. Claim 11

Asserted claim 11 teaches:

> A method for fabricating a plurality of denial incremental position adjustment appliances, said method comprising:
>
> providing an initial digital data set representing an initial tooth arrangement;
>
> providing a final digital data set representing a final tooth arrangement;
>
> producing a plurality of successive digital data sets based on both of the previously provided initial and final digital data sets, wherein said plurality of digital data sets represent a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement; and
>
> fabricating appliances based on at least some of the produced digital data sets.

(JX-003 at 16:19-34)

Align's position: Align asserts that the preamble of claim 11 is not limiting, as it merely states the purpose of the claimed method. (Citing *Pitney Bowes,* 182 F.3d at 1305) Align continues that Respondents have not asserted the contrary in their Prehearing Brief and have therefore waived such a position. Align concludes that an infringement analysis of the preamble is unnecessary.

Alternatively, Align asserts that, if the preamble is found to be limiting, Respondents practice the preamble by their joint method of designing, making and selling clear aligners.

Align asserts that CCUS and CCPK practice the first element of claim 11, which requires "providing an initial digital data set...," for the same reason the identical element is met for claim 1.

Align avers that CCPK practices the second element of claim 11, which requires "providing a final digital data set ...," when it {

} *See* Sec. I.E.5, 9 and 10; CX-1150C at Q. 192.

Align asserts that CCPK practices the third element of claim 11, which requires "producing a plurality...," for the same reasons CCPK practices the fifth element of claim 1.

Align asserts that CCPK practices the fourth element of claim 11, which requires "fabricating appliances..." for the same reasons CCPK practices the sixth element of claim 1.

Align contends that CCUS's aligners are made according to each of claimed steps by the joint CCUS/CCPK process, and are sold, offered for sale, and used in the U.S. (Citing Tr. at 312:20-314:3) Align concludes, as a result, that CCUS's aligners directly infringe under 35 U.S.C. § 271(g). Align continues that CCPK contributorily infringes under the four-part *Fujitsu* test, where part 1 is met by CCUS's direct infringement and the remaining parts are also met, as discussed above.

Align disagrees with Respondents' argument that CCUS "does not directly infringe because it does not produce a plurality of 'digital sets'" in view of claim 11's preamble. Align says that the preamble is not a claim limitation and, if it were, there is no requirement that CCUS practice a limitation itself to infringe under § 271(g). Align continues that contrary to Respondents' arguments', the preamble to claim 11 does not require "facilitating a tooth repositioning dental treatment . . . ," and thus, Respondents' respective arguments are irrelevant.

Respondents' Position: Respondents assert that they do not infringe claim 11 because Align asserts that the first and fourth elements of the claims are performed only by CCUS in the

United States (citing Tr. at 542:2-15; CX-1150C at Q.194) while the second and third elements are performed by CCPK in Pakistan. (Citing CX-1150C at Q.192; CX-1150C at Q 193)

Respondents assert that as described above in the analysis of claim 1, neither CCUS nor CCPK can, as a matter of law, provide dental treatment. Respondents say that only a licensed Clinician may provide dental treatment. Respondents argue that CCUS and CCPK do not directly practice the preamble and therefore they do not directly infringe this claim. Respondents say that CCUS does not directly infringe because it does not produce a plurality of "digital sets" or digital information that represents a "plurality of tooth arrangements." (Citing RX-0129C at Q. 58)

Respondents assert that CCPK does not practice the element requiring "providing an initial digital data set representing an initial tooth arrangement." Respondents say that Mr. Beers states that both CCUS and CCPK perform this step. (Citing CX-1150C at Q. 190) Respondents argue that assuming that this step is performed by scanning "a 3D physical model of a patient's teeth taken from dental impressions" and subsequently sending that information to another party, there is no evidence that CCPK performs this limitation.

Respondents assert that CCUS does not practice the element requiring "providing a final digital data set representing a final tooth arrangement." Respondents argue that a "final" tooth arrangement can only be a projection at the treatment stage prior to active treatment, meaning the projection may not actually be the final location of the patient's teeth. (Citing Tr. at 778:5-23; RX-0129C at Q. 58.) Respondents say that Mr. Beers states that both CCUS and CCPK perform this step. (Citing CX-1150C at Q. 192) Respondents continue that there is no evidence that CCUS practices this claim limitation. (Citing RX-0129C at Q. 57.) Respondents add that one skilled in the art would understand that the "final digital data" in this element is the same as the

"final digital data" identified in the following element that is used to "produce" the "plurality" of "successive tooth arrangements" and CCUS does not meet this limitation.

Respondents assert that the element "producing a plurality of successive digital data sets based on both of the previously provided initial and final digital data sets, wherein said plurality of digital data sets represent a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement; and" requires production of a "plurality of successive digital data sets" that represent a "plurality" of "successive tooth arrangements" "progressing" from the "initial tooth arrangement" to the "final tooth arrangement." Respondents argue that a "final tooth arrangement" can only be a projection at the treatment stage prior to active treatment. (Citing Tr. at 778:5-23; RX-0129C at Q. 58.) Respondents say that CCUS's process is phase-based. (Citing RX-0129C at Q 58.) Respondents say that the Clinician does not determine the successive tooth arrangements that are required until after the initial appliances have been fabricated and after treatment has begun; rather the Clinician makes this determination based upon based upon an evaluation of the patient's progress and the Clinician's prescription. (Citing Tr. at 416:8-17) Respondents argue that their phase-based system therefore does not meet this limitation. (Citing RX-0129C at Q. 58.) Respondents say that Mr. Beers only identifies conduct by CCPK as meeting this limitation and there is no evidence that CCUS practices this claim limitation. (Citing CX-1150C at Q. 193)

Respondents assert that the claim element "fabricating appliances based on at least some of the produced digital data sets" in the context of the previous limitation, requires that all of the "digital data sets" be produced prior to active treatment, together with the fabrication of the appliances. Respondents argue that CCUS's phase-based system does not meet this limitation.

(Citing RX-0129C at Q. 58; Tr. at 416:8-17.) Respondents say that Mr. Beers only identifies conduct by CCUS as meeting this limitation. (Citing CX-1150C at Q. 194)

Staff's Position: Staff says that for claim 11 of the '325 patent; (i) the claim preamble, if limiting, is performed by CCUS and CCPK (Citing CX-1150C at Q. 189-190; CX-1198C at 117-119); (ii) the first claim element is performed by both CCUS and CCPK (Citing CX-1150C at Q. 191- 190;[1] CX-1198C at 119-121); (iii) the second claim element is performed by CCPK (Citing CX-1150C at Q. 192; CX-1198C at 121-123); (iv) the third claim element is performed by CCPK (Citing CX-1150C at Q. 193; CX-1198C at 123-126); and (v) the fourth claim element is performed by CCUS (Citing CX-1150C at Q. 194; CX-1198C at 126-127).

Analysis and Conclusions: I find that the evidence shows that the CCUS and CCPK process practices asserted claim 11. Similar to claim 1, I find that the preamble of claim 11 is not a limitation. Claim 11 is complete without the preamble, and the preamble merely explains what is obvious based on the actual claim language—the claim is directed to a method for fabricating a plurality of dental appliances.

Assuming, *arguendo*, that the preamble of claim 11 is a limitation, I find that the preamble is practiced by CCUS and CCPK based on the same evidence discussed in Section V.B.2, *supra*, that showed that the preamble of claim 1 is practiced by CCUS and CCPK.

In Section V.B.2, *supra*, I found that Mr. Jarrett Pumphrey admitted that {

} Based on this admission and document, I

find that CCPK and CCUS practice the first element of claim 11 when {

}

Mr. Arif, an employee of CCPK, explained that the {

} (Tr. at 170:25-172:14) Based on this admission, I find that CCPK practices the second element of claim 11 when {

}

Mr. Arif testified that {

} (Tr. at 172:15-173:8) Based on this admission, I find that CCPK practices the third element of claim 11 when {

}

Mr. Pumphrey testified that {

} These admissions make clear that CCUS practices the fourth element of claim 11 when CCUS fabricates thermoformed aligners for patients.

As explained in Section V.B.2, *supra*, Respondents' "all aligners" and "facilitating treatment" arguments are not persuasive. Based upon all of the foregoing, I find that Align has

shown by a preponderance of the evidence that the concerted efforts of CCUS and CCPK practice each and every limitation of claim 11 when the digital data sets created by CCPK are used by CCUS to fabricate aligners.

6. Claim 13

Dependent claim 13 recites:

> A method as in claim 11, wherein the step of providing a digital data set representing a final tooth arrangement comprises:
>
> defining boundaries about at least some of the individual teeth; and
>
> moving at least some of the tooth boundaries relative to the other teeth in an image based on the digital data set to produce the final data set.

(JX-003 at 16:39-46)

Align's position: Align avers that claim 13 is similar to dependent claim 3 and asserts that CCPK practices this claim for the same reasons. Align says that Respondents infringe this claim for the same reason as claim 11.

Respondents' Position: Respondents argue that they do not infringe dependent claim 13 because they do not infringe the independent claim. Respondents continue that because claim 13 of the '325 patent depends from claim 11, some of the elements of claim 13 of the '325 patent are alleged to be practiced by CCUS in the United States, and other elements are alleged to be practiced by CCPK in Pakistan and therefore is not infringed.

Respondents assert that Claim 13 further recites "defining boundaries about at least some of the individual teeth." Respondents say that "individual teeth" means a representation of a three-dimensional model that resembled an actual tooth, and not a three-dimensional object that includes a tooth crown and sectioned gum material. (Citing CX-0889C; Tr. 330:13 to 332:19) Respondents argue that this limitation is not met by the Respondents.

Respondents assert that Claim 13 further recites "moving at least some of the tooth boundaries relative to the other teeth in an image based on the digital data set to produce the final data set." Respondents assert that they do not "move" the "tooth boundaries" "relative to other teeth" in an "image." (Citing CX-0889C; Tr. 330:11 to 333:9) Respondents argue this limitation is not met by the Respondents.

Staff's Position: Staff says that for claim 13 of the '325 patent, the evidence shows that the additional claim elements recited in claim 13 of the '325 patent, which depends from claim 11 of the '325 patent, are performed by CCPK. (Citing CX-1150C at Q. 196; CX-1198C at 127-130)

Analysis and Conclusions: If I had found that Align had failed to prove that Respondents infringe claim 11, it would follow that Align failed to prove infringement of claim 13, which depends from claim 11. *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n. 9 (Fed. Cir. 1989) ("One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim.")

Nevertheless, I have found that Respondents infringe asserted claim 11. Claim 13 depends from claim 11. I find that claim 13 is substantively identical to claim 3 discussed in Section V.B.2, *supra*, and I find that it is practiced by CCPK based on the same evidence that established that claim 3 is practiced by CCPK. I find in Section V.B.2, *supra*, that Respondents' "individual teeth" argument is not persuasive. I incorporate and reaffirm that finding and rationale here.

7. Claim 14

Dependent claim 14 recites:

> A method as in claim 11, wherein the step of producing a plurality of successive digital data sets comprises determining positional differences

between the initial data set and the final data set and interpolating said differences.

(JX-003 at 16:47-50)

Align's position: Align asserts that CCPK practices claim 14 when it generates the successive tooth arrangements using the "generate steps" function in FreeForm. (Citing CX-1150C at Q. 198) Align says that Respondents admit that this "generating" is done by linear interpolation. (Citing Tr. at 676:23-677:6)

Align disagrees with Respondents' arguments that the {

} (Citing RX-0129C at Q. 62) Align asserts that Respondents' argument is wrong because neither Respondents, nor Dr. Mah, provide any particular evidence to support their argument. Align says that {

} Align adds that even if there were proof of after-occurring modification, it does not change the fact that {

} and that interpolation falls within the scope of claim 14. Align concludes, as a result that Respondents infringe claim 14 for the same reason as claim 11.

Align disagrees with Respondents argument that they do not infringe claim 14 of the '325 patent because {

} Align says that Respondents did not propose a construction that requires operators not to use independent judgment in the SRJCCC. Align continues that although Respondents seek to limit the scope of "interpolating" to automatic interpolation, they fail to identify any intrinsic

support for such a limitation. Align adds that Respondents' argument that they do not perform "interpolation" conflicts with admissions made during the hearing. (Citing Tr. at 676:23-677:6) Align says that {

} and is therefore irrelevant to infringement.

Respondents' Position: Respondents assert that they do not infringe dependent claim 14 because they do not infringe the independent claim. Respondents say that the claims cannot be infringed because Align contends that some elements are practiced by CCUS in the United States while others are practiced by CCPK in Pakistan. Respondents continue that claim 14 further recites "A method as in claim 11, wherein the step of producing a plurality of successive digital data sets comprises determining positional differences between the initial data set and the final data set and interpolating said differences." Respondents argue that their phase-based system does not produce the requisite "successive digital data sets" required by this limitation. (Citing RX-0129C at Q. 62; Tr. 416:8-17) Respondents add that the operators use their individual judgment to adjust the teeth locations, which means that the "positional differences between the initial data set and the final data set" are not interpolated. (Citing Tr. 336:8 to 338:17)

Staff's Position: Staff says that for claim 14 of the '325 patent, the evidence shows that the additional claim element recited in claim 14 of the '325 patent, which depends from claim 11 of the '325 patent, is performed by CCPK. (Citing CX-1150C at Q. 198; CX-1198C at 130-132)

Analysis and Conclusions: If I had found that Align had failed to prove that

Respondents infringe claim 11, it would follow that Align failed to prove infringement of claim 14, which depends from claim 11. *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n. 9 (Fed. Cir. 1989) ("One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim.")

Nevertheless, I have found that Respondents infringe asserted claim 11. I also find that Respondents infringe claim 14. Respondents argue unpersuasively that because {

} they do not "determin[e] positional differences between the initial data set and the final data set and interpolat[e] said differences," as required by claim 14 of the '325 patent. (JX-0003 at 16:47-50) Respondents essentially contend that the word "interpolating" forecloses any human intervention. Respondents cite no support for this position, and did not propose a construction for "interpolating" in the SRJCCC. As a result, Respondents waived any claim construction arguments on this claim term.

Additionally, Jarrett Pumphrey admitted that in the accused process, {

} Respondents' argument that they do not perform "interpolation" also conflicts with admissions made during the hearing. (Tr. at 676:23-677:6) Therefore, I find that CCPK practices a step of interpolating the differences between the two tooth positions. Because claim 14 is a "comprising" or open-ended claim, the mere fact that another step is completed after interpolation does not defeat a finding of infringement. Rather,

the Federal Circuit has explained that "[t]he transition 'comprising' in a method claim indicates that the claim is open-ended and allows for additional steps." *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1368 (Fed. Cir. 2003). As a result, I find that Align has shown by a preponderance of the evidence that CCPK practices dependent claim 14 of the '325 patent.

8. Claim 21

Claim 21 teaches:

> A method for fabricating a polymeric shell dental appliance for moving a patient's teeth, said method comprising:
>
> providing a digital data set representing a modified tooth arrangement for a patient, wherein the modified tooth arrangement comprises a repositioned tooth arrangement for a plurality of the patient's teeth;
>
> controlling a fabrication machine based on the digital data set to produce a positive model of the modified tooth arrangement; and
>
> producing the polymeric shell dental appliance as a negative of the positive model, wherein the polymeric shell appliance covers a plurality of teeth in an upper or lower jaw of the patient, and wherein the polymeric shell appliance is configured to move at least some of the patient's teeth substantially to the modified tooth arrangement.

(JX-003 at R1:65-R2:14)

Align's position: Align asserts that Respondents practice each and every limitation of claim 21. Align says that the preamble of claim 21 is not limiting, as it merely states the purpose of the claimed method. Align continues that Respondents have not asserted the contrary in their Prehearing Brief, and have therefore waived this argument. Align reasons, therefore, that an infringement analysis of the preamble is unnecessary.

Alternatively, Align contends that if the preamble is found to somehow be limiting, CCUS practices the preamble of claim 21 by making and selling clear aligners. (Citing CX-1150C at Q. 179) Align says, Alternatively, Respondents jointly practice the preamble by their

joint method of designing, making and selling clear aligners, where CCPK designs all steps of a patient's treatment, and CCUS then makes and sells the aligners.

Align asserts that CCUS practices the first element of claim 21, which requires "providing a digital data set …," by providing the digital data sets representing a modified tooth arrangement to the fabrication machine for generating the physical embodiments of the successive digital data sets it obtains from CCPK. (Citing CX-1150C at Q. 180) Align adds that CCPK practices this element by {

}. (Citing CX-1150C at Q. 180)

Align contends that CCUS practices the second element of claim 21, which requires "controlling a fabrication machine…," because {

} (Citing CX-1150C at Q. 183) Align says that Respondents did not contest that they infringe this element in their interrogatory responses or in the pre-hearing briefing, and thus cannot assert its non-infringement now.

Align asserts that CCUS practices the third element of claim 21, which requires producing the polymeric…," because {

} *See* Sec. I.E.10; CX-1150C at Q. 183. Respondents assert their "all aligner" argument, which is incorrect as discussed above in Sec. IV.D.

Align asserts that CCUS practices each element of claim 21, and thus infringes under 35 U.S.C. § 271(a). Align continues that CCUS's aligners are made according to each of claimed

steps and are sold, offered for sale, and used in the U.S. (Citing Tr. at 312:20-314:3) Align concludes that CCUS's aligners directly infringe under 35 U.S.C. § 271(g). Align adds that CCPK contributorily infringes under the four-part *Fujitsu* test, where part 1 is met by CCUS's direct infringement and the remaining parts are met for the reasons explained above.

Align says that Respondents have applied their "final tooth arrangement" argument to the recited "modified tooth arrangement" in claims 21 and 30 arguing that "final" is equivalent to "modified." Align asserts that there is no intrinsic support for such equivalence, and Respondents have not cited any supporting evidence for such a proposition.

Respondents' Position: Respondents assert that they do not infringe claim 21. Respondents say that Align asserts that certain elements of claim 21 are allegedly performed at least in part by CCPK in Pakistan and other elements are performed by CCUS in the United States. (Citing CX-1150C at Q. 180, 183; Tr. at 545:1-5, 545:6-16)

Respondents assert that they do not practice the preamble and first element of claim 21. Respondents say that one skilled in the art would understand that the modified tooth arrangement claimed here would be the same as the projected "final tooth arrangement" because the patent's disclosure only teach modifying the "initial tooth arrangement" to make a projected "final tooth arrangement." Respondents say that a "final tooth arrangement" can only be a projection at the treatment stage prior to active treatment, meaning the projection may not actually be the final location of the patient's teeth. (Citing Tr. at 778:5-23) Respondents say that CCUS's process is phase-based and does not meet this limitation. (Citing Tr. at 416:8-17; RX-0129C at Q. 63)

Respondents assert that they do not practice the element requiring "controlling a fabrication machine based on the digital data set to produce a positive model of the modified tooth arrangement; and producing the polymeric shell dental appliance as a negative of the

positive model, wherein the polymeric shell appliance covers a plurality of teeth in an upper or lower jaw of the patient, and wherein the polymeric shell appliance is configured to move at least some of the patient's teeth substantially to the modified tooth arrangement." Respondents argue that based on the context of the patent and the related prosecution history, one skilled in the art would understand that the modified tooth arrangement claimed here would be the same as the projected "final tooth arrangement" described above. Respondents say that one skilled in the art would understand that these limitations require that the appliance that represents the "modified" or "final tooth arrangement" be fabricated prior to active treatment. Respondents conclude that the phase-based system of the Respondents does not meet these limitations. Tr. 416:8-17.

Staff's Position: Staff argues that under Align's § 271(a) infringement theory, the evidence supports finding infringement of claim 21 of the '325 patent under my rulings regarding patent infringement under Section 337 (and under the Staff's understanding of the legal standards of patent infringement). Staff says that applying my rulings or the Staff's understanding, the evidence demonstrates that CCUS directly infringes claim 21 of the '325 patent by performing each element of the claimed method in the United States (specifically, Texas). (Citing CX-1150C at Q. 178-184; CX-1198C at 132-140)

Staff argues that under Align's § 271(g) infringement theory, the evidence supports finding infringement of claim 21 of the '325 patent under my rulings regarding patent infringement under Section 337 (but not the Staff's understanding of the legal standards of patent infringement). Staff says that applying my rulings, the evidence demonstrates that CCUS directly infringes claim 21 of the '325 patent by selling or using aligners in the United States that are made by the joint CCUS / CCPK process (as above with the Asserted Claims of Group A of the '325 patent). Staff explains that the evidence shows that CCPK also performs the preamble,

if limiting, and the first claim element of claim 21 of the '325 patent. (Citing CX-1150C at A.178-184; CX-1198C at 132-140)

Staff argues that based on CCUS's direct infringement, the evidence shows that CCPK contributes to that infringement by creating the digital data sets that are used by CCUS in creating aligners. Staff argues that the evidence shows, *inter alia*, the following relationship between CCUS and CCPK: {

} (Citing CX-1150C at Qs. 92-145; Tr. at 168:14-170:11, 170:18-173:24, and 177:2-193:6; Tr. at 312:20-322:12; Tr. at 442:5-443:10)

Staff asserts that the evidence shows that the relationship between CCUS and CCPK is such that their activities are closely coordinated and that the actions of CCPK are directed and controlled by CCUS. (Citing CX-1150C at Q. 92-145; Tr. at 306:25-311:23; Tr. at 398:5-404:5; Tr. at 427:12-437:2, 442:5-444:3, and 444:19-445:11) Staff further explains that the evidence shows that {

} (Citing CX-0511C; CX-0671C; CX-0800C; CX-0803C)

Staff continues that the evidence also shows that {

}. (Citing CX-0337C; CX-0338C; CX-0339C; CX-384C; CX-0511C; CX-0531C; CX-679C; CX-0685C; CX-0686C; CX-804C; CX-1160C.4 at 676:25-677:7 and 687:9-14) Staff adds that the evidence shows that {

} (Citing CX-0116C; CX-0376C; CX-0377C; CX-0460C; CX-1162C.3 at 128:5-135:10)

Staff additionally argues that the evidence shows that, since the formation of CCPK, {

} (Citing CX-0300C; CX-493C; CX-0655C; CX-1151C.1 at 110:16-111:25, 114:10-23, 115:25-116:20, 117:3-118:22, 130:23-131:13, 136:16-22, and 197:20-23; CX-1160C.4 at 682:6-683:1, 769:20-770:17, and 787:18-788:19; CX-1162C.2 at 311:21-312:11, 313:4-16, and 314:11-14; CX-1162C.3 at 54:12-16, 54:21-23, 97:1-14, 107:14-19, and 171:14-17; CX-1164C.1 at 128:25-129:19; Tr. at 177:2-193:6, 445:1-9) Staff adds that the evidence also demonstrates that { } (Citing CX-1160C.4 at 720:10-16; CX-1162C.1 at 196:3-5, 196:18-20, and 208:12-18)

Staff argues that in addition to demonstrating that {

} (Citing CX-0111C; CX-0479C; CX-0848C, CX-0853C; CX-1160C.4 at 742:24-743:3; Tr. at 419:7-15)

Staff says that Respondents argue that they do not infringe claims 21, 31, and 32 of the '325 patent because some elements of a claim are performed by CCUS and other elements of the claim are performed by CCPK. Staff contends that while the evidence shows that some elements of a claim are performed by CCUS and other elements of the claim are performed by CCPK, the evidence also shows that (i) all of the elements of claim 21 are performed by CCUS, and (ii) all of the elements of claims 31 and 32 are performed by CCPK.

Analysis and Conclusions: I find that CCUS independently practices each and every limitation of asserted claim 21. Similar to claims 1 and 11, I find that the preamble of claim 21 is not a limitation. Claim 21 is complete without the preamble, and the preamble merely explains what is obvious based on the actual claim language—the claim is directed to a method for fabricating shell dental appliances for moving teeth.

Assuming, *arguendo*, that the preamble of claim 21 is a limitation, I find that CCUS practices the preamble of claim 21. Mr. Pumphrey admitted that {

} (Tr. at 316:12-318:11) I find that this shows CCUS fabricates polymeric shell dental appliances for moving a patient's teeth.

Based on the evidence discussed above in Section V.B.2, *supra*, regarding Respondents' process, I find that CCUS practices the first and second elements of claim 21. Mr. Pumphrey admitted that {

} I find that admissions of Mr. Pumphrey also

show shows that CCUS practices the third element of claim 21. {

} (*Id.*) As a result, I find that Align has shown by a preponderance of the evidence that CCUS practices claim 21 of the '325 patent.

I additionally find that the evidence shows that CCPK and CCUS act in concert to practice claim 21 of the '325 patent. In addition to reading on the activities of CCUS, element 1 of claim 21 also reads on {

.} (*Id.*) The remaining elements of claim 21 are practiced by CCUS, as discussed above. Based upon the foregoing, I find that Align has shown by a preponderance of the evidence that the concerted efforts of CCUS and CCPK practice each and every limitation of claim 21 when the digital data sets created by CCPK are used by CCUS to fabricate aligners.

9. Claim 30

Claim 30 teaches:

> A method as in claim 21, wherein the digital data set represents substantially accurate shapes of the patient's actual teeth in the modified tooth arrangement.

(JX-003 at R2:24-26)

Align's position: Align asserts that CCUS alone (or both CCUS and CCPK) practice claim 30 because the teeth in the digital data sets representing modified tooth arrangements are based on the initial 3D digital scan of a model of the patient's teeth, and are thus substantially accurate representations thereof. (Citing CX-1150C at Q. 186) Align says that Respondents did

not contest that they infringe this element. (Citing RPHB at 22; RX-0129C at Q. 65) Align contend that Respondents infringe this claim for the same reason they infringe claim 21.

Respondents' Position: Respondents assert that they do not infringe dependent claim 30 because they do not infringe the independent claim. Respondents add that the claim cannot be infringed because Align contends that some elements are practiced by CCUS in the United States while others are practiced by CCPK in Pakistan. (Citing CX-1150C at Q. 186)

Respondents assert that Align attempts to advance for the first time new theories of infringement never disclosed. Specifically Respondents say that Align now argues that CCUS practices claim 30 of the '325 patent. Respondents argue that these new theories were introduced by Align because Align's arguments that CCUS induces infringement were stricken as not properly raised.

Staff's Position: Staff says that for claim 30 of the '325 patent, the evidence shows that the additional claim elements recited in claim 30 of the '325 patent, which depends from claim 21 of the '325 patent (discussed below), are performed by CCPK. (Citing CX-1150C at Q. 186; CX-1198C at 141-142)

Staff says that Complainant alleges in its Post-Hearing Brief that CCUS infringes claim 30 under 35 U.S.C. § 271(a) by performing each claimed step in Texas. Staff argues that because Complainant did not make these allegations in its Pre-Hearing Brief, they should not be considered now. (Citing CPHB at 202-203, 205-206, and 218-219)

Analysis and Conclusions: If I had found that Align had failed to prove that Respondents infringe claim 21, it would follow that Align failed to prove infringement of claim 30, which depends from claim 21. *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n. 9 (Fed. Cir. 1989) ("One who does not infringe an independent claim cannot infringe a claim

dependent on (and thus containing all the limitations of) that claim.")

Nevertheless, I have found that Respondents infringe asserted claim 21. I also find that CCUS practices claim 30 of the '325 patent. Mr. Beers provided unrebutted testimony that the teeth in the modified tooth arrangements are substantially accurate representations of the patient's teeth. (CX-1150C at Q. 186) As a result, I find that Align has shown by a preponderance of the evidence that CCUS independently, and CCUS and CCPK, acting in concert, practice dependent claim 30 of the '325 patent.

10. Claim 31

Claim 31 teaches:

> A method for facilitating a tooth repositioning dental treatment of a patient by use of a series of successive tooth positioning appliances, including producing a plurality of digital data sets representing a plurality of tooth arrangements and providing a plurality of the digital data sets to a fabrication operation for fabricating the treatment, said method comprising:
>
> providing an initial digital data set representing an initial tooth arrangement;
>
> presenting a visual image based on the initial data set;
>
> manipulating the visual image to reposition individual teeth in the visual image;
>
> producing a final digital data set representing the final tooth arrangement with repositioned teeth as observed in the image;
>
> producing a plurality of intermediate digital data sets representing a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement;
>
> and providing a plurality of the produced intermediate digital data sets to a fabrication operation to facilitate the tooth repositioning dental treatment of the patient with a series of successive tooth repositioning appliances.

(JX-003 at R2:27-50)

Align's position: Align asserts that Respondents practice each and every limitation of claim 31. Align asserts that the preamble of claim 31 is not limiting, as it merely states the purpose of the claimed method. Align says that Respondents have not asserted the contrary in their Prehearing Brief, and have therefore waived such a position. Align reasons that an infringement analysis of the preamble is unnecessary.

Alternatively, Align asserts that if the preamble is found to somehow be limiting, Respondents practice the preamble by their method of designing aligners and creating digital data sets, under which CCPK designs all steps of a patient's treatment and provides them to CCUS.

Align asserts that Respondents practice the first element of claim 31, which is identical to the first element of claim 1. Align avers that Respondents did not contest that they infringe this element in their interrogatory responses.

Align asserts that the second element of claim 31 is identical to the second element of claim 1, and is practiced by CCPK. Align says that Respondents do not contest they infringe this element in their pre-hearing brief or contention interrogatory responses. (Citing RPHB at 36; RX-0129C at Q. 68).

Align asserts that the third element of claim 31 is identical to the third element of claim 1, and is practiced by CCPK. Align adds that Respondents did not contest that they infringe this element in their interrogatory responses.

Align asserts that the fourth element of claim 31 is identical to the fourth element of claim 1, and is practiced by CCPK. Align adds that Respondents did not contest that they infringe this element in their interrogatory responses.

Align asserts that the fifth element of claim 31 is identical to the fifth element of claim 1, and is practiced by CCPK. Align adds that Respondents did not contest that they infringe this claim element in their interrogatory responses.

Align asserts that CCPK practices the sixth element of claim 31, which requires "providing a plurality…," when it sends CCUS the plurality of intermediate digital data sets through CCUS's server. (Citing CX-1150C at Q. 169) Align says that CCUS then uses the digital data sets to fabricate a series of successive tooth repositioning appliances, which facilitates tooth repositioning treatment. (Citing CX-1150C at Q. 169)

Align concludes that CCPK's digital data is made according to each of the elements required by claim 31 and are imported, sold, offered for sale, and used in the U.S. (Citing Tr. at 312:20-314:3) Align reasons, as a result, that CCPK's digital data directly infringes under 35 U.S.C. § 271(g) and violates 19 U.S.C. § 1337(a)(1)(B)(i). Align adds that such importation and sale is also a violation of 19 U.S.C. § 1337(a)(1)(B)(ii). Align contends that CCUS uses the digital data sets in the U.S. and therefore also directly infringes under 35 U.S.C. § 271(g).

Align says that Respondents should be precluded from contesting infringement of claims 31 and 32 because they were not identified in response to Align's Interrogatory No. 33 for the reasons advanced in Align's *Motion in Limine* No. 3. Align disagrees with Respondents' argument that CCUS "does not produce a plurality of 'digital sets'" and CCPK "does not produce appliances" in view of claim 31's preamble. Align says that it does not assert the former, and claim 31 does not require the latter. Align adds that the preamble is not a claim limitation and, if it were, there is no requirement that CCPK practice a limitation itself to infringe under, *e.g.*, § 271(g) or § 337(a)(1)(B)(ii).

Align says that Respondents also argue that there can be no violation of § 337(a)(1)(B)(ii) of Claim 31 by CCPK because it requires aligner fabrication. Align contends that there is no such requirement in claim 31; rather, it only requires "providing" the digital data "to a fabrication operation …" and there is no requirement in the claim that aligners be produced. (Citing JX-0003 at 27 (2:24-50))

Respondents' Position: Respondents assert that neither CCUS nor CCPK infringes claim 31. Respondents say that Align contends the first and fifth elements are practiced by CCUS in the United States and the second, third and fourth elements are practiced by CCPK in Pakistan. (Citing Tr. at 545:22 – 546:19) Respondents continue that with respect to Align's theory under 19 USC 1337(a)(1)(B)(ii), at least part of the first element of claim 31 – "providing an initial data set representing an initial tooth arrangement" – is practiced by CCUS when it scans the physical model of the patient's teeth and at least part of the last element – "providing a plurality of the produced intermediate digital data sets to a fabrication operation" – also occurs in the U.S., where the fabrication operation is located. Respondents reason, as a result, that 19 USC 1337(a)(1)(B)(ii) does not apply.

Respondents assert that they do not practice the preamble of claim 31 because the limitation of "facilitating a tooth repositioning dental treatment" requires that a patient receive dental treatment. Respondents say that only a licensed clinician may provide dental treatment and CCUS and CCPK do not provide dental treatment and cannot directly infringe the claim. (Citing CX-0084C; Tr. 349:21-351:6; RX-0129C at Q. 66)

Respondents argue that CCUS does not produce a plurality of "digital sets" or digital information that represents a "plurality of tooth arrangements." (Citing Tr. 329:11-341:21)

Respondents continue that CCPK does not produce appliances, so it too does not infringe this claim limitation. (Citing Tr. 341:18-21)

Respondents assert that they do not practice the claim element requiring "providing an initial digital data set representing an initial tooth arrangement." Respondents say that Mr. Beers states that both CCUS and CCPK perform this step. Respondents argue that assuming that this step is performed by scanning "a 3D physical model of a patient's teeth taken from dental impressions" and subsequently sending that information to another party, there is no evidence that CCPK performs this limitation. (Citing RX-0129C at Q. 67)

Respondents assert that they do not practice the claim element requiring "presenting a visual image based on the initial data set." Respondents assert that Mr. Beers only identifies conduct by CCPK as meeting this limitation and there is no evidence that CCUS practices this claim limitation. (Citing RX-0129C at Q. 68)

Respondents assert that they do not practice the claim element requiring "manipulating the visual image to reposition individual teeth in the visual image." Respondents argue that this limitation requires that a "visual image" be manipulated in order to reposition individual teeth. Respondents say that Mr. Beers states that when new coordinates for a defined tooth position are entered, the visual image is "manipulated". Respondents assert that {

} but, this is not "manipulating the visual image". (Citing RX-0129C at Q. 69) Respondents add that Mr. Beers only identifies conduct by CCPK as meeting this limitation and there is no allegation or evidence that CCUS practices this claim limitation.

Respondents assert that they do not practice the claim element requiring "producing a final digital data set representing the final tooth arrangement with repositioned teeth as observed

in the image." Respondents argue that a "final" tooth arrangement can only be a projection at the treatment stage prior to active treatment, meaning the projection may not actually be the final location of the patient's teeth. (Citing Tr. at 778:5-23) Respondents say that CCUS's process is phase-based and does not meet this limitation. (Citing Tr. at416:8-17; RX-0129C at Q. 70) Respondents say that Mr. Beers only identifies conduct by CCPK as meeting this limitation and there is no allegation or evidence that CCUS practices this claim limitation. (Citing RX-0129C at Q. 70)

Respondents assert that they do not practice the claim element requiring "producing a plurality of intermediate digital data sets representing a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement." Respondents argue that this limitation requires that the "plurality" of "successive tooth arrangements" represent a series of successive tooth arrangements "progressing from the initial tooth arrangement to the "final tooth arrangement". Respondents say that CCUS's process is phase-based and CCPK does not produce a series of digital data sets representing a series from the initial to final tooth arrangement. (Citing RX-0129C at Q. 71) Respondents add that Mr. Beers only identifies conduct by CCPK as meeting this limitation and there is no allegation or evidence that CCUS practices this claim limitation.

Respondents assert that they also do not practice the claim element requiring "providing a plurality of the produced intermediate digital data sets to a fabrication operation to facilitate the tooth repositioning dental treatment of the patient with a series of successive tooth repositioning appliances." Respondents argue that the language of this limitation requires that the "produced intermediate data sets", representing all data sets from the initial to final data sets, must be prepared before being provided to the fabrication operation and CCUS's phase-based system

does not meet this limitation. (Citing RX-0129C at Q. 72) Respondents add that Mr. Beers only identifies conduct by CCUS as meeting this limitation and there is no allegation or evidence that CCPK practices this claim limitation.

Respondents assert that Align attempts to advance for the first time new theories of infringement never disclosed. Specifically Respondents say that Align now argues CCUS infringes claim 31 of the '325 patent under 271(g). Respondents argue that these new theories were introduced by Align because Align's arguments that CCUS induces infringement were stricken as not properly raised.

Staff's Position: Staff says that under Align's § 271(g) infringement theory, the evidence supports finding infringement of claim 31 of the '325 patent under my rulings regarding patent infringement under Section 337 (but not under the Staff's understanding of the legal standards of patent infringement). Staff says that applying my rulings, the evidence shows that CCPK directly infringes claim 31 of the '325 patent by selling digital data sets. (Citing CX-1150C at Q. 149-172; CX-1198C at 142-159)

Staff continues that the same evidence also supports finding infringement of claim 31 of the '325 patent under Align's infringement theory under 19 U.S.C. § 1337(A)(1)(B)(ii) (based on the Staff's understanding of the legal standards of patent infringement). Staff explains that CCPK practices each element of claim 31 of the '325 patent and imports the digital data sets that are produced by the claimed method. (Citing CX-1150C at Q. 149-172; CX-1198C at 142-159)

Staff says that Complainant alleges in its Post-Hearing Brief that CCUS infringes claim 32 under 35 U.S.C. § 271(g) by importing or using the digital data in the United States. (Citing CIB at 74) Staff argues that because Complainant did not make these allegations in its Pre-

Hearing Brief, they should not be considered now. (Citing CPHB at 202-203, 205-206, and 218-219)

Analysis and Conclusions: I find that CCPK practices each and every limitation of independent claim 31 in Pakistan when it produces digital data sets and transmits those digital data sets to CCUS. Similar to claims 1, 11, and 21, I find that the preamble of claim 31 is not a limitation. Claim 31 is complete without the preamble, and the preamble merely restates what is already provided in the body of the claim. As a result, I find that the preamble of claim 31 is not limiting.

Assuming, *arguendo*, that the preamble of claim 31 is a limitation, based on the admissions of Mr. Arif, I find that CCPK practices the preamble of claim 31 by {

} (Tr. at 172:15-173:8) The first through fifth elements of claim 31 are identical to the first through fifth elements of claim 1. Based on my findings and rationale in Section V.B.2, *supra*, regarding the first through fifth elements of claim 1, which I incorporate and reaffirm here, I find that CCPK independently practices these elements of claim 31.

Turning to the sixth element of claim 31, I note that Mr. Arif testified that {

} (Tr. at 316:12-318:11) Based on these admissions by employees of CCPK and CCUS, I find that CCPK practices the sixth

element of claim 31 when it transmits the intermediate data sets to CCUS, which in turn fabricates aligners based on the data sets. As a result, I find that Align has shown by a preponderance of the evidence that CCPK independently practices claim 31 of the '325 patent.

In section V.B.2, *supra*, I find that Respondents' "facilitating treatment" and "manipulating a visual image" arguments are unpersuasive. I incorporate and reaffirm those findings and the rationales for them here.

11. Claim 32

Claim 32 teaches:

> A method as in claim 31, wherein the produced digital data sets represent substantially accurate shapes of the patient's actual teeth.

(JX-003 at R2:51-53)

Align's position: Align asserts that claim 32 is similar to claim 30, and is practiced by CCPK. Align says that Respondents did not contest that they infringe this element in their pre-hearing brief or in their interrogatory responses. (Citing RPHB at 38; RX-0129C at Q. 73) Align concludes that Respondents infringe and violate Section 337 for the same reasons as claim 31.

Respondents' Position: Respondents assert that they do not infringe dependent claim 32 because they do not infringe the independent claim. Respondents say that the claims also cannot be infringed because Align contends that some elements are practiced by CCUS in the United States while others are practiced by CCPK in Pakistan. Respondents continue that claim 32 recites "A method as in claim 31, wherein the produced digital data sets represent substantially accurate shapes of the patient's actual teeth." Respondents say that there is no evidence that CCUS would practice this step. Align agrees.

Respondents assert that Align attempts to advance for the first time new theories of infringement never disclosed. Specifically Respondents say that Align now argues that CCUS infringes claim 32 of the '325 patent under 271(g). Respondents argue that these new theories were introduced by Align because Align's arguments that CCUS induces infringement were stricken as not properly raised.

Staff's Position: Staff says that under Align's § 271(g) infringement theory, the evidence supports finding infringement of claim 32 of the '325 patent under my rulings regarding patent infringement under Section 337 (but not under the Staff's understanding of the legal standards of patent infringement). Staff says that applying my rulings, the evidence shows that CCPK directly infringes claim 32 of the '325 patent by selling digital data sets. (Citing CX-1150C at Q. 149-172; CX-1198C at 142-159)

Staff continues that the same evidence also supports finding infringement of claim 32 of the '325 patent under Align's infringement theory under 19 U.S.C. § 1337(A)(1)(B)(ii) (based on the Staff's understanding of the legal standards of patent infringement). Staff explains that CCPK practices each element of claim 32 of the '325 patent and imports the digital data sets that are produced by the claimed method. (Citing CX-1150C at Q. 149-172; CX-1198C at 142-159)

Staff says that Complainant alleges in its Post-Hearing Brief that CCUS infringes claim 32 under 35 U.S.C. § 271(g) by importing or using the digital data in the United States. (Citing CIB at 74) Staff argues that because Complainant did not make these allegations in its Pre-Hearing Brief, they should not be considered now. (Citing CPHB at 202-203, 205-206, and 218-219)

Analysis and Conclusions: If I had found that Align had failed to prove that Respondents infringe claim 31, it would follow that Align failed to prove infringement of claim

32, which depends from claim 31. *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n. 9 (Fed. Cir. 1989) ("One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim.")

Nevertheless, I have found that Respondents infringe asserted claim 31. CCPK also infringes dependent claim 32. Mr. Beers provided unrebutted testimony that the teeth in the modified tooth arrangements are substantially accurate representations of the patient's teeth. (CX-1150C at Q. 172) As a result, I find that Align has shown by a preponderance of the evidence that CCPK practices dependent claim 32 of the '325 patent.

12. Claim 33

Claim 33 teaches:

> A method as in claim 31, further comprising fabricating a plurality of successive tooth repositioning appliances based on at least a plurality of said produced digital data sets provided to the fabrication operation.

(JX-003 at R2:54-57)

Align's position: Align asserts that CCUS practices claim 33 by fabricating a plurality of successive dental incremental position adjustment appliances based on the series of intermediate and final digital data sets produced by and provided by CCPK. (Citing CX-1150C at Q. 174) Align asserts that CCUS's aligners are made according to each of claimed steps by the joint CCUS/CCPK process as recited in claims 31 and 33, and are sold, offered for sale, and used in the U.S. (Citing Tr. at 312:20-314:3) Align concludes that CCUS's aligners directly infringe under 35 U.S.C. § 271(g). Align adds that CCPK contributorily infringes under the four-part *Fujitsu* test, where part 1 is met by CCUS's direct infringement and the remaining parts are met as explained above.

Respondents' Position: Respondents assert that they do not infringe dependent claim 33 because they do not infringe the independent claim. Respondents say that the claims cannot be infringed because Align contends that some elements are practiced by CCUS in the United States while others are practiced by CCPK in Pakistan. Respondents say claim 33 requires that the "plurality of said produced digital data sets", which includes all of the intermediate digital data sets from the initial to the final data sets, be produced prior to fabrication and CCUS's phase-based system does not meet this limitation. (Citing RX-0129C at Q. 74) Respondents add that there is no evidence that CCPK fabricates appliances.

Staff's Position: Staff says that for claim 33 of the '325 patent, the evidence shows that the additional claim element recited in claim 33 of the '325 patent, which depends from claim 31 of the '325 patent (discussed below), is performed by CCUS. (Citing CX-1150C at Q. 174; CX-1198C at 159-161)

Analysis and Conclusions: If I had found that Align had failed to prove that Respondents infringe claim 31, it would follow that Align failed to prove infringement of claim 33, which depends from claim 31. *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n. 9 (Fed. Cir. 1989) ("One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim.")

Nevertheless, I have found that Respondents infringe asserted claim 31. CCUS practices dependent claim 33 when it fabricates aligners based on the digital data sets. I find that CCUS practices claim 33 based on Mr. Pumphrey's admission that {

} (Tr. at 316:12-318:11) As a result, I find that Align has shown by

a preponderance of the evidence that CCUS practices claim 33 of the '325 patent. Because CCPK practices the limitations of claim 31, which are also required by claim 33 as a result of their dependency on claim 31, I find that CCPK and CCUS act in concert to infringe claim 33.

13. Claim 34

Claim 34 teaches:

> A method as in claim 33, wherein fabricating the successive tooth repositioning appliances comprises fabricating polymeric shell appliances.

(JX-003 at R2:58-60)

Align's position: Align asserts that CCUS practices claim 34 by fabricating the plurality of successive dental incremental position adjustment appliances based on the series of intermediate and final digital data sets produced by and provided by CCPK. (Citing CX-1150C at Q. 176) Align says that CCUS fabricates these appliances by thermoforming polyurethane material over positive models of successive tooth arrangements of a patient's teeth to create polymeric shell appliances. (Citing CX-1150C at Q. 176) Align concludes that Respondents infringe claim 34 for the same reason as claim 33.

Respondents' Position: Respondents assert that they do not infringe dependent claim 34 because they do not infringe the independent claim. Respondents say that the claims cannot be infringed because Align contends that some elements are practiced by CCUS in the United States while others are practiced by CCPK in Pakistan. Respondents continue that based on the context of the patent and the related prosecution history, the claim limitation requires the "successive tooth repositioning appliances" be produced prior to active treatment. Respondents say that CCUS's phase-based system involves the production of appliances over time, as the treatment progresses, and therefore does not meet this limitation. (Citing RX-0129C at Q. 75)

Respondents add that there is no evidence that CCPK fabricates appliances, and therefore it does not practice this limitation.

Staff's Position: Staff says that for claim 34 of the '325 patent, the evidence shows that the additional claim element recited in claim 34 of the '325 patent, which depends from claim 33 of the '325 patent, is performed by CCUS. (Citing CX-1150C at Q. 176; CX-1198C at 161-162)

Analysis and Conclusions: If I had found that Align had failed to prove that Respondents infringe claims 31 or 33, it would follow that Align failed to prove infringement of claim 34, which depends from claim 31 via claim 33. *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n. 9 (Fed. Cir. 1989)

Nevertheless, I have found that Respondents infringe asserted claims 31 and 33. I find that CCUS practices dependent claim 34 when it fabricates aligners based on the digital data sets. Mr. Pumphrey admitted that {

} (Tr. at 316:12-318:11) As a result, I find that Align has shown by a preponderance of the evidence that CCUS practices claim 34 of the '325 patent. Because CCPK practices the limitations of claim 31 and CCUS practices the limitations of claim 33, which are also required by claim 34 as a result of its dependency on claims 31 and 33, I find that CCPK and CCUS act in concert to infringe claim 34.

14. Claim 35

Claim 35 teaches:

> A method for fabricating a plurality of successive dental incremental position adjustment appliances, said method comprising:
>
> providing an initial digital data set representing an initial tooth arrangement;

providing a final digital data set representing the final tooth arrangement;

producing a plurality of successive digital data sets based on both of the previously provided initial and final digital data sets, wherein said plurality of digital data sets represent a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement;

controlling a fabrication machine based on the successive digital data sets to produce successive positive models of the successive tooth arrangements; and

producing the successive dental appliances as negatives of the positive models.

(JX-002 at R2:61-R3:11)

Align's position: Align asserts that Respondents practice each and every limitation of claim 35. Align says that the preamble of claim 35 is not limiting, and Respondents have not asserted the contrary in their *Prehearing Brief*, therefore waiving such a position. Align continues that an infringement analysis of the preamble is therefore unnecessary.

Alternatively, Align asserts that if the preamble is found to be limiting, Respondents practice the preamble by their joint method of designing, making and selling clear aligners.

Align asserts that the first element of claim 35 is identical to the first element of claim 1, and is practiced by both CCUS and CCPK. Align says that Respondents take no issue with Align's identification of CCUS's infringing actions; but argue that CCPK does not perform this limitation. (Citing RPHB at 24) Align contends that Respondents are wrong. Align adds that Respondents did not contest they infringe this element in their interrogatory responses.

Align asserts that the second element of claim 35 is identical to the second element of claim 11, and it is practiced by CCPK.

Align asserts that the third element of claim 35 is similar to the fifth element of claim 1, and is practiced by CCPK.

Align asserts that the fourth and fifth elements of claim 35 are similar to the second and third elements of claim 21, and are practiced by CCUS. Align says that Respondents' "all data sets" non-infringement argument is incorrect.

Align asserts that CCUS's aligners are made by the joint CCUS/CCPK process, which practices each of the elements required by claim 35, and are sold, offered for sale, and used in the U.S. (Citing Tr. at 312:20-314:3) Align concludes that CCUS's aligners directly infringe under 35 U.S.C. § 271(g).

Respondents' Position: Respondents assert that neither CCUS nor CCPK infringes claim 35. Respondents say that Align contends the first and fifth elements are practiced by CCUS in the United States and the second, third and fourth elements are practiced by CCPK in Pakistan. (Citing CX-1150C at Q. 222-226) Respondents continue that they do not practice the preamble. Respondents say that based on the context of the patent and the related prosecution history, one skilled in the art would understand that this limitation would require that all of the "plurality" of "dental incremental position adjustment appliances" be fabricated prior to active treatment. Respondents say that a "final tooth arrangement" can only be a projection at the treatment stage prior to active treatment and CCUS's phase-based process means the Clinician evaluates the patient's progress and the Clinician's prescription. (Citing Tr. at 778:5-23; Tr. 416:8-17) Respondents conclude that their phase-based system does not meet this limitation. (Citing RX-0129C at Q. 76)

Respondents assert that they do not practice the first element of claim 35. Respondents say that Mr. Beers has indicated that CCUS or CCPK performs this step. Respondents continue that assuming that this step is performed by scanning "a 3D physical model of a patient's teeth

taken from dental impressions" and subsequently sending that information to another party, there is no evidence that CCPK performs this limitation.

Respondents also argue that they do not practice the second element of claim 35. Respondents say that a "final tooth arrangement" can only be a projection at the treatment stage prior to active treatment. (Citing Tr. at 778:5-23) Respondents continue that one skilled in the art would understand that the "final digital data" in this element is the same as the "final digital data" identified in the following element that is used to "produce" the "plurality" of "successive tooth arrangements." Respondents say that because CCUS uses a phase-based system, it does not use a "final digital data set," if at all, until long after the patient's treatment begins. (Citing RX-0129C at Q. 78)

Respondents assert that they do not practice the third element of claim 35. Respondents say that the language of this limitation requires the production of all of the "plurality" of data sets representing "successive tooth arrangements" "progressing from the initial tooth arrangement to the final tooth arrangement." Respondents continue that CCUS's phase-based system does not involve producing all of the intermediate data sets at the same time and does not meet this limitation. (Citing RX-0129C at Q. 79; Tr. 416:8-17) Respondents add that Mr. Beers only identifies conduct by CCPK as meeting this limitation and there is no allegation or evidence that CCUS practices this claim limitation.

Respondents assert that they do not practice the claim element requiring fourth and fifth elements of claim 35. Respondents say that these limitations require that all of the "successive digital data sets" be produced prior to fabrication of the appliances and active treatment. Respondents argue that CCUS's phase-based system does not meet this limitation. Respondents

add that Mr. Beers only identifies conduct by CCUS as meeting this limitation and there is no allegation or evidence that CCPK practices this claim limitation.

Staff's Position: Staff says that for Claim 35 of the '325 patent; (i) the claim preamble, if limiting, is performed by CCUS and CCPK (Citing CX-1150C at Q. 217-218; CX-1198C at 162-164); (ii) the first claim element is performed by both CCUS and CCPK (Citing CX-1150C at Q. 219-221; CX-1198C at 164-166); (iii) the second claim element is performed by CCPK (Citing CX-1150C at Q. 222; CX-1198C at 166-169); (iv) the third claim element is performed by CCPK (Citing CX-1150C at Q. 223; CX-1198C at 169-171); (v) the fourth claim element is performed by CCUS (Citing CX-1150C at Q. 224-226; CX-1198C at 171-172); and (vi) the fifth claim element is performed by CCUS (Citing CX-1150C at Q. 224-226; CX-1198C at 172-174).

Analysis and Conclusions: I find that CCUS and CCPK act in concert to practice each and every limitation of independent claim 35 of the '325 patent. Similar to claims 1, 11, 21, and 31, I find that the preamble of claim 35 is not a limitation. Claim 35 is complete without the preamble, and the preamble merely restates what is apparent from the final two elements of the claim itself—the claimed method is a method for fabricating a plurality of successive dental appliances. As a result, I find that the preamble of claim 35 is not limiting.

Assuming, *arguendo*, that the preamble of claim 35 is a limitation, I find that the preamble is practiced by CCUS and CCPK based on the same evidence discussed in Section V.B.2, *supra*, that showed that the preamble of claim 1 is practiced by CCUS and CCPK. The first through third elements of claim 35 are identical to the first through third elements of claim 11. Based on the findings and rationale in Section V.B.5, *supra*, which I incorporate and reaffirm here, I find that CCPK and CCUS practice the first and second elements of claim 35 and CCPK practices the third element of claim 35.

Mr. Pumphrey admitted that {

} (Tr. at 316:12-318:11) Based on these admissions, I find that CCUS practices the fourth and fifth elements of claim 35. Based upon all of the foregoing, I find that Align has shown by a preponderance of the evidence that the concerted efforts of CCUS and CCPK practice each and every limitation of claim 35 when the digital data sets created by CCPK are used by CCUS to fabricate aligners.

15. Claim 38

Claim 38 teaches:

> A method for fabricating a plurality of successive, polymeric shell, dental incremental position adjustment appliances for repositioning at least some of a patient's teeth, said method comprising:
>
> providing an initial digital data set representing substantially accurate shapes of the patient's actual teeth in an initial tooth arrangement;
>
> providing a final digital data set representing substantially accurate shapes of the patient's actual teeth in a final tooth arrangement;
>
> producing a plurality of successive digital data sets based on both of the previously provided initial and final digital data sets, wherein said plurality of digital datasets represents substantially accurate shapes of the patient's actual teeth in a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement;
>
> and fabricating a plurality of successive, polymeric shell, dental incremental position adjustment appliances based on at least some of the produced digital data sets.

(JX-003 at R3:21-R4:19)

Align's position: Align asserts that Respondents practice each and every limitation of claim 38. Align says that the preamble of claim 38 is not limiting, and Respondents have not

asserted the contrary in their *Prehearing Brief*, therefore waiving such a position. Align contends, as a result, that an infringement analysis of the preamble is unnecessary.

Alternatively, Align asserts that if the preamble is limiting, Respondents practice the preamble by their joint method of designing, making and selling clear aligners.

Align asserts that the first element of claim 38 is similar to the first element of claim 1, and is practiced by both CCUS and CCPK. Align says that the digital data sets are based on the initial 3D digital scan of a model of the patient's teeth, and are thus substantially accurate representations thereof. (Citing CX-1150C at Q. 230) Align continues that Respondents take no issue with Align's identification of CCUS's infringing actions, but argue that "there is no evidence that [CCPK] performs this limitation." (citing RPHB at 26) Align says that Respondents are wrong for the same reasons discussed above.

Align asserts that the second element of claim 38 is similar to the second element of claim 11, and is practiced by CCPK. Align says that the digital data sets are based on the initial 3D digital scan of a model of the patient's teeth, and are thus substantially accurate representations thereof. (Citing CX-1150C at Q. 233)

Align asserts that the third element of claim 38 is similar to the fifth element of claim 1, and is practiced by CCPK. Align says that the digital data sets are based on the initial 3D digital scan of a model of the patient's teeth, and are thus substantially accurate representations thereof. (Citing CX-1150C at Q. 234)

Align asserts that the fourth element of claim 38 is similar to the sixth element of claim 1, and is practiced by CCPK. Align concludes that CCUS's aligners are made by the joint CCUS/CCPK process and practice each element of claim 38, and are sold, offered for sale, and used in the U.S. (Citing Tr. at 312:20-314:3) Align contends that CCUS's aligners directly

infringe under 35 U.S.C. § 271(g). Align adds that CCPK contributorily infringes under the four-part *Fujitsu* test, where part 1 is met by CCUS's direct infringement and the remaining parts are met as explained above.

