

*In the Matter of*

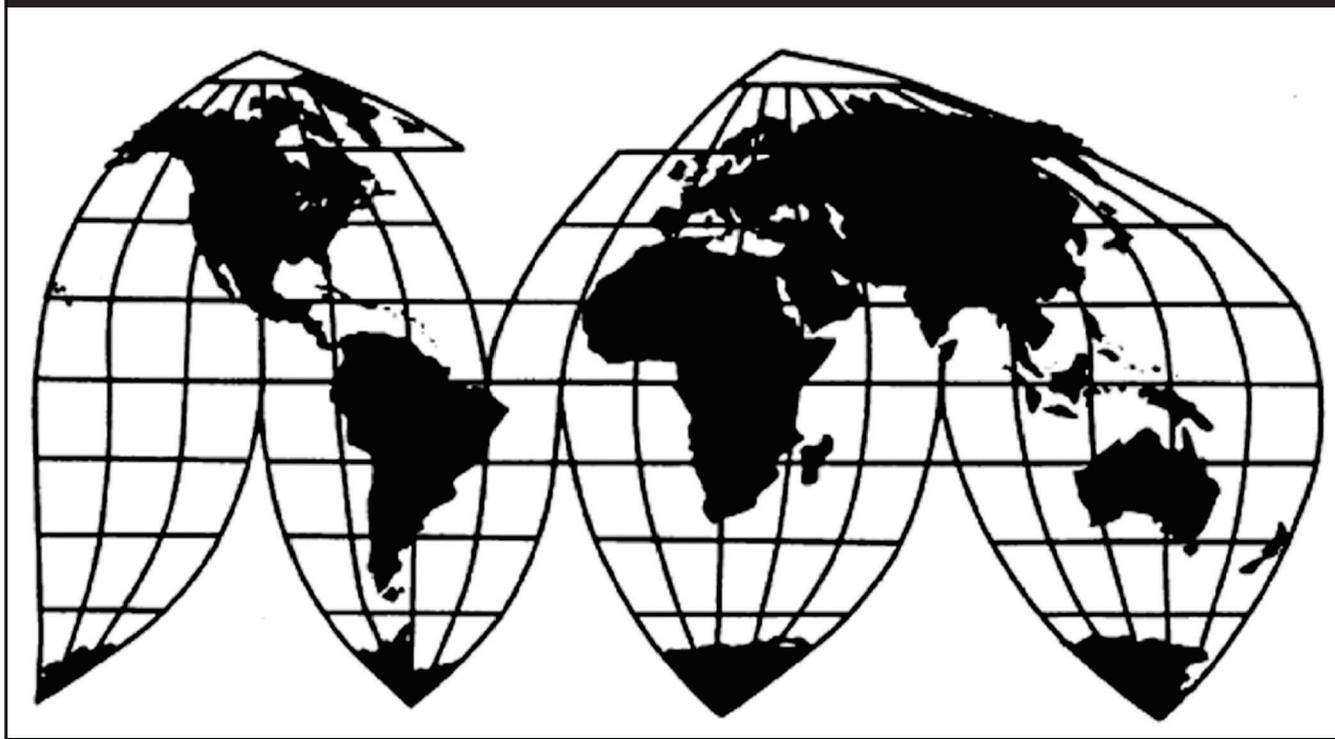
**CERTAIN COLOR INTRAORAL SCANNERS  
AND RELATED HARDWARE AND  
SOFTWARE**

337-TA-1091

Publication 5076

June 2020

**U.S. International Trade Commission**



Washington, DC 20436

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

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United States International Trade Commission  
Washington, DC 20436**

# U.S. International Trade Commission

Washington, DC 20436  
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## **CERTAIN COLOR INTRAORAL SCANNERS AND RELATED HARDWARE AND SOFTWARE**

337-TA-1091



**UNITED STATES INTERNATIONAL TRADE COMMISSION**  
**Washington, D.C.**

**In the Matter of**

**CERTAIN COLOR INTRAORAL SCANNERS  
AND RELATED HARDWARE AND  
SOFTWARE**

**Investigation No. 337-TA-1091**

**NOTICE OF A COMMISSION 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 determined to affirm, with modified reasoning, the final initial determination's ("ID") finding of no violation of section 337 has occurred.

**FOR FURTHER INFORMATION CONTACT:** Amanda Pitcher Fisherow, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW, Washington, D.C. 20436, telephone (202) 205-2737. 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, SW, Washington, D.C. 20436, telephone (202) 205-2000. General information concerning the Commission may also be obtained by accessing its Internet server at <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 the underlying investigation on December 20, 2017, based on a complaint filed on behalf of Align Technology, Inc. of San Jose, California ("Align"). 82 FR (Dec. 20, 2017). 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 color intraoral scanners and related hardware and software by reason of infringement of certain claims of U.S. Patent Nos. 8,363,228 ("the '228 patent"); 8,451,456 ("the '456 patent"); 8,675,207 ("the '207 patent"); 9,101,433 ("the '433 patent"); 9,48,931 ("the '931 patent"); and 6,685,470 ("the '470 patent"). *See id.* The

complaint named 3Shape A/S and 3Shape Inc. as the respondents. On March 15, 2018, the ALJ granted Align's unopposed motion to amend the complaint and notice of investigation to add as an additional respondent in this investigation 3Shape Trios A/S of Copenhagen, Denmark (respondents are collectively referred to as "3Shape"). See 83 FR 13781-82 (March 30, 2018), *unreviewed*, Notice (March 27, 2018). The Office of Unfair Import Investigations did not participate in the investigation.

On March 1, 2019, the ALJ issued his final ID finding that no violation of section 337 has occurred. On March 18, 2019, Align filed a petition for review and 3Shape filed a contingent petition for review of the ID. On March 26, 2019, all of the parties filed responses to the respective petitions for review.

On July 18, 2019, the Commission determined to review the final ID in part. Specifically, the Commission determined to review the ID's findings on the following issues: (1) importation; (2) the construction of "processor"; (3) the construction of "confocal imaging techniques"; (4) all findings concerning infringement; (5) all findings concerning invalidity; (6) all findings concerning whether Align's products practice one or more claims of the asserted patents; and (7) all findings concerning whether Align's financial investments and activities relating to Align's products meet the domestic industry requirement. The Commission requested briefing on some of the issues under review, and requested submissions from the parties, government agencies and the public on remedy, bonding, and the public interest. 84 FR 35688 (July 25, 2019). On July 30, 2019, Align and 3Shape filed their written responses to the Commission's request for briefing. On August 6, 2019, Align and 3Shape filed their reply submissions.

The Commission has examined the record of this investigation, including the ALJ's final ID, the petitions for review, and the responses thereto, and filings in response to the Commission's request for briefing. The Commission affirms in part, with modified reasoning as discussed in the accompanying opinion, the ID's finding of no violation of section 337. Specifically, the Commission determines: (1) claim 1 of each of the '228, '456, and '207 patents is infringed; (2) claim 26 of the '228 patent is infringed; (4) claim 15 of the '456 patent is not infringed; (5) claim 12 of the '433 is not infringed; (6) the asserted claims of the '228 and '456 patents are invalid for failing to meet the written description requirement; (7) the '228, '456, and '433 patents are not invalid as anticipated or obvious; (8) the asserted claim of the '207 patent is invalid as obvious; (9) Align's products do not practice the '228, '456, and '207 patents; (10) Align's products practice claim 12 of the '433 patent; (11) the importation requirement is met for 3Shape Trios A/S; (12) to take no position on whether 3Shape A/S and 3Shape Inc. have met the importation requirement; (13) to take no position on whether claim 4 of the '228 patent is infringed; (14) to take no position on secondary considerations for the '228, '456, and '433 patents; and (15) to take no position on whether Align's investments and activities relating to Align's products meet the domestic industry requirement. The Commission also affirms, without modification, the ID's finding of no violation for the '931 and '470 patents. The investigation is terminated.

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

By order of the Commission.

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

Lisa R. Barton  
Secretary to the Commission

Issued: November 22, 2019

**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 22, 2019**.



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.:**

Blair M. Jacobs, Esq.  
**PAUL HASTINGS LLP**  
875 15<sup>th</sup> Street, NW  
Washington, DC 20005

- Via Hand Delivery  
 Via Express Delivery  
 Via First Class Mail  
 Other: \_\_\_\_\_

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

Goutam Patnaik, Esq.  
**PEPPER HAMILTON LLP**  
200 K Street, NW, Suite 600  
Washington, DC 20006

- Via Hand Delivery  
 Via Express Delivery  
 Via First Class Mail  
 Other: \_\_\_\_\_

**In the Matter of**

**CERTAIN COLOR INTRAORAL SCANNERS  
AND RELATED HARDWARE AND  
SOFTWARE**

**Investigation No. 337-TA-1091**

## **COMMISSION OPINION**

### **I. INTRODUCTION**

On March 1, 2019, the presiding administrative law judge (“ALJ”) (Judge Cheney) issued his final initial determination (“ID”) in this investigation, finding no violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 (“section 337”), with respect to U.S. Patent Nos. 8,363,228 (“the ’228 patent”); 8,451,456 (“the ’456 patent”); 8,675,207 (“the ’207 patent”); 9,101,433 (“the ’433 patent”); 6,948,931 (“the ’931 patent”); and 6,685,470 (“the ’470 patent”) by respondents, 3Shape A/S of Copenhagen, Denmark; 3Shape Inc. of Warren, New Jersey; and 3Shape Trios A/S of Copenhagen, Denmark (collectively, “3Shape” or “Respondents”). *See* ID at 6, 7-8, 146-48. On July 18, 2019, the Commission determined to review the ID in part and requested briefing from the parties on some of the issues under review and on remedy, bonding, and the public interest. The Commission affirms the ID’s determination that no violation of section 337 has occurred, on modified grounds as discussed herein. The Commission adopts the ID’s findings on importation as to respondent 3Shape Trios A/S, infringement of claim 26 of the ’228 patent, non-infringement of dependent claim 15 of the ’456 patent, non-infringement of claim 12 of the ’433 patent, indirect infringement, invalidly

based on anticipation and/or obviousness (various references) of the '228, '456, '433 and '207<sup>1</sup> patents, indefiniteness of the '207 patent, non-infringement by the monochromatic scanning systems, and the technical prong of domestic industry for the '433 patent without further discussion. The Commission takes no position on whether 3Shape A/S and 3Shape Inc. have met the importation requirement, dependent claim 4 of the '228 patent is infringed, secondary considerations for the '228, '456, and '433 patents, and the economic prong of domestic industry. The Commission further adopts the findings in the ID that are not inconsistent with this opinion.

## II. PROCEDURAL HISTORY

The Commission instituted the underlying investigation on December 20, 2017, based on a complaint filed on behalf of Align Technology, Inc. of San Jose, California ("Align" or "Complainant"). 82 *Fed. Reg.* 60418 (Dec. 20, 2017). 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 color intraoral scanners and related hardware and software by reason of infringement of certain claims of the '228 patent, the '456 patent, the '207 patent, the '433 patent, the '931 patent, and the '470 patent. *See id.* at 60418-19. The complaint named 3Shape A/S and 3Shape Inc. as the respondents. On March 15, 2018, the ALJ granted Align's unopposed motion to amend the complaint and notice of investigation to add 3Shape Trios A/S as an additional respondent in this investigation. Order No. 11; *see also* 83 *Fed. Reg.* 13781-82 (March 30, 2018). On July 10, 2018, the ALJ granted Align's motion for partial termination of the investigation as to claim 7 of the '456 patent; claims 1-4, 7 and 10 of

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<sup>1</sup> The Commission addresses the parties' arguments in their petitions for review of the ID's findings as to secondary considerations for the '207 patent in Part IV.E. herein.

the '433 patent; claims 4-12 of the '470 patent; and claims 4-12 of the '931 patent. Order No. 27, (July 10, 2018), *unreviewed* Notice (Aug. 6, 2018). The Office of Unfair Import Investigations did not participate in the investigation.

The ALJ held an evidentiary hearing on September 17-21, 2018.

On March 1, 2019, the ALJ issued his final ID finding no violation. The ID's findings are summarized in the chart below:

<b>Summary of the ID's Findings</b>			
<b>Patent</b>	<b>Infringed</b>	<b>Invalid</b>	<b>Technical Prong Met</b>
'228 Patent	Yes	Yes (Written Description)	No
'456 Patent	Yes	Yes (Written Description)	No
'207 Patent	Yes	Yes (Obvious)	No
'433 Patent	No	No	Yes

ID at 146-49. In addition, the ID found that the economic prong of the domestic industry was met. *Id.* The ALJ also found no violation with respect to the '931 and '470 patents because they were set to expire before the original target date of the investigation, which has now past. *Id.* at 148.

On March 18, 2019, Align filed a petition for review and 3Shape filed a contingent petition for review of the ID.<sup>2</sup> On March 26, 2019, the parties filed responses to the respective petitions for review.<sup>3</sup>

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<sup>2</sup> Complainant Align Technology, Inc.'s Petition for Review of the Initial Determination ("Align Pet."); and Respondents 3Shape A/S, 3Shape Trios A/S, and 3Shape Inc.'s Contingent Petition for Review ("3Shape Pet.").

<sup>3</sup> Complainant Align Technology, Inc.'s Response to Respondents' Contingent Petition for Review ("Align Resp."); Respondents 3Shape A/S, 3Shape Trios A/S, and 3Shape Inc.'s Response to Align Technology Inc.'s Petition for Review of Initial Determination ("3Shape Resp.").

On July 18, 2019, the Commission determined to review the ID in part. Specifically, the Commission determined to review (1) importation; (2) the construction of “processor;” (3) the construction of “confocal imaging techniques;” (4) all findings concerning infringement; (5) all findings concerning invalidity; (6) all findings concerning whether Align’s products practice one or more claims of the asserted patents; and (7) all findings concerning whether Align’s financial investments and activities relating to Align’s products meet the domestic industry requirement. 84 FR 35688 (July 24, 2019). The Commission asked the parties to address questions related to the construction of the term “processor,” infringement, and domestic industry, and requested briefing from the parties, government agencies, and the public on remedy, bonding, and public interest. *Id.* The parties did not petition for review of the ID’s finding of no violation of the ’931 and ’470 patents and the Commission determined not review the ID’s termination from the investigation the ’931 and ’470 patents. *See id.*

On July 30, 2019, Align and 3Shape filed their written responses to the Commission’s request for briefing.<sup>4</sup> On August 6, 2019, Align and 3Shape filed their reply submissions.<sup>5</sup>

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<sup>4</sup> Complainant Align Technology, Inc.’s Written Submission in Response to the Commission’s Determination to Review-In-Part the Final Initial Determination (“Align Br.”); and Respondents 3Shape A/S, 3Shape Trios A/S, and 3Shape Inc.’s Initial Written Submission In Response to the Commission’s Determination to Review In-Part the Final Initial Determination (“3Shape Br.”).

<sup>5</sup> Complainant Align Technology, Inc.’s Written Submission in Reply to the Commission’s Determination to Review-In-Part the Final Initial Determination (“Align Resp. Br.”); and Respondents 3Shape A/S, 3Shape Trios A/S, and 3Shape Inc.’s Response to Complainant Align Technology, Inc.’s Written Submission In Response to the Commission’s Determination to Review In-Part the Final Initial Determination (“3Shape Resp. Br.”).

### **III. BACKGROUND**

#### **A. The Asserted Patents**

Align asserts two categories of patents in this investigation: (1) the color scanner patents (the '228, '456, '207, and '433 patents) and (2) the gingival deformation patents (the '931 and '470 patents). The Commission determined not to review the termination of the gingival deformation patents by the ALJ, so we do not address these patents herein.

All of the color scanner patents are directed to systems or methods for creating a color image of a three-dimensional structure, particularly by combining color and depth data to provide a three-dimensional color model. *See, e.g.,* JX-0003 at Abstract. The color scanner patents share identical specifications and claim priority to the same parent application. There is also substantial overlap in the asserted claims of three of these patents, *i.e.*, the '228 patent, the '456 patent, and the '207 patent.

Generally, the asserted claims of the '228 patent are apparatus claims directed to a system for determining the surface topology and associated color of a three-dimensional structure. *See* JX-0003 at claims 1, 4, 26. The asserted claims of the '456 patent are substantially similar apparatus claims that include language specifying that the three-dimensional structure is a “dental structure.” *See* JX-0004 at claims 1, 15. The asserted claim of the '207 patent is a method claim that describes a method for determining the surface topology and associated color of a three-dimensional dental structure by using the apparatus described in the asserted claims of the '456 patent. *See* JX-0005 at claim 1.

Align asserts independent claim 1 and dependent claims 4 and 26 of the '228 patent.

Independent claim 1 recites:

[P]<sup>6</sup> 1. A system for determining the surface topology and associated color of at least a portion of a three dimensional structure, comprising:

[1] a hand-held device comprising:

[2] (a) a scanning system configured to provide depth data of said portion, the depth data corresponding to a plurality of data points defined on a plane substantially orthogonal to a depth direction;

[3] (b) an imaging system configured to provide two-dimensional color image data of said portion associated with said plurality of data points; and

[4] (c) a processor configured to associate the depth data with the color image data.

Align asserts independent claim 1 and dependent claim 15 of the '456 patent.

Independent claim 1 recites:

[P] 1. A system for determining the surface topology and associated color of at least a portion of a three-dimensional dental structure, comprising:

[1] a hand-held device comprising:

[2] (a) a scanning system configured to provide depth data of said portion, the depth data corresponding to a plurality of data points defined on a plane substantially orthogonal to a depth direction;

[3] (b) an imaging system configured to provide two-dimensional color image data of said portion associated with said plurality of data points; and

[4] (c) a processor configured to associate the depth data with the color image data, wherein the depth data and the color image data represent the surface topology and the color of the portion of the three-dimensional dental structure.

Align asserts independent claim 1 of the '207 patent, which recites:

[P] 1. A method for determining the surface topology and associated color of at least a portion of a three-dimensional dental structure, comprising:

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<sup>6</sup> The ID uses the labeling added herein. We use this labeling for consistency and add it to the claims which the ID does not reproduce in full.

[1] providing a hand-held device comprising:

[2] (a) a scanning system configured to provide depth data of said portion, the depth data corresponding to a plurality of data points defined on a plane substantially orthogonal to a depth direction;

[3] (b) an imaging system configured to provide two-dimensional color image data of said portion associated with said plurality of data points; and

[4] (c) a processor configured to associate the depth data with the color image data, wherein the depth data and the color image data represent the surface topology and the color of the portion of the three-dimensional dental structure.

[5] operating the hand-held device.

The asserted claim of the '433 patent is also an apparatus claim directed to a system for determining the surface topology and associated color of a three-dimensional structure. *See* JX-0006 at claim 12. The elements of the system recited in the asserted claim of the '433 patent are distinct from those recited in the asserted claims of the other three color scanner patents.

