

*In the Matter of*

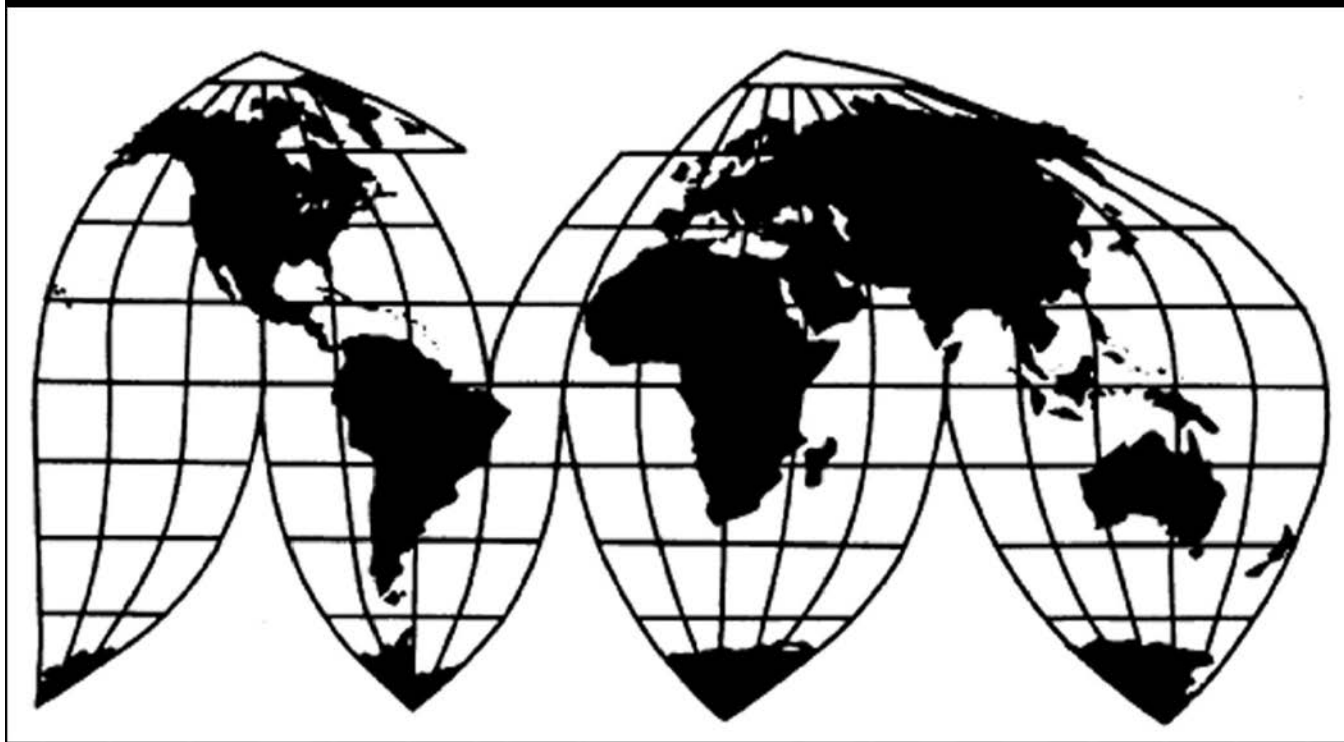
**CERTAIN DIGITAL MODELS, DIGITAL  
DATA, AND TREATMENT PLANS FOR USE  
IN MAKING INCREMENTAL DENTAL  
POSITIONING ADJUSTMENT APPLIANCES**

337-TA-833

Publication 4555

November 2017

**U.S. International Trade Commission**



Washington, DC 20436

# **U.S. International Trade Commission**

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**United States International Trade Commission**  
**Washington, DC 20436**

# U.S. International Trade Commission

Washington, DC 20436  
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*In the Matter of*

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

337-TA-833



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.

A handwritten signature in black ink, appearing to read 'Lisa R. Barton', written in a cursive style.

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.

A handwritten signature in black ink, appearing to read "Lisa R. Barton". The signature is fluid and cursive, with the first name "Lisa" being the most prominent part.

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).<sup>1</sup> 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,

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<sup>1</sup> 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.



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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  
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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.

A handwritten signature in black ink, appearing to read "Lisa R. Barton", written in a cursive style.

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](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.<sup>1</sup>

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,

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<sup>1</sup> 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](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.<sup>1</sup>

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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<sup>1</sup> 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.

A handwritten signature in black ink, appearing to read "Lisa R. Barton", written in a cursive style.

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**



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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**

**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.<sup>1</sup> The Commission’s determination rested on findings of infringement with respect to five patents owned by complainant Align

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<sup>1</sup> 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.<sup>2</sup> 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

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<sup>2</sup> 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.*<sup>3</sup>

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<sup>3</sup> 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

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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.<sup>4</sup> 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

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<sup>4</sup> 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.

A handwritten signature in black ink, appearing to read "Lisa R. Barton". The signature is stylized and cursive.

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  
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**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

## PUBLIC VERSION

(“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.<sup>1</sup> 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.<sup>2</sup> 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

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<sup>1</sup> 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.

<sup>2</sup> Resp’ts’ Mot. to Stay Cease and Desist Orders (May 2, 2014) (“ClearCorrect Mot.”).

## PUBLIC VERSION

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.<sup>3</sup> 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.

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<sup>3</sup> 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").

## PUBLIC VERSION

### 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 it 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).

## PUBLIC VERSION

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.<sup>4</sup> 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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<sup>4</sup> *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.<sup>5</sup>

#### 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.<sup>6</sup>

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<sup>5</sup> 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).

<sup>6</sup> 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.



## PUBLIC VERSION

### 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 Pakistani operations.<sup>7</sup>

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.

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<sup>7</sup> 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.*

## PUBLIC VERSION

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.<sup>8</sup>

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<sup>8</sup> 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.

## PUBLIC VERSION

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.<sup>9</sup> 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).<sup>10</sup> 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

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<sup>9</sup> 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.

<sup>10</sup> Comm'n Op. 148-52.

## PUBLIC VERSION

balance, we do not find that the public interest arguments raised in the briefings on stay weigh heavily in either direction.<sup>11</sup>

### 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.<sup>12</sup>

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.<sup>13</sup> Our historical experience demonstrates that the circumstances of most

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<sup>11</sup> 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.

<sup>12</sup> 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.

<sup>13</sup> 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.

**PUBLIC VERSION**

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.

A handwritten signature in black ink, appearing to read 'Lisa R. Barton', written in a cursive style.