Respondents' Position: Respondents assert that CCUS and CCPK do not infringe claim 38 because Align contends the first and fourth elements are practiced by CCUS in the United States while the second and third elements are practiced by CCPK in Pakistan. (Citing CX-1150C at Q.231-237) Respondents assert that they do not practice the claim element requiring "[a] method for fabricating a plurality of successive, polymeric shell, dental incremental position adjustment appliances for repositioning at least some of a patient's teeth, said method comprising" because based on the context of the patent and the related prosecution history, one skilled in the art would readily understand that this limitation would require that all of the "plurality" of "dental incremental position adjustment appliances" be fabricated prior to active treatment. Respondents say that CCUS's process is phase-based and the appliances are not all created until after the patient has started treatment. (Citing Tr. 416:8-17) Respondents reason, as a result, that they do not meet this limitation. (Citing RX-0129C at Q. 81)

Respondents assert that there is no evidence that CCPK performs the limitation requiring "providing an initial digital data set representing substantially accurate shapes of the patient's actual teeth in an initial tooth arrangement." Respondents say that Mr. Beers indicates that CCUS or CCPK performs this step. Respondents argue that assuming that this step is performed by scanning "a 3D physical model of a patient's teeth taken from dental impressions" and subsequently sending that information to another party, there is no evidence that CCPK performs this limitation. (Citing RX-0129C at Q. 82)

Respondents assert that they do not practice the limitation that requires "providing a final digital data set representing substantially accurate shapes of the patient's actual teeth in a final tooth arrangement." Respondents say that a "final tooth arrangement" can only be a projection at the treatment stage prior to active treatment, meaning that the patient's teeth may not ever reach the projected arrangement. Respondents argue that one skilled in the art would understand that the "final digital data" in this element is the same as the "final digital data" identified in the following element that is used to "produce" the "plurality" of "successive tooth arrangements." Responds conclude that CCUS does not meet this limitation. (Citing RX-0129C at Q. 82)

Respondents contend that they do not practice the limitation that requires "producing a plurality of successive digital data sets based on both of the previously provided initial and final digital data sets, wherein said plurality of digital data sets represents substantially accurate shapes of the patient's actual teeth in a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement." Respondents say that this limitation requires the production of digital data sets in a series representing the tooth arrangements "progressing from the initial tooth arrangement to the final tooth arrangement". Respondents continue that in CCUS's phase-based process the Clinician does not determine the successive tooth arrangements that are required until after treatment has begun. Respondents reason as a result that the phase-based system of the Respondents does not meet this limitation. (Citing RX-0129C at Q. 84) Respondents add that Mr. Beers only identifies conduct by CCPK as meeting this limitation and there is no allegation or evidence that CCUS practices this claim limitation.

Respondents assert that they do not practice the claim limitation requiring "fabricating a plurality of successive, polymeric shell, dental incremental position adjustment appliances based on at least some of the produced digital data sets." Respondents say that this limitation requires

that all of the "polymeric shell, dental incremental position adjustment appliances" be produced prior to active treatment. Respondents continue that CCUS's phase-based system does not meet this limitation. Respondents add that Mr. Beers only identifies conduct by CCUS as meeting this limitation and there is no evidence that CCPK practices this claim limitation.

Staff's Position: Staff says that for claim 38 of the '325 patent; (i) the claim preamble, if limiting, is performed by CCUS and CCPK (Citing CX-1150C at Q. 228-229; CX-1198C at 174-176); (ii) the first claim element is performed by both CCUS and CCPK (Citing CX-1150C at Q. 230; CX-1198C at 176-178); (iii) the second claim element is performed by both CCUS and CCPK (Citing CX-1150C at Q. 231-233; CX-1198C at 178-181); (iv) the third claim element is performed by CCPK (Citing CX-1150C at Q. 234; CX-1198C at 181-183); and (v) the fourth claim element is performed by CCUS (Citing CX-1150C at Q. 235-237; CX-1198C at 183-186).

Analysis and Conclusions: I find that Align has shown by a preponderance of the evidence that CCUS and CCPK act in concert to practice each and every limitation of independent claim 38 of the '325 patent. Similar to claims 1, 11, 21, 31, and 35, I find that the preamble of claim 38 is not a limitation. Claim 38 is complete without the preamble, and the preamble merely restates what is apparent from the final two elements of the claim itself—the claimed method is a method for fabricating a plurality of successive polymeric shell dental appliances for moving a patient's teeth. As a result, I find that the preamble of claim 38 is not limiting.

Assuming, *arguendo*, that the preamble of claim 38 is a limitation, CCUS and CCPK both practice the preamble when they produce dental appliances pursuant to their process to fabricate of plurality of aligners discussed in Section V.B.2, *supra*, regarding claim 1.

Employees of CCUS and CCPK admitted that {

} Based on these admissions and documents, I find that CCUS practices the first element of claim 1 {

}

{

}

Mr. Arif admitted that {

} (Tr. at 172:15-173:8) Mr. Beers provided unrebutted testimony that the teeth in the modified tooth arrangements are substantially accurate representations of the patient's teeth. (CX-1150C at Q. 234) Based on these admissions of Mr. Arif and the unrebutted testimony of Mr. Beers, I find that CCPK practices the third element of

claim 38 by producing a plurality of successive digital data sets based on the initial data set from CCUS and the "treatment setup" data set.

Mr. Pumphrey admitted that {

} (Tr. at 316:12-318:11) Based on Mr. Pumphrey's admissions, I find that CCUS practices the final element of claim 38. Based upon all of the foregoing, I find that Align has shown by a preponderance of the evidence that the concerted efforts of CCUS and CCPK practice each and every limitation of claim 38 when the digital data sets created by CCPK are used by CCUS to fabricate aligners.

16. Claim 39

Claim 39 teaches:

> A method as in claim 38, wherein the appliances are fabricated based on individual ones of at least a corresponding plurality of the produced digital data sets.

(JX-003 at R4:20-22)

Align's position: Align asserts that CCUS practices claim 39 by fabricating a plurality of successive, polymeric shell, dental incremental position adjustment appliances based on the series of intermediate and final digital data sets produced by and provided by CCPK. (Citing CX-1150C at Q. 239) Align concludes that Respondents infringe claim 39 for the same reason as claim 38.

Respondents' Position: Respondents assert that they do not infringe dependent claim 39 because they do not infringe the independent claim. Respondents continue that the claims also cannot be infringed because Align contends that some elements are practiced by CCUS in the

United States while others are practiced by CCPK in Pakistan. Respondents add that Claim 39 recites "[a] method as in claim 38, wherein the appliances are fabricated based on individual ones of at least a corresponding plurality of the produced digital data sets" and one skilled in the art would readily understand that this limitation would require that the "appliances" be produced prior to active treatment. Respondents argue that CCUS's phase-based system does not meet this limitation and there is no infringement of claim 39. (Citing RX-0129C at Q. 86) Respondents continue that Align does not contend that CCPK practices the dependent limitation of claim 39 and there is no evidence that it does so.

Staff's Position: Staff says that for claim 39 of the '325 patent, the evidence shows that the additional claim element recited in claim 39 of the '325 patent, which depends from claim 38 of the '325 patent, is performed by CCUS. (Citing CX-1150C at Q. 239; CX-1198C at 186-188)

Analysis and Conclusions: If I had found that Align had failed to prove that Respondents infringe claim 38, it would follow that Align failed to prove infringement of claim 39, which depends from claim 38. *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n. 9 (Fed. Cir. 1989)

Nevertheless, I have found that Respondents infringe asserted claim 38. Align has introduced evidence that demonstrates that CCUS practices dependent claim 39. Mr. Pumphrey testified that {

} (Tr. at 316:12-318:11) As a result, I find that Align has shown by a preponderance of the evidence that CCUS practices claim 39 of the '325 patent.

17. Contributory Infringement

Align's Position: Align says that CCPK contributorily infringes claims 1, 2, 3, 11, 13, 14, 21, 30, 33, 34, 35, 38, and 39 under the four-part *Fujitsu* test, where part 1 is met by CCUS's and/or CCPK's direct infringement.[44] (Citing *Fujitsu Ltd. v. Netgear Inc.*, 620 F.3d 1321 (Fed. Cir. 2010))

Align argues that part 2 of the *Fujitsu* test is satisfied because CCPK has known of Align's asserted patents for years. Align avers that CCPK knew of the '880 and '511 Patents since its formation in 2009, as those patents were asserted in a 2006 ITC Investigation involving Align and OrthoClear (Inv. No. 337-TA-562), where OrthoClear Pakistan's country head was the current CEO of CCPK - Mudassar Rathore. (Citing Tr. at 441:9-442:1; CX-0978 at 32, 38, 40) Align continues that during the initial set-up of CCPK, its founders and managers expressed concerns to CCUS about infringing Align's patents. (Citing Tr. at 431:13-432:9; CX-0511C at 4, 20-21) Align adds that CCPK also became aware of each of the asserted patents when Align sued CCUS in Texas in 2011 (Citing Tr. at 427:6-11) and, at the latest, when it received the complaint and filed a response in this Investigation. (Citing Tr. at 426:16-427:5) Align contends that such knowledge supports a finding of contributory infringement. (Citing *Lone Star Document Mgmt., LLC v. Atalasoft, Inc.*, 2012 U.S. Dist. LEXIS 129979, at *9 (E.D. Tex. Sept. 11, 2012) (defendants received notice of their alleged infringement when plaintiffs served them with the lawsuit))

Align asserts that parts (3) and (4) of the *Fujitsu* test are also satisfied. Align says that the Supreme Court has found that "[o]ne who makes and sells articles which are only adapted to be used in a patented combination will be presumed to intend the natural consequences of his

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[44] Align addresses contributory infringement for all patents-in-suit in a single section.

acts; he will be presumed to intend that they shall be used in the combination of the patent." (Citing *Metro-Goldwyn-Mayer Studios, Inc. v. Grokster, Ltd.*, 545 U.S. 913, 932 (2005)) Align says that the imported digital data sets are a material part of CCUS's process and have no substantial non-infringing uses. (Citing Tr. at 320:2-9, 320:20-321:15, 442:24-443:10, 443:25-444:3; CX-1162C.3 at 97:1-14; CX-1160C.4 at 645:15-646:4) Align explains that courts generally focus not on the "specifically adapted" language but instead on whether there is a substantial non-infringing use. (Citing *Fromberg, Inc. v. Thornhill*, 315 F.2d 407 (5th Cir. 1963) (Court found that although the alleged product could be used for another purpose, it had been designed specifically for an infringing purpose)) Align contends that here, Respondents have not introduced any evidence of a non-infringing use; rather, they have only offered conjecture. Align continues that intent is presumed where, as here, there is no use other than an infringing one for the component. (Citing *Alloc, Inc.*, 342 F.3d at 1374)

Align asserts that CCPK elected to produce digital data sets for CCUS based only on CCUS's conclusory statement that there was no infringement (*i.e.*, without receiving any specific reason that CCUS believed it did not infringe or related legal opinions or analysis). (Citing CX-511C at 3; and Tr. at 320:2-9, 320:12-15, 442:19-23)

Align says that Respondents argue, without citation to precedent, that "Align's burden to show induced or contributory infringement is very high." (Citing RIB at 12) Align continues that Respondents cite three cases that discuss the requirements to show inducement under § 271(b) and attempt to graft these requirements to a showing of contributory infringement under § 271(c). (Citing RIB at 13) Align asserts that contributory infringement has only a "minimal intent requirement." (Citing *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1303 (Fed. Cir. 2006)) Align says that this is exemplified by part 2 of the *Fujitsu* test, which requires that "the accused

infringer had knowledge of the patent." (Citing *Fujitsu*, 620 F.3d at 1326) Align argues that *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 SCt. 2060 (2011) cited by Respondents, does not hold differently, as it addresses § 271(c) only in the context of explaining that knowledge of the patent is required for indirect infringement under both §§ 271(c) and (b). (Citing 131 S. Ct. 2060, 2067-68 (2011))

Align notes that while *Fujitsu* does indicate that part of the contributory infringement analysis here would include a showing by Align that CCPK knows "that the combination for which [its] component was especially designed was both patented and infringing," any necessary intent on CCPK's behalf is presumed where, as here, there is no use other than an infringing one for the component. (Citing *Fujitsu*, 620 F.3d at 1330; *Metro-Goldwyn-Mayer Studios, Inc. v. Grokster, Ltd.*, 545 U.S. 913, 932 (2005); *Spansion*, 629 F.3d at 1353 (distilling the knowledge requirement to a showing that "the accused device has no substantial non-infringing uses")). Align asserts that even without such a presumption, CCPK's actions meet the knowledge requirement for contributory infringement because CCPK knew of the asserted patents, suspected that CCUS's process was infringing, and elected to continue creating digital data sets for CCUS without any explanation of why CCUS did not infringe.

Align alleges that Respondents' witnesses testified that the imported digital data sets are a material part of CCUS's process and have no substantial non-infringing uses. (Citing Tr. at 320:24-321:2, 442:24-443:10; CX-1162C.3 at 97:1-14; CX-1160C.4 at 645:15-646:4) Align says that Respondents do not argue that the digital data sets are not a material part of their process (citing RIB at 12-16); rather, Respondents' argument is that:

> There can be no contributory infringement because the computer files at issue here are common three-dimensional files of a type that are widely used in

> dentistry and have uses for treatment planning, record keeping, and applications for dental procedures involving root canals, crowns and bridges.

(Citing RIB at 16) Align contends that this argument is irrelevant because it is directed to the vague category of "three-dimensional files," not the specific digital data sets at issue here, and the offered "testimony" is conjecture and there is no evidence that any relevant digital data sets were actually used in the manner described, or that they have any use besides in Respondents' infringing process. Align continues that the evidence confirms the opposite; neither CCUS nor CCPK uses the digital files for any purpose besides making aligners and the digital data sets themselves are useful only to one particular patient (Citing Tr. at 320:20-321:2, 442:24-443:10; CX-1160C.4 at 645:15-646:4)

Align argues that the Federal Circuit has confirmed that "non-infringing uses are substantial when they are not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental." (Citing *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1327 (Fed. Cir. 2009)). Align continues that in assessing whether a use is substantial, the fact-finder may consider "the use's frequency, ... the use's practicality, the invention's intended purpose, and the intended market." (Citing *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 851 (Fed. Cir. 2010) Aligns says that Respondents have provided no such evidence of any particular non-infringing use of the digital data sets, let alone a substantial one. Align contends that courts often confirm that there are no substantial non-infringing uses where, as here, there is no evidence of the product having actually been used in the non-infringing manner. (Citing *Mentor H/S, Inc. v. Med. Device Alliance, Inc.*, 244 F.3d 1365, 1379-80 (Fed. Cir. 2001); *Regents of Univ. of Cal. v. Hansen*, 1999 WL 33268423, at *8 (E.D. Cal. Nov. 8, 1999); *EWP Corp. v. Reliance Universal Inc.*, 1983 WL 219 (S.D. Ohio Nov. 4, 1983), *rev'd on other grounds by* 755 F.2d 898 (Fed. Cir. 1985))

Align asserts that Respondents attempt to escape liability by citing to *Certain Electronic Devices With Image Processing Systems*, Inv. No. 337-TA-724, Comm'n Op. at 10 (Dec. 21, 2011) ("Electronic Devices"). *RespPostHB* at 16-17. Align says that Respondents misread *Electronic Devices*, which actually supports Align's assertions. Align continues that in *Certain Electronic Devices*, the Commission expressly stated that "infringement, direct or ***indirect***, must be based on the articles as imported to satisfy the requirements of Section 337." (Citing *Certain Electronic Devices* Comm'n Op. *at* 14 (emphasis added by Align)) Align adds that in footnote 9, the Commission indicated that an example of an indirectly infringing article is one that is contributorily infringing, citing *Spansion* (discussed above in Sec. IV.D). (Citing *id.* at 14 n.9) Align contends that it is asserting that Respondents' digital data sets are contributorily infringing or inducing infringement at the time of their importation – the very approach approved by *Spansion*. Align argues that in *Electronic Devices*, the Commission found that the imported article did not infringe the asserted method claim (*id.* at 18) at importation, but found that "S3G might have proved a violation of section 337 if it had proved indirect infringement of method claim 16." (Citing *Id.* at 18)

Align asserts that violations have been found based on "indirect" infringement where a domestic entity uses an imported product created by a foreign entity to manufacture a product that infringes. (Citing *Certain Minoxidil Powder*, Inv. No. 337-TA-267, 1988 ITC LEXIS 19, at *16-17 (Feb. 16, 1988); *Certain Systems For Detecting & Removing Viruses Or Worms*, Inv. No. 337-TA-510, I.D. at 27, 28, 33, 34 (May 9, 2005)) Align continues that violations have also been found where a Respondent has imported an article that is then used to infringe a method claim within the U.S. (Citing *Certain Wireless Commc'n Devices*, Inv. No. 337-TA-745, I.D. at 10, 11, 30-32, 50-52 (Apr. 24, 2012); *Certain Personal Data & Mobile Commc'n Devices*, Inv.

No. 337-TA-710, I.D. at 7, 8, 58 (July 15, 2011); *Certain Digital Televisions*, Inv. No. 337-TA-617, I.D. at 26, 27 (Nov. 17, 2008); *aff'd by* Comm'n Op. at 4, 5 (Nov. 17, 2008)) Align says that Respondents have not addressed or distinguished any of this precedent, despite its presence in Align's *Prehearing Brief*.

Align asserts that Respondents also violate § 337(a)(1)(B)(ii) in view of claims of the '325 patent that are directed to methods of producing digital data sets. Align says that Respondents argue that Align's claims that include a step of aligner fabrication cannot be asserted under § 337(a)(1)(B)(ii) because the aligner fabrication occurs in the U.S. Align argues that it has not asserted claims that require aligner fabrication under § 337(a)(1)(B)(ii). Align says that Respondents also argue that "there can be no violation of Section 337(a)(1)(B)(ii) if part of the patented process is performed in the United States" without any support. Align says that Section 337(a)(1)(B)(ii) requires only that the relevant product be made by the patented process—it does not require that every step be performed by one entity or in one location. (Citing *Certain Circuit Board Testers*, Inv. No. 337-TA-342, I.D. on Mot. for Temp. Relief, 1993 ITC LEXIS 44 (Jan. 11, 1993))

Respondents' Position: Respondents say that the Federal Circuit recently emphasized that a claim of induced or contributory infringement requires evidence of direct infringement. (Citing *Akamai Tech., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301, 1307 (Fed. Cir. 2012); *Novartis Pharm. Corp. v. Eon Labs Mfg.*, 363 F.3d 1306, 1308 (Fed. Cir. 2004)) Respondents argue that for each claim where Align has not met its burden of establishing any direct infringement, its arguments based on induced or contributory infringement also fail.

Respondents assert that Align's pleadings and discovery responses preclude any argument that CCUS indirectly infringes any of the asserted patents. Respondents say that

Align's complaint alleges throughout only that that CCPK induces and/or contributes to CCUS' direct infringement. (Citing Complaint at ¶¶ 4, 73, 77, 89, 93) Respondents say that Align does not allege that CCUS induces or contributes to infringement by CCPK. Respondents continue that Align's sworn response also states that it is not asserting that CCUS induces infringement. (Citing Align's Response to CCUS's Fifth Set of Interrogatories in Inv. 337-TA-833, No. 56) Respondents say that I held that "Align may not submit evidence or present arguments that CCUS induces infringement with respect to the asserted claims of the '325 patent, the '863 patent, the '666 patent, the '487 patent, and the '874 patent." (Citing Tr. at 36:10-15) Respondents say that I should reject any theory of infringement based on induced infringement by CCUS as to those patents. The same reasoning applies to bar any contention that CCUS contributes to infringement of any of the asserted patent claims to the extent Align advances such an argument. Respondents submit that the same ruling should also apply to the '880 and '511 patents, for the reasons set forth in their Motion in Limine No. 1.

Respondents assert that Align's burden to show induced or contributory infringement is very high. Respondents say that In *Global-Tech Appliances v. SEB SA*, 131 S. Ct. 2060 (2011), the Supreme Court held that "induced infringement under § 271(b) requires knowledge that the induced acts constitute patent infringement." (Citing 131 S. Ct. at 2068) Respondents continue that the Federal Circuit has likewise held that mere knowledge of possible infringement by others does not amount to inducement and that the patent owner carries the burden to prove specific intent and action to induce infringement. (Citing *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1363 (Fed. Cir. 2003)) Respondents add that the Federal Circuit has held the Complainant bears the burden to show a Respondent's "affirmative intent to cause direct infringement." (Citing *Kyocera Wireless Corp. v. Int'l Trade Comm'n*, 545 F.3d 1340, 1354 (Fed. Cir. 2008))

Respondents say that to satisfy contributory infringement's scienter requirement, it is necessary to establish that "the accused contributory infringer knows that its component is included in a combination that is patented and infringing," which requires knowledge of the patent. (Citing *Global-Tech*, 131 S.Ct. at 2068)

Respondents argue that Align failed to carry its heavy burden of establishing the necessary intent. Respondents say that the evidence admitted at the hearing disproves that CCUS could have had any "affirmative intent to cause direct infringement." Respondents aver that Dr. Pumphrey testified how he spent tens of thousands for dollars of his own money in legal fees for research about Align's patent portfolio. (Citing Tr. 394:1-5) Respondents continue that Dr. Pumphrey was confident that CCUS's procedure did not infringe Align's patents. (Citing Tr. 394:10-14)

Respondents say that CCUS also attempted to test its position that it did not infringe by filing a suit for declaratory judgment during February of 2009. (Citing Tr. 232:5-17) Respondents say that CCUS brought that suit to obtain a judicial ruling that it did not infringe Align's patents. (Citing Tr. 363:24-364:7) Respondents continue that Align effectively prevented any judicial determination about infringement by encouraging CCUS to dismiss its suit because Align had no reason to believe CCUS was infringing any of Align's patents. (Citing Tr. 364:8-15) Respondents aver that CCUS dismissed its suit as a result of Align's representations. (Citing Tr. 364:8-15) Respondents say that CCUS then built its business and operated for approximately two years without any objection from Align. (Citing Tr. 364:16-19) Respondents conclude that the evidence shows that CCUS conducted research, came to the conclusion that its procedure did not infringe Align's patents, and then did everything possible to validate its position that it did not infringe, which was effectively validated when Align stated

that it had no reason to think CCUS was infringing and demanded dismissal of the suit for declaratory judgment. Respondents say that under these facts, CCUS could not have believed that it was infringing Align's patents and, therefore, could not have had an "affirmative intent to cause direct infringement."

Respondents argue that the evidence admitted at the hearing disproves that CCPK could have induced CCUS to infringe any of Align's patents. Respondents say that Dr. Pumphrey founded CCUS during 2006. (Citing Tr. at 391:21-23) Respondents continue that it was not until 2009 that CCPK was formed by Mudassar Rathore to provide CCUS with computer files. (Citing Tr. at 269:9-11, 398:5-11) Respondents aver that by that time, CCUS was already using digital technology to model the projected treatment and CCPK's services were used only to "scale-up" CCUS's existing operations. (Citing Tr. at 307:1-5) Respondents say that Align presented the Court with no evidence that Mr. Rathore or anyone who was later affiliated with CCPK was creating computer files to model orthodontic treatment during the interim period between 2006 to 2009; rather, during this almost three-year interim period, Mr. Rathore was in the auto parts business "running a kind of workshop that makes auto parts." (Citing Tr. at 448:24-449:4)

Respondents say that a focal point of Align's examination of Dr. Willis Pumphrey involved his e-mail exchange with Mr. Rathore. Respondents continue that Mr. Rathore's e-mail demonstrates that CCUS had already used its process to treat several cases, any concern had by CCPK that the process infringed Align's patents were put to rest by a legal opinion CCUS claimed to possess and CCUS had "complete confidence" that its process did not infringe. (Citing Tr. at 403:1-12)

Respondent argue that Align's theory of intent, for both induced and contributory

infringement, is merely that CCUS and CCPK had an awareness of Align's patent portfolio generally and were on notice of Align's infringement claims since the time Align filed a patent infringement suit or the ITC investigation. Respondents say that this precise theory was recently considered and rejected by the Commission in *Certain Mobile Devices, Associated Software, and Components Thereof*, Inv. No. 337-TA-744, 2012 WL 3715788 (U.S. Intern. Trade Com'n, June 5, 2012). Respondents say that the Commission rejected Microsoft's argument that "[b]ecause MMI had indisputable actual knowledge of the '566 patent and the operation of the Android system, inducement liability should have been a foregone conclusion" and cited ample authority contradicting Microsoft's position. (Citing *Id.*) Respondents argue that Align has offered no evidence other than that the Respondents had some awareness of Align's patent portfolio; but included with that evidence were demonstrations of the Respondents' belief that CCUS's process did not infringe and that its attempt to validate that belief was frustrated by Align itself.

Respondents assert that "deliberate indifference to a known risk" was rejected as a standard by the Supreme Court in *Global-Tech*. Respondents say that in *DSU Medical Corp. v. JMS Co.*, 471 F.3d 1293, 1305 (Fed. Cir. 2006), the Federal Circuit held *en banc* that, for indirect liability, "specific intent and action to induce infringement must be proven." Respondents continue that *Global-Tech* confirmed this requirement by holding indirect liability requires "knowledge that the induced acts constitute patent infringement." (Citing 131 S. Ct. at 2068)

Respondents argue that a good-faith belief that a patent is invalid defeats this specific intent requirement. (Citing *Kinetic Concepts, Inc. v. Blue Sky Med. Group, Inc.*, 554 F.3d 1010, 1025 (Fed. Cir. 2009) ("a defendant's belief that it can freely practice inventions found in the public domain" forms a defense to inducement)) Respondents continue that even where a

defendant's "product was ultimately found to infringe," a defendant may nonetheless show that it "did not induce infringement because it lacked the required intent." (Citing *Ecolab, Inc. v. FMC Corp.*, 569 F.3d 1335, 1351 (Fed. Cir. 2009))

Respondents assert that in *Global-Tech*, the Supreme Court rejected the test applied by the Federal Circuit and applied a test of willful blindness. Respondents say that the Court held that in order to show willful blindness, two requirements must be met: (1) the defendant must subjectively believe that there is a high probability that a fact exists and (2) the defendant must take deliberate actions to avoid learning of that fact. Respondents continue that Align did not even show that the Respondents met these requirements. Respondents reason that the record does not support a finding of induced infringement.

Respondents argue that Align does not allege in its Posthearing Brief any acts by CCUS that could be considered unfair acts in the importation of articles into the U.S., even if it had the requisite intent. Respondents assert that to the extent Align argues that CCUS induces infringement, Align never explains what the "imported articles" are or how the infringement relates to importation.

Respondents assert that the intent required to show contributory infringement is at least as high, if not higher, than the standard for induced infringement. (Citing *Global-Tech*, 131 S.Ct. at 2067) Respondents say that the statute itself requires actually "knowing" that the component is "especially made or especially adapted for use in an infringement." (Citing 35 USC 271(c)) Respondents assert that the *Grokster* presumption of knowledge is rebutted by a showing of good faith reliance on advice of counsel that its conduct was not infringing. (Citing *Bose Corp. v. SDI Technologies Imation Corp.*, 2012 WL 2862057 (D. Mass. 2012))

Respondents assert that the *Grokster* presumption must be considered in tandem with the *Global-Tech* willful blindness standard, since *Global-Tech* was decided after *Grokster*.

Respondents say that "[i]n the context of a claim of contributory infringement under § 271(c), a substantial non-infringing use is any use that is 'not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental.'" (Citing *Vita-Mix Corp. v. Basic Holdings, Inc.*, 581 F.3d 1317, 1327-29 (Fed. Cir. 2009)) Respondents continue that there can be no contributory infringement because the computer files at issue here are common three-dimensional files of a type that are widely used in dentistry and have uses for treatment planning, record keeping, and applications for dental procedures involving root canals, crowns and bridges. (Citing Tr. 366:1 to 367:13)

Respondents assert that Align has failed to show the elements of 271(c) have been met. Respondents say that Align must show that the Respondents have offered to sell or sold in the United States, or imported into the United States, "a component of a patented machine, manufacture, combination or combination or composition, or a material or apparatus for use in practicing a patented process." (Citing 35 USC 271(c)) Respondents continue that Align only alleges that the importation of electronic files and digital data sets contribute to infringement; those are not components, materials or apparatuses. Respondents say that Align must show that the articles in question have no substantial non-infringing use. Respondents continue that "[i]n the context of a claim of contributory infringement under § 271(c), a substantial non-infringing use is any use that is 'not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental.'" (Citing *Vita-Mix Corp. v. Basic Holdings, Inc.*, 581 F.3d 1317, 1327-29 (Fed. Cir. 2009)) Respondents assert that there can be no contributory infringement because the computer files at issue here are common three-dimensional files of a type that are widely used in

dentistry and have uses for treatment planning, record keeping, and applications for dental procedures involving root canals, crowns and bridges. (Citing Tr. 366:1 to 367:13)

Respondents assert that Align's post-hearing brief does not legitimately address the uncontested evidence concerning the non-infringing uses. Respondents say that Align only suggests that these uses are "conjecture." Respondents say the hearing evidence was unequivocal that the treating physicians review and approve the digital files showing the teeth in the projected locations instructed by the doctor's prescription—clear evidence that the files are used by the doctor for both treatment planning and record keeping. (Citing Tr. at 171:4 to 172:19). Respondents continue that the hearing evidence is also replete with other non-infringing uses for these computer files, including the planning and modeling of dental restorations (Citing RX-102C; RX-103C), creation of dental study models, tooth orientation appraisals, evaluations of treatment progress, communications to third parties, creation of expert diagnostic and evaluative systems, dental arch alignment, occlusal rehabilitation, evaluation of dental prosthodontic treatment, evaluation of pedodontic treatment and evaluation of periodontal treatment (Citing RX-0095 at 8:38 to 9:47)

Staff's Position: Staff says that the evidence shows that each element claimed in claims 1, 2, 3, 11, 13, 14, 30, 33, 34, 35, 38, and 39 of the '325 patent is performed by CCUS and/or CCPK. Staff continues that in addition to demonstrating CCUS's direct infringement of claims 1, 2, 3, 11, 13, 14, 30, 33, 34, 35, 38, and 39 of the '325 patent, the evidence also demonstrates that CCPK had knowledge of the '325 patent. (Citing CX-1162C.1 at 94:10; CX-1151C.1 at 56:10-13; CX-1163C.1 at 50:7-15; CX-1164C.1 at 72:18-21) Staff says that the evidence further demonstrates that the digital data sets that are created by CCPK are a material part of the process

of creating the aligners by CCUS and have no substantial non-infringing uses. (Citing CX-1160C at 174:20-175:4, 645:15-646:4; CX-1162C at 97:1-14)

Staff argues that based on CCUS's direct infringement, the evidence shows that CCPK contributes to that infringement by creating the digital data sets that are used by CCUS in creating aligners. Staff says that the evidence shows that CCPK also performs the preamble of claim 21, if limiting, and the first claim element of claim 21 of the '325 patent. (Citing CX-1150C at Q. 178-184; CX-1198C at 132-140) Staff continues that in addition to demonstrating CCUS's direct infringement of claim 21 of the '325 patent, the evidence also demonstrates that CCPK had knowledge of the '325 patent. (Citing CX-1162C.1 at 94:10; CX-1151C.1 at 56:10-13; CX-1163C.1 at 50:7-15; CX-1164C.1 at 72:18-21) Staff asserts that the evidence further demonstrates that the digital data sets that are created by CCPK are a material part of the process of creating the aligners by CCUS and have no substantial non-infringing uses. (Citing CX-1160C at 174:20-175:4, 645:15-646:4; CX-1162C at 97:1-14)

Staff argues that when applying my rulings regarding patent infringement under Section 337, the evidence shows that (i) CCUS directly infringes claims 1, 2, 3, 11, 13, 14, 21, 30, 33, 34, 35, 38, and 39 of the '325 patent under 35 U.S.C. § 271(g) by selling or using aligners in the United States that are made by the joint CCUS / CCPK process, and CCPK contributes to that infringement under 35 U.S.C. § 271(c) by creating the digital data sets that are used by CCUS, and (ii) CCPK directly infringes claims 31-32 of the '325 patent under 35 U.S.C. § 271(g) by selling digital data sets. Staff continues that when applying Staff's understanding of the legal standards of patent infringement, the evidence shows that (i) CCUS directly infringes claim 21 of the '325 patent under 35 U.S.C. § 271(a) by performing each step of the claimed method in the United States (Texas), and CCPK contributes to that infringement under 35 U.S.C. § 271(c) by

creating the digital data sets that are used by CCUS; and (ii) CCPK directly infringes claims 31-32 of the '325 patent under 19 U.S.C. § 1337(A)(1)(B)(ii) by importing the digital data sets that are produced by these claimed methods. Staff concludes that the evidence demonstrates that CCUS and CCPK violate U.S.C. §1337(a)(1)(B) by importing or causing the importation of digital data sets.

Staff says that the evidence shows that the relationship between CCUS and CCPK is such that their activities are closely coordinated and that the actions of CCPK are essentially directed and controlled by CCUS.

Staff says that Respondents argue that CCUS's belief that it was not infringing Align's patents "was effectively validated when Align stated that it had no reason to think that ClearCorrect was infringing and demanded dismissal of the suit for declaratory judgment." Staff says that this argument is another attempt by Respondents to further argue that they did not intend to infringe the patents in suit because of the alleged covenant not to sue that was given in the context of the suit for declaratory judgment. Staff continues that I have determined that Respondents are precluded from making this particular argument. (Citing Tr. at 32:22-33:3)

Staff asserts that Respondents' reliance on *Mobile Devices* is misplaced because the facts of that investigation are inapposite. Staff says that the Commission in *Mobile Devices* determined that "[Complainant] Microsoft's argument before the ALJ in support of its assertion that [Respondent] Motorola had requisite knowledge sufficient to establish induced infringement was essentially limited to one paragraph," including, in pertinent part:

> Here, the end users of MMI's devices directly infringe the asserted method claims through the routine use of these products. MMI encourages such use by making available manuals instructing users to use the products in an infringement [sic] manner. *See Arthrocare Corp. v. Smith & Nephew, Inc.*, 406 F.3d 1365, 1377 (Fed. Cir. 2005) (manuals can be evidence of inducement). MMI had notice of the asserted patents and Microsoft's infringement theories at least as early as the

> service of Microsoft's Complaint in this Investigation, yet it continues to import and offer the accused products for sale, and continues to make available manuals that instruct users to use the accused product in an infringing manner.

(Citing *Mobile Devices*, Inv. No. 337-TA-744, Comm'n Opinion at 17 (June 5, 2012)) Staff says that Contrary to Respondents' argument, the evidence demonstrates that Align has set forth more facts, and different facts, than those in *Mobile Devices* to support its allegations of indirect infringement. Staff continues that the facts support finding that Respondents had the requisite knowledge and intent for indirect infringement. Staff reasons that unlike *Mobile Devices*, the evidence in this investigation shows, *inter alia*, that there is a long litigious history between Align and CCUS and CCPK, and that the relationship between CCUS and CCPK is such that their activities are closely coordinated.

Staff says that Respondents argue that Align cannot meet its burden of establishing the absence of substantial non-infringing uses for proving contributory infringement. Staff explains that Respondents argue that "the computer files at issue here are common three-dimensional files of a type that are widely used in dentistry and have uses for treatment planning, record keeping, and applications for dental procedures involving root canals, crowns, and bridges." Staff asserts that Respondents' argument is not supported by their citation to the hearing transcript. Staff contends that there is no evidence demonstrating that the computer files are actually used in any manner other than for manufacturing models for fabricating aligners; rather, the evidence demonstrates that there are no substantial non-infringing uses of the digital data sets at issue.

Analysis and Conclusions: I find that CCPK contributorily infringes claims 1, 2, 3, 11, 13, 14, 21, 30, 33, 34, 35, 38, and 39 because the digital data sets created by CCPK and imported into the United States contribute to CCUS's and CCPK's concerted effort to practice claims 1, 2,

3, 11, 13, 14, 21[45], 30, 33, 34, 35, 38, and 39. Contributory infringement requires the patentee to prove that: (1) there is an act of direct infringement in violation of section 337; (2) the accused device has no substantial non-infringing uses; (3) the component is a material part of the invention; and (4) the accused infringer imported, sold for importation, or sold after importation within the United States, the accused components that contributed to another's direct infringement. *Certain Electronic Devices With Image Processing Systems, Components Thereof, and Associated Software*, Inv. No. 337-TA-724; Comm'n Op. (Dec. 21, 2011) at n.9 (citing *Spansion, Inc. v. Int'l Trade Comm'n*, 629 F.3d 1331, 1353 (Fed. Cir. 2010)).

As noted above, I have found that there is an act of direct infringement of claims 1, 2, 3, 11, 13, 14, 21, 30, 33, 34, 35, 38, and 39 of the '325 patent when CCUS and CCPK act in concert to create digital data sets or to fabricate appliances using the digital data sets provided by CCPK. I also have found that there is an act of direct infringement of claims 21 and 30 when CCUS practices all of the elements of claims 21 and 30 to fabricate aligners using the data sets provided by CCPK.

I find that the digital data sets provided by CCPK are imported into the United States and have no substantial non-infringing use and are a material part of the claimed invention. Mr. Mudassar Rathore, an employee of CCPK, testified that after CCPK creates the digital data sets, it sends the digital data sets { } to CCUS { } (Tr. at 442:5-442:23) As a result, I find that the digital data sets are imported. I also find that the digital data sets created by CCPK are a material part of the process of creating the aligners pursuant to claims 1, 2, 3, 11, 13, 14, 21, 30, 33, 34, 35, 38, and 39. The asserted claims make

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[45] To be noted, in Section V.B.8-9, *supra*, I find that in addition to reading on CCPK's and CCUS's concerted efforts, claims 21 and 30 read on steps taken solely by CCUS using data sets provided by CCPK. This provides a separate basis to find CCPK contributes to CCUS' infringement.

clear that once the digital data set(s) is (are) created, the only step remaining is to manufacture the aligners based on the digital data set(s). For example, five of the six elements in claim 1 are directed to preparing, processing, or creating digital data sets. (JX-0003 at R1:29-48) As a result, there is no question that the digital data sets are a material part of the claimed inventions of claims 1, 2, 3, 11, 13, 14, 21, 30, 33, 34, 35, 38, and 39.[46]

I also find that the digital data sets have no substantial non-infringing uses. Jarrett Pumphrey, an employee of CCUS, testified that {

} (RRB at 7 (emphasis added))

Respondents' arguments that the digital data sets have substantial non-infringing uses are not persuasive. For support, Respondents cite to testimony from Mr. Jarrett Pumphrey that states the digital data sets "could" be used as treatment records or progress records, or could be used to project treatment or for dental applications other than orthodontic treatment. (Tr. at 366:8-22) Mr. Jarrett Pumphrey offered nothing to substantiate these statements. (*See id.*) These hypothetical uses cannot qualify as a substantial non-infringing use. *Cf. D.O.C.C., Inc. v. Spintech, Inc.*, 36 U.S.P.Q.2d 1145, 1155 (S.D.N.Y. 1994). Mr. Jarrett Pumphrey's testimony is further diminished by the fact that he also testified that the digital data sets are ***only*** used by CCUS for making aligners. (Tr. at 320:24-321:2) Combined with Respondents' argument in

[46] The digital data sets also are a material part of the inventions of the '511, '880, and '874 patents. The asserted claims of the '511, '880, and '874 patents make clear that the only step remaining once the digital data sets have been created is fabricating appliances using those digital data sets. (*See* JX-002 at 22:12-29, JX-001 at 11:4-19, and JX-006 at 32:37-56)

briefing that the digital data sets are "essentially instructions for making physical aligners" and that the digital data sets have "no separate commercial value," I find that the digital data sets prepared by CCPK for CCUS have no substantial non-infringing uses.

There is no question that CCUS and CCPK had knowledge of the '325 patent. On February 28, 2011, Align filed a patent infringement complaint in the Southern District of Texas against CCUS, which alleged infringement of, *inter alia*, the '325 Patent. (CX-0999 at 1, 2) As a result, CCUS was aware of the '325 patent on or about February 28, 2011, and was aware that Align believed that one or more claims of the '325 patent were infringed by CCUS. Dr. Rathore, the CEO of CCPK, testified that he was aware of this complaint, which asserted, *inter alia*, the '325 patent.[47] (Tr. at 427:6-11) Align has also introduced evidence that CCPK was aware of Align's patents generally. Dr. Rathore signed a consent order stipulation in Inv. No. 337-TA-562, which involved two of Align's patents that are at also issue in this investigation (the '880 and '511 patents). (Tr. at 441:9-442:4) I find that this also provided notice to Dr. Rathore that Align had patents directed to clear aligners and the process of designing and manufacturing clear aligners, as well as Align's infringement theories based on those patents. As a result, I find that CCPK, like CCUS, had knowledge of the '325 patent. *See Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 488-491 (1964) (holding that the knowledge requirement was satisfied when the alleged infringer received a letter from the patent holder alleging infringement of the patent-in-suit). Based upon all of the foregoing, I find that by sending into the United States the digital data sets, CCPK has contributed to the infringement of claims 1, 2, 3, 11, 13, 14, 21, 30, 33, 34, 35, 38, and 39 of the '325 patent.

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[47] The complaint also alleged infringement of the '511 patent, the '863 patent, the '880 patent, and the '874 patent. (CX-999 at 3) As a result, I also find that CCUS and CCPK had knowledge of the '511 patent, the '863 patent, the '880 patent, and the '874 patent and were aware of Align's infringement allegations.

18. Violation of Section 1337(a)

The Positions of the parties on violation of Section 1337(a) based on the '325 patent are discussed in Section V.B.1, *supra*. I find that Respondents' infringement results in a violation of Section 337. 19 U.S.C. § 1337(a)(1)(B)(ii) prohibits "[t]he importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that: . . . (ii) are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent." By importing digital data sets that are made by CCPK (as found in Section II.C, *supra*), which practices the entire process of claims 31 and 32 in Pakistan (as found in Section V.B.13-14, *supra*), Respondents have violated 19 U.S.C. § 1337(a)(1)(B)(ii).

I have found that there is an act of direct infringement of asserted claim 21 and 30 of the '325 patent in the United States when CCUS practices all of the claim elements of claims 21 and 30 to fabricate appliances using data sets created by CCPK. In Section V.B.17, *supra*, I find that CCPK contributes to this infringement. 19 U.S.C. § 1337 (a)(1)(B)(i) prohibits "[t]he importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that: (i) infringe a valid and enforceable United States patent or a valid and enforceable United States copyright registered under title 17." The Commission has explained that "section 337(a)(1)(B)(i) covers imported articles that directly or indirectly infringe when it refers to 'articles that -- infringe.' ***We also interpret the phrase 'articles that – infringe' to reference the status of the articles at the time of importation.*** Thus, infringement, direct or indirect, must be based on the articles as imported to satisfy the requirements of section 337." *Certain Electronic Devices With Image Processing Systems, Components Thereof, And Associated Software*, Inv. No. 337-TA-724, Comm'n Op.

(Dec. 21, 2011) (emphasis added). Because the digital data sets from CCPK contribute to CCUS practicing claims 21 and 30 of the '325 patent, and the digital data sets are imported into the United States (as found in Section II.C, *supra*), I find that Respondents have violated 19 U.S.C. § 1337(a)(1)(B)(i).

I have found that there is an act of direct infringement of asserted claims 1, 11, 21, 33, 34, 35, and 38 of the '325 patent when CCUS and CCPK act in concert to create digital data sets and fabricate appliances using the data sets. Because CCUS and CCPK act in concert to infringe claim 1, 11, 21, 35, and 38, I find that CCUS and CCPK also act in concert to infringe dependent claims 2, 3, 13, 14, 30, and 39. Respondents' infringement results in a violation of Section 337. 19 U.S.C. § 1337(a)(1)(B)(ii) prohibits "[t]he importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that: . . . (ii) are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent." By acting in concert to create appliances using imported digital data sets that are made by the process of claims 1, 2, 3, 11, 13, 14, 21, 30, 33, 34, 35, 38 and 39 (as found above), and the digital data sets are imported into the United States (as found in Section II.C, *supra*), Respondents have violated 19 U.S.C. § 1337(a)(1)(B)(ii).

C. The '880 Patent

1. Claim 1

Claim 1 teaches:

> A method for making a predetermined series of dental incremental position adjustment appliances, said method comprising:
>
> a) obtaining a digital data set representing an initial tooth arrangement;

b) obtaining a repositioned tooth arrangement based on the initial tooth arrangement;

c) obtaining a series of successive digital data sets representing a series of successive tooth arrangements; and

d) fabricating a predetermined series of dental incremental position adjustment appliances based on the series of successive digital data sets, wherein said appliances comprise polymeric shells having cavities shaped to receive and resiliently reposition teeth, and said appliances correspond to the series of successive tooth arrangements progressing from the initial to the repositioned tooth arrangement.

(JX-002 at 22:12-29)

Align's Position: Align asserts that the preamble of claim 1 is not limiting, as it merely states the purpose of the claimed method. (Citing *See, e.g., Pitney Bowes,* 182 F.3d at 1305) Align says that Respondents have not asserted the contrary in their *Prehearing Brief*, and have therefore waived such a position. Align concludes, as a result, that an infringement analysis of the preamble is unnecessary.

Alternatively, Align contends that if the preamble is found to somehow be limiting, CCUS practices the preamble by designing, making and selling clear aligners that are to be worn by a patient in a predetermined order. (CX-1150C at Q. 262) In addition to citing to Evidence Categories 1, 3, 4, 5, 7, 9, and 10 for support, Align says that respondents use various computer workstations, servers, and computer-operated machinery in order to access, create, store, manipulate, and use for fabrication the 3D digital models of the patient's dentition. (Citing Tr. at 170:22-171:15, 177: 9-178:5, 315:2-318:7; CX-1157C.1 at 31:1-32:25; CX-1157C.1-3 at 41:24-44:7; CX-0862C; CX-0871C; CX-0883C; CX-0900C; CX-0090C; CDX-0010C; CDX-0011C) Align continues that the computers run software including, {

} (Citing Tr. at 179:11-21; 315:2-318:7, 325:21-326:9; CX-

0862C; CX-871C; CX-0883C; CX-0900C; CX-1157C.1-3 and CX-1158C.1-3) Align adds that one or more of these software programs – which require a computer with a processor, memory, and a monitor – are used in every critical step of Respondents' process. (Citing CX-1150C at Q. 120; see, e.g., Tr. at 179:11-21; 315:2-318:7, 325:21-326:9; CX-1157C.1-3 at 41:24-80:13; CX-1158C.1-3 at 48:4-23, 91:2-101:23, 102:18-103:20) Align refers to this evidence regarding respondents' use of various computer workstations, servers, and computer-operated machinery to access, create, store, manipulate, and use for fabrication the 3D digital models of the patient's dentition as evidence category number 2.

Align asserts that when moving the teeth into a final position, {

} (Citing CX-090C at 28; *see also* Tr. at 319:7-17, 321:16-322:8; CX-0110C at 5; CX-0086C at 2; CX-0075C at 4; CX-1157C.1-3 at 54:21-25) Align refers to this evidence regarding movement limitations as evidence category number 6.

Align says that Respondents often incorporate engagers, "also known as 'attachments,'" where certain types of movements are difficult to accomplish. (Citing CX- 0413C at 1) Align explains that, for example, where it is difficult to rotate a round tooth or pull a tooth upward,

{

} (Citing CX-413C at 1-2; see also CX-1160C.1 at 93:12-15) Align refers to this evidence regarding the use of attachments as evidence category number 8.

Align asserts that CCPK initially designs each step of the patients' entire treatment, and CCUS then makes and sells at least one phase, consisting of four steps, of the patient's aligners at a time. (Citing Evidence Categories 7 and 10; CX-1150C at Q. 262)

Align says that Respondents generally assert their "predetermined series ..." argument. Align argues that even if Respondents' proposed construction of "predetermined series ..." from the *SRJCCC* is adopted, CCUS still infringes, because the entire four steps of Respondents' "Phase 1" are fabricated before using any of the phase, and are "fabricated prior to the outset of treatment." Align continues that if Staff's proposed construction is adopted, these four steps, and the entire full case, are also "fabricated according to data sets which are determined at the outset."

Align contends that CCUS practices the first element of claim 1 ("a) obtaining a digital data set …") {

} (Citing Evidence Categories 1 and 9; CX-1150C at Q. 263) Align avers that Respondents do not appear to dispute infringement of this element. (Citing RPHB at 87-88; RX-0129C at Q. 136-140)

Align argues that CCPK practices the second element of claim 1 ("b) obtaining a repositioned tooth arrangement …") when {

} (Citing Evidence Categories 4 and 5; CX-1150C at Q. 264) Align says that this "after" model can be the "repositioned tooth arrangement." (Citing CX-1150C at Q. 264) Alternatively, Align says that CCPK practices this claim element when {

} all of which may be considered a "repositioned tooth arrangement." (Citing Evidence Category 7; CX-1150C at Q. 264) As another alternative, Align contends that ***CCUS*** practices this claim element {

}

(Citing Evidence Categories 7 and 9; CX-1150C at Q. 264) Align says that Respondents do not appear to dispute infringement of this element. (Citing RPHB at 87-88; RX-0129C at Q. 136-140)

Align contends that CCPK practices the third element of claim 1("c) obtaining a series of successive digital data sets ...") when {

} (Citing Evidence Category 9; CX-1150C at Q. 266) Align continues that CCUS eventually obtains all the steps, including the final, of a patient's treatment.

Align avers that Respondents have not disputed that they practice this element – either during discovery or in their *Prehearing Brief*, and are precluded from doing so now. Align says that Respondents failed to provide any supporting testimony regarding non-infringement of this element.

Align asserts that CCUS practices the fourth element of claim 1 ("fabricating a predetermined series of dental . . .") when it generates appliances by {

}

(Citing Evidence Category 10; CX-1150C at Q. 267) Align continues that Respondents do not appear to specifically dispute infringement of this element. (Citing RPHB 87-88; RX-0129C at Q. 136-140)

Align argues that in one alternative, CCUS practices each step of the claimed method in the U.S., and therefore directly infringes under 35 U.S.C. § 271(a). Alternatively, Align argues that CCUS offers to sell, sells, or uses aligners in the U.S. that are made according to each of claimed steps by the joint CCUS/CCPK process, and therefore directly infringes under 35 U.S.C. § 271(g). As a third alternative, Align continues that CCUS also effectuates the joint

CCUS/CCPK process that practices each step of the claimed method, which provides the requisite direct infringement under 35 U.S.C. § 271(b) pursuant to the Federal Circuit's *Akamai* decision.

Align states that Respondents also argue that their process for making "phase-based" aligners does not meet the "ordered sequence" supposedly required by claim 1 of the '880 Patent. Align disagrees, asserting that Respondents did not offer any constructions that would require such an "ordered sequence" in the *SRJCCC*, and have therefore waived this argument. Align continues, arguing that Respondents' position is legally incorrect. Align says that Claim 1 of the '880 Patent does not specify such an order, as sequential numbering or lettering of the steps within a method claim does not suffice to demonstrate a requisite sequence of performance. (Citing *Personalized Computer Model LLP v. Google Inc.*, No. 09-525-LPS, 2012 WL 295048, at *28 (D. Del. Jan. 25, 2012); and *Kemin Foods, L.C. v. Pigmentos Vegetales del Centro S.A. de C.V.*, 301 F. Supp. 970, 990-91 (S.D. Iowa 2004)) Align avers that claim 1 is quite similar to the claim in *Kemin Foods*, which used the open transition "comprising" along with lettered process steps. Align asserts that unless the steps of a method claim actually specify an order in which they are to be performed, they ordinarily do not require one. (Citing *Interactive Gift Exp., Inc. v. CompuServe Inc.*, 256 F.3d 1323, 1342 (Fed. Cir. 2001))

Align asserts that Respondents' "individual teeth" non-infringement argument is also incorrect. Align says that the construction for "individual teeth" was not identified in the SRJCCC and was excluded. (Citing RX-0129C at Q.53) As an example, Align explains that Respondents assert they do not infringe claims 3 and 13 of the '325 patent because the phrase "individual teeth" in the claims must be "a three-dimensional model that resembled an actual tooth, and not a three-dimensional object that includes a tooth crown and sectioned gum

material." Align argues that "teeth" is generally used in the asserted patents inclusively for the tooth and surrounding gum material (citing JX-0002 at 12:51-56 and CX-1150C at Q. 123, 348) and Respondents themselves use "teeth" in such an inclusive manner. (Citing CX-1157C.1 at 54:1- 9; CX-0090C at 14)

Align asserts that Respondents would still infringe even if "tooth" only included a "tooth," and not any gum material. Align says that claim 1 of the '325 patent recites "manipulating the visual image to reposition individual teeth in the visual image." (Citing JX-0003 at 27 (1:36-37)) Align contends that regardless of whether "tooth" were defined to mean: a tooth or a tooth plus surrounding gum material, the tooth itself would still be repositioned. Align adds that claim 3 of the '325 patent recites "defining boundaries about at least some of the individual teeth." JX-0003 at 15:40-41. Align contends that if one defined boundaries around the tooth that included the tooth itself or the tooth plus some gum material, the boundary would still be defined around the tooth.

Align says that Respondents use the "Create Planes" feature to section the model, which cuts between the teeth and all the way through the gum material. (Citing CX-1157C.1-3 at 51:1-11) Align continues that Respondents do not only "cut" the top portion or the "crown" of the tooth as suggested by Respondents. Align reasons that although not visible in the image, the gum material merely covers the root structure, which is also being repositioned with the rest of the tooth object.

Align argues that "tooth" or "teeth" is not utilized in the asserted patents as being equivalent only to a tooth with a crown and root and no gum material as Respondents assert. As an example, Align says that the '325 patent discusses obtaining an initial "digital data set representing an initial tooth arrangement" by scanning a plaster cast of the patient's teeth.

(Citing JX-0003 at 9:17-42) Align continues that the results of such a scan – the "initial tooth arrangement" – would include gum material covering the root structure, but would not actually show the root structure. Align says that the other asserted patents are similar. (Citing JX-0002 at 12:53-56 ("the crown of the tooth, as well as the gingivae tissue immediately below the crown are . . . treated as an individual unit referred to as a tooth")), and this usage is consistent with both: (i) Mr. Beers' opinion that people in this industry refer to the crown and gum objects defined by CCUS in Freeform as "individual teeth" (Citing CX-1150C at Q. 348); and (ii) Respondents' ***own*** documents (Citing CX-1157C.1 at 54:1-9; CX-0090C at 14).

Align disagrees with Respondents' "All Aligners" non-infringement argument. Align says that Respondents assert they do not infringe claims of at least the '325, '487, '874, and '880 Patents because phrases such as: (i) "plurality of successive tooth repositioning appliances;" (ii) "successive tooth repositioning appliances;" (iii) "shell appliances;" (iv) "successive appliances;" and (v) "predetermined series of dental incremental position adjustment appliances" require that "all" of the appliances "be produced prior to active treatment" and that "ClearCorrect's phase-based system does not meet this limitation." Align says that this is a claim construction argument not identified in the *SRJCCC*, and has already been excluded on this basis. (Citing RX-0129C at Q. 51, 161) Align continues that neither Respondents nor Dr. Mah cite to any supporting evidence. Align adds that Respondents fail to explain why the claimed "appliances" do not read on their "phase-based" approach. Align argues that they cannot because each of the above phrases reads literally on either a single phase of four consecutive aligners (*e.g.*, "Phase 1") or a group of all the "phases" prepared by Respondents. (Citing CX-1150C at Q. 347) Align says that at least Respondents' "Phase 1" is fabricated prior

to a patient's treatment and because there is no temporal requirement in the claims, it reads on Respondents' entire treatment system, regardless of the fact they are shipped in phases.