*Compare* JX-0006 at claim 12 *with* JX-0003 at claims 1, 4, 26; JX-0004 at claims 1, 15; *and* JX-0005 at claim 1. Align asserts independent claim 12 of the '433 patent, which recites:

[P] 12. A system for determining surface topology and associated color of at least a portion of a three-dimensional structure, the system comprising:

[1] an apparatus comprising an image gathering member to generate depth data of the structure portion corresponding to a two-dimensional reference array substantially orthogonal to a depth direction; and

[2] one or more processors configured to cause the system to at least:

[3] receive, from the apparatus, the depth data of the structure portion corresponding to the two-dimensional reference array substantially orthogonal to a depth direction;

[4] receive, from the apparatus, two-dimensional image data of the structure portion associated with the two-dimensional reference array for each of a plurality of focal lengths relative to the image gathering member; and

[5] selectively map the image data to the depth data for the two-dimensional reference array based on the plurality of focal lengths and the depth data such that the resulting associated color of the structure portion is in focus relative to the structure portion for a plurality of distances in the depth direction.

**B. The Accused Products**

Align defines the accused products as Respondents' "TRIOS3 and Accused Software Products."<sup>7</sup> ID at 14. Align defines "Accused Software Products" as "Respondents' Ortho and Dental System software." *Id.* In addition, Align defines "TRIOS3" as "Respondents' TRIOS3 scanners identified at JX-0265C at 7-8." *Id.* Align accuses the Trios scanners of infringing the color scanner patents, and the Accused Software Products of infringing the gingival deformation patents. *Id.* We note that the Trios scanners come in both color and monochrome versions. Because the ID terminated the investigation with respect to the gingival deformation patents (and the Commission did not review these findings), the Trios scanners are the only remaining accused products in this investigation. *Id.* at 15.

**C. The Domestic Industry Products**

Align contends that its iTero Element<sup>8</sup> scanners practice the inventions claimed in the color scanner patents in satisfaction of the technical prong of the domestic industry requirement. *Id.* at 15.

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<sup>7</sup> We refer to the TRIOS 3 as "Trios" or the "accused products."

<sup>8</sup> We refer to the iTero Element as "iTero" or the "domestic industry products."

#### IV. THE COLOR SCANNER PATENTS<sup>9</sup>

##### A. The “Processor” Term: Construction and Written Description

The ID’s claim construction and written description findings for the term “processor” are intertwined; therefore, the Commission discusses both issues together below. The term “processor” appears in asserted claim 1 of the ’228, ’456, and ’207 patents, and claim 12 of the ’433 patent. The parties’ dispute regarding claim construction is only directed to the use of the term in the ’228, ’456, and ’207 patents, not the ’433 patent. The ID’s findings and Align’s corresponding petition on written description is only directed to the asserted claims of the ’228 and ’456 patents, not the ’207 or ’433 patents. The Commission determined to review the term “processor” and sought briefing from the parties, as summarized below.

##### 1. The ID

##### (a) Claim Construction of “Processor”

The ID explained that Align sought to give the term its plain and ordinary meaning, while 3Shape sought a means-plus-function construction under 35 U.S.C. § 112, ¶ 6 of the term “processor.” ID at 40. 3Shape also sought to include a requirement that the imaging system obtain 2D-color-image data separately from depth data obtained by the scanning system. *Id.*

The ID found that with respect to the means-plus-function dispute, the specification includes many examples of processors, “which strongly indicates that a person of ordinary skill in the art would understand ‘processor’ in the context of the asserted patents to connote a definite structure.” *Id.* (citing JX-0003 at 5:39, 8:42, 13:13; *Diebold Nixdorf, Inc. v. Int’l Trade Comm’n*, 899 F.3d 1291, 1298 (2018)).

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<sup>9</sup> Both parties proposed different levels of ordinary skill in the art and the ID found both proposals suitably indicative of the level of skill in the art. ID at 27-28. No party petitioned for review of these findings.

The ID explained that 3Shape relied on *Finisar Corp. v. DirecTV Grp., Inc.*, 523 F.3d 1323, 1340 (Fed. Cir. 2008), for the proposition that a processor “programmed” to associate data sets must necessarily be subject to 35 U.S.C. § 112, ¶ 6. *Id.* at 40. The ID determined that “*Finisar* is a case about indefiniteness of a term under § 112, ¶ 6; it did not establish a rule that a claim to a programmed processor is necessarily presumed to invoke § 112, ¶ 6. *Finisar* is inapposite to the question of when to apply § 112, ¶ 6 to a term that does not use the word ‘means.’” *Id.* at 41.

The ID concluded that in the absence of any evidence that a person of ordinary skill in the art would not understand the “processor” in claim 1 to connote a definite structure or class of structures, the presumption that § 112, ¶ 6 should not apply has not been overcome. *Id.* The ID construed “processor” to have its plain and ordinary meaning. *Id.*

While not in the section titled claim construction, the ID also repeatedly found that the processor must be included on the hand-held device for the claims of the '228, '456, and '207 patents. *See, e.g., id.* at 54 n.4 (infringement), 87-88 (obviousness). The ID addressed this issue in more detail in its discussion of written description. For example, the ID stated:

To avoid later confusion, I note that the processor of element [4] must be part of the hand-held device recited as element [1]. There has been some dispute among the parties about the relationship of the processor to the handheld device. To be clear, element [1], the hand-held device is comprised of elements [2]-[4]. That means the hand-held device must, at a minimum, have all three of those elements, including “a processor configured to associate the depth data with the color image data.” The hand-held device may have any number of other additional elements. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 811 (Fed. Cir. 1999).

*Id.* at 87 (written description).

**(b) Written Description**

The ID found that the asserted claims of the '228 and '456 patents are invalid for lack of written description. *Id.* at 97-104, 105. We address the ID's findings in the context of the '228 patent as the ID incorporated these findings for the '456 patent. *Id.* at 105.

The ID concluded that the phrase "a hand-held device comprising . . ." requires that the invention must have a hand-held device that is made-up of the components recited after the word "comprising." *Id.* at 98 (citing *Vivid*, 200 F.3d at 811). The ID explained that the device may be formed of additional components but it must have at least those that are explicitly recited. *Id.* The ID noted, with respect to claim 1 of the '228 patent, the preamble also uses the word "comprising" to describe the elements of a "system for determining the surface topology and associated color of at least a portion of a three dimensional structure," and therefore, the overall system of claim 1 may include additional elements beyond the hand-held device. *Id.* at 98-99. For example, the ID contemplated that the additional elements could include a personal computer with its own processor and nothing in the claim prohibits the presence of such an element. *Id.* at 99.

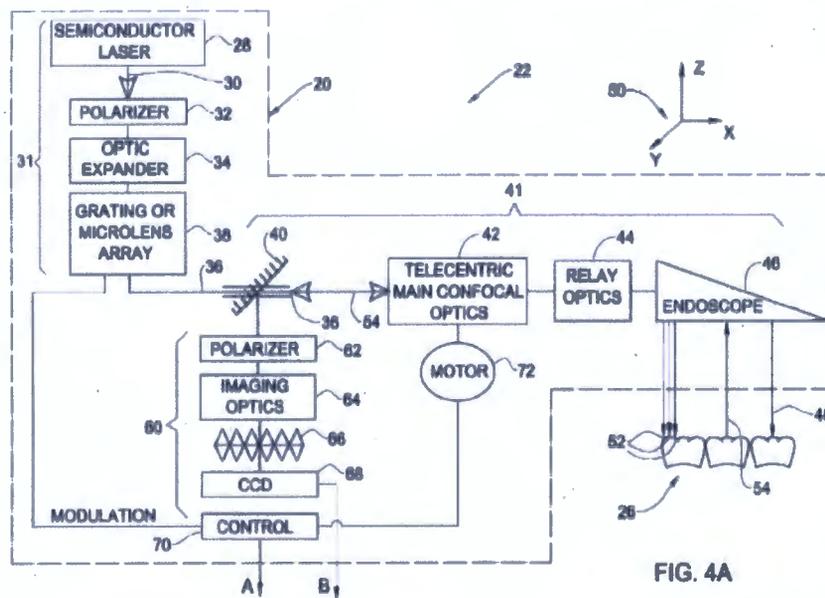
The ID acknowledged Align's argument that a person of ordinary skill in the art would interpret "comprising" in the claims as not limited to a processor on the hand-held device. *Id.* However, the ID found an unrecited element, like a processor in a personal computer that is not on the hand-held device, cannot satisfy the explicit requirement in the claim for a hand-held device with a processor. *Id.* The ID noted that Align cited no legal support for its position. *Id.*

The ID also considered Align's second argument that the specification clearly discloses a processor on the hand-held device. *Id.* The ID noted that there is only one reference to a hand-held device in the specification:

The endoscope 46, the illumination unit 31, the main optics 41, color illumination 71 and tri-color sequence generator are preferably included together in a unitary device, typically a hand-held device. The device preferably includes also the detector optics 60, though the latter may be connected to the remainder of the device via a suitable optical link such as a fibre optics cable.

*Id.* at 100 (quoting JX-0003 at 24:48-54). The ID determined that this passage clearly discloses a collection of components that the patentee contemplated as part of the hand-held device but does not include a processor. *Id.* Therefore, the ID found that the text of the specification does not provide support for a hand-held device with a processor as one of its components. *Id.* at 100-102

The ID also considered the figures and found Figures 4A and 4B instructive. *Id.*



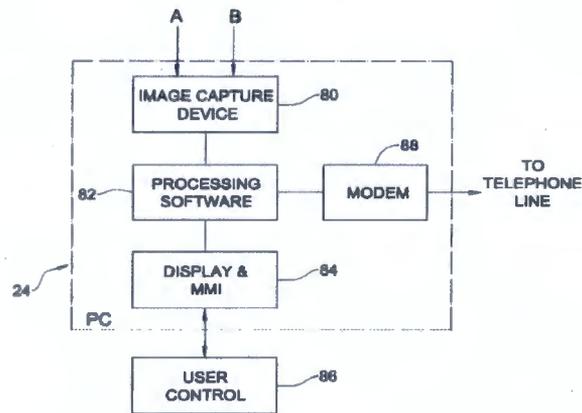


FIG. 4B

*Id.* at 101 (reproducing JX-0003 at Fig. 4A and 4B). The ID explained that these figures show the processor on a PC rather than the hand-held device:

Figures 4A and 4B show two distinct groupings of components, each surrounded by a dashed line. In figure 4A, the grouping is labeled both as element 20, which is “the system,” and element 22, which is “an optical device.” JX-0003 at 14:45-46. In figure 4B, the grouping is labeled element 24, which is a “processor,” and is labeled “PC” (for personal computer) in the lower left corner. *See id.* The specification describes the optical device being coupled to the processor. *See id.* Nothing in this description suggests that the processor is a component of the optical device, and in fact, the distinct groupings of the components in the figures tend to suggest the opposite, that the disclosed processor, which appears to be a personal computer, is not a component of the optical device. Given that the optical device includes most of the components described as being within a *unitary* hand-held device, *id.* at 24:48-54, I find that figures 4A and 4B, along with their associated descriptions in the specification, tend to show that the patentee did not contemplate including a processor among the components of the hand-held device. Those figures tend to indicate that the patentee possessed an invention where the processor was a separate, general purpose, personal computer.

*Id.* at 102. The ID next considered Figure 1, reproduced below, and found that it shows optical device 22 with less details. *Id.* at 103.

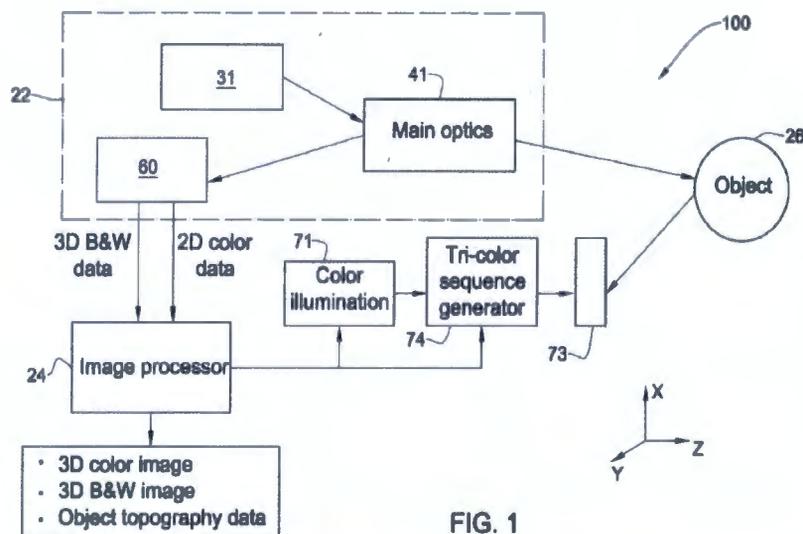


FIG. 1

*Id.* (reproducing JX-0003 at Fig. 1). According to the ID, Figure 1 makes clear that processor 24 is not a component of the optical device 22. *Id.* While the processor 24 is coupled to detector optics 60, the ID found that there is nothing to suggest that the image processor would be included in the hand-held variant of the optical device 22. *Id.*

The ID determined that a person of ordinary skill in the art would not conclude from the '228 patent that its inventor actually possessed the invention claimed in claim 1. *Id.* at 104. Therefore, the ID concluded that 3Shape established by clear and convincing evidence that claim 1 is invalid. *Id.* The ID also determined that because claims 4 and 26 depend from claim 1, that those claims are also invalid for failure to comply with the written description requirement. *Id.* As stated above, the ID incorporated these findings for the '456 patent.

## 2. 3Shape's Petition

3Shape argues that the ID erred by finding that the "processor" is not subject to means-plus-function treatment. 3Shape Pet. at 38. 3Shape argues that the term fails to recite sufficiently definite structure but instead recites a function without reciting sufficient structure for performing that function. *Id.* at 39. 3Shape criticizes the ID's reliance on the examples in

the specification because they are mostly single lines in the specification that merely use the word “processor,” which by itself is not structure. *Id.* at 40-41. 3Shape argues that the processor must be disclosed with the algorithm used to perform the claimed function. *Id.* at 41-42.

### **3. Align’s Petition**

#### **(a) Claim Construction**

Align argues that the ID erred by finding that the “processor” of the ’228, ’207 and ’456 patents must be physically enclosed in the hand-held device. Align Pet. at 15-16 (citing ID at 54 n.6, 87, 88). Align asserts that the ID incorrectly interprets the term “comprising” in the claims to require that all three elements, including the processor, must be physically contained inside a single enclosure or “included” in the hand-held device. *Id.* at 16. Align asserts that neither the claim language nor the rest of the intrinsic record supports the ID’s exclusion of a processor that performs the required association while connected to but off the hand-held device. *Id.* at 16-18.

#### **(b) Written Description**

With regard to written description, Align argues that the ID erred by finding that claims 1, 4, and 26 of the ’228 patent and claims 1 and 15 of the ’456 patent lack written description. Align Pet. at 56. Align first argues that 3Shape did not meet its burden to establish lack of written description by clear and convincing evidence. *Id.* at 57-59. Next, Align contends that the ID erred by requiring the specification to expressly disclose the physical location of the claimed processor. *Id.* at 59-66. Align contends that in this instance, the patentee had possession of the processor and its claimed functionality. *Id.* at 62. Finally, Align argues that the specification provides adequate disclosure of a processor located on the hand-held device. *Id.* at 67-74. Align explains that the ID focused on the specification’s description of the components preferably included on the hand-held device. *Id.* at 68 (citing ID at 100 and quoting JX-0003 at

24:48-54). Align criticizes the ID for providing no analysis of the meaning of “preferably” or why the disclosure would not connote to a person of ordinary skill that the processor could not be on the hand-held device when every other component of Figure 1 may preferably be located on the hand-held device. *Id.* Align also argues that the ID improperly disregarded expert testimony regarding the knowledge of person of ordinary skill in the art. *Id.* at 72.

#### **4. Analysis**

##### **(a) Claim Construction**

3Shape argues that the term “processor” should be construed under 35 U.S.C § 112, ¶ 6. To determine whether § 112, ¶ 6 applies to a claim limitation, a Court first considers the presence or absence of the word “means.” *Williamson v. Citrix Online*, 792 F.3d 1339, 1348 (Fed. Cir. 2015). When a claim limitation does not use the word “means,” there is a rebuttable presumption that §112, ¶ 6 does not apply. *Id.* This presumption can be overcome. Here, the claim term does not include the term “means.” *Williamson* explains that the inquiry then is “whether the words of the claim are understood by persons of ordinary skill in the art to have a sufficiently definite meaning as the name for structure.” *Williamson*, 792 F.3d at 1348. It is 3Shape’s burden to establish that the presumption that the term is not subject to means-plus-function treatment has been overcome. A party advocating that a term is subject to means-plus-function treatment can do so solely by reference to evidence intrinsic to the patent. *Diebold*, 899 F.3d at 1299-1300.

A survey of cases construing the term “processor” reveals that courts generally find that “processor” is a term that has an associated structure. In *Techno View*, the district court surveyed cases that analyzed whether “processor” invokes means-plus-function treatment and found that, for the most part, courts determine that “processor” is not subject to means-plus-function

treatment. *Techno View IP, Inc. v. Facebook Tech., LLC*, Civil Action No. 17-386-CFC-CJB, 2018 WL 6427874, \*4-6 (D. Del 2018). The Court explained that in cases where courts have found that “processor” is subject to means-plus-function treatment, the specification failed to convey to persons of ordinary skill in the art anything about the internal components, operation, or structure of the processor. *Id.* at \*6. The court explained that cases that do not invoke means-plus-function often include claim language that describe how the processor interacts with other components and the specification provides structural information regarding the processor such that the processor is not a simple “black box recitation of structure for providing the same specified function as if the term ‘means’ has been used.” *Id.* at \*5.

The Commission affirms the ID, as discussed herein, and finds that 3Shape has not met its burden. The Commission finds that that “processor” here is not subject to means-plus-function treatment. Instead, the Commission construes the term “processor” as having its plain and ordinary meaning.

We begin with the language of the claims. Claim 1 of the '228 patent recites “a **processor** configured to associate depth data with the color image data.” Non-asserted dependent claim 11 of the '228 patent recites, “a **processor** coupled to the detector and configured to: determine for each of the returned light beams a spot specific position, each spot specific position corresponding to a position of a respective focal plane in the plurality of focal planes, each respective focal plane corresponding to a maximum intensity of each respective returned light beam in the plurality of returned light beams; and generate, based on the determined spot specific positions, data representative of a topology of the portion.” Non-asserted dependent claim 25, which depends from claim 11, further recites “a **processor** coupled to the detector and configured to conformally map the color image data to the depth data to

produce a color, three-dimensional numerical entity comprising a plurality of data points, each data point comprising three-dimensional surface coordinate data associated with color data.” Claim 1 of both the ’456 and ’207 patents provide no additional structural limitations. Both the ’456 and ’207 have similar dependent claims to those recited in the ’228 patent. *See, e.g.,* JX-0004 at 27:12-15 (claim 15); JX-0005 at 28:8-15 (claim 15). This language of the claims describes what the claimed “processor” is required to do and includes information on the inputs and outputs.