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**

**TABLE OF CONTENTS**

**I. BACKGROUND..... 1**

**A. Procedural History..... 1**

**B. Related Cases..... 4**

**C. The Patents ..... 7**

**D. The Groups of Asserted Claims..... 15**

**E. The Accused Products and Processes..... 16**

**II. STANDARD FOR DETERMINATION ON REVIEW..... 21**

**III. DISCUSSION ..... 21**

**A. “Importation . . . of Articles”..... 21**

**B. Claim Construction..... 55**

**C. Infringement..... 69**

**D. Invalidity..... 115**

**E. Estoppel Defense (Including Defense of Implied License or Patent Exhaustion)..... 136**

**F. Domestic Industry - - Economic Prong..... 139**

**G. Domestic Industry - - Technical Prong ..... 139**

**IV. REMEDY, THE PUBLIC INTEREST, AND BONDING ..... 144**

**A. Remedy..... 144**

**B. The Public Interest..... 149**

**C. Bonding..... 153**

**V. CONCLUSION..... 153**



**PUBLIC VERSION**

Abbreviation	Full Name
ID	Initial Determination
RD	Recommended Determination
Align Pet.	Complainant Align Technology, Inc.'s Petition and Contingent Petition for Review of the Initial Determination
Resps. Pet.	Respondents' Petition for Review
IA Pet.	Petition of the Office of Unfair Import Investigations for Review of the Initial Determination on Violation of Section 337
Align Resp. to Resps.	Complainant Align Technology, Inc.'s Response to Respondents' Petition for Review of the Initial Determination
Align Resp. to IA	Complainant Align Technology, Inc.'s Response to the Office of Unfair Import Investigations' Petition for Review of the Initial Determination
Resps. Resp.	Respondents' Response to Align's Petition for Review and Contingent Petition for Review of the Initial Determination and Response to Petition of the Office of Unfair Import Investigations for Review of the Initial Determination
IA Resp.	Response of the Office of Unfair Import Investigations to the Private Parties' Petitions for Review of the Initial Determination on Violation of Section 337
Align Sub.	Complainant Align Technology, Inc.'s Written Submission on Issues Under Review and on Remedy, the Public Interest and Bonding
Resps. Sub.	Respondents' Response to the Notice of the Commission's Determination to Review the Final Initial Determination of the Administrative Law Judge
IA Sub.	Response of the Office of Unfair Import Investigations to the Commission's Request for Written Submissions on Issues Under Review
Align Reply Sub.	Complainant Align Technology, Inc.'s Reply to Respondents' and Staff's Written Submissions on Issues Under Review and on Remedy, Public Interest and Bonding
Resps. Reply Sub.	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
IA 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
Align Add. Sub.	Complainant Align Technology, Inc.'s Written Submission on the Commission's January 17, 2014 Questions
Resps. Add. Sub.	[Respondents'] Response to the Commission's January 17, 2014 Notice

**PUBLIC VERSION**

IA Add. Sub.	OUII's Response to the Commission's Request for Additional Written Submissions
MPAA Sub.	Submission on Behalf of Motion Picture Association of America in Response to Commission's January 17, 2014 Notice
Google Sub.	Submission of Non-Party Google Inc. in Response to Commission's Request for Public Comments
Katz Sub.	Memorandum Providing Public Comment In Response To Notice Of Commission Determination To Extend The Target Date For Completion Of The Investigation; Schedule For Filing Of Additional Written Submissions From The Parties And The Public
Align. Reply Add. Sub.	Complainant Align Technology, Inc.'s Reply Written Submission on the Commission's January 17, 2014 Questions
Resps. Reply Add. Sub.	Respondents' Non-Confidential Reply to Written Submissions in Response to the Commission's January 17, 2014 Notice
IA Reply Add. Sub.	Response of the Office of Unfair Import Investigations to the Additional Written Submissions from the Parties and the Public
MPAA Reply Sub.	Reply Comments Filed on Behalf of Motion Picture Association of America
AAP Sub.	Association of American Publishers Reply Comments
Nokia Sub.	Reply Written Submission of Non-Party Nokia Corp. to the Submissions in Response to the Commission's Request for Public Comments

## PUBLIC VERSION

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.<sup>1</sup> 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

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<sup>1</sup> Commissioner Johanson has filed a dissenting opinion, post.

## PUBLIC VERSION

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.

## PUBLIC VERSION

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).<sup>2</sup> 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.

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<sup>2</sup> Mr. Katz is an attorney of the law firm Belles Katz LLC in Horsham, Pennsylvania.

## PUBLIC VERSION

### 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<sup>3</sup> 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.

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<sup>3</sup> 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.

## PUBLIC VERSION

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.

## PUBLIC VERSION

Align further alleged that both CCUS and CCPK are “successor[s], assign[s], or agent[s]” of the original OrthoClear respondents. *Id.* ¶ 24, 31.<sup>4</sup> 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.

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<sup>4</sup> ClearCorrect USA and ClearCorrect Pakistan have denied these allegations. Response of CCUS to Enforcement Complaint ¶ 24; Response of CCPK to Enforcement Complaint ¶ 31.



## PUBLIC VERSION

### 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.<sup>5</sup> *See, e.g.*, '880 Patent Abstract.<sup>6</sup> 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,<sup>7</sup> 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.*

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<sup>5</sup> The asserted patents note that "the appliances can be braces, polymeric shells, or other forms of orthodontic appliances." '511 patent Abstract.

<sup>6</sup> The asserted patents have different specifications, but are from the same family.

<sup>7</sup> JX-3.

## PUBLIC VERSION

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 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.

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

### **2. The '880 Patent**

The '880 patent,<sup>8</sup> 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

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<sup>8</sup> JX-2.

## PUBLIC VERSION

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.*

## PUBLIC VERSION

### 3. The '487 Patent

The '487 patent,<sup>9</sup> 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.

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<sup>9</sup> JX-7.

## PUBLIC VERSION

*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,<sup>10</sup> entitled "Defining Tooth-Moving Appliances Computationally," issued on October 29 2002, based on Application No. 09/169,034, filed by Muhammad Chishti, Elena I. Pavlovskaja, 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

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<sup>10</sup> JX-1.

## PUBLIC VERSION

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,<sup>11</sup> 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

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<sup>11</sup> JX-4.

## PUBLIC VERSION

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,<sup>12</sup> 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

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<sup>12</sup> JX-5.

## PUBLIC VERSION

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,<sup>13</sup> 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

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<sup>13</sup> JX-6.



## PUBLIC VERSION

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.<sup>14</sup>

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<sup>14</sup> 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.”);

## PUBLIC VERSION

### 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.

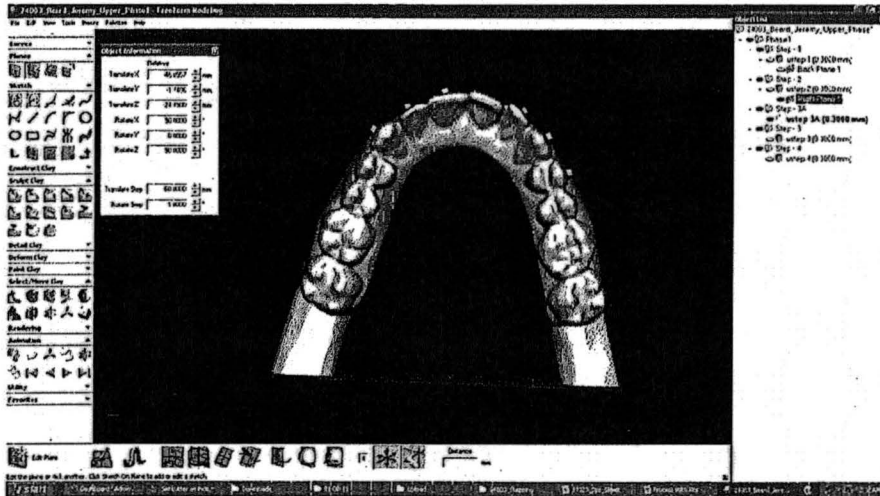
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Respondents' Reply To The OUII & Align's Response To Notice Of The Commission's Determination To Review The Final Initial Determination Of The ALJ and Exhibits ("Resps. Reply Sub."); Response of the Office of Unfair Import Investigations to Written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