Align disagrees with Respondents' argument that they do not infringe claims of the '880 patent because they "do not 'move' the 'tooth boundaries' 'relative to other teeth' in an 'image.'" Align says that Respondents do not provide any explanation as to why Respondents process of moving the teeth using FreeForm (as described in regards to their "manipulating the visual image" argument) does not satisfy these claims. Align continues that the record citation identified by Respondents is to testimony from Jarrett Pumphrey as to the use of Freeform to section and move teeth in Freeform (citing Tr. at 330:11-333:9). This sectioning and moving is the claimed "moving," and therefore fails to support Respondents' argument. Align argues that to the extent that this argument is based on Respondents' "individual teeth" argument, it is incorrect for the reasons discussed above.

Align says that in addition to their improper argument based on "predetermined series," Respondents advance two additional arguments of little consequence - that: (1) claim 1 requires an "ordered sequence," and (2) the term "based on" requires each "subsequent arrangement to be based on the arrangement immediately preceding it." *RespPostHB* at 83-84. Align asserts that these are claim construction issues that were not disclosed in the *SRJCCC*, and are therefore improperly raised here. Indeed, the "ordered sequence" argument was specifically excluded pursuant to Align's Motion in Limine No. 1, and Respondents cannot now argue it. (Citing RX-0129C at Q. 138; Tr. at 8:4-9:4) Align contends that as for the "based on" construction, Respondents failed to raise this argument in their PreHearing Brief, and it is therefore waived. (Citing GR 8.2) Align says that it is also irrelevant, as indicated by Mr. Beers, because Respondents base all tooth arrangements on the initial tooth arrangement when they use the

"Generate Steps" function to interpolate between the initial and final arrangements. (Citing CX-1150C at Q. 263-267) Moreover, Respondents fail to support either argument with any intrinsic or extrinsic evidence.

Align says that Respondents also assert that CCPK does not make appliances in regards to Claim 3. (Citing RIB at 84) Align argues that, Claim 3 depends from Claim 1, wherein Align asserts that CCUS makes the appliances, not CCPK. Align concludes that because all global and one-off non-infringement arguments are improper or unsupported (or both), Respondents have no infringement defense.

Respondents' Position: Respondents argue that because certain parts of claim 1 are performed outside of the United States, there is no infringement under 271(a). Respondents say that the first, second and third elements of claim 1 are allegedly performed by CCPK in Pakistan. (Citing Tr. at 547:23-549:17; 550:11-20; CX-1150C at Q. 263) Respondents continue that the fourth element of the claim, concerning the fabrication of appliances, would only be practiced by CCUS in the United States. (Citing Tr. 341:14-21) Respondents reason that because CCUS is alleged to perform at least some of the steps in the United States and CCPK is alleged to perform at least in part some of the steps in Pakistan, there can be no infringement of this method claim.

Respondents assert that claim 1 is a method for "making a predetermined series of dental incremental position adjustment appliances." Respondents say that the plain and ordinary meaning of "predetermined" is determined *before* a specific event. Respondents reason that the only logical meaning here is before the commencement of patient treatment. Respondents aver that they do not make a predetermined series of appliances because they do not make all the appliances before patient treatment begins. (Citing Tr. 347:25 to 348:7; RX-0129C at Q.137, 139-140) Rather, Respondents say that they use a phase-based process where the appliances are

made as the patient's treatment progresses to allow the Clinician to make any necessary changes. (Citing Tr. 416:8-17)

Respondents say that Align resists this result and has argued that a subset of the CCUS system, a "phase," is a "predetermined series." Respondents assert that even a phase does not meet the ordered sequence required by claim one of the '880 Patent. Respondents say that claim 1 involves: (1) obtaining a first data set, (2) obtaining a repositioned tooth arrangement, (3) obtaining a series of data sets, and (4) making the "predetermined series" of appliances from those data sets. Respondents say that a phase is made up of four sets. Respondents continue that Align's argument requires it to show that the fourth set of appliances is based on the initial tooth arrangement. Respondents contend that the evidence disproves any such notion. Respondents say that the evidence shows that the technicians begin moving the teeth from the initial position to a first modified arrangement. Respondents assert that each subsequent arrangement is based on the arrangement immediately preceding it. Respondents conclude, as a result, that the fourth set of appliances in a series would be based on the preceding, third set of tooth arrangements and not on the initial tooth arrangement. (Citing Tr. 341:21-329:17; 352:7-354:6)

Respondents say that Align's post hearing brief makes significant misstatements concerning the manner in which CCPK operators make the computer files, the functions of the FreeForm software, and the manner in which CCUS receives the computer files from CCPK and when those files can be used to actually make orthodontic appliances. Respondents say that CCUS uses a phase-based system that is much different from the "predetermined series" described in the independent claim of the '880 patent. Respondents add that because Align bases its infringement arguments on its misstatements about the Respondents' process, it has failed to meet its burden of proof.

Respondents state that the second element of the independent claim requires "obtaining a repositioned tooth arrangement based on the initial tooth arrangement." Respondents argue that Align's theory of infringement on this element is squarely at odds with Dr. Valley's attempt to save Align's claims from invalidity. Respondents say they addressed the inconsistency between Dr. Valley's opinions concerning invalidity and Align's theories of infringement in the invalidity section of their brief. Align reasons that should the Respondents be found to infringe the second element of the '880 patent based on Align's characterization of the evidence, then the infringed claims must also be found invalid in light of the prior art.

Staff's Position: Staff argues that based on Staff's understanding of the legal standards of patent infringement, (a) Align's § 271(g) and § 271(b) infringement theories are legally improper (for the reasons stated in SIB Section III.B), and (b) Align's § 271(a) based infringement theory is the only viable infringement theory under 19 U.S.C. § 1337(a)(1)(B)(i). Staff continues that when applying Staff's understanding of the legal standards of patent infringement to Align's infringement theories, Staff is of the view that (i) CCUS would not infringe under 35 U.S.C. § 271(g) (and, thus, CCPK would not infringe under 35 U.S.C. § 271(c)); and (ii) CCUS would not infringe under 35 U.S.C. § 271(b) (as a result of the absence of any direct infringement) any Asserted Claim of the '880 patent (as a matter of law). Staff contends, however, that with respect to Align's allegations of infringement based on 35 U.S.C. § 271(a), based on a proper claim construction, the evidence supports finding infringement of claim 1 of the '880 patent (as discussed below). Staff says that applying my rulings regarding patent infringement under Section 337 and a proper claim construction, Staff is of the view that the evidence supports finding infringement of claims 1 and 3 of the '880 patent (as discussed below).

Staff asserts that the evidence supports finding infringement of claim 1 of the '880 patent under the ALJ's rulings regarding patent infringement under Section 337 (and the Staff's understanding of the legal standards of patent infringement). Staff continues that the evidence demonstrates that CCUS directly infringes claim 1 of the '880 patent by performing each element of the claimed method in the United States (specifically, Texas). (Citing CX-1150C at Q. 262-268; CX-1198C at 260-272)

Staff contends that under Align's § 271(g) infringement theory, the evidence supports finding infringement of claim 1 of the '880 patent under the ALJ's rulings regarding patent infringement under Section 337 (but not the Staff's understanding of the legal standards of patent infringement). Staff continues that applying my rulings, the evidence shows that CCUS directly infringes claim 1 of the '880 patent by selling or using aligners in the United States that are made by the joint CCUS / CCPK process. (Citing CX-1150C at Q. 262-268; CX-1198C at 260-272)

Staff argues that under Align's § 271(b) infringement theory, the evidence supports finding infringement of claim 1 of the '880 patent under my rulings regarding patent infringement under Section 337 (but not the Staff's understanding of the legal standards of patent infringement). Staff continues that applying my rulings, the evidence shows that CCUS induces the infringement of claim 1 of the '880 patent by performing some steps of the claimed method and causing CCPK to perform the remaining steps of the claimed method. (Citing CX-1150C at Q. 262-268; CX-1198C at 260-272) Staff adds that the evidence shows that CCUS had knowledge of the '880 patent as a result of its litigious history with Align. (Citing CX-1161C.1 at 50:1-51:3, 51:10-20, 59:1-60:23, 81:2-21; CX-0999, CX-0674C, CX-0165C, CX-0164C) Staff says that as discussed in Section 1.B, *infra*, the relationship between CCUS and CCPK is

closely coordinated such that the actions of CCPK are essentially directed and controlled by CCUS.

Staff asserts that Respondents' non-infringement argument for the '880 patent advances a claim construction that was not properly identified in the Second Revised Joint Claim Construction Chart (and, thus, is waived) and is not properly supported by any intrinsic (or extrinsic) evidence. Staff says that Respondents argue that the term "predetermined series of dental incremental position adjustment appliances" requires, *inter alia*, that the series make up the system of all of the appliances that are designed to reposition teeth from the initial tooth arrangement to final tooth arrangement.

Staff says that Respondents also argue that they do not infringe claim 1 of the '880 patent because Complainant alleges that CCUS practices some steps of the claimed method while CCPK practices the other steps of the claimed method. Staff asserts that Complainant also alleged (in its Pre-Hearing Brief) that CCUS practices all of the steps of the claimed method in the United States. Staff contends that the evidence shows such practice, as alleged by Complainant.

Analysis and Conclusions: First, addressing Respondents' incorporation by reference of their general defenses, I incorporate and reaffirm the analysis and conclusions reached in section V.B.1, *supra*, treating the three issues relevant to the asserted claims of the '880 patent, to wit: (1) whether or not all steps of a method claim must be performed in the same country; (2) whether or not digital data sets are "articles" within the scope of 19 U.S.C. § 1337; and (3) whether or not Align can meet its burden of proving infringement through the testimony of Mr. Beers.

I find that Align has shown by a preponderance of the evidence that Respondents infringe claim 1 of the '880 patent. No party has asserted that the preamble of claim 1 is limiting. Claim 1 is complete without the preamble, and the preamble merely restates what is apparent from the final element of the claim itself—the claimed method is a method for fabricating a predetermined series of dental incremental position adjustment appliances. As a result, I find that the preamble of claim 1 is not limiting.

Assuming, *arguendo*, that the preamble of claim 1 is a limitation, I find that Respondents' process practices the preamble of claim 1. In Section III.B.2, *supra*, I found that "a predetermined series of dental incremental position adjustment appliances"[48] means "two or more dental appliances to be used successively to adjust the position of teeth between an initial tooth arrangement and a repositioned tooth arrangement, the digital data sets on which they are based having been created before any of said two or more dental appliances in the series are fabricated." Thus, the preamble of claim 1 requires a method for making two or more dental appliances to be used successively to adjust the position of teeth between an initial tooth arrangement and a repositioned tooth arrangement, the digital data sets on which they are based having been created before any of said two or more dental appliances in the series are fabricated. Credible testimony and documents introduced at trial show by a preponderance of the evidence that Respondents' process includes such a method.

Employees of CCUS and CCPK admitted that {

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[48] This term also appears in the fourth element of claim 1.

}

Mr. Arif also admitted that {

} (*See* Tr. at 192:18-25) The foregoing admissions of employees of Respondents, along with Respondents' own

documents, show that the Respondents' process results in the creation of digital data sets that progress from an initial position to a final position at the end of treatment, i.e., the "treatment setup" data set. The admissions further show that the digital data sets from the initial position to the final position are created before any of the aligners are manufactured. As a result, I find that Align has shown by a preponderance of the evidence that Respondents' process practices the preamble of claim 1.

I also find that Respondents' process practices the first element of claim 1. As noted above, Mr. Jarrett Pumphrey admitted that {

} (Tr. at 315:19-23) Based on these admissions, I find that CCUS obtains a digital data set representing an initial tooth arrangement, as required by the first element of claim 1, when {

}

Respondents' do not contest that they practice the first element of claim 1 in in their post-hearing briefing.

Respondents' process also practices the second element of claim 1. Mr. Arif admits that {

} (Tr. at 170:25-

172:14) Based on these admissions, I find that CCUS obtains[49] a repositioned tooth arrangement based on the initial tooth arrangement when it receives the "treatment setup" data set from CCPK and CCPK practices this element of claim 1 when it creates the "treatment setup" data set.

Respondents also practice the third element of claim 1. Mr. Arif admitted that {

} (Tr. at 192:3-193:8) The foregoing admissions make clear that CCPK practices the third element of claim 1 when {

}

I find that Respondents practice the fourth element of claim 1 when CCUS fabricates the final appliances to be used in treatment of a patient. In light of the construction in Section III.C.2, supra, the fourth element of claim 1 requires:

> Fabricating [two or more dental appliances to be used successively to adjust the position of teeth between an initial tooth arrangement and a repositioned tooth arrangement, the digital data sets on which they are based having been created before any of said two or more dental appliances in the series are fabricated] based on the series of successive digital data sets, wherein said appliances comprise polymeric shells having cavities shaped to receive and resiliently reposition teeth, and

---

[49] Claim 1 of the '880 patent is directed to a "method for making a predetermined series of dental incremental position adjustment appliances." It is not directed to a "method for *calculating* data sets." There is no indication in the language of the claim that the phrase "obtaining a repositioned tooth arrangement" should be limited to "*calculating* a repositioned tooth arrangement." The same is true for the other claim limitations that use the term "obtaining." As a result, I find that the act of receiving "a repositioned tooth arrangement" from CCPK is sufficient to find that CCUS practices this claim element.

> said appliances correspond to the series of successive tooth arrangements progressing from the initial to the repositioned tooth arrangement.

(JX-002 at 22:21-29) As noted above, Mr. Pumphrey admitted that {

} Based upon these admissions, I find that CCUS practices the fourth element of claim 1 when it fabricates the final appliances to be used in treatment of a patient.

The fact that a "mid-course correction" may occur during treatment under Respondents' process does not preclude a finding of infringement. Respondents admitted that a "mid-course correction," under which changes are made to the treatment of a patient after treatment has begun, is not made in every case. (Tr. at 224:11-13; *See also* Tr. at 213:9-21) As a result, even if "mid-course corrections" resulted in a course of treatment being stopped, it would only apply to a subset of all cases handled by Respondents. Also, Respondents admitted that {

} (Tr. at 195:7-196:4, 205:24-206:15, 224:14-21, 318:21-319:3) {

}

The fact that "festooning" is carried out on the stepped data sets also does not change my conclusion. Mr. Arif testified that {

} (Tr. at 193:9-194:6) As a result, because there are no changes to the location of a patient's teeth in the data sets during festooning, I find that the appliances are "based" on the data sets created in the stepping process, even if the datasets are "cleaned up" between the stepping process and fabrication.

In Section III.C.2, I found that the four elements of claim 1 must be performed in order. Based on the findings above, I find that Respondents practice the elements of claim 1 in the order.

Based upon all of the foregoing, I find that because CCUS independently practices each and every limitation of claim 1, CCUS infringes claim 1 of the '880 patent. I also find that Align has shown by a preponderance of the evidence that the concerted efforts of CCUS and CCPK

practice each and every limitation of claim 1 when the digital data sets created by CCPK are used by CCUS to fabricate aligners.

2. Claim 3

Claim 3 depends from claim 1 and teaches:

> A method as in claim 1, wherein the step of obtaining a digital data set representing a repositioned tooth arrangement comprises:
>
> defining boundaries about at least some of the individual teeth; and
>
> moving at least some of the tooth boundaries relative to the other teeth in an image based on the digital data set to produce the repositioned data set.

(JX-002 at 22:33-41)

Align's Position: Align reasons that the preamble of claim 3 is not limiting because it merely is a statement of dependency. Align says that Respondents have not asserted the contrary in their *Prehearing Brief* (citing RPHB at 93-95) and have waived such a position (Citing GR 8.2). Align concludes, as a result, that an infringement analysis is unnecessary. Align says that as explained above, CCUS either alone or in conjunction with CCPK practice each element of claim 1.

Align asserts that CCPK practices the first claim element of claim 3 ("defining boundaries ...") when {

} (Citing Evidence Category 4; CX-1150C at Q. 270) Align disagrees with Respondents' "individual teeth" non-infringement argument, citing to their discussion in CIB Section IV.D.

Align says that CCUS offers to sell, sells, or uses aligners in the U.S. that are made according to each of claimed steps by the joint CCUS/CCPK process, and therefore directly infringes claim 3 under 35 U.S.C. § 271(g). Alternatively, Align says that CCUS also effectuates the joint CCUS/CCPK process that practices each step of the claimed method, which provides the requisite direct infringement under 35 U.S.C. § 271(b) pursuant to the Federal Circuit's *Akamai* decision, as explained above.

Align contends that when claim 3 is read on a product made by the joint process of CCUS and CCPK (§ 271(g)), CCPK contributorily infringes claim 3 under the four-part *Fujitsu* test, for the reasons discussed above. Align alternatively argues that when claim 3 is read on CCUS and CCPK's joint performance of the claimed process, CCUS induces the infringement of claim 3 under 35 U.S.C. § 271(b) in view of *Akamai*, for the reasons discussed above.

Align says that Respondents assert a number of other inapplicable non-infringement positions, including: (i) there is no "joint" infringement by CCUS and CCPK; (ii) CCPK performs some steps in Pakistan; (iii) 35 U.S.C. § 271(g) claims cannot be advanced in the ITC; (iv) "transmission of information" and "digital data" is not covered by § 271(g); (v) there is a material change between the digital data sets and physical aligners such that the defences of § 271(g) apply (*id.*). Align says that Respondents are wrong on each count, as described in CIB Section IV.E.

Respondents' Position: Respondents assert that because claim 1 is not infringed for the reasons stated above, dependent claim 1 is also not infringed. Respondents add that because some of the elements of claims 1 and 3 of the '880 patent are alleged to be practiced solely by CCUS in the United States, and other elements are alleged to be practiced solely by CCPK in Pakistan, claim 3 of the '880 patent, a method claim, is not infringed.

Respondents argue that the term "individual teeth," according to its plain and ordinary meaning, refers to a representation of an actual tooth. Respondents continue that "moving" a boundary defined about "individual teeth" therefore refers to the movement of an individual tooth, and not to a component that included gum material. Respondents say that Align asserts that the evidence establishes that the Respondents do not define boundaries around "individual teeth" and subsequently move those boundaries. (Citing CX-0889C; Tr. 330:11 to 333:9) Respondents argue that Align's expert, Mr. Beers, only identifies conduct by CCPK as meeting this limitation and does not identify any conduct by CCUS as meeting this limitation. Respondents continue that there is no evidence that CCPK makes the orthodontic appliances that are the subject of the '880 patent, claims 1 and 3.

Respondents say that Align's post hearing brief makes significant misstatements and assertions that CCPK operators "manipulate visual images" or "define boundaries" around individual teeth. Respondents argue that CCPK operators do not "define boundaries" around individual teeth and, instead, identify subsets of data that include soft tissue (gums), a tooth crown, and portions of adjacent tooth crowns. Respondents reason that because Align bases its infringement arguments on misstatements concerning the CCPK operators' actual conduct, it has failed to meet its burden of proof on the dependent claims' associated elements.

Staff's Position: Staff asserts that under Align's § 271(g) infringement theory, the evidence supports finding infringement of claim 3 of the '880 patent under my rulings regarding patent infringement under Section 337 (but not the Staff's understanding of the legal standards of patent infringement). Staff says that applying my rulings, the evidence demonstrates that CCUS directly infringes claim 3 of the '880 patent by selling or using aligners in the United States that

are made by the joint CCUS / CCPK process. (Citing CX-1150C at Q. 270; CX-1198C at 272-275)

Staff argues that under Align's § 271(b) infringement theory, the evidence supports finding infringement of claim 3 of the '880 patent under my rulings regarding patent infringement under Section 337 (but not the Staff's understanding of the legal standards of patent infringement). Staff continues that applying my rulings, the evidence show that CCUS induces the infringement of claim 3 of the '880 patent by performing some steps of the claimed method and causing CCPK to perform the remaining steps of the claimed method (as above with respect to claim 1 of the '880 patent). (Citing CX-1150C at Q. 270; CX-1198C at 272-275) Staff says that its discussion of the elements of induced infringement with respect to claim 1 of the '880 patent also applies with respect to claim 3 of the '880 patent.

Analysis and Conclusions: If I had found that Align had failed to prove that Respondents infringe claim 1, it would follow that Align failed to prove infringement of claim 3, which depends from claim 1. *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n. 9 (Fed. Cir. 1989) ("One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim.")

Nevertheless, I have found that Respondents infringe asserted claim 1. I also find that Align has shown by a preponderance of the evidence that Respondents infringe claim 3 of the '880 patent

Respondents argue unpersuasively that they do not infringe claim 3 because the second element of claim 3 requires that the individual teeth be a representation of a three-dimensional model that resembled an actual tooth, and not a three-dimensional object that includes a tooth crown and sectioned gum material. First, I find that Respondents have waived the right to offer a

construction for the term "defining boundaries about at least some of the individual teeth." Respondents did not propose a construction for "defining boundaries about at least some of the individual teeth" in the Second Revised Joint Claim Construction Chart. (*See* SRJCCC) Moreover, the portion of Dr. Mah's testimony addressing this construction was excluded. (RX-0129C at Q. 141) Respondents cite no evidence that shows a clear intent to limit the meaning of this limitation as Respondents' propose. As a result, I reject this argument by Respondents.

Treating the substance of the assertion, the evidence introduced at the hearing shows that Respondents' process includes a step of "defining boundaries about at least some of the individual teeth." Mr. Jarrett Pumphrey admitted that {

} the claim does not preclude including gum tissue within the "defin[ed] boundaries." All that is required is "defining boundaries about" individual teeth. (JX-002 at 22:33-41) Based on the foregoing testimony and evidence introduced during the hearing, I find that CCPK meets this limitation.

Respondents also argue unpersuasively that they do not "mov[e] at least some of the tooth boundaries relative to the other teeth in an image based on the digital data set to produce the repositioned data set," as required by claim 3. Mr. Jarrett Pumphrey admitted that {

} (Tr. at 332:20-333:9; CX-0889C) Based on this testimony, I find that CCPK practices this limitation of claims 3.

Based upon the foregoing, I find that Align has shown by a preponderance of the evidence that CCPK practices each and every limitation of claim 3. Because I find in Section V.C.1, *supra*, that CCUS and CCPK act in concert[50] to practice the limitations of claim 1, which are also required by claim 3 as a result of their dependency on claim 1, I find that CCPK and CCUS act in concert to infringe claim 3.

3. Inducement and Contributory Infringement

Align's Position: Align argues that when claim 1 is read on CCUS's practice of each claimed step, or on a product made by the joint CCUS/CCPK process, CCPK contributorily infringes under the four-part *Fujitsu* test, where part 1 is met by CCUS's direct infringement and the remaining factors are met as shown in Sec. IV.B of CIB. Align continues that when claim 1 is read on CCUS and CCPK's joint performance of the claimed process, CCUS induces the infringement of claim 1 under 35 U.S.C. § 271(b) in view of *Akamai*. Align says that, as shown in Sec. IV.C of CIB, CCUS had the requisite knowledge and intent to do so.

Align argues that CCUS induces the infringement of the '880 and '511 Patents by its practice of the joint CCUS/CCPK process in view of *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301, 1309 (Fed. Cir. 2012) (finding that "a party who performs some of the steps itself and induces another to perform the remaining steps that constitute infringement has precisely the same impact on the patentee as a party who induces a single person to carry out all of the steps").

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[50] In Section V.C.1, *supra*, I also find that claim 1 reads on the activities of CCUS independent of the activities of CCPK.

Align avers that the Federal Circuit set forth a roadmap for asserting inducement involving multiple parties under *Akamai*, explaining that a party can be found liable for inducing infringement if: (i) it knew of the asserted patents; (ii) it induced the performance of all claimed steps or some of the claimed steps where it performed the remainder; and (iii) each step was performed. (Citing *Id.* at 1318) Align says that regarding element (i), CCUS knew of the asserted patents. (Citing CIB at 34-35) Align continues that regarding element (ii), Respondents concede that CCUS performs some steps of the joint process while CCPK performs the remainder. Align says that regarding element (iii), while Respondents contest the legal conclusion that certain claim elements read on particular steps of their process, it is undisputed that they perform those steps. (Citing RIB at 8 ("Align's expert, Mr. Beers, combines the conduct of the Respondents to reach his conclusion..."), 82-84, 106-108) Align says that it is therefore clear that CCUS induces the infringement of the asserted claims of the '880 and '511 patents.

Align disagrees with Respondents' argument that Align has not carried "its heavy burden of establishing the necessary intent" for inducement because "the evidence admitted at the hearing disproves that ClearCorrect could have had any 'affirmative intent to cause direct infringement.'" (Citing RIB at 13) Align says that Respondents fail to address the requisite knowledge and intent for inducement where the direct infringement is performed by multiple parties under *Akamai*. Rather, Align says that Respondents cite only to the knowledge and intent requirements specified by other cases, such as *DSU Medical Corp.* and *Global-Tech Appliances*. Align continues that in *DSU*, the Federal Circuit held that "'inducement requires that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement.'" (Citing 471 F.3d at 1306) Align says that in *Global-Tech*, the Supreme Court

found that the knowledge and intent requirement includes knowledge of the asserted patent, 131 S. Ct. at 2067-68, and can be satisfied by a "wilfully blind" infringer (*i.e.*, "one who takes deliberate actions to avoid confirming a high probability of wrongdoing and who can almost be said to have actually known the critical facts," (Citing *id.* at 2070-71) Align argues that in any case, circumstantial evidence of such actions may suffice. (Citing *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010))

Align asserts that CCUS induces infringement under *DSU* and *Global-Tech* because: **(i)** both CCUS and CCPK knew of the asserted patents long before this Investigation (Citing Tr. at 384:25-385:16, 389:22-391:5); (ii) CCUS was concerned about infringing the asserted patents (Citing Tr. at 393:21-25; CX-0511C at 20); (iii) despite being concerned about infringement, CCUS did not obtain a formal opinion of counsel as to non-infringement or undertake its own internal analysis (Citing CX-1160C.2 at 268:7-269:5, 275:14-19, 276:19-277:4; CX-1160C.3 at 590:6-10; CX-1160C.4 at 736:23-737:21; *Broadcom Corp. v. Qualcomm, Inc.*, 543 F.3d 683, 699 (Fed. Cir. 2008) ("Because opinion-of-counsel evidence, along with other factors, may reflect whether the accused infringer 'knew or should have known' that its actions would cause another to directly infringe, we hold that such evidence remains relevant to the second prong of the intent analysis.")); (iv) principals of CCUS believed that they found an "opening" in Align's patent portfolio after "hundreds" of hours of study (citing CX-0955 at 2; CX-0674C at 2) but did not explain what this "opening" was; and (v) when CCPK was being set up, it warned CCUS that it was worried the process was infringing (citing CX-0511C at 4; CX-1163C.1 at 99:5-9; CIB at 34-35)

Align argues that the record reflects that: (i) CCUS *designed* all steps of its process (Citing Tr. at 460:18-461:13); (ii) CCUS *instructed* CCPK exactly as to how it was supposed to

perform the process (Citing Tr. at 321:21-322:8, 445:7-11, 472:9-13); (iii) {

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Align contends that these are precisely the factors that have led courts to find inducement. (Citing*i4i Ltd. P'ship*, 598 F.3d at 852 (finding that defendants' training materials and instructions as to how to use the infringing system, along with internal e-mails showing knowledge of the asserted patent and the similarity between it and defendants' process, was enough for a jury to find inducement); *MEMC Elec. Materials, Inc. v. Mitsubishi Materials Silicon Corp.*, 420 F.3d 1369, 1379-80 (Fed. Cir. 2005) (holding that a reasonable jury could find inducement where the alleged inducer knew of the patent and provided specific instructions for an infringing use of its system))

Align says that in their *PostHearing Brief*, Respondents strain the evidentiary record in an attempt to avoid a finding of inducement. Align says that Respondents first argue that the evidence shows CCUS had no intent because:

> Dr. Pumphrey testified how he spent tens of thousands for dollars of his own money in legal fees for research about Align's patent portfolio. Tr. 394:1-5. Based on that initial research, Dr. Pumphrey was confident that ClearCorrect's procedure did not infringe Align's patents. Tr. 394:10-14.

(Citing RIB at 13) Align says that the cited statements were made by Dr. Pumphrey in an interview publicizing his company (Citing CX-0955 at 2) – hardly a situation where he would

indicate his true worries. In contrast, Align says that {

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Align disagrees with Respondents' argument that CCUS "attempted to test its position that it did not infringe" by filing "a suit for declaratory judgment during February of 2009." (Citing RIB at 13) Align argues that this was not a real attempt to resolve any issue by CCUS. Align says that CCUS sought a declaration of non-infringement and invalidity of virtually the entirety of Align's patent portfolio (citing *ClearCorrect Inc. v. Align Tech. Inc.*, 4:09-cv-00470 ("Texas Action"), *Complaint*, Dkt. No. 1 (S.D. Tex. Feb. 17, 2009)), but failed to cite any facts demonstrating that there was an actual case or controversy. Align says that the *Complaint* was therefore insufficient on its face, and improperly filed as a matter of law. (Citing *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1335 (Fed. Cir. Aug. 15, 2008)) Align explains that it moved to dismiss the complaint due to its legal insufficiency. (Citing Texas Action, *Defendant Align Technology, Inc.'s Motion to Dismiss Plaintiff's Claims for Lack of Subject Matter Jurisdiction or in the Alternative, for Failure to State a Claim*, Dkt. No. 14 (S.D. Tex. Mar. 26, 2009)0 Align continues that contrary to Respondents' assertion that "Align encouraged ClearCorrect to dismiss its suit because Align had no reason to believe ClearCorrect was infringing any of Align's patents" (RIB at 13), nowhere did the *Motion to Dismiss* indicate, or

even imply, that there was no infringement.

Align says that Respondents cite Mr. Pumphrey's testimony that "my understanding is Align said that they really didn't have any intention of suing us for patent infringement [and] had no reason to think we were infringing their patents" as being determinative of CCUS's intent. (RIB at 14) Align argues that this self-serving testimony is belied by the record. Align says that Respondents have not identified or produced any communication from Align that would lead Respondents to believe that Align had no intention of suing for infringement. (Citing Tr. at 374:17-375:8) Rather, Align says after the case was dismissed, Respondents did not act as if they were unconcerned with infringement; rather, they sought patent infringement insurance (citing CX-0164C, CX-0165C) and tried to keep CCPK secret (citing CX-0305C). Align continues that this alleged clearance from Align did not find its way into the timeline of CCUS's 2011 Prospectus (citing CX-0505C at 3) – where one would expect to see such a significant fact.

Align says that Respondents next baldly state that CCUS "did everything possible to validate its position that it did not infringe." (Citing RIB at 14) Align says that Respondents provided no evidence or argument that they: (i) engaged in any dialogue with Align regarding any particular patent; (ii) sought re-examination of Align's patents; (iii) obtained relevant opinions of counsel (citing CX-1160C.2 at 275:14-19, 276:19-277:4; CX-1160C.3 at 590:6-10; CX-1160C.4 at 736:23-737:21); or (iv) compared Align's claims with their process (citing CX-1160C.2 at 268:7-269:5).

Align concludes, as a result, that the evidence shows that CCUS actively induces CCPK to infringe Align's patents, or at the very least operated with deliberate indifference to a known risk that the patents exist and that they may infringe. (Citing Tr. at 319:22-320:1; *Akamai*, 692 F.3d at 1308; *Global-Tech*, 131 S. Ct. at 2068-72)

Align disagrees with Respondents' argument that CCPK does not induce CCUS. Align says that it is no longer asserting such inducement. Align says that Respondents also argue that Align's inducement claims based on the '880 and '511 Patents are improper in view of their *Motion in Limine* No. 1. (Citing RIB at 11-12) Align contends that I already disagreed with Respondents–based on the fact that they were aware of these inducement claims before the end of fact discovery. (Citing Align's Opp. to Respondents' MIL No. 1, EDIS Doc. No. 502127, at 1-3)

Respondents' Position: Respondents assert that Align's burden to show induced or contributory infringement is very high. Respondents say that In *Global-Tech Appliances v. SEB SA*, 131 S. Ct. 2060 (2011), the Supreme Court held that "induced infringement under § 271(b) requires knowledge that the induced acts constitute patent infringement." (Citing 131 S. Ct. at 2068) Respondents continue that the Federal Circuit has likewise held that mere knowledge of possible infringement by others does not amount to inducement and that the patent owner carries the burden to prove specific intent and action to induce infringement. (Citing *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1363 (Fed. Cir. 2003)) Respondents add that the Federal Circuit has held the Complainant bears the burden to show a Respondent's "affirmative intent to cause direct infringement." (Citing *Kyocera Wireless Corp. v. Int'l Trade Comm'n*, 545 F.3d 1340, 1354 (Fed. Cir. 2008)) Respondents say that to satisfy contributory infringement's scienter requirement, it is necessary to establish that "the accused contributory infringer knows that its component is included in a combination that is patented and infringing," which requires knowledge of the patent. (Citing *Global-Tech*, 131 S.Ct. at 2068)

Respondents argue that Align failed to carry its heavy burden of establishing the necessary intent. Respondents say that the evidence admitted at the hearing disproves that

CCUS could have had any "affirmative intent to cause direct infringement." Respondents aver that Dr. Pumphrey testified how he spent tens of thousands for dollars of his own money in legal fees for research about Align's patent portfolio. (Citing Tr. 394:1-5) Respondents continue that Dr. Pumphrey was confident that CCUS's procedure did not infringe Align's patents. (Citing Tr. 394:10-14)

Respondents say that CCUS also attempted to test its position that it did not infringe by filing a suit for declaratory judgment during February of 2009. (Citing Tr. 232:5-17) Respondents say that CCUS brought that suit to obtain a judicial ruling that it did not infringe Align's patents. (Citing Tr. 363:24-364:7) Respondents continue that Align effectively prevented any judicial determination about infringement by encouraging CCUS to dismiss its suit because Align had no reason to believe CCUS was infringing any of Align's patents. (Citing Tr. 364:8-15) Respondents aver that CCUS dismissed its suit as a result of Align's representations. (Citing Tr. 364:8-15) Respondents say that CCUS then built its business and operated for approximately two years without any objection from Align. (Citing Tr. 364:16-19) Respondents conclude that the evidence shows that CCUS conducted research, came to the conclusion that its procedure did not infringe Align's patents, and then did everything possible to validate its position that it did not infringe, which was effectively validated when Align stated that it had no reason to think CCUS was infringing and demanded dismissal of the suit for declaratory judgment. Respondents say that under these facts, CCUS could not have believed that it was infringing Align's patents and, therefore, could not have had an "affirmative intent to cause direct infringement."

Respondents argue that the evidence admitted at the hearing disproves that CCPK could have induced CCUS to infringe any of Align's patents. Respondents say that Dr. Pumphrey

founded CCUS during 2006. (Citing Tr. at 391:21-23) Respondents continue that it was not until 2009 that CCPK was formed by Mudassar Rathore to provide CCUS with computer files. (Citing Tr. at 269:9-11, 398:5-11) Respondents aver that by that time, CCUS was already using digital technology to model the projected treatment and CCPK's services were used only to "scale-up" CCUS's existing operations. (Citing Tr. at 307:1-5) Respondents say that Align presented the Court with no evidence that Mr. Rathore or anyone who was later affiliated with CCPK was creating computer files to model orthodontic treatment during the interim period between 2006 to 2009; rather, during this almost three-year interim period, Mr. Rathore was in the auto parts business "running a kind of workshop that makes auto parts." (Citing Tr. at 448:24-449:4)

Respondents say that a focal point of Align's examination of Dr. Willis Pumphrey involved his e-mail exchange with Mr. Rathore. Respondents continue that Mr. Rathore's e-mail demonstrates that CCUS had already used its process to treat several cases, any concern had by CCPK that the process infringed Align's patents were put to rest by a legal opinion CCUS claimed to possess and CCUS had "complete confidence" that its process did not infringe. (Citing Tr. at 403:1-12)

Respondent argue that Align's theory of intent, for both induced and contributory infringement, is merely that CCUS and CCPK had an awareness of Align's patent portfolio generally and were on notice of Align's infringement claims since the time Align filed a patent infringement suit or the ITC investigation. Respondents say that this precise theory was recently considered and rejected by the Commission in *Certain Mobile Devices, Associated Software, and Components Thereof*, Inv. No. 337-TA-744, 2012 WL 3715788 (U.S. Intern. Trade Com'n, June 5, 2012). Respondents say that the Commission rejected Microsoft's argument that "[b]ecause

MMI had indisputable actual knowledge of the '566 patent and the operation of the Android system, inducement liability should have been a foregone conclusion" and cited ample authority contradicting Microsoft's position. (Citing *Id.*) Respondents argue that Align has offered no evidence other than that the Respondents had some awareness of Align's patent portfolio; but included with that evidence were demonstrations of the Respondents' belief that CCUS's process did not infringe and that its attempt to validate that belief was frustrated by Align itself.

Respondents assert that "deliberate indifference to a known risk" was rejected as a standard by the Supreme Court in *Global-Tech.* Respondents say that in *DSU Medical Corp. v. JMS Co.*, 471 F.3d 1293, 1305 (Fed. Cir. 2006), the Federal Circuit held *en banc* that, for indirect liability, "specific intent and action to induce infringement must be proven." Respondents continue that *Global-Tech* confirmed this requirement by holding indirect liability requires "knowledge that the induced acts constitute patent infringement." (Citing 131 S. Ct. at 2068)

Respondents argue that a good-faith belief that a patent is invalid defeats this specific intent requirement. (Citing *Kinetic Concepts, Inc. v. Blue Sky Med. Group, Inc.*, 554 F.3d 1010, 1025 (Fed. Cir. 2009) ("a defendant's belief that it can freely practice inventions found in the public domain" forms a defense to inducement)) Respondents continue that even where a defendant's "product was ultimately found to infringe," a defendant may nonetheless show that it "did not induce infringement because it lacked the required intent." (Citing *Ecolab, Inc. v. FMC Corp.*, 569 F.3d 1335, 1351 (Fed. Cir. 2009))

Respondents assert that in *Global-Tech*, the Supreme Court rejected the test applied by the Federal Circuit and applied a test of willful blindness. Respondents say that the Court held that in order to show willful blindness, two requirements must be met: (1) the defendant must

subjectively believe that there is a high probability that a fact exists and (2) the defendant must take deliberate actions to avoid learning of that fact. Respondents continue that Align did not even show that the Respondents met these requirements. Respondents reason that the record does not support a finding of induced infringement.

Respondents argue that Align does not allege in its Posthearing Brief any acts by CCUS that could be considered unfair acts in the importation of articles into the U.S., even if it had the requisite intent. Respondents assert that to the extent Align argues that CCUS induces infringement, Align never explains what the "imported articles" are or how the infringement relates to importation.

Staff's Position: Staff asserts that based on CCUS's direct infringement of claims 1 and 3 of the '880 patent, Staff submits that the evidence shows that CCPK contributes to that infringement by creating the digital data sets that are used by CCUS in creating aligners. Staff says that as with CCUS's direct infringement of claims 1 and 3 of the '880 patent, the evidence shows that CCPK also performs some of the steps of the claimed methods. (Citing CX-1150C at Q. 262-2268, 270; CX-1198C at 260-275) Staff continues that its discussion of the elements of contributory infringement with respect to the '325 Patent, *supra*, also applies here with respect to claim 1 of the '880 patent.

Staff asserts that Align's arguments are merely an attempt by Respondents to argue that they did not intend to infringe the Asserted Patents because of the alleged covenant not to sue that was given in the context of the suit for declaratory judgment. Staff says that I found that Respondents are precluded from making this particular argument. (Tr. at 32:22-33:3)

Staff says that Respondents rely on *Certain Mobile Devices, Associated Software, and Components Thereof* ("*Mobile Devices*"), Inv. No. 337-TA-744, to support their argument that

Align's theory of intent for proving indirect infringement should be rejected. Staff argues that Respondents' reliance on *Mobile Devices* is misplaced because the facts of that investigation are inapposite. Staff says that the Commission in *Mobile Devices* determined that "[Complainant] Microsoft's argument before the ALJ in support of its assertion that [Respondent] Motorola had requisite knowledge sufficient to establish induced infringement was essentially limited to one paragraph," including, in pertinent part:

> Here, the end users of MMI's devices directly infringe the asserted method claims through the routine use of these products. MMI encourages such use by making available manuals instructing users to use the products in an infringement [sic] manner. *See Arthrocare Corp. v. Smith & Nephew, Inc.*, 406 F.3d 1365, 1377 (Fed. Cir. 2005) (manuals can be evidence of inducement). MMI had notice of the asserted patents and Microsoft's infringement theories at least as early as the service of Microsoft's Complaint in this Investigation, yet it continues to import and offer the accused products for sale, and continues to make available manuals that instruct users to use the accused product in an infringing manner.

(Citing *Mobile Devices*, Inv. No. 337-TA-744, Comm'n Opinion at 17 (June 5, 2012)) Staff continues that, contrary to Respondents' argument, the evidence demonstrates that Align has set forth more facts, and different facts, than those in *Mobile Devices* to support its allegations of indirect infringement. Staff asserts that such facts support finding that Respondents had the requisite knowledge and intent for indirect infringement. Staff says that unlike *Mobile Devices*, the evidence in this investigation shows, *inter alia*, that there is a long litigious history between Align and CCUS and CCPK, and that the relationship between CCUS and CCPK is such that their activities are closely coordinated.

Analysis and Conclusions: As noted above in Section V.C.1, *supra*, I find that there is an act of direct infringement when CCUS and CCPK act in concert to fabricate appliances using digital data sets provided by CCPK. I also have found that there is an act of direct infringement

of claim 1 when CCUS independently practices all of the elements of claim 1 to fabricate aligners using the data sets provided by CCPK.

I find that CCPK contributorily infringes claims 1 and 3 of the '880 patent. I find that the digital data sets provided by CCPK are imported into the United States, have no substantial non-infringing use and are a material part of the claimed invention. Mr. Mudassar Rathore, an employee of CCPK, testified that after CCPK creates the digital data sets, it sends the digital data sets on a daily basis to CCUS through FTP or through ClearCom. (Tr. at 442:5-442:23) As a result, I find that the digital data sets are imported.

In Section V.B.17, I found that the digital data sets are a material part of the claimed invention, have no substantial non-infringing uses and CCUS and CCPK had knowledge of the '880 patent. I incorporate and reaffirm those findings and rationale here. Based upon all of the foregoing, I find that by sending into the United States the digital data sets used by CCUS to fabricate aligners, CCPK has contributed to the infringement of claims 1 and 3 of the '880 patent.

I find that Align has failed to carry its burden to show CCUS induces infringement of claims 1 and 3 of the '880 patent. In *DSU Med. Corp. v. JMS Co., Ltd.*, the Federal Circuit clarified the intent requirement necessary to prove inducement. 471 F.3d 1293 (Fed. Cir. 2006). As the Federal Circuit more recently explained:

> In *DSU Med. Corp. v. JMS Co.*, this court clarified en banc that the specific intent necessary to induce infringement "requires more than just intent to cause the acts that produce direct infringement. Beyond that threshold knowledge, the inducer must have an affirmative intent to cause direct infringement."

Kyocera Wireless Corp. v. Int'l Trade Comm'n, 545 F.3d 1340, 1353-54(Fed. Cir. 2008) (citations omitted).

After a review of the evidence submitted by Align, I find that Align has not met its burden to demonstrate the specific intent needed to find inducement. *See Lucent Techs. Inc. v. Gateway, Inc.*, 2007 WL 925510, at *2-3 (S.D. Cal. Mar. 21, 2007) ("Proof of inducing infringement requires the establishment of a high level of specific intent."). Align failed to prove that CCUS, by providing instructions and support to CCPK to assist CCPK in creating the digital data sets that are imported and used by CCUS to fabricate aligners had "an affirmative intent to cause direct infringement." *DSU*, 471 F.3d at 1306. While Respondents were aware of the '880 patent, it does not follow that an affirmative intent to cause direct infringement can be inferred. This is consistent with my conclusions regarding the issue of copying discussed in Section IV.B.3, *supra* in connection with the objective indicia of non-obviousness.

4. Violation of Section 1337(a)

Align's Position: Align says that Respondents also argue that "there can be no violation of Section 1337(a)(1)(B)(***ii***) at the time of importation" because their process is not complete. Align says that it is not asserting a violation of §1337(a)(1)(B)(ii) with respect to the '880 Patent. Rather, Align says that it is asserting a violation under §1337(a)(1)(B)(i).

Align argues that Respondents violate 337(a)(1)(B)(i) in view of the '880 Patent as follows:

> **Case (i)** CCUS directly infringes claim 1 under 35 U.S.C. § 271(a) by performing each claimed step in Texas. CCPK contributes to that infringement under 35 U.S.C. § 271(c) by creating the digital data used by CCUS in its process.
>
> **Case (ii)** CCUS directly infringes claims 1 and 3 under 35 U.S.C. § 271(g) by offering to sell, selling, or using aligners in the U.S. that are made by the joint CCUS/CCPK process. CCPK contributes to that infringement under 35 U.S.C. § 271(c) by creating the digital data.
>
> **Case (iii)** CCUS induces the infringement of claims 1 and 3 under 35 U.S.C. § 271(b), by performing some steps of the asserted claims and causing CCPK to perform the remaining steps – a basis expressly approved by the Federal Circuit's

recent *Akamai* decision. The related "direct" infringement is the joint CCUS/CCPK process.

Align contends that in each case (i)-(iii), the imported product is the indirectly infringing digital data sets. Align says that Respondents' acts of importation, sale for importation, or sale after importation of the digital data sets are described in their discussion on jurisdiction in CIB Section II.C.

Respondents' Position: Respondents assert that Section 1337(a)(1)(B)(i) does not apply to Align's method claims, which are the vast majority of the asserted claims (other than the three claims of the '487 patent directed to "treatment plans"). Respondents say that to the extent that Align argues that CCUS is inducing conduct by CCPK, Section 337(a)(1)(B)(i) does not apply because Align is essentially arguing an unfair act in the exportation of information or computer files from the U.S. to Pakistan. Respondents say that this is not an unfair act in the importation of articles into the United States, and would be outside of the Commission's jurisdiction.

Respondents argue that for method claims, a complainant must prove infringement at the time of importation in order to demonstrate a violation of Section 337. (Citing *Electronic Devices* at 17) Respondents say that the Commission noted in *Electronic Devices* that "[m]erely importing a device that may be used to perform a patented method does not constitute direct infringement of a claim to that method." (Citing *Id.* at 12) Respondents conclude that there can be no violation of Section 337(a)(1)(B)(ii) if part of the patented process is performed in the United States. Respondents add that there can be no violation of Section 337(a)(1)(B)(ii) at the time of importation for the asserted method claims that are directed to fabricating orthodontic appliances. Respondents say that it is undisputed that those appliances are not fabricated until after the digital information prepared in Pakistan is received in the United States and no dental

appliances have been made, and thus no allegedly infringing product exists, that has been "made, produced, processed, or mined under, or by means of" a process patent at the time of "importation."

Staff's Position: Staff argues that when applying my rulings regarding patent infringement under Section 337, the evidence shows that (i) CCUS directly infringes claims 1 and 3 of the '880 patent under 35 U.S.C. § 271(g) by selling or using aligners in the United States made by the joint CCUS / CCPK process, and CCPK contributes to the infringement under 35 U.S.C. § 271(c) by creating the digital data sets that are used by CCUS, and (ii) CCUS induces infringement of claims 1 and 3 of the '880 patent by performing some steps and causing CCPK to perform the remaining steps of the claimed methods. Staff continues that when applying Staff's understanding of the legal standards of patent infringement, the evidence shows that CCUS directly infringes claim 1 of the '880 patent under 35 U.S.C. § 271(a)) by performing each step of the claimed method in the United States (Texas), and CCPK contributes to the infringement 35 U.S.C. § 271(c) by creating the digital data sets that are used by CCUS. Staff concludes, as a result, that the evidence demonstrates that CCUS and CCPK violate U.S.C. §1337(a)(1)(B) by importing or causing the importation of digital data sets.

Analysis and Conclusions: Respondents' concerted efforts to practice claims 1 and 3 of the '880 patent results in a violation of Section 337. 19 U.S.C. § 1337(a)(1)(B)(ii) prohibits "[t]he importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that: . . . (ii) are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent." By acting in concert to create appliances that use digital data sets that are made by the process of claims 1 and 3 and are imported into the United States

(as found in Section II.C, *supra*), Respondents have violated 19 U.S.C. § 1337(a)(1)(B)(ii).

CCUS's independent practice of claim 1 also results in a violation of Section 337. 19 U.S.C. § 1337 (a)(1)(B)(i) prohibits "[t]he importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that: (i) infringe a valid and enforceable United States patent or a valid and enforceable United States copyright registered under title 17." The Commission has explained that "section 337(a)(1)(B)(i) covers imported articles that directly or indirectly infringe when it refers to 'articles that -- infringe.' ***We also interpret the phrase 'articles that – infringe' to reference the status of the articles at the time of importation.*** Thus, infringement, direct or indirect, must be based on the articles as imported to satisfy the requirements of section 337." *Certain Electronic Devices With Image Processing Systems, Components Thereof, And Associated Software*, Inv. No. 337-TA-724, Comm'n Op. (Dec. 21, 2011) (emphasis added). Because the digital data sets contribute to CCUS's practice of claim 1 inside the United States and the digital data sets are imported into the United States (as found in Section II.C, *supra*), I find that Respondents have violated 19 U.S.C. § 1337(a)(1)(B)(i).

D. The '487 Patent

1. Claim 1

Claim 1 teaches:

> A method of planning orthodontic treatment of a patient comprising use of incremental tooth repositioning appliances, the method comprising:
>
> receiving an initial digital data set representing an initial arrangement of the patient's teeth;
>
> producing a final digital data set representing the patient's teeth in a desired or prescribed arrangement;

producing a plurality of intermediate digital data sets representing intermediate arrangements of the patient's teeth, wherein at least some of the intermediate tooth arrangements represent different orthodontic treatment stages as the patient's teeth are moved from the initial arrangement toward the final arrangement.

(JX-007 at 10:61-11:6)

Align's Position: Align submits that the preamble of claim 1 is not limiting, as it merely states the purpose of the claimed method. (Citing *Pitney Bowes,* 182 F.3d at 1305) Align says that Respondents have not asserted the contrary in their *Prehearing Brief* and have therefore waived such a position, and an infringement analysis of the preamble is unnecessary. Alternatively, Align asserts that if the preamble was found to somehow be limiting, Align submits that CCPK performs this preamble by (1) preparing a treatment setup, (2) preparing the DPS, and (3) stepping the case to obtain the intermediate tooth arrangements. (Citing Evidence Categories 1, 4, 5, and 7; CX-1150C at Q. 242) Align says that Respondents assert only their "treatment plan" argument as a non-infringement basis, but this is incorrect.

Align says that Respondents assert they do not infringe the claims of the '487 patent because the phrase "treatment plan" should be construed to require that an orthodontist or clinician formulate the treatment plan. Align says that Respondents stated "No Construction Proposed" in the SRJCCC for this phrase, and cannot, therefore, advance this new construction now. (Citing Tr. at 8:4-16) Align continues that neither Respondents nor Dr. Mah cite to any supporting intrinsic evidence. Align adds that the proposed construction is nonsensical in view of the intrinsic record. Align explains that the "treatment plans" of the asserted claims refer to "intermediate digital data sets" that represent "intermediate arrangements of the patient's teeth." Align says that nothing in the '487 patent discloses, much less requires, that an orthodontist plan out the treatment or prepare the digital models used to create the aligners. Rather, Align says

that they teach that most of the treatment planning is done by a technician interacting with a computer and following established protocols. (CitingJX-0006 at 10:12–15; JX-0007 at 5:29-32; see also JX-0003 at 12:33-38 ("treatment plan will ultimately produce the series of INTDDS's and FDDS"); CX-1150C at Qs. 242, 251, 316)

Align argues that Respondents ignore the intrinsic evidence and instead piece together their new construction based on unsupported statements from Dr. Mah along with an irrelevant argument regarding unauthorized practice of dentistry. Align says that such extrinsic evidence is of little value in view of the clear intrinsic record. (Citing *Advanced Fiber*, 674 F.3d at 1375) Align continues that Respondents' arguments also ignore their own documents which specify that they – not their orthodontists – prepare "treatment plans." (Citing CX-0055 ("ClearCorrect maps out a complete treatment plan . . ."); CX-0090C at 28 ("a [DPS] sheet is used to make a treatment plan. . . ."); CX-078 at 64-68 (Treatment plan paperwork shipped with each phase))

Align asserts that CCPK practices the first element of claim 1 {

} Align says that Respondents have not disputed that CCPK practices this element. (Citing RPHB at 110)

Align contends that CCPK practices the second element of claim 1 {

} Align says that Respondents assert only their "final tooth arrangement" argument as a non-infringement basis. Align asserts that Respondents' "final tooth arrangement" non-infringement argument is incorrect. Align says that Respondents assert they do not infringe the claims of the '487 patent because the phrase "final tooth arrangement" in the claims "can only be a projection at the treatment stage prior to active

treatment." Align continues that Respondents appear to argue that the "final tooth arrangement" projected by Respondents' process is not really a "final tooth arrangement" because the clinician has the ability to change the course of treatment, and thus, a "final tooth arrangement" can only be the patient's actual tooth positions at the end of his treatment. Align contends that this construction was not identified in the SRJCCC and neither Respondents nor Dr. Mah cite to any supporting evidence. Align continues that the "final tooth arrangement" contemplated by the patents in suit is simply the {

}

Align says that Respondents' construction necessarily excludes preferred embodiments of the specification, and should be rejected. Align continues that planning a final position of teeth is exactly what Respondents' process does by manipulating the image into a final position according to the clinician's prescription and receiving approval. Align says that even in the event of {

}

Align contends that CCPK practices the third element of claim 1 {

} Align says that Respondents assert only their "final tooth arrangement" (discussed above) and their "all aligners" arguments as non-infringement bases, but these are incorrect. Align asserts that Respondents' "all aligners" non-infringement argument is incorrect. Align says that Respondents assert they do not infringe the claims of the '487 patent because the phrases (i) "plurality of successive tooth repositioning appliances;" (ii) "successive tooth repositioning appliances;" (iii) "shell appliances;" (iv) "successive appliances;" and (v)

"predetermined series of dental incremental position adjustment appliances" require that "all" of the appliances or shells "be produced prior to active treatment." Align asserts that this is a claim construction argument not identified in the SRJCCC and neither Respondents nor Dr. Mah cite to any supporting evidence. Align says that Respondents fail to distinguish the claimed "appliances" from their "phase-based" approach because this phrase reads literally on either a single phase of four consecutive aligners (*e.g.*, "Phase 1") or a group of all the "phases" prepared by Respondents. (Citing CX-1150C) Align says that Respondents fail to explain why the claimed "appliances" do not read on their "phase-based" approach. Align continues that at least Respondents' "Phase 1" is fabricated prior to a patient's treatment and because there is no temporal requirement in the claims, it reads on Respondents' entire treatment system, regardless of the fact they are shipped in phases.

Respondents' Position: Respondents argue that claim 1 cannot be infringed because Align contends that some elements are practiced by CCUS in the United States while others are practiced by CCPK in Pakistan.

Respondents say that because an "orthodontic treatment" can only be planned by a Clinician, and because neither of the Respondents treats patients or creates a "treatment plan," the Respondents do not practice the preamble of claim 1.

Respondents argue that neither CCUS nor CCPK produce a final digital data set, and therefore they do not practice the second claim limitation of claim 1. Respondents say that a "final" tooth arrangement can only be a projection at the treatment stage prior to active treatment, meaning the projection may not actually be the final location of the patient's teeth. (Citing Tr. at 778:5-23) Respondents continue that they do not know when a case is finished until the treating Clinician determines the case is completed. (Citing Tr. at 344:21 to 345:10)

Respondents reason, as a result, that the case may not be "final" even if the patient's teeth reach the positions described in the doctor's prescription. (Citing Tr. at 344:21-345:10)

Respondents argue that based on the context of the patent and the related prosecution history, one skilled in the art would understand that the third limitation would require that all of the "plurality" of "intermediate tooth arrangements" that "move" from the initial tooth arrangement to the "final" tooth arrangement as projected be produced prior to active treatment. Respondent say that CCUS's process is phase-based. (Citing Tr. at 416:8-17) Respondents reason that this means that the clinician does not determine the successive tooth arrangements that are required until after the initial appliances have been fabricated and after treatment has begun. (Citing Tr. at 416:8-17) Respondents continue that the clinician makes this determination based upon based upon an evaluation of the patient's progress and the clinician's prescription. Respondents conclude that the Respondents' phase-based system therefore does not meet this limitation.

Respondents argue that Align's arguments for infringement of claims 1, 3, and 5 are based on its misstatements about the CCPK operators' creation of the computer files at issue. Respondents say that CCUS uses a phase-based system that is much different from the methods described in the claims of the '487 patent. Respondents argue that because Align bases its infringement arguments on its misstatements about Respondents' process, it has failed to meet its burden of proof.

Respondents assert that Align's infringement theories are at odds with Dr. Valley's opinions concerning validity. Respondents say that should the Respondents be found to infringe the first independent claim of the '487 patent based on Align's characterization of the evidence, then the infringed claim must also be found invalid in light of the prior art.

Staff's Position: Staff argues that Align's § 271(g) infringement theory is legally improper and CCPK would not infringe under 35 U.S.C. § 271(g). Staff says that under Align's 35 U.S.C. § 271(a) and 19 U.S.C. § 1337(a)(1)(B)(ii) infringement theories, Staff believes that the evidence supports finding infringement of each of the Asserted Claims of the '487 patent.

Staff says that based on my rulings regarding infringement in Order No. 20 (as well as Order No. 58 of Inv. No. 337-TA-562 (Enforcement Proceeding)), Align's § 271(g) infringement theory under 19 U.S.C. § 1337(a)(1)(B)(i) may be determined to be legally proper. Staff continues that the Staff considers below all of Align's infringement theories under 19 U.S.C. § 1337(a)(1)(B)(i) and Align's alternative infringement theory under 19 U.S.C. § 1337(a)(1)(B)(ii)). Applying the ALJ's rulings regarding patent infringement and a proper claim construction, the Staff is of the view that the evidence supports finding infringement of each of the Asserted Claims of the '487 patent (as discussed below).

Staff asserts that under Align's § 271(g) infringement theory, the evidence supports finding infringement of claims 1, 3, and 5 of the '487 patent under my rulings regarding patent infringement under Section 337 (but not under the Staff's understanding of the legal standards of patent infringement). Staff says that applying my rulings, the evidence demonstrates that CCPK directly infringes claims 1, 3, and 5 of the '487 patent by selling digital data sets in the United States. Staff continues that the evidence shows that CCPK performs each of the steps of the claimed methods. (Citing CX-1150C at Q. 241-250; CX-1198C at 292-303)

Staff contends that the same evidence also supports finding infringement of claims 1, 3, and 5 of the '487 patent under Align's infringement theory under 19 U.S.C. § 1337(a)(1)(B)(ii) (based on the Staff's understanding of the legal standards of patent infringement). (Citing CX-1150C at Q. 241-250; CX-1198C at 292-303)

Staff says that it agrees with Complainant's conclusions on infringement of the Asserted Claims of the '487 patent, except for Complainant's allegation that CCUS directly infringes the Asserted Claims of the '487 patent under 35 U.S.C. § 271(g) by importing or using the digital data sets, digital models, or treatment plans in the United States because these allegations were not in Complainant's Pre-Hearing Brief. (Citing CPRB at 376-377, 384-385, and 387-388)

Staff asserts that Respondents' non-infringement arguments advance claim constructions that were not properly identified in the Second Revised Joint Claim Construction Chart (and, thus, are waived) and are not properly supported by any intrinsic (or extrinsic) evidence. Staff says that Respondents argue that they do not infringe claims 1-3 of the '487 patent because the phrase "a final digital data set" requires "a final tooth arrangement" that can only be a projection at the treatment stage prior to active treatment. Staff continues that Respondents also made this argument with respect to the '325 patent, and Staff contends that this argument should be rejected for the same reasons stated with respect to the '325 patent.

Staff says that Respondents also argue that they do not infringe claims 1, 3, and 5 of the '487 patent because the claimed "orthodontic treatment" can only be planned by a clinician. (Citing RIB at 92) Staff disagrees, saying that the term "orthodontic treatment" was not properly identified in the Second Revised Joint Claim Construction Chart. Staff argues that Respondents are precluded from presenting any arguments in this regard and that Respondents (and Dr. Mah) do not identify any intrinsic evidence that would support their proposed construction.

Staff says that Respondents also argue that they do not infringe claims any of the Asserted Claims of the '487 patent because the claimed "plurality of intermediate digital data sets representing intermediate arrangements of the patient's teeth" requires, *inter alia*, that all of the plurality of intermediate tooth arrangements be produced prior to active treatment. (Citing

RIB at 92-93) Staff asserts that this argument should be rejected because this term was not properly identified in the Second Revised Joint Claim Construction Chart. Staff continues that even if raised properly, this argument should be rejected because Respondents (and Dr. Mah) do not identify any intrinsic evidence that would support a construction seeking to add such a limitation to the claims. (Citing RX-0129C at Q. 159) Staff adds that this argument is based on testimony in Dr. Mah's Rebuttal Witness Statement that was excluded by the ALJ. (Citing RX-0129C at Q. 159)

Staff says that Respondents argue that they do not infringe claims 1, 3, and 5 of the '487 patent because some elements of a claim are performed by CCUS and other elements of the claim are performed by CCPK. Staff contends that while the evidence shows that CCUS performs one claim element, the evidence further shows that CCPK also performs that claim element and all of the remaining claim elements.

Analysis and Conclusions: First, addressing Respondents' incorporation by reference of their general defenses, I incorporate and reaffirm the analysis and conclusions reached in section V.B.1, *supra*, treating the three issues relevant to the asserted claims of the '487 patent, to wit: (1) whether or not all steps of a method claim must be performed in the same country; (2) whether or not digital data sets are "articles" within the scope of 19 U.S.C. § 1337; and (3) whether or not Align can meet its burden of proving infringement through the testimony of Mr. Beers.

I find that Align has shown by clear and convincing evidence that CCPK practices each and every limitation of claim 1.

Align waived its right to allege direct infringement of claim 1 by CCUS by failing to address the issue in its prehearing brief. (See CPHB at 376-377) Align did not waive its right to

assert CCPK directly infringes claim 1. Based on the evidence before me, I find that CCPK practices each and every limitation of claim 1 and therefore directly infringes.

First, I find that CCPK practices the preamble of claim 1. Although neither party has explicitly argued that the preamble of claim 1 is a limitation, Respondents have asserted non-infringement arguments based on the phrase "orthodontic treatment" in the preamble. Respondents have not provided any explanation regarding why the preambles of claim 1 is limiting. As a result, any such argument has been waived. Assuming, *arguendo*, that the argument was not waived, I find that the preamble of claim 1 is not a limitation. Claim 1 is complete without the preamble and the preamble merely restates what is apparent from the final element of the claim itself—the claimed method is a method for planning the treatment of a patient using intermediate digital data sets, which represent intermediate tooth arrangements for a patient's teeth. As a result, I find that the preamble of claim 1 is not limiting.

Assuming, *arguendo*, that the preamble of claim 1 is limiting, CCPK's process practices the preamble. {

}

Documents created by CCUS in the ordinary course of business that were submitted to the Food and Drug Administration by CCUS to show CCUS's process state that the digital data sets representing the initial tooth arrangement are imported into FreeForm Modeling software, which is a 3D modeling program. (CX-078 at 55; Tr. at 248:9-249:3) {

} (Tr. at 170:25-172:14)

{

} These admissions and documents show that CCPK generates a digital rendition showing the final tooth position of a patient, and then generate a series of intermediate data sets reflecting tooth positions for an orthodontics patient in between the initial position and final position. The admissions also show that these data sets are used to make incremental appliances for treating the orthodontics patient.

Respondents' arguments that CCPK's process is not a method for planning orthodontic treatment are unpersuasive. First, Respondents failed to identify the term "orthodontic treatment" in the SRJCCC as needing construction, and therefore is waived. Assuming,

arguendo, that Respondents had proposed the term "orthodontic treatment" for construction, Respondents' arguments that an orthodontic treatment can only be prepared by a clinician are rejected for the same reasons that Respondents' arguments regarding construction of "treatment plan" in claim 7 were rejected in Section III.D.2, *supra*. As a result, I find that CCPK practices the preamble of claim 1.

I also find that CCPK practices the first element of claim 1. {

} (Tr. at 315:19-23) As a result, I find that CCPK "receiv[es] an initial digital data set" from CCUS that "represent[s] an initial arrangement of the patient's teeth."

I also find that Respondents' process practices the second element of claim 1. {

}

Respondents' arguments that the "treatment setup" data set is not a "final digital data set" because it may be different from the actual final position of the patient's teeth are unpersuasive. First, Respondents did not propose a construction for "final digital data set" in the SRJCCC. Second, assuming, *arguendo*, that Respondents had proposed a construction for "final digital data set," there is nothing in the claims that require such a limited construction. Rather, the claims merely require that the "final digital data set" represent the patient's teeth in a desired or

prescribed arrangement. Mr. Arif admitted that the final digital data set is sent to the treating professional for approval—this clearly falls within the scope contemplated by the claim—"a desired or prescribed arrangement." (*See id.*) As a result, Respondents' arguments are wide of the mark. Based upon the foregoing, I find that CCPK practices the second element of claim 1.

Finally, I find that CCPK practices the third element of claim 1 when it generates intermediate digital data sets using the "stepping" process. {

}

Respondents' arguments that this limitation is not met are unpersuasive. Respondents assert, incorrectly, that because Respondents' process of producing aligners is phase based, they do not generate all of the digital data sets from the initial tooth arrangement to the final tooth arrangement before treatment begins. First, claim 1 does not require the production of all digital data sets from the initial tooth arrangement to the final tooth arrangement. Rather, claim 1 merely requires that "***some*** [not all] of the [produced] intermediate tooth arrangements represent different orthodontic treatment stages as the patient's teeth are moved from the initial arrangement toward the final arrangement." (JX-007 at 11:1-6)

The fact that a "mid-course correction" may occur during treatment under Respondents' process does not preclude a finding of infringement. Respondents admitted that a "mid-course correction," under which changes are made to the treatment of a patient after treatment has begun, is not made in every case. (Tr. at 224:11-13; *See also* Tr. at 213:9-21) As a result, even if "mid-course corrections" resulted in a course of treatment being stopped, it would only apply to a subset of all cases handled by Respondents. Also, Respondents admitted that when a "mid-course correction" does take place, the entire accused process is executed again, using new initial and new final tooth positions, between which intermediate data sets are generated. (Tr. at 195:7-196:4, 205:24-206:15, 224:14-21, 318:21-319:3) For any given patient for whom "mid-course corrections" are provided, there will necessarily be a final "mid-course correction" after which no additional "mid-course corrections" will take place in his treatment. After this final "mid-course correction," Respondents will generate intermediate digital data sets between the new initial and new final tooth positions that will be used for all of the remaining treatment series.

Additionally, I find that CCPK does generate all intermediate digital data sets between the initial tooth position and the final tooth position before any intermediate digital data sets are sent to CCUS for fabrication. Respondents' argument essentially is that because only four intermediate digital data sets are festooned and sent to CCUS at a time, Respondents cannot meet this limitation. {

} The mere fact that "festooning" is carried out on the stepped data sets before they are sent to CCUS does not change the fact that CCPK generated all of the intermediate digital data sets during the "stepping process." Rather, Mr. Arif testified that in CCPK's "phase

process," {

} (Tr. at 193:9-194:6) Based upon all of the foregoing, I find that CCPK practices the third element of claim 1.

As a result, I find that Align has shown by a preponderance of the evidence that the CCPK practices each and every limitation of claim 1.

2. Claim 3

Claim 3 teaches:

> The method of claim 1, wherein the intermediate digital data sets for different orthodontic treatment stages are configured for facilitating fabrication of shell appliances for a corresponding treatment stage.

(JX-007 at 11:7-9)

Align's Position: Align asserts that CCPK practices claim 3 because the intermediate digital data sets it provides to CCUS are for fabricating a plurality of successive dental incremental position adjustment appliances. (Citing Evidence Categories 7, 9, and 10; CX-1150C at Q. 247) Align continues that Respondents assert only their "all data sets" argument as a non-infringement basis. (Citing RIB at 111) Align says that Respondents assert they do not infringe the claims of the '487 patent because phrases such as: (i) "a plurality of successive digital data sets;" (ii) "intermediate tooth arrangements;" (iii) "intermediate digital data sets;" (iv) "intermediate arrangements;" (v) "intermediate positions;" (vi) "series of discrete tooth arrangements;" (vii) "modified digital models;" and (viii) "models" require that ***all*** data sets for a

patient's treatment be "produced prior to active treatment." Align says that this construction was not identified in the SRJCCC. Align continues that Respondents cite to no supporting evidence for such a construction. Align contends that Respondents still infringe under this construction because CCPK completes the stepping or staging for all stages prior to CCUS making the first set of appliances for active treatment ("phase 1"). (Citing CX-1150C at Q. 130-136, 347, 352) Align says that, in other words, while CCUS says it forms aligner sets only four at a time (a "phase"), CCPK prepares all of the tooth arrangements for all aligners in all phases before treatment begins. Align argues that Respondents infringe and violate Section 337 for the same reasons as claim 1.

Respondents' Position: Respondents assert that because claim 3 is dependent on claim 1, the Respondents do not infringe claim 3, for the same reasons as discussed above for claim 1. Respondents say that because claim 3 of the '487 patent depends from claim 1, some of the elements of claim 3 are allegedly practiced at least in part by CCUS in the United States, and other elements are allegedly practiced only by CCPK in Pakistan. Respondents argue that claim 3 of the '487 patent, a method claim, is not infringed.

Respondents contend that based on the context of the patent and the related prosecution history, as discussed above, one skilled in the art would understand that claim 3 requires that all of the "intermediate digital data sets" be produced prior to active treatment. Respondents say that CCUS's phase-based system does not meet this limitation.

Staff's Position: Staff addresses claims 1, 3, and 5 together, as reflected in Staff's Position regarding claim 1.

Analysis and Conclusions: If I had found that Align had failed to prove that Respondents infringe claim 1, it would follow that Align failed to prove infringement of claim 3,

which depends from claim 1. *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n. 9 (Fed. Cir. 1989) ("One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim.")

Nevertheless, I have found that Respondents infringe asserted claim 1. I also find that CCPK practices each and every element of claim 3 and therefore directly infringes claim 3. {

} (Tr. at 316:12-318:11) Based on these admissions, I find that CCPK practices claim 3 because the intermediate digital data sets generated by CCPK's stepping process are used to fabricate shell appliances for a corresponding treatment stage. For the same reasons found *supra* regarding claim 1, which I incorporate and reaffirm here, Respondents' arguments that all "intermediate digital data sets" must be produced prior to active treatment are unpersuasive.

3. Claim 5

Claim 5 teaches:

> The method of claim 1, further comprising providing a plurality of the intermediate digital data sets to a fabrication operation for fabrication of a series of successive tooth repositioning appliances.

(JX-007 at 11:19-22)

Align's Position: Align asserts that CCPK practices claim 5 when it provides CCUS the above described plurality of intermediate digital data sets, which are used to fabricate appliances.

(Citing Evidence Categories 7, 9, and 10; CX-1150C at Q. 249) Align says that Respondents advance only their "all aligners" argument as a non-infringement basis, which is incorrect for the reasons discussed regarding claim 1. Align concludes that Respondents infringe and violate Section 337 for the same reasons as claim 1.

Respondents' Position: Respondents argue that because claim 5 is dependent on claim 1, the Respondents do not infringe claim 5 for the same reasons as discussed above for claim 1.

Respondents say that Align alleges that the additional limitations of claim 5 are practiced both by CCUS in the U.S. and CCPK in Pakistan. (Citing CX-1198C-087) Respondents argue that because claim 5 of the '487 patent depends from claim 1, some of the elements of claim 5 are allegedly practiced at least in part by CCUS in the United States, and other elements are allegedly practiced only by CCPK in Pakistan. Respondents conclude that that claim 5 of the '487 patent, a method claim, is not infringed.

Respondents argue that based on the context of the patent and the related prosecution history, one skilled in the art would understand that claim 5 requires that all of the "plurality" of "successive tooth repositioning appliances" be produced prior to active treatment. Respondents say that like the final element of claim 1, CCUS's phase-based system does not meet this limitation.

Staff's Position: Staff addresses claims 1, 3, and 5 together, as reflected in Staff's Position regarding claim 1.

Analysis and Conclusions: If I had found that Align had failed to prove that Respondents infringe claim 1, it would follow that Align failed to prove infringement of claim 5, which depends from claim 1. *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n. 9 (Fed. Cir. 1989) ("One who does not infringe an independent claim cannot infringe a claim

dependent on (and thus containing all the limitations of) that claim.")

Nevertheless, I have found that Respondents infringe asserted claim 1. I find that CCPK also practices claim 5. {

}

Respondents' argument that all of the intermediate appliances be fabricated before treatment begins is unpersuasive. There is no requirement in claims 1 or 5 of the '487 patent that any appliances be fabricated, much less ***all*** appliances be fabricated prior to the beginning of treatment. Rather, claim 1 merely requires "receiving and initial digital data set . . . ," "producing a final digital data set . . . ," and "producing a plurality of intermediate digital data sets . . . ." (JX-007 at 10:61-11:6) Claim 5 merely requires that "a plurality" of intermediate digital data sets be sent to the "fabrication operation," not all of the intermediate digital data sets. (JX-007 at 11:19-22) Moreover, Claim 5 does not actually require any appliances be fabricated; rather, claim 5 merely requires that the data sets be provided to a fabrication ***for*** fabrication of a series of successive tooth repositioning appliances. (*Id.*) Thus, CCPK meets this limitation when it sends intermediate digital data sets to CCUS.

Assuming, *arguendo*, that there was a requirement that appliances actually be fabricated before treatment begins, Respondents do not contest that the four intermediate digital data sets in

the first phase for a patient are fabricated before treatment for that patient begins. As a result, even if fabrication were required, I find that CCPK practices claim 5 because CCPK transmits a plurality of intermediate digital data sets to CCUS in a first phase, and CCUS fabricates all of the appliances in that phase before the start of treatment.

Based upon all of the foregoing, I find that CCPK infringes claim 5 of the '487 patent.

4. Claim 7

Claim 7 teaches:

> An orthodontic treatment plan for repositioning a patient's teeth using incremental tooth repositioning appliances, the treatment plan residing on a computer readable storage media and comprising a plurality of intermediate digital data sets representing intermediate arrangements of the patient's teeth,
>
> wherein at least some of the intermediate tooth arrangements represent different orthodontic treatment stages as the patient's teeth are moved from an initial arrangement toward a final arrangement representing the patient's teeth in a desired or prescribed arrangement.

(JX-007 at 11:26-35)

Align's Position: Align asserts that Respondents practice the first element of claim 7 because CCPK produces a plurality of intermediate digital data sets representing intermediate arrangements of the patient's teeth for CCUS. (Citing Evidence Categories 1, 5, and 7; CX-1150C at Q. 251) Align says that paperwork describing how the treatment plan for each phase is to work is produced and provided with the custom made aligners. (Citing CX-078 at 64-68; CX-1150C at Q. 251) Align says that respondents' assert only their "treatment plan" argument as a non-infringement basis, which is incorrect for the reasons discussed regarding claim 1.

Align argues that the second element of claim 7 reads on Respondents' treatment plan, as

{

} (Citing Evidence Categories 7 and 10; CX-1150C at Q. 253)

Align says that Respondents assert their "all data sets," "final tooth arrangement," and "treatment plan" arguments as non-infringement bases, but these are incorrect as discussed above regarding claims 1 and 3.

Align asserts that CCPK directly infringes claim 7 because it reads on Respondents' "treatment plan" and CCPK offers to sell or sells these treatment plans in the U.S. Align also contends that CCUS directly infringes claim 7 because CCUS uses these "treatment plans" in the U.S.

Respondents' Position: Respondents say that the second element of claim 7 recites "the treatment plan residing on a computer readable storage media and comprising a plurality of intermediate digital data sets representing intermediate arrangements of the patient's teeth." Respondents say that Mr. Beers testified that "I have analyzed this element and conclude that {

} Respondents argue that Align has produced no evidence that CCPK uses, offers to sell, or sells within the United States, or imports into the United States, the

claimed treatment plans. Respondents conclude that Align fails to meet its burden of showing that there is an unfair act in the importation of the CCUS "treatment plans" into the U.S.

Respondents argue that an "orthodontic treatment" is only planned by a Clinician. Respondents say that because neither of the Respondents treats patients or creates a "treatment plan" as that term is understood by those skilled in the art, the Respondents do not infringe this claim element.

Respondents argue that based on the context of the patent and the related prosecution history, one skilled in the art would understand that claim 7 requires that all of the "plurality" of "intermediate arrangements" that "move" from the initial tooth arrangement toward the "final" tooth arrangement as projected be produced prior to active treatment. Respondents say that CCUS's phase-based system does not meet such a limitation because the data files for the last group of appliances would not be completed until possibly years after the treatment begins. (Citing Tr. 341:22 to 343:14) Respondents reason that because "orthodontic treatment" is only planned by a Clinician and neither of the Respondents treats patients or creates a "treatment plan" as that term is understood by those skilled in the art, the Respondents do not infringe this limitation.

Respondents argue that claim 7, requires that the "treatment plan" reside "on a computer readable storage media." Respondents say that the uncontested evidence presented at the hearing established that CCUS does not receive any data from CCPK through a tangible device, such as a thumb drive, hard drive or disk. (Citing Tr. at 344:7-20) Respondents continue that Align has effectively conceded that there is no importation of such a storage device. Respondents say that Mr. Beers testified that {

} (Citing CX-1150C at Q. 252; Tr. at 554:7-23) Respondents say that neither the workstation nor the server is imported. (Citing Tr. at 554:24-555:9)

Respondents argue that Align's post hearing brief offers nothing to salvage its infringement claims and simply recites the hearing testimony that any "treatment plan" would reside only on CCPK workstations in Pakistan or on CCUS's server in Texas. Respondents say that CCUS has produced no evidence that CCPK uses, offers to sell, or sells within the United States, or imports into the United States, the claimed treatment plans. Respondents conclude that Align fails to meet its burden of showing that there is an unfair act in the importation of the CCUS "treatment plans" into the U.S. and has therefore failed to meet its burden of proof concerning independent claim number 7 as well as the claims that depend on it, claims 8 and 9.

Staff's Position: Staff says that under Align's § 271(a) infringement theory, the evidence support finding infringement of claims 7-9 of the '487 patent under the ALJ's rulings regarding patent infringement under Section 337 (as well as under the Staff's understanding of the legal standards of patent infringement). Staff continues that Applying my rulings (or the Staff's understanding), the evidence shows that CCPK directly infringes claims 7-9 of the '487 patent by selling its treatment plans. (Citing CX-1150C at Q. 250-260; CX-1198C at 303-311)

Staff says that under Align's § 271(c) infringement theory, the evidence supports finding infringement of claims 7-9 of the '487 patent under my rulings regarding patent infringement under Section 337 (as well as under the Staff's understanding of the legal standards of patent infringement). Staff continues that Based on CCUS's direct infringement of claims 7-9 of the '487 patent (discussed below), the evidence demonstrates that CCPK contributes to that infringement by creating its treatment plans. (Citing CX-1150C at Q. 250-260; CX-1198C at

303-311) Staff incorporates its discussion of the elements of contributory infringement with respect to the '325 Patent.

Staff says that under Align's § 271(a) infringement theory, the evidence to supports finding infringement of claims 7-9 of the '487 patent under my rulings regarding patent infringement under Section 337 (as well as under the Staff's understanding of the legal standards of patent infringement). Applying my rulings (or the Staff's understanding), the evidence demonstrates that CCUS directly infringes claims 7-9 of the '487 by using CCPK's treatment plans. (Citing CX-1150C at Q. 250-260; CX-1198C at 303-311)

Staff says that Respondents argue that they do not infringe claims 7-9 of the '487 patent because the claimed "treatment plan" can only be planned by a clinician. Staff disagrees because even though the term "treatment plan" was identified in the Second Revised Joint Claim Construction Chart, Respondents did not propose a construction for the term. Thus, as discussed in the Staff's Post-Hearing Brief, the Staff is of the view that Respondents are precluded from presenting any arguments in this regard and that Respondents (and Dr. Mah) do not identify any intrinsic evidence that would support their proposed construction.

Analysis and Conclusions: I find that the intermediate digital data sets produced by CCPK meet each and every limitation of claim 7 when they are stored on CCPK or CCUS computers, servers, or other forms of "computer readable storage media."

First, I find that the first element of claim 7 reads on the intermediate digital data sets produced by CCPK, when they are stored on computers, servers, or other forms of "computer readable storage media" at CCPK or CCUS. In Section III.D.2, *supra*, I found that the phrase "treatment plan" means "two or more successive digital data sets representing arrangements of a patient's teeth progressing from an initial tooth arrangement toward a final tooth arrangement."

As noted regarding claim 1, *supra*, {

}

{

} Based on these admissions, I find that the complete set of festooned intermediate digital data sets that is sent to CCUS (*i.e.*, all phases of treatment) are two or more successive digital data sets that represent arrangements of a patient's teeth progressing from an initial tooth arrangement toward a final tooth arrangement. Additionally, I find that at least some of these data sets represent intermediate tooth arrangements at different orthodontic stages as the patient's teeth are moved from the initial position toward the final prescribed position. When stored on a computer, server, or other "computer readable storage media," this complete set of digital data sets meets the first and second elements of claim 7.

The fact that a "mid-course correction" may occur during treatment under Respondents' process does not preclude a finding of infringement. Respondents admitted that a "mid-course correction," under which changes are made to the treatment of a patient after treatment has

begun, is not made in every case. (Tr. at 224:11-13; *See also* Tr. at 213:9-21) As a result, even if "mid-course corrections" resulted in a course of treatment being stopped, it would only apply to a subset of all cases handled by Respondents. Also, Respondents admitted that {

} (Tr. at 195:7-196:4, 205:24-206:15, 224:14-21, 318:21-319:3) For any given patient for whom "mid-course corrections" are provided, there will necessarily be a final "mid-course correction" after which no additional "mid-course corrections" will take place in his treatment. After this final "mid-course correction," Respondents will generate intermediate digital data sets between the new initial and new final tooth positions that will be used for all of the remaining treatment series.

Respondents arguments that a "treatment plan" must be created by a clinician are unpersuasive, as explained in Section III.D.2, supra.

Respondents assert, incorrectly, that because Respondents' process of producing aligners is phase based, they do not generate all of the digital data sets from the initial tooth arrangement to the final tooth arrangement before treatment begins. There is no limitation in claim 7 that specifies that all digital data sets must be generated before treatment begins. (*See* JX-007 at 11:26-35) Even assuming, arguendo, that claim 7 did require that all data sets be generated before the beginning of treatment, {

) (Tr. at 172:15-173:8, 190:20-191:25) As explained *supra* regarding claim 1, the mere fact that "festooning" is carried out on the stepped data sets before they are sent to CCUS does not change the fact that CCPK generated all of the intermediate digital data sets during the "stepping process."

This does not, however, end the inquiry. The Commission has explained that "section 337(a)(1)(B)(i) covers imported articles that directly or indirectly infringe when it refers to 'articles that -- infringe.' ***We also interpret the phrase 'articles that – infringe' to reference the status of the articles at the time of importation.*** Thus, infringement, direct or indirect, must be based on the articles as imported to satisfy the requirements of section 337." *Certain Electronic Devices With Image Processing Systems, Components Thereof, And Associated Software*, Inv. No. 337-TA-724, Comm'n Op. (Dec. 21, 2011) (emphasis added). Claim 7 requires that the treatment plan "resid[e] on a computer readable storage media." The evidence shows that the digital data sets are imported by being transmitted ***electronically***, not on a computer readable storage media. Thus, at the time of importation, the accused digital data sets do not meet each and every limitation of claim 1. As a result, I find that the digital data sets transmitted from CCPK to CCUS do not infringe claim 7 of the '487 patent.

5. Claim 8

Claim 8 teaches:

> The orthodontic treatment plan of claim 7, wherein the intermediate digital data sets for different orthodontic treatment stages are configured for facilitating fabrication of shell appliances for a corresponding treatment stage.

(JX-007 at 11:36-39)

Align's Position: Align asserts that claim 8 reads on Respondents' treatment plan because the digital data sets described above are configured so CCUS can fabricate the molds used to make the shell appliances for each treatment stage. (Citing Evidence Category 10; CX-1150C at Q. 256) Align says that Respondents advance only their "all data sets" argument as a non-infringement basis, which is incorrect for the reasons discussed regarding claim 3. Align argues that because claim 8 reads on Respondents' treatment plans, both infringe for the same reasons identified in claim 7.

Respondents' Position: Respondents asset that because claim 8 depends on claim 7, dependent claim 8 is not infringed for the same reasons as claim 7. Respondents say that they do not create the treatment plan. Respondents continue that based on the context of the patent and the related prosecution history, one skilled in the art would understand that this limitation would require that all of the "intermediate digital data sets" be produced prior to active treatment. Respondents say that CCUS's phase-based system does not meet this limitation. Respondents argue that CCUS's phase-based system does not meet such a limitation because the data files for the last group of appliances would not be completed until possibly years after the treatment begins. (Citing Tr. 341:22 to 343:14)

Staff's Position: Staff addresses claims 7, 8, and 9 together, as reflected in Staff's Position regarding claim 7.

Analysis and Conclusions: Because I find that Align has failed to prove that Respondents' digital data sets infringe claim 7, it follows that Align failed to prove infringement of claim 8, which depends from claim 7. *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n. 9 (Fed. Cir. 1989) ("One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim.")

Assuming, *arguendo*, that Respondents' digital data sets infringe asserted claim 7, I would find that Respondents' digital data sets infringe claim 8. {

} Based on these admissions, if Align had proven that Respondents' digital data sets infringe claim 7, I would find that the intermediate digital data sets generated by CCPK's stepping process are configured for fabricating shell appliances for a corresponding treatment stage, as required by claim 8. For the same reasons found in Section V.D.5, *supra* regarding claim 7, which I incorporate and reaffirm here, Respondents' arguments that all "intermediate digital data sets" must be produced prior to active treatment are unpersuasive.

6. Claim 9

Claim 9 teaches:

> The orthodontic treatment plan of claim 8, wherein the shell appliances comprise a plurality of successive appliances having teeth receiving cavities, and wherein cavities of at least two successive appliances have different geometries shaped to receive and reposition the patient's teeth.

(JX-007 at 11:40-44)

Align's Position: Align contends that claim 9 reads on Respondents' treatment plan because the intermediate digital data sets of the treatment plan are configured for fabricating successive shell appliances incrementally reposition teeth into a desired arrangement. (Citing Evidence Category 10; CX-1150C at Q. 259) Align says that Respondents advance only their

"all aligners" argument as a non-infringement basis, which is incorrect for the reasons discussed in regarding claim 1. Align argues that because claim 9 reads on Respondents' treatment plans, both infringe for the same reasons identified in claim 7.

Respondents' Position: Respondents argue that because claim 9 is dependent on claims 7 and 8, claim 9 is not infringed for the same reasons as claims 7 and 8. Respondents say that based on the context of the patent and the related prosecution history, one skilled in the art would understand that this limitation would require that all of the "shell appliances" be produced prior to active treatment. Respondents argue that CCUS's phase-based system does not meet this limitation. Respondents add that the Respondents do not create the orthodontic treatment plan.

Staff's Position: Staff addresses claims 7, 8, and 9 together, as reflected in Staff's Position regarding claim 7.

Analysis and Conclusions: Because I find that Align has failed to prove that Respondents infringe claim 7, it follows that Align failed to prove infringement of claim 9, which depends from claim 7 by way of claim 8. *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n. 9 (Fed. Cir. 1989) ("One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim.")

Assuming, *arguendo*, that Respondents' digital data sets infringe asserted claims 7 and 8, I would find that Respondents' digital data sets infringe claim 9. A document submitted by CCUS to the FDA regarding Respondents' process states that: "The ClearCorrect device is fabricated of clear, thin, thermoformed polyurethane plastic in a sequential series of trays to progressively reposition the teeth. Corrective force to straighten the teeth is delivered via minor changes into a position in each subsequent aligner." (CX-078 at 25) Based on the foregoing, if Align had proven that Respondents' digital data sets infringe claims 7 and 8, I would find that

the CCUS appliances have teeth receiving cavities which include "minor changes" in each subsequent aligner, as required by claim 9, and therefore Respondents' digital data sets, on which the appliances are based, would infringe claim 9.

7. Violation of Section 1337(a)

Align's Position: Align asserts that Respondents violate 337(a)(1)(B)(ii) by importing, selling for importation, or selling after importation the digital data sets made according to claims 1, 3, and 5 of the '487 Patent. Align alternatively asserts that Respondents also violate 337(a)(1)(B)(i) in view of the '487 as follows: (i) CCPK directly infringes claim 1, 3 and 5 of the '487 Patent under 35 U.S.C. § 271(g) by importing, offering to sell, or selling digital data sets, digital models, or treatment plans in the U.S.; (ii) CCUS directly infringes claim 1, 3 and 5 of the '487 Patent under 35 U.S.C. § 271(g) by importing or using digital data sets, digital models, or treatment plans in the U.S.; (iii) CCPK directly infringes claim 7, 8 and 9 of the '487 Patent under 35 U.S.C. § 271(a) by offering to sell, selling, or importing the claimed treatment plans; (iv) CCUS directly infringes claim 7, 8 and 9 of the '487 Patent under 35 U.S.C. § 271(a) by importing or using the claimed treatment plans.

Staff's Position: Staff says that when applying the ALJ's rulings regarding patent infringement under Section 337, the evidence shows that CCPK directly infringes claims 1, 3, and 5 of the '487 patent under 35 U.S.C. § 271(g) by selling digital data sets. Staff continues that when applying the Staff's understanding of the legal standards of patent infringement, the evidence demonstrates that (i) CCPK directly infringes claims 1, 3, and 5 of the '487 patent under 19 U.S.C. § 1337(a)(1)(B)(ii) by importing the digital data sets that are produced by these claimed methods; (ii) CCPK directly infringes claims 7-9 of the '487 patent under 35 U.S.C. § 271(a) by selling its treatment plans, and (iii) CCUS directly infringes claim 7-9 of the '487

patent under 35 U.S.C. § 271(a) by using CCPK's treatment plans, and CCPK contributes to that infringement by creating the treatment plans. Staff concludes that the evidence demonstrates that CCUS and CCPK violate U.S.C. §1337(a)(1)(B) by importing the treatment plans.

Analysis and Conclusions: 19 U.S.C. § 1337(a)(1)(B)(ii) prohibits "[t]he importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that: . . . (ii) are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent." By importing digital data sets (as found in Section II.C, *supra*) that are made by CCPK, which practices the entire process of claims 1, 3, and 5 in Pakistan to produce the digital data sets (as found in Section V.D.1-3, *supra*), Respondents have violated 19 U.S.C. § 1337(a)(1)(B)(ii).

19 U.S.C. § 1337 (a)(1)(B)(i) prohibits "[t]he importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that: (i) infringe a valid and enforceable United States patent or a valid and enforceable United States copyright registered under title 17." Because I found *supra*, the accused intermediate digital data sets produced by CCPK and imported into the United States (as found in section II.C, *supra*) do not infringe apparatus claims 7, 8, and 9, I find that CCPK and CCUS do not violate section 337(a)(1)(B)(i) based on apparatus claims 7, 8, and 9.

E. The '511 Patent

1. Claim 1

Claim 1 recites:

> A computer-implemented method for segmenting an orthodontic treatment path into segments, comprising:

for each tooth in a set of teeth, receiving a tooth path for the motion of the tooth from an initial position to a final position;

calculating a segmentation of the aggregate tooth paths into a plurality of treatment segments so that each tooth's motion within a segment stays within threshold limits of linear and rotational translation; and

generating a plurality of appliances, at least one or more appliances for each treatment segment, wherein the appliances comprise polymeric shells having cavities and wherein the cavities of successive shells have different geometries shaped to receive and resiliently reposition the teeth from one arrangement to a successive arrangement.

(JX-001, 11:4-19)

Align's position: Align contends that asserted claim 1 is a process claim with straightforward language. Align argues that Respondents' process infringes this claim, as "explained in full" in the direct testimony of Align's expert, Andrew Beers (Citing CX-1150, Qs. 332-338, 351, 356) and the detailed "claim chart" comparison of the claim language with Respondents' process. (Citing CX-1198 at 189-198)

Align submits that the preamble is not limiting, because it merely states the purpose of the claimed method. (Citing *Pitney Bowes*, 182 F.3d at 1305 (Fed. Cir. 1999)). Align says that Respondents have not asserted the contrary in their *Prehearing Brief*, and have therefore waived such a position. Align reasons, thus, an infringement analysis of the preamble is unnecessary.

Align continues, if the preamble is found to somehow be limiting, then Respondents practice the preamble by designing, making and selling clear aligners that are to be worn by a patient in a predetermined order. {

} (Citing CX-1150C, Qs. 332, 351) Align argues that Respondents' "computer implemented" and "tooth path" arguments at RPHB, 139-140, 233, are improper as discussed in CIB section IV.D and the introduction to section VIII.

Align argues that {

}

Align says that Respondents assert their "computer-implemented" argument as a basis for finding non-infringement, which is incorrect for the reasons discussed in CIB section IV.D. Align adds that Respondents dispute the construction of "threshold limits…" as discussed in CIB section VIII.A.4, and argue that "the ClearCorrect protocol of moving teeth in .3mm increments or 1 degree for rotations is not a threshold limit as would be understood by one skilled in the art," because they are "determined by the clinical experience of ClearCorrect based on the thermoformed materials and are not a computer algorithm." (Citing RPHB at 141) Align argues that Respondents' construction is improper for the reasons discussed above, and their argument is therefore unsupported. (Citing CIB section I.E.6)

Align asserts that CCUS practices the third element of asserted claim 1, when it

{

} (Citing CIB section I.E.10; and CX-1150C, Q. 337) Align alleges that Respondents did not contest that they infringe this element. (Citing RPHB at 139-142; and RX-129C, Qs. 87-100)

Align contends that CCUS offers to sell, sells, or uses aligners in the U.S. that are made according to each of claimed steps by the joint CCUS/CCPK process, and therefore directly infringes under 35 U.S.C. § 271(g). Align says that when claim 1 is read on a product made by the joint CCUS/CCPK process, CCPK contributorily infringes under the four-part *Fujitsu* test, where factor (1) is met by CCUS's direct infringement and the remaining factors are met as shown in CIB section IV.B. Align adds that alternatively, CCUS effectuates the joint CCUS/CCPK process that practices each step of the claimed method, which provides the requisite direct infringement, knowledge, and intent under 35 U.S.C. § 271(b) pursuant to the Federal Circuit's *Akamai* decision, as explained in CIB section IV.C.

Align says that Respondents assert a number of other inapplicable non-infringement

positions, including: (i) CCPK performs some steps in Pakistan (Citing RPHB at 144-146); and (ii) 35 U.S.C. § 271(g) claims cannot be advanced in the ITC (*id.* at 145-146). Align says that Respondents are wrong on each count, as described in CIB section IV.E.

In its reply brief Align says that Respondents generally assert their global non-infringement arguments with respect to this claim, which are incorrect for the reasons discussed in Section V.B.1, *supra.* Align adds that Respondents assert "two one-off non-infringement arguments."

Regarding element 1, Align says that Respondents argue that the claim covers only an "actual" tooth path after treatment, rather than the projected tooth path of their system, in conjunction with their unsupported claim construction in CIB section VIII.A.5; but, as described above and in CIB at 104, {

}

Regarding element 2, Align says that Respondents seek to differentiate their assertion that { } is not a threshold limit as would be understood by one skilled in the art"[51] from the claimed threshold limits. (Citing RIB at 108) Align contends that the only evidence Respondents have to support this argument is a citation to irrelevant testimony from Align's invalidity expert, Dr.

[51] Align says Respondents have failed to provide any evidentiary support for this position.

Valley. Align adds that the cited testimony does not involve a comparison of the claim element with Respondents' process.

Respondents' Position: Respondents incorporate by reference the discussion of their general defenses in RIB Sections 3.3.1.1 to 3.3.1.14.

Respondents note that Align contends that the first and second elements are practiced by CCPK in Pakistan, and that the third element is practiced by CCUS in the United States. (Citing CX-1150C, Qs. 333-337) Respondents reason, therefore, claim 1, a method claim, is not infringed based upon their argument in RIB section 3.3.1.3.

Respondents assert that claim 1 requires that all of its steps must be "computer-implemented;" but Respondents contend that {

} (Citing Tr. 329:11-341:21; and RX-129C, Qs.88-92)

Regarding the first element of asserted claim 1, Respondents say that Mr. Beers suggests an Operator, using {

} Respondents add that during and following phases of tooth movement, Clinicians observe the newly repositioned tooth positions and may respond accordingly. (Citing Tr. 416:8-17)

Focusing on the second element of asserted claim 1, Respondents contend there is no receipt of any "tooth path" in their process. Respondents say this missing element is especially conspicuous in light of the limitation requiring that the tooth paths be aggregated. Respondents say that {

} Respondents refer to the testimony of Dr. Valley that it is well known in the practice of orthodontics that application of extreme forces or rates of movement can have detrimental effects. (Tr. 709:16-710:7)

In their reply brief Respondents focus on the second element of claim 1 and reiterate that there is no evidence that the tooth movements are restrained by anything in the software or related to the computer system. Respondents conclude that there is no "computer implemented method" that limits any tooth movement.

Staff's Position: Staff is of the view that Align's § 271(g) and § 271(b) infringement theories are legally incorrect for the reasons stated in SIB Section III.B. Applying the Staff's understanding of the legal standards of patent infringement to Align's infringement theories, the

Staff believes that CCUS would not infringe claim 1 under 35 U.S.C. § 271(g), and CCPK would not infringe under 35 U.S.C. § 271(c).

Staff continues that, given the ALJ's rulings regarding patent infringement under Section 337 in Order No. 20 (as well as Order No. 58 of Inv. No. 337-TA-562 (Enforcement Proceeding)), it appears to the Staff that Align's § 271(g) and § 271(b) infringement theories may be determined to be legally proper.

Staff says applying the ALJ's rulings, cited *supra*, the evidence demonstrates that CCUS directly infringes asserted claim 1 by selling or using aligners that are made by the joint CCUS/CCPK process. (Citing CX-1150C, Qs. 332-338; and CX-1198C at 1189-1198)

Staff says that the evidence demonstrates that CCUS induces infringement of asserted claim 1 by performing one step and causing CCPK to perform the remaining steps of the claimed method, and that the related "direct" infringement is the joint CCUS/CCPK process. (Citing CX-1150C, Qs. 332-338; and CX-1198C at 1189-1198) Staff adds that its discussion of the elements of induced infringement with respect to claim 1 of the '880 patent, *supra*, also applies here with respect to asserted claim 1 of the '511 patent.

Staff continues that based on CCUS's infringement of asserted claim 1, the evidence demonstrates that CCPK contributes to that infringement by creating the digital data sets. Citing CX-1150C, Qs. 332-338; and CX-1198C at 1189-1198) Staff adds that its discussion of the elements of contributory infringement with respect to Group A of the '325 Patent, *supra*, also applies here with respect to claim 1 of the '511 patent.

Staff reasons that when applying the ALJ's rulings regarding patent infringement under Section 337, the evidence demonstrate that (i) CCUS directly infringes claim 1 of the '511 patent under 35 U.S.C. § 271(g) by selling or using aligners in the United States that are made by the

joint CCUS/CCPK process, and CCPK contributes to the infringement under 35 U.S.C. § 271(c) by creating the digital data sets; and (ii) CCUS induces infringement of claim 1 of the '511 patent by performing one step and causing CCPK to perform the remaining steps of the claimed method.

Staff concludes, therefore, the evidence demonstrates that CCUS and CCPK violate U.S.C. §1337(a)(1)(B) by importing or causing the importation of digital data sets. (Citing SIB sections I.B and II.C)

In its reply brief, Staff expresses the view that Respondents' arguments of non-infringement of claim 1 of the '511 patent are based on claim constructions that are contradicted by the intrinsic evidence, as discussed in the SIB Section VII.B. Staff reasons, "applying the ALJ's rulings regarding Section 271 and Section 337 and a proper claim construction", the Staff submits that the evidence supports finding infringement of claim 1 of the '511 patent.[52]

Analysis and Conclusions: I find that Align has shown by a preponderance of the evidence that Respondents infringe asserted claim 1 of the '511 patent.

First, addressing Respondents' incorporation by reference of their general defenses, I incorporate and reaffirm the analysis and conclusions reached in section V.B.1, *supra*, treating the three issues relevant to the asserted claim of the '511 patent, to wit: (1) whether or not all steps of a method claim must be performed in the same country; (2) whether or not digital data sets are "articles" within the scope of 19 U.S.C. § 1337; and (3) whether or not Align can meet its burden of proving infringement through the testimony of Mr. Beers.

Next, I find that the preamble of asserted claim 1 is limiting. Whether to treat a claim

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[52] Based on the Staff's understanding of the legal principles of patent infringement, the Staff submits that the evidence does not support finding infringement of the Asserted Claim of the '511 patent. (Citing SIB, Sections III.B and VII.C)

preamble as a limitation is a determination made after a review of the entire patent. *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002). In *Catalina*, the Federal Circuit stated:

> In general, a preamble limits the invention if it recites essential structure or steps, or if it is "necessary to give life, meaning, and vitality" to the claim. Conversely, a preamble is not limiting "where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention."

Id. (citations omitted). The court went on to explain that "a preamble generally is not limiting when the claim body describes a structurally complete invention such that deletion of the preamble phrase does not affect the structure or steps of the claimed invention." *Id.* at 809.

The invention at issue in *Catalina* was a system for distributing coupons to consumers through kiosks. The court had to determine whether the phrase "located at predesignated sites such as consumer stores" was a limitation when it appeared in the preamble. *Id.* at 807-808. The court found that the phrase was not a claim limitation. The court examined the specification and found that the location of the kiosks was not an essential feature of the invention. *Id.* at 810. The applicants did not rely on the preamble to distinguish the invention from the prior art during prosecution. *Id.* Importantly, the court found that the claim was complete without the preamble:

> Moreover, deletion of the disputed phrase from the preamble of Claim 1 does not affect the structural definition or operation of the terminal itself. The claim body defines a structurally complete invention. The location of the terminals in stores merely gives an intended use for the claimed terminals.

Id.

In *Corning Glass Works v. Sumitomo Electric U.S.A., Inc.*, 868 F.2d 1251, 1256 (Fed. Cir. 1989), the claim preamble was "[a]n optical waveguide comprising." The court found that the preamble served as a limitation because the specification was clear that the invention was limited to fibers working as waveguides. As the court explained: "[t]he invention is restricted to

those fibers that work as waveguides as defined in the specification, which is not true with respect to fibers constructed with the limitations of paragraphs (a) and (b) only." *Id.* at 1257.

I find that the situation before me is closer to *Corning Glass* than *Catalina*. Here, the term "computer implemented method" is necessary to give meaning to the claims. The entire '511 patent is clearly devoted to a computer implemented method for completing the steps in the asserted claims. (*See generally* JX-001) The term makes clear that all of the elements listed in the claim body must be performed using a computer. This term adds a limitation that is not otherwise present in the claim. This is supported by the specification, which repeatedly describes using a computer to perform the steps of the methods described in the claims. (*See e.g.* JX-001; 1:62-67, 2:4-12, 2:34-39, 3:36-39, 3:47-58) The preamble is the only place in asserted claim 1 at which the use of a computer to perform the steps in the claim is required.

Respondents contend that their processes are not "computer implemented" as required by the limitation in the preamble, and through this argument they attempt to offer a construction the term "computer implemented method." I reaffirm my rejection of that attempt and my rationale for that rejection detailed, *supra*, at section III.E.3.

Based upon the construction adopted at section III.E.3, I find that Respondents clearly practice the limitation of the preamble that teaches a "computer implemented method." This is best demonstrated by the testimony of Jarrett Pumphrey, CEO of CCUS, in which he admitted that Respondents' process is implemented using computers and digital data, and described in detail the portions of the process that are automated and the portions that are interactive. (Tr. 314:4-320-15; 322:17-326:9; 329:11-339:10; 249:1-3; and CX-78 at p. 055, *et seq.*)

First, I find that Respondents have waived their right to address the issue of whether or not they practice the first element of asserted claim 1. I warned the respondents that they "will

not be permitted to introduce evidence or assert that claim elements are not infringed, if those claim elements were not identified as contested in response to Interrogatory Number 33." (Tr. at 1323-14:2) Respondents' responses to Interrogatory No. 33 were not admitted as evidence, but they were attached as exhibits to Align's Motion In Limine No. 3. Respondents failed to include that element in their responses to contention interrogatories No. 33 submitted to CCUS and CCPK, respectively. (*See* Mot. Docket No. 833-046, Exs. K, L, M, and N) As a result, I find that Respondents waived their right to address whether or not they practice the first element of asserted claim 1.

Assuming *arguendo* that one were to find that Respondents have not waived their right to contest this issue, I would find that Align has demonstrated by a preponderance of evidence that Respondents practice the first element of claim 1. Align's expert, Dr. Beers, opined that this element is met. He testified that {

} (CX-1150C, Q. 335) Dr. Beers also cited to CX-1198C to support his testimony. CX-1198C treats this issue in the form of a claim chart at pages 190-194.

Muhammad Tariq Latif testified on behalf of Respondents as a 30(b)(6) witness at a deposition held in this investigation on October 13, 2012. Mr. Latif was designated to testify for CCPK on the subject of the operation of CCPK's software. (CX-1158C.1, 7:7-15) Mr. Latif

testified that {

}

{

}

{

} (*Id.*)

Asserted claim 1 of the '511 patent is directed at segmenting an orthodontic treatment plan into segments. That segmenting is done according to a computer implemented method. The first step is for the computer to "receive" a tooth path for the motion of the tooth from an initial position to a final position. As Mr. Latif demonstrated, this is accomplished {

}

{

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{

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Based upon the foregoing, I find that CCPK practices the first element of asserted claim 1, when {

}

Respondents did not dispute that they practice the third element of asserted claim 1, and I find that Align has produced credible evidence that this element practiced when {

} (See CX-1150C, Q. 337; and RX-129C, Qs. 87-93, 97-100)

Based upon the foregoing, I find that Align has shown by a preponderance of the evidence that the concerted efforts of CCUS and CCPK practice each and every limitation of claim 1 when the digital data sets created by CCPK are used by CCUS to fabricate aligners.

2. Violation of Section 1337(a)

Based upon all of the foregoing I have found that there is an act of direct infringement of asserted claim 1 of the '511 patent when CCUS and CCPK act in concert to fabricate appliances using the data containing the segmented tooth paths created by CCPK. I have found, too, that CCPK contributorily infringes the preamble, and the first and second elements of asserted claim 1 of the '511 patent.

In section V.B.17, I described in detail how the elements required to demonstrate contributory infringement are met by Respondents, and I concluded that those elements have been met for the '511 patent. I will not repeat that discussion here; but I reaffirm my findings and the rationale for them.

Respondents' infringement results in a violation of Section 337. 19 U.S.C. § 1337(a)(1)(B)(ii) prohibits "[t]he importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that: . . . (ii) are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent." By creating appliances using the method described in asserted claim 1, using digital data sets that are made by the process of claim 1 and imported into the United States (as found in Section II.C, supra), Respondents have violated 19 U.S.C. § 1337(a)(1)(B)(ii).

F. The '666 Patent

1. Claim 1

Claim 1 teaches:

> A method for producing a plurality of digital data sets representing a series of discrete tooth arrangements progressing from an initial to a final arrangement, said method comprising:
>
> providing a computer system;
>
> providing to the computer system an initial digital data set representing an initial tooth arrangement;
>
> defining boundaries about at least some of the individual teeth on a visual image provided by the computer system based on the initial data set;
>
> moving at least some of the tooth boundaries relative to the other teeth in the visual image to produce a final data set; and

> producing using the computer system a plurality of successive digital data sets based on both of the previously provided initial and final digital data sets, wherein said plurality of successive digital data sets represents a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement.

(JX-004 at 15:27-47)

Align's Position: Align argues that the preamble of claim 1 is not limiting, as it merely states the purpose of the claimed method. (Citing *Pitney Bowes*, 182 F.3d at 1305) Align says that Respondents have waived any contrary position in their Prehearing Brief and an infringement analysis of the preamble is unnecessary.

Alternatively, Align argues that if the preamble were limiting, CCPK practices the preamble by producing a plurality of intermediary steps using FreeForm. (Citing Evidence Categories 1, 2, 3, 4, 5, 7; CX-1150C at Q. 273) Align disagrees with Respondents' "all data sets" and "final tooth arrangement" arguments.

Align says that Respondents assert they do not infringe the claims of the '666 patent because phrases such as: (i) "a plurality of successive digital data sets;" (ii) "intermediate tooth arrangements;" (iii) "intermediate digital data sets;" (iv) "intermediate arrangements;" (v) "intermediate positions;" (vi) "series of discrete tooth arrangements;" (vii) "modified digital models;" and (viii) "models" require that all data sets for a patient's treatment be "produced prior to active treatment." Align says that this construction was not identified in the SRJCCC. Align continues that Respondents cite to no supporting evidence for such a construction. Align contends that Respondents still infringe under this construction because CCPK completes the stepping or staging for all stages prior to CCUS making the first set of appliances for active treatment ("phase 1"). (Citing CX-1150C at Q. 130-136, 347, 352) Align says that, in other

words, while CCUS says it forms aligner sets only four at a time (a "phase"), CCPK prepares all of the tooth arrangements for all aligners in all phases before treatment begins.

Align says that Respondents assert they do not infringe the claims of the '666 patent because the phrase "final tooth arrangement" in the claims "can only be a projection at the treatment stage prior to active treatment." Align continues that Respondents appear to argue that the "final tooth arrangement" projected by Respondents' process is not really a "final tooth arrangement" because the clinician has the ability to change the course of treatment, and thus, a "final tooth arrangement" can only be the patient's actual tooth positions at the end of his treatment. Align contends that this construction was not identified in the SRJCCC and neither Respondents nor Dr. Mah cite to any supporting evidence. Align continues that the "final tooth arrangement" contemplated by the patents in suit is simply the planned "final" position of the teeth, which is preferably according to a clinician's prescription. (Citing JX-0003 at 10:36-43; JX-0004 at 6:7-17; CX-1150C at Q. 347) Align says that Respondents' construction necessarily excludes preferred embodiments of the specification, and should be rejected. Align continues that planning a final position of teeth is exactly what Respondents' process does by manipulating the image into a final position according to the clinician's prescription and receiving approval. Align says that even in the event of a "mid-course corrections," or change to the course of treatment, Respondents must start the entire process over again to obtain a new "final" tooth arrangement. (Citing CX-1150C at Q. 137)

Align asserts that CCPK practices the first element ("providing a computer system") when { } (Citing Evidence Category 2; CX-1150C at Q. 274)

Align says that CCPK practices the second element ("providing to the computer system an initial digital data set …") by {

} (Citing Evidence Categories 1 and 2; CX-1150C at Q. 275) Align adds that Respondents have not disputed that they practice these elements in their Prehearing Brief. (Citing RPHB at 158, 167; RX-0129C at Q. 104)

Align argues that CCPK practices the third element ("defining boundaries …") by {

} (Citing Evidence Categories 3 and 4; CX-1150C at Q. 276) Align says that Respondents assert only their "individual teeth" argument as a non-infringement basis, which is incorrect.

Align says that the construction for "individual teeth" was not identified in the SRJCCC and was excluded. (Citing RX-0129C at Q.53) As an example, Align explains that Respondents assert they do not infringe claims 3 and 13 of the '325 patent because the phrase "individual teeth" in the claims must be "a three-dimensional model that resembled an actual tooth, and not a three-dimensional object that includes a tooth crown and sectioned gum material." Align argues that "teeth" is generally used in the asserted patents inclusively for the tooth and surrounding gum material (citing JX-0002 at 12:51-56 and CX-1150C at Q. 123, 348) and Respondents themselves use "teeth" in such an inclusive manner. (Citing CX-1157C.1 at 54:1- 9; CX-0090C at 14)

Align asserts that Respondents would still infringe even if "tooth" only included a "tooth," and not any gum material. Align says that claim 1 of the '325 patent recites "manipulating the visual image to reposition individual teeth in the visual image." (Citing JX-0003 at 27 (1:36-37)) Align contends that regardless of whether "tooth" were defined to mean: a tooth or a tooth plus surrounding gum material, the tooth itself would still be repositioned. Align

adds that claim 3 of the '325 patent recites "defining boundaries about at least some of the individual teeth." JX-0003 at 15:40-41. Align contends that if one defined boundaries around the tooth that included the tooth itself or the tooth plus some gum material, the boundary would still be defined around the tooth.

Align says that Respondents use the {

} Align reasons that although not visible in the image, the gum material merely covers the root structure, which is also being repositioned with the rest of the tooth object.

Align argues that "tooth" or "teeth" is not utilized in the asserted patents as being equivalent only to a tooth with a crown and root and no gum material as Respondents assert. As an example, Align says that, for example, the '325 patent discusses obtaining an initial "digital data set representing an initial tooth arrangement" by scanning a plaster cast of the patient's teeth. (Citing JX-0003 at 9:17-42) Align continues that the results of such a scan – the "initial tooth arrangement" – would include gum material covering the root structure, but would not actually show the root structure. Align says that the other asserted patents are similar. (Citing JX-0002 at 12:53-56 ("the crown of the tooth, as well as the gingivae tissue immediately below the crown are . . . treated as an individual unit referred to as a tooth")), and this usage is consistent with both: (i) Mr. Beers' opinion that "people in this industry refer to the crown and gum objects defined by CCPK in Freeform as "individual teeth" (Citing CX-1150C at Q. 348); and (ii) Respondents' own documents (Citing CX-1157C.1 at 54:1-9; CX-0090C at 14).

Align asserts that CCPK practices the fourth element ("moving at least …") by {

} (Citing Evidence Categories 3, 4 and 5; CX-1150C at Q. 277) Align says that Respondents allege that this element does not read on their process because "Respondents do not 'move' the 'tooth boundaries' 'relative to other teeth' in an 'image.'" Align disagrees, saying that this conclusory statement, without explanation, is insufficient to advance any particular argument, and Respondents' non-infringement arguments for this element are waived.

Align argues that CCPK practices the fifth element ("producing using the computer …") when using { } (Citing Evidence Category 7; CX-1150C at Q. 278) Align says that Respondents assert their "all data sets" and "final tooth arrangement" arguments as non-infringement bases. Align says that the "final tooth arrangement" arguments are incorrect as discussed above.

Align says that Respondents assert they do not infringe the claims of the '666 patent because phrases such as: (i) "a plurality of successive digital data sets;" (ii) "intermediate tooth arrangements;" (iii) "intermediate digital data sets;" (iv) "intermediate arrangements;" (v) "intermediate positions;" (vi) "series of discrete tooth arrangements;" (vii) "modified digital models;" and (viii) "models" require that all data sets for a patient's treatment be "produced prior to active treatment." Align says that this construction was not identified in the SRJCCC. Align continues that Respondents cite to no supporting evidence for such a construction. Align contends that Respondents still infringe under this construction because {

} (Citing CX-1150C at Q. 130-136, 347, 352) Align says that, in other

words, while CCUS says it forms aligner sets only four at a time (a "phase"), CCPK prepares all of the tooth arrangements for all aligners in all phases before treatment begins.

Align says that Respondents also assert that, "[u]nder the Respondents' "phase-based system, the Clinician exercises professional judgment as to the design of the successive orthodontic appliances to be used after active treatment has begun[, and] this judgment is not 'based on both of the previously provided initial and final digital data sets" (id. at 159-160, 169). This argument is unsupported as {

} (Citing Evidence Category 7)

Align concludes that because CCPK imports, offers to sell, or sells digital data sets in the U.S. that are made according to each of claimed steps by the joint CCUS/CCPK process, CCPK directly infringes under 35 U.S.C. § 271(g). Align says that Respondents' importation is also a violation of 19 U.S.C. § 1337(a)(1)(B)(ii). Alternatively, Align says that CCUS uses those digital data sets in the U.S., and therefore also directly infringes under 35 U.S.C. § 271(g).

Align notes that Respondents point out that the claim uses the word "to" instead of the word "toward," and assert that Respondents' "phase-based" system does not satisfy this language. Align argues that this argument is simply a reworded version of Respondents' "all data sets" argument, and is therefore improper and unsupported for at least the reasons discussed above. Align continues that it is irrelevant, as CCPK produces all of the discrete tooth arrangements before treatment begins.

Respondents' Position: Respondents say that Align contends the second element of the claim is practiced by CCUS in the United States (Citing Tr. at 557:3-4; 557:13-18) and the

remaining elements are practiced by CCPK in Pakistan. (Citing CX-1150C at Q. 274-278). Respondents argue as a result that claim 1 of the '666 patent, a method claim, is not infringed.

Respondents argue that based on the context of the patent and the related prosecution history, one skilled in the art would understand that the preamble would require that all of the "plurality" of "discrete tooth arrangements" "progress" from the "initial" tooth arrangement to the "final" tooth arrangement as projected and be produced prior to active treatment. Respondents continue that the claim language expressly requires the production of digital data sets representing a series of tooth arrangements progressing "from an initial arrangement to a final arrangement;" in contrast, other asserted patent claims use the language "towards" a final arrangement." Respondents say that the phase-based system of Respondents does not produce data sets representing a series of tooth arrangements from the initial to the final arrangement, as the claim language requires. Respondents conclude that CCUS's phase-based system does not meet this limitation. (Citing RX-0129C at Q. 103)

Respondents contend that based on the plain meaning of the claim language, "individual teeth" in the third element of claim 1 means a representation of a three-dimensional model that resembles an actual tooth, and not a three-dimensional object that includes a tooth crown and sectioned gum material. Respondents say that Dr. Valley testified an actual tooth includes the root. (Citing Tr. at 707:25-708:6) Respondents say that CCPK sections and manipulates only part of a tooth, and it therefore moves only parts of teeth. Respondents continue that they "section" models by cutting individual objects that include soft tissue of the gums and there do not define boundaries around individual teeth. (Citing CX-0889C; Tr. 330:11 to 333:9)

Respondents say that Respondents do not "move" the "tooth boundaries" "relative to other teeth" in an "image" "to produce the final data set," as required by the fourth element of claim 1. Respondents argue, as a result, that this limitation is not met by the Respondents.

Respondents argue that the plain language of the fifth element of claim 1 requires production of a plurality of digital data sets representing tooth arrangements progressing from the "initial" tooth arrangement to the "final" tooth arrangement, in contrast to other claims which use the language "towards" a final arrangement. Respondents say that CCUS's phase-based system does not meet this limitation. Respondents say that under the Respondents phase-based system, the clinician exercises professional judgment as to the design of the successive orthodontic appliances to be used after active treatment has begun. (Citing Tr. 416:8-17) Respondents say that this judgment is not "based on both of the previously provided initial and final digital data sets." Respondents continue that in the majority of cases, the appliance design is changed after active treatment has begun. (Citing RX-0129C at Q. 107) Respondents conclude that they do not practice this limitation.

Respondents say that claim 1 concerns a method for making digital data sets for tooth arrangements that progress from an initial to a final arrangement. Respondents continue that the fifth element concerns data sets that are "based on" the initial and final tooth arrangements. Respondents add that the final element concerns tooth arrangements that progress from the initial to the final arrangement. Respondents argue that Align's arguments for infringement of the claim are again based on its misstatements about the CCPK operators' creation of the computer files at issue. Respondents say that Align's post hearing brief makes significant misstatements concerning the manner in which CCPK operators make the computer files, the functions of the FreeForm software, and the manner in which CCUS receives the computer files from CCPK and

when those files can be used to actually make orthodontic appliances. Respondents continue that they use a phase-based system that is much different from the method described in the first independent claim of the '666 patent. Respondents argue that because Align bases its infringement arguments on its misstatements about the Respondents' process, it has failed to meet its burden of proof.

Respondents say that the element requiring that the digital data sets be "based on" the initial and final digital data sets is squarely at odds with Dr. Valley's attempt to save Align's claims from invalidity. Respondents contend that should the Respondents be found to infringe the first independent claim of the '666 patent based on Align's characterization of the evidence, then the infringed claim must also be found invalid in light of the prior art.

Staff's Position: Staff says that based on my rulings (Citing Hearing Tr. at 36:10 and 42:3-17), Align is precluded from, *inter alia*, (i) presenting any argument that CCUS induces infringement of the '666 patent, and (ii) offering any evidence that CCUS or CCPK infringes the '666 patent under the doctrine of equivalents.

Staff says that Align asserts, *inter alia,* infringement of claims 1, 3, 7, and 9 of the '666 patent as follows:

- CCPK directly infringes claims 1, 3, 7, and 9 of the '666 patent under 35 U.S.C. § 271(g) by offering to sell or selling digital data sets, digital models, or treatment plans in the United States.

Staff says that (a) Align's § 271(g) infringement theory under 19 U.S.C. § 1337(a)(1)(B)(i) is legally improper (citing SIB Section III.B), and (b) only Align's alternative infringement theory under 19 U.S.C. § 1337(a)(1)(B)(ii) is legally proper. Staff continues that when applying the Staff's understanding of the legal standards of patent infringement to Align's allegations of infringement under 19 U.S.C. § 1337(a)(1)(B)(i), CCPK would not infringe under

35 U.S.C. § 271(g) the Asserted Claims of the '666 patent. Staff says that with respect to Align's alternative allegations under 19 U.S.C. § 1337(a)(1)(B)(ii), the Staff is of the view that, based on a proper claim construction, the evidence supports finding infringement of the Asserted Claims of the '666 patent (as discussed below).

Staff notes, however, that based on my rulings regarding patent infringement under Section 337 in Order No. 20 (as well as Order No. 58 of Inv. No. 337-TA-562 (Enforcement Proceeding)), Align's § 271(g) infringement theory under 19 U.S.C. § 1337(a)(1)(B)(i) may be determined to be legally proper. Staff says that it considers that theory below and Align's alternative infringement theory under 19 U.S.C. § 1337(a)(1)(B)(ii). Staff continues that applying my rulings regarding patent infringement and a proper claim construction, the evidence supports finding infringement of the Asserted Claims of the '666 Patent (as discussed below).

Staff says that based on Align's § 271(g) infringement theory, the evidence supports finding infringement of claims 1, 3, 7, and 9 of the '666 Patent under the ALJ's rulings regarding patent infringement under Section 337 (but not under the Staff's understanding of the legal standards of patent infringement). Staff says applying my rulings, the evidence demonstrates that CCPK directly infringes each of the Asserted Claims of the '666 patent by selling digital data sets. (Citing CX-1150C at Q. 272-279 and CX-1198C at 199-210 (collectively discussing claim 1 of the '666 patent); CX-1150C at Q. 280-218 and CX-1198C at 210-212 (collectively discussing claim 3 of the '666 patent); CX-1150C at Q. 282-288 and CX-1198C at 212-221 (collectively discussing claim 7 of the '666 patent); and CX-1150C at Q. 289-290 and CX-1198C at 221-225 (collectively discussing claim 9 of the '666 patent))

Staff says that the same evidence supports finding infringement of claims 1, 3, 7, and 9 of the '666 patent under Align's infringement theory under 19 U.S.C. § 1337(a)(1)(B)(ii) (based on

the Staff's understanding of the legal standards of patent infringement). Staff explains that the evidence shows that CCPK practices each element of claims 1, 3, 7, and 9 and imports the digital data sets that are produced by these claimed methods.

Staff argues that Respondents' arguments of non-infringement of the Asserted Claims of the '666 patent are based on claim constructions that are contradicted by the intrinsic evidence, as discussed in the Staff's Post-Hearing Brief. Staff says that Respondents also argue that they do not infringe the Asserted Claims of the '666 patent because the term "defining boundaries about at least some of the individual teeth" requires that "individual teeth" be "a representation of a three three-dimensional model that resembles an actual tooth, and not a three-dimensional object that includes a tooth crown and sectioned gum material." Staff say that Respondents made this same argument with respect to the '325 patent and for the reasons stated with respect to the '325 patent, this argument should be rejected.

Staff continues that Respondents also argue that they do not infringe the Asserted Claims of the '666 patent because Align contends that some elements of a claim are performed by CCUS and other elements of the claim are performed by CCPK. Staff disagrees, saying that Align also contends that CCPK practices all of the steps of the claimed methods. Staff says that the evidence shows such practice, as alleged by Complainant.

Analysis and Conclusions: First, addressing Respondents' incorporation by reference of their general defenses, I incorporate and reaffirm the analysis and conclusions reached in section V.B.1, *supra*, treating the three issues relevant to the asserted claims of the '666 patent, to wit: (1) whether or not all steps of a method claim must be performed in the same country; (2) whether or not digital data sets are "articles" within the scope of 19 U.S.C. § 1337; and (3)

whether or not Align can meet its burden of proving infringement through the testimony of Mr. Beers.

I find that Align has shown by a preponderance of the evidence that CCPK infringes asserted claim 1 of the '666 patent. Claim 1 is complete without the preamble, and the preamble merely restates what is apparent from the final two elements of the claim itself—the claimed method is a method for generating a plurality of digital data sets that represent tooth positions progressing from the initial tooth position to the final toot position. As a result, I find that the preamble of claim 1 is not limiting.

Assuming, *arguendo*, that the preamble of claim 1 is a limitation, I find that Respondents' process practices the preamble of claim 1. Employees of CCUS and CCPK admitted that {

}

{

} The foregoing admissions of employees of Respondents, along with Respondents' own documents, show that the CCPK, in executing the "stepping" process, produces a plurality of digital data sets representing a series of discrete tooth arrangements progressing from an initial (the scan of the stone model) to a final (the "treatment setup") arrangement.

Respondents argument that the preamble is not practiced because the claim language expressly requires the production of digital data sets representing a series of tooth arrangements progressing "from an initial arrangement to a final arrangement" while other asserted patent claims use the language "towards" a final arrangement" is not persuasive. As noted above, Mr. Arif admitted {

} (Tr. at 172:15-173:8, 190:20-191:25) Thus, it is clear that CCPK produces a complete set of digital data sets from the initial position to the final position before any appliances are worn by a patient.

The admissions of employees of Respondents, along with Respondents' own documents, discussed above also show that CCPK meets the first and second elements of claim 1. Mr. Rathore admitted that CCPK has purchased computer workstations for creating digital data sets. (Tr. at 443:15-444:15) This shows that CCPK "provid[es] a computer system." Additionally, as noted above, CCUS documents further state that {

}

(CX-078 at 55; Tr. at 248:9-249:3) By importing the initial digital data sets into FreeForm Modeling software running on CCPK's computers, CCPK practices the second element of claim 1. Respondents do not contest that these elements are practiced.

I find that CCPK also practices the third element of claim 1. Respondents argue unpersuasively that they do not practice this element because the term "individual teeth" means a representation of a three-dimensional model that resembles an actual tooth, and not a three-dimensional object that includes a tooth crown and sectioned gum material. First, I find that Respondents have waived the right to offer a construction for the term "individual teeth." Respondents did not propose a construction for "individual teeth" in the Second Revised Joint Claim Construction Chart. (*See* SRJCCC) Also, Respondents cite no evidence that shows a clear intent to limit the meaning of this limitation as Respondents' propose. As a result, I reject this argument by Respondents.

Treating the substance of the assertion, the evidence introduced at the hearing shows that Respondents' process includes a step of "defining boundaries about at least some of the individual teeth on a visual image provided by the computer system based on the initial data set." {

} the claim does not preclude including gum tissue within the "defin[ed] boundaries." All that is required is "defining boundaries about" individual teeth. (JX-004 at 15:35-37) Based on the foregoing testimony and evidence introduced during the hearing, I find that CCPK meet this limitation.

I also find that CCPK practices the fourth element of claim 1. Respondents argue unpersuasively that they do not "mov[e] at least some of the tooth boundaries relative to the other teeth in the visual image to produce a final data set," as required by claim 1. {

} Based on this testimony, I find that Respondents' process meets this limitation of claim 1.

I find that CCPK practices the fourth element of claim 1 when it conducts the "stepping" process. As noted above, {

} The foregoing admissions make clear that CCPK practices the fourth element of claim 1 when it completes the stepping process and creates data sets for all of the steps between the initial position and the final position. Respondents' arguments based on the requirement that digital data sets representing a series of tooth arrangements progressing "from the initial tooth

arrangement to the final tooth arrangement" be produced before any appliances are worn is not persuasive for the same reasons discussed above regarding the preamble of claim 1.

The fact that a "mid-course correction" may occur during treatment under Respondents' process does not preclude a finding of infringement. Respondents admitted that a "mid-course correction," under which changes are made to the treatment of a patient after treatment has begun, is not made in every case. (Tr. at 224:11-13; *See also* Tr. at 213:9-21) As a result, even if "mid-course corrections" resulted in a course of treatment being stopped, it would only apply to a subset of all cases handled by Respondents. Also, Respondents admitted that {

} (Tr. at 195:7-196:4, 205:24-206:15, 224:14-21, 318:21-319:3) For any given patient for whom "mid-course corrections" are provided, there will necessarily be a final "mid-course correction" after which no additional "mid-course corrections" will take place in his treatment. After this final "mid-course correction," Respondents will generate intermediate digital data sets between the new initial and new final tooth positions that will be used for all of the remaining treatment series.

The fact that a Clinician may "exercise[] professional judgment" in generating the intermediate digital data sets does not prevent the intermediate digital data sets from being "based on" the initial and final digital data sets. The admission and documents discussed above show that {

} An exercise of "professional judgment" does not change the fact that the intermediate digital data sets are based on the initial and final digital data sets. Based upon all of the foregoing, I find that CCPK directly infringes claim 1 when it creates intermediate digital data sets in Pakistan using Respondents' process.

2. Claim 3

Claim 3 teaches:

> A method as in claim 1, wherein the step of producing a plurality of successive digital data sets comprises determining positional differences between the initial data set and the final data set and interpolating said differences.

(JX-004 at 15:52-55)

Align's Position: Align argues that CCPK practices claim 3 when generating the successive, intermediate tooth arrangements {

} Align continues that Respondents argue that they do not infringe because: (i) a phase-based system does not produce the requisite "successive digital data sets;" and (ii) {

} (Citing RPHB at 160, 169-70). Align says that regarding (i), this appears to be Respondents' "all data sets" argument, and is incorrect for the reasons discussed above. Align continues that regarding (ii), neither Respondents nor Dr. Mah provide any particular evidence to support their argument. Align says that {

}

Align concludes that Respondents infringe and violate Section 337 for the same reasons as claim 1.

Respondents' Position: Respondents argue that they do not infringe claim 3 because they do not infringe the independent claim. Respondents add that {

} (Citing Tr. 336:8 to 338:17) Respondents conclude, as a result, that Respondents do not meet this limitation. (Citing RX-0129C at Q. 108)

Respondents contend that claim 3 requires the interpolation between the initial and final digital data sets. Respondents say that the only evidence Align cites concerning this element is the CCPK operators' use of the "Generate Steps" function of the FreeForm software. Respondents say that Align's post hearing brief makes significant misstatements concerning the operation and use of the "Generate Steps" software feature. Respondents continue that the interpolation does not actually occur as Align suggests; rather the evidence shows {

} Respondents conclude that Align bases its infringement arguments on its misstatements about the way CCPK operators use the "Generate Steps" function and has therefore failed to meet its burden of proof.

Staff's position: Staff addresses claims 1 and 3 together, as reflected in Staff's Position regarding claim 1.

Analysis and Conclusions: : If I had found that Align had failed to prove that Respondents infringe claim 1, it would follow that Align failed to prove infringement of claim 3, which depends from claim 1. *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n. 9 (Fed. Cir. 1989) ("One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim.")

Nevertheless, I have found that Respondents infringe asserted claim 1. I also find that Align has shown by a preponderance of the evidence that CCPK infringes asserted claim 3 of the '666 patent. Respondents argue unpersuasively that because Respondents' technicians use independent judgment in the staging process, they do not "determin[e] positional differences between the initial data set and the final data set and interpolat[e] said differences," as required by claim 3 of the '666 patent. Respondents essentially contend that the word "interpolating" forecloses any human intervention. Respondents cite no support for this position, and did not propose a construction for "interpolating" in the SRJCCC. As a result, Respondents waived any claim construction arguments on this claim term.

{

} Respondents' argument that they do not perform "interpolation" also conflicts with admissions made during the hearing. (Tr. at 676:23-677:6) Based upon all of the foregoing, I find that Respondents' process includes a step of interpolating the differences between the two tooth positions. Because claim 3 is a "comprising" or open-ended claim, the mere fact that another step is completed after interpolation does not defeat a finding of infringement. Rather, the Federal Circuit has explained that "[t]he transition 'comprising' in a method claim indicates that the claim is open-ended and allows for additional steps." *Invitrogen Corp. v. Biocrest Mfg.*, L.P., 327 F.3d 1364, 1368 (Fed. Cir. 2003). As a

result, I find that Align has shown by a preponderance of the evidence that CCPK practices dependent claim 3 of the '666 patent. Based upon all of the foregoing, I find that CCPK directly infringes claim 3 when it creates intermediate digital data sets in Pakistan using Respondents' process.

3. Claim 7

Claim 7 teaches:

> A method for producing a plurality of digital data sets representing a series of discrete tooth arrangements progressing from an initial to a final arrangement, said method comprising:
>
> providing a computer system;
>
> providing to the computer system digital data set representing an initial tooth arrangement;
>
> providing to the computer system a digital data set representing a final tooth arrangement;
>
> interpolating positional differences between the teeth in the initial and final data sets using the computer system to produce a plurality of successive digital data sets, wherein said plurality of successive digital data sets represents a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement.

(JX-004 at 15:64-16:13)

Align's Position: Align asserts that the preamble of claim 7 is not limiting, as it merely states the purpose of the claimed method. (Citing *Pitney Bowes,* 182 F.3d at 1305) Align says that Respondents have waived any contrary position in their Prehearing Brief and an infringement analysis of the preamble is unnecessary.

Alternatively, Align argues that if the preamble were limiting, CCPK practices the preamble by producing a plurality of digital data sets representing a series of discrete tooth arrangements progressing from an initial to a final arrangement. (Citing Evidence Categories 1,

2, 5, 7; CX-1150C at Q. 273) Align says that Respondents assert their "all data sets" and "final tooth arrangement" arguments as non-infringement bases, which are incorrect as discussed above regarding claim 1.

Align argues that Respondents practice the first element of claim 7 because it is identical to the first element of claim 1, and is practiced by CCPK as discussed in Sec. IX.B.1.b. See Sec. I.E.2; CX-1150C at Q. 284. The second element ("providing to the computer …") is similar to the second element of claim 1, and is practiced by CCPK as discussed regarding claim 1. (Citing Evidence Categories 1 and 2; CX-1150C at Q. 285) Align says that Respondents do not dispute that they practice these elements. (Citing RPHB at 161, 170; RX-0129C at Q. 110)

Align asserts that CCPK practices the third element ("providing to the computer system a digital data set representing a final tooth arrangement"), using FreeForm, by providing the predetermined final tooth arrangement to the Generate Steps function. (Citing Evidence Categories 5 and 7; CX-1150C at Q. 286) Align says that {

} (Citing Evidence Categories 5, 9 and 10; CX-1150C at Q. 286) Align says that Respondents argue that they do not infringe because "'provide' does not mean 'generate'," but provide no further explanation. (Citing RPHB at 161, 171)

Align contends that CCPK practices the fourth element ("interpolating positional differences…") by {

} (Citing Evidence Category 7; CX-1150C at Q. 287) Align says that Respondents admit that { } (Citing Tr. at 676:23-677:5)

Align says that Respondents argue that they do not infringe because: (i) a phase-based system does not produce the requisite "successive digital data sets;" and (ii) the operators' "use of their individual judgment to adjust the teeth locations to avoid collisions means that the 'positional differences …' are not interpolated." Align says that regarding (i), this appears to be Respondents' "all data sets" argument, and is incorrect for the reasons identified above regarding claim 1. Align says that regarding (ii), neither Respondents nor Dr. Mah provide any particular evidence to support their argument. Rather, Align says that the "individual judgment" cited by Respondents is applied by operators before they use FreeForm when preparing the DPS. Align continues that even if this after-occurring modification does occur, it does not change the fact that interpolation is performed by Freeform according to Respondents' process, and that interpolation falls within the scope of this claim.

Align concludes that because CCPK imports, offers to sell, or sells digital data sets in the U.S. that are made according to each of claimed steps by the joint CCUS/CCPK process, CCPK directly infringes under 35 U.S.C. § 271(g). Align continues that Respondents' importation is also a violation of 19 U.S.C. § 1337(a)(1)(B)(ii). Alternatively, Align says that CCUS uses those digital data sets in the U.S., and therefore also directly infringes under 35 U.S.C. § 271(g).

Align says that Respondents advance yet another new claim construction that "provide" does not mean "create" or "generate" and that CCPK's creation of a final tooth arrangement is not "providing" the arrangement. Align disagrees, saying that Respondents misrepresent Align's argument. Align says that it asserts CCPK practices the third element by providing the final tooth arrangement to the "Generate Steps" function in FreeForm. (Citing CX-1150C at Q. 286) Align avers that this is different from producing the final tooth arrangement using FreeForm.

Align says that Respondents do not address the action identified by Align, and therefore have no defense to it.

Respondents' Position: Respondents argue that because claim elements of claim 7 are performed by both CCUS in the United States and CCPK in Pakistan, claim 7 of the '666 patent, a method claim, is not infringed.

Respondents contend that based on the context of the patent and the related prosecution history, one skilled in the art would understand the preamble would require that all of the "plurality" of "discrete tooth arrangements" "progress" from the "initial" tooth arrangement to the "final" tooth arrangement as projected and be produced prior to active treatment. Respondents say that CCUS's process is phase-based. (Citing Tr. at 416:8-17) Respondents continue that this means that the clinician does not determine the successive tooth arrangements that are required until after the initial appliances have been fabricated and after treatment has begun. (Citing Tr. at 328:1-329:10; 416:8-17) Respondents say that the clinician makes this determination based upon an evaluation of the patient's progress and the Clinician's prescription. (Citing Tr. at 328:1-329:10; 416:8-17) Respondents conclude, as a result, that CCUS's phase-based process does not meet this limitation. (Citing RX-0129C at Q. 109)

Respondents argue that neither CCUS nor CCPK "provide" a digital data set representing a final tooth arrangement to a computer system, as required by the second element of claim 7. Respondents say that the evidence demonstrates that CCPK operators create a digital model of the patient's teeth as they would be arranged in accordance with the doctor's prescription. (Citing Tr. 329:11 to 341:21) Respondents assert that this is not "providing" the data set to a computer, it is using the computer to "create" or "generate" such a data set. Respondents

continue that one skilled in the art would understand "provide" does not mean "generate" and this limitation is not met by the Respondents.

Respondents say that the operators' use of their individual judgment to adjust the teeth locations to avoid collisions means that the "positional differences between the initial data set and the final data set" are not interpolated, as required by the fourth element of claim 7. Respondents conclude, as a result, that they do not meet the fourth limitation. (Citing RX-0129C at Q. 112)

Respondents contend that the plain meaning of the fourth element of claim 7 requires all of the tooth arrangements progressing from the "initial tooth arrangement" to the "final tooth arrangement" to be produced as a series. Respondents say that CCUS's phase-based process does not meet this limitation. (Citing Tr. at 416:8-17; RX-0129C at Q. 113)

Respondents argue that claim 7, contains elements requiring digital data sets progressing from the initial to final positions and interpolation to create the data sets. Respondents say that Align failed to establish these elements for the same reasons described above regarding claims 1 and 3: (1) the method of creating digital data sets required by the claim does not correspond to the evidence of the Respondents' phase-based system and (2) Align's arguments about interpolation does not match the actual evidence about the way CCPK operators use the "Generate Steps" function of the software.

Staff's position: Staff addresses claims 1, 3, and 7 together, as reflected in Staff's Position regarding claim 1.

Analysis and Conclusions: I find that Align has shown by a preponderance of the evidence that CCPK infringes asserted claim 7 of the '666 patent. The preamble of claim 7 is identical to the preamble of claim 1. Like Claim 1, claim 7 is complete without the preamble,

and the preamble merely restates what is apparent from the final two elements of the claim itself—the claimed method is a method for generating a plurality of digital data sets that represent tooth positions progressing from the initial tooth position to the final toot position. As a result, I find that the preamble of claim 7 is not limiting.

Assuming, *arguendo*, that the preamble of claim 7 is a limitation, based on the evidence discussed in Section V.F.1, *supra*, regarding the identical preamble of claim 1, which I incorporate and reaffirm here, I find that the preamble of claim 7 is practiced by CCPK.

The first and second elements of claim 7 are identical to the first and second elements of claim 1. Based on the evidence discussed regarding claim 1 in Section V.F.1, *supra*, which I incorporate and reaffirm here, I find that the first and second elements of claim 7 are practiced by CCPK.

The third element of claim 7 is practiced by CCPK when {

} Respondents' arguments on this element are not persuasive. As noted above, {

} practice the third element of claim 7.

I find that CCPK practices the fourth element of claim 7 when it conducts the "stepping" process. As noted above, {

} (CX-107C at 5:33) Respondents' argument that they do not perform "interpolation" also conflicts with admissions made during the hearing. (Tr. at 676:23-677:6) The foregoing admissions make clear that CCPK practices the fourth element of claim 1 when it completes the stepping process and creates data sets for all of the steps between the initial position and the final position. Respondents' arguments based on the requirement that digital data sets representing a series of tooth arrangements progressing "from the initial tooth arrangement to the final tooth arrangement" be produced before any appliances are worn is not persuasive for the same reasons discussed above regarding the preamble of claim 1.

The fact that a "mid-course correction" may occur during treatment under Respondents' process does not preclude a finding of infringement. Respondents admitted that a "mid-course correction," under which changes are made to the treatment of a patient after treatment has begun, is not made in every case. (Tr. at 224:11-13; *See also* Tr. at 213:9-21) As a result, even if "mid-course corrections" resulted in a course of treatment being stopped, it would only apply

to a subset of all cases handled by Respondents. Also, Respondents admitted that when a "mid-course correction" does take place, the entire accused process {

} (Tr. at 195:7-196:4, 205:24-206:15, 224:14-21, 318:21-319:3) For any given patient for whom "mid-course corrections" are provided, there will necessarily be a final "mid-course correction" after which no additional "mid-course corrections" will take place in his treatment. After this final "mid-course correction," Respondents will {

}

The fact that a Clinician may "exercise[] professional judgment" in generating the intermediate digital data sets does not prevent the intermediate digital data sets from being "based on" the initial and final digital data sets. The admission and documents discussed above show that the FreeForm software uses the initial digital data set and the final digital data set, or "treatment setup," in generating the intermediate digital data sets. An exercise of "professional judgment" does not change the fact that the intermediate digital data sets are based on the initial and final digital data sets. Based upon all of the foregoing, I find that CCPK directly infringes claim 7 when it creates intermediate digital data sets in Pakistan using Respondents' process.

4. Claim 9

Claim 9 teaches:

> A method as in claim 7, wherein the step of providing a digital data set representing a final tooth arrangement comprises:
>
> defining boundaries about at least some of the individual teeth on a visual image provided by the computer system;
>
> and moving at least some of the tooth boundaries relative to the other teeth in the visual image to produce the final data set.

(JX-004 at 16:18-27)

Align's Position: Align argues that CCPK practices the first element of claim 9 by using FreeForm to section up the 3D digital scan into individual tooth objects. (Citing Evidence Categories 3 and 4; CX-1150C at Q. 289) Align says that Respondents assert only their "individual teeth" argument as a non-infringement basis (Citing RPHB at 163, 172), which is incorrect for the reasons discussed regarding claim 1.

Align contends that CCPK practices the second element of claim 9 by {

} (Citing Evidence Categories 3 and 4; CX-1150C at Q. 289) Align says that Respondents have not disputed that they practice this element in their Prehearing Brief. (Citing RPHB at 163, 172) Align concludes that Respondents infringe and violate Section 337 for the same reasons as claim 7.

Respondents' Position: Respondents argue that they do not infringe dependent claim 9 because they, as stated above, do not infringe the independent claim. Respondents say that CCUS's process does not define boundaries about "individual teeth" or move tooth boundaries "relative to the other teeth," and, accordingly, this limitation is not met by the Respondents.

Respondents contend that claim 9 contains elements requiring "defining boundaries" around teeth and moving those "tooth boundaries." Respondents say that Align's post hearing brief makes significant misstatements and assertions that CCPK operators "manipulate visual images" or "define boundaries" around individual teeth. Respondents continue that other things, CCPK operators do not "define boundaries" around individual teeth and, instead, identify subsets of data that include soft tissue (gums), a tooth crown, and portions of adjacent tooth crowns. Respondents assert that because Align bases its infringement arguments on misstatements

concerning the CCPK operators' actual conduct, it has failed to meet its burden of proof on the dependent claim's associated elements.

Staff's position: Staff addresses claims 1, 3, 7, and 9 together, as reflected in Staff's Position regarding claim 1.

Analysis and Conclusions: If I had found that Align had failed to prove that Respondents infringe claim 7, it would follow that Align failed to prove infringement of claim 9, which depends from claim 7. *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n. 9 (Fed. Cir. 1989) ("One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim.")

Nevertheless, I have found that Respondents infringe asserted claim 7. I also find that Align has shown by a preponderance of the evidence that CCPK infringes asserted claim 9 of the '666 patent.

Respondents argue unpersuasively that they do not practice the first element of claim 9 because the term "individual teeth" means a representation of a three-dimensional model that resembles an actual tooth, and not a three-dimensional object that includes a tooth crown and sectioned gum material. First, I find that Respondents have waived the right to offer a construction for the term "individual teeth." Respondents did not propose a construction for "individual teeth" in the Second Revised Joint Claim Construction Chart. (*See* SRJCCC) Respondents cite no evidence that shows a clear intent to limit the meaning of this limitation as Respondents' propose. As a result, I reject this argument by Respondents.

Treating the substance of the assertion, the evidence introduced at the hearing shows that Respondents' process includes a step of "defining boundaries about at least some of the individual teeth on a visual image provided by the computer system." Mr. Jarrett Pumphrey

admitted that {

} Although the cut up sections depicted in CX-0889C include portions of gum tissue, the claim does not preclude including gum tissue within the "defin[ed] boundaries." All that is required is "defining boundaries about" individual teeth. (JX-004 at 15:35-37) Based on the foregoing testimony and evidence introduced during the hearing, I find that CCPK meet this limitation.

I also find that CCPK practices the second element of claim 9. Respondents argue unpersuasively that they do not "mov[e] at least some of the tooth boundaries relative to the other teeth in the visual image to produce the final data set," as required by claim 9. Mr. Jarrett Pumphrey admitted that {

} (Tr. at 332:20-333:9; CX-0889C) Based on this testimony, I find that Respondents' process meets this limitation of claim 9. Based upon all of the foregoing, I find that CCPK directly infringes claim 9 when it creates intermediate digital data sets in Pakistan using Respondents' process.

5. Violation of Section 1337(a)

Align's Position: Align asserts that Respondents violate 337(a)(1)(B)(ii) by importing, selling for importation, or selling after importation the digital data sets made according to claims 1, 3, 7 and 9 of the '666 Patent. Alternatively, Align contends that CCPK violates 337(a)(1)(B)(i) by directly infringing claims 1, 3, 7 and 9 of the '666 Patent under 35 U.S.C. §

271(g) by importing, offering to sell, or selling digital data sets made by Respondents' process. Align adds that because CCUS uses those same digital data sets, CCUS therefore also violates 337(a)(1)(B)(i) for similar reasons.

Staff's position: Staff argues that when applying my rulings regarding patent infringement under Section 337, the evidence demonstrates that CCPK directly infringes each of the Asserted Claims of the '666 patent under 35 U.S.C. § 271(g) by selling digital data sets. Staff continues that when applying the Staff's understanding of the legal standards of patent infringement, the evidence shows that CCUS and CCPK directly infringes each of the Asserted Claims under 19 U.S.C. § 1337(A)(1)(B)(ii) by importing the digital data sets that are produced by the claimed methods. Staff concludes that the evidence shows that CCUS and CCPK violate 19 U.S.C. § 1337(A)(1)(B) by importing digital data sets.

Analysis and Conclusions: 19 U.S.C. § 1337(a)(1)(B)(ii) prohibits "[t]he importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that: . . . (ii) are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent." By importing digital data sets (as found in Section II.C, *supra*) that are made by CCPK, which practices the entire process of claims 1, 3, 7, and 9 in Pakistan to produce the digital data sets (as found in Section V.F.1-4, *supra*), Respondents have violated 19 U.S.C. § 1337(a)(1)(B)(ii).

G. The '863 Patent

1. Claim 1

Claim 1 recites:

> A method for producing digital models of dental positioning appliances, said method comprising:

providing a digital model of a patient's dentition;

producing a plurality of modified digital models of the dentition, wherein the modified models represent successive treatment stages of an orthodontic treatment and wherein each modified model or a product of such model is to be used in fabrication of a distinct successive incremental dental positioning appliance associated with the respective treatment stage of that modified model;

providing a digital model of at least one attachment device; and

positioning the digital model of the attachment device on at least some of the plurality of modified digital models.

(JX-005 at R1:55-67)

Align's Position: Align asserts that the preamble of asserted claim 1 is not limiting, as it merely states the purpose of the claimed method. (Citing *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999)) Align continues that Respondents have not asserted the contrary in their Prehearing Brief, and have therefore waived such a position. Align concludes, as a result, that an infringement analysis of the preamble is unnecessary.

Alternatively, Align asserts that, if the preamble is found to be limiting, one of ordinary skill in the art would interpret the preamble to refer to the digital models discussed in the patent, which are of a patient's dentition used to fabricate the aligner, and not the actual aligner. Align notes that the second element of claim 1 specifically refers to "models of the dentition." Align contends that one of skill would not, as Respondents allege, read the claim as being limited to digital models of "appliances." Align argues that CCPK practices the preamble by producing a plurality of digital models representing a plurality of tooth arrangements using FreeForm, which are used by CCUS to fabricate appliances. (Citing CIB at Sec. I.E.1 and 7-10; CX-1150C at Q. 292)

Regarding the first element of claim 1, Align contends that CCPK practices this element {

} (Citing CIB at Sec. I.E.1 and 9; CX-1150C at Q. 293)

Align says that Respondents do not contest Align's identification of CCPK's infringing actions. (Citing RPHB at 187)

Align refers to Evidence Category No. 1 – "Initial Digital Data Set." In that evidence category, Align says that {

}

{

} (Citing CX-937C; Tr. at 247:14-248:5; CX-1164C.1 at 101:6-18)

Align also refers to Evidence Category No. 9 – "Transfer of Digital Data Sets." In that evidence category, Align avers that {

} (Citing CX-090C at 28-49; CX-1158C.1-3 at 54:1-83:18; CX-107C; CDX-020C-21C) Align avers that the tooth arrangement in

each "step" (*i.e.*, the resulting intermediate tooth arrangement) represents an aligner step in the patient's treatment. More specifically, Align says that each step contains an intermediate digital data set which will be used by CCUS to make an aligner.

Align describes the process of {

}

{

}

Align contends that {

}

{

} (Citing CX-

1150C at Q. 134, 198, 280, 287, 313; CX-090C at 44-47; CX-107C; CX-087C at 1-2; CX-1158C.1-3 at 71:11-72:18)

{

} (Citing CX-1158C.1-3 at 71:11-72:18)

With respect to the second element of claim 1, Align disagrees with Respondents' "final tooth arrangement" non-infringement argument. (Citing RPHB at 187) Align says that Respondents assert they do not infringe the claims of the '863 patent because the phrase "final tooth arrangement" in the claims "can only be a projection at the treatment stage prior to active treatment." (Citing RPHBB at 16) Align asserts that Respondents appear to argue that the "final tooth arrangement" projected by Respondents' process is not really a "final tooth arrangement" because the clinician has the ability to change the course of treatment, and thus, a "final tooth arrangement" can only be the patient's actual tooth positions at the end of his treatment.

First, Align argues that Respondents' construction was not identified in the SRJCCC. Second, Align asserts that neither Respondents nor Dr. Mah cite to any supporting evidence. Third, the "final tooth arrangement" contemplated by the patents is simply the planned "final" position of the teeth, which is preferably according to a clinician's prescription. (Citing JX-003 at 10:36-43; JX-004 at 6:7-17; CX-1150C at Q. 347) Align submits that Respondents' construction necessarily excludes preferred embodiments of the specification, and should be rejected. Align continues that planning a final position of teeth is exactly what Respondents' process does – it manipulates the image into a final position according to the clinician's prescription and receives approval. Align argues that, even in the event of a "mid-course

corrections," or change to the course of treatment, Respondents must start the entire process over again to obtain a new "final" tooth arrangement. (Citing CX-1150C at Q. 137)

With respect to the second element of claim 1, Align disagrees with Respondents "all data sets" non-infringement argument. Align says that Respondents assert they do not infringe the claims of the '863 patent because phrases such as "modified digital models" and "models" require that *all* data sets for a patient's treatment be "produced prior to active treatment." (Citing RPHB at 16, 110-11, 119-20, 159, 189-90) First, Align asserts that this construction was not identified in the SRJCCC. Second, Align says Respondents cite to no supporting evidence. Third, Align argues that Respondents still infringe under this construction, because CCPK completes the stepping or staging for all stages prior to CCUS making the first set of appliances for active treatment ("phase 1"). (Citing CX-1150C at Q. 130-136, 347, 352) Align contends that, while CCUS says it forms aligner sets only four at a time (a "phase"), CCPK prepares all of the tooth arrangements for all aligners in all phases before treatment begins.

Regarding the third and fourth elements of claim 1, Align argues that CCPK practices these elements when {

}

Align argues that, when used, the aligner must be designed with a corresponding receptacle for the attachment device. Align says that, to do this, {

} (Citing CX-413C at 1-2; CX-1160C.1 at 93:12-15) Align says that Respondents do not contest Align's identification of CCPK's infringing actions. (Citing RPHB at 188; RX-129C at Q. 65)

In its reply brief, Align says that in their PreHearing Brief, Respondents asserted they do not infringe claims of the '863 patent because phrases such as "modified digital models" and "models" require that *all* data sets for a patient's treatment be "produced prior to active treatment." (Citing RPHB at 26, 93, 120) Align avers that Respondents present a new argument in their PostHearing Brief that:

> ClearCorrect's process is phase-based, meaning the Clinician does not determine all of the successive tooth arrangements that are required until after treatment has begun, based upon the patient's progress. (Citing Tr. at 416:8-17) ClearCorrect's phase-based system does not meet this limitation.

(Citing RIB at 22; 25, 37, 93, 120, 125, 139) Align asserts that, while Respondents provide no further explanation for why their "phase-based system does not meet this limitation," it appears

that they are: (i) seeking to graft onto the claim a requirement that a "clinician"[53] must determine the successive tooth arrangements; and (ii) arguing that, because a clinician *might* request changes be applied to phases occurring after phase 1, that the successive tooth arrangements originally determined by CCPK become somehow irrelevant.

Align argues that all of Respondents' arguments are meritless. First, Align says that neither the construction advanced in the PreHearing Brief nor that advanced in the PostHearing Brief was identified in the SRJCCC. Align maintains that both arguments are therefore improper. (Citing Tr. at 8:4-9:4) Align notes that the construction advanced in their PreHearing Brief has already been excluded on this basis. (Citing RX-0129C at Q. 50) Second, Align submits that positions advanced in the PostHearing Brief regarding these elements were not identified in the PreHearing Brief, and are therefore waived. (Citing G.R. 8.2) Third, Align asserts that Respondents cite to no supporting intrinsic evidence for any of their varying constructions.

Align continues that, even if either of Respondents' arguments (i.e., the PreHearing Brief or PostHearing Brief arguments) is accepted, Respondents' process would still infringe. Align argues that {

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[53] Align objects to Respondents reliance on factual statements unsupported by evidentiary citations, and that were specifically excluded from Dr. Mah's statement pursuant to Align's *Motion in Limine* No. 3, for example which state that a "Clinician does not determine all of the successive tooth arrangements that are required until after treatment has begun, based upon the patient's progress," and that "[t]he Clinician makes this determination based upon based upon an evaluation of the patient's progress and the Clinician's prescription." (Citing *Compare RIB* at 22, 25, 26, 28, 31, 35, 37, 93, 113, 120, 125, and 139 *with e.g.* RX-129C at Q. 50 (excluded portion))

} (Citing CIB at 12-16) Align argues that it does not matter if subsequent phases are later changed – CCPK has already performed the step of determining the intermediate tooth arrangements.

Align also asserts that, even where a clinician alters the treatment plan after treatment has begun (which does not happen all the time), it must be done through a "mid-course correction," wherein the entire process begins again. (Citing CX-1150C at Q. 137) Align contends that a "mid-course correction" includes preparing a new initial, a new final, and "stepping" the case all over again from the initial to the final. (Citing *id.*; Tr. at 205:21-206:15)

Respondents' Position: Respondents argue that neither CCUS nor CCPK infringes claim 1 of the '863 patent. First, Respondents say that Align contends the first element and part of the second element are practiced by CCUS in the United States. (Citing Tr. at 559:9-560:19; CX-1150C at Q. 294) Respondents say Align contends that part of the second element and the third and fourth elements are practiced by CCPK in Pakistan. (Citing Tr. at 541:23-542:1; 545:6-10; 546:12-19; CX-1150C at Q. 295) Therefore, Respondents argue that claim 1 of the '863 patent, a method claim, is not infringed. (Citing RIB at Sec. 3.3.1.3)

Second, Respondents assert that the following steps are not performed by CCUS and/or CCPK for the additional reasons set forth below. Respondents assert that they do not infringe the preamble of claim 1, "A method for producing digital models of dental positioning appliances, said method comprising," because they do not produce digital models of "dental positioning appliances." (Citing Tr. 348:8-22; RX-0129C at Q. 118) Regarding the first element of claim 1, "providing a digital model of a patient's dentition," Respondents aver that CCUS scans the physical model of the patient's teeth. (Citing Tr. 329:17 to 330:8) Respondents assert that there is no evidence that CCPK performs this limitation. (Citing RX-0129C at Q. 119)

Regarding the second element of claim 1,

> producing a plurality of modified digital models of the dentition, wherein the modified models represent successive treatment stages of an orthodontic treatment and wherein each modified model or a product of such model is to be used in fabrication of a distinct successive incremental dental positioning appliance associated with the respective treatment stage of that modified model;

Respondents argue that, based on the context of the patent and the related prosecution history, one skilled in the art would understand that this limitation would require that all of the "plurality" of "modified digital models" progress successively from the initial tooth arrangement to the final tooth arrangement and be produced prior to active treatment. Respondents assert that a final tooth arrangement can only be a projection at the treatment stage prior to active treatment. (Citing Tr. at 778:5-23; RX-0129C at Q. 120) Respondents argue that this means that the Clinician does not determine the successive tooth arrangements that are required until after treatment has begun. (Citing Tr. 416:8-17) Respondents assert that the Clinician makes this determination based upon an evaluation of the patient's progress and the Clinician's prescription. Respondents argue that the phase-based system of the Respondents does not meet this limitation. (Citing RX-129C at Q. 120) Respondents say that Mr. Beers only identifies conduct by CCPK as meeting this limitation. (Citing *id.*) Respondents argue that there is no evidence that CCUS practices this claim limitation.

Regarding the third element of claim 1, Respondents say that Mr. Beers only identifies conduct by CCPK as meeting this limitation. (Citing RX-129C at Q. 121) Respondents argue that there is no evidence that CCUS practices this claim limitation, and Align agrees. (Citing CPHB at 523; RX-129C at Q. 121)

In its reply brief, Respondents argue that they do not make digital models of appliances as the preamble of independent claim 1 recites. (Citing RIB at § 8.3.1) Respondents quote the transcript in support of its assertion:

> Q. Does ClearCorrect made digital models of the appliance?
> A. No.
>
> Q. Does ClearCorrect Pakistan make digital models of the appliance?
> A. No.
>
> Q. And the appliance is the aligner, right?
> A. That's right.
>
> Q. Has ClearCorrect USA ever made a digital to your knowledge of an appliance?
> A. No.
>
> Q. Or Pakistan, has it?
> A. No.

(Citing Tr. at 348:9-24) Respondents contend that there is no dispute in this case that CCUS uses digital models of a patient's dental arch to fabricate physical models of that arch. (Citing Tr. at 341: 2-21) Respondents assert that the actual orthodontic appliances, the aligners, are made by thermoforming a sheet of plastic over that physical model. (Citing Tr. at 341: 2-21) Respondents say that no digital model of the actual appliance ever exists. Respondents contend that Align disregards the claim's language requiring a digital model of the appliance. (Citing CIB at 121) Respondents argue that Align failed to prove the creation of a digital model of any appliance, which means that it has failed to prove infringement of independent claim 1.

Staff's Position: Applying the ALJ's rulings, Staff contends that the evidence demonstrates that CCPK directly infringes claim 1 of the '863 patent by selling digital data sets. (Citing CX-1150C at Q. 291-296 and CX-1198C at 226-238 (collectively discussing claim 1 of the '863 patent))

In its reply brief, Staff asserts that Respondents' arguments of non-infringement of the asserted claim of the '863 patent advance claim construction arguments that were not properly identified in the Second Joint Revised Claim Construction Chart and are not properly supported by any intrinsic (or extrinsic) evidence. In particular, Staff says that Respondents argue that they do not infringe, *inter alia*, claim 1 of the '863 patent because the claimed "plurality of modified digital models" requires that all of the modified digital models progress from the initial tooth arrangement to final tooth arrangement and be produced prior to active treatment. (Citing RIB at 120) Staff says that Respondents made a similar argument with respect to the '325 patent, and for the same reasons stated with respect to the '325 patent, Staff asserts that Respondents' argument should be rejected.

Analysis and Conclusions: First, addressing Respondents' incorporation by reference of their general defenses, I incorporate and reaffirm the analysis and conclusions reached in section V.B.1, *supra*, treating the three issues relevant to the asserted claims of the '863 patent, to wit: (1) whether or not all steps of a method claim must be performed in the same country; (2) whether or not digital data sets are "articles" within the scope of 19 U.S.C. § 1337; and (3) whether or not Align can meet its burden of proving infringement through the testimony of Mr. Beers.

I find that Align has proven by a preponderance of the evidence that Respondents' process for producing digital models of dental positioning appliances infringes asserted independent claim 1. Align has introduced evidence that CCPK practices each and every element by making digital models according to claim 1.

Regarding the preamble, I find that Respondents waived the argument that the preamble is limiting because Respondents did not make this argument in either its prehearing brief or the

SRJCCC. *See* G.R. 8.2 ("Any contentions not set forth in detail as required herein shall be deemed abandoned or withdrawn.") Moreover, even if Respondents did not waive their right to argue that the preamble is limiting, I find that the preamble is not limiting because it merely states the purpose of the claimed method, and thus an infringement analysis is not necessary. *Pitney Bowes, Inc. v. Hewlett-Packard Company*, 182 F.3d 1298, 1305 (Fed. Cir. 1999) (citing *Rowe v. Dror*, 112 F.3d 473 (Fed. Cir. 1997)). In *Pitney*, the Federal Circuit found that, if the body of the claim "fully and intrinsically" sets forth the complete invention, including all of its limitations, and the preamble offers "no distinct definition of any of the claimed invention's limitations, but rather merely states, for example, the purpose or intended use of the invention, then the preamble is of no significance to claim construction because it cannot be said to constitute or explain a claim limitation." *Id.* The preamble should only be construed if, when read in the context of the entire claim, recites limitations of the claim, or if it is "necessary to give life, meaning, and vitality" to the claim. *Id.*

Here, I find that the preamble's statement that the patent claims a method for "producing digital models of dental positioning appliances" is merely a statement that describes the invention's intended field of use. Each element of the claim can be understood without reference to context of the preamble. (*See contra id.* (discussing that the term "the generated shapes" that appeared for the first time in the last limitation of the claim at issue could only be understood in the context of the preamble statement which provided the antecedent basis))

Alternatively, even if the preamble is limiting, the evidence demonstrates that CCPK practices the preamble. In the context of the claim language, I find that one of ordinary skill in the art would understand the preamble to refer to digital models of the patient's dentition which

are used to fabricate aligners. (JX-005 at R1:59-61[54]) The first element of claim 1 recites "providing a digital **model of a patient's dentition**," and the second element of claim 1 recites "producing a plurality of modified **digital models of the dentition**." (*Id.* (emphasis added.) Also, Mr. Andrew Beers, Align's technical expert, testified that one of ordinary skill in the art would interpret the preamble to refer to the digital models discussed in the patent, which are of the patient's dentition used to fabricate the aligner, and not of the actual aligner. (CX-1150C at Q. 292) Thus, I find Respondents' argument unpersuasive that one of ordinary skill in the art would understand the preamble, and the rest of the claim as being limited to digital models of "appliances."

Interpreting the preamble to refer to digital models of the patient's dentition, I find that Align has introduced credible evidence, including testimony and documents, that CCPK practices the preamble. Mr. Beers, Align's technical expert, testified that CCPK produces a plurality of digital models representing a plurality of tooth arrangements, using software called "FreeForm." Mr. Beers testified that CCUS uses those digital models to fabricate custom made successive tooth positioning appliances. (CX-1150C at Q. 292)

Mr. Arif, the clinical director of orthodontics at CCPK, testified that the aligners made by CCUS are made using the digital models provided by CCPK. (Tr. 205:17-20; 168:1-169-2) In explaining that process, he testified that {

[54] *See* Ex Parte Reexamination Certificate ("the Reexamination Certificate") appended to the '863 patent. The designation "R" will be used to refer to the Reexamination Certificate.

}

{

}

Finally, the evidence shows that CCUS submitted a premarket submission to the U.S. Food and Drug Administration ("the FDA submission") to show CCUS's system, which was prepared in the ordinary course of business. (CX-078; Tr. 248:9-249:3) The FDA submission states that using "FreeForm Modeling," a 3D modeling program from SensAble Technologies, a certified dental lab technician creates a treatment setup following a dentist's prescription. (CX-

078 at 55) The submission states that the technician sections up the digital model as he would a physical model. (*Id.*) The submission also states that a treatment setup shows how the teeth will look after the dentist's prescribed treatment occurs, and that the treatment setup shows the 3D models of the teeth in an untreated state and the teeth in a fully treated state. (*Id.*) The submission continues that CCUS sends this treatment setup to the prescribing doctor for review and approval. (*Id.*) The FDA submission shows that, after the doctor approves the treatment setup, CCPK creates intermediate models using FreeForm, which take the case from the untreated state to the fully treated state. (*Id.*) The submission explains that each 3D model has very minor change from the model before it. The submission also states that Clear Correct then fabricates physical models using the digital models. (*Id.* at 56)

I find that credible testimony shows that CCPK practices the first element of asserted claim 1. Mr. Beers testified that {

} Thus, Align has shown by a preponderance of evidence that CCPK practices "providing a digital model of a patient's dentition."