Turning to the disclosures of the specification, here the specification discusses and illustrates the functions of the processor as well as the inputs and outputs of the processor. Indeed, the specification states that “the color mapping operation to create entity I may be executed by any suitable microprocessor means, typically processor **24** of the device **100** (FIG. 4B).” JX-0003 at 14:32-35 (emphasis in patent). The mere fact that a disputed limitation includes functional language does not automatically convert the words into means for performing such functions. *Zeroclick, LLC v. Apple*, 891 F.3d 1003, 1008 (Fed. Cir. 2018).

In addition to an explicit description of structure, “[s]tructure may also be provided by describing the claim limitation’s operation, such as its input, output, or connections. The limitation’s operation is more than just its function; it is how the function is achieved in the context of the invention.” *Apple Inc. v. Motorola, Inc.*, 757 F.3d 1286, 1299-1300 (Fed. Cir. 2014) (*overruled on other grounds*).

Here, the specification of the patents explains how the processor interacts with other components, as well as the inputs and outputs. There are only a few instances in the specification where the term “processor” is used. The following are all of the references to the

processor from the detailed description section of the specification, with the processor term bolded:

- The detection optics **60** receives image data from the main optics **41** and the image **processor 24** determines the depth Z values for each X-Y point illuminated on the object **26** based on this image data. In this manner, a manipulable three-dimensional numerical entity E comprising the surface coordinates of the object **26**. JX-0003 at 13:2-7.
- The **processor 24** then processes the three differently colored monochromatic images and combines the same to provide a full color 2D image of the object. *Id.* at 13:13-16.
- The **processor 24** aligns the 2D color image with the 3D entity previously created, and then provides color values to this entity by mapping color values to the entity at aligned X-Y points. Such alignment is straightforward because both the 3D data and the 2D color data are referenced to the same X-Y frame of reference. Referring to FIGS. 2A, 2B, 2C, the mapping procedure is performed as follows. A three-dimensional numerical entity E is obtained by determining depth Z-values for a grid of X-Y points, illuminated via main optics **41** and determined by image **processor 24**. The entity E thus comprises an array of (X, Y, Z) points, as illustrated in FIG. 2A. *Id.* at 13:20-31.
- Typically, the image **processor**, or another computer, will attempt to align the outer border of the object **26** as seen along the Z-axis and encoded in entity E with optical elements in the 2D color image encoded in entity N. Thereafter, the color value C of each X'-Y' coordinate of entity N is mapped to the appropriate data point of entity E having the aligned X-Y coordinates corresponding thereto. The color mapping operation to create entity I may be executed by any suitable microprocessor means, typically **processor 24** of the device **100** (FIG. 4B). *Id.* at 14:26-35.
- The main optics **41**, main illumination source **31**, detection optics **60** and image **processor 24** are now described with reference to FIGS. 4A and 4B which illustrate, by way of a block diagram an embodiment of a system **20** for confocal imaging of a three dimensional structure according to WO 00/08415 assigned to the present assignee, the contents of which are incorporated herein. Alternatively, any suitable confocal imaging arrangement may be used in the present invention.

The system **20** comprises an optical device **22** coupled to a **processor 24**. *Id.* at 14:36-46.

- The CCD camera is connected to the image-capturing module **80** of **processor unit 24**. Thus, each light intensity measured; in each of the sensing elements of

the CCD camera is then grabbed and analyzed, in a manner to be described below, by processor 24. *Id.* at 15:66-16:3.

These portions of the specification explain that the image processor 24 is connected to the optical device 22 and the CCD camera is connected to the image capturing module of the processor. *Id.* at 14:36-46. Each light intensity measured in each of the sensing elements of the CCD camera is grabbed and analyzed by processor 24. *Id.* at 15:66-16:3. The detection optics 60 receives image data from the main optics 41 and the image processor 24 determines the depth Z values for each X-Y point illuminated on the object 26 based on the image data received from the main optics. *Id.* at 13:2-7. The processing by the processor 24 includes the three differently colored monochromatic images and combines the same to provide a full color 2D image of the object. *Id.* at 13:13-16. In addition, the image processor 24 also creates the three-dimensional data using the collected image data. *Id.* at 14:26-35.

In addition, to these discussions of the “processor,” Figure 1 also illustrates the processor 24 in the scheme of the invention. Figure 1 is reproduced below and it shows the inputs to the image processor 24 are the 3-D black and white data and the 2-D color data, the outputs can include a 3-D color image, 3-D black and white image, and object topography data, and the image processor is connected to the color illumination 71 and the tri-color sequence generator:

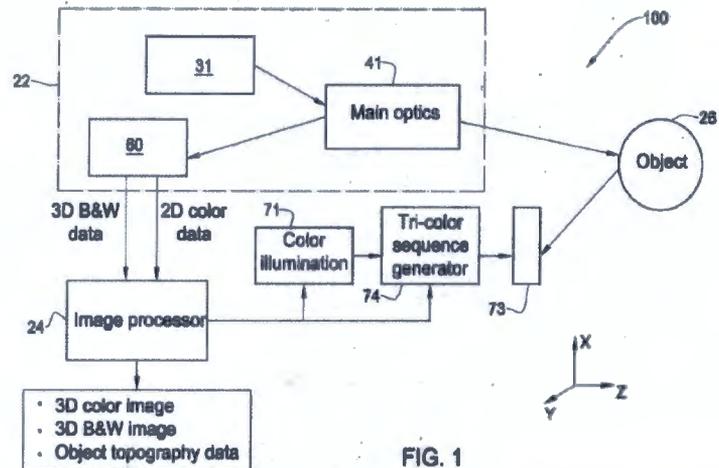


FIG. 1

*Id.* at Fig. 1. Finally, the abstract also mentions the processor stating: “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.” JX-0003 at Abstract. This indicates that the processor receives two types of input data, color data and depth data, and outputs a three-dimensional color model. In addition, to these uses of “processor,” the background of the specification also uses the term repeatedly to note that a “processor” is used to implement the appropriate processing techniques. *Id.* at 1:39-42, 2:33-40.

The parties’ experts understandably disagree on whether the claimed “processor” would be understood by a person of ordinary skill in the art. Given the specifications’ discussion of the functions, inputs, outputs, and connections of the processor and the use of the term in the claims, the Commission finds that a person of ordinary skill in the art would understand the term “processor” as the name for a structure. Dr. Stevenson’s expert declaration in support of Align’s claim construction brief, for example, supports this finding. Align’s Responsive Claim Construction Brief, EDIS Doc ID 643487, at Ex. I, ¶ 18. In addition, the specification explicitly states “[t]he color mapping operation to create entity I may be executed by any suitable

microprocessor means, typically processor 24 of the device 100 (FIG. 4B).” JX-0003 at 14:32-35. Accordingly, the Commission finds that 3Shape has not met its burden to show that this term is subject to means-plus-function treatment.

Align petitions for review of the ID’s finding that the processor must be on the hand-held device for the asserted claims of the ’228, ’456, and ’207 patents. The Commission agrees with the ID that the processor must be located on the hand-held device. The ID’s finding is consistent with the language of the claims. Claim 1 of the ’288, ’456, and ’207 patents claim “a hand-held device comprising . . . (c) a processor configured to associate the depth data with the color image data.” JX-0003 at claim 1; JX-0004 at claim 1; JX-0005 at claim 1. The claim language plainly recites that the processor must be located within the hand-held device. Align tries to frame its argument as a claim construction issue of the term “processor” but the real issue is what does the transitional phrase “comprising” means. The Commission finds that the term has historically been interpreted to mean “including but not limited to.” *Cias, Inc. v. Alliance Gaming Corp.*, 504 F.3d 1356, 1360 (Fed. Cir. 2007) (“[T]he term ‘comprising’ is well understood to mean ‘including but not limited to.’”). Align’s reading of the claim would read out the term “comprising.” The Commission notes that its interpretation stems from the format of the claims selected by the patentee during prosecution and that it follows the rule that a device comprising a number of elements must have at least those elements. Indeed, the patentee even labeled the three elements that are required to be in the hand-held device with (a), (b), and (c), with (c) being the processor. The Commission is required to interpret the claims as issued and cannot rewrite the claims for Align.

Align’s second argument challenges the ID’s finding that the processor must be physically enclosed in the hand-held device for the ’228, ’456, and ’207 patents because that

finding is purportedly inconsistent with the ID's finding that the processor lacks written description support. *See* *Align Pet.* at 15-16 (citing ID at 54 n.6, 87, 88). The Commission affirms the ID's finding that the processor must be located on the hand-held device, which is based on the well-known meaning of the transitional term "comprising." *See* ID at 87, 98 (citing *Vivid*, 200 F.3d at 811); *see also* *Cias*, 504 F.3d at 1360. The patentee, by using the word "comprising," required that the processor be located on the hand-held device. *See, e.g., Vivid Techs.*, 200 F.3d at 811.

**(b) Written Description**

The Commission determined to review the ID's findings on written description for the '288 and '456 patents and requested additional briefing from the parties. The Commission hereby affirms the ID's determination that the '288 and '456 patents lack written description of the hand-held device that physically includes a processor for the reasons discussed herein and adopts the ID's findings to the extent they are not inconsistent with this opinion.

A determination on whether a claimed invention is supported by the written description requires "an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. Based on that inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed." *Ariad Pharm., Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (*en banc*). The Federal Circuit explained:

the written description requirement does not demand either examples or an actual reduction to practice; a constructive reduction to practice that in a definite way identifies the claimed invention can satisfy the written description requirement. Conversely, we have repeatedly stated that actual "possession" or reduction to practice outside of the specification is not enough. Rather, as stated above, it is the specification itself that must demonstrate possession. And while the description requirement does not demand any particular form of disclosure, or that

the specification recite the claimed invention *in haec verba*, a description that merely renders the invention obvious does not satisfy the requirement.

*Id.* at 1352 (citations omitted). As the Federal Circuit further explains in *Rivera v. Int'l Trade Comm'n*, 857 F.3d 1315, 1322 (Fed. Cir. 2017):

the written description inquiry looks to “the four corners of the specification” to discern the extent to which the inventor(s) had possession of the invention as broadly claimed. *Ariad*, 598 F.3d at 1351; *see also Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1571 (Fed. Cir. 1997) (“It is the disclosures of the applications that count.”). The knowledge of ordinary artisans may be used to inform what is actually in the specification, *see Lockwood*, 107 F.3d at 1571, but not to teach limitations that are not in the specification, even if those limitations would be rendered obvious by the disclosure in the specification. *Id.* at 1571–72.

*Id.* In *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997), the Federal Circuit explained that while the exact claim terms do not need to be used *in haec verba*, “the specification must contain an equivalent description of the claimed subject matter.” Compliance with the written description requirement is a question of fact and “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*, 598 F.3d at 1251.

In its petition for review, Align requests that the Commission review and reverse the ID’s findings for four reasons: (1) the ID applies an erroneous claim construction requiring the processor to be located on the hand-held device; (2) the ID wrongly shifts the burden of proof, failing to require 3Shape to meet the high burden of proof by not analyzing, addressing or even mentioning the required factual considerations regarding the state of the art and knowledge of a person of skill in the art; (3) the ID fails to properly credit the specification’s written description support of a processor located in the hand-held device and ignores the law establishing that an applicant is not required to describe in the specification every conceivable and possible future

embodiment of the invention; and (4) the ID applies the incorrect legal test for written description by improperly requiring *in haec verba* support for the physical location of the claimed processor;. See Align Pet. at 56-74.

With respect to Align's argument (1), for the reasons discussed in Part IV.A.4(a) above, the Commission affirms the ID's finding that the hand-held device must include the processor under governing Federal Circuit precedent. We turn next to Align's arguments (2) through (4) as to whether this limitation is supported by the specification.

In argument (2), Align contends that because the processor is not an important inventive aspect of the invention, the specification was not required to adequately disclose the claimed processor in a hand-held device. Align Pet. at 63-65. However, Align's position would read the element "a hand-held device comprising..." out of the claims. See, e.g., *Merck & Co v. Pharms. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005) ("A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so."). Further, this cannot be the proper interpretation for the reasons discussed above.

Further with respect to argument (2), Align argues that the ID's analysis is not conducted from the perspective of a person of ordinary skill in the art, and thus improperly shifted the burden to Align. Align Pet. at 66. The Commission disagrees with Align's argument that the ID did not consider the perspective of a person of ordinary skill in the art. Neither of the parties' experts' testimony is expressly stated to be from the perspective a person of ordinary skill in the art. However, only the testimony of Dr. Schaafsma, respondents' expert, is consistent with the disclosures of the specification. Align does not argue, nor can it, that its own expert provided rebuttal testimony that a person of ordinary skill in the art would understand the specification to disclose the location of the processor on the hand-held device.

Dr. Schaafsma, 3Shape's expert, testified that he did not find anything in the specification's description of the hand-held device to include the processor. Tr. at 1279:25-1282:16. Instead, he testified that Figure 4B discloses a processor on a "PC." *Id.* However, in his testimony, Dr. Schaafsma did not expressly link his analysis to the perspective of a person of ordinary skill in the art, with the exception of stating that a person of ordinary skill in the art would understand "PC" to be a personal computer. However, the ID considered Dr. Schaafsma's testimony that Align attacks, and concluded that Dr. Schaafsma's testimony is consistent with the teachings in the specification. ID at 103-04; *see also* Tr. at 1279:25-1282:16. While Dr. Schaafsma's testimony is not expressly from the perspective of what a person of ordinary skill in the art would understand, the Commission agrees with the ID that it is consistent with the specification, which is discussed in detail below. The Commission further finds that it would be reasonable to conclude that the testimony is from the perspective of a person of ordinary skill in the art. *See generally*, ID at 104.

With regard to Align's argument (3) as to the express disclosures of the specification as to the location of the processor, Align and 3Shape disagree whether the specification discloses the processor on the hand-held device. The parties dispute whether the Figures 1, 4A, and 4B and the specification disclose a processor on or off the hand-held wand. The expert testimony from the parties on this issue is not particularly helpful. The specification itself, as discussed above, discusses a preferred embodiment in which the processor is not included on the hand-held wand. JX-0003 at 24:48-54. There is only one paragraph in the specification that describes the hand-held device. The ID heavily relied on this paragraph to reach the conclusion that the processor is not described as being part of the hand-held device.

Figure 1 is described as illustrating the main elements of the preferred embodiment of the invention. *Id.* at 12:12-13. The first sentence of the Detailed Description states “Reference is first being made to FIG. 1 which illustrates the general relationship between the various elements of the device of the invention, generally designated with the numeral **100**, according to the embodiments described herein.” *Id.* at 12:56-59. This statement, as well as the various references to the “device 100” of the invention clearly refer to the device of the whole invention. Align argues that device 100 must include the hand-held device and thereby, the processor. This argument, however, does not align with the numerous references to device 100 in the specification.

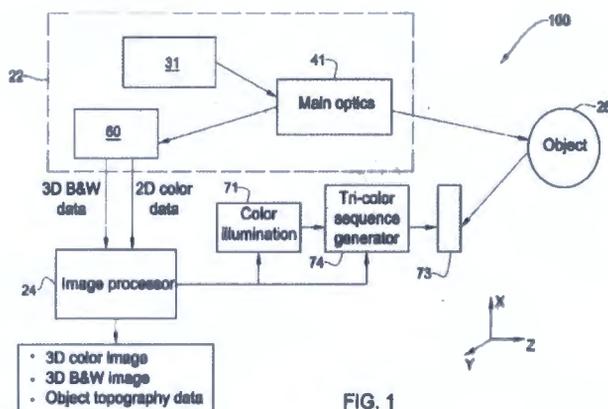
For example, Align relies on various teachings in the specification to argue that device 100 must be the hand-held device, including the processor. *Align Pet.* at 69-71. For example, one teaching upon which Align relies provides as follows:

The endoscope 46, the illumination unit 31, the main optics 41, color illumination 71 and tri-color sequence generator are preferably included together in a unitary device, typically a hand-held device. The device preferably includes also the detector optics 60, though the latter may be connected to the remainder of the device via a suitable optical link such as a fibre optics cable.

JX-0003 at 24:48-54. However, this is the main passage upon which the ID relies to inform its claim construction notably because this passage recites the sole reference in the specification to a hand-held device and because this text unquestionably does not include a processor among the constituent components of that hand-held device. This paragraph describes that the hand-held device, which is not identified as including a processor, is “connected to the remainder of the device” via a suitable link. Align emphasizes the use of word “preferably” in this passage to argue that the processor could be located on the hand-held device. However, the four corners of

the specification do not provide any indication that the inventors contemplated the processor being located on the hand-held device.

Figures 1, 4A, and 4B, and the discussion thereof, also do not support Align's position. Figure 1, reproduced below, shows device 100 having an optical device 22 and separate image processor 24:



JX-0003 at Fig. 1. Contrary to Align's assertion, there is nothing in the specification or this figure that illustrates that the processor is included on the hand-held wand. Indeed, the specification's description of Figure 1 does not include a discussion of what is included on the hand-held wand at all. *See, e.g., id.* at 12:56-13:25, 16:41-55.

Similarly, Figures 4A and 4B do not illustrate a processor included on the hand-held wand:

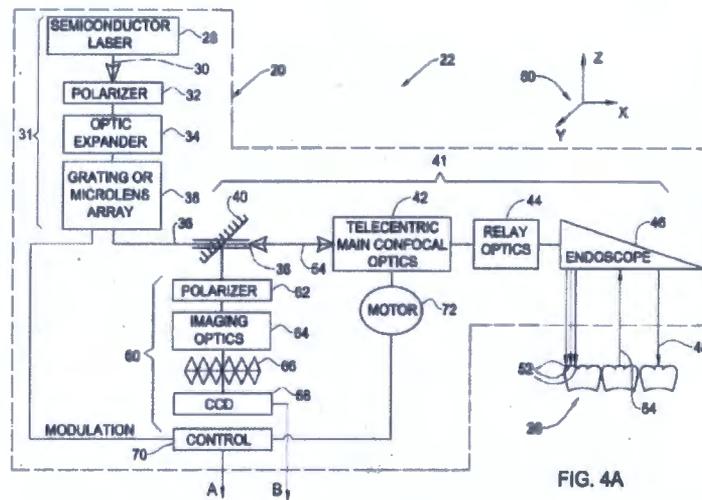


FIG. 4A

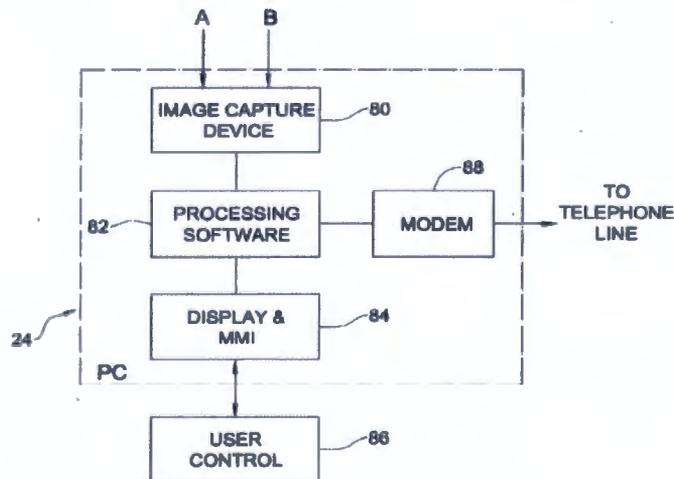


FIG. 4B

*Id.* at Figs. 4A and 4B. Instead, Figure 4B illustrates processor 24 on a PC. Align argues that Figures 4A and 4B illustrate the prior art but Figures 4A and 4B are described as “schematically illustrat[ing] the main elements of a portion of the invention used for providing a three dimensional monochrome entity.” JX-0003 at 12:21-23. There is nothing in the description of Figures 4A and 4B that indicates that the processor could be on a hand-held wand. *See, e.g., id.* at 14:32-16-42.

In addition, Align contends that the ID ignored un rebutted evidence that a person of ordinary skill in the art would know that processors can be located on or off a hand-held device and the location was a design choice. Align Pet. at 66. The testimony from Align's expert does not and cannot make up for the inadequacies in the specification. Dr. Stevenson, Align's expert, testified that a person of ordinary skill in the art would know to use a processor on a hand-held wand but he does not testify that the specification discloses to a person of ordinary skill in the art that the inventor had possession of a hand-held device including a processor for associating depth data with color image data. Tr. at 513:17-514:12, 1419:19-1420:6.

In contrast, the testimony of 3Shape's expert, Dr. Schaafsma, focuses on the lack of express teaching of the processor on the hand-held wand. Tr. at 1279:3-1284:11. As Align notes, Dr. Schaafsma's testimony did not explicitly state that a person of ordinary skill in the art would not understand the inventor to have possession of a processor on a hand-held device. However, Dr. Schaafsma's testimony is more in line with the teachings in the specification which do not explicitly, either in its description or figures, disclose a processor on the hand-held device.

Align argues that the ID also failed to address an admission from 3Shape's expert, Dr. Zavislan, who admitted that the specification discloses a processor on a hand-held device. Tr. at 1135:4-1136:4. 3Shape argues that Dr. Zavislan admitted that the claims require a processor on the hand-held wand but that he did not provide an opinion as to the location of processor 24 relative to the hand-held wand as described in the specification. 3Shape Resp. Br. at 16-17. The Commission agrees with 3Shape that Dr. Zavislan admitted that the claims require a processor on the hand-held wand and agree with Align that Dr. Zavislan admitted that the processor in the specification is also on the hand-held wand. However, this snippet of testimony from Dr.

Zavislan, admitting that the specification discloses a processor on the hand-held wand, is not consistent with the teaching of the hand-held device within the four corners of the specification, and thus, the Commission does not find it credible.

Based on the express teachings in the specification and the figures and on testimony from Dr. Schaafsma, the Commission finds that Align has not rebutted 3Shape's clear and convincing evidence that the specification does not disclose the processor on the hand-held device. The cases cited by Align, Align Pet. at 61, do not negate the statutory requirement that the invention must be adequately described within the four corners of the specification.

Finally, Align's argument (4) is that the ID improperly requires *in haec verba* support for the physical location of the claimed processor. As the Federal Circuit explains in *Rivera*, 857 F.3d at 1322:

the written description inquiry looks to "the four corners of the specification" to discern the extent to which the inventor(s) had possession of the invention as broadly claimed. *Ariad*, 598 F.3d at 1351; *see also Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1571 (Fed. Cir. 1997) ("It is the disclosures of the applications that count."). The knowledge of ordinary artisans may be used to inform what is actually in the specification, *see Lockwood*, 107 F.3d at 1571, but not to teach limitations that are not in the specification, even if those limitations would be rendered obvious by the disclosure in the specification. *Id.* at 1571-72.

This is just the case here. The Commission has focused on the four corners of the specification and testimony from the experts presented and finds that the ID did not improperly require *in haec verba* support for the physical location of the claimed processor. Accordingly, the Commission affirms the ID's findings as discussed herein, and adopts the ID's findings not inconsistent with this discussion.

**B. Construction of the Term "Confocal Imaging Techniques"**

The term "confocal imaging techniques" appears in dependent claim 4 of the '228 patent, which recites "A system according to claim 1, wherein the operation of the scanning system is

based on **confocal imaging techniques.**” The parties’ challenge to the meaning of this term is explained below.

**1. The ID**

The ID explained that “the parties’ dispute regarding the term ‘confocal imaging techniques’ is narrow. Both parties agree that the term requires conjugate focal planes. The dispute is whether the term also requires point illumination of a point onto an object to produce an image detected through a point detector.” ID at 41. The ID found that it does. *Id.*

The ID determined that the intrinsic record provides little guidance about the meaning of “confocal imaging.” *Id.* Specifically, the ID explained, “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. *See, e.g.,* JX-0003 at 2:61-3:3; 5:18-27, 15:51-65. The single claim in which the term appears provides no guidance.” *Id.* at 41-42.

The ID did not find the expert testimony to be helpful in resolving the dispute. *Id.* at 42. However, the ID found that the references relied upon by the experts to show the state of the art are instructive and persuasive. *Id.* The three references discussed and considered are (1) an academic text entitled “Confocal Microscopy” by Wilson (RX-0741); (2) the academic text entitled “Confocal Scanning Optical Microscopy and Related Imaging Systems” by Corle and Kino (RX-1100); and (3) U.S. Patent No. 3,013,467 issued to Minsky (“Minsky”) (JX-0107). The ID explains that “[a]ll three of the exhibits listed above describe confocal microscopy in conjunction with point illumination, imaging, and detection.” *Id.*

The ID reproduces the following figure illustrating different arrangements in optical microscopes from the Wilson book:

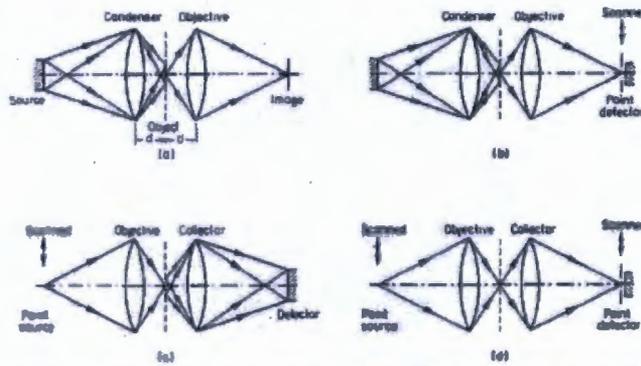


Figure 1.7. The optical arrangement of various forms of scanning optical microscopes. (a) Conventional microscope. (b) A form of conventional scanning microscope. (c) A form of conventional scanning microscope. (d) The confocal optical system.

*Id.* at 42-43 (reproducing RX-0741 at .0004). The ID noted that the textbook caption states that only configuration (d), which utilizes point illumination, point imaging, and point detection is confocal. *Id.* at 43. The ID further explained “[t]he remainder of the text on the same page further connects point illumination, imaging, and detection to confocal imaging.” *Id.* The ID next reproduced a figure from the Corle and Kino book:

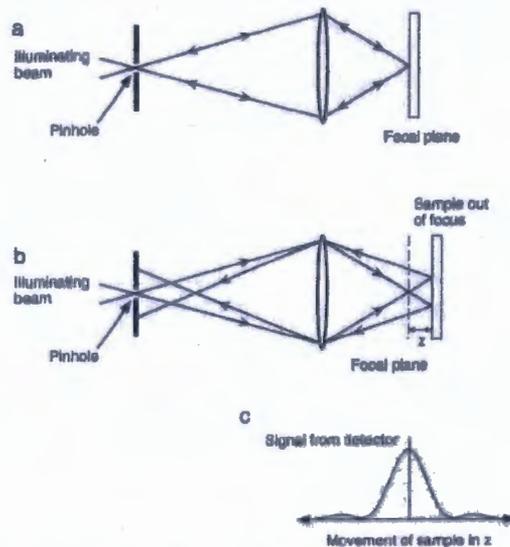
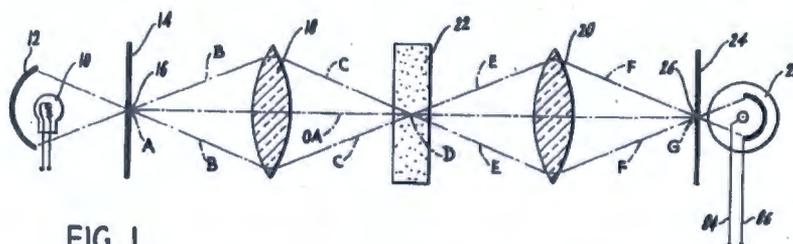


Figure 1.1 Simplified schematic of a confocal scanning optical microscope showing the sample (a) in the focal plane of the objective and (b) out of focus. (c) The form of the signal output from the detector as a function of sample defocus.

*Id.* at 44 (reproducing RX-1100 at .0006). The ID then quoted the text of that page in the text book: “*Confocal Microscopy* The basic principle of confocal microscopy, illustrated in Fig.

1.1(a), is to illuminate only one spot on the sample at a time through a pinhole. The light reflected from the sample is imaged by the objective back to the pinhole.” *Id.*

The ID found that the Minsky patent also illustrates the use of point illumination, imaging, and detection in its Figure 1:



*Id.* at 45 (reproducing JX-0107 at p.1). The ID explained that Minsky makes numerous references to a pinhole aperture, an illuminated point, and point sources of light. *Id.* (citing JX-0107 at 1:10-17). The ID stated “[t]o summarize, all three of the references identified by the parties as bearing on the meaning of ‘confocal imaging’ tell the same story: A ‘confocal imaging’ system requires conjugal focal planes as well as point illumination, imaging, and detection.” *Id.*

The ID explained that Align’s insistence that the term does not require conjugal focal planes as well as point illumination, imaging, and detection is not persuasive. *Id.* The ID noted that Align summarily argued, through Dr. Stevenson, that the term “confocal” comes from the idea of creating conjugate focal planes, and therefore all that is required by the term “confocal imaging” in the color scanner patents is conjugate focal planes. *Id.* The ID found that this argument conflates what is necessary with what is sufficient. *Id.* The ID noted that both parties agree that the term “confocal imaging” in the color scanner patents requires conjugate focal planes. *Id.* The ID concluded that “conjugate 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 45-46. The ID found that this is clear in the text of Corle and Kino, which describes the ambiguity that would follow if conjugate focal planes were the only requirement for confocal imaging:

In summary, the basic requirements for the [confocal scanning optical microscope (“CSOM”)] are point illumination, point detection, a scanned image, and a confocal lens system.

Strictly speaking, the word confocal can apply to both a standard optical microscope and the CSOM. Both instruments can use a high-numerical-aperture lens to illuminate and image the sample; thus both microscopes fit the definition of confocal, two lenses sharing a common focus. The terminology confocal microscope as a synonym for the CSOM is, however, firmly fixed in the literature so we will use it throughout this book.

*Id.* at 46 (quoting RX-1100 at .0014). The ID explained that this clarified that in:

the optical arts, that is not how the term is used; it is “firmly fixed in the literature” that a confocal device “require[s]” “point illumination, point detection, a scanned image, and a confocal lens system.” *Id.* Thus, if “confocal imaging” is reduced down to the literal meaning of “confocal,” it would include techniques such as conventional microscopy that those skilled in the art do not consider to be included within the scope of “confocal imaging.”

*Id.* Therefore, the ID found that the meaning of “confocal imaging” in the relevant art requires both conjugate focal planes and point illumination, imaging, and detection. *Id.* at 47.

## 2. Analysis

As discussed above, the ID consulted extrinsic evidence to find that the term “confocal imaging techniques” requires “point illumination” and “point detection.” ID at 41-47. Despite Align’s contention, the extrinsic evidence on which the ID relied to construe this claim term is consistent with the intrinsic record. *See, e.g.*, Align Pet. at 22-23; ID at 41-42. Align argues that the term “confocal imaging techniques” should be limited to using a pinhole or pinhole array under the ID’s construction. *See, e.g.*, Align Pet. at 26-28. However, the ID construes the “confocal imaging techniques” to require “point illumination, imaging and detection.” ID at 47.

As 3Shape correctly explains in its response to Align’s petition, there are multiple ways to achieve point illumination and point detection and the ID’s construction is not limited to the use of pinholes. 3Shape Resp. at 12 (explaining that a point source such as a laser, or a point sourced multiplexed through a microlens array, can achieve point illumination). The ID’s construction is not as limited as Align now argues. Indeed, the ID’s construction is consistent with the testimony that “confocal imaging” does not require the use of pinholes. Tr. at 1111:16-25, 1105:15-1106:13, 474:9-20; JX-0077C at 179:16-25, 180:4-10; *see also, e.g.*, JX-0003 at 2:61-3:3, 5:18-27, 15:51-65. Align even acknowledges this point. Align Post-Hearing Br. at 19. Accordingly, the Commission adopts the ID’s construction of this term and adopts the ID’s findings that are not inconsistent with this opinion.

**C. Infringement**

Align asserts infringement of the following claims by 3Shape, with the independent claims in bold:

<b>'228 Patent</b>	<b>'456 Patent</b>	<b>'207 Patent</b>	<b>'433 Patent</b>
Claims 1, 4, 26	Claims 1, 15	Claim 1	Claim 12

ID at 50. In sum, the ID found that the accused Trios color scanners infringe the following claims: (1) claims 1 and 26, but not claim 4, of the '228 patent; (2) claim 1, but not claim 15, of the '456 patent; (3) claim 1 of the '207 patent; but (4) not claim 12 of the '433 patent. *See, e.g.*, ID at 146-48. The ID also found that the monochromatic Trios scanners do not infringe.

Align petitioned for review of the ID’s findings of non-infringement of claim 4 of the '228 patent, claim 15 of the '456 patent, and claim 12 of the '433 patent. In addition, Align argues that the ID improperly found that the monochromatic Trios scanners do not infringe. 3Shape petitioned for review of all of the ID’s findings that the Trios color scanners infringe the

asserted claims. 3Shape presented its petition for the '228, '456 and '207 patents together, so we will likewise address the arguments together. We will not address the elements not in dispute. The ID's findings on direct infringement can be found at pages 50-70. We address the asserted independent claims below.

**1. Claim 1 of the '228, '456, and '207 Patents**

The Commission determined to review all of the ID's findings on infringement. Claim 1 of each of these three patents are very similar. The ID notes that the parties agree that the disputes regarding infringement of claim 1 of the '456 patent are coextensive with the disputes regarding infringement of claim 1 of the '228 patent and claim 1 of the '207 patent. ID at 61. As illustrated in the chart included in the ID, and reproduced below, claim 1 of the '228 patent and claim 1 of the '456 patent are nearly identical:

**Comparison of Claim 1 of '228 and Claim 1 of '456**

U.S. Pat. No. 8,363,228	U.S. Pat. No. 8,451,456
1. A system for determining the surface topology and associated color of at least a portion of a three dimensional structure, comprising:	1. A system for determining the surface topology and associated color of at least a portion of a three-dimensional dental structure, comprising:
a hand-held device comprising:	a hand-held device comprising:
(a) a scanning system configured to provide depth data of said portion, the depth data corresponding to a plurality of data points defined on a plane substantially orthogonal to a depth direction;	(a) a scanning system configured to provide depth data of the portion, the depth data corresponding to a plurality of data points defined on a plane substantially orthogonal to a depth direction;
(b) an imaging system configured to provide two-dimensional color image data of said portion associated with said plurality of data points; and	(b) an imaging system configured to provide color image data of the portion associated with said plurality of data points; and
(c) a processor configured to associate the depth data with the color image data.	(c) a processor configured to associate the depth data with the color image data.
	wherein the depth data and the color image data represent the surface topology and the color of the portion of the three-dimensional dental structure.

*Id.* at 62. Similarly, the chart included in the ID, and reproduced below, shows that the language of claim 1 of the '207 patent and claim 1 of the '456 patent are nearly identical:

## Comparison of Claim 1 of '456 and Claim 1 of '207

U.S. Pat. No. 8,451,456	U.S. Pat. No. 8,675,207
1. A system for determining the surface topology and associated color of at least a portion of a three-dimensional dental structure, comprising:	1. A <b>method</b> for determining the surface topology and associated color of at least a portion of a three-dimensional dental structure, comprising:
a hand-held device comprising:	<b>providing</b> a hand-held device comprising:
(a) a scanning system configured to provide depth data of the portion, the depth data corresponding to a plurality of data points defined on a plane substantially orthogonal to a depth direction;	(a) a scanning system configured to provide depth data of the portion, the depth data corresponding to a plurality of data points defined on a plane substantially orthogonal to a depth direction;
(b) an imaging system configured to provide color image data of the portion associated with said plurality of data points; and	(b) an imaging system configured to provide color image data of the portion associated with said plurality of data points; and
(c) a processor configured to associate the depth data with the color image data.	(c) a processor configured to associate the depth data with the color image data.
wherein the depth data and the color image data represent the surface topology and the color of the portion of the three-dimensional dental structure.	wherein the depth data and the color image data represent the surface topology and the color of the portion of the three-dimensional dental structure.
	<b>operating the hand-held device</b>

*Id.* at 65. Thus, the issues discussed with respect to the '228 patent equally apply to the '456, and '207 patents. The ID's analysis of the additional elements found in claim 1 of the '456 and '207 patents are discussed below.

### (a) The ID

#### (i) Claim 1 of the '228 Patent

The ID explained that Align organized its argument by breaking the claim into the preamble labeled [P] and four elements labeled [1]-[4] (as shown above). The ID found that all limitations of independent claim 1 are met by the Trios color scanner.

The ID focused on element [4] and determined that the Field Programmable Gate Array ("FPGA") in the Trios products satisfied the "processor" limitation of claim 1. *Id.* at 54. The ID explained that the disputed question was whether the FPGA associates the depth data and color image data as required by claim 1. *Id.* The ID relied on testimony from Dr. Stevenson to establish that the FPGA associates depth data and color image data. *Id.* (relying on and reproducing Tr. 469:7-470:5). The ID also considered the cross-examination testimony of

3Shape's expert, Dr. van der Poel (also relied on by Align), to confirm Dr. Stevenson's understanding of the way [REDACTED].  
[REDACTED]. *Id.* at 54-55 (citing Tr. 958:19-959:4, 967:6-11). The ID also considered the deposition testimony of Drs. Roselund and Hansen, who were designated as corporate representatives for 3Shape. *Id.* at 55. The ID reproduced Dr. Roselund's testimony, which states:

Q. So then after we [REDACTED]

A. Exactly, and then the [REDACTED]

*Id.* (quoting JX-074C at 79:13-19). And Dr. Hansen states:

Q. And then how does the color come into the model?

A. [REDACTED]

\* \* \*

Q. Okay, so what is the [REDACTED]?

A. That is, that is [REDACTED]. I believe it is [REDACTED]

Q. Okay.

A. So yes that will tell us [REDACTED]

Q. Okay. So that information tells you, is [REDACTED]

A. The [REDACTED]

Q. [REDACTED], okay. So for [REDACTED], is that right?

A. Yes.

*Id.* at 55-56 (quoting JX-0057 43:7-10; 133:13-134:3). The ID considered all of this evidence and determined that the testimony tended to demonstrate that the FPGA associates depth and color image information [REDACTED]

[REDACTED]. *Id.* at 56.

The ID explained that 3Shape “contends that Align is factually wrong in arguing that depth information and color information are sent from the scanner wand to the external computer in a single packet.” *Id.* The ID considered the testimony cited by 3Shape, from Dr. Hansen, “to support a conclusion that when he mentioned a [REDACTED] in the passage above [REDACTED]

[REDACTED] *Id.* The ID noted that “3Shape also points to an additional portion of Dr. Roselund’s deposition testimony to establish that there are [REDACTED]

[REDACTED] *Id.* (citing JX-0074C 57:20-61:13, 79:13-19). The ID considered all of this testimony and reaffirmed its conclusion that Align has established that the Trios products practice element [4] of claim 1. *Id.* The ID noted that Dr. Hansen’s trial testimony appears to contradict the deposition testimony that 3Shape sought to rely on. *Id.* (citing Tr. at 819:23-821:7 (testifying that [REDACTED]

[REDACTED])). The ID explained that “[h]aving reviewed the excerpts of Dr. Hansen’s deposition testimony submitted in this investigation, it is not clear that his answers during his deposition were directed to packages received from ScanSuite interface, as 3Shape proposes.” *Id.* The ID did not find the contradictory testimony persuasive. *Id.* at 57.

The ID also considered the testimony of Dr. Roselund, stating:

First, Dr. Roselund acknowledges that the [REDACTED] . JX-0074C at 57:17-58:2. Then, speaking about the creation of [REDACTED], Dr. Roselund explains that that FPGA [REDACTED]. *Id.* at 60:5-60:16. I note that, in the same exchange, Dr. Roselund appears to testify that [REDACTED]. *See id.* at 60:19-21. Dr. Roselund apparently understood the discrepancy in his answer as he goes on, without prompting, to clarify that the [REDACTED]. *Id.* at 60:24-61:1. I have reviewed the rest of Dr. Roselund's testimony cited by 3Shape, but it provides little additional clarity.

It appears to me that Dr. Roselund's understanding of what it means for [REDACTED]. However, I also understand Dr. Roselund's testimony to be [REDACTED].

*Id.* at 57. The ID concluded that this testimony was not "inconsistent with the conclusion that association of [REDACTED] and image data (*i.e.*, depth and color image data) occurs in the FPGA. The evidence shows that the two types of data are associated [REDACTED]. *Id.* at 58 (citing JX-0074C at 57:17-58:2, 60:11-16).

The ID next turned to 3Shape's argument that "depth data" should be construed in a way to exclude lens position information [REDACTED] value. *Id.* The ID found that 3Shape was attempting to limit the term "depth data" to a particular embodiment in the specification and 3Shape did not proffer a specific construction, but instead suggested a possible construction whereby depth data must be a Z-coordinate of the structure being scanned. *Id.* The ID declined to adopt 3Shape's construction because it appeared to be a request to limit the broad term "depth data" to the types of data obtained in certain exemplary embodiments. *Id.*

Finally, the ID noted that 3Shape made one additional non-infringement argument with respect to its Trios monochromatic scanners: “Trios 3 Mono scanners are configured with different software that ignores the color information and is ‘only capable of outputting monochromatic data,’” which is inconsistent with the requirement in claim element [3] for an imaging system configured to obtain color image data. *Id.* The ID acknowledged that the Trios monochromatic scanners can be modified at a 3Shape factory to add color scanning functionality, but finds that “[b]ecause modifications are required to enable to color functionality, [the Trios monochromatic scanners] cannot be found to infringe.” *Id.* at 58-59.

Therefore, the ID concluded that Align has established, by a preponderance of the evidence, that claim 1 of the ’228 patent is infringed by the Trios color scanners but that Align has not established, by a preponderance of the evidence, that the Trios monochromatic scanners infringe the claim. *Id.* at 59.

**(ii) Additional Limitations of Claim 1 of the ’456 Patent**

The ID noted that claim 1 of the ’456 patent additionally requires that the depth data and color image data represent the surface topology and color of a dental structure. *Id.* at 62. The ID determined that “Align has produced un rebutted evidence to show that depth data and color image data in the 3Shape Trios scanners represent the surface topology and color of teeth, in accordance with claim 1 of the ’456 patent.” *Id.* However, the ID found as follows: “[b]ased on the undisputed evidence presented by Align with respect to claim 1 of the ’456 patent, and consistent with the evidence and reasoning laid out with respect to claim 1 of the ’228 patent, I find that Align has established, by a preponderance of the evidence, that the Trios color scanners practice claim 1 of the ’456 patent.” *Id.*

**(iii) Additional Limitations of Claim 1 of the '207 Patent**

The ID found that Align has produced un rebutted evidence to show that 3Shape employees practice the method of claim 1 of the '207 patent with Trios, particularly at trade shows. *Id.* at 65. With regard to the unique element of the claim, the ID found that Align established, by a preponderance of the evidence, that 3Shape infringes the claim when it uses the accused Trios scanners. *Id.* The ID also determined that 3Shape's resellers infringe the claim when they provide training to others. *Id.* at 65-66. Therefore, the ID concluded that 3Shape, its resellers, and end-user customers practice and infringe the method in claim 1 of the '207 patent when they use Trios. *Id.* at 66.

**(b) 3Shape's Petition**

3Shape argues that there are three reasons that the ID's findings should be reversed: (1) 3Shape contends that the ID improperly ignored the patentee's disclaimer based on U.S. Patent No. 7,098,435 ("Mueller") during prosecution and the un rebutted testimony that Trios uses the same approach as the prior art system; (2) 3Shape asserts that the [REDACTED] is not depth data; (3) 3Shape contends that the FPGA in the Trios hand-held wand does not associate the depth data with the color data as the ID found; and (4) 3Shape argues that the ID applied the erroneous claim constructions for "scanning system," "imaging system," and "processor" and if the Commission determines to review the ID's constructions, it should also determine to review the infringement findings. *See, e.g.,* 3Shape Pet. at 3, 9-22. The Commission addresses arguments (1)-(3) in detail below. Argument (4), with respect to the "processor," is addressed with arguments (1)-(3) because the Commission only determined to review the construction of "processor." The Commission did not determine to review the claim constructions for

“scanning system,” and “imaging system,” and thus does not address 3Shape’s contingent arguments as to infringement of these claim limitations.

**(c) Analysis**

**(i) Disclaimer Based on Mueller**

3Shape argues that during prosecution, the patentee disclaimed the system disclosed in Mueller that obtains a series of two-dimensional color images of an object and processes those images to obtain a three-dimensional model of the surface of the object. 3Shape Pet. at 9.

3Shape explains that during prosecution of the ’228 patent, which is the parent of the ’456 patent and grandparent of the ’207 patent, the examiner rejected the pending claims as anticipated in view of Mueller. *Id.* The patentee amended the claim 1 as follows:

1. (Currently Amended) A system Device for determining the surface topology and associated color of at least a portion of a three dimensional structure, comprising:
  - a hand-held device comprising:
    - (a) a scanning system configured to provide means adapted for providing depth data of said portion, the depth data corresponding to a plurality of data points defined on a plane two-dimensional reference array substantially orthogonal to a depth direction;
    - (b) an imaging system configured to provide means adapted for providing two-dimensional color image data of said portion associated with said plurality of data points reference array; and
    - (c) a processor configured to associate the depth data with the color image data 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.

*Id.* at 10 (reproducing JX-0009 at Align-1091\_00003096; *see also id.* at 3103-4). 3Shape asserts that the ID only considered whether the patentee’s statements regarding Muller require the “scanning system” and “imaging system” to separately obtain depth and 2D color image data. *Id.* (citing ID at 35-37, 40). 3Shape claims that the ID failed to consider its argument that in

“disclaiming Mueller, regardless of the specific claim element to which that disclaimer is linked, the patentee also disclaimed Trios 3 because it operates so similarly to Mueller.” *Id.*

In making its argument that Trios cannot infringe based on the disclaimer before the Commission, 3Shape focuses on how similar its products are to the prior art. The Federal Circuit has repeatedly made clear that infringement rests on comparing the limitations in the claims to the accused product, and not by comparing the accused product to the prior art. *See, e.g., Baxter Healthcare Corp. v. Spectramed, Inc.*, 49 F.3d 1575, 1583 (Fed. Cir. 1995); *Tate Access Floors, Inc. v. Interface Architectural Res., Inc.*, 279 F.3d 1357, 1365-66 (Fed. Cir. 2002). The Commission finds this argument unpersuasive and sees no error in the ID’s decision not to address it.

**(ii) Depth Data/Processor**

One of 3Shape’s arguments is that the [REDACTED] is not the claimed “depth data.” Generally, 3Shape argues that the data from the lens position and [REDACTED] do not meet the “depth data” limitation. The ID rejected this position, finding that 3Shape’s argument is an improper attempt to limit “depth data” to a specific embodiment in the specification. ID at 58. The Commission affirms the ID’s determination for the reasons discussed herein and adopts the ID’s findings not inconsistent with the Commission’s analysis.

3Shape asserts that the claims themselves make clear that the depth data associated with color image data is the depth data “of the three-dimensional structure” based on the language of the independent claims. 3Shape Pet. at 13-14. Align agrees that there is no question that the claims require a system capable of “determining a surface topology” of “at least a portion of a three dimensional structure” and “a scanning system configured to provide depth data of said

portion.” Align Br. at 30 (citing JX-0003 at 25:41-47). However, Align asserts that the reference to the “depth data of said portion” “connotes the unsurprising notion that the depth data is related to the generation of surface topology. Indeed, depth data is essential for determining the surface topology, but it is not merely a final world coordinate ( $x, y, z$ ) of the 3D model, as Respondents erroneously contend.” *Id.* at 30-31. Specifically, Align argues:

In the context of the preferred embodiment using a confocal focusing method, the scanning system must provide depth data before  $z$ -values can be determined. As described in connection with FIGs. 4A and 4B, endoscope 46 “emits a plurality of incident light beams 48 impinging on to the surface of the teeth section.” (JX-0003 at 15:28-29.) “Incident light beams 48 form an array of light beams arranged in an  $X$ - $Y$  plane, in the Cartesian frame 50, propagating along the  $z$  axis.” (*Id.* at 15:30-32.) In this way, the incident light array “is arranged to provide depth data at a plurality of predetermined spatial coordinates substantially corresponding to the spatial disposition of said incident light beams.” (*Id.* at 5:45-48.)

Because the incident light beams strike an uneven surface (e.g. the tooth), the illuminated spots 52 are displaced from one another along the  $Z$ -axis, at different  $(x_i, y_i)$  locations. “Thus, while a spot at one location may be in focus of the optical element 42, spots at other locations may be out-of-focus.” (*Id.* at 15:35-37.) For each illuminated spot, a plurality of measurements of light intensity are made at different positions along the  $Z$ -axis and for each of such  $(x_i, y_i)$  location in the following manner:

In a single sequence of operation, control unit 70 induces motor 72 to displace the optical element 42 to change the focal plane location along the  $Z$ -axis, induce laser 28 to generate a light pulse, and, at the same time, synchronize image-capturing module 80 to grab data representative of the light intensity from each of the sensing elements. (*Id.* at 16:4-15.) Control unit 70 thus monitors the position of optical element 42 and its focal plane position along the  $Z$ -axis.

Then, in subsequent sequences, the focal plane will change in the same manner and the data capturing will continue over a wide focal range. (*Id.* at 16:15-18.) By determining the  $z_i$  corresponding to when a certain light spot is in-focus (a spot-specific position or SSP), the relative position of each light spot along the  $Z$ -axis can be determined. (*Id.* at 16:19-27.) The position of each SSP in an  $X$ - $Y$  frame of reference is thus known and by knowing the relative positions of the focal plane, the  $Z$  or depth coordinate can be associated with each spot. Finally, by knowing the  $X$ - $Y$ - $Z$  coordinates of each spot the surface topology can be generated. (*Id.* at 3:30-37.)

Thus, according to this embodiment, each SSP is determined based on a set of intensity value data captured by corresponding sensing elements of the image sensor. This in-focus data, however, is not alone sufficient to provide an indication of depth; one must know the relative distance from the scanner to each SSP. That data comes from the controller, which **synchronized** capture of intensity data and the displacement of the optical element 42, which physically corresponds to the relative focal plane position. This link in the timing of image capture and optical element positioning allows a SSP to be associated to relative focal plane position. Indeed, the claims capture such an embodiment where the depth data corresponds “to a plurality of data points [such as the SSPs] defined on a plane orthogonal to a depth direction.” Respondents have provided no explanation of why such data (which is indicative of the depth of the scanned portion) should not be considered “depth data” in the context of the claims. As can be seen, the claimed “depth data” can be more than the depth of the three-dimensional object and Respondents’ proposed limited interpretation of this term wrongly excludes certain embodiments of the patents’ specification. “A claim construction that excludes a preferred embodiment . . . is rarely, if ever correct and would require highly persuasive evidentiary support.” *EPOS Techs. Ltd. v. Pegasus Techs. Ltd.*, 766 F.3d 1338, 1347 (Fed. Cir. 2014) (internal quotation marks and citation omitted) (vacating a construction that “read[] out preferred embodiments and [] [was] not supported by ‘highly persuasive’ evidence”); *MBO Labs., Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323, 1333 (Fed. Cir. 2007).

*Id.* at 31-32. The Commission finds this reasoning persuasive in light of the teachings in the specification and the language of the claims.

In addition, there is also a notable distinction between claim 1 of the '228 patent and claim 1 of the '456 and '207 patents in that the latter patents’ claims also require that the “depth data and color image data represent the surface topology of the color of the portion of the three-dimensional structure.” *Compare* JX-0003 at 25:41-52 (claim 1) *with* JX-0004 at 25:55-26:3 (claim 1) and JX-0005 at 26:19-35 (claim 1). Further, dependent claim 7 of the '228 patent, recites similar language. JX-0003 at 26:1-4. The difference in claim language between these claims illustrates that “depth data” must be interpreted to be broader than the “surface topology,” and is not required to be the coordinates of the surface topology. Similarly, dependent claim 25 of the '228 patent, which ultimately depends from independent claim 1, requires “a processor coupled to the detector and configured to conformally map the color image data to the depth data

to produce a color, three-dimensional numerical entity comprising a plurality of data points, each data point comprising three-dimensional surface coordinate data associated with color data.” Because the claim requires that the 3D entity be derived from the “depth data” and the patent claims differentiate “depth data” from “surface coordinate data” and “three-dimensional numerical entity,” 3Shape’s interpretation would render some of these other claim limitations superfluous. 3Shape’s interpretation cannot be correct based on the language of the claims themselves.

Align’s interpretation of the claim language is also consistent with the teachings in the specification. As Align accurately explains, 3Shape ignores the disclosures regarding “depth data” in the patent specification that describe “depth data” as data gathered or acquired from the scan of the translatable lens that reflects the distance of the object. Align Resp. at 12 (citing JX-0003 at 4:54-5:48, 8:42-45, 9:1-3, 9:7-29, 21:43-45); *see also* Align Br. at 30-32. 3Shape’s attempt to limit the depth data to the coordinates of the scanned object “is inconsistent with the specification because it forces the scanning system to perform a function described as performed by the processor.” Align Br. at 30 (citing JX-0003 at 13:2-5 (“The detection optics 60 receives image data from the main optics 41 and the image processor 24 determines the depth  $z$  values for each  $x, y$  point illuminated on the object 26 based on this image data.”)). While there is no doubt that the specification does discuss the derivation of coordinate data, the specification contemplates various methods for arriving at that data, including a preferred embodiment using a confocal focusing method, using a translatable lens. *See, e.g., id.* at 30-32. 3Shape’s interpretation would exclude this preferred embodiment, discussed with respect to Figures 4A and 4B, from the scope of the claims.

Turning to the question of infringement by Trios, 3Shape argues that the [REDACTED] in the Trios is a measure of the lens position and this measurement cannot be the depth data. 3Shape Pet. at 14-15. Align contends that this measurement is not just the lens position but that it indicates the distance to the object because the lens position determines the focal plane depth and this data is used by a processor to determine the Z value. Align Resp. at 12. While 3Shape attacks the ID for failing to provide an analysis of how the [REDACTED] “corresponds to a plurality of data points defined on a plane substantially orthogonal to the depth direction,” the ID reasonably credits the testimony of Dr. Stevenson that the depth data and color data are [REDACTED]. ID at 54-56; 3Shape Pet. at 16. The ID also finds additional support from other witnesses. ID at 54-56 (quoting testimony from Dr. Roselund and Dr. Hansen and citing to testimony from Dr. van der Poel).

3Shape further argues that the expert testimony does not support the ID’s findings. Yet, while the ID extensively addresses the expert testimony, 3Shape merely points to a short excerpt of Dr. Stevenson’s testimony to argue that the “[REDACTED] is not the depth of the object.” *Id.*; 3Shape Pet. at 16. Dr. Stevenson, however, testified that the [REDACTED] is “depth data.” Tr. at 545:25-547:1. The ID’s reliance on this evidence is correct and the Commission affirms the ID’s findings on infringement.

**(iii) Association of Depth Data and Color Image Data**

Finally, 3Shape argues that the hand-held wand does not associate the depth data and color image data. 3Shape Pet. at 18. 3Shape explains that [REDACTED]  
[REDACTED]  
[REDACTED] *Id.* In response, Align argues that the “ID correctly concludes that the FPGA on the Trios hand-held wand associates [REDACTED]

[REDACTED] Align Resp. at 15. Align further contends that 3Shape's arguments are new and thus waived. *Id.*

While 3Shape argues that the relationship [REDACTED] [REDACTED], the testimony says otherwise. 3Shape Pet. at 19 (citing Tr. at 1099:3-24, 819:4-820:11). 3Shape's expert testified:

Q: Do you recall Dr. Stevenson pointed to [REDACTED] that he testified was performed on the FPGA?

Do you recall generally that testimony?

A: Yes.

Q: Do you believe that characterization was correct or incorrect, Doctor?

A: I don't believe it's correct. I believe that the [REDACTED] [REDACTED]. But it's my understanding through testimony from 3Shape and documentation that [REDACTED]

And then through the [REDACTED]

Tr. at 1099:3-24. This testimony establishes that the [REDACTED]

[REDACTED]. The ID's finding that the [REDACTED]

[REDACTED] is reasonable. See ID at 57-58.

3Shape also argues that the ID's findings are inconsistent with the teachings of the specification. 3Shape Pet. at 20-22. Specifically, 3Shape contends that the "association" must be the "matching of the depth data with the corresponding image data," which it alleges [REDACTED] [REDACTED]. *Id.* 3Shape did not present this as a claim construction argument

to the ALJ and has therefore waived this issue. In any event, 3Shape appears to be relying on the specific embodiments in the specification to construe “association” more narrowly than its plain and ordinary meaning. The ID’s determination that Trios “associates” the depth data and the color data by [REDACTED] is supported by substantial evidence. The Commission affirms this finding in the ID.

**2. '433 Patent: Independent Claim 12**

**(a) The ID**

The ID found that Align did not present evidence sufficient to show that Trios practices element [5]—the “selectively map” limitation. ID at 67. The ID explained that Align relied exclusively on the testimony of its expert, Dr. Stevenson, to show that this element is practiced by Trios. *Id.* The ID found that Dr. Stevenson’s testimony, under Align’s construction, does not demonstrate that the Trios scanners include a processor that receives image data, receives depth data, and selectively maps the received image data “to” the received depth data. *Id.* at 67-68 (reproducing Tr. at 493:19-494:19). The ID found that instead, “Dr. Stevenson’s testimony is that a processor in the Trios scanners derives, from ‘each’ [REDACTED] [REDACTED]. The derivation of color information and depth information is not consistent with the limitation of element [5], which Align construes to require ‘matching’ of depth data and image data.” *Id.* (citation removed). The ID observed that Dr. Stevenson does not testify that a processor in the Trios scanners matches depth data to image data. *Id.*

The ID explained that “Align also presented an argument of infringement via the doctrine of equivalents under 3Shape’s proposed construction.” *Id.* at 69. The ID noted that “[t]he primary difference between [n] 3Shape’s construction and Align’s is a requirement that the image

data be monochrome.” *Id.* The ID found that “Align’s equivalence argument is directed only to establishing that any difference between mapping color image data and mapping monochrome image data is insubstantial” and “[n]othing in that argument remedies the flaw in Align’s literal infringement theory.” *Id.* at 69-70. Finally, the ID concluded:

Even if the difference between mapping color image data and mapping monochrome data was insubstantial, Align’s equivalents theory still does not show a processor that maps received image data to received depth data. Accordingly, Align’s equivalence argument fails for at least the same reasons its literal infringement argument fails.

In sum, Align has not met its burden to show infringement of claim 12 of the ’433 patent.

*Id.* at 70.

**(b) Analysis**

Align petitions for review of the ID’s finding of non-infringement and argues that: (1) the ID ignores testimony from Dr. Stevenson, (2) the testimony of 3Shape’s engineer, Mr. Roselund, supports finding infringement, and (3) 3Shape did not present any evidence of non-infringement.

Align’s post-hearing brief only cites to minimal evidence to support its argument. Specifically, Align cites to testimony from Dr. Stevenson (Tr. 493:19-494:19, 495:1-17) and it reproduces CDX-008.55 and CDX-008.56, which cites JX-0047C and CX-0533C at 4. Align Post-Hearing Br. at 62-64. Align asserts that the ID was improper for failing to consider the evidence and testimony on which Dr. Stevenson relied during his testimony. While Dr. Stevenson refers back to what he had previously discussed, Tr. at 493:19-494:19, Dr. Stevenson did not mention any specific testimony or documents that he was relying on. Nor did Align add citations in its briefing before the ALJ to any of that previous testimony Dr. Stevenson referenced, now discussed at length in its petition for review. Align Pet. at 37. Align’s position amounts to requiring the ALJ to comb through the record looking for the other testimony and

documents that Dr. Stevenson was referencing. Align asserts that this is the fourth patent that Dr. Stevenson may have been testifying about and much of the testimony is repetitive. *Id.* However, the limitation in dispute here, “selectively map the image data to the depth data for the two-dimensional reference array based on the plurality of focal lengths and the depth data such that the resulting associated color of the structure portion is in focus relative to the structure portion for a plurality of distances in the depth direction,” is not a limitation in the asserted claims of the other color scanner patents. Accordingly, the Commission affirms the ID’s finding that Align did not present sufficient evidence to establish infringement of element [5].

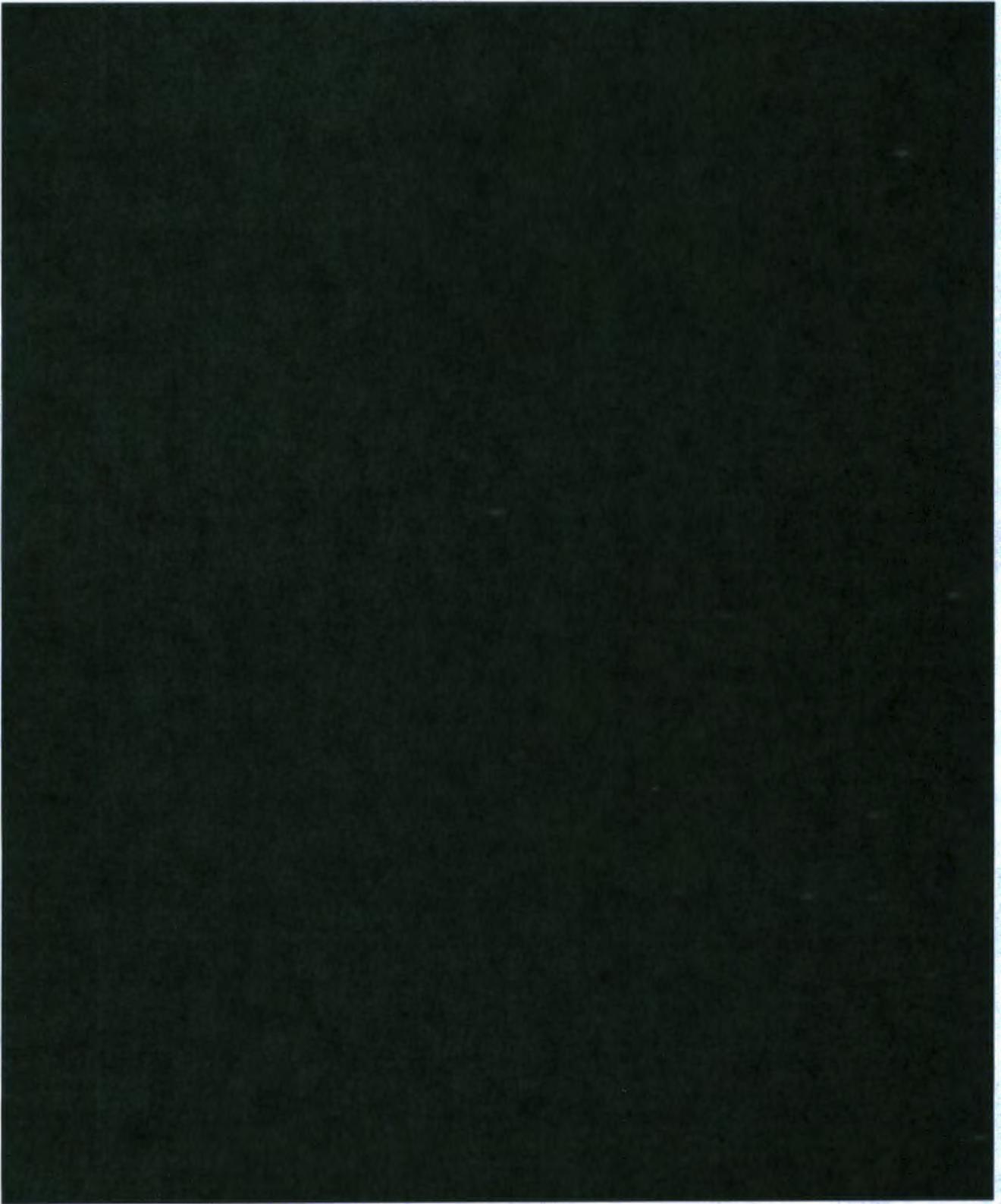
**D. Domestic Industry—Technical Prong**

**1. The ’228, ’456, and ’207 Patents**

The parties presented their petition arguments on whether the technical prong of the domestic industry was met for the ’228, ’207, and ’456 patents together, so we do the same. The parties’ dispute is over whether the domestic industry product, the iTero, has the claimed “processor.”

**(a) The ID**

The ID explained that the parties’ dispute centered on whether the iTero has a processor as claimed in claim 1 of the ’228 patent. ID at 77. The ID explained that Align relied on the [REDACTED] to argue this element was met. *Id.* The ID asserted that the following block diagram and text describe the operation [REDACTED]:



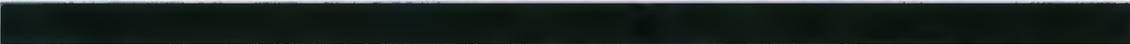
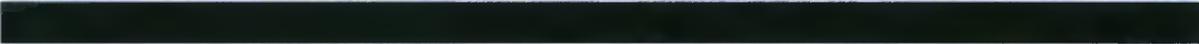
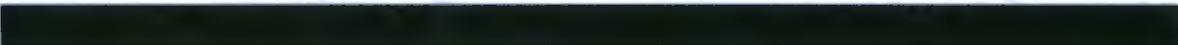


*Id.* at 78-79 (reproducing JX-0102C at 00684145-46). The ID explained that the text, following the diagram, describes a process by which [REDACTED]



[REDACTED]. *Id.* at 79.

The ID found that here, unlike with respect to the Trios color scanners, there was no indication in the evidence cited by Align that the iTero associates color and depth data as required by the claim. *Id.* [REDACTED]



[REDACTED] *Id.* The ID noted that both parties presented competing expert testimony regarding

[REDACTED]. *Id.* at 80. The ID

considered the testimony and evidence presented by Align but found that it does not show an association of the data. *Id.* at 80-81. Therefore, the ID found that Align failed to show that its iTero products practice element [4] of claim 1 of the '228 patent. *Id.*

The ID noted that Align also made an argument that its products practice element [4] under the doctrine of equivalents by pointing to [REDACTED] but finds this argument meritless. *Id.* at 81. The ID explained that “the requirement of a handheld device with a processor configured to associate depth and color image data was added during prosecution to overcome a prior art rejection. Prosecution history estoppel precludes the equivalence argument Align now attempts to make.” *Id.* (citations removed). The ID found that Align did not explain why estoppel does not apply. *Id.* Therefore, the ID found that Align did not establish that the iTero practices element [4] of claim 1 of the '228 patent under the doctrine of equivalents. *Id.* The ID concluded that Align has not established, by a preponderance of the evidence, that its iTero element product practices claim 1 of the '228 patent. *Id.* Similarly, the ID determined that because claims 4 and 26 depend from claim 1, it also found that Align did not establish, by a preponderance of the evidence, that its iTero practices those claims. *Id.* The ID further explained that Align provided no additional argument or evidence with respect to the iTero Element 2 or the Element Flex products and therefore, the ID concluded that Align did not establish, by a preponderance of the evidence, that its iTero Element 2 and Element Flex products practice claims 1, 4, or 26 of the '228 patent. *Id.*

The ID further explained that Align argued that its iTero products practice claims 1 and 15 of the '456 patent and claim 1 of the '207 patent. *Id.* at 82-83. The ID noted that Align relied on the same arguments it advanced with respect to claim 1 of the '228 patent, including the same “processor” argument. *Id.* Therefore, the ID concluded that Align did not demonstrate that its iTero products satisfy the technical prong of the domestic industry requirement with respect to the '228, '456, and '207 patents. *Id.*

**(b) Align's Petition**

Align argues that the ID improperly found that the iTero does not practice the asserted claims of the '228, '207, and '456 patents because the ID found that the "processor" limitations are not met. Align Pet. at 41. Align first argues that the claims do not require a "processor" on the hand-held wand and therefore, this limitation is met. *Id.* at 41-42.

Second, Align argues that even if it is determined that the asserted claims require processing on the "hand-held" device, [REDACTED] meets the processor limitations. *Id.* at 42. Align explains that it introduced at least three documents and the testimony of its expert that demonstrate that the iTero associates color and depth as required by the claim. *Id.* Align concludes that the ID misinterpreted the evidence and is clearly erroneous in its conclusion. [REDACTED]. *Id.* at 44-45. Therefore, Align concludes it is clear that iTero satisfies the technical prong for the same reasons the Trios infringes. *Id.* at 42-43.

Align argues that at the hearing it presented evidence that the iTero practices the asserted claims of the '288, '456, and '207 patents both literally, and under the doctrine of equivalents. *Id.* at 48. Finally, Align argues that the ID committed clear legal error by misapplying *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002), without performing the legally-required analysis to conclude that Align has not met its burden under the doctrine of equivalents. *Id.* Align contends that the ID concluded in a single conclusory sentence, that Align's doctrine of equivalents argument was precluded by prosecution history estoppel under *Festo*. *Id.* at 45-46. Align asserts that the ID is flawed because it fails to address the legal requirements established by the Supreme Court and the Federal Circuit for determining when *Festo* applies. *Id.* at 46-47. Align argues that the ID erred because the ID provided no analysis

of the prosecution history, no examination of why the amendment was made, and no discussion of the rejection that provoked the amendment. *Id.* at 49.

Align contends that the *Festo* presumption does not apply and that if the ID had properly performed the *Festo* analysis, it would have been apparent that the claim amendment is a clarifying amendment that does not fall into the limited circumstances where *Festo* applies because no intent to surrender claim scope is evidenced. *Id.* at 50-52.

Align next contends that even if the *Festo* presumption is found to apply, it is rebutted. *Id.* at 53. Specifically, Align asserts that the patentee's remarks and the examiner's Reasons for Allowance establish that the amendment bears no more than a tangential relation to the equivalent in question. *Id.* Align also asserts that an examination of the prosecution history reveals no evidence that the equivalent was disclaimed. *Id.* at 54.

Align argues that the evidence mandates a finding that iTero practices the claims under the doctrine of equivalents. *Id.* Align explains that iTero is insubstantially different from the claimed processor and/or it matches the function, way, result requirements. *Id.* at 54-56.

### **(c) Analysis**

As discussed above in § IV.A.4(b), the Commission finds that the asserted independent claims of the '228 and '456 patents are invalid for lack of written description. The Commission also affirms, as noted above in §§I., IV.E.4, the ID's findings that the asserted claims of the '207 patent are invalid as obvious. Thus, the technical prong of domestic industry cannot be met for those patents. The Commission also finds that even if the claims were valid, Align has not met its burden to establish that its domestic industry products practice the '228, '456, and '207 patents.

Align first argues that under the correct construction of processor, it is undisputed that iTero practices the claims. As we discussed above, the Commission finds that claim 1 of the '228, '456, and '207 patents require the processor to be located on the hand-held wand.

Second, Align argues that the ID misinterpreted the evidence of record that establishes that iTero meets the claimed "processor" element under the ID's claim construction. 3Shape, on the other hand, asserts that Align, in its post-hearing brief, only argued that the [REDACTED] meets the "processor" limitation by [REDACTED] and that Align is now attempting to introduce a new theory [REDACTED] scans. 3Shape Resp. at 19. Having considered the parties' responses to the Commission's request for briefing, the Commission finds that Align's argument with respect to the time stamps was covered by the documents cited to the ALJ (and discussed in the ID) but was not articulated, as it now argues in its petition for review. *See, e.g.*, Align Post Hearing Br. at 51-52. We agree with 3Shape that Align now relies on evidence that was not presented to the ALJ. The Commission finds that any evidence that was not cited before the ALJ was waived but considers it nonetheless as discussed below.

After considering all the evidence presented, including the new evidence that Align now relies on before the Commission, the Commission affirms the ID's finding that Align did not establish with sufficient evidence that the [REDACTED].

As discussed above in more detail, the ID found that Align failed to present evidence that the [REDACTED], and thereby concluded that Align failed to meet its burden of proof for this limitation. ID at 79. Align points to, and the ID considered, the testimony of Dr. Stevenson to argue that [REDACTED]. However, Dr. Stevenson's testimony is

very conclusory: [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Tr. at 503:14-504:10. The only link that the ID finds was missing is evidence

that the [REDACTED]. There is no record evidence that

“combined” and “associate” are the same. The Commission agrees with the ID’s analysis. Dr.

Stevenson’s testimony is extremely conclusory and he does not explain how [REDACTED]

[REDACTED]. Exhibits JX-0102C and JX-

0090C discussed in the ID, at 78-80, do not provide any clarity on how the [REDACTED]

[REDACTED]. Align now also relies on additional testimony from Dr. Stevenson, and

several additional exhibits to explain that the [REDACTED]

[REDACTED]. While Align presents significant evidence now regarding how [REDACTED]

[REDACTED], Align Pet. at 43-45, the evidence and/or testimony on how

such association occurs [REDACTED]. For the accused Trios,

there is testimony that the association occurs [REDACTED]

[REDACTED] products. This is a failure on Align’s part to meet its burden of

proof.

In addition to JX-0090C and JX-0102C, Align relied on JX-0091C before the ALJ.

However, JX-0091C also suffers from the same flaws as the exhibits discussed in the ID.

Specifically, JX-0091C does not mention any [REDACTED]

[REDACTED]. Align now also relies on JX-100C but again this evidence does not establish

that [REDACTED]. Instead, JX-100C shows the addition [REDACTED]

[REDACTED]. But there is no discussion or illustration that shows association [REDACTED].

Align also now relies on JX-0101C and JX-0371C which discuss various sets of data [REDACTED] but again neither of these documents provide any information on [REDACTED]

[REDACTED]. The failure to describe or illustrate the association is not remedied by expert testimony, as discussed above. Dr. Stevenson's conclusory testimony is not sufficient to support the factual findings that Align seeks without record support. *See, e.g., Dominion Energy, Inc. v. Alstom Grid, LLC*, 725 Fed. Appx. 980, 986 (Fed. Cir. 2018) (expert testimony "just saying that something is so does not make it true, especially when there is no record support"). In addition, during the hearing Align even conceded that Dr. Stevenson had no literal infringement theory where the [REDACTED] satisfied the "processor" limitation. Tr. at 506:6-512:9.

Align also relies on testimony from one of its own employees, Mr. Ofer Saphier, who was deposed on many of the documents discussed herein, to establish that the processing occurs [REDACTED]. Mr. Saphier, like Dr. Stevenson, also does not make up for the inadequacies of the exhibits offered by Align. However, in one portion of his testimony, Mr. Saphier admits that the [REDACTED]. JX-0077C at 136:1-137:1 [REDACTED]

[REDACTED]. Accordingly, the Commission finds that iTero does not practice the '228, '456, and '207 patents literally.

The second argument that Align presents is that the ID improperly applied *Festo* to determine that the doctrine of equivalents does not apply. The ID's analysis regarding the doctrine of equivalents and *Festo* is somewhat limited. ID at 84-82. However, it is worth noting

that Align's argument on this issue has also been minimal. For example, for the '228 patent, Align only argued the following in its post-hearing brief:

In addition, Dr. Stevenson testified that should the processor element be construed to require the association of the depth data and color information to occur on the wand, [REDACTED] (HT:513:17-514:5.) Dr. Stevenson testified that as to the different constructions, [REDACTED]. *Id.* Accordingly, the processor element of the claims is satisfied even if the processor is on the PC.

Align Post-Hearing Br. at 53. The Commission finds that Align's arguments before the ALJ are insufficient to meet its burden. Indeed, Align does not even mention *Festo* in either of its two post-hearing briefs. Nonetheless, the Commission addresses Align's doctrine of equivalent arguments.

Prosecution history estoppel is a "rule of patent construction" that requires interpreting granted claims in light of claims "that have been cancelled or rejected." *Festo* 535 U.S. at 733, 736-737, 740-41 (quoting *Schriber-Schroth Co. v. Cleveland Trust Co.*, 311 U.S. 211, 220-221 (1940)) (quotation marks omitted). Prosecution history estoppel arises from "a narrowing amendment made to comply with any provision of the Patent Act, including § 112." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1366 (Fed. Cir. 2003) ("*Festo IX*"). While the doctrine of equivalents "allows the patentee to claim those insubstantial alterations that were not captured in drafting the original patent claim," the patentee cannot rely on subject matter surrendered during prosecution. *Id.* at 733.

Determining whether prosecution history estoppel applies is a two-step process. The first step is to determine whether the amendment at issue was a narrowing amendment. *Festo IX*, 344 F.3d at 1366. "A rejection indicates that the patent examiner does not believe the original claim could be patented," and the patentee's "decision to forgo an appeal and submit an amended claim

is taken as a concession that the invention as patented does not reach as far as the original claim.” *Festo*, 535 U.S. at 734. The second step is to determine whether the patentee made the narrowing amendment for a substantial reason relating to patentability. *Id.* If the reason for the narrowing amendment is not apparent from the prosecution history, it is presumed to have been made for a “substantial reason relating to patentability.” *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 33 (1997); *see also Festo IX*, 344 F.3d at 1366-67.

As discussed above, the ID found that the “requirement of a handheld device with a processor configured to associate depth and color image data was added during prosecution to overcome a prior art rejection.” ID at 81. The amendment that added the requirement of the hand-held device with a processor was a narrowing amendment and a review of the prosecution history supports this finding. For example, prior to the amendment, the elements of the originally-filed claim 1 could be found anywhere in the “[d]evice for determining the surface topology and associated color of at least a portion of a three dimensional structure,” and the claim did not even mention a “hand-held device” or a “processor,” as illustrated below:

1. (Original) Device for determining the surface topology and associated color of at least a portion of a three dimensional structure, comprising:

(a) scanning means adapted for providing depth data of said portion corresponding to a two-dimensional reference array substantially orthogonal to a depth direction;

(b) imaging means adapted for providing two-dimensional color image data of said portion associated with said reference array;

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.

JX-0009 at Align-1091\_00002951. The patentee amended the claim to require the claimed “system for determining the surface topology and associated color of at least a portion of a three dimensional structure” comprising a “hand-held device,” which now included a “processor configured to associate the depth data with the color image data,” as shown below:

1. (Currently Amended) ~~A system~~ Device for determining the surface topology and associated color of at least a portion of a three dimensional structure, comprising:  
~~a hand-held device comprising:~~

(a) ~~a scanning system configured to provide means adapted for providing depth data of said portion, the depth data corresponding to a plurality of data points defined on a plane~~ two-dimensional-reference-array substantially orthogonal to a depth direction;

(b) ~~an imaging system configured to provide means adapted for providing two-dimensional color image data of said portion associated with said plurality of data points reference-array; and~~

(c) ~~a processor configured to associate the depth data with the color image data 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.~~

JX-0009 at Align-1091\_00003096. Align’s claim that the patentee’s boilerplate statement that “independent claim 1 has been amended to further expedite prosecution” proves the amendment was not narrowing is not persuasive. *See Bai v. L & L Wings, Inc.*, 160 F.3d 1350, 1355 (Fed. Cir. 1998) (patentee’s boilerplate remark to examiner that the amendment was not narrowing is not persuasive). Here, the patentee chose to amend the claims to overcome the rejection and the patentee referenced the new “processor” limitation during prosecution to advance the application. JX-0009 at Align-1091\_00003104. While neither the examiner nor Align, in the prosecution history, focused on the amendment of the hand-held device, both focused on all three elements (*i.e.*, scanning system, imaging system, and processor) of the hand-held device in making the claims allowable. We do not find the lack of argument regarding the added hand-held device to be meaningful. Accordingly, the Commission finds that this amendment was narrowing.

The ID explained that the amendment was made “to overcome a prior art rejection” and the Commission finds that it was substantially related to patentability. ID at 81; *see Festo IX*, 344 F.3d at 1366. Specifically, Align amended the claim to overcome the examiner’s rejection based on Mueller, and provided accompanying remarks. Nothing in the prosecution history, other than

the single boilerplate remark, suggests that the amendments were not made for the purpose of securing patentability. As 3Shape argues, “[t]o the extent this reason is not apparent, the amendment is presumed to have been made for a ‘substantial reason relating to patentability.’ See, e.g., *Warner-Jenkinson Co.*, 520 U.S. at 33; see also *Festo IX*, 344 F.3d at 1366-67.” 3Shape Resp. at 25. Prosecution history estoppel presumptively applies when an applicant has made a narrowing amendment related to patentability. *Festo*, 535 U.S. at 736-37. Because the amendment was substantially related to patentability, the Commission finds that prosecution history applies.

After it is determined that prosecution history estoppel applies, the Commission must determine the scope of the subject matter surrendered. The original claims as filed do not include any “hand-held device” or “processor” limitations, while the amended claims do include these requirements. Thereby, the Commission agrees that the patentee surrendered the entire scope of the originally submitted claim beyond “a hand-held device comprising...a processor,” including systems and methods with a processor outside the hand-held device on an external computer. The presumption that the patentee surrendered all territory between the original claim limitation and the amended claim limitation further supports this conclusion. See *Festo*, 535 U.S. at 740.

A patentee bears the burden to rebut the presumptive application of prosecution history estoppel by establishing one of the following three exceptions:

First, “[t]he equivalent may have been unforeseeable at the time of the application.” Second, “the rationale underlying the amendment may bear no more than a tangential relation to the equivalent in question.” Third, “there may be some other reason suggesting that the patentee could not reasonably be expected to have described the [equivalent].”

*Integrated Tech. Corp., v. Rudolph Tech., Inc.*, 734 F.3d 1352, 1356 (Fed. Cir. 2013).

Align argues in its petition for review for the first time that any *Festo* presumption is rebutted. Align Pet. at 53-54. Align has waived this argument by failing to present it to the ALJ. Order No. 16, Ground Rules §11.2, 14.1, 14.2 (April 23, 2018). It is Align's burden to overcome the *Festo* burden and it cannot do so for the first time before the Commission.

Nonetheless, Align argues, as an initial matter, that the amendment only bears a tangential relation to the equivalent in question because the patentee made several other amendments to the claims. The tangential relation exception is narrow. *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 480 F.3d 1335, 1342 (Fed. Cir. 2007). As 3Shape explains, the proper inquiry is "whether the reason for the narrowing amendment was peripheral, or not directly relevant, to the alleged equivalent." *Festo IX*, 344 F.3d at 1369. "[A]n amendment made to avoid prior art that contains the equivalent in question is not tangential." *Chimie v. PPG Indus. Inc.*, 402 F.3d 1371, 1383 (Fed. Cir. 2005) (quoting *Festo IX*, 344 F.3d at 1369). "It does not follow, however, that equivalents not within the prior art must be tangential to the amendment." *Id.*

Again, as 3Shape correctly explains "[w]hen a patentee has amended its claim to include two new limitations and expressly relied upon one to distinguish the prior art, the Federal Circuit has rejected the argument that the limitation the patentee did not expressly rely upon to distinguish the prior art was tangential." 3Shape Resp. at 27 (citing *Integrated Tech. Corp.*, 734 F.3d at 1358 (The Court reasoned that the patentee "could easily have simply amended" the original claim to recite only the non-tangential limitation, yet the patentee chose to recite both, and thus, both were non-tangential.)).

Here, the patentee relied on various limitations in distinguishing the amended claim over the Mueller prior art:

Mueller, however, fails to at least teach a scanning system configured to provide depth data, an imaging system configured to provide two dimensional color image data, and a processor configured to associate the depth data with the color data. Thus, Mueller fails to anticipate claim 1.

JX-0009 at Align-1091\_00003104. This argument establishes that Align's amendments to the claim convey to the public that it relied on a scanning system, imaging system, and the processor to overcome the prior art. *See Integrated Tech.*, 734 F.3d at 1359. Despite Align's argument that only the scanning and imaging systems were necessary to overcome the prior art, the public relied on the actual statements in the prosecution history. Therefore, Align has not proven that the amendment was only tangentially related to the equivalent.

Align's second argument is difficult to understand. Align Pet. at 54. To the extent Align's argument can be understood, the Commission interprets Align's argument to be that the *Festo* presumption should not apply because the equivalent was unforeseeable. "The patentee may rebut the application of prosecution history estoppel by establishing that the equivalent would have been objectively unforeseeable to one of ordinary skill in the art at the time of the amendment." *Integrated Tech. Corp.*, 734 F.3d at 1359. But when the patentee "originally claimed the subject matter alleged to infringe but then narrowed the claim in response to a rejection, he may not argue that the surrendered territory comprised unforeseen subject matter." *Id.* Align presents no record evidence or argument that a processor on an external PC was objectively unforeseeable to one of ordinary skill in the art at the time of the amendment (especially when it was disclosed in the patent specification). Align merely argues that the claim as originally filed would not have covered "the FPGA and a processor on the host computer." Align Pet. 54. This argument, does not prove unforeseeability, and Align does not have any evidence to support its assertion. Accordingly, the Commission finds that Align has not rebutted

the *Festo* presumption. The Commission affirms the ID's findings that Align is foreclosed from arguing the technical prong of domestic industry is met under the doctrine of equivalents.

**E. Validity: Secondary Considerations of the '207 Patent**

**1. The ID**

The ID explained that Align argued that the commercial success of its iTero is evidence that the asserted claims of the color scanner patents are not obvious. ID at 113. The ID noted that 3Shape did not challenge this assertion. *Id.* The ID found, "consistent with my findings regarding the technical prong of the domestic industry requirement, Align has only shown that the iTero Element practices claim 12 of the '433 patent. It has not shown that the iTero Element practices any claim of the '228, '456, or '207 patents." *Id.* Therefore, the ID only found evidence of a nexus between the commercial success of iTero and claim 12 of the '433 patent, and concluded that Align's commercial success evidence tended to support the conclusion that claim 12 of the '433 patent is not obvious. *Id.*

Consistent with this finding, the ID also found that Align presented un rebutted evidence of others praising its iTero product. *Id.* at 114. The ID determined that the evidence relied upon by Align was objective evidence tending to support a conclusion that claim 12 of the '433 patent is not obvious. *Id.* at 114-15. The ID concluded, however, that the evidence was not probative of the other color scanner patents. *Id.* at 115.

The ID also considered Align's evidence relating to long-felt but unresolved need and copying and declined to rely on the evidence of these factors. *Id.* at 113-14, 115-16.

**2. Align's Petition: Commercial Success**

Align argues that the ID correctly found that Align provided sufficient evidence to show that Align's iTero Element had commercial success and was praised by others. Align Pet. at 74

(citing ID at 113-15). Align contends that the ID only credited this testimony with respect to claim 12 of the '433 patent and erred by not crediting this evidence with respect to the claims of the '228, '456, and '207 patents. *Id.* Therefore, Align argues that the evidence of commercial success and praise by others should apply to all of the asserted claims. *Id.*

Align argues that the ID improperly dismissed its evidence of long-felt but unresolved need as “hardly objective evidence.” *Id.* (citing ID at 114). Align contends that the undisputed objective evidence is that many people had recognized the problems with associating color information with depth data from a 3D scan. *Id.* at 75. Align contends that 3Shape does not dispute the objectivity of the evidence. *Id.*

Align next argues that the ID’s finding of no copying is clear error. *Id.* Align asserts that 3Shape admits that it analyzed Align’s patents in [REDACTED] of 3Shape’s Trios. *Id.* Indeed, Align argues that 3Shape disassembled an iTero scanner, studied Align’s patent, and received [REDACTED] about infringement. *Id.* Align asserts that this is circumstantial evidence of copying. *Id.* at 75-76.

### **3. 3Shape’s Petition: Commercial Success**

3Shape explains that the ID found commercial success of Align’s iTero that bears a nexus to the invention of claim 12 of the '433 patent based on its finding that the iTero practices claim 12. 3Shape Pet. at 48. However, 3Shape argues that the evidence that the ID cites does not show commercial success, nor does it link the alleged commercial success to the iTero, as opposed to its predecessor products. *Id.* 3Shape further argues that the ID cited “testimony from Align’s CEO, Mr. Joseph Hogan, on the overall alleged growth and commercial success of Align and the iTero from Align’s founding in 1998 to the present day.” *Id.* (citing ID at 113 (citing Tr. 412:13-415:17)). 3Shape explains that Align, however, did not commercially release iTero until

late 2015 and therefore, this testimony is not relevant to the first 17 years of Align's "commercial success" that Mr. Hogan posited. *Id.* 3Shape explains that the ID also relied on a competitor's report commenting on Align's marketing strategy but 3Shape contends that this report actually shows that iTero was "still generations behind." *Id.* Therefore, 3Shape concludes that the two pieces of evidence that the ID relied on do not support findings of either commercial success or a nexus between that commercial success and claim 12 of the '433 patent. *Id.* at 48-49.

#### 4. Analysis

The Commission does not take a position on the secondary considerations for the '433, '456, and '228 patents, because the Commission does not find these patents invalid based on obviousness. We only address the '207 patent herein.

The ID's findings of lack of commercial success and praise by others for the '207 patent is tied to the finding that the domestic industry products do not practice this patent. ID at 113, 114-15. Align's petition is similarly tied to its arguments that the domestic industry products practice the '228, '456, or '207 patents. The Commission finds that the domestic industry products do not practice the '207 patent. Therefore, the Commission affirms the ID's finding that Align has not established commercial success and praise by others for the '207 patent.

Turning to long-felt but unresolved need, the ID found that the primary evidence that Align relies on is citations to the '228 patent itself and finds that this evidence is not objective. *Id.* at 113-14. We agree with the ID and 3Shape that evidence in the patents themselves, which is how the inventor viewed the patented device, not the public, is not persuasive. *See Arkie Lures, Inc. v. Gene Lawrew Tackle, Inc.*, 119 F.3d 953, 957 (Fed. Cir. 1997) ("The so-called 'secondary considerations' provide evidence of how the patented device is viewed by the

interested public: not the inventor, but persons concerned with the product in the objective arena of the marketplace.”). Accordingly, the Commission affirms the ID’s finding that Align has not established long-felt but unresolved need for the ’207 patent.

Lastly, the ID found there is no evidence of copying. Part of Align’s petition for review with respect to copying is based on the alleged improper exclusion of evidence by the ALJ. The Commission determined not to review the ALJ’s evidentiary ruling, thereby mooting that portion of Align’s petition. There is no question that 3Shape conducted a market study of intraoral scanners in 2007-2009, purchased an iTero, and was aware of the patents in the market. However, the evidence of record is not sufficient to establish copying by 3Shape. *See* ID at 115-16 (considering and rejecting Align’s evidence and citing Tr. at 731:18-733:20). Instead, the evidence shows that 3Shape analyzed Align’s patents in [REDACTED] [REDACTED] but it did so in the context of ensuring that it did not infringe any patents. *See e.g.*, JX-0054C at 23:4-24:1; Tr. 733:15-20, 757:15-758:2. Accordingly, the Commission affirms the ID’s findings that there is no evidence of copying.

**F. Validity: Written Description of “selectively map” in the ’433 Patent**

3Shape asserts that during claim construction it argued that the “selectively map” term renders claim 12 of the ’433 patent invalid under 35 U.S.C. § 112, ¶ 1 for lack of written description and under 35 U.S.C. § 112, ¶ 2 as indefinite. 3Shape Pet. at 47. 3Shape asserts that contrary to the ID’s finding, ID at 48, 3Shape did argue that “selectively map” lacks written description both in its opening and rebuttal claim construction briefs. *Id.* 3Shape argues that it maintained this position both before and after the hearing. *Id.* 3Shape argues that the ID erred for not considering its position. *Id.*

The Commission finds that 3Shape waived this argument. In its opening claim construction brief, pre-hearing brief, and both its initial and responsive post-hearing briefs, 3Shape does not assert that the term lacks written description. *See, e.g.*, 3Shape Opening Claim Construction Br. at 30-32; 3Shape Post-Hearing Br. at 15; 3Shape Post-Hearing Reply Br. at 11-12; 3Shape Pre-Hearing Br. at 295-96. At most, in its initial post-hearing brief, 3Shape generically argues that the specification does not provide support for the “selectively map” term but this was in the context of its indefiniteness argument. 3Shape Post-Hearing Br. at 15. However, for other claim terms, 3Shape had sections specifically concerning written description, and if 3Shape had intended to present written description arguments, it should have presented fulsome and clear arguments. *See, e.g., id.* at 34-37. The Commission finds that 3Shape has waived this argument by failing to present it in its pre- and post-hearing briefs. Order No. 16, Ground Rule §11.2, 14.1, 14.2 (April 23, 2018).

## V. CONCLUSION

For the foregoing reasons, the Commission affirms the ID’s findings, as discussed herein, to determine that no violation of section 337 has occurred.

By order of the Commission.



Lisa R. Barton  
Secretary to the Commission

Issued: December 19, 2019

**PUBLIC CERTIFICATE OF SERVICE**

I, Lisa R. Barton, hereby certify that the attached **OPINION** has been served upon the following parties as indicated, on **December 19, 2019**.



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.:**

Blair M. Jacobs, Esq.  
**PAUL HASTINGS LLP**  
875 15<sup>th</sup> Street, NW  
Washington, DC 20005

- Via Hand Delivery
- Via Express Delivery
- Via First Class Mail
- Other: \_\_\_\_\_

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

Goutam Patnaik, Esq.  
**PEPPER HAMILTON LLP**  
200 K Street, NW, Suite 600  
Washington, DC 20006

- Via Hand Delivery
- Via Express Delivery
- Via First Class Mail
- Other: \_\_\_\_\_

**UNITED STATES INTERNATIONAL TRADE COMMISSION  
Washington, D.C.**

**In the Matter of**

**CERTAIN COLOR INTRAORAL SCANNERS  
AND RELATED HARDWARE AND  
SOFTWARE**

**Investigation No. 337-TA-1091**

**NOTICE OF A COMMISSION DETERMINATION TO REVIEW IN-PART THE FINAL  
INITIAL DETERMINATION; REQUEST FOR BRIEFING**

**AGENCY:** U.S. International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the U.S. International Trade Commission has determined to review the final initial determination (“ID”) in-part and requests briefing from the parties.

**FOR FURTHER INFORMATION CONTACT:** Amanda Pitcher Fisherow, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW, Washington, D.C. 20436, telephone (202) 205-2737. 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, SW, Washington, D.C. 20436, telephone (202) 205-2000. General information concerning the Commission may also be obtained by accessing its Internet server at <https://www.usitc.gov>. The public record for this investigation may be viewed on the Commission’s electronic docket (EDIS) at <https://edis.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission’s TDD terminal on (202) 205-1810.

**SUPPLEMENTARY INFORMATION:** The Commission instituted the underlying investigation on December 20, 2017, based on a complaint filed on behalf of Align Technology, Inc. of San Jose, California (“Align”). 82 FR (Dec. 20, 2017). 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 color intraoral scanners and related hardware and software by reason of infringement of certain claims of U.S. Patent Nos. 8,363,228 (“the ’228 patent”); 8,451,456 (“the ’456 patent”); 8,675,207 (“the ’207 patent”); 9,101,433 (“the ’433 patent”); 9,48,931; and 6,685,470. *See id.* The complaint named 3Shape A/S and 3Shape Inc. as the respondents. On March 15, 2018, the ALJ granted Align’s unopposed motion

to amend the complaint and notice of investigation to add 3Shape Trios A/S of Copenhagen, Denmark as an additional respondent in this investigation. *See* 83 FR 13781-82 (March 30, 2018), *unreviewed*, Notice (March 27, 2018). The Office of Unfair Import Investigations did not participate in the investigation.

On March 1, 2019, the ALJ issued his final ID finding that no violation of section 337 has occurred. On March 18, 2019, Align filed a petition for review and 3Shape filed a contingent petition for review of the ID. On March 26, 2019, all of the parties filed responses to the respective petitions for review.

Having examined the record of this investigation, including the ALJ's final ID, the petitions for review, and the responses thereto, the Commission has determined to review the final ID in-part. Specifically, the Commission has determined to review the ID's findings on (1) importation; (2) the construction of "processor"; (3) the construction of "confocal imaging techniques"; (4) all findings concerning infringement; (5) all findings concerning invalidity; (6) all findings concerning whether Align's products practice one or more claims of the asserted patents; and (7) all findings concerning whether Align's financial investments and activities relating to Align's products meet the domestic industry requirement.

In connection with its review, the Commission is interested in responses to the following questions from the parties:

1. Discuss whether the "processor" term of the asserted claims is understood by persons of ordinary skill in the art to have a sufficiently definite meaning as the name for structure? Is the "processor" of the asserted claims a general purpose processor? Please discuss and identify any expert testimony addressing these questions.
2. If the Commission determines that the claimed "processor" of the asserted claims is subject to means-plus-function treatment under 35 U.S.C. § 112, ¶ 6, please identify the corresponding structure(s) in the specification and the proper construction for each of the asserted patents.
3. Did Respondents show by clear and convincing evidence that a person of ordinary skill in the art would not find, from reading the specification, that the inventor had "possession" of a hand-held device having the claimed processor for the '228, '456, and '207 patents? *See Ariad Pharm., Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). Include citations to expert testimony in your response.
4. Does the language of claim 1 of the '228, '456, and '207 patents require that the "depth data" be the depth of the scanned three-dimensional object? *See* 3Shape Pet. at 13-14.
5. Did Align waive its argument that its domestic industry products practice the asserted patents by introducing a new theory/evidence for the first time in its petition for review? *See* Align Pet. at 43-45; 3Shape Resp. at 19-20.

6. For the '228, '456, and '207 patents, is the evidence relied on by the parties before the ALJ sufficient to establish that the domestic industry products “associate the depth data with the color image data”? Please discuss all relevant evidence.
7. Did Respondents waive their challenge to the specific percentages used to determine the significance of Align’s domestic industry investments? Align Resp. at 45.
8. In analyzing domestic industry, did the ID improperly credit expenses that were incurred after the filing of the complaint in this investigation or expenses that were unrelated to the domestic industry products? *See* 3Shape Pet. at 53-54. If certain expenses were improperly included in the analysis, please discuss whether Align’s investments without the improper expenses were significant.

The parties are requested to brief only the discrete issues above, with reference to the applicable law and evidentiary record. 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 Commission may (1) issue an order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) issue one or more cease and desist orders that could result in 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 (December 1994).

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

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

**WRITTEN SUBMISSIONS:** The parties to the investigation are requested to file written submissions on the issues identified in this notice. Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such submissions should address the recommended determination by the ALJ on remedy and bonding. Complainant is requested to submit proposed remedial orders for the Commission's consideration. Complainant is also requested to state the date that the subject patents expire and the HTSUS numbers under which the accused products are imported. Complainant is further requested to supply the names of known importers of the Respondents' products at issue in this investigation.

The written submissions and proposed remedial orders must be filed no later than close of business on Tuesday, July 30, 2019. Reply submissions must be filed no later than the close of business on Tuesday, August 6, 2019. Opening submissions are limited to 75 pages. Reply submissions are limited to 50 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 and submit eight true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) Of the Commission's Rules of Practice and Procedure (19 C.F.R. 2.10.4(f)). Submissions should refer to the investigation number ("Inv. No. 337-TA-1091") in a prominent place on the cover page and/or the first page. (See Handbook for Electronic Filing Procedures, [http://www.usitc.gov/secretary/fed\\_reg\\_notices/rules/handbook\\_on\\_electronic\\_filing.pdf](http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf)). Persons with questions regarding filing should contact the Secretary (202-205-2000).

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. 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,<sup>1</sup> solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

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

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<sup>1</sup> All contract personnel will sign appropriate nondisclosure agreements.

By order of the Commission.

A handwritten signature in black ink, appearing to read "Lisa R. Barton".

Lisa R. Barton  
Secretary to the Commission

Issued: July 18, 2019

**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 18, 2019**.



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.:**

Blair M. Jacobs, Esq.  
**PAUL HASTINGS LLP**  
875 15<sup>th</sup> St. NW  
Washington, DC 20005

- Via Hand Delivery
- Via Express Delivery
- Via First Class Mail
- Other: \_\_\_\_\_

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

Goutam Patnaik, Esq.  
**PEPPER HAMILTON LLP**  
200 K Street, NW, Suite 600  
Washington, DC 20006

- Via Hand Delivery
- Via Express Delivery
- Via First Class Mail
- Other: \_\_\_\_\_

**PUBLIC VERSION**

**UNITED STATES INTERNATIONAL TRADE COMMISSION**

**Washington, D.C.**

**In the Matter of**

**CERTAIN COLOR INTRAORAL SCANNERS  
AND RELATED HARDWARE AND SOFTWARE**

**INV. NO. 337-TA-1091**

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

Administrative Law Judge Clark S. Cheney

(March 1, 2019)

**Appearances:**

*For the Complainant Align Technology, Inc.:*

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

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

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

Joshua M. Bennett, Esq. of Paul Hastings LLP of New York, NY.

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

Goutam Patnaik, Esq., Tuhin Ganguly, Esq., David J. Shaw, Esq. of Pepper Hamilton LLP of Washington, DC.

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

Charles F. Koch, Esq. of Pepper Hamilton LLP of Redwood City, CA.

S. Lloyd Smith, Esq., Kimberly E. Coghill, Esq., Kyle Tsui, Esq. of Buchanan Ingersoll & Rooney PC of Alexandria, VA.

Philip L. Hirschhorn, Esq. of Buchanan Ingersoll & Rooney PC of New York, NY.

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<b>CDX</b>	Complainant's demonstrative exhibit
<b>CIB</b>	Complainant's initial post-hearing brief
<b>CPB</b>	Complainant's pre-hearing brief
<b>CPX</b>	Complainant's physical exhibit
<b>CRB</b>	Complainant's reply post-hearing brief
<b>CX</b>	Complainant's exhibit
<b>Dep.</b>	Deposition
<b>JX</b>	Joint Exhibit
<b>RDX</b>	Respondent's demonstrative exhibit
<b>RIB</b>	Respondent's initial post-hearing brief
<b>RPX</b>	Respondent's physical exhibit
<b>RPB</b>	Respondent's Pre-hearing brief
<b>RRB</b>	Respondent's reply post-hearing brief
<b>RRX</b>	Respondent's rebuttal exhibit
<b>RX</b>	Respondent's exhibit
<b>SIB</b>	Staff's initial post-hearing brief
<b>SPB</b>	Staff's Pre-hearing brief
<b>SRB</b>	Staff's reply post-hearing brief
<b>Tr.</b>	Transcript

**PUBLIC VERSION**

**UNITED STATES INTERNATIONAL TRADE COMMISSION**

**Washington, D.C.**

**In the Matter of**

**CERTAIN COLOR INTRAORAL SCANNERS  
AND RELATED HARDWARE AND SOFTWARE**

**INV. NO. 337-TA-1091**

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

Administrative Law Judge Clark S. Cheney

(March 1, 2019)

Pursuant to the Notice of Investigation, 82 Fed. Reg. 60418 (Dec. 20, 2017), this is the final Initial Determination in the matter of *Certain Color Intraoral Scanners and Related Hardware and Software*, Investigation No. 337-TA-1091. 19 C.F.R. §§ 210.10(b), 210.42(a)(1)(i).

For the reasons stated herein, I have determined that no violation of section 337 of the Tariff Act of 1930, as amended, has occurred in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain color intraoral scanners and related hardware and software alleged to infringe U.S. Patent No. 8,363,228 (“the ’228 patent”); U.S. Patent No. 8,451,456 (“the ’456 patent”); U.S. Patent No. 8,675,207 (“the ’207 patent”); U.S. Patent No. 9,101,433 (“the ’433 patent”). I have further determined that the investigation should be terminated with respect to articles alleged to infringe U.S. Patent No. 6,948,931 (“the ’931 patent”); and U.S. Patent No. 6,685,470 (“the ’470 patent”), without a finding of violation.

## PUBLIC VERSION

### I. INTRODUCTION

#### A. Procedural History

On November 14, 2017, complainant Align Technology, Inc. of San Jose, California (“Align”) filed a complaint alleging 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 color intraoral scanners and related hardware and software by reason of infringement of one or more of U.S. Patent No. 8,363,228 (“the ’228 patent”); U.S. Patent No. 8,451,456 (“the ’456 patent”); U.S. Patent No. 8,675,207 (“the ’207 patent”); U.S. Patent No. 9,101,433 (“the ’433 patent”); U.S. Patent No. 6,948,931 (“the ’931 patent”); and U.S. Patent No. 6,685,470 (“the ’470 patent”). 82 Fed. Reg. 60418 (Dec. 20, 2017).

On December 20, 2017, the Commission instituted this investigation to determine:

whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain color intraoral scanners and related hardware and software by reason of infringement of one or more of claims 1, 2, 4, 5, 7, 18, 20, 21, and 26 of the ’228 patent; claims 1–8 and 15–18 of the ’456 patent; claims 1, 2, 4, and 15–21 of the ’207 patent; claims 1, 4, 7, 10, 12, and 14 of the ’433 patent; and claims 1–12 of the ’931 patent; and claims 1–12 of the ’470 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337.

*Id.*

The named respondents were 3Shape A/S of Copenhagen, Denmark; and 3Shape Inc. of Warren, New Jersey. *See id.* at 60419. On March 15, 2018, I granted Align’s unopposed motion to amend the complaint and notice of investigation to add 3Shape Trios A/S of Copenhagen, Denmark as an additional respondent in this investigation. Order No. 11; *see also* Notice of a Commission Determination not to Review an Initial Determination Granting a Motion for Leave to Amend the Complaint and Notice of Investigation to Add Respondent (Mar. 26, 2018) (EDIS

## PUBLIC VERSION

Doc. ID 640017). Throughout the investigation, all parties have referred to the three 3Shape entities collectively as “3Shape,” and I follow that convention in this determination.

The Commission investigative staff is not a party to this investigation.

On, May 18, 2018, I denied 3Shape’s motion for summary determination and termination of the investigation based on a forum selection clause in a Scanner Agreement between Align and 3Shape Trios A/S. Order No. 23. On July 10, 2018, I granted Align’s unopposed motion for termination of the investigation with respect to claim 7 of the ’456 patent; claims 1-4, 7, and 10 of the ’433 patent; claims 4-12 of the ’470 patent; and claims 4-12 of the ’931 patent. Order No. 27; *see also* Notice of a Comm’n Det. not to Review an Initial Det. Granting a Mot. for Partial Term. of the Inv. Based on Withdrawal of Certain Claims (Aug. 7, 2018) (EDIS Doc. ID 652179). On July 11, 2018, I denied 3Shape’s motion for summary determination of no violation with respect to the entity 3Shape Inc. Order No. 28. On September 6, 2018, I denied 3Shape’s motion to terminate the investigation with respect to the ’470 and ’931 patents on the basis that those patents would expire six days before the May 20, 2019, target date then in effect for this investigation. Order No. 34.

I convened an evidentiary hearing on September 17-21, 2018, to determine whether section 337 has been violated by reason of the importation into the United States, the sale for importation, or the sale within the United States after importation of allegedly infringing color intraoral scanners and related hardware and software. Following the close of the evidentiary hearing, a lapse in government appropriations from December 22, 2018, through January 25, 2019, caused the Commission to temporarily cease regular operations, which precluded completion of this initial determination. On January 29, 2019, I issued an initial determination extending the target date in

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this investigation to July 1, 2019, which correspondingly extended the deadline for certifying the record and a final initial determination on violation to March 1, 2019. Order No. 39.

**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. 2d Am. Compl. at ¶ 13. Align is the owner by assignment of the asserted patents in this investigation. *See* JX-0001 at Cover; JX-0002 at Cover; JX-0039 (assignment record); JX-0040 (assignment record); JX-0041 (assignment record).

**2. The 3Shape Respondents**

3Shape A/S, 3Shape Trios A/S, and 3Shape Inc. are “sister” corporations that are wholly-owned subsidiaries of 3Shape Holdings A/S. *See* RPB at 13.

***a) 3Shape Trios A/S***

3Shape Trios A/S is a Danish corporation with its principal place of business at Holmens Kanal 7, 1060 Copenhagen K, Denmark. 3Shape Trios A/S develops and sells the accused Trios scanners, including the Trios application software and ScanSuite Trios software included on those scanners. *See* RPB at 13.

***b) 3Shape A/S***

3Shape A/S is a Danish corporation with its principal place of business at Holmens Kanal 7, 1060 Copenhagen K, Denmark. 3Shape represents that 3Shape A/S develops and sells certain “lab scanner” products not accused in this investigation. 3Shape A/S also develops, sells, and licenses 3Shape’s accused Dental System and Ortho System software. *See* RPB at 13.

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**c) 3Shape Inc.**

3Shape Inc. is a Delaware corporation with a principal place of business at 10 Independence Boulevard, Suite 150, Warren, New Jersey 07059. 3Shape represents that “3Shape Inc. is 3Shape’s regional support entity for North America. It supports 3Shape’s U.S. distributors, or ‘resellers’ by providing marketing and after-sales support and training, including administering 3Shape’s warranty, repair, and replacement program.” RPB at 13.

**C. The Asserted Patents**

Align asserts two categories of patents in this investigation: (1) the color scanner patents and (2) the gingival deformation patents.

**1. The Color Scanner Patents**

The parties refer to the ’228, ’456, ’207, and ’433 patents collectively as “the color scanner patents.”

United States Patent Number 8,363,228, entitled “Method and Apparatus for Colour Imaging a Three-Dimensional Structure,” issued to Noam Babyoff on January 29, 2013. JX-0003 at cover page. The patent issued from Application Number 13/333,351, filed on December 21, 2011, and claims priority to provision application No. 60/580,109, filed on June 17, 2004, and provisional application No. 60/580,108 filed on June 17, 2004. *Id.* The patent, on its face, is assigned to Cadent Ltd. *Id.* Align acquired ownership of the patent through assignment. *See* JX-0039.

United States Patent Number 8,451,456 entitled “Method and Apparatus for Colour Imaging a Three-Dimensional Structure,” issued to Noam Babyoff on May 28, 2013. JX-0004 at cover page. The patent issued from Application Number 13/620,159, filed on September 14, 2012, and claims priority to provisional application No. 60/580,109, filed on June 17, 2004, and

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provisional application No. 60/580,108 filed on June 17, 2004. *Id.* The patent, on its face, is assigned to Cadent Ltd. *Id.* Align acquired ownership of the patent through assignment. *See* JX-0039.

United States Patent Number 8,675,207 entitled “Method and Apparatus for Colour Imaging a Three-Dimensional Structure,” issued to Noam Babyoff on March 18, 2014. JX-0005 at cover page. The patent issued from Application Number 13/868,926, filed on April 23, 2013, and claims priority to provisional application No. 60/580,109, filed on June 17, 2004, and provisional application No. 60/580,108 filed on June 17, 2004. *Id.* The patent, on its face, is assigned to Cadent Ltd. *Id.* Align acquired ownership of the patent through assignment. *See* JX-0039.

United States Patent Number 9,101,433 entitled “Method and Apparatus for Colour Imaging a Three-Dimensional Structure,” issued to Noam Babyoff on August 11, 2015. JX-0006 at cover page. The patent issued from Application Number 14/511,091, filed on October 9, 2014, and claims priority to provisional application No. 60/580,109, filed on June 17, 2004, and provisional application No. 60/580,108 filed on June 17, 2004. *Id.* at cover page–p. 2. The patent, on its face, is assigned to Align Technology, Inc. *Id.* at cover page

The color scanner patents are all directed to systems or methods for creating a color image of a three dimensional structure, particularly by combining color and depth data to provide a three-dimensional color model. *See, e.g.,* JX-0003 at Abstract. The color scