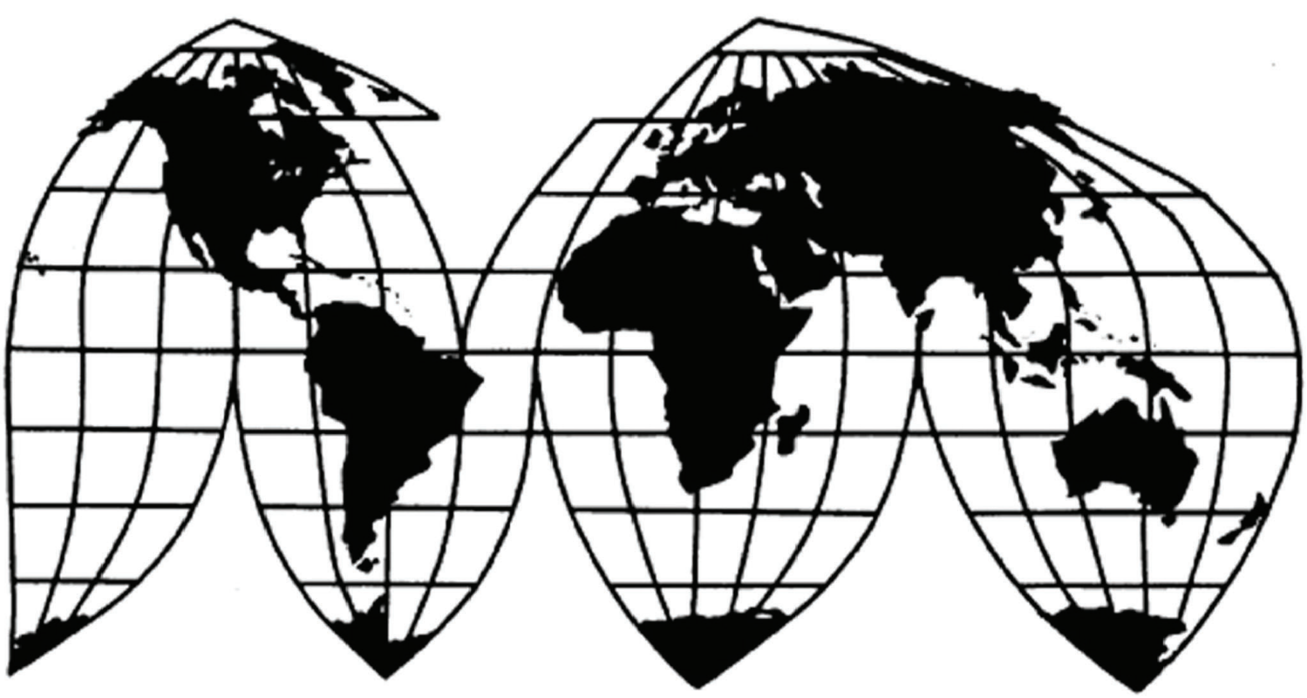
In the Matter of

CERTAIN DENTAL AND ORTHODONTIC SCANNERS AND SOFTWARE

Investigation No. 337-TA-1144

Publication 5300 **March 2022**

U.S. International Trade Commission



Washington, DC 20436

U.S. International Trade Commission

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UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN DENTAL AND ORTHODONTIC SCANNERS AND SOFTWARE**	**Investigation No. 337-TA-1144**

NOTICE OF THE COMMISSION'S FINAL DETERMINATION FINDING NO VIOLATION OF SECTION 337; TERMINATION OF THE INVESTIGATION

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has found no violation of section 337 of the Tariff Act of 1930, as amended. The investigation is hereby terminated.

FOR FURTHER INFORMATION CONTACT: Robert Needham, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 708-5468. 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: The Commission instituted this investigation on March 5, 2019. 84 FR 7933-34 (March 5, 2019) based on a complaint filed on behalf of Align Technology, Inc. of San Jose, California ("Align"). The complaint alleges 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, or the sale within the United States after importation of certain dental and orthodontic scanners and software by reason of infringement of one or more claims of U.S. Patent Nos. 9,299,192 ("the '192 patent"); 7,077,647 ("the '647 patent"); 7,156,661 ("the '661 patent"); 9,848,958 ("the '958 patent"); and 8,102,538 ("the '538 patent"). *Id.* The complaint further alleges that a domestic industry exists. *Id.* The Commission's notice of investigation named as respondents 3Shape A/S of Copenhagen, Denmark; 3Shape, Inc. of Warren, New Jersey; and 3Shape Trios A/S of Copenhagen, Denmark (together, "3Shape"). *Id.* The Office of Unfair Import Investigations is not participating in the investigation. *Id.*

The Commission subsequently terminated the investigation with respect to the ’958 patent based on Align’s withdrawal of those complaint allegations. Order No. 17 (Jul. 2, 2019), *not reviewed* Notice (Jul. 23, 2019). On October 8, 2019, Align stated that it would no longer pursue a violation with respect to claims 4 and 20 of the ’647 patent, claims 1 and 19 of the ’661 patent, and claims 1, 3-5, and 22 of the ’192 patent. On October 21, 2019, Align stated that it would no longer pursue a violation with respect to claim 2 of the ’647 patent. Accordingly, at the time of the Final ID, Align asserted claims 1 and 18 of the ’647 patent, claims 2 and 20 of the ’661 patent, claims 1 and 2 of the ’538 patent, and claims 2, 28, and 29 of the ’192 patent.

On April 30, 2020, the ALJ issued the Final ID finding a violation of section 337 with respect to the ’647 and ’661 patents, and no violation with respect to the ’538 and ’192 patents. Specifically, the ALJ found that claims 1 and 18 of the ’538 patent are not infringed and that claims 2, 28, and 29 of the ’192 patent are invalid. The ALJ found that Align satisfied the remaining requirements for a violation with respect to the ’538 and ’192 patents.

On May 12, 2020, 3Shape and Align each filed a petition for review of the Final ID. On May 20, 2020, the parties responded to each other’s petitions. The Commission also received four comments on the public interest.

On January 31, 2020, the Commission determined to review the Final ID in part. Specifically, the Commission determined to review the following issues: (1) the findings regarding importation and induced infringement; (2) the construction of limitation 1.5/18.5 of the ‘647 patent (“individually matching [match] each of the dental objects in the subsequent digital model with a dental object in the initial digital model to determine corresponding dental objects, the matching comprising [including instructions to]”) in the asserted claims of the ’647 patent, and the application of that construction regarding infringement, invalidity, and the technical prong of the domestic industry; (3) the findings regarding whether the asserted claims of the ’647 and ’661 patents are directed to patentable subject matter; (4) the construction of the limitation “wherein the device is configured for maintaining a spatial disposition with respect to the portion that is substantially fixed during operation of the optical scanner and imaging means” in the asserted claims of the ’538 patent, and the application of that construction regarding infringement, invalidity, and the technical prong of the domestic industry requirement; (5) the findings regarding whether Okamato anticipates the asserted claims of the ’538 patent; (6) the findings regarding whether Paley-Kriveshko anticipates or renders obvious the asserted claims of the ’192 patent; and (7) the findings regarding the satisfaction of the economic prong of the domestic industry requirement.

Having examined the record of this investigation, including the Final ID, the petitions, responses, and other submissions from the parties, the Commission has determined that Align has failed to show a violation of section 337. Specifically, the Commission has determined to: (1) modify the Final ID’s findings on importation; (2) reverse the Final ID’s finding that Align showed induced infringement for the ’647 and ’661 patents; (3) modify the Final ID’s interpretation of the limitation “to determine corresponding dental objects” in the asserted claims of the ’647 patent, but find that the modification does not affect the application of the construction to infringement, the domestic industry, or invalidity; (4) take no position on the Final ID’s finding that the asserted claims of the ’647 and ’661 patents are directed to patentable subject matter; (5) modify the ALJ's construction of "wherein the device is configured for maintaining a spatial disposition with respect to the portion that is substantially fixed during operation of the optical scanner and the imaging means" of the asserted claims of the '538 patent, and find that, under the modified construction, Align established infringement and the technical prong of the domestic industry requirement but that the asserted claims are invalid; (6) reverse the Final ID's finding that the asserted claims of the '538 patent are not anticipated by Okamoto; (7) reverse the Final ID's finding that the asserted claims of the '192 patent are not anticipated by Paley-Kriveshko, and affirm the Final ID's finding that the asserted claims are invalid as obvious under modified reasoning; and (8) take no position on whether Align satisfied the economic prong of the domestic industry requirement.

Accordingly, the Commission finds no violation of section 337. Specifically, the Commission finds that Align failed to establish a violation with respect to the asserted claims of the '647 and '661 patents because Align failed to show infringement; that Align failed to establish a violation with respect to the asserted claims of the '538 patent because Align failed to show infringement and because the claims are invalid; and that Align failed to establish a violation with respect to the asserted claims of the '192 patent because the claims are invalid. The Commission's determinations are explained more fully in the accompanying Opinion. All other findings in the ID under review that are consistent with the Commission's determinations are affirmed. The investigation is hereby terminated.

The Commission vote for these determinations took place on November 17, 2020.

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 CFR part 210).

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: November 17, 2020

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **NOTICE** has been served upon the following parties as indicated, on **November 17, 2020.**

Lisa R. Barton, Secretary
U.S. International Trade Commission
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Washington, DC 20436

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UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN DENTAL AND ORTHODONTIC SCANNERS AND SOFTWARE**	**Investigation No. 337-TA-1144**

COMMISSION OPINION

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The Commission has determined that there has been no violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, with respect to U.S. Patent Nos. 9,299,192 ("the '192 patent"); 7,077,647 ("the '647 patent"); 7,156,661 ("the '661 patent"); and 8,102,538 ("the '538 patent") on review of the final initial determination ("ID") of the presiding administrative law judge ("ALJ"). This opinion sets forth the Commission's reasoning in support of that determination.

I. BACKGROUND

A. Procedural History

On March 5, 2019, the Commission instituted this investigation based on a complaint filed on behalf of Align Technology, Inc. of San Jose, California ("Align"). 84 Fed. Reg. 7933-34 (March 5, 2019). The complaint alleged violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain dental and orthodontic scanners and software by reason of infringement of one or more claims of the '192, '647, '661, and '538 patents, as well as U.S. Patent No. 9,848,958 ("the '958 patent"). The Commission's notice of investigation named as respondents 3Shape A/S of Copenhagen, Denmark; 3Shape, Inc. of Warren, New Jersey; and 3Shape Trios A/S of Copenhagen, Denmark (together, "3Shape"). *Id.* The Office of Unfair Import Investigations did not participate in this investigation. *Id.*

The Commission subsequently terminated the investigation with respect to the '958 patent based on Align's withdrawal of those allegations. Order No. 17 (Jul. 2, 2019), *unreviewed* Notice (Jul. 23, 2019). At the time of the ID, Align asserted claims 1 and 18 of the '647 patent, claims 2 and 20 of the '661 patent, claims 1 and 2 of the '538 patent, and claims 2, 28, and 29 of the '192 patent.

On April 30, 2020, the ALJ issued the ID finding a violation of section 337 with respect to the asserted claims of the '647 and '661 patents, and no violation with respect to the '538 and '192 patents. Specifically, the ALJ found that claims 1 and 18 of the '538 patent are not infringed and that claims 2, 28, and 29 of the '192 patent are invalid. The ALJ found that Align satisfied the remaining requirements for a violation with respect to the '538 and '192 patents.

On May 12, 2020, 3Shape and Align each filed a petition for review of the ID. On May 20, 2020, the parties responded to each other's petitions. On July 28, 2020, the Commission determined to review: (1) the findings regarding importation and induced infringement; (2) the construction of limitation 1.5/18.5 in the asserted claims of the '647 patent ("individually matching [match] each of the dental objects in the subsequent digital model with a dental object in the initial digital model to determine corresponding dental objects, the matching comprising [including instructions to]"), and the application of that construction regarding infringement, invalidity, and the technical prong of the domestic industry; (3) the findings regarding whether the asserted claims of the '647 and '661 patents are directed to patentable subject matter; (4) the construction of the limitation "wherein the device is configured for maintaining a spatial disposition with respect to the portion that is substantially fixed during operation of the optical scanner and imaging means" in the asserted claims of the '538 patent, and the application of that construction regarding infringement, invalidity, and the technical prong of the domestic industry requirement; (5) the findings regarding whether Okamato anticipates the asserted claims of the '538 patent; (6) the findings regarding whether Paley-Kriveshko anticipates or renders obvious the asserted claims of the '192 patent; and (7) the findings regarding the satisfaction of the economic prong of the domestic industry requirement. Notice, 85 Fed. Reg. 46713-14 (Aug. 3, 2020).

The Commission requested briefing on certain issues under review and on remedy, the public interest, and bonding. On August 11, 2020, the Commission received initial submissions from Align and 3Shape.[1] On August 18, 2020, the Commission received reply submissions from Align and 3Shape.[2] The Commission received no submissions from third parties.

B. The Asserted Patents

The technology at issue in this investigation relates to imaging and software for orthodontia and dentistry. U.S. Patent No. 7,077,647 is entitled "Systems and Methods for Treatment Analysis by Teeth Matching." It was filed on August 22, 2002. Align asserted claims 1 and 18, which are independent claims for a method and a computer readable medium containing code for using a first digital dental model to create planned dental positions, and then comparing a subsequent digital dental model after treatment and calculating differences between the planned and actual positions of the teeth.

U.S. Patent No. 7,156,661 is a continuation-in-part of the '647 patent and is also entitled "Systems and Methods for Treatment Analysis by Teeth Matching." It claims priority to the '647 patent application's filing date of August 22, 2002. Align asserted claims 2 and 20, which are claims for a method and a computer readable medium containing code for using

[1] Complainant Align Technology, Inc.'s Written Submission in Response to the Issues Identified in the Notice of Commission Determination to Review in Part a Final Initial Determination Finding a Violation of Section 337 (Aug. 11, 2020) ("Align Init. Sub.") and Respondents 3Shape A/S, 3Shape TRIOS A/S, and 3Shape Inc.'s Written Submission in Response to Commission's Determination to Review in Part the Initial Determination (Aug. 11, 2020) ("3Shape Init. Sub."), respectively.

[2] Complainant Align Technology, Inc.'s Reply to Respondents Response to the Issues Identified in the Notice of Commission Determination to Review in Part a Final Initial Determination Finding a Violation of Section 337 (Aug. 18, 2020) ("Align Rep. Sub.") and Respondents 3Shape A/S, 3Shape TRIOS A/S, and 3Shape Inc.'s Response to Align Technology, Inc.'s Written Submission to the Commission Determination to Review in Part the Initial Determination ("3Shape Rep. Sub."), respectively.

matched regions to compare the positions of teeth in an initial and a subsequent dental model.

U.S. Patent No. 8,102,538 is entitled "Method and Apparatus for Colour Imaging a Three-Dimensional Structure," and claims priority to two provisional applications, both of which were filed on June 17, 2004 and a nonprovisional application filed on June 17, 2005. Align asserted claims 1 and 2 of the '538 patent, which cover a device with an optical scanner for obtaining depth data and an imaging device obtaining color data with respect to a two-dimensional array in order to produce a three-dimensional color model.

U.S. Patent No. 9,299,192 is entitled "Method and Systems for Creating and Interacting with Three Dimensional Virtual Models," and claims priority to a provisional application filed on July 19, 2010. Align asserted claims 2, 28, and 29 of the '192 patent, which cover a method and system for allowing a user to select and replace a portion of a first virtual model with a second portion of a second virtual model.

C. The Accused Products

The accused products for each patent are as follows:

'647 Patent: TRIOS Intraoral Scanner with TRIOS Patient Monitoring ("TPM") (additionally with Ortho System)

'661 Patent: TRIOS Intraoral Scanner with Patient Monitoring or Ortho System Compare Model Sets ("CMS")

'538 Patent: TRIOS Intraoral Scanner

'192 Patent: TRIOS Intraoral Scanner with TRIM tool, and the TRIOS Application's implant workflow, post and core workflow, and preparation workflow

Final ID at xxiii. The specific accused TRIOS Intraoral Scanners are all versions of the TRIOS 3 and TRIOS 4 scanners. *Id.* at xxiv. The TRIOS scanners are physical devices, whereas TPM, Ortho System, CMS, the TRIM tool, and the TRIOS application are software that can be used with the TRIOS scanners.

D. The Domestic Industry Products

The asserted domestic industry products for each patent are as follows:

’647 Patent: iTero Element Intraoral scanner with Progress Assessment

’661 Patent: iTero Element Intraoral scanner with TimeLapse

’538 Patent: iTero Element Intraoral scanner

’192 Patent: Align’s Eraser software on iTero

Final ID at xxiii. The iTero Element Intraoral scanner (“iTero”) is a physical device, and Progress Assessment, TimeLapse, and Eraser are all software that can be used with the iTero. *Id.* at 26-31.

II. STANDARD OF REVIEW

With respect to the issues under review, “the Commission may affirm, reverse, modify, set aside or remand for further proceedings, in whole or in part, the initial determination of the administrative law judge.” 19 C.F.R. § 210.45(c). The Commission also “may take no position on specific issues or portions of the initial determination,” and “may make any finding or conclusions that in its judgment are proper based on the record in the proceeding.” *Id.*

III. ANALYSIS

The Commission’s findings, conclusions, and supporting analysis follow. The Commission affirms and adopts the ID’s findings, conclusions, and supporting analysis that are not inconsistent with the Commission’s opinion.

A. Importation

1. Overview

A violation of section 337 based on patent infringement requires a showing of “importation into the United States, the sale for importation, or the sale for importation within the United States after importation . . . of articles that infringe a valid and enforceable United

States patent." 19 U.S.C. § 1337(a)(1)(B)(i). Here, the ID found that 3Shape imported the TRIOS 3 scanner, the TRIOS 4 scanner, the Ortho System software, the TPM software, and the TRIM tool. ID at 7-12. The Commission determined to review the ID's findings on importation. Notice, 85 Fed. Reg. 46713-14 (Aug. 3, 2020).

2. Analysis

The Commission finds that 3Shape has imported the TRIOS 3 scanner, the TRIOS 4 scanner, the Ortho System software, and the TRIM tool, but that Align has not proven that 3Shape imported the TPM software. As an initial matter, the Commission notes that 3Shape stipulated that it imported the TRIOS 3 and 4 scanners. CX-2164C (Joint Stipulation Regarding Importation of TRIOS 3 and TRIOS 4 Products). 3Shape also admitted that it has imported the Ortho System software and the TRIM tool software by [ ] [ ]. 3Shape Pet. at 7 (admitting that 3Shape has imported the Ortho System software); *id.* at 7 n.7 (admitting that 3Shape has imported the TRIM tool). 3Shape contends, however, that the importation requirement is not satisfied with respect to the Ortho System software because 3Shape subsequently [ ] [ ]. *Id.* at 7-8. The Commission disagrees. The "importation" language recited in section 337(a) in reference to an accused article is satisfied by proof of a single act of importation. *See, e.g., Certain Trolley Wheel Assemblies*, Inv. No. 337-TA-161, USITC Pub. 1605, Comm'n Op. at 7-8 (1984) (finding that the importation of a single infringing trolley wheel was sufficient for the importation requirement).

The Commission, however, finds that Align failed to show that 3Shape has imported the TPM software. The ID acknowledged that there is "no direct evidence" that the TPM software has been imported. ID at 10. While the ID found that the importation requirement is satisfied through circumstantial evidence, the ID relied solely on the testimony of 3Shape witnesses who stated at times that [ ] [ ]. ID at 11-12 (citing Tr. 643:3-5 and 10-21; 662:24-663:4, 1169:11-25, 1175:24-1176:7, 1178:1-1179:7). But regardless of the ID's views on the credibility of 3Shape's testimony, that testimony is not affirmative evidence that the TPM software is imported. Accordingly, neither the ID nor Align identified any affirmative evidence showing that the TPM software was imported.

Align has the burden to establish that the importation requirement is satisfied. 19 C.F.R. § 210.37(a) ("The proponent of any factual proposition shall be required to sustain the burden of proof with respect thereto."). Here, by failing to present any evidence that the TPM software is imported, Align failed to meet that burden with respect to the TPM software. Although the ID stated that 3Shape failed to corroborate its witness testimony and "failed to disprove Align's theory and evidence," ID at 11, 3Shape did not bear the burden of proof.

Accordingly, the Commission finds that Align established that 3Shape has imported the TRIOS 3, TRIOS 4, the Ortho System software, and the TRIM tool, but failed to establish that 3Shape has imported the TPM software.

B. Induced Infringement

1. Overview

The ID found that Align showed that 3Shape induced infringement with respect to the '647, '661, and '192 patents, but failed to show that 3Shape induced infringement with respect to the '538 patent. ID at 246-57. The ID relied on 3Shape's provision of manuals and training materials, but did not explain how those manuals and materials induced infringement of the '647 and '661 patents. *Id.* at 246-52. The ID also relied on evidence that Patterson Dental, an entity that resells 3Shape products, instructs end users on how to infringe the '647 patent, but did not tie that instruction to 3Shape. *Id.* at 249-50. The Commission determined to review the ID's findings on induced infringement. Notice, 85 Fed. Reg. 46713-14 (Aug. 3, 2020).

2. Analysis

The Commission finds that Align failed to show that 3Shape induced infringement of the asserted claims of the '647 or '661 patents. To establish induced infringement, the patent owner must show evidence of the accused infringer's "intent to encourage infringement," such as through evidence that the accused infringer recommended, encouraged, or promoted an infringing use of its product. *Takeda Pharms U.S.A., Inc. v. West-ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015);[3] *see also Certain Vision-Based Driver Assistance System Cameras, Components Thereof, and Products Containing the Same*, Inv. No. 337-TA-907, USITC Pub. 4866, Comm'n Op. at 23 (Dec. 1, 2015) ("complainant must show an affirmative act that encourages another's direct infringement"); *Certain Electronic Imaging Devices*, Inv. No. 337-TA-850, USITC Pub. 4846, Comm'n Op. at 11-12 (Apr. 21, 2014) (finding that the complainant must have evidence that a respondent specifically intended that others infringe the patent to establish induced infringement). Here, the Commission finds that the evidence supplied by Align and relied upon in the ID fails to establish that 3Shape recommended, encouraged, or promoted that its products be used to infringe the asserted claims of the '647 or '661 patents.

The ID first relied upon 3Shape's provision of manuals and training. ID at 248-49, 251-52. Align's post-hearing briefing argued that 3Shape induces infringement based on the provision of manuals and training materials, but failed to explain how those manuals and training

[3] *See also ePlus, Inc. v. Lawson Software, Inc.*, 789 F.3d 1349, 1360 (Fed. Cir. 2015) ("A seller does not induce infringement of a method claim by merely selling an apparatus capable of performing the method . . . . Inducement requires such steps as 'encourage[ing],' 'recommend[ing],' or 'promot[ing]' an infringing use.") (internal citations omitted).

materials encourage or instruct users on how to the infringe the ’647 or ’661 patents. Complainant Align Technology, Inc.’s Post-Hearing Br. (Dec. 3, 2019) at 26-27, 48-49. Furthermore, none of the evidence cited by Align or in the ID explains how these manuals and training materials encourage or instruct users to infringe the specific asserted claims of the ’647 or ’661 patents. *Id.*[4] The relevant issue is not whether 3Shape provided manuals and training, which is not disputed, but rather whether those manuals and training recommended, encouraged, or promoted others to infringe the asserted claims of the ’647 and ’661 patents. *See Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1328-29 (Fed. Cir. 2009) (holding that the patentee failed to show induced infringement based on manuals that did not encourage customers to infringe). Because Align failed to explain how the manuals and training materials recommended, encouraged, or promoted such infringement, and finding no such evidence in the record, the Commission concludes that this evidence of manuals and training alone fails to establish that 3Shape induced infringement of the asserted claims of the ’647 and ’661 patents.

The ID also relied on a 3Shape user manual stating that the TPM software is intended to track a patient’s treatment plan as evidence of infringement of the ’647 patent. ID at 249.[5] But neither the ID nor Align explain why that language recommends, encourages, or promotes the infringement of the asserted claims of the ’647 patent. *Id.*; Align Post-Hearing Br. at 27. For

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[5] Citing CX-0923.0003 (a TPM manual stating that TPM can be used to track an orthodontic treatment plan).

example, neither the ID nor Align explain what it means to track a treatment plan, or why such tracking would result in the infringement of the asserted claims of the ’647 patent. Because there is no evidence as to why the tracking of a treatment plan would result in infringement, the Commission finds that this evidence fails to establish that 3Shape induced infringement of ’647 patent.

The ID further relied on evidence that a reseller of 3Shape products, Patterson Dental, induces end users to infringe the asserted claims by demonstrating how to make a Virtual Setup file in Ortho System and import that file into the TPM software, ID at 249-50.[6] The Virtual Setup file is required to infringe under Align’s infringement theory for the ’647 patent. *Id.* at 39-43, 54-55. But 3Shape is not liable for the acts of third parties such as Patterson Dental. *Microsoft Corp. v. DataTern, Inc.*, 755 F.3d 899, 905 (Fed. Cir. 2014) (holding that Microsoft is not liable for induced infringement based on third-party documentation encouraging infringement). Here, neither the ID nor Align cite any evidence that 3Shape recommended or encouraged Patterson Dental to demonstrate such functionality to end users. *Id.*; Align Post-Hearing Br. at 27. And even if 3Shape’s products are capable of being used in an infringing manner, that is not sufficient to establish induced infringement unless 3Shape encouraged such direct infringement. *See Microsoft*, 755 F.3d at 905 (“Nothing in the record suggests that Microsoft encouraged the acts accused of direct infringement, and simply selling a product capable of being used in an infringing manner is not sufficient”). Because there is no evidence that 3Shape recommended, encouraged, or promoted the actions of Patterson Dental or end users to infringe the asserted claims of the ’647 patent, the Commission finds that this evidence fails to establish that 3Shape induced infringement of ’647 patent.

[6] Citing CX-0026 (Lake Decl.). at 3(i)(iii) (describing general steps of the demonstration).

The ID additionally relied on evidence that, [ ] [ ] [ ] [ ]. ID at 249-50. Under the ALJ's direct infringement findings, direct infringement of claims 1 and 18 of the '647 patent requires that an end user load a Virtual Setup file from Ortho System into the TPM software in order to satisfy the limitations relating to "planned positions" for the set of dental objects. ID at 39-44, 54-57. Here, the evidence shows [ ] [ ] [ ]. Tr. 821:14-826:25. The evidence also shows that the restriction could be circumvented [ ] [ ] [ ]. *Id.* Align also failed to present any evidence that 3Shape encouraged or taught its customers to circumvent these restrictions. The Commission finds that 3Shape's imperfect attempt to prevent infringement does not constitute evidence that 3Shape recommended, encouraged, or promoted end users to directly infringe the asserted claims of the '647 patent.

Accordingly, the Commission finds that Align failed to show that 3Shape induced infringement of the asserted claims of the '647 and '616 patents. As discussed above, the alleged evidence of inducement chiefly consists of: (1) unexplained manuals and training; (2) an unexplained statement that TPM is intended to track a treatment plan; (3) evidence that a third party encourages infringement; and (4) evidence that 3Shape (imperfectly) attempted to preclude infringement. Moreover, Align's arguments and the ID's findings with respect to the inducement of the ’661 patent are conclusory. Align Post-Hearing Br. at 48-49; ID at 251-52. The Commission finds, therefore, that this evidence does not demonstrate that 3Shape recommended, encouraged, or promoted others to infringe the asserted claims of the ’647 and ’661 patents, and further finds that Align failed to carry its burden on induced infringement for the ’647 and ’661 patents.

C. The Construction of Limitation 1.5/18.5 of the ’647 patent

1. Overview

The fifth limitation of claims 1 and 18 (“Limitation 1.5/18.5”) of the ’647 patent recites the following:

Limitation 1.5	Limitation 18.5
individually matching each of the dental objects in the subsequent digital model with a dental object in the initial digital model **to determine corresponding dental objects**, the matching comprising;	individually match each of the dental objects in the subsequent digital model with a dental object in the initial digital model **to determine corresponding dental objects**, including instructions to;

(emphasis added). Additional substeps in claims 1 and 18 further describe the above-mentioned “matching.” Those substeps require:

- “identify[ing] one or more reference points on each set of corresponding dental objects in the initial and subsequent digital models;”
- “approximately match[ing] each set of corresponding dental objects by approximately aligning corresponding reference points on corresponding dental objects”; and
- “match[ing] each set of corresponding dental objects more closely by iteratively minimizing error between corresponding reference points on corresponding dental objects.”

The ID found that the language “to determine corresponding dental objects” is a mere intended result of three substeps. ID at 46-47. The ID then concluded that there was no need for Align to show that the accused products practiced the limitation “to determine corresponding dental objects.”

2. Analysis

The Commission has determined to vacate the ALJ's finding that Align need not show the limitation "to determine corresponding dental objects" because it is an intended result. Literal infringement requires that "the patentee must show that the accused device contains every limitation in the asserted claims." *Riles v. Shell Exploration and Prod. Co.*, 298 F.3d 1302, 1308 (Fed. Cir. 2002). Accordingly, Align is required to show every limitation of claims 1 and 18, including the fifth limitation, in order to establish infringement.

The Federal Circuit has found that certain claim language is not limiting if the language merely expresses "the intended result of a process step positively recited." *Hoffer v. Microsoft Corp.*, 405 F.3d 1326, 1329 (Fed. Cir. 2005). That exception, however, does not apply if the claim language "is more than the intended result of a process step" but rather is "a part of the process itself." *Id.* at 1330. Here, the Commission finds that the "to determine corresponding dental objects" language is a part of the claimed process because it is recited as a part of a step, and therefore is a limitation that must be shown. *See Aristocrat Techs. Australia Pty Ltd. v. Int'l Game Tech.*, 709 F.3d 1348, 1362 (Fed. Cir. 2013) (holding that "a patentee must prove that each and every step of the method or process was performed").

But while the Commission finds that the "to determine corresponding dental objects" is a limitation that must be shown, the Commission also finds that the limitation will necessarily be shown if each of the substeps is shown. The substeps require "individually matching each of the dental objects in the subsequent digital model with a dental object in the initial digital model," which necessarily determines which dental objects "correspond" to each other between the initial and subsequent models.

Accordingly, while the Commission disagrees with the ID's reasoning that the "to determine corresponding dental objects" is an intended result, the Commission ultimately agrees with the ID's conclusion that the limitation can be met by a showing of "individually matching each of the dental objects in the subsequent digital model with a dental object in the initial digital model" by performing the three substeps. The Commission's modification of this reasoning therefore does not affect the ALJ's application of this limitation to infringement, invalidity, or the domestic industry requirement, so the Commission affirms those findings under the modified reasoning set forth above.

D. The Construction of the "Spatial Disposition . . ." Limitation of the '538 Patent

1. Overview

The asserted claims of the '538 patent recite "[a] device for determining the surface topology and associated color of at least a portion of a three dimensional structure," where the device comprises an "optical scanner" and "imaging means," and "wherein the device is configured for maintaining a spatial disposition with respect to the portion that is substantially fixed during operation of the optical scanner and the imaging means." The ID construed the latter "spatial disposition" limitation to require that "operation by the optical scanner and the imaging means is at least substantially or effectively simultaneous such that movement (*i.e.*, a change in spatial disposition) can be ignored and depth data and color data correspond to the same reference array," and that "substantially or effectively simultaneous" means "concurrently or separated by a small duration of time." Order 36, Appx. A at 36.

The ID acknowledged that the term's plain and ordinary meaning requires that the device experience little to no movement with respect to the scanned object during the operation of the "optical scanner" and "imaging means," but found that the patentee acted as a lexicographer to arrive at the above construction. *Id.* at 65. Specifically, the ALJ relied on the following passage in the specification:

> wherein the device is adapted for maintaining a spatial disposition with respect to said portion that is substantially fixed during operation of said scanning means and said imaging means. **In other words, operation of the scanning means and the imaging means is substantially or effectively simultaneous** in practical terms, and thus **the actual time interval** that may exist between operation of the two means is **so short** that the amplitude of any mechanical vibration of the device or **movement of the oral cavity will be so small as can be ignored**.

'538 patent at 4:61-5:3 (emphasis added). The Commission determined to review the ALJ's construction and its application.

2. Written Submissions

The Commission sought written submissions on whether the term "wherein the device is configured for maintaining a spatial disposition with respect to the portion that is substantially fixed during operation of the optical scanner and the imaging means" should be construed to mean "the operation of the optical scanner and imaging means is substantially or effectively simultaneous." That construction deletes the portion of the ALJ's construction about the reason why the operation must be simultaneous. The parties were also asked to explain how the construction would affect its application on infringement, the domestic industry, and invalidity.

Align contends that the Commission's proposed construction is not appropriate and argues that the Commission should adopt the ALJ's construction. Align Init. Sub. at 1-5. Align argues that the ALJ's construction closely tracks the "in other words" language in the specification and is consistent with the specification's recitation of preferred time intervals. *Id.* at 2. Align also argues that 3Shape never challenged that portion of the construction before the ALJ. *Id.* at 5.

3Shape argues that the Commission's proposed construction is not appropriate because there should not be any timing requirement. 3Shape Init. Sub. at 1-6. 3Shape argues that the "maintaining a spatial disposition" limitation is readily understandable on its face and does not need construction. *Id.* at 1. Although 3Shape acknowledges that the specification describes operating the optical scanner and imaging means substantially simultaneously as a preferred embodiment for "maintaining a spatial disposition," 3Shape argues that the substantially simultaneous time interval is not required by the claims. 3Shape Rep. Sub. at 1.

3. Analysis

a. Claim Construction

The Commission has determined that the term "wherein the device is configured for maintaining a spatial disposition with respect to the portion that is substantially fixed during operation of the optical scanner and the imaging means" needs no construction. The Commission finds that the meaning of the term is readily understood from the plain language of the claim, and that the patentee did not act as a lexicographer to change that meaning.

Patent claims are "generally given their ordinary and customary meaning" because "it is unjust to the public, as well as an evasion of the law, to construe [them] in a manner different from the plain import of [their] terms." *Philips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (*en banc*) (internal citations omitted). Here, as the ID found, there is no dispute that the plain and ordinary meaning of the above limitation relating to maintaining a substantially fixed spatial disposition is readily understood. As the ALJ acknowledged, the plain and ordinary meaning simply means that the device does not substantially move with respect to the scanned object while the optical scanner and imaging means are operating. Order No. 36 (Oct. 1, 2019), Appx. A at 65.

The ID found, and Align argues, that the inventor acted as a lexicographer to require that maintaining a substantially fixed spatial disposition must be accomplished by operating the optical scanner and imaging means substantially simultaneously. To act as a lexicographer, however, the patentee must "clearly set forth a definition of the disputed claim term other than its plain and ordinary meaning." *Thorner v. Sony Comput. Ent'mt Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012). Here, as discussed above, the ID and Align base their lexicography reasoning on the specification's use of a sentence beginning with "[i]n other words" that describes the simultaneous operation of the scanning means and imaging means. The Commission finds that, while that sentence describes an embodiment that uses the simultaneous operation of the optical scanner and imaging means to accomplish the maintenance of a substantially fixed spatial disposition, the specification does not clearly define the limitation to require simultaneous operation. Accordingly, the Commission finds no basis that the patentee acted as a lexicographer to modify the plain and ordinary meaning of the claim.

Moreover, other portions of the specification show that the substantially simultaneous operation of the means in a short interval is merely a preferred embodiment for maintaining a substantially fixed spatial disposition between the device and the scanned portion of the object. For example, the specification states that "[t]he present invention is directed to a method" requiring "(c) ensuring that a spatial disposition with respect to said portion during steps (a) and (b) is substantially fixed," and that "[p]referably, in step (c), a minimum time interval is allowed between acquisition of said depth and acquisition of said image data." '538 patent 8:56-9:3. Elsewhere, the specification states that "the present invention" operates the two means "typically within a short time interval." *Id.* at 3:58-60. If the patentee believed that it had clearly defined the maintenance of a spatial disposition as requiring the substantially simultaneous operation of means in a short time interval, there would be no need to refer to the time interval at all, let alone as a preferred or typical embodiment.

In conclusion, the Commission finds that the term "wherein the device is configured for maintaining a spatial disposition with respect to the portion that is substantially fixed during operation of the optical scanner and the imaging means" is easily understood and should be given its plain and ordinary meaning. The specification does not clearly define the spatial disposition limitation to require a particular timing or speed, whether it be a substantially simultaneous operation or a short time interval, and the Commission declines to read such a limitation from the specification into the claim.[7] Align chose to recite a limitation requiring a substantially fixed spatial disposition and chose not to recite a limitation requiring substantially simultaneous operation or a short time interval, and 3Shape, the Commission, and the public should be able to rely upon those choices.

b. Infringement and Technical Prong of the Domestic Industry Requirement

The Commission finds that Align showed that the accused products and domestic industry products satisfy the "maintaining spatial disposition" limitation under the plain and ordinary meaning of the term. The Commission's construction is broader than the ID's, and permits any method of maintaining a spatial disposition, including the substantially simultaneous time interval required in the ALJ's construction. Accordingly, the accused products and domestic industry products satisfy this limitation for the same reasons set forth in the ID—[ ]

[ ]

[ ]

[ ]. ID at 149-52, 166-67.

E. Anticipation by Okamoto of the Asserted Claims of the '538 Patent

The Commission's claim construction of the "maintaining spatial disposition" limitation,

[7] *See, e.g., SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004) ("Though understanding the claim language may be aided by the explanations contained in the written descriptions, it is important not to import into a claim limitations that are not part of the claim.").

however, does affect whether the asserted claims are invalid as anticipated.

1. Overview

The ID found that Japanese Unexamined Patent Application Publication No. 2001-82935 ("Okamoto") (RX-0180) disclosed every limitation of the asserted claims except for the limitation "wherein the device is configured for maintaining a spatial disposition with respect to the portion that is substantially fixed during operation of the optical scanner and the imaging means." ID at 170-84. The ID found that its construction of that limitation required that the optical scanner and imaging means operate "at least substantially or effectively simultaneous such that movement (i.e., a change in spatial disposition) can be ignored and depth data and color data correspond to the same reference array," but found that there was no evidence that Okamoto disclosed such a requirement. *Id.* at 183-84. The ID, however, stated that whether Okamoto anticipated the claims was a "close question." *Id.* at 169.

2. Analysis

As noted above, the Commission has determined to modify the ID's construction of the "maintaining spatial disposition" limitation. Under the Commission's plain and ordinary construction of the term, the Commission finds that 3Shape showed that Okamoto teaches this limitation by clear and convincing evidence.

Okamoto describes a confocal microscope and three-dimensional measurement device that measures a sample on a sample stage. *See generally* Okamoto. As the ALJ found, and Align did not dispute, Okamoto describes a confocal optical scanner for obtaining depth data and an imaging means photo receptor for obtaining color data. ID at 171-72. The disclosed scanner has a scanning lens and sample stage, whereby the sample stage may be "driven in the Z direction" to change "the relative position" between the lens and the sample. *Id.* at [0018]. Okamoto explains that the device functions by measuring the depth data [*i.e.*, "height data"] and color data from the scanned object with the sample stage at an initial level, and then lowers the sample stage by one level and repeats the process. *Id.* at [0039]-[0040]. Because the optical scanner and photo receptor are located on a fixed location on the microscope and the scanned object is located on a fixed sample stage level during the scanning operation, the positional difference between the scanned object and the scanning sensors does not change during the scanning operation. Accordingly, Okamoto describes a device that "maintain[s] a spatial disposition . . . that is substantially fixed" between the scanning sensors and scanned item "during operation of the optical scanner and the imaging means," and thereby satisfies the limitation. Because the ID found that Okamoto satisfied every other limitation of claims 1 and 2 of the '538 patent, the Commission finds that Okamoto anticipates those claims.

F. Anticipation and Obviousness by Paley-Kriveshko of the Asserted Claims of the '192 Patent

1. Overview

The ID found that 3Shape failed to show that the asserted claims of the '192 patent are anticipated by U.S. Patent Application Publication No. US 2007/0172112 (RX-0226) ("Paley"), which incorporates by reference U.S. Patent Application Publication No. US 2007/0236494 (RX-0227) ("Kriveshko") (together, "Paley-Kriveshko"). ID at 225-28. The ID found that Align only challenged whether Paley-Kriveshko disclosed the limitation "replacing at least said identified portion of the first virtual model with a corresponding portion of the second virtual model," and therefore waived a challenge to all other limitations. *Id.* at 221-22. Although the ID found that Paley-Kriveshko discloses combining two models into a single representation, the ID found that Paley-Kriveshko fails to satisfy the disputed limitation because the limitation's recitation of "replacing" requires deletion or removal, and Paley-Kriveshko does not expressly disclose deletion or removal. *Id.* at 225-26.

The ID concluded, however, that 3Shape showed that Paley-Kriveshko renders the asserted claims obvious. The ID found that 3Shape showed that it would be trivial to adapt the combining step of Paley-Kriveshko to delete and replace a portion of the virtual model. *Id.* at 225-26. Although the ID noted that 3Shape failed to provide a clear motivation to make that modification, the ID found that the Paley-Kriveshko reference provided that motivation by repeatedly stating that its purpose is to fix scans that contain incomplete, inaccurate, or insufficient data without having to complete an entirely new scan of the whole area. *Id.* at 237.

2. Written Submissions

The parties were asked to provide submissions on whether the record supports finding a motivation to modify Paley-Kriveshko to include deletion. Align argues that there is simply no evidence that a person of ordinary skill would have modified Paley-Kriveshko to include deletion—the ALJ struck all of 3Shape's relevant expert testimony, so 3Shape's only evidence was mere attorney argument that adding deletion was trivial. Align Init. Sub. at 12-14. Align also argues that Paley-Kriveshko already provided accurate models, so there is no reason to modify Paley-Kriveshko to include deletion. *Id.* at 15-17. Additionally, Align contends that 3Shape's pre-hearing brief relied solely upon its expert for the motivation to combine, so once that expert testimony was stricken, 3Shape was left with no evidence and cannot change theories now. Align Rep. Sub. at 3-7.

3Shape contends that there is motivation to modify Paley-Kriveshko to allow for deleting. 3Shape argues that Paley-Kriveshko discloses a desire for error-free models, and a person of ordinary skill in the art would have found it obvious to delete inaccurate scan data to achieve that goal. 3Shape Init. Sub. at 10-13. 3Shape also argues that its expert showed that deletion is a well-known concept. *Id.* at 13-15.

3. Analysis

The Commission has determined to reverse the ID's finding that Paley-Kriveshko does not anticipate the asserted claims of the '192 patent and to find that 3Shape showed by clear and convincing evidence that Paley-Kriveshko anticipates those claims. The ID finds, and Align does not dispute, that Paley-Kriveshko taught every limitation of the asserted claims except the limitation "replacing at least said identified portion of the first virtual model with a corresponding portion of the second virtual model." ID at 221-22. The ID concluded that Paley-Kriveshko did not satisfy that limitation because Paley-Kriveshko does not disclose deletion. *Id.* at 226-28.

Nothing in the asserted claims, however, requires deletion. The claim text requires "replacing," not deleting. Moreover, unasserted dependent claim 5 recites that the above limitation further comprises "causing the computer system to **at least one of delete, remove, or replace** said identified portion of the first virtual model" (emphasis added), which demonstrates that "deleting" is not the same thing as "replacing." Accordingly, there is no basis to conclude that the asserted claims of the '192 patent require deletion.

After removing the ID's requirement for deletion, the ID's findings demonstrate that Paley-Kriveshko replaces a portion of the first virtual model. The ID found that Paley-Kriveshko describes "a process for identifying a portion of a first virtual model having incomplete, inaccurate, or insufficient data," "a process of rescanning the corresponding structure thereby generating a second virtual model," and "the creation of a single modified virtual model" using both the first and second virtual model. ID at 227. The ID also found that Paley-Kriveshko discloses updating a "void" of omitted or missing scan data with new data. *Id.* at 228 n. 97. In our view, these findings demonstrate that a portion of the first virtual model is replaced with a corresponding portion of the second virtual model, as required by the claim limitation.

The ID's findings are consistent with the teachings of Paley-Kriveshko. Paley describes that it can detect "omitted or missing scan data," as well as "regions of incomplete scan data, inaccurate scan data, insufficient scan detail . . . and the like." RX-0226 at [0059]. Paley then explains that a user can select such areas to "permit a user to return to data acquisition, *e.g.*, the scanning mode of FIG. 4 where a void or deviation is detected," which allows "a user to select a specific point on the surface of the digital model . . . where the continuous scan is to be reacquired from the subject." *Id.* at [0060]. Paley also explains that its general process is to capture incremental data, derive three-dimensional data from the incremental data, and register the incremental data into a single common coordinate system with the remaining old data. *Id.* at [0006]. In other words, Paley-Kriveshko teaches allowing the user to replace a portion of a virtual model containing bad or missing data with new data, thereby satisfying the limitation "replacing at least said identified portion of the first virtual model with a corresponding portion of the second virtual model."[8] Because the ID found that Paley-Kriveshko discloses all other limitations of the asserted claims, the Commission finds that Paley-Kriveshko anticipates the asserted claims of the '192 patent.

The Commission also affirms the ID's finding of obviousness under modified reasoning. The Federal Circuit has held that "it is well settled that 'a disclosure that anticipates under § 102 also renders the claim invalid under § 103, for 'anticipation is the epitome of obviousness.'" *Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1373 (Fed. Cir. 2019). Accordingly, because the

[8] Even under the ID's view that "replacing" requires "deleting," the ID stated that the overwriting of old data would necessarily result in its deletion. ID at 227 n.96. The above citations demonstrate that Paley-Kriveshko discloses such overwriting.

Commission finds that the asserted claims are anticipated, they are also rendered obvious.[9]

G. Patentable Subject Matter and the Economic Prong

As discussed above, the Commission has already found that Align failed to establish a violation of section 337 based on the dispositive issues of patent invalidity and the failure to show induced infringement. That final determination of no violation is unchanged regardless of whether Align satisfied the economic prong of the domestic industry requirement or whether 3Shape established that the asserted claims of the '647 and '661 patents are directed to patentable subject matter. Accordingly, the Commission has determined to take no position on whether Align satisfied the economic prong of the domestic industry requirement and on whether the asserted claims of the '647 and '661 patents are directed to patentable subject matter.[10] *See Beloit Corp. v. Valmet Oy*, 742 F.2d 1421, 1423 (Fed. Cir. 1984) (holding that the Commission need not address every issue when certain issues are case-dispositive).

IV. CONCLUSION

For the reasons set forth herein, the Commission determines that Align failed to establish a violation of section 337 by 3Shape with respect to any asserted claim. Specifically, the Commission finds that the asserted claims of the '647 and '661 patents are not infringed, that the asserted claims of the '538 patent are invalid and not infringed, and the asserted claims of the '192 patent are invalid. The Commission also determined to take no position on whether the

[9] Align waived its arguments relating to secondary considerations of non-obviousness. ID at 238.

[10] Chair Kearns finds that information on how investments in the United States with respect to the article at issue compare on a quantitative basis to investments outside the United States – as reflected in measures such as relative dollar amounts invested in plant, equipment, capital, employment, or the percentage of the article's value that is added in the United States – is particularly important to his evaluation of whether U.S. investments are significant under section 337(a)(3).

asserted claims of the ’647 and ’661 patents are directed to patentable subject matter and whether Align satisfied the economic prong of the domestic industry requirement. Accordingly, the investigation is terminated with a finding of no violation of section 337.

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: December 3, 2020

CERTAIN DENTAL AND ORTHODONTIC SCANNERS AND SOFTWARE **Inv. No. 337-TA-1144**

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **OPINION, COMMISSION** has been served upon the following parties as indicated, on **December 3, 2020.**

Lisa R. Barton, Secretary
U.S. International Trade Commission
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UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of CERTAIN DENTAL AND ORTHODONTIC SCANNERS AND SOFTWARE	Investigation No. 337-TA-1144

NOTICE OF A COMMISSION DETERMINATION TO REVIEW IN PART A FINAL INITIAL DETERMINATION FINDING A VIOLATION OF SECTION 337; REQUEST FOR WRITTEN SUBMISSIONS ON THE ISSUES UNDER REVIEW AND ON REMEDY, THE PUBLIC INTEREST, AND BONDING; EXTENSION OF THE TARGET DATE

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission ("Commission") has determined to review in part a final initial determination ("ID") of the presiding administrative law judge ("ALJ"). The Commission requests written submissions from the parties on the issues under review and submissions from the parties, interested government agencies, and interested persons on the issues of remedy, the public interest, and bonding, under the schedule set forth below. The target date is extended to September 28, 2020.

FOR FURTHER INFORMATION CONTACT: Robert Needham, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street S.W., Washington, D.C. 20436, telephone (202) 708-5468. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov*. For help accessing EDIS, please email EDIS3Help@usitc.gov. General information concerning the Commission may also be obtained by accessing its Internet server at *https://www.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: The Commission instituted this investigation on March 5, 2019. 84 FR 7933-34 (March 5, 2019) based on a complaint filed on behalf of Align Technology, Inc. of San Jose, California ("Align"). The complaint alleges 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, or the sale within the United States after importation of certain dental and orthodontic scanners and software by reason of infringement of one or more claims of U.S. Patent Nos. 9,299,192 ("the '192 patent"); 7,077,647 ("the '647 patent"); 7,156,661 ("the '661 patent"); 9,848,958 ("the '958 patent"); and 8,102,538 ("the '538 patent"). *Id.* The complaint further alleges that a domestic industry exists. *Id.* The Commission's notice of investigation named as respondents 3Shape A/S of Copenhagen, Denmark; 3Shape, Inc. of Warren, New Jersey; and 3Shape Trios A/S of Copenhagen, Denmark (together, "3Shape"). *Id*. The Office of Unfair Import Investigations ("OUII") is not participating in the investigation. *Id.*

The Commission subsequently terminated the investigation with respect to the '958 patent based on Align's withdrawal of those allegations. Order No. 17 (Jul. 2, 2019), *not reviewed* Notice (Jul. 23, 2019). On October 8, 2019, Align stated that it would no longer pursue a violation with respect to claims 4 and 20 of the '647 patent, claims 1 and 19 of the '661 patent, and claims 1, 3-5, and 22 of the '192 patent. On October 21, 2019, Align stated that it would no longer pursue a violation with respect to claim 2 of the '647 patent. Accordingly, at the time of the Final ID, Align asserted claims 1 and 18 of the '647 patent, claims 2 and 20 of the '661 patent, claims 1 and 2 of the '538 patent, and claims 2, 28, and 29 of the '192 patent.

On April 30, 2020, the ALJ issued the Final ID finding a violation of section 337 with respect to the '647 and '661 patents, and no violation with respect to the '538 and '192 patents. Specifically, the ALJ found that claims 1 and 18 of the '538 patent are not infringed and that claims 2, 28, and 29 of the '192 patent are invalid. The ALJ found that Align satisfied the remaining requirements for a violation with respect to the '538 and '192 patents.

On May 12, 2020, 3Shape and Align each filed a petition for review of the Final ID. On May 20, 2020, the parties responded to each other's petitions. The Commission also received four comments on the public interest.

Having reviewed the record of the investigation, including the final ID and the parties' petitions and responses, the Commission has determined to review the ID in part. Specifically, the Commission has determined to review: (1) the findings regarding importation and induced infringement; (2) the construction of limitation 1.5/18.5 of the '647 patent ("individually matching [match] each of the dental objects in the subsequent digital model with a dental object in the initial digital model to determine corresponding dental objects, the matching comprising [including instructions to]") in the asserted claims of the '647 patent, and the application of that construction regarding infringement, invalidity, and the technical prong of the domestic industry; (3) the findings regarding whether the asserted claims of the '647 and '661 patents are directed to patentable subject matter; (4) the construction of the limitation "wherein the device is configured for maintaining a spatial disposition with respect to the portion that is substantially fixed during operation of the optical scanner and imaging means" in the asserted claims of the '538 patent, and the application of that construction regarding infringement, invalidity, and the technical prong of the domestic industry requirement; (5) the findings regarding whether Okamato anticipates the asserted claims of the ’538 patent; (6) the findings regarding whether Paley-Kriveshko anticipates or renders obvious the asserted claims of the ’192 patent; and (7) the findings regarding the satisfaction of the economic prong of the domestic industry requirement.

In connection with its review, the Commission requests responses to the following questions. The parties are requested to brief their positions with reference to the applicable law and the existing evidentiary record.

(1) Please explain whether it is proper to construe the limitation “wherein the device is configured for maintaining a spatial disposition with respect to the portion that is substantially fixed during operation of the optical scanner and imaging means” to mean “the operation of the optical scanner and imaging means is substantially or effectively simultaneous.” Please note that this proposed construction removes the following requirement of the ALJ’s construction: “such that movement (*i.e.*, a change in spatial disposition) can be ignored and depth data and color data correspond to the same reference array.” Additionally, please explain how the above construction would impact findings on infringement, invalidity, and the domestic industry requirement.

(2) Please explain, with citations to the record, whether there is a motivation to modify Paley-Kriveshko in a way that renders invalid as obvious the asserted claims of the ’192 patent.

(3) What information, if any, is contained in the record concerning Align’s employee headcount and salary and compensation expenditures outside the United States pertaining to Align’s DI Products? What information, if any, is contained in the record concerning the value added in the United States to Align’s DI Products?

(4) Please explain, with citations to the record, whether Align’s investments in plant and equipment under a sales-based allocation are significant.

The parties are invited to brief only the discrete issues requested above. The parties are not to brief other issues on review, which are adequately presented in the parties’ existing filings.

In connection with the final disposition of this investigation, the statute authorizes issuance of, *inter alia,* (1) an exclusion order that could result in the exclusion of the subject articles from entry into the United States; and/or (2) cease and desist orders that could result in the respondents 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 7-10 (Dec. 1994).

The statute requires the Commission to consider the effects of that remedy upon the public interest. The public interest factors the Commission will consider include the effect that an exclusion order 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 U.S. Trade Representative, as delegated by the President, has 60 days to approve, disapprove, or take no action on the Commission's determination. *See* Presidential Memorandum of July 21, 2005, 70 FR 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.

In its initial submission, Complainant is also requested to identify the remedy sought and to submit proposed remedial orders for the Commission's consideration. Complainant is further requested to state the dates that the Asserted Patents expire, the HTSUS subheadings under which the accused products are imported, and to supply the identification information for all known importers of the products at issue in this investigation. The initial written submissions and proposed remedial orders must be filed no later than close of business on August 11, 2020. Reply submissions must be filed no later than the close of business on August 18, 2020. No further submissions on these issues will be permitted unless otherwise ordered by the Commission. Initial submissions are limited to 40 pages. Reply submissions are limited to 20 pages. No further submissions on any of these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. The Commission's paper filing requirements in 19 CFR 210.4(f) are currently waived. 85 FR 15798 (March 19, 2020). Submissions should refer to the investigation number (Inv. No. 337-TA-1144) in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf*). Persons with questions regarding filing should contact the Secretary, (202) 205-2000.

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. See 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. A redacted non-confidential version of the document must also be filed simultaneously with any confidential filing. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection on EDIS.

The target date is extended to September 28, 2020.

The Commission vote for this determination took place on July 28, 2020.

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 CFR Part 210).

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: July 28, 2020

CERTAIN DENTAL AND ORTHODONTIC SCANNERS AND SOFTWARE **Inv. No. 337-TA-1144**

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **NOTICE** has been served upon the following parties as indicated, on **July 28, 2020**.

Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112
Washington, DC 20436

On Behalf of Complainant Align Technology, Inc.:

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On Behalf of Respondents 3Shape A/S, 3Shape Trios A/S, and 3Shape Inc.:

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UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of **CERTAIN DENTAL AND ORTHODONTIC SCANNERS AND SOFTWARE**	**Inv. No. 337-TA-1144**

INITIAL DETERMINATION ON VIOLATION OF SECTION 337 AND RECOMMENDED DETERMINATION ON REMEDY AND BOND

Administrative Law Judge MaryJoan McNamara

(April 30, 2020)

Appearances:

For the Complainant Align Technology, Inc.:

Blair M. Jacobs, Esq., Christina A. Ondrick, Esq., Elizabeth Bernard, Esq., John S. Holley, Esq., Stuart McCommas, Esq., and Mark Consilvio, Esq. of Paul Hastings LLP, Washington, DC.

Thomas A. Counts, Esq. of Paul Hastings LLP, San Francisco, CA.

Raymond W. Stockstill of Paul Hastings LLP, Costa Mesa, CA.

For the Respondents 3Shape A/S, 3Shape Trios A/S, and 3Shape, Inc.:

Goutam Patnaik, Esq., Tuhin Ganguly, Esq. David J. Shaw, Esq., Arvind Iyengar, Esq., and Gerar M. Mazarakis, Esq. of Pepper Hamilton LLP, Washington, DC.

William D. Belanger, Esq. Gregory D. Len, Esq., Frank D. Liu, Esq., Brittanee L. Friedman, Esq., and L. Andrew Tseng, Esq. of Pepper Hamilton LLP, Boston, MA.

S. Lloyd Smith, Esq., Kimberly E. Coghill, Esq., and Bryan J. Cannon, Esq. of Buchanan Ingersoll & Rooney PC, Alexandria, VA.

SELECTED SUMMARY FINDINGS

Pursuant to the Notice of Investigation, 84 Fed. Reg. 7933, dated March 5, 2019, this is the Initial Determination ("ID") of the Investigation in the Matter of Certain Dental and Orthodontic Scanners and Software, United States International Trade Commission Investigation No. 337-TA-1144. *See* 19 C.F.R. § 210.42(a).

It is a finding of this ID that Complainant Align Technology, Inc. ("Align" or "Complainant") has proven by a preponderance of evidence that Respondents 3Shape A/S, 3Shape Trios A/S, and 3Shape, Inc. (collectively, "3Shape" or "Respondents," and with Align, the "Parties") have violated subsection (b) of Section 337 of the Tariff Act of 1930, in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain dental and orthodontic scanners and software

It is a finding of this ID that 3Shape has infringed asserted claims 1 and 18 of U.S. Patent No. 7,077,647 ("the '647 patent"). It is a finding of this ID that the asserted claims of the '647 patent are valid.

It is a finding of this ID that 3Shape has infringed asserted claims 2 and 20 of U.S. Patent No. 7,156,661 ("the '661 patent"). It is a finding of this ID that the asserted claims of the '661 patent are valid.

It is a finding of this ID that 3Shape has not infringed asserted claims 1 and 18 of U.S. Patent No. 8,102,538 ("the '538 patent"). It is a finding of this ID that the asserted claims of the '538 patent are valid.

It is a finding of this ID that 3Shape has infringed asserted claims 2, 28, and 29 of U.S. Patent No. 9,299,192 ("the '192 patent"). It is a finding of this ID that asserted claims 2, 28, and 29 of the '192 patent are invalid.

It is a finding of this ID that one or more of Align's domestic industry products have satisfied the technical industry prong of the domestic industry requirement for the '647, '661, '538, and '192 patents. It is a finding of this ID that Align has satisfied the economic prong of the domestic industry requirement under Section 337(a)(3)(A) and (B).

The ID contains a recommendation that the Commission issue a Limited Exclusion Order and a Cease and Desisting Order against the infringing Respondents. A bond has not been recommended for the Presidential Review Period.

TABLE OF CONTENTS

ABBREVIATIONS

The following shorthand references to the parties, related U.S. agencies, and related proceedings are used in this Initial Determination:

Complainant or Align	Complainant Align Technology, Inc.
Respondents or 3Shape	Respondents 3Shape A/S, 3Shape Trios A/S, and 3Shape, Inc., collectively
CBP	U.S. Customs and Border Protection
USPTO or PTO	U.S. Patent and Trademark Office
PTAB	Patent Trial and Appeal Board
1090 Investigation	*Certain Intraoral Scanners and Related Hardware and Software*, Inv. No. 337-TA-1090
1091 Investigation	*Certain Color Intraoral Scanners and Related Hardware and Software*, Inv. No. 337-TA-1091

The following abbreviations for pleadings, exhibits, briefs, transcripts, and Orders are used in this Initial Determination:

Compl.	Complaint
Resp.	Response of Respondents to the Notice of Investigation and Complaint Under Section 337 of the Tariff Act of 1930, as Amended
CX	Complainant's exhibit
CDX	Complainant's demonstrative exhibit
CPX	Complainant's physical exhibit
CPBr.	Complainant's Pre-Hearing Brief
CBr.	Complainant's Initial Post-Hearing Brief

CRBr.	Complainant's Post-Hearing Reply Brief
CPSt.	Complainant's Pre-Hearing Statement
JX	Joint exhibit
RX	Respondents' exhibit
RDX	Respondents' demonstrative exhibit
RPX	Respondents' physical exhibit
RPBr.	Respondents' Pre-Hearing Brief
RBr.	Respondents' Initial Post-Hearing Brief
RRBr.	Respondents' Post-Hearing Reply Brief
RPSt.	Respondents' Pre-Hearing Statement
Tr.	Evidentiary hearing transcript
Dep. Tr.	Deposition transcript
COMBr.	Complainant's Opening *Markman* Brief
ROMBr.	Respondents' Opening *Markman* Brief
CSMBr.	Complainant's Supplemental *Markman* Brief
RSMBr.	Respondents' Supplemental *Markman* Brief
Joint CC Chart	Joint Post-Hearing Final Claim Construction Chart (Doc. ID No. 685923 (Aug. 21, 2019))
***Markman* Order**	Order No. 36 (Oct. 1, 2019)

The following shorthand references to certain products and patents at issue are used in this Initial Determination:

'647 patent	U.S. Patent No. 7,077,647

’661 patent	U.S. Patent No. 7,156,661
’538 patent	U.S. Patent No. 8,102,538
’192 patent	U.S. Patent No. 9,299,192
647 Accused Products	TRIOS Intraoral scanner with TRIOS Patient Monitoring (additionally with Ortho System)
661 Accused Products	TRIOS Intraoral scanner with Patient Monitoring or Ortho System Compare Model Sets
538 Accused Products	TRIOS Intraoral scanner
192 Accused Products	TRIOS Intraoral scanner with TRIM tool, and the TRIOS Application’s implant workflow, post and core workflow, and pre-preparation workflow
647 DI Products	iTero Element Intraoral scanner with Progress Assessment
661 DI Products	iTero Element Intraoral scanner with TimeLapse
538 DI Products	iTero Element Intraoral scanner
192 DI Product	Align’s Eraser software on iTero
Asserted Patents	’647 patent, ’661 patent, ’538 patent, and ’192 patent, collectively
Accused Products	TRIOS, TRIOS with TRIM, TRIOS with TPM, TRIOS with Ortho System with Virtual Setup and CMS
CMS	TRIOS with Ortho System and Compare Model Sets software
DI Products	iTero, iTero with Outcome Simulator with Progress Assessment, iTero with TimeLapse, iTero with Eraser, and/or Align’s Invisalign System (including Treat)
Eraser	Align’s Eraser software on iTero
Invisalign System	Align’s clear aligner treatment process (including Treat)
iTero	Align’s iTero Element scanner, including the Element, Element 2, and Element Flex, and related software (including the Progress Assessment, TimeLapse and Eraser tools)

Progress Assessment	Align's Progress Assessment software on iTero
TimeLapse	Align's TimeLapse software on iTero TRIM TRIOS with TRIM tool software workflows
TPM	TRIOS with TRIOS Patient Monitoring software
TRIM	TRIOS with TRIM tool software workflows for placing crowns and bridges
TRIOS	All versions of 3Shape's TRIOS 3 or TRIOS 4 scanners
Virtual Setup	TRIOS with Ortho System and Virtual Setup software

I. SUMMARY OF FINDINGS

A summary of this decision's finding is provided below.

Table No. 1: Summary of Findings

Products	Patent	Claims	Determination
647 Accused Products	’647 patent	1 and 18	Infringement of valid claims
661 Accused Products	’661 patent	2 and 20	Infringement of valid claims
538 Accused Products	’538 patent	1 and 2	No infringement of valid claims
192 Accused Products	’192 patent	2, 28, and 29	Infringement of invalid claims
647 DI Products	’647 patent	1 and 18	Satisfied
661 DI Products	’661 patent	2 and 20	Satisfied
538 DI Products	’538 patent	1 and 2	Satisfied
192 DI Products	’192 patent	2, 28, and 29	Satisfied

II. BACKGROUND

A. Institution and Selected Procedural History

On December 10, 2018, Align Technology, Inc. filed a complaint ("Complaint") under Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, alleging infringement of claims 1-13 and 18-21 of the ’647 patent, claims 1-9 and 19-26 of the ’661 patent, claims 1 and 2 of the ’538 patent, claims 1-32 of the ’192 patent, and claims 1-20 of U.S. Patent No. 9,848,958 ("the ’958 patent"). (Doc. ID No. 663673 (Compl.) at ¶¶ 2, 72, 77, 82, 87 (Dec. 10, 2018).).

The Commission instituted this Investigation pursuant to subsection (b) of Section 337 of the Tariff Act of 1930, as amended, on March 5, 2019. 84 Fed. Reg. 7933 (Mar. 5, 2019). The Notice of Investigation ("NOI") names as complainant: Align Technology, Inc. of San Jose, California ("Complainant"). *Id*. The NOI names as respondents: 3Shape A/S of Copenhagen, Denmark; 3Shape Trios A/S of Copenhagen, Denmark; and 3Shape, Inc. of Warren, New Jersey. *Id.* The Office of Unfair Import Investigations is not a party in this Investigation. *Id.*

On April 2, 2019, 3Shape filed a response to the Complaint and NOI ("Response"). (Doc. ID No. 672037 (Resp.) (Apr. 2, 2019).). In its Response, 3Shape identified 10 affirmative defenses ("3Shape's Affirmative Defenses"). (Resp. at 22-26.).

On April 22, 2019, the Parties filed a joint motion setting certain dates by which to reduce the number of asserted claims in the Investigation. (Doc. ID No. 673766 (Apr. 22, 2019); *see also* Order No. 6 (Apr. 23, 2019).). The Parties agreed that Align would begin reducing the number of asserted claims to 45 or less by May 13, 2019, and then reduce the number of asserted claims again to 30 or fewer by June 20, 2019. (Doc. ID No. 673766 (Apr. 22, 2019).). The Parties also agreed that a third and final reduction of the number of asserted claims should occur on or before August 9, 2019. (*Id.*).

On June 20, 2019, Align filed an unopposed motion for partial termination of this Investigation against 3Shape with respect to the asserted claims of the '958 patent, which was granted. (Motion Docket No. 1144-009 (June 20, 2019); Order No. 17 (July 2, 2019).). Subsequently, Align filed notices indicating that it would no longer be asserting certain asserted claims.[1] (Doc. ID No. 690717 (Oct. 8, 2019); Doc. ID No. 691640 (Oct. 21, 2019).). As a result, the remaining claims of Asserted Patents that are the subject of this decision are claims 1

[1] 3Shape also filed notices regarding dropped prior art references. (Doc. ID No. 690724 (Oct. 8, 2019); Doc. ID No. 691640 (Oct. 18, 2019).).

and 18 of the '647 patent, claims 2 and 20 of the '661 patent, claims 1 and 2 of the '538 patent, and claims 2, 28 and 29 of the '192 patent. (Doc. ID No. 691640 (Oct. 21, 2019); CBr. at 9, 37, 55, 77.).

A *Markman* hearing was held on August 8, 2019. (*See* Doc. ID No. 684877 (Aug. 9, 2019).). On October 1, 2019, a *Markman* Order issued that construed the claim terms in dispute. (Order No. 36 ("*Markman* Order") (Oct. 1, 2019).).

Align initially filed five (5) motions *in limine* ("MILs"). (Motion Docket Nos. 1144-044 (Sept. 16, 2019), 1144-045 (Sept. 16, 2019), 1144-046 (Sept. 16, 2019), 1144-047 (Sept. 16, 2019), 1144-048 (Sept. 16, 2019).). Align withdrew its MIL Nos. 3 (Motion Docket No. 1144-046) and 4 (Motion Docket No. 1144-047). (Doc. ID No. 691797 (Oct. 21, 2019); Order No. 38 (Oct. 16, 2019).).

3Shape initially filed four (4) MILs. (Motion Docket Nos. 1144-043 (Sept. 16, 2019), 1144-049 (Sept. 16, 2019), 1144-050 (Sept. 16, 2019), 1144-051 (Sept. 16, 2019).). 3Shape withdrew its MIL No. 4 (Motion Docket No. 1144-051). (Doc. ID No. 688910 (Sept. 23, 2019).).

Align's and 3Shape's MILs, and the rulings on these motions, are summarized in Table Nos. 2 and 3 below.

Table No. 2: Align's MILs

MIL No.	Issue	Ruling
MIL No. 1 (Motion Docket No. 1144-044)	MIL to Preclude Undisclosed and Unreliable Expert Testimony Regarding Invalidity	Denied in-part, granted in-part. (Oct. 10, 2019 Teleconference Tr. ("10/10/19 Teleconf. Tr.") at 29:18-32:9.).
MIL No. 2	MIL to Preclude Arguments and Evidence Regarding	Denied in-part, granted in-part. (10/10/19 Teleconf. Tr. at 42:5-43:4,

MIL No.	Issue	Ruling
(Motion Docket No. 1144-045)	3Shape's Untimely Non-Infringement and Domestic Industry Theories Regarding the '538 Patent	47:14-52:25.).
MIL No. 5 (Motion Docket No. 1144-048)	MIL to Preclude Opinions Regarding Prosecution History Estoppel	Granted. (10/10/19 Teleconf. Tr. at 56:6-57:13.).

Table No. 3: 3Shape's MILs

MIL No.	Issue	Ruling
MIL No. 1 (Motion Docket No. 1144-043)[2]	MIL to Exclude Align's Improper Designations of Personal Deposition Testimony	Resolved by the Parties. (Oct. 17, 2019 Teleconference Tr. ("10/17/19 Teleconf. Tr.") at 6:4-7:11.).
MIL No. 2 (Motion Docket No. 1144-050)[3]	MIL to Exclude Designations of Testimony Outside the Scope of Witness' 30(b)(6) Topics	Having considered 3Shape's motion, 3Shape's MIL No. 2, Motion Docket No. 1144-050, is hereby *denied*.
MIL No. 3 (Motion Docket No. 1144-049)	MIL to Exclude Align's Improper Counter-Designation of Deposition Testimony from Align's Own Foreign Witnesses	Having considered 3Shape's motion, 3Shape's MIL No. 3, Motion Docket No. 1144-049, is hereby *denied*.

The evidentiary hearing ("Hearing") was held on October 24-25, 28-30, 2019. (*See* Doc. ID No. 671056 at Ex. 1 (Mar. 22, 2019); Order No. 4 (Mar. 25, 2019).). During and immediately after the Hearing, Align filed four (4) motions to strike ("MTSs") evidence presented during the

[2] This MIL was partially withdrawn. (Doc. ID No. 688761 (Sept. 20, 2019).).

[3] This MIL was partially withdrawn. (Doc. ID No. 688761 (Sept. 20, 2019).).

Hearing. Align's MTSs, and rulings on these motions, are summarized in Table No. 4 below.

Table No. 4: Align's Motions to Strike

Motion	Issue	Ruling
Motion Docket No. 1144-058	Motion to Strike Dr. Saber's Provision Testimony Regarding a Rejected Claim Construction	Denied. (Order No. 46 (Dec. 18, 2019).).
Motion Docket No. 1144-059	Motion to Strike Testimony Concerning Invalidity Theories for U.S. Patent No. 8,102,538	Denied. (Order No. 46 (Dec. 18, 2019).).
Motion Docket No. 1144-061	Motion to Strike Dr. Saber's Provisional Testimony Offering Previously Undisclosed Validity Opinions and Analysis	Granted. (Order No. 46 (Dec. 18, 2019).).
Motion Docket No. 1144-062	Motion to Strike Testimony Regarding Non-Infringement of Claim 2 of U.S. Patent No. 8,102,538	Denied. (Order No. 46 (Dec. 18, 2019).).

B. The Parties

1. Complainant Align Technology, Inc.

Align is a publicly traded corporation organized and existing under the laws of the State of Delaware, with its principal place of business located at 2820 Orchard Parkway, San Jose, California 95134. (*See, e.g.*, Compl. at ¶ 14; CPBr. at 1-2.).

Align described itself and its products as follows:

> Align was founded in 1997 when two visionary business students ambitiously set out to create the pioneering invisible aligner dental market, leading to the introduction of the Invisalign System. Created as an alternative to braces, Invisalign uses a series of clear aligners that patients swap out every two weeks to straighten their teeth. For more than 18 years, Align has been in the business of

> researching, designing, developing, and selling innovative scanners and image processing devices for the dental and orthodontic industries. In 2011, Align acquired Cadent Holdings Inc. and its pioneering iTero intraoral scanner. Today Align offers an integrated digital platform of digital dentistry solutions.

(*Id.* at 2; *see also* Compl. at ¶¶ 3-6, 15-17.).

2. Respondents 3Shape A/S, 3Shape Trios A/S, and 3Shape, Inc.

3Shape A/S and 3Shape Trios A/S are Danish corporations with their principal place of business at Holmens Kanal 7, 1060 Copenhagen K, Denmark. (Resp. at ¶¶ 18, 20.). 3Shape A/S and 3Shape Trios A/S are "sister" corporations that are wholly-owned subsidiaries of 3Shape Holdings A/S. (*Id.* at ¶ 20.).

3Shape A/S develops and sells 3Shape's unaccused lab scanner products. (*See, e.g.*, RPBr. at 2.). 3Shape A/S also develops and sells and/or licenses Ortho System. (*Id.*). Additionally, 3Shape A/S developed TPM. (*Id.*). 3Shape Trios A/S develops and sells 3Shape's Trios 3/4 scanners and the Trios App software and ScanSuite Trios software. (*Id.*).

3Shape, Inc. is a Delaware corporation with a principal place of business at 10 Independence Boulevard, Suite 150, Warren, New Jersey 07059. (Resp. at ¶ 19.).

3Shape Inc. is 3Shape's regional support entity for North America. (RPBr. at 2.). 3Shape Inc. supports 3Shape's U.S. distributors, or "resellers," by providing marketing and sales support and training. (*Id.*).

III. JURISDICTION, IMPORTATION, AND STANDING

A. The Commission Has Jurisdiction

To have the authority to decide a case, a court or agency must have both subject matter jurisdiction and jurisdiction over either the parties or the property involved. *See Certain Steel Rod Treating Apparatus and Components Thereof*, Inv. No. 337-TA-97, Comm'n Opinion, 215 U.S.P.Q. 229, 231 (U.S.I.T.C. 1981). For the reasons discussed below, the facts support a finding that the Commission has jurisdiction over this Investigation.

1. Subject Matter Jurisdiction

The Commission has subject matter jurisdiction over this Investigation because Align alleged that 3Shape has violated 19 U.S.C. §1337(a)(1)(B). *See Amgen v. U. S. Int'l Trade Comm'n*, 902 F.2d 1532, 1536 (Fed. Cir. 1990). 3Shape did not contest that the Commission has subject matter jurisdiction. (*See* RPBr. at 8.).

2. Personal Jurisdiction

3Shape did not dispute that the Commission has personal jurisdiction over 3Shape. (*See* RPBr. at 8.). Moreover, 3Shape appeared and responded to the Complaint and NOI, and fully participated in this Investigation, which included participating in discovery and the Hearing, and by filing motions. Thus, the Commission has personal jurisdiction over 3Shape. *See, e.g.*, *Certain Windshield Wiper Devices and Components Thereof* ("*Wiper Devices*"), Inv. No. 337-TA-881, Initial Determination at 5 (May 8, 2014) (unreviewed in relevant-part) (Doc. ID No. 534255).

3. Importation

As described in detail below in Section V.A., the Accused Products in this case include TRIOS 3 scanners, TRIOS 4 scanners, TRIM software, Patient Monitoring ("TPM") software, and Ortho System software which includes CMS and Virtual Setup.

3Shape did not dispute, and in fact stipulated to, the importation of TRIOS 3 and TRIOS 4 scanners. (RPBr. at 8 (*citing* (CX-2164C (Joint Stipulation Regarding Importation of TRIOS 3 and TRIOS 4 Products) Doc. ID No. 686112 at ¶ 1 and Appendix A (August 21, 2019)) ("Importation Stipulation")).). However, 3Shape argued that the importation requirement was not satisfied for the Ortho System software because since February or March of 2018, the Ortho

System was not pre-loaded onto the TRIOS 3 and TRIOS 4 scanners when the scanners were imported. (RPBr. at 8-13; RRBr. at 1-8.).

3Shape also argued that the importation requirement has not been satisfied for the TPM software because TPM was never imported as pre-installed software on a TRIOS 3 or TRIOS 4 scanner. (RPBr. at 9; RRBr. at 6-7.). However, 3Shape did not advance *any* arguments in its Pre-Hearing Brief or Post-Hearing Reply Brief to oppose Align's importation allegations with respect to the TRIM tool. Therefore, the only Accused Products for which the importation requirement was contested were the Ortho System and TPM software. For the reasons described below, I find that 3Shape's arguments with respect to the Ortho System and TPM software are misplaced. Moreover, 3Shape has waived arguments with respect to the importation of the TRIM tool software pursuant to Ground Rules 7.2 and 10.1.

a) Importation Satisfied for Ortho System Software

Despite 3Shape's arguments, Align has proven factually, and it is a finding that the importation requirement has been satisfied for the Ortho System. 3Shape stipulated that the Ortho software was used at least once in the United States between December 10, 2018, and October 31, 2019. (*Accused Product Stipulation* at ¶ 3.). 3Shape also stipulated that at least one non-basic TRIOS 3 accused scanner exists in the United States with a license to the Ortho System software. (*Id.* at ¶ 4.).

Align also presented evidence in its original Complaint in the form of a Declaration by Dr. John Dovgan[4] in which he attested to his purchase and use in the United States in October

[4] In his Declaration dated November 13, 2017, Dr. John Dovgan identified himself as a cosmetic dentist in Phoenix, AZ, who purchased a "3Shape TRIOS 3 Wired Pod with pen-grip scanner" and "a Dell Alienware laptop loaded with certain Dental System software including the TRIOS, Ortho Analyzer, Implant Studio Planner, Planning Model Builder, and Appliance Designer software." (Dovgan Declaration at ¶¶ 1-2.).

2017 of a TRIOS 3 scanner with the Ortho System functionality as part of the system. (Compl. at ¶ 96; CX-0020C (Declaration of Dr. John Dovgan) at ¶¶ 1-3 and 7 ("Dovgan Declaration").). While Dr. Doygan's Declaration does not specify whether the TRIOS 3 scanner was imported with the Ortho System software pre-installed, his Declaration suggests that the TRIOS 3 scanner was enabled with the Ortho System. (*See id.* at ¶¶ 1-3 and 7.). In view of Mr. Mikael Petersen's Declaration that "all TRIOS scanners" using Ortho System software that were imported to the U.S. prior to February or March of 2018 had the Ortho System pre-installed prior to importation, the TRIOS 3 scanner of the Dovgan Declaration appears to be at least one example of a scanner which had Ortho System capability installed prior to importation into the United States.[5]

The Stipulations, together with Hearing testimony, and the Dovgan Declaration, together support a finding that not only was it [redacted] importation, but that at least one TRIOS scanner was imported into the U.S. with the Ortho System pre-installed.

3Shape attempted to undermine Align's evidence supporting importation of scanners with pre-installed Ortho Software prior to February or March 2018, by eliciting testimony from its expert Mr. Petersen, about the *current* supply chain for TRIOS 3 scanners at the Ortho System as of the date of the hearing. (Tr. (Petersen) at 1134:13-15, 1138:12-24, 1141:10-16, 1141:17-1142:7.). However, none of that testimony proved that the supply chain *prior to* February or March 2018 did not pre-install the Ortho System on TRIOS scanners prior to U.S. importation.

[5] When he testified during the Hearing in this Investigation on October 29, 2019, Mr. Mikael Petersen held the position of Senior Vice President at 3Shape A/S. (Tr. at 1131-1:16.). 3Shape identified Mr. Petersen as a fact witness expected to testify regarding 3Shape's supply chain for the accused products. (RPSt. at 2.).

Moreover, 3Shape did not submit any evidence, such as documentation or internal directives, other than single witness testimony to support its claim that the Ortho software was no longer uploaded to the scanners prior to U.S. importation. (Tr. (Petersen) at 1179:9-1182:9.). 3Shape's evidence was both insufficient and unsatisfactory. Therefore, Align successfully demonstrated, given the weight of the evidence, at least one instance of the importation of a TRIOS 3 scanner with the Ortho System pre-installed. For that reason, the importation requirement has been met for the Ortho System.

b) Importation Satisfied for TPM Software

With respect to the TPM software, Align also proved factually, and it is a finding, that the importation requirement has been satisfied. Indeed, no direct evidence in the form of exhibits was presented by either party which explicitly showed that TPM was pre-installed on a TRIOS 3 or TRIOS 4 scanner, and then imported to the U.S. However, the circumstantial evidence that Align presented is sufficient to support that conclusion.

3Shape stipulated that, in addition to the TRIOS 3 scanners, TRIOS 4 scanners, TRIM tool software, and Ortho System software, the TPM software was used at least once in the United States between December 10, 2018, and October 31, 2019. (Accused Product Stipulation at ¶ 3.). 3Shape also stipulated that at least one non-basic TRIOS 3 accused scanner exists in the United States with a license to the Ortho System software. (*Id.* at ¶ 4.). Align also established during cross-examination of Mr. Petersen that [redacted]. (Tr. (Petersen) at 1167:19-1169:6.). Although both Mr. Petersen and Dr. Rune Fisker[6] both testified that [redacted]

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[6] When he testified during the Hearing on October 28, 2019, Mr. Rune Fisker, Ph.D. was 3Shape's Senior

[redacted], their testimony has been given little weight because they contradicted themselves and each other. (*See* Tr. (Petersen) at 1175:24-1176:7, 1178:1-1179:7; Tr. (Fisker) at 643:3-5, 10-21, 662:24-663:4.). Neither witness provided testimony supported by documentation let alone clear testimony either alone or together. For example, notwithstanding his seeming certainty during the Hearing, during his May 2019 deposition, Mr. Petersen was not certain whether the TPM software was part of the Dental Desktop software that was uploaded onto the TRIOS 3 and TRIOS 4 scanners. He stated that he would need to consult with Dr. Fisker to verify the information. (Tr. (Petersen) at 1169:11-25.). However, Dr. Fisker testified during his July 2019 deposition that he would need to verify with Mr. Petersen whether the TPM was a part of the Dental Desktop software that was pre-loaded onto the scanners prior to importation. (Tr. (Fisker) at 643:10-21; *id.* Tr. (Fisker) at 643:3-5, 662:24-663:4.).

Dr. Fisker's and Mr. Petersen's testimony suggests that neither witness knew the answer to a straightforward issue. Apparently, each was identified has having knowledge about the components of the TRIOS 3 and TRIOS 4 scanners, yet neither had categorical knowledge. At the time of their depositions, neither party seemed to know the answer. That changed during the Hearing, when they testified that TPM was not [redacted], all while pointing to each other as having enlightened the other person. 3Shape did not provide any documentation, in the form of waybills, invoices, or other information, to support their witnesses' uncorroborated testimony.

3Shape failed to disprove Align's theory and evidence supporting the importation of

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Vice President of Product Strategy. Mr. Fisker was 3Shape's corporate witness who testified about the Parties' interactions; 3Shape's equitable defenses; 3Shape's products; and related issues. (CPSt. at 6; RPSt. at 2; Tr. (Fisker) at 637-38.).

scanners with pre-installed TPM Software. 3Shape's evidence was largely circumstantial and unsupported. It was less persuasive than Align's. 3Shape failed to present internal documents or testimony that TPM is not pre-loaded before U.S. importation. (Tr. (Petersen) at 1170:7-22, 1179:9-1182:9.). On direct examination, Dr. Fisker testified that TPM was "announced" in 2016, but not "commercially released" until 2019, [redacted] as the reason for the delay. (Tr. (Fisker) at 638:23-639:5.). Yet, 3Shape failed to support even this testimony with documentation or exhibits to show when TPM entered the market. Part of this timeframe is before 2018 during the time in which Mr. Petersen testified that essentially all software was installed in Poland before being imported into the United States. 3Shape undermined its own evidence with other confusing or contradictory evidence.

Therefore, based upon the more substantial, albeit circumstantial, evidence, Align successfully demonstrated at least one instance of the importation of a TRIOS 3 or TRIOS 4 scanner with the TPM software pre-installed. The importation requirement has been met for the TPM System.

c) Importation Satisfied for Ortho System and TPM Software Under *Suprema*

Align's alternative theory for the importation of the Ortho System and TPM software relies upon post-importation infringement as the Federal Circuit explained in *Suprema, Inc. v. Int'l Trade Comm'n*, 796 F.3d 1338, 1352 (Fed. Cir. 2015) (en banc) ("*Suprema*"). In *Suprema,* the Federal Circuit held that for the purpose of satisfying the importation requirement, "articles that infringe" include "goods that were used by an importer to directly infringe post-importation as a result of the seller's inducement." *Suprema*, 796 F.3d at 1352. The Federal Circuit has upheld the Commission's application of *Suprema* in a subsequent case. *See Comcast Corp. v.*

Int'l Trade Comm'n, 951 F.3d 1301, 1308 (Fed. Cir. Mar. 2, 2020). The Commission has interpreted *Suprema* to have "repudiated a time-of-importation requirement." *See Certain Beverage Dispensing Systems and Components Thereof*, Inv. No. 337-TA-1130, Comm'n Op. at 15 (Mar. 26, 2020). In other words, as the Federal Circuit has held, so long as the imported articles are combined and used post-importation to infringe the claims of a U.S. patent, the imported articles still meet the importation requirement even if they do not infringe the patent claims at the time of importation.

Importation is a separate inquiry from infringement, and the two inquiries, while related, should not be conflated. With respect to the Ortho System and TPM software, Align argued that even if 3Shape could establish that the TRIOS 3 and TRIOS 4 scanners were not imported with pre-installed Ortho System or TPM software, the fact that the imported scanner was later combined with the separately imported Ortho System or TPM software satisfied the importation requirement under *Suprema*. (CPBr. at 12-16; CBr. at 3-7.).

Align presented evidence that 3Shape imports and has imported the accused TRIOS 3 and TRIOS 4 scanners at least once into the United States, consistent with Section 337(a)(1)(B). First, Align submitted photographic and written evidence that 3Shape imports TRIOS 3 with its initial Complaint as supported by Dr. Dovgan's Declaration. (Compl. at ¶ 96; CX-0020C.). Dr. Dovgan attested that he purchased a "3Shape TRIOS 3 Wired Pod with pen-grip scanner" and "a Dell Alienware laptop loaded with certain Dental System software including the TRIOS, Ortho Analyzer, Implant Studio Planner, Planning Model Builder, and Appliance Designer software" on October 17, 2017, and the corresponding software licenses on October 23, 2017. (Dovgan Declaration at ¶¶ 2-3.).

Second, 3Shape stipulated to both importing and using TRIOS 3 or TRIOS 4 type scanners, both Accused Products, between December 2018 and at least June 2019. (Importation Stipulation at ¶¶ 1-4; Accused Product Stipulation at ¶¶ 1-3.). Therefore, to the extent that 3Shape's attempted to dispute later the importation of the TRIOS 3 and TRIOS 4 scanners, these arguments are precluded by its own stipulations.

Align also presented evidence that the accused TRIOS 3 and TRIOS 4 scanners are combined with allegedly infringing Ortho System and TPM and software in the U.S. after the scanners have been imported. For example, the TRIOS 3 scanner that Dr. Dovgan purchased in 2017 was at some point combined with the Ortho System software. (Dovgan Declaration at ¶¶ 2-3.). He was not exactly clear when, but he did used the software in combination with the hardware. Moreover, 3Shape stipulated to "using" the accused Ortho System and the TPM software *in* the U.S. between December 10, 2018 and October 31, 2019, and to the existence of "TRIOS 3 accused scanner…in the United States with a license to the Ortho System software. (Accused Product Stipulation at ¶¶ 1-4.).

Align presented evidence that 3Shape induced the resellers and/or end users to combine the accused TRIOS 3 or TRIOS 4 scanners with the allegedly infringing software systems by importing the USB dongle, which had the license key for accused hardware scanners to gain access to the accused Ortho System or TPM software. (Dovgan Declaration at 16 and ¶ 7; Tr. (Fisker) at 643:10-645:9; Tr. (Petersen) at 1153:10-15, 1165:9-11.). Therefore, under *Suprema*, the importation requirement is satisfied for the accused TRIOS 3 and TRIOS 4 scanners and the accused TRIM, TPM, and Ortho System software because the hardware and software elements are imported separately, but later combined to infringe the Asserted Patents.

In response, 3Shape argued that the importation requirement is not satisfied because since at least April 2018, 3Shape and/or its downstream users in the U.S. download the accused Ortho

System and TPM software into the United States through the internet. (RRBr. at 2-5.). 3Shape's theory that the importation requirement is not satisfied relies upon the Federal Circuit's holding in *ClearCorrect Operating LLC v. Int'l Trade Comm'n*, 810 F.3d 1283, 1286 (Fed. Cir. 2015) ("*ClearCorrect*"). *ClearCorrect* holds that for the purposes of Section 337, "articles" do not include "electronically transmitted digital data." However, *ClearCorrect* is distinguishable from the facts in this Investigation in at least one critical aspect. *ClearCorrect* contemplates an importation scenario in which accused products are only "digital models" made by a process which allegedly infringed a patented process. *ClearCorrect*, 810 F.3d at 1287. As the panel in *ClearCorrect* noted: "The *only* purported 'article' found to have been imported was digital data that was transferred electronically, i.e., not digital data on a physical medium such as a compact disk or thumb drive" (emphasis added). *Id.* at 1290.

ClearCorrect's "digital model" distinction does not apply here. In this case, the Accused Products to which 3Shape and Align stipulated include TRIOS 3 and TRIOS 4 scanner hardware. (Importation Stipulation at ¶ 4.). The Federal Circuit's comment that distinguishes "digital data that was transferred electronically" from "digital data on a physical medium such as a . . . thumb drive," it is also relevant here. Both of 3Shape's experts, Mr. Petersen and Mr. Fisker, seemed to agree (notwithstanding the lack of clarity in other parts of their testimony) that a thumb drive (USB "dongle"), that contains the data to enable access to the accused Ortho System or TPM software, is imported with the accused TRIOS 3 and TRIOS 4 scanners. (Tr. (Fisker) at 643:10-645:9; Tr. (Petersen) at 1153:10-15, 1165:9-11.). *ClearCorrect* should not control in this case because it would lead to the consequence cautioned against by the *en banc* decision in *Suprema*: it would provide "an open invitation to various foreign entities … to circumvent Section 337 by importing articles in a state requiring post-importation combination or modification before direct infringement could be shown." *Suprema*, 796 F.3d at 1352.

Finally, the testimony of 3Shape's two experts, Mr. Fisker and Mr. Petersen, is ultimately inconclusive ***solely*** on the issue of importation of the accused TPM software because both witnesses seemed to defer to each other on the facts. Neither of them knew the facts.

Although Mr. Petersen testified on re-direct examination during the Hearing that TPM software is not loaded onto the TRIOS 3 or TRIOS 4 scanners before importation Mr. Petersen undermined his own testimony by his own subsequent testimony during re-cross-examination that he would need to defer to Mr. Fisker to verify the facts with respect to when and how 3Shape's TPM software is downloaded now. (*See* Tr. (Petersen) at 1175:24-1176:7, 1178:1-1179:7.). Similarly, although Mr. Fisker testified during direct examination during the Hearing that TPM software is not currently loaded onto the TRIOS 3 or TRIOS 4 scanners prior to importation, he too undermined his own testimony during cross-examination because he said he learned this information from Mr. Petersen who, in turn, testified he relied upon Mr. Fisker's testimony. (Tr. (Fisker) at 643:10-21; *id.* Tr. (Fisker) at 643:3-5, 662:24-663:4.). Indeed, Mr. Fisker even testified that he was "surprised" to learn that Mr. Petersen implicated him as the proper source for such information during his May 2019 deposition. (*See* Tr. (Fisker) at 667:11-22.).

In other words, neither Mr. Petersen nor Mr. Fisker seemed to know during their depositions in May 2019 and July 2019, respectively, whether TPM software was pre-loaded onto the TRIOS 3 or TRIOS 4 scanners prior to their importation into the United States. Moreover, both witnesses then testified during the Hearing that they learned from each other that TPM software was not pre-loaded prior to U.S. importation. This makes their testimony on the issue of whether TPM is imported separately from a TRIOS 3 or TRIOS 4 scanner inconclusive and unreliable.

Accordingly, the weight of the evidence supports a finding that the Accused Products in this Investigation have been imported into the United States. 3Shape's Ortho System and TPM software that 3Shape imports are "articles that infringe" under *Suprema*.

4. *In Rem* Jurisdiction

Section 337(a)(1)(B) applies to the "[t]he importation into the United States, the sale for importation, or sale within the United States after importation" of articles that infringe a valid and enforceable United States patent." 19 U.S.C. § 1337(a)(1)(B). A single instance of importation is sufficient to satisfy the importation requirement of Section 337. *Certain Optical Disc Drives, Components Thereof, and Prods. Containing the Same*, Inv. No. 337-TA-897, Order No. 101 at 3 (Sept. 22, 2014) (citations omitted) (EDIS Doc. 543438); *Certain Wiper Devices*, Inv. No. 337-TA-881, Init. Det. at 5 (*in rem* jurisdiction exists when importation requirement is satisfied).

In rem jurisdiction is contested in this case. Align argued that the importation requirement is satisfied because the accused TRIOS 3 and TRIOS 4 scanners have been imported with the accused TRIM, TPM, and/or Ortho software pre-loaded. (CPBr. at ix, 1, and 9-14; CBr. at ix, and 1-3.). Align argued as an alternative theory of importation that the accused TRIOS 3 and TRIOS 4 scanners have been imported and then combined with the accused TRIM, TPM, and/or Ortho software *after* importation to form an infringing product, which was then sold in the United States. (CBr. at 2-7.).

Align also established certain facts during the Hearing during the cross-examination of one of 3Shape's witnesses, Mr. Mikael Petersen,[7] that support a finding that *in rem* jurisdiction is satisfied for the Ortho System Software.

Mr. Petersen testified that prior to February or March 2018, "all TRIOS scanners" which used Ortho System software were imported to the U.S. with the Ortho System pre-installed. (Tr. (Petersen) at 1162:7-21, 1163:7-14.). Mr. Petersen also testified that as of April 2018, some four (4) months after Align initiated the 1091 Investigation[8] and (8) months before Align filed its Complaint in this Investigation, the Ortho System software was [redacted]. (Tr. (Petersen) at 1165:17-23, 1166:14-16.). Mr. Petersen also testified that 3Shape's co-Chief Executive Officer ("CEO"), Mr. Nikolaj Deichmann, instructed him in December 2017 as a legal matter to change the importation process for U.S. bound scanners and software. Mr. Deichmann's instruction occurred approximately one (1) month after Align sued 3Shape in the 1091 Investigation. (Tr. (Petersen) at 1166:17-1167:14.). According to Mr. Petersen, as of September 2018, everywhere in the world, except the U.S., where 3Shape sells TRIOS scanners with the Ortho System Software, the Ortho System software [redacted] into the destination country. (Tr. (Petersen) at 1166:7-13.). 3Shape did not offer documentation that reflected the change to which Mr. Petersen testified.

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[7] When he testified during the Hearing on October 29, 2019, Mr. Mikael Petersen was 3Shape's Senior Vice President of Supply Chain, Group IT and Facilities. Mr. Petersen was 3Shape's corporate witness who testified about 3Shape's supply chain for the Accused Products, importation, and related issues. (CPSt. at 9; RPSt. at 2; Tr. (Petersen) at 1131.).

[8] There are two (2) previous Investigations involving Align and 3Shape that are relevant to the present Investigation. *See Certain Intraoral Scanners & Related Hardware and Software*, Inv. No. 337-TA-1090, Initial Determination (Apr. 26, 2019) (the "1090 Investigation"); *Certain Intraoral Scanners & Related Hardware & Software*, Inv. No. 337-TA-1091, Initial Determination (Mar. 1, 2019) (the "1091 Investigation").

3Shape's attempts to rebut that there is *in rem* jurisdiction by attempting to apply *ClearCorrect* are unpersuasive and unsupported. Moreover, 3Shape stipulated that a variety of TRIOS 3 and TRIOS 4 scanners have been imported to the U.S. (*See* Importation Stipulation at ¶ 1, App. A.). As noted above, 3Shape stipulated that each accused product, including the Ortho and TPM software, was used at least once in the U.S. between December 10, 2018 and October 31, 2019. (Accused Product Stipulation at ¶ 3.). 3Shape also failed to support the expert testimony of Mr. Petersen with documented evidence that the importation process had been changed to import the scanners to the U.S. without pre-installed Ortho software. (Tr. (Petersen) at 1180:9-1182:9.).

Thus, the weight of the evidence supports a finding that the Commission has *in rem* jurisdiction over the Accused Products.

B. Align Has Standing in the Commission

Jurisdiction also requires standing. *See SiRF Technology, Inc. v. Int'l Trade Comm'n*, 601 F.3d 1319, 1326 (Fed. Cir. 2010) (standing to bring an infringement suit is the same under Commission Rules as it would be in a Federal District Court case); *Certain Optical Disc Drives, Components Thereof and Prods. Containing Same*, Inv. No. 337-TA897, Opinion Remanding the Investigation at 4 (Jan. 7, 2015). Commission Rule 210.12 requires that intellectual property-based complaints filed by a private complainant "include a showing that at least one complainant is the exclusive license of the subject intellectual property." 19 C.F.R. § 210.12(a)(7).

Align has standing to bring suit for infringement under Section 337 because Align Technology, Inc. owns by assignment the full right, title and interest in the Asserted Patents. (*See* CX-2165; CX-2166; CX-2167; CX-2168; CX-2169; CX-2170; CX-2294; JX-0001-JX-0004.). *See SiRF Tech.,* 601 F.3d at 1327-28 (finding that "[t]he recording of an assignment with the PTO . . . creates a presumption of validity as to the assignment and places the burden to rebut such a showing on one challenging the assignment”).

IV. THE ASSERTED PATENTS

A. Overview of the Technology

The technology claimed in the Asserted Patents generally relates to analyzing an orthodontic treatment by using digital models of teeth; the modification of virtual models created by using scanning systems; and a system that generates color three-dimensional (3D) models of an object. (Doc. ID No. 679910 (Joint Technology Stipulation) at 1 (July 1, 2019).).

B. Overview of U.S. Patent Nos. 7,077,647 (“the ’647 Patent”) and 7,156,661 (“the ’661 Patent”)

The ’647 patent, titled “Systems and Methods for Treatment Analysis by Teeth Matching,” was filed on August 22, 2002, as U.S. Patent Application Serial No. 10/225,889 (“the ’889 application”). (JX-0001 at (21), (22), (54).). The ’889 application issued as the ’647 patent on July 18, 2006, and names Woncheol Choi, Jihua Cheng, and Eric Kuo as the inventors, and Align Technology, Inc. as the assignee. (*Id.* at (10), (45), (75).).

The ’661 patent, also titled “Systems and Methods for Treatment Analysis by Teeth Matching,” was filed on August 12, 2003, as U.S. Patent Application Serial No. 10/640,439 (“the ’439 application”). (JX-0002 at (21), (22), (54).). The ’439 application issued as the ’661 patent on January 2, 2007, and like the ’647 patent, names Woncheol Choi, Jihua Cheng, and Eric Kuo as the inventors. (*Id.* at (10), (45), (75).). The ’661 claims priority to the ’889 application, which issued as the ’647 patent.[9] (*Id.* at (63).).

The’647 and ’661 patents describe matching computer models of two (2) sets of teeth.

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[9] The ’439 application is a continuation-in-part of the ’889 application. (JX-0002 at (63).).

(*See, e.g.*, JX-001 at Abstract; JX-0002 at Abstract.). The ’661 patent is a continuation-in-part of the ’647 patent, and thus shares portions of the same specification. (JX-0002 at (63).). The claimed inventions generally relate to the field of orthodontics and more specifically to systems and methods for the measurement of teeth movements. (JX-0001 at 1:7-9; JX-0002 at 1:13-15.). Methods for digitizing plaster models of teeth of a patient were well-known and described in the patent and medical literature. (JX-0001 at 1:44-2:3.).

The ’647 and ’661 patents teach that one advantage of the digital model are that they provide more accurate measurements. (JX-0001 at 2:4-5; JX-0002 at 2:9-11.). The patents disclose that, traditionally, in the prior art, dentists depended upon manual measurement to measure dental features and orthodontic properties. (JX-0001 at 2:5-7; JX-0002 at 1:34.). In prior art, dentists used a ruler on teeth impressions or on X-ray images. The process they used was a manual process, and the dental measurements were two-dimensional only. (JX-0001 at 2:7-10; JX-0002 at 1:34-37.). Thus, according to the ’647 and ’661 patents, the prior art measurements were incomplete and imprecise, because, for example, the rotation of a tooth is difficult to measure. (JX-0001 at 2:10-11; JX-0002 at 1:38-39.).

Contrary to the teachings in the prior art, the digital models disclosed in the ’647 and ’661 patents describe the performance of precise measurement and movement analysis. (JX-0001 at 2:11-15; JX-0002 at 2:10-11.). Specifically, using three-dimensional rigid body analysis, the patents teach that accurate and complete movement of a tooth or the entire jaw can be calculated. (JX-0001 at 2:11-13; JX-0002 at 2:11-15.). In order to accurately compare two (2) digital models (for example, a digital model of a patient’s tooth, teeth and/or jaw), accurate matching of the two models is necessary before measuring positional differences. The ’647 and ’661 patents provide methods and systems to match two (2) digital models to measure positional and shape differences in a patient's dentition.

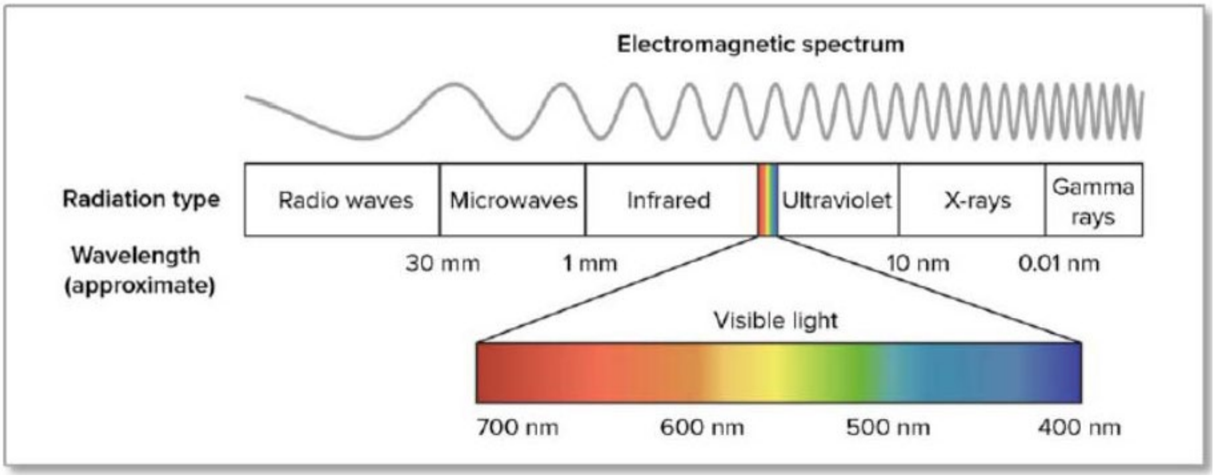
C. Overview of U.S. Patent No. 8,102,538 ("the '538 Patent")

The '538 patent, titled "Method and Apparatus for Colour Imaging a Three-Dimensional Structure," was filed on April 29, 2010, as U.S. Patent Application Serial No. 12/770,379 ("the '379 application"). (JX-0003 at (21), (22), (54).). The '379 application issued as the '538 patent on January 24, 2012, and names Noam Babayoff as the sole inventor, and Align Technology, Inc.'s predecessor, Cadent Ltd. ("Cadent"), as the assignee. (*Id.* at (10), (45), (75); Compl. at ¶¶ 7, 16; CX-2167.0002 (assignment from Cadent Ltd. to Align Technology, Inc.).).

The '538 patent "relates to optical scanners, particularly for providing a digital representation of three-dimensional objects including color." (*Id.* at 1:18-20.). Finding particular application in the surveying of teeth in the intraoral cavity, the '538 patent notes that "[m]any methods have been developed for obtaining the three-dimensional location of surface points of an object," but that those methods generate a "three-dimensional surface model that is inherently monochromatic, i.e., no color information is obtained in the imaging process." (*Id.* at 1:20-21, 1:25-45.).

Below is a diagram that illustrates the electromagnetic spectrum, which includes ultraviolet, visible, and infrared light.

Figure 1: Electromagnetic Spectrum



(Join Tech. Stip. at 2 (citing https://www.khanacademy.org/science/biology/photosynthesis-in-plants/the-light-dependent-reactions-of-photosynthesis/a/light-and-photosyntheic-pigments).).

As the '538 patent noted, the human eye can detect light that has a wavelength in the range of about 400nm (violet) to 700nm (red). (*Id.*). Two ways of capturing 2D color images include: (i) illuminating an object with white light and capturing the light from the object with a color image sensor (e.g., an array of sensor elements sensitive to different regions of the visible spectrum, such as red, green, and blue); and (ii) illuminating an object with a sequence of different illuminations and capturing the light from the object with a monochromatic image sensor at different times. (*Id.*).

D. Overview of U.S. Patent No. 9,229,192 ("the '192 Patent")

The '192 patent, titled "Methods and Systems for Creating and Interacting with Three Dimensional Virtual Models," was filed on March 29, 2016, as U.S. Patent Application Serial No. 13/574,723 ("the '723 application"). (JX-0004 at (21), (22), (54).). The '723 application issued as the '192 patent on March 29, 2016, and names Avi Kopelman as the sole inventor, and Align Technology, Inc. as the assignee. (*Id.* at (10), (45), (75).).

The ’192 patent is directed to a method and system that displays a first virtual model generated from 3D scan data of a physical structure (e.g., a patient’s tooth, teeth or jaw), where the first virtual model fails to properly represent a first physical part of the physical structure. (Joint Tech. Stip. at 3.). To remedy this failure of representation, the ’192 patent noted that the method and system receives user input identifying a portion of the first virtual model the user desires to modify, receives a second virtual model also generated from 3D scan data (i.e., by rescanning at least a portion of the physical structure), and finally modifies the first virtual model by replacing at least the identified portion the user desires to modify with a corresponding portion of the second virtual model, resulting in a modified virtual model. (*Id.* at 3-4.).

V. THE PRODUCTS AT ISSUE

A. 3Shape’s Accused Products

Align and 3Shape stipulated that the Accused Products in this case are “Trios 3 and Trios 4 intraoral scanners and certain software, specifically 3Shape’s Trim Tool, Ortho System, and Patient Monitoring.” (*See* Joint Stipulation Regarding Accused 3Shape Products, Doc. ID No. 692907 at ¶ 1 (October 31, 2019)) (“Accused Product Stipulation”). The Accused Product Stipulation does not specifically mention the Compare Model Sets (“CMS”) software, the “Virtual Setup” tool, the “lab scanner” hardware, or the Dental System software.

Both Align and 3Shape characterized the CMS software as a part of the accused Ortho System. (CPBr. at ix; CBr. at ix; RPBr. at xii; RRBr. at viii.). Therefore, CMS is also an accused product.

With respect to the Virtual Setup tool, Align clarified in both its Pre-Hearing Brief and Post-Hearing Brief that the accused Ortho System software includes the Virtual Setup tool (CPBr. at ix, x, and 9-11; CBr. at ix, x, 10.). However, 3Shape claimed that the Virtual Setup tool was "unaccused." (RPBr. at 21; RRBr. at 11.). That argument is unavailing.

Based upon the list of "Defined Terms" and arguments included in Align's Pre-Hearing Brief, 3Shape was well aware when the Accused Product Stipulation was filed on October 31, 2019, that Align interpreted the Virtual Setup tool to be part of the "Ortho System" software. As such, 3Shape had the opportunity to clarify or disclaim "Virtual Setup" from consideration as an accused product. However, 3Shape failed to do so. 3Shape failed to support its claim with any detailed contentions explaining why Virtual Setup is not an accused product. Align interpreted the accused "Ortho System" software to include the "Virtual Setup" tool in its Pre-Hearing and Post-Hearing briefs. 3Shape did not advance any detailed arguments to the contrary aside from merely characterizing the tool as "unaccused. Since Align and 3Shape stipulated to the "Ortho System" being an accused product, the Virtual Setup tool is an accused product in this case.

With respect to the "lab scanner" hardware, Align included the 3Shape "lab scanner" in the Complaint, to the extent that the "lab scanner" used the accused Dental System software. (Compl. at ¶¶ 1, 33, 95.). More specifically, Align initially accused the Dental System software of infringing the '958 patent. (*Id.* at ¶ 1.). However, Align indicated in its Pre-Hearing Brief that the '958 patent was no longer being asserted in the litigation. (CPBr. at 1.). Moreover, Align did not include the "lab scanner" or the Dental System software in the list of Accused Products in its Pre-Hearing Brief or Post-Hearing Brief. (CPBr. at ix; CBr. at ix.). 3Shape has consistently described the "lab scanner" as "unaccused." (Resp. at 7; RPBr. at 2, 9; RRBr. at 2.). Therefore, the "lab scanner" is not an accused product in this case.

The Dental System software ("Dental Desktop"), while not an accused product in this case, is accused only to the extent that it includes the Patient Monitoring ("TPM") software. Align accused TPM of infringing the '641 and '647 patents. (CPBr. at 9.). Indeed, both Align and 3Shape stipulated that TPM is an accused product. (*Accused Product Stipulation* at ¶ 1.). However, Align also argued that "TPM source code [redacted]." (*See* CBr. at 13 (Footnote 11) and 25.). 3Shape seemed to acknowledge the argument advanced by Align, but 3Shape denied the validity the argument. (RRBr. at 22.). Further, neither Align nor 3Shape associated the Dental Desktop software separately or individually with their respective definitions of the term "Accused Products" used in their Pre-Hearing, Post-Hearing, or Post-Hearing Reply Briefs. As such, Dental Desktop is not wholly an accused product in this case, except to the extent that it incorporates the accused TPM software.

Therefore, the full array of Accused Products in this case includes TRIOS 3 scanners, TRIOS 4 scanners, TRIM software, TPM software, and Ortho System software which includes CMS and Virtual Setup.

B. Align's Domestic Industry Products

Align relied upon the following Domestic Industry ("DI") Products: iTero, iTero with Outcome Simulator with Progress Assessment, iTero with TimeLapse, iTero with Eraser, and Align's Invisalign System (including Treat). (*See, e.g.*, CBr. at ix.).

1. iTero with Progress Assessment, iTero with TimeLapse, and Invisalign with Treat

Align's iTero intraoral scanning system comes with two (2) features, one is called Progress Assessment and one is called TimeLapse. (*See* CX-2125C (Badler Expert Rpt.) at ¶¶ 129-144.).[10]

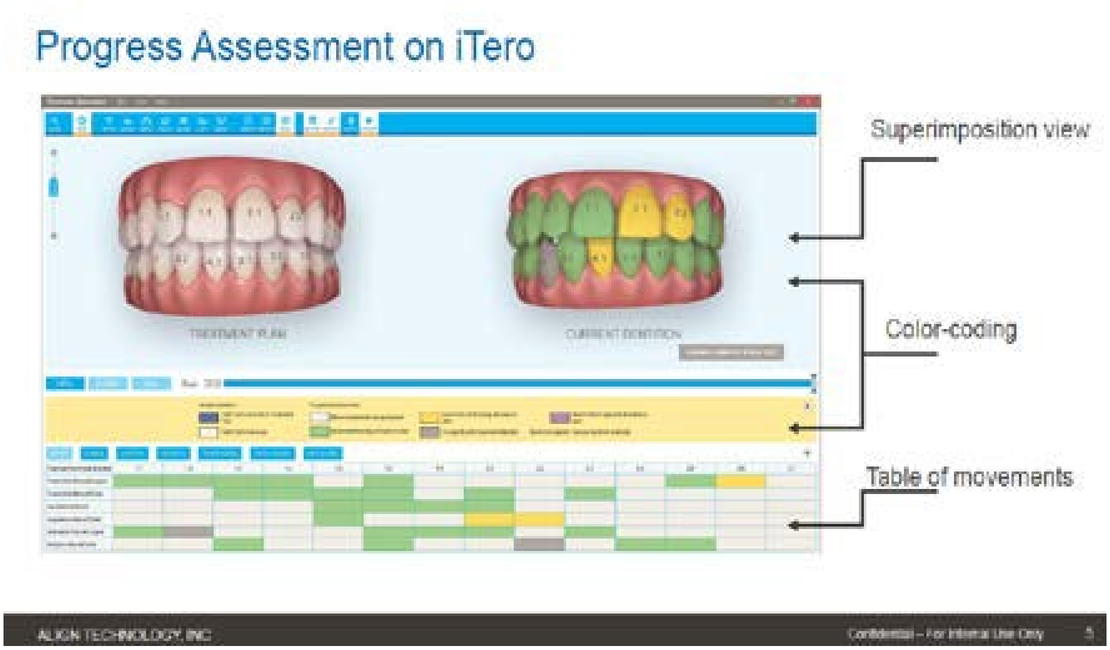
[10] When he testified during the Hearing on October 25, 2019, Dr. Norman Badler was a Professor at the University of Pennsylvania in the Department of Computer and Information Science. (CPSt. at Ex. 1.). Align identified Dr. Badler as an expert to testify with respect to the technical background of the '192 patent, the '647 patent, the '661 patent; the interpretation of claims in those patents; the design, manufacture, structure, function, and operation of the Accused Products and any article or method

Align argued that: (i) its iTero system with Progress Assessment and Invisalign Treat practice claims 1 and 18 of the ’647 patent; while (ii) its iTero system with TimeLapse practices claims 2 and 20 of the ’661 patent. (CPBr. at 7; CBr. at 28-37.). Progress Assessment (a feature of Outcome Simulator) and TimeLapse are software tools for the iTero Element Intraoral scanner, and Treat is the software for the Invisalign System. (*See, e.g.*, CPBr. at 7.).

With Progress Assessment in Figure 2, below, a practitioner can track the progress of an Invisalign treatment plan by comparing a patient’s current dentition to the treatment plan and seeing color-coded changes in movement as compared to the plan. (*See, e.g.*, CX-1839; CX-1798C; CX-1801C; CX-1237C; CX-1789C.). With TimeLapse in Figure 3, below, a practitioner can compare historical scans to a current scan to see changes in tooth wear, tooth movement and changes in gingiva over time. (*See, e.g.*, CX-1967C; CX-1956C; CX-1582C.).

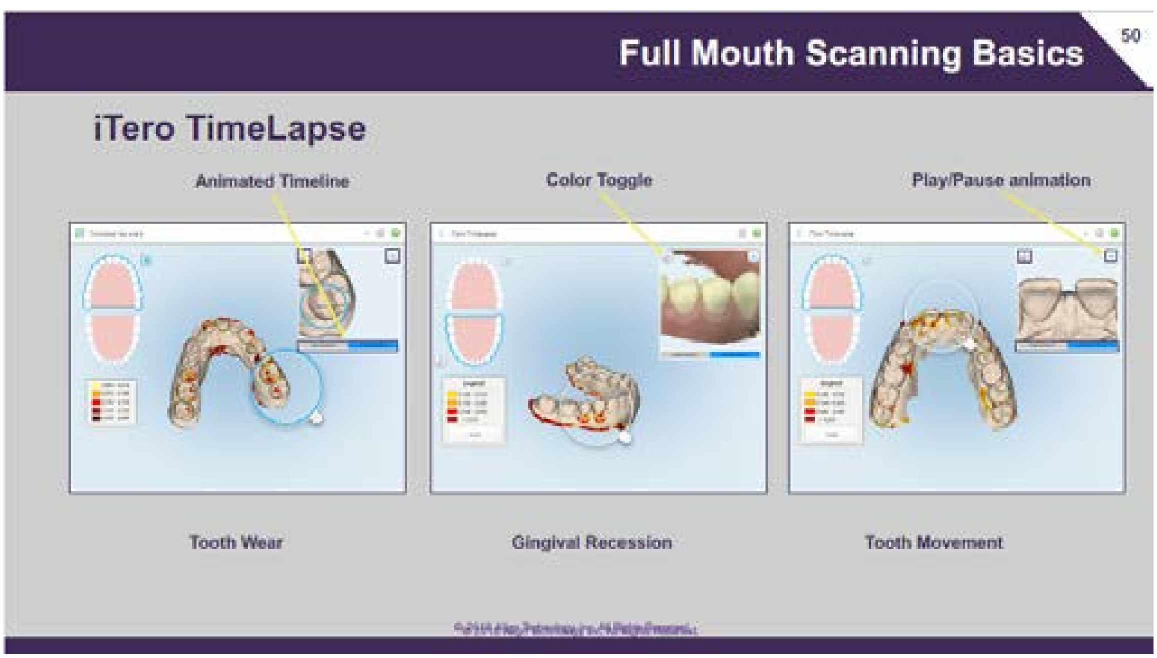
asserted to be protected by the Asserted Patents. Additionally, Dr. Badler was identified as a person of ordinary skill in the who was called to testify to the scope of the prior art and issues in connection with infringement, validity, enforceability and/or the technical prong of the domestic industry requirement. (*Id.* at 3.).

Figure 2: iTero Progress Assessment



(CX-1789C.0005.).

Figure 3: iTero TimeLapse



(CX-1967C.0050.).

Invisalign's Treat feature also tracks the progress of an Invisalign treatment plan by comparing a patient's current dentition to the treatment plan and by comparing changes in the movement as compared to the plan. (CX-1784C; CX-1789C.).

2. iTero Element Scanner

The iTero Element family, depicted below in Figure 4, consists of the iTero Element, iTero Element 2, iTero Element Flex, and iTero Element 5D.[11] Each member of the iTero family generates color three-dimensional models of the dentition that may be used in conjunction with the production of dental devices (e.g., aligners, braces, appliances, etc.) and accessories. (*Id.*). 3Shape did not dispute that the iTero Element is representative product for purposes of this investigation. (Tr. (Robert Louis Stevenson)[12] at 946:10-950:6; CX-0311; CX-1853.0003 (depicting stand and monitor differences for Element and Element 2, and Flex as the portable version); CDX-0014C.0058.). Align uses and sells the iTero in the United States. (Tr. (Zelko Relic)[13] at 211:14-20, 356:18-357:15.).

[11] Align represented that Element 5D is currently sold outside the United States but that Align is in the process of obtaining Food and Drug Administration ("FDA") approval for sale in the United States. (CX-2274C (Saphier Dep. Tr. (May 30, 2019)) at 14:25-15:3.).

[12] When he testified during the Hearing on October 28-29, 31, 2019, Dr Robert Louis Stevenson was the Associate Chair, Director of the Undergraduate Studies Department of Electrical Engineering at University of Notre Dame, as well as a Professor in the Department of Electrical Engineering at the University of Notre Dame. (CPSt. at Ex. 3.). Align identified Dr. Stevenson as an expert to testify with respect to the technical background of the '538 patent; the interpretation of the asserted claims in the Asserted Patents; the design, manufacture, structure, function, and operation of the Accused Products and any article or method asserted to be protected by the Asserted Patents. Align identified Dr. Stevenson as a person of ordinary skill in the art who Align called to testify with respect to the scope of the prior art, and to issues related to infringement, validity, enforceability and/or the technical prong of the domestic industry requirement; and any other technical matters at issue. (*Id.* at 11-12.).

[13] When he testified during the Hearing on October 28, 2019, Mr. Zelko Relic was Align's Chief Technology Officer ("CTO") and senior vice president of global research and development. (Tr. (Relic) at 194:23-195:1.). Align identified Mr. Relic as a fact witness to testify on Align's background and business and Align's interactions with 3Shape. Mr. Relic was also called to provide rebuttal to 3Shape's

The iTero includes a [redacted]. (Tr. (Stevenson) at 947:10-950:6; Tr. (Ofer Saphier)[14] at 256:5-257:20, 258:14-22, 260:1-16; CDX-0014C.0061.). The [redacted]. (Tr. (Stevenson) at 948:5-12; Tr. (Saphier) at 265:18-266:25, 269:24-270:15; CDX-0014C.0062.). To calculate depth, the iTero [redacted]. (Tr. (Stevenson) at 948:13-951:2; Tr. (Saphier) at 259:14-19; CDX-0014C.0063-64.). The encoder in the iTero provides the [redacted]. (Tr. (Stevenson) at 950:20-951:21; Tr. (Saphier) at 260:17-261:6, 260:24-270:15; CX-1238C.0020.).

The [redacted]. (Tr. (Saphier) at 270:16-272:19; Tr. (Stevenson) at 948:5-951:24.). To calculate color for each point in the surface topology, the iTero [redacted]. (Tr. (Stevenson) at 949:3-952:11; Tr. (Saphier) at 270:16-25; CDX-0014C.0063, .0065.).

The [redacted]. (Tr. (Stevenson) at 952:12-23; CDX-

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equitable defenses, Align's domestic industry in the Asserted Patents. He was called to testify to the non-obviousness of Align's iTero Element, Invisalign System, and its digital ecosystem. Finally, Mr. Relic was called to testify on remedy and bond and related issues. (CPSt. at 10.).

[14] When Mr. Ofer Saphier provided his deposition and hearing testimonies on May 30, 2019 and October 24, 2019, respectively, he was an employee of Align Technology, Inc. (Tr. (Saphier) at 254:24-25; CX-2274C (Saphier Dep. Tr. (May 30, 2019)) at 16:5-8.).

0014C.0066.). The

. (Tr. (Stevenson) at 952:24-953:10; CDX-0014C.0067.).

Figure 4: iTero Product Family

3. iTero Eraser

Align's Eraser tool is error-correction software. It allows the user to "correct" the initial scan of the patient's teeth by removing unwanted "artifacts" (i.e. saliva, debris, collapsed gingiva, or margin line) which appear in the scan. (CX-2125C (Badler Expert Rpt.) at ¶ 805.). After the virtual model from the scan has been created, the user reviews the scan for accuracy. (*Id*. at ¶ 807.). If the user notices any unwanted detail included by the scan in the initial model, the user can select the area of that detail in the initial model. (*Id*. at ¶¶ 805-807.). After the area with the undesired detail has been marked by the user, another scan of the patient's teeth is conducted in order to produce a second model. (*Id.*). In the second model, the selected defective areas in the initial model are then filled in with hopefully more accurate information from the second scan. (*Id.*).

This error correction process is iterative and can be repeated until the user is satisfied with the final model. (*Id.* at ¶ 806.). Such correction provides an enhanced model more accurate than the model produced by the initial scan. (*Id*. at ¶ 796.).

VI. PERSON OF ORDINARY SKILL IN THE ART[15]

A. Definition of a Person of Ordinary Skill in the Art

The Parties stipulated to the following definitions of a personal of ordinary skill in the art. (Doc. ID No. 692583 (Joint POSITA Stipulation) (Oct. 29, 2019).).

For the ’647, ’661, and ’192 patents, the Parties agreed that a personal of ordinary skill in the art “would have had at least a bachelor's degree in electrical engineering, computer science, applied mathematics, or an equivalent field, as well as at least one or two years of industry experience in three-dimensional modeling, or at least five years of comparable industry experience in three-dimensional modeling, or an equivalent combination of academic study and work experience.” (*Id.*).

For the ’538 patent, the Parties agreed that a person of ordinary skill in the art “would have (1) at least a bachelor’s degree in electrical engineering, computer science, applied mathematics, or an equivalent field, as well as at least one or two years of industry experience in optical scanning, (2) at least five years of comparable industry experience in optical scanning, or (3) an equivalent combination of academic study and work experience.” (*Id.*).

VII. U.S. PATENT NO. 7,077,647

A. Infringement

1. Infringement Overview

Align accused 3Shape of directly infringing claims 1 and 18 of the ’647 patent, both literally and under the doctrine of equivalents (“DOE”). (CPBr. at 27-37; CBr. at 9-25.). Align

[15] The legal standard for the level of ordinary skill in the art can be found in the *Markman* Order. (*See Markman* Order at 19-20.).

also accused 3Shape of indirectly infringing claims 1 and 18 of the ’647 patent by inducing infringement and contributing to the infringement of these asserted claims.

Specifically, Align asserted that 3Shape’s TRIOS intraoral scanner with TPM[16] and Ortho System software including Virtual Setup and CMS[17] practice claims 1 and 18 of the ’648 patent. (CPBr. at 9; CBr. at 9, 25.).

As shown in Table No. 5 below, the elements recited in claim 1 drawn to a “method for determining progress of a dental treatment” are almost identical to the elements recited in claim 18, which are drawn to a “computer readable medium containing code for matching computer models of dental objects to determine progress of a dental treatment.” Thus, the claim elements are addressed together in Section VII.A.3. below (e.g., elements [1.1] / [18.1], [1.2] / [18.2], etc.).

Table No. 5: Comparison of Claims 1 and 18 of the ’647 Patent

Cl. 1	Element	Cl. 18	Element
[1.1]	A method for determining progress of a dental treatment, the method comprising:	[18.1]	A computer readable medium containing code for matching computer models of dental objects to determine progress of a dental treatment, the computer readable medium comprising instructions to:
[1.2]	providing an initial digital model of a set of dental objects;	[18.2]	receive an initial digital model of a set of dental objects;
[1.3]	determining planned positions for the set of dental objects;	[18.3]	determine planned positions for a [sic] the set of dental objects;

[16] TPM is an acronym and stands for 3Shape’s TRIOS Patent Monitoring software.

[17] CMS is an acronym and stands for the Compare Model Sets tool offered by 3Shape’s Ortho System software. (*See, e.g.*, CX-0827C.0123-.0127.). Virtual Setup is also a tool offered by 3Shape’s Ortho System software. (*Id.* at .0128-.0132.).

Cl. 1	Element	Cl. 18	Element
[1.4]	providing a subsequent digital model of the set of dental objects in their moved positions after at least some of them have been moved by the dental treatment;	[18.4]	receive a subsequent digital model of the set of dental objects, wherein at least some of the dental objects have new positions in the subsequent model, relative to their positions in the initial model;
[1.5]	individually matching each of the dental objects in the subsequent digital model with a dental object in the initial digital model to determine corresponding dental objects, the matching comprising;	[18.5]	individually match each of the dental objects in the subsequent digital model with a dental object in the initial digital model to determine corresponding dental objects, including instructions to;
[1.6]	identifying one or more reference points on each set of corresponding dental objects in the initial and subsequent digital models:	[18.6]	identify one or more reference points on each set of corresponding dental objects in the initial and subsequent digital models;
[1.7]	approximately matching each set of corresponding dental objects by approximately aligning corresponding reference points on corresponding dental objects;	[18.7]	approximately match each set of corresponding dental objects by approximately aligning corresponding reference points on corresponding dental objects;
[1.8]	and matching each set of corresponding dental objects more closely by iteratively minimizing error between corresponding reference points on corresponding dental objects;	[18.8]	and match each set of corresponding dental objects more closely by iteratively minimizing error between corresponding reference points on corresponding dental objects;
[1.9]	matching the subsequent digital model as a whole with the initial digital model;	[18.9]	match the subsequent digital model with the initial digital model;
[1.10]	and calculating one or more positional differences between the moved and planned positions of at least some of the corresponding dental objects.	[18.10]	and calculate one or more positional differences between the moved and planned positions of the corresponding dental objects.

For the reasons discussed in Section VII.A.3 below, Align has met its burden and proven by a preponderance of evidence that the 647 Accused Products practice claims 1 and 18.

2. Direct Infringement: Legal Standards

a) Literal Infringement

"Determination of infringement is a two-step process which consists of determining the scope of the asserted claim (claim construction) and then comparing the accused product . . . to the claim as construed." *Certain Sucralose, Sweeteners Containing Sucralose, and Related Intermediate Compounds Thereof*, Inv. No. 337-TA-604, Comm'n Opinion at 36 (U.S.I.T.C., April 28, 2009) (citing *Litton Sys., Inc. v. Honeywell, Inc.*, 140 F.3d 1449, 1454 (Fed. Cir. 1998)).

An accused device literally infringes a patent claim if it contains each limitation recited in the claim exactly. *Litton*, 140 F.3d at 1454. Each patent claim element or limitation is considered material and essential. *London v. Carson Pirie Scott & Co.*, 946 F.2d 1534, 1538 (Fed. Cir. 1991). In a Section 337 investigation, the complainant bears the burden of proving infringement of the asserted patent claims by a preponderance of the evidence. *Enercon GmbH v. Int'l Trade Comm'n,* 151 F.3d 1376, 1384 (Fed. Cir. 1998). If any claim limitation is absent, there is no literal infringement of that claim as a matter of law. *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1247 (Fed. Cir. 2000).

b) Infringement Under Doctrine of Equivalents

Where literal infringement is not found, infringement can still be found under the doctrine of equivalents. The Supreme Court has described the essential inquiry of the doctrine of equivalents analysis in terms of whether the accused product or process contains elements identical or equivalent to each claimed element of the patented invention. *Warner-Jenkinson*

Co., Inc. v. Hilton Davis Chemical Co., 520 U.S. 17, 40 (1997). According to the Federal Circuit:

> Infringement under the doctrine of equivalents may be found when the accused device contains an "insubstantial" change from the claimed invention. Whether equivalency exists may be determined based on the "insubstantial differences" test or based on the "triple identity" test, namely, whether the element of the accused device "performs substantially the same function in substantially the same way to obtain the same result." The essential inquiry is whether "the accused products or process contain elements identical or equivalent to each claimed element of the patented invention[.]"

TIP Sys., LLC v. Phillips & Brooks/Gladwin, Inc., 529 F.3d 1364, 1376-77 (Fed. Cir. 2008) (citations omitted).

3. The 647 Accused Products Practice Claims 1 and 18 of the '647 Patent

a) Claims 1 and 18

i. [1.1] / [18.1]: "A method for determining progress of a dental treatment, the method comprising" / "A computer readable medium containing code for matching computer models of dental objects to determine progress of a dental treatment, the computer readable medium comprising instructions to"[18]

Align's expert, Dr. Badler, testified that the accused TPM is used to track an orthodontic treatment to see if a patient is on track with the treatment plan. (Tr. (Badler) at 381:14-24, 385:9-386:1; CX-0923.0003; CX-2125C (Badler Expert Rpt.) at ¶¶ 149-53; CDX-0011C.0010.). 3Shape's witness, Dr. Rune Fisker,[19] testified during the Hearing that a user of TPM can create a digital orthodontic treatment plan using a scan of the patient's mouth and compare that treatment

[18] The Parties agreed that the terms "dental object / dental objects" mean "tooth" / "teeth," respectively. (*Markman* Order, App. A. at 42.).

[19] When he testified during the Hearing on October 28, 2019, Dr. Rune Fisker was the Senior Vice President of 3Shape A/S. (Tr. (Fisker) at 637:17-18, 637:25:638:3.). 3Shape identified Dr. Fisker as a fact witness to testify about 3Shape's interactions with Align, the market for intraoral scanners and 3Shape's design and development of its Trios intraoral scanners, and 3Shape's Patient Monitoring software. (RPSt. at 2.).

plan to a current scan to make any necessary adjustments to the plan if the patient is off track.

> Q. Now, a user of 3Shape's Patient Monitoring can obtain a digital treatment plan using an initial digital set-up and compare that to actual scans of a patient's dentition using a DCM or STL file importation process. That's correct, isn't it, sir?
>
> A. Yes.
>
> Q. And if the patient is not on track with regard to an intended treatment plan, a user can make adjustments to the treatment plan to put them back on track using Patient Monitoring. That's correct, isn't it, sir?
>
> A. In theory, yes.

(Tr. (Fisker) at 661:2-20, 688:6-689:5.).

Evidence adduced in this Investigation indicates that 3Shape either loads the software on the TRIOS Intraoral scanner hardware or transmits the software to users to load onto the hardware. (Tr. (Badler) at 410:25-411:24; CX-0923.0003, .0032.). Thus, TPM comprises instructions and code stored on a computer. Moreover, 3Shape's resellers confirmed that they sell and use TPM in the United States. (CX-0025 (Charlie Mozeko Decl.);[20] CX-0026 (Richard Lake Decl.).).[21] Therefore, there is a computer readable medium in the United States with accused instructions for TPM.

3Shape argued that Mr. Mozeko's and Mr. Lake's "declarations should be given little to no weight because the declarants lack sufficient knowledge and expertise on the Asserted Patents

[20] Mr. Charlie Mozeko, the Products Manager for Great Lakes Dental Technologies, Ltd. ("Great Lakes"), provided a declaration at Align's request. (CX-0025 (Mozeko Decl.) at ¶ 1.). Based on his personal knowledge, Mr. Mozeko affirmed that "Great Lakes offers more than 4,000 products and services, including products developed and manufactured by 3Shape[.]" (*Id.* at ¶ 4.).

[21] Mr. Richard Lake, the Senior Cateory manager of Patterson Dental Holdings, Inc. ("Patterson"), provided a declaration at Align's request. (CX-0026 (Lake Decl.) at ¶ 1.). Mr. Lake averred that he is "responsible for overseeing Patterson' marketing efforts in connection with a portfolio of products that include 3Shape products[.]" (*Id.*). He also affirmed that based on his personal knowledge, "Patterson through its wholly-owned subsidiary Patterson Dental Supply Inc is a reseller of 3Shape products in the United States." (*Id.* at ¶ 3.).

and Accused Products." (RRBr. at 8.). Specifically, 3Shape based this argument, *inter alia*, on the fact that Mr. Lake and Mr. Mozeko did not personally prepare the declarations and they relied on others to provide information regarding 3Shape's products. (*Id.* (citations omitted).). 3Shape's contention is unavailing. Both declarants testified that although they did not draft the declarations, they reviewed the declarations, and confirmed with the assistance of knowledgeable people that the information contained in the declarations were true.

> Q. And it's probably fair to say that you personally did not draft this Declaration; is that right?
>
> A. I did not draft the Declaration.
>
> Q. Does that affect the truth of the information that you attested to based on your personal knowledge?
>
> A. I would say that I didn't draft the Declaration, but I reviewed the Declaration and I was satisfied in signing it.
>
> Q. Satisfied that the information inside of the Declaration is true?
>
> A. Correct.

(RX-2420C (Lake Dep. Tr.) at 15:9-21.).

> Q. Mr. Mozeko, counsel asked you about the fact that you had not personally drafted the declaration. Do you recall that?
>
> A. Yes.
>
> Q. You did take the opportunity to verify the information in the declaration and to make sure that it was all accurate from your perspective before you signed and submitted it; right?
>
> A. I verified that part with some of our technical people and they indicated that was correct.
>
> Q. And you mentioned technical support people. They are people who you trust with having knowledge --
>
> A. Yes.
>
> Q. -- to provide those types of statements. Fair enough, sir?

A. Yes.

(Tr. (Mozeko) at 764:2-17.).

Accordingly, for the reasons discussed above, Align has proven by a preponderance of evidence that the 647 Accused Products meet preambles [1.1] and [18.1] of claims 1 and 18, respectively, of the ’647 patent.

ii. [1.2] / [18.2]: "providing an initial digital model of a set of dental objects" / "receive an initial digital model of a set of dental objects"; [1.3] / [18.3]: "determining planned positions for the set of dental objects" / "determine planned positions for a [sic] the set of dental objects"[22]

3Shape’s witnesses and resellers acknowledged during the Hearing that TPM provides the claimed initial digital model of a set of teeth. (Tr. (Fisker) at 649:18-23, 652:18-653:25, 660:22-661:20; Tr. (Alen Bogdanic)[23] at 818:22-819:3, 822:9-823:19; Tr. (John Mellor)[24] at 1745:17-20, 1749:10-1750:1.). Documentary evidence and testimony elicited during the Hearing together confirm that TPM loads TRIOS scans and treatment plans from Virtual Setup through Dental Desktop in the form of both STL and DCM files that provide models of a treatment plan

[22] The Parties agreed that the terms “dental object” and “dental objects” mean “tooth” and “teeth,” respectively. (*Markman* Order, App. A at 42.). The Parties also agreed that the term “planned positions” means “target positions.” (*Id.*).

[23] When he testified during the Hearing on October 28, 2019, Mr. Alen Bogdanic was an employee of 3Shape A/S and held the position of project manager of the TPM product. (Tr. (Bogdanic) at 809:22-810:6.). 3Shape identified Mr. Bogdanic as a fact witness to testify about 3Shape’s design and development of its Patient Monitoring software and the structure, function, and operation of that software. (RPSt. at 3.).

[24] When he testified during the Hearing on October 31, 2019, Dr. John P. Mellor, Ph.D. was the Department Head of Computer Science and Software Engineering at the Rose-Hulman Institute of Technology. (RPSt. at Ex. C.). 3Shape identified Dr. Mellor as an expert to testify about 3Shape’s non-infringement of the asserted claims of the ’647 and ’661 patents and the technical prong with respect to those patents. (*Id.* at 5.).

or target positions for comparison.[25] (Tr. (Badler) at 386:2-387:2, 388:2-389:16; *see also* CX-0772C; CX-0906C.0001; CX-0908C.0001; CX-0915C.0001; CX-0923.0001-.0005; CX-2220C (Fisker Dep. Tr.) at 40:11-41:1, 46:18-47:5, 51:15-24, 80:2-81:2, 83:7-22, 102:2-8, 116:1-8, 122:9-16, 139:11-24, 143:20-144:17; CX-2229C (Bardur Isleifsson Dep. Tr.)[26] at 28:19-22, 31:14-20; CX-2233C (Marat Khaitov Dep. Tr.)[27] at 45:4-47:19, 50:1-6.).

The described functionality for loading a single model is also confirmed in the source code in [redacted]. (Tr. (Badler) at 388:19-24; CPX-0208C; CX-2229C (Isleifsson Dep. Tr.) at 24:3-29:17, 54:1-12.). The evidence also indicates that a user of TPM has imported a "Virtual Setup" file into TPM for comparison. (*See* CX-0026 (Lake Decl.) at ¶ 3(i), (iii).). 3Shape's expert, Dr. Mellor, conceded that he no longer offered the opinion that TPM is not configured to load virtual models created by the Virtual Setup tool in Ortho System. (Tr. (Mellor) at 1747:23-1750:14.).

Dr. Badler explained that TPM then determines planned or target positions from the treatment plan as shown in the source code in [redacted], which confirms loading the

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[25] Dr. Badler explained that an STL file is "a common format for exchanging 3-D models[.]" (Tr. (Badler) at 388:2-6; *see also* CX-2220C (Fisker Dep. Tr.) at 47:23-24 ("Q. STL files . . . contain 3D mesh data, right? A. Yes.").). It is referred to "stereolithographic format" or "simple triangle list." (*Id.*). 3Shape's fact witness, Dr. Fisker, confirmed that DCM files also "contain 3D mesh data." (CX-2220C (Fisker Dep. Tr.) at 47:14-15.).

[26] When he provided his deposition testimony on June 12, 2019, Mr. Bardur Isleifsson was an employee of 3Shape A/S and held the position of a software developer. (CX-2229C (Isleifsson Dep. Tr.) at 8:15-9:3.). Mr. Isleifsson confirmed that Alen Bogdanic was his project manager. (*Id.* at 9:23-24.). His job responsibilities included writing software for TPM, reviewing software, and writing specifications. (*Id.* at 9:7-12.).

[27] When he provided his deposition testimony on June 13, 2019, Mr. Marat Khaitov was an employee of 3Shape A/S and 3Shape Ukraine. (CX-2233C (Khaitov Dep. Tr.) at 9:14-16.). Specifically, Mr. Khaitov was the software architect for the Ortho System. (*Id.* at 9:21-22.). His job responsibilities included, *inter alia*, "maintaining software specifications" and "[d]ecisions on technologies used by [the] Ortho System." (*Id.* at 9:23-10:4.).

models from an active patient. (Tr. (Badler) at 389:12-392:15; CPX-0127C.). He testified that once loaded, the TPM source code at [redacted] loads the models, and the upper and lower jaws are identified, linked, and ordered. (Tr. (Badler) at 389:12-392:15; Tr. (Mellor) at 1706:21-1707:9; CPX-0202C.).

Dr. Badler also testified that following this initial processing, the code performs segmentation of individual teeth. (Tr. (Badler) at 389:12-392:15; CDX-0011C.0022; CPX-0044C; CX-0923.0006-.0009; CX-2229C (Isleifsson Dep. Tr.) at 55:25-56:18.). He explained that segmentation of the model enables the software to identify and compare each tooth individually. (Tr. (Badler) at 389:17-391:24, 817:1-8; CX-0923.0006-.0009; CX-2220C (Fisker Dep. Tr.) at 67:15-68:3; CX-2229C (Isleifsson Dep. Tr.) at 55:4-56:18.). 3Shape's expert, Dr. Mellor, testified that TPM's segmentation establishes individual teeth so "you know what tooth you are talking about." (Tr. (Mellor) at 1706:1-13.). Moreover, 3Shape's software specifications demonstrate that [redacted] that are then used in subsequent processing in TPM, e.g., an array of determined positions for teeth. (Tr. (Badler) at 390:17-391:21; Tr. (Mellor) at 1752:2-1753:13; CX-0887C.0008-.0014; CX-0912C.0008-.0014; *see also* CX-2229C (Isleifsson Dep. Tr.) at 56:6-18, 59:7-23.).

Dr. Mellor appears to have misunderstood Dr. Badler's testimony with respect to the claimed "providing an initial digital model" and "determining planned positions" elements. During the Hearing, Dr. Mellor characterized Dr. Badler's infringement theory as "alleging that loading a model with teeth ***in planned position*** and then determining tooth number via segmentation meets those two limitations." (Tr. (Mellor) at 1702:16-19 (emphasis added).). Based on that understanding, Dr. Mellor opined that "[i]f you load an initial model and the teeth

are in planned position, they can't be in planned positions because the next claim element requires determining planned positions from the teeth that you just loaded in the initial model. ***If they were in planned positions, then there wouldn't be anything to do for that second step***."

(*Id.* at 1702:20-1703:1 (emphases added).).

Dr. Mellor's testimony is not an accurate characterization of Dr. Badler's testimony. Dr. Badler did not testify that the teeth in the "initial digital model" created by the 647 Accused Products are ***already*** in the planned or target positions. Rather, he explained that Patient Monitoring (TPM) loads a virtual model, i.e., initial digital model, created in the Ortho Analyzer's virtual setup tool.

> Q. All right. So now moving to claim element 1.2. Have you formed an opinion as to whether claim element 1.2 is satisfied by Patient Monitoring?
>
> A. Yes, the parties agree that dental objects can be construed as teeth, and I will often use that construction. So the very first step in the exemplary embodiment is illustrated in the flowchart from [Fig.3 of] the patent, is, in fact, met by Patient Monitoring, because it loads a virtual model created in Ortho Analyzer's virtual setup tool that I just mentioned. And therefore it provides an initial digital model of the set of dental objects.

(Tr. (Badler) at 386:2-14.).

Dr Badler testified that the TRIOS Intraoral scanner working in conjunction with the Ortho System provides options through Virtual Setup to simulate orthodontic treatment by moving teeth in a patient's TRIOS scan, thus providing target positions for the teeth and an initial digital model or an original treatment case for comparison. (Tr. (Badler) at 383:13-23; CX-0772C.0012-.0014; CX-0827C.0127-.0142, .0155-.0156; CX-2233C (Marat Khaitov Dep. Tr.) at 31:23-32:1, 32:24-33:1; CX-2125C (Badler Expert Rpt.) at ¶¶ 116-122, 161-162.).

Additionally, the evidence discussed above establishes that when using Ortho System and Virtual Setup, a user can modify an initial digital model from a patient before treatment to create and simulate the planned or target positions and then load the initial digital model file with the target positions into TPM for comparison. (*See, e.g.*, *supra*; *see also* Tr. (Badler) at 383:13-23; Tr. (Fisker) at 661:2-20; Tr. (Bogdanic) at 822:9-823:15; (Tr. (Mellor) at 1746:15-1747:21, 1749:10-1750:1; CX-0827C.0127-.0142; CX-2125C (Badler Expert Rpt.) at ¶¶ 116-22, 161-62.). Evidence presented during the Hearing also demonstrates that 3Shape's resellers perform exactly these steps and load Virtual Setup files into TPM. (CX-0026 (Lake Decl.) at ¶ 3(i)-(j); CX-2040C.). Accordingly, the 647 Accused Products literally meet these claim elements.

Dr. Badler testified that if the 647 Accused Products do not literally satisfy these limitations, they do under the doctrine of equivalents because any differences between the claim elements and TPM are insubstantial. (Tr. (Badler) at 386:2-387:2, 389:12-392:9.). However, as 3Shape pointed out, Dr. Badler did not address the prosecution history of the '647 patent. (RRBr. at 13 (citing JX-0005.0112, .0116-.0018).). During prosecution, the applicant amended at least claim 1 to include "determining planned positions for the set of dental objects" (JX-0005.0112), which was a narrowing amendment. With respect to such instances, the Federal Circuit explained that:

> A narrowing amendment made for a substantial reason relating to patentability gives rise to a presumption that the patentee has surrendered all subject matter between the original claim limitation and the amended claim limitation. If the narrowing amendment was the addition of a ***new claim limitation***, as in the case before us, equivalents are ***presumptively*** not available with respect to that limitation.
>
> A patentee may rebut the presumption of surrender by showing that at the time of the amendment one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent. The Supreme Court identified three ways in which the patentee may overcome the presumption. The patentee may show that the alleged equivalent would have been unforeseeable at the time of the amendment, that the rationale underlying the amendment bore no more than a tangential relation to the equivalent in question, or that there was "some other reason" that the patentee could not reasonably have been

expected to have described the alleged equivalent.

Biagro W. Sales, Inc. v. GrowMore, Inc., 423 F.3d 1296, 1305 (Fed. Cir. 2005) (emphases added) (citing *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 741 (2002); *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359 (Fed. Cir. 2003) (en banc); *Honeywell Int'l Inc. v. Hamilton Sundstrand Corp.*, 370 F.3d 1131, 1141 (Fed. Cir. 2004).

Because Align failed to rebut the presumption raised by the narrowing amendment by any of the means the Supreme Court and the Federal Circuit identified, Align has not shown that the 647 Accused Products meet these claim elements under DOE.

Nevertheless, Align has proven by a preponderance of evidence that the 647 Accused Products literally practice elements [1.2] / [18.2] and [1.3] / [18.3] of claims 1 and 18, respectively, of the '647 patent.

iii. [1.4] / [18.4]: "providing a subsequent digital model of the set of dental objects in their moved positions after at least some of them have been moved by the dental treatment" / "receive a subsequent digital model of the set of dental objects, wherein at least some of the dental objects have new positions in the subsequent model, relative to their positions in the initial model"

Align presented evidence that demonstrates that TPM provides a subsequent digital model of the set of teeth in their positions moved by dental treatment because it can compare the scan of a current visit with a previously created treatment plan. (Tr. (Badler) at 392:16-393:24; CX-0923.0003, .0011, .0017; CX-2125C (Badler Expert Rpt.) at ¶¶ 166-71.). The source code in [redacted], confirms this functionality for loading a single model. (Tr. (Badler) at 392:16-393:24; CPX-0208C; CX-2229C (Isleifsson Dep. Tr.) at 24:3-29:17, 54:1-12.). As Dr. Badler explained, tracking an orthodontic treatment requires providing or loading a model taken at a later time, when the patient's teeth are at a different position. (Tr. (Badler) at 392:16-393:24; CX-0923.0003.). Thus, TPM presents a visual representation of the changes between a plan and a scan taken at a subsequent visit, showing changes in tooth movement. (*See* CX-2220C (Fisker Dep. Tr.) at 39:25-41:1, 46:18-48:24.).

3Shape appears to have conceded that TPM meets these claim elements because Dr. Mellor did not address these limitations during the Hearing. (*See* Tr. (Mellor) at 1701:10-1704:25; *see also* RRBr. at 13.).

For the reasons discussed above, Align has proven by a preponderance of evidence that the 647 Accused Products practice elements [1.4] and [18.4] of claims 1 and 18, respectively, of the ’647 patent.

iv. [1.5] / [18.5]: “individually matching each of the dental objects in the subsequent digital model with a dental object in the initial digital model to determine corresponding dental objects, the matching comprising” / “individually match each of the dental objects in the subsequent digital model with a dental object in the initial digital model to determine corresponding dental objects, including instructions to”[28]

Evidence adduced in this Investigation establishes that TPM “individually match[es]” under the adopted construction. TPM first segments the model into individual teeth models as discussed above with respect to claim elements [1.3] /[18.3]. (*See* Section VII.A.3.ii, *supra*.). Subsequently, TPM individually matches tooth-by-tooth, through the execution of the three claimed sub-steps by the Automatic Alignment process, to determine for each tooth the relative position of a tooth in one model to the corresponding tooth in the other model using reference points. (Tr. (Badler) at 394:4-395:22; CX-2125C (Badler Expert Rpt.) at ¶¶ 172-79; *see also* CX-0887C.0014; CX-0912C.0014.).

[28] The terms “individually matching / match each of the dental objects” were construed to mean “for each of the teeth in the subsequent digital model, using the identified reference points to determine the position of a tooth in the subsequent digital model relative to the corresponding tooth in the initial digital model.” (*Markman* Order, App. A at 19.).

Specifically, Dr. Badler explained that as an initial step in the TPM workflow, segmentation is used to identify the teeth of each model. (Tr. (Badler) at 389:12-392:15; CX-0887C.0011; CX-0923.0006-.0009.). Dr. Badler testified that performing segmentation enables TPM to determine each tooth individually and to align and compare each tooth individually going forward in the process, which was confirmed by 3Shape's witnesses. (Tr. (Badler) at 389:12-392:15, 394:4-22; CPX-0044C; CX-0887C.0008-0014; CX-2220C (Fisker Dep. Tr.) at 67:15-68:3 ("Q. And the segmentation identifies each individual tooth in the 3D model, right? A. It segments each tooth, yes. Q. Okay. Performing this segmentation process on each 3D model enables Patient Monitoring to compare each tooth individually, right? A. Yes."); CX-2229C (Isleifsson Dep. Tr.) at 41:1-20, 55:4-56:5 ("Q. And the segmentation step identifies each individual tooth in the 3D model, right? A. Correct. Q. Performing the segmentation process on each 3D model enables Patient Monitoring to identify and compare each tooth individually, right? THE WITNESS: Correct.").).

3Shape's non-infringement theories primarily rely upon the claim language "to determine corresponding dental objects," recited in claim elements [1.5] / [18.5]. Dr. Mellor opined that TPM does not meet these elements because in TPM, "segmentation is the mechanism for determining the correspondences between teeth," and "does not perform the three substeps in the process of determining correspondences." (Tr. (Mellor) at 1706:1-13.).

However, as Align pointed out, the plain claim language of claim element [1.5] states "individually matching . . . to determine corresponding dental objects" is "the matching, comprising" the three following sub-steps.[29] (JX-0001 at cl. 1.). Thus, by the express language,

[29] Claim element [18.5] states "individually match . . . to determine corresponding dental objects,

the "determining corresponding" teeth is accomplished through the claimed matching process, as Dr. Badler testified. (Tr. (Badler) at 405:24-406:11, 520:5-521:18, 527:8-12.). There is no separate "process of determining correspondences" as asserted by Dr. Mellor, because claim elements [1.5] and [18.5] do not positively recite any "determining" step. Rather, the "to determine corresponding" teeth language describes the intended result of the three sub-steps.

For the foregoing reasons, Align has proven by a preponderance of evidence that the 647 Accused Products practice elements [1.5] and [18.5] of claims 1 and 18, respectively, of the '647 patent.

v. [1.6] / [18.6]: "identifying one or more reference points on each set of corresponding dental objects in the initial and subsequent digital models" / "identify one or more reference points on each set of corresponding dental objects in the initial and subsequent digital models"[30]; [1.7] / [18.7]: "approximately matching each set of corresponding dental objects by approximately aligning corresponding reference points on corresponding dental objects" / "approximately match each set of corresponding dental objects by approximately aligning corresponding reference points on corresponding dental objects"[31]

TPM default Automatic Alignment satisfies the referenced claim elements under the adopted constructions of "reference points" and "approximately matching / match each set of corresponding dental objects." (*See* Tr. (Badler) at 395:23-400:20; CX-0923.0010-.0011; CX-

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including instructions to" perform the following sub-steps. (JX-0001 at cl. 1.).

[30] The term "reference points" was construed to mean "points used to determine the position of a digital model, or part thereof, relative to another digital model, or part thereof." (*Markman* Order, App. A at 22-23.).

[31] The Parties agreed that the phrases "approximately matching / match each set of corresponding dental objects" mean "initially aligning / align each set of corresponding teeth." (*Markman* Order, App. A at 42.).

2125C (Badler Expert Rpt.) at ¶¶ 180-92.). Automatic Alignment [redacted]. The Parties' experts agreed that TPM [redacted]. (Tr. (Badler) at 396:19-397:6; Tr. (Mellor) at 1707:18-1709:9.). Thus, there is no dispute that TPM identifies "points used to determine the position of a digital model or part thereof relative to another digital model or part thereof." (*See* Tr. (Bogdanic) at 817:1-818:15; CPX-0117C; CPX-0194C; CX-2229C (Isleifsson Dep. Tr.) at 72:21-75:3, 80:8-25, 75:11-76:25, 79:8-82:18, 84:15-85:18, 90:4-20, 91:14-92:23, 97:11-101:5.).

Mr. Isleifsson testified during his deposition that TPM [redacted]. (CX-2229C (Isleifsson Dep. Tr.) at 74:2-75:3.). TPM's project manager, Mr. Bogdanic, also confirmed that the accused product's [redacted]. (Tr. (Bogdanic) at 817:1-818:15; *see also* Tr. (Fisker) at 656:11-17.). Moreover, Dr. Badler showed this functionality in 3Shape's source code through operation of [redacted]. (Tr. (Badler) at 399:23-400:14; CPX-0194C.). Dr. Mellor acknowledged that TPM Automatic Alignment performs an initial alignment using [redacted]. (Tr. (Mellor) at 1756:9-1757:9.).

Nevertheless, Dr. Mellor testified that the "identifying" reference points element is not satisfied because "all three of the substeps use the same reference point language and [TPM uses] different reference points." (Tr. (Mellor) at 1707:18-1709:3, 1754:9-20.). In other words, 3Shape argued that the sub-steps require the use of the same reference points. However, no claim construction supports 3Shape's position and the claim language does not recite such a requirement. As Align pointed out, there is no antecedent basis for "reference points" in the claimed steps. (JX-0001 at 10:8-18.). Nor is there any claim language that requires the same reference points must be used. (*Id.*).

Moreover, as Dr. Mellor acknowledged, the plain claim language states identifying "one or more" reference points and does not limit the identified reference points to one set of reference points. (*Id.*; Tr. (Mellor) at 1754:1-8.). Dr. Mellor also agreed that Figure 4, describing an embodiment of the patent, illustrates a process that uses different reference points for the approximate alignment and the iterative process. (Tr. (Mellor) at 1754:21-1755:23; JX-0001 at 5:45-6:14, Fig. 4.). This is consistent with Dr. Badler's testimony that it is highly unlikely that the same reference points would be used for the sub-steps because one of ordinary skill in the art would recognize the need for more reference points to do the alignment. (Tr. (Badler) at 404:15-19.). Therefore, nothing prevents the same points from being used in both steps. As Mr. Isleifsson explained, the [redacted].[32] (CX-2229C (Isleifsson Dep. Tr.) at 75:11-76:14, 80:11-81:18, 82:13-18.).

Accordingly, Align has proven by a preponderance of evidence that the 647 Accused

[32] [redacted] (*See, e.g.*, Tr. (Badler) at 401:11-15; *see also* CX-2229C (Isleifsson Dep. Tr.) at 86:5-25; CDX-0011C.0034; CX-0948).).

Products practice elements [1.6] / [18.6] and [1.7] / [18.7] of claims 1 and 18, respectively, of the ’647 patent.

vi. [1.8] / [18.8]: “matching each set of corresponding dental objects more closely by iteratively minimizing error between corresponding reference points on corresponding dental objects” / “match each set of corresponding dental objects more closely by iteratively minimizing error between corresponding reference points on corresponding dental objects”[33]

TPM Automatic Alignment practices these claim elements under the adopted construction of “iteratively minimizing error.” TPM uses 3Shape’s [redacted] to more closely match each set of teeth in the two models. (Tr. (Badler) at 400:21-404:23; CPX-0194C at line 51; CX-2229C (Isleifsson Dep. Tr.) at 75:11-76:25, 79:8-82:18, 84:15-85:18, 86:5-25, 87:11-22, 88:14-92:4, 93:4-16, 97:11-101:5; CX-2125C (Badler Expert Rpt.) at ¶¶ 193-98.). As Dr. Badler generally explained, [redacted]. (Tr. (Badler) at 402:5-403:23.). [redacted] to align the whole as discussed further below for claim element 1.9. (*Id.*).

Following the [redacted], i.e., “reference points.” (Tr. (Badler) at 403:25-404:23; CPX-0194C at line 51; CX-2229C (Isleifsson Dep. Tr.) at 75:11-76:25, 84:15-18, 87:5-10 (“Q. [redacted]

[33] The term “iteratively minimizing error” was construed to mean “repeating a process to minimize the error until the error is less than a termination criterion or a maximum number of iterations has been reached.” (*Markman* Order, App. A at 28.).

[redacted]). According to 3Shape's corporate witness, Mr. Isleifsson, the [redacted] aligns two sets of data. (CX-2229C (Isleifsson Dep. Tr.) at 86:5-90:15.). The first step in [redacted]. (*Id.*). [redacted]. (*Id.*). [redacted] more closely aligned corresponding teeth. (*Id.*). Dr. Badler confirmed this operation in the [redacted] source code during the Hearing, which after the [redacted]. (Tr. (Badler) at 403:25-404:10; CPX-0194C.). Dr. Mellor did not dispute that TPM Automatic Alignment uses [redacted]. (*See* Tr. (Mellor) at 1709:5-17, 1758:4-1759:9.).

For the foregoing reasons, Align has proven by a preponderance of evidence that the 647 Accused Products practice elements [1.8] and [18.8] of claims 1 and 18, respectively, of the '647 patent.

vii. [1.9] / [18.9]: "matching the subsequent digital model as a whole with the initial digital model" / "match the subsequent digital model with the initial digital model"[34]

TPM Automatic Alignment practices these claim elements under the adopted construction for "determining the position of the subsequent digital model as a whole relative to

[34] The phrase "matching the subsequent digital model as a whole with the initial digital model" was construed to mean "determining the position of the subsequent digital model as a whole relative to the initial digital model." (*Markman* Order, App. A at 32.).

the initial digital model." (Tr. (Badler) at 406:12-408:11; CX-2125C (Badler Expert Rpt.) at ¶¶ 199-205.). As discussed above, Automatic Alignment performs [redacted]. As Dr. Badler demonstrated in the [redacted] source code during the Hearing and in his demonstrative exhibit (CDX-0011C.0037), the separate and final step of the [redacted].

Figure 5: Dr. Badler's Demonstrative Showing Matching

[redacted]

(CDX-0011C.0037; Tr. (Badler) at 406:12-408:11; CPX-0194C at line 66.).

In this step, TPM Automatic Alignment [redacted]. (Tr. (Badler) at 406:12-408:11; CPX-0194C at line 66*; see also, e.g.*, JX-0001 at 7:51-55 [redacted]). TPM can then match the models as a whole because [redacted]. (Tr. (Badler) at 406:12-407:14; *see also* JX-0001 at Fig. 3, (208), 5:33-44.). 3Shape's corporate representative, Mr. Isleifsson, [redacted]. (CX-2229C (Isleifsson Dep. Tr.) at 87:1-4 [redacted]; Tr (Mellor) at 1759:10-13.).

Nevertheless, Dr. Mellor contended during the Hearing that "Align is pointing to the exact same code to satisfy this third sub-element or substep and the next claim element." (Tr. (Mellor) at 1709:5-1709:23.). However, Dr. Badler found that claim elements [1.8] / [18.8] [redacted], and claim elements [1.9] / [18.9], [redacted]. (Tr. (Badler) at 400:20-404:19, 406:12-408:11, 411:3-24; CPX-0194C at lines 40-68.). 3Shape provided no contrary testimony or evidence to disputing Dr. Badler's testimony that TPM [redacted]. (CPX-0194C at lines 40-68.). Because claim elements [1.8] / [18.8] only require a repeated process or steps to "more closely" match each set of teeth models using reference points, [redacted], is a separate step of determining the position of one model as a whole relative to the other.

TPM also meets these claim elements by [redacted], as shown in the Measurements view. (*See* JX-0001 at Fig. 3 (208), 5:33-44.). TPM's Compare Scan and Measurements tool superimposes the two models in their entirety as shown in the TPM user guide, where the primary and secondary 3D models are overlaid and thus are placed in the same coordinate system and matched as a whole. (CX-0923.0017-.0026.). Because the tools can be used to display and measure the differences between two (2) scans to calculate changes in both tooth surface and movement, the evidence presented during the Hearing demonstrates that the models must be positioned in the same coordinate system to enable the calculations and display the differences, thereby confirming that the whole models have been matched. (CX-2229C (Isleifsson Dep. Tr.) at 95:6-97:10 (in TPM, models are placed in the same coordinate system for comparison following alignment [redacted], 102:24-104:6 ([redacted].).

For the reasons explained above, Align has proven by a preponderance of evidence that the 647 Accused Products practice elements [1.9] and [18.9] of claims 1 and 18, respectively, of the '647 patent.

viii. [1.10] / [18.10]: "calculating one or more positional differences between the moved and planned positions of at least some of the corresponding dental objects" / "calculate one or more positional differences between the moved and planned positions of the corresponding dental objects"

As discussed above in Section VII.A.3.ii for claim elements [1.2] / [18.2] and [1.3] / [18.3], the evidence demonstrates that TPM loads models of a treatment plan, i.e., planned or target positions, and a subsequent patient model of moved teeth for comparison. (*See also* Tr. (Bogdanic) at 823:16-19; CX-2125 (Badler Expert Rpt.) at ¶¶ 206-13.). After a Virtual Setup model is imported into TPM, it can be compared to the subsequent model. (Tr. (Fisker) at 688:14-23; *see also* CX-0881C.). For example, TPM's Scan Comparison tool calculates movements of teeth, as shown in the [redacted] and thus calculates positional differences between teeth in the two models. (Tr. (Badler) at 408:13-410:19; CX-0923.0023; *see also* CPX-0061C; CX-0885C; CX-0901C.0003-.0011; CX-0905C.0001-.0007; CX-0912C.0014; CX-2220C (Fisker Dep. Tr.) at 49:16-50:21; CX-2229C (Isleifsson Dep. Tr.) at 122:9-139:9; CX-2265C (Katrina Rindom Dep. Tr.)[35] at 92:18-25.). The Tooth Comparison tool measures positional differences on individual teeth by [redacted]. (Tr. (Bogdanic) at 820:8-821:9; CX-0887C.0014; CX-0895C; CX-0912C.0014; CX-0920C; CX-0923.0021-.0022; CX-2229C (Isleifsson Dep. Tr.) at 143:3-147:5.).

3Shape's witnesses confirmed TPM's calculation of positional differences between corresponding teeth in the moved and planned models. Dr. Fisker testified that TPM determines changes to individual teeth and that the comparison of two models in TPM calculates movements in the teeth from the first model to the second model, showing that distance measure in a difference map. (Tr. (Fisker) at 655:8-24; CX-2220C (Fisker Dep. Tr.) at 49:16-50:21, 75:8-25.) He clarified that the distance map allows a user to calculate positional differences in millimeters.

[35] When she gave her deposition testimony on May 10, 2019, Ms. Katrina Rindom held the position of Global Academy Program Manager at 3Shape. (CX-2265C (Rindom Dep. Tr.) at 11:16-17, 12:10-11.). As Global Academy Program Manager, Ms. Rindom's overall responsibilities included "production of training material packages and online training setting the didactic direction for academy." (*Id.* at 12:10-14.).

(Tr. (Fisker) at 655:25-656:3.). Additionally, Mr. Bogdanic confirmed that TPM performs measurements, including determining the differences in distance between a virtual model and a current scan of a patient's dentition and tooth movement. (Tr. (Bogdanic) at 819:4-20, 820:20-821:9.). Mr. Bogdanic also confirmed that the Scan Comparison tool presents in millimeters the differences ***between teeth*** in the models.

> Q. And the Scan Comparison tool would show a user in millimeters the differences between one scan and another scan and, for example, you could use that to show the differences between teeth in an actual model and a virtual model. Fair enough?
>
> A. Yeah. So it would show any change.

(*Id.* at 831:16-21.).

3Shape's expert, Dr. Mellor, testified that TPM does not meet these claim limitations because the Scan Comparison code [redacted] (Tr. (Mellor) at 1711:1-19.). As an initial matter, the claim elements do not require [redacted]. (*See* JX-0001 at cls. 1, 18.). Nor does the claim language prevent a global comparison and calculation of differences of the entire jaw, as this will necessarily include "at least some of the corresponding" teeth. (*See id.*).