I find that the credible testimony and documentary evidence demonstrate that CCPK practices the second element of asserted claim 1. Mr. Beers testified that {

}

{

}

In addition, Align has presented a video clip that show a {

}

{

}

{

} (*Id.*)

Mr. Beers explained that {

}

{

}

Thus, Align has shown by a preponderance of evidence that CPPK practices "producing a plurality of modified digital models of the dentition, wherein the modified models represent successive treatment stages of an orthodontic treatment, and wherein each modified model or a product of such model is to be used in fabrication of a distinct successive incremental dental positioning appliance associated with the respective treatment stage of that modified model."

I find unpersuasive Respondents "all data sets" non-infringement argument. Respondents assert they do not infringe this element because it requires that all data sets for a patient's treatment be "produced prior to active treatment." (RIB at 120) First, I find that Respondents have waived the right to offer a construction for any term contained in this claim element. Respondents only offered "plain and ordinary meaning" as a construction for the term "distinct successive incremental dental appliance" in both the SRJCC and its post-hearing brief. (SRJCCC at 8; RIB at 119) As I found in Section III.F.3, assertion of "plain and ordinary meaning," without further elaboration, does not rise to the level of a proposed construction. *See, e.g., O2 Micro Int'l Ltd. v. Beyond Innovation Technology Co., Ltd.*, 521 F.3d 1351, 1360 (Fed. Cir. 2008).

In Section III.F.3, I rejected Respondents argument that they do not infringe this claim element because it requires that all of the 'plurality' of 'modified digital models' progress successively from the initial tooth arrangement to the final tooth arrangement and be produced *prior* to active treatment." (RIB at 120) As discussed in claim construction for the '863 patent, the third limitation of the second element only requires that one digital model (representing a single "treatment stage") is used to fabricate one dental appliance. The claim element recites in pertinent part that "each modified model … is to be used in fabrication of *a* distinct successive incremental dental positioning appliance associated with the respective treatment stage of that modified model." (JX-005 at R1:63-67 (emphasis added)) Nothing in this limitation requires that a specific total number of models be produced before the fabrication of dental positioning appliances.

Credible evidence demonstrates that Respondents infringe even under their own construction. Mr. Beers testified that {

} (CX-1150C at Q. 130-136, 347, 352) I find, too, that Dr. Mah's testimony regarding this claim element is conclusory and without corroboration. Dr. Mah merely states that CCUS's process is phase-based, and that in his opinion, the phase-based system of Respondents does not meet this limitation. (RX-129C at Q. 120)

Similarly, I find unpersuasive Respondents' "final tooth arrangement" non-infringement argument. Respondents argue that they do not infringe the claims of the '863 patent because, in their process a clinician has the ability to change the course of treatment during a mid-course correction, after treatment has already begun. I find, as I did with respect to the '325 patent, that Respondents admitted that mid-course corrections are not made in every case. (Tr. at 224:11-13) Respondents also admitted that when a mid-course correction takes place, the accused process is executed again, using new initial and new final tooth positions, between which intermediates data models are generated. (Tr. at 195:7-196:4; 205:24-206:15; 224:14-21; 318:21-319:3) Thus, immediately after a mid-course correction, Respondents generate intermediate digital models that represent successive treatment stages of an orthodontic treatment and infringe the second element of claim 1.

Regarding the third and fourth elements of claim 1, I find that credible evidence shows that CCPK practices these elements. Mr. Beers testified that {

}

{

} (CX-413C at 1-2)

Based on all the foregoing, I find that Align has proven by a preponderance of the evidence that CCPK infringes independent claim 1 when it produces the data sets in Pakistan according to the process set forth in this claim.

2. Claim 4

Claim 4, which depends from claim 1, states:

> A method as in claim 1, wherein producing a plurality of modified digital models of the dentition comprises:
>
> presenting a visual image based on the digital model of the patient's dentition;
>
> manipulating the visual image to reposition individual teeth in the visual image;
>
> producing a digital data set representing the final tooth arrangement with repositioned teeth as observed in the image; and
>
> producing the plurality of modified digital models as a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement.

(JX-005 at 14:4-16)

Align's Position: Regarding the preamble of claim 4, Align argues that the preamble is not limiting, and Respondents have waived any such position in their Prehearing Brief. Align asserts that CCPK practices each of the elements of claim 1.

Align contends that CCPK practices the first element of asserted claim 4 when using FreeForm to present a visual image on screen of the 3D scanned digital image of the patient's dentition. (Citing CIB Sec. I.E. 1 and 3; CX-1150C at Q. 297) As described above with respect to the first element of claim 1 for Evidence Category 1 – "Initial Digital Data Set," {

{

}

{

}

} { } { } { } Align says that the term "tooth" is used in the asserted patents { } as inclusive of the tooth and such additional materials. (Citing JX-002 at 12:51-56 ("The crown of the tooth, as well as the gingivae tissue immediately below the crown are separated from the rest of the geometry, and treated as an individual unit, referred to

as a tooth."); {

}

{

}

(Citing CX-1157C.1-3 at 60:20-63:4, 63:15-69:3, 72:22-77:14; CX-1158C.1-3 at 100:19-101:21; CX-105C; CX-106C)

Align asserts that Respondents assert their "manipulating a visual image" argument as a non-infringement basis, which is incorrect. (Citing RPHB at 188) Align says that Respondents assert they do not infringe the claims of the '863 patents because "manipulating a visual image" cannot include manipulation by entering coordinates. (Citing RPHB at 15, 188) First, Align argues that this is a claim construction argument not identified in the SRJCCC. Second, Align asserts that the intrinsic record shows the opposite of Respondents' position. {

} (JX-003 at 13:64-14:11; CX-1150C at Q. 124-125). Third, Align contends that, as admitted by Dr.

Mah, { }

(Citing RX-129C at Q. 48) Align avers that Respondents did not contest that CCPK practices this element. (Citing RPHB at 188; RX-129C at Q. 65)

Regarding the third element of claim 4, Align argues that CCPK practices this element, { }

(Citing CIB at Sec. I.E.5; CX-1150C at Q. 299) Alternatively, Align contends that CCPK practices this claim {

} (Citing CIB at Sec. I.E.5; CX-1150C at Q. 299)

Align refers to Evidence Category No. 5: "Final Digital Data Set." In that evidence category, Align submits that {

}

Align argues that, {

(Citing CX-090C at 44-47; CX-087C at 1-2; CX-1158C.1-3 at 51:4-83:21; CX-107C)

Align disagrees with Respondents' "final tooth arrangement" non-infringement argument, which Align argues fails for the reasons as described above with respect to the second element of in claim 1. (Citing RPHB at 188; RX-129C at Q. 65)

Regarding the fourth element of claim 4, Align argues that CCPK practices this element using {

} Align disagrees with Respondents' "all data sets," "final tooth arrangement," and "clinician determination" arguments as non-infringement bases, for the reasons described above with respect to the second element of claim 1. (Citing RPHB at 189)

Thus, Align asserts that Respondents infringe claim 4 and violate Section 337 for the same reasons as claim 1.

Respondents' Position: Regarding claim 4, Respondents argue that they do not infringe this dependent claim because they do not infringe independent claim 1. In addition, Respondents assert that there is no infringement of claim 4 because certain steps in claims 1 and 4 are alleged

to take place in Pakistan, and certain steps in the U.S. (Citing RIB at Sec. 3.3.1.3) Respondents continue that CCUS and/or CCPK do not practice the following limitations of claim 4 for the reasons set forth below.

Regarding the preamble and the first limitation of claim 4, Respondents say that Mr. Beers only identifies conduct by CCPK as meeting this limitation. Respondents argue that there is no evidence that CCUS practices this limitation, and that Align agrees. (Citing CPHB at 532; RX-129C at Q. 122)

Regarding the second element of claim 4, Respondents argue that this limitation requires that a "visual image" be manipulated in order to reposition individual teeth. Respondents say that the visual image reflects the coordinates that have been entered. Respondents maintain that, { } Respondents state that this is not "manipulating the visual image." (Citing RX-129C at Q. 123) Respondents say that Mr. Beers only identifies conduct by CCPK as meeting this limitation. Respondents argue that there is no evidence that CCUS practices this claim limitation, and Align agrees. (Citing CPHB at 532)

Regarding the third element of claim 4, Respondents argue that a "final tooth arrangement" can only be a projection at the treatment stage prior to active treatment. (Citing RX-129C at Q. 124) Respondents assert that their phase-based system does not meet this limitation. Under the Respondents phase-based system, Respondents say aver that the Clinician exercises professional judgment as to the design of the successive orthodontic appliances to be used after active treatment has begun. (Citing Tr. 416:8-17) Respondents say that the digital data sets are not finalized until perhaps years after the patient's active treatment begins. (Citing

Tr. 342:24 to 343:14) Respondents argue that there is no evidence that CCUS practices this claim limitation, and Align agrees. (Citing CPHB at 532)

Regarding the fourth element of claim 4, Respondents argue that the plain meaning of the claim language requires production of a series of tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement, which would cover everything between the initial and final tooth arrangements. Respondents argue that this is distinct from the language of other claims that use "toward" rather than "to." Respondents aver that CCUS's phase-based method does not produce such a series. (Citing RX-129C at Q. 125) Respondents argue that there is no evidence that CCUS practices this claim limitation, and Align agrees. (Citing CPHB at 532)

In their reply brief, Respondents assert that because the actual evidence demonstrates that CCUS's phase based system is significantly different from the method described in Align's claims, and because Align bases its infringement arguments on misstatements about the Respondents' process, Align has failed to meet its burden of proof. Respondents also note that dependent claim 4 contains an element relating to "manipulating a visual image" on a computer screen. Respondents argue that Align's post hearing brief makes misstatements and assertions that CCPK operators "manipulate visual images." (Citing RRB at § 3.F.3) Respondents aver that CCPK operators use a dialog box to enter tooth movements and do not alter the visual image by, for example, clicking a mouse and dragging an image of a tooth crown. Respondents assert that, because Align bases its infringement arguments on misstatements concerning the CCPK operators' actual conduct, it has failed to meet its burden of proof on the independent claims' associated elements.

Staff's Position: Applying the ALJ's rulings, Staff contends that the evidence demonstrates that CCPK directly infringes claim 4 of the '863 patent by selling digital data sets. (Citing CX-1150C at Q. 297-301 and CX-1198C at 238-245 (collectively discussing claim 4 of the '863 patent))

In its reply brief, Staff says that Respondents argue that they do not infringe claim 4 of the '863 patent because (i) the claimed "manipulating the visual image to reposition individual teeth in the visual image" requires that a "visual image" actually be manipulated in order to reposition individual teeth; (ii) the claimed "final tooth arrangement" requires a projection at the treatment stage prior to active treatment; and (iii) the claimed "individual teeth" requires a representation of a three-dimensional model that resembled an actual tooth, and not a three-dimensional object that includes a tooth crown and sectioned gum material. (Citing RIB at 121-125) Staff says that Respondents made these same arguments with respect to the '325 patent. For the same reasons stated with respect to the '325 patent, Staff asserts that these arguments should be rejected.

Analysis and Conclusions: If I had found that Align had failed to prove that Respondents infringe claim 1, it would follow that Align failed to prove infringement of claim 4, which depends from claim 1. *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n. 9 (Fed. Cir. 1989) ("One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim.")

Nevertheless, I have found that Respondents infringe asserted claim 1. I also find that Align has shown by a preponderance of evidence that CCPK infringes asserted claim 4 of the '863 patent. Regarding the preamble, I find that Respondents waived the argument that the preamble is limiting because Respondents did not make this argument in either its prehearing

brief or the SRJCCC. Moreover, even if Respondents did not waive their right to argue that the preamble is limiting, I find that the preamble is not limiting because it merely states the purpose of the claimed method, and thus an infringement analysis is not necessary. *Pitney Bowes*, 182 F.3d at 1305. Also as discussed above, even if the preamble is limiting, credible evidence demonstrates that CCPK practices the preamble, which, in the context of the claim language, refers to digital models of the patient's dentition which are used to fabricate the aligner. (JX-005 at R1:59-61; CX-1150C at Q. 292)

I find that credible evidence shows that CCPK practices the first element of claim 4. Mr. Beers testified that {

} The video clip presented by Align shows the same. (CX-1157C.3 at 50:23)

I find that credible evidence shows that CCPK practices the second element of claim 4. Mr. Beers testified that {

}

{

}

I find unpersuasive Respondents "manipulating a visual image" non-infringement argument. (RPHB at 188) Respondents assert they do not infringe claims of at least the '325 and '863 Patents because "manipulating a visual image" cannot include manipulation by entering coordinates. (RPHB at 15, 188) First, I find that Respondents have waived the right to offer a construction for any term contained in this claim element. Respondents did not offer any construction for the term "manipulating a visual image" in either the SRJCC or its post-hearing brief. Second, the portion of Dr. Mah's testimony addressing this construction was excluded. (RX-0129C at Qs. 48, 69) Third, Dr. Mah admits that {

}

Regarding the third element of claim 4, I find that credible evidence shows that CCPK practices this element. Mr. Beers testified that CCPK practices this element, using FreeForm, by manipulating the image to reposition the teeth into a final tooth arrangement. (CX-1150C at Q. 299) Mr. Beers explained that {

}

{

}

Respondents "final tooth arrangement" non-infringement argument, fails for the same reasons as described above with respect to the second element of claim 1.

I find that credible evidence shows that CCPK practices the fourth element of claim 4. Mr. Beers testified that CCPK uses the "Generate Steps" function in FreeForm to generate intermediary digital models, i.e. a plurality of modified digital models. Mr. Beers testified that

{

} Video presented by Align shows the same. (CX-1158C.1-3 at 72:13-18, 78:11-79:14)

I find unpersuasive Respondents' "all data sets" and "final tooth arrangement" non-infringement arguments for the same reasons as described above with respect to the second element of claim 1. I also find unpersuasive Respondents' "clinician determination" non-infringement argument that, {

}

Based upon the foregoing, I find that Align has shown by a preponderance of evidence that CCPK infringes claim 4 when it produces the data sets in Pakistan according to the process set forth in this claim.

3. Claim 5

Claim 5, which depends from claim 4, states:

> A method as in claim 4, wherein the manipulating step comprises:
>
> defining boundaries about at least some of the individual teeth; and
>
> moving at least some of the tooth boundaries relative to the other teeth in an image based on the digital data set.

(JX-005 at 14:18-23)

Align's Position: Align contends that CCPK practices this claim using FreeForm by sectioning up the 3D scan in order to individually move the teeth, as described above with

respect to the second element of claim 4. (Citing CIB at Sec. I.E.4; CX-1150C at Q. 302) Align asserts that {

}

Align disagrees with Respondents' "individual teeth" non-infringement argument. Align says that Respondents assert they do not infringe claims of the '863 patent because the phrase "individual teeth" in the claims must be "a three-dimensional model that resembled an actual tooth, and not a three-dimensional object that includes a tooth crown and sectioned gum material." (Citing RPHB at 17, 158, and 189)

First, Align argues that this construction was not identified in the SRJCCC. Second, Align asserts that Respondents cite to no supporting evidence. Third, Align contends that "teeth" is generally used in the asserted patents inclusively for the tooth and surrounding gum material (Citing JX-002 at 12:51-56 and CX-1150C at Q. 123, 348). Fourth, Align avers that Respondents themselves use "teeth" in such an inclusive manner. (Citing CX-1157C.1 at 54:1-9; CX-090C at 14)

Align also argues that Respondents also provide, without explanation, a conclusory statement that "Respondents do not 'move' the 'tooth boundaries' 'relative to other teeth' in an 'image.'" (Citing RPHB at 190) Align asserts that this is insufficient. Thus, Align contends that Respondents infringe claim 5 and violate Section 337 for the same reasons as claim 1.

Respondents' Position: Regarding claim 5, Respondents say they do not infringe this dependent claim because they do not infringe independent claim 1. Respondents argue that there is no infringement of claim 5 because certain steps in claims 1, 4 and 5 are alleged to take place in Pakistan, and certain steps in the U.S. (Citing RIB at Sec. 3.3.1.3) Respondents continue that

CCUS and/or CCPK do not practice the following limitations of claim 5 for the reasons set forth below.

Regarding the preamble and the first limitation, Respondents argue that based on the plain meaning of the claim language, "individual teeth" means a representation of a three-dimensional model that resembled an actual tooth, and not a three-dimensional object that includes a tooth crown and sectioned gum material. Respondents say that Dr. Valley testified an actual tooth includes the root. (Citing Tr. at 707:25-708:6) Respondents aver that what CCPK sections, and manipulates, is only part of a tooth, and it therefore moves only parts of teeth. Respondents continue that {

} Respondents say Mr. Beers only identifies CCPK as practicing this limitation. (Citing CX-1150C at Q. 302) Respondents argue that there is no evidence that CCUS practices this claim limitation.

Regarding the second element of claim 5, Respondents argue that, for the reasons discussed immediately above, the Respondents do not "move" the "tooth boundaries" "relative to other teeth" in an "image" "to produce the final data set." Accordingly, Respondents say this limitation is not met by the Respondents. Also, Respondents aver that Mr. Beers only identifies CCPK as practicing this limitation. (Citing CX-1150C at Q. 302) Respondents argue that there is no evidence that CCUS practices this claim limitation.

In its reply brief, Respondents note that dependent claim 5 contains an element relating to "defining boundaries" around individual teeth. Respondents argue that Align's post hearing brief makes misstatements and assertions that CCPK operators "define boundaries" around individual teeth. (Citing RRB at § 3.F.3) Respondents aver that CCPK operators do not "define

boundaries" around individual teeth and, instead, identify subsets of data that include soft tissue (gums), a tooth crown, and portions of adjacent tooth crowns. Respondents assert that, because Align bases its infringement arguments on misstatements concerning the CCPK operators' actual conduct, it has failed to meet its burden of proof on the independent claims' associated elements.

Staff's Position: Applying the ALJ's rulings, Staff contends that the evidence demonstrates that CCPK directly infringes claim 5 of the '863 patent by selling digital data sets. (Citing CX-1150C at Q. 302-303 and CX-1198C at 245-248 (collectively discussing claim 5 of the '863 patent))

Analysis and Conclusions: If I had found that Align had failed to prove that Respondents infringe claim 1 and/or claim 4, it would follow that Align failed to prove infringement of claim 5, which depends from claim 4 (which depends from claim 1). *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n. 9 (Fed. Cir. 1989) ("One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim.")

Nevertheless, I have found that Respondents infringe asserted claims 1 and 4. I also find that Align has shown by a preponderance of evidence that CCPK infringes asserted claim 5 of the '863 patent. Mr. Beers testified that {

}

Respondents miss the mark when they assert that the phrase "individual teeth" in the claims must be "a three-dimensional model that resembled an actual tooth, and not a three-dimensional object that includes a tooth crown and sectioned gum material." (RPHB at 17, 158, and 189) First, I find that Respondents have waived the right to offer a construction for any term contained in this claim element. Respondents did not offer any construction for the term "individual teeth" in either the SRJCC or its post-hearing brief. Moreover, the portion of Dr. Mah's testimony addressing this construction was excluded. (RX-0129C at Qs. 53, 60) Respondents cite no evidence that shows a clear intent to limit the meaning of this limitation as Respondents' propose. As a result, I reject this argument by Respondents.

Treating the substance of the assertion, the evidence introduced at the hearing shows that Respondents' process includes a step of "defining boundaries about at least some of the individual teeth." {

} All that is required is "defining boundaries about" individual teeth. (JX-005 at

14:20) Based on the foregoing testimony and evidence introduced during the hearing, I find that Respondents meet this limitation.

Thus, I find that Align has shown by a preponderance of evidence that CCPK infringes claim 5 when it produces the data sets in Pakistan according to the process set forth in this claim.

4. Claim 6

Claim 6, which depends from claim 1, states:

> A method as in claim 1, wherein producing a plurality of modified digital models of the dentition comprises:
>
> providing a computer system having at least one processor and memory;
>
> providing to the computer system the digital model of the patient's dentition;
>
> providing to the computer system a digital model set representing a final tooth arrangement;
>
> producing using the computer system the plurality of models based on both of the previously provided initial and final digital data sets.

(JX-005 at 14:24-35)

Align's Position: Align asserts that the preamble of claim 6 is not limiting, and Respondents have waived any such position in their Prehearing Brief. As explained above, Align argues that CCPK practices each of the elements of claim 1.

Regarding the first and second elements of claim 6, Align argues that {

}

Align submits that Respondents do not contest infringement of this element. (Citing RPBH at 190; RX-0129C at Q. 65)

Regarding the third element of claim 6, Align argues that {

}

Align says that Respondents assert their "all digital sets," "final tooth arrangement," and "clinician determination" non-infringement arguments. Align argues that the "all digital sets" and "final tooth arrangement" arguments are incorrect for the reasons discussed above in claim 1. Align further contends that Respondents assert that, {

} Align asserts that Respondents presented no evidence to support this argument. Align also asserts that {

In its reply brief, Align argues that Mr. Beers testified that the element of providing to the computer system a digital model representing a final tooth arrangement is satisfied by CCPK providing the predetermined final tooth arrangement to the Generate Steps function. (Citing CX-1150C at Q. 306) Align submits that Respondents fail to address this evidence. Align continues that Respondents' improperly construed the term "based on" to assert that each appliance must be based on the immediately preceding appliance, not the initial, and must fail for at least that reason.

Thus, Align argues that Respondents infringe claim 6 and violate Section 337 for the same reasons as claim 1.

Respondents' Position: Regarding claim 6, Respondents say they do not infringe this dependent claim because they do not infringe independent claim 1. Respondents add that there is no infringement of claim 6 because certain steps in claims 1 and 6 are alleged to take place in Pakistan, and certain steps in the U.S. (Citing RIB at Sec. 3.3.1.3) Respondents continue that they do not practice the following limitations of claim 6 for the reasons set forth below.

Regarding the preamble and the first element of claim 6, Respondents say that Mr. Beers states that CCPK performs this step. (Citing CX-1150C at Q. 304 and 305; RX-129C at Q. 128) Respondents argue that, assuming, as Mr. Beers suggests, that this step is performed by scanning "a 3D physical model of a patient's teeth taken from dental impressions" and subsequently sending that information to another party, there is no evidence that CCPK performs this limitation. (Citing RX-129C at Q. 128)

Regarding the second element of claim 6, Respondents argue that neither CCUS nor CCPK "provide" a digital data set representing a final tooth arrangement to a computer system. Respondents aver that the evidence demonstrates that CCPK operators create a digital model of the patient's teeth as they would be arranged in accordance with the doctor's prescription. (Citing Tr. 329:11 to 341:21) Respondents contend that this is not "providing" the data set to a computer, it is using the computer to "create" or "generate" such a data set. Respondents argue that one skilled in the art would understand "provide" does not mean "generate" and this limitation is not met by the Respondents. Respondents say that Mr. Beers only identifies conduct by CCPK as meeting this limitation. (Citing CX-1150C at Q. 306; RX-129C at Q. 129) Respondents argue that there is no evidence that CCUS practices this claim limitation. (Citing RX-129C at Q. 129)

Regarding the third element of claim 6, Respondents argue that, based on the context of the patent and the related prosecution history, one skilled in the art would understand that this limitation would require that all of the "plurality" of models be produced prior to active treatment.

Respondents assert that a "final" tooth arrangement can only be a projection at the treatment stage prior to active treatment. Respondents say that their process is phase-based. (Citing Tr. 416:8-17) Respondents aver that this means that the Clinician does not determine the successive tooth arrangements that are required until after the initial appliances have been fabricated and after treatment has begun. (Citing Tr. at 416:8-17) Respondents maintain that

{

}

Respondents submit that the design of the appliances is not "based on" both of the "previously

provided initial and final digital data sets." Instead, Respondents contend that {

} Additionally, Respondents say Mr. Beers only identifies conduct by CCPK as meeting this limitation. There is no evidence that CCUS practices this claim limitation, and Align agrees. (Citing CX-1150C at Q. 307; CPHB at 545)

Staff's Position: Applying the ALJ's rulings, Staff contends that the evidence demonstrates that CCPK directly infringes claim 6 of the '863 patent by selling digital data sets. (Citing CX-1150C at Q. 304-308 and CX-1198C at 248-256 (collectively discussing claim 6 of the '863 patent))

In its reply brief, Staff asserts that Respondents' arguments of non-infringement of the asserted claim of the '863 patent advance claim construction arguments that were not properly identified in the Second Joint Revised Claim Construction Chart and are not properly supported by any intrinsic (or extrinsic) evidence. In particular, Staff says that Respondents argue that they do not infringe claim 6 of the '863 patent because the claimed "plurality of modified digital models" requires that all of the modified digital models progress from the initial tooth arrangement to final tooth arrangement and be produced prior to active treatment. (Citing RIB at 120) Staff says that Respondents made a similar argument with respect to the '325 patent. For the same reasons stated with respect to the '325 patent, Staff asserts that this argument should be rejected.

In its reply brief, Staff also says that Respondents argue that they do not infringe claim 6 of the '863 patent because (i) the claimed "manipulating the visual image to reposition individual

teeth in the visual image" requires that a "visual image" actually be manipulated in order to reposition individual teeth; (ii) the claimed "final tooth arrangement" requires a projection at the treatment stage prior to active treatment; and (iii) the claimed "individual teeth" requires a representation of a three-dimensional model that resembled an actual tooth, and not a three-dimensional object that includes a tooth crown and sectioned gum material. (Citing RIB at 121-125) Staff says that Respondents made these same arguments with respect to the '325 patent. For the same reasons stated with respect to the '325 patent (above), Staff asserts that these arguments should be rejected.

Analysis and Conclusions: If I had found that Align had failed to prove that Respondents infringe claim 1, it would follow that Align failed to prove infringement of claim 6, which depends from claim 1. *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n. 9 (Fed. Cir. 1989) ("One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim.")

Nevertheless, I have found that Respondents infringe asserted claim 1. I also find that Align has shown by a preponderance of evidence that CCPK infringes asserted claim 6 of the '863 patent. Regarding the first and second elements of claim 6, I find that credible evidence shows that CCPK practices these elements. Mr. Beers testified that {

}

{

}

Thus, Align has shown by a preponderance of evidence that CCPK practices "providing a computer system having at least one processor and memory" and "providing to the computer system the digital model of the patient's dentition."

I find that credible evidence shows that CCPK practices the third element of claim 6. Mr. Beers testified that {

}

I find that credible demonstrates that CCPK practices the fourth element of asserted claim 6. Mr. Beers testified that {

}

Furthermore, Mr. Arif testified that the aligners made by CCUS are made using the digital models provided by CCPK. (Tr. 205:17-20; 168:1-169-2) In explaining that process, he testified that {

}

Moreover, the CCUS FDA submission states that using "FreeForm Modeling," a certified dental lab technician creates a treatment setup following a dentist's prescription. (CX-078 at 55) The submission states that a treatment setup shows how the teeth will look after the dentist's prescribed treatment occurs, and that the treatment setup shows the 3D models of the teeth in an

untreated state and the teeth in a fully treated state. (*Id.*) The submission shows that, after the doctor approves the treatment setup, CCPK creates intermediate models using FreeForm, which take the case from the untreated state to the fully treated state. (*Id.*)

I find unpersuasive Respondents' "all data sets" and "final tooth arrangement" non-infringement arguments, for the same reasons as described above with respect to the second element of claim 1. I also find unpersuasive Respondents' "clinician determination" non-infringement argument for the same reasons as described above with respect to the fourth element of claim 4.

Thus, I find that Align has shown by a preponderance of evidence that CCPK infringes claim 6 when it produces the data sets in Pakistan according to the process set forth in this claim.

5. Claim 7

Claim 7, which depends from claim 6, recites:

> A method as in claim 6, wherein the step of providing a digital model set representing a final tooth arrangement comprises:
>
> defining boundaries about at least some of the individual teeth on a visual image provided by the computer system; and
>
> moving at least some of the tooth boundaries relative to the other teeth in the visual image to produce the final data set.

(JX-005 at 14:36-44)

Align's Position: Align asserts that CCPK practices this claim {

}

Align says Respondents assert their "individual teeth" non-infringement argument, which is incorrect for the reasons discussed in claim 5. Align adds that Respondents also provide, without explanation, a conclusory statement that "Respondents do not 'move' the 'tooth boundaries' 'relative to other teeth' in an 'image.'" (Citing RPHB at 192) Align argues that this is insufficient to raise an infringement defense. Thus, Align contends that Respondents infringe claim 7 and violate Section 337 for the same reasons as claims 1 and 6.

Respondents' Position: The Respondents say they do not infringe dependent claim 7 because they do not infringe independent claim 1. In addition, Respondents say there is no infringement of claim 7, because certain steps in claims 1, 6 and 7 are alleged to take place in Pakistan, and certain steps in the U.S. (Citing RIB at Sec. 3.3.1.3) Respondents continue that they do not practice the following limitations for the reasons set forth below.

Regarding the preamble and first limitation of claim 6, Respondents refer to their discussion concerning claim 4, and contend that Respondents' process does not define boundaries about "individual teeth." Also, Respondents say Mr. Beers only identifies conduct by CCPK as meeting this limitation. (Citing CX-1150C at Q. 310) Respondents assert that there is no evidence that CCUS practices this claim limitation, and Align agrees. (Citing CPHB at 552)

Respondents refer to their argument concerning claim 4 and contend they do not practice the second element of claim 7, because they do not "move" the "tooth boundaries" "relative to other teeth" in an "image." Respondents add that Mr. Beers only identifies conduct by CCPK as meeting this limitation. (Citing CX-1150C at Q. 310) Respondents say that there is no evidence that CCUS practices this claim limitation, and Align agrees. (Citing CPHB at 552)

In its reply brief, Respondents note that dependent claim 7 contains elements relating to "manipulating a visual image" on a computer screen or "defining boundaries" around individual

teeth. Respondents argue that Align's post hearing brief makes misstatements and assertions that CCPK operators "manipulate visual images" or "define boundaries" around individual teeth. (Citing RRB at § 3.F.3) Among other things, Respondents aver that {

} Respondents assert that, because Align bases its infringement arguments on misstatements concerning the CCPK operators' actual conduct, it has failed to meet its burden of proof on the independent claims' associated elements.

Staff's Position: Applying the ALJ's rulings, Staff contends that the evidence demonstrates that CCPK directly infringes claim 7 of the '863 patent by selling digital data sets. (Citing CX-1150C at Q. 309-311 and CX-1198C at 256-259 (collectively discussing claim 7 of the '863 patent))

Analysis and Conclusions: If I had found that Align had failed to prove that Respondents infringe claim 1 and/or claim 6, it would follow that Align failed to prove infringement of claim 7, which depends from claim 6 (which depends from claim 1). *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n. 9 (Fed. Cir. 1989) ("One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim.")

Nevertheless, I have found that Respondents infringe asserted claims 1 and 6. I also find that Align has shown by a preponderance of evidence that CCPK infringes asserted claim 7 of the '863 patent. I find that credible evidence shows that CCPK practices each and every element

of claim 7. Mr. Beers testified that {

}

Mr. Pumphrey testified that {

}

I find unpersuasive Respondents "individual teeth" non-infringement argument for the same reasons as describe above with respect to claim 5.

Thus, I find that Align has shown by a preponderance of evidence that CCPK infringes claim 7 when it produces the data sets in Pakistan according to the process set forth in this claim.

6. Claim 8

Claim 8, which depends from claim 6, teaches:

> A method as in claim 6, wherein the step of producing the plurality of models comprises determining positional differences between the initial digital model and the final digital model and interpolating said differences.

(JX-005 at 14:45-48)

Align's Position: Align asserts that CCPK practices the element of claim 8 when { } for the reasons described with respect to the second element of claim 1. (Citing CIB at Sec. I.E.7; CX-1150C at Q. 313) Align avers that Respondents admit that this "generating" is done by { } (Citing Tr. at 676:23-677:5) Align says Respondents argue that they do not infringe because: (i) a phase-based system does not produce the requisite "successive digital data sets;" and (ii) the operators' "use of their individual judgment to adjust the teeth locations means that the 'positional differences ...' are not interpolated" (Citing RPHB at 192)

Regarding (i), Align asserts that this appears to be Respondents' "all data sets" argument, and is incorrect as described in claim 1. Regarding (ii), Align contends that Respondents fail to provide any particular evidence to support their argument. Align avers that their argument is contrary to the evidence. Align argues that { } according to Respondents' process. Align argues that Respondents infringe claim 8 and violate Section 337 for this claim, for the same reasons as claims 1 and 6.

Respondents' Position: Regarding claim 8, Respondents say that they do not infringe this dependent claim because they do not infringe independent claim 1. Respondents add there is no infringement of claim 8, because certain steps in claims 1, 6 and 8 are alleged to take place in Pakistan, and certain steps in the U.S. (Citing RIB at Sec. 3.3.1.3) Respondents recite claim 8 and aver that the operators' use of their individual judgment to adjust the teeth locations to avoid collisions, as described at the hearing, means that the "positional differences between the initial

data set and the final data set" are not interpolated. (Citing JX-005, 14:45-48; and Tr. 336:8 to 338:17) Respondents assert that the {

} (Citing RX-129C at Q. 133) Respondents add that Mr. Beers only identifies conduct by CCPK as meeting this limitation. (Citing CX-1150C at Q. 313) Respondents argue that there is no evidence that CCUS practices this claim limitation, and Align agrees. (Citing CPHB at 556)

In their reply brief, Respondents contend that dependent claim 8 contains an element requiring the interpolation between initial and final digital models. Respondents argue that the only evidence Align cites concerning this element is the {

} Respondents assert that Align's post hearing brief makes significant misstatements concerning the operation and use of the "Generate Steps" software feature. (Citing RRB § 3.F.1) Respondents say that the interpolation does not actually occur as Align suggests. Rather, Respondents aver that the evidence shows {

} Respondents argue that Align bases its infringement arguments on its misstatements about the way CCPK operators use the "Generate Steps" function and has therefore failed to meet its burden of proof. Respondents contend that, {

} Align has not established the interpolation element.

Staff's Position: Applying the ALJ's rulings, Staff contends that the evidence demonstrates that CCPK directly infringes claim 8 of the '863 patent by selling digital data sets.

(Citing CX-1150C at Q. 313-314 and CX-1198C at 259 (collectively discussing claim 8 of the '863 patent))

Analysis and Conclusions: If I had found that Align had failed to prove that Respondents infringe claim 1 and/or claim 6, it would follow that Align failed to prove infringement of claim 8, which depends from claim 6 (which depends from claim 1). *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n. 9 (Fed. Cir. 1989) ("One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim.")

Nevertheless, I have found that Respondents infringe asserted claims 1 and 6. I also find that Align has shown by a preponderance of evidence that CCPK infringes asserted claim 8 of the '863 patent. I find that credible evidence shows that CCPK practices this claim. Mr. Beers testified that {

} Respondents' argument that they do not perform "interpolation" also conflicts with admissions made during the hearing. (Tr. at 676:23-677:6)

I find unpersuasive Respondents' arguments that they do not infringe because: (i) a phase-based system does not produce the requisite "successive digital data sets;" and (ii) {

} Regarding (i), this appears to be Respondents' "all data sets" non-infringement argument, and is incorrect for the same reasons as described with respect to the second element of claim 1. Regarding (ii), Respondents fail to provide any particular evidence to support their argument, and the evidence shows the contrary. I find persuasive Align's argument that {

} Even if there were modifications after FreeForm is used, it does not change the fact that interpolation is performed by Freeform according to Respondents' admitted process. (*Id.*)

Thus, I find that Align has shown by a preponderance of the evidence that CCPK infringes claim 8 when it produces the data sets in Pakistan according to the process set forth in this claim.

7. Violation of Section 1337(a)

Align's Position: Align argues that Respondents violate 337(a)(1)(B)(ii) by importing, selling for importation, or selling after importation the digital data sets made according to claims 1 and 4-8 of the '863 patent. Alternatively, Align argues that CCPK violates 337(a)(1)(B)(i) by directly infringing claims 1 and 4-8 of the '863 patent under 35 U.S.C. § 271(g) by importing, offering to sell, or selling digital data sets made by Respondents' process. Finally, Align argues that "CCUS uses those same digital data sets, and therefore also violates 337(a)(1)(B)(i) for similar reasons."

Align says that Respondents admit that, { }, digital data from CCPK has been sent to CCUS in the U.S. for the purpose of making the physical models used to fabricate

aligners for sale to U.S. providers. (Citing Tr. at 320:2-9, 320:12-15, 364:20-365:12, 442:19-23) Align asserts that CCPK receives payment from CCUS for that digital data. (Citing Tr. at 320:2-9, 364:20-365:12, 373:24-374:4; CX-1160C.2 at 278:2-9, 294:2-7, 296:3-7; CX-1160C.3 at 422:25-423:8) Thus, Align argues that CCPK sold or offered to sell the digital data in the U.S., and that these digital data sets were brought into the U.S. {

} (Citing Tr. at 316:4-22, 320:12-15, 442:19-23; CX-1160C.1 at 97:22-98:2; CX-1160C.3 at 472:3-17) Align avers that these digital data sets are then used by CCUS to fabricate the infringing aligners that it sells in the U.S. Based on the foregoing, Align asserts that Respondents have jointly or individually imported into the U.S., sold for importation into the U.S., and/or sold in the U.S. after importation the accused digital data sets.

Respondents' Position: Respondents assert the general defense that Respondents cannot infringe the asserted claims of the '863 patent where part of the method is performed in the US and part of the method is performed in Pakistan. Respondents assert that the Federal Circuit has held that "[u]nder section 271(a), the concept of 'use' of a patented method or process is fundamentally different from the use of a patented system or device." (Citing *NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1317 (Fed. Cir. 2005)) Respondents argue that the Federal Circuit held:

> We therefore hold that a process cannot be used 'within' the United States as required by section 271(a) unless each of the steps is performed within this country.

(Citing *id.* at 1318) Respondents contend that the principle, "if a private party practiced even one step of a patented process outside the United States, it avoided infringement liability" has

long been recognized by the Federal Circuit. (Citing *id.* (citing *Zoltek Corp. v. United States*, 51 Fed. Cl. 829, 836 (2002))

Respondents argue that there can be no infringement under 271(a) if any part of a step is performed outside of the U.S. Respondents acknowledge that I held that it is not necessary to show underlying infringement under Section 271 in order to establish a violation of Section 337(a)(1)(B)(i), but disagree with my statutory interpretation. Respondents say that Align has chosen to rely on the substantive provisions of 271 (a), (b) and (g) as the basis for its infringement allegations. Accordingly, Respondents submit that the case law interpreting those provisions applies.

Respondents assert that, even if 271(g) did apply in Section 337 investigations, it would not apply in a case of "divided infringement" where part of the process is performed in the U.S. For example, Respondents say that a federal court declined to apply § 271(g) to domestically-manufactured goods since § 271(a) covers those uses by providing the patentee with a cause of action against the domestic suppliers who use the process in the U.S. to make the CCUS products. (Citing *Asahi Glass Co., Ltd. v. Guardian Indus. Corp.*, 813 F.Supp.2d 602, 613-14 (D. Del. 2011)) Respondents contend that the plain language of § 271(g) also requires importation of "a product which is made by a process patented in the United States." Respondents submit that, if a part of the process is done in the U.S. after importation, there would be no product made by a patented process at the time of importation under § 271(g). Accordingly, Respondents argue that Align's arguments of infringement should be denied as to any patent claims that are practiced, at least in part, both in the United States and in Pakistan.

Staff's Position: Staff says that Align asserts infringement of claims 1 and 4-8 of the '863 patent under 19 U.S.C. § 1337(a)(1)(B)(i) as follows:

> CCPK directly infringes claims 1 and 4-8 of the '863 patent under 35 U.S.C. § 271(g) by offering to sell or selling digital data sets, digital models, or treatment plans in the United States.

Staff says that Align also alleges, in the alternative, infringement under 19 U.S.C. § 1337(a)(1)(B)(ii) for claims 1 and 4-8 of the '863 patent.

Based on the Staff's understanding of the legal standards of patent infringement, Staff is of the view that: (a) Align's § 271(g) infringement theory under 19 U.S.C. § 1337(a)(1)(B)(i) is legally improper, and (b) only Align's alternative infringement theory under 19 U.S.C. § 1337(a)(1)(B)(ii) is legally proper. When applying the Staff's understanding of the legal standards of patent infringement to Align's allegations of infringement under 19 U.S.C. § 1337(a)(1)(B)(i), Staff is of the view that CCPK would not infringe the asserted claims of the '863 patent under 35 U.S.C. § 271(g).

Staff says, however, that given my rulings regarding patent infringement under Section 337 in Order No. 20 (as well as Order No. 58 of Inv. No. 337-TA-562 (Enforcement Proceeding)), Align's § 271(g) infringement theory under 19 U.S.C. § 1337(a)(1)(B)(i) may be determined to be legally proper. Staff asserts, that when applying the ALJ's rulings regarding patent infringement under 19 U.S.C. § 1337(a)(1)(B)(i), the evidence demonstrates that CCPK directly infringes each of the asserted claims of the '863 patent under 35 U.S.C. § 271(g) by selling digital data sets.

Additionally, Staff asserts that the same evidence supports a finding of direct infringement of each of the asserted claims of the '863 patent under 19 U.S.C. § 1337(a)(1)(B)(ii). In particular, Staff argues that the evidence shows that CCPK practices each element of the asserted claims of the '863 patent, and that the evidence demonstrates that CCUS

and CCPK violate 19 U.S.C. § 1337(a)(1)(B)(ii) by importing digital data sets that are produced by the claimed methods of the '863 patent.

Analysis and Conclusions: 19 U.S.C. § 1337(a)(1)(B)(ii) prohibits "[t]he importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that: . . . (ii) are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent." By importing digital data sets (as found in Section II.C, *supra*) that are made by CCPK, which practices the entire process of claims 1, 4, 5, 6, 7, and 8 in Pakistan to produce the digital data sets (as found in Section V.G.1-6, *supra*), Respondents have violated 19 U.S.C. § 1337(a)(1)(B)(ii).

H. The '874 Patent

1. Claim 1

Claim 1 recites:

> A computer-implemented method for use in creating a treatment plan to reposition a patient's teeth from a set of initial tooth positions to a set of final tooth positions, the method comprising:
>
> receiving an initial digital data set representing the teeth at the initial positions, wherein receiving the initial digital data set comprises receiving data obtained by scanning the patient's teeth or a physical model thereof;
>
> generating a set of intermediate positions toward which the teeth will move while moving from the initial positions toward the final positions; and
>
> generating a plurality of successive appliances having cavities and wherein the cavities of successive appliances have different geometries shaped to receive and reposition teeth from the initial positions toward the final positions,

> wherein the plurality of successive appliances is generated at a stage of treatment prior to the patient wearing any appliance of said plurality so as to reposition the teeth.

(JX-006, 32:37-56)

Align's Position: Align submits that the preamble is not limiting, because it merely states the purpose of the claimed method. (Citing *Pitney Bowes*, 182 F.3d at 1305) Align says that Respondents have not asserted the contrary in their *Prehearing Brief*, and have therefore waived such a position.

Align adds that if the preamble was found to somehow be limiting, Respondents practice the preamble when {

} Citing CIB Sections I.E.1, 7 and 10; and CX-1150C, Q. 316) Align notes that Respondents generally assert their "computer implemented" and "treatment plan" arguments as non-infringement bases, which are incorrect for the reasons discussed in CIB section IV.D.

Focusing on the first element of asserted claim 1, Align asserts that CCPK practices this element when it {

} (Citing CIB section I.E.1, 9; and CX-1150C, Q. 317) Align alleges that Respondents do not contest that they infringe this element. (Citing RPHB at 226, 233-34; and RX-129C, Q. 145)

Regarding the second element of asserted claim 1, Align contends that CCPK practices this claim element when {

} (Citing CIB section I.E.7; and CX-1150C, Q. 318) Align says that Respondents generally assert their "all data sets" and "final tooth arrangement" arguments

(Citing RPHB at 226-27, 234) as the bases for their non-infringement arguments, which are incorrect for the reasons discussed in CIB section IV.D.

Align says that CCUS practices the third element of asserted claim 1 when it {

} (Citing CIB section I.E.10; and CX-1150C, Q. 319) Align adds that Respondents assert their "all aligners" argument (Citing RPHB at 227, 234) as a non-infringement basis, which is incorrect for the reasons discussed in CIB section IV.D.

Turning to the fourth element of asserted claim 1, Align argues that CCUS practices this element, because {

} (Citing CIB sections I.E.7, 10; and CX-1150C, Q. 320) Align says that Respondents assert their "all aligners" argument (Citing RPHB at 227-28, 235) as a basis for their non-infringement position, which is incorrect for the reasons discussed in CIB section IV.D.

In its reply brief, Align says that Respondents have asserted only their global non-infringement arguments as to claims 1 and 2.

Respondents' Position: Respondents incorporate by reference the discussion of their general defenses in Sections 3.3.1.1 to 3.3.1.14, *supra*.

Respondents say that Align contends the first and third elements of the claim are practiced by CCUS in the United States and the first and second elements are practiced by CCPK in Pakistan. (Citing Tr. at 585:22-586:13) Respondents reason, therefore, claim 1 of the '874 patent, a method claim, is not infringed. (Citing RIB section 3.3.1.3)

Respondents turn to the preamble of asserted claim 1, and argue that a PHOSITA "would understand a computer-implemented method to require an automated process carried out by

computer programs." Respondents contend that this limitation does not mean a manual method carried out with the assistance of a computer, but rather requires that each step be computationally implemented on a computer. Respondents refer to the discussion of the '511 patent, claim 1, at RIB section 6.2.2, and aver that they do not use a computer implemented method because { } (Citing Tr. 329:17 to 341:21; and RX-129C, Q. 144)

Respondents add that they do not create orthodontic treatment plans. Referring to their argument in the discussion of the '487 patent, Respondents say a "treatment plan" is only created by a Clinician during the treatment of patients. Respondents reason that, because neither of them treats patients nor creates a "treatment plan" "as that term is understood by those skilled in the art," they do not meet this limitation.

Skipping to the second element of asserted claim 1, Respondents argue that, a PHOSITA would understand that this limitation requires that all of the "set" of "intermediate positions" "toward which the teeth will move" from the "initial position" to the "final position" as projected be produced prior to active treatment. Respondents contend that a "final position" can only be a projection at the treatment stage prior to active treatment. Respondents add that {

} Respondents say that the Clinician makes this determination based upon an evaluation of the patient's progress and the Clinician's prescription. Respondents argue that the phase-based system of the Respondents does not meet this limitation. (Citing RX-129C, Q. 146) Respondents conclude that Mr. Beers only identifies conduct by CCPK as meeting this limitation. (Citing CX-1150C, Q. 318) Respondents argue there is no evidence that CCUS practices this claim limitation.

Turning to the third element of asserted claim 1, Respondents argue that a PHOSITA would understand that this limitation requires that all of the "plurality" of "successive appliances" be produced prior to active treatment. Respondents contend that CCUS's phase-based system does not meet this limitation, because the appliances are made as patient treatment progresses. (Citing Tr. 416:8-17; and RX-129C, Q. 147) Respondents add that Mr. Beers only identifies conduct by CCUS as meeting this limitation, and there is no evidence that CCPK practices this claim limitation. (Citing CX-1150C, Q. 319)

Focusing on the fourth element of asserted claim 1, Respondents argue that this limitation requires that "the plurality of successive appliances" be generated prior to the "wearing of any appliance" of "said plurality." Respondents continue that the "stage of treatment that comes after the wearing of an appliance is called 'active treatment.'" Respondents say that stages of treatment are not defined by CCUS's phase-based delivery of aligners, and "the plurality" refers to the entire series of aligners. Respondents aver that this is confirmed by the statements made by Align during the prosecution of this patent, and CCUS's phase-based system does not meet this limitation, {

} (Citing Tr. 416:8-17) Respondents argue that nothing in the patent specification or prosecution history suggests that "stages of treatment" was meant to indicate phase-based delivery of aligners rather than its ordinary meaning to a PHOSITA. (Citing RX-129C, Q. 148) Respondents say that Mr. Beers only identifies conduct by CCUS as meeting this limitation, and there is no evidence that CCPK practices this claim limitation. (Citing CX-1150C, Q. 320)

In their reply brief, Respondents reiterate that they do not prepare "treatment plans," and argue that Align's post hearing brief asks "the Court to apply a different definition of the phrase

that is inconsistent with its plain and ordinary meaning, the evidence introduced in the case, and state law concerning the corporate practice of medicine."

Referring to RRB section 3.F.2, Respondents say that Align's post hearing brief "makes significant misstatements concerning the manner in which [CCPK] operators make the computer files, the functions of the FreeForm software, and the manner in which [CCUS] receives the computer files from [CCPK] and when those files can be used to actually make orthodontic appliances." Respondents reiterate that CCUS uses a phase-based system that is much different from the method claimed in the independent claim of the '874 patent.

Respondents add that RRB section 3.G.1-2 describes the inconsistency between Dr. Valley's opinions concerning invalidity and Align's theories of infringement. Respondents argue that if Respondents are found to infringe based on Align's characterization of the evidence concerning the creation of "digital data sets," the infringed claims must also be found invalid in light of the prior art.

Respondents say the foregoing reasoning applies equally to the dependent claims 2, 38, 39, 41 and 62 of the '874 patent.

Staff's Position: Staff says that Align asserts CCUS directly infringes claims 1, 2, 38, 39, 41, and 62 of the '874 patent "under 35 U.S.C. § 271(g)" by offering to sell, selling, or using aligners in the United States that are made by the joint CCUS/CCPK process, and CCPK contributes to that infringement "under 35 U.S.C. 271(c)" by creating the digital data.

Staff says that based on their understanding of the legal standards of patent infringement, Align's section 271(g) infringement theory is legally improper for the reasons stated in SIB section III.B. Staff expresses the view that, when applying the Staff's understanding of the legal standards of patent infringement to Align's infringement theory, CCUS would not infringe under

35 U.S.C. § 271(g), and thus CCPK would not infringe under 35 U.S.C. § 271(c), any Asserted Claim of the '874 patent.

Staff concedes that, given "the ALJ's rulings regarding patent infringement under Section 337 in Order No. 20 (as well as Order No. 58 of Inv. No. 337-TA-562 (Enforcement Proceeding))", Align's section 271(g) infringement theory may be determined to be legally proper. Staff applies the rulings of Order No. 20, along with "a proper claim construction," and on that basis expresses the views, *infra*.

Staff says that the evidence supports finding infringement of each of the Asserted Claims of the'874 patent "regarding patent infringement under Section 337." Staff continues that the evidence demonstrates that CCUS directly infringes each of the Asserted Claims of the '874 patent by selling or using aligners in the United States that are made by the joint CCUS/CCPK process. Staff cites CX-1150C, Qs. 315-331; and CX-1198C at 276-291 in support of their view.

Staff continues that based upon CCUS' infringement of the Asserted Claims of the '874 patent, the evidence shows that CCPK contributes to the infringement by creating the digital data sets. (Citing "CPRB, pp. 604 (CX exhibits cited for claim 1), 608 (CX exhibits cited for claim 2), 612 (CX exhibits cited for claim 38), 616 (CX exhibits cited for claim 39), 619 (CX exhibits cited for claim 41), and 622 (CX exhibits cited for claim 62); CX-1150C, Qs. 315-331; and CX-1198C at 276-291) Staff adds that its discussion of the elements of contributory infringement with respect to Group A of the '325 Patent, *supra*, also applies here with respect to the Asserted Claims of the '874 patent.

In its reply brief, Staff says that Respondents' arguments of non-infringement of the Asserted Claim of the '874 patent are based on claim constructions that are contradicted by the intrinsic evidence, as discussed in the SIB section X.B. Staff contends that applying the ALJ's

rulings regarding Section 271 and Section 337 and a proper claim construction, the evidence supports finding infringement of the Asserted Claim of the '874 patent.

Analysis and Conclusions: I find that Align has shown by a preponderance of the evidence that Respondents infringe asserted claim 1 of the '874 patent.

First, addressing Respondents' incorporation by reference of their general defenses, I incorporate and reaffirm the analysis and conclusions reached in section V.B.1, *supra*, treating the three issues relevant to the asserted claim of the '874 patent, to wit: (1) whether or not all steps of a method claim must be performed in the same country; (2) whether or not digital data sets are "articles" within the scope of 19 U.S.C. § 1337; and (3) whether or not Align can meet its burden of proving infringement through the testimony of Mr. Beers.

Next, I find that the preamble of asserted claim 1 is limiting. Whether to treat a claim preamble as a limitation is a determination made after a review of the entire patent. *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002). In *Catalina*, the Federal Circuit stated:

> In general, a preamble limits the invention if it recites essential structure or steps, or if it is "necessary to give life, meaning, and vitality" to the claim. Conversely, a preamble is not limiting "where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention."

Id. (citations omitted). The court went on to explain that "a preamble generally is not limiting when the claim body describes a structurally complete invention such that deletion of the preamble phrase does not affect the structure or steps of the claimed invention." *Id.* at 809.

The invention at issue in *Catalina* was a system for distributing coupons to consumers through kiosks. The court had to determine whether the phrase "located at predesignated sites such as consumer stores" was a limitation when it appeared in the preamble. *Id.* at 807-808. The

court found that the phrase was not a claim limitation. The court examined the specification and found that the location of the kiosks was not an essential feature of the invention. *Id.* at 810. The applicants did not rely on the preamble to distinguish the invention from the prior art during prosecution. *Id.* Importantly, the court found that the claim was complete without the preamble:

> Moreover, deletion of the disputed phrase from the preamble of Claim 1 does not affect the structural definition or operation of the terminal itself. The claim body defines a structurally complete invention. The location of the terminals in stores merely gives an intended use for the claimed terminals.

Id.

In *Corning Glass Works v. Sumitomo Electric U.S.A., Inc.*, 868 F.2d 1251, 1256 (Fed. Cir. 1989), the claim preamble was "[a]n optical waveguide comprising." The court found that the preamble served as a limitation because the specification was clear that the invention was limited to fibers working as waveguides. As the court explained: "[t]he invention is restricted to those fibers that work as waveguides as defined in the specification, which is not true with respect to fibers constructed with the limitations of paragraphs (a) and (b) only." *Id.* at 1257.

I find that the situation before me is closer to *Corning Glass* than *Catalina*. Here, the term "computer implemented method" is necessary to give meaning to the claims. The entire '874 patent is clearly devoted to a computer implemented method for completing the steps in the asserted claims. (*See generally* JX-006) The term makes clear that all of the elements listed in the claim body must be performed using a computer. This term adds a limitation that is not otherwise present in the claim. This is supported by the specification, which repeatedly describes using a computer to perform the steps of the methods described in the claims. (*See e.g.* JX-006; 3:7-9, 3:35-47, 4:3-9, 6:61-7:14, 10:12-15, 12:4-15) The preamble is the only place in asserted claim 1 at which the use of a computer to perform the steps in the claim is required.

Respondents contend that their processes are not "computer implemented" as required by the limitation in the preamble, and through this argument they attempt to offer a construction the term "computer implemented method." I reaffirm my rejection of that attempt and my rationale for that rejection detailed, *supra*, at section III.E.3.

Based upon the construction adopted at section III.E.3, I find that Respondents clearly practice the limitation of the preamble that teaches a "computer implemented method." This is best demonstrated by the testimony of Jarrett Pumphrey, CEO of CCUS, in which he admitted that Respondents' process is implemented using computers and digital data, and described in detail the portions of the process that are automated and the portions that are interactive. (Tr. 314:4-320-15; 322:17-326:9; 329:11-339:10; 249:1-3; and CX-78 at p. 055, *et seq.*)

Respondents' contention that they do not create orthodontic treatment plans is another disingenuous attempt to argue construction after having failed to provide a construction for this term in the SRJCCC, and it is rejected as waived. Nevertheless, assuming arguendo that one were to find that the Respondents' construction of the term "treatment plan" was not waived, I find that their proposed construction is clearly incorrect. I refer to the discussion of construction of the term "treatment plan" set forth in section III.G.3, *supra*, and I reaffirm the construction applied to the term "treatment plan" and the rationale for it.

Applying the correct construction of the term to the term "treatment plan," I find that CCPK practices the preamble of asserted claim 1 by {

}

Respondents did not dispute that they practice the first element of asserted claim 1, and I find that the evidence offered by Align demonstrates that this element practiced when {

} (CX-1157C.1, 41:24-47-5, 47:22-50-17; CX-1157C.2)

Turning to the second element of asserted claim 1, as discussed in section V.E, *supra*, Align's expert, Dr. Beers, opined that this element is met. He testified that {

}

{

} which is discussed in detail in section V.E, *supra*. In the interest of brevity, I will not repeat Mr. Latif's testimony and my discussion of it here; but by this reference I incorporate the testimony and my analysis of it into the instant discussion.

{

} His testimony is set forth in section V.E., *supra*. In the interest of brevity, I will not repeat Dr. Arif's relevant testimony and my discussion of it here; but by this reference I incorporate the testimony and my analysis of it into the instant discussion.

Asserted claim 1 of the '874 patent teaches a computer implemented method of creating a treatment plan to reposition a patient's teeth from a set of initial tooth positions to a set of final desired positions. The second element of asserted claim 1 is met when data for individual tooth paths has been entered into FreeForm by the operator, and the operator causes FreeForm to generate the aggregate tooth paths into a set of intermediate positions toward which the teeth will move while moving from the initial positions toward a final position. The fact that asserted claim 1 does not specifically teach the interactive approach used by CCPK in entering the toot path data for each individual tooth prior to generating the set of intermediate positions does not detract from this finding. Asserted claim 1 states "the method comprising," and that term is well understood in patent law to mean "including but not limited to." (*See e.g. Exergen Corp v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1319 (Fed. Cir. 2009)

Regarding the third element of asserted claim 1, Respondents assert that their system does not generate a plurality of appliances "from the initial positions toward the final positions," because their system is phased and the appliances are made as patient treatment progresses. It is obvious from Respondents' asserted defense that they are confusing the terms "to" and "toward" as they relate to the movement of a patient's teeth in the scheme of the '874 patent.

The term "to" generally means that the object reaches a destination, and the term "toward" generally means that the object is moving in the direction of a destination. (*Crane Co. et al. v. Sandenvendo America, Inc.*, 2009 U.S. Dist. LEXIS 47509 at *20-21 (E.D. Tex. June 5,

2009)) Both terms are used in asserted claim 1. In the preamble the claim refers to repositioning a patient's teeth from initial positions ***to*** final positions. In the second and third elements of asserted claim 1, the inventor describes the movement (or repositioning) of the patient's teeth "from the initial positions **toward** the final positions." (JX-006, 32:39, 32:46-47, and 32:52-53)

The use of these two different terms within the claim makes clear that the method is to be used to create a treatment plan to achieve the final result of moving the patient's teeth from an initial position to reach a final position. In accomplishing this goal, the elements of the claim teach, *inter alia*, generating a plurality of intermediate positions to assist the teeth to move in the direction of the desired final position. In addition, the claim requires generating a plurality of appliances designed to move teeth from the initial positions in the direction of the final position.

The claim does not teach that the plurality of intermediate positions or the plurality of the successive appliances about which it speaks must, in fact, move the teeth from the initial position to actually reach the final position. The claim anticipates the specific set of facts present here in which the plurality of positions and appliances are directed at a partial movement toward the final goal.

Respondents do not deny that they generate a plurality of successive appliances as described in the third element; they only deny that they produce all of the appliances needed to move the patient's teeth from the initial positions to reach the final positions. Achieving this result is not a requirement of the third element of asserted claim 1. I find that CCUS practices the third element of asserted claim 1 when it generates a plurality of appliances as described in the third element to reposition teeth from the initial positions in the direction of the final positions. (CX-1150C, Q. 319)

Consistent with my finding regarding the third element, I find that the fourth element of asserted claim 1 is practiced as long as the plurality of successive appliances is generated at a stage of treatment prior to the patient wearing any appliance of "said plurality" so as to reposition the teeth. This limitation does not require that all of the successive appliances necessary to cause the teeth to reach their final positions be generated before the patient wears the first appliance. Respondents concede that Mr. Beers identifies conduct by CCUS as meeting this limitation. (Citing CX-1150C, Q. 320)

Align's argument and my conclusion regarding the third and fourth elements of claim 1 are wholly consistent with Align's position when processing the application that resulted in the '874 patent. Align argued that neither of the two references cited by the examiner contemplated making a plurality of appliances at the outset of treatment. They taught making one set of appliances at a time. Align did argue that claim 1 taught:

> "...generating, **at the outset of treatment**, a plurality of sets of appliances having cavities and wherein the cavities of successive appliances have different geometries shaped to receive and reposition teeth *from the initial positions* ***to*** *the final positions*."

(JX-016, at 273)(underlined bold in original)(italics added)

> Subsequently, the applicant submitted an amended claim wherein the third element read:
>
> "generating a plurality of sets of appliances having cavities and wherein the cavities of successive appliances have different geometries shaped to receive and reposition teeth from the initial positions to the final positions,"

(JX-016, at 293)

A further amendment was submitted, however, that contained the language of the third and fourth elements of claim 1 as it appears in the '874 patent, omitting *inter alia* the word "to" and substituting for it the word "toward." This change was part of an amendment that occurred

at the suggestion of the examiner during a telephone interview between the examiner and the applicant's representative. (*See* JX-016, at 309 and 300 respectively) Ultimately the patent issued with the word "toward" in the third element of claim 1. (JX-016, at 382)

It is apparent from the discussions chronicled in the application wrapper, that the focus was primarily on the difference between creating one set of appliances at the outset of treatment versus creating a plurality of appliances. (*See e.g.* JX-016, at 273, 274, 300) Thus, while it is true that the applicant did use the word "to" at one point during the discussion, that was not the basis for the final action issuing the '874 patent, which ultimately issued using – at the apparent suggestion of the examiner – the word "toward."

Based upon the foregoing, I find that Align has shown by a preponderance of the evidence that the concerted efforts of CCUS and CCPK practice each and every limitation of claim 1 when the digital data sets created by CCPK are used by CCUS to fabricate aligners.

2. Claim 2

Asserted claim 2 depends from claim 1 and recites:

> The method of claim 1, wherein receiving the initial digital data set comprises receiving data obtained by scanning a physical model of the patient's teeth.

(JX-006, 32:57-59)

Align's position: Align contends that CCUS practices this element by {

} (Citing CIB sections I.E.1 and 9; and CX-1150C, Q. 322) Align alleges that Respondents did not contest that they infringe this element.

(Citing RPHB at 228, 235; and RX-129C, Q. 149) Align concludes that "Respondents infringe for the same reason as claim 1."

Respondents' Position: The Respondents contend that they do not infringe this dependent claim, because they do not infringe the independent claim. Respondents add that there is no infringement of claim 2, because "certain steps in claims 1 and 2 are alleged to take place in Pakistan, and certain steps in the U.S." (Citing RIB section 3.3.1.3)

Analysis and Conclusions: Respondents do not deny that CCUS digitally scans a physical model of the patient's teeth. They merely argue that they do not infringe this dependent claim based upon their argument that they do not infringe asserted claim 1 from which claim 2 depends.

If I had found that Align had failed to prove that Respondents infringe claim 1, it would follow that Align failed to prove infringement of claim 2, which depends from claim 1. *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n. 9 (Fed. Cir. 1989) ("One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim.")

Nevertheless, I have found that Respondents infringe asserted claim 1. In addition, Align has produced credible evidence that CCPK practices this element by {

} (See testimony of Atif Kiyyani at CX-1157C.1, 18:22-19:8, 23:15-16, 26:2-16, 41:24-47-5, 47:22-50-17; and CX-1157C.2, all of which is discussed in detail in section V.H.1, *supra*)

I find, therefore, that CCPK practices the element of asserted claim 2 of the '874 patent.

3. Claim 38

Asserted claim 38 depends from claim 1 and recites:

> The method of claim 1, wherein generating the set of intermediate positions includes receiving data indicating restraints on movement of the patient's teeth and applying the data to generate the intermediate positions.

(JX-006, 34:56-59)

Align's position: Align argues that CCPK practices this element when {

} (Citing, CIB section I.E.6; and CX-1150C, Q. 324) Align says that Respondents assert their "computer-implemented" argument as a non-infringement basis, which is incorrect for the reasons discussed in CIB section IV.D. (Citing RPHB at 228, 235-36) Align says that Respondents also argue that the "data indicating restraints on movement" does not include bridges or other objects that are not moved. (*Id.* at 228, 236) Align says Respondents' argument is unclear; "but this appears to be an improperly raised claim construction issue that is unsupported by any particular evidence." Align concludes "Respondents infringe for the same reason as claim 1."

In its reply brief Align says that Respondents' arguments regarding claim 38 attempt to read in the "computer-implemented" requirement to the claim, which is a claim construction argument not properly raised, and therefore waived. (Citing CRB section IV.F.4) Align adds that "Respondents seem to apply a restrictive construction of the term "restraints" – to apply only to teeth, and not simulated tooth objects (bridges) – which Respondents also failed to raise in the *SRJCCC*, and is therefore waived." (Citing Tr. at 8:4-9:4)

Respondents' Position: Respondents reiterate that they do not infringe this dependent claim, because they do not infringe the independent claim, and there is no infringement of claim 38 because certain steps in claims 1 and 38 are alleged to take place in Pakistan, and certain steps in the U.S. (Citing RIB section 3.3.1.3)

Respondents continue, Mr. Beers relies solely upon the case submission form that includes a prescription from a Clinician. (Citing CX-1150C, Q. 324) Respondents say that Mr. Beers states that because a {

} that this limitation is met by the Respondents. Respondents assert that claim 1 requires a "computer-implemented method" for receiving "data indicating restraints on movement of the patient's teeth" and for "applying the data to generate the intermediate positions." Respondents argue that an operator reading a prescription would not meet this limitation. Respondents add that this limitation requires that the "data indicating restraints on movement" apply to the teeth that are being moved, not bridges or other objects that are not moved. Respondents reason that this limitation is not met by the Respondents, (Citing RX-129C, Q. 150) and there is no evidence that CCUS practices this limitation.

Analysis and Conclusions: If I had found that Align had failed to prove that Respondents infringe claim 1, it would follow that Align failed to prove infringement of claim 38, which depends from claim 1. *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n. 9 (Fed. Cir. 1989) ("One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim.")

Nevertheless, I have found that Respondents infringe asserted claim 1. In addition, Align has produced credible evidence that CCPK practices this element. I found in section V.E. and I here reaffirm that, {

}

{

}

Based upon the foregoing, I find that CCPK practices the element of asserted claim 38.

4. Claim 39

Asserted claim 39 depends from claim 1 and recites:

> The method of claim 1, wherein generating the set of intermediate positions includes determining the minimum amount of transformation required to move each tooth from the initial position toward the final position and creating the intermediate positions to require the minimum amount of movement.

(JX-006, 34:60-65)

Align's position: Align contends that CCPK practices this element when {

} Align says that rather than addressing this, Respondents take issue with Mr. Beers' description of their process, and argue that they do not infringe because the linear translation is not necessarily the most "effective" treatment. (Citing

RPHB at 229, 236; and RX-129C, Q. 151) Align asserts that "effective" does not appear in claim 39, and Respondents' argument is therefore irrelevant. Align says that Respondents also argue that {

}

(Citing RPHB at 229, 236; and RX-129C, Q. 151) Align contends that Respondents presented no evidence to support this argument and adds that this after-occurring modification does not change the fact that {

} Align concludes that "Respondents infringe for the same reason as claim 1."

In its reply brief Align says that it presented sufficient evidence through the testimony of Mr. Beers and CCPK's operator, Mr. Latif, to show that {

} (Citing CX-1150C, Qs. 135, 326, 328; and CX-1158C.1-3 at 62:25–75:13) Align says that Respondents seek to apply their "individual judgement" argument to this element; but it is unsupported in view of the cited evidence. Align adds that such an adjustment is irrelevant, as the infringing action has already occurred. Align concludes that Respondents have no infringement defense for this claim.

Respondents' Position: Respondents argue that they do not infringe this dependent claim, because they do not infringe the independent claim. Respondents reiterate that there is no infringement of claim 39, because certain steps in claims 1 and 39 are alleged to take place in Pakistan, and certain steps in the U.S. (Citing RIB section 3.3.1.3)

Respondents add that the evidence demonstrates the CCPK operators manually dictate the projected tooth movement. (Citing Tr. 329: 11-341:21) Respondents aver that the CCPK

{

} (Citing Tr. 329:17-341:21) Respondents say the process described at the hearing was detailed; but never included any discussion of "minimum amounts of transformation required" or "creating the intermediate positions to require the minimum amount of movement." Respondents conclude that this limitation is not met by the Respondents. (Citing RX-129C, Q. 151) Respondents add that there is no evidence that CCUS practices this limitation.

Analysis and Conclusions: If I had found that Align had failed to prove that Respondents infringe claim 1, it would follow that Align failed to prove infringement of claim 39, which depends from claim 1. *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n. 9 (Fed. Cir. 1989) ("One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim.")

Nevertheless, I have found that Respondents infringe asserted claim 1. In addition, Align has produced credible evidence that CCPK practices this element. Mr. Latif testified about how

{

} (CX-1158C.1; 48:9-21, 49:9-18, 51:4-10, 58:10-21, 62:25-63:5, 76:1-5)

Based upon the foregoing, I find that CCPK practices the element of asserted claim 39.

5. Claim 41

Asserted claim 41 depends from claim 1 and recites:

> The method of claim 1, wherein generating the set of intermediate positions includes generating intermediate positions for at least one tooth between which the tooth undergoes translational movements of equal sizes.

(JX-006, 35:4-7)

Align's position: Align argues that CCPK practices this element when {

} (Citing Tr. at 676:23-677:5) Align contends that by definition, "a linear interpolation along a straight line translational movements of equal sizes." Align says that Respondents again argue that {

} Align concludes that "Respondents infringe for the same reason as claim 1."

In its reply brief Align says that regarding claim and 41, Align presented sufficient evidence through the testimony of Mr. Beers and CCPK's operator, Mr. Latif, to show that {

} but it is unsupported in view of the cited evidence. Align adds that such an adjustment is irrelevant, as the infringing action has already occurred. Align concludes that "Respondents have no infringement defense for these claims."

Respondents' Position: Respondents argue that they do not infringe this dependent claim, because they do not infringe the independent claim. Respondents add there is no infringement of claim 41, because certain steps in claims 1 and 41 are alleged to take place in

Pakistan, and certain steps in the U.S. (Citing RIB section 3.3.1.3) Respondents assert that there is no competent evidence that the Respondents generate "intermediate positions for at least one tooth between which the tooth undergoes translational movements of equal sizes." To the contrary, Respondents say the evidence demonstrates the {

} (Citing Tr. 329:17-341:21) Respondents say the process described at the hearing included no discussion of "generating intermediate positions for at least one tooth between which the tooth undergoes translational movements of equal sizes." Respondents add that Align's reference to the "generate next steps" function of the Freeform software is also unavailing because the evidence demonstrated that {

} (Citing Tr. 336:8-338:5)

Respondents conclude there is no real evidence of tooth movement of equal sizes, and therefore, this limitation is not met by the Respondents. (Citing RX-129C, Q. 152) Finally, Respondents argue there is no evidence that CCUS performs this this limitation.

Analysis and Conclusions: If I had found that Align had failed to prove that Respondents infringe claim 1, it would follow that Align failed to prove infringement of claim 41, which depends from claim 1. *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n. 9 (Fed. Cir. 1989) ("One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim.")

Nevertheless, I have found that Respondents infringe asserted claim 1. In addition, Align has produced credible evidence that CCPK practices this element. Align contends that by

definition, "a linear interpolation along a straight line translational movements of equal sizes." Jarrett Pumphrey admitted that in the accused process, {

} (CX-107C at 5:33) Respondents' argument that they do not perform "interpolation" also conflicts with admissions made during the hearing. (Tr. at 676:23-677:6)

The evidence shows that CCPK practices this element of claim 41 when its {

}

I find that CCPK practices the element of asserted claim 41.

6. Claim 62

Asserted claim 62 depends from claim 1 and recites:

> The method of claim 1, further comprising delivering data identifying the intermediate treatment positions to an appliance fabrication system for use in fabricating at least one orthodontic appliance structured to move the patient's teeth toward the final position.

(JX-006, 36:12-16)

Align's position: Align contends that CCPK practices this element when {

} (Citing CIB sections I.E.9 and 10; and CX-1150C, Q. 330) Align alleges that Respondents did not contest that they infringe this element. (Citing RPHB at 230, 237; RX-129C, Q. 153) Align concludes that "Respondents infringe for the same reason as claim 1."

Respondents' Position: Respondents argue that they do not infringe dependent claim 62, because they do not infringe the independent claim. Respondents continue that there is no infringement of claim 62, because certain steps in claims 1 and 62 are alleged to take place in Pakistan, and certain steps in the U.S. (Citing RIB section 3.3.1.3) Respondents contend they do not meet this claim limitation, because even under Align's case theory there are not "final positions." Respondents aver that the evidence shows that the goal position for patients has always been the arrangement stated in the doctor's prescription. (Citing Tr. 353:5-23) Respondents assert that there have never been "final positions" in CCUS's process. Respondents conclude that Align has not offered any evidence that CCPK fabricates an appliance or practices this claim limitation.

Analysis and Conclusions: If I had found that Align had failed to prove that Respondents infringe claim 1, it would follow that Align failed to prove infringement of claim 62, which depends from claim 1. *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n. 9 (Fed. Cir. 1989) ("One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim.")

Nevertheless, I have found that Respondents infringe asserted claim 1. In addition, Align has produced credible evidence that CCPK practices this element. I found in section V.H.1 that Respondents do not deny that they generate a plurality of successive appliances as described in the third element; they only deny that they produce all of the appliances needed to move the patient's teeth from the initial positions to reach the final positions. At the hearing on this matter, Respondents' witness, Jarrett Pumphrey, testified that {

} (Tr. 315:24-318:3)

Based upon the foregoing, I find that CCUS directly infringes asserted claim 62.

7. Violation of Section 1337(a)

Based upon all of the foregoing I have found that there is an act of direct infringement of asserted claim 1 of the '874 patent when CCUS and CCPK act in concert to fabricate appliances using the data sets created by CCPK in the method described in the preamble and the first and second elements of asserted claim 1 and subsequently imported into the United States. I have found that CCPK practices the preamble, and the first and second elements of asserted claim 1 of the '874 patent. In addition I have found that CCUS practices all limitations added by dependent claims 2 and 62, and that CCPK practices all limitations added by dependent claims 38, 39 and 41. Because CCUS and CCPK act in concert to infringe claim 1, I find that CCUS and CCPK also act in concert to infringe dependent claims 2, 38, 29, 41 and 62 (infringement of which includes practice of all elements of claim 1). CCPK contributes to this infringement by providing digital data sets for importation, as explained below.

In section V.B.17, I described in detail how the elements required to demonstrate contributory infringement are met by Respondents, and I concluded that those elements have been met for the '874 patent. I will not repeat that discussion here; but I reaffirm my findings and the rationale for them.

Respondents' infringement results in a violation of Section 337. 19 U.S.C. § 1337(a)(1)(B)(ii) prohibits "[t]he importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of

articles that: . . . (ii) are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent." By creating appliances using the method described in asserted claim 1, importing and using digital data sets that are made by the process of claim 1 (as found in Section II.C, *supra*), Respondents have violated 19 U.S.C. § 1337(a)(1)(B)(ii).

VI. DOMESTIC INDUSTRY

A. Applicable Law

In patent-based proceedings under section 337, a complainant must establish that an industry "relating to the articles protected by the patent...exists or is in the process of being established" in the United States. 19 U.S.C. § 1337(a)(2) (2008). Under Commission precedent, the domestic industry requirement of Section 337 consists of an "economic prong" and a "technical prong." *Certain Data Storage Systems and Components Thereof*, Inv. No. 337-TA-471, Initial Determination Granting EMC's Motion No. 471-8 Relating to the Domestic Industry Requirement's Economic Prong (unreviewed) at 3 (Public Version, October 25, 2002).

The "economic prong" of the domestic industry requirement is satisfied when it is determined that the economic activities set forth in subsections (A), (B), and/or (C) of subsection 337(a)(3) have taken place or are taking place. *Certain Variable Speed Wind Turbines and Components Thereof*, Inv. No. 337-TA-376, USITC Pub. No. 3003, 1996 ITC LEXIS 556, Comm'n Op. at 21 (Nov. 1996). With respect to the "economic prong," 19 U.S.C. § 1337(a)(2) and (3) provide, in full:

> (2) Subparagraphs (B), (C), (D), and (E) of paragraph (1) apply only if an industry in the United States, relating to the articles protected by the patent, copyright, trademark, mask work, or design concerned, exists or is in the process of being established.
>
> (3) For purposes of paragraph (2), an industry in the United States

> shall be considered to exist if there is in the United States, with respect to the articles protected by the patent, copyright, trademark, mask work, or design concerned-
>
> (A) significant investment in plant and equipment;
>
> (B) significant employment of labor or capital; or
>
> (C) substantial investment in its exploitation, including engineering, research and development, or licensing.

Given that these criteria are listed in the disjunctive, satisfaction of any one of them will be sufficient to meet the domestic industry requirement. *Certain Integrated Circuit Chipsets and Products Containing Same*, Inv. No. 337-TA-428, Order No 10, Initial Determination (Unreviewed) (May 4, 2000), citing *Certain Variable Speed Wind Turbines and Components Thereof*, Inv. No. 337-TA-376, Commission Op. at 15, USITC Pub. 3003 (Nov. 1996).

To meet the technical prong, the complainant must establish that it practices at least one claim of the asserted patent. *Certain Point of Sale Terminals and Components Thereof*, Inv. No. 337-TA-524, Order No. 40 (April 11, 2005). "The test for satisfying the 'technical prong' of the industry requirement is essentially same as that for infringement, i.e., a comparison of domestic products to the asserted claims." *Alloc v. Int'l Trade Comm'n*, 342 F.3d 1361, 1375 (Fed. Cir. 2003). The technical prong of the domestic industry can be satisfied either literally or under the doctrine of equivalents. *Certain Excimer Laser Systems for Vision Correction Surgery and Components Thereof and Methods for Performing Such Surgery*, Inv. No. 337-TA-419, Order No. 43 (July 30, 1999).

B. Economic Prong

Align's position: Align says that Respondents do not contest domestic industry, and Align believes it is not at issue. Align says that its primary business is the development, design,

manufacture, sale and marketing of its Invisalign system in the U.S. (Citing CX-1235C at Q. 19; CX-1236C at Q. 8; CX-1237C at Q. 18)

Align asserts that it has made significant investment in plant, equipment, labor, and capital. Align says that it is headquartered in San Jose, California ("California Facility"). (Citing CX-1236C at Q. 4) Align continues that the California Facility has approximately {

} (Citing CX-1237C at Q. 26) Align says that most of {

} work at the California Facility. (Citing *Id.* at Q. 27) Align continues that it {

} (Citing *id.*) Align's says that its California Facility { } (Citing *Id.*)

Align says that it currently employs approximately { } employees in the U.S., including {

} (Citing *Id.* at Q. 30) Align says that the U.S.-based R&D employees design and improve Align's process, including the proprietary "Treat" suite of software applications. (Citing *Id.* at Q. 31) Align continues that its "Treat" software, which has been developed, upgraded, and maintained on a continuing basis since Align's inception, assists its technicians in preparing treatment plans for the planned movement of patients' teeth. (Citing CX-1236C at Q. 15-21; CX-1237C at Q. 33) Align says that as of 2010, Align had {

} R&D employees developing, upgrading, and testing "Treat." (Citing CX-1236C at Q. 24; CX-1237C at Q. 31) Align continues that in 2010 alone, Align's {

} (Citing CX-1237C at Q. 32)

Align says that it has also {

} (Citing *Id.* at Q. 52) Align says that in 2010 and 2011, Align {

} (Citing *id.*) Align says that all of the technology that is used {

} (Citing CX-1236C at Q. 11-14; CX-1237C at Q. 52)

Align asserts that because Align's primary business is the development, design, manufacture, sale, and marketing of its Invisalign system and its various elements, and because all of the asserted patents pertain to the Invisalign system, most of Align's business activities constitute exploitation of the asserted patents in the U.S., as well as overseas. Align says that it has { } in developing the manufacturing capacity and software necessary to create highly customized, highly precise, medical-quality aligners in volume. (Citing CX-1236C at Q. 10) Align says that since 2005, Align has {

} (Citing CX-1237C at Q. 37-38) Align says that as a result of these investments, over 1.2 million patients in the U.S. have entered treatment with Invisalign. (Citing *Id.* at Q. 50)

Align says that it directly supports the academic and research community through funding and grants for Invisalign-related scientific research. For example, Align {

} to better understand orthodontic treatment with clear aligners. (Citing *id.* at Q. 37)

Align says that it also { } to train and certify over 67,000 dental professionals in the U.S. on the use of its Invisalign

system. (Citing *Id.* at Q. 41-42) Align continues that a U.S. team of Align personnel is devoted to developing and implementing the training and certification of dental professionals. (Citing *Id.* at Q. 40)

Align avers that it made significant investments to create and establish a U.S. market for Invisalign. Align says that its U.S. marketing consists of direct-to-consumer marketing, including print, television, and social media advertising; materials for use in doctors' offices; presentations at events; direct-to-doctor advertising; and e-mail campaigns. (Citing *Id.* at Q. 44-45) Align says that in 2010 alone, { } to market Invisalign in the U.S. (Citing *id.* at Q. 46)

Align contends that it also has an extensive patent portfolio and an in-house team that works with outside counsel to manage that portfolio. (Citing *id.* at Q. 55) Align says that it has spent considerable amounts of money to defend its intellectual property rights, including for example, { } pursuing patent and trade secret infringement suits in multiple venues against OrthoClear. (Citing *id.*) Align continues that Align previously offered a license to OrthoClear for Invisalign technology, although that deal was never consummated. (Citing *id.* at Q. 57) Align says that it estimates it likely { } engaging in those licensing negotiations. (Citing *id.*)

Align argues that it has introduced more than enough evidence to prove that the economic prong of Domestic Industry is satisfied and Staff agrees. (Citing SIB at 115-17) Align says that although Respondents cannot contest Align's showing (Tr. at 47:6-8, 78:13-19, 79:9-17.), they argue that:

> [w]hile Align has presented evidence of expenditures relating to its Treat software and its business generally, it has not made a prima facie showing of how those expenditures relate to each of the specific patents asserted in this investigation

(Citing RIB at 148)

Align argues that Respondents' argument is contrary to the applicable precedent, which does not require expenditures to be segregated on a per patent basis. (Citing *Certain Wireless Commc'n Devices,* Inv. No. 337-TA-745, I.D. at 365 (Apr. 24, 2012) ("the Commission recognizes those who hold intellectual property rights do not usually account for expenses and profit on a per patent basis"); *Certain Stringed Musical Instruments*, Inv. No. 337-TA-586, Comm'n Op. at 26 (Dec. 2009) ("A precise accounting is not necessary, as most people do not document their daily affairs in contemplation of possible litigation."))

Respondents' Position: Respondents' Position: Respondents say that while Align has presented evidence of expenditures relating to its Treat software and its business generally, it has not made a prima facie showing of how those expenditures relate to each of the specific patents asserted in this investigation. Respondents conclude, as a result, that Align has failed to make a prima facie case that it meets the economic prong of the domestic industry requirement.

Respondents say that Align's Post-Hearing Brief has presented evidence of expenditures relating to its Treat software and its business generally, but still has not made a prima facie showing of how those expenditures relate to each of the specific patents asserted in this investigation.

Staff's Position: Staff says that I determined that Respondents have waived their right to contest the issue of domestic industry in this investigation and that Align only has to put on a *prima facie* case demonstrating that there is domestic industry. (Citing Tr. at 47:20-48:4)

Staff contends that the evidence supports finding that Align has made significant investment in both (i) plant and equipment and (ii) labor and capital with respect to Align's Invisalign System. Staff says that Align's principal place of business is located in San Jose,

California ("California Facility"), and consists of approximately { } (Citing CX-1237C at Q. 25-26) Staff continues that the California Facility is home to Align's {

} (Citing *id.*) Staff says that the California Facility {

} (Citing *id.*) Staff continues that Align's {

} (Citing *id.*) Staff says that prior to moving into the California Facility, Align rented a facility in Santa Clara, California that was approximately {

} (Citing *id.*)

Staff says that in 2010, Align had over {

} (Citing CX-1237C at Q. 30 and 32) Staff continues that the U.S.-based research and development employees work to design and improve Align's process, including Align's proprietary software. (Citing CX-1237C at Q. 31 and 33) Staff says that in 2010, Align {

} (Citing CX-1237C at Q. 32 and 37) Staff continues that Align also { } to train dental professionals in the United States on how to use Invisalign and {

} to market Invisalign in the United States. (Citing CX-1237C at Q. 42 and 46) Staff says that between 2005 and 2011, Align { } to develop and upgrade its software. (Citing CX-1237C at Q. 38) Staff continues that over 1.2

million patients in the United States have entered treatment with Invisalign. (Citing CX-1237C at 50)

Staff concludes that the evidence supports finding that Align has made significant investment in both (i) plant and equipment and (ii) labor and capital with respect to Align's Invisalign System.

Staff says that based on my ruling that Respondents have waived their right to contest the issue of domestic industry (Citing Tr. at 47:20-48:4), Respondents' arguments on domestic industry should be rejected. Staff says that Respondents did not Respondents did not dispute (and did not rebut) Align's evidence. Staff concludes as a result that Complainant has made a *prima facie* case showing that there is a domestic industry with respect to each Asserted Patent. (Citing *Certain Bulk Welding Wire Containers*, Inv. No. 337-TA-686, Final Initial Determination on Violation of Section 337 at 286-292 (July 29, 2010); *Certain Self-Cleaning Litter Boxes*, Inv. No. 337-TA-625, Final Initial Determination on Violation of Section 337 at 190 (Dec. 1, 2008))

Analysis and Conclusions: I found that Respondents waived the right to contest the issue of domestic industry. (Tr. at 46:20-48:4; *see also* Tr. at 72:10-82:7) Because of this waiver, I instructed Align that it only needed to make a prima facie showing of domestic industry. (*Id.*) I find that Align has made the required *prima facie* showing that it meets the economic prong of the domestic industry requirement. In Section VI.C, *infra*, I find that Align practices claims of 6 of the 7 patents in suit by using software to design and manufacture dental aligners. Align { } on its facility in California (CX-1237C at Q.25-26) which is home to Align's {

} (CX-1237C at Q. 27) Align's

research and development employees work to design and improve Align's processes, including the "treat" suite of software applications it uses to practice the patents in suit discussed above. (See CX-1237C at Q. 31) Based on this evidence, I find that Align has made a *prima facie* showing that it has made a significant investment in plant and equipment related to the articles protected by the patents in suit.

Align employs { } who "work to design and improve Align's process, including the proprietary 'treat' suite of software applications." (CX-1237C at Q. 31) Align pays its { } (CX-1237C at Q. 32). Based on this evidence, I find that Align has made a *prima facie* showing that it has made significant employment of labor or capital in the United States related to the articles protected by the patents in suit.

Because Align has made a prima facie showing that it has made a significant investment in plant and equipment and has made significant employment of labor or capital in the United States, I find that Align has established that the Economic Prong of Domestic Industry is met. *See* 19 U.S.C. §§ 1337(a)(2) and (3).

C. Technical Prong

1. The '325 Patent (claim 21)

Align's position: Align asserts that Respondents do not contest domestic industry, and thus Align believes it is not at issue. (Citing Tr. at 618:21-619:2) Align says that because I instructed Align to present a *prima facie* case of domestic industry, Align submitted substantial evidence (as outlined in the chart below) that it practices at least claim 21 of the '325 patent. (Citing Tr. at 47:6-13)

CLAIM	ALIGN METHOD
21. A method for fabricating a polymeric shell dental appliance for moving a patient's teeth, said method comprising:	Align fabricates a series of individualized, custom-created polymeric aligners, used to reposition teeth. CX-1235C at Q. 20, 23.
providing a digital data set representing a modified tooth arrangement for a patient, wherein the modified tooth arrangement comprises a repositioned tooth arrangement for a plurality of the patient's teeth;	{ }
controlling a fabrication machine based on the digital data set to produce a positive model of the modified tooth arrangement; and	Using the digital data set of the digital model with a modified tooth arrangement, Align fabricates a positive model of the patient's teeth in the modified arrangement. CX-1235C at Q. 20, 23.
producing the polymeric shell dental appliance as a negative of the positive model, wherein the polymeric shell appliance covers a plurality of teeth in an upper or lower jaw of the patient, and wherein the polymeric shell appliance is configured to move at least some of the patient's teeth substantially to the modified tooth arrangement.	Align fabricates at least one dental aligner as a negative of the positive model by molding polymeric material over the positive model. CX-1235C at Q. 23. Each aligner covers a plurality of teeth in an upper or lower jaw of the patient, and the polymeric shell appliance is configured to move at least some of the patient's teeth substantially to the modified tooth arrangement. *Id.* at Q. 20, 23.

Align argues that this chart is sufficient, by itself, to provide a *prima facie* case of domestic industry. (Citing *Certain Inkjet Ink Supplies*, Inv. No. 337-TA-691, Order No. 18 at 25-26 (Aug. 2010)) Align says that Align's expert witness on the technical prong of the domestic industry requirement, Dr. Valley, provided unrebutted testimony that Align practices each of the asserted claims (including claim 21 of the '325 patent), and that Invisalign is the commercial embodiment of Align's asserted patents. Align continues that Dr. Valley's testimony is based upon: (i) her familiarity with Align's products and methods for designing and manufacturing these products and (ii) her review of the declaration of Dr. Eric Kuo and Align's domestic industry charts (both of which set forth, in detail, Align's processes) for the patents in suit in this Investigation; and (iii) an application of both parties' proposed claim constructions. (Citing Tr. at 803:15-18, 807:20-808:1; CX-1247C at Q. 45-46; 70-74, 486-488; CX-1254C at 8-9, 11-12, 79-80) Align contends that this testimony is enough to establish a *prima facie* case for domestic industry. (Citing *Certain Self-Cleaning Litter Boxes*, Inv. No. 337-TA-625, I.D. at 190 (Oct.

2011) (Rogers, J.); *Certain Bulk Welding Wire Containers*, Inv. No. 337-TA-686, I.D. at 290-91 (July 2010) (Rogers, J.))

Align argues that Respondents cannot contest Align's showing. (Citing Tr. at 47:6-8, 79:9-17)

Respondents' Position: Respondents assert that Align failed to make a prima facie case that it satisfies the technical prong requirement with regard to at least one claim of each of the patents in suit. Respondents say that Align's evidence relating to the technical prong as it relates to each patent, a portion of the witness statement of Eric Kuo, was stricken as improper expert testimony. (Citing Tr. 45:12-48:4) Respondents continue that Align is left with conclusory statements that do not satisfy its burden of proof. Respondents conclude, as a result, that Align has failed to show that it meets the technical prong of the domestic industry requirement with respect to each asserted patent.

Staff's Position: Staff says that I determined that Respondents have waived their right to contest the issue of domestic industry in this investigation and that Align only has to put on a *prima facie* case demonstrating that there is domestic industry with respect to the '325 patent. (Citing Hearing Tr. at 47:20-48:4)

Staff argues that the evidence supports finding that the "technical prong" of the domestic industry requirement with respect to the '325 patent is met with Align's practice of at least claim 21 of the '325 patent. Staff says that the evidence demonstrates the following: (1) Align practices the preamble of claim 21 of the '325 patent, if limiting, when Align fabricates a series of individualized, custom-created aligners used to reposition teeth. (Citing CX-1235C at Q. 20-23; Corrected Complaint at Ex. L); (2) Align practices the first element of claim 21 of the '325 patent when Align {

) (Citing CX-1235C at Q. 20-23; Corrected Complaint at Ex. L); (3) Align practices the second element of claim 21 of the '325 patent when Align fabricates a positive model of the patient's teeth in the modified arrangement, using the digital data set of the digital model with a modified tooth arrangement. (Citing CX-1235C at Q. 20-23; Corrected Complaint at Ex. L); and (4) Align practices the third element of claim 21 of the '325 patent when Align fabricates at least one dental aligner as a negative of the positive model by molding polymeric material over the positive model. Each aligner covers a plurality of teeth in an upper or lower jaw of the patient, and the polymeric shell appliance is configured to move at least some of the patient's teeth substantially to the modified tooth arrangement. (Citing CX-1235C at Q. 20-23; Corrected Complaint at Ex. L)

Staff says that Respondents argue that Complainant has failed to show that it satisfies the (i) "technical prong" requirement with respect to each Asserted Patent and (ii) the "economic prong" requirement. Staff contends that based on my ruling that Respondents have waived their right to contest the issue of domestic industry (Citing Hearing Tr. at 47:20-48:4), Respondents' arguments should be rejected.

Staff contends that, as shown above, the evidence supports finding that Complainant has made a *prima facie* case demonstrating that there is a domestic industry with respect to each Asserted Patent. Staff says that Respondents do not contest the testimony explaining Align's processes provided by Eric Kuo (CX-1235C at Q. 20-23) or the "Domestic Industry Claim Charts" for the patents in suit attached to the Corrected Complaint (Exhibits L-R). Staff continues that Respondents do not contest the testimony that Align's Invisalign product practices asserted claims of the patents in suit provided by Complainant's expert Maureen Valley. (Citing

RX-1247C at Q. 70-74 and 486-488) Staff says that while Respondents do contest the commercial success of Align's Invisalign product, Respondents do not contest that Align's Invisalign product is a commercial embodiment of asserted claims of the patents in suit. (Citing RIB at 70-72) Staff reasons that because Respondents did not dispute (and did not rebut) such evidence, the Staff is of the view that Complainant has made a *prima facie* case showing that there is a domestic industry with respect to each Asserted Patent. (Citing *Certain Bulk Welding Wire Containers*, Inv. No. 337-TA-686, Final Initial Determination on Violation of Section 337 at 286-292 (July 29, 2010); *Certain Self-Cleaning Litter Boxes*, Inv. No. 337-TA-625, Final Initial Determination on Violation of Section 337 at 190 (Dec. 1, 2008))

Analysis and Conclusions: I find that Align has made a *prima facie* showing that it practices claim 21. I explained at the prehearing conference that Align needed only to put on a prima facie case on how they met the domestic industry requirement, and that Respondents cannot offer a defense "because they have already stated that they waived it." (Tr. at 47:2-48:4) Respondents' argument that the exclusion of Dr. Kuo's concluding opinion on whether or not Align's process practices the claims of the patents is unpersuasive. At the hearing I said that Align "will have to put on a factual case about how their product works. Align can then argue how that relates to the patent." (Tr. at 47:21-24) Dr. Kuo's witness statement explains Align's process and Align identifies how the process matches the elements of asserted claim 21 in its post-hearing brief. (CX-1235C at Qs. 20-23; CIB at 74-75) Therefore, I find that Align has made a *prima facie* showing that it practices claim 21 of the '325 patent, as demonstrated in the following claim chart:

CLAIM	ALIGN METHOD
21. A method for fabricating a polymeric shell dental appliance for moving a patient's teeth, said method comprising:	Align fabricates a series of individualized, custom-created polymeric aligners, used to reposition teeth. CX-1235C at Q. 20, 23.

providing a digital data set representing a modified tooth arrangement for a patient, wherein the modified tooth arrangement comprises a repositioned tooth arrangement for a plurality of the patient's teeth;	{ }
controlling a fabrication machine based on the digital data set to produce a positive model of the modified tooth arrangement; and	Using the digital data set of the digital model with a modified tooth arrangement, Align fabricates a positive model of the patient's teeth in the modified arrangement. CX-1235C at Q. 20, 23.
producing the polymeric shell dental appliance as a negative of the positive model, wherein the polymeric shell appliance covers a plurality of teeth in an upper or lower jaw of the patient, and wherein the polymeric shell appliance is configured to move at least some of the patient's teeth substantially to the modified tooth arrangement.	Align fabricates at least one dental aligner as a negative of the positive model by molding polymeric material over the positive model. CX-1235C at Q. 23. Each aligner covers a plurality of teeth in an upper or lower jaw of the patient, and the polymeric shell appliance is configured to move at least some of the patient's teeth substantially to the modified tooth arrangement. *Id.* at Q. 20, 23.

2. The '880 Patent (claim 1)

Align's Position: Align argues that Respondents do not contest domestic industry, and thus Align believes it is not at issue. (Citing RJSCI ¶ 39; Tr. at 618:21-619:2) Align says that Respondents affirmatively state that Align practices claim 1 of the '880 Patent as part of their claim construction analysis. (Citing RPHB at 87) Align continues that, because I instructed Align to present a *prima facie* case of domestic industry, Align submitted substantial evidence (as outlined in the chart below) that it practices at least claim 1 of the '880 patent. (Citing Tr. at 47:6-13)

CLAIM ELEMENT	ALIGN METHOD
1. A method for making a predetermined series of dental incremental position adjustment appliances, said method comprising:	Align fabricates a series of individualized, custom-created aligners, used to incrementally reposition teeth, wherein the geometries of each of the appliances in the series are determined prior to fabrication. CX-1235C at Q. 20, 23.
a) obtaining a digital data set representing an initial tooth arrangement;	Align obtains an initial digital data set representing an initial tooth arrangement by { }
b) obtaining a repositioned tooth	{

CLAIM ELEMENT	ALIGN METHOD
arrangement based on the initial tooth arrangement;	}
c) obtaining a series of successive digital data sets representing a series of successive tooth arrangements; and	{ }
d) fabricating a predetermined series of dental incremental position adjustment appliances based on the series of successive digital data sets, wherein said appliances comprise polymeric shells having cavities shaped to receive and resiliently reposition teeth, and said appliances correspond to the series of successive tooth arrangements progressing from the initial to the repositioned tooth arrangement.	Align fabricates a series of custom-created aligners based on the plurality of digital data sets, wherein each aligner comprises polymeric shells having cavities shaped to receive and resiliently reposition teeth, and said aligners correspond to the series of successive tooth arrangements progressing from the initial to the repositioned tooth arrangement. CX-1235C at Q. 20, 23.

Align contends that this chart is sufficient, by itself, to provide a *prima facie* case of domestic industry. (Citing *Certain Inkjet Ink Supplies*, Order No. 18 at 25-26) Align says that its expert witness on the technical prong of the domestic industry requirement, Dr. Valley, provided unrebutted testimony that Align practices each of the asserted claims (including claim 1 of the '880), and that Invisalign is the commercial embodiment of Align's asserted patents. Align continues that Dr. Valley's testimony is based upon: (i) her familiarity with Align's products and methods for designing and manufacturing these products and (ii) her review of the declaration of Dr. Eric Kuo and Align's domestic industry charts (both of which set forth, in detail, Align's processes) for the asserted patents in this Investigation; and (iii) an application of both parties' proposed claim constructions. (Citing Tr. at 803:15-18: 807:20-808:1; CX-1247C at Q. 45-46; 70-74, 486-488; CX-1254C at 8-9, 11-12, 79-80) Align argues that this testimony is enough to establish a *prima facie* case for domestic industry. (Citing *Certain Self-Cleaning Litter Boxes*, I.D. at 190; *Certain Bulk Welding Wire Containers*, I.D. at 290-91)

Align says that Respondents cannot contest Align's showing. (Citing Tr. at 47:6-8, 78:13-19, 79:9-17)

Respondents' Position: Citing to their arguments regarding the '325 patent, Respondents assert that Align has failed to show that it meets the technical prong of the domestic industry requirement with respect to the '880 patent.

Staff's Position: Staff says that I determined that Respondents have waived their right to contest the issue of domestic industry in this investigation and that Align only has to put on a *prima facie* case demonstrating that there is domestic industry with respect to the '880 patent. (Citing Tr. at 47:20-48:4)

Staff says that the evidence supports finding that the "technical prong" of the domestic industry requirement with respect to the '880 patent is met with Align's practice of at least claim 1 of the '880 patent. Staff says that the evidence shows the following:

- Align practices the preamble of claim 1 of the '880 patent, if limiting, when Align fabricates a series of individualized, custom-created aligners used to incrementally reposition teeth, wherein at least part of the aligners are predetermined. (Citing CX-1235C at Qs. 20-23; Corrected Complaint at Ex. P)
- Align practices the first element of claim 1 of the '880 patent when Align obtains an initial digital data set representing an initial tooth arrangement {

  }
- Align practices the second element of claim 1 of the '880 patent when Align {

  }
- Align practices the third element of claim 1 of the '880 patent when Align {

  }

- Align practices the fourth element of claim 1 of the '880 patent when Align fabricates a series of aligners based on the plurality of digital data sets, wherein each aligner comprises polymerics shells having cavities shaped to receive and resiliently reposition teeth, and the aligners correspond to the series of successive tooth arrangements progressing from the initial to a final tooth arrangement. (Citing CX-1235C at Qs. 20-23; Corrected Complaint at Ex. P)

Staff says that Respondents argue that Complainant has failed to show that it satisfies the (i) "technical prong" requirement with respect to each Asserted Patent and (ii) the "economic prong" requirement. Staff contends that based on my ruling that Respondents have waived their right to contest the issue of domestic industry (Citing Hearing Tr. at 47:20-48:4), Respondents' arguments should be rejected.

Staff contends that, as shown above, the evidence supports finding that Complainant has made a *prima facie* case demonstrating that there is a domestic industry with respect to each Asserted Patent. Staff says that Respondents do not contest the testimony explaining Align's processes provided by Eric Kuo (CX-1235C at Qs. 20-23) or the "Domestic Industry Claim Charts" for the patents in suit attached to the Corrected Complaint (Exhibits L-R). Staff continues that Respondents do not contest the testimony that Align's Invisalign product practices asserted claims of the patents in suit provided by Complainant's expert Maureen Valley. (Citing RX-1247C at Qs. 70-74 and 486-488) Staff says that while Respondents do contest the commercial success of Align's Invisalign product, Respondents do not contest that Align's Invisalign product is a commercial embodiment of asserted claims of the patents in suit. (Citing RIB at 70-72) Staff reasons that because Respondents did not dispute (and did not rebut) such evidence, the Staff is of the view that Complainant has made a *prima facie* case showing that there is a domestic industry with respect to each Asserted Patent. (Citing *Certain Bulk Welding Wire Containers*, Inv. No. 337-TA-686, Final Initial Determination on Violation of Section 337

at 286-292 (July 29, 2010); *Certain Self-Cleaning Litter Boxes*, Inv. No. 337-TA-625, Final Initial Determination on Violation of Section 337 at 190 (Dec. 1, 2008))

Analysis and Conclusions: I find that Align has made a *prima facie* showing that it practices claim 1 of the '880 patent. I explained at the prehearing conference that Align needed only to put on a prima facie case on how they met the domestic industry requirement, and that Respondents cannot offer a defense "because they have already stated that they waived it." (Tr. at 47:2-48:4) Respondents' argument that the exclusion of Dr. Kuo's concluding opinion on whether or not Align's process practices the claims of the patents is unpersuasive. At the hearing I said that Align "will have to put on a factual case about how their product works. Align can then argue how that relates to the patent." (Tr. at 47:21-24) Dr. Kuo's witness statement explains Align's process and Align identifies how the process matches the elements of asserted claim 1 in its post-hearing brief. (CX-1235C at Qs. 20-23; CIB at 86-87) Therefore, I find that Align has made a *prima facie* showing that it practices claim 1 of the '880 patent, as demonstrated in the following claim chart:

CLAIM ELEMENT	ALIGN METHOD
1. A method for making a predetermined series of dental incremental position adjustment appliances, said method comprising:	Align fabricates a series of individualized, custom-created aligners, used to incrementally reposition teeth, wherein the geometries of each of the appliances in the series are determined prior to fabrication. CX-1235C at Q. 20, 23.
a) obtaining a digital data set representing an initial tooth arrangement;	Align obtains an initial digital data set representing an initial tooth arrangement by taking a { }
b) obtaining a repositioned tooth arrangement based on the initial tooth arrangement;	{ }
c) obtaining a series of successive digital data sets representing a series of	{

CLAIM ELEMENT	ALIGN METHOD
successive tooth arrangements; and	}
d) fabricating a predetermined series of dental incremental position adjustment appliances based on the series of successive digital data sets, wherein said appliances comprise polymeric shells having cavities shaped to receive and resiliently reposition teeth, and said appliances correspond to the series of successive tooth arrangements progressing from the initial to the repositioned tooth arrangement.	Align fabricates a series of custom-created aligners based on the plurality of digital data sets, wherein each aligner comprises polymeric shells having cavities shaped to receive and resiliently reposition teeth, and said aligners correspond to the series of successive tooth arrangements progressing from the initial to the repositioned tooth arrangement. CX-1235C at Q. 20, 23.

3. The '487 Patent (claim 7)

Align's Position: Align asserts that Respondents do not contest domestic industry, and thus Align believes it is not at issue. (Citing RJSCI ¶ 62; Tr. at 618:21-619:2.) Align says that because I instructed Align to present a *prima facie* case of domestic industry, Align submitted substantial evidence (as outlined in the chart below) that it practices at least claim 7 of the '487 patent. (Citing Tr. at 47:6-13)

CLAIM	ALIGN METHOD
7. An orthodontic treatment plan for repositioning a patient's teeth using incremental tooth repositioning appliances, the treatment plan residing on a computer readable storage media and comprising a plurality of intermediate digital data sets representing intermediate arrangements of the patient's teeth, wherein at least some of the intermediate tooth arrangements represent different orthodontic treatment stages as the patient's teeth are moved from an initial arrangement toward a final arrangement representing the patient's teeth in a desired or prescribed arrangement.	Align receives from a dental provider a desired or prescribed arrangement for a patient's teeth. CX-1235C at Q. 21. Align technicians generate an orthodontic treatment plan for repositioning a patient's teeth to the desired arrangement using a series of individualized, custom-created aligners. CX-1235C at Q. 20, 22. { }

Align asserts that this chart is sufficient, by itself, to provide a *prima facie* case of domestic industry. (Citing *Certain Inkjet Ink Supplies*, Order No. 18 at 25-26) Align says that Align's expert witness on the technical prong of the domestic industry requirement, Dr. Valley, also provided unrebutted testimony that Align practices each of the asserted claims (including claim 7 of the '487), and that Invisalign is the commercial embodiment of Align's asserted patents. Align says that Dr. Valley's testimony is based upon: (i) her familiarity with Align's products and methods for designing and manufacturing these products and (ii) her review of the declaration of Dr. Eric Kuo and Align's domestic industry charts (both of which set forth, in detail, Align's processes) for the asserted patents in this Investigation; and (iii) an application of both parties' proposed claim constructions. (Citing Tr. at 803:15-18; 807:20-808:1; CX-1247C at Q. 45-46; 70-74, 486-488; CX-1254C at 8-9, 11-12, 79-80) Align argues that this testimony is enough to establish a *prima facie* case for domestic industry. (Citing *Certain Self-Cleaning Litter Boxes*, I.D. at 190; *Certain Bulk Welding Wire Containers*, I.D. at 290-91)

Align says that Respondents cannot contest Align's showing. (Citing Tr. at 47:6-8, 78:13-19, 79:9-17)

Respondents' Position: Respondents argue that Align has failed to show that it meets the technical prong of the domestic industry requirement with respect to the '487 patent. (Citing RIB Section 3.4) Respondents say that Align has failed to make a prima facie case that the technical prong of the domestic industry requirement is satisfied for the '487 patent. Align says that the claim upon which Align bases its domestic industry argument is claim number 7, an independent claim requiring an orthodontic treatment plan residing on a computer readable storage media. Align continues that as described in RRB section 4.1.1, the plain and ordinary meaning of a treatment plan is a treatment strategy composed by the treating doctor. Align

argues that such a meaning is consistent with applicable state laws, the evidence presented at the hearing, and Align's provisional application for which priority of the '487 patent is asserted. Respondents say that Align's domestic industry argument asserts that Align receives a desired or prescribed arrangement for a patient's teeth from "a dental provider." Respondents contend that the phrase "dental provider" makes no sense. Alternatively, Respondents say that assuming "dental provider" means the treating doctor, Align has still failed to establish the technical prong because it has offered no evidence or argument that the doctor's treatment plan resides on a computer readable storage media. (Citing CX-1235C at Q. 21) Respondents say that the only suggestion Align makes concerning data residing on a computer relates to the digital models created by Align technicians which, by definition, cannot be a treatment plan.

Staff's position: Staff says that I determined that Respondents have waived their right to contest the issue of domestic industry in this investigation and that Align only has to put on a *prima facie* case demonstrating that there is domestic industry with respect to the '487 patent. (Citing Tr. at 47:20-48:4) Staff continues that the evidence supports finding that the "technical prong" of the domestic industry requirement with respect to the '487 patent is met with Align's practice of at least claim 7 of the '487 patent. Staff explains that the evidence shows that Align practices all of the claim elements as follows: (i) Align receives from a dental provider a desired arrangement for a patient's teeth; (ii) Align generates an orthodontic treatment plan for repositioning a patient's teeth to a desired arrangement using a series of aligners; (iii) Align,

{

} (Citing CX-1235C at Q. 20-23; Corrected Complaint at Ex. R)

Analysis and Conclusions: I find that Align has made a *prima facie* showing that it practices claim 7 of the '487 patent. I explained at the prehearing conference that Align needed only to put on a prima facie case on how they met the domestic industry requirement, and that Respondents cannot offer a defense "because they have already stated that they waived it." (Tr. at 47:2-48:4) Respondents' argument that the exclusion of Dr. Kuo's concluding opinion on whether or not Align's process practices the claims of the patents is unpersuasive. At the hearing I said that Align "will have to put on a factual case about how their product works. Align can then argue how that relates to the patent." (Tr. at 47:21-24) Dr. Kuo's witness statement explains Align's process and Align identifies how the process matches the elements of asserted claim 1 in its post-hearing brief. (CX-1235C at Qs. 20-23; CIB at 86-87) Therefore, I find that Align has made a *prima facie* showing that it practices claim 7 of the '487 patent, as demonstrated in the following claim chart:

CLAIM	ALIGN METHOD
7. An orthodontic treatment plan for repositioning a patient's teeth using incremental tooth repositioning appliances, the treatment plan residing on a computer readable storage media and comprising a plurality of intermediate digital data sets representing intermediate arrangements of the patient's teeth, wherein at least some of the intermediate tooth arrangements represent different orthodontic treatment stages as the patient's teeth are moved from an initial arrangement toward a final arrangement representing the patient's teeth in a desired or prescribed arrangement.	Align receives from a dental provider a desired or prescribed arrangement for a patient's teeth. CX-1235C at Q. 21. Align technicians generate an orthodontic treatment plan for repositioning a patient's teeth to the desired arrangement using a series of individualized, custom-created aligners. CX-1235C at Q. 20, 22. { }

In addition to being waived, Respondents' arguments that Align has not established that it creates a "treatment plan" is based on Respondents' incorrect construction for the term "treatment plan." As explained in Section III.D.2, *supra*, there is no requirement that a "treatment plan" be created by a clinician. As noted above, Align has made a prima facie showing that it generates a plurality of intermediate digital data sets and stores those intermediate digital data sets on a computer. As a result, Respondents' arguments are unpersuasive.

4. The '511 Patent (claim 1)

Align's position: Align notes that Respondents do not contest domestic industry, and Align believes it is not at issue. (Citing Tr. at 618:21-619:2) Nevertheless, Align argues that it has submitted substantial evidence (as outlined in the chart below) that it practices at least claim 1 of the '511 patent. (Citing Tr. at 47:6-13)

CLAIM	ALIGN METHOD
1. A computer-implemented method for segmenting an orthodontic treatment path into segments, comprising:	Align technicians use computer software to generate a malocclusion treatment plan, consisting of segments, to reposition a patient's teeth from the initial tooth position to a final tooth position. CX-1235C at Q. 20, 22.
for each tooth in a set of teeth, receiving a tooth path for the motion of the tooth from an initial position to a final position;	Align technicians use computer software to generate a malocclusion treatment plan wherein a tooth path is determined for the motion of each tooth from an initial position to a final position. CX-1235C at Q. 20, 22.
calculating a segmentation of the aggregate tooth paths into a plurality of treatment segments so that each tooth's motion within a segment stays within threshold limits of linear and rotational translation; and	{ }
generating a plurality of appliances, at least one or more appliances for each treatment segment, wherein the appliances comprise polymeric shells having cavities and wherein the cavities of successive shells have different geometries shaped to receive and resiliently reposition the teeth from one arrangement to a successive arrangement.	Align fabricates a series of individualized, custom-created aligners, one for each treatment segment. The aligners are polymeric shells having cavities of different geometries shaped to receive and resiliently reposition the patient's teeth from one arrangement to a successive arrangement. CX-1235C at Q. 20, 23.

Align contends that the foregoing chart is sufficient, by itself, to provide a *prima facie* case of domestic industry. (Citing *Certain Inkjet Ink Supplies*, Order No. 18 at 25-26) Align adds that its expert witness on the technical prong of the domestic industry requirement, Dr. Valley, provided unrebutted testimony that Align practices each of the asserted claims (including claim 1 of the '511 patent), and that Invisalign is the commercial embodiment of Align's asserted patents. Align refers to Dr. Valley's testimony, and says it is based upon: (i) her familiarity with Align's products and methods for designing and manufacturing these products and (ii) her review of the declaration of Dr. Eric Kuo and Align's domestic industry charts (both of which set forth, in detail, Align's processes) for the asserted patents in this Investigation; and (iii) an

application of both parties' proposed claim constructions. (Citing Tr. at 803:15-18; 807:20-808:1; CX-1247C, Qs. 45-46; 70-74, 486-488; and CX-1254C at 8-9, 11-12, 79-80) Align argues that this testimony is enough to establish a *prima facie* case for domestic industry. (Citing *Certain Self-Cleaning Litter Boxes*, I.D. at 190; and *Certain Bulk Welding Wire Containers*, I.D. at 290-91)

In its reply brief, Align notes that Respondents cannot contest Align's showing. (Citing Tr. at 47:6-8, 78:13-19, 79:9-17)

Staff's Position: Staff notes that I determined that Respondents have waived their right to contest the issue of domestic industry in this investigation and that Align is only required to put on a *prima facie* case demonstrating that there is domestic industry with respect to the '511 patent. (Citing Tr. at 47:20-48:4)

The Staff is of the view that the evidence supports finding that the "technical prong" of the domestic industry requirement with respect to the '511 patent is met with Align's practice of at least claim 1 of the '511 patent. Staff summarizes the evidence to show the following:

- Align practices the preamble of claim 1 of the '511 patent, if limiting, when Align uses its software to generate a malocclusion treatment plan consisting of segments to reposition teeth from an initial position to a final position. (Citing CX-1235C, Qs. 20-23)
- Align practices the first element of claim 1 of the '511 patent when Align uses its software to generate a malocclusion treatment plan wherein a tooth path is determined for the motion of each tooth from an initial position to a final position. (Citing CX-1235C, Qs. 20-23)
- Align practices the second element of claim 1 of the '511 patent when Align {

  } (Citing CX-1235C, Qs. 20-23)
- Align practices the third element of claim 1 of the '511 patent when Align fabricates for each treatment segment individualized, custom-created aligners that are polymeric shells having cavities of different geometries shaped to receive and resiliently reposition the teeth from one arrangement to a successive arrangement.

(Citing CX-1235C, Qs. 20-23)

Analysis and Conclusions: I find that Align has made a *prima facie* showing that it practices claim 1 of the '511 patent. I explained at the prehearing conference that Align needed only to put on a prima facie case on how they met the domestic industry requirement, and that Respondents cannot offer a defense "because they have already stated that they waived it." (Tr. at 47:2-48:4) At the hearing I said that Align "will have to put on a factual case about how their product works. Align can then argue how that relates to the patent." (Tr. at 47:21-24) Dr. Kuo's witness statement explains Align's process and Align identifies how the process matches the elements of claim 1 in its post-hearing brief. (CX-1235, Qs. 20-23; CIB at 106-107) Therefore, I find that Align has made a *prima facie* showing that it practices claim 1 of the '511 patent, as demonstrated in the claim chart displayed above.

5. The '666 Patent (claim 7)

Align's Position: Align says that Respondents do not contest domestic industry, and thus Align believes it is not at issue. (Citing RJSCI ¶ 108; Tr. at 618:21-619:2) Align says that because I instructed Align to present a *prima facie* case of domestic industry, Align submitted substantial evidence (as outlined in the chart below) that it practices at least claim 7 of the '666 patent. (Citing Tr. at 47:6-13)

CLAIM	ALIGN'S METHOD
7. A method for producing a plurality of digital data sets representing a series of discrete tooth arrangements progressing from an initial to a final arrangement, said method comprising:	Align fabricates a series of individualized, custom-created aligners used to reposition teeth. CX-1235C at Q. 20, 23. Align fabricates these aligners by producing a plurality of digital data sets representing a series of discrete tooth arrangements progressing from an initial to a final arrangement. *Id.*
providing a computer system;	Align's technicians use a computer system for running the Align software used to produce the tooth arrangements. CX-1235C at Q. 20, 23.
providing to the computer system digital data set representing an initial tooth arrangement;	Align provides an initial digital data set to the computer system representing an initial tooth arrangement by [redacted]

	} CX-1235C at Q. 21.
providing to the computer system a digital data set representing a final tooth arrangement;	{ } produce a digital data set representing the final tooth arrangement. CX-1235C at Q. 20, 23.
interpolating positional differences between the teeth in the initial and final data sets using the computer system to produce a plurality of successive digital data sets, wherein said plurality of successive digital data sets represents a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement.	{ } interpolate positional differences between the teeth in the initial and final data sets using the computer system. CX-1235C at Q. 20, 23. This is used to produce a plurality of successive digital data sets, wherein the plurality of digital data sets represent a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement. *Id.*

Align asserts that this chart is sufficient, by itself, to provide a *prima facie* case of domestic industry. (Citing *Certain Inkjet Ink Supplies*, Order No. 18 at 25-26) Align says that Align's expert witness on the technical prong of the domestic industry requirement, Dr. Valley, provided unrebutted testimony that Align practices each of the asserted claims (including claim 7 of the '666), and that Invisalign is the commercial embodiment of Align's asserted patents. Dr. Valley's testimony is based upon: (i) her familiarity with Align's products and methods for designing and manufacturing these products and (ii) her review of the declaration of Dr. Eric Kuo and Align's domestic industry charts (both of which set forth, in detail, Align's processes) for the asserted patents in this Investigation; and (iii) an application of both parties' proposed claim constructions. (Citing Tr. at 803:15-18, 807:20-808:1; CX-1247C at Q. 45-46; 70-74, 486-488; CX-1254C at 8-9, 11-12, 79-80) Align contends that this testimony is enough to establish a *prima facie* case for domestic industry. (Citing *Certain Self-Cleaning Litter Boxes*, I.D. at 190; *Certain Bulk Welding Wire Containers*, I.D. at 290-91.)

Align argues that Respondents cannot contest Align's showing. (Citing Tr. at 47:6-8, 78:13-19, 79:9-17)

Respondents' Position: Respondents argue that Align has failed to show that it meets the technical prong of the domestic industry requirement with respect to the '666 patent. (Citing RIB Section 3.4)

Staff's Position: Staff says that I determined that Respondents have waived their right to contest the issue of domestic industry in this investigation and that Align only has to put on a *prima facie* case demonstrating that there is domestic industry with respect to the '666 patent. (Citing Tr. at 47:20-48:4) Staff argues that the evidence supports finding that the "technical prong" of the domestic industry requirement with respect to the '666 patent is met with Align's practice of at least claim 7 of the '666 patent. Staff says that the evidence shows the following:

- Align practices the preamble of claim 7 of the '666 patent, if limiting, when Align fabricates a series of individualized, custom-created aligners for repositioning teeth by producing a plurality of digital data sets representing a series of discrete tooth arrangement progressing from an initial to a final arrangement. CX-1235C (Kuo) at Q. 20-23; Corrected Complaint at Ex. N.
- Align practices the first element of claim 7 of the '666 patent when Align uses a computer system to run its software used for producing the tooth arrangements. CX-1235C (Kuo) at Q. 20-23; Corrected Complaint at Ex. N.
- Align practices the second element of claim 7 of the '666 patent when Align provides an initial digital data set representing an initial tooth arrangement by {

  } CX-1235C (Kuo) at Q. 20-23; Corrected Complaint at Ex. N.
- Align practices the third element of claim 7 of the '666 patent when Align {

  } produce a digital data set representing the final tooth arrangement. CX-1235C (Kuo) at Q. 20-23; Corrected Complaint at Ex. N.
- Align practices the fourth element of claim 7 of the '666 patent when Align {
  } interpolating positional differences between the teeth in the initial and final data sets to produce a plurality of successive digital data sets representing a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement. CX-1235C (Kuo) at Q. 20-23; Corrected Complaint at Ex. N.

Staff says that Respondents argue that Complainant has failed to show that it satisfies the (i) "technical prong" requirement with respect to each Asserted Patent and (ii) the "economic

prong" requirement. Staff contends that based on my ruling that Respondents have waived their right to contest the issue of domestic industry (Citing Hearing Tr. at 47:20-48:4). Respondents' arguments should be rejected.

Staff contends that, as shown above, the evidence supports finding that Complainant has made a *prima facie* case demonstrating that there is a domestic industry with respect to each Asserted Patent. Staff says that Respondents do not contest the testimony explaining Align's processes provided by Eric Kuo (CX-1235C at Q. 20-23) or the "Domestic Industry Claim Charts" for the patents in suit attached to the Corrected Complaint (Exhibits L-R). Staff continues that Respondents do not contest the testimony that Align's Invisalign product practices asserted claims of the patents in suit provided by Complainant's expert Maureen Valley. (Citing RX-1247C at Q. 70-74 and 486-488) Staff says that while Respondents do contest the commercial success of Align's Invisalign product, Respondents do not contest that Align's Invisalign product is a commercial embodiment of asserted claims of the patents in suit. (Citing RIB at 70-72) Staff reasons that because Respondents did not dispute (and did not rebut) such evidence, the Staff is of the view that Complainant has made a *prima facie* case showing that there is a domestic industry with respect to each Asserted Patent. (Citing *Certain Bulk Welding Wire Containers*, Inv. No. 337-TA-686, Final Initial Determination on Violation of Section 337 at 286-292 (July 29, 2010); *Certain Self-Cleaning Litter Boxes*, Inv. No. 337-TA-625, Final Initial Determination on Violation of Section 337 at 190 (Dec. 1, 2008))

Analysis and Conclusions: I find that Align has not made a *prima facie* showing that it practices claim 7 of the '666 patent. I explained at the prehearing conference that Align needed only to put on a prima facie case on how they met the domestic industry requirement, and that Respondents cannot offer a defense "because they have already stated that they waived it." (Tr.

at 47:2-48:4) Respondents are incorrect when they argue that, the exclusion of Dr. Kuo's concluding opinion on whether or not Align's process practices the claims of the patents defeats Align's effort to show that it meets the technical prong. At the hearing I said that Align "will have to put on a factual case about how their product works. Align can then argue how that relates to the patent." (Tr. at 47:21-24) Dr. Kuo's witness statement explains Align's process and Align identifies how the process matches the elements of asserted claim 7 in its post-hearing brief. (CX-1235C at Qs. 20-23; CIB at 116-18) Dr. Kuo's witness statement does not, however, provide any evidence that Align's process includes the step of interpolating positional differences between the initial and final position of teeth. (See CX-1235C at Q.20-23) The testimony of Dr. Valley does not fill this gap - rather, Dr. Valley's testimony is conclusory and merely states that Align's products "practice the inventions of the patent claims asserted in this investigation." (CX-1247C at Q. 487-488) Therefore, I find that Align has not made a *prima facie* showing that it practices claim 7 of the '666 patent.

6. The '863 Patent (claim 1)

Align's position: Align asserts that Respondents do not contest domestic industry, and thus Align believes it is not at issue. (Citing Tr. at 618:21-619:2) Align says that because I instructed Align to present a *prima facie* case of domestic industry, Align submitted substantial evidence (as outlined in the chart below) that it practices at least claim 1 of the '863 patent. (Citing Tr. at 47:6-13)

CLAIM ELEMENT	ALIGN'S METHOD
1. A method for producing digital models of dental positioning appliances, said method comprising:	Align produces digital models representing a series of discrete tooth arrangements progressing from an initial to a final tooth arrangement used for fabricating aligners for repositioning teeth. CX-1235C at Q. 20, 22, 23.
providing a digital model of a patient's dentition;	Align provides a digital model representing an initial tooth arrangement of a patient's dentition by {

	} CX-1235C at Q. 21.
producing a plurality of modified digital models of the dentition, wherein the modified models represent successive treatment stages of an orthodontic treatment and wherein each modified model or a product of such model is to be used in fabrication of a distinct successive incremental dental positioning appliance associated with the respective treatment stage of that modified model;	Align's technicians use Align software to produce a plurality of modified digital models of the patient's dentition based on the initial tooth arrangement, wherein the modified models represent successive treatment stages of an orthodontic treatment. CX-1235C at Q. 20, 22. Each modified model or a product of such model is to be used in fabrication of a distinct successive incremental dental positioning appliance associated with the respective treatment stage of that modified model. *Id.* at Q. 20, 23.
providing a digital model of at least one attachment device; and	{ }. CX-1275 at 11.
positioning the digital model of the attachment device on at least some of the plurality of modified digital models.	{ }. CX-1275 at 11.

Align argues that this chart is sufficient, by itself, to provide a *prima facie* case of domestic industry. (Citing *Certain Inkjet Ink Supplies*, Inv. No. 337-TA-691, Order No. 18 at 25-26 (Aug. 2010)) Align says that Align's expert witness on the technical prong of the domestic industry requirement, Dr. Valley, provided unrebutted testimony that Align practices each of the asserted claims (including claim 1 of the '863 patent), and that Invisalign is the commercial embodiment of Align's asserted patents. Align continues that Dr. Valley's testimony is based upon: (i) her familiarity with Align's products and methods for designing and manufacturing these products and (ii) her review of the declaration of Dr. Eric Kuo and Align's domestic industry charts (both of which set forth, in detail, Align's processes) for the patents in suit in this Investigation; and (iii) an application of both parties' proposed claim constructions. (Citing Tr. at 803:15-18, 807:20-808:1; CX-1247C at Q. 45-46; 70-74, 486-488; CX-1254C at 8-9, 11-12, 79-80) Align contends that this testimony is enough to establish a *prima facie* case for domestic industry. (Citing *Certain Self-Cleaning Litter Boxes*, Inv. No. 337-TA-625, I.D. at 190 (Oct.

2011) (Rogers, J.); *Certain Bulk Welding Wire Containers*, Inv. No. 337-TA-686, I.D. at 290-91 (July 2010) (Rogers, J.))

Respondents' Position: Respondents assert that Align failed to make a *prima facie* case that it satisfies the technical prong requirement with regard to at least one claim of each of the asserted patents. Respondents say that Align's evidence relating to the technical prong as it relates to each patent, a portion of the witness statement of Eric Kuo, was stricken as improper expert testimony. (Citing Tr. 45:12-48:4) Respondents continue that Align is left with conclusory statements that do not satisfy its burden of proof. Respondents conclude, as a result, that Align has failed to show that it meets the technical prong of the domestic industry requirement with respect to each asserted patent.

Staff's Position: Staff says that I determined that Respondents have waived their right to contest the issue of domestic industry in this investigation and that Align only has to put on a *prima facie* case demonstrating that there is domestic industry with respect to the '863 patent. (Citing Hearing Tr. at 47:20-48:4)

Staff argues that the evidence supports finding that the "technical prong" of the domestic industry requirement with respect to the '863 patent is met with Align's practice of at least claim 1 of the '863 patent. Staff says that the evidence demonstrates the following:

- Align practices the preamble of claim 1 of the '863 patent, if limiting, when Align produces digital models representing a series of discrete tooth arrangement progressing from an initial to a final tooth arrangement used for fabricating aligners for repositioning teeth. CX-1235C (Kuo) at Q. 20-23; Corrected Complaint at Ex. O.

- Align practices the first element of claim 1 of the '863 patent when Align provides a digital model representing an initial tooth arrangement of a patient's teeth by {

  }. CX-1235C (Kuo) at Q. 20-23; Corrected Complaint at Ex. O.

- Align practices the second element of claim 1 of the '863 patent when Align uses its software to produce a plurality of modified digital models of the patient's dentition based on the initial tooth arrangement, wherein the models represent successive treatment stages of an orthodontic treatment and each model is used in fabrication of an incremental dental positioning appliance that is associated with the respective treatment stage. CX-1235C (Kuo) at Q. 20-23; Corrected Complaint at Ex. O.

- {

}. CX-1235C (Kuo) at Q. 20-23; Corrected Complaint at Ex. O.

- {

}. CX-1235C (Kuo) at Q. 20-23; Corrected Complaint at Ex. O.

Analysis and Conclusions: I find that Align has made a *prima facie* showing that it practices claim 1 of the '863 patent. I explained at the prehearing conference that Align needed only to put on a *prima facie* case on how they met the domestic industry requirement. I further explained that Respondents cannot offer a defense "because they have already stated that they waived it." (Tr. at 47:2-48:4) Respondents miss the point when they argue that the exclusion of Dr. Kuo's concluding opinion on whether or not Align's process practices the claims of the patents defeats Align's ability to show that it meets the technical prong. At the hearing I said that Align "will have to put on a factual case about how their product works. Align can then argue how that relates to the patent." (Tr. at 47:21-24) Dr. Kuo's witness statement explains Align's process and Align identifies how the process matches the elements of asserted claim 1 in its post-hearing brief. (CX-1235C at Qs. 37-40; CIB at 128-129) Therefore, I find that Align has made a *prima facie* showing that it practices claim 1 of the '863 patent, as demonstrated by the following claim chart:

CLAIM ELEMENT	ALIGN'S METHOD
1. A method for producing digital models of dental positioning appliances, said method comprising:	Align produces digital models representing a series of discrete tooth arrangements progressing from an initial to a final tooth arrangement used for fabricating aligners for repositioning teeth. CX-1235C at Q. 20, 22, 23.
providing a digital model of a patient's dentition;	Align provides a digital model representing an initial tooth arrangement of a patient's dentition by { }. CX-1235C at Q. 21.
producing a plurality of modified digital models of the dentition, wherein the modified models represent successive treatment stages of an orthodontic treatment and wherein each modified model or a product of such model is to be used in fabrication of a distinct successive incremental dental positioning appliance associated with the respective treatment stage of that modified model;	Align's technicians use Align software to produce a plurality of modified digital models of the patient's dentition based on the initial tooth arrangement, wherein the modified models represent successive treatment stages of an orthodontic treatment. CX-1235C at Q. 20, 22. Each modified model or a product of such model is to be used in fabrication of a distinct successive incremental dental positioning appliance associated with the respective treatment stage of that modified model. *Id.* at Q. 20, 23.
providing a digital model of at least one attachment device; and	{ }. CX-1275 at 11.
positioning the digital model of the attachment device on at least some of the plurality of modified digital models.	{ }. CX-1275 at 11.

7. The '874 Patent (claim 1)

Align's position: Align notes that Respondents did not contest domestic industry, and Align believes it is not at issue. (Citing Tr. at 618:21-619:2) Nevertheless, Align contends that it has submitted substantial evidence (as outlined in the chart below) that it practices at least claim 1 of the '874 patent. (Citing Tr. at 47:6-13)

CLAIM	ALIGN'S METHOD
1. A computer-implemented method for use in creating a treatment plan to reposition a patient's teeth from a set of initial tooth positions to a set of final tooth positions, the method comprising:	Align's technicians use computer software to generate a malocclusion treatment plan consisting of stages to reposition a patient's teeth from a set of initial tooth positions to a set of final tooth positions. CX-1235C at Q. 20, 22.
receiving an initial digital data set representing the teeth at the initial positions, wherein receiving the initial digital data set comprises receiving data obtained by scanning the patient's teeth or a physical model thereof;	{ }. CX-1235C at Q. 21.
generating a set of intermediate positions toward which the teeth will move while moving from the initial positions toward the final positions; and	{ }. *Id.*
generating a plurality of successive appliances having cavities and wherein the cavities of successive appliances have different geometries shaped to receive and reposition teeth from the initial positions toward the final positions,	Align then fabricates a series of successive aligners, each having cavities with different geometries of which are shaped to receive and reposition the teeth according to a treatment path segment, from the initial towards the final positions. CX-1235C at Q. 20, 23.
wherein the plurality of successive appliances is generated at a stage of treatment prior to the patient wearing any appliance of said plurality so as to reposition the teeth.	Align fabricates at least some aligners prior to the patient wearing any of the appliances. CX-1235C at Q. 20, 23.

Align asserts that this chart is sufficient, by itself, to provide a *prima facie* case of domestic industry. (Citing *Certain Inkjet Ink Supplies*, Order No. 18 at 25-26) Align adds that its expert witness on the technical prong of the domestic industry requirement, Dr. Valley, provided unrebutted testimony that Align practices each of the asserted claims (including claim 1

of the '874 patent), and that Invisalign is the commercial embodiment of Align's asserted patents. Align avers that Dr. Valley's testimony is based upon: (i) her familiarity with Align's products and methods for designing and manufacturing these products and (ii) her review of the declaration of Dr. Eric Kuo and Align's domestic industry charts (both of which set forth, in detail, Align's processes) for the asserted patents in this Investigation; and (iii) an application of both parties' proposed claim constructions. (Citing Tr. at 803:15-18; 807:20-808:1; CX-1247C, Qs. 45-46; 70-74, 486-488; and CX-1254C at 8-9, 11-12, 79-80) Align argues that this testimony is enough to establish a *prima facie* case for domestic industry. (Citing *Certain Self-Cleaning Litter Boxes*, I.D. at 190; and *Certain Bulk Welding Wire Containers*, I.D. at 290-91)

In its reply brief, Align says that Respondents cannot contest Align's showing. (Citing Tr. at 47:6-8, 78:13-19, 79:9-17)

Staff's Position: Staff is of the view that the evidence supports finding that the "technical prong" of the domestic industry requirement with respect to the '874 patent is met with Align's practice of at least claim 1 of the '874 patent. Staff asserts that the evidence shows the following:

- Align practices the preamble of claim 1 of the '874 patent, if limiting, when Align uses its software to generate a treatment plan consisting of stages to reposition teeth from a set of initial tooth positions to a set of final tooth positions. (Citing CX-1235C, Qs. 20-23)

- Align practices the first element of claim 1 of the '874 patent when Align {

  }.

  (Citing CX-1235C, Qs. 20-23)

- Align practices the second element of claim 1 of the '874 patent when Align {

  }.

  (Citing CX-1235C, Qs. 20-23)

- Align practices the third element of claim 1 of the '874 patent when Align fabricates a series of successive aligners, each having cavities with different geometries for receiving and repositioning the teeth from the initial positions to the final positions. (Citing CX-1235C, Qs. 20-23)

- Align practices the fourth element of claim 1 of the '874 patent when Align fabricates at least some of the aligners prior to the patient wearing any aligner. (Citing CX-1235C, Qs. 20-23)

Analysis and Conclusions: I find that Align has made a *prima facie* showing that it practices claim 1 of the '874 patent. I explained at the prehearing conference that Align needed only to put on a prima facie case on how they met the domestic industry requirement, and that Respondents cannot offer a defense "because they have already stated that they waived it." (Tr. at 47:2-48:4) At the hearing I said that Align "will have to put on a factual case about how their product works. Align can then argue how that relates to the patent." (Tr. at 47:21-24) Dr. Kuo's witness statement explains Align's process and Align identifies how the process matches the elements of asserted claim 21 in its post-hearing brief. (CX-1235, Qs. 20-23; CIB at 140-141) Therefore, I find that Align has made a *prima facie* showing that it practices claim 1 of the '874 patent, as demonstrated in the chart displayed above.

VII. REMEDY & BONDING

A. Limited Exclusion Order

Align's position: Align says that the Commission "has broad discretion in selecting the form, scope, and extent of the remedy in Section 337 proceedings." (Citing *Certain Integrated Circuit Telecomm. Chips*, Inv. No. 337-TA-337, 1993 WL 13033517, at *20 (June 22, 1993)) Align continues that after issuing an I.D. on a violation of Section 337, the ALJ must also issue a recommended determination concerning his views on permanent relief and bonding. (Citing 19 C.F.R. § 210.42(a)(l)(ii)) Align says that consistent with Commission practice and out of

deference to Customs, Align does not request an exclusion order prohibiting the electronic transmission of the infringing digital data sets at this time, provided an appropriate cease and desist order is issued.

Respondents' Position: Respondents argue that Align has not demonstrated that it is entitled to an exclusion order, insofar as it has failed to establish a violation of Section 1337. Respondents say that they understand that Customs generally takes the position that it will not enforce exclusion orders relating to electronic transmissions, even if such orders were within the Commission's jurisdiction and authority. Respondents continue that even if a violation of Section 1337 was proven, the Commission should decline to issue an exclusion order. Respondents further submit that there is no basis for a certification provision in any exclusion order that might be issued in this investigation.

Staff's Position: Staff says that Complainant seeks issuance of a limited exclusion order barring the importation and sale of infringing digital data sets in any tangible medium. (Citing CPHB at 652) Staff says that consistent with the Commission's prior precedence, and in deference to Customs, Complainant does not seek issuance of an order barring the importation on infringing digital data sets via electronic transmission, provided an appropriate cease and desist order is issued. Staff says that it agrees with Complainant's proposed relief. Staff says that the Commission has previously considered and rejected requests that exclusion orders cover electronic transmissions of software. (Citing *Certain Hardware Logic Emulation Systems and Components Thereof*, Inv. No. 337-TA-383, Commission Opinion at 19-20, USITC Pub. 3089 (March 1998) ("*Hardware Logic*") (refusing to bar electronic transmissions out of deference to Customs, which would have no way to enforce the order); *Certain Systems for Detecting and Removing Viruses or Worms, Components Thereof, and Products Containing the Same*, Inv. No.

337-TA-510, Commission Opinion at 4-5 (Aug. 8, 2005) ("*Viruses and Worms*") (same)) Staff says that as discussed in those decisions, Customs has no way to enforce an order barring electronic transmissions (e.g., by searching every e-mail entering the United States). Staff says that Complainant's suggestion that it will try to enforce the order misses the point: an exclusion order, by definition, directs Customs to exclude infringing products, 19 U.S.C. § 1337(d)(1), which is something that it cannot do with respect to electronic transmissions.

Staff says that if a Section 337 violation is found, the Staff recommends the issuance of a limited exclusion order containing a certification provision. 19 U.S.C. § 1337(d).

Analysis and Conclusions: If the Commission finds a violation of Section 337, I do not recommend that the Commission issue a limited exclusion order to the imported digital data sets. The accused digital data sets are imported by electronic transmission. In *Certain Hardware Logic Emulation Systems and Components Thereof*, Inv. No. 337-TA-383, the Commission refused to bar electronic transmissions out of deference to Customs because Customs would have no way to enforce the order. Comm'n Op. at 20, USITC Pub. 3089 (March 1998) ("*Hardware Logic*"). As a result, I do not recommend that the Commission issue a limited exclusion order.

B. Cease & Desist Order

Align's position: Align says that Section 337(f) permits the Commission to issue a cease and desist orders directing Section 337 violators "to cease and desist from engaging in the unfair methods or acts involved." 19 U.S.C. § 1337(f). Align contends that such orders are warranted for respondents who maintain commercially significant U.S. inventories of the infringing product. (Citing *Certain Crystalline Cefadroxil Monohydrate*, Inv. No. 337-TA-293, Doc. No. 217255 at 37-42 (Mar. 15, 1990)) Align continues that those orders can preclude any activity "reasonably related to the importation of infringing products." (Citing *Certain Hardware*, Inv.

No. 337-TA-383, 1998 WL 307240, at *14 (Feb. 28, 1998)) Align requests that the Commission issue a cease and desist order prohibiting each Respondent from importing, selling, offering for sale, using, demonstrating, promoting, marketing, or advertising in the U.S., or otherwise transferring outside the U.S. for sale in the U.S. the accused digital data sets and aligners, along with any components thereof, that infringe one or more claims of the asserted Patents.

Align says that Respondents' sole quarrel with such relief is their argument that Align must show the existence of "commercially significant inventories" of the digital data sets in the U.S. to obtain a cease and desist order. Align argues that such an argument is wrong, for several reasons.

Align says that a cease and desist order is appropriate against "any person violating [Section 337], or believed to be violating this section[.]" (Citing 19 U.S.C. § 1337(f)) Align continues that the ITC generally issues such orders where a Respondent has a "'commercially significant' amount of infringing, imported product in the U.S. that could be sold" – in tandem with an ***exclusion order***. (Citing *Certain Protective Cases*, Inv. No. 337-TA-780, Comm'n Op. at 28 (Nov. 19, 2012), I.D. at 119 (June 29, 2012)) Align continues that the cease and desist order prevents sale of products already in the U.S. and precludes the infringing party from continuing to profit from its infringement.

Align says that here, Respondents import the accused digital data sets through electronic transmission. Align continues that the Commission has previously determined that the only available remedy for electronic transmission is a cease and desist order. (Citing *Certain Hardware Logic*, Comm'n Op. at 20; *see also Certain Protective Cases*, Inv. No. 337-TA-780, Comm'n Op. at 28 (Nov. 19, 2012), I.D. at 120 (June 29, 2012) (extending cease and desist orders to internet activities and sales)) Align concludes that the cease and desist order sought by

Align would be the primary bar against Respondents' importation (and related sales) as it would not issue in tandem with an exclusion order. Align says that the imposition of a "commercially significant" inventory requirement would leave no practical mechanism to prevent importation. (Citing *Certain Hardware Logic*, Comm'n Op. at 28 ("Indeed, a cease and desist order that did not prohibit electronic transmission would be meaningless as to the software since respondents would be free simply to transmit the software electronically to a U.S. customer...")).

Align says that nevertheless, should the presiding ALJ believe that the "commercially significant" requirement must be satisfied, the evidence is that {

} Align avers that in *Certain Gaming and Entertaining Consoles*, the ALJ found that the respondent had a significant domestic inventory when it had distribution centers that it regularly replenished with inventory stock from China. (Citing *Certain Gaming and Entertaining Consoles*, Inv. No. 337-TA-752, Recommended Determination on Remedy and Bonding at 4-5 (May 7, 2012)) Align continues that on any one day, a commercially significant inventory of infringing digital data sets is { } waiting to be used to fabricate aligners, and a commercially significant inventory of aligners is waiting to be shipped to the prescribing dentists. Align says that Respondents did not introduce any contrary evidence.

(Citing Certain Reducted Ignition Proclivity Cigarette Paper Wrappers, Inv. No. 337-TA-756, I.D. at 299 (Feb. 17, 2012) (finding commercially significant inventory where respondent failed to directly dispute the evidence presented))

Align says that Staff's position is that a cease and desist order should not be issued to CCPK because the Commission would have difficulty enforcing such an order. Align says that the case law cited by Staff is directed to the issuance of a cease and desist order in conjunction with an exclusion order, and is therefore factually distinguishable. Align says that the only remedy available against CCPK is a cease and desist order, and such an order should issue at least to enable Align to file a subsequent enforcement action should CCPK continue its infringing conduct. Align says that the Commission has previously issued a cease and desist order against a foreign respondent in an analogous situation where that respondent's domestic distributor has maintained a commercially significant inventory in the U.S. (Citing *Certain Toner Cartridges*, Inv. No. 337-TA-740, Comm'n Op. at 7-8 (Oct. 5, 2011) (citing *Certain Abrasive Products*, Inv. No. 337-TA-449, Comm'n Op. at 7-8 (May 2, 2002)))

Align says that the principals and managing employees of Respondents have engaged, many of them for the second time, in a deliberate, calculated and improper effort to circumvent Align's patents and other intellectual property protections. Align therefore requests that these individuals, including at least Jarrett Pumphrey, Willis Pumphrey, Mudassar Rathore, Nadeem Arif, Waqas Wahab and Asim Waheed be named with specificity in the *Cease and Desist Order*.

Respondents' Position: Respondents contend that there is no basis for imposing a cease and desist order in this investigation. Respondents say that in order to justify a cease and desist order, the Commission typically requires a complainant to establish the existence of commercially significant inventories of infringing products in the United States and that, absent a

cease and desist order, the exclusion order would be circumvented. (Citing *Certain Cigarettes & Packaging Thereof*, USITC Pub. 3366, Inv. No. 337-TA-424 (Nov. 2000); *Certain Nonwoven Gas Filter Elements*, USITC Pub. 2129, Inv. No. 337-TA-275 (Sept. 1988); *Certain High Intensity Retroreflective Sheeting*, USITC Pub. 2121, Inv. No. 337-TA-268, Comm'n Op. at 9 (Sept. 1988)) Respondents continue that Align presented no evidence at the hearing that the Respondents maintain commercially significant inventories in the United States of any of CCUS products. Therefore, Respondents conclude that Align is not entitled to a cease and desist order against the Respondents.

Respondents say that Align admits that cease and desist orders are warranted only for respondents who "maintain significant U.S. inventories of the infringing product." (Citing CIB at 146) Respondents continue that Align fails to meet its burden of showing that there are any U.S. inventories of infringing product, let alone commercially significant ones. Respondents say that Staff agrees no cease and design order should issue against CCPK since it's located outside the U.S. (Citing SIB at 118) Respondents say that Align provides no evidence of inventories that would warrant a cease and desist order against CCUS and, as a result, there is no basis for imposing a cease and desist order in this investigation.

Staff's Position: Staff says that Complainant also seeks issuance of a cease and desist order "prohibiting each Respondent from importing, selling, offering for sale, using, demonstrating, promoting, marketing, or advertising in the United States, or otherwise transferring outside the United States for sale in the United States the accused digital data sets and aligners, along with any components thereof, that infringe one or more claims of the asserted Patents." Staff agrees that a cease and desist order directed to CCUS would be appropriate in the event that a violation is found. Staff submits, however, that a cease and desist order should not

be directed to CCPK. Staff says that as a matter of prudence, the Commission does not issue cease and desist orders to foreign companies that do not have a domestic inventory because it would have no effective means of enforcing such an order. (Citing *Certain Flash Memory Circuits and Products Containing Same,* Inv. No. 337-TA-382, Commission Opinion at 25, USITC Pub. 3046 (July 1997) ("It is our practice to issue cease and desist orders only to domestic respondents, particularly in light of the difficulty of enforcing such orders against foreign entities."); *see also, e.g., Certain Composite Wear Components and Products Containing Same,* Inv. No. 337-TA-644, Commission Opinion at 8-9 (Nov. 24, 2009), *citing Microsphere Adhesives,* Commission Opinion at 22-23 ("[A] cease and desist order is typically an *in personam* order directed to a party in the United States and enforced by the Commission in U.S. district courts. Thus, unless a party in the United States can be compelled to do some act or refrain from doing some act by U.S. courts a cease and desist order is inappropriate.")) Staff says that although the Commission has prohibited electronic transmissions in cease and desist orders, these orders were all issued to domestic companies. (Citing *Viruses or Worms,* Order to Cease and Desist at 1; *Hardware Logic,* Order to Cease and Desist at 1)

Analysis and Conclusions: If the Commission finds a violation of Section 337, I recommend the entry of a cease and desist against CCUS and CCPK as well as all of their affiliated companies, parents, subsidiaries, or other related business entities, or their successors or assigns, that prohibits importation (electronically or otherwise) into the United States, the sale for importation, or the sale within the United States after importation of certain digital models, digital data, and treatment plans for use in making incremental dental positioning adjustment appliances, the appliances made therefrom, and the use of the methods of making the same, that infringe one or more claims of the patents in suit.

Section 337 provides that the Commission may issue a cease and desist order as a remedy for violation of Section 337. *See* 19 U.S.C. § 1337(f)(1). The Commission generally issues a cease and desist order directed to a domestic respondent when there is a "commercially significant" amount of infringing, imported product in the United States that could be sold so as to undercut the remedy provided by an exclusion order. *See Certain Crystalline Cefadroxil Monohydrate*, Inv. No. 337-TA-293, USITC Pub. 2391, Comm'n Op. on Remedy, the Public Interest and Bonding at 37-42 (June 1991); *Certain Condensers, Parts Thereof and Products Containing Same, Including Air Conditioners for Automobiles*, Inv. No. 337-TA-334, Comm'n Op. at 26-28 (Aug. 27, 1997). The complainant bears the burden of proving that a respondent has a commercially significant inventory in the United States. *Certain Integrated Repeaters, Switches, Transceivers & Products Containing Same*, Inv. No. 337-TA-435, Comm'n Op., 2002 WL 31359028 (Aug. 16, 2002).

I find that Align has shown that CCUS has a commercially significant inventory in the United States. {

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The Commission has granted cease and desist orders directed to the electronic transmission of software in previous cases. In *Certain Hardware Logic Emulation Systems and Components Thereof*, the Commission issued a Cease and Desist order that "prohibit[ed] the

electronic transmission of respondents' software." Inv. No. 337-TA-383, Comm'n Op. at 28 (March 1998). The software at issue in *Hardware Logic* could be used to infringe certain claims once imported. *Id.* at 27-28. The Commission noted that "[o]ur remedial authority extends to the prohibition of all acts reasonably related to the importation of infringing products and is not limited to articles that directly infringe a United States patent," and found that because there is a direct nexus between the imported contributorily infringing components, including the software, and infringement of the patents in issue, a cease and desist order covering respondents' contributorily infringing software was warranted. *Id.* The Commission also has issued a cease and desist order against a foreign entity. *See, e.g., Certain Abrasive Products*, Inv. No. 337-TA-449, COmm'n Op. (May 9, 2002). There, the Commission issued a cease and desist order against Kinik Company of Taipei, Taiwan, prohibiting the company from selling or engaging in various other commercial activities relating to such products within the United States. (*Id.*)

Similar facts present themselves here. I find in Section V *supra*, that the digital data sets imported by Respondents contributorily infringe some claims of the patents in suit, and there is a direct nexus between the digital data sets and the infringement—all that remains to complete infringement is manufacturing aligners based on the digital data sets. I also found in Section V *supra*, that the digital data sets directly infringe some claims of the patents in suit. Based upon the foregoing, if the Commission finds a violation of Section 337, I recommend the entry of a cease and desist against CCUS and CCPK as well as all of their affiliated companies, parents, subsidiaries, or other related business entities, or their successors or assigns, that prohibits importation (electronically or otherwise) into the United States, the sale for importation, or the sale within the United States after importation of certain digital models, digital data, and treatment plans for use in making incremental dental positioning adjustment appliances, the

appliances made therefrom, and the use of the methods of making the same, that infringe one or more claims of the patents in suit.

Align requests that principles and managing employees of CCUS and CCPK be named with specificity in the *Cease and Desist Order*. If the Commission finds a violation of Section 337, I do not recommend that the cease and desist order extend beyond CCPK and CCUS, because the principles and managing employees of CCUS and CCPK were not named as respondents in the notice of investigation.

C. Bonding

Align's position: Align says that if the Commission provides relief under Section 337(d)-(g), Respondents may continue to import and sell their products during the 60-day Presidential Review period under a bond in an amount determined by the Commission to be "sufficient to protect the complainant from any injury." (Citing 19 U.S.C. § 1337(j)(3); 19 C.F.R. § 210.50) Align says that a bond of 100% of the entered value (*i.e.*, the domestic value of the articles entered or sold on a given day) for any importation of infringing products in the review period should be imposed. Align argues that a 100% bond is appropriate where the digital data sets are a component of the final product and it is difficult to usefully compare the prices of the infringing digital data sets to the products in the domestic industry. (Citing *Certain Neodymium-Iron-Boron Magnets*, Inv. No. 337-TA-372, 1996 WL 1056324, at *13 (Apr. 30, 1996)) Align says that that twice the average monthly revenue received by CCPK from CCUS during the last twelve months of data available is an appropriate bond for the 60-day review period. Align continues that on average, {

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Align says that Respondents contend a bond is appropriate "only if the Commission were to issue an exclusion order" but offer no legal support for this contention. Align says that Staff argues that Align has not provided any authority for calculating the bond amount using CCPK's average revenue. (Citing SIB at 119) Align disagrees and says that its methodology and the evidence it relies upon were previously identified. (Citing CIB at 146-47)

Align says that Respondents argue that "[e]ven if the Commission were to find that the digital data sets are imported articles, they have no entered value." Align continues that this is a curious position for Respondents, who have consistently maintained that CCPK is a mere "vendor" of CCUS. Align says that if that is true, the digital data sets must have some intrinsic value measured by the amount CCUS pays for them. Align continues that the evidence shows that CCUS believes the digital data sets have value as it has stated that it is about four times cheaper to manufacture the digital data in Pakistan than in the U.S. (Citing Tr. at 312:15-19; CX-0595C)

Align says that { } (Citing Tr. at 445:12-24) Align says that all of CCPK's revenue is derived from payments by CCUS (Citing Tr. at 443:11-14), and those payments are for the digital data CCPK sends to CCUS. (Citing Tr. at 320:2-9, 364:20-365:12, 373:24-374:4; CX-1160C.2 at 278:2-9, 294:2-7, 296:3-7; CX-1160C.3 at 422:25-423:8) Align continues that the { } must reflect the sum total of the costs of the digital data sets for that month. Align says that because the Review period lasts two months, Align proposes to set two months' worth of average revenue as the bond amount{ - .}

Respondents' Position: Respondents assert that "[t]he complainant has the burden of supporting any proposition it advances, including the amount of bond." (Citing *Certain Rubber*

Antidegradants, Components Thereof & Prods. Containing Same, USITC Pub. 3975, Inv. No. 337-TA-533, Comm'n Op. at 40 (April 2008); *Certain Silicone Microphone Packages & Prods. Containing Same*, Inv. No. 337-TA-629, Initial Determination at 222 (Feb. 2009) (finding complainant had "failed to meet its burden in supporting its argument that a 100% bond is appropriate"))

Respondents say that a bond would be appropriate only if the Commission were to issue an exclusion order. Respondents continue that they are unaware of any basis in the record for a bond, either based on a royalty rate or price differentials with respect to the CCPK imported products, which are digital data sets. Respondents say that even if the Commission were to find that the digital data sets are imported articles, they have no entered value and therefore there is no basis for imposing a bond. Respondents continue that the "bond" proposed by Align, based on "twice the average monthly revenue" received by CCPK from CCUS, bears no relationship to individual transmissions of data, even if they were "importations," and therefore is not a viable bond proposal.

Staff's Position: Staff contends that should the Commission determine to issue a remedial order, then the affected articles shall still be entitled to entry and sale under bond during the Presidential review period. Staff says that the amount of such bond must be sufficient to protect the complainant from any injury. (Citing 19 U.S.C. § 1337(j)) Staff says that should remedial orders be issued, a bond in the amount that is deemed appropriate based on the record evidence should be entered in this investigation.

Staff says that the evidence does not support setting the amount of bond based on the price differential between the imported products (digital data sets) and the domestic products (aligners) or on a reasonable royalty. Staff says that the digital data sets are a component of the

aligners, and the evidence does not specifically establish the entered value for importation of digital data sets. Staff says that Align argues that twice the average monthly revenue that is received by CCPK from CCUS during the last twelve months is an appropriate amount of bond. (Citing CPHB at 654) Staff asserts that Align has not provided any authority for calculating the amount of bond in this particular manner and has not pointed to any evidence establishing that this calculated amount of bond is appropriate or necessary to protect it from any injury. Staff concludes that Align has not met its burden of establishing that its proposed amount of bond is appropriate. (Citing *Certain Liquid Crystal Display Devices and Products Containing Same*, Inv. No. 337-TA-631, Comm'n Opinion at 27-28 (July 14, 2009))

Analysis and Conclusions: The administrative law judge and the Commission must determine the amount of bond to be required of a respondent, pursuant to section 337(j)(3), during the 60-day Presidential review period following the issuance of permanent relief, in the event that the Commission determines to order a remedy. The purpose of the bond is to protect the complainant from any injury. 19 C.F.R. §§ 210.42(a)(1)(ii), 210.50(a)(3). The complainant has the burden of supporting any bond amount it proposes. *Certain Rubber Antidegradants, Components Thereof, and Products Containing Same*, Inv. No. 337-TA-533, Comm'n Op., 2006 ITC LEXIS 591 (Jul. 21, 2006).

When reliable price information is available, the Commission has often set the bond by eliminating the differential between the domestic product and the imported, infringing product. *See Certain Microsphere Adhesives, Processes for Making Same, and Products Containing Same, Including Self-Stick Repositionable Notes*, Inv. No. 337-TA-366, Comm'n Op. a 24 (1995). In other cases, the Commission has turned to alternative approaches, especially when the level of a reasonable royalty rate could be ascertained. *See, e.g., Certain Integrated Circuit*

Telecommunication Chips and Products Containing Same, Including Dialing Apparatus, Inv. No. 337-TA-337, Comm'n Op. at 41 (1995).

The Commission has set a bond of 100% when the evidence supported a finding that it would be difficult or impossible to calculate a bond based on price differentials. *Certain Variable Speed Wind Turbines and Components Thereof*, Inv. No. 337-TA-376, Comm'n Op., 1996 WL 1056209 (Sept. 23, 1996) (finding that a bond of 100% was appropriate "because of the difficulty in quantifying the cost advantages of respondents' imported Enercon E-40 wind turbines and because of price fluctuations due to exchange rates and market conditions."); *Certain Systems For Detecting and Removing Viruses or Worms, Components Thereof, and Products Containing Same*, Inv. No. 337-TA-510, Comm'n Op., 2007 WL 4473083 (Aug. 2007) (imposing a bond of 100% based on a finding that the parties had numerous models and products lines, and that a price comparison would be difficult because respondent's products were a combination of hardware and software while the complainant's products were software only); *Certain Flash Memory Circuits and Products Containing Same*, Inv. No. 337-TA-382, USITC Pub. No. 3046, Comm'n Op. at 26-27 (July 1997) (a 100% bond imposed when price comparison was not practical because the parties sold products at different levels of commerce, and the proposed royalty rate appeared to be *de minimis* and without adequate support in the record).

In *Certain Rubber Antidegradants*, the Commission did not require a bond. The presiding administrative law judge had set no bond, finding, "no evidence in the record to support any bond to offset any competitive advantage resulting from the unfair acts of [respondents] from their importations." *Certain Rubber Antidegradants*, 2006 ITC LEXIS 591, at *59.

The respondent argued that the lack of pricing information was due to the complainant's failure to adduce such evidence during the hearing and complainant should not be able to benefit from that failure. (*Id.* at 60.) In response, the complainant argued that it had no burden of proof with respect to bonding, and that the existence of a violation is sufficient to support a 100% bond. (*Id.*) In deciding the issue, the Commission stated:

> We find the ALJ's recommendation appropriate in the circumstances here and have determined not to require that a bond be posted for temporary importation. In our view, the complainant has the burden of supporting any proposition it advances, including the amount of the bond. [The complainant] did not meet that burden.

(*Id.*)

If the Commission finds a violation of Section 337, I do not recommend a bond during the two month review period. The burden is on Align to support the amount of the bond it seeks. Although Align argues that a 100% bond is appropriate because it is difficult to compare the prices of the infringing digital data sets to the products in the domestic industry, Align cites no evidence supporting its argument or to demonstrate any effort on its part to develop facts necessary to calculate a reasonable bond. Rather, Align merely states that "it is difficult to usefully compare the prices of the infringing digital data sets to the products in the domestic industry." (CIB at 146)

Align does not explain why it could not compare the { } to its own costs for producing digital data sets in the treatment of patients to establish the appropriate bond. Because Align has not met its burden to support the 100% bond it proposes, if the Commission finds a violation of Section 337, I do not recommend a bond during the two month review period.

VIII. MATTERS NOT DISCUSSED

This Initial Determination's failure to discuss any matter raised by the parties, or any portion of the record, does not indicate that it has not been considered. Rather, any such matter(s) or portion(s) of the record has/have been determined to be irrelevant, immaterial or meritless. Arguments made on brief which were otherwise unsupported by record evidence or legal precedent have been accorded no weight.

IX. CONCLUSIONS OF LAW

1. The Commission has subject matter jurisdiction, *in rem* jurisdiction, and *in personam* jurisdiction.

2. There has been an importation into the United States, sale for importation, or sale within the United States after importation of the accused digital data sets, which are the subject of the alleged unfair trade allegations.

3. An industry does exist in the United States that exploits U.S. Pat. Nos. 6,217,325; 6,722,880; 8,070,487; 6,471,511; 6,705,863; and 7,134,874 as required by 19 U.S.C. § 1337(a)(2).

4. An industry does not exist in the United States that exploits U.S. Pat. No. 6,626,666 as required by 19 U.S.C. § 1337(a)(2).

5. Claims 1, 2, 3, 11, 13, 14, 21, 30, 31, 32, 33, 34, 35, 38, and 39 of U.S. Pat. No. 6,217,325 are not invalid pursuant to 35 U.S.C. §§ 102 and 103.

6. Claims 1 and 3 of U.S. Pat. No. 6,722,880 are not invalid pursuant to 35 U.S.C. §§ 102 and 103.

7. Claims 1, 3, 5, 7, 8, and 9 of U.S. Pat. No. 8,070,487 are not invalid pursuant to 35 U.S.C. §§ 102 and 103.

8. Claim 1 of U.S. Pat. No. 6,471,511 is not invalid pursuant to 35 U.S.C. §§ 102 and 103.

9. Claims 1, 3, 7, and 9 of U.S. Pat. No. 6,626,666 are not invalid pursuant to 35 U.S.C. §§ 102 and 103.

10. Claims 1, 4, 5, 6, 7, and 8 of U.S. Pat. No. 6,705,863 are not invalid pursuant to 35 U.S.C. §§ 102 and 103.

11. Claims 1, 2, 38, 39, 41, and 62 of U.S. Pat. No. 7,134,874 are not invalid pursuant to 35 U.S.C. §§ 102 and 103.

12. The accused digital models, digital data sets, and treatment plans for use in making incremental dental positioning adjustment appliances, the appliances made therefrom, and the methods of making the same, infringe claims 1, 2, 3, 11, 13, 14, 21, 30, 31, 32, 33, 34, 35, 38, and 39 of U.S. Pat. No. 6,217,325.

13. The accused digital models, digital data sets, and treatment plans for use in making incremental dental positioning adjustment appliances, the appliances made therefrom, and the methods of making the same, infringe claims 1 and 3 of U.S. Pat. No. 6,722,880.

14. The accused digital models, digital data sets, and treatment plans for use in making incremental dental positioning adjustment appliances, the appliances made therefrom, and the methods of making the same, infringe claims 1, 3, and 5 of U.S. Pat. No. 8,070,487.

15. The accused digital models, digital data sets, and treatment plans for use in making incremental dental positioning adjustment appliances, the appliances made therefrom, and the methods of making the same, do not infringe claims 7, 8, and 9 of U.S. Pat. No. 8,070,487.

16. The accused digital models, digital data sets, and treatment plans for use in making incremental dental positioning adjustment appliances, the appliances made therefrom, and the

methods of making the same, infringe claim 1 of U.S. Pat. No. 6,471,511.

17. The accused digital models, digital data sets, and treatment plans for use in making incremental dental positioning adjustment appliances, the appliances made therefrom, and the methods of making the same, infringe claims 1, 3, 7, and 9 of U.S. Pat. No. 6,626,666.

18. The accused digital models, digital data sets, and treatment plans for use in making incremental dental positioning adjustment appliances, the appliances made therefrom, and the methods of making the same, infringe claims 1, 4, 5, 6, 7, and 8 of U.S. Pat. No. 6,705,863.

19. The accused digital models, digital data sets, and treatment plans for use in making incremental dental positioning adjustment appliances, the appliances made therefrom, and the methods of making the same, infringe claims 1, 2, 38, 39, 41, and 62 of U.S. Pat. No. 7,134,874.

20. There is a violation of 19 U.S.C. § 1337(a)(1)(B) with respect to U.S. Pat. Nos. 6,217,325; 6,722,880; 8,070,487; 6,471,511; 6,705,863, and 7,134,874.

X. ORDER

Based on the foregoing, and the record as a whole, it is my Final Initial Determination that there is a violation of 19 U.S.C. § 1337(a)(1)(B) in the sale for importation and the importation into the United States of certain digital models, digital data sets, and treatment plans, and the sale of incremental dental positioning adjustment appliances made using the digital models, digital data sets, and treatment plans after importation thereof.

I hereby **CERTIFY** to the Commission my Final Initial and Recommended Determinations together with the record consisting of the exhibits admitted into evidence. The pleadings of the parties filed with the Secretary, and the transcript of the pre-hearing conference and the hearing, as well as other exhibits, are not certified, since they are already in the Commission's possession in accordance with Commission rules.

It is further **ORDERED** that:

In accordance with Commission Rule 210.39, all material heretofore marked *in camera* because of business, financial and marketing data found by the administrative law judge to be cognizable as confidential business information under Commission Rule 201.6(a), is to be given *in camera* treatment continuing after the date this investigation is terminated.

The initial determination portion of the Final Initial and Recommended Determination, issued pursuant to Commission Rule 210.42(a)(1)(i), shall become the determination of the Commission sixty (60) days after the service thereof, unless the Commission, within that period, shall have ordered its review of certain issues therein, or by order, has changed the effective date of the initial determination portion. If the Commission determines that there is a violation of 19 U.S.C. § 1337(a)(1), the recommended determination portion, issued pursuant to Commission Rule 210.42(a)(1)(ii), will be considered by the Commission in reaching a determination on remedy and bonding pursuant to Commission Rule 210.50(a).

On or before May 17, 2013, the parties shall submit to the Office of Administrative Law Judges ***a joint statement*** regarding whether or not they seek to have any portion of this document deleted from the public version. The parties' submission shall be made by hard copy and must include a copy of this Initial Determination with red brackets indicating any portion asserted to contain confidential business information to be deleted from the public version. The parties' submission shall include an index identifying the pages of this document where proposed redactions are located. The parties' submission concerning the public version of this document need not be filed with the Commission Secretary.

SO ORDERED.

Issued: 5/6/2013
DATE

Robert K. Rogers, Jr.
Administrative Law Judge

CERTAIN DIGITAL MODELS, DIGITAL DATA, AND TREATMENT PLANS FOR USE IN MAKING INCREMENTAL DENTAL POSITIONING ADJUSTMENT APPLIANCES, THE APPLIANCES MADE THEREFROM, AND METHODS OF MAKING SAME

Inv. No. 337-833

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **ORDER** was served upon **Vu Bui, Esq.**, Commission Investigative Attorney, and the following parties via first class mail delivery on

JUN 14 2013

Lisa R. Barton, Acting Secretary
U.S. International Trade Commission
500 E Street SW, Room 112A
Washington, D.C. 20436

FOR COMPLAINANT ALIGN TECHNOLOGY, INC.:

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CERTAIN DIGITAL MODELS, DIGITAL DATA, AND TREATMENT PLANS FOR USE IN MAKING INCREMENTAL DENTAL POSITIONING ADJUSTMENT APPLIANCES, THE APPLIANCES MADE THEREFROM, AND METHODS OF MAKING SAME

Inv. No. 337-833

PUBLIC CERTIFICATE OF SERVICE PAGE 2

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