## PUBLIC VERSION

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.*

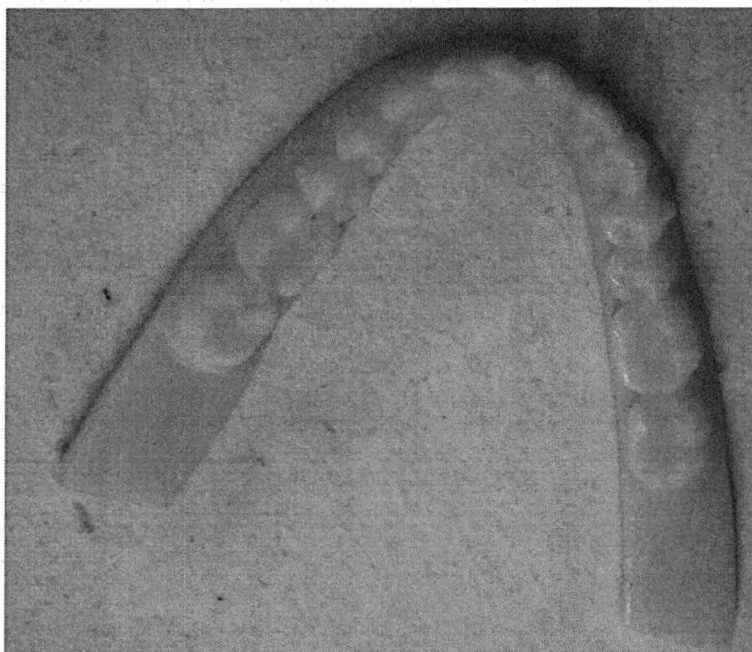
Below is an image of a computer model of the teeth.



CX-90C at 54.

## PUBLIC VERSION

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).

**PUBLIC VERSION**

**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-

## PUBLIC VERSION

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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## PUBLIC VERSION

### 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,

## PUBLIC VERSION

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).



## PUBLIC VERSION

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.<sup>15</sup> *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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<sup>15</sup> 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.

## PUBLIC VERSION

### 2. Arguments<sup>16</sup>

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

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<sup>16</sup> 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>.

## PUBLIC VERSION

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)).

## PUBLIC VERSION

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

## PUBLIC VERSION

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

## PUBLIC VERSION

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

## PUBLIC VERSION

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

## PUBLIC VERSION

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.



## PUBLIC VERSION

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 Nuijten*, 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

## PUBLIC VERSION

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

## PUBLIC VERSION

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

## PUBLIC VERSION

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.<sup>17</sup> 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

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<sup>17</sup> 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.

## PUBLIC VERSION

(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).<sup>18</sup> 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.<sup>19</sup> 78 *Fed. Reg.* 46611 (Aug. 1, 2013); 79 *Fed. Reg.* 4174 (Jan. 24, 2014).

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<sup>18</sup> 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).

<sup>19</sup> 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

## PUBLIC VERSION

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 (7<sup>th</sup> 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.

## PUBLIC VERSION

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

## PUBLIC VERSION

§ 47.38 (7<sup>th</sup> 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



## PUBLIC VERSION

“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.<sup>20</sup> 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).<sup>21</sup> 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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<sup>20</sup> 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.

<sup>21</sup> 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”).

## PUBLIC VERSION

(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 (7<sup>th</sup> 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 (7<sup>th</sup>

## PUBLIC VERSION

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

## PUBLIC VERSION

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 (1<sup>st</sup> 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

## PUBLIC VERSION

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 (2<sup>nd</sup> 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.<sup>22</sup> 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

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<sup>22</sup> 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)).

## PUBLIC VERSION

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.<sup>23</sup> *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).<sup>24</sup> Commenters have cited a number of industry and academic papers that have treated digital goods as articles of commerce.<sup>25</sup> 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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<sup>23</sup> 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.

<sup>24</sup> 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).

<sup>25</sup> *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).

## PUBLIC VERSION

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*

## PUBLIC VERSION

*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



## PUBLIC VERSION

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 (7<sup>th</sup> 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

## PUBLIC VERSION

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

## PUBLIC VERSION

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

## PUBLIC VERSION

‘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.<sup>26</sup> 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.

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<sup>26</sup> 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.

## PUBLIC VERSION

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,<sup>27</sup> 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)).<sup>28</sup> 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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<sup>27</sup> The Trade Adjustment Assistance Act (“TAA”) was part of the Trade Expansion Act of 1962, Pub. L. 87-794, 76 Stat. 883.

<sup>28</sup> 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 Trade 1983), the CIT held that employees who provide automotive services do not engage in production of a new and different article.

## PUBLIC VERSION

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.<sup>29</sup> 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

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<sup>29</sup> 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.”).

## PUBLIC VERSION

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 (7<sup>th</sup> 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 Nuijten*, 500 F.3d 1346, 1353 (Fed. Cir. 2007)).

## PUBLIC VERSION

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*.<sup>30</sup> 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.<sup>31</sup> 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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<sup>30</sup> 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).

<sup>31</sup> 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.



## PUBLIC VERSION

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.

## PUBLIC VERSION

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*

## PUBLIC VERSION

*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.<sup>32</sup> 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).

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<sup>32</sup> 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).

## PUBLIC VERSION

### 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.*

## PUBLIC VERSION

(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

## PUBLIC VERSION

(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.

## PUBLIC VERSION

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).*

## PUBLIC VERSION

### 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.<sup>33</sup>

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

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<sup>33</sup> 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.



## PUBLIC VERSION

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.

## PUBLIC VERSION

Pet. at 61-62 (citing ID at 475, 512).<sup>34</sup> 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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<sup>34</sup> 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.

## PUBLIC VERSION

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*

## PUBLIC VERSION

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, *see 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

## PUBLIC VERSION

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).

## PUBLIC VERSION

### 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)<sup>35</sup>; *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.

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<sup>35</sup> 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.

## PUBLIC VERSION

### 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)<sup>36</sup>

##### 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

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<sup>36</sup> 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.

## PUBLIC VERSION

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.<sup>37</sup> 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**

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<sup>37</sup> 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.



## PUBLIC VERSION

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

## PUBLIC VERSION

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,

## PUBLIC VERSION

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 (9<sup>th</sup> 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-

## PUBLIC VERSION

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

## PUBLIC VERSION

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

## PUBLIC VERSION

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.<sup>38 39</sup> 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.

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<sup>38</sup> Align overlooks the fact that this issue was raised by Respondents in their Post-Hearing Reply Brief. *See infra.*

<sup>39</sup> 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).

## PUBLIC VERSION

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*,

## PUBLIC VERSION

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.



## PUBLIC VERSION

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

## PUBLIC VERSION

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

## PUBLIC VERSION

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.”

*Spancion, 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. *Spancion*, 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).<sup>40</sup> 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.

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<sup>40</sup> 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.

## PUBLIC VERSION

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.*<sup>41</sup> This common meaning of the term “material” is reflected in a plurality of dictionary definitions. *See, e.g.,* FUNK & WAGNALLS NEW STANDARD

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<sup>41</sup> *Accord* Webster’s New Collegiate Dictionary (1979) (defining “material” as “data that can be worked into a more finished form.”).

## PUBLIC VERSION

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”);<sup>42</sup> 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)).<sup>43</sup>

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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<sup>42</sup> Accord NEW OXFORD AMERICAN DICTIONARY (3rd ed. 2010) (defining “material” as “facts, information, or ideas for use in creating a book or other work . . .”).

<sup>43</sup> Accord WEBSTER’S NEW COLLEGIATE DICTIONARY (1979) (defining “material” to be “the elements, constituents, or substances of which something is composed.”).

## PUBLIC VERSION

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 (2<sup>nd</sup> 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* (4<sup>th</sup> ed. 1951) (defining “materials” as “the substance or matter of which anything is made”).<sup>44</sup> *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.”)<sup>45</sup> *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

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<sup>44</sup> Contemporary editions are in accord. *See, e.g., BLACK’S LAW DICTIONARY* (9<sup>th</sup> ed. 2009), (defining “material” as “[o]f or relating to matter; physical . . .”).

<sup>45</sup> *Accord Webster’s New Collegiate Dictionary* (1979) (defining “material” to be “the elements, constituents, or substances of which something is composed.”).