Moreover, Dr. Mellor's position is not only contradicted by 3Shape's own witnesses (e.g., Tr. (Bogdanic) at 831:16-21), but also by documentation that explicitly states that the Scan Comparison tool can be used to measure the difference between any two scans on a timeline, along with changes in tooth movement (e.g., CX-0923.0023 ("The Scan comparison tool can be used to measure the difference between any two scans on the timeline along with changes in both tooth surface and tooth movement.")). The Scan Comparison tool clearly allows a user to determine the distance between two models by individual teeth, as it displays the differences by teeth, not just mesh with no discernible teeth. (*See, e.g.*, CX-0923.0023.). 3Shape's source code corporate representative, Mr. Isleifsson, confirmed that the [redacted]. (CX-2229C (Isleifsson Dep. Tr.) at 123:6-124:13, 133:6-135:6, 138:13-142:23.). Therefore, the calculations of positional differences are necessarily done for sets of teeth in millimeters.

Dr. Mellor also opined that TPM is just "calculating point-to-point differences" and thus does not meet these claim elements. (Tr. (Mellor) at 1711:7-24.). Pointing to Figures 9A and 9B of the '647 patent, Dr. Mellor testified that the patent discusses "shape differences" and "positional differences" differently, and claimed "the shape difference is defined as the distance between the sampled point on one tooth and its projection on the other tooth." (*Id.* at 1713:4-17; JX-0001 at 7:63-67.). However, Dr. Mellor selectively described only a portion of the passage and failed to acknowledge that in the next sentence, it states that "[f]or displaying the difference in ***teeth position variance***[,] a color-coded model and a transparent tooth model are used in these exemplary figures." (JX-0001 at 8:1-3 (emphasis added); *see also id.* at 7:59-62.). Thus, there is no support for Dr. Mellor's opinion that the "shape differences" discussed in the '647 patent for Figures 9A and 9B are different than positional variances or differences. Like TPM, the '647 patent discloses an embodiment calculating deviation between two models in millimeters, which is sufficient to meet claim elements [1.10] / [18.10]. (*See* JX-0001 at Figs. 9A and 9B.)

Accordingly, Align has proven by a preponderance of evidence that the 647 Accused Products practice elements [1.10] and [18.10] of claims 1 and 18, respectively, of the '647 patent.

B. Technical Prong of Domestic Industry

1. Legal Standard

A complainant in a patent-based Section 337 investigation must demonstrate that it is practicing or exploiting the patents at issue. *See* 19 U.S.C. § 1337(a)(2) and (3); *Certain Microsphere Adhesives, Process for Making Same, and Prods. Containing Same, Including Self-Stick Repositionable Notes*, Inv. No. 337-TA-366, Comm'n Op. at 8, Pub. No. 2949 (U.S.I.T.C. Jan. 16, 1996) ("*Microsphere Adhesives*"). "In order to satisfy the technical prong of the domestic industry requirement, it is sufficient to show that the domestic industry practices any claim of that patent, not necessarily an asserted claim of that patent." *Certain Ammonium Octamolybdate Isomers* ("*Certain Isomers*"), Inv. No. 337-TA-477, Comm'n Op. at 55 (U.S.I.T.C. Jan. 5, 2004).

The test for claim coverage for the purposes of the technical prong of the domestic industry requirement is the same as that for infringement. *Certain Doxorubicin and Preparations Containing Same*, Inv. No. 337-TA-300, Initial Determination at 109, 1990 WL 710463 (U.S.I.T.C. May 21, 1990), *aff'd*, Views of the Commission at 22 (October 31, 1990) ("*Doxorubicin*"). "First, the claims of the patent are construed. Second, the complainant's article or process is examined to determine whether it falls within the scope of the claims." *Id.* The technical prong of the domestic industry can be satisfied either literally or under the doctrine of equivalents. *Certain Dynamic Sequential Gradient Devices and Component Parts Thereof*, Inv. No. 337-TA-335, Initial Determination at 44, Pub. No. 2575 (U.S.I.T.C. Nov. 1992).

2. The 647 DI Products Practice Claims 1 and 18 of the ’647 Patent

a) Claims 1 and 18

i. [1.1] / [18.1]: “A method for determining progress of a dental treatment, the method comprising” / “A computer readable medium containing code for matching computer models of dental objects to determine progress of a dental treatment, the computer readable medium comprising instructions to”

Align’s documentation explains that a practitioner can “track progress” of a treatment by using the Progress Assessment feature of the iTero Intraoral scanner with Outcome Simulator to compare a patient’s current dentition with the treatment plan. (Tr. (Badler) at 415:12-416:11; CX-1237C; CX-1782C; CX-1789C; CX-1790C; CX-1798C; CX-1800C; CX-1839.0037-.0048; CX-2266C (Roman Roschin Dep. Tr.)[36] at 27:22-28:17; CX-2125C (Badler Expert Rpt.) at ¶¶ 413-19.). The Treat software of the Invisalign System [redacted] and is intended to be used by Align technicians to create virtual treatment plans that include using a progress tracking tool to compare progress scans and active treatment. (CX-1783C; CX-1784C; CX-1786C; CX-1792C.). These are methods for determining progress of a dental treatment.

For the reasons explained above, Align has proven by a preponderance of evidence that the 647 DI Products meet preambles [1.1] and [18.1] of claims 1 and 18, respectively, of the ’647 patent.

[36] When he gave his deposition testimony on July 11, 2019, Mr. Roman Roschin was the Senior Director of software development for the Moscow branch of Align Technology. (CX-2266C (Roschin Dep. Tr. at 8:25-9:5.). His job responsibilities included “organiz[ing] the process of, . . . project execution as it relates to implementation of the software.” (*Id.* at 9:9-14.). Mr. Roschin confirmed that he and his team worked on the source code for Align’s Outcome Simulator, Treat, and Progress Assessment software tools. (*Id.* at 10:11-11:2.). Align identified Mr. Roschin as a fact witness to provide testimony about the background and business of Align, domestic industry of the Asserted Patents, and related issues. (CPSt. at 10.).

ii. [1.2] / [18.2]: "providing an initial digital model of a set of dental objects" / "receive an initial digital model of a set of dental objects"; [1.3] / [18.3]: "determining planned positions for the set of dental objects" / "determine planned positions for a [sic] the set of dental objects"

Align presented evidence that Progress Assessment and Treat can load a simulated model of the patient's dentition to practice "providing an initial digital model of a set of teeth." (Tr. (Badler) at 416:12-417:15; CX-1784C; CX-1839.0037-.0048; CX-2266C (Roschin Dep. Tr.) at 29:2-36:12; CX-2125C (Badler Expert Rpt.) at ¶¶ 420-24.). Historical files or any stage of treatment plans, or several treatment plans, may be provided. (CX-2266C (Roschin Dep. Tr.) at 29:2-36:12.). This is shown in the source code [redacted]. (Tr. (Badler) at 416:12-24; CPX-0332C.). [redacted]. (Tr. (Badler) at 417:16-418:6; CPX-0315C; CX-2125C (Badler Expert Rpt.) at ¶¶ 425-30; CDX-0011C.0055 (showing the code at line 33).). The software [redacted]. (Tr. (Badler) at 417:20-418:11; CX-2266C (Roschin Dep. Tr.) at 36:13-38:5, 38:21-25, 40:17-43:14 ([redacted]).).

The iTero Intraoral scanner with Outcome Simulator that includes the Progress Assessment feature and Invisalign System including Treat also provide an initial digital model of a set of teeth as both provide for the simulation of the movement of teeth to their final positions and set up of a prescribed final position of a patient's teeth. (Tr. (Badler) at 412:16-414:12; CX-1784C; CX-1839.0037-.0048; CX-2266C:11 (Roschin Dep. Tr.) at 8-14, 23:2-11 (Progress Assessment is a part of Outcome Simulator and [redacted] functionality is found in Treat), 115:15-23.). In this manner, Outcome Simulator on the iTero and Treat in the Invisalign System also determines planned positions under 3Shape's interpretation of the claim elements because the features provide an alignment plan or simulated outcome for a patient that constitutes planned or target positions for teeth that is loaded in Progress Assessment or the progress tracking tool of Treat. (CX-1397C; CX-1784C; CX-1839.0026-.0036; CX-2266C (Roschin Dep. Tr.) at 27:22-30:6, 107:25-110:9.).

Accordingly, Align has proven by a preponderance of evidence that the 647 DI Products practice elements [1.2] / [18.2] and [1.3] / [18.3] of claims 1 and 18, respectively, of the '647 patent.

iii. [1.4] / [18.4]: "providing a subsequent digital model of the set of dental objects in their moved positions after at least some of them have been moved by the dental treatment" / "receive a subsequent digital model of the set of dental objects, wherein at least some of the dental objects have new positions in the subsequent model, relative to their positions in the initial model"

Align offered testimonial and documentary evidence that Progress Assessment and Treat provide a subsequent digital model of the set of teeth in their positions moved by the dental treatment as they load and compare a current scan to a treatment plan. (Tr. (Badler) at 418:12-419:12; CX-2266C (Roschin Dep. Tr.) at 28:1-29:23; CX-2125C (Badler Expert Rpt.) at ¶¶ 431-35.). This is shown in the source code [redacted]. (Tr. (Badler) at 418:12-419:12; CPX-0299C.). For Progress Assessment, the user can "perform a complete scan of the patient's current dentition just as [was done] at the beginning of the treatment process" using the iTero scan functionality. (CX-1839.0037.). The Invisalign System including Treat provides a new scan or achieved positions and thus provides a subsequent digital model of the set of teeth after at least some of them have been moved by treatment. (CX-1784C.0009.).

3Shape's expert, Dr. Mellor, did not provide an analysis of these claim elements during the Hearing. (Tr. (Mellor) at 1716:10-1717:11.)

For the reasons discussed above, Align has proven by a preponderance of evidence that the 647 DI Products practice elements [1.4] and [18.4] of claims 1 and 18, respectively, of the ’647 patent.

iv. [1.5] / [18.5]: “individually matching each of the dental objects in the subsequent digital model with a dental object in the initial digital model to determine corresponding dental objects, the matching comprising” / “individually match each of the dental objects in the subsequent digital model with a dental object in the initial digital model to determine corresponding dental objects, including instructions to”

Align elicited testimony and presented documentary/source code evidence that Progress Assessment and Treat “individually match” to determine corresponding teeth. (Tr. (Badler) at 419:3-421:14; CX-2125C (Badler Expert Rpt.) at ¶¶ 436-42.). In the source code for Progress Assessment and Treat, [redacted]. (CX-2266C (Roschin Dep. Tr.) at 39:24-46:11.). [redacted]. (*Id.*). [redacted]. (*Id.* at 41:23-42:9; CPX-0326C.). Subsequently, the software [redacted]. (CX-2266C (Roschin Dep. Tr.) at 42:1-20.). [redacted], CPX-0329C), the [redacted]. (CX-2266C (Roschin Dep. Tr.) at 40:17-42:20.). The [redacted]. (*Id.* at 42:1-43:14.).

[redacted]. (Tr. (Badler) at 420:4-15; CPX-0276C; CX-2266C (Roschin Dep. Tr.)

at 45:13-46:11.). The [redacted]. (CPX-0276C; CX-1839.0037; CX-2266C (Roschin Dep. Tr.) at 46:13-56:16.). The [redacted]. (CX-2266C (Roschin Dep. Tr.) at 48:20-59:1.). This is confirmed in the documentation and source code that show [redacted]. (Tr. (Badler) at 420:21-421:6; CPX-0280C; CPX-0286C; CPX-0317C; CX-1791C.0004; CDX-0011C.0059.).

As discussed in Sections VII.B.2.a.v-viii below for the following steps, Progress Assessment and Treat's [redacted] Specifically, [redacted] as discussed in Section VII.B.2(a)(vi) below. (CX-2266C (Roschin Dep. Tr.) at 55:24-57:8 [redacted]).

For the foregoing reasons, Align has proven by a preponderance of evidence that the 647 DI Products practice elements [1.5] and [18.5] of claims 1 and 18, respectively, of the ’647 patent.

v. [1.6] / [18.6]: "identifying one or more reference points on each set of corresponding dental objects in the initial and subsequent digital models" / "identify one or more reference points on each set of corresponding dental objects in the initial and subsequent digital models"; [1.7] / [18.7]: "approximately matching each set of corresponding dental objects by approximately aligning corresponding reference points on corresponding dental objects" / "approximately match each set of corresponding dental objects by approximately aligning corresponding reference points on corresponding dental objects"

Both documentary and testimonial adduced in this Investigation demonstrate that Progress Assessment and Treat meet these claim elements. (Tr. (Badler) at 421:15-423:4; CX-2125C (Badler Expert Rpt.) at ¶¶ 443-53.). The [redacted]. (*See, e.g.*, CX-2266C (Roschin Dep. Tr.) at 37:21-76:23.). [redacted]. (*See, e.g.*, *id.* at 52:1-53:25.). [redacted]. (*See, e.g.*, Tr. (Badler) at 420:4-422:5; CPX-0276C; CX-1817C; CX-1965C; CX-2266C (Roschin Dep. Tr.) at 44:2-58:19.). As discussed above, [redacted]. (CX-2266C (Roschin Dep. Tr.) at 44:2-51:10.). As discussed in detail below in Sections VII.B.2.a.v-viii, Progress Assessment and Treat also [redacted]. (Tr. (Badler) at 421:15-422:9; CX-2266C (Roschin Dep. Tr.) at 59:2-76:23.).

Progress Assessment and Treat then [redacted]. (Tr. (Badler) at 422:10-423:4;

CPX-0275C; CX-2266C (Roschin Dep. Tr.) at 51:5-59:1; CX-2125 (Badler Expert Rpt.) at ¶¶ 449-53.). The [redacted]. (CPX-0275C; CX-2266C (Roschin Dep. Tr.) at 51:5-59:1; CDX-0011C.0061 (showing the code).). The [redacted] as discussed below in Sections VII.B.2.a.v-viii. (CX-2266C (Roschin Dep. Tr.) at 56:24-57:19.).

Accordingly, Align has proven by a preponderance of evidence that the 647 DI Products practice elements [1.6] / [18.6] and [1.7] / [18.7] of claims 1 and 18, respectively, of the ’647 patent.

vi. [1.8] / [18.8]: “matching each set of corresponding dental objects more closely by iteratively minimizing error between corresponding reference points on corresponding dental objects” / “match each set of corresponding dental objects more closely by iteratively minimizing error between corresponding reference points on corresponding dental objects”

Align offered evidence that Progress Assessment and Treat practice these claim elements. (Tr. (Badler) at 423:5-424:10; CX-2125C (Badler Expert Rpt.) at ¶¶ 454-58.). Progress Assessment and Treat [redacted]. (CX-2266C (Roschin Dep. Tr.) at 58:20-76:23.). [redacted]. (*Id.*; CPX-0303C; CDX-0011C.0062 (showing the code).). [redacted], as discussed above in Section VII.A.3.a.vi, generally is [redacted]

[redacted]. (CX-2266C (Roschin Dep. Tr.) at 69:14-77:1.). Progress Assessment and Treat [redacted]. (Tr. (Badler) at 423:10-23; CX-2266C (Roschin Dep. Tr.) at 58:20-69:13.). [redacted]. (Tr. (Badler) at 423:10-23; CX-2266C (Roschin Dep. Tr.) at 58:20-69:13.).

Dr. Mellor disagreed with Dr. Badler's opinion regarding claim elements [1.6] / [18.6], [1.7] / [18.7], and [1.8] / [18.8], because in Dr. Mellor's opinion, the claims require the same "reference points" to be used and that the process determines "correspondences." (Tr. (Mellor) at 1717:8-1719:10.). However, as discussed above in Section VII.B.2.a.vi, the claims do not require that the same reference points be used in the initial alignment and the more closely aligning steps. (*See, e.g.*, Tr. (Badler) at 424:7-10.).

Moreover, this [redacted]. (Tr. (Badler) at 423:10-424:19; CX-2266C (Roschin Dep. Tr.) at 58:20-77:1.). As a result, the above three sub-steps (claim elements [1.6] / [18.6], [1.7] / [18.7], and [1.8] / [18.8]) [redacted]. (Tr. (Badler) at 423:10-424:19.).

For the reasons explained above, Align has proven by a preponderance of evidence that the 647 DI Products practice elements [1.8] and [18.8] of claims 1 and 18, respectively, of the

’647 patent.

vii. *[1.9] / [18.9]: “matching the subsequent digital model as a whole with the initial digital model” / “match the subsequent digital model with the initial digital model”*

Align presented testimony and evidence that Progress Assessment and Treat practice the referenced claim elements. (Tr. (Badler) at 424:20-425:6; CX-2125C (Badler Expert Rpt.) at ¶¶ 459-65.). Progress Assessment and Treat [redacted]. (Tr. (Badler) at 424:20-425:6; CPX-0280C at line 255 ([redacted] function); CX-1791C.0004-.0005; CX-2266C (Roschin Dep. Tr.) at 77:10-85:18 [redacted]).). This is illustrated in the source code [redacted]. (CX-2266C (Roschin Dep. Tr.) at 77:10-85:1.). The [redacted]. (Tr. (Badler) at 424:20-425:6; CX-1791C.0004.). [redacted]. (CX-2266C (Roschin Dep. Tr.) at 77:25-85:18, 122:10-124:24.). Progress Assessment also [redacted]. (*See, e.g.*, CX-1789C; CX-1839.0046; *see also* CX-2266C (Roschin Dep. Tr.) at 119:13-122:7 [redacted]; CPX-0332C.). Treat also has [redacted]. (CX-1784C.0011; CPX-0332C.).

3Shape did not dispute that Progress Assessment and Treat practice these elements, because Dr. Mellor did discuss these elements during the Hearing. (Tr. (Mellor) at 1718:9-1719:15.). 3Shape has waived any argument on this issue pursuant to Ground Rule 10.2.

For the reasons discussed above, Align has proven by a preponderance of evidence that the 647 DI Products practice elements [1.9] and [18.9] of claims 1 and 18, respectively, of the ’647 patent.

viii. [1.10] / [18.10]: “calculating one or more positional differences between the moved and planned positions of at least some of the corresponding dental objects” / “calculate one or more positional differences between the moved and planned positions of the corresponding dental objects”

As discussed above in Section VII.B.2.a.ii, Progress Assessment and Treat load models of a treatment plan and a subsequent patient model of moved teeth for comparison. Progress Assessment practices these claim elements by providing a report panel showing its calculations of specific movements per tooth. (Tr. (Badler) at 425:7-24; CX-1789C; CX-1839.0043-.0048; CX-2125C (Badler Expert Rpt.) at ¶¶ 466-70.). Treat also has a teeth table view report that shows achieved movements per tooth. (CX-1784C; CX-1791C; CPX-0294C; CPX-0320C; CPX-0332C.). [redacted]. (CPX-0294C; CPX-0320C; CX-2266C (Roschin Dep. Tr.) at 117:6-119:11; CDX-0011C.0065 (showing code).).

Dr. Mellor did not dispute that the described functionality exists in Progress Assessment and Treat, but again claimed that the calculation of point-to-point distances between teeth are not “positional” differences. (Tr. (Mellor) at 1719:9-1720:9.). As discussed above, Dr. Mellor is incorrect. Measuring tooth movement satisfies the claim elements.

Accordingly, Align has proven by a preponderance of evidence that the 647 DI Products practice elements [1.10] and [18.10] of claims 1 and 18, respectively, of the ’647 patent.

C. Invalidity

1. Invalidity Overview

3Shape alleged that asserted claims 1 and 18 of the ’647 patent are obvious in view of Rubbert WO (RX-2037),[37] alone or in combination with Rusinkiewicz (CX-0948).[38] (RBr. at 15.). In its Pre-Hearing Brief, Align only disputed that Rubbert WO, alone or in combination with Rusinkiewicz, teach elements [1.5] / [18.5], [1.6] / [18.6], [1.7] / [18.7], [1.8] / [18.8], [1.9] / [18.9], or [1.10] / [18.10]. (CPBr. at 45-52.). Thus, any argument on elements [1.1] / [18.1], [1.2] / [18.2], [1.3] / [18.3], and [1.4] / [18.4] is waived under Ground Rule 7.2.

For the reasons discussed below in Section VII.C.3, 3Shape failed to meet its burden that either prior art reference discloses by clear and convincing evidence elements [1.5] / [18.5], [1.6] / [18.6], [1.7] / [18.7], [1.8] / [18.8], [1.9] / [18.9], or [1.10] / [18.10] of the ’647 patent. 3Shape also failed to present clear and convincing evidence that a person of ordinary skill in the art at the time of invention would have been motivated to, or had a reason to, combine Rubbert WO with “ICP” or Rusinkiewicz and would have a reasonable expectation of success.

3Shape also asserted that the language “to determine corresponding dental objects” recited in claims 1 and 18 is indefinite and/or lacks written description support in the specification of the ’647 patent. (RBr. at 14.). As discussed below in Section VII.C.4, the specification and plain claim language explains how the steps (i.e., claim elements [1.6] / [18.6],

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[37] International Publication No. WO 01/80761 A2.

[38] Szymon Rusinkiewicz & Marc Levoy, *Efficient Variants of the ICP Algorithm*, Stanford University (article not dated).

[1.7] / [18.7], [1.8] / [18.8]) result in the determination of corresponding dental objects through the positioning and repositioning of the same teeth from two models.

Additionally, 3Shape contended that the asserted claims of the '647 and '661 patents are directed to patent-ineligible subject matter. (RBr. at 6.). For the reasons discussed below in Section VII.C.5, the asserted claims of the '647 and '661 patents are directed to non-abstract solutions to a problem specific to virtual dentistry and orthodontics. Moreover, the claims are not directed to simply invoking a generic computer for the performance of well-known techniques.

2. Legal Standards

a) Obviousness

Under 35 U.S.C. § 103(a), a patent is valid unless "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made" to a person having ordinary skill in the art. 35 U.S.C. § 103(a). The ultimate question of obviousness is a question of law, but "it is well understood that there are factual issues underlying the ultimate obviousness decision." *Richardson-Vicks*, 122 F.3d 1476, 1479 (Fed. Cir. 1997) (citing *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17 (1966)).

After claim construction, "[t]he second step in an obviousness inquiry is to determine whether the claimed invention would have been obvious as a legal matter, based on underlying factual inquiries including: (1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between the claimed invention and the prior art, and (4) secondary considerations of non-obviousness." *Smiths Indus. Med. Sys., Inc. v. Vital Signs, Inc.*, 183 F.3d 1347, 1354 (Fed. Cir. 1999) (citing *Graham*, 383 U.S. at 17).

The existence of secondary considerations of non-obviousness does not control the obviousness determination; a court must consider "the totality of the evidence" before reaching a decision on obviousness. *Richardson-Vicks*, 122 F.3d at 1483.

The Supreme Court clarified the obviousness inquiry in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007). The Supreme Court said:

> When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. *Sakraida* and *Anderson's-Black Rock* are illustrative–a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions.
>
> Following these principles may be more difficult in other cases than it is here because the claimed subject matter may involve more than the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for the improvement. Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit.
>
> * * *
>
> The obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents. The diversity of inventive pursuits and of modern technology counsels against limiting the analysis in this way. In many fields it may be that there is little discussion of obvious techniques or combinations, and it often may be the case that market demand, rather than scientific literature, will drive design trends. Granting patent protection to advances that would occur in the ordinary course without real innovation retards progress and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility.

KSR, 550 U.S. at 417-19.

The Federal Circuit has since held that when a patent challenger contends that a patent is invalid for obviousness based on a combination of several prior art references, "the burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make the composition or device, or carry out the claimed process, and would have had a reasonable expectation of success in doing so." *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007) (citations omitted).

> The TSM[39] test, flexibly applied, merely assures that the obviousness test proceeds on the basis of evidence--teachings, suggestions (a tellingly broad term), or motivations (an equally broad term)--that arise before the time of invention as the statute requires. As *KSR* requires, those teachings, suggestions, or motivations need not always be written references but may be found within the knowledge and creativity of ordinarily skilled artisans.

Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc., 520 F.3d 1358, 1365 (Fed. Cir. 2008).

b) Written Description

Patents are presumed valid. 35 U.S.C. § 282. The first paragraph of Section 112 states: "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same. . . ." 35 U.S.C. § 112. To comply, a patent applicant must "convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the [claimed] invention." *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991) (emphasis omitted). "The form and presentation of the description can vary with the nature of the invention[.]" *In re Skvorecz*, 580 F.3d 1262, 1269 (Fed. Cir. 2009).

[39] TSM is an acronym that stands for teaching, suggestion, motivation.

"[T]he applicant [for a patent] may employ 'such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention.'" *Id.* (citing *In re Alton*, 76 F.3d 1168, 1172 (Fed. Cir. 1996)). The adequacy of the description depends on content, rather than length. *In re Hayes Microcomputer Prods., Inc. Patent Litig.*, 982 F.2d 1527, 1534 (Fed. Cir. 1992). "Specifically, the level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology." *Ariad Pharms., Inc. v. Eli Lilly & Co*., 598 F.3d 1336, 1352 (Fed. Cir. 2010) (en banc).

Compliance with the written description requirement is a question of fact, and in order to overcome the presumption of validity a party must set forth clear and convincing evidence. *Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341, 1347 (Fed. Cir. 2011). The Federal Circuit has also held with respect to the written description requirement that "[a] claim will not be invalidated on section 112 grounds simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language." *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1366 (Fed. Cir. 2006) (quoting *LizardTech, Inc. v. Earth Resource Mapping, PTY, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005)).

c) Indefiniteness

A patent specification must "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as [the] invention." 35 U.S.C. § 112, ¶ 2. Previously, the Federal Circuit held that a patent claim is not indefinite "so long as the claim is amenable to construction, and the claim, as construed, is not insolubly ambiguous." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S.Ct. 2120, 2124 (2014). More recently, the U.S. Supreme Court determined that this standard lacks precision. *Id.* at 2130.

Instead, the Supreme Court held:

> [W]e read § 112, ¶ 2 to require that a patent's claims, viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty. The definiteness requirement, so understood, mandates clarity, while recognizing that absolute precision is unattainable. The standard we adopt accords with opinions of this Court stating that "the certainty which the law requires in patents is not greater than is reasonable, having regard to their subject-matter."

Id. at 2129 (citations omitted).

A party seeking to invalidate a patent claim must do so by clear and convincing evidence. *See, e.g., Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1327 (Fed. Cir. 2008) (citing *Hybritech Inc. v. Monoclonal Antibodies, Inc*., 802 F.2d 1367, 1375 (Fed. Cir. 1986)).

d) Patent Eligibility

Section 101 of the Patent Act states: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101. In *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014), the Supreme Court explained that, the application of section 101 requires courts to "distinguish between patents that claim the 'buildin[g] block[s]' of human ingenuity and those that integrate the building blocks into something more." *Id.* at 2354 (quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S.Ct. 1289, 1294 (2012)). To make this distinction, courts must first "determine whether the claims at issue are directed to a patent-ineligible concepts," such as the "laws of nature, natural phenomena, and abstract ideas." *Id.* at 2355 (citing *Mayo*, 132 S.Ct. at 1296-1297)). If so, courts must examine the elements of the claim to determine whether it contains an 'inventive concept' sufficient to 'transform' the claimed abstract idea into a patent-eligible application." *Id.*

"[T]he prohibition against patenting abstract ideas cannot be circumvented by attempting to limit the use of the idea to a particular technological environment." *Id.* at 2358 (quoting *Bilski v. Kappos*, 561 U.S. 593, 610-611 (2010)). In other words, "transformation into a patent-eligible application requires 'more than simply stat[ing] the [abstract idea] while adding the words 'apply it.'" *Id.* at 2357 (alteration in original) (citing *Mayo*, 132 S.Ct. at 1294).

However, "[a]t some level, 'all inventions . . . embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.' Thus, an invention is not rendered ineligible for patent simply because it involves an abstract concept." *Id.* at 2354 (quoting *Mayo*, 132 S.Ct. at 1293-94; citing *Diamond v. Diehr*, 450 U.S. 175, 187 (1981)). "'[A]pplication[s]' of such concepts 'to a new and useful end' . . . remain eligible for patent protection." *Id.* (quoting *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972).

3. Rubbert WO (RX-0237) Alone or in Combination with Rusinkiewicz (RX-2276) Do Not Render Obvious Claims 1 and 18 of the '647 Patent

a) [1.5] / [18.5]: "individually matching each of the dental objects in the subsequent digital model with a dental object in the initial digital model to determine corresponding dental objects, the matching comprising" / "individually match each of the dental objects in the subsequent digital model with a dental object in the initial digital model to determine corresponding dental objects, including instructions to"

3Shape contended that Rubbert WO teaches the "individually matching" element recited in claim elements [1.5] / [18.5] in the disclosures at RX-0237.102:31-103:2. (RBr. at 18.). Specifically, 3Shape argued that the following description in Rubbert WO discloses "individually matching each of the teeth in two models." (*Id.*).

stages as defined earlier. These differences can be quantified with precision. For example, a point on the tooth in the current model is selected, and the model of the tooth at the original malocclusion is overlaid on the screen. The superposition of the two teeth allows

> the user to view the change in position that has occurred. The measurement marker features described earlier allow the user to quantify precisely the amount of movement.

(*Id.* (citing RX-0237.102:31-103:2) (emphasis added by 3Shape); Tr. (Parris Egbert)[40] at 1087:10-24).).

3Shape also asserted that Rubbert WO discloses matching a subsequent model with a model with teeth in their expected or target positions. (*Id.*).

> Any deviations between the therapeutic result that is observed and the expected result can be captured precisely and at an early stage in treatment using the scanning and treatment planning features described herein, and corrected for. For example, the orthodontist may need to place additional bends in the archwire. Such additional bends can be performed by simulating the wire shape on the screen, displaying the wire only on the screen, and printing out the screen and using it as a template for bending the wire. The current situation could also be forwarded to the precision appliance center for manufacture of a new appliance. Of course, these monitoring and treatment corrections are applicable to any type of appliance selected for the patient.

(*Id.* (citing RX-0237.103:3-11 (emphasis added by 3Shape).).

However, as Align contended, these disclosures upon which 3Shape relied do not disclose matching tooth-by-tooth, but rather, describe selecting a point on ***one*** tooth and superimposing ***two*** teeth, not each set of corresponding teeth in a computer model of a patient's jaw. (CRBr. at 12-13.). 3Shape' expert, Dr. Parris Egbert, opined during the Hearing that Rubbert WO describes "select[ing] a point on ***one*** tooth, and then match[ing] the corresponding tooth to that tooth that you've selected." (Tr. (Egbert) at 1083:12-18 (emphasis added).).

Additionally, 3Shape argued that Rubbert WO teaches individually matching each of the teeth in the current and original models to precisely measure tooth erosion.

[40] When he testified during the Hearing on October 29, 2019, Dr. Parris Egbert, Ph.D. was a Professor in the Computer Science Department at Brigham Young University. (RPSt., Ex. A at 2.). 3Shape identified Dr. Egbert as an expert to testify about the invalidity of the '647 and '661 patents. (RPSt. at 4.).

patient is converted into a three-dimensional virtual model. The individual teeth are optically separated into virtual three-dimensional tooth objects as described above. Either this original virtual model of the entire dentition or the set of virtual three-dimensional tooth objects can be considered as a template. Over the course of time, the dentition is scanned again periodically and converted into a three-dimensional virtual model as described above. The individual teeth (or the dentition as a whole) is compared to the template to identify differences due to wearing of teeth. This can be performed by overlaying the two models, each in a different color or tones, and visually detecting where tooth surfaces were present initially but are not present in the current virtual model. Alternatively, measuring tools can

(*Id.* (citing RX-0237.81:30-82:5 (emphasis added by 3Shape).).

However, as Align pointed out, 3Shape's "template" argument based on the disclosure found at RX-0237.81:30-82:5 is waived and abandoned under Ground Rule 7.2 because 3Shape did not raise this argument its Pre-Hearing Brief. (*See* Ground Rule 7.2.). *See also Certain Graphic Systems, Components Thereof, & Consumer Products Containing the Same*, Inv. No. 337-TA-1044, ID at 126-27 (U.S.I.T.C. Oct. 17, 2019).

Accordingly, 3Shape has failed to meet its burden of proving that Rubbert WO teaches these claim elements by clear and convincing evidence.

b) [1.6] / [18.6]: "identifying one or more reference points on each set of corresponding dental objects in the initial and subsequent digital models" / "identify one or more reference points on each set of corresponding dental objects in the initial and subsequent digital models"

3Shape asserted that Rubbert WO, alone or in combination with Rusinkiewicz, renders obvious these claim elements. (RBr. at 19-20.). 3Shape relied on the same disclosure of Rubbert WO at RX-0237.102:31-32 for "individually matching." (*Id.* at 20 (citing RX-0237.102:31-32).). However, as discussed above with respect to claim elements [1.5] / [18.5], Rubbert WO fails to disclose "individually matching" because the reference only discloses superimposing two teeth, and not each set of corresponding teeth in the jaw. For the same reasons, Rubbert WO fails to disclose the "identifying" reference points elements. (*See* RX-0237.102:30-103:1.). Moreover, Dr. Egbert only provided conclusory testimony during the Hearing that "Rubbert states that he does that." (Tr. (Egbert) at 1089:16-1090:12.).

In an attempt to remedy this lack of disclosure of the claimed "identifying" reference points in Rubbert WO, 3Shape relied upon generic ICP disclosed in Rusinkiewicz. (RBr. at 20.). However, Rusinkiewicz generally examines several variants of ICP and does not disclose identifying references points on each set of corresponding teeth of a computer model of a patient's jaw, as Dr. Egbert confirmed. (CX-00948.0001.).

> Q. Now, you would agree with me that the ICP paper Rusinkiewicz that you relied on itself doesn't give any examples in use in the field of dentistry; correct?
>
> A. I believe that's correct. He talks about applications of ICP. I don't think he mentions dentistry.

(Tr. (Egbert) at 1104:1-5.).

Dr. Egbert again provided only conclusory testimony regarding ICP, stating that the ICP algorithm consists of six steps, one of which is the "selection of some of the points." He then concluded that this disclosure meets the "identifying" reference points element.

> Q. And where in Rusinkiewicz is the identifying step of -- substep of claim 1?
>
> A. If you look at the bottom figure there, there's a – there's six steps that are done. In that first step, that is when the selection of some of the points is performed. And that meets the claim element of identifying one or more reference points on each set of the corresponding teeth in the initial and subsequent digital models.

(Tr. (Egbert) at 1090:4-12.).

However, in his conclusory testimony, Dr. Egbert failed to identify any disclosure in Rusinkiewicz that identifies points on corresponding sets of teeth. (*Id.*). Because the only record evidence of implementation of ICP is Rusinkiewicz, 3Shape failed to present sufficient evidence that "ICP," as a purported "well-known" algorithm, identifies references points on each set of corresponding teeth on a computer model of a patient's dentition.

For the reasons explained above, 3Shape has failed to meet its burden of proving by clear and convincing evidence that Rubbert WO teaches the referenced claim elements.

c) [1.7] / [18.7]: "approximately matching each set of corresponding dental objects by approximately aligning corresponding reference points on corresponding dental objects" / "approximately match each set of corresponding dental objects by approximately aligning corresponding reference points on corresponding dental objects"

3Shape contended that Rubbert WO, alone or in combination with Rusinkiewicz, renders obvious these claim elements. (RBr. at 22.). 3Shape first argued that Rubbert WO alone renders these claim elements obvious because a person of ordinary skill in the art in 2002 would know to use "ICP" to match 3D models. (*Id.*). However, as explained above in Section VII.C.3(a), Rubbert WO does not disclose "individually matching," there is no evidence supporting the use of ICP to match 3D models of ***teeth***, and Rubbert WO does not disclose an "initial alignment" because it discloses only ***one*** single superimposition.

To remedy the lack of disclosure, Dr. Egbert relied upon ICP disclosed in Rusinkiewicz. (Tr. (Egbert) at 1090:21-24.). Dr. Egbert testified that in Rusinkiewicz, ICP performs an "initial guess" to approximately match two objects – i.e., an initial alignment. (*Id.* at 1090:21-1091:11 ("He says that you start with the two 3D models, you then perform an initial guess . . . .").). However, as Align pointed out, Rusinkiewicz explicitly states that "[i]n this paper, we ***assume*** that a rough initial alignment is always available." (CX-0948.0001 (emphasis added); *see also id.* ("ICP starts with two meshes ***and*** an initial guess for their relative rigid body transform") (emphasis added).). Thus, because Rusinkiewicz does not clearly and convincingly disclose an "initial alignment," the prior art reference fails to teach the claimed "initial alignment" using corresponding reference points on each set of corresponding teeth as disclosed in the ’647 patent

For these reasons, 3Shape has failed to meet its burden of proving that Rubbert WO teaches these claim elements by clear and convincing evidence.

d) [1.8] / [18.8]: “matching each set of corresponding dental objects more closely by iteratively minimizing error between corresponding reference points on corresponding dental objects” / “match each set of corresponding dental objects more closely by iteratively minimizing error between corresponding reference points on corresponding dental objects”

3Shape contended that Rubbert WO, alone or in combination with Rusinkiewicz, renders obvious these claim elements. (RBr. at 22.). For the reasons discussed above for claim elements [1.5] / [18.5], [1.6] / [18.6], and [1.7] / [18.7], neither Rubbert WO nor Rusinkiewicz discloses the preceding claim elements, that is, “individually matching,” “identifying” reference points on each set of teeth, and “initially aligning.” As a result, Rubbert WO, “ICP,” and Rusinkiewicz also fail to disclose the “matching each set” of teeth more closely claim element.

Moreover, as discussed above, ICP does not disclose a matching of sets of teeth in two models using reference points. Dr. Egbert did not even provide any testimony or opinion that Rusinkiewicz or ICP disclose matching two sets of teeth closer together.

> Q. And what art did you use to address the next substep, which is “matching each set of corresponding dental objects more closely by iteratively minimizing error between corresponding reference points on corresponding dental objects”?
>
> A. I used Rusinkiewicz for that disclosure.
>
> Q. Moving to slide 60. How did Rusinkiewicz inform your analysis with respect to this matching substep of claim 1?
>
> A. Once you have the models aligned initially with a rough match, then the next step that you do in Rusinkiewicz, and this is shown in step number 6, in the top box there, the next thing you do, then, is to iteratively match the two objects closer together using the error metric that we talked about.

> Q. And can you explain a little more about the error metric?
>
> A. Yeah. So when you do the initial match, you get the two objects fairly close together but probably not as accurate as you want. The next step, then, is to iteratively just slightly move them to bring them closer together. And again, you do that either until the error that you get -- and the error you compute by looking at the differences between the two models. You continue the process either until that error is small enough or you reach some number of iterations and you want to stop at that point.

(Tr. (Egbert) at 1091:22-1092:23.).

3Shape cannot remedy the lack of disclosure of "teeth" with Dr. Egbert's testimony because his testimony is conclusory hindsight unsupported by the evidence. [41] Additionally, 3Shape did not provide any explanation why one of skill in the art would look to ICP or Rusinkiewicz for more closely aligning when Rubbert WO does not disclose or suggest any additional alignment beyond a single generic superimposition or use of any algorithm.

For the foregoing reasons, 3Shape has failed to meet its burden of proving that Rubbert WO teaches these claim elements by clear and convincing evidence.

e) [1.9] / [18.9]: "matching the subsequent digital model as a whole with the initial digital model" / "match the subsequent digital model with the initial digital model"

3Shape asserted that Rubbert WO teaches the referenced claim elements. (RBr. at 23.). Rubbert WO on its face discloses superimposition of two teeth but does not disclose the two-step matching process of the claim. It is improper for 3Shape to rely on the same "superimposition" step for two matching steps in the claimed process. *See, e.g.*, *Lantech, Inc. v. Keip Machine Co.*, 32 F.3d 542, 546 (Fed. Cir. 1994) ("When claiming a combination where more than one of a certain element, here a conveyor [means], is included in the combination, the term 'at least two' sets forth the minimum number of a particular element required. This interpretation gives full effect to the recitation of two distinct elements in the claimed structure. Therefore, properly interpreted, all claims at issue require two or more conveyor structures, not one.").

Moreover, Dr. Egbert supported this proposition by conceding that the mere disclosure of "superimposing" using a single point on a tooth would not necessarily provide any sort of precise matching or alignment of the teeth. (Tr. (Egbert) at 1103:13-17 ("Q. Now, you would agree with me that this superimposition disclosed by Rubbert using a single point on a tooth would not provide any sort of precise matching or alignment of the teeth? A. It may or may not.").).

Accordingly, 3Shape has failed to meet its burden of proving by clear and convincing evidence that Rubbert WO teaches the referenced claim elements.

f) [1.10] / [18.10]: "calculating one or more positional differences between the moved and planned positions of at least some of the corresponding dental objects" / "calculate one or more positional differences between the moved and planned positions of the corresponding dental objects"

3Shape relied solely on Rubbert WO for the referenced claim limitations. (RBr. at 27.). However, Rubbert WO does not disclose or teach the claimed "calculating . . . positional differences." (RX-0237.102:30-103:1 (disclosing a single superimposition of one tooth using a single point).). 3Shape's expert, Dr. Egbert, merely provided conclusory testimony that Rubbert WO discloses the "calculating . . . positional differences" element based on the reference's modest disclosure that "the differences can be quantified with precision."

> Q. How did Rubbert inform your analysis with respect to the calculating step of claim 1?
>
> A. So Rubbert discloses being able to take the two models, match them together and then compute differences between them. He says, "the differences can be quantified with precision," and he talks about one of the features of his system, the measurement marker feature, allows the user to quantify precisely the amount of movement.

(Tr. (Egbert) at 1094:1-8.).

The Rubbert disclosure is insufficient, however, because it fails to provide any description of how any differences can be quantified. (RX-0237.102:30-103:1.). Dr. Egbert's reference to the "measurement marker feature" fails to meet the claimed "calculating . . . positional differences," because Dr. Egbert acknowledged during the Hearing that the mere disclosure of "superimposing" by Rubbert WO using a single point on a tooth would not guarantee any sort of precise matching or alignment of the teeth. (Tr. (Egbert) at 1103:13-17.).

For the reasons discussed above, 3Shape has failed to meet its burden of proving by clear and convincing evidence that Rubbert WO teaches these claim elements by clear and convincing evidence.

g) 3Shape Failed to Present Any Evidence of Motivation to Combine or Reasonable Expectation of Success

3Shape failed to present clear and convincing evidence that a person of ordinary skill in the art at the time of invention would have been motivated to, or had a reason to, combine Rubbert WO with "ICP" or Rusinkiewicz and would have had a reasonable expectation of success. The entirety of Dr. Egbert's testimony regarding motivation to combine during the Hearing consisted of one brief answer.

> Q. And Dr. Egbert, why, if at all, would one of ordinary skill in the art have been moved to combine Rubbert and Rusinkiewicz in the way you've just described?
>
> A. Rubbert describes the system, then, for taking the two computer models and matching them together and then allowing the orthodontist to monitor the movements and see how things have changed, either tooth by tooth or as a whole. Rubbert doesn't go into a lot of detail as to exactly how you do that. At the time of Rubbert, the technique that was typically used to do this operation is ICP. And so it would be obvious for a person to use the ICP technique for doing those matching steps.

(Tr. (Egbert) at 1094:9-21.).

Dr. Egbert's testimony on its face fails to meet the clear and convincing standard because it does not include any analysis with facts that a combination would have a "reasonable expectation of success." *See, e.g.*, *In re Stepan*, 868 F.3d 1342, 1345-46 (Fed. Cir. 2017) ("An obviousness determination requires finding both 'that a skilled artisan would have been motivated to combine the teachings of the prior art . . . and that the skilled artisan would have had a reasonable expectation of success in doing so.'") (citation omitted); *PharmaStem*, 491 F.3d 1342 at 1360.

Moreover, Rubbert WO's disclosure consists of a few lines that at best describes selecting a point on one tooth and superimposing two teeth, not each set of corresponding teeth in a jaw. (RX-0237.102:30-103:1.). In an attempt to backfill this disclosure, 3Shape argued that: (i) "a POSITA at the time would have known to use ICP to match 3D models" (RBr. at 20); or (ii) "a POSITA would have been motivated to combine Rubbert WO with Rusinkiewicz" (*id.* at 21).

3Shape's contentions are not supported by the evidence. During the Hearing, Dr. Egbert acknowledged that he was not aware of any evidence that ICP was being used in applications related to dentistry or orthodontics in 2002.

> Q. And you are not aware of any evidence that ICP was being used in applications related to dentistry in 2002; correct, sir?
>
> A. I'm not aware of them. It would be the obvious thing to do, because ICP was a well-known technique at the time, used for matching any 3D models.
>
> Q. Okay. Sir, but my question was, you are not aware of any evidence that ICP was being used in applications related to dentistry in 2002; correct?
>
> A. I -- I don't believe I'm aware of any.
>
> Q. And you don't know if ICP was being used in orthodontics -- orthodontics in August 2002; right?

> A. Again, I'm not aware of specifics, but it would be the logical thing to use.
>
> Q. Sir, my question again was, you don't know if ICP was being used in orthodontics in August 2002; correct?
>
> A. And I think I answered that, yeah. I'm not aware of any specific, but ICP would be the logical thing to use for an orthodontics application of 3D models.

(Tr. (Egbert) at 1104:11-1105:4.).

Dr. Egbert also conceded that none of the references 3Shape identified in either the field of orthodontics or dentistry mention the use of ICP. (Id. at 1104:6-10 ("Q. Now, in fact, none of the references that you've presented for your opinion today in the field of orthodontics or dentistry cite the use of ICP; isn't that correct, sir? A. None of them cite ICP specifically.").).

Additionally, 3Shape's assertion fails because motivation to combine arguments "cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR*, 550 U.S. at 418 (citations omitted). 3Shape failed to identify any factual underpinning in Rubbert WO's disclosure to support a conclusion that it would have been obvious to modify Rubbert WO with ICP. Indeed, Dr. Egbert testified that "Rubbert doesn't go into a lot of details as to exactly how you do that." (Tr. (Egbert) at 1094:9-21.). Thus, 3Shape's arbitrary selection of ICP from the vast field of alignment techniques constitutes impermissible hindsight bias. Absent hindsight, there is no suggestion or motivation to combine Rubbert WO with ICP. *See, e.g.*, *In re Rouffet*, 149 F.3d 1350, 1358 (Fed. Cir. 1998) (noting that "the suggestion to combine requirement is a safeguard against the use of hindsight combinations to negate patentability").

Moreover, it is not sufficient that ICP simply existed and was known at the time. Although 3Shape argued that "ICP was the dominant technique typically used to match 3D objects at the time of the patent" (RBr. at 21), it failed to "identify a ***reason*** that would have prompted a person of ordinary skill in the relevant field to combine the elements in a way the claimed new invention does . . . because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." *KSR*, 550 U.S. at 418-19 (emphasis added). Neither 3Shape nor Dr. Egbert provided an explanation of how one of ordinary skill in the art would have a reasonable expectation of success in combining Rubbert WO with ICP or Rusinkiewicz, especially where Rubbert WO does not provide detail in its disclosures for matching a single tooth to another that amounts to a disclosure that it can be done. *See Broadcom Corp. v. Emulex Corp.*, 732 F.3d 1325, 1335 (Fed. Cir. 2013).

For the reasons explained, 3Shape's arguments, which rely upon conclusory and hindsight testimony, are inadequate to support its claim of obviousness. *See, e.g.*, *KSR*, 550 U.S. at 418.

4. Claims 1 and 18 of the '647 Patent Are Not Indefinite and Do Not Lack Written Description

3Shape contended in two (2) conclusory paragraphs that the language "to determine corresponding dental objects" of the '647 patent is indefinite and/or lacks written description support. (RBr. at 14-15.). 3Shape relied solely on similarly conclusory testimony of its expert, Dr. Egbert, to support this position.

> Q. Dr. Egbert is, which portion of claim 1 is indefinite, in your opinion?
>
> A. The portion where it states, "individually matching each of the dental objects in the subsequent digital model with a dental object in the initial digital model to determine corresponding dental objects."
>
> Q. And why, in your opinion, is that portion of claim 1, which also appears in claim 18, indefinite?
>
> A. That's correct. If you look at the wording in that portion of claim 1, it says that you need to 'individually match each of the teeth in the subsequent digital model

> with a tooth in the initial digital model.' And so the idea is you have to match two teeth together. The next part of the phrase, though, states the reason you do that is to determine corresponding dental objects. In order to do the matching, you have to have already determined those corresponding dental objects. You can't do a match if you haven't determined that two things correspond. And so the language in the claim states that you do the match in order to determine the corresponding dental objects, but you can't do the match without having those corresponding dental objects.
>
> Q. And Dr. Egbert, in your opinion, does claim 1 -- does this portion of claim 1 find written description support in the '647 patent?
>
> A. No. I could not find any.
>
> Q. And same question with respect to claim 18 of the '647 patent. Does the "individually match each of the dental objects in the subsequent digital model with a dental object in the initial digital model to determine corresponding dental objects" step, including the substeps, find written description support in the '647 patent?
>
> A. I could not find any.

(Tr. (Egbert) at 1098:5-1099:14.).

However, when the claim language is read correctly, in light of the specification, 3Shape's contention is unavailing. As an initial matter, from a legal perspective, the patent's requirement of "to determine corresponding dental objects" is an intended result. This is clear from the plain language "individually matching . . . to determine corresponding dental objects . . . the matching comprising." (JX-0001 at 10:4-18.).

Moreover, by the plain language of the claims, "to determine corresponding dental objects" is accomplished through the three sub-steps of the "individually matching . . . the matching comprising" claim element. (JX-0001 at 10:4-18; Tr. (Badler) at 405:24-406:11, 424:11-19.). Specifically, the patent specification describes an approximate positioning of the teeth and then an iterative process that involves positioning and repositioning teeth until the distance is minimized after which the process has found the corresponding teeth and matched them more closely through the three sub-steps. (*See, e.g.*, JX-0001 at 5:62-6:14, Figs. 3-4; Tr. (Badler) at 405:24-406:11, 424:11-19.). This is consistent with the adoped claim construction of "individually matching," which was construed to mean "for each of the teeth in the subsequent digital model, using the identified reference points to determine the position of a tooth in the subsequent digital model relative to the corresponding tooth in the initial digital model." (*Markman* Order, App. A. at 19.).

The specification and plain claim language thus plainly explain how the steps result in the determination of corresponding dental objects through the positioning and repositioning of the same teeth from two models. (*See* JX-0001 at 5:6-7:62.). *See also Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1345 (Fed. Cir. 2016) (finding the exact terms appearing in the claim "need not be used in haec verba" for written description support); *Cordis Corp. v. Medtronic Ave, Inc.*, 339 F. 3d 1352, 1364-65 (Fed. Cir. 2003) (same).

3Shape's assertion rests on an interpretation of the claims that "each sub-step requires that the corresponding dental objects are already determined." (RBr. at 14.). However, no such requirement exists in the claims and 3Shape did not seek a claim construction consistent with this position. (*See id.* at 14-15.). Instead, 3Shape misquoted the claim language. (*Id.* at 15.). For example, the claim language does not state that the "corresponding dental objects" "are determined by: (i) identifying corresponding dental objects." (*Id.*; JX-0001 at 10:8-10.). The plain language is "identifying one or more reference points on each set of corresponding dental objects in the initial and subsequent models." (JX-0001 at 10:8-10.). This is easily understood, because as detailed in the specification, the process is done for each tooth on two models of the teeth of a patient. (*Id.* at 5:6-6:14.). The process therefore places points on corresponding teeth as the models are two models of the same patient's teeth and the claims require that the references points are identified on each set of teeth. (JX-0001 at 10:8-10.).

3Shape's expert, Dr. Egbert, provided only conclusory opinions to support this position. However, conclusory testimony by an expert is not clear and convincing evidence of invalidity. *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1339, n.8 (Fed. Cir. 2016). For example, Dr. Egbert failed to address Dr. Badler's testimony regarding his understanding of the "to determine corresponding dental objects" claim language and did not address any of the portions of the patent specification or any of the Figures and embodiments described therein. Rather than examining the language of the patent, Dr. Egbert stated that "I could not find any" written description support. (Tr. (Egbert) at 1099:4-7.). This conclusory testimony is insufficient to meet 3Shape's burden to prove indefiniteness or failure of written description. *WBIP*, 829 F.3d at 1339, n.8; *Koito Mfg. Co. v. Turn-Key-Tech*, LLC, 381 F.3d 1142, 1155 (Fed. Cir. 2004).

For the foregoing reasons, 3Shape has failed to prove by clear and convincing evidence that asserted claims 1 and 18 of the '647 patent are invalid.

5. The '647 and '661 Patents Claim Patent Eligible Subject Matter

a) *Alice* Step 1: The '647 and '661 Patents Claim a Specific Technological Improvement

As explained in the specification of the '647 and '661 patents, the asserted claims of the '647 and '661 patents are directed to non-abstract solutions to a problem specific to virtual dentistry and orthodontics. Prior art conventional methods of orthodontics and teeth movement involved manual processes. (JX-0001 at 2:4-11; JX-0002 at 1:32-47.). Traditionally, practitioners relied on using rulers on 2D x-ray images of a patient over time and the manual 2D measurements were not precise and were incomplete. (JX-0001 at 2:4-11.). Although 3D digital scans of a patient's jaw were known (*see id.* at 1:44-65), there is no evidence of any known methods of matching and comparing 3D digital scans and treatment plan models of a patient's jaw to calculate positional differences as claimed in the '647 and '661 patent claims. (*See, e.g.*, *id.* at 2:4-26.).

One of the named inventors on the '647 and '661 patents, Dr. Eric Kuo,[42] testified that at the time of the invention, Align faced the novel problem of patients going off track from aligner treatment and was trying to figure out how to get a patient back on track.

> Q. Was there a particular problem that you were trying to address when you came up with the idea that led to the filing of this patent application?
>
> A. Yes. So when we were looking at the progress results of how treatments were going, one of the things we learned was that sometimes the appliances, the aligners, they weren't fitting on the patient's teeth as well as the doctor would like. And at the time initially, the manufacturing lead time was pretty long, and the cost to make these aligners was pretty expensive. So the doctors would have a whole bunch of these trays sitting in the office that they couldn't use because the cases were going off track. So we were trying to come up with a way to get the patient to get back on track to the rest of the aligners that were already manufactured and sitting in the doctor's office.

(Tr. (Kuo) at 69:7-23.).

Dr. Kuo explained that as a practitioner, he understood that in order to solve this problem, a doctor would need to scan the patient and then find a way to match the scan to a treatment stage to figure out what teeth are not on track. (*Id.* at 69:24-70:13.). He testified that at the time,

[42] When he testified during the Hearing on October 24, 2019, Dr. Eric Kuo was an orthodontist as well as an orthodontic consultant. (Tr. (Kuo) at 65:13-14.). From 1999 until March of 2013, Dr. Kuo was an Align full-time employee. (*Id.* at 67:5-7.). He was hired initially as an associate clinical director. In that role, Dr. Kuo "primarily focused on supervising technicians in the manufacturing operations." (*Id.* at 67:10-11.). Dr. Kuo's last role at Align was Vice President of clinical technology. (*Id.* at 67:18-19.). Align identified Dr Kuo as a fact witness to testify about Align's background and business; domestic industry in the Asserted Patents; background and development of the technology disclosed in the '661 and '647 patents; validity of the Asserted Patents, including nonobviousness and secondary considerations of the '661 and '647 patents; standing and ownership of the Asserted Patents; Align's iTero Element and Invisalign System; and related issues. (CPSt. at 8.).

the known way for measuring teeth movement was the manual method that yielded limited and imprecise results. (*Id.* at 70:14-71:10; JX-0001 at 2:4-26.).

Dr. Kuo testified that while different ways to match scans existed, those that existed to match did not meet his need for a tool that match teeth quickly and accurately. (Tr. (Kuo) at 71:11-72:18, 84:11-17.). Dr. Kuo stated that the 2D traditional solution was "problematic" because of the need for precision and accuracy and "you will end up with trays that don't fit." *(Id.* at 72:19-73:8.).

Beyond providing known orthodontic knowledge to others, Dr. Kuo recognized and anticipated a new problem specific to clear aligners and worked iteratively with the other inventors to come up with the exact solution to solve the unique problem. (Tr. (Kuo) at 68:16-76:5, 84:8-15.). The '647 and '661 patents claim a specific solution for precise calculation of positional differences and tracking of a treatment plan of teeth, that is, a two-step matching process and calculation process using reference points on individual teeth or non-tooth, non-moving regions of the computer model. (*See* JX-0001 at 9:63-10:23; JX-0002 at 13:8-30.). The weight of the evidence reflected that in prior art and conventional techniques, 3D "matching," calculations and tracking were not performed at all. As the evidence reflected, to the extent that there was matching, the process was performed manually by practitioners and resulted in incomplete and inaccurate results. (Tr. (Kuo) at 72:19-73:8; JX-0001 at 2:4-11; JX-0002 at 2:41-44.). Using the specific matching steps and calculation steps described in the patents, the inventions provide improved solutions. (*See* JX-0001 at 2:53-58, 6:41-60, 10:59-67.).

As a result, the inventions here are not abstract, specific methods and improvements to solve problems in existing technological processes and computer technology and do not simply invoke the use of a generic computer. *Alice* at 2355, 2357. 3Shape is mistaken that any improvement lies only in the use of a computer to perform 3D calculations. 3Shape did not present evidence to support its contention that the patents are directed to well-known and conventional techniques. 3Shape presented only attorney argument. (RBr. at 6-7.).

Specifically, 3Shape did not offer evidence that the two-step matching and calculation process of the claimed inventions was well-known or conventional. To the contrary, traditional orthodontic measurements were performed manually and the inventors did not simply take the traditional method using a ruler and invoke a computer. (*See* Section IV.A.).

The claims here are analogous to the claims that were held to be patent eligible in *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 837 F.3d 1299 (Fed. Cir. 2016). In *McRO*, the court found claims directed to a process for lip-synching animated characters that used specific rules to automate a previously subjective manual process patent eligible. *Id.* at 1313-16. The Federal Circuit found that "[w]hen looked at as a whole, claim 1 is directed to patentable, technological improvement over the existing, manual 3-D animation techniques." *Id.* at 1316; *see also Koninklijke KPN N.V. v. Gemalto M2M GmbH*, 942 F.3d 1143, 1151 (Fed. Cir. 2019) (finding patent eligible claims that recite a specific implementation of an existing tool that improved the functionality of the technological process); *Thales Visionix, Inc. v. United States*, 850 F.3d 1343, 1348 (Fed. Cir. 2017); *Diamond v. Diehr*, 450 U.S. 175, 187 (1981).

The cases 3Shape cited are inapposite. 3Shape relied solely on cases where, unlike the claims here, the "improvement" recited by the claims was at such a level of result-oriented generality that the claims amounted to mere implementation of an abstract idea on a computer, not to a specific solution and method that improves the relevant technology, or involved processes were there was evidence that the claims could be performed by a human. *See, e.g.*, *Intellectual Ventures I LLC v. Symantic Corp.*, 838 F.3d 1307, 1313-18 (Fed. Cir. 2016) (claims directed to human practicable concepts as confirmed by specification); *SAP Am., Inc. v. InvestPic, LLC*, 898 F.3d 1161, 1167 (Fed. Cir. 2018) (claims directed to merely performing certain statistical analysis of information); *Elec. Power Grp. v. Alstom S.A.*, 830 F.3d 1350, 1353-54 (Fed. Cir. 2016) (claims directed generally to analyzing and displaying information without any new source or techniques); *see also Koninklijke*, 942 F.3d at 1151-53 (distinguishing cases).

In its Post-Hearing Brief, 3Shape repeatedly argued that the concepts in the claims amount to no more than the use of a generic computer to apply "conventional 3D modelling techniques" to assess movement of teeth and do not claim improvements over known orthodontic procedures or dentistry software. (RBr. at 6, 7, 9, 11, 12.). However, the evidence presented during the Hearing establishes that the claims are specific methods and solutions that are technological improvements in known orthodontic practices and dentistry software. (*See* Section IV (regarding description of patents.). 3Shape did not cite to evidence to support its conclusory attorney argument for the position they advance here. (RBr. at 6, 7, 9, 11, 12.).

Because the inventions here are non-abstract, specific methods and improvements to solve problems in existing technological processes and computer technology, 3Shape's argument under *Alice* Step 1 fails.

b) *Alice* Step 2: The '647 and '661 Patents Claim an Inventive Concept

As explained for Step 1, the claims are not directed to simply invoking a generic computer for the performance of well-known techniques. To the contrary, evidence presented during the Hearing demonstrates that the claims provide a specific method and solution that is a technological improvement to known orthodontics and dentistry procedures and software. (*See*

Section IV, *supra*.). 3Shape's position disregards the specific teeth matching or non-tooth region matching and measurement recitations of the claims.

Because the claims capture an improvement to conventional practice and are directed to a technological improvement not attributable to a computer, but to the inventive concept of the specific claimed process of matching and calculating, 3Shape's argument under *Alice* Step 2 also fails.

VIII. U.S. PATENT NO. 7,156,661

A. Infringement

1. Infringement Overview

Align accused 3Shape of directly infringing claims 2 and 20 of the '661 patent,[43] both literally and under DOE. (CPBr. at 58-70; CBr. at 37-55.). Align also accused 3Shape of indirectly infringing claims 2 and 20 of the '661 patent by inducing infringement and contributing to the infringement of these asserted claims.[44] (CBr. at 47-49.).

Claims 2 and 20 depend from independent claims 1 and 19, respectively. Thus, an analysis of each of the elements of claims 1 and 19 are provided in Section VIII.A.2(a) below. Moreover, as shown in Table Nos. 6 and 7 below, the elements recited in claim 1 drawn to a "method for matching computer models of a jaw" are nearly identical to the elements recited in claim 19, which are drawn to a "tangible computer readable medium containing code for matching computer models of a jaw." Thus, the claim elements are addressed together in

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[43] In its Pre-Hearing Brief, Align alleged that the 661 Accused Products infringe both literally and under DOE. (CPBr. at 58-70.). However, Align did not raise DOE against the asserted claims of the '661 patent in its Initial Post-Hearing. Thus, Align has waived any argument on this issue under Ground Rule 10.2.

[44] Indirect infringement for all Asserted Patents is addressed in Section XI.B, *infra*.

Section VIII.A.2(a) below (e.g., elements [1.1] / [19.1], [1.2] / [19.2], etc.). The additional elements contained in dependent claims 2 and 20 are also substantially similar and like claims 1 and 19, are addressed together in Section VIII.A.2(b) below.

Table No. 6: Comparison of Claims 1 and 19 of the ’661 Patent

Cl. 1	Element	Cl. 19	Element
[1.1]	A method for matching computer models of a jaw, the method comprising:	[19.1]	A tangible computer readable medium containing code for matching computer models of a jaw, the tangible computer readable medium comprising instructions to:
[1.2]	loading a first computer model of a jaw having teeth in initial positions;	[19.2]	load a first computer model of a jaw having teeth in initial positions;
[1.3]	loading a second computer model of the jaw, wherein positions of at least some of the teeth in the second computer model are different than the initial positions;	[19.3]	load a second computer model of the jaw, wherein positions of at least some of the teeth in the second computer model are different than the initial positions;
[1.4]	identifying at least one reference point on a region of the first computer model, the region comprising a portion of the jaw other than the teeth;	[19.4]	identify at least one reference point on a region of the first computer model, the region comprising a portion of the model other than the teeth;
[1.5]	identifying a corresponding reference point on a corresponding region of the second computer model for each point identified on the first model;	[19.5]	identify a corresponding reference point on a corresponding region of the second computer model for each point identified on the first model;
[1.6]	matching the region of the first computer model with the corresponding region of the second computer model, using the identified reference points;	[19.6]	ma[t]ch the region of the first computer model with the corresponding region of the second computer model, using the identified reference points;
[1.7]	matching the first and second computer models as a whole, using	[19.7]	match the first and second computer models as a whole, using the

Cl. 1	Element	Cl. 19	Element
	the matched regions;		matched regions;
[1.8]	and calculating positional differences between the teeth in their initial positions and the teeth in their positions in the second computer model, using the matched regions as non-moving reference regions.	[19.8]	and calculate positional differences between the teeth in their initial positions and the teeth in their positions in the second computer model, using the matched regions as non-moving reference regions.

Table No. 7: Comparison of Claims 2 and 20 of the '661 Patent

Cl. 2	Element	Cl. 20	Element
[2.1]	The method of claim 1, further comprising: displaying the positional differences between the teeth in the first and second models.	[20.1]	The medium of claim 19, further comprising instructions to: display the positional differences between the teeth in the first and second models.

For the reasons discussed in Section VIII.A.2(b) below, Align has met its burden and proven that the 661 Accused Products practice claims 2 and 20.

2. The 661 Accused Products Practice Claims 2 and 20 of the '661 Patent

a) Claims 1 and 19

i. [1.1] / [19.1]: "A method for matching computer models of a jaw, the method comprising" / "A tangible computer readable medium containing code for matching computer models of a jaw, the tangible computer readable medium comprising instructions to"

Align presented evidence that TPM and CMS perform methods for matching computer models of a jaw. (CX-0827C.0123-.0127; CX-0923; CX-2125C (Badler Expert Rpt.) at ¶¶ 284-88.). The user guides for TPM and CMS enable a user to compare intraoral scans or models of a patient over time or to compare a current scan to a treatment plan. ((CX-0827C.0123-.0127; CX-

0923; Tr. (Badler) at 430:14-432:6.).

3Shape did not dispute that the 661 Accused Products meet the preambles of these claim elements in its Post-Hearing Reply Brief. (RRBr. at 27.). Thus, 3Shape has waived any argument on this issue under Ground Rule 10.1.

For these reasons, Align has proven by a preponderance of evidence that the 661 Accused Products meet preambles [1.1] and [19.1] of claims 1 and 19, respectively, of the ’661 patent.

ii. [1.2] / [19.2]: “loading a first computer model of a jaw having teeth in initial positions” / “load a first computer model of a jaw having teeth in initial positions”; [1.3] / [19.3]: “loading a second computer model of the jaw, wherein positions of at least some of the teeth in the second computer model are different than the initial positions” / “load a second computer model of the jaw, wherein positions of at least some of the teeth in the second computer model are different than the initial positions”

Evidence adduced in this Investigation establishes that both TPM and CMS allow a user to select a patient and to load computer models of a patient’s jaw from the list of TRIOS scans or models created over time and over different visits, including a treatment plan. (Tr. (Badler) at 432:7-434:3; CX-0827C.0123-.0127; CX-0923.0003-.0005; CPX-0208C; CX-2220C (Fisker Dep. Tr.) at 40:17-41:1, 48:10-24; CX-2229C (Isleifsson Dep. Tr.) at 24:14-26:19; CX-2233C (Khaitov Dep. Tr.) at 77:24-81:9; CX-2261C (Tommy Poulsen Dep. Tr.)[45] at 153:14-155:15.). The source code for TPM in [redacted], as discussed above in Section VII.A.3(a), and [redacted] for CMS confirm the model scans that occur during different visits that comprise a treatment

[45] When he was deposed on June 7, 2019, Mr. Tommy Paulsen was a Director at 3Shape. (CX-2261C (Poulsen Dep. Tr.) at 14:17-15:3.). Prior to becoming a Director, Mr. Poulsen was, *inter alia*, a software developer, project manager, group manager, and department manager at 3Shape. (*Id.* at 13:16-18, 14:17-15:3.).

plan. (CPX-0208C; CPX-0235C; CPX-0248C.).

In its Post-Hearing Reply Brief, 3Shape did not contest that the 661 Accused Products meet these claim elements. (RRBr. at 27.). Because 3Shape did not address the issues on which it has the burden of proof until its Reply Brief, 3Shape has waived any argument on this issue pursuant to Ground Rule 10.1.

Accordingly, Align has proven by a preponderance of evidence that the 661 Accused Products practice elements [1.2] / [19.2] and [1.3] / [19.3] of claims 1 and 19, respectively, of the '661 patent.

iii. [1.4] / [19.4]: "identifying at least one reference point on a region of the first computer model, the region comprising a portion of the jaw other than the teeth" / "identify at least one reference point on a region of the first computer model, the region comprising a portion of the model other than the teeth"[46]; [1.5] / [19.5]: "identifying a corresponding reference point on a corresponding region of the second computer model for each point identified on the first model" / "identify a corresponding reference point on a corresponding region of the second computer model for each point identified on the first model"

TPM 3-Point Alignment allows a user to align initially a region of a model by manually selecting three (3) corresponding points on an area on each scan, such as the preferred, non-moving or immovable rugae region.[47] (Tr. (Badler) at 434:25-436:20; Tr. (Bogdanic) at 812:22-813:4, 814:1-8; Tr. (Mellor) at 1761:11-1762:20, 1763:17-24; CPX-0165C; CX-0884C; CX-

[46] The term "reference point" was construed to mean "a point used to determine the position of a computer model, or part thereof, relative to another computer model, or part thereof." (*Markman* Order, App. A at 7.). The term "region(s)" was construed to mean "area." (*Id.* at 11.). The Parties agreed that the phrases "comprising a portion of the jaw / model other than the teeth" mean "including at least a non-tooth portion of the jaw." (*Markman* Order, App. A at 19.).

[47] Dr. Badler described the rugae as part of the jaw, other than the teeth, and are "like a fingerprint almost on the roof of the mouth." (Tr. (Badler) at 434:19-24; *see also e.g.*, CDX-0011C.0088.).

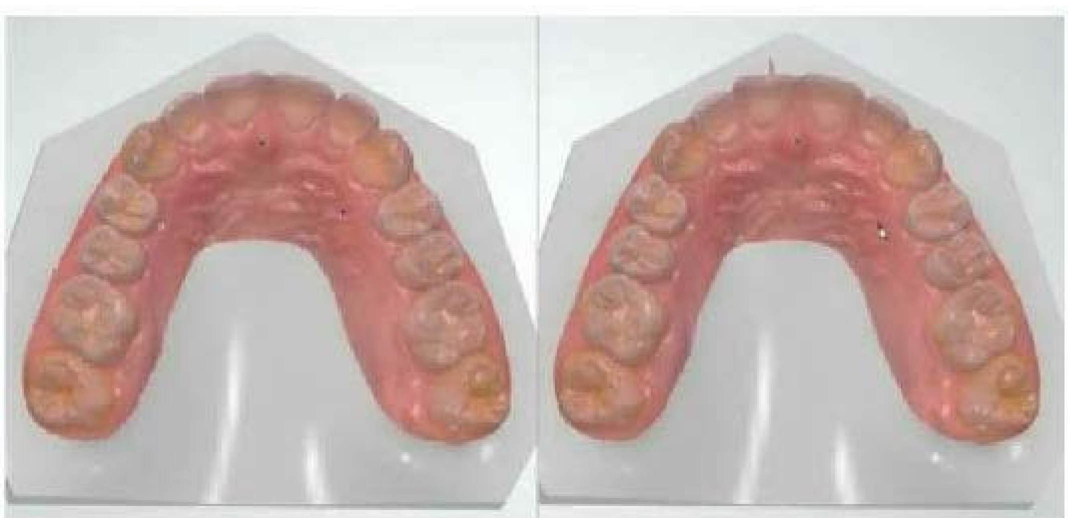
0891C.0001; CX-0917C.0001; CX-0923.0012; CX-2220C (Fisker Dep. Tr.) at 69:18-70:25; CX-2229C (Isleifsson Dep. Tr.) at 61:23-65:16; CX-2230C (Isleifsson Dep. Tr.) at 223:20-224:12; CDX-0011C.0081.).

The user can also select a region to optimize the initial alignment to align the jaw as a whole, which [redacted], as discussed below in Section VIII.A.2(a)(v). (Tr. (Badler) at 814:13-20, 1763:25-1764:12; CX-0923.0013.). TPM allows the user to choose three corresponding points anywhere on the primary and secondary jaw models. (CX-0923.0011-.0014; Tr. (Badler) at 435:17-436:8, 813:5-12, 1762:24-1763:1; CX-2220C (Fisker Dep. Tr.) at 69:18-70:25.). The user manual explains that the points should be placed on areas of the jaw that did not undergo changes during the time interval between scans, thus instructing the user to place the points on non-moving regions or areas of the jaw model, such as the rugae area. (CX-0923.0012, .0014; Tr. (Badler) at 434:25-435:16.).

3Shape's corporate witnesses acknowledged that the user can place three (3) points anywhere on the computer models of the jaws, including portions of the jaw such as the gingiva or rugae. This is also supported by 3Shape's technical documents. (CX-2229C (Isleifsson Dep. Tr.) at 63:2-64:13; CX-2220C (Fisker Dep. Tr.) at 69:18-70:25; *see also* Tr. (Badler) at 435:17-436:8; CX-0891C.0001; CX-0917C.0001.). 3Shape's source code confirms this in [redacted]. (Tr. (Badler) at 436:9-20; CPX-0165C; CX-2230C (Isleifsson Dep. Tr.) at 223:5-224:12.). As Dr. Badler testified, placing points on the rugae meets the adopted construction of "reference points" because, as discussed below in Section VIII.A.2(a)(v), the reference points will be used initially to position or match the regions or rugae of the two computer models and the construction of "area" for region, as the rugae is an area on the computer model and additionally satisfies the remainder of the claim language, which only requires the "region" to be a non-tooth portion on the model. (Tr. (Badler) at 434:4-436:20, 509:2-15, 512:13-513:13; *see also* JX-0002 at 13:16-18 ("identifying at least one reference point ***on a region of the first computer model***, ***the region comprising a portion of the jaw other than the teeth***") (emphasis added).)

CMS also offers multiple model alignment methods, including Surface 1-Point and Surface 3-Point. (Tr. (Badler) at 436:21-438:16, 1765:15-1766:16; CX-0767C; CX-0827C.0123-.0127; CX-2233C (Khaitov Dep. Tr.) at 81:14-86:2; CX-2261C (Poulsen Dep. Tr.) at 110:9-116:1.). For both methods, the user can identify corresponding points on each model for alignment and optionally select the surface for a better alignment as a whole. (TR. (Badler) at 436:21-438:16, 1765:15-1766:16; CX-0827C.0123-.0127; CX-2233C (Khaitov Dep. Tr.) at 89:18-90:4.). 3Shape's documentation indicates that the placement of the corresponding points can be on non-tooth areas of the models, including the rugae.

Figure 6: 3Shape Ortho Analyzer Manual



(CX-0775.0036-.0038.)

Thus, if the user selects three (3) points on the rugae region using the Surface 3-Point alignment method, for example, the rugae region is [redacted]. (Tr. (Mellor) at 1766:21-1767:1; CX-2233C (Khaitov Dep. Tr.) at 128:21-129:1.). 3Shape's corporate witness, Mr. Khaitov, confirmed that a user can select points on the rugae of each of the computer models for the reason that it may be immovable and a good reference region, and the resulting alignment may be more precise. (CX-2233C (Khaitov Dep. Tr.) at 87:2-88:3*; see also* Tr. (Badler) at 436:21-438:16; Tr. (Mellor) at 1767:2-12.). This is shown in the source code in [redacted]. (Tr. (Badler) at 438:3-10; CPX-0152C; CPX-0153C; CPX-0154C; CX-2233C (Khaitov Dep. Tr.) at 84:5-85:16.).

For the reasons discussed above, Align has proven by a preponderance of evidence that the 661 Accused Products practice elements [1.4] / [19.4] and [1.5] / [19.5] of claims 1 and 19, respectively, of the '661 patent.

iv. [1.6] / [19.6]: "matching the region of the first computer model with the corresponding region of the second computer model, using the identified reference points" / "ma[t]ch the region of the first computer model with the corresponding region of the second computer model, using the identified reference points"[48]

TPM determines the position or matches the region or area of the first computer model relative to the second computer model using the identified points by [redacted], as an example. (Tr. (Badler) at 438:17-441:25; CX-2125C (Badler Expert Rpt.) at ¶¶ 335-49.). In 3-Point Alignment, the points are chosen in an area that will be matched or aligned [redacted]. (Tr. (Bogdanic) at 814:13-

[48] The terms "matching / match . . . using the identified reference points" was construed to mean "using the identified reference points to determine the position of a region of the first computer model relative to the corresponding region of the second computer model." (*Markman* Order, App. A at 14.).

816:2; Tr. (Mellor) at 1763:17-24; CX-2230 (Khaitov Dep. Tr.) at 228:1-231:21; CPX-0165C; CX-0891C.0001; CX-0917C.0001.). As discussed below in Section VIII.A.2(a)(v), [redacted] or alignment of the jaw as a whole. (CX-2229C (Isleifsson Dep. Tr.) at 87:1-15.).

Moreover, for example, the points are used to match the [redacted]. (Tr. (Badler) at 439:8-441:23; Tr. (Mellor) at 1763:2-24; CX-2230C (Isleifsson Dep. Tr.) at 223:20-227:25.). Thus, using the three (3) points, the [redacted]. (*Id.*). The [redacted]. (*Id.*). Dr. Badler demonstrated this during the Hearing and confirmed this in the source code [redacted].

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[49] The [redacted]. (*See, e.g.*, CX-2230C (Isleifsson Dep. Tr.) at 226:6-12.).

Figure 7: 3-Point Alignment

[redacted]

(CDX-0011C.0094; *see also* Tr. (Badler) at 439:8-441:25; CPX-0165C starting at line 107; CX-2230C (Isleifsson Dep. Tr.) at 223:20-227:25; CDX-0011C.0087-0093.).

Dr. Mellor conceded during the Hearing that the alignment using the three (3) points in each model is an "initial" alignment and if the user puts the points on the rugae regions, it is the rugae regions that are brought into more close proximity as part of the process. (Tr. Mellor) at 1763:2-24.).

CMS also matches the region or the area of the first and second computer models using the identified points by aligning the corresponding points on the rugae. (Tr. (Badler) at 442:1-18.). Mr. Khaitov confirmed that when Surface 1-Point or Surface 3-Point alignment methods are used, 3Shape's software will [redacted]. (CX-2233C (Khaitov Dep. Tr.) at 81:14-83-11.). After the point(s) are identified, the user will draw a surface area that is going to define some additional region that will refine the matching. (*Id.*). For example, if the user selects three (3) points in the rugae region, the rugae regions are matched [redacted]. (*Id.* at 89:18-90:4, 128:21-129:1; Tr. (Mellor) at 1767:17-1768:18; CX-0767C.). This is supported by the same code identified for claim elements [1.4] and [1.5]. (Tr. (Badler) at 442:13-18; CPX-0152C; CPX-0153C; CPX-0154C.).

Accordingly, Align has proven by a preponderance of evidence that the 661 Accused Products practice elements [1.6] and [19.6] of claims 1 and 19, respectively, of the ’661 patent.

v. [1.7] / [19.7]: “matching the first and second computer models as a whole, using the matched regions” / “match the first and second computer models as a whole, using the matched regions”

As discussed above, TPM uses the reference points initially to match a region. (Tr. (Badler) at 438:17-441:25; Tr. (Mellor) at 1763:17-24; CX-2125C (Badler Expert Rpt.) at ¶¶ 350-61.). TPM first matches a non-tooth region, e.g., rugae, using the points, and then the software performs [redacted] to better align the jaw in its entirety. (Tr. (Badler) at 442:19-444:24; Tr. (Mellor) at 1763:25-1764:12; CX-2229C (Isleifsson Dep. Tr.) at 66:23-67:12; CX-2230C (Isleifsson Dep. Tr.) at 223:5-244:21.). [redacted].[50] (CX-2230C (Isleifsson Dep. Tr.) at 228:1-18; Tr. (Mellor) at 1763:25-1764:12; CX-0891C.0001; CX-0917C.0001; CX-2229C (Isleifsson Dep. Tr.) at 113:1-6; CX-2230C (Isleifsson Dep. Tr.) at 238:24-241:6.). [redacted], because it needs an “initial guess” to better align the jaw in its entirety. (Tr. (Badler) at 444:1-9, 445:21-24; Tr. (Mellor) at 1764:13-15; CX-

[50] The term “optimization” is used here in the context of optimizing alignment of the selected points. (*See, e.g.*, Tr. (Mellor) at 1764:5-12.).

2229C (Isleifsson Dep. Tr.) at 88:14-19; CX-2230C (Isleifsson Dep. Tr.) at 258:17-259:2; CX-0948.0001 [redacted] that aligns or positions the models as a whole. (Tr. (Badler) at 443:10-13; Tr. (Bogdanic) at 814:23-815:8, 830:8-19.).

Additionally, as discussed above in Section VII.A.3(a)(vii) for the ’647 patent for claim element [1.9] / [18.9], TPM also has a Measurements view that shows the two (2) computer models of the patient’s jaw overlaid and positioned as a whole in the same coordinate system. (Tr. (Badler) at 444:10-24; CX-0923.0019-.0026; CX-2229C (Isleifsson Dep. Tr.) at 95:6-97:10, 103:24-104:12; CDX-0011C.0098.). In Measurements view, for example, TPM has a Scan Comparison tool that can be used to measure the difference between two (2) scans to calculate changes and tooth movement. (CX-0923.0023.). This Scan Comparison tool demonstrates that the models are matched as a whole, using the matched regions, because the regions are matched in the first step and if using the non-movable regions, such as the rugae, it will result in better alignment and thus better calculation and display of changes or differences. (Tr. (Bogdanic) at 813:13-25; CX-2229C (Isleifsson Dep. Tr.) at 72:9-24.).

CMS also matches the first and second computer models as a whole, using the matched regions. In this manner, CMS functions the same as TPM. (Tr. (Badler) at 444:25-446:16.). After the points are used [redacted], the user defines a surface area matching so that a finer alignment based on a user-selected area can then be performed. This area matching will then align the models as a whole. (CX-2233C (Khaitov Dep. Tr.) at 81:14-83:11, 128:21-129:1; CX-2261C (Poulsen Dep. Tr.) at 110:9-116:1; Tr. (Mellor) at 1768:19-1769:20.). The models are matched using the matched regions because as explained above, [redacted]. Additionally, 3Shape's corporate witness verified that [redacted] and thus CMS uses the matched regions for matching as a whole. (CX-2261C (Poulsen Dep. Tr.) at 113:22-115:7; CX-0775.0038 (3Shape's training guide showing how to use the initially matched rugae region for optimization).).

Additionally, the models in CMS can be overlaid such that they are shown in the same coordinate system as shown in the alignment code and thus are matched as a whole. (CX-2233C (Khaitov Dep. Tr.) at 90:19-91:16.). This permits the user to visualize the model separately or overlay them on top of each other. (*Id.* at 91:12-92:22.). 3Shape's witness, Mr. Poulsen, confirmed that a user can superimpose one model over the other model as well as compare the upper and lower jaw of a second model. (CX-2261C (Poulsen Dep. Tr.) at 150:15-152:6.). The regions are also used to match before the models are overlaid, and as discussed for claim elements [1.4] and [1.5], selecting points on the rugae region of each of the computer models and using those matched regions results in a more precise alignment and display. (CX-2233C (Khaitov Dep. Tr.) at 87:2-88:3; Tr. (Badler) at 436:21-438:16.).

For the foregoing reasons, Align has proven by a preponderance of evidence that the 661 Accused Products practice elements [1.7] and [19.7] of claims 1 and 19, respectively, of the '661 patent.

vi. ***[1.8] / [18.8]: "calculating positional differences between the teeth in their initial positions and the teeth in their positions in the second computer model, using the matched regions as non-moving reference regions" / "calculate positional differences between the teeth in their initial positions and the teeth in their positions in the second computer model, using the matched regions as non-moving reference regions"***

As discussed in Section VII.A.3(a)(viii) for the '647 patent claim element [1.10], in the Measurements view, a user can compare and perform measurements between two (2) selected scans using various tools, such as Scan Comparison. (CX-0923.0016-.0026; CX-2125C (Badler Expert Rpt.) at ¶¶ 362-72.). TPM's Scan Comparison tool calculates movements of teeth, as shown in [redacted] distance between two points. (Tr. (Badler) at 446:17-447:9; CPX-0061C; CX-2229C (Isleifsson Dep. Tr.) at 122:9-139:9.). Mr. Bogdanic confirmed during the Hearing that the Scan Comparison tool shows in millimeters the differences between teeth in the models. (Tr. (Bogdanic) at 831:16-21.). The changes are calculated using the non-moving regions as a reference region because as discussed above, the non–moving regions, e.g., rugae or gingiva areas, allow for more accurate alignment and better results for calculating positional differences or changes. (Tr. (Badler) at 447:10-16.). TPM also displays the changes in movement with different colors for user calculations, with the non-moving regions as references as they are colored differently. (CX-0923.0016-.0026.). The user is encouraged to select the region on which to place the points (i.e., the "matched region") as a non-moving reference region for better alignment and thus better calculations. (Tr. (Badler) at 446:17-447:16; CX-0923.0012.).

Similarly, CMS can be used to compare scans over time to determine differences in movement between the two (2) models. (Tr. (Badler) at 447:20-448:14.). This is shown expressly by the difference map in the Ortho System manual. (*See* CX-0827C.0123-.0127.).

Once the models are matched, the user can see a map that shows the differences between the teeth on the first model and the teeth on the second model. (*Id.*). The models are overlaid and values indicate whether the tooth has moved inside or backwards, or forward or outside. (CX-2233C (Isleifsson Dep. Tr.) at 90:5-96:2.). The matching and resulting calculation are done using non-moving reference regions because, as discussed above, a user may select points on the rugae, which [redacted]. 3Shape's witness, Mr. Isleifsson verified that a user can choose the rugae precisely because it may be immovable and that the alignment and any resulting calculation performed is more precise if the user selected the immovable part. (*Id.* at 87:3-89:1.)

As discussed above in Section VII.A.3(a) with respect to claim 1 of the '647 patent, Dr. Mellor's analysis is incorrect that 3Shape's TPM and CMS products only calculate "shape" differences and not positional differences. Dr. Mellor acknowledged that Scan Comparison is identified in the TPM manual as measuring tooth movement and that Mr. Bogdanic confirmed it shows in millimeters the differences between teeth in the models. (Tr. (Mellor) at 1760:10-1761:6; CX-2233C (Isleifsson Dep. Tr.) at 90:5-96:2.).

Moreover, as with Figures 9A and 9B discussed above in Section VII.A.3(a), Dr. Mellor's own testimony belies his position. Dr. Mellor pointed to Figure 10F of the '661 patent as showing "positional differences" as ostensibly opposed to "shape differences" in Figures 9A and 9B. (Tr. (Mellor) at 1730:5-22.). But, Figure 10F clearly shows "move" and "deviation" calculations—"positional" differences under Dr. Mellor's own definition. (*See* JX-0002 at Fig. 10F.). The patent specification confirms and clearly states that Figure 10F shows "an exemplary data analysis of teeth positional variances." (*Id.* at 10:58-61.). The patent specification also defines "deviation" as "the distance between the sampled point on one tooth and its projection point on the other tooth." (*Id.* at 9:8-10.). This is a calculation performed by TPM and CMS.

Accordingly, Align has proven by a preponderance of evidence that the 661 Accused Products practice elements [1.8] and [19.8] of claims 1 and 19, respectively, of the '661 patent.

b) Claims 2 and 20

i. [2.1] / [20.1]: "The method of claim 1, further comprising: displaying the positional differences between the teeth in the first and second models." / "The medium of claim 19, further comprising instructions to: display the positional differences between the teeth in the first and second models."

Claim 2 depends from claim 1, which is directed to a method for matching computer models of a jaw. As discussed above for claim elements [1.7] and [1.8] of the '661 patent, TPM and CMS display the positional differences between the teeth in the models by displaying a difference map and highlighting changes on the computer screen. (Tr. (Badler) at 448:15-449:22; CX-0827C.0123-.0127; CX-0923.).

Dr. Mellor did not provide testimony during the Hearing to dispute that TPM and CMS meet this claim element. (Tr. (Mellor) at 1731:13-19.).

Claim 20 depends from claim 19, which is directed to a computer readable medium containing code for matching computer models of a jaw. TPM and CMS are software tools for the TRIOS Intraoral scanner hardware that enable a user to compare intraoral scans and treatment plans to monitor a patient's state and track changes as discussed above. 3Shape either loads the software on hardware or transmits the software to users to load onto hardware. (*See, e.g.*, Tr. (Badler) at 449:23-450:14; CX-0827C.0008-.0016; CX-0923.0003, .0032.). Thus, TPM and CMS are code stored on a computer.

Dr. Mellor did not provide testimony or opinion to dispute that TPM and CMS include instructions on a computer readable medium. (Tr. (Mellor) at 1731:21-1732:6.).

For the foregoing reasons, Align has proven by a preponderance of evidence that the 661 Accused Products practice the additional elements [2.1] and [20.1] recited in claims 2 and 20, respectively, of the ’661 patent.

B. Technical Prong of Domestic Industry

1. The 661 DI Products Practice Claims 2 and 20 of the ’661 Patent

a) Claims 1 and 19

i. [1.1] / [19.1]: “A method for matching computer models of a jaw, the method comprising” / “A tangible computer readable medium containing code for matching computer models of a jaw, the tangible computer readable medium comprising instructions to”

iTero TimeLapse allows for comparison of a patient’s jaw scans over time. (Tr. (Badler) at 451:5-453:5; CX-2251C (Mikhail Minchenkov Dep. Tr.)[51] at 85:13-18; CX-2125C (Badler Expert Rpt.) at ¶¶ 547-50.). As discussed in the iTero Element manual, two (2) models of a jaw from the same patient may be selected by the user: “Once two scans are selected, the option ‘Compare Selected’ will become enabled and pressing it will launch the Comparison Tool.” (CX-1967C.0049-.0050.). For example, an historical scan can be compared to the current scan of the same patient. (CX-1956C.0005-.0007.). After analyzing the two (2) selected scans, TimeLapse “will provide a color map in the areas where significant change exists between the 2 scans.” (*Id.*; *see also* CX-1581C; CX-1582C; CX-1952C.0028-.0029; CX-1955C.0013-.0015; CX-1957C; CX-1958C; CX-1969C; CX-1823C; CX-1829C; CX-1830C; CX-1831C.). These

[51] When he was deposed on July 12, 2019, Mr. Mikhail Minchenkov was a senior manager at Align Technology. (CX-2251C (Minchenkov Dep. Tr.) at 14:15-20.). Mr. Minchenkov had been employed by Align for 10 years. His role as senior manager included leading the algorithmic team, the application team, and the back- end infrastructure team. (*Id.* at 18:13-18.). Align identified Mr. Minchenkov as a fact witness to testify about the background and business of Align; the domestic industry with respect to the Asserted Patents; and related issues. (CPSt. at 9.).

functionalities are methods for matching computer models of a jaw. (CX-2251C (Minchenkov Dep. Tr.) at 88:7-19.).

Accordingly, Align has proven by a preponderance of evidence that the 661 DI Products preambles [1.1] and [19.1] of claims 1 and 19, respectively, of the '661 patent.

ii. [1.2] / [19.2]: "loading a first computer model of a jaw having teeth in initial positions" / "load a first computer model of a jaw having teeth in initial positions"; [1.3] / [19.3]: "loading a second computer model of the jaw, wherein positions of at least some of the teeth in the second computer model are different than the initial positions" / "load a second computer model of the jaw, wherein positions of at least some of the teeth in the second computer model are different than the initial positions"

3Shape did not dispute that TimeLapse meets claim elements [1.2] / [19.2] and [1.3] / [19.3] of the '661 patent. (RPBr. at 53.). Moreover, Dr. Mellor did not address these claim elements in his testimony during the Hearing. (Tr. (Mellor) at 1732:12-1734:22.).

TimeLapse allows a user to select two (2) models of a jaw from the same patient to compare the two models, including comparing a historical scan to the current scan of the same patient. (Tr. (Badler) at 454:1-23; CX-1967C.0049-.0050; CX-2251C (Minchenkov Dep. Tr.) at 88:21-99:21; CX-2125C (Badler Expert Rpt.) at ¶¶ 551-59.). The source code [redacted]. (CPX-0268C; CX-2251C (Minchenkov Dep. Tr.) at 88:21-99:21.). When the teeth have moved, the earlier model will show the teeth in historical positions, while the later model will show teeth in different positions. (CX-1967C.0049-.0050; *see also id.* at .0034-.0048; CPX-0268C; CPX-0269C; CX-2251C (Minchenkov Dep. Tr.) at 88:21-99:21.)

For the foregoing reasons, Align has proven by a preponderance of evidence that the 661 DI Products practice elements [1.2 / [19.2] and [1.3] / [19.3] of claims 1 and 19, respectively, of the ’661 patent.

iii. [1.4] / [19.4]: “identifying at least one reference point on a region of the first computer model, the region comprising a portion of the jaw other than the teeth” / “identify at least one reference point on a region of the first computer model, the region comprising a portion of the model other than the teeth”; [1.5] / [19.5]: “identifying a corresponding reference point on a corresponding region of the second computer model for each point identified on the first model” / “identify a corresponding reference point on a corresponding region of the second computer model for each point identified on the first model”

TimeLapse practices these “identifying” claim elements under the adopted construction of “reference point” and “region.” (Tr. (Badler) at 455:25-458:14; CX-2125C (Badler Expert Rpt.) at ¶¶ 560-74.). TimeLapse [redacted]. (Tr. (Badler) at 455:25-456:16; CPX-0298C; CX-2251C (Minchenkov Dep. Tr.) at 99:23-105:2.). TimeLapse [redacted]. (Tr. (Badler) at 456:17-458:14; CPX-0309C; CX-2251C (Minchenkov Dep. Tr.) at 105:3-115:18.).

TimeLapse’s [redacted] (CX-2251C (Minchenkov Dep. Tr.) at 99:23-105:2.). This is shown in the source code in [redacted]. (*Id.*; CPX-0298C.). TimeLapse [redacted]. (CX-2251C (Minchenkov Dep. Tr.) at 105:3-110:15; CPX-0309C at line 57.). The [redacted]. (Tr. (Badler) at 457:17-458:14; CX-2251C (Minchenkov

Dep. Tr.) at 105:3-110:15; CPX-0309C.). In addition, the [redacted]. (CX-2251C (Minchenkov Dep. Tr.) at 99:23-105:2, 119:13-122:5.).

Thus, [redacted]. (*See id.*). In other words, because the [redacted]. (Tr. (Badler) at 455:25-456:10.). There is [redacted]. (*See* CX-2251C (Minchenkov Dep. Tr.) at 155:6-20.).

Dr. Mellor did not provide any testimony to dispute this functionality of TimeLapse during the Hearing. He merely testified that TimeLapse does not "subdivide" the second model into regions. (Tr. (Mellor) at 1732:12-1733:18.). However, there is no such requirement in the claim language for identifying or subdividing regions, only that the points are identified on corresponding regions. (JX-0002 at 13:16-21.). Dr. Badler's testimony with respect to how TimeLapse identifies reference points on corresponding regions thus is unrebutted.

For the reasons discussed above, Align has proven by a preponderance of evidence that the 661 DI Products practice elements [1.4] / [19.4] and [1.5] / [19.5] of claims 1 and 19, respectively, of the '661 patent.

iv. [1.6] / [19.6]: "matching the region of the first computer model with the corresponding region of the second computer model, using the identified reference points" / "ma[t]ch the region of the first computer model with the corresponding region of the second computer model, using the identified reference points"

TimeLapse matches the region or portion of the first and second computer models using the identified reference points. (Tr. (Badler) at 458:15-459:18; CX-2125C (Badler Expert Rpt.) at ¶¶ 575-81.). As discussed above in Section VIII.B.1(a)(i), TimeLapse [redacted]. (*See* CX-2251C (Minchenkov Dep. Tr.) at 99:23-110:15.). The [redacted]. (CPX-0323C; CX-2251C (Minchenkov Dep. Tr.) at 106:11-110:15.). [redacted]. (CPX-0324C ([redacted] at lines 77-93); CX-2251C (Minchenkov Dep. Tr.) at 106:11-110:15.). The [redacted]. (*Id.* at 111:4-115:18.). The [redacted]. (*Id.*; CPX-0309C at line 283.). The [redacted]. (Tr. (Badler) at 458:15-459:14; CPX-0309C at line 71, 283.). Thus, [redacted]. (CX-2251C (Minchenkov

Dep. Tr.) at 105:3-115:18.).

Accordingly, Align has proven by a preponderance of evidence that the 661 DI Products practice elements [1.6] and [19.6] of claims 1 and 19, respectively, of the ’661 patent.

v. [1.7] / [19.7]: “matching the first and second computer models as a whole, using the matched regions” / “match the first and second computer models as a whole, using the matched regions”

TimeLapse next matches the first and second computer models as a whole, using the matched regions. (Tr. (Badler) at 459:19-460:13; CX-2251C (Minchenkov Dep. Tr.) at 115:19-119:12; CX-2125C (Badler Expert Rpt.) at ¶¶ 582-88.). The [redacted]. (Tr. (Badler) at 459:19-460:13; CX-2251C (Minchenkov Dep. Tr.) at 115:19-119:12.).

Specifically, [redacted]. (Tr. (Badler) at 459:19-460:13; CX-2251C (Minchenkov Dep. Tr.) at 115:19-119:12.). There is [redacted]. (CX-2251C (Minchenkov Dep. Tr.) at 117:1-119:12; CPX-0309C at lines 11, 160-72.). TimeLapse [redacted]. (CX-2251C (Minchenkov Dep. Tr.) at 115:19-119:12; CPX-0309C.). Dr. Badler confirmed that this is illustrated in [redacted]. (Tr. (Badler) at 459:19-460:15.).

Moreover, the [redacted]. (CX-2251C (Minchenkov Dep. Tr.) at 115:9-116:25.).

For these reasons, Align has proven by a preponderance of evidence that the 661 DI Products practice elements [1.7] and [19.7] of claims 1 and 19, respectively, of the ’661 patent.

vi. [1.8] / [18.8]: "calculating positional differences between the teeth in their initial positions and the teeth in their positions in the second computer model, using the matched regions as non-moving reference regions" / "calculate positional differences between the teeth in their initial positions and the teeth in their positions in the second computer model, using the matched regions as non-moving reference regions"

TimeLapse calculates positional differences between the two (2) models, using the matched regions as non-moving reference regions. (Tr. (Badler) at 460:19-462:8; CX-1967C.0049-.0050; CX-2251C (Minchenkov Dep. Tr.) at 115:9-116:25, 121:16-122:5; CX-2125C (Badler Expert Rpt.) at ¶¶ 589-97.). TimeLapse can show tooth movement, gingival recession, and tooth wear. (CX-1967C.0049-.0050; CX-1798C; CX-1839.). To show these changes to the user, TimeLapse must calculate positional differences between the models. This is supported by the source code that [redacted]. (CPX-0306C; *see also* CX-1829C; CX-1582C.).

The [redacted]

[redacted]. (Tr. (Badler) at 460:19-462:18; CX-2251C (Minchenkov Dep. Tr.) at 115:9-116:25, 121:16-122:5.). This improves the accuracy of positional differences computed by the application. (Tr. (Badler) at 460:19-462:18; CPX-0306C; CX-2251C (Minchenkov Dep. Tr.) at 121:16-122:5.). In TimeLapse, [redacted]. (CPX-0309C; CX-2251C (Minchenkov Dep. Tr.) at 115:9-116:25, 121:16-122:5.). Thus, TimeLapse [redacted]. (Tr. (Badler) at 461:21-462:5; CPX-0309C at line 231.). This is illustrated and supported in [redacted]. (CPX-0306C at line 34.).

Accordingly, Align has proven by a preponderance of evidence that the 661 DI Products practice elements [1.8] and [19.8] of claims 1 and 19, respectively, of the ’661 patent.

b) Claims 2 and 20

i. [2.1] / [20.1]: "The method of claim 1, further comprising: displaying the positional differences between the teeth in the first and second models." / "The medium of claim 19, further comprising instructions to: display the positional differences between the teeth in the first and second models."

Claim 2 depends from claim 1, which is directed to a method for matching computer models of a jaw. TimeLapse displays the positional differences between the teeth by displaying and highlighting changes on a computer screen. (*See, e.g.*, Tr. (Badler) at 462:9-25; CX-1967C.0050.). This is shown and supported in [redacted] (CPX-0270C.).

Claim 20 depends from claim 19, which is directed to a computer readable medium containing code for matching computer models of a jaw comprising the claimed instructions. TimeLapse is a software tool for the iTero Element scanner hardware that enables a user to compare intraoral scans to monitor that patient's state and track changes. (CX-1967C.0003-.0007.). The software is loaded onto the computer and TimeLapse is thus code stored on a computer. (Tr. (Badler) at 463:1-13.). Additionally, TimeLapse includes instructions to display the positional differences between the teeth in the first and second models, as discussed for claim 19.

For the foregoing reasons, Align has proven by a preponderance of evidence that the 661 DI Products practice the additional elements [2.1] and [20.1] recited in claims 2 and 20, respectively, of the '661 patent.

C. Invalidity

1. Invalidity Overview

3Shape alleged that the claims 2 and 20 are invalid as obvious the combination of Commer (RX-0240)[52] with Ashmore (RX-0239).[53] (RBr. at 30-41; Tr. (Egbert) at 1077:16-1079:5.). For the reasons discussed below, 3Shape failed to demonstrate by clear and convincing evidence that Commer and Ashmore disclose all the elements of the asserted claims. Furthermore, 3Shape has not presented clear and convincing evidence that a person of ordinary

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[52] P. Commer, C. Bourauel, K. Maier, & A. Jager, *Construction and testing of a computer-based intraoral laser scanner for determining tooth positions*, Medical Engineering & Physics 22 (2000) 625-635 (received Oct. 5, 2000; accepted Nov. 22, 2000).

[53] Jennifer L Ashmore, DDS, MSD, Brenda F. Kurland, MS, EdM, Gregory J, King, DMD, DMSc, Timothy T. Wheeler, DMD, PhD, Joseph Ghafari, DMD, & Douglas S. Ramsay, DMD, PhD, MSD, *A 3-Dimensional Analysis of Molar Movement During Headgear Treatment*, Am J Orthod Dentofacial Orthop 2002;121:18-30 (2002).

skill in the art at the time of invention would have been motivated to combine Commer with Ashmore and would have had any reasonable expectation of success.

2. Obviousness

a) Claims 1 and 19[54]

i. [1.1] / [19.1]: "A method for matching computer models of a jaw, the method comprising" / "A tangible computer readable medium containing code for matching computer models of a jaw, the tangible computer readable medium comprising instructions to"

3Shape relied upon Commer as prior art for the preamble. (RBr at 31; Tr. (Egbert) at 1078:1-20.). However, Commer does not teach or suggest the claimed "method for matching computer models of a jaw." 3Shape's expert, Dr. Egbert, acknowledged that "[Commer] uses those pallet regions as he does the matching." (Tr. (Egbert) at 1120:2-9.). He conceded that "a pallet by itself is not a jaw." (*Id.* at 1107:4-7; *see also id.* at 1108:16-19.).

Accordingly, 3Shape has failed to meet its burden of proving by clear and convincing evidence that Commer teaches the preambles of claims 1 and 19.

ii. [1.2] / [19.2]: "loading a first computer model of a jaw having teeth in initial positions" / "load a first computer model of a jaw having teeth in initial positions"; [1.3] / [19.3]: "loading a second computer model of the jaw, wherein positions of at least some of the teeth in the second computer model are different than the initial positions" / "load a second computer model of the jaw, wherein positions of at least some of the teeth in the second computer model are different than the initial positions"

3Shape relied upon Commer for these limitations. (RBr. at 31-33; Tr. (Egbert) at 1078:1-20.). As Align pointed out, Commer does not teach or suggest the first and second "computer

[54] 3Shape did not separately address the elements of claim 19 in its Initial Post-Hearing Brief. (RBr. at 31-40.).

model of a jaw" as recited in the claim elements. To the contrary, Commer discloses separate models for the palate and molars for its method for determining molar movement. In particular, Commer discloses that "the data sets have been segmented ***into separate clouds*** of the palate, the moved molar and two further molars." (RX-0240.0008 (emphasis added).). A point cloud is a type of computer model, which Dr. Egbert acknowledged. (Tr. (Egbert) at 1106:7-9.). Thus, these are separate computer models.

Dr. Egbert also confirmed that Commer creates separate models for the palate and molars. (*Id.* at 1043:16-1044:11 ("[s]o once the two scans of teeth have been entered into the computer, the next thing that Commer does is separates the pallet points from the other points"); *see also id.* at 1107:16-24 ("Q. . . . Now, I want to take a look at a passage from Commer. As you can see, we have highlighted here, it states, 'surfaces have been generated from the point clouds and the data sets have been segmented into separate clouds of the palate, the moved polar and two further molars.' Did I read that correct, sir? A. I believe so.").). In other words, prior to any matching, Commer discloses creating separate models that are less than a jaw from the data sets, in particular, a palate model and separate molar models. (*See, e.g.*, RX-0240.0008.). Dr. Egbert confirmed this during cross-examination. (Tr. (Egbert) at 1107:1-12, 1107:25-1108:15.). Furthermore, Dr. Egbert testified that "[Commer] ***uses those pallet regions*** as he does the matching." (*Id.* at 1120:2-9 (emphasis added).).

3Shape's reliance on Figure 5 in Commer is misplaced because it appears that this figure is not relevant to Commer's disclosure for determining molar movement. (*Compare* RX-0240.0005-6 (discussing acquisition of data) *with* RX-0240.0008-9 (the method for determining tooth movements); *see also id.* at .0010 (Figure 8 illustrating the separate palate and molar models).). In fact, Dr. Egbert conceded on cross-examination that he was "not sure what figure 5 is" (Tr. (Egbert) at 1125:14-19) and that "Figure 8 does show what happens when you apply [Commer's] three steps" for determining molar movement (*id.* at 1125:20-23). (*See also id.* at 1125:24-1126:13.).

Because a model of a palate as disclosed in Commer is not a model of a jaw, 3Shape has failed to meet its burden of proving by clear and convincing evidence that Commer teaches these elements of claims 1 and 19.

iii. [1.4] / [19.4]: "identifying at least one reference point on a region of the first computer model, the region comprising a portion of the jaw other than the teeth" / "identify at least one reference point on a region of the first computer model, the region comprising a portion of the model other than the teeth"; [1.5] / [19.5]: "identifying a corresponding reference point on a corresponding region of the second computer model for each point identified on the first model" / "identify a corresponding reference point on a corresponding region of the second computer model for each point identified on the first model"

3Shape relied upon Ashmore for these limitations. (RBr. at 33-35; Tr. (Egbert) at 1078:1-20.). Ashmore does not teach or suggest the "identifying . . . on . . . [first/second] computer model" as recited in the claim elements. Rather, Ashmore discloses identifying points on plaster models prior to acquiring a digital model. In particular, Ashmore discloses that points were identified on a plaster cast models and "[t]he points were [then] marked with a 0.3-mm graphite pencil" prior to digitizing the points. (RX-0239.0003.). 3Shape appears to have disregarded this disclosure, and argued that "Ashmore's computer identifies reference points on non-tooth regions of the computer model ***during*** the digitization step." (RBr. at 34 (emphasis added).). 3Shape's argument is unsupported because Ashmore does not disclose an identification step of reference points occurring on a computer model. (*See generally*, RX-0239.0001-11.).

3Shape attempted to overcome this deficiency of Ashmore by advancing a new argument it did not raise in its Pre-Hearing Brief. (RPBr at 59-60; RBr. at 33-35.). In its Initial Post-Hearing Brief, 3Shape contended that these claim elements are met because "Ashmore further confirms that the digitized points are identified and present on the first computer model, e.g., the T1 computer model." (RBr. at 35.). 3Shape's argument is waived under Ground Rule 7.2. (*See also Certain Graphic Systems*, ID at 126-27.).

Because identifying points on a plaster model as disclosed in Ashmore is not identifying points on a computer model, 3Shape has failed to meet its burden of proving by clear and convincing evidence that Ashmore teaches these elements of claims 1 and 19.

iv. [1.6] / [19.6]: "matching the region of the first computer model with the corresponding region of the second computer model, using the identified reference points" / "ma[t]ch the region of the first computer model with the corresponding region of the second computer model, using the identified reference points"

3Shape relied upon Ashmore for this limitation. (RBr. at 35-36; Tr. (Egbert) at 1078:1-20.). The Commer-Ashmore combination does not teach or suggest the "matching the region of the first computer model [of a jaw] with the corresponding region of the second computer model, using the identified reference points" as required by the asserted claims.

As discussed above for claim elements [1.2] / [19.2] and [1.3] / [19.3], Commer does not disclose a computer model of a jaw. Therefore, to the extent one of ordinary skill in the art would have "exchange[d] Commer's matching step with Ashmore's matching step" as 3Shape asserted (RBr. at 35-36), this matching step in the combination would have occurred on a first and second model of a palate—not the jaw—as disclosed in Commer. (*See, e.g.*, RX-0240.0008.).

Accordingly, 3Shape has failed to meet its burden of proving by clear and convincing evidence that Ashmore teaches these elements of claims 1 and 19.

v. [1.7] / [19.7]: "matching the first and second computer models as a whole, using the matched regions" / "match the first and second computer models as a whole, using the matched regions"

3Shape relied upon Commer for this claim element. (RBr. at 36-37; Tr. (Egbert) at 1078:1-20.). Commer does not teach or suggest the second "matching the first and second computer models [of a jaw] as a whole, using the matched regions" as required by the asserted claims. 3Shape identified Commer's "final matching procedure" for this claim element. (RBr. at 36.). However, Commer does not disclose or suggest any matching of a first and second computer models as a whole. Rather Commer's final matching procedure merely operates on each individual molar.

For instance, Commer discloses that "[f]inal matching procedures of all transformed teeth of cast 2 to the corresponding teeth of cast 1 ***deliver*** the movement parameters (X, Y, Z, ϕ, θ , Ψ) from the function minimization ***for each individual molar***." (RX-0240.0008-9 (emphases added).). Commer also states that "[t]he result [of the final matching procedure] is shown in Fig. 8c" (*id.* at 0008), and Figure 8 describes that 8c is the "matching of the ***moved molar*** and the ***reference teeth***" (*id.* at 0010) (emphases added). In other words, Commer's final matching procedure is applied to each of the tooth models, i.e., three molars, for "deliver[ing] the [tooth] movement parameters" and, thus, only uses points in those tooth models and does not result in the superimposition of the whole jaw models as shown in Figure 8c. (RX-0240.0008-10.). Dr. Egbert acknowledged this on cross-examination, testifying that "a molar [i.e., tooth] is not a jaw" (Tr. (Egbert) at 1107:8-15) and that "a model of three molars [is not] an entire jaw" (*id.* at

1109:2-4.). Dr. Egbert also testified that in "figure 8, the entire jaw is not shown there." (*Id.* at 1110:3-13.).

Additionally, Commer does not disclose or suggest any matching of a first and second computer models as a whole, using the matched regions. As discussed directly above, Commer's final matching is applied to each of the tooth models to obtain the tooth movement parameters. (*See, e.g.*, RX-0240.0008-9.). Specifically, Commer discloses that these parameters are obtained "from the function minimization for each individual molar." (*Id.*). Commer provides that this function minimization (i.e., surface-surface matching) "defines the distance between the point clouds by the sum of the distances of each individual point in cloud one and two." (RX-0240.0008.). The final matching step as disclosed by Commer thus obtains the movement parameters for each individual molar by using only those points in the transformed individual molar of cast 2 to the corresponding individual molar of cast 1. (RX-0240.0008.). Dr. Egbert conceded this on cross-examination, agreeing that for this limitation "the region has to be more than—has to comprise the portion of the jaw other than the teeth." (Tr. (Egbert) at 1111:20-1112:12.). Because Commer's final matching step only involves matching of the teeth models, it cannot disclose or suggest this limitation for this additional reason.

Because any matching individual molar teeth disclosed in Commer is not the claimed matching the first and second computer model of a jaw as a whole, 3Shape has failed to meet its burden of proving by clear and convincing evidence that Commer teaches these claim elements.

vi. [1.8] / [18.8]: "calculating positional differences between the teeth in their initial positions and the teeth in their positions in the second computer model, using the matched regions as non-moving reference regions" / "calculate positional differences between the teeth in their initial positions and the teeth in their positions in the second computer model, using the matched regions as non-moving reference regions"

3Shape relied upon Commer for this claim element. (RBr. at 37-38; Tr. (Egbert) at 1078:1-20.). Commer does not teach or suggest "calculating positional differences between the teeth in their initial positions and the teeth in their positions in the second computer model, using the matched regions as non-moving reference regions" as required by the asserted claims. 3Shape asserted that "Commer teaches this element by describing a method that ***calculates*** translational and rotational 'movement parameters' – i.e., positional differences – of the moved teeth ***after*** the 'final' matching step." (RBr. at 37 (emphases added).).

3Shape mischaracterized Commer's disclosure to support its argument.[55] Contrary to 3Shape's assertion, Commer discloses that "[f]inal matching procedures of all transformed teeth of cast 2 to the corresponding teeth of cast 1 ***deliver*** the movement parameters (X, Y, Z, ϕ, θ, Ψ) from the function minimization ***for each individual molar***." (RX-0240.0008-9 (emphases added).). In other words, the final matching step in Commer delivers the tooth movement parameters for each individual molar. Thus, 3Shape is mapping a single prior art element in Commer to two claim elements, i.e., claim elements [1.7] / [19.7] and [1.8] / [19.8]. (*Compare* RBr. at 36 *with* RBr. at 37.).

Moreover, Commer determines movement parameters by using only the points on a

[55] 3Shape either mischaracterized Commer or erroneously attempted to use Commer to support its position when it does not. Commer should not have been used as prior art. This is the type of miscasting that is occurring far too frequently. There is line between "colorable" advocacy and that which is not.

tooth, which are not the claimed "matched regions." (*See, e.g.*, RX-0240.0008-9.). Dr. Egbert acknowledged on cross-examination that "the [matched] region has to be more than—has to comprise the portion of the jaw other than the teeth." (Tr. (Egbert) at 1111:20-1112:12.).

Because 3Shape relied upon the same disclosure of Commer for two (2) distinct limitations and because Commer fails to disclose or suggest "calculating positional differences . . . using the matched regions as non-moving reference regions," 3Shape has failed to meet its burden of proving by clear and convincing evidence that Commer teaches these claim elements.

b) Claims 2 and 20

i. [2.1] / [20.1]: "The method of claim 1, further comprising: displaying the positional differences between the teeth in the first and second models." / "The medium of claim 19, further comprising instructions to: display the positional differences between the teeth in the first and second models."

3Shape relied upon Commer for these claims. (RBr. at 38-39, 40-41; Tr. (Egbert) at 1078:23-1079:5.). Commer does not teach or suggest the "display[ing] the positional differences between the teeth in the first and second models." Commer merely discloses a figure illustrating the different stages in aligning point clouds—e.g., an initial model in white and a later model in black. (RX-0240.0010.).

3Shape appears to have relied upon Commer for the specific "computer readable medium" limitation. (RBr. at 40-41; Tr. (Egbert) at 1079:18-1080:4.). Commer does not contain any discussion of a computer readable medium and also is devoid of discussion of code or storing code for matching computer models. (RX-0240.0008.). To the extent that 3Shape relied upon Ashmore, Ashmore also does not contain a discussion of a computer readable medium, code or storing code for matching computer models. (RX-0239.0002-4.). Dr. Egbert failed to explain how Commer or Ashmore discloses or suggests a computer readable medium for storing code for matching computer models. (*See, e.g.*, Tr. (Egbert) at 1079:25-1080:10.).

Accordingly, 3Shape has failed to meet its burden of proving by clear and convincing evidence that either Commer or Ashmore teaches these claim elements.

3. 3Shape Failed to Present Any Evidence of Motivation to Combine or Reasonable Expectation of Success

3Shape failed to present clear and convincing evidence that a person of ordinary skill in the art at the time of invention would have been motivated to, or had a reason to, combine Commer with Ashmore and would have a reasonable expectation of success. 3Shape argued that one of ordinary skill in the art would have combined Commer with Ashmore because "a POSITA would have recognized that the Ashmore modification results in a more accurate matching" and by "us[ing] a select number (e.g., eight) of reference points on a specifically stable region [would] improve processing speed and reduce processing burden." (RBr. at 40.).

3Shape's rationale for combining Ashmore with Commer ignores that Ashmore expressly teaches away from using its disclosed methodology for matching two models. *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994) ("A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be ***discouraged*** from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant . . . [or] if it suggests that the line of development flowing from the reference's disclosure is ***unlikely to be productive of the result sought*** by the applicant.") (emphases added).).

Here, Ashmore expressly discloses that its methodology is undesirable for application in orthodontics because of poor results in measuring molar movements. (RX-0239.0001; *see also* Tr. (Egbert) at 1112:21-1113:5.). For example, Ashmore states "[t]he ***reliability*** of the method for computing rotation of maxillary molars was ***poor***." (RX-0239.0006 (emphases added); *see also* Tr. (Egbert) at 1113:6-16, 1113:21-1114:11.). In particular, "the large standard deviations for rotations (7°- 11°) indicate an ***unacceptably large measurement error***." (RX-0239.0006 (emphasis added); *see also* (Tr. (Egbert) at 1113:6-1115:2.).

Moreover, one of ordinary skill in the art would not have been motivated to incorporate Ashmore's methodology into Commer's for measuring molar displacement where the combination of Ashmore would make Commer "inoperable for its ***intended purpose***." *Plas-Pak Indus., Inc. v. Sulzer Mixpac AG*, 600 F. App'x 755, 758 (Fed. Cir. 2015) (emphasis added). As Commer discloses, precision and accuracy in the measurement of molar displacement is an indisputably important factor in orthodontics. (RX-0240.0009 (stating that the error should ideally be zero).). Commer states that "[a]n error [in measurement] of up to 10% should be adequate" for orthodontic application where the tooth movement can range up to "several 10 degrees for rotations." (RX-0240.0009; Tr. (Egbert) at 1116:20-1117:7.). Despite these disclosures in Commer, Dr. Egbert testified that he was "not sure exactly what that accuracy needs to be," or what the reliability needs to be, for measuring rotation in the field orthodontics. (Tr. (Egbert) at 1118:22-1119:8.).

3Shape offered the combination of Commer and Ashmore "to exchange Commer's matching step, which uses all points of the segmented palate point cloud, with Ashmore's matching step, which uses the digitized reference points on the palatal rugae." (RBr. at 39-40.).

However, as Align noted, 3Shape did not provide provide any weighting or balancing of benefits, both lost and gained, for this alleged combination. *See, e.g.*, *Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1349 at n.8 (Fed. Cir. 2000). Furthermore, 3Shape violated the "longstanding principle that the prior art must be considered for all its teachings, not selectively" because 3Shape neither considered the intended purpose of Commer nor the express criticisms in Ashmore. *See, e.g., Merck & Cie v. Gnosis S.p.A.*, 808 F.3d 829, 834-35 (Fed. Cir. 2015). 3Shape merely relied upon the unsubstantiated testimony of its expert that he has not "experimented with putting [Commer and Ashmore]" together (Tr. (Egbert) at 1116:10-19), he had not "writt[en] any software program that involve superimposing two or more digital models" (*id.* at 1105:17-20), and he does not have any experience with applying techniques in computer graphics to dentistry or orthodontics (*id.* at 1105:17-20). Thus, 3Shape did not offer any credible evidence to support 3Shape's conclusory contention that Commer combined with Ashmore would improve both its efficiency and accuracy.

For the reasons discussed above, 3Shape has failed to prove by clear and convincing evidence that asserted claims 2 and 20 of the '661 patent are invalid.

IX. U.S. PATENT NO. 8,102,538

A. Infringement

1. Infringement Overview

Align has failed to prove by a preponderance of the evidence that the 538 Accused Products satisfy the limitations of claims 1 and 2 of the '538 patent.

Specifically, the 538 Accused Products lack the claimed "optical scanner" that is separate and distinct from the claimed "imaging means." The '538 patent teaches the use of an optical scanner to capture depth data and a distinct imaging means to capture color data. (JX-0003 ('538 patent) at 25:11-14 ("any suitable means for providing 3D scanning can be used so long as the 3D scan and the color 2D scan correspond substantially to the same object or portion thereof being scanned, and the same frames of references are maintained.").).

The 538 Accused Products operate not by separating these functionalities, but instead by combining them, such a single mechanism is used to *capture* a cohesive set of pixel information used to calculate both the color *and* depth contours of a scanned object. Specifically, the 538 Accused Products: [redacted]. In other words, the 538 Accused Products possess only the claimed "imaging means." There is no separate "optical scanner" for capturing only depth data.

Table No. 8: Claims 1 and 2 of the '538 Patent

Cl. 1	Element	Satisfied (Y/N)
[1.1] (preamble)	A device for determining the surface topology and associated color of at least a portion of a three dimensional structure, comprising:	Y
[1.2]	optical scanner configured for providing depth data of the portion corresponding to a two-dimensional reference array substantially orthogonal to a depth direction;	N
[1.3]	imaging means configured for providing two-dimensional color image data of the portion associated with the reference array;	Y
[1.4]	wherein the device is configured for maintaining a spatial disposition with respect to the portion that is substantially fixed during operation of the optical scanner and the imaging means.	N
Cl. 2	Element	
[2]	The device according to claim 1, wherein the operation of the optical scanner is based on confocal imaging techniques.	Y

2. The Accused Products Do Not Practice Claims 1 and 2 of the '538 Patent Literally or Under the Doctrine of Equivalents

a) [1.1]: "A device for determining the surface topology and associated color of at least a portion of a three dimensional structure, comprising:"

As shown below in Figure 8, the 538 Accused Products[56] are devices for "determining the surface topology and associated color of at least a portion of a three dimensional structure." (Tr. (Stevenson)[57] at 863:1-864:13; CDX-0014C.0028-29.). Dr. Stevenson testified, and 3Shape's engineer, Mr. Kristian Hansen,[58] verified, that the TRIOS scanner [redacted] in order to render a 3D model of a 3D object (e.g., teeth, gums, etc.). (Tr. (Stevenson) at 860:5-23; Tr. (Hansen) at 1238:19-23; CDX-0014C.0026; CX-0351C.0002.). 3Shape's expert, Dr. James Zavislan,[59] corroborated that the TRIOS scanners "are devices for

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[56] The Accused TRIOS scanners include all versions of the TRIOS 3 and TRIOS 4 currently for sale in the United States. (Tr. (Stevenson) at 846:12-24; Joint Stipulation Regarding Representativeness of the TRIOS 3 Products ("Trios 3 Rep. Product Stip.") (Doc ID No. 691981 (Oct. 23, 2019)); CX-2164C; CX-0387C; CX-0388C; CX-0389C; CX-0391C; CX-0392C; CX-0975C.).

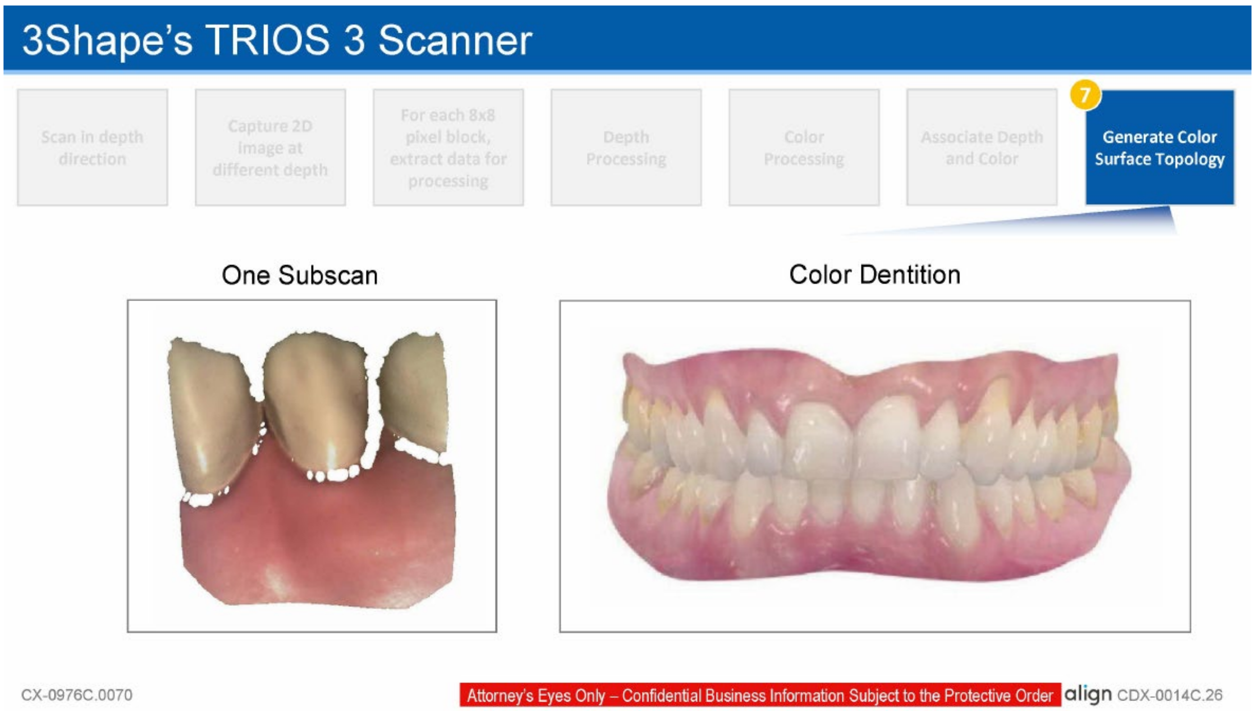
[57] When he testified during the Hearing on October 28, 2019, Dr. Robert Stevenson was an Associate Chair of the Department of Electrical Engineering at the University of Notre Dame. (CPSt. at Ex. 3.). Align identified Dr. Stevenson as an expert witness to testify to "the technical background of the '538 Patent; the interpretation of claims in those patents; the design, manufacture, structure, function, and operation of the accused products and any article or method asserted to be protected by the asserted patents; the knowledge of a person of ordinary skill in the art; the scope of the prior art; other issues in connection with infringement, validity, enforceability and/or the technical prong of the domestic industry requirement; and any other technical issues that may arise." (CPSt. at 11.). Align indicated that Dr. Stevenson "may also be called to rebut the testimony of Respondents' expert or fact witness, should any be presented, regarding the same." (CPSt. at 12.).

[58] When he testified during the Hearing on October 30, 2019, Mr. Kristian Hansen was a project manager at 3Shape A/S. (Tr. (Hansen) at 1183:25-1184:4.). 3-Shape identified Mr. Hansen as a fact witness to testify "regarding 3Shape's design and development of its Trios intraoral scanners and the structure, function, and operation of those products." (RPSt. at 2.).

[59] When he testified during the Hearing on October 31, 2019, Dr. James Zavislan was an Associate Professor of Optics at the University of Rochester Institute of Optics, having worked in that position since 2002. (Tr. (Zavislan) at 1614:3-13.). Prior to his career as a professor, Dr. Zavislan earned his Ph.D. from the University of Rochester in 1988 and worked for five years at IBM Almaden Research Center.

determining the surface topology and an associated color of at least a portion of a three-dimensional structure." (Tr. (Zavislan) at 1681:7-11.). Certain 3Shape documents confirm that the TRIOS meets the preamble of claim 1. (CX-0318C.0001, 3; CX-0333C; CX-0386C.0003; CX-0388C.0003, 5; CX-0397C.0002; CX-0810C.0011; CX-0815C.0035.).

Figure 8: Align's Depiction of the 538 Accused Products Determining "Surface Topology" and Associated Color of Scanned Object



(CDX-0014C.0026 (introduced during the testimony of Dr. Stevenson).).

In its Reply Post-Hearing Brief, 3Shape contended that the 538 Accused Products fail to satisfy the preamble of claim 1 because they do not determine "surface topology." (RRBr. at 59-60.). However, 3Shape did not raise or address this argument in its Pre-Hearing Brief and thus

(*Id.* at 1613:1-25.). He also co-founded a medical imaging company called Lucid and led the optical development on the VivaScope 1000 system, which performed in vivo measurement of skin and oral tissues for cancer diagnoses. (*Id.*). 3-Shape identified Dr. Zavislan as an expert witness to testify "regarding the invalidity of Align's U.S. Patent No. 8,102,538 (the ''538 patent')." (RPSt. at 5.).

waived the argument pursuant to Ground Rule 7.2. (RPBr. at 103-104.).

Accordingly, Align has proven by a preponderance of evidence that the 538 Accused Products practice element [1.1] of the ’538 patent.

b) [1.2]: “optical scanner configured for providing depth data of the portion corresponding to a two-dimensional reference array substantially orthogonal to a depth direction;”

i. Align Failed to Prove Literal Infringement of “Optical Scanner”

The Parties’ disputed whether the 538 Accused Products possess the claimed “optical scanner” required by asserted claims 1 and 2. According to Align, referencing the contested *Markman* construction of this term, each 538 Accused Product is “a device that uses light projection to capture data other than color image data,” literally or under the doctrine of equivalents. (CBr. at 80-89; *Markman* Order, App. A at 42.). 3Shape challenged this description and argued that the 538 Accused Products cannot possess an “optical scanner” because the [redacted] that Align identified as purportedly part of the “optical scanner” enables the scanner to *capture* precisely what the claim construction says an “optical scanner” cannot *capture*: color image data. (RRBr. at 51 (citing Tr. (Mike van der Poel)[60] at 1584:7-1585:18, 1609:22-1610:6, 1610:10-24; (Tr. (Zavislan) at 1634:21-1635:4, 1635:14-1636:7, 1656:7-15, 1658:18-1659:7, 1659:12-1660:16) (emphasis added).).

However, the 538 Accused Products do not contain an “optical scanner,” literally or under the doctrine of equivalents. What Align identifies as the “optical scanner” captures color

[60] When he testified during the Hearing on October 31, 2019, Mr. Mike van der Poel held the position of Scanner Manager and Director of New Business Ventures with 3Shape. (Tr. (Poel) at 1577:5-20; CX-2276 at 10:25-11:9.). 3Shape identified Mr. Van der Poel as a fact witness who was called to testify regarding 3Shape’s design and development of its TRIOS intraoral scanners and the structure, function, and operation of those products. (RPSt. at 3.).

image data in violation of the claim construction for that term.

Figure 9: Align's Depiction of the Accused TRIOS Scanner Showing [redacted]

[redacted]

(CDX-0014C.0019 (introduced during Dr. Stevenson's testimony).).

To obtain depth and color information for a portion of an object, the 538 Accused Products perform subscans, as shown below in Figure 10. (CX-0558C.0005-6; Tr. (Hansen) at 1185:9-1188:9.). A subscan consists of a [redacted]. (CX-0386C.0008 ("A 3D image (scan) is obtained by [redacted]."); CX-0558C.0009 ("a single subscan [redacted]"); Tr. (van der Poel) at 1602:11-15.). The 538 Accused Products generate a subscan by using: (1) [redacted]; and

(2) [redacted] that comprise the subscan. (RX-0569C.0008; Tr. (Zavislan) at 1631:22-1632:10.).

Figure 10: Align's Depiction of 538 Accused Products Performing Multiple Subscans and, for Each Scan, [redacted]

[redacted]

(CDX-0014C.0022 (introduced during the testimony of Dr. Stevenson).).

The 2D subscans capture data that are then used to determine the 3D depth and color of the resulting 3D model. (RRBr. at 50.). For 3D depth data, [redacted]

[61] The image sensor consists of a set of red, green, and blue color filters arranged in front of the photosensors in the image sensor. (RX-0430C at 51:5-52:25; Tr. (van der Poel) at 1591:20-1592:16, 1631:9-18.). The [redacted]. (RX-0430C at 63:14-64:17; Tr. (van der Poel) at 1591:20-1592:16.).

[redacted] are used. [redacted], as shown below in Figure 11. (CX-1204C.0010, 21.).

To determine depth for a single point, [redacted]. (Tr. (Stevenson) at 851:13-852:6, 856:23-859:4; RPBr. at 94; CDX-0014C.0022-23.). [redacted]. (Tr. (Stevenson) at 848:3-17; CDX-0014C.0019.). The images each [redacted]. [redacted]. (Tr. (Stevenson) at 856:23-858:18; CDX-0014C.0023.). The 538 Accused Products use [redacted] to calculate depth measurements. (CBr. at 79.).

Figure 11: Align's Depiction of Depth Processing in the 538 Accused Products

[redacted]

(CDX-0014C.0023 (introduced during the testimony of Dr. Stevenson).).

To collect color data, the image sensor includes pixels fitted with red, green, and blue filters. (Tr. (Stevenson) at 848:3-17.). As shown below in Figure 12, the 538 Accused Products calculate color using the red, green, and blue pixels [redacted]. (Tr. (Stevenson) at 859:4-860:4; CDX-0014C.0025.). The color values of those particular red, green, and blue pixels [redacted]. (Tr. (Stevenson) at 858:19-859:4; CDX-0014C.0024.). The color is then associated with the depth [redacted]. (Tr. (Stevenson) at 859:4-860:4; CDX-0014C.0025.). The 538 Accused Products then stitch together information from multiple subscans to create a 3D model. (Tr. (Stevenson) at 860:5-23; CDX-0014C.0026.).

Figure 12: Align's Depiction of Color Processing in the 538 Accused Products

[redacted]

(CDX-0014C.0024 (introduced during the testimony of Dr. Stevenson).).

3Shape contended, as shown above in Figure 12, that the color image sensor in the 538 Accused Products *captures* all the light reflected from the scanned object, using red, green, and blue pixels of the color image sensor. (Tr. (Stevenson) at 983:17-984:2, 995:9-16; Tr. (van der Poel) at 1584:7-1585:18; Tr. (Zavislan) at 1635:14-1636:7, 1658:18-1659:7.). Yet, as explained above, [redacted]. Instead, Dr. Stevenson and Dr. Zavislan agreed, as shown above in Figure 12, that the 538 Accused Products derive depth data by [redacted] when a subscan is performed.[62] (Tr. (Stevenson) at 849:18-850:4, 851:13-852:6, 858:13-18, 865:3-867:15, 987:4-8; CDX-0014C.0032-36; Tr. (Zavislan) at 1660:1-16; CX-0668C; CX-0978C.0006; CX-1204C.0009; Tr. (Hansen) at 1241:24-1242:7; Tr. (van der Poel) at 1603:17-23.).

Moreover, [redacted]. (Tr. (Stevenson) at 859:4-860:4; CDX-0014C.0025.). To Align, the [redacted] demonstrates the independence of depth and color data in the 538 Accused Products. (CBr. at 82-83.).

Against this backdrop, Align asserted that its expert, Dr. Stevenson, "testified that the

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[62] The 538 Accused Products generate depth data using a [redacted]. (Tr. (van der Poel) at 1582:13-1583:10; CX-0554C.0005.). [redacted]. (Tr. (van der Poel) at 1582:13-1583:10; CX-0554C.0005; *see also* Tr. (Zavislan) at 1620:14-1621:15; RDX-0007.0007.). The 538 Accused Products use [redacted]. (Tr. (van der Poel) at 1582:13-1583:10.).

TRIOS provides depth data by [redacted] (CBr. at 80 (emphasis added).). This attempted sleight of hand is a mischaracterization of the record. Dr. Stevenson actually testified that the "optical scanner" of the TRIOS [redacted]. His exacts words were: "it is an optical scanner configured to [redacted] (Tr. (Stevenson) at 865:25-866:2 (emphasis added).).

Align's mischaracterization of Dr. Stevenson's testimony, together with its distortive wordsmithing illustrates how Align's infringement position flies in the face of the *Markman* Order without formally challenging the claim construction that was adopted. The *Markman* Order clearly explains that "the 'optical scanner' does not capture color image data." Moreover, the *Markman* Order also explains that the adopted construction of "optical scanner" "effectively restores the depth and color data independence touted by the patentee and used by the patentee to overcome Mueller," a prior art reference that the patentee distinguished during prosecution of a related patent. (*Markman* Order, App. A at 54.).

In line with the *Markman* Order, Dr. Stevenson did not testify that the purported "optical scanner" of the TRIOS *captures* "data other than color image data." He could not have testified in this way without deviating from either the facts or the *Markman* Order. Nevertheless, in direct contravention of the *Markman* Order, and without the support of either expert, Align insisted on mapping the "optical scanner" limitation onto functionality that explicitly captures color image data and, thus, cannot be an "optical scanner."

Align also stated wrongly that its infringement theory is in line with "[t]he rationale behind the court's claim construction." (CBr. at 82 ("The function of the claimed 'optical scanner' is to [redacted] Order No. 36 at 46 (citing JX-0003 at 12:21-23.). This is [redacted]).). In so doing, Align made a critical error. Align ignored the express language of the adopted claim construction, which targets what data are *captured* by the "optical scanner:" "a device that uses light projection to capture data other than color image data." (*Markman* Order, App. A at 42.).

Within the 538 Accused Products, the purported "optical scanner" clearly [redacted], as Dr. Stevenson acknowledged. Therefore, the Accused Products cannot satisfy the claim construction contrary to Align's unsuccessful attempt at revisionism. (Tr. (Stevenson) at 983:13-984:2 (conceding that the output of the pixels of a color image sensor would constitute color image data).). As 3Shape explained: [redacted] constitute color image data. … The fact that only the [redacted] derive depth does not change the fact that the captured image data is color image data." (RRBr. at 51-52 (citing Tr. (van der Poel) at 1592:17-21; Tr. (Zavislan) at 1660:1-16).).

Align also tried to suggest that the '538 patent discloses embodiments that operate like the 538 Accused Products. (CBr. at 82.). Align argued:

> For example, the '538 patent discloses a color CCD for capturing red, green, and blue reflected from white illumination and using the red channel to determine depth. … Thus, this embodiment illustrates the dual use of [white light] image data—for both depth data and 2D color image data.

(*Id*.).

Align's diversionary tack is unavailing for two (2) reasons. First, the time for claim construction passed months ago. The *Markman* Order states that: "the 'optical scanner' does not capture color image data" and that the adopted construction of "optical scanner" "effectively restores the depth and color data independence touted by the patentee[.]" (*Markman* Order, App. A at 54.). To the extent that Align tried to use embodiments disclosed in the specification of the '538 patent to reargue claim construction, it is too late. Moreover, Align has not addressed the relevance of these embodiments in light of the prior art, Mueller and, in particular, the patentee's comments during prosecution with respect to how the claimed invention overcame Mueller. (*Markman* Order, App. A at 54.).

Second, it appears that none of the embodiments from the '538 patent to which Align cited describes deriving depth data from a color image sensor capturing white illumination. (Tr. (Zavislan) at 1686:19-22.). Where the '538 patent describes the use of white light illumination and a color image sensor, the '538 patent does so in the context of capturing a 2D color image. (*See* JX-0003 ('538 patent) at 23:43-46 ("According to a second technique for providing the aforesaid 2D color image ….").). Passages in the '538 patent that Align cited describe the use of a color CCD in conjunction with monochromatic (not white light) illuminations. (*See* JX-0003 at 24:13-17 (referring to the sixth embodiment, described at 23:6-42, which describes the use of red, blue, or green illuminating radiations for obtaining depth data).). Align also cited to embodiments that use different monochromatic illuminations and a monochromatic image sensor. (*See* JX-0003 ('538 patent) at 16:37-23:42 (using different colored illuminations and a monochrome image sensor), 19:44-48 (generating monochromatic data from a monochromatic illumination).). Yet, missing from the specification is an embodiment that functions like the 538 Accused Products.

Thus, based upon the explanations and distinctions provided above, Align's bald attempt to read "optical scanner" on the 538 Accused Products fails because Align's argument is not supported by the operation of the 538 Accused Products, by the constructions in the *Markman* Order, or the intrinsic evidence. Align should not have asserted this argument. It involved testimony mischaracterization and an unfortunate twisting of the *Markman* Order, not to mention the patent specification.

ii. Align Failed to Prove Infringement of "Optical Scanner" Under the Doctrine of Equivalents

Align also failed to prove by a preponderance of the evidence that the 538 Accused Products possess an "optical scanner" under the doctrine of equivalents. Align recognized that the patentee's previously discussed amendment over Mueller led to the narrowing claim construction that thwarted Align's attempt to prove literal infringement, as explained above. (CBr. at 87.). Align nevertheless argued that "'the rationale underlying the … amendment [bears] no more than a tangential relationship to the equivalent in question.'" (*Id*. (citing *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd*., 344 F.3d 1359, 1369–70 (Fed. Cir. 2003).). According to Align, "[i]n allowing the claims, the Examiner stated that Mueller disclosed 'using the color information from a series of two dimensional color images to derive the three dimensional location in space of the surface points which produced the color images.'" (*Id*. (citing CX-2178.0239).). By contrast, the 538 Accused Products purportedly "associate two independent sets of data, the exact limitation that was added to overcome Mueller." (*Id*.).

Align's argument here is unavailing because it selectively focuses on the language of the claim amendment while ignoring the patentee's justification for the amendment. As the patentee explained in making the amendment, "depth data is *obtained independently* of the colour data, and the two sets of data are combined by conformally mapping or associating the colour data with the depth data for a given two-dimensional array of points." (CX-2178 at 170-72 (emphasis added).). As shown below in Figure 13, and as discussed at length above, the 538 Accused Products do not capture or obtain depth data independently of color data. Instead, the 538 Accused Products collect [redacted], on the one hand, and [redacted], on the other hand. They then [redacted]. The underlying data comes from a cohesive source – the subscans.

Figure 13: Align's Depiction of Collecting a [redacted]

[redacted]

(CDX-0014C.0025 (introduced during the testimony of Dr. Stevenson).).

In other words, the 538 Accused Products determine depth data directly from, not independent of, captured color image data. (Tr. (van der Poel) at 1592:17-21, 1610:2-6, 1656:7-

15, 1658:18-1659:7.). Indeed, "[t]he Trios 3/4 captures [redacted] [.]" (RRBr. at 51-52 (citing Tr. (van der Poel) at 1592:17-21; Tr. (Zavislan) at 1660:1-16).). Consequently, the operation of the 538 Accused Products is a substantial departure from the claimed "optical scanner," which is explicitly forbidden from capturing color image data. (Order No. 36, Appx A at 54.).

Pursuant to patent prosecution principles, Align is barred from using the doctrine of equivalents to recapture subject matter the patentee disavowed during prosecution. *Augme Technologies, Inc. v. Yahoo! Inc.*, 755 F.3d 1326, 1335 (Fed. Cir. 2014) (DOE cannot "encompass a structural feature that is the opposite of, or inconsistent with, the recited limitation"). Notwithstanding Align's assertions to the contrary, using 2D color scans to derive 3D depth and color topology is the same concept the patentee disclaimed during prosecution. (CX-2178. at 238 ("Mueller discloses using the color information from a series of two dimensional color images to drive the three dimensional location in space of the surface points which produced the color images").). Align cannot now, in the throes of litigation, reclaim claim scope that it previously abandoned.

Based on the analysis above, Align has failed to prove that the 538 Accused Products satisfy the "optical scanner" limitation of claims 1 and 2 under the doctrine of equivalents.

iii. Align Proved Infringement of the Remainder of Element [1.2]: "configured for…"

According to Align, the 538 Accused Products are "configured for providing depth data of the portion corresponding to a two-dimensional reference array substantially orthogonal to a depth direction." (CBr. at 84.). Dr. Stevenson's testimony and supporting documentary evidence prove that, as shown below in Figure 14, the 538 Accused Products provide depth data such that depth direction is defined by the [redacted]. (Tr. (Stevenson) at 931:8-933:17; CX-0722C; CX-0723C; CX-0978C.0006; CDX-0014C.0037-39, 41; CX-0464C; CX-0978C.0016; CX-2279C:21:10-15; CX-2276C:155:25-156:14.). The supporting documents together with Dr. Stevenson's testimony are consistent with the language of the '538 patent, which states that the image sensor may define a two-dimensional (X-Y) "frame of reference." (JX-0003 ('538 patent) at 10:55-57, 12:65-13:1 ("Detection optics 60 comprises an image sensor, typically a CCD…, and which typically defines the X-Y frame of reference."), 15:30-65, 21:48-50 ("the depth scan is obtained by displacing the objective [lens] 166 along the Z-direction in a continuous or stepped motion").). Dr. David Schaafsma,[63] 3Shape's invalidity expert, and Dr. van der Poel, a 3Shape technical employee, agreed that the claimed two-dimensional reference array can reside at the image sensor. (Tr. (Schaafsma) at 1348:8-11; Tr. (van der Poel) at 1594:17-1595:4.).

[63] When he testified during the Hearing on October 31, 2019, Dr. David Schaafsma was the President of California Optical Engineering, Inc. (RPSt. at Ex. E.). 3Shape identified Dr. Shaafsma as an expert called to testify with respect to the invalidity of the '538 patent.

Figure 14: Align's Depiction of How the 538 Accused Products Satisfy the "Configured For …" Language of Claim Element [1.2] of the '538 Patent

[redacted]

[redacted]

(CDX-0014C.0037, 39 (introduced during the testimony of Dr. Stevenson).).

In its Reply Post-Hearing Brief, 3Shape did not dispute Align's assertion that the 538 Accused Products satisfy the "configured for …" portion of limitation [1.2]. (RRBr. at 50-60.). Thus, 3Shape has waived any such argument for all purposes pursuant to Ground Rule 10.1.

Accordingly, based upon the evidence and the analysis provided, Align has proven by a preponderance of evidence that the 538 Accused Products practice the "configured for …" portion of limitation [1.2] of the '538 patent, but not the "optical scanner" portion of that limitation.

c) [1.3]: "imaging means configured for providing two-dimensional color image data of the portion associated with the reference array;"

Align has proven that the 538 Accused Products possess the claimed "imaging means." (Tr. (Stevenson) at 938:15-939:14; CDX-0014C.0042.). The 538 Accused Products provide two-dimensional color image data via the [redacted], as explained above in Section IX.A.2(b)(i). (Tr. (Stevenson) at 938:15-939:14, 940:6-22; CX-0722C; CX-0723C; CX-0978C.0006.). Dr. Stevenson testified that, as shown below in Figure 15, the 538 Accused Products include [redacted] for providing 2D color image data. (Tr. (Stevenson) at 939:15-940:22; *see also* CX-0427C; CX-0428C; CX-0430C; CX-0431C; CX-0547C; CX-0722C; CX-0723C; CX-0978C.0006; CDX-0014C.0043.). The 538 Accused Products also include a color image sensor [redacted] that detects the intensity of the white illumination reflecting from the scanned object. (Tr. (Stevenson) at 849:7-17, 940:6-22; CX-0382C.0001; CX-0460C; CX-0462C; CX-0723C; CX-0863C; CX-0976C.0012; CX-0978C.0006; CDX-0014C.0044.). The "imaging means" provide two-dimensional color image data by using information collected by the sensor's red, green, and blue pixels and, in particular, by using only the [redacted]. (Tr. (Stevenson) at 851:13-852:6, 856:15-21, 939:7-11.).

Figure 15: Align's Depiction of "Imaging Means" of Claim Element [1.3] of the '538 Patent

[redacted]

(CDX-0014C.0044 (introduced during the testimony of Dr. Stevenson).).

Based upon the evidence presented and corresponding testimony, there is no dispute that the 538 Accused Products include the structure recited in element [1.3].

However, in its Reply Post-Hearing Brief, 3Shape made a tortured argument about how the claimed "reference array" in element [1.2] (for the "optical scanner") must, but does not, match the claimed "reference array" in element [1.3] (for the "imaging means"). (RRBr. at 58-59.). 3Shape claimed that, while the 538 Accused Products calculate depth data using [redacted], the Accused Products calculate color image data for each [redacted]

[redacted]. (*Id*.). This argument is suspect on its face[64] and akin in archery to an assertion that, within a single target, the yellow bull's eye, on the one hand, and surrounding rings, on the other hand, are not part of the same frame of reference for an archer. Moreover, pursuant to Ground Rule 7.2, 3Shape waived the argument by not raising it in its Pre-Hearing Brief. (*See* RPBr. at 110-111).

Accordingly, based on the analysis provided, Align has proven by a preponderance of evidence that the 538 Accused Products practice element [1.3] of the '538 patent.

d) [1.4]: "wherein the device is configured for maintaining a spatial disposition with respect to the portion that is substantially fixed during operation of the optical scanner and the imaging means."

The 538 Accused Products satisfy this claim element. (Tr. (Stevenson) at 940:23-943:16; CX-0395C.0001; CX-0979C.0002; CX-2279C (van der Poel Dep. Tr.) at 105:10-22; CDX-0014C.0046-47.). In those Accused Products, the operation of the optical scanner and imaging means "is at least substantially or effectively simultaneous such that movement (i.e., a change in spatial disposition) can be ignored and depth data and color data correspond to the same reference array." (*Markman* Order, App. A at 64-65; Tr. (Stevenson) at 942:17-943:16; CDX-0014C.0048-49.). This is because, as Dr. Stevenson testified, the 538 Accused Products

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[64] Element [1.2] requires "providing depth data of the portion corresponding to a two-dimensional reference array." (JX-0003 ('538 patent), cl. 1.). Element [1.3] requires "providing two-dimensional color image data of the portion associated with the reference array." (*Id*.). According to the '538 patent, the purpose of the reference array is "associating said color data with said depth data." (*Id*. at 5:14-15.). Based on the description above with respect to how the 538 Accused Products operate, the two-dimensional image sensor in general, and the [redacted] generated by the image sensor in particular, clearly serve to match the color and depth data within a (X-Y) "frame of reference" delineated by the [redacted]. Elements [1.2] and [1.3] merely require that depth data and color data "correspond[] to" or "associate[] with" the required reference array. (*Id*., cl. 1.). In the 538 Accused Products, that matching occurs at the level of a [redacted]. Claim 1 does not require that the matching of color or depth occur on a pixel-by-pixel basis. (*Id*.).

complete a subscan in [redacted]. (Tr. (Stevenson) at 940:23-941:25; CX-0352C.0002; CX-0395C.0001; CX-0979C.0001; CDX-0014C.0046.).

That level of speed is consistent with the teachings of the patent, in which 50 milliseconds is offered as an example of a time interval for “acquisition of said depth data and said color image data such that substantially no significant relative movement between said device and said portion occurs,” as shown below in Figure 16. (JX-0003 (’538 patent at 5:7-12; *see also* Tr. (Stevenson) at 845:4-846:1; CDX-0014C.0015.). Additional proof was provided by 3Shape’s corporate representative, Dr. Mike van der Poel, [65] who stated that the 538 Accused Products [redacted] (CX-2279 (van der Poel Dep. Tr.) at 105:10-22, 106:5-7, 123:11-125:24.).

[65] Mr. Mike van der Poel gave his deposition testimony on June 12, 2019. (CX-2279.). As recently as May 24, 2018, he held the position of Scanner Manager and Director of New Business Ventures with 3Shape. (CX-2276 at 10:25-11:9.).

Figure 16 Align's Depiction of the Speed At Which the 538 Accused Products Perform Subscans (Capable of Performing a Subscan [redacted])

[redacted]

(CDX-0014C.0046 (introduced during the testimony of Dr. Stevenson).).

Moreover, as explained above, the 538 Accused Products function such that there is little risk of movement causing a mismatch of depth and color data. That is so for [redacted]. (Tr. (Stevenson) at 859:4-860:4 (color is calculated using the [redacted], 943:3-10; CX-0722C; CX-0723C; CDX-0014C.0025, .0049.). A 3D color topology is created by processing myriad 2D images within a subscan and, from those images, choosing and assembling only the [redacted] (including their [redacted]). (Tr. (Stevenson) at 859:4-860:23; CDX-0014C.0025-26.). That is why movement of a 538 Accused Product during a subscan can cause distortions in the spatial disposition of the reference array, making it difficult to assemble a [redacted].[66] (*See id*.). However, within a given 2D image, color and depth data are captured simultaneously such that, within that 2D image, spatial disposition of the reference array necessarily remains fixed. (*See* Tr. (Stevenson) at 859:4-860:4, 943:3-10; CX-0722C; CX-0723C; CDX-0014C.0025, .0049.).

This operational detail relates to why the 538 Accused Products do not satisfy element [1.4] of the ’538 patent. By using a single mechanism to *capture* color and depth data within a given 2D image, the 538 Accused Products distinguish themselves from the distinct depth and color collection mechanisms described and claimed in the ’538 patent.

As discussed in detail above, the ’538 patent teaches the use of an optical scanner to *capture* depth data and a distinct imaging means to *capture* color data. (JX-0003 (’538 patent) at 25:11-14 (“any suitable means for providing 3D scanning can be used so long as the 3D scan and the color 2D scan correspond substantially to the same object or portion thereof being scanned, and the same frames of references are maintained.”).). As the *Markman* Order explained: “[s]pecifying that the ‘optical scanner’ does not capture color image data effectively restores the depth and color data independence touted by the patentee and used by the patentee to overcome Mueller.” (*Markman* Order, App. A at 54.). The Abstract of the ’538 patent echoes the consequences of this arrangement, explaining that “[a] processor combines the color data and depth data for each point in the array, thereby providing a three-dimensional color virtual model of the surface of the structure.” (JXM-0003 (’538 patent) at Abstract.).

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[66] Indeed, the 538 Accused Products “include a motion detection algorithm, which stops the addition of a captured subscan if the user moves the scanner too fast over the dentition. (Tr. (Stevenson) at 942:17-943:3; CX-0351C.0002; CDX-0014C.0048.).

Against this backdrop, 3Shape contended that the 538 Accused Products cannot satisfy the optical scanner *and* imaging means limitations required by elements [1.2] and [1.3] and reiterated in the wherein clause of element [1.4]. (RRBr. at 59 (citing JX-0003 ('538 patent) at cl. 1 (emphasis added)).). In particular, 3Shape asserted that "[b]ecause Align failed to show that Trios includes the claimed 'optical scanner' and the 'imaging means,' Align likewise cannot show that Trios meets the wherein clause of claim 1." (*Id.*).

3Shape is partially correct. Align has proven that the 538 Accused Products possess "imaging means," but Align has also failed to prove that these Products possess an "optical scanner." Likewise, here, Align has proven by a preponderance of the evidence that the 538 Accused Products satisfy all of element [1.4] except the existence of an distinct "optical scanner." For this reason, and this reason only, Align has not proven by a preponderance of evidence that the 538 Accused Products practice element [1.4] of the '538 patent.

e) [2]: "The device according to claim 1, wherein the operation of the optical scanner is based on confocal imaging techniques."

Claim 2 is a dependent claim that adds the following limitation to claim 1: "wherein the operation of the optical scanner is based on confocal imaging techniques." (JX-0003 ('538 patent), cl. 2.). The *Markman* Order construed "confocal imaging techniques" as "'imaging techniques characterized by illumination and detection paths with conjugate focal planes." (*Markman* Order, App. A at 69.). Measuring the "illumination path" from the [redacted] found in the 538 Accused Products, as shown below in Figure 17, Align asserted that "the optical scanner of the TRIOS is based on confocal imaging techniques[.]" (CBr. at 91.). Measuring the "illumination path" from the [redacted] source in the 538 Accused Products, 3Shape asserts that these Products do not possess conjugate illumination and detection paths. (RRBr. at 60-61.). As explained below, Align has the stronger argument on this issue.

Figure 17: Align's Depiction of Confocal Imaging in the 538 Accused Products

[redacted]

(CDX-0014C.0053 (introduced during the testimony of Dr. Stevenson).).

3Shape reads the claim limitation too narrowly. The *Markman* construction requires "illumination and detection paths with conjugate focal planes," not that the illumination source is necessarily in a plane conjugate to the plane of the image detector. (*Markman* Order, App. A at 69.). The Parties' experts agreed that, within the 538 Accused Products, "the [redacted] is optically conjugate to the [redacted] [.]" (RRBr. at 60; Tr. (Stevenson) at 944:5-946:16; Tr. (Zavislan) at 1608:6-13, 1630:16-20, 1682:23-1683:1.). Even documentary evidence that 3Shape provided and together with its witnesses confirmed this. (CX-0722; CX-0723C; CDX-0014C.0053-55; CX-2279C (van der Poel Dep. Tr.) at 94:6-12, 106:21-107:1; CX-2287C (1090 Investigation Hearing Tr.) at 187:3-15.). Indeed, 3Shape's [redacted]

[redacted] (*See, e.g.*, CX-0557C.0025.).

According to 3Shape, "Align's interpretation would fail to give the term 'confocal imaging techniques' any meaning, as there are multiple conjugate relationships in any optical system." (RRBr. at 61 (citing Tr. (Zavislan) at 1690:24-1691:2).). However, 3Shape failed to flesh out this statement in any meaningful way by, for example, identifying all of the "planes" in the illumination and detection paths of the 538 Accused Products and determining the number of possible combinations of illumination and detection planes that exhibit a conjugate relationship.[67] Without more, conclusory statements cannot pass muster here.

Thus, Align has proven by a preponderance of the evidence that the 538 Accused Products possess "confocal imaging techniques" as defined as "imaging techniques characterized by illumination and detection paths with conjugate focal planes." However, the 538 Accused Products do not satisfy claim 2 of the '538 patent because they do not satisfy claim 1 from which claim 2 depends. In particular, the 538 Accused Products lack the required "optical scanner."

f) The TRIOS 3 Mono Does Not Infringe

According to 3Shape, with the 538 Accused Products, the Trios 3 Mono does not infringe because it does not provide color data and cannot generate a color 3D virtual model. (RRBr. at 61 (citing Tr. (Hansen) at 1208:9-14); JX-0003 ('538 patent), cls. 1, 2.). Align argued that the Trios 3 Mono infringes because it can be upgraded to a Trios 3 Color Scanner and is "reasonably capable" of generating a 3D color model without "significant alteration."[68] (CBr. at 77-78

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[67] Align also pointed out: "The fallacy in Respondents' position regarding non-infringement is exposed by their position on domestic industry, where Respondents do not dispute and have never disputed that the microlens array of the iTero, rather than the laser (i.e., the light source), is one of the conjugate focal planes." (CBr. at 92.). Whether the iTero satisfies claims 1 and 2 of the '538 patent is addressed below.

[68] 3Shape argued that Align waived this argument by not raising it in its Pre-Hearing Brief. (RRBr. at 61-

(citing *Ericsson, Inc. v. D-Link Sys*., 773 F.3 1201, 1217 (Fed. Cir. 2014).). According to Align, "TRIOS 'mono' differs [from the other 538 Accused Products] only in that [redacted] (CBr. at 77 (citing CX-2279C (van der Poel Dep. Tr. (6/12/2019)) at 60:21-62:4, 63:3-64:19; Tr. (Stevenson) at 945:17-946:4; CDX-0014C.0057; CX-2276C (van der Poel Dep. Tr. (5/24/2018)) at 49:7-51:1).).

Align's argument fails here for the same reasons it failed in the 1091 Investigation. In the 1091 Investigation, Judge Cheney found in his Initial Determination on Violation that "Trios 3 Mono scanners are configured with different software that [redacted] and is 'only capable of outputting monochromatic data.'" Or, in the Commission's words, the Commission affirmed that "the Trios monochromatic scanners can be modified at a 3Shape factory to add color scanning functionality[.]" (*Certain Color Intraoral Scanners and Related Hardware and Software*, 337-TA-1091, Commission Op. at 42 (Nov. 22, 2019) (citing underlying Initial Determination at 58-59 ("*1091 Investigation*").). Judge Cheney concluded that "[b]ecause modifications are required to enable to color functionality, [the Trios monochromatic scanners] cannot be found to infringe." (*Id*.). The Commission adopted that finding without substantive review. (*Id*. at 2.).

The same reasoning applies here. 3Shape offers a color upgrade program for the Trios 3 Mono scanners, which activates the scanners' latent color functionality. (CX-2279C (van der Poel Dep. Tr. (6/12/2019)) at 60:21-62:4, 63:3-64:19; CX-1173C.0004; CX-0810C.0025; CX-0333C.0027; CX-0388C.0005; CX-0398C.0103-106.). However, upgrading the Trios 3 Mono to include color requires sending the Trios 3 Mono back to 3Shape, where the scanner receives a

62.). That is plainly wrong, because the argument appeared in a footnote in Align's Pre-Hearing Brief. (CPBr. at 105 n. 40.).

[redacted]. (Tr. (Hansen) at 1208:9-21; CX-2276C (van der Poel Dep. Tr. (5/24/2018)) at 163:11-22.). Thus, from a user's perspective, the Trios 3 Mono is not "reasonably capable" of generating a 3D color model. Contrary to Align's position, a "significant alteration" is required to convert the Trios 3 Mono into a color scanner. *See Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201, 1217 (Fed. Cir. 2014) (system "reasonably capable" of infringing "if a user followed the accused infringer's own instructions" to make necessary modification); *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316 (Fed. Cir. 2001) ("[T]hat a device is capable of being modified to operate in an infringing manner is not sufficient, by itself, to support a finding of infringement."). This makes sense from a business perspective because 3Shape presumably would not want customers who paid for a monochrome scanner to be able to modify that scanner unilaterally and receive the benefits of a color scanner.

For the reasons described above, and based upon the weight of the evidence, the TRIOS 3 Mono scanners do not infringe claims 1 and 2 of the '538 patent.

B. Technical Prong of Domestic Industry

It is undisputed that Align's iTero Element ("iTero") is representative of all the 538 DI Products, including the iTero Element, the iTero Element 2, and the iTero Element Flex. (Tr. (Stevenson) at 946:10-950:6; CX-0311; CX-1853.0003 (depicting stand and monitor differences for Element and Element 2, and Flex as the portable version); CDX-0014C.0058.). All of these intraoral scanners work identically in that they all practice the asserted claims. (*Id.*). Align uses and sells the iTero in the United States. (Tr. (Relic) at 211:14-20; Tr. (Kling) at 356:18-357:15.). During the Hearing, 3Shape's expert, Dr. Zavislan, did not present testimony or evidence regarding the iTero.

Figure 18: Align's DI Products

a) [1.1]: "A device for determining the surface topology and associated color of at least a portion of a three dimensional structure, comprising:"

The iTero is "[a] device for determining the surface topology and associated color of at least a portion of a three dimensional structure." Dr. Stevenson testified that the iTero is a device that determines the surface topology (i.e., the three-dimensional outer surface of an object) and associated color (i.e., corresponding visible color for each location on the surface) of at least a portion of a three-dimensional structure (where the three-dimensional is a patient's dentition or tooth). (Tr. (Stevenson) at 956:21-958:21; CX-1238C.0004; CX-1410.0003; CX-1409.0032; CX-1731C.0001; CDX-0014C.0069.). Align's technical documents support a finding that the iTero Element takes multiple subscans in order to produce a surface topology of a dentition. (*See,* e.g., CX-1866.0003.). 3Shape did not dispute that the iTero meets the preamble. (RPBr. at 110-111.).

Figure 19: Topology in iTero Element Wand

In its Reply Post-Hearing Brief, 3Shape did not dispute Align's assertion that the iTero satisfies the element [1.1] of the '538 patent. (RRBr. at 63-64.). Thus, 3Shape has waived any such argument pursuant to Ground Rule 10.1.

Accordingly, based upon the weight of the evidence and as explained in the analysis, Align has proven by a preponderance of evidence that the iTero practices element [1.1] of the '538 patent.

b) [1.2]: "optical scanner configured for providing depth data of the portion corresponding to a two-dimensional reference array substantially orthogonal to a depth direction;"

The iTero includes an "optical scanner" that "uses light projection to capture data other than color image data." (Tr. (Stevenson) at 958:23-959:13; Tr. (Saphier) at 256:5-257:20, 258:14-22, 260:1-16; CX-1236C.0004, 7, 9; CX-1242C.0008; CX-1238C.0016, 0019; CX-1304C; CX-1361.0005; CX-1386C.0005; CX-1683C.0016; CX-1866C.0016; CDX-

0014C.0071.) The iTero does indeed [redacted] for light projection (i.e., a pattern of red spots) onto the tooth. (Tr. (Stevenson) at 949:19-950:3; CDX-0014C.0063-64.). The pattern of spots is [redacted]. (Tr. (Stevenson) at 948:13-951:2.). The iTero provides depth data by capturing [redacted]. (Tr. (Stevenson) at 949:19-950:19, 959:19-25; CDX-0014C.0072.). None of that data is used for generating color. (Tr. (Stevenson) at 959:19-25; Tr. (Saphier) at 269:24-270:15; CX-1236C; CX-1238C.0019; CX-1683C.0021, 22, CX-1865C.0159; CDX-0014C.0072.). The iTero thus "captures data other than color image data."[42] (Tr. (Stevenson) at 948:5-951:24, 959:19-25; Tr. (Saphier) at 269:24-270:15; CX-1238C.0016, 0019; CX-1683C.0016; CX-1732.0016; CDX-0014C.0072; *see also* JX-0003 at 12:21-23.). In addition, and for the same reasons discussed above in the context of the 538 Accused Products, the [redacted] at a certain point in time, which provides depth data that is not used for color. (Tr. (Stevenson) at 950:20-951:24, 960:1-11; Tr. (Saphier) at 260:17-261:7; CX-2273C:96:1-97:16; CX-1865C.0159; CDX-0014C.0072.).

Figure 20: Depth Processing in iTero Element Wand

The iTero Element "provid[es] depth data of the portion corresponding to a two-dimensional reference array substantially orthogonal to a depth direction." Dr. Stevenson testified that the image sensor of the iTero provides a two-dimensional reference array that is substantially orthogonal to the optical axis and hence the depth direction. (Tr. (Stevenson) at 960:12-17, 961:3-962:1; CX-1236C.0014; CX-1238C.0016, 19; CX-1242C.0007; CDX-0014C.0073-74; *see also* JX-0003 at 12:60-13:7.). In addition to the documentary evidence, Dr. Stevenson testified that the iTero provides depth data for the portion of the object being scanned that corresponds to the reference array. (Tr. (Stevenson) at 961:3-962:1; CX-1236C; CX-1238C.0019; CX-1242C; CX-1732C.0007; CDX-0014C.0073.). Mr. Ofer Saphier, the technical director of algorithms at Align, also testified that the image sensor provides a two-dimensional reference array that is perpendicular to the depth direction (i.e., along the optical axis or z-direction). (Tr. (Saphier)[69] at 261:7-21, 267:16-268:5, 268:11-269:11, 287:14-288:10; CX-2273C at 60:8-25, 96:22-98:17, 112:4-8, 140:15-141:2; *see also* CX-2202C at 59:2-11, 109:4-110:10.).

3Shape disputed that Dr. Stevenson identified a proper "reference array." (Tr. (Stevenson) at 960:12-17.). This is because the data the image sensor on the iTero collects is [redacted] before it functions as the "reference." (Tr. (Saphier) at 278:19-21.). Specifically, Align's director of algorithms, Mr. Saphier, testified that the [redacted] (Tr. (Saphier) at 278:19-279:23.). [redacted]. (RX-0440C at 906; Tr. (Saphier) at 278:19-281:9.). A [redacted]. (CPBr. at 118, 122-123; Tr. (Saphier) at 281:7-9, 281:18-282:3.). In other words, 3Shape argued that [redacted] as claim 1 of the '538 patent requires.

3Shape's position shows a fundamental misreading of claim 1. The "optical scanner" limitation in claim 1 requires "depth data of the portion *corresponding to* a two-dimensional reference array substantially orthogonal to a depth direction[.]" (JX-0003 ('538 patent), cl. 1.). 3Shape seeks to rewrite the claim language to require "depth data of the portion *embodying* a

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[69] When he testified during the Hearing on October 24, 2019, Mr. Ofer Saphier was Director of Algorithms at Align. (Tr. (Saphier) at 255:5-10.). Align identified Mr. Saphier as a fact witness who Align called to testify on Align's background and business, Cadent's background and business, and the domestic industry in the Asserted Patents. Align also called Mr. Saphier to testify with respect to the validity of the Asserted Patent, including the topics of non-obviousness and secondary considerations, as they apply to Align's iTero Element and Invisalign System. (CPSt. at 11.).

two-dimensional reference array substantially orthogonal to a depth direction[.]" By using "corresponding to … a reference array" in reference to the data collected by the "optical scanner," claim 1 provides the scope for an intraoral scanner, such as the iTero, to collect depth data and manipulate or translate it in a predictable way such that it matches the same "reference array" used by the "imaging means."[70]

Align argued, in the alternative, that the iTero satisfies the "optical scanner" requirement under the doctrine of equivalents. (CBr. at 98.). It was not necessary that Align provide an alternative argument. The iTero literally satisfies the "optical scanner" limitation.

Also, for the sake of clarity, a comparison of the "optical scanner" in the 538 Accused Products and the iTero is warranted. As explained above in the context of infringement, the Accused Products lack an "optical scanner" that captures "data other than color image data" because, in the 538 Accused Products, depth and color data are *captured* at the exact same time on the same scans. By contrast, in the iTero, depth and color data are captured at different time on different scans, as shown below in Figure 21, below.

[70] This is true given the broad treatment of "reference array" herein in the context of infringement and invalidity. Specially, the claimed "reference array" is not confined to the face of an image sensor or, for that matter, to a plane immediately above the surface of a scanner object.

Figure 21: Data Extraction in iTero Element Wand

[redacted]

Accordingly, based upon the weight of the evidence as explained in the analysis, Align has proven by a preponderance of evidence that the iTero practices element [1.2] of the ’538 patent.

c) [1.3]: “imaging means configured for providing two-dimensional color image data of the portion associated with the reference array;”

The iTero includes “imaging means configured for providing two-dimensional color image data of the portion associated with the reference array.” (Tr. (Stevenson) at 962:17-967:17; CX-1236C.0014; CX-1238C.0020; CDX-0014C.0076.). Dr. Stevenson explained that the iTero includes “white illumination, optics, and a color image sensor (e.g., a color CCD) for detecting intensity of the white illuminating radiation after reflection from the portion.” (Tr. (Stevenson) at 966:6-967:17; CDX-0014C.0077-78.). Specifically, the iTero includes [redacted]. (Tr. (Stevenson) at 966:6-16; 270:16-25; CX-1236C.0014;

CX-1238C.0020; CX-1330C; CDX-0014C.0077.). The iTero also has optics (e.g., the [redacted]) and a color image sensor. (Tr. (Stevenson) at 966:17-967:10; CX-1236C.0014; CX-1238C.0020; CX-1242C.0007, 11; CX-1683C.0022, 26; CX-1724C; CDX-0014C.0078.).

Dr. Stevenson testified that the iTero provides two-dimensional color image data of the portion associated with the reference array (i.e., the same array are used for providing depth data). (Tr. (Stevenson) at 962:23-963:5.) The two-dimensional color image data is derived from certain red, blue, and green pixels in the two images collected at the end of the subscan. (Tr. (Stevenson) at 951:25-952:11, 962:22-963:19, 964:7-25, 965:25-966:5.)

Figure 22: Color Processing in iTero Element Wand

[redacted]

In its Reply Post-Hearing Brief, 3Shape did not dispute Align's assertion that the iTero satisfies the element [1.3] of the '538 patent. (RRBr. at 63-64.). Thus, 3Shape has waived any such argument for all purposes pursuant to Ground Rule 10.1.

Accordingly, based upon the weight of the evidence, as explained in the analysis provided, Align has proven by a preponderance of evidence that the iTero practices element [1.3] of the ’538 patent.

d) [1.4]: “wherein the device is configured for maintaining a spatial disposition with respect to the portion that is substantially fixed during operation of the optical scanner and the imaging means.”

The iTero “is configured for maintaining a spatial disposition with respect to the portion that is substantially fixed during operation of the optical scanner and the imaging means.” Dr. Stevenson testified that the “operation by the optical scanner and the imaging means” of the iTero Element “is at least substantially or effectively simultaneous,” because each subscan occurs [redacted]. (Tr. (Stevenson) at 967:18-968:20; Tr. (Saphier) 271:12-23, 272:9-272:19; CX-1236C.0014; CX-1238C.0012; CX-1242C.0008; CX-1410.0003; CX-1666C.0012; CX-1683C.0025; CX-1731C.0016; CDX-0014C.0080.). The depth data and color data correspond to the same reference array because both depth data and color data are collected by the image sensor during a subscan. (Tr. (Stevenson) at 969:25-970:9; CX-1238C.0016, 19; CDX-0014C.0083.). The iTero operates such that movement (i.e., a change in spatial disposition) can be ignored. (Tr. (Stevenson) at 968:21-970:9; CX-1238C.0016, 19; CX-1730C.0004; CX-1732C.0016; CX-1743C.0004; CX-1863C.0003; CX-1865C.0033; CDX-0014C.0081-83.). The iTero includes [redacted] and, similar to the 538 Accused Products, [redacted]. (Tr. (Stevenson) at 952:14-23; 968:21-969:24; Tr. (Saphier) at 272:23-273:12; CX-1362.0017; CX-1863C.0003; CDX-0014C.0081-

82.).

Figure 23: iTero Depth and Color

[redacted]

In its Reply Post-Hearing Brief, 3Shape did not dispute Align's assertion that the iTero satisfies the element [1.4] of the '538 patent. (RRBr. at 63-64.). Thus, 3Shape has waived any such argument for all purposes pursuant to Ground Rule 10.1.

Based upon the weight of the evidence, as explained in the analysis provided, Align has proven by a preponderance of evidence that the iTero practices element [1.4], and the entirety of claim 1, of the '538 patent.

e) [2]: "The device according to claim 1, wherein the operation of the optical scanner is based on confocal imaging techniques."

The "operation of the optical scanner is based on confocal imaging techniques." (Tr. (Stevenson) at 971:12-972:1; CX-1360C.0004; CX-1387C; CDX-0014C.0087, .0089.). The iTero uses "imaging techniques characterized by illumination and detection paths with conjugate focal planes." (Tr. (Stevenson) at 971:12-23; CX-1236C.0003; CX-1866C.0009; CDX-0014C.0087.) The [redacted]. (*Id*.; Tr. (Saphier) at 256:5-257:20.). Align's technical documents confirm that the iTero uses confocal imaging techniques. (*See*, e.g., CX-1236C.0003; CX-1238C.0016, .0019; CX-1250C.0006-13; CX-1684C.0006-13; CX-1866C.).

In its Reply Post-Hearing Brief, 3Shape did not dispute Align's assertion that the iTero satisfies claim 2 of the '538 patent. (RRBr. at 63-64.). Thus, 3Shape has waived any such argument pursuant to Ground Rule 10.1.

As explained in the analysis, Align has proven by a preponderance of evidence that the iTero practices claim 2 of the '538 patent.

C. Invalidity

1. Invalidity Overview

3Shape raised an inordinate number of invalidity grounds for claims 1 and 2 of the '538 patent. This is reflected in Table No. 9, below. This was unnecessary and risked wasting precious resources of all involved. It may have been prudent for 3Shape to raise most, if not all, of these invalidity grounds in its Pre-Hearing Brief filed on August 30, 2019, prior to the issuance of the *Markman* Order, which settled the Parties' claim construction disputes. However, once the *Markman* Order issued on October 1, 2019, 3Shape should have dropped most of its invalidity grounds for the asserted claims of the '538 patent. This is clear from Align's cross examination of 3Shape's expert, Dr. Schaafsma, which laid bare the gaps in 3Shape's invalidity arguments.

As suggested in Table No. 9, below and the analysis that follows, it should be evident that most of 3Shape's invalidity grounds suffer from one or more conspicuous shortcomings. Nevertheless, 3Shape nearly proved by clear and convincing evidence that Okamoto anticipates claims 1 and 2 of the '538 patent. Consequently, the bulk of the invalidity analysis below pertains to this single ground for invalidity.

Table No. 9: Invalidity Grounds Raised by 3Shape for the '538 Patent

Invalidity Ground	Reference(s)	Outcome
Anticipation	Okamoto	Unsuccessful (close question)
Anticipation	Xu	Unsuccessful
Obviousness	Okamoto	Unsuccessful
Obviousness	Okamoto and "Nontranslational three dimensional profilometry by chromatic confocal microscopy with dynamic configurable micromirror scanning," Appl. Opt. 39:2605-2613 (Cha)	Unsuccessful
Obviousness	Xu	Unsuccessful
Obviousness	WIPO Publication No. WO 00/08415 (Babayoff) and Okamoto	Unsuccessful
Obviousness	Babayoff, Okamoto, and U.S. Patent No. 6,594,539 (Geng)	Unsuccessful
Obviousness	Babayoff and Xu	Unsuccessful
Obviousness	Babayoff, Xu, and Geng	Unsuccessful

2. Legal Standards

a) Anticipation

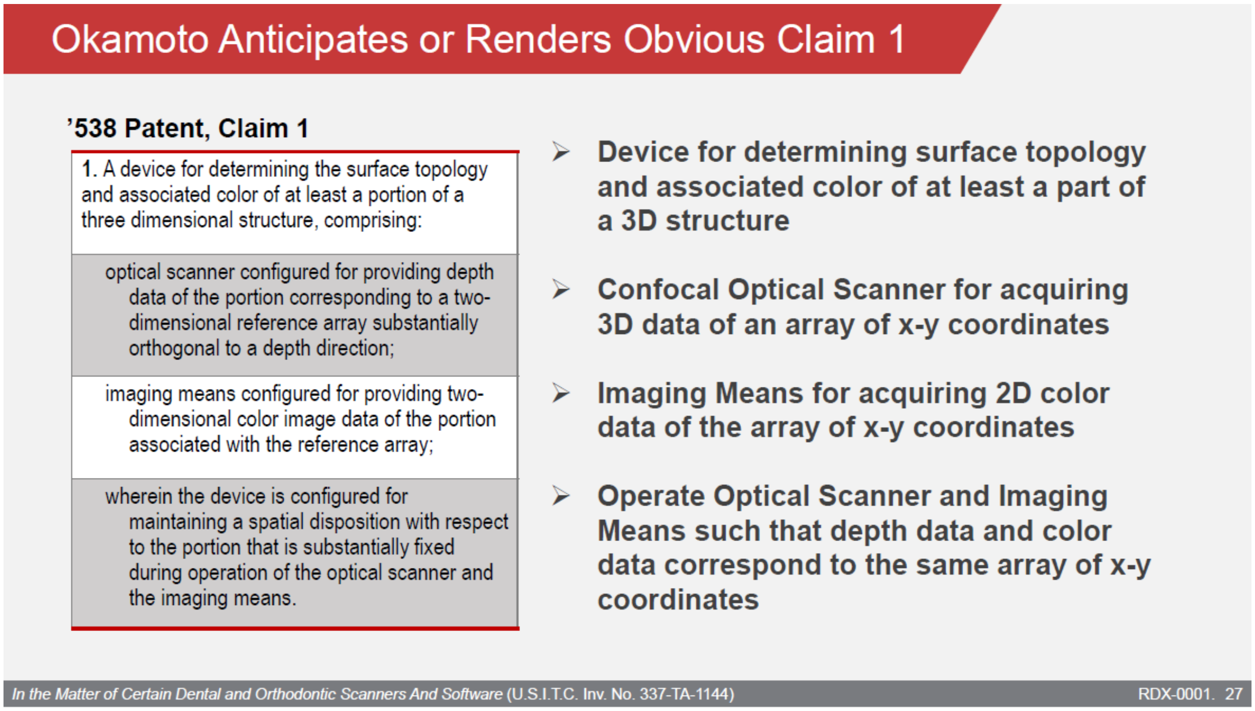
A determination that a patent is invalid as being anticipated under 35 U.S.C. § 102 requires a finding, based upon clear and convincing evidence, that each and every limitation is found either expressly or inherently in a single prior art reference. *See, e.g.*, *Celeritas Techs. Inc. v. Rockwell Int'l Corp.*, 150 F.3d 1354, 1361 (Fed. Cir. 1998). Anticipation is a question of fact, including whether a limitation, or element, is inherent in the prior art. *In re Gleave*, 560 F.3d 1331, 1334-35 (Fed. Cir. 2009). The limitations must be arranged or combined the same way as in the claimed invention, although an identity of terminology is not required. *Id.* at 1334 (noting, "the reference need not satisfy an *ipsissimis verbis* test"); MPEP § 2131.

In addition, a prior art reference's disclosure must enable one of ordinary skill in the art to practice the claimed invention "without undue experimentation." *Gleave*, 560 F.3d at 1334-35. A prior art reference that allegedly anticipates the claims of a patent is presumed enabled; however, a patentee may present evidence of non-enablement to overcome this presumption. *Impax Labs., Inc. v. Aventis Pharms. Inc.*, 468 F.3d 1366, 1382 (Fed. Cir. 2006). "[W]hether a prior art reference is enabling is a question of law based upon underlying factual findings." *Gleave*, 560 F.3d at 1335.

3. Okamoto Does Not Anticipate Claims 1 and 2 of the '538 Patent

Okamoto is a Japanese patent application filed on September 10, 1999 and published on March 30, 2001. (RX-0180cv (Okamoto) at Cover.). Okamoto's publication date is more than one year before the claimed June 17, 2004 priority date of the '538 patent, and thus qualifies as prior art under 35 U.S.C. § 102(b). Okamoto was cited (but not discussed) by the examiner during the prosecution of the '538 patent. (JX-0003 ('538 patent) at 2 (citing JP 2001-82935); JX-0007 ('538 patent prosecution history).). Yet, if the examiner had focused on Okamoto, he likely would have appreciated that the '538 patent and Okamoto bear striking similarities. An overview of these similarities is set forth below. For this overview, Figure 24 below provides a comparison of the essential requirements of claim 1 of the '538 patent in bullet-pointed fashion with Okamoto.

Figure 24: 3Shape's Depiction of the Requirements of Claim 1 of the '538 Patent



(RDX-0001.0027 (introduced during the testimony of Dr. Schaafsma).).

<u>Device for surface topology and associated color of 3D structure</u>. Both Okamoto and the '538 patent attempt to solve the problem of providing color 3D scans. Okamoto distinguished prior art approaches that used shading and color gradation to display depth contour and how it was "not necessarily easy on eyes." (RX-0180 (Okamoto) ¶¶ 5-6.). The '538 patent states that the problem of "conformally mapping the two-dimensional color information onto the three dimensional surface model is difficult and it is common for mismatching of the color with three-dimensional points to occur." (JX-0003 ('538 patent) at 1:50-54.).

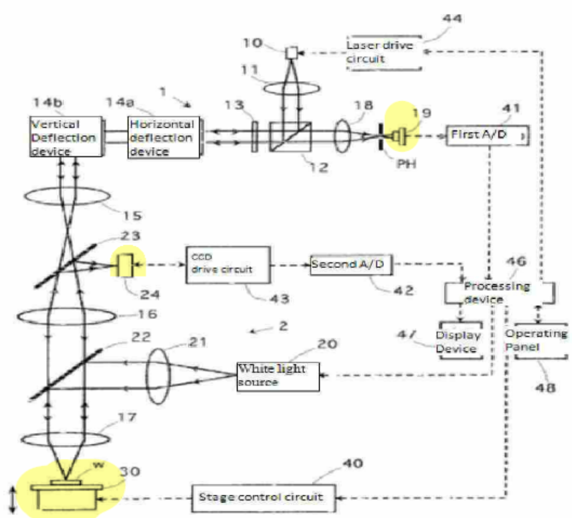
<u>Optical scanner for providing depth data and separate imaging means for proving 2D color data</u>. Okamoto and the '538 patent propose similar solutions. Okamoto teaches "using a photo receptor" to "obtain[] 3-dimensional surface shape … based on the light reception

information" and a separate "color filming means that obtains color of the measurement target object[.]" (RX-0180 (Okamoto) at ¶ 8.). The '538 patent teaches "a scanner for providing depth data for points along a two-dimensional array substantially orthogonal to the depth direction, and an image acquisition means for providing color data for each of the points of the array, while the spatial disposition of the device with respect to the structure is maintained substantially unchanged." (JX-0003 ('538 patent) at Abstract.).

Figure 25: Abstract and Figure 1 of Okamoto Showing the Scanned Object (W), Photo Receptor (19) for Obtaining Depth Data, and Color CCD (24) for Obtaining Color Data

(54) [Title of Invention] 3-dimensional Measurement Device

(57) [Abstract]
[Topics] A 3-dimensional measurement device is provided that is easy to understand the corresponding relationship of the site of the actual means target object and the site of the surface shape that is displayed on the display device.
[Solution means] A confocal microcopy, which is a 3 dimensional measurement device, comprises: a photo receptor 19 which receives the light from the measurement target object w through confocal light system 1 that includes object lens 17; color CCD 24 that obtains for each pixel the color information of measurement target object w; Z direction displacement mechanism 30 that enables the change of the relative position of measurement target object w with respect to focal point of object lens 17 at optical axis direction; scanning mechanisms 14a, 14b that scan the measurement target object w by the light from light source 10 in XY direction that is vertical to optical axis direction; processing device 46 that seeks and stores for each pixel the height information and color information that correspond to the relative position in the optical axis direction of the measurement target object w when the light reception amount is maximized; and display device 47 that uses height information and color information for each pixel and engages in color 3 dimensional display of the surface shape of the measurement target object w.



(RX-0180 (Okamoto) at Cover (highlighting added for emphasis).).

<u>Maintaining special disposition such that depth and color data correspond</u>. Okamoto and the '538 patent both appear to coordinate the matching of depth and color information using a X-Y reference plane. Okamoto teaches depth scanning "in XY direction … vertical to optical axis direction" and using color information "for each pixel" to color the "3-dimensional display of surface shape[.]" (RX-0180 (Okamoto) at Abstract at ¶ 8.). The '538 patent teaches "combin[ing] the color data and depth data for each point" in a "two-dimensional array

substantially orthogonal to the depth direction." (JX-0003 ('538 patent) at Abstract.).
It is clear that claims 1 and 2 of the '538 patent reflect a desire by the patentee to obtain broad claim scope coverage. As explained below, that breadth almost reads on Okamoto.

Perhaps appreciating the precariousness of its position, Align attempted to distinguish Okamoto not based on claim limitations, but instead based on unclaimed and thus irrelevant differences between the systems taught in Okamoto and the '538 patent, on the other hand.

For example, Align asserted that Okamoto lacks a "reference array" because it uses pixel-by-pixel raster scanning to obtain depth data instead of using an image sensor with a X-Y planar surface. (CRBr. at 51-52.). However, Align's argument adds a requirement for "reference array" that is not found in the *Markman* Order or otherwise supported by the '538 patent. Discussed and rejected below are this and other examples of Align's artificial attempts to narrow the broad asserted claims of the '538 patent to escape invalidity and Okamoto.

Nevertheless, Align raised one persuasive point of novelty that sets claims 1 and 2 apart from Okamoto. That point pertains to the speed at which depth and color data are collected. Situated in a patent pertaining to intraoral scanners, claims 1 and 2 require that "operation by the optical scanner and the imaging means is at least substantially or effectively simultaneous such that movement (*i.e.*, a change in spatial disposition) can be ignored and depth data and color data correspond to the same reference array." (*Markman* Order at 64-65.). There is nothing in Okamoto, a patent application directed to microscopes, about the speed of the disclosed "optical scanner" and "imaging means." Moreover, the Parties' experts disagreed over the speed at which the optical system disclosed in Okamoto would operate from the perspective of one of ordinary skill in the art. On balance, this is not the type of clear and convincing evidence required for anticipation. Thus, Okamoto does not anticipate claims 1 and 2 of the '538 patent.

a) [1.1] (Preamble): "A device for determining the surface topology and associated color of at least a portion of a three dimensional structure, comprising:"

Okamoto determines a surface topology and associated color for a scanned object. The system obtains 3D surface shape information for a portion of the object using a confocal optical system and associated color of that portion using a non-confocal optical system. (*See, e.g.*, RX-0180 at ¶¶ 8, 9, 12, 15, 21, 28-30, 46, Fig. 1 at ref. nos. 1 and 2; Tr. (Schaafsma) at 1287:15-1288:24, 1303:11-13, 1332:5-13.). The 3D surface shape information and 2D color information are then combined to create a color 3D model that is displayed on a screen. (*Id*. at ¶¶ 8, 33; Tr. (Schaafsma) at 1277:25-1278:7.).

Align contended that Okamoto does not disclose "a device for determining the surface topology…of at least a portion of a three-dimensional structure" because the object is scanned from a single perspective. (CBr. at 50-51; Tr. (Stevenson) at 1791:16-1792:3.). It appears that, in Align's view, the "surface topology" in the preamble of claims 1 and 2 of the '538 patent requires scanning an object from multiple perspectives. (*Id*.).

Yet, the '538 patent does not support Align's interpretation. Instead, the '538 patent contemplates a 3D representation of an object generated from a depth scan from a single perspective, noting that "[t]he 2D color image is taken at substantially the same angle and orientation with respect to the structure as the case when the 3D scan was taken." (JX-0003 ('538 patent) at 3:61-63.). Reflecting this understanding, claim 1 states that the "device is configured to maintain a spatial disposition with respect to the portion that is substantially fixed during operation of the optical scanner and the imaging means." (JX-0003, cl. 1; *see also* Tr. (Stevenson) at 1004:20-25.). Align's interpretation that "surface topology" is obtained from multiple perspectives is also inconsistent with the *Markman* Order. That Order rejected a limitation, requested by Align, that the claimed device be "movable." (*Markman* Order at 68-69.).

Finally, Align attempted to draw a distinction between "surface shape information" in Okamoto and "surface topology" in the '538 patent. (CRBr. at 50-51.). Align likens this distinction to a contrast, drawn within the context of the '538 patent, between "depth data" and "surface topology." (*Id*.). Yet, this comparison in inapt and actually cuts against Align's argument.

Okamoto teaches the display of "surface shape information," and the '538 patent teaches the display of "surface topology," making these respective concepts comparable. (RX-0180 (Okamoto) at Abstract; JX-0003 ('538 patent) at 16:19-33, Fig. 4B.). Also, Align's suggestion, based on extrinsic evidence, that a scan from a single perspective does not generate a 3D representation is directly contradicted by the intrinsic evidence and, thus, unavailing. (CRBr. at 50-51); *see Vitronics Corp. v. Conceptronic, Inc*., 90 F. 3d 1576, 1584 (Fed. Cir. 1996) (extrinsic evidence cannot be used to contradict the claims of specification).

Based upon the evidence and the analysis provided, 3Shape has proven by clear and convincing evidence that Okamoto discloses element [1.1] of the '538 patent.

b) [1.2]: "optical scanner configured for providing depth data of the portion corresponding to a two-dimensional reference array substantially orthogonal to a depth direction;"

Okamoto teaches a confocal optical system configured to provide depth data of a portion of an object. (Tr. (Schaafsma) at 1286:20-1290:1, 1302:10-1303:2,1303:9-13, 1303:25-1304:13; RX-0180 at ¶¶ 16-24, Fig. 1, ref. no. 1.).

As shown below in Figure 26, the confocal optical system includes a laser beam as a light source 10, which is deflected in the X- and Y-direction to different X-Y positions within a plane orthogonal to the depth direction. (*See, e.g.*, RX-0180 at ¶¶ 2-4, 8, 15-24, Fig. 1, ref. no. 1; Tr. (Schaafsma) at 1286:29-1290:1, 1303:3-8.). The laser beam is focused to a focal point by objective lens 17. (RX-0180 at ¶¶ 17, 19.). Laser light is reflected from the surface of the object back through objective lens 17 and a spatial filter (pinhole, labeled "PH") to photo detector 19. (RX-0180 at ¶ 20.). The photo detector measures the intensity of the laser light reflected back to the photo detector.[71] (*Id.*)

As the confocal optical system scans the object, the focal point of objective lens 17 is displaced relative to the sample along the optical axis direction (Z or height direction) by either: (1) moving the object relative to the objective lens 17 (e.g., by driving the sample stage 30 in the Z direction): or (2) moving the objective lens relative to the object (e.g., by driving the objective lens in the Z-direction along the optical axis). (RX-0180 at ¶¶ 12, 18-19; Tr. (Schaafsma) at 1304:15-20.). The intensity of the laser light reflected back to the photo detector is measured as the focal point of the objective lens is displaced in the Z-direction relative to the sample, and the surface of the object is detected when the measured intensity peaks for a given pixel. (RX-0180 at ¶ 22, Fig. 2.). Surface height (Z) information of the pixel is derived from the optical characteristics at which the maximum intensity occurs. (RX-0180 at ¶¶ 20-24, Figs. 2, 5; Tr. (Schaafsma) at 1286:20-1290:1.).

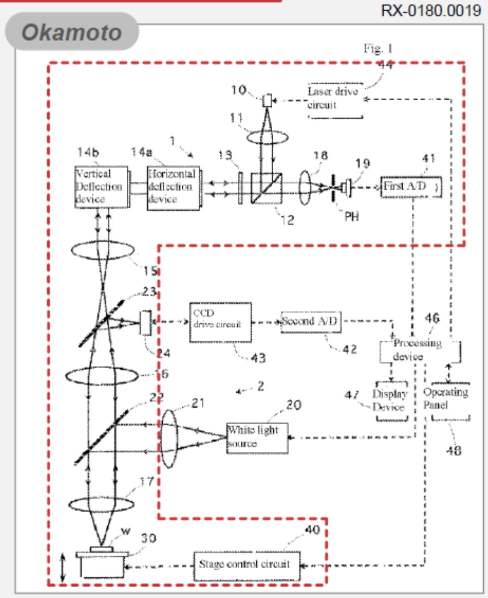
[71] Importantly, in compliance with the claim construction, Okamoto's confocal "optical scanner" captures data "other than color image data." (*Markman* Order, App. A at 42.). Separately, Okamoto uses a non-confocal optical system to capture color, which uses a white light source to illuminate the scanned object and a CCD to capture color data. (RX-0180 at Fig. 1 ref no. 2 at ¶¶ 28-31; Tr. (Schaafsma) at 1286:20-1290:14.).

Figure 26: 3Shape's Depiction of Okamoto Satisfying the Optical Scanner Limitation

Okamoto Anticipates the Optical Scanner Limitation

'538 Patent, Claim 1

Limitation	Court's Construction
optical scanner configured for providing depth data of the portion corresponding to a two-dimensional reference array substantially orthogonal to a depth direction	• "a device that uses light projection to capture data other than color image data"



In the Matter of Certain Dental and Orthodontic Scanners And Software (U.S.I.T.C. Inv. No. 337-TA-1144) RDX-0001. 28

(RDX-0001.0028 (introduced during the testimony of Dr. Schaafsma).).

Align contended that Okamoto's confocal optical system does not include the claimed "reference array" because it uses a photodetector that takes measurements point-by-point along an X-Y plane instead of using a 2D image sensor. (CRBr. at 51.). According to Align, in contrast to the image sensor disclosed in the '538 patent, "Okamoto's photodiode indisputably is not a 2D reference array." (*Id.*; *see also* JX-0003 ('538 patent) at 12:54-13:2 ("[d]etection optics 60 comprises an image sensor, typically a CCD, …, and which typically defines the X-Y frame of reference."), 13:31-33 ("The X-Y plane of entity E is substantially parallel to the sensing face of the image sensing means of the detection optics 60, typically a CCD.").).

Yet, Align's position improperly limits "reference array" to a physical instantiation in the form of an image sensor. As an initial matter, the Parties did not identify "reference array" as a disputed claim term during claim construction. (Joint Claim Construction Chart at 3-5.).

Moreover, nothing in the ’538 patent, including the passages that Align cited above, necessarily ties the “reference array” to a specific location or to a particular part of an optical system, such as an image sensor. 3Shape is correct that at least one part of the specification refers to a reference array at the object being scanned: “an array range of X-Y points (according to a known frame of reference) along the surface of the object.” (JX-0003 at 12:60-13:1; see also Tr. (Schaafsma) at 1348:8-1349:16.).

During cross-examination, Dr. Schaafsma aptly captured the breadth of the ’538 patent’s “reference array” and how the term is defined not by location but function:

> Q. And you told me it could be the CCD; right?
>
> A. I believe I recall that I did tell you it could be the CCD. I think the ’538 patent has a number of statements about where it could be.
>
> Q. And you told me it could be a raster scan; right?
>
> A. I think I probably told you that as well, yes.
>
> Q. You told me it could be any number of things; right?
>
> A. I think -- and I think I told you that, because I think that a person of skill in the art would understand what the function of that was, the two-dimensional reference array, was to scan the physical geometry of the surface and come up with measurement of actual physical characteristics of the object being scanned.
>
> Q. And so it was your opinion that the point of having the 2D reference array is so you can overlap two things; right?
>
> A. Well, I think that's in the construction that’s been applied to the claim language. I think that the function of having a 2D -- of having this reference array, which I think the definition for which is somewhat ambiguous in the ’538 patent, or at least there are different interpretations at different locations in that patent. I think that the purpose is really what a person of skill in the art would come back to. And the purpose is to be able to align these two sets of data so that they're looking at the same part of the structure.
>
> Q. So a reference array could be any number of things is what you said, sir?

A. I think there are a number of interpretations for it, but I don't think that the actual location is as important as the function that has been ascribed to it.

(Tr. (Schaafsma) at 1348:8-1349:16.).

Against this backdrop, there is little doubt that the Okamoto uses a "reference array" to match depth and color data. It is axiomatic that each pixel for which depth and color are matched in Okamoto is part of the X-Y plane that is identified in Okamoto. Specifically, the laser light source in Okamoto's confocal scanning system is used to measure the object's depth in the Z-direction at different X-Y locations along a X-Y plane. (RX-0180 at ¶ 24; Tr. (Schaafsma) at 1346:4-11.). This X-Y plane constitutes a "reference array" in terms of organizing measured depth (Z) values for an array of X-Y points in the same way that depth Z values are organized at different X-Y points in the '538 patent. (*See* RX-0180 at ¶¶ 4, 24; JX-0003 ('538 patent) at 3:28-32; 3:50-52.)

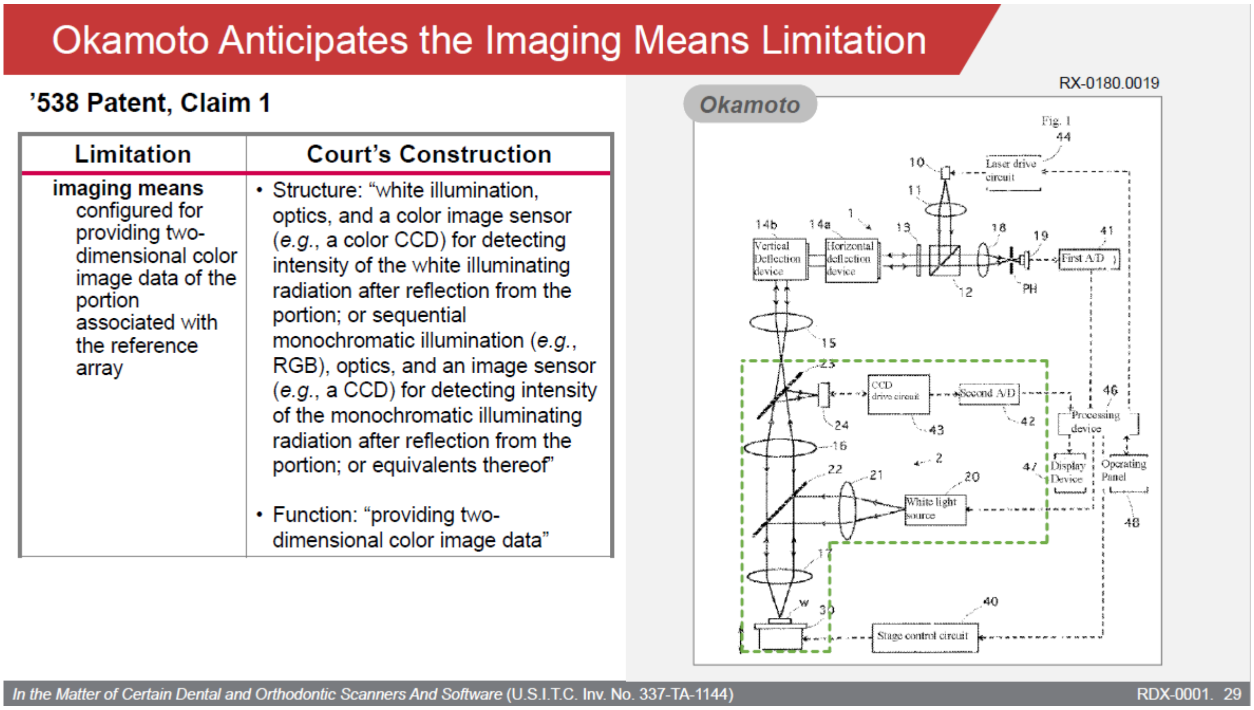
The depth data in Okamoto corresponds to "a two-dimensional reference array substantially orthogonal to a depth direction" because depth is measured with respect to the X-Y plane. (Tr. (Schaafsma) at 1303:9-1304:13, 1338:18-1339:2, 1343:2-15, 1346:4-11.). The laser beam is deflected along an X-Y plane, with each position on this X-Y plane corresponding to the object's depth. (RX-0180 at ¶¶ 4, 24; Tr. (Schaafsma) at 1286:20-1288:6.). This X-Y plane is substantially orthogonal to a depth direction, as depth is measured along the Z direction (optical axis direction) orthogonal to the X-Y plane. (Tr. (Schaafsma) at 1286:20-1290:1, 1303:9-1304:20; RX-0180 at ¶ 23.)

Based upon the evidence and the analysis of the evidence, 3Shape has proven by clear and convincing evidence that Okamoto discloses element [1.2] of the '538 patent.

c) **[1.3]: "imaging means configured for providing two-dimensional color image data of the portion associated with the reference array;"**

Okamoto discloses the claimed function: "providing two-dimensional color image data of the portion associated with the reference array." As reflected below in Figure 27, Okamoto's non-confocal optical system captures 2D color image data by illuminating the object with white light and capturing the light reflected from the object with a color CCD. (*See* RX-0180 at ¶¶ 28-33; Tr. (Schaafsma) at 1288:15-1289:13, 1304:21-1307:5; Tr. (Stevenson) at 1820:4-9; RDX-0001.29.). On a pixel-by-pixel basis, the CCD 24 collects the 2D color image data that corresponds to the depth information collected for each X-Y point on the measured sample W, and as such, the 2D color image data is "of the portion associated with the reference array." (RX-0180 at ¶¶ 30, 35, 39 ("The received light quantity data, the color data and the height data (Z direction location) for each picture in the X-Y scanning range are respectively stored in light memory 51, the color memory 52, and the height memory 53 (step 103)"); Tr. (Schaafsma) at 1288:15-1289:13, 1306:7-22.).

Figure 27: 3Shape's Depiction of Okamoto Satisfying the Imaging Means Limitation



(RDX-0001.0029 (introduced during the testimony of Dr. Schaafsma).).

Okamoto's non-confocal optical system discloses the claimed structure. The Okamoto non-confocal system has "a white light source 20, optics (e.g., lenses 16 and 17), and a color CCD 24 that detects the white light reflected from the sample. (RX-0180 at ¶¶ 28-30; Tr. (Schaafsma) at 1304:21-1306:22.). This system shares the same objective lens 17 as used in the confocal optical system addressed above because both systems share the same optical axis. (RX-0180 at ¶ 28.)

Align contended that Okamoto does not disclose the claimed "imaging means" because Okamoto does not disclose the claimed "two-dimensional reference array." (CRBr. at 53-54.). However, as discussed above, Okamoto discloses the claimed "two-dimensional reference array" because it uses an X-Y plane where each point or pixel in that X-Y plane has both depth and color information. (RX-0180 at ¶¶ 31, 39; Tr. (Schaafsma) at 1288:15-1289:13.).

Based upon the evidence and as explained in the analysis, 3Shape has proven by clear and convincing evidence that Okamoto discloses element [1.3] of the '538 patent.

d) [1.4]: "wherein the device is configured for maintaining a spatial disposition with respect to the portion that is substantially fixed during operation of the optical scanner and the imaging means."

Okamoto does not disclose this element. The element pertains to a specific problem identified in (and supposedly solved by) the '538 patent:

> Associating color information with three-dimensional objects is not straightforward, particularly when the position information is obtained by using a three dimensional scanning method, while the color information is obtained by using a two dimensional scanning method. The problem of conformally mapping the two dimensional color information onto the three dimensional surface model is difficult and it is common for mismatching of the color with three-dimensional points to occur. Essentially, where two-dimensional color detectors are used for obtaining the color information, it is difficult to accurately associate color information from the detectors with the correct points on the three dimensional surface model, particularly where relative movement between the object and the device occurs between the acquisition of the three-dimensional topological data and acquisition of the two-dimensional image data.

(JX-0003 ('538 patent) at 1:45-55.).

The '538 patent purports to solve this problem as follows:

> operation of the scanning means and the imaging means is substantially or effectively simultaneous in practical terms, and thus the actual time interval that may exist between operation of the two means is so short that the amplitude of any mechanical vibration of the device or movement of the oral cavity will be so small as can be ignored.

(*Id*. at 4:61-5:3.).

The *Markman* Order construed element [1.4] to require: "operation by the optical scanner and the imaging means is at least substantially or effectively simultaneous such that movement (i.e., a change in spatial disposition) can be ignored and depth data and color data correspond to the same reference array." (*Markman* Order at 64-65.).

In Okamoto, at each focal position along the optical axis (Z direction), the confocal optical system performs a raster scan across the X-Y plane to collect height data (depth data), either before or after the capture of 2D color image data by the non-confocal optical system. (RX-0180 at ¶¶ 38-40, Fig. 4; Tr. (Schaafsma) at 1288:15-1290:14; 1307:8-1309:2, 1365:25-1366:14; RDX-0001.31). Figure 4 of Okamoto shows that "the color data, and the height data (Z direction location) for each picture element in the XY scanning range" are received in their respective memories in the same step. (RX-0180, ¶ 39; Tr. (Schaafsma) at 1365:25-1367:6.).

Yet there is limited evidence that this process is performed in real-time such that the operation of the optical scanner and imaging means is effectively simultaneous and movement can be ignore to "ensure[] that the [depth and color] data come from the same points on the surface of the structure" (i.e., correspond to the same XY reference frame). (Tr. (Schaafsma) at 1308:1-13; RX-0180 at ¶¶ 31, 38-40.). Dr. Schaafsma did testify that the confocal optical system in Okamoto can scan "very fast," at several frames per second. (Tr. (Schaafsma) at 1361:11-1362:7.). However, the speed of the 3D scan alone does not address the simultaneity of the optical scanner and imaging means, or the luxury of ignoring movement, which is what the asserted claims require.

There is also evidence that the system in Okamoto would not operate at a sufficiently fast speed to satisfy the asserted claims. Dr. Stevenson testified that, although Dr. Schaafsma "implied that these things could be built to go fast," "[t]hat's not really my experience." (Tr. (Stevenson) at 1795:20-25.). Dr. Stevenson explained that "the raster scan is mirrors moving and stages moving," which is "generally a slow operation." (*Id.*). Documentary evidence and testimony from other witnesses during the Hearing support Dr. Stevenson's testimony. (*See* CX-1894 ¶ 0007 (3Shape's patent stating raster scanners are unsuitable for use in a handheld intraoral device); Tr. (Noam Babayoff)[72] at 97:13-20 (microscope scanners were too slow), 99:6-100:7; RX-0182.003 (raster scan as "relatively slow").).

Based upon the evidence and the analysis provided, 3Shape has not by clear and proven by convincing evidence that the microscope system disclosed in Okamoto even contemplated, much less satisfied, the sort of speed requirements required by the asserted claims.

For this reason alone, Okamoto does not disclose element [1.4] of the '538 patent and does not anticipate claims 1 or 2 of the '538 patent.

e) [2]: "The device according to claim 1, wherein the operation of the optical scanner is based on confocal imaging techniques."

Okamoto satisfies this additional limitation found in claim 2. The optical system in Okamoto is based upon confocal imaging techniques because the laser light source is conjugate to the pinhole detector (PH). (RX-0180 at ¶¶ 16-20 ("Focused laser beam goes through pin hole of pinhole plate PH placed at the focal position of the image forming 18 and enters into 1st photo receptor 19"), Fig. 1; Tr. (Schaafsma) at 1328:16-1329:11.). In its Pre and Post-Hearing Briefs, Align did not dispute that this limitation is met by Okamoto. Therefore, Align has waived any such argument pursuant to Ground Rules 7.2 and 10.1. (CPBr. at 128; CRBr. at 57.)

4. Xu Does Not Anticipate Claims 1 and 2 of the '538 Patent

Xu is U.S. Patent No. 5,912,735, which issued on June 15, 1999, more than one year before the claimed June 17, 2004 priority date of the '538 patent. Xu therefore qualifies as prior art under 35 U.S.C. § 102(b).

Xu is like Okamoto in certain respects. Xu discloses an imaging device that uses a

[72] Mr. Noam Babayoff was the former Vice President of R & D and Operations of Cadent, which was later acquired by Align. (Tr. (Babayoff) at 91:16-18, 93:17-20, 94:1-3.). Align identified Mr. Babayoff as a fact witness to testify about the technology disclosed in the '538 patent; the Cadent/Align products; the history of Cadent and related issues. (CPSt. at 2.).

conventional white light system to obtain color of an examined sample and a laser confocal microscope system for performing raster scans to provide 3D data about the sample. (RX-0166 at 2:21-56, 3:40-46.).

However, unlike Okamoto, Xu is not directed to the problem of providing color 3D imagery. Instead, purporting to "analyze defects on semiconductor wafers, or other objects having surface defects," Xu teaches an "imaging system capable of simultaneously [but separately] producing white light and laser confocal images" without the imaging distortions found in prior art solutions. (*Id*. at 3:26-36.). The system can "produce a complete XY-scanned laser image, in a single plane of focus, at video rates" and display the resulting 2D image "on a high resolution monitor, also in real time," allowing the operator to "scan through different levels of focus in real time, as with a conventional microscope." (*Id*. at 6:5-12.).

However, Xu does not disclose the generation of a 3D topography at "video rates." Instead, "[t]o obtain a three dimensional image, the following process takes place:

> the optics head works with the fine z-stage control (not shown) to develop an expanded depth-of-field image. The sample height is stepped over a pre-selected vertical interval (typically 12 nm or some multiple thereof) using the fine z-stage control. After each complete raster scan at a particular sample height, the height of the sample is changed using the fine z-stage control, and a new raster scan performed, as described above, to obtain a map of light intensity in the focal plane of objective lens 14 (at the new sample height) by measuring the light intensity at each XY location of the raster scan.

(*Id.* at 9:28-38.).

Xu also does not disclose the combination of depth data and color data to produce a 3D color scan of an object. Instead, "the microscope image is displayed on a computer display (simultaneously with the laser image, if desired), either in a separate window on computer display (not shown), using appropriate software, or on a separate video monitor display (not shown).” (*Id.* at 10:7-12.).

Against this backdrop, Xu fails to disclose at least two elements of claims 1 and 2. First, Xu lacks express disclosure a device capable of “determining the surface topology and associated color” of a portion of a 3D structure, as required by the preamble. Dr. Schaafsma failed to provide any testimony on the preamble (element [1.1]), perhaps because he could not identify a disclosure that color and 3D information are associated in any way.[73] (Tr. (Schaafsma) at 1352:24-1353:17.).

Second, Xu lacks an express disclosure that “operation by the optical scanner and the imaging means is at least substantially or effectively simultaneous,” as required by element [1.4]. While, as explained above, the system disclosed in Xu can perform a single X-Y raster scan simultaneous with the collection of color information, there is no indication in Xu that the plethora of raster scans required to generate 3D topology is performed with sufficient haste “such that movement (i.e., a change in spatial disposition) can be ignored and depth data and color data correspond to the same reference array.” (*Markman* Order at 64-65.).

Dr. Schaafsma failed to provide any testimony on this important concept within element [1.4]. Instead, he focused on the simultaneity of color acquisition and a *single* raster scan:

> Q. Dr. Schaafsma, can you explain why you consider Xu to anticipate or render obvious the wherein clause of claim 1?
>
> A. Yeah. As I’ve just described, if we’re intending to take data simultaneously from the same portion of the sample, then this is a system that does exactly that. Literally the two imaging systems can be on at the same time and taking the data at the same time.
>
> Q. And in your opinion, Dr. Schaafsma, is that data of the color imaging system

[73] Pursuant to Ground Rule 7.2, 3Shape waived argument that Xu discloses the preamble because their Pre-Hearing Brief merely contends that Xu discloses one system for color and another for 3D information with no mention of surface topology or associated color. (RPBr. at 122.).

> and the depth -- the optical scanning system in Xu taken of a same reference array?
>
> A. Well, as I've said, I think that the function of the reference array discussion isto say that there's a particular portion of the surface of the sample that we're looking at, and we want to make sure we're looking at the same portion or same area between those two exposures, the two different images. And this -- this system basically does that.

(Tr. (Schaafsma) at 1318:1-18.).

Dr. Schaafsma's discussion of a "reference array" is particularly telling. "[T]his system basically does that" is not clear and convincing evidence of disclosure in Xu. Moreover, on cross examination, Dr. Schaafsma undermined his tepid identification of a "reference array" in Xu by acknowledging that Xu lacked disclosure of the underlying reason why a "reference array" exists in the first place in the '538 patent: to relate depth and color data. (Tr. (Schaafsma) at 1354:24-1353:17 ("I don't recall an express disclosure or anything like that in Xu, but I would -- I would go back and look again."); *see also* RX-0166 at 10:7-11.).

Based on the weight of the evidence, 3Shape has not proven by clear and convincing evidence that the system disclosed in Xu even contemplated, much less satisfied, the surface topology and speed requirements required by the asserted claims. For these reasons, Xu does not disclose elements [1.1] and [1.4] of the '538 patent and does not anticipate claim 1 or 2 of the '538 patent.

5. Neither Okamoto Nor Xu Alone or in Combination of Okamoto and Cha, Render the Asserted Claims Obvious

According to 3Shape, replacing Okamoto's or Xu's raster confocal scanning system with a faster confocal scanning technique (such as the one found in Cha) would have been obvious in light of the knowledge of a person of ordinary skill in the art. (RBr. at 74-76 (citing Tr. (Schaafsma) at 1330:10-1332:2, 1361:15-1363:4, 1365:2-1366:1).).

3Shape made a similar argument in its combination of Okamoto with Cha. (*Id*.). Cha is prior art under 35 U.S.C. § 102(b). (*See* RX-2276.). Cha describes using a confocal microscope where scanning is performed by a digital micromirror device (DMD). (*Se*e RX-0743.) A DMD can be used to create an array of light beams that are directed in different directions using electronic signals. (*Id*.)

3Shape argued that a person of ordinary skill in the art would have understood that instead of using a relatively "slow" raster scanning technique to obtain depth data, as disclosed in Okamoto or Xu, he or she could have used a staring confocal optical scanner. (RBr. at 74-76 (citing Tr. (Schaafsma) at 1330:10-24).). Such a scanner would generate parallel beams to illuminate a portion of an entire of an object. (*Id*.). According to 3Shape, replacing Okamoto's or Xu's raster scanning confocal system with a staring scanner would also require the use of a CCD image sensor to detect the illumination beams reflecting back from the object. (*Id*. (citing Tr. (Schaafsma) at 1365:5-24).).

3Shape's alleged motivation to modify Okamoto or Xu in this way falls short. 3Shape frames the obviousness inquiry as whether a person of ordinary skill in the art could modify Okamoto or Xu to get a faster microscope. (RBr. at 74-76.). However, that is not the proper inquiry. *See Broadcom Corp. v. Emulex Corp*., 732 F.3d 1325 (Fed. Cir. 2013) (stating that "[a]n invention is not obvious just "because all of the elements that comprise the invention were known in the prior art";[] rather a finding of obviousness at the time of invention requires a "plausible rational[e] [sic] as to why the prior art references would have worked together"). 3Shape improperly assumes that a person in the art of the invention would seek to modify microscope technology in Okamoto or Xu to create scanning technology. (CX-2277C at 275:21-276:1 (3Shape's engineer testifying that a microscope is not a 3D scanner).).

3Shape did not present clear and convincing evidence of such motivation. Instead, Dr. Schaafsma testified to likelihood of success, not motivation.

> Q. Dr. Schaafsma, in your opinion, would it have been obvious to one of ordinary skill in the art to replace the optical scanner of Xu with a staring confocal system?
>
> A. I believe that, yes, that a person of skill in the art would know that that had been done.
>
> * * *
>
> Q. And the same question for Okamoto. Would it have been obvious to one of ordinary skill in the art to have replaced the optical scanner of Okamoto with a staring confocal system?
>
> A. I think that, yes, a person of skill in the art would know that that could be done and had been done.

(Tr. (Schaafsma) at 1330:5-1331:15.).

In short, 3Shape has failed to prove by clear and convincing evidence "that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention[.]" *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367–68 (Fed. Cir. 2016).

Consequently, 3Shape has failed to prove that the asserted claims are rendered obvious by Okamoto or Xu alone, or by the former in combination with Cha.

6. 3Shape's Invalidity Arguments Based on Babayoff Fail for Lack of Evidence

3Shape's invalidity arguments based upon Okamoto and Xu have been addressed above. As shown below in Figure 28, what remains are 3Shape's invalidity arguments based on Babayoff. Babayoff is a named inventor on the '538 patent. In addition to the grounds listed in Figure 28 (combinations of Babayoff and another reference), it appears that 3Shape argued that the asserted claims were obvious based on Babayoff alone. (RBr. at 76.).

Figure 28: Align's Depiction of 3Shape's Grounds for Invalidity

Alleged Prior Art Grounds

Alleged Prior Art		Asserted Grounds
Okamoto *RX-0180*	Microscope	1. Okamoto anticipation 2. Okamoto obviousness 3. Okamoto in view of Cha
Xu *RX-0166*	Microscope	4. Xu anticipation 5. Xu obviousness
Babayoff *RX-0338*	Monochromatic Intraoral Scanner	6. Babayoff in view of Okamoto 7. Babayoff in view of Okamoto and Geng '539 8. Babayoff in view of Xu 9. Babayoff in view of Xu and Geng '539

align CDX-0015.5

(CDX-0015.0005 (introduced during the testimony of Dr. Stevenson).).

Babayoff is prior art under 35 U.S.C. § 102(b). It describes a method and confocal apparatus for non-contact imaging of 3D objects, including teeth, by "confocal focusing an array of light beams," to determine the surface topology of the scanned 3D structure. (*See, e.g.*, RX-0338 at Abstract, 3.). Babayoff essentially discloses the monochrome 3D scanner of the '538 patent. The '538 patent states that Babayoff describes an embodiment of the "optical scanner." (JX-0003 at 25:7-11.).

Babayoff determines the surface topology of a 3D structure by illuminating the surface with an array of incident light beams. (*Id.* at 3:3-4:14.) These arrays of incident light beams are formed by a laser beam passed through a grating or a microlens array. (*Id.* at 8:26-9:2.). The light beams are then passed through telecentric confocal optics connected to a motor which changes the relative location of the focal plane of the optics along the Z-axis (i.e., the plane at which the light beams are focused can be scanned along the Z-direction). (*Id.* at 9:18-24, 11:10-13.)

When the array of incident light beams impinge on the surface of the scanned 3D structure, a corresponding array of illumination spots form on the surface of the scanned object at spatially separate X-Y positions. (*See id*. at 5:1-21, 9:18-24, 11:10-13.). These illumination spots are in-focus if the surface of the 3D structure is coincident with the focal plane, or out-of-focus if the surface of the 3D structure is not coincident with the focal plane. (*Id.*). Whether the illumination spot is in-focus is determined by measuring the intensity of light returned from each spot as the focal plane is shifted along the Z-direction. Where the intensity is maximum corresponds to the in-focus position. (*Id.* at 4:18-29.)

The intensity of each returned light beam is measured by passing it through a corresponding pinhole in pinhole array 66. (*Id.* at 10:29-11:5.). The pinhole acts as a spatial filter to exclude out-of-focus light from the image sensor, allowing the pixels in the image sensor to measure intensity differences in the returned light as the focal plane moves in the Z-direction. (*Id.*). This is well-known and conventional in confocal scanning. (Tr. (Schaafsma) at 1277:3-1278:18.)

The surface topology of the scanned 3D structure is obtained from the maximum measured intensities because "[t]he SSP for each illuminated spot will be different for different spots" – i.e., the in-focus position of each illuminated spot is independent from other spots. (*Id.* at 5:1-6.). This is also a part of conventional confocal scanning systems. (Tr. (Schaafsma) at 1369:18-1371:2.)

In addition to Babayoff, 3Shape makes prior art combinations based on Geng '539. Geng '539, or U.S. Patent No. 6,594,539, is prior art under 35 U.S.C. § 102(a) and § 102(e). Geng

’539 describes an intra-oral imaging system that produces both 3D and color 2D images of dental structures. (*See, e.g.*, RX-0168 at 3:23-32.).

According to 3Shape, “[i]f a POSITA would not have been motivated to combine the white light imaging systems of Okamoto or Xu with Babayoff’s intraoral confocal scanning system because Okamoto and Xu are directed to microscopes, Geng ’539 provides additional motivation.” (RBr. at 84.). 3Shape continued: “Geng ’539 would motivate a POSITA to incorporate a 3D scanner and a 2D color imaging system into a hand-held device for intraoral use, and teaches that such a combination was feasible and within the level of ordinary skill.” (*Id.* (citing Tr. (Schaafsma) at 1326:13-1327:8).). From 3Shape’s perspective, Geng ’539 is a bridging or mapping reference of sorts.

Yet the substantive value of Geng ’539 is far from clear and convincing. Geng does not explain why a person of ordinary skill in the art would have looked to combine the 3D scanner technology of Babayoff with microscope references such as Okamoto and Xu. Geng is directed to a “mechanical structure and optical design [that] are very simple and reliable” because there is “no scanning mechanism or moving parts” such as a translating lens. (RX-0168 at 5:63-64; Tr. (Schaafsma) at 1356:12-25.). Thus, Geng ’539 does not direct a person of ordinary skill in the art toward microscopes with scanning mechanisms (i.e., x-y raster scanner and z-stage scanner). Even 3Shape acknowledged that the asserted claims of the ’538 patent do not require what Geng ’539 appears to offer in terms of “a hand-held device, a movable device, a processor, or the ability to scan teeth.” (RBr. at 84.). Thus, the obviousness combination of Babayoff with Okamoto or Xu, for which Geng ’539 supposedly created a motivation, also need not disclose these unclaimed features. (Tr. (Stevenson) at 1804:11-1805:1; *see also* Order No. 36, Appx. A at 68.).

Setting aside Geng ’539, it is clear that Babayoff alone cannot render the asserted claims obvious. Dr. Schaafsma testified that Babayoff does not teach a device “for determining surface topology and associated color,” the “imaging means” feature, and the “spatial disposition” clause of claim 1. (Tr. (Schaafsma) at 1319:21-1321:1.).

While 3Shape attempted to manufacture a disclosure of color scanning in Babayoff, no such disclosure exists. During the Hearing, Mr. Noam Babayoff[74] himself testified that the Babayoff reference was monochromatic. (Tr. (Babayoff) at 115:2-117:20, 121:19-123:10). His testimony is consistent with the express teachings of the ’538 patent that the Babayoff reference is monochromatic and does not capture color data. (JX-0003 at 1:40-45). While the Babayoff patent does disclose using light of three different wavelengths, nothing in Babayoff indicates that these wavelengths refer to red, green, and blue illuminations used for color imaging. Instead, these “different wavelengths” are used to reduce measurement time by focusing different wavelengths simultaneously to different planes. (Tr. (Babayoff) at 121:10-123:10; RX-0028 at 14:3-20; RX-0155 at 1:63-2:39.). Indeed, a set of three narrow-band wavelengths will not produce a color image. (Tr. (Babayoff) at 116:17-117:20.).

3Shape fares no better with combinations of Babayoff with Okamoto or Xu. 3Shape failed to provide clear and convincing evidence of a motivation to make either of these combinations. “Whether a skilled artisan would be motivated to make a combination includes whether he would select particular references in order to combine their elements.” *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1337 (Fed. Cir. 2016).

As Judge Cheney found in the 1091 Investigation, Babayoff and Okamoto (referred to as

[74] When he testified during the Hearing on October 24, 2019, Mr. Noam Babayoff was a named inventor of the ’538 patent. He testified with respect to the ’538 patent and its technology.

Yoichi therein) are from different fields and "seemingly dissimilar inventions." (*See* 1091 Investigation, Initial Determination at 96.). Okamoto and Xu, which emerged from the field of microscopy, and Babayoff, which emerged from commercial intraoral scanning, are directed to different problems, different applications, and have different design configurations.

As Mr. Babayoff explained during the Hearing, raster scanning microscopes (such as those disclosed in Okamoto and Xu) were slow and not suitable for intraoral scanners. (Tr. (Babayoff) at 97:13-20; *see also* Tr. (Stevenson) at 1795:20-25 (expert testimony describing raster scan as "slow operation").). Indeed, when filing its own patent on a color intraoral scanner in 2015, 3Shape denigrated the same x-y raster scanning technique as used by Okamoto and Xu. (CX-1894 at ¶0007.).

Against this backdrop, 3Shape has failed to explain why a person of ordinary skill in the art seeking to add color imaging to the monochromatic 3D scanning of Babayoff would turn for support to prior art microscopes with known flaws. "Known disadvantages in old devices which would naturally discourage search for new inventions may be taken into account in determining obviousness." *United States v. Adams*, 383 U.S. 39, 52 (1966). 3Shape's engineer and intraoral scanner developer, Dr. van der Poel, testified that one would not look to a microscope to design an intraoral scanner. (CX-2277C at 275:12-276:2.).

3Shape has provided nothing more than cursory expert opinion in support of its argument that a personal of ordinary skill in the art would have a reasonable expectation of success in actually making the obviousness combinations. (Tr. (Schaafsma) at 1323:8-1326:12; *see also* RDX-0001.41); *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1327 (Fed. Cir. 2012) (affirming non-obviousness when expert's opinions were "conclusory and factually unsupported" because he "failed to explain how specific references could be combined, which combination(s) of elements in specific references would yield a predictable result, or how any specific combination would operate or read on the asserted claims" and therefore his opinion was "insufficient"). With respect to the Xu combination, Dr. Schaafsma merely stated that changing out scanning and imaging systems was an "idea…available to a person at the time." (Tr. (Schaafsma) at 1326:5-12; *see also* RX-0116 at Fig. 1; RDX-0001.41.). Dr. Schaafsma provide similarly cursory testimony on the Okamoto combination. (*Id*. (Schaafsma) at 1324:5-20; *see also* RX-0180 at Fig. 1; RDX-0001.41.). Cursory testimony is not clear and convincing evidence.

The shortcomings in 3Shape's obviousness combinations are also compounded by the fact that the Okamoto and Xu references, standing alone, are missing claim elements that 3Shape contended are present in those references.

X. U.S. PATENT NO. 9,299,192

A. Infringement

1. Infringement Overview

Align accused 3Shape of directly infringing claims 2, 28, and 29 of the '192 patent, both literally and under the doctrine of equivalents.[75] (CPBr. at 82-89; CBr. at 55-68.). Align also accused 3Shape of indirectly infringing claims 2, 28, and 29 of the '192 patent by inducing infringement of these asserted claims.

Claims 2 and 29 depend from independent claim 1 and 28, respectively. Thus, in addition to addressing the asserted claims, an analysis of each of the elements of unasserted claim 1 is provided in Section X.A.2 below. Moreover, as shown in Table No. 10 below, the

[75] DOE was not reached because the 192 Accused Products have been found to infringe literally the asserted claims of the '192 patent.

elements recited in claim 1 drawn to a "method for generating a modified virtual model of a physical structure" are nearly identical to the elements recited in claim 28, which are drawn to a "system to generate a modified virtual model of a physical structure." Thus, the claim elements are addressed together in Section X.A.2(a) below (e.g., elements [1.1] / [28.1], [1.2] / [28.2], etc.).

Table No. 10: Comparison of Claims 1 and 28 of the '192 Patent

Cl. 1	Element	Cl. 28	Element
[1.1]	A method for generating a modified virtual model of a physical structure, comprising:	[28.1]	A system to generate a modified virtual model of a physical structure, comprising:
[1.2]	(A) displaying an image of a first virtual model on a display operatively connected to a computer system, wherein the first virtual model is generated from first 3D scan data of the physical structure, and wherein said first virtual model fails to properly represent a first physical part of the physical structure;	[28.2]	a display to display images of said modified virtual model; and a computer system operatively connected to the display and comprising a program that, when executed by the computer system, causes the computer system to, display an image of a first virtual model generated from first 3D scan data of the physical structure on the display, wherein said first virtual model fails to properly represent a first physical part of the physical structure,
[1.3]	(B) receiving user input identifying at least a portion of the first virtual model that is desired to be modified, wherein the user input is generated by user interaction with the image on the display;	[28.3]	receive user input identifying at least a portion of the first virtual model that is desired to be modified, the user input generated by user interaction with the image of the first virtual model on the display,
[1.4]	(C) receiving a second virtual model of the physical structure with the computer system, the second virtual model generated from second 3D scan data of the physical structure;	[28.4]	receive a second virtual model of the physical structure, the second virtual model generated from second 3D scan data of the physical structure, and

Cl. 1	Element	Cl. 28	Element
	and		
[1.5]	(D) modifying the first virtual model with the computer system by replacing at least said identified portion of the first virtual model with a corresponding portion of the second virtual model, thereby generating the modified virtual model.	[28.5]	modify the first virtual model by replacing at least said identified portion of the first virtual model with a corresponding portion of the second virtual model, thereby providing the modified virtual model.

For the reasons discussed in Sections X.A.2(a-c) below, Align has met its burden and proven that the 192 Accused Products practice claims 2, 28, and 29.

2. The 192 Accused Products Practice Practice Claims 2, 28, and 29 of the '192 Patent

a) Claims 1 and 28[76]

i. [1.1] / [28.1]: "A method for generating a modified virtual model of a physical structure, comprising" / "A system to generate a modified virtual model of a physical structure, comprising"[77]

There is no dispute that the 192 Accused Products meet preambles [1.1] and [28.1]. (Tr. (Badler) at 484:12-485:2; CX-2125C (Badler Expert Rpt.) at ¶¶ 684-95.). Dr. Badler confirmed that a user of the TRIM tool identifies and removes an inaccuracy in the first virtual model and then "replace[s] that portion . . . by rescanning" in order to end up with "a unified or modified whole virtual model." (Tr. (Badler) at 467:9-22; *see also id.* at 484:12-485:2, 489:17-490:15.). 3Shape's technical documents describe deleting the marked area from the model and, after

[76] 3Shape did not separately address the elements recited in claim 28.

[77] The Parties agreed that the term "virtual model" should be given its plain and ordinary meaning, which is "3D virtual representation." (*Markman* Order, App. A at 6.).

trimming, the user can "continue scanning on the rest of the model." (CX-1093.0001-2; *see also* CX-1106C.0027 (user manual); CX-0417:1:47-2:27 (3Shape training video); CDX-0011C.0208.).

As Dr. Eli Saber explained,[78] the TRIM tool "provides the user the ability to trim away and replace certain sections from a virtual model of a patient's teeth." (Tr. (Saber) at 1485:9-12.). Moreover, he testified that "when you go back and rescan, you can obtain an updated virtual model that represents what you are doing." (*Id.* at 1488:13-22.). In short, the user is "creat[ing] a new virtual model for that area." (*Id.* at 1496:16-1497:2.).

For these reasons, Align has proven by a preponderance of evidence that the 192 Accused Products meet preambles [1.1] and [28.1] of claims 1 and 28, respectively, of the '192 patent.

ii. [1.2] / [28.2]: "displaying an image of a first virtual model on a display operatively connected to a computer system, wherein the first virtual model is generated from first 3D scan data of the physical structure, and wherein said first virtual model fails to properly represent a first physical part of the physical structure" / "a display to display images of said modified virtual model; and a computer system operatively connected to the display and comprising a program that, when executed by the computer system, causes the computer system to, display an image of a first virtual model generated from first 3D scan data of the physical structure on the display, wherein said first virtual model fails to properly represent a first physical part of the physical structure"

The Parties agreed that the claimed "virtual model" means a "3D virtual representation." (*Markman* Order, App. A at 6.). Evidence adduced in this Investigation establishes that TRIOS

[78] When he testified during the Hearing on October 30, 2019, Dr. Eli Saber was a Professor in Department of Electrical and Microelectronic Engineering at the Kate Gleason College of Engineering. (RPSt. at Ex. D.). 3Shape identified Dr. Saber as an expert to testify about the invalidity of the '192 patent, 3Shape's non-infringement of the asserted claims of the '192 patent, and Align's failure to satisfy the technical prong with respect to the '192 patent. (RPSt. at 4.).

displays an image of the first virtual model. (Tr. (Badler) at 478:17-480:8, 485:3-487:22; Tr. (Kristian Hansen)[79] at 1216:6-1217:8, 1219:17-1220:9; Tr. (Saber) at 1452:14-21; CX-2225C (Hansen Dep. Tr.) at 147:4-8, 150:16-21, 151:14-20, 165:12-166:2, 184:18-22; CX-1093.0001; CX-0417 (TRIOS video) at 2:22; CDX-0011C.0206, .0210.). Dr. Badler, one of Align's experts, explained that [redacted] (Tr. (Badler) at 481:25-482:1.). Mr. Hansen, a 3Shape fact witness, confirmed that [redacted] (Tr. (Hansen) at 1221:12-16.). He also testified that an "image of the model [is] displayed on the computer screen connected to the TRIOS scanner." (CX-2225C (Hansen Dep. Tr.) at 147:4-8; CDX-0011C.0219.).

As Dr. Badler and Mr. Hansen both testified, the first virtual model is generated from first 3D scan data of the physical structure. (Tr. (Badler) at 486:3-25; CX-2225C (Hansen Dep. Tr.) at 150:1-7; CDX-011.0222.). Mr. Hansen confirmed that the TRIOS application software is "responsible for receiving scanner data and constructing three-dimensional models." (Tr. (Hansen) at 1184:10-16.). According to a 3Shape document, this 3D scan data "is obtained by [redacted] and these images are transformed "into 3D surface information." (CX-1095C.0008; *see also* CX-2225C (Hansen Dep. Tr.) at 64:1-7; CX-0953C.0009-10 (§ 1.4.1), 5-6 (§ 1.1), 15 (Fig. 1.12).). Each [redacted] has [redacted], which provides the [redacted] orientation in 3D space as determined by

[79] When he testified during the Hearing on October 29-30, 2019, Mr. Kristian Hansen was employed by 3Shape TRIOS AS a project manager of the TRIOS application software. (Tr. (Hansen) at 1183:25-1184:4.). 3Shape identified Mr. Hansen as a fact witness to testify about 3Shape's design and development of its TRIOS intraoral scanners and the structure, function, and operation of those products. (RPSt. at 2.).

the scanner's geometry. (CX-2225C (Hansen Dep. Tr.) at 32:25-33:16; Tr. (Badler) at 481:13-482:5 (discussing [redacted]), 487:23-488:13 (same); Tr. (Hansen) at 1242:17-1243:10 (the package sent to the computer contains gyroscope information); CX-0953C.0013-14 at § 1.5.3; CPX-0168.0002-3.)

The first virtual model generated from this 3D scan data may have some area that the user does not like, and the user can erase that area using the TRIM tool. (CX-2225C (Hansen Dep. Tr.) at 150:16-151:20.). For example, if there is "blood," "saliva," or "too much soft tissue obstructing [the doctor's] work," then you remove those portions of the model with the TRIM tool. (*Id.*; *see also* Tr. (Badler) at 484:12-22, 659:1-4; CX-2125C (Badler Expert Rpt.) at ¶¶ 670-71; CX-0417C (TRIOS video) at 2:22-2:31.). Blood, saliva, and too much soft tissue on the model are examples of the first virtual model failing to properly represent a first physical part (tooth or margin line) of the physical structure (jaw), as claimed. (JX-0004 at 5:45-51; 8:57-63; 12:9-15; 14:44-48; 20:42-49.).

Accordingly, Align has proven by a preponderance of evidence that the 192 Accused Products practice elements [1.2] and [28.2] of claims 1 and 28, respectively, of the '192 patent.

iii. [1.3] / [28.3]: "receiving user input identifying at least a portion of the first virtual model that is desired to be modified, wherein the user input is generated by user interaction with the image on the display" / "receive user input identifying at least a portion of the first virtual model that is desired to be modified, the user input generated by user interaction with the image of the first virtual model on the display"[80]

The Parties agreed that "identifying at least a portion of the first virtual model that is

[80] The Parties agreed that the phrase "identifying at least a portion of the first virtual model that is desired to be modified" means "identifying at least a portion on the first virtual model that is desired to be replaced." (*Markman* Order, App. A at 6.).

desired to be modified" means "identifying at least a portion on the first virtual model that is desired to be replaced." Dr. Fisker, 3Shape's expert, confirmed there are instances where the first 3D model has "an unwanted area such as blood or collapsed gingiva" and the "TRIM tool allows the user to delete the area from the first model." (Tr. (Fisker) at 658:23-659:7; *see also* CX-2220C (Fisker Dep. Tr.) at 230:15-233:20.). Other witnesses confirmed this, testifying that the user identifies a portion on the first virtual model that is desired to be replaced using the TRIM tool. (Tr. (Badler) at 478:17-480:8, 485:3-487:22; Tr. (Hansen) at 1216:6-1217:8, 1219:17-1220:9; Tr. (Saber) at 1452:14-21; CX-2225C (Hansen Dep. Tr.) at 147:4-8, 150:16-21, 151:14-20, 165:12-166:2, 184:18-22; CX-1093.0001; CX-0417 (TRIOS video) at 2:22; CDX-0011C.0206, .0210.).

As Dr. Badler, Align's expert, explained, when the user invokes the TRIM tool the user "work[s] on the screen to indicate some area of that model . . . that we'd like to rescan" and the "inaccurate portion is removed." (Tr. (Badler) at 467:3-22; *see also id.* at 468:20-25, 470:19-471:9, 479:9-480:8.). Dr. Badler and Mr. Hansen confirmed that the [redacted] file allows the user to manually mark and delete a part of the model on the screen using the TRIM tool. (Tr. (Badler) at 483:11-16; Tr. (Hansen) at 1217:9-12.). Mr. Hansen also testified "when the user uses the TRIM tool, they [redacted] on the displayed model by using their finger. (Tr. (Hansen) at 1246:1-12; *see also id.* at 1193:25-1194:3; CX-2225C (Hansen Dep. Tr.) at 165:12-166:2.). Dr. Badler's and Mr. Hansen's factual testimonies are confirmed in 3Shape's technical documentation, which requires the ability to "draw on the scan," and when the user stops drawing, "then the marked area must be deleted from the scan." (CX-1093.0001; CDX-0011C.0225.).

Accordingly, Align has proven by a preponderance of evidence that the 192 Accused

Products practice elements [1.3] and [28.3] of claims 1 and 28, respectively, of the ’192 patent.

iv. [1.4] / [28.4]: “receiving a second virtual model of the physical structure with the computer system, the second virtual model generated from second 3D scan data of the physical structure” / “receive a second virtual model of the physical structure, the second virtual model generated from second 3D scan data of the physical structure”[81]

Align presented supported, compelling evidence that the ’192 Accused Products infringe claim elements [1.4] / [28.4]. (Tr. (Badler) at 487:23-489:16; CX-2125C (Badler Expert Rpt.) at ¶ 725-42.). The term “second virtual model” was construed to mean “second 3D virtual representation.” (*Markman* Order, App. A at 1.). Both experts, Dr. Badler, Dr. Saber3 together with 3Shape’s fact witness, Mr. Hansen all agreed that point clouds are “virtual models.” Dr. Badler testified that output of the scanner is [redacted] (Tr. (Badler) at 488:2-10.). As Dr. Badler explained, the [redacted] (*Id.*). Simply put, “the second virtual model is generated from new 3D scan data in the same manner that the first model was generated from scan data.” (Tr. (Badler) at 489:3-7.).

Mr. Hansen confirmed that the TRIOS uses 3D scan data to construct a “virtual representation” (i.e., a second virtual model) that is later added to a combined model. (Tr. (Hansen) at 1184:10-16.). He testified that from the 3D scan data, the TRIOS constructs a three-dimensional point cloud that is [redacted] (*Id.* at 1184:21-1185:8.).

Dr. Saber also testified that a three-dimensional point cloud is “a virtual representation.”

[81] The term “second virtual model” was construed to mean “second 3D virtual representation.” (*Markman* Order, App. A at 1.).

(Tr. (Saber) at 1493:17-19; *see also id.* at 1491:13-1492:4.). He described it as "3D digitized data." (*Id.* at 1495:17-20.). As Dr. Saber expressed, when the user rescans, they "create a new virtual model for that area." (*Id.* at 1496:16-1497:2; CX-0558C.0006; CDX-0025.0010.).

The original model and the newly created virtual model are generated from a different data scans, i.e., the original scan and the rescan, respectively. Dr. Saber testified that during rescanning the scanner is adding [redacted]. (Tr. (Saber) at 1507:5-1508:6.). Mr. Hansen confirmed that the 192 Accused Products obtain "at least a second 3D representation by scanning at least a modified part of the object after modification." (CX-2225C (Hansen Dep. Tr.) at 184:23-185:5.). Dr. Fisker echoed this testimony, stating that the TRIOS will "obtain a second 3D representation by rescanning the object after modification." (Tr. (Fisker) at 660:1-8.).

Additionally, Dr. Fisker confirmed that a [redacted] obtained by rescanning "can be interpreted as a model." (Tr. (Fisker) at 659:12-21.). Dr. Fisker agreed during his deposition that "of course you can interpret [redacted] as a second model." (CX-2220C (Fisker Dep. Tr.) at 233:8-234:12.). This is because the newly acquired sub scans are "a different model than the initial model." (*Id.*). Dr. Badler confirmed these facts by referring to the following 3Shape source code files: [redacted] (Tr. (Badler) at 488:11-13.). Dr. Saber failed to opine on this source code.

Mr. Mozeko, a witness who testified on behalf of a 3Shape reseller, Great Lakes, confirmed through his technical team that the TRIM tool and TRIOS allow a user to "rescan[] the deleted area on the jaw to receive a second virtual model." (CX-0025 at ¶ 4(u)(i)(4); Tr. (Mozeko) at 752:15-753:5; 760:22-761:7; see also CX-0026 ¶ 3(i)(i).)

In sum, the TRIM tool allows the user to avoid "rescanning the entire object" exactly like the '192 patent's disclosure. (Tr. (Fisker) at 657:13-658:1; JX-0004 at 2:15-24, 15:13-16, 16:37-42, 25:3-12, 27:24-29, 29:8-15.). 3Shape's documentation confirms that the user is "only allowed to scan within a certain distance from the marked preparation," which allows the user to avoid rescanning the entire object. (CX-0356C.).

For the reasons discussed above, Align has proven by a preponderance of evidence that the 192 Accused Products practice elements [1.4] and [28.4] of claims 1 and 28 respectively, of the '192 patent.[82]

v. [1.5] / [28.5]: "modifying the first virtual model with the computer system by replacing at least said identified portion of the first virtual model with a corresponding portion of the second virtual model, thereby generating the modified virtual model" / "modify the first virtual model by replacing at least said identified portion of the first virtual model with a corresponding portion of the second virtual model, thereby providing the modified virtual model"

Evidence proffered in this Investigation demonstrates that the 192 Accused Products practice these claim elements. (Tr. (Badler) at 489:17-490:23; CX-2125C (Badler Expert Rpt.) at ¶¶ 743-51.). Dr. Badler testified that infringement of claim element [1.5] is "evidenced both by Mr. Hansen's testimony that TRIOS allows you to align first and second 3D representations, and that the first representation is modified with data from the second representation, and that's exactly what the workflow produces." (Tr. (Badler) at 489:21-490:2; CX-2225C (Hansen Dep. Tr.) at 184:23-185:5.).

For the volumetric scanning technique, "when the user is done using the TRIM tool, the

[82] Dr. Badler testified that "[t]o the extent that claim element 1.4 is not literally infringed, it's infringed under DOE, [because the accused products] provide[] substantially the same function in the same way with the same result of allowing the acquisition of new scan data to correct inaccurate scan data, therefore provide better scan quality." (Tr. (Badler) at 391:25-392:9.).

changes are [redacted] (Tr. (Hansen) at 1219:17-1220:1.). Consistent with Mr. Hansen's testimony, Dr. Badler confirmed that "the [redacted]" and when the user does local rescanning of the area to be re-built, "that creates [redacted]" that "can then be [redacted]" (Tr. (Badler) at 470:19-471:9; *see also id.* at 560:17-562:6.). Dr. Badler explained that both the [redacted] only need to be modified locally because "the unmodified parts of the first model" are retained "when the modified model is generated." (Tr. (Badler) at 471:10-21.).

Dr. Badler's analysis is supported by the pertinent source code. For example, Dr. Balder commented that with respect to [redacted] meaning that the code [redacted] (Tr. (Badler) at 471:22-472:13; CPX-0088C at line 247.). He also expressed that [redacted] (Tr. (Badler) at 472:14-473:3; CPX-0088C at line 362.).

With respect to the surface scanning technique, Mr. Hansen confirmed that "when the user begins scanning again with the surface scanning mode, the TRIOS [redacted] . . . ." (Tr. (Hansen) at 1246:13-17; *see also id.* at 1251:5-8, 1506:19-1508:6; CX-0351C.0002.). He explained that rescanning "only affect[s] [redacted]" (Tr. (Hansen) at 1246:22-1247:4; *see also id.* at 1251:12-22, 1261:1-6; CX-0351C.0002.). In other words, the model updating occurs locally and the model remains unchanged in areas where no new sub scans are coming in. (*Id.*).

Dr. Fisker confirmed that after using the TRIM tool, the user has a first model without the undesirable portion. (CX-2222C (Fisker Dep. Tr.) at 289:4-17.). Subsequently, the user "need[s] to fill that in" to have "an accurate scan" so the user performs a second 3D scan to obtain the second 3D virtual representation. (*Id.* at 289:4-24.). The end result, as detailed extensively above, is a modified virtual model that is generated from different data scans (e.g., the first scanning session and the rescanning session). (CX-0352C.0014 ("new scan data must be appended to the model" and the "[p]ost processed scan should contain scan data from both first and second scanning"); CX-0351.0009 (upon rescanning "[t]he model must continue being built from the location where you previously stopped" and the "3D mod[e]l must be built up in real time").)

Great Lakes' Mr. Mozeko confirmed that the TRIM tool and TRIOS allow a user to "modify[] the initial model with the second model obtained during the rescanning to provide a modified virtual model." (CX-0025 ¶ 4(u)(i)(5); Tr. (Mozeko) at 752:15-753:5, 760:22-761:7 (The "information was given to [him] by [Great Lakes's] technical support people.").).

For the foregoing reasons, Align has proven by a preponderance of evidence that the 192 Accused Products literally practice elements [1.5] and [28.5] of claims 1 and 28, respectively, of the '192 patent.[83]

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[83] Dr. Badler testified that "to the extent claim element 1.5 is not infringed literally, it's infringed under DOE. Again, [the '192 Accused Products] perform[] substantially the same function of modifying the first virtual model by stitching the first virtual model together with the selected modified portion and the second virtual model generated from the same scanning system that results in a modified virtual model." (Tr. (Badler) at 490:3-15; CX-2225C (Hansen Dep. Tr.) at 184:23-185:5; CX-0417 (TRIOS video) at 2:22; CX-1093C.0002 ("start to scan the trimmed area" and "must be able to continue scanning on [the] rest of the model."); CX-0025 ¶ 4(u)(i)(5) ("modifying the initial model with the second model obtained during the rescanning to provide a modified virtual model."); CX-2222C (Fisker Dep. Tr.) at 268:3-9, 280:8-12; 281:14-23; CX-0558.0006; CDX-0011C.0234.).

b) Claim 2

i. "The method according to claim 1, wherein said physical structure comprises any one of an intra-oral cavity of a patient or a physical dental model representative of said intra-oral cavity."

Align presented evidence that the 192 Accused Products practice the additional limitation recited in claim 2, which 3Shape did not separately dispute. (Tr. (Badler) at 490:24-491:7; CX-2125C (Badler Expert Rpt.) at ¶¶ 752-53; RRBr. at 42.). Thus, there is no dispute that the TRIOS is an intraoral scanner for scanning physical structures such as a patient's intraoral cavity. (Tr. (Avi Kopelman)[84] at 155:2-4; Tr. (Badler) at 490:24-491:7 (Tr. (Fisker) at 651:5-13, 654:12-24, 685:3-17; Tr. (Hansen) at 1209:25-1210:4.).

Accordingly, Align has proven by a preponderance of evidence that the 192 Accused Products practice the additional limitation recited in claim 2 of the '192 patent.

c) Claim 29

i. "The system according to claim 28, wherein the at least said identified portion of the first virtual model and the corresponding portion of the second virtual model are each representative of a physical portion of the physical structure, the first virtual model providing a deficient representation of the physical portion and the second virtual model providing an adequate representation of the physical portion."

The '192 Accused Products infringe the additional limitations recited in claim 29, which

[84] When he testified during the Hearing on October 24, 2019, Mr. Avi Kopelman was a Vice President and Chief Scientist for Align. (Tr. at 126:14-18.). Align identified Mr. Kopelman as a fact witness expected to testify on the background and business of Align; background and business of Cadent; Align's interactions with 3Shape; equitable defenses; domestic industry in the Asserted Patents; the background and development of the technology in asserted '538 and '192 patents; Align's domestic industry products; validity of asserted patents including non-obviousness and secondary considerations; standing and ownership of Asserted Patents; Align's iTero Element and Eraser Tool; and related issues. (CPSt. at 7-8.).

3Shape did not separtely contest. (Tr. (Badler) at 491:22-493:5; CX-2125C (Badler Expert Rpt.) at ¶¶ 781-83; RRBr. at 42; *see also* Tr. (Saber) at 1471:20-1472:2.). 3Shape teachs TRIOS users that when the first virtual model is deficient because it is distorted by blood or saliva, the distorted portion can be replaced by the second virtual model, which is adequate because it more accurately represents the patient's dentition. (CX-0417C (TRIOS video) at 2:00-2:31; CX-0413C (TRIO video) at 2:50-4:50; CX-0416C (TRIOS video); Tr. (Badler) at 491:22-492:21.).

For the foregoing reasons, Align has proven by a preponderance of evidence that the 192 Accused Products practice the additional limitation recited in claim 29 of the '192 patent.

B. Technical Prong of Domestic Industry

1. The 192 DI Product Practice Claims 2, 28, and 29 of the '192 Patent

a) Claims 1 and 28

i. [1.1] / [28.1]: "A method for generating a modified virtual model of a physical structure, comprising" / "A system to generate a modified virtual model of a physical structure, comprising"[85]

Align presented evidence that the 192 DI Product practices preambles [1.1] and [28.1]. (Tr. (Kopelman) at 138:24-139:17, 140:17-142:7; Tr. (Badler) at 497:1-10, 501:18-23; CX-1809C; CDX-0005.0011; CDX-0011C.0252-54; CX-2125C (Badler Expert Rpt.) at ¶¶ 792-813.). As Dr. Badler explained, the iTero Element's Eraser tool receives user input on a touch screen to identify at least a portion of a first virtual model, or 3D virtual representation, that requires modification. (Tr. (Badler) at 495:8-496:4, 498:12-499:2; CDX-0011C.0241-49; CX-1809C; CX-1909; Eraser_actor.cpp; eraser_region_logic.cpp.).

The [redacted]

[85] The Parties agreed that the term "virtual model" should be given its plain and ordinary meaning, which is "3D virtual representation." (*Markman* Order, App. A at 6.).

[redacted]. (Tr. (Badler) at 495:8-496:4, 498:12-499:2; CDX-0011C.0245-50.). [redacted]. (Tr. (Badler) at 495:8-496:4, 498:12-499:2; CDX-0011C.0245-50; [redacted].). Dr. Badler explained that the new scan data is: (i) [redacted]. (Tr. (Badler) at 495:19-496:4 ([redacted]), 499:3-500:6; CX-2251C (Minchenkov Dep. Tr.) at 135:21-139:4, 145:16-146:5; CDX-0011C.0247, .0250.).

After rescanning in Scan Mode, [redacted]. (Tr. (Badler) at 496:5-25 ([redacted]), 499:3-500:6; CX-2251C (Minchenkov Dep. Tr.) at 126:25-129:21, 135:21-139:4, 145:16-146:5; CDX-0011C.0248, .0251.). View Mode [redacted]. (Tr. (Badler) at 496:5-25; CDX-0011C.0251; CX-2251C (Minchenkov Dep. Tr.) at 135:21-139:4, 150:5-151:14; CX-1909.0292, .0293, .0308.). [redacted]. (Tr. (Badler) at 496:5-25, 499:12-500:6; CDX-0011C.0248, .0251-52; CX-2251C (Minchenkov Dep. Tr.) at 138:17-139:11.). As Dr. Badler testified, the [redacted] is a "modified virtual model" [redacted] from the first and second virtual models, as Dr. Badler explained. (Tr. (Badler) at 496:5-25, 499:12-500:6, 500:24-501:23; CDX-0011C.0248, .0251-52.).

For these reasons, Align has proven by a preponderance of evidence that the 192 DI

Product meets preambles [1.1] and [28.1] of claims 1 and 28, respectively, of the ’192 patent.

ii. [1.2] / [28.2]: “displaying an image of a first virtual model on a display operatively connected to a computer system, wherein the first virtual model is generated from first 3D scan data of the physical structure, and wherein said first virtual model fails to properly represent a first physical part of the physical structure” / “a display to display images of said modified virtual model; and a computer system operatively connected to the display and comprising a program that, when executed by the computer system, causes the computer system to, display an image of a first virtual model generated from first 3D scan data of the physical structure on the display, wherein said first virtual model fails to properly represent a first physical part of the physical structure”

Align offered evidence in this Investigation that the 192 DI Product practices claim element 1.2. (Tr. (Badler) at 497:11-498:11; CDX-0011C.0255-59; CX-2125C (Badler Expert Rpt.) at ¶¶ 814–25; *see also* Section X.B.1(a)(I), *supra*, regarding preambles [1.1] / [28.1].). After the user scans the jaw, a “[redacted].” (CX-1351.0087.). Dr. Badler explained that the Eraser tool allows the user to “correct mistakes in the scanned model, such as blood or saliva on the margin line.” (Tr. (Badler) at 493:21-494:1, 497:11-498:11, 495:6-7 ([redacted]); CX-1909.0086 (showing moisture and artifacts on the margin line).). 3Shape’s expert, Dr. Saber, testified that “the iTero Element and its Eraser tool [will] display an image of the model” that is “generated from three-dimensional scan data of patient’s teeth.” (Tr. (Saber) at 1501:4-15.). Align’s and 3Shape’s experts agreed that the Eraser tool allows the user to erase a portion of the model and update it by rescanning. (Tr. (Saber) at 1501:12-21.; Tr. (Badler) at 498:3-11; CDX-0011C.0256.).

Accordingly, Align has proven by a preponderance of evidence that the 192 DI Product practices elements [1.2] and [28.2] of claims 1 and 28, respectively, of the ’192 patent.

iii. [1.3] / [28.3]: "receiving user input identifying at least a portion of the first virtual model that is desired to be modified, wherein the user input is generated by user interaction with the image on the display" / "receive user input identifying at least a portion of the first virtual model that is desired to be modified, the user input generated by user interaction with the image of the first virtual model on the display"[86]

The '192 DI Product practices claim elements [1.3] and [28.3]. (Tr. (Badler) at 495:8-15, 498:12-499:2; CDX-0011C.0260-62; CX-2125C (Badler Expert Rpt.) at ¶¶ 826-36; *see also* Sections X.B.1(a)(i-ii), *supra*, regarding claim elements [1.1] / [28.1], [1.2] / [28.2].). The iTero's touch screen allows the user to "select the area to erase on the screen." (CX-1909.0099, .0027, .0085, .0094.). In View Mode, the user activates the Eraser tool by pressing on the "Eraser" button and then marking a region on the model using the touch screen. (CX-1351C.0088; CX-1814C.0001.). The "marked area becomes a hole." (CX-1814C.0001; *see also* CX-1351C.0088; Tr. (Badler) at 498:21-499:2.). Dr. Badler explained that [redacted] performs the erasing functionality. (Tr. (Badler) at 495:8-9.). Moreover, he testified that [redacted] (*Id.* at 494:22-495:18.).

Accordingly, Align has proven by a preponderance of evidence that the 192 DI Product practices elements [1.3] and [28.3] of claims 1 and 28, respectively, of the '192 patent.

[86] The Parties agreed that the phrase "identifying at least a portion of the first virtual model that is desired to be modified" means "identifying at least a portion on the first virtual model that is desired to be replaced." (*Markman* Order, App. A at 6.).

iv. [1.4] / [28.4]: "receiving a second virtual model of the physical structure with the computer system, the second virtual model generated from second 3D scan data of the physical structure" / "receive a second virtual model of the physical structure, the second virtual model generated from second 3D scan data of the physical structure"[87]

Evidence adduced in this Investigation demonstrate that the 192 DI Product practices claim elements [1.4] / [28.4] literally, or in the alternative, under the doctrine of equivalents. (Tr. (Badler) at 499:3-500:23; CDX-0011C.0263-67; CX-2125C (Badler Expert Rpt.) at ¶¶ 837–58; *see also* Sections X.B.1(a)(i-iii), *supra*, for claim elements [1.1] / [28.1] – [1.3] / [28.3].). As Dr. Badler explained, when rescanning, "the scan only appears in the erased area." (Tr. (Badler) at 495:19-496:4 (citing [redacted]), 499:12-21; CX-1351C.0064 at step 24.). He testified that [redacted] (Tr. (Badler) at 499:12-21.). In other words, the [redacted] (*Id.* at 499:22-500:6 (discussing CDX-0011C.0265).). Dr. Badler explained that the Eraser tool is "more than just an eraser, it's selective," i.e., "it allows a user to define what will be replaced" by "creating a second model in the relevant areas to be replaced, the initial model is updated." (*Id.* at 500:24-501:10; CX-1809; CX-1952C.0019.). When the second model is created, the software [redacted] (CX-1351C.0064.).

For the reasons discussed above, Align has proven by a preponderance of evidence that the 192 DI Product practices elements [1.4] and [28.4] of claims 1 and 28 respectively, of the

[87] The term "second virtual model" was construed to mean "second 3D virtual representation." (*Markman* Order, App. A at 1.).

'192 patent.[88]

v. [1.5] / [28.5]: "modifying the first virtual model with the computer system by replacing at least said identified portion of the first virtual model with a corresponding portion of the second virtual model, thereby generating the modified virtual model" / "modify the first virtual model by replacing at least said identified portion of the first virtual model with a corresponding portion of the second virtual model, thereby providing the modified virtual model"

Evidence adduced in this Investigation indicates that the 192 DI Product practices claim elements [1.5] / [28.5]. (Tr. (Badler) at 494:22-496:25, 500:24-502:5; CDX-0011C.0249-51, .0268-70; CX-2125C (Badler Expert Rpt.) at ¶¶ 859-78; *see also* Sections X.B.1(a)(i-iv) regarding claim elements [1.1] / [28.1] –[1.4] / [28.4].).

Without reviewing Align's code or Align products, 3Shape's expert, Dr. Saber, opined that "the original model is discarded and a new model is created." (Tr. (Saber) at 1476:3-9, 20-24.). However, there is no support in the patent or in the record evidence for Dr. Saber's opinion. During the Hearing, Dr. Saber referred to Mr. Minchenkov's deposition at page 135, line 21 to page 136, line 1 and page 150, line 17 to page 151, line 14, to support this position. (Tr. (Saber) at 1476:10-23.). In context, Dr. Saber's first cite reflects that Mr. Minchenkov described a "cancel eraser" function in the View Mode, which is equivalent to an undo. (CX-2251C (Minchenkov Dep. Tr.) at 134:19-136:14 (the "cancel eraser functionality is available before you go to [Scan Mode]" and once the user has identified the surface area to be deleted they go back to "Scan Mode"); CX-1351C.0088 at steps 11-13 (describing the cancel easer functionality); CX-1769C.0005 ("the user can Cancel his selection of marked scans***, or choose***

[88] 3Shape argued that the 192 DI Product also practices the claim element under the doctrine of equivalents. (Tr. (Badler) at 500:15-23; CDX-0011C.0267.).

Apply to delete the marked scans") (emphasis added).). Dr. Saber disregarded Mr. Minchenkov's testimony and evidence with respect to the deleted, erased area after the user re-scans the erased area in Scan Mode and then re-enters View Mode. (CX-1769C.0006 ("the selected sections will be deleted from the model").).

When read in context, Dr. Saber's second cite described that the original model with an error is "essentially discarded" after the user creates a modified model with the good parts from the first and second models. (CX-2251C (Minchenkov Dep. Tr.) at 150:5-151:5.). The source code and technical documents confirm that the [redacted]. (CX-2251C (Minchenkov Dep. Tr.) at 150:1-151:14; CX-1769C.0006.). Mr. Minchenkov testified that upon re-entering View Mode after rescanning, [redacted]. (CX-2251C (Minchenkov Dep. Tr.) at 150:1-20.). In other words, upon re-entering View Mode, iTero [redacted]. (*Id.* at 135:21-139:4, 150:5-151:14.).

Dr. Badler discussed the Align software with Mr. Minchekov; he reviewed Mr. Minchenkov's deposition testimony; and he examined the relevant Align source code. (Tr. (Badler) at 494:22-496:22; 497:1-10; CX-2125C (Badler Expert Rpt.) at ¶¶ 860-78.). Dr. Badler also reviewed Align's technical documentation and analyzed the 192 DI Products. This lead to Dr. Badler's opinion and conclusion that with respect to Align's Eraser tool, "the first and second models [are] combined." (Tr. (Badler) at 496:23-25.). Dr. Badler's opinions are consistent with a straightforward and accurate reading of Mr. Minchenkov's testimony. (*Id.* at 493:6-504:2; CDX-0011C.0249-51, 268-270; CX-2125C (Badler Expert Rpt.) at ¶¶ 860-78.).

Specifically, after scanning to capture the second model, the user returns to View Mode where the [redacted] (CX-1815C.). Dr. Badler explained that iTero [redacted]. (Tr. (Badler) at 494:22-496:25, 499:12-502:5; CDX-0011C.0249-51, .0268-270; *see also* CX-2251C (Minchenkov Dep. Tr.) at 126:25-129:21, 135:21-139:11, 150:5-151:14; CX-1909.0292, .0293, .0308.). As Dr. Badler testified, [redacted] (Tr. (Badler) at 496:5-22.). He also explained that:

> [redacted]

(*Id.*).

In sum, the "first and second models are combined" to generate a modified virtual model. (*Id.* at 496:23-25; 501:2-23; CDX-0011C.0268-69.).

For the foregoing reasons, Align has proven by a preponderance of evidence that the 192 DI Product literally practices elements [1.5] and [28.5] of claims 1 and 28, respectively, of the '192 patent.[89]

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[89] Dr. Badler opined that "[t]o the extent claim element 1.5 is not met literally, it's met under DOE, because it provides substantially the same function in the same way with the same result of generating a modified virtual model. (Tr. (Badler) at 502:2-5; CDX-0011C.0270.).

b) Claim 2

i. "The method according to claim 1, wherein said physical structure comprises any one of an intra-oral cavity of a patient or a physical dental model representative of said intra-oral cavity."

Align presented evidence that the 192 DI Product practices the additional limitation recited in claim 2, which 3Shape did not contest. (Tr. (Badler) at 502:6-16; CDX-0011C.0271; CX-2125C (Badler Expert Rpt.) at ¶¶ 879-80; RRBr. at 45.). Thus, there is no dispute that the iTero Element is an intraoral scanner for scanning an intra-oral cavity of a patient.

Accordingly, Align has proven by a preponderance of evidence that the 192 DI Product practices claim 2 of the '192 patent.

c) Claim 29

i. "The system according to claim 28, wherein the at least said identified portion of the first virtual model and the corresponding portion of the second virtual model are each representative of a physical portion of the physical structure, the first virtual model providing a deficient representation of the physical portion and the second virtual model providing an adequate representation of the physical portion."

Align offered evidence that the 192 DI Product practices claim 29. (Tr. (Badler) at 503:3-504:2; CDX-0011C.0273-74; CX-2125C (Badler Expert Rpt.) at ¶¶ 919-38.). Dr. Badler confirmed that when the first virtual model is deficient, the distorted portion can be replaced by the second virtual model, which is adequate because it more accurately represents the patient's dentition. (Tr. (Badler) at 503:3-504:2; CDX-0011C.0273-74; CX-2125C (Badler Expert Rpt.) at ¶¶ 919-38.).

Accordingly, Align has proven by a preponderance of evidence that the 192 DI Product literally practices claim 29 of the ’192 patent.[90]

C. Invalidity

1. Invalidity Overview

3 Shape argued that the asserted claims of the ’192 patent (claims 2, 28, and 29) are invalid as anticipated, obvious, not enabled, and directed to patent ineligible subject matter. (RBr. at 41; Joint Chart of Subst. Legal Issues (Doc. ID No. 697190) at 4 (Dec. 13, 2019).). Specifically, 3Shape argued that the asserted claims of the ’192 patent were anticipated by Paley (RX-0226) (which incorporates Kriveshko (RX-0227) by reference, hereinafter “Paley-Kriveshko”), and Rubbert (RX-0229). (RBr. at 44-53.). 3Shape argued that the asserted claims of the ’192 patent were obvious in view of Paley-Kriveshko or Rubbert individually. (*Id*. at 54.).

Based upon the analysis that follows:

1) 3Shape has not proven by clear and convincing evidence that the asserted claims of the ’192 patent are anticipated in light of the references Paley-Kriveshko or Rubbert.

2) 3Shape has proven by clear and convincing evidence that the asserted claims of the ’192 patent are obvious in view of Paley-Kriveshko.

3) 3Shape has not proven by clear and convincing evidence that the asserted claims of

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[90] Dr. Badler opined that “[t]o the extent this claim element is not literally infringed by Accused Product when used as intended the Accused Product infringes under the doctrine of equivalents. (CX-2125C (Badler Expert Rpt.) at ¶¶ 782; *see also* Tr. (Badler) at 491:22-493:5.). “[A]ny differences between this claim limitation and the Accused Product are insubstantial changes from that which is claimed. . . . The TRIOS permits the user to trim away unwanted portions of a virtual model and then fill in that trimmed away portion of the model with newly acquired new scan data or 3D images. Additionally, the Accused Product performs substantially the same function (receiving updated scan data to correct for scan data that is defective because it represents a tooth that is obscured by blood salvia debris or some other foreign object) in substantially the same way (replacing a deficient representation from the first virtual model with an adequate representation from the second virtual model) to achieve substantially the same result (generating a modified virtual model) and therefore are equivalent.” (CX-2125C (Badler Expert Rpt.) at ¶ 782.).

the ’192 patent are obvious in view of Rubbert.

4) 3Shape has not proven by clear and convincing evidence that the asserted claims of the ’192 patent are not enabled, or that they are directed to ineligible subject matter.

Notably, Align did not elicit expert testimony during the Hearing on the invalidity of the ’192 patent. Align’s arguments, to the extent that Align made them, were attorney arguments. To the extent Align’s critical arguments of 3Shape’s evidence were accurate, they were considered. For the rest, Align’s arguments suffered from a failure of proof. 3Shape’s evidence and, therefore, 3Shape’s ability to meet its burden of proof is largely the basis for the invalidity findings in the sections below.

2. Legal Standard

a) Enablement

To satisfy the enablement requirement a patent specification must “contain a written description of the invention . . . to enable any person skilled in the art . . . to make and use the same.” 35 U.S.C. §112, ¶1. The specification must enable a person of ordinary skill in the art to practice the claimed invention without undue experimentation. *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Contractors USA, Inc.*, 617 F.3d 1296, 1305 (Fed. Cir. 2010). Although a specification need not disclose minor details that are well known in the art, this is “merely a rule of supplementation, not a substitute for a basic enabling disclosure.” *Auto. Tech. Int’l Inc., v. BMW of N. Am.*, 501 F.3d 1274, 1283 (Fed. Cir. 2007) (quoting *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997)). “It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement.” *Auto. Tech.*, 501 F.3d at 1283.

Enablement is a question of law with underlying questions of fact regarding undue experimentation. *Transocean*, 617 F.3d at 1305. The factors weighed by a court in determining whether a disclosure requires undue experimentation include: (1) the quantity of experimentation necessary, (2) the amount of direction provided, (3) the presence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability of the art, and (8) the breadth of the claims. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). Undue experimentation is "a matter of degree" and "not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." *PPG Indus., Inc, v. Guardian Indus. Corp.*, 75 F.3d 1558, 1564 (Fed. Cir. 1996); *Northpoint Tech, Ltd. v. MDS Am, Inc.*, 413 F.3d 1301, 1318 (Fed. Cir. 2005).

3. Overview of the Prior Art

a) Paley

Paley was filed on September 3, 2007, and published July 27, 2007. (RX-0226.). Paley is prior art to the '192 patent under 35 U.S.C. §102(b).[91] *See Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1353 (Fed. Cir. 2016) ("[a]n invention is unpatentable by reason of anticipation if it was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States" (citing pre-AIA §102(b)). Paley relates to "continuous scanning in which incremental three-dimensional data is acquired and assembled into a full three-

[91] In passing the Leahy–Smith America Invents Act ("AIA"), Congress amended § 102, and 103. *See* Pub. L. No. 112-29, § 3(b-c), 125 Stat. 284, 285–87 (2011). However, because the application that led to the '192 patent was filed before March 16, 2013, the pre-AIA § 102(b) and § 103 applies. *See id.* § 3(n)(1), 125 Stat. at 293.

dimensional model." (RX-0226 at ¶ 5.). Paley discloses a three-dimensional intraoral scanning system that uses "visual feedback techniques to assist in acquiring and analyzing three-dimensional data." (*Id*. at ¶¶ 12, 21.). Errors in a three-dimensional digital model, such as "regions of incomplete scan data, inaccurate scan data, [and/or] insufficient scan detail" can be visually identified and then corrected. (*Id*. at ¶¶ 59-60.). To correct errors, the user can "return to data acquisition . . . to acquire additional data where a void or deviation is detected." (*Id*. at ¶ 60.). Paley expressly incorporates Kriveshko by reference on the topic of reacquiring scanning data to supplement the original three-dimensional model of Paley. (*Id*. at ¶¶ 60, 73, 77.).

b) Kriveshko

Kriveshko was filed on January 20, 2006 and published on October 11, 2007. (RX-0227.). Kriveshko is prior art to the '192 patent under 35 U.S.C. §102(b). Kriveshko relates to the acquisition of three-dimensional intraoral scan data and subsequent incorporation of that data into an existing three-dimensional model. (*Id*. at ¶¶ 9, 59.). Kriveshko discloses "recover" and "landing" modes to facilitate corrections in a three-dimensional model. (*Id*. at ¶ 59.). In the "recover" mode, the system "test fit[s] new scan data to previously acquired scan data, and provid[es] visual feedback to a user to assist in navigating back to a scan location on the subject where the re-acquisition is being attempted." (*Id*.). In the "landing mode" a user may attempt to initiate a new scan in connection with an existing three-dimensional model; the user is able to "select a point on the original three-dimensional model for re-acquisition of a scan." (*Id*. at ¶¶ 59, 97.)

c) Rubbert

Rubbert was filed on March 27, 2003 and published on November 13, 2003. (RX-0229.). Rubbert is prior art to the '192 patent under 35 U.S.C. § 102(b). Rubbert discloses an apparatus and method of verifying and displaying the location of a dental appliance within a three-dimensional model of teeth. (*Id*. at Abstract; 1:10-16.). Rubbert describes scanning a patient's dentition to generate a three-dimensional virtual model, which can be used to monitor the progress of orthodontic treatment. (*Id*. at 1:22-24, 2:8-21, 6:1-13.). This virtual model contains tooth scan data, as well as scan data of orthodontic brackets bonded to the teeth. (*Id*. at 21:20-21; Fig. 7). Under Rubbert, an operator may delete scan data near a bracket model. (*Id*. at 14:32-15:1, 29:12-30:10.). Tooth scan data from a pre-existing second virtual model of the patient's dentition can be registered to the current virtual model, producing an updated virtual model including the tooth underlying the bracket in the original model. (*See id*.).

4. Anticipation

a) The Asserted Claims Are Not Anticipated by Paley-Kriveshko

3Shape argued that Paley-Kriveshko anticipates claims 2, 28, and 29 of the '192 patent. (RBr. at 44-50.).[92] Align disagreed. (CRBr. at 35-39.). 3Shape mapped the Paley disclosure onto the elements of the asserted claims of the '192 patent. (RBr. at 44-50.).[93] In response, Align challenged the application of Paley-Kriveshko to the limitation of "replacing at least said identified portion of the first virtual model with a corresponding portion of the second virtual model," that the independent claims 1 and 28 recite. (CRBr. at 37-39.).

Claim 1 is representative of how the "replacing at least …" limitation is used in claim 28,

[92] The Parties stipulated that a person of ordinary skill in the art for the '192 patent "would have had at least a bachelor's degree in electrical engineering, computer science, applied mathematics, or an equivalent field, as well as at least one or two years of industry experience in three-dimensional modeling, or at least five years of comparable industry experience in three-dimensional modeling, or an equivalent combination of academic study and work experience." (Joint Stip. Regarding Person of Ordinary Skill in the Art (Doc. ID No. 692583) at ¶ 2 (Oct. 23, 2019).).

[93] While not asserted, the Parties' anticipation and obviousness arguments are mainly directed to claim 1 of the '192 patent. Asserted claim 2 of the '192 patent depends from claim 1.

and recites:

> A method for generating a modified virtual model of a physical structure, comprising:
>
> (A) displaying an image of a first virtual model on a display operatively connected to a computer system, wherein the first virtual model is generated from first 3D scan data of the physical structure, and wherein said first virtual model fails to properly represent a first physical part of the physical structure;
>
> (B) receiving user input identifying at least a portion of the first virtual model that is desired to be modified, wherein the user input is generated by user interaction with the image on the display;
>
> (C) receiving a second virtual model of the physical structure with the computer system, the second virtual model generated from second 3D scan data of the physical structure; and
>
> (D) modifying the first virtual model with the computer system by *replacing at least said identified portion of the first virtual model with a corresponding portion of the second virtual model*, thereby generating the modified virtual model.

(JX-0004 ('192 patent), cl. 1 (emphasis added).).

Align did not contest the remaining aspects of 3Shape's anticipation argument for Paley-Kriveshko, thereby waiving unraised challenges on this issue for all purposes pursuant to Ground Rules 10.1 and 10.2. (CRBr. at 35-39; Ground Rules 10.1 and 10.2, Order No. 2 (Mar. 14, 2019).).

3Shape argued that Paley discloses the display of an image of a first virtual model generated from three-dimensional scan data, as visualized below:

Figure 29: Figure 5 of Paley

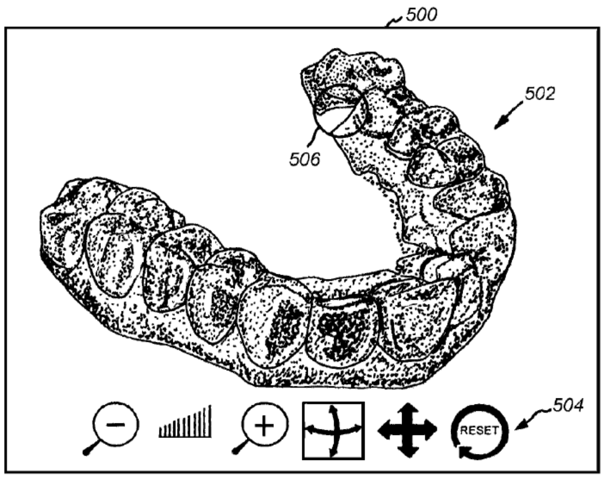

Fig. 5

(RBr. at 44-45 (citing RX-0226 at Fig. 5, ¶¶ 28-29, 30, 32, 58, 70, 74.).

3Shape identified Paley's teachings that the display of a first virtual model "may include gross errors in the digital model, such as a region with omitted data, fuzziness, incomplete scan data, or inaccurate scan data." (*Id*. (citing RX-0226 at ¶ 59).). Nonetheless, 3Shape asserted that Paley discloses that these gross errors are portions of the virtual model, which corresponds to limitation 1[a] of the '192 patent. (*Id*.)

3Shape argued that Paley teaches a "system that receives user input identifying a portion on the first virtual model (such as a void or a region with inaccurate scan data) that is desired to be replaced." (*Id*. at 45-46 (citing RX-0226 at Fig. 5, ¶ 60).). 3Shape argued this disclosure corresponds to limitation 1[b] of the '192 patent. (*Id*.). 3Shape next pointed to a disclosed rescanning mode called "landing mode" that represents limitation 1[c] of the '192 patent. (*Id*. at 46-47.). 3Shape asserted that landing mode allows for the reacquisition of scanning data to correct the identified error in the virtual model. 3Shape also asserted that Paley expressly incorporates "Kriveshko by reference specifically when talking about how to reacquire continuous scan data from the subject to update a void or deviation." (*Id*.).[94] According to 3Shape, Kriveshko discloses that in landing mode, "supplemental 3D scan data of the physical structure is acquired and then assembled into a supplemental 3D virtual model," which corresponds to the "second virtual model" of limitation 1[c] of the '192 patent. (*Id*. at 46-47 (citing RX-0227 at ¶¶ 74, 97.).

3Shape argued that the "supplemental 3D virtual model" of Kriveshko is "then registered with or fit to the original 3D virtual model" that Paley teaches. (*Id*. at 47-48 (citing RX-0227 at ¶¶ 74, 86, 97).). 3Shape pointed to the testimony of its expert, Dr. Eli Saber, to demonstrate that a person of ordinary skill in the art would understand Kriveshko to describe claim limitation 1[d]. (*Id*. at 48 (citing Tr. (Saber) at 1402:22-1403:17).).[95] Dr. Saber testified that considering the "replacing at least …" limitation, 3Shape asserted that "replacing" in 1[d] "simply requires that new data replace the original data [of the first virtual model] – not the deletion or removal of that original data." (*Id*. at 48 (citing Tr. (Saber) at 1427:20-1428:12).). 3Shape argued that Dr. Saber provided unrebutted testimony that Paley (incorporating Kriveshko) "discloses both overwriting inaccurate or deficient data and replacing a void with new data" and therefore teaches claim 1 of the '192 patent. (*Id*. at 48-49 (citing Tr. (Saber) at 1402:18-1403:17, 1427:22-24, 1428:10-12, 1443:10-15; RX-0226 at Fig. 5, ¶ 60).).

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[94] In relevant part, Paley recites that "where the continuous scan is to be reacquired from the subject, as described for example in commonly-owned U.S. application Ser. No. 11/337,182 filed on Jan. 20, 2006 [Kriveshko], the entire content of which is incorporate herein by reference." (RX-0226 at ¶ 60.). Align did not dispute that Paley expressly incorporates Kriveshko, nor did it contest the consideration of Paley and Kriveshko together in an anticipation analysis.

[95] When he testified during the Hearing on October 30, 2019, Dr. Eli Saber was a professor at the Electrical and Microelectronic Engineering Department of the Rochester Institute of Technology. (Tr. (Saber) at 1377:17-23.). 3Shape identified Dr. Saber as an expert witness expected to testify regarding the invalidity of the '192 patent, non-infringement of the asserted claims of the '192 patent, and the technical prong of the domestic industry requirement for the '192 patent. (RPSt. at 4.).

3Shape argued that these disclosures collectively anticipate claim 1 of the ’192 patent, and that asserted claims 2, 28, and 29 were likewise anticipated. (*Id*. at 44-50.). 3Shape asserted that Paley-Kriveshko teaches an intraoral scanner used to scan a patient’s dentition, or a model thereof, disclosing claim 2. (*Id*. at 49 (citing RX-0226 at ¶ 30, Fig. 5).). For claim 28, 3Shape stated the claim relates to an apparatus (i.e. a system) that is fully disclosed for the reasons discussed in its claim 1 analysis. (*Id*. (citing JX-0004 at cl. 28).). Regarding claim 29, 3Shape argued that Paley-Kriveshko discloses “that a supplemental virtual model may replace an inaccurate (‘deficient’) region on its virtual teeth model.” (*Id*.). 3Shape asserted that the supplemental model of Paley-Kriveshko is generated with corrections to replace deviations in a first virtual model, corresponding to the teachings of claim 29. (*Id*. at 49-50 (citing RX-0226 at ¶¶ 59-60; Tr. (Saber) at 1405:1-17).). Thus, 3Shape argued that Paley-Kriveshko anticipates all asserted claims. (*Id*. at 49-50.).

Align focused its criticism on Paley-Kriveshko by contending that it does not expressly disclose “*replacing* at least said identified portion of the first virtual model with a corresponding portion of the second virtual model.” (CRBr. at 37.). Because this “replacing at least …” limitation is not expressly disclosed, Align argued that 3Shape is limited to an inherent anticipation argument with Paley-Kriveshko. (*Id*. (citing *Finnigan Corp. v. Int’l Trade Comm’n*, 180 F.3d 1354, 1365 (Fed. Cir. 1999).). Align asserted that because Paley-Kriveshko does not necessarily disclose this “replacing at least …” limitation, there can be no anticipation. (*Id*. at 37-38 (citing *United States Water Servs. v. Novozymes A/S*, 843 F.3d 1345, 1350 (Fed. Cir. 2016).). 3Shape did not make an “inherency” argument.

According to Align, replacing a portion of the first virtual model is distinguishable from modifying, or adding data to, said first virtual model. (CRBr. at 37-39.). Align argued that

3Shape's own expert acknowledged that "replacement is different from adding," and that Kriveshko frequently recites examples of "adding" reacquisition data to the original three-dimensional model. (*Id*. at 38-39 (citing Tr. (Saber) at 1427:14-16; RX-0227 at ¶ 23).). Align asserted that 3Shape's expert further testified that "replacing" a portion of a three-dimensional model with new data involves a deletion or removal step. (*Id*. at 38-39 (citing Tr. (Saber) at 1427:9-13, 1427:20-1428:12).).

Align contended that under Paley-Kriveshko, updating a void in an original three-dimensional model does not involve replacing data as described in claim limitation 1[d]. (*Id*. at 39.). Align argued that a void arises from "omitted or missing scan data" according to Paley. (*Id*. (citing RX-0226 at ¶ 59, Fig. 5).).

Align asserted that a user would be unable to identify unscanned data on the first virtual model for replacement. Moreover, a user would not be able to delete "non-existent data" when performing the claimed replacement of a void. (*Id*.). Align argued that the "replacing" of claim limitation 1[d] was not necessarily present in Paley-Kriveshko, and therefore the claim was not anticipated. Because this limitation is present in each of the asserted claims, Align argued that none of the asserted claims were anticipated by Paley-Kriveshko. (*Id*. at 37-39.).

Align's argument that "replacing is different from adding" is persuasive. (*See* CRBr. at 38.). The recited limitation of "replacing at least said identified portion of the first virtual model with a corresponding portion of the second virtual model" in claim 1 describes something different than the mere addition of data from the second virtual model to the corresponding portion of the first virtual model. (*See* JX-0004 at cl. 1.). The term "replacing" conveys that the portion of the original virtual model identified as having incomplete, inaccurate, or insufficient data is ultimately discarded or deleted as a result of the method of claim 1 of the '192 patent.

This is consistent with the testimony that 3Shape's expert, Dr. Saber gave, when he stated that the replaced portion of the first virtual model would be "overwritten." (*See* Tr. (Saber) at 1427:20-1428:12.).[96] In short, the process of claim 1 produces a modified virtual model with the previously identified erroneous data substituted with the corrected data for the relevant portion. (*See* JX-0004 at cl. 1.).

Paley-Kriveshko does not uniformly require the deletion of old model data. Paley-Kriveshko clearly describes a process for identifying a portion of a first virtual model having incomplete, inaccurate, or insufficient data. (*See* RX-0226 at ¶¶ 59-60.). Paley-Kriveshko also discloses a process of rescanning the corresponding physical structure thereby generating a second virtual model. (*See* RX-0227 at ¶¶ 74, 86.). Paley-Kriveshko recites that all or some of the second virtual model may then be "registered to the original three-dimensional model," thereby producing a modified virtual model. (*Id.*). Paley-Kriveshko describes the registration process generally: "a scanning process can be divided into abstract steps of incremental data capture, incremental derivation of three-dimensional data, and registration of the incremental data to a common coordinate system. The final registration step brings the incremental data together into a single three-dimensional model of a scan subject." (RX-0226 at ¶ 6; RX-0227 at ¶ 5.). Thus, the disclosed "registration" of Paley-Kriveshko describes the creation of a single modified virtual model, without explicitly teaching that data from the original three-dimensional

[96] 3Shape and its expert argued that "overwriting" original virtual model data was distinguishable from the "deletion or removal" of the same. RBr. at 48 (citing Tr. (Saber) at 1427:20-1428:12).). Claim 1 does not recite a discrete data deletion or removal step. Nevertheless, the claim term "replacing" does convey that the older, erroneous model data is not present in the final modified virtual model. (*See* JX-0004 at cl. 1.). 3Shape did not offer a compelling argument why overwriting old model data would not result in its deletion or removal.

model is deleted.[97]

Kriveshko identifies one scenario in which multiple models are combined to produce a single modified virtual model with overlapping portions:

> In one embodiment multiple scans of an object, including scans taken at different times, may be interpreted as a single scan. For example, in a dental application, a tooth surface may be scanned before and after a surface preparation for dental prosthetic. By starting the second, post-preparation scan, by reacquiring a scan of an unprepared tooth surface, the pre-scan and post-scan structure of the prepared surface may be combined into a single surface representation that encloses a space to be filled by the dental prosthetic.

(RX-0227 at ¶ 99.).

Here, Paley-Kriveshko describes a situation where the modified virtual model contains both old and new data, thereby undermining 3Shape's position that the references teach the replacement of data. 3Shape relied on Dr. Saber's expert testimony that a person of ordinary skill in the art "would have understood that [Kriveshko] describes the same material as claim 1(d) of the '192 patent," but then Dr. Saber failed to provide explicit support in either reference for his argument or opinion. (RBr. at 47-48 (citing Tr. (Saber) at 1402:22-1403:17).). Paley-Kriveshko does not directly instruct that old model data is deleted in the modified virtual model. Therefore, it does not teach the limitation of "replacing at least said identified portion of the first virtual model with a corresponding portion of the second virtual model." (*See* JX-0004 at cl. 1.). As described previously, this limitation is present in each of claims 2, 28, and 29. If claim 1 is not met, neither are claims 2, 28 ad 29.

Based upon the analysis provided above, it is a finding here that 3Shape has not proven

[97] The same is true when a "void" in a model is updated under Paley-Kriveshko. Paley-Kriveshko describes a "void" as a region of omitted or missing scan data. (*See* RX-0226 at ¶¶ 59-60; Fig. 5.). 3Shape did not \ demonstrate persuasively that updating a void under Paley-Kriveshko requires the deletion or removal of data from the original three-dimensional model.

clear and convincing evidence that Paley-Kriveshko anticipates asserted claims 2, 28, and 29 of the '192 patent.

b) The Asserted Claims Are Not Anticipated by Rubbert

3Shape argued that Rubbert anticipates the asserted claims of the '192 patent. (RBr. at 50-53.). Align disagreed. (CRBr. at 39-43.). 3Shape asserted that Rubbert discloses "a method for generating a modified virtual model of a tooth." (RBr. at 50 (citing RX-0229 at Abstract, 1:7-16, 19:21-20:31, 29:28-30:29; Tr. (Saber) at 1411:2-16).). 3Shape described the process of Rubbert as:

> (i) displaying a first virtual model (i.e., showing the patient's teeth in the current state after some treatment has occurred);
>
> (ii) deleting a portion of the first virtual model to create a void;
>
> (iii) receiving a second virtual model of the tooth from the patient's record prior to treatment; and
>
> (iv) combining the current first virtual model (with the void) and the retrieved second virtual model to construct a new virtual model by filling the void in.

(*Id*. (citing RX-0229 at Figs. 16-19; 14:30-15:1; 17:30-18:3, 19:21-20:31, 29:28-31:3).).

With respect to claim 1, 3Shape argued that Rubbert discloses "intraoral scanning to create a 3D virtual image of a patient's dentition, which is then displayed on a display operatively connected to a computer system." (*Id*. (citing RX-0229 at 10:4-11).). According to 3Shape, Rubbert teaches that this virtual tooth model may contain incomplete or inaccurate three-dimensional surface information. (*Id*. at 50-51 (citing RX-0229 at 3:9-4:18).). 3Shape contended that the virtual tooth model of Rubbert discloses claim limitation 1[a] of the '192 patent. (*Id*. (citing Tr. (Saber) at 1411:2-7).).

3Shape argued that Rubbert teaches "(i) a user interface including a keyboard and a mouse for performing tooth registration and (ii) that the first step of the tooth registration process includes deleting scan data that is in close vicinity to the registered bracket model to provide a virtual tooth model with a data void." (*Id*. at 51 (citing RX-0229 at 14:30-15:1; 30:9-11).). According to 3Shape, this teaches the limitations in claim 1[b]. (*Id*. (citing Tr. (Saber) at 1411:24-1412:3).).

For limitation 1[c], 3Shape identified Rubbert's disclosure of a library of patient records, including prior information relating to the three-dimensional tooth models of existing patients. (*Id*. (citing RX-0229 at 17:30-18:3; 30:16-25).). 3Shape argued that these patient records represent the second virtual model of claim 1[c]. (*Id*. (citing Tr. (Saber) at 1411:1-16).). 3Shape contended that the '192 patent does not require that the claimed second virtual model be generated after the first virtual model, and that the '192 patent is not directed to a specific order of steps. (*Id*. at 51-52 (citing JX-0004 at 29:38-41).).

For limitation 1[d], 3Shape noted that Rubbert teaches that the virtual tooth model retrieved from the patient's records is "registered" to the new virtual tooth model containing a void. (*Id*. at 52 (citing JX-0004 at 30:25-31:3).). 3Shape argued that registering the two models generates a modified virtual tooth model that fills in the void using data from the patient's records. (*Id*. (citing JX-0004 at Figs. 16-18, 8:30-9:16, 17:4-18:24, 27:22-28:30, 30:25:31:3).). 3Shape relied upon its expert to show that a person of ordinary skill in the art would understand these teachings of Rubbert to disclose claim limitation 1[d]. (*Id*. (citing Tr. (Saber) at 1411:1-16).). According to 3Shape, Rubbert consistently discloses that the patient's teeth which are scanned and rescanned corresponds to the "physical structure" of claim 1 of the '192 patent. (*Id*. (citing Tr. (Saber) at 1434:15-25).).

3Shape argued that these disclosures collectively anticipate claim 1 of the '192 patent, and that asserted claims 2, 28, and 29 were likewise anticipated. (*Id*. at 52.). For claim 2, 3Shape identified Rubbert's disclosure that an intraoral scanner is used to generate a virtual model of a patient's dentition. (*Id*. at 53 (citing RX-0229 at 10:4-10).). 3Shape asserted that claim 28 recites apparatus claims that largely overlap with the method recited in claim 1 and described above. (*Id*. (citing RX-0229 at Figs. 1B, cl. 1, 10:3-25, 31:6-34:24.). Regarding claim 29, 3Shape contended that Rubbert disclosed a virtual model of a patient's teeth generated "after some orthodontic treatment has occurred," which represents the "first virtual model providing a deficient representation of the physical portion" of claim 29. (*Id*. (citing RX-0229 at 3:9-19, 4:11-18, 21:31-22:4); *see also* Tr. (Saber) at 1413:2-16 (describing the undesirable bracket assembly as "deficient" because it obscures the underlying tooth portion).). For these reasons, 3Shape asserted that the asserted claims were anticipated by Rubbert.

Align responded with two (2) challenges to 3Shape's interpretation of Rubbert's disclosures. (CRBr. at 41-43.). First, Align argued that Rubbert discloses scanning a different "physical structure" between the first and second virtual models, in contrast to claim 1 of the '192 patent. (*Id*. at 41.). Align contended that under Rubbert, the first virtual model corresponds to a patient's teeth "with brackets bonded to them," while the second virtual model corresponds to the patient's teeth before brackets had been applied. (*Id*. (citing RX-0229 at 19:21-26, 19:32-33, 20:26-27, 21:18-21).). Align asserted that 3Shape's expert, Dr. Saber, admitted that "the physical structures being scanned to generate the first and second virtual models are 'different physical structures.'" (*Id*. (citing Tr. (Saber) at 1436:5-22).). Align argued that because Rubbert teaches the scanning of separate physical structures, the reference does not anticipate the '192 patent.

Second, Align argued that Rubbert does not disclose the user identification of a portion on the first virtual model to be replaced. (*Id*. at 42.). Align contended that the keyboard and mouse in Rubbert was not disclosed in connection to the replacement of data in a first virtual model. (*Id*.). According to Align, 3Shape relies on Rubbert's keyboard and mouse in connection with the tooth registration process for "a model of a patient's tooth with a virtual model of a bracket." (*Id.* (citing RBr. at 51; RX-0229 at 23:11-34; 28:31-29:6; Figs. 14, 15).). Furthermore, Align argued that Rubbert's tooth registration process does not disclose user identification of a portion of any model for replacement. (*Id*.). Align asserted that Rubbert is "silent on whether the user is involved in the 'tooth registration' process." (*Id*.). Align argued that the keyboard and mouse allow a user to select the second virtual model (i.e. the pre-treatment scan data), while software "finds the best fit between the two models." (*Id*. (citing RX-0229 at 16:13-21; 30:16-29.). Align contended that Rubbert fails to disclose the user identification of a virtual model portion to be replaced, and therefore it does not anticipate. (*Id*.).

For these reasons, Align argued that Rubbert did not anticipate claim 1 of the '192 patent. (*Id*. at 41-43.). Align contended that independent claim 28 is valid because 3Shape's analysis for the claim relies on its flawed analysis of claim 1. (*Id*. at 43.). Likewise, Align asserted that dependent claims 2 and 29 are valid because of their dependence from claims 1 and 28, respectively. (*Id*.).

Align's argument that Rubbert describes scanning two (2) separate physical structures is persuasive. Independent claims 1 and 28 of the '192 patent are directed to a "modified virtual model of a physical structure," a "first virtual model . . . generated from first 3D scan of the physical structure," and a "second virtual model generated from second 3D scan data of the physical structure." (JX-0004 at cls. 1, 28.). Thus, the asserted claims of the '192 patent describe first and second virtual models of the same physical structure.

In contrast, Rubbert discloses a first virtual model showing a patient's teeth after some treatment has occurred (*i.e.* with one or more brackets bonded to the surface of the patient's teeth), and a second virtual model of a patient's teeth prior to any treatment. (RX-0229 at Figs. 16-19; 14:30-15:1; 17:30-18:3, 19:21-20:31, 29:28-31:3.). Three-dimensional data from the second virtual model is registered to the first virtual model, producing a modified virtual tooth model. (RX-0229 at 30:25-30.). Thus, Rubbert discloses a method of generating a modified virtual tooth model that combines scan data from one model of brackets bonded to a patient's teeth, and one model of teeth without brackets.

While 3Shape's expert, Dr. Saber, opined that the underlying teeth are the scanned physical structure in both virtual models of Rubbert, this position does not withstand scrutiny. 3Shape's expert previously conceded that the first and second virtual models of Rubbert "potentially" relate to different physical structures.

> Q. So you understand that in figure 6, the user will obtain some scan data and then generate a 3D model; right?
>
> A. Yes.
>
> Q. And you understand that at this point in time, there's actually no brackets on the patient's teeth; right?
>
> A. Yes.
>
> Q. And so it's actually a different physical structure that's being scanned. True?
>
> A. Potentially, yes.

(Tr. (Saber) at 1436:9-22; CX-2138C (Saber Dep. Tr.) at 408:20-409:5.).[98]

3Shape also argued that the brackets around the teeth in Rubbert were analogous to the "saliva as discussed in the '192 patent itself." (RBr. at 52.). These comparisons are not

[98] Dr. Saber's deposition was taken pursuant to Commission Rule 210.28 on August 13, 2019.

analogous and 3Shape's argument is unavailing.

For example, claim 1 of the '192 patent recites a method where the "first virtual model fails to properly represent a first physical part of the physical structure[.]" (JX-0004 at cl.1.). The '192 patent contemplates instances where part of a physical structure surface "was obscured with a material including one or more of saliva, debris, [or] blood," thereby producing an inaccurate first virtual model. (*See, e.g.*, JX-0004 at 5:45-51, 8:58-63, 12:10-15.).

The '192 patent describes removing such material as saliva and blood, that is other than the teeth alone, to obtain unobstructed access to the physical structure surface before generating a second virtual model. (*Id.*). Rubbert, in contrast, does not disclose the removal of brackets around the teeth to obtain unobscured access to the patient's teeth for a virtual model. Critically, Rubbert does not disclose "delet[ing] the scan data that is in close vicinity to the registered bracket model" because the scan data "fails to properly represent" the physical structure, as recited by the '192 patent. Instead, in the example 3Shape cited, Rubbert is concerned with generating a modified virtual model showing the position and orientation of a tooth without the bracket currently bonded to it. (*See* RBr. at 52 (citing RX-0229 at 29:28-31:3).). In other words, the brackets in Rubbert are part of the physical structure being scanned, not an obstruction that prevents the first virtual model from "properly represent[ing]" the underlying physical structure. (JX-0004 at cl. 1.). (*See* Tr. (Saber) at 1432:18-20; 1434:5-14; RX-0229 at 19:32-33, 20:26-27, 21:18-21.).

Ultimately, it is not clear that a person of ordinary skill in the art would understand Rubbert to disclose first and second virtual models of the same physical structure, as recited by independent claims 1 and 28, and dependent claims 2 and 29. Accordingly, 3Shape has not proven by clear and convincing evidence that Rubbert anticipates asserted claims 2, 28, and 29 of the '192 patent.

5. Obviousness

a) The Asserted Claims are Obvious Under Paley-Kriveshko

3Shape argued that Paley-Kriveshko renders asserted claims 2, 28, and 29 obvious. (RBr. at 54.). 3Shape asserted that only "trivial differences" exist between Paley-Kriveshko and the asserted claims such that a person of ordinary skill in the art would have found it obvious to modify Paley-Kriveshko to incorporate such differences. (*Id*.). Considering the deletion of data, 3Shape identified Dr. Saber's expert testimony as supporting a finding that deleting portions of a model was well known in the art and that it would have been obvious to a person of ordinary skill in the art to overwrite existing data, or alternatively, to delete old model and then add new data. (*Id*. (citing Tr. (Saber) at 1407:21-1408:4, 1427:2-1428:12, 1443:2-1443:15).).

In response, Align contended that 3Shape relied upon Dr. Saber's conclusory expert testimony to prove obviousness without providing references in support. (CRBr. at 44.). Align asserted that Dr. Saber's opinion regarding overwriting data was tainted with hindsight bias and could not support obviousness. (*Id*.). Align also argued that 3Shape and its expert failed to explain why modification of Paley-Kriveshko to include the "replacing at least …" limitation would be obvious. (*Id*. at 44-45.). Align contended that the available record "does not suggest a benefit or rationale that would have caused a skilled artisan to modify Paley-Kriveshko to delete and replace data." (*Id*. at 45.). For these reasons, Align argued that Paley Kriveshko does not render the asserted claims obvious. (*Id*.).

Under *KSR*, an obviousness inquiry involves a flexible analysis reflecting, among other things, that "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR*, 550 U.S. at 416-18. As discussed above in Section X.C.4(a),

Paley-Kriveshko explicitly discloses all limitations of claim 1 aside from the "replacing at least …" element of limitation 1[d]. As described above, Paley-Kriveshko does not explicitly describe the deletion of original inadequate model data after the creation of a modified virtual model. However, 3Shape argued persuasively that overwriting, deleting, or otherwise removing such old model data in the modified virtual model represents a only a small change from the explicit disclosures of Paley-Kriveshko. While Paley-Kriveshko does disclose one embodiment of a modified virtual model having both old and new model data (*see* RX-0227 at ¶ 99), there is no teaching away from the "replacing at least …" limitation in Paley-Kriveshko. Furthermore, 3Shape, through its expert Dr. Saber, successfully demonstrated that overwriting, or deleting and then adding, data was well known in the art at the time. (*See* Tr. (Saber) at 1445:12-22).). Thus, Paley-Kriveshko does not require significant modification to reach the "replacing at least …" element of limitation 1[d].

At the same time, Align correctly noted that 3Shape and its expert, Dr. Saber, are less than clear about why a person of ordinary skill in the art would be motivated to make this modification. It is 3Shape's burden to demonstrate "that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so." *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367–68 (Fed. Cir. 2016) (quoting *Kinetic Concepts, Inc. v. Smith & Nephew, Inc*. 688 F.3d 1342, 1360 (Fed. Cir. 2012)). Following *KSR*, "some kind of motivation must be shown from some source, so that the jury can understand why a person of ordinary skill would have thought of either combining two or more references or modifying one to achieve the patented [invention]." *Innogenetics, N.V. v. Abbott*

Labs., 512 F.3d 1363, 1374 (Fed .Cir. 2008).

However, "a reason 'to modify a reference can come from . . . the prior art reference itself, or from the nature of the problem to be solved.'" *Microsoft Corp. v. Parallel Networks Licensing, LLC*, 715 F. App'x 1013, 1022 (Fed. Cir. 2017) (quoting *SIBIA Neurosciences, Inc. v. Cadus Pharm. Corp*., 225 F.3d 1349, 1356 (Fed. Cir. 2000)). Here, Paley-Kriveshko is directed to correcting "omitted or missing scan data" as well as "incomplete scan data, inaccurate scan data, insufficient scan detail . . . and the like." (RX-0226 at ¶¶ 59-60.). Paley-Kriveshko is described as having an advantage over prior art methods wherein "[u]nrecoverable errors or gaps in incremental data cannot be identified and fixed without initiating a new scan, possibly a full scan *to completely replace the defective results*." (*Id*. at ¶ 7 (emphasis added).). Moreover, Paley-Kriveshko teaches that "[t]he system may be used to aid in error-free completion of three-dimensional scans." (RX-0227 at ¶ 8, Abstract.).

Paley-Kriveshko highlights the priority of generating accurate virtual models. A person of ordinary skill in the art would understand that Paley-Kriveshko teaches the undesirability of omitted or inadequate scan data. (*See* Tr. (Saber) at 1392:7-1393:12 (regarding inaccurate data in Paley, "you would like to replace that inaccurate data with accurate data").). Paley-Kriveshko supplies a person of ordinary skill in the art with motivation to overwrite or delete omitted or inadequate scan data, as part of generating error-free virtual models. In application, a person of ordinary skill in the art would be motivated to slightly modify the method of Paley-Kriveshko and generate an error-free modified virtual model that replaced inaccurate data from a first virtual model. Furthermore, a person of ordinary skill in the art would have a reasonable expectation of success from such a modification, because replacing or deleting data was well-established in the art. (*See* Tr. (Saber) at 1445:12-22).).[99]

For these reasons, the "replacing at least …" element of claim limitation 1[d] is obvious in view of Paley-Kriveshko. As described above in Section X.C.4, Paley-Kriveshko explicitly recites the remaining limitations in the asserted claims. Accordingly, 3Shape has met its burden of providing clear and convincing evidence that Paley-Kriveshko establishes a *prima facie* case of obviousness as to asserted claims 2, 28, and 29 of the '192 patent under 35 U.S.C. §103.

i. Secondary Considerations

In its Pre-Hearing brief, Align identified evidence that was allegedly relevant to secondary considerations of non-obviousness for the '192 patent. (*See* CPBr. at 101-102.). However, Align does not address secondary considerations of non-obviousness for the '192 patent in its post-hearing briefs and has therefore waived any arguments as to that issue. (*See* CBr. at 55-76; CRBr. at 34-48; *see also* Ground Rules 10.1, 10.2). Accordingly, Align has not shown secondary considerations of non-obviousness that overcome the finding that Paley-Kriveshko renders claims 2, 28, and 29 of the '192 patent obvious.

b) The Asserted Claims are Not Obvious Under Rubbert

3Shape argued that a person of ordinary skill in the art would have found it obvious to modify Rubbert to overcome any "trivial differences" between it and the asserted claims of the '192 patent. (RBr. at 54.). Unlike its Paley-Kriveshko position, 3Shape's obviousness argument for Rubbert was wholly conclusory and without any citation to record evidence. (*Id.*). Accordingly, 3Shape failed to show by clear and convincing evidence that Rubbert rendered

[99] Dr. Saber's opinions directed to obviousness of the '192 patent in view of Paley-Kriveshko, which have been stricken by Order No. 46, have not been given any weight in this analysis. Consistent with Order No. 46, Dr. Saber's testimony has been considered only to the extent it pertains to the teachings of Paley-Kriveshko, and the knowledge of a person of ordinary skill in the art at the time of the invention.

obvious asserted claims 2, 28, and 29 of the '192 patent.

6. Enablement

3Shape argued that the asserted claims of the '192 patent are invalid for lack of enablement. (RBr. at 54-55.). 3Shape contended that a person of ordinary skill in the art could not practice the full scope of independent claims 1 and 28 without undue experimentation because of the "wherein said first virtual model fails to properly represent a first physical part of the physical structure" limitation found in these claims. (*Id*.; JX-0004 at cls. 1, 28.). Specifically, 3Shape and its expert, Dr. Saber, asserted that a person of ordinary skill in the art would not recognize "when the first virtual model fails to 'properly' represent a physical part." (*Id*. (citing Tr. (Saber) at 1390:19-1391:11.). 3Shape contended that a person of ordinary skill in the art for the '192 patent lacks a background in dentistry and could not overcome the omissions of the '192 patent. (RBr. at 55).[100] 3Shape asserted that dependent claims 2 and 29 are invalid for the same reasons. (*Id*.).

Align argued that 3Shape did not analyze the *Wands* factors required for a showing of undue experimentation. (CRBr. at 45.). Align noted that 3Shape and its expert admitted that enabled embodiments existed, and that 3Shape failed to identify a single embodiment that is not enabled. (*Id*. (citing RBr. at 54-55.)). Align asserted that the specification discloses that "the virtual part DVM1 [the undesirable part of virtual model VM1] may be distorted or otherwise

[100] The Parties stipulated that a person of ordinary skill in the art for the '192 patent "would have had at least a bachelor's degree in electrical engineering, computer science, applied mathematics, or an equivalent field, as well as at least one or two years of industry experience in three-dimensional modeling, or at least five years of comparable industry experience in three-dimensional modeling, or an equivalent combination of academic study and work experience." (Joint Stip. Regarding Person of Ordinary Skill in the Art, Doc. ID No. 692583 at ¶ 2 (Oct. 23, 2019).). Therefore, 3Shape waived its right to make an argument that undermines its own Stipulation about a person of ordinary skill. Clearly, dentistry would be encompassed in the "industry experience" or in "an equivalent combination of academic study and work experience" that the Parties agreed upon.

defective and does not properly correspond to the real part DRM1 [the dental surface part that was inadequately scanned], for example due to some defect in the actual scanning process." (CRBr. at 46 (citing JX-0004 at 20:50-54).). Align argued that the specification expressly teaches instances in which a three-dimensional intraoral scan produces a model with some unacceptable portion corresponding to a physical dental surface. (*Id*. (citing JX-0004 at 20:39-49).).

3Shape's argument does not establish that the asserted claims of the '192 patent are invalid for lack of enablement by clear and convincing evidence. To satisfy the enablement requirement, a patent specificaiton must "contain a written description of the invention . . . to enable any person skilled in the art . . . to make and use the same." 35 U.S.C. §112, ¶1.[101] In this regard, the specification must enable a person of ordinary skill in the art to practice the claimed invention without undue experimentation. *See Transocean*, 617 F.3d 1296 at 1405. 3Shape's argument is rooted in its contention that a person of ordinary skill in the art would not be able to identify every instance that a first visual model fails to properly identify an underlying physical structure. This is unpersuasive. Here, a person or ordinary skill in the art has "at least one or two years of industry experience in three-dimensional modeling," or as much as five years of similar experience. (*See* Doc. ID 692583 at ¶ 2.). 3Shape and its expert, Dr. Saber, do not adequately explain why someone with this background would be unable to determine whether a scanned physical dental surface is accurately and clearly depicted by a corresponding three-dimensional virtual intraoral model.

Additionally, 3Shape does not address why one of ordinary skill in the art would be

[101] Because the '192 patent has an effective filing date prior to March 16, 2013, enablement is examined under pre-AIA §112.

uanble to practice the claimed subject matter absent undue experimentation. Indeed, 3Shape's briefing does not examine the various factors considered when assessing undue experimentation (*i.e.* the *Wands* factors). *See In re Wands*, 858 F.2d at 737. Accordingly, 3Shape has failed to prove by clear and convincing evidence that asserted claims 2, 28, and 29 of the '192 patent are invalid for lack of enablement.

7. Patent Eligibility

3Shape argued that the asserted claims of the '192 patent are invalid under 35 U.S.C. § 101. (RBr. at 55-56.). Specifically, 3Shape asserted that the creation and modification of a plaster model of a patient's teeth was a "well-known procedure" and that the '192 patent simply applies a computer to this method. (RBr. at 55.). According to 3Shape, the "creation and modification of a virtual model . . . involves the use of a general purpose computer to perform mathematical calculations." (*Id*.). 3Shape contended that the asserted claims fail *Alice* step one because they are directed to an abstract concept such as "mathematical formulae." (*Id*.; *see also Alice Corp. Pty. v. CLS Bank Int'l*, 573 U.S. 208, 220. (2014)).

3Shape also contended that the asserted claims fail *Alice* step two because "they do not offer a technical improvement or inventive step sufficient to transform the patent ineligible concept of the independent claims into patent-eligible subject matter." (*Id*. at 56.). 3Shape argued that the asserted claims contemplate only the use of a generic computer functioning in a routine manner, and are therefore ineligible. (*Id*. at 56.).

In response, Align noted that 3Shape offered no expert opinion and virtually no record evidence in support of its argument. (CRBr. at 47.). Align argued that the inventor of the '192 patent, Mr. Ari Kopelman, testified that the claims were directed to an improved method that was not well-understood, routine, or conventional. (*Id*. (citing Tr. (Kopelman) at 129:5-142:7).).

Specifically, Align asserted that Mr. Kopelman demonstrated that the '192 patent recites a novel superior technique for modeling a patient's teeth in a manner that was not possible with analog models. (*Id*. (citing Tr. (Kopelman) at 129:5-142:7).).

Align argued that 3Shape's position is based on attorney argument without any rigorous analysis of either step one or step two of *Alice*. (CRBr. at 47.). Align contended that 3Shape's lack of analysis and nonexistent consideration of the evidence is fatal to its eligibility argument. (*Id.* at 48.).

3Shape's argument is unpersuasive. The '192 patent is directed generally to a "computer-based method for modifying a virtual model of a physical structure . . . using additional 3D data from the physical structure being modeled." (JX-0004 at 4:4-15.). Considering *Alice* step one, 3Shape submitted virtually no analysis on this point, and relied on a single cite to the '192 patent's "Background of the Invention" section. (*See* RBr. (citing JX-0004 at 1:63-2:3).). This is insufficient to demonstrate that the asserted claims are limited to an abstract idea under *Alice* step one. 3Shape's position on *Alice* step two is similarly deficient. 3Shape offered only conclusory attorney argument, without any meaningful discussion of whether there is an inventive concept in the claim elements, considered individually or as an ordered combination. *See Alice*, 573 U.S. at 217-18 (2014). In sum, 3Shape's approach fails to establish that asserted claims 2, 28, and 29 of the '192 patent are ineligible under §101 by clear and convincing evidence.

XI. INDIRECT INFRINGEMENT

A. Legal Standard

1. Induced Infringement

"Whoever actively induces infringement of a patent shall be liable as an infringer." 35

U.S.C. § 271(b). A patentee asserting a claim of inducement must show: (i) that there has been direct infringement and (ii) that the alleged infringer "knowingly induced infringement and possessed specific intent to encourage another's infringement." *Minnesota Mining & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1304-05 (Fed. Cir. 2002); *see also DSU Med. Corp. v. JMS Co*., 471 F.3d 1293, 1306 (Fed. Cir. 2006) ("*DSU*"). With respect to the direct infringement requirement, the patentee "must either point to specific instances of direct infringement or show that the accused device necessarily infringes the patent in suit." *ACCO Brands, Inc. v. ABA Locks Mfrs. Co., Ltd.*, 501 F.3d 1307, 1313 (Fed. Cir. 2007) (citation omitted). This requirement may be shown by circumstantial evidence. *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1326 (Fed. Cir. 2009). "[A] finding of infringement can rest on as little as one instance of the claimed method being performed during the pertinent time period." *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1317 (Fed. Cir. 2009); *Toshiba Corp. v. Imation Corp.*, 681 F.3d 1358, 1364 (Fed. Cir. 2012) (citing *Lucent Techs.*, 580 F.3d at 1317).).

The specific intent requirement for inducement necessitates a showing that the alleged infringer was aware of the patent, induced direct infringement, and that he knew that his actions would induce actual direct infringement. *Commil USA, LLC v. Cisco Sys., Inc.*, 720 F.3d 1361, 1367 (Fed. Cir. 2013), *aff'd and vacated in part on other grounds*, 135 S. Ct. 1920, 1926-28 (2015); *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060, 2068-70 (2011). Specific intent can be shown by, for example: (1) changes in importation practices effectuated to shift infringement liability;[102] (2) the infringer's copying of patented technology; and (3) the

[102] There is some evidence, that Align changed its practice of importing the TRIOS with software sometime after April 2018. The exact date is unclear. *See* Section III.A on *In Rem* Jurisdiction and Importation.

infringer's willful blindness of the underlying direct infringement. *Certain Network Devices, Related Software and Components Thereof (I)*, Inv. No. 337-TA-944, Initial Determination at 82; *see also Commil USA, LLC v. Cisco Sys., Inc.*, 135 S. Ct. 1920, 1924-25 (2015) ("It was not only knowledge of the existence of [the asserted] patent that led the Court to affirm the liability finding but also it was the fact that [the accused infringer] copied 'all but the cosmetic features of the [patented product],' demonstrating [the accused infringer] kn[ew] it would be causing customers to infringe [the asserted] patent.") (quoting *Global-Tech*, 131 S. Ct. at 2071).).

Willful blindness, which also constitutes "knowledge," has two basic requirements: "(1) the defendant must subjectively believe that there is a high probability that a fact exists"; and "(2) the defendant must take deliberate actions to avoid learning of that fact." *Global-Tech*, 131 S. Ct. at 2070. The intent to induce infringement may be proven with circumstantial or direct evidence and may be inferred from all the circumstances. *Commil*, 720 F.3d at 1366; *Global-Tech*, 131 S. Ct. 2071-72.

2. Contributory Infringement

Like induced infringement, contributory infringement requires knowledge of the patent in suit and knowledge of patent infringement. *Commil USA, LLC v. Cisco Sys., Inc.*, 575 U.S. 632, 135 S. Ct. 1920, 1926, 191 L. Ed. 2d 883 (2015) (quoting *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 488, 84 S.Ct. 1526, 12 L.Ed.2d 457 (1964)).

35 U.S.C. § 271(c) sets forth the rules for contributory infringement:

> 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.

35 U.S.C. § 271(c).

Specifically, with respect to Section 337 investigations, the Federal Circuit has held that "to prevail on contributory infringement in a Section 337 case, the complainant must show *inter alia*: (1) there is an act of direct infringement in violation of Section 337; (2) the accused device has no substantial non-infringing uses; and (3) the accused infringer imported, sold for importation, or sold after importation within the United States, the accused components that contributed to another's direct infringement." *Spansion, Inc. v. Int'l Trade Comm'n*, 629 F.3d 1331, 1353 (Fed. Cir. 2010). "[N]on-infringing uses are substantial when they are not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental." *Vita-Mix*, 581 F.3d at 1327. To determine whether a use is substantial, an Administrative Law Judge may evaluate "the use's frequency, . . . the use's practicality, the invention's intended purpose, and the intended market." *i4i Ltd. Partnership v. Microsoft Corp.*, 598 F.3d 831, 851 (Fed. Cir. 2010). Section 271(c) also requires knowledge of the existence of the patent that is infringed. *Global-Tech*, 131 S. Ct. at 2068.

To satisfy the contributory infringement's knowledge requirement, it is necessary to establish that "the accused contributory infringer knows that its component is included in a combination that is patented and infringing[,]" which requires knowledge of the patent. *Global-Tech*, 131 S. Ct. at 2068. In addition, the Federal Circuit has held that it is not sufficient to know of the patent and the relevant acts, but must also know that "these acts constituted infringement." *Fujitsu Ltd. v. LG Elecs.*, 620 F.3d 1321, 1320 (Fed. Cir. 2010). For purposes of contributory infringement, knowledge is inferred when the article at issue has no substantial non-infringing uses. *See Certain Semiconductor Chips with Minimized Chip Package Size and Prods. Containing Same*, Inv. No. 337-TA-605, Comm'n Op., 2009 WL 8144934, at *28 (June 3, 2009).

Where infringement allegations address a "separate and distinct" feature of a product, the contributory infringement analysis (for example, with respect to the existence of non-infringing uses) may address the particular feature in question rather than the product as a whole. *See i4i Partnership v. Microsoft Corp.*, 598 F.3d 831, 849 (Fed. Cir. 2010); *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1320-21 (Fed. Cir. 2009); *Ricoh Co. Ltd. v. Quanta Comput. Inc.*, 550 F.3d 1325, 1338 (Fed. Cir. 2008) ("*Ricoh*").

B. 3Shape Indirectly Infringed the '647, '661, and '192 Patents

1. '647 Patent

Align argued that it has proven that 3Shape induced infringement and contributory infringement of the '647 patent. (CBr. at 26-28.). With respect to inducement, Align argued that 3Shape had actual knowledge of the '647 patent since at least the filing of the Complaint in this Investigation on December 10, 2018. (CBr. at 26.). Alternatively, Align contended that 3Shape demonstrated willful blindness in connection with its launch of the TPM product, despite having knowledge that the TPM product infringes an Align patent. (*Id*. at 27-28 (citing Tr. (Bogdanic)[103] at 824:11-828:6; CX-2220C (Fisker Dep. Tr.) at 122:9-13).). Align asserted that 3Shape "[knew] or should have known that their actions would induce actual infringement of the asserted claims of the '647 patent. (*Id*. at 26).

According to Align, 3Shape "provide[s] training manuals, user guides, online instruction

[103] When he testified during the Hearing on October 28, 2019, Mr. Alen Bogdanic was a Project Manager at 3Shape. (Tr. at 810:4-6.). 3Shape identified Mr. Bogdanic as a fact witness who was called to testify with respect to 3Shape's design and development of its Patient Monitoring software and the structure, function, and operation of that software. (RPSt. at 3.).

videos, and other training materials that encourage resellers and end users in the U.S. to infringe the asserted claims." (*Id*. (citing Tr. (Mozeko)[104] at 751:6-20; CX-0025 (Mozeko Decl.); CX-0026 (Lake Decl.); RX-2420 (Lake Dep. Tr.) [105] at 20:2-22:2.). Align contended that 3Shape's actions included instruction on "Virtual Setup and TPM's segmentation, alignment and comparison functionality." (*Id*. at 26-27.). Align noted that the "alignment feature is disabled by default and the accused Automatic Alignment is the default choice for the user." (*Id*. at 27 (citing CX-0923.0010; CX-2220C (Fisker Dep. Tr.) at 68:18-69:7).).

Align also identified evidence that 3Shape's customers and end users of TPM and Ortho System in the United States follow 3Shape's training and instruction. 3Shape's customers buy and sell the TRIOS scanner and software, thereby directly infringing the '647 patent. (*Id*.).[106] According to Align, 3Shape's training and instruction involves leading "customers and end users to load a treatment plan into TPM for comparison, as the user guide explicitly states that it is the intended use of the product to track a treatment plan." (*Id*. (citing CX-0923.0003).).

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[104] When he testified during the Hearing on October 28, 2019, Mr. Charlie Mozeko was a Products Manager at Great Lakes Dental Technologies Ltd. ("Great Lakes"). (Tr. at 747:3-748:17.). Align identified Mr. Mozeko as a corporate representative of Great Lakes, who was called to testify with respect to 3Shape's U.S. sales activity, infringement of the Asserted Patents, and related activity. (CPSt. at 5.).

[105] At the time of Mr. Richard Lake's deposition that was taken on November 20, 2019 on behalf of Patterson Dental, and held pursuant to Commission Rule 210.28, Mr. Lake was the Senior Category Manager at Patterson Dental Holdings, Inc. (RX-2420C at 6:20-9:22.). As Senior Category Manager, he was responsible for overseeing the marketing efforts at Patterson Dental in connection with 3Shape products and was familiar with Patterson Dental's recordkeeping practices. (*Id*.).

[106] Align additionally argued that "each 3Shape entity induces the other 3Shape entities to import, test, service, download, flash, repair, operate, demonstrate, offer to sell, and/or sell TPM and Ortho System in the U.S. that directly infringe the '647 patent." (CBr. at 28.). Align thus accused each named 3Shape Respondent as well as non-party 3Shape Manufacturing of inducing each other to directly infringe the asserted claims of the '647 patent. (*Id*.). Yet, Align did not offer evidence in support of its claims against these entities. Align failed to specify precisely how one Respondent induces another (or non-party 3Shape Manufacturing) to infringe the '647 patent. Align also made similar threadbare arguments for the '661 and '538 patents. (CBr. at 49, 93.). Align has not proven that these entities induced each other's infringement using this generalized approach.

With respect to contributory infringement, Align asserted that evidence shows instances of direct infringement by 3Shape's resellers and end users in the United States. (*Id*.). Align contended that 3Shape had knowledge that its actions would lead to infringement of Align's patent. (*Id*. at 28.). Align argued that there are no substantial non-infringing uses of TPM, noting that the accused Automatic Alignment feature is the default and easier method of alignment. (*Id*. (citing CX-0923.0010; CX-2220C (Fisker Dep. Tr.) at 68:18-69:7).).

Contrary to Align's arguments, 3Shape argued that TPM does not directly infringe the '647 patent, making indirect infringement impossible. (RBr. at 23.). 3Shape argued that Align has not proven that 3Shape encourages the importation of a "virtual setup" into TPM or the comparison of a "virtual setup" with an actual scan. (*Id*.). 3Shape contended that it discourages these activities with resellers. (*Id*. (citing (CX-2229C (Isleifsson Dep. Tr.) at 45:12-47:14, 47:18-48:11, 50:16-52:7.)). 3Shape also contended that Align asserted that only one of three alignment methods of TPM infringes, and that this too has substantial non-infringing uses. (*Id*. (citing CX-0923.10).).

As described above, Align presented evidence that demonstrated at least one instance of direct infringement of the asserted claims of the '647 patent. *See Lucent Techs.*, 580 F.3d at 1317; *Toshiba Corp.*, 681 F.3d at 1364. With respect to inducement, 3Shape did not dispute that it had knowledge of the '647 patent since at least December 10, 2018, the date that Align filed the Complaint in this Investigation. (*See* RRBr. at 23.). The weight of the evidence supports a finding that 3Shape's instruction and training efforts encouraged resellers and end users to infringe the '647 patent. The evidence also reflects that 3Shape provides a range of training materials to resellers and end users that include step-by-step instruction and demonstration of the functionality of 3Shape's TRIOS products. (*See, e.g.,* CX-0025 (Mozeko Decl.); CX-0026 (Lake

Decl.); Tr. (Mozeko) at 751:6-20; 2275C (Siandre Dep. Tr.)[107] at 13:18-15:10, 24:15-25:1-23, 27:2-19, 28:9-29:17, 31:16-33:22, 35:7-21, 41:22-42:12, 67:17-68:19.). 3Shape trains users on all features of a TRIOS scanner, including TPM and Ortho System. (*See* CX-2265C (Rindom Dep. Tr.) at 56:15-22, 57:10-25; CX-2275C (Siandre Dep. Tr.) at 28:9-29:17.).

As part of its training, 3Shape instructs and intends that resellers and end users operate the TPM and Ortho System products in the manner described in 3Shape's training materials. (*See* CX-2265C (Rindom Dep. Tr.) at 51:21-53:5, 80:19-81:2.). At least one third-party reseller affirmed that it uses 3Shape's training materials and instructions to train and teach customers and end users on the TRIOS product, including the functionality of TPM with Ortho System. (*See* CX-0026 (Lake Decl.).). 3Shape's user manual explicitly recites that an intended use of TPM is to track a patient's treatment plan. (*See* CX-0923.0003.). Patterson Dental demonstrates this product by loading a patient's treatment plan into TPM for comparision to a virtual model. (*See* CX-0026 (Lake Decl.) at ¶ 3(i)(iii).).

The evidence is compelling that 3Shape's instruction and training efforts result in its resellers and end users directly infringing the accused claims of the '647 patent. 3Shape's counter-argument is that it discourages the importation of Virtual Setup into TPM, or a comparison of a Virtual Setup with an actual scan. (RRBr. at 23.). 3Shape's argument is supported only by testimony by its software developer. (*See* CX-2229C (Isleifsson Dep. Tr.) at 45:12-47:14, 47:18-48:11, 50:16-52:7.). However, this argument and testimony is unpersuasive and does not refute the weight of the evidence As an initial matter, 3Shape merely argued that it

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[107] When she provided her deposition testimony on May 31, 2019, Ms. Simone Siandre was an employee of 3Shape, Inc. and held the title of Training Manager, North America. (2275C at 7:12-11:7). Her job responsibilities included handling logistics for trainers and responding to reseller and customer training needs. (*Id*. at 11:1-16.).

merely "discourages" this practice. (RBr. at 23.). Furthermore, the evidence 3Shape cited reveals that a user may import a Virtual Setup by taking some "extra steps." (*See id.* at 51:25-52:7.). This evidence does not overcome evidence that Patterson Dental regularly uses a Virtual Setup with TPM. (*See* CX-0026 (Lake Decl.) at ¶ 3(i)(iii).).

Moreover, the combined documentary and testimonial evidence demonstrates that 3Shape possessed the specific intent requirement for induced infringement. As described above, 3Shape had knowledge of the '647 patent by at least December 10, 2018. It induced direct infringement by resellers and end users as described above. There is also evidence that 3Shape attempted to [redacted]. (*See* Tr. (Bogdanic) at 824:11-828:6; CX-2220C (Fisker Dep. Tr.) at 122:9-13).). The evidence of 3Shape's actions strongly indicate that 3Shape was aware that the actions it induced would lead to direct infringement of Align's patent. *See Commil*, 720 F.3d at 1366. Thus, Align offered sufficient evidence that 3Shape "knowingly induced infringement and possessed specific intent to encourage another's infringement." *Minnesota Mining*, 303 F.3d at 1304-05; *DSU*, 471 F.3d at 1306. For these reasons, 3Shape induced infringement of the '647 patent.

With respect to contributory infringement, the evidence is that TPM contains three alignment methods: Automatic Alignment, 3-Point Alignment, and Manual Alignment. (CX-0923.10.). Of these, only the Automatic Alignment method is accused of infringing the '647 patent. "[N]on-infringing uses are substantial when they are not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental." *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1327 (Fed. Cir. 2009). Here, while the Automatic Alignment is the default method, the other two (2) non-infringing methods are accessible and can also "be used to perform Lower and Upper Jaw Alignment." (CX-0923.0010.). Thus, the two available non-infringing methods qualify as "substantial." Because TPM has substantial non-infringing uses, Align has not proven contributory infringement of the '647 patent.

2. '661 Patent

Align contended that it has proven that 3Shape committed both induced infringement and contributory infringement of the '661 patent. (CBr. at 48-49.). Align relied on virtually the same arguments and evidence it cited to support it claims of 3Shape's induced and contributory infringement of the '647 patent. (*Id.*). Align added that 3Shape instructed resellers and end users how to use "Compare Model Sets and TPM's segmentation, alignment and comparison functionality," leading to direct infringement. (*Id.*). Align noted that CMS does not have a substantial non-infringing use, thereby supporting Align's claims that 3Shape's actions constitute contributory infringement. (*Id.* at 49 (citing CX-0827C.0123-.017).).

In response, 3Shape contended that TPM and CMS do not directly infringe the '661 patent, thereby precluding indirect infringement. (RRBr. at 34.). 3Shape asserted that Align did not establish the intent necessary for a finding of induced infringement. (*Id.*). 3Shape also argued that TPM and CMS have substantial non-infringing uses, citing the default alignment method of TPM and the manual alignment method of CMS. (*Id.*). 3Shape asserted that there was no contributory infringement because of these substantial non-infringing uses. (*Id.*).

As described above, Align presented evidence that demonstrated at least one instance of direct infringement of the asserted claims of the '661 patent. Regarding inducement, 3Shape had knowledge of the '661 patent since at least the December 10, 2018 filing of the Complaint in this Investigation. Evidence shows that 3Shape's instruction and training efforts also result in its resellers and end users directly infringing the accused claims of the '661 patent. (*See* Section

VIII.A.2.). "[S]pecific intent may be inferred from circumstantial evidence where a defendant has both knowledge of the patent and specific intent to cause the acts constituting infringement." *Ricoh Co. v. Quanta Computer Inc*., 550 F.3d 1325, 1342 (Fed. Cir. 2008) (citing *MEMC Elec. Materials, Inc. v. Mitsubishi Materials Silicon Corp*., 420 F.3d 1369, 1378 n. 4 (Fed. Cir. 2005)); *see also DSU*, 471 F.3d at 1306. Such is the case here. Thus, 3Shape possessed the specific intent required for induced infringement.

Accordingly, the weight of the evidence supports a finding that 3Shape had knowledge of the '661 patent and acted with the specific intent to induce resellers and end users into directly infringing. For these reasons, 3Shape induced infringement of the '661 patent.

With respect to contributory infringement, 3Shape persuasively argued that Align accuses only certain alignment methods of TPM. 3Shape contended that it thereby has established substantial non-infringing uses. Indeed, Align did not argue that threre was no substantial non-infringing use for TPM. Align only made the "no substantial non-infringing use for CMS." (*See* CBr. at 49.). Accordingly, Align has waived argument with respect to "substantial non-infringing uses" for TPM pursuant to Ground Rule 10.1. Moreover, the availability of the default Automatic Alignment method in TPM represents a substantial non-infringing use. (*See* CX-0923.10.). Thus because TPM has at least one substantial non-infringing use, Align has not proven that 3Shape is liable for contributory infringement of the '661 patent.

3. '538 Patent

Align argued that 3Shape is liable for induced infringement and contributory infringement of the '538 patent. (CBr. at 92-93.). Align argued that 3Shape had actual knowledge of the '538 patent since at least as of Align's filing of the Complaint in this Investigation. Align also argued that that by then, 3Shape also knew or was willfully blind that the TRIOS product infringes the '538 patent. (*Id.*). Align contended that 3Shape induced end users and resellers to directly infringe by "making, using, selling, and/or offering to sell the TRIOS." (*Id.* at 93 (citing Tr. (Mozeko) at 750:10-17, 751:25-752:14; CX-0026C (Lake Decl.); CX-2113C; CX-2114C; CX-2265C (Rindom Dep. Tr.) at 22:9-87:7; CX-2220C (Fisker Dep. Tr.) at 215:5-219:20; CX-2275C (Siandre Dep. Tr.) at 12:12-29:17, 94:4-104:21.). Align also argued that 3Shape provided training and instruction to end users and resellers in the United States that encouraged infringement of the asserted claims. (*Id.* (citing Tr. (Mozeko) at 751:6-24; CX-2264C (Rindom Dep. Tr.) 72:13-20.).

With respect to contributory infringement, Align asserted that "Respondents offer to sell or sell in the United States or import into the United States the TRIOS scanners." (*Id.* (citing Tr. (Petersen) at 1137:15-19, 1139:9-1140:5; CX-2164C).). Align contended that the "TRIOS scanner constitutes a material part of the inventions of the '538 patent, and does not have any substantial non-infringing use." (*Id.* (citing CX-2276C (Van der Poel Dep. Tr.) 99:21-100:18).).[108]

In response, 3Shape argued that Align has not proven that TRIOS directly infringes the asserted claims of the '538 patent, precluding any indirect infringement. (RRBr. at 62-63.). Considering induced infringement, 3Shape contended that Align did not submit evidence of the intent necessary for inducement. (*Id.* at 62-63.).

As described above in Section IX.A.2, Align has failed to establish that TRIOS directly infringes claims 1 and 2 of the '538 patent. (*See* Sections IX.A.2, *supra.*). Thus, Align cannot establish that 3Shape induced infringement. *Limelight Networks v. Akamai Techs*., 134 S. Ct.

[108] When he gave his deposition testimony on May 24, 2018, Mr. Mike van der Poel held the position of Scanner Manager and Director of New Business Ventures with 3Shape. (CX-2276 at 10:25-11:9.).

2111, 2117 (2014) ("[O]ur case law leaves no doubt that inducement liability may arise 'if, but only if, [there is]…direct infringement.").

In the alternative, should the Commission determine that the 538 Accused Products practice one or more claims of the '538 patent, an analysis of induced infringement is included.

The available evidence demonstrates that 3Shape possesed the specific intent requirement to induce infringement. As described above, 3Shape had knowledge of the '538 patent by at least December 10, 2018. There is compelling evidence that 3Shape induced its resellers and end users to use, sell, and/or offer to sell the TRIOS, that resulted in direct infringement by 3Shape's resellers and end users. (*See, e.g.,* Tr (Mozeko) at 750:10-17, 751:25-752:14; CX-0026C (Lake Decl.); CX-2113C; CX-2114C; CX-2265C (Rindom Dep. Tr.) at 35:24-37:21, 56:7-57:25, 65:3-68:1; CX-2220C (Fisker Dep. Tr.) at 215:5-219:20; CX-2275C (Siandre Dep. Tr.) at 12:12-29:17, 94:4-104:21.). Because 3Shape had knowledge of the '538 patent when it induced infringing actions, the specific intent required for induced infringement is present here. *See Ricoh*, 550 F.3d at 1342; *DSU*, 471 F.3d at 1306.

Accordingly, Align has proven each of the necessary elements of induced infringement, other than direct infringement. If the Commission were to ultimately find direct infringement of the asserted claims of the '538 patent, then Align would have successfully demonstrated induced infringement of the asserted claims of the '538 patent.

Like induced infringement, contributory infringement requires proof of an act of direct infringement. *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek*, 424 F.3d 1293, 1312 (Fed. Cir. 2005). As discussed above, Align has failed to establish that TRIOS directly infringes the '538 patent, thus precluding a finding of contributory infringement. (*See* Section IX.A.2 *supra*.).

In the alternative, should the Commission determine on review that 3Shape's resellers and/or end users directly infringe the ’538 patent, an analysis of contributory infringement is included. The weight of the evidence is that 3Shape offers to sell or sells the TRIOS products in the United States. (Tr. (Petersen) at 1137:15-19, 1139:9-1140:5; CX-2164C.). 3Shape was aware of the ’538 patent, and potential infringement by the 538 Accused Products, at least by December 10, 2018, when Align filed the Complaint in this Investigation. (CX-2280C (Van der Poel Dep. Tr.) at 11:20-13:4.). The record evidence supports a finding that the TRIOS scanner is used only for infringing intraoral scanning. (*See, e.g.,* CX-2276C (Van der Poel Dep. Tr.) at 99:21-100:18). Moreover, 3Shape did not contend that the TRIOS scanner possesses substantial non-infringing uses. (*See* RPBr. at 109; RRBr. at 63.). Therefore, 3Shape has waived this argument pursuant to Ground Rule 10.2.

For the reasons explained above, Align has shown by a preponderance of the evidence each of the necessary elements of contributory infringement. If the Commission were to ultimately find direct infringement of asserted claims 1 and 2 of the ’538 patent, then Align would have successfully demonstrated contributory infringement of asserted claims 1 and 2 of the ’538 patent.

4. ’192 Patent

Align argued that it has shown 3Shape induced infringement of the ’192 patent. (CBr. at 68.). Align contended that 3Shape had knowledge of the ’192 patent as early as November 2017, when it was asserted against 3Shape in a Federal District Court proceeding. (*Id*. (citing D. Del. Case No. 17-cv-1646-LPS).).

Align argued that 3Shape conducts [redacted] training in the United States, and that it [redacted] (*Id*. (citing CX-2265C (Rindom Dep. Tr.) at 65:19-24; CX-2309C (Ellersgaard Dep.

Tr.) at 18:10-13.).[109] Align argued that 3Shape [redacted] to help users operate the TRIM tool, which includes "how to remove blood and saliva from a model to make it more accurate." (*Id*. (citing CX-2265C (Rindom Dep. Tr.) at 9:18-25, 60:24-61:5).). Additionally, Align argued that 3Shape provided "numerous TRIOS level 1 and level 2 trainings in the United States in 2019" that taught users how to use the TRIM tool and the Pre-Preparation Workflows. (*Id*. (citing CX-1116C at 2-8; CX-1145C).). According to Align, 3Shape indirectly infringes the asserted claims of the '192 patent by demonstrating the [redacted], Align also argued that 3Shape then induces others to infringe as those users independently [redacted]. (*Id.*).

In response, 3Shape contended the TRIOS software does not directly infringe the '192 patent, thereby precluding induced infringement. (RRBr. at 42.). Additionally, 3Shape challenged Align's reliance on Mr. Mozeko's testimony. (*Id*. at 42-43.). 3Shape noted that Mr. Mozeko admitted that he had not drafted his own declaration and did not have knowledge of how models in the TRIOS App are modified. (*Id*. at 43 (citing Tr. (Mozeko) at 760:5-14, 761:15-17).). Additionally, 3Shape argued that Mr. Mozeko did not have access to 3Shape source code, the '192 patent, or its file history, which undermined his testimony with respect to infringement. (*Id*. (citing Tr. (Mozeko) at 759:15-760:4; 764:24-765:8).).

As described above, Align presented evidence that demonstrated at least one instance of direct infringement of the asserted claims of the '192 patent. Regarding inducement, 3Shape had

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[109] When she gave her deposition testimony on April 11, 2018, Ms. Sophie Ellersgaard held the position of Director of Customer Care at 3Shape A/S. (CX-2309C at 13:24-16:2.). In this position, Ms. Ellersgaard was responsible for 3Shape A/S's customer support team and its training team, which manages both internal and external training. (*Id*. at 14:14-17:7.).

knowledge of the ’192 patent since at least November 14, 2017, when Align previously accused 3Shape of infringing the ’192 patent in a Federal District Court case. (*See* Compl., Case. No. 17-cv-1646 (D. Del.).). The complaint in this district court case specifically alleged that TRIOS products are associated with the direct and induced infringement of the ’192 patent. (*See id*.)

The adduced evidence indicates that 3Shape knowingly administers or distributes training programs that induce actual infringement by its resellers and/or end users. 3Shape’s criticism of Mr. Mozeko’s testimony is unpersuasive. It does not undermine Align’s evidence of 3Shape’s inducement.[110] Mr. Mozeko testified that although he did not draft his declaration, he reviewed his declaration, and confirmed with the assistance of knowledgeable people that the information contained in his declaration was true. (*See* Tr. (Mozeko) at 764:2-17.). Because 3Shape had knowledge of the ’192 patent when it induced infringing actions, the specific intent required for induced infringement is present here. *See Ricoh*, 550 F.3d at 1342; *DSU*, 471 F.3d at 1306.

Accordingly, the weight of the evidence supports a finding that 3Shape had knowledge of the ’192 patent and acted with the specific intent to induce resellers and end users into directly infringing. For these reasons, 3Shape induced infringement of the ’192 patent.

XII. DOMESTIC INDUSTRY REQUIREMENT: ECONOMIC PRONG

A. Legal Standard

The Commission may only find a violation of Section 337 “if an industry in the United States relating to the articles protected by the patent . . . exists or is in the process of being established.” 19 U.S.C. § 1337(a)(2) (emphases added). Typically, a complainant must show

[110] As a representative of Great Lakes Dental Technologies, Ltd., Mr. Mozeko may properly relate what his company’s sales and technical support staff have observed during demonstrations of the TRIM tool functionality. (*See* Tr. (Mozeko) at 752:15-753:2, 760:22-761:7.). Align has not shown why knowledge of its source code, the ’192 patent, or the file history is required for Mr. Mozeko to testify about Great Lakes’ demonstrations of the TRIM tool on the TRIOS scanner. (*See* CX-0025 (Mozeko Decl.) at 4.u.i.).

that a domestic industry existed at the time the complaint was filed. *See Motiva LLC v. Int'l Trade Comm'n*, 716 F.3d 596, 601 n.6 (Fed. Cir. 2013).

The domestic industry requirement consists of a "technical prong" and an "economic prong." *See, e.g.*, *Certain Elec. Devices, Including Wireless Commc'n Devices, Portable Music & Data Processing Devices, & Tablet Computs.*, Inv. No. 337-TA-794, Order No. 88, 2012 WL 2484219, at *3 (June 6, 2012); *Certain Unified Commc'ns Sys., Prods. Used with Such Sys., and Components Thereof*, Inv. No. 337-TA-598, Order No. 9 at 2 (Sept. 5, 2007) ("*Communications Systems*"). A complainant satisfies the "technical prong" of the domestic industry requirement when it proves that its activities relate to an article "protected by the patent." *See Communications Systems*, Order No. 9 at 2. A complainant satisfies the "economic prong" of the domestic industry requirement when it demonstrates that the economic activities set forth in subsections (A), (B), and/or (C) of Section 337(a)(3) have taken place or are taking place with respect to the protected articles. *See id.*

Subsection 337(a)(3) states that:

> (3) For purposes of paragraph (2), and industry in the United States shall be considered to exist if there is in the United States, with respect to the articles protected by the patent, copyright, trademark, mask work, or design concerned –
>
> (A) significant investment in plant and equipment;
> (B) significant employment of labor, or capital; or
> (C) substantial investment in its exploitation, including engineering, research and development, or licensing.

19 U.S.C. § 1337(a)(3).

Because the criteria are listed in the disjunctive, satisfaction of any one of them will be sufficient to meet the economic prong of the domestic industry requirement. *Certain Integrated Circuits, Chipsets and Prods. Containing Same*, Inv. No. 337-TA-428, Order No. 10, Initial

Determination (May 4, 2000) ("*Integrated Circuits*") (unreviewed). Establishment of the "economic prong" is not dependent on any "minimum monetary expenditure" and there is no need for a complainant "to define the industry itself in absolute mathematical terms." *Certain Stringed Musical Instruments and Components Thereof*, Inv. No. 337-TA-586, Comm'n Op. at 25-26 (May 16, 2008) ("*Stringed Instruments*"). However, a complainant must substantiate the nature and the significance of its activities with respect to the articles protected by the patent at issue. *Certain Printing and Imaging Devices and Components Thereof*, Inv. No. 337-TA-690, Comm'n Op. at 30 (Feb. 17, 2011) ("*Imaging Devices*").

The Commission has interpreted Sections 337(a)(3)(A) and (B) to concern "investments in plant and equipment and labor and capital with respect to the ***articles*** protected by the patent." *Certain Ground Fault Circuit Interrupters and Prods. Containing Same,* Inv. No. 337-TA-739, 2012 WL 2394435, at *50, Comm'n Op. at 78 (June 8, 2012) ("*Circuit Interrupters*") (emphasis in original) (quoting 19 U.S.C. §§ 1337(a)(3)(A), (B)).

When a complainant proceeds under Section 337(a)(3)(C), it is not sufficient for the "substantial investment" under subsection (C) to merely relate to articles protected by the asserted patents. Rather, "the complainant must establish that there is a nexus between the claimed investment and asserted patent regardless of whether the domestic-industry showing is based on licensing, engineering, research and development." *Certain Integrated Circuit Chips & Prods. Containing*, Inv. No. 337-TA-845, Final Initial Determination, 2013 WL 3463385, at *14 (June 7, 2013).

In addition, the Commission has definitively stated that investments in plant and equipment or labor and capital that relate to engineering and research and development ("R&D") (that are expressly identified under subsection (C)), are properly considered under subsections

(A) and (B):

> The statutory text of section 337 does not limit sections 337(a)(3)(A) and (B) to investments related to manufacturing or any other type of industry. It only requires that the domestic investments in plant and equipment, and employment of labor or capital be "with respect to the articles protected by the patent." 19 U.S.C. § 1337(a)(3). Moreover, even though subsection (C) expressly identifies "engineering" and "research and development" as exemplary investments in the "exploitation" of the patent, that language does not unambiguously narrow subsections (A) and (B) to exclude those same types of investments.

Certain Solid State Storage Drives, Stacked Elecs. Components, and Prods. Containing Same, Inv. No. 337-TA-1097, Comm'n Op. at 8 (June 29, 2018) ("*Storage Drives*"); *see also, e.g.*, *Certain Marine Sonar Imaging Devices, Including Downscan and Sidescan Devices, Prods. Containing the Same, and Components Thereof*, Inv. No. 337-TA-921, Comm'n Op. at 57-64 (Jan. 6, 2016) ("*Sonar Imaging Devices*").

There is no mathematical threshold test or a "rigid formula" for determining whether a domestic industry exists. *Certain Male Prophylactic Devices, Inc*., Inv. No. 337-TA-292, Comm'n Op. at 39, USITC Pub. 2390 (June 1991) ("*Male Prophylactic Devices*"). However, to determine whether investments are "significant" or "substantial," the actual amounts of a complainant's investments or a quantitative analysis must be performed. *Lelo Inc. v. Int'l Trade Comm'n*, 786 F.3d 879, 883-84 (Fed. Cir. 2015). Even after *Lelo*, which requires some quantification of a complainant's investments, there is still no bright line as to a threshold amount that might satisfy an economic industry requirement.

It is the complainant's burden to show by a preponderance of evidence that each prong of the domestic industry requirement is satisfied. *Certain Prods. Containing Interactive Program Guide and Parental Control Tech.*, Inv. No. 337-TA-845, Final Initial Determination, 2013 WL 3463385, at *14 (June 7, 2013.). Moreover, the Commission makes its determination by "an examination of the facts in each investigation, the article of commerce, and the realities of the marketplace." *Male Prophylactic Devices*, Comm'n Op. at 39 (quoting *Certain Double Sided-Floppy Disk Drives and Components Thereof*, Inv. No. 337-TA-215, Comm'n Op. at 17, USITC Pub. 1859 (May 1986)).

B. Align's Investments in Plant and Equipment Are Significant Under Section 337 (a)(3)(A)

Align made and continues to make significant domestic investments in the iTero DI Products[111] in the form of facility and equipment costs in relation to activities that include R&D, product development, and management.[112] Align is headquartered in San Jose, California, and has purchased additional facilities in Raleigh, North Carolina. (Tr. (Morici) at 589:5-590:6, 703:6-705:13.).[113] To prove it has significant investments under Subsection 337(a)(3)(A), Align relies upon its plant and equipment expenses related to these two (2) referenced U.S. facilities.

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[111] The relevant DI Products are the Element, Element 2, and Element Flex versions of Align's iTero scanner. (Tr. (Kling) at 356:18-23; Tr. at 705:14-18 (Bakewell).). Align and its expert argued in the alternative that Align's "Invisalign System" is a domestic industry product. (CBr. at 104; Tr. at 738:4-739:4.). However, neither Align nor Mr. Bakewell articulated this argument with any significant detail or specificity during the Hearing. (*See* Tr. (Bakewell) at 705:16-706:9, 738:4-25.). Furthermore, as detailed below, the domestic industry issue can be resolved without considering the Invisalign System as a domestic industry product.

[112] In two (2) previous Investigations involving Align and 3Shape, administrative law judges ("ALJs") determined that Align established a domestic industry related to its iTero scanners under both Subsections 337(a)(3)(A) and (B). *See* 1090 Investigation, Initial Determination (Apr. 26, 2019); 1091 Investigation, Initial Determination (Mar. 1, 2019). The Commission vacated the Initial Determination in the 1090 Investigation on unrelated grounds (*see* 1090 Investigation, Comm'n Op. (Aug. 20, 2019), and took no position on the economic prong findings of the 1091 Investigation. *See* 1091 Investigation, Comm'n Op. at 2 (Nov. 22, 2019).

[113] When he testified during the Hearing on October 28, 2019, Mr. John Morici was Align's Chief Financial Officer. (Tr. (Morici) at 580:14-19.). Align identified Mr. Morici as a fact witness to testify on the background and business of Align; domestic industry in the Asserted Patents; secondary considerations of non-obviousness; issues related to remedy and bond; and related issues. (CPSt. at 9.).

(CBr. at 108.).

Mr. W. Christopher Bakewell,[114] Align's expert witness on the economic requirement of domestic industry, analyzed Align's investments at its two U.S. facilities between 2015 to the December 10, 2018 filing date of the Complaint in this Investigation. (Tr. (Bakewell) 726:5-727:17; CDX-0013C.0030-31.). The San Jose facility is Align's worldwide headquarters, and serves as a significant location for engineering and product development. (Tr. (Bakewell) at 703:6-18; CDX-0013C.0006.). Align's Raleigh facility performs similar engineering and product development functions. (*Id*.).

Mr. Bakewell began his analysis by calculating Align's total plant and equipment acquisition costs for the San Jose and Raleigh facilities. (Tr. (Bakewell) at 726:5-727:17; CX 2147C; CX-0107C; CX-0108C; CDX-0013C.0030-31.). He then determined the depreciation and rental costs of these acquisition expenses from 2015 to December 10, 2018, referring to these as "period costs." (*Id*.).[115] Mr. Bakewell valued Align's plant and equipment period costs as [redacted]. (Tr. (Bakewell) at 726:5-727:25; CX 2147C; CX-0107C; CX-0108C; CDX-0013C.0030-31.). Align's period costs are summarized below in Table No. 11.

Table No. 11: Align's Period Costs

[114] When he testified during the Hearing on October 28, 2019, Mr. W. Christopher Bakewell was the Managing Director and the leader of the intellectual property advisory services practice at Duff & Phelps. (CPSt. Ex. 2.). Align identified Mr. Bakewell as an expert to testify about the economic prong of the domestic industry requirement, as well as the appropriate remedy and bond. (CPSt. at 3-4).

[115] The Commission has previously granted summary determination on the economic prong of a domestic industry inquiry based in part upon depreciation in manufacturing facilities, factory equipment, and buildings. *See Certain Crawler Cranes & Components Thereof*, Inv. No. 337-TA-887, Order No. 17, ID at 4 (Feb. 14, 2014); Comm'n Notice (Mar. 20, 2014) (upholding Order No. 17).

[redacted]

(CDX-0013C.0031 (citing CX-2147C, CX-0107C, CX-0108C.).

Mr. Bakewell conducted a floor plan allocation of these period costs based on his review of Align's office space dedicated to R&D generally. (Tr. (Bakewell) at 728:1-730:12; CDX-0013C.0032-37.). Mr. Bakewell testifies that [redacted] of Align's current San Jose facility is attributable to R&D. (Tr. (Bakewell) at 728:7-21; CDX-0013C.0032.). At Align's previous San Jose facility that was used in 2015 and 2016 as part of the "period costs," Mr. Bakewell testified that between [redacted] of the area was used for R&D. (Tr. (Bakewell) at 728:22-729:9; CDX-0013C.0033.). He opined that the aggregate results were "pretty much the same" regardless of whether a [redacted] allocation rate was used for the older San Jose facility, and ultimately attributed [redacted] of both Align's San Jose facilities to R&D. (Tr. (Bakewell) at 728:22-729:9.). Mr. Bakewell conducted a similar analysis of Align's Raleigh facility by focusing on the space used by individual R&D employees. He calculated an R&D allocation of roughly [redacted] of space for 2015, 2016, 2017, and the year ending on December 10, 2018 respectively. (Tr. (Bakewell) at 729:10-730:12; CX-2147C.0001; CDX-0013C.0034, .0036.). Mr. Bakewell testified that the allocated portion of Align's facilities relating to R&D, taken together, totaled roughly [redacted] million from 2015-January 2018. (Tr. (Bakewell) at 729:21-730:16; CX-2147C.0002 CDX-0013C.0037.). The floor plan-based allocation of Align's period costs is summarized below in Table No. 12.

Table No. 12: Floor Plan-Based Allocation of Align's Period Costs

[redacted]

(CDX-0013C.0037 (citing CX-2147C).).

Mr. Bakewell applied three (3) different allocation methodologies to determine the investment amounts attributable to the DI Products.[116] The first method is a sales-based allocation, the second method is a management-based allocation, and the third method is a responsibilities-based allocation. (Tr. (Bakewell) at 730:17-732:1.).

For the sales-based allocation, Mr. Bakewell determined that U.S. sales of the DI Products ranged between [redacted] of Align's total revenue. (Tr. (Bakewell) at 717:18-718:12, 730:17-731:10; CX-0100C; CDX-0013C.0020.). This figure excludes international iTero sales, clear Aligner sales, scanner-related services, and software renewals. (Tr. (Bakewell) at 717:18-

[116] These three (3) methodologies were selected in part because Align does not track its expenses by product. (*See* Tr. (Morici) at 584:17-585:9, (Bakewell) at 717:18-718:12.).

719:8; CX-0100C; CDX-0013C.0020.). Using a [redacted] allocation of Align's revenue to iTero scanners for 2015, a [redacted] allocation for 2016, a [redacted] allocation for 2017, and a [redacted] allocation for 2018, Mr. Bakewell allocated roughly [redacted] for plant and equipment investments for the DI Products. (Tr. (Bakewell) at 730:17-731:10; CX-0100C; CX-2143C.).

Align relied for its management-based allocation on the testimony of Align's CFO, John Morici. (Tr. (Bakewell) at 720:8-721:9.). Mr. Morici testified that Align splits its revenue and costs between [redacted] (Tr. (Morici) at 583:13-17.). Mr. Morici analyzed the division of labor between these two (2) segments by: (a) reviewing financial materials; (b) consulting with other employees; (c) reviewing the history of Align's 2011 acquisition of Cadent (including Cadent's iTero scanners); and (d) relying on Mr. Morici's familiarity with Align's business operations. (*Id.* at 582:13-584:16; CX-0233.). While the majority of Align employees perform work in both segments, Mr. Morici testified that at least [redacted] of the work performed by Align's U.S. workforce during this time, i.e. 2015-2018, was dedicated to the iTero. (Tr. (Morici) at 584:17-25; CX-2146C; CX0021C; CDX-0013C.0023.).

Mr. Bakewell considered this analysis and concluded it was a reasonable means to allocate Align's domestic industry investments. (Tr. (Bakewell) at 720:8-722:15.). Applying a [redacted] allocation rate, Mr. Bakewell opined that by using the management-based allocation, he valued Align's plant and equipment investments in the DI Products at roughly [redacted]. (*Id.* at 731:13-21; CX-2146C.0002; CDX-0013C.0039.).

The responsibilities-based allocation represents a "person-by-person" or "operations center by operations center" examination of employee functions. (*Id.* at 710:23-712:3.). This method is based upon a review of human resources and financial records, performed by five (5) Align executives: Mr. Zelko Relic, Ms. Kerri Kling, Ms. Sree Kolli (VP of Information

Technology), Mr. Srini Kaza (VP of Product Innovation), and Mr. Eric Meyer (VP of Software). (*Id*. at 710:23-712:3; 722:16-723:10; CX-1838C; CX-2154C; CX-2155C; CX-0116C; CX-0117C.). Mr. Bakewell examined their data, spoke to the individuals who prepared the data, and concluded that a responsibilities-based allocation was a reasonable means by which to allocate Align's domestic industry investments. (*Id*. at 710:23-712:3; 722:16-723:10.). Using a responsibilities-based allocation, Mr. Bakewell evaluated how much time Align employees dedicated to the DI Products, and allocated Align's plant and equipment investments accordingly. (*Id*. at 731:13-732:8.). Mr. Bakewell opined that using a responsibilities-based allocation, he valued Align's plant and equipment investments in the DI Products at roughly [redacted] during the time period specified in Table No. 13, below. (*Id*. at 731:13-732:8; CX-2146C.0002; CDX-0013C.0039.).

The comparative results of Mr. Bakewell's three (3) allocations are summarized below in Table No. 13.

Table No. 13: Align's Allocated Domestic Industry Investments in Plant and Equipment

[redacted]

(CDX-0013C.0039 (annotated) (citing CX-2146C).)[117]

3Shape and its expert, Mr. Philip Green,[118] disputed Mr. Bakewell's allocations of Align's domestic industry investments for several reasons. (RRBr. at 67-78.). While the challenges to Mr. Bakewell's management-based and responsibilities-based allocations will be discussed in connection with Section 337(a)(3)(B) below, Section XII.B, 3Sharp also disagreed with Mr. Bakewell's floor plan-based allocations. (*Id*. at 77-78.). Specifically, 3Sharp objected to the application of a [redacted] floor space allocation factor for Align's former San Jose facility, despite Mr. Bakewell's estimate that R&D accounted for a range of [redacted] of floor space in that facility. (*Id*.). 3Sharp pointed out that if the [redacted] allocation is used for the former San Jose facility, Mr. Bakewell's management-based allocation should be reduced by approximately [redacted] (*Id*. (citing CDX-0013C.0039 n.3.). 3Shape's argument has merit. There is a large swing both a [redacted] allocation and a [redacted] allocation.

Nonetheless, even if the lower floor space allocation of [redacted] is applied to Align's former San Jose facility, the weight of the evidence supports a finding that Align has met its burden of proving that its domestic industry investments in support of Subsection 337(a)(3)(A) are significant from both a quantitative and a qualitative standpoint. Even applying the full [redacted] reduction to the management-based allocation that 3Sharp urged, the management-based and responsibilities-based allocations yield plant and equipment expenditures of roughly

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[117] Align stated that the chart in CDX-0013C.0039 "has a column labeled 'Jan.-Mar. 2018,' but those numbers reference allocations from January through December 10, 2018." (CBr. at 108 n. 53.).

[118] When he testified during the Hearing on October 30, 2019, Mr. Philip Green was a Principal of Hoffman Alvary & Company LLC. (RPSt. at Ex. B.). 3Shape identified Mr. Green as an expert to testify about the economic prong of the domestic industry requirement as well as the appropriate remedy and bond. (RPSt. at 4.).

[redacted] million dollars, respectively, from 2015 to December 10, 2018.[119] These figures are quantitatively significant. *See Lelo*, 786 F.3d at 883-884. Evidence shows that these amounts (as well as Align's underlying R&D period costs) steadily increased during this time period. (*See* CX-2146C; Tr. (Bakewell) at 730:13-16.).

Align's allocated plant and equipment investments are significant when considered in the context of its foreign facilities. Between Q1 2015 and Q4 2018, Align has facilities in Russia, Mexico, Costa Rica, and Israel. Align reported unallocated accumulated depreciation values for these facilities as approximately [redacted] respectively.[120] (CX-2157C; Tr. (Bakewell) at 737:5-738:3.). While 3Shape correctly noted that these unallocated depreciation figures exclude foreign rent, they are still evidence of quantitative significance. (RRBr. at 80-81; citing Tr. (Bakewell) at 790:12-21.). Align's allocated domestic industry plant and equipment investments are significant when compared to Align's unallocated depreciation values for its foreign facilities, both individually and in the aggregate.[121] Qualitatively, the evidence demonstrates that Align's allocated domestic industry plant and

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[119] Align's cited investments it made between 2015 and up to the filing date of the Complaint in this Investigation relate to developing a domestic industry under Subsections 337(a)(3)(A) and (B). *See Motiva LLC*, 716 F.3d at 601 n.6.

[120] Align maintained other international facilities during this time. (Tr. (Bakewell) at 787:11-24.). Mr. Bakewell considered that "the direction of global activities really occurs from the United States" when he compared Align's U.S. investments to its facilities in Russia, Mexico, Costa Rica, and Israel. (Tr. (Bakewell) at 732:19-733:15.). He further testified that the [redacted] (Tr. (Bakewell) at 732:19-733:15; 787:11-24.).

[121] As Align explained certain values, Align's unallocated values represent total investments in an area, whereas allocated values approximate the portion of the total investment relating to the DI Products. (*See* CBr. at 106; Tr. (Bakewell) at 710:23-712:7.).

equipment expenditures are important to the DI Products because they facilitate the coordination of domestic and global R&D activities for software and hardware underlying the DI Products. (*See, e.g*. Tr. (Relic) at 216:13-217:6; (Morici) 589:5-22.).

For these reasons, Align has met its burden and proven that its investments in plant and equipment for the DI Products under the management-and responsibilities-based models are significant.[122]

C. Align's Investments in Employment of Labor and Capital Are Significant Under Section 337(a)(3)(B)

Align made and continues to make significant domestic investments in labor and capital to support its DI Products. Align relies on the its U.S. workforce employee salary and compensation expenditures as they pertained to Align's DI Products between 2015 to December 10, 2018. (Tr. (Bakewell) at 713:2-714-24, CX-2154C.). As of December 10, 2018, Align had approximately [redacted] employees of whom some [redacted] work in the United States. (*See* Tr. (Bakewell) at 703:6-705:13; CX-2158C.). Mr. Bakewell analyzed which of Align's U.S. employees performed work on the DI Products, and then used the same three (3) allocation methods described above that he applied to Align's investments in plant and equipment. (Tr. (Bakewell) at 710:23-712:7.).

Mr. Bakewell's analysis identified the following relevant categories of Align's U.S. employees for the years 2015-2018: Engineering (R&D), Product Development, and Clinical Education. (Tr. (Bakewell) at 703:6-705:13; CDX-0013.6, 13.). Mr. Bakewell described Engineering as the most "upstream" employee category (i.e. closely related to engineering of the

[122] There is insufficient evidence to determine the significance of Align's roughly [redacted] investment under the sales-based model. (*See* CDX-0013C.0039 (annotated) (citing CX-2146C).).

DI Products), followed by Product Development and Clinical Education in that order. (Tr. (Bakewell) at 703:6-705:13, 712:8-713:1; CDX-0013.6, 13.). Mr. Bakewell excluded other employees, including those in technical sales and marketing, general management, legal, part-time employees, contractors, and marketing-oriented employees. (Tr. (Bakewell) at 703:6-705:13, 712:8-713:1; CDX-0013.6, 13.). Mr. Bakewell determined the relevant head counts of U.S. Align employees in the Engineering (R&D), Product Development, and Clinical Education groups based upon: (a) reports taken from Align's payroll system; (b) interviews with Align executives Mr. Relic, Ms. Kling, Ms. Kolli, Mr. Kaza, and Mr. Meyer; (c) an examination of the activities performed by U.S. employees; and (d) whether each employee directed her efforts towards the DI Products, Invisalign, or both. (Tr. (Bakewell) at 713:2-714:13.). Mr. Bakewell's employee categorizations and head counts are summarized below in Table No. 14.

Table No. 14: Categorization of and Head Counts of Align's U.S. Employees

[redacted]

(CDX-0013C.0013 (citing CX-2154C; CX-2156C).).

At the same time, Mr. Bakewell used salary and compensation data for relevant U.S.

Align employees to determine Align's domestic investment in labor for the Engineering (R&D), Product Development, and Clinical Education groups. (Tr. (Bakewell) at 713:2-714:13.). Mr. Bakewell opined that between 2015 and 2018, Align's unallocated U.S. labor investments for the Engineering (R&D), Product Development, and Clinical Education groups totaled approximately [redacted]. (Tr. (Bakewell) at 714:14-715:1.). These unallocated U.S. labor expenses are summarized below in Table No. 15.

Table No. 15: Align's Relevant Unallocated Investments in Labor

[redacted]

(CDX-0013C.0015 (citing CX-2154C; CX-2155C; CX-0166C).).

Mr. Bakewell then allocated these amounts to the DI Products using the same methodologies deployed for his section 337(a)(3)(A) analysis. (CBr. at 117.). Using the sales-based allocation, Align's domestic industry labor investment is approximately [redacted]. Using the management-based allocation, Align's domestic industry labor investment is roughly [redacted]. Applied to labor and capital expenditures, Mr. Bakewell's responsibilities-based allocation classifies Align employees as iTero-dedicated, Invisalign-dedicated, or split between the two. (Tr. (Bakewell) at 774:11-15.). Under a responsibilities-based allocation, Mr. Bakewell allocated approximately [redacted] of investments related to relevant split employees, and 100% of investments related to relevant iTero-dedicated employees, yielding a total allocation factor of roughly [redacted].[123] (*See* CX-2152 at n.2; CX 2154C; CX-0099C.). Using the responsibilities-based allocation, Align's domestic industry labor investment is about [redacted] million. (Tr. (Bakewell) at 719:9-19, 723:11-725:15; CX-0099C; CDX-0013C.0021, .0027.). The results of Mr. Bakewell's three allocations are summarized below in Tables Nos. 16 and 17.

Table No. 16: Align's Domestic Industry Investments in Plant and Equipment – Sales-Based Allocation

[redacted]

(CDX-0013C.0021 (annotated) (citing CX-0099C).).

[123] Align testified that its Clinical Education employees' duties include training and educating customers on its scanners. (Tr. (Kling) at 336:10-337:19.). While these employees likely also have other duties that are not relevant to the domestic industry analysis (*see* RRBr. at 75-76), the Clinical Education category contributed the least of the three (3) categories to Align's allocated DI Product employment of labor. (*See* CX-2152C.). Mr. Bakewell's responsibilities-based allocation may, therefore, overstate Align's true employment of labor but not to a degree that calls his ultimate opinion into question.

Table No. 17: Align's Domestic Industry Investments in Plant and Equipment – Management-Based and Responsibilities-Based Allocations

[redacted]

(CDX-0013C.0027 (annotated) (citing CX-0099C).).

3Shape and its expert challenged the reasonableness of Mr. Bakewell's allocations. (RRBr. at 67-76.). 3Shape urged that Mr. Bakewelll's allocations conflict with Align's public financial disclosures, and that the Align executives' analysis of efforts dedicated to the DI Products cited by Mr. Bakewell are insufficient. (*Id*.). 3Shape claimed that it is unreasonable to rely upon a handful of Align executives to accurately assess the fraction of work attributable to the DI Products for the Align workforce and that the true allocation factor is likely far lower than what Mr. Bakewell opines. (*Id*.).

3Shape's focus on deviations from Align's "ordinary course financials," such as its 10-K Securities and Exchange Commission ("SEC") disclosures, overlooks the realities of Align's business operations as well as different reporting requirements for SEC disclosures. (*See* RRBr. at 67-79 (citing CX-0059).). Align's 10-K disclosures reflect that Align has two (2) primary business segments, Scanners and Services (which include the DI Products) and Clear Aligners;

Align employees are [redacted] of these two (2) segments. (*See* CX-0059.0004-7, CX-0021C at 2-3; Tr. (Morici) at 623:10-18, 633:17-634:8.). However, Mr. Morici testified that despite this [redacted] classification for SEC purposes, [redacted]. (Tr. (Morici) at 588:2-25; 633:9-634:8.). Approximately [redacted] of Align's employees' efforts are directed to both business segments. (Tr. (Morici) at 584:17-585:6.). SEC reporting involves a different set of accounting standards than those Mr. Bakewell used for this Investigation.

3Shape failed to show that Mr. Bakewell's allocations are unreasonable. Mr. Bakewell's allocation methods for his management-based and responsibilities-based methods are based upon the analysis and assessment of multiple Align executives who reported their information to him. This is uncontroversial. Align executives, working independently or with subordinates, are well-positioned to examine and determine where labor was dedicated in the recent past. These determinations appear credible and reasonable. The remaining issues that 3Shape identified relate to the margins of Mr. Bakewell's management-based and responsibilities-based methods but do not call his ultimate opinions into question. 3Shape did not raise a serious challenge to Mr. Bakewell's sales-based allocation.

The weight of the evidence supports a finding that Align's expenditures in support of Subsection 337(a)(3)(B) are significant from both a quantitative and a qualitative standpoint. Mr. Bakewell's sales-based method indicates that Align's domestic industry labor investment is approximately [redacted], the management-based method yields roughly [redacted], and the responsibilities-based method yields about [redacted]. Quantitatively, even if taken separately all three (3) methods demonstrate significant employment of labor and capital between 2015 and

December 10, 2018. *See Lelo*, 786 F.3d at 883-84. These figures are also supported by the fact that roughly [redacted] of Align's U.S. labor force is focused on the DI Products. (*See* Tr. (Bakewell) at 734:17-735:23; CX-2154C; CX-2158C (allocating [redacted] of split employees to the DI Products); CDX-0013C.0043.).

Align's labor and capital expenditures are qualitatively significant as well.[124] Many of Align's top executives are based in the U.S., where they make product development and R&D decisions for the DI Products that impact the entire company. (Tr. (Relic) at 216:13-217:6, 589:5-22, 732:19-733:15.). The U.S. dental market is recognized as "the most advanced dental market in the world." According to unrebutted testimony, Align's U.S. workforce typically leads development of new product features and innovations, ultimately distributing them worldwide. (Tr. 343:5-17 (Kerri Kling), 216:13-217:6.).[125]

Evidence also reflects that Align's average U.S. labor costs are substantially higher than its average labor costs worldwide. Between 2015 and 2018, Align's average domestic labor cost per person was about [redacted] times that of its average worldwide labor cost per person. (Tr. (Bakewell) at 733:16-734:10; CX-2158C; CX-0123C; CDX-0013C.0041.). This trend is reflected in Align's U.S. DI Product workforce, which comprised about [redacted] of Align's

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[124] Align's Mr. Bakewell suggested that Align's U.S. executives add "value" to Align's operations, but without conducting a metric analysis of the value that those executives added. *See*, e.g. *Certain Beverage Dispensing Systems and Components Thereof*, Inv. No. 337-TA-1130, Comm'n Op. at 20 (Mar. 11, 2020) (noting that when evaluating significance, it is appropriate to "consider[] the value added to the product from a complainant's activities in the United States" (quotation omitted)).

[125] When she testified during the Hearing on October 25, 2019, Ms. Kerri Kling was the vice president of global marketing, education, laboratory and strategic accounts for Align. (Tr. (Kling) at 326:24-327:4.). Align identified Ms. Kling as a fact witness to testify on the background and business of Align; background and business of Cadent; domestic industry in the Asserted Patents; and related issues. (CPSt. at 7.).

worldwide labor force while accounting for more than [redacted] of its worldwide labor expenditures.[126] (Tr. (Bakewell) at 734:17-735:23; CX-2158C; CX-0123C; CDX-0013C.0043.). Align's share of its U.S. labor-related expenditures is indicative of the qualitative significance of Align's U.S. workforce to the DI Products.

For the reasons explained, Align has proven that its employment of labor and capital in relation to the DI Products is significant.

XIII. REMEDY AND BOND

This determination recommends: (1) a Limited Exclusion Order; and (2) a Cease and Desist Order with a standard service and repair exception. A bond is not recommended during the Presidential Review Period.

A. Legal Standard

Pursuant to Commission Rule 210.42, an Administrative Law Judge ("ALJ") must issue a recommended determination on: (i) an appropriate remedy if the Commission finds a violation of Section 337, and (ii) an amount, if any, of the bond to be posted. 19 C.F.R. § 210.42(a)(1)(ii). When a Section 337 violation has been found, as has been found in this Investigation, "the Commission has the authority to enter an exclusion order, a cease and desist order, or both." *Certain Flash Memory Circuits and Prods. Containing the Same*, Inv. No. 337-TA-382, Comm'n Op. on the Issues Under Review and on Remedy, the Public Interest and Bonding, at 26 (June 9, 1997).

B. A Limited Exclusion Order Is Warranted

Upon a finding of infringement, the Commission's enabling statute, 19 U.S.C. § 1337(d)

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[126] This comparison relies on a total domestic industry labor expense for 2015 to 2018 of roughly [redacted] million for 2015-2018, which appears to reflect Mr. Bakewell's responsibilities-based method. (*See* CX-0123C.0001.).

provides for a Limited Exclusion Order ("LEO"), that can be directed to any articles that infringe one or more claims of the asserted patent(s) of any of the named respondents. 19 U.S.C. § 1337(d). A limited exclusion order instructs the U.S. Customs and Border Protection ("CBP") to exclude from entry all articles that are covered by the patent at issue that originate from a named respondent in the investigation. *Fuji Photo Film Co. Ltd. v. 1nt'l Trade Comm'n*, 474 F.3d 1281, 1286 (Fed. Cir. 2007).

Align requested that the Commission issue a LEO which would bar the entry of all the Accused Products found to infringe the Asserted Patents. (CBr. at 122-23.). Specifically, Align requested that the Commission issue a LEO directed to "all named Respondents, as well as any affiliated entities, including 3Shape Manufacturing." (*Id.* at 122.).

In response, 3Shape asserted that the Commission should limit any issued LEO to exempt products that were imported prior to the effective date of any exclusion order. (RRBr. at 91.). 3Shape argued that the replacement and refurbished parts and devices it holds in or sends into the United States also should be exempt from a LEO in order to mitigate harm to 3Shape's existing customers. (*Id*.). 3Shape also requested that a LEO, if issued, should include a certification provision. (*Id*.).

The recommendation here is that the Commission issue a LEO directed to 3Shape's Accused Products that infringe one or more claims of the Asserted Patents. However, including non-party entities within the scope of the LEO is contrary to settled law. *Kyocera Wireless Corp. v. Int'l Trade Comm'n*, 545 F.3d 1340, 1356 (Fed. Cir. 2008) ("[I]f a complainant wishes to obtain an exclusion order operative against articles of non-respondents, it must seek a GEO by satisfying the heightened evidentiary burdens of §§ 1337(d)(2)(A) and (B).")("*Kyocera*"). Moreover, Align has not requested a General Exclusion Order. *Kyocera* does not apply here.

3Shape also seeks to allow the continued importation of its Accused Product models prior to the effective date of a LEO. (RRBr. at 91 (citing *Certain Baseband Processor Chips and Chipsets, Transmitter and Receiver (Radio) Chips, Power Control Chips, and Prods. Containing Same, Including Cellular Telephone Handsets*, Inv. No. 337-TA-543, Comm'n Op at 28, 124, 151-54 (June 7, 2007)("*Certain Baseband Chips*".). *Certain Baseband Chips* discusses an exemption related to possible adverse effects on the public interest. The public interest factors have not been delegated for fact-finding or consideration by the ALJ in this instant case. *See* Notice of Institution (Doc. ID No. 669028 (Mar. 9, 2019).). Accordingly, any exemption to the recommended LEO based upon public interest factors is beyond the scope of the recommendation here. Similarly, 3Shape's requested exemption for replacement and refurbished parts and devices cites a prior Investigation that also implicates public interest factors. *See Certain Automated Mechanical Transmission Sys. for Medium-Duty and Heavy-Duty Trucks and Components Thereof*, Inv. No. 337-TA-503, Comm'n Op. at 4-5 (May 9, 2005). (RRBr. at 91.).

For similar reasons, the recommendation here does not take a position on the application of public interest factors to a LEO. However, as discussed below, 3Shape's existing domestic inventory is significant and suitable for warranty, replacement, and repair. Therefore, a modification is warranted to allow 3Shap to service, repair and replace its existing Accused Products in the United States. (*See, e.g.*, RRBr. at 92 (citing CX-2259C (Mikael Petersen Dep. Tr.) at 69:4-14).).[127]

Finally, 3Shape requested a certification provision. (RRBr. at 91). Yet, 3Shape failed to

[127] When he testified during his deposition taken pursuant to Commission Rule 210.28 on May 9, 2019, on behalf of 3Shape, Mr. Mikael Petersen was 3Shape's Vice President for supply chain, group IT, and facilities. (CX-2259 at 7:4-8:15.). 3Shape identified Mr. Petersen as a corporate designee for 3Shape who was called to testify with respect to 3Shape's supply chain for the Accused Products. (RPSt. at 2.).

provide an explanation why a certification provision would be warranted. In sum, the recommendation here is that a LEO issue without the exemptions and certifications that 3Shape requested.

C. A Cease and Desist Order Is Warranted

Section 337 provides that in addition to, or in lieu of, the issuance of an exclusion order, the Commission may issue a Cease and Desist Order ("CDO") as a remedy for violation of Section 337. *See* 19 U.S.C. § 1337(f)(1). The Commission generally issues a cease and desist order directed to a domestic respondent when there is a "commercially significant" amount of infringing, imported product in the United States that could be sold so as to undercut the remedy provided by an exclusion order. *See Certain Crystalline Cefadroxil Monohydrate*, Inv. No. 337-TA-293, Comm'n Op. on the Issue Under Review, and on Remedy, the Public Interest and Bonding at 37-42, Pub. No. 2391 (U.S.I.T.C., June 1991). Cease and desist orders have been declined when the record contains no evidence concerning infringing inventories in the United States. *Certain Condensers, Parts Thereof and Prods. Containing Same, Including Air Conditioners for Automobiles*, Inv. No. 337-TA-334, Comm'n Op. at 28 (U.S.I.T.C. Aug. 27, 1997).

Align requested that the Commission issue a CDO because 3Shape "maintain[s] a 'commercially significant' inventory of infringing products in the United States and there are significant domestic operations that could undercut the remedy provided by an exclusion order." (CBr. at 123.). The Parties stipulated to the amount of 3Shape's U.S. inventory of the Trios 3 and Trios 4 products as of September 11, 2019. (CX-2296C.). Align's expert testified that 3Shape's domestic inventory could be sold in the U.S., and that the Trios Accused Products are "relatively expensive." (Tr. (Bakewell) at 739:19-740:24.). 3Shape did not provide an estimate of the value of its inventory in the United States, or otherwise dispute Mr. Bakewell's testimony with respect to the value of the Trios Accused Products. (RRBr. at 91-92). Therefore, it is unclear what Mr. Bakewell meant when he described 3Shape's inventory in the United States as "relatively expensive." Align argued that the quantity of 3Shape's domestic inventory is undisputed and that it is commercially significant. (CBr. at 123 (citing CX-2296C; Tr. (Bakewell) at 739:19-740:24).).

3Shape has waived any argument on the issue of the value of its inventory pursuant to Ground Rule 10.2. 3Shape only responded that its domestic inventory [redacted] that are "for warranty, replacement, repair, training, and demonstration, not for sale." (RRBr. at 92 (citing CX-2259C (Petersen Dep. Tr.) at 69:4-14).). 3Shape argued that because its domestic inventory is not intended for sale, it is not commercially significant. (RRBr. at 91-92). 3Shape requested that a CDO should not prohibit it from providing technical support to U.S. customers, or from honoring its existing warranty and service obligations. (*Id.*).

The recommendation here is that the Commission issue a CDO. The Parties' stipulation on the quantity of 3Shape's inventory contains [redacted] but does not clearly indicate whether each item corresponds to a component or fully assembled Trios scanner units with software. (*See* CX-2296C.). Despite Mr. Petersen's inexact testimony, the Parties stipulated that 3Shape [redacted], which is the better evidence. (*See* RRBr. at 92 (citing CX-2259C (Petersen Dep. Tr.) at 69:4-14).). Given the quantity of 3Shape's domestic inventory, and Mr. Bakewell's testimony with respect t its value and ability to be sold in the United States, there is no compelling reason to decline Align's request for a CDO. (*See* CX-2296C; Tr. (Bakewell) at 739:19-740:24.).

Additionally, it is the recommendation here that a CDO contain a limited service and repair exception. 3Shape's uses part of its inventory in the United States to facilitate its service and repair activities. (*See* CX-2259C (Petersen Dep. Tr.) at 69:4-14). A limited service and repair exception would protect 3Shape customers who use 3Shape's Accused Products under existing service and warranty agreements. Such an arrangement would be consistent with Commission precedent. *See Certain Systems for Detecting and Removing Viruses or Worms, Components Thereof, and Prods. Containing Same*, Inv. No. 337-TA-510, Comm'n Op. at 6 (Aug. 23, 2005) (excepting from a CDO "service and replacement parts" on the ground that consumers might otherwise suffer).

D. A Bond During the Presidential Review Period Is Not Warranted

During the Presidential Review Period, imported articles otherwise subject to a remedial order are entitled to conditional entry under bond. *See Certain Beverage Dispensing Sys. & Components Thereof*, Comm'n Opinion, Inv. No. 337-TA-1130 at 26 (Mar. 26, 2020) (citing 19 U.S.C. § 1337(j)(3)). The amount of bond is determined by the Commission and must be enough to protect the complainant from any injury. *See id.* "The Commission typically sets the bond based on the price differential between the imported infringing product and the domestic industry article or based on a reasonable royalty. However, where the available pricing or royalty information is inadequate, the bond may be set at one hundred (100) percent of the entered value of the infringing product." *Certain Loom Kits for Creating Linked Articles*, Inv. No. 337-TA-923, Comm'n Op., 2015 WL 5000874, *11 (citations omitted).

As Complainant, Align bears the burden of establishing the need for a bond, including the amount of bond. *See, e.g.*, *Certain L-Tryptophan, L-Tryptophan Products, and their Methods of Production*, Inv. No. 337-TA-1005, Comm'n Op. at 53 (Jan. 11, 2018) ("*L-Trypophan*") (setting zero bond where a complainant failed to show why a 100% bond was warranted, or to properly explain why price comparison or reasonable royalty was impractical); *Certain Rubber Antidegradants, Components Thereof & Prods. Containing Same*, USITC Pub. No. 3975, Inv. No. 337-TA-533, Comm'n Opinion at 40 (April 2008); *Certain Coenzyme Q10 Prods. and Methods of Making Same*, Inv. No. 337-TA-790, Initial and Recommended Determination (Sept. 27, 2012) (recommending Commission not impose a bond because complainant failed in its burden to demonstrate the appropriate bond amount).

Align urged that the Commission impose a 100% bond during the Presidential Review Period. (CBr. at 124-25).). Align contended that it competes directly with 3Shape in the same market and with the same products. (*Id*. at 124 (citing Tr. (Bakewell) at 740:25-741:5).). However, Align argued that "a price comparison is not a practical approach" to determine a bond amount. (*Id*. at 125 (citing Tr. (Bakewell) at 741:6-743:11).). Align discouraged a price comparison because the Parties "have different business models and selling strategies," and "sell multiple versions of their respective products for varying ranges of prices." (CBr. at 125.). Align also argued that the record evidence does not permit a reasonable royalty analysis. (*Id*. (citing Tr. (Bakewell) at 743:12-744:7).). Align argued that, because "a bond rate cannot be readily calculated," and it will be harmed by the continued importation of 3Shape's infringing products, a 100% bond rate is appropriate. (*Id.*).

3Shape disputed that a price comparison is impractical and argued instead that such a comparison of 3Shape's and Align's products is possible. (RRBr. at 93.). To that end, 3Shape identified Patterson Dental as a U.S. reseller of both 3Shape and Align scanners. (*Id*. (citing RX-2330); *see also* CX-2071C.). 3Shape argued that Patterson Dental had price lists for both 3Shape and Align products. (RRBr. at 93 (citing RX-2420C (Richard Lake Dep. Tr.) at 45:16-

25).).[128] 3Shape argued that a price differential analysis would not be impacted by the fact that Align and 3Shape sell multiple versions of their products. (RRBr. at 93 (citing *Certain Robotic Vacuum Cleaning Devices and Components Thereof Such as Spare Parts*, Inv. No. 337-TA-1057, Comm'n Op. at 70-71 (Feb. 1, 2019) (holding a price differential analysis may be conducted where product lines are not identical). 3Shape did not perform its own price differential analysis. Additionally, 3Shape did not provide a product-by-product comparison for which it argued conceptually. As a result, it was not possible to determine which 3Shape models were comparable in price to Align's models. That analysis was missing.

3Shape also argued that Align declined to evaluate reasonable royalty evidence found in a [redacted], in favor of an assertion that a 100% bond was appropriate. 3Shape cited an [redacted] as containing evidence relevant to a reasonable royalty analysis, without advancing its own reasonable royalty proposal. (RRBr. at 93 (citing (CX-1752C).).[129] Align also did not explain with any clarity of detail why a sole royalty rate was applicable here.

3Shape did not argue for a specific royalty rate. (RRBr. at 93.). 3Shape argued only that Align did not demonstrate why the referenced agreement was not considered in a reasonable

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[128] At the time of his deposition on November 20, 2019, on behalf of Patterson Dental, held pursuant to Commission Rule 210.28, Mr. Richard Lake was the Senior Category Manager at Patterson Dental Holdings, Inc. (RX-2420C at 6:20-9:22.). As Senior Category Manager, he was responsible for overseeing the marketing efforts at Patterson Dental in connection with 3Shape products and was familiar with Patterson Dental's recordkeeping practices. (*Id*.).

[129] The [redacted] (*See* CX-1752.).

royalty analysis. (*Id.*). Accordingly, 3Shape argued that Align did not meet its evidentiary burden, and that no bond should be imposed. (*Id.* at 92-94.).

Here, Align has not satisfied its burden of establishing an amount of a bond that should enter. Align's position rests on limited conclusory testimony from its expert about the obstacles to a price comparison. (*See* Tr. (Bakewell) at 740:25-741:5.). Mr. Bakewell's testimony is largely unpersuasive, and on the issue of differing product models, unsupported by precedent. *See, e.g., Certain Dental Ceramics, Products Thereof and Methods of Making the Same*, Inv. No. 337-TA-1050, Initial Determination at 107-110 (Aug. 28, 2018) (differences in distribution models did not prevent experts from conducting price comparisons based on retail prices). Furthermore, evidence indicates that at least one reseller sells both iTero and Trios scanners to end users. Align did not adequately establish why a price differential analysis could not be performed. (*See* Tr. (Bakewell) at 768:22-769:4; RX-2330; CX-2071C; RX-2420C (Lake Dep.) at 45:16-25).).

Similarly, Align and its expert disregarded evidence related to a reasonable royalty estimation without offering meaningful discussion or legal authority in support. Mr. Bakewell's unsupported assertion that the [redacted] was not "a good benchmark for a royalty" is not compelling. (Tr. (Bakewell) at 743:12-744:7)). Ultimately, the weight of the evidence supports a finding that Align declined to rigorously pursue a price differential or reasonable royalty analysis. Furthermore, Align has not demonstrated that it faces sufficient harm from the continued sales of 3Shape scanners to warrant a bond of 100%.

Thus, Align has not satisfied its burden of proof that a bond is justified. *See L-Tryptophan*, Comm'n Op. at 5. Based upon the explanation of the evidence discussed above, this Initial Determination recommends that a bond should not issue during the Presidential Review Period.

XIV. WAIVER OR WITHDRAWAL OF 3SHAPES' DEFENSES

3Shape did not raise in its Pre-Hearing Brief or offer any evidence during the Hearing to support its following Affirmative Defenses: (i) Fourth Affirmative Defense of Disclaimer and Prosecution History Estoppel (except where noted with respect to the '538 patent); (ii) Seventh Affirmative Defense of Waiver, Laches, Equitable Estoppel, Unclean Hands and/or Acquiescence; and (iii) Eighth Affirmative Defense of License and/or Exhaustion. (Resp. at 25-26.).

Consequently, it is a finding of this decision that 3Shape has withdrawn, waived and/or abandoned its Fourth, Seventh, and Eighth Affirmative Defenses consistent with Ground Rules 7.2 and 10.1. *Kinik Co. v. Int'l Trade Comm'n*, 362 F.3d 1359, 1367 (Fed. Cir. 2004).

XV. CONCLUSIONS OF FACT OR LAW: THIS INITIAL DETERMINATION FINDS A SECTION 337 VIOLATION BASED UPON INFRINGEMENT OF U.S. PATENT NO. 7,188,751

1. Jurisdiction and standing requirements are satisfied;
2. Claims 1 and 18 of U.S. Patent No. 7,077,647 are valid and satisfied by the 647 Accused Products;
3. Claims 2 and 20 of U.S. Patent No. 7,156,661 are valid and satisfied by the 661 Accused Products;
4. Claims 1 and 2 of U.S. Patent No. 8,102,538 are valid but not satisfied by the 538 Accused Products;
5. Claims 2, 28, and 29 of U.S. Patent No. 9,299,192 are invalid and satisfied by the 192 Accused Products;
6. Align's domestic activities with respect to its DI Products are found to satisfy the economic prong of the domestic industry requirement under 19 U.S.C. § 337(a)(3)(A) and (B);

7. At least one of Align's DI Products practices one or more claims of U.S. Patent Nos. 7,077,647; 7,156,661; 8,102,538; and 9,299,192; and

8. 3Shape has violated Section 337 of the Tariff Act of 1930, as amended, by importing into the United States, selling for importation, or selling within the United States after importation certain dental and orthodontic scanners and software by infringing claims 1 and 18 of U.S. Patent No. 7,077,647; claims 2 and 20 of U.S. Patent No. 7,156,661; and claims 2, 28, and 29 of U.S. Patent No. 9,299,192.

9. A Limited Exclusion Order and Cease and Desist Orders, with repair and warranty exceptions, are recommended based upon the evidence and findings of infringement.

10. A Bond is not recommended because of Align's failure to meet its burden of proof.

The lack of discussion of any matter raised by the Parties, or any portion of the record, does not indicate that it has not been considered. Rather, any such matter(s) or portion(s) of the record has/have been determined to be irrelevant, immaterial or meritless. Arguments made on briefs, which were otherwise unsupported by record evidence or legal precedent, have been accorded no weight.

XVI. CONCLUSION AND ORDER

This Initial Determination on Violation of Section 337 of the Tariff Act of 1930 is certified to the Commission. All orders and documents, filed with the Secretary, including the exhibit lists enumerating the exhibits received into evidence in this Investigation, that are part of the record, as defined in 19 C.F.R. § 210.38(a), are not certified, since they are already in the Commission's possession in accordance with Commission Rules. *See* 19 C.F.R. § 210.38(a). In accordance with 19 C.F.R. § 210.39(c), all material found to be confidential under 19 C.F.R. § 210.5 is to be given *in camera* treatment.

After the Parties have provided proposed redactions of confidential business information ("CBI") that have been evaluated and accepted, the Secretary shall serve a public version of this

ID upon all parties of record. The Secretary shall serve a confidential version upon counsel who are signatories to the Protective Order (Order No. 1) issued in this Investigation.

Pursuant to 19 C.F.R. § 210.42(h), this Initial Determination shall become the determination of the Commission unless a party files a petition for review pursuant to 19 C.F.R. § 210.43(a) or the Commission, pursuant to 19 C.F.R. § 210.44, orders on its own motion a review of the Initial Determination or certain issues therein.

Within fourteen (14) days of the date of this document, the Parties shall submit to the Office of Administrative Law Judges a joint statement through McNamara337@usitc.gov whether or not they seek to have any portion of this document deleted from the public version. The Parties' submission must include a copy of this ID with yellow highlighting, with or without red brackets, indicating any portion asserted to contain CBI to be deleted from the public version. The Parties' submission shall also include an index identifying the pages of this document where proposed redactions are located. If the Parties disagree, they should explain why, again by identifying the pages of the disagreement. The Parties' submission concerning the public version of this document need not be filed with the Commission Secretary.

SO ORDERED.

MaryJoan McNamara
Administrative Law Judge

CERTAIN DENTAL AND ORTHODONTIC SCANNERS AND SOFTWARE **Inv. No. 337-TA-1144**

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **INITIAL DETERMINATION** has been served upon the following parties as indicated, on **June 1, 2020**.

Lisa R. Barton, Secretary
U.S. International Trade Commission
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UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of **CERTAIN DENTAL AND ORTHODONTIC SCANNERS AND SOFTWARE**	**Inv. No. 337-TA-1144**

ORDER NO. 36: **CONSTRUING CERTAIN TERMS OF THE ASSERTED CLAIMS OF THE PATENTS AT ISSUE (*MARKMAN* CLAIM CONSTRUCTION)**

(October 1, 2019)

Table of Contents

Attachments

Appendix A	*Markman* Chart: Court's Adopted Constructions of Agreed-Upon and Disputed Claims Terms

Table of Abbreviations

Complainant Align Technology, Inc.	Align
Respondents 3Shape A/S, 3Shape Trios A/S, and 3Shape Inc.	3Shape
Parties	Align and 3Shape
COMBr.	Align's Opening Claim Construction Brief (in abbreviation, "M" stands for *Markman*)
CRMBr.	Align's Reply Claim Construction Brief (in abbreviation, "M" stands for *Markman*)
ROMBr.	3Shape's Opening Claim Construction Brief (in abbreviation, "M" stands for *Markman*)
RRMBr.	3Shape's Rebuttal Claim Construction Brief (in abbreviation, "M" stands for *Markman*)
Joint CC Chart	Joint Post-Hearing Final Claim Construction Chart (Doc. ID No. 685923 (Aug. 21, 2019))
CPBr.	Align's Pre-Hearing Brief

I. RELEVANT BACKGROUND AND SUMMARY OF CLAIM CONSTRUCTION PROCEEDINGS

The Complaint in this Investigation was filed on December 10, 2018. (*See* Doc. ID No. 663673 (Dec. 10, 2018).). The Complaint was filed by Align Technology, Inc. ("Align" or "Complainant") and names as Respondents 3Shape A/S ("3Shape A/S"), 3Shape, Inc. ("3Shape US") and 3Shape Trios A/S ("3Shape Trios," collectively, "3Shape" or "Respondents," and with Align, "the Parties.").

On June 19, 2019, consistent with Order No. 4 (Doc. ID No. 671192 (Mar. 25, 2019)), the Parties filed a Revised Joint Claim Construction Chart, (Doc. ID No. 678972 (June 19, 2019)). On the same day, 3Shape filed its Opening Claim Construction Brief ("ROMBr."). (Doc. ID No. 678980 (June 19, 2019).). One day later, on June 20, 2019, Align filed its Opening Claim Construction Brief ("COMBr."). (Doc. ID No. 679028 (June 20, 2019).).
On June 28, 2019, Align filed a Reply Claim Construction Brief ("CRMBr."). (Doc. ID No. 679765 (June 28, 2019).). The same day 3Shape filed a Rebuttal Claim Construction Brief ("RRMBr."). (Doc. ID No. 679756 (June 28, 2019).).

Order No. 21 issued on July 10, 2019, which scheduled the *Markman* hearing for August 8, 2019. (Doc. ID No. 680811 (July 10, 2019).). On August 5, 2019, the Parties filed a Joint Claim Construction Chart "identifying the construction of those terms on which the parties agree and are no longer in dispute," "the terms in dispute that will be argued during the *Markman* hearing," and "each party's proposed construction of the disputed terms." (Doc. ID No. 684285 (Aug 5, 2019).).

A *Markman* hearing took place on August 8, 2019. (*Markman* Hearing Tr. at 1 (Doc. ID No. 684877 (Aug. 9, 2019).). Shortly thereafter, the Parties filed a Joint Post-Hearing Final Claim Construction Chart ("Joint CC Chart"). (Doc. ID No. 685923 (Aug. 21, 2019).). The

Joint CC Chart identifies the claim terms for which the Parties agree on a meaning and the claim terms for which a meaning remains in dispute.[1] (*Id.*).

In their Joint CC Chart, the Parties identified twelve (12) disputed terms, and eight (8) terms upon which they agree. (*See id.*). Each of those patents and claim terms is addressed in Appendix A to this Order. The evidentiary hearing ("Hearing") in this Investigation is scheduled to occur on October 24-25, 2019 and October 28-30, 2019. (Order No. 4 at 1.).

II. PATENTS AND CLAIMS AT ISSUE

Align's Complaint in this Investigation alleges 3Shape's infringement of the following five (5) patents: (1) U.S. Patent No. 9,299,192 ("the '192 patent"); (2) U.S. Patent No. 7,077,647 ("the '647 patent"); (3) U.S. Patent No. 7,156,661 ("the '661 patent"); (4) U.S. Patent No. 9,848,958 ("the '958 patent"); and (5) U.S. Patent No. 8,102,538 ("the '538 patent"). *See, e.g.*, 84 Fed. Reg. 7933 (Mar. 5, 2019). Align initially alleged 3Shape's infringement of approximately 88 claims: claims 1–32 of the '192 patent; claims 1–13 and 18–21 of the '647 patent; claims 1–9 and 19–26 of the '661 patent; claims 1–20 of the '958 patent; and claims 1 and 2 of the '538 patent. (*See id.*).

On July 2, 2019, Order No. 17 issued as an Initial Determination which granted Align's "unopposed motion for partial termination of this Investigation ... with respect to allegations of infringement of the asserted claims of U.S. Patent No. 9,848,958[.]" Consequently, the four (4) patents remaining in this Investigation ("the Asserted Patents") are: (1) the '192 patent; (2)

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[1] Following the *Markman* hearing, and consistent with the Parties' discussions during the *Markman* hearing, the Parties met and conferred on two terms to see if they could reach a compromise construction with respect to two (2) claim terms: (1) "individually matching each/match each of the dental objects" in the '647 patent; and (2) "region(s)" in the '661 patent. However, the Parties reported that they were unable to reach an agreement on a compromise construction for these 2 claim terms. (Joint CC Chart at 1.).

the '647 patent; (3) the '661 patent; and (4) the '538 patent. It appears that, across these four (4) patents, as of July 2019, approximately 68 asserted patent claims remain in this Investigation.

In its Pre-Hearing Brief ("CPBr."), Align has whittled down its infringement case. (Doc. ID No. 686919 (Aug. 30, 2019) at 27-116.).

However, ***Align's case is still too unwieldy for the upcoming five-day Hearing.***[2] As reflected in below in Table No. 1, Align has alleged that 3Shape has infringed 19 claims ("the Asserted Claims"): (1) 8 claims of the '192 patent; (2) 5 claims of the '647 patent; (3) 4 claims of the '661 patent; and (4) 2 claims of the '538 patent. (*Id.*). It appears that, as of the filing of Pre-Hearing Briefs, each of the disputed claims identified in the Joint CC Chart remains in dispute. (*Id.* at 27 (addressing '674 patent: "The terms and proposed constructions at issue, as well as the agreed-upon terms, are listed in the parties' August 21, 2019 Joint Post-Hearing Claim Construction Chart."), 58 (same for '661 patent), 82 (same for '192 patent), 104 (same for '538 patent).).

Table No. 1: Presently Asserted Patents and Asserted Claims

Asserted Patents	**Asserted Claims**
'192 patent	1–5, 22, 28-29 (8 claims)
'647 patent	1-2, 4, 18, 20 (5 claims)
'661 patent	1-2, 19-20 (4 claims)

[2] On September 3, 2019, Align filed a "contingent" motion for more Hearing time, to which 3Shape objects. (*See* Motion Docket No. 1144-038 (Sept. 3, 2019), and Doc. ID No. 687187 (Sept. 4, 2019), respectively. An Order on Align's Motion has not yet issued. However, there are too many patents and claims even if an additional day is added. Align is urged to winnow its case by the end of this week.

'538 patent	1–2 (2 claims)

(*Id.*).

The '192 patent, which issued on March 29, 2016, is entitled "Methods and Systems for Creating and Interacting with Three Dimensional Virtual Models." (JX-0004 ('192 patent) at Cover.). The '192 patent pertains to "[s]ystems and methods are provided for modifying a virtual model of a physical structure with additional 3D data obtained from the physical structure to provide a modified virtual model." (*Id.*). Align is the assignee named on the '192 patent. (*Id.*).

The related '661 and '647 patents are entitled "Systems and Methods for Treatment Analysis by Teeth Matching." (JX-0001 ('647 patent) at Cover; JX-0002 ('661 patent) at Cover.). The '661 patent is a continuation-in-part of the '647 patent and shares most of the '647 patent's specification. (*Id.*). Align is the assignee named on the '661 and '647 patents. (*Id.*).

The '647 patent issued on July 18, 2006, and pertains to "[s]ystems and methods … for matching computer models of two sets of teeth includes calculating a difference for two sets of teeth shapes; finding the position of one set of teeth with respect to the other set of teeth; calculating a positional difference of the corresponding teeth; and finding a corrective path to bring one set of teeth to the other set of teeth." (JX-0001 ('647 patent) at Cover.).

The '661 patent issued on January 2, 2007, and pertains to "[s]ystems and methods … for matching computer models of two sets of teeth each having corresponding matching regions includes calculating a difference for two sets of teeth shapes; finding the position of one set of teeth with respect to the other set of teeth; calculating a positional difference of the corresponding teeth based on the matching regions; and finding a corrective path to bring one set of teeth to the other set of teeth." (JX-0002 ('661 patent) at Cover.).

Finally, the '538 patent issued on January 24, 2012, and is entitled "Method and Apparatus for Colour Imaging a Three-Dimensional Structure." (JX-0003 ('538 patent) at Cover.). The '538 patent pertains to:

> a device for determining the surface topology and associated color of a structure, such as a teeth segment, including a scanner for providing depth data for points along a two-dimensional array substantially orthogonal to the depth direction, and an image acquisition means for providing color data for each of the points of the array, while the spatial disposition of the device with respect to the structure is maintained substantially unchanged. A processor combines the color data and depth data for each point in the array, thereby providing a three-dimensional color virtual model of the surface of the structure. A corresponding method for determining the surface topology and associated color of a structure is also provided.

(*Id.*).

Align is not the named assignee on the face of the '538 patent; instead the named assigned is Cadent Ltd ("Cadent"). (*Id.*). However, in its Pre-Hearing Brief, Align asserted that "[o]n October 24, 2014, Cadent assigned the '538 patent to Align." Align filed a copy of the assignment of the '538 patent with its Complaint. (CPBr. at 6; Compl. Ex. 10.).

III. TERMS CONSTRUED IN THIS ORDER

A. Claim Construction and Current Ground Rules

Claim terms are construed in this Order solely for the purposes of this Section 337 Investigation. Only claim terms in controversy need to be construed, and then only to the extent necessary to resolve the controversy. *Vanderlande Indus. Nederland BV v. Int'l Trade Comm.*, 366 F.3d 1311, 1323 (Fed. Cir. 2004); *Vivid Tech., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

As this Investigation proceeds, the Parties will be limited to the constructions adopted in this Order. This applies to the Hearing, during which no new arguments will be permitted. Ground Rule 1.14 states that "[t]he parties will be bound by their claim construction positions set forth on the date they are required to submit a joint list showing each party's final proposed construction of the disputed claim terms and will not be permitted to alter these absent a timely showing of good cause." Modified or new constructions which the Parties attempt to set forth will not be considered, and will be considered to have been waived.

Similarly, it will not be appropriate for any party to seek additional claim construction during the Hearing or merely to state that a claim term implicated in an expert report or expert testimony has either a "plain or ordinary" meaning, or that a claim term is "indefinite." (*See* Order No. 2 at 8; G.R. 1.14.).

B. *Markman* Chart in Appendix A

The *Markman* Chart attached as Appendix A contains terms for which the Parties have agreed to a construction *and* terms by patent for which the Parties dispute the proper construction. The Parties' agreed-upon claim constructions have been adopted without a rationale or explanation. (*See* App. A, *Markman* Chart.).

For disputed terms, there are five (5) columns in the chart: (1) Claim Term to be Construed; (2) Align's Proposed Construction; (3) 3Shape's Proposed Construction; (4) Adopted Construction; and (5) Support for Construction. (*See id.*).

IV. APPLICABLE LAW[3]

Claim construction begins with the language of the claims themselves. Claims should be given their ordinary and customary meaning as understood by a person of ordinary skill in the art, viewing the claim terms in the context of the entire patent. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005). In some cases, the plain and ordinary meaning of claim language is readily apparent and claim construction will involve little more than "the application

[3] The constructions in the *Markman* Chart of Appendix A generally follow and apply the law as described above. To the extent possible, the case law that applies to a construction is either identified explicitly, or implicitly in adopting a party's argument or construction.

of the widely-accepted meaning of commonly understood words." *Id.* at 1314. In other cases, claim terms have a specialized meaning and it is necessary to determine what a person of ordinary skill in the art would have understood disputed claim language to mean by analyzing "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, as well as the meaning of technical terms, and the state of the art." *Id.* (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004)).

The claims themselves provide substantial guidance with regard to the meaning of disputed claim language. *Phillips*, 415 F.3d at 1314. "[T]he context in which a term is used in the asserted claim can be highly instructive." *Id.* Similarly, other claims of the patent at issue, regardless of whether they have been asserted against respondents, may show the scope and meaning of disputed claim language. *Id.*

In cases in which the meaning of a disputed claim term in the context of the patent's claims was uncertain, the specification was used as the "single best guide to the meaning of a disputed term." *Id.* at 1321. Moreover, "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Id.* at 1316. As a general rule, however, the particular examples or embodiments discussed in the specification are not to be read into the claims as limitations. *Id.* at 1323.

The prosecution history may also explain the meaning of claim language, although "it often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Id.* at 1317. The prosecution history consists of the complete record of the patent examination proceedings before the U.S. Patent and Trademark Office, including cited prior art.

Id. The prosecution history may reveal "how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.*

If the intrinsic evidence is insufficient to establish the clear meaning of a claim, a court may resort to an examination of the extrinsic evidence. *Zodiac Pool Care, Inc. v. Hoffinger Indus., Inc.*, 206 F.3d 1408, 1414 (Fed. Cir. 2000). Extrinsic evidence may shed light on the relevant art, and "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Phillips*, 415 F.3d at 1317. In evaluating expert testimony, a court should disregard any expert testimony that is conclusory or "clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent." (*Id.* at 1318.). Moreover, expert testimony is only of assistance if, with respect to the disputed claim language, it identifies what the accepted meaning in the field would be to one skilled in the art. *Symantec Corp. v. Comput. Assocs. Int'l, Inc.*, 522 F.3d 1279, 1289 n.3., 1290-91 (Fed. Cir. 2008). Testimony that recites how each expert would construe the term should be accorded little or no weight. *Id.* Extrinsic evidence is inherently "less reliable" than intrinsic evidence, and "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Phillips*, 415 F.3d at 1318-19.

Extrinsic evidence is a last resort: "[i]n those cases where the public record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996).

V. PERSON OF ORDINARY SKILL IN THE ART

A hypothetical person of ordinary skill in the art is a person of ordinary skill and "ordinary creativity." *KSB Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 420 (2007). "Factors that may be considered in determining [the] level of ordinary skill in the art include: (1) the educational level of the inventor[s]; (2) type of problems encountered in the art; (3) prior art solutions to the problems; (4) rapidity with which inventions are made; (5) sophistication of the technology; and (6) educational level of active workers in the field." *Envtl. Designs Ltd. v. Union Oil Co. of California*, 713 F.2d 693, 696-97 (Fed. Cir.) (citations omitted). "These factors are not exhaustive but merely a guide to determining the level of ordinary skill in the art." *Daiichi Sankyo Co. v. Apotex, Inc.*, 501 F3d 1254, 1256 (Fed. Cir. 2007).). The hypothetical person of skill is also separately presumed to have knowledge of all the relevant prior art in the field. *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 693, 697 (Fed. Cir. 1983).

As set forth below in Table No. 2, the Parties disagree with respect to the qualifications of a person of ordinary skill in the art for the Asserted Patents. The Parties have not clearly articulated the reasons for their disagreement. (*See, generally*, COMBr.; CRMBr.; ROMBr.; RRMBr.).

Table No. 2: Competing Person of Ordinary Skill in the Art ("POSA") Definitions

Asserted Patents	Align's Definition	3Shape's Definition
'192 / '647 / '661 patents	"would have had (1) at least a bachelor's degree in electrical engineering, computer science, applied mathematics, or an equivalent field, as well as at least one or two years of industry experience in three-dimensional modeling, (2) at least five years of comparable industry experience in three-dimensional modeling, or (3) an equivalent combination of academic study and work experience"	"would have at least (1) a bachelor's degree in electrical and/or computer engineering, or computer science (or equivalent course work) with two to three years of work experience in computer modelling of physical structures or (2) a master's degree in electrical and/or computer engineering, or computer science (or equivalent course work) with a focus in computer modelling of physical structures"
'538 patent	"would have had (1) at least a bachelor's degree in electrical engineering, computer science,	"would have (1) a bachelor's degree in electrical engineering, optical engineering, or physics (or equivalent

	physics or an equivalent field, as well as at least one or two years of industry experience in optical scanning, (2) at least five years of comparable industry experience in optical scanning, or (3) an equivalent combination of academic study and work experience"	course work) and two to three years of work experience in the areas of optical imaging systems and image processing, or (2) a master's degree in electrical engineering or physics (or equivalent course work) with a focus in the area of optical imaging systems and image processing"

(COMBr. at 7-8; ROMBr at 8-9, 26, 38, 54.).

This Order does not resolve the definition of a person of ordinary skill in the art because it is not germane to the claim construction that the Parties have requested. In arguing for their proposed constructions of disputed terms, the Parties have appropriately focused on other matters, such as the intrinsic evidence. None of the Parties has indicated in any of their filed documents that the person of ordinary skill in the art definition is necessary or dispositive for construction of the disputed claim terms.

To the extent this issue could affect the outcome of the Hearing, the Parties should attempt to agree on a person of ordinary skill in the art definition for each of the Asserted Patents. If the Parties instead reserve their person of ordinary skill in the art positions for the Hearing, at the Hearing they must address each of the factors set forth in *Envtl. Designs, supra.* The Parties will be expected to state during the Hearing: (1) why their POSA definition should be applied and they will be required to cite to the factors described above; and (2) whether their definition of POSA would eliminate any of the experts in this Investigation.

VI. FUTURE PROCEEDINGS

A. Supplementation in Response to This Order

The Parties may not file supplemental expert reports in response to this Order. No additional discovery will be permitted because of this Order. No re-argument of constructions announced in this Order may occur.

As the Investigation proceeds, the Parties will be expected to notify Chambers, through a filing on EDIS, of any issues that have become moot or have been eliminated for any reason. The Parties' substantive issue outlines (Ground Rule 7.3) must identify any issues, claims, defenses, prior art, theories, or any other content that was originally asserted or argued that have been dropped or become moot. Similarly, the Parties should identify also all issues or contentions and patents that have been dropped or become moot for any reason.

The Parties should redact from expert reports, and from any other documents upon which they intend to rely, any issues, claims, defenses, prior art, theories, or any other content that has been rendered moot or disallowed as a result of this or other Orders or because of the termination of patent claims or allegations from this Investigation. The Parties must file on EDIS any expert reports or other documents upon which they intend to rely that have been redacted for the reasons stated above, and additionally provide two (2) copies to Chambers.

B. Streamlining the Investigation

To the extent that this *Markman* Order will enable the Parties to streamline the Investigation, the Parties are encouraged to drop issues now in advance of the Hearing. Moreover, the Parties are encouraged to resolve promptly each issue in this Investigation for which there is no reasonable dispute or little, or weak, evidentiary support.

C. Settlement

The Parties should engage in serious settlement discussions.

VII. CONCLUSION

The constructions of claim terms contained in Appendix A to this Order are incorporated by reference as part of this Order.

SO ORDERED.

MaryJoan McNamara
Administrative Law Judge

APPENDIX A

APPENDIX A to ORDER NO. 36
Markman Order
Inv. No. 337-TA-1144

Chart 1. Constructions of Disputed Claim Terms with Adoption of Agreed-Upon Claim Terms

1. U.S. PATENT NO. 9,299,192 [1]

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
"second virtual model"	Plain and ordinary meaning, which is "second 3D virtual representation"	"A singular and collected three-dimensional virtual depiction of a real object in a computer environment separate from the first virtual model."	"second 3D virtual representation"	Align asserted that the adopted construction of "second virtual model" should remain consistent with the agreed-upon construction of "virtual model," which is "3D virtual representation." (COMBr. at 33-34.). Indeed, Align's proposed construction is "second 3D virtual representation." (*Id.*). 3Shape, on the other hand, rejected Align's proposed construction for lacking "distinctions between the first virtual model and second virtual model." (ROMBr. at 38-39.). Those purported "distinctions" are that: (1) the second virtual model is "separate" from the first virtual model; (2) the "second virtual model is not simply a manipulated version of the first virtual model"; and (3) "the claims, specification, and prosecution history consistently describe the 'second virtual model' as . . . [a] singular and collected 3D virtual depiction of a real object." (*Id.*). As explained below, each of 3Shape's purported

[1] All references to briefs in this Appendix A are consistent with the abbreviated terms that are identified in the Table of Abbreviations in Order No. 36.

Claim Terms to Be Construed	**Align's Proposed Construction**	**3Shape's Proposed Construction**	**Adopted Construction**	**Support for Construction**
				distinctions lacks merit, and Align's construction is adopted. As Align noted, language found in the asserted claims accounts for 3Shape's first two (2) purported distinctions. (CRMBr. at 21-22.). Each independent claim refers to "the first virtual model [] generated from first 3D scan data" and "the second virtual model [] generated from second 3D scan data," thereby distinguishing the first virtual model and the second virtual model in terms of being distinct models generated from distinct scans. (JXM-0004 ('192 patent), cls. 1, 28, 30.). "Where a claim lists elements separately, the clear implication of the claim language is that those elements are distinct components of the patent invention." *Becton, Dickinson & Co. v. Tyco Healthcare Group, LP*, 616 F.3d 1249, 1254 (Fed. Cir. 2010) (internal quotation marks and citations omitted). In other words, the claim language makes clear that the second virtual model is not simply a manipulated version of the first virtual model. Each independent claim of the '192 patent unambiguously requires that the first and second virtual models are generated from different data scans.

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
				With respect to 3Shape's third and final distinction, the intrinsic evidence simply does not characterize the "second virtual model" as "singular and collected." The words "singular" and "collected" do not appear in the claims or specification of the '192 patent. (*See, generally*, JXM-0004 ('192 patent).). The words "singular" and "collected" do not appear verbatim, in any meaningful way, in the prosecution history of the '192 patent. (*See, generally*, JXM-0009 ('192 patent prosecution history).). Consistent with this dearth of intrinsic evidence in favor of 3Shape's "singular and collected" distinction, it is also unclear exactly what "singular and collected," if included in the adopted construction, would actually mean in the context of the '192 patent. 3Shape is correct that, in response to a rejection during patent prosecution, the patentee amended claims during prosecution of the '192 patent to add the "second virtual model" limitation. (ROMBr. at 40-42; JXM-0009 ('192 patent prosecution history) at 317.). The patentee apparently did so to distinguish prior art that purportedly invalidated pending claims prior to their amendment. (JXM-0009 ('192 patent prosecution history) at 290.). The

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
				prior art purportedly taught modification of an existing virtual model with "additional 3D data obtained from the physical structure," without specifying the source of the "additional 3D data." (*Id.*). To overcome the prior art, the patentee amended the pending claims to specify that a second 3D scan was the source of the additional 3D data. (*Id.* at 317.). That amendment distinguished the first virtual model and the second virtual model in terms of being distinct models generated from distinct scans. (*Id.* at 308-15.). In other words, the amendment already provided narrowing claim limitations of the sort that 3Shape now seeks to import via a construction of "second virtual model." This claim construction does not adopt a construction of "second virtual model" that would introduce such redundancy. *MEMS Tech. Berhad v. Int'l Trade Comm'n*, 447 F. App'x 142, 151 (Fed. Cir. 2011) (constructions which introduce redundancy are "disfavored"). Likewise, nothing in the prosecution history of the '192 patent suggests that Align's construction of "second virtual model" would amount to an inappropriate recapture of

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
				previously disavowed claim scope. (ROMBr. at 42.). To the contrary, Align's seemingly broad construction of "second virtual model" is constrained by surrounding claim language added by the aforementioned amendment to pending claims made during prosecution. 3Shape's assertion to the contrary is plainly inconsistent with the intrinsic record. On the other hand, Align's construction adopted herein ("second virtual model" means "second 3D virtual representation") is consistent with the agreed-upon construction that a "virtual model" is a "3D virtual representation." There is copious binding authority on the importance of construing claim terms found in a given patent in a way that preserves internal consistency. *See, e.g.*, *Callicrate v. Wadsworth Mfg., Inc.*, 427 F.3d 1361, 1371 (Fed. Cir. 2005) ("interpret[] claim terms consistently throughout various claims of the same patent"); *Research Plastics, Inc. v. Fed. Packaging Corp.*, 421 F.3d 1290, 1295 (Fed. Cir. 2005) ("claim terms are presumed to be used consistently throughout the patent, such that the usage of a term in one claim can often illuminate the meaning of the same term in other claims."); *Phonometrics, Inc. v.*

Claim Terms to Be Construed	**Align's Proposed Construction**	**3Shape's Proposed Construction**	**Adopted Construction**	**Support for Construction**
				Northern Telecom Inc., 133 F.3d 1459, 1465 (Fed. Cir. 1998) ("[a] word or phrase used consistently throughout a claim should be interpreted consistently"). Moreover, the specification of the '192 patent supports the agreed-upon construction of "virtual model" and Align's construction of "second visual model." Specifically, the specification defines "virtual models" as "three-dimensional virtual representations." (JXM-0004 ('192 patent) at 1:30-36.). The specification also explains that "[t]he term '3D virtual model' is used herein synonymously with digital model, virtual model, 3D virtual model, 3D model, . . . 3D representation, and other such terms" (*Id.* at 3:26-38). This definitional guidance from the specification confirms the correctness of Align's proposed construction and supports its adoption.
"virtual model"	**Agreed:** Plain and ordinary meaning, which is "3D virtual representation"			n/a
"identifying at least a portion of the first virtual model that is desired to be modified"	**Agreed:** "identifying at least a portion on the first virtual model that is desired to be replaced"			n/a

2. U.S. PATENT NO. 7,156,661

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
"reference point"	No construction necessary If the ALJ believes construction is necessary, the proper construction is plain and ordinary meaning, which is "points used to determine the position of a computer model relative to another computer model"	"a point on a stable anatomical structure"	"a point used to determine the position of a computer model, or part thereof, relative to another computer model, or part thereof"	According to Align, this term required no construction because it was clear and had a plain meaning understood by those skilled in the art. (COMBr. at 13.). In the alternative, Align proposed a construction that identified the purported function of a "reference point" as set forth in the '661 patent: determining the position of a computer model relative to another computer model. (*Id.* at 14 (citing JXM-0002 ('661 patent) at 6:56-7:25).). In rebuttal, 3Shape asserted that Align's proposed construction misrepresented the function of a "reference point" and ignored specification disclosures included in the '661 patent (but omitted from the related '647 patent) that purportedly clarified that a "reference point" must be located "on a stable anatomical structure." (ROMBr. at 26-27.). A close examination of the '661 patent specification reveals that neither of 3Shape's arguments has merit. As explained below, "reference point" warrants a broad construction, and none of the additional specification material included in the '661 patent (but omitted from the related '647 patent) requires otherwise.

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
				As an initial matter, a construction of the term "reference point" is necessary because the Align and 3Shape dispute the term's meaning. *O2 Micro Intern. Ltd. v. Beyond Innovation Technology Co., Ltd.*, 521 F.3d 1351, 1360 (Fed. Cir. 2008). 3Shape concedes that the '661 patent teaches a two-step matching process. (ROMBr. at 36.). The first step involves matching individual teeth or individual regions across models. (*See, e.g.*, JXM-0002 ('661 patent) at 6:18-24, 9:14-20.). The second step involves "jaw matching." (*Id.* at 6:32-34, 9:21-23.). The second step "is performed to determine the position of the new jaw relative to the original coordinate system[.]" (*Id.* at 6:32-34.). To complete the second step, "the entire jaw needs an external reference to set the position. A fixed external reference such as rugae in the patient's mouth can be used. If a fixed external reference is not available, some teeth can be used for the reference as well." (*Id.* at 8:66-9:2.). For example, in the context of using certain teeth as an external reference, for "positioning of the new

Claim Terms to Be Construed	**Align's Proposed Construction**	**3Shape's Proposed Construction**	**Adopted Construction**	**Support for Construction**
				jaw in the original coordinate system," "the process generates various sample points on the reference teeth and corresponding points on the current teeth (344). Next, it calculates position transformation using the sample points (346)." (*Id.* at 7:36-39.). 3Shape appears to suggest that "reference point" in the '661 patent is used only in the context of "stable teeth" or "[s]table structures such as the palatal rugae." (ROMBr. at 27 ("The '661 patent further establishes that a 'reference point' relates to stable and anatomic structures"); JXM-0002 ('661 patent) at 11:2-3.). The problem with this argument is that the '661 patent discloses using "reference points" in the context of non-stable anatomic structures. For example, the '661 patent teaches a first step of tooth matching, including teeth that move or shift, whereby "[t]he process finds *points* on the original tooth crown and finds *corresponding points* on the current tooth." (JXM-0002 ('661 patent) at 7:10-15 (emphasis added).). This teaching is also found in the related '647 patent. (JXM-0001 ('647 patent) at 6:2-4.). Consequently, the specification of the '661 patent as a whole, including any additional material included in the '661 patent (but omitted from the

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
				related '647 patent) does not restrict the location of a "reference point" to "a stable anatomical structure." This interpretation is consistent with the language of claim 1 of the '661 patent, where "reference point" appears in the context of "using the matched regions as non-moving reference regions." (JXM-0002 ('661 patent) at 13:30.). Under 3Shape's unsupported construction of "reference point" as "a point on a stable anatomical structure," the phrase "using the matched regions as non-moving reference regions" would appear to be somewhat redundant. *See MEMS*, 447 F. App'x at 151 (constructions which introduce redundancy are "disfavored"). Next, 3Shape argues that "[w]hile the claims [of the '661 patent] teach using the matched regions to match the computer models as a whole, Align's proposed construction would effectively read out the explicit two-step matching process taught by the '661 patent claims." (ROMBr. at 29.). Here, 3Shape's argument has merit. As discussed above, "reference points" can play a role in both the first and second matching steps. However, Align's proposed construction ("points used to determine the position of a computer model relative to another computer model") could be interpreted to cover only instances in

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
				which "reference points" are used in the second matching step to match jaw models. A minor modification of Align's construction addresses 3Shape's valid concern in this regard, while preserving the breadth of "reference point" as disclosed in the '661 patent specification. Based on the above, "reference point" in the '661 patent is "a point used to determine the position of a computer model, or part thereof, relative to another computer model, or part thereof." This construction covers the use of a "reference point" to match individual teeth, for example, in a first matching step and the use of a "reference point" to match jaw models in a second matching step.
"region(s)"	No construction necessary If the ALJ believes construction is necessary, the proper construction is plain and ordinary meaning, which is "area"	"portion(s)"	area	According to Align, this term requires no construction because it is clear and had a plain meaning understood by those skilled in the art. (COMBr. at 15-16.). In the alternative, Align proposed a construction that "region(s)" be construed as "area." (*Id.* at 14 (citing JXM-0002 ('661 patent) at 2:41-50 (describing "nontooth areas").). In rebuttal, 3Shape asserted that its "construction establishes that matching the 'region(s)' cannot be the same limitation as matching the computer

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
				models as a whole." (ROMBr. at 32.). According to 3Shape, Align's proposed construction "would effectively read out the expressly recited two-step matching process required by the '661 patent claims." (*Id.*). 3Shape argued that Align abandoned a one-step matching process during prosecution, where, to distinguish a prior art reference, the patentee "amended claim 1 [of the '661 patent] to include the two-step matching process of first using reference points to match corresponding regions, and then using matched regions to match the computer models as a whole." (*Id.* at 33.). As an initial matter, a construction of the term "region(s)" is necessary because Align and 3Shape dispute the term's meaning. *O2 Micro Intern.*, 521 F.3d at 1360. 3Shape's proposed construction, "portion(s)," is problematic for at least two reasons. First, the term "portion" is already found in the claims of the '661 patent alongside "region(s)," suggesting that the patentee sought to draw a distinction between "portion" and "region(s)." *See Takeda Pharm. Co. Ltd. v. Zydus Pharms. USA, Inc.*, 743 F.3d 1359, 1365 (Fed. Cir. 2014) (refusing to

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
				limit claim when inventors knew to include those limitations "when they so desired"). Second, 3Shape need not construe "region(s)" to narrow its scope to "portion(s)." Claim 1 already requires that the claimed "regions" comprise only a "portion of the jaw other than the teeth" and not the entire jaw. (JXM-0002 ('661 patent), cl. 1.). The parties agreed that "portion of the jaw other than the teeth" means "including at least a non-tooth portion of the jaw." (Joint Post-Hearing Final Claim Construction Chart ("Revised Joint CC Chart") (Doc. ID No. 685923 (Aug. 21, 2019)) at 4.). Thus, the express language of claim 1 prevents Align's broad construction of "region(s)" from collapsing the '661 patent's two-step matching process into only one step. In other words, adopting 3Shape's construction of "region(s)" would introduce redundancy. *See MEMS*, 447 F. App'x at 151 (constructions which introduce redundancy are "disfavored"). Based on the explanation provided above, 3Shape's argument is rejected that Align's construction of "area" "provides no clarity as to whether "region(s)" can be the entire computer model." (ROMBr. at 32.). A proper

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
				construction need not provide this clarity because the surrounding claim language already makes clear that the claimed "region(s)" cannot consist of entire jaw models. Align's construction of "region(s)," which does not introduce redundancy, is hereby adopted.
"matching/match … using the identified reference points"	No construction necessary If the ALJ believes construction is necessary, the proper construction is plain and ordinary meaning, which is "matching the region on the first and second computer models using the identified points to determine the position of a computer model relative to another computer model"	"positioning/position … using the identified points on the stable anatomical structures"	"using the identified reference points to determine the position of a region of the first computer model relative to the corresponding region of the second computer model"	According to Align, this term required no construction because it is clear and has a plain meaning understood by those skilled in the art. (COMBr. at 17-18.). In the alternative, Align proposed that "matching/match … using the identified reference points" be construed as "matching the region on the first and second computer models using the identified points to determine the position of a computer model relative to another computer model." (*Id.* at 19.). 3Shape disagreed. (ROMBr. at 35.). 3Shape asserted that Align's construction merely rearranged words found in the claim term and did so in a manner that left out key terms and created ambiguity around whether the construction "reads out the claimed two-step matching process of using the identified corresponding reference points to match corresponding regions – not the models as a whole." (*Id.* at 36.). According to 3Shape, "the '661 patent

Claim Terms to Be Construed	**Align's Proposed Construction**	**3Shape's Proposed Construction**	**Adopted Construction**	**Support for Construction**
				specification teaches that the corresponding regions are 'positioned' during the process of matching corresponding regions [and not entire models] using the identified reference points." (*Id.*). While 3Shape has a valid point, its substitution of "positioning/position" for "matching /match" is misplaced. 3Shape is correct that the specification appears to equate use of these terms in at least one snippet. (JXM-0002 ('661 patent) at 9:17-20 ("These points are then matched such that the models are positioned so they closely align in the regions around the points (i.e. the rugae region), by applying a transform T_{ref} to one of the models.").). It appears from the specification of the '661 patent that "positioning" and "matching" are related concepts. (*See, e.g., id.* at 6:32-34 ("a second matching operation is performed to determine the position of the new jaw relative to the original coordinate system").). However, other parts of the specification, and in particular Figures 4 and 5, indicate that "matching/match" is nevertheless distinct from "positioning/position." (*See id.* at 7:6-13 ("The process of FIG. 4 positions the current teeth with respect to original teeth using an approximate

Claim Terms to Be Construed	**Align's Proposed Construction**	**3Shape's Proposed Construction**	**Adopted Construction**	**Support for Construction**
				position. In one embodiment, the process positions two teeth approximately based on each crown center and tooth local coordinate system. Then, for each tooth, a matching operation is performed. The matching operation is an iteration process that minimizes an error value while trying to find the appropriate tooth location."), Figs. 4-5.). This repeated use of "positioning" and "matching" in the specification, mostly as distinct terms, suggests that the patentee knew that substituting "positioning" for "matching" in a claim would result in a change of claim scope. *See Takeda*, 743 F.3d at 1365. In one, non-limiting embodiment found in the '661 patent (and the '647 patent as well), "matching" appears to relate to both computation and positioning/repositioning based on that computation (e.g., by way of a transform). (*See, e.g., id.* at 6:56-7:51.). The adopted construction attempts to reference both of these concepts without limiting "matching/match" to a single disclosed embodiment or denying the patentee the full scope of its invention. The adopted construction is also consistent with the adopted construction of "reference point" set forth above.

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
				Next, the phrase "stable anatomical structures," found in 3Shape's proposed construction, is not warranted for the reasons set forth above in the context of "reference point." The specification of the '661 patent as a whole, including any additional material omitted from the related '647 patent, does not restrict the location of a "reference point" to "a stable anatomical structure." To the contrary, the specification of the '661 patent teaches the use of "reference points" to match non-stable structures, such as moving teeth, across models. (*Id.* at 7:10-15 (emphasis added).). This interpretation is consistent with the language of claim 1 of the '661 patent, where the patentee explicitly constrained the claimed use of the "reference point" to a "non-moving reference region." (*Id.* at 13:30.). This fettered use of "reference point" also makes clear that it would be redundant to adopt 3Shape's construction of "matching/match … using the identified reference points" as requiring "a point on a stable anatomical structure." *See MEMS*, 447 F. App'x at 151 (constructions which introduce redundancy are "disfavored"). However, 3Shape is correct that Align's proposed construction falls short. Specifically,

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
				the construction substituted "identified points" for "identified reference points," creating a hint of ambiguity with respect to the identity of the "identified points."[2] Align's construction also creates some ambiguity around whether claims of the '661 patent cover using the "identified reference points" to match computer models, as opposed to just selected regions of those models. Align's construction could be interpreted to read out the claimed two-step matching process, the first of which uses identified reference points to match corresponding regions across models, not models. (JXM-0002 ('661 patent), cl. 1.). Consequently, Align's proposed construction is adopted with appropriate modifications. In particular, the adopted construction clarifies that "identified points" are indeed "identified reference points" and that the "matching/match … using the identified reference points" limitation refers to the first of two matching steps, whereby matching occurs over corresponding regions of models and not across the rest of the models.

[2] Yet, it appears that 3Shape's proposed construction contains the same ambiguous "identified points" language.

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
"comprising a portion of the jaw/model other than the teeth"	**Agreed:** "including at least a non-tooth portion of the jaw"			n/a

3. U.S. PATENT NO. 7,077,647

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
"individually matching/match each of the dental objects"	Plain and ordinary meaning, which is "matching tooth by tooth"	"one by one, positioning/position each of the dental objects"	"for each of the teeth in the subsequent digital model, using the identified reference points to determine the position of a tooth in the subsequent digital model relative to the corresponding tooth in the initial digital model"	Align asserted that the plain and ordinary meaning of this term is "matching tooth by tooth." (COMBr. at 23.). Align lifted this language directly from the specification. (JXM-0001 ('647 patent) at 5:19-23 ("The process 206 of FIG.3 matches data using a *tooth by tooth* approach. By matching *tooth by tooth*, the process determines the difference between tooth geometry in two different impressions.") (emphasis added), Fig. 8 (item 406); *see also id.* at 5:66-67 ("Then, for each tooth, a matching operation is performed."), Fig. 4 (item 302).). By contrast, "one my one," the corresponding language offered in 3Shape's proposed construction, does not appear in the specification of the '647 patent. The remainder of 3Shape's

Claim Terms to Be Construed	**Align's Proposed Construction**	**3Shape's Proposed Construction**	**Adopted Construction**	**Support for Construction**
				proposed construction attempts to characterize "matching/match" as "positioning/ position." (ROMBr. at 11.). For the reasons explained below, neither of the Parties' constructions has been adopted verbatim. First, for the reasons explained above in the context of "matching/match … using the identified reference points" found in the '661 patent, 3Shape's attempt to equate "matching/match" with "positioning/position" was misplaced. Next, 3Shape's "one by one" language is rejected in favor of the "tooth by tooth" language used in Align's construction and the specification of the '647 patent. As Align noted, "3Shape cites no claim language or limiting disclosure in the specification or the file history that requires the injection of a 'one by one' limitation into the claims." (CRMBr. at 4.). To the extent that the "one by one" language was an attempt by 3Shape to impose a specific order of operations as part of the "matching" process (e.g., matching teeth separately and in succession), that is improper because it is not rooted in the intrinsic evidence.

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
				However, 3Shape is correct that Align's construction appears to read out the requirement that "matching" occur "for each of the dental objects" or teeth in the "subsequent digital model." (*See* JXM-0001 ('647 patent) at cl. 1 ("individually matching each of the dental objects in the subsequent digital model with a dental object in the initial digital model").). Consequently, to avoid any ambiguity, the adopted construction substitutes "for each of the teeth" in place of "tooth by tooth." 3Shape is also correct that Align's construction does not adequately address the meaning of "matching/match." 3Shape is entitled to guidance with respect to 'the metes and bounds' of "matching/match" limitations because the Align and 3Shape appear to dispute the proper scope of those limitations. *O2 Micro Intern.*, 521 F.3d at 1360. As addressed above, in the context of a first matching step required in claim 1 of the '661 patent, "matching/match … using the identified reference points" means "using the identified reference points to determine the position of a region of the first computer model relative to the corresponding region of the second computer

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
				model." In the context of the '647 patent, the first matching step entails "individually matching/match each of the dental objects" or teeth, not "matching/match" regions. Thus, to remain consistent across the related '661 and '647 patents, the proper construction of "matching/match each of the dental objects" requires "using identified reference points to determine the position of a tooth in the subsequent digital model relative to the corresponding tooth in the initial digital model." Importantly, this construction is copacetic with limitations of claim 1 of the '647 patent that "compris[e]" the "individually matching/match each of the dental objects" step. These limitations include "identifying … reference points," "approximately matching each set of corresponding dental objects," and "matching each set of corresponding dental objects more closely by iteratively minimizing error …." JXM-0001 ('647 patent) at cl. 1.).
"reference points"	No construction necessary If the ALJ believes construction is	"sample points on the tooth surface"	"points used to determine the position of a digital model, or part thereof,	According to Align, this term does not require construction because it is clear and has a plain meaning understood by those skilled in the art. (COMBr. at 24-25.). In the alternative, Align has proposed a construction that incorporates the

Claim Terms to Be Construed	**Align's Proposed Construction**	**3Shape's Proposed Construction**	**Adopted Construction**	**Support for Construction**
	necessary, the proper construction is plain and ordinary meaning, which is "points used to determine the position of a digital model relative to another digital model"		relative to another digital model, or part thereof"	purported function of a "reference point" as set forth in the '647 patent: determining the position of a digital model relative to another digital model. (*Id.* at 26-27.). In rebuttal, 3Shape argued that Align's proposed construction misrepresented the function of a "reference point" and ignored specification disclosures in the'647 patent that purportedly clarified that a "reference point" must locate "on" the tooth surface." (ROMBr. at 12.). A close examination of the '647 patent specification reveals that neither of 3Shape's arguments has much merit. For the reasons stated above in the context of the construction of "reference point" in the '661 patent, "reference points" here warrants a broad construction, and none of the specification disclosures (in either the '647 patent or the '661 patent) require otherwise. As an initial matter, a construction of the term "reference points" is necessary because Align and 3Shape dispute the term's meaning. *O2 Micro Intern.*, 521 F.3d at 1360. 3Shape conceded that the '647 patent teaches a two-step matching process. (ROMBr. at 15.).

Claim Terms to Be Construed	**Align's Proposed Construction**	**3Shape's Proposed Construction**	**Adopted Construction**	**Support for Construction**
				The first step involves matching individual teeth or individual regions across models. (*See, e.g.*, JXM-0001 ('647 patent) at 5:19-25.). The second step involves "jaw matching" or, stated another way, the matching of one jaw model to another jaw model. (*Id.* at 6:32-34.). The second step "is performed to determine the position of the new jaw relative to the original coordinate system[.]" (*Id.*). 3Shape appeared to suggest that "reference points" in the '647 patent is used only in the context of the first matching step using "sample points" located on "a tooth's surface." (ROMBr. at 13 ("passages in the '647 patent specification that correspond to this particular series of steps establishes that 'reference points' in the claims refers to the 'sample points' in the '647 patent specification"); *see also* JXM-0001 ('647 patent) at 5:49-61.). The problem with this argument is that the '647 patent appears to disclose using "reference points" also in the context of the second "jaw matching" step. For example, the '647 patent describes using an "external reference," including teeth, in the second matching step, for "positioning of the

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
				new jaw in the original coordinate system." (JXM-0001 ('647 patent) at 6:15-16, 7:55-59.). In one embodiment, "the process generates various sample points on the reference teeth and corresponding points on the current teeth (344)." (*Id.* at 6:25-27.). However, in another embodiment, a "rugae in the patients mouth can be used" as an "external reference."[3] (*Id.* at 7:55-59.). Thus, a person of ordinary skill in the art would appreciate that sample points (or reference points) could be used to perform the jaw-matching step with a rugae, which is not located on the surface of a tooth. Moreover, as Align notes, 3Shape's proposed construction presents ambiguity with respect to what constitutes the "tooth's surface." (COMBr. at 25-26.). In particular, it is unclear whether 3Shape's proposed construction is limited to the portion of the teeth that are visible or includes the root. According to Align, one of ordinary skill in the art would likely understand that the claimed "tooth" is not limited to only the crown "surface," but can also include the crown and the root. (*Id.*).

[3] "Rugae" means roof of the mouth. (CXM-0035 (Declaration of Norman Badler, PhD.) at 12.).

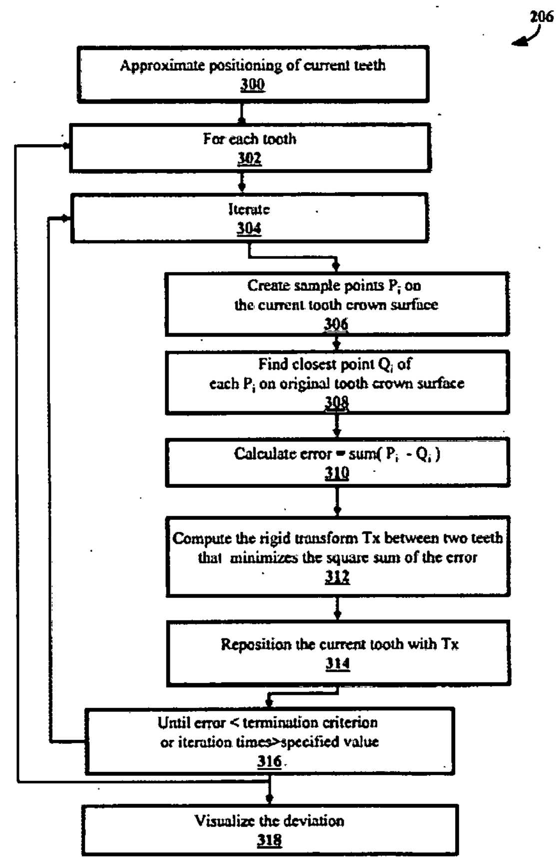
Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
				Consequently, 3Shape's proposed construction fails. The specification of the '647 patent does not restrict the location of a "reference point" to "a tooth's surface." To the contrary, as explained above, the specification of the '647 patent uses "reference points" broadly to match tooth and non-tooth structures. This interpretation is consistent with the language of claim 1 of the '647 patent, where the patentee specified the location of the "reference points": "on each set of corresponding dental objects" or teeth. (JXM-0001 ('647 patent) at 10:8-10.). Under 3Shape's unsupported construction of "reference points" as "sample points on the tooth surface," it seems that the qualifying phrase "on each set of corresponding dental objects" would be redundant, at least in part. *See MEMS*, 447 F. App'x at 151 (constructions which introduce redundancy are "disfavored"). Next, 3Shape argued that Align's proposed construction would effectively read out the explicit two-step matching process taught by the '647 patent claims." (ROMBr. at 15.). Here, 3Shape has a legitimate point. Align's construction could be interpreted to cover only instances in which "reference points" were used in the second matching step to match jaw

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
				models. As discussed above, "reference points" can play a role in both the first and second matching steps. A minor modification of Align's construction addresses 3Shape's valid concern in this regard, while preserving the breadth of "reference points" as disclosed in the '647 patent specification. Based on the above, "reference points" in the '647 patent is construed as "points used to determine the position of a digital model, or part thereof, relative to another digital model, or part thereof." The juxtaposition of this construction with the above-mentioned construction of "reference point" in the context of the '661 patent reveals that, in this situation, "3Shape cannot propose a different construction for the same term of a patent family." (COMBr. at 14.). For the reasons stated above, 3Shape is mistaken that the new matter added to the '661 patent expressly justifies restricting "reference point" to a location on a "stable anatomical structure" in the context of the '661 patent, while restricting the location of the nearly identical term "reference points" to "on the tooth surface" in the context of the '647 patent.

Claim Terms to Be Construed	**Align's Proposed Construction**	**3Shape's Proposed Construction**	**Adopted Construction**	**Support for Construction**
				Moreover, as discussed above, not only is the misalignment of 3Shape's constructions for nearly identical claim terms unjustified, an examination of each construction in isolation reveals that the corresponding specification does not support the narrowness of 3Shape's proposed construction. In both cases, it appears that 3Shape is trying not to hew to the intrinsic evidence, but instead to manufacture non-infringement arguments.
"iteratively minimizing error"	Plain and ordinary meaning, which is "repeating a process to minimize the distance"	"repeatedly minimizing, until a criteria is met, the sum of distances"	"repeating a process to minimize the error until the error is less than a termination criteria or a maximum number of iterations has been reached"	For constructions of this term, Align and 3Shape each attempted to read in limitations from a single, disclosed embodiment. *See Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 913 (Fed. Cir. 2004) ("[I]t is improper to read limitations from a preferred embodiment described in the specification—even if it is the only embodiment—into the claims absent a clear indication in the intrinsic record that the patentee intended the claims to be so limited."). Align attempted to limit the claimed "error" to a "distance." (COMBr. at 27-28.). 3Shape on the other hand attempted to import a particular metric for measuring error, namely "a sum of distances." (ROMBr. at 17.). For the reasons

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
				explained below, neither construction comports with the intrinsic evidence. The specification of the '647 patent discloses what Align describes as an "exemplary embodiment" teaching "iteratively minimizing error." (COMBr. at 27.). That embodiment is described as follows: "Referring onto FIG. 4, the matching of the original teeth data with the current teeth data of box 206 is detailed. In FIG. 4, the process approximates the current positioning of the current teeth (300). Next, the process (304) is iterated for each tooth in 302. The process 304 creates sample points Pi on the current tooth crown surface (306). Next, it finds the corresponding closet point Qi for each Pi on the original tooth crown surface (308). The process then calculates an error of value in this case, the error value is computed as the sum of the distance between Pi and Qi (310). The process then computes a rigid transformation between two teeth that minimizes the error (312). The current tooth is then repositioned with the transform (314). The process of FIG. 4 is repeated until an error value is less than a predetermined termination criterion or the number of iterations exceeds a predetermined value (316). Finally, the process provides a

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
				visual report of the deviation (318)." (JXM-0001 ('647 patent) at 5:45-61; *see also id.* at 5:62-6:14.). According to Align, the "parties appear to agree that 'iteratively' means repeating a process to minimize the error." (CRMBr. at 9.). We are in agreement. Moreover, Align is correct that "iteratively minimizing error" does not require a specific iterative method, but only that the iteration minimize the error between two corresponding reference points to match the teeth. (COMBr. at 28.). As shown below in Figure 4 of the '647 patent, and as described in a corresponding portion of the specification, "[t]he above steps are iterated until the error is less than termination criteria or a maximum number of iteration is reached." (JXM-0001 ('647 patent) at 6:11-13, Fig. 4.).

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
				 FIG. 4

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
				The claims of the '647 patent do not require a specific error calculation. (*See, e.g., id.*, cl. 1 ("iteratively minimizing error between corresponding reference points on corresponding dental objects").). Nowhere does the specification commit to a particular error calculation, such as "minimizing the distance" or "minimizing … the sum of distances." By contrast, Figure 8 discloses a variety of ways to "specify[] an error reference (420)," including "translation, rotation, move dist, deviation[.]" (*Id.* at Fig. 8.). Rotation presumably entails a measurement in degrees, not units of distance. Therefore, the proper construction of "iteratively minimizing error" set forth above retains the agreed-upon concept of repeating a process to minimize the error while omitting, and rejecting, the Parties' attempts to confine the term to a particular type of error calculation.
"matching the subsequent digital model as a whole with the initial digital model"	No construction necessary If the ALJ believes construction is necessary, the proper construction is plain	"superimposing in its entirety the second digital model after some dental treatment with the first digital model	"determining the position of the subsequent digital model as a whole relative to the initial digital model"	According to Align, this term requires no construction because it is clear and has a plain meaning understood by those skilled in the art. (COMBr. at 29.). In the alternative, Align proposed construing this term as "matching the jaw of the subsequent digital model with the initial digital model." (*Id.*). In rebuttal, 3Shape

Claim Terms to Be Construed	**Align's Proposed Construction**	**3Shape's Proposed Construction**	**Adopted Construction**	**Support for Construction**
	and ordinary meaning, which is "matching the jaw of the subsequent digital model with the initial digital model"	before treatment is complete."		argued that Align's proposed construction fails to address the meaning of "matching/match," specify that the "matching" occurs after a dental treatment, and recognize that this second jaw-matching step means superimpose/superimposing" entire models, "a more specific type of positioning" than the "positioning/position" purportedly used in the context of the first matching step (individual matching of teeth). (ROMBr. at 12.). As an initial matter, a construction of the limitation "matching the subsequent digital model as a whole with the initial digital model" is necessary because Align and 3Shape dispute the term's meaning. *O2 Micro Intern.*, 521 F.3d at 1360. A close examination of the intrinsic evidence reveals that 3Shape's arguments have little merit with one notable exception: a construction of "matching" is warranted. While generally consistent with the intrinsic evidence, Align's proposed construction is flawed insofar as it lacks a description of "matching" and fails to

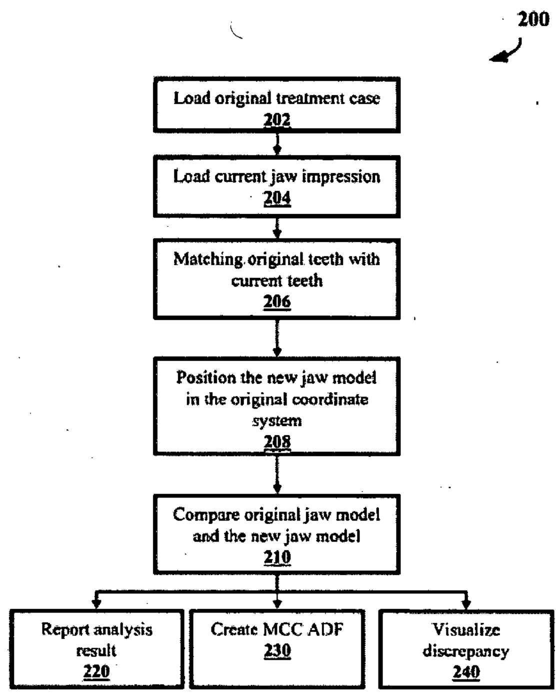
Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
				clarify that the second matching step (jaw[4] matching) involves the matching of at least the subsequent digital model as a whole with (all or part of) the initial digital model. Align is correct that "3Shape's construction attempts to inject yet another definition for 'matching' into the claims[.]" (CRMBr. at 10.). In particular, while 3Shape construed "matching" as "positioning" in the context of the first matching step (tooth by tooth matching) addressed above, here 3Shape construed "matching" as "superimposing." This sort of claim construction inconsistency is disfavored. *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1342 (Fed. Cir. 2001) ("[A] claim term should be construed consistently with its appearance in other places in the same claim or in other claims of the same patent."); *Phonometrics, Inc. v. Northern Telecom Inc.*, 133 F.3d 1459, 1465 (Fed. Cir. 1998) ("A word or phrase used consistently through a claim should be interpreted consistently.").

[4] As Align noted, "[t]he 'jaw' is easily understood as the upper or lower teeth of the patient's dentition." (CRMBr. at 12 (citing 3:24-58, Figs. 1, 2A).). The specification explains that "jaws" can refer to both the upper and lower jaws together, while "jaw" can refer to either the upper or lower jaw." (JXM-0001 ('647 patent) at 3:27-32 ("The upper jaw bone 22 is associated with an upper jaw 101, while the lower jaw bone 20 is associated with a lower jaw 100. A computer model of the jaws 100 and 101 is generated, and a computer simulation models interactions among the teeth on the jaws 100 and 101.").).

Claim Terms to Be Construed	**Align's Proposed Construction**	**3Shape's Proposed Construction**	**Adopted Construction**	**Support for Construction**
				Additionally, 3Shape's proposed construction of "matching" finds no support in the intrinsic record. The term "superimposing" is mentioned only twice in the specification and only in the background of the invention. (JXM-0001 ('647 patent) at 2:19-25.). "Superimposed" is used once in the specification, but only in the context of the first matching step, not the second matching step addressed here. (JXM-0001 ('647 patent) at 7:44-48 ("The search algorithm finds the relative position of the teeth by minimizing the distance between two superimposed teeth. The matching process is completed throughout the entire teeth of a jaw.").). Consequently, 3Shape has provided little justification for adopting fundamentally different "matching" constructions (positioning v. superimposing) for the first and second matching steps. As explained above, in the context of the first matching step, the adopted construction of the "matching/match" limitation was "using identified reference points to determine the position of a tooth in the first computer model relative to the corresponding tooth in the second computer model." Consistent with this construction, in the context of the second

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
				matching step of the '647 patent, the "matching" limitation is properly construed as "determining the position of the subsequent digital model as a whole relative to the initial digital model." The specification provides explicit support for synchronizing constructions of the "matching" limitations, with slight modifications to account for distinct claim language used in each limitation, by explaining that the first "matching" step "provides a foundation for" the second matching step. (*See id.* at 7:51-53 ("This teeth matching provides a foundation for jaw matching so that each new tooth position can be represented relative to the original tooth position.").). That said, the adopted constructions for the first and second matching steps are not identical. The term "reference point(s)" is not included in the construction of the second "matching" step because the second matching step in the independent claims of the '647 patent does not explicitly require the use of "reference points." Moreover, as depicted below in Figure 3 of the '647 patent, the intrinsic evidence makes clear that the second matching step entails matching jaws at the model level, not at the level of "regions" of jaw models or individual teeth of

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
				jaw models as in the first matching step. (*Id.* at 2:43-45 ("Finding the position can include placing two jaw impressions in a single coordinate system; selecting a positioning reference"); 5:11-12 ("the new jaw data is positioned in the original coordinate system (208).")).). Nevertheless, the crux of matching in the '647 patent—determining the position of one thing relative to another—appears in both adopted constructions, for the first and for the second matching steps.

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
				 FIG. 3 Finally, language in 3Shape's proposed construction pertaining to the timing of the

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
				second matching step is unnecessary. The claim language already confirms that the second matching step occurs after a dental treatment. For example, claim 1 of the '647 patent requires "providing a subsequent digital model of the set of dental objects in their moved positions after at least some of them have been moved by the dental treatment." *MEMS*, 447 F. App'x at 151 (constructions which introduce redundancy are "disfavored"). This interpretation finds additional support in the specification. (JXM-0001 ('647 patent) at 7:34-36 ("[t]he above described system matches two different impressions of a patient, one before treatment and one after treatment.").). Moreover, there is no support in the intrinsic evidence for 3Shape's proposed limitation that the second matching step occur before treatment is complete. The claims are directed to "determining/determine" the progress of a dental treatment, but are not limited to any point in time regarding the progress of the dental treatment, e.g., "before treatment is complete." Here, it appears that 3Shape is trying to manufacture from attorney argument a non-infringement position that finds no support in the patent. (ROMBr. at 21.).

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
				Finally, as Align has requested, clarification is appropriate with respect to the term "as a whole." (CRMBr. at 12 ("Align would not object to a minimal clarifying construction").). According to Align, "because the subsequent and initial digital models are of the same patient dentition, Align's proposed construction is easily understood as matching the 'jaw" (upper *or* lower) of both models.'" (*Id.* (emphasis added)). 3Shape appeared to disagree, asserting that "the '647 patent claims require that the two digital models are matched 'as a whole'" and "[t]he '647 patent specification explains this means the entire jaw is matched." (ROMBr. at 21.). On this issue, Align prevails in part. Contrary to 3Shape's position, the claims require the performance of the second matching step on "the subsequent digital model as a whole," not the jaw as a whole. Claim 1 of the '647 patent clarifies that the subsequent digital model, like the initial digital model, pertains to a "set of dental objects" and not necessarily to all of the dental objects available to scan in a particular mouth. (JXM-0001 ('647 patent), cl. 1.). The matching steps build upon the claimed models. (*Id.*). Thus, claim 1 does not require the performance of the first and

Claim Terms to Be Construed	**Align's Proposed Construction**	**3Shape's Proposed Construction**	**Adopted Construction**	**Support for Construction**
				second matching steps on an entire set of teeth available in a particular set of jaws or even all teeth available in an upper jaw or a lower jaw. That said, the express language of claim 1 requires that, for the second matching step, at least the whole of the subsequent digital model be matched with the initial digital model. (*Id.*). Importantly, the inverse is not explicitly required—that is, matching the whole of the initial digital model with the subsequent digital model. (*Id.*). This interpretation is consistent with the claimed first matching step, which requires "individually matching each of the dental objects in the subsequent digital model with a dental object in the initial digital model," not the inverse. (*Id.*). These distinctions suggest that claim 1 of the '647 patent could read on a scenario where the subsequent digital model is less comprehensive than the initial digital model in terms of dental objects modeled, so long as the initial digital model contains all the dental objects found in the subsequent digital model. In other words, claim 1 appears broader than the scenario envisioned by Align, where "subsequent and initial digital models are of the same patient dentition." (CRMBr. at 12.).

APPENDIX A to ORDER NO. 36
Markman Order
Inv. No. 337-TA-1144

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
"dental object" / "dental objects"	**Agreed:** "tooth" / "teeth"			n/a
"approximately matching/match each set of corresponding dental objects"	**Agreed:** "initially aligning/align each set of corresponding teeth"			n/a
"statistical filtering"	**Agreed:** "teeth with small standard error as reference teeth"			n/a
"sum of the differences"	**Agreed:** "sum of the distances"			n/a
"planned positions"	**Agreed:** "target positions"			n/a

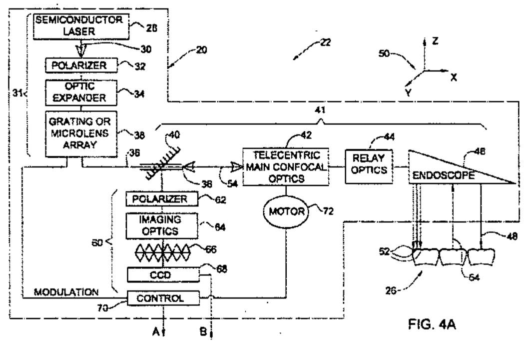
4. U.S. PATENT NO. 8,102,538

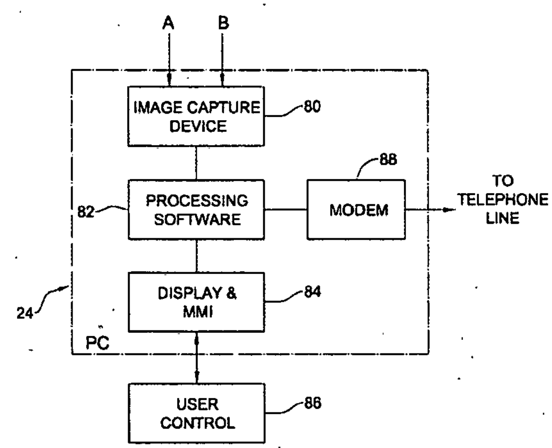
Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
"optical scanner"	Plain and ordinary meaning, which is "a device that uses light projection and image capture for scanning" Alternatively, if subject to 112, 6th ¶: <u>Function:</u>	*means-plus-function term subject to construction under 35 U.S.C. § 112, ¶6* **structure**: "confocal optical system, including one or more lasers and an image sensor for	Not subject to § 112, ¶6. "a device that uses light projection to capture data other than color image data"	Align asserted that "optical scanner" was not subject to § 112, ¶ 6 treatment and instead possessed a broad meaning: "a device that uses light projection and image capture for scanning." (COMBr. at 38.). According to 3Shape, "[t]he term 'optical scanner' fails to connote sufficient structure to a person of ordinary skill in the art, and as such, should be interpreted to be limited to the structures disclosed in the specification for performing the

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
	"providing depth data of the portion corresponding to a two-dimensional reference array substantially orthogonal to a depth direction" <u>Structure:</u> "a probing member, a light source for providing arrayed illumination along said depth direction; light focusing optics defining one or more focal planes forward said probing member at a position changeable by said optics; a translation mechanism for displacing said focal plane relative to the structure along the depth direction; an image sensor for	receiving returned light through a spatial filter" **function**: providing depth data of the portion If the term is not found to be means-plus-function, then: "laser confocal scanner, operating separately from an imaging means"		claimed function." (ROMBr. at 55.). As explained below, the proper construction of "optical scanner" is a modified version of Align's construction that accounts for statements of claim scope disavowal made by the patentee during the prosecution of a related patent. The first order of business is determining whether § 112, ¶ 6 applies. There is a presumption against treating this claim term, which does not recite the word "means," as a means-plus-function term. *Williamson v. Citrix Online LLC*, 792 F.3d 1339, 1348 (Fed. Cir. 2015) ("the failure to use the word 'means' . . . creates a rebuttable presumption . . . that § 112, [¶] 6 does not apply."). 3Shape bears the burden of overcoming that presumption. *Id.* To escape § 112, ¶ 6 treatment, "optical scanner" need only convey to one of ordinary skill in the art a variety of structures encompassed by that term. *Personalized Media Commc'ns, LLC v. Int'l Trade Comm'n*, 161 F.3d 696, 703 (Fed. Cir. 1998) ("Even though the term 'detector' does not specifically evoke a particular structure, it does convey to one knowledgeable in the art a variety of structures

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
	measuring intensity of light returning from the portion of the three-dimensional structure; and a processor coupled to the image sensor for determining for each region of the three-dimensional structure an in-focus position, and based on the determined in-focus positions, generating data representative of the topology of said portion or equivalents thereof" *See, e.g.*, '538 patent at 5:17-44, 12:60-13:5.			known as 'detectors.'"). Moreover, "a term need not connote a precise physical structure in order to avoid the ambit of" § 112, ¶ 6. *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1370 (Fed. Cir. 2002); *Watts v. XL Sys., Inc.*, 232 F.3d 877, 880 (Fed. Cir. 2000). As set forth below, 3Shape failed to carry its burden of showing that the "optical scanner" limitation lacked "sufficiently definite structure' or else recites 'function without reciting sufficient structure for performing that function.'" *Williamson*, 792 F.3d at 1348. 3Shape is correct that, when viewed in isolation, claim 1 of the '538 patent identifies the function of "optical scanner" without revealing much corresponding structure. (ROMBr. at 56.). Specifically, claim 1 requires an "optical scanner configured for providing depth data of the portion corresponding to a two-dimensional reference array substantially orthogonal to a depth direction[.]" (JXM-0003 ('538 patent), cl. 1.). However, when read within the context of the '538 patent specification, "optical scanner" possesses a clear structural identity. Specifically, the '538 patent references several

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
				prior art 3D scanners. (*Id.* at 1:25-2:40 ("Many methods have been developed for obtaining the three dimensional location of surface points of an object, for a host of applications including, inter alia, the intraoral cavity. … Such systems typically include an optical probe coupled to an optical pick-up or receiver such as charge coupled device (CCD) and a processor implementing a suitable image processing technique to design and fabricate virtually the desired product. Such methods include, for example, confocal imaging techniques as described in WO 00/08415 assigned to the present assignee. These methods provide a digital three-dimensional surface model that is inherently monochromatic, i.e., no color information is obtained in the imaging process.").). Notably, against this prior art backdrop, the '538 patent explains that "any suitable means for providing 3D scanning can be used so long as the 3D scan and the color 2D scan correspond substantially to the same object or portion thereof being scanned, and the same frames of references are maintained." (*Id.* at 25:7-16.) In addition to referencing the prior art, the '538 patent explicitly discloses embodiments of the

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
				invention with "optical scanner" structural components. (*See, e.g., id.* at 5:16-6:9.). For example, Figures 4A and 4B of the '538 patent shown below "schematically illustrate the main elements of a portion of the invention used for providing a three dimensional monochrome entity," which is the function of the claimed "optical scanner." (*Id.* at 12:21-23.).  FIG. 4A

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
				 FIG. 4B Based on the discussion above, the '538 patent appears to disclose an adequate structure for the claimed "optical scanner configured for providing depth data of the portion corresponding to a two-dimensional reference array substantially orthogonal to a depth direction[.]" This structural detail distinguishes the case cited by 3Shape in support of applying § 112, ¶ 6. In that case, there was no record evidence that the limitation at issue, "lever moving element," had "a known structure in the

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
				lock art." *Mas-Hamilton Group v. LaGard, Inc.*, 156 F. 3d 1206, 1213-1214 (Fed. Cir. 1998). Consequently, the term could cover "any device that can cause the lever to move." (*Id.*). Here, by contrast, the specification of the '538 patent confirms that "optical scanner" had a known structure in the prior art. (JXM-0003 ('538 patent) at 1:25-2:40.). 3Shape next argued that "prosecution history of the application leading to the '538 patent further confirms that the term 'optical scanner' should be construed as a means-plus-function term." (ROMBr. at 56.). 3Shape's primary argument here is that "optical scanner" should receive § 112, ¶ 6 treatment because claim 1 of the '538 patent was originally claimed in a means-plus-function format. (*See* JXM-0008 ('538 patent prosecution history) at 175.). However, there is little factual or legal support for 3Shape's position that amending claim 1 to remove the word "means" amounted to a disavowal of claim scope. The amendment was not based on a rejection or otherwise offered to traverse prior art. (*Id.* at 149.). Instead, the amendment was made post-allowance and had the effect of broadening, not narrowing, claim

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
				scope. (*Id.* at 149, 175.). *See, e.g., Interactive Pictures Corp. v. Infinite Pictures, Inc.*, 44 274 F.3d 1371, 1378 (Fed. Cir. 2001) ("[T]he amendment was not made for a 'substantial reason related to patentability' and thus does not create prosecution history estoppel."); *TurboCare Div. of Demag Delaval Turbomachinery Corp. v. Gen. Elec. Co.*, 264 F.3d 1111, 1126 (Fed. Cir. 2001). For the above reasons, § 112, ¶ 6 does not apply to the term "optical scanner." 3Shape next argued that the Court should adopt a construction that limits "optical scanner" to a "laser confocal scanner" that "operat[es] separately from an imaging means." (ROMBr. at 54.). Align, as mentioned above, offered a broad construction of "optical scanner": "a device that uses light projection and image capture for scanning." (COMBr. at 38.). A claim term, such as "optical scanner," is ordinarily accorded its plain and ordinary meaning. *Hill-Rom Servs. v. Stryker Corp.*, 755 F.3d 1367, 1371 (Fed. Cir. 2014). "There are only two exceptions to this general rule: 1) when a patentee sets out a definition and acts as

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
				his own lexicographer or 2) when the patentee disavows the full scope of the claim term either in the specification or during prosecution." *Id.*; *see also Thorner v. Sony Computer Entertainment America LLC*, 669 F.3d 1362, 1367 (Fed. Cir. 2012) ("The patentee is free to choose a broad term and expect to obtain the full scope of its plain and ordinary meaning unless the patentee explicitly redefines the term or disavows its full scope."). 3Shape argued that Align could not claim a broad "optical scanner" because the patentee disavowed such claim scope in the prosecution history. In particular, during prosecution of an earlier patent application in the '538 patent family,[5] in response to a rejection, the patentee amended a claim to overcome the Mueller prior art reference (U.S. Patent No. 7,098,435). (RXM-0010 ('829 patent file history) at 127, 158.). The patentee's amendment was limited to the addition of the following language: "processing means for associating said color data with said depth data for corresponding data

[5] That application issued as U.S. Patent No. 7,511,829 ("the '829 patent"). The '829 patent and '538 patent have the same sole inventor, Noam Babayoff, and specification. (*See, generally,* JXM-0003 ('538 patent); RXM-0010 ('829 patent file history).). Both patents also claim priority to the same provisional application. (*See id.*).

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
				points of said reference array." (*Id.* at 158.). As the patentee explained, in the pending claim, "depth data is obtained independently of the colour data, and the two sets of data are combined by conformally mapping or associating the colour data with the depth data for a given two-dimensional array of points." (*Id.* at 170-72.). In Mueller, obtaining depth data was not independent of obtaining color data. (*Id.* at 171-72.). Instead, Mueller taught processing multiple 2D color images taken from different angles of displacement to create 3D surface models. (*Id.* at 238 ("Mueller discloses using the color information from a series of two dimensional color images to drive the three dimensional location in space of the surface points which produced the color images").). Thus, according to the patentee, Mueller lacked (and even taught away from) the extra processing step of combining independently-obtained depth and color data. (*Id.* at 171.). The examiner agreed. (*Id.* at 237.). The critical issue here is whether the patentee disavowed scope of "optical scanner" during prosecution of the related '829 patent. According to 3Shape, Align did clearly disavow claim scope and is now trying to "claim a

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
				generic 3D scanner, without acknowledging the distinctions the patentee [drew] to overcome the prior art – that the claimed invention captures a color 3D scan through two systems: one for 3D depth and one for 2D color." (RRMBr. at 25.). 3Shape's concern in this regard is warranted. Mueller is cited as prior art in the '538 patent and thus presumably was considered by the examiner during prosecution of the '538 patent, just as it was considered during the prosecution of the '829 patent (indeed the same examiner oversaw both prosecutions). (*See, generally*, JXM-0003 ('538 patent); RXM-0010 ('829 patent file history).). Yet, the treatment of Mueller was inconsistent across the prosecution histories of the '829 and '538 patents. During the prosecution of the '829 patent, Mueller was cited as invalidating prior art. (RXM-0010 ('829 patent file history) at 127.). However, during the relatively uneventful prosecution of the '538 patent (claims rejected only once based on double patenting), Mueller was not cited as invalidating prior art. (*See, generally*, JXM-0008 ('538 patent file history).). This was the case even though at least one claim pending during prosecution of the '829 patent (and eventually amended as explained above to

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
				overcome Mueller) was nearly identical to issued claim 1 of the '538 patent. (RXM-0010 ('829 patent file history) at 56; JXM-0003 ('538 patent), cl. 1.). Indeed, the former was arguably narrower than the latter insofar as the former recited "optical scanning means" in place of "optical scanner." (*Id.*) Consequently, statements of claim scope disavowal made to overcome Mueller during the prosecution of the '829 patent are applicable here in the context of the '529 patent. In particular, as the patentee explained during the prosecution of the '829 patent, "depth data is obtained independently of the colour data[.]" (RXM-0010 ('829 patent file history) at 170.). The Abstract of the '538 patent echoes the consequences of this arrangement, explaining that "[a] processor combines the color data and depth data for each point in the array, thereby providing a three-dimensional color virtual model of the surface of the structure." (JXM-0003 ('538 patent) at Abstract.). However, this critical concept of depth and color data independence does not explicitly appear in claim 1 of the '538 patent. In other words, claim 1 could in theory read on a device

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
				with an "optical scanner" and separate "imaging means," where the former collects depth and color data and never combines that data with 2D imaging data provided by the imaging means to create a 3D color model. That possibility poses a problem for Align's claim construction. The adopted construction of "optical scanner" is an opportunity to set the record straight. To prevent the patentee from recapturing claim scope disavowed during prosecution, "optical scanner" is construed as "a device that uses light projection to capture data other than color image data." Specifying that the "optical scanner" does not capture color image data effectively restores the depth and color data independence touted by the patentee and used by the patentee to overcome Mueller. However, 3Shape's additional arguments with respect to the narrowing of "optical scanner" are without merit. They amount to attempts to limit the claims to preferred embodiments. *SanDisk Corp. v. Memorex Prods., Inc.*, 415 F.3d 1278, 1286 (Fed. Cir. 2005) ("[r]eferences to a preferred embodiment, such as those often present in a specification, are not claim limitations.") (quoting *Laitram Corp. v.*

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
				Cambridge Wire Cloth Co., 863 F.2d 855, 865 (Fed. Cir. 1988)); *Gillette Co. v. Energizer Holdings, Inc.*, 405 F.3d 1367, 1374 (Fed. Cir. 2005) (cautioning against "limiting the claimed invention to preferred embodiments or specific examples in the specification.") (quoting *Texas Instruments, Inc. v. U.S. Int'l Trade Comm'n*, 805 F.2d 1558, 1563 (Fed. Cir. 1986)). For example, pursuant to the doctrine of claim differentiation, the claimed "optical scanner" is not limited to a "confocal" technique because claim 2 of the '538 patent specifically recites that "the operation of the optical scanner is based on confocal imaging techniques." *See SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1122 (Fed. Cir. 1985) (en banc) ("It is settled law that when a patent claim does not contain a certain limitation and another claim does, that limitation cannot be read into the former claim term in determining either validity or infringement."); *see also Phillips v. AWH Corp.*, 415 F.3d 1303, 1314-15 (Fed. Cir. 2005) ("For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim.").

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
				Moreover, as discussed above, the specification describes a variety of prior art optical scanners, including those using confocal and non-confocal imaging techniques. (JXM-0003 ('538 patent) at 1:18-2:37.). The '538 patent does not limit itself to laser or confocal scanners and instead teaches that "any suitable means for providing 3D scanning can be used so long as the 3D scan and the color 2D scan correspond substantially to the same object or portion thereof being scanned, and the same frames of references are maintained." (*Id.* at 25:11-14; *see also id.* at 4:32-35 ("the device of the invention provides advantages over monochrome 3D scanners, including [but not limited to] such scanners that are based on confocal focusing techniques.").). Finally, in claim 1 of the '538 patent, there is no requirement that the "optical scanner" operate "separately" from the "imaging means." (RRMBr. at 27.). According to Align, this purported requirement advanced by 3Shape amounts to an assertion that the "optical scanner" and "imaging means" must operate at different times—i.e., acquire depth data and color image data at different times. (CRMBr. at 38.). Yet, in direct contravention of 3Shape's

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
				construction, the '538 patent contemplates concurrent, or at least overlapping, operation of the "optical scanner" and "imaging means." (JXM-0003 ('538 patent) at 21:55-57 ("a set of [color] images is taken (concurrently with or alternately with the depth scan)"), 21:46-47 ("one or more color scans may also be taken during the depth scan").). The '538 patent also teaches using some of the same components for both the optical scanner and color imaging means. (*See, e.g.*, *id.* at 17:27-31 ("In particular such operations include the transmission of the illuminating radiation for the confocal focusing operations, and also the transmission of reflected light from the object 26 to the main optics 41 to provide the 3D entity or the 2D color entity."), 19:44-48 ("red laser is used as the illumination source 31 for the main optics 41 when creating the 3D entity. As such, and as in other embodiments, this illumination means is also used to obtain the red monochromatic image for the creation of the 2D color image."), 24:13-14 ("Alternatively, the CCD of the detection optics 60 is a color CCD and is also used for the 2D scan.").). These disclosures eviscerate 3Shape's separateness argument.

Claim Terms to Be Construed	**Align's Proposed Construction**	**3Shape's Proposed Construction**	**Adopted Construction**	**Support for Construction**
				Consequently, based on discussion above, the proper construction of "optical scanner" is a modified version of Align's construction that accounts for statements of the claim scope disavowal (and corresponding amendment) made by the patentee during the prosecution of a nearly identical claim in a related patent.
"imaging means"	Subject to 112, 6th ¶: <u>Function:</u> "providing two-dimensional color image data of the portion associated with the reference array" <u>Structure:</u> "white illumination and a color image sensor (*e.g.*, a color CCD) for detecting intensity of the white illuminating radiation after reflection from the	*means-plus-function term subject to construction under 35 U.S.C. § 112, ¶6* **structure**: (1) one or more light sources sequentially illuminating the 3D structure with three or more different colored illuminations, optics, and an image sensor; OR (2) a white light source, separate from	Subject to 112, ¶ 6. <u>Function:</u> "providing two-dimensional color image data of the portion associated with the reference array" <u>Structure:</u> "white illumination, optics, and a color image sensor (*e.g.*, a color CCD) for detecting intensity of the white illuminating radiation after	Align and 3Shape agree that "imaging means" is subject to 35 U.S.C. § 112, ¶ 6. (COMBr. at 53; ROMBr. at 66.). They also agree that the specification of the '538 patent discloses two categories of associated structures for performing the function of "providing two-dimensional color image data," one directed to using white light illumination and the other directed to individual color illumination applied in sequence. (*Id.*). However, Align and 3Shape disagree on the contours of these illumination categories. Align proposed relatively broad categories. 3Shape took the opposite approach. For example, in the context of the sequential color illumination category, 3Shape's construction required that the light illuminate "the 3D structure" and consist of "three or more different colored

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
	portion; or sequential monochromatic illumination (*e.g.*, RGB) and an image sensor (e.g., a CCD) for detecting intensity of the monochromatic illuminating radiation after reflection from the portion; or equivalents thereof" *See, e.g.*, '538 patent at 6:26- 31, 6:31-36, 6:36-38, 6:49-53, 7:29-33, 7:35-40, 7:41-43, 7:43-48, 7:48-53, 7:57-59, 7:60-8:1, 8:6-8, 8:9-20, 13:8- 13:13, 13:33-38, 13:38-42, 16:33-41, 16:41-47, 17:12-15, 17:15-19, 17:20-23, 17:23-25, 17:61-64, 17:64-66, 18:21-30, 18:30-33; 18:41-51, 19:3-6,	and in addition to the light source of the optical scanner, optics, and an image sensor **function**: providing two-dimensional color image data	reflection from the portion; or sequential monochromatic illumination (*e.g.*, RGB), optics, and an image sensor (e.g., a CCD) for detecting intensity of the monochromatic illuminating radiation after reflection from the portion; or equivalents thereof" '538 patent at 6:26-31, 6:31-36, 6:36-38, 6:49-53, 7:29-33, 7:35-40, 7:41-43, 7:43-48, 7:48-53, 7:57-59, 7:60-8:1, 8:6-8, 8:9-20, 13:8- 13:13, 13:33-38, 13:38-42, 16:33-41, 16:41-47, 17:12-15, 17:15-19, 17:20-	illuminations." (ROMBr. at 66.). In the context of the white light illumination category, 3Shape's construction required that the white light source be "separate from and in addition to the light source of the optical scanner." (*Id.*). Unlike Align, 3Shape failed to cite to portions of the '538 patent specification that discloses specific structure for the two illumination categories. (*Id.*). 3Shape's construction also required that the corresponding structure include "optics." (*Id.*). By contrast, Align's construction does not include "optics" as a requirement but nevertheless cites to specific structure (including optics) in the specification. (COMBr. at 53.). Aside from the omission of "optics," Align's § 112, ¶ 6 construction hews to the intrinsic evidence. For the reasons set forth below, 3Align's construction is adopted with the addition of "optics" as required structure. Construing a means-plus-function claim term is a two-step process. The court must first identify the claimed function. *Noah Sys., Inc. v. Intuit*

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
	19:6-14, 19:44-51, 19:51-55, 19:55-58, 19:58-61, 19:61-65, 20:19-46, 20:46-49, 20:55-64, 22:6-14, 22:28-33, 22:34-41, 23:8-14, 23:32-37, 23:43-46, 23:46-52, 24:3-7, 24:13-14, 24:23-29, 24:33-36, 24:36-39, 24:39-41.		23, 17:23-25, 17:61-64, 17:64-66, 18:21-30, 18:30-33; 18:41-51, 19:3-6, 19:6-14, 19:44-51, 19:51-55, 19:55-58, 19:58-61, 19:61-65, 20:19-46, 20:46-49, 20:55-64, 22:6-14, 22:28-33, 22:34-41, 23:8-14, 23:32-37, 23:43-46, 23:46-52, 24:3-7, 24:13-14, 24:23-29, 24:33-36, 24:36-39, 24:39-41, including figures cited therein.	*Inc.*, 675 F.3d 1302, 1311 (Fed. Cir. 2012). Then, the court must determine what structure, if any, disclosed in the specification corresponds to the claimed function. *Williamson*, 792 F.3d at 1352. "Structure disclosed in the specification qualifies as 'corresponding structure' if the intrinsic evidence clearly links or associates that structure to the function recited in the claim." *Id.* (citing *Noah Sys.*, 675 F.3d at 1311). Align and 3Shape did not agree on the entirety of the claimed function. According to 3Shape, the claimed function was only "providing two-dimensional color image data." (ROMBr. at 66-67.). According to Align, quoting verbatim from the asserted claims of the '538 patent, 3Shape's claimed function was incomplete and should included the qualifying phrase: "of the portion associated with the reference array." (COMBr. at 53-54.). According to 3Shape, this qualifying phrase "merely describes the characteristics of the 'two-dimensional color image data' and does not describe the claimed function and, as such, 3Shape's proposed construction more concisely reflects the claimed function." (ROMBr. at 67.). Yet, as 3Shape noted, "[d]espite these differences in the parties'

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
				identified functions, the difference does not appear to be a material one." (*Id.*). For the sake of adhering to the verbatim claim language provided by the patentee in describing the metes and bounds of the invention, this Order adopts Align's full version of the claimed function and not 3Shape's "concise" one. *See In re Teles AG Informationstechnologien*, 747 F.3d 1357, 1367-68 (Fed. Cir. 2014) ("[t]he statute does not permit limitation of a means-plus-function claim by adopting a function different from that explicitly recited in the claim") (citing *Micro Chem., Inc. v. Great Plains Chem. Co.*, 194 F.3d 1250, 1258 (Fed. Cir. 1999)). Turning to corresponding structure, the intrinsic evidence belies 3Shape's attempt to import narrowing limitations. As an initial matter, the asserted claims require that "color image data" collected via illumination relate to "the portion associated with the reference array" identified in the "optical scanner" limitation, not that light illuminate "the 3D structure," as 3Shape asserted. (JXM-0003 ('538 patent), cl. 1.). Additionally, disclosed embodiments of the sequential color illumination category associated with the "imaging means" do not require "three

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
				or more different colored illuminations," as 3Shape contended. While the specification does describe forming a color image from three or more monochromatic light sources, there is no requirement that the "imaging means" provide all three light sources. (*Id.* at 26:35-40.). Instead, the specification of the '538 patent discloses an embodiment in which the "imaging means" sequentially illuminates with only two different colored illuminations while the "optical scanner" provides a third colored illumination. (*Id.* at 6:49-53 ("[t]he color illumination means may comprise second illumination means for providing two said second illuminating radiations, and wherein said first illumination means provides another said second illuminating radiation each said second illuminating radiation being of a different color.").). Thus, 3Shape's construction is rejected in this regard for failing to include a disclosed embodiment. *See Oatley Co. v. IPS Corp.*, 514 F.3d 1271, 1276 (Fed. Cir. 2008) ("We normally do not interpret claim terms in a way that excludes embodiments disclosed in the specification."). Next, disclosed embodiments of the white light illumination category associated with "imaging means" do not require that the white light source

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
				be "separate from and in addition to the light source of the optical scanner," as 3Shape contended. (*Id.*). The '538 patent discloses an embodiment that uses white light illumination for collecting both depth data by the "optical scanner" and color image data by the "imaging means." (*See, e.g.*, JXM-0003 ('538 patent) at 24:33-47 (describing the illumination source 31 of device 100 as "white light illumination means" that may be used to "in order to provide the 3D surface topology data.").). Thus, 3Shape's construction is rejected in this regard for failing to include a disclosed embodiment. *See Oatley Co. v. IPS Corp.*, 514 F.3d 1271, 1276 (Fed. Cir. 2008) ("We normally do not interpret claim terms in a way that excludes embodiments disclosed in the specification."). Finally, 3Shape asserted that the required structure included "optics." (ROMBr. at 66.). While Align omitted this term from its construction, it appears that the corresponding structure cited by Align invariably included optics. (JXM-0003 ('538 patent) at 13:35-38 ("The second illumination means may comprise radiation transmission elements that are configured to be located out of the path of said light beams or said returned light beam at least

Claim Terms to Be Construed	**Align's Proposed Construction**	**3Shape's Proposed Construction**	**Adopted Construction**	**Support for Construction**
				within said light focusing *optics*.") (emphasis added), 16:41-47, 23:49-58, 24:48-52 ("In each of the embodiments described herein, the illumination radiation that is used for obtaining the 2D color image is injected into the optical axis OA of the confocal *optics* 42 without affecting the operation thereof or degrading the 3D image capture.") (emphasis added).). Thus, optics is included as a structural requirement in the adopted construction. For the reasons explained above, Align's construction is adopted with the addition of "optics" as required structure.
"wherein the device is configured for maintaining a spatial disposition with respect to the portion that is substantially fixed during operation of the optical scanner and the imaging means"	Plain and ordinary meaning, which is "a movable device where the operation by the optical scanner and the imaging means is at least substantially or effectively simultaneous such that movement (*i.e.*, a change in spatial disposition) can be	"wherein the device is configured for maintaining a spatial disposition with respect to the portion that is substantially fixed during the separate operations of the optical scanner and the imaging means"	"operation by the optical scanner and the imaging means is at least substantially or effectively simultaneous such that movement (*i.e.*, a change in spatial disposition) can be ignored and depth data and color data correspond to the	Align asserted that the plain and ordinary meaning of this term requires a limitation that the device is "movable" along with a clarification that the operation of the "optical scanner" and "imagine means" is "at least substantially or effectively simultaneous." (COMBr. at 56.). By contrast, 3Shape's construction consisted of a nearly verbatim recitation of the claim term modified slightly to require separate operation of "the optical scanner and the imaging means." (ROMBr. at 71-72.). For the reasons stated below, the adopted construction incorporates much of

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
	ignored and depth data and color data correspond to the same reference array"		same reference array"	Align's construction while rejecting the separateness argument in 3Shape's construction. As mentioned above in the context of "optical scanner," 3Shape is mistaken that "[t]he specification describes that there is a short time interval between the operation of the optical scanner to obtain depth data and the imaging means to obtain 2D color image data." (*Id.* at 72.). The specification provides examples of concurrent operation of the "optical scanner" and "imaging means." (JXM-0003 ('538 patent) at 21:55-57 ("a set of [color] images is taken concurrently with or alternately with the depth scan"), 21:46-47 ("Advantageously, one or more color scans may also be taken during the depth scan").). Such a concurrent operation undermines any attempt by 3Shape to inject a required separateness (e.g., non-zero period of time or, stated another way, in seriatim and not simultaneous) with respect to the operation of the "optical scanner" and "imaging means." The plain and ordinary meaning of the claim term in dispute is that the device would experience little or no movement during the operation of the "optical scanner" and "imaging means." However, in the specification, the

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				patentee explained that the meaning of the term in dispute is related to, but a bit different from, the plain and ordinary meaning. *See Bell Atl. Network Services, Inc. v. Covad Commc'ns Group, Inc.*, 262 F.3d 1258, 1269 (Fed. Cir. 2001) ("[T]he patentee may act as his own lexicographer by using the specification to define terms either expressly or by implication."); *Phillips*, 415 F.3d at 1316 ("[T]he specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs."). The patentee explained: "operation of the scanning means and the imaging means is *substantially or effectively simultaneous* in practical terms, and thus the actual time interval that may exist between operation of the two means is so short that the amplitude of any mechanical vibration of the device or movement of the oral cavity will be so small as can be ignored." (JXM-0003 ('538 patent) at 4:61-5:3 (emphasis added); *see also id.* at 8:56-65 (explaining that the spatial disposition with respect to the scanned tooth is substantially fixed with respect to the capturing of the depth

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
				data and the two-dimensional image data); *id.* at 13:33-38 (same).). This definition is clear. It is also sufficiently broad such that the "optical scanner" and "imaging means" can operate concurrently or separated by a small duration of time. The '538 patent also provides examples of specific time intervals that qualify as "effectively simultaneous," such as "about 0 seconds to about 100 milliseconds, for example 5, 10, 20, 30, 40, 50, 60, 70; 80, 90 or 100 milliseconds, and preferably between about 0 to about 50 milliseconds, and more preferably between about 0 and 20 milliseconds." (*Id.* at 5:7-12; see also id. at 16:46-51 (same).). "[M]aintaining a spatial disposition with respect to the portion that is substantially fixed during operation" serves the important purpose of facilitating the combination of the depth and color data corresponding to or associated with a "two-dimensional reference array" of x-y coordinates. (*See id.* at 13:49-57 (explaining that the three-dimensional information and the two-dimensional information are obtained almost simultaneously so the coordinates of the three dimensional and two-dimensional

Claim Terms to Be Construed	**Align's Proposed Construction**	**3Shape's Proposed Construction**	**Adopted Construction**	**Support for Construction**
				information represent the same part of the tooth); *id.* at 3:58-4:11 (same); 13:20-25 (same); 25:11-23 (so long as "the same frames of references are maintained" when capturing the three-dimensional scan and the two-dimensional scan, then "color values at particular x, y coordinates of the 2D color image" can be "matched to the same x, y coordinates of the 3D images which also have a z coordinate."). Based on the explanation provided above, most of Align's construction is adopted. However, this construction explicitly rejects and we decline to import a limitation that the device is "movable." While the specification speaks of "relative movement between the device and the intra oral cavity," it appears that none of the intrinsic evidence characterizes the claimed device alone as "movable." (*Id.* at 10:53-54.). Further, Align provides no explanation for why the limitation is necessary other than by citing to extrinsic evidence. (CRMBr. at 31 ("One of ordinary skill would understand that the phrase depth data relates to data indicating depth in three dimensional space, and the phrase optical scanner includes a scanner, with the terms collectively referring to a movable 3D scanner in the context of the preamble and the

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				specification of the patent. (CXM-0036 (Stevenson Declaration) at ¶¶ 15-18.").).
"confocal imaging techniques"	Plain and ordinary meaning, which is "a technique that uses an optical scanner with the illumination and detection paths sharing the same focus"	"techniques that use point illumination and point detection"	"imaging techniques characterized by illumination and detection paths with conjugate focal planes"	Align's proposed construction remains true to the meaning of "confocal," sharing a common focus, but also imported an "optical scanner" limitation. (CRMBr. at 46.). 3Shape's proposed construction, on the other hand, tethered "confocal" not to the sharing of a common focus, but instead to point illumination and detection. (RRMBr. at 35.). Faced with limited intrinsic evidence, both constructions draw support from the extrinsic record. For the reasons set forth below, Align's proposed construction is adopted, in-part, while 3Shape's proposed construction is rejected. By way of background, dependent claim 2 contains the claim term in question: "The device according to claim 1, wherein the operation of the optical scanner is based on *confocal imaging techniques*." (JXM-0003 ('538 patent), cl. 2 (emphasis added).). Unfortunately, the intrinsic evidence does not explicitly define "confocal imaging techniques" or even "confocal." Based on the structure of the word "con-focal," which combines the

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				prefix "con" with the root "focal," it is clear that the term refers to a common or shared focus of some kind. (*See, e.g.*, CXM-0024 (Dictionary of Computer Vision and Image Processing, 2nd Ed.) ("confocal: In optics, two lens that share the same focal plane or focal point (i.e., co-incident focal)"); *see also* CXM-0026 (Dictionary of Science and Technology) at 497 ("confocal: Mathematics. having the same focus or foci").). Align's construction reflects this; 3Shape's construction does not. Importantly, nothing in the specification of the '538 patent explicitly restricts confocal imaging techniques to point illumination/detection.[6] The specification does disclose using relatively

[6] Align made a similar but a more narrow point that "nothing in the specification restricts the confocal imaging techniques to a *single* point of illumination, yet 3Shape's proposed construction mandates such a restriction." (COMBr. at 61 ("The patent specification also discloses one embodiment that uses a grating or microlens array to form an array of spots on an object and an arrayed image sensor to detect the returning light, which is not a *single* point illumination and point detection.") (emphasis added), 63 ("As such, the specification of the '538 patent provides examples of confocal imaging arrangements which are not restricted by the user of pinholes nor the use of a *single* point of illumination or detection, in direct contradiction of 3Shape's claim construction.") (emphasis added); CRMBr. at 47 ("Beyond this, nothing in the specification restricts the confocal imaging techniques to a *single* point of illumination, yet 3Shape's proposed construction mandates such a restriction. ... 3Shape's proposed construction is incorrect because nothing in the specification limits confocal imaging techniques to a *single* point of detection.") (emphasis added).). However, in response, 3Shape clarified that its proposed construction covered 'techniques that use [multiple] point illumination and point detection' – not 'single point illumination' or 'single point detection.' Rather, confocal systems often have arrays of pinholes for illumination and detection." (RRMBr. at 39.). In other words, Align's "*single* point of illumination" critique of 3Shape's construction appears to be moot.

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				narrow apertures for obtaining 3D depth data as compared to 2D color data. (JXM-0003 ('538 patent) at 9:49-52 ("Preferably, the illumination sources are configured to have a relatively low numerical aperture compared with that of the first array of light beams.").). As the '538 patent explains, using narrow apertures results in more accurate scanning. (*Id.* at 20:8-11 ("the numerical aperture of the confocal system itself is relatively high to maximize accuracy of the depth measurements, and thus provides a relatively narrower depth of field.").). However, a disclosed preference for narrow apertures is not an express requirement. In certain embodiments, the specification refers to the use of illuminated "spots" to collect 3D depth data. (*See, e.g.*, 2:67-3:12, 14:65-15:5 ("The aperture in the mirror 40 improves the measurement accuracy of the apparatus. As a result of this mirror structure the light beams will yield a light annulus on the illuminated area of the imaged object as long as the area is not in focus; and the annulus will turn into a completely illuminated spot once in focus. This will ensure that a difference between the measured intensity when out-of- and in-focus

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				will be larger").). In its argument, 3Shape equates "spots" and "points." (RRMBr. at 36 ("In particular, confocal imaging uses point (spot) illumination, which is achieved by illuminating an object through a pinhole located at a focal plane and detecting the illumination point through a pinhole located at a focal plane and detecting the illumination point through a pinhole located at a focal plane.").). However, the specification explicitly uses the term "point(s)" only in the context of array coordinates associated with 3D depth and 2D color data, not specific techniques used to obtain 3D depth data. (*See, e.g.*, Abstract ("a scanner for providing depth data for points along a two-dimensional array … and an image acquisition means for providing color data for each of the points of the array").). In support of 3Shape's proposed construction, the specification of the '538 patent appears to describe an embodiment with point detection. In particular, the specification describes light returning from "spots" and passing through a "pinhole array" en route to an image sensor. (*Id.* at 15:51-65 ("The returned polarized light beam 54 pass through … a matrix 66

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				comprising an array of pinholes. CCD camera has a matrix or sensing elements each representing a pixel of the image and each one corresponding to one pinhole in the array").). Based on disclosures such as these, 3Shape stated that a "person of ordinary skill in the art would understand the claimed "confocal imaging technique" to refer to a technique that uses point illumination *and* point detection." (ROMBr. at 75 (emphasis added).). However, according to Align, 3Shape's point illumination/ detection restriction on "confocal imaging techniques" excludes disclosed embodiments within the '538 patent. (COMBr. at 62.). For example, the specification purportedly teaches using "a grating or microlens array—not point illumination—to form an array of illumination beams." (CRMBr. at 47 (citing JXM-0003 ('538 patent) at 5:49-52).). Moreover, the use of pinholes, in the context of "sensing elements," appears to be optional. (JXM-0003 ('538 patent) at 6:5-9 ("Typically, the sensing elements are an array of charge coupled devices (CCD). The detector unit *may* comprise a pinhole array, each pinhole corresponding to one of the CCDs in the CCD array.").).

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				In rebuttal, citing only extrinsic evidence in the form of an expert declaration, 3Shape asserted that "all of the examples cited by Align as using a grating or microlens array in place of pinholes are still using the grating, microlens array, or other structures as spatial filters that *perform the same function of* pinholes, namely to filter out unwanted light." (RRMBr. at 39 (citing RXM-0029 (Zavislan Rebuttal Decl.) at ¶ 27) (emphasis added).). Yet, what 3Shape did not say is that the '538 patent's "array of illumination beams" embodiment necessarily satisfies 3Shape's criteria for "confocal imaging techniques," namely "point illumination *and* point detection." This appears to be a key admission by omission. Consequently, it appears that adopting 3Shape's construction would amount to importing point illumination *and* detection (and by association, "pinholes") into the term "confocal imaging techniques," without a clear justification in the intrinsic evidence to do so. This would run contrary to the teachings of the specification, which appears to disclose a system flexible enough to perform 3D depth scanning using

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				varying imaging techniques, with a declared preference for confocal imaging using narrow aperture scanning to increase accuracy. (JXM-0003 ('538 patent) at 9:49-52.). Align's WO 00/08415 application, referenced in the '538 specification, appears to support this conclusion that 3Shape is attempting impermissibly to restrict the scope of asserted claims to certain disclosed embodiments. In that application, independent claim 1 recites "a plurality of illuminated spots." (CXM-0033 (WO 00/08415 application) at 17.). However, "detector unit comprises a pinhole array" appears only in a dependent claim. (*Id.* at 21.). In 3Shape's favor, the extrinsic evidence does appear to link "confocal" and point illumination / detection via a discussion of "high-numerical-aperture," at least in the context of confocal microscopy. A technical book 3Shape cites that compares and contrasts a standard optical microscope and a CSOM (confocal scanning optical microscope) states that "[b]oth instruments *can use* a high-numerical-aperture lens to illuminate and image the sample; thus both microscopes fit the definition of confocal,

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				two lenses sharing a common focus."[7] (RXM-0015 (Excerpts from Corle, Timothy R. and Gordon S. Kino, "Confocal Scanning Optical Microscopy and Related Imaging Systems" (1996)) at 14.) (emphasis added).). However, "can use" is not "must use." Also, the link drawn by this reference between point illumination/detection and "confocal" is tenuous because the reference separately makes clear that a confocal scanning microscope using "point illumination" and "point detection" is not synonymous with "a confocal lens system." (*Id.*). "Strictly speaking," both a confocal scanning microscope and conventional microscope are considered "confocal." (*Id.*). However, the former appears distinct from the

[7] This is reflected in an Initial Determination on Violation issued in 337-TA-1091, which construed "confocal imaging techniques" in the context of a continuation patent in the same family as the '538 patent. (*Certain Color Intraoral Scanners and Related Hardware and Software*, Inv. No. 337-TA-1091, Initial Determination, Doc. ID No. 668859 (Mar. 1, 2019).). There, Judge Cheney found, based on extrinsic evidence, that "a 'confocal imaging' system requires conjugal focal planes as well as point illumination, imaging, and detection." (*Id.* at 47.). This *Markman* Order agrees with the 1091 ID that "the specification makes it clear that the use of point illumination, imaging, and detection is consistent with confocal imaging, but it is not clear from the specification that those elements are required." (*Id.* at 41-42.). Yet, based mostly on intrinsic evidence, this *Markman* Order respectfully departs from the 1091 ID's finding that "[c]onjugate focal planes on their own, however, are not sufficient to define a 'confocal imaging' technique or system within the context of the color scanner patents." (*Id.* at 45.). For the reasons set forth above this *Markman* Order finds that "[c]onjugate focal planes" are sufficient. It should be noted that the 1091 ID is on appeal with the Commission. Since Judge Cheney's *Markman* construction of "confocal imaging techniques" has been appealed, the Commission's decision, which is due shortly, may affect the construction adopted in this Order.

Claim Terms to Be Construed	Align's Proposed Construction	3Shape's Proposed Construction	Adopted Construction	Support for Construction
				latter insofar as the former is characterized by pinhole illumination and detection: "(CSOM) differs from a conventional optical microscope in that it illuminates and images the object one point at a time through a pinhole[.]" (*Id.* at 12.). Consequently, it appears that 3Shape falls short in its attempt to equate point illumination / detection with "confocal imaging" as used in the '538 patent. The above-mentioned technical book does describe "confocal microscope" as a synonym for CSOM, but this disclosure (much like most of 3Shape's extrinsic evidence) is of little relevance here because the '538 patent is directed to confocal imaging in general, not confocal microscopy. (RXM-0015 (Excerpts from Corle, Timothy R. and Gordon S. Kino, "Confocal Scanning Optical Microscopy and Related Imaging Systems" (1996)) at 6; RXM-0014 (Excerpts from Wilson, T., "Confocal Microscopy" (1990)) at 8.). Moreover, at least one piece of extrinsic evidence identified by Align appears to disclose an "alternative confocal arrangement" that does "not require point illumination or detection (since, for example, projection and detection of

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				parallel stripes, which are alternatively clear and opaque, might be used.)." (CXM-0032 (Declaration of Robert Stevenson) ¶ 61 (citing CXM-0028 (U.S. Patent No. 5,381,236) at 5:9-12).). While 3Shape provided extrinsic evidence that this "alternative confocal arrangement[]" still "required spatial filters that *perform the same function of pinholes*, namely to filter out unwanted light," this evidence did not demonstrate that the "arrangement[]" satisfied 3Shape's criteria for "confocal imaging techniques," namely "point illumination *and* point detection." (RXM-0029 (Declaration of James Zavislan) ¶ 27 (emphasis added).). Finally, Align's proposed construction includes "an optical scanner." This appears redundant. *See MEMS*, 447 F. App'x at 151 (constructions which introduce redundancy are "disfavored"). The term under construction, "confocal imaging techniques," appears in claim 2 of the '538 patent. As Align acknowledged, "[t]he express (and sole) requirement of claim 2 is that "the operation of the optical scanner [required in claim 1] is based on confocal imaging techniques." (COMBr. at 45; cl. 2.). In other words, based on the express language of claim

Claim Terms to Be Construed	**Align's Proposed Construction**	**3Shape's Proposed Construction**	**Adopted Construction**	**Support for Construction**
				2, "there can be little doubt that the claimed confocal imaging technique uses an optical scanner[.]" (*Id.* at 59.). Thus, to avoid redundancy, the adopted construction does not include "an optical scanner." The adopted construction is "imaging techniques characterized by illumination and detection paths with conjugate focal planes." This construction departs from Align's construction only to remove a redundant "optical scanner" requirement and to clarify what Align means by "the same focus."

CERTAIN DENTAL AND ORTHODONTIC SCANNERS AND SOFTWARE **Inv. No. 337-TA-1144**

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **ORDER** has been served upon the following parties as indicated, on **October 1, 2019**.

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U.S. International Trade Commission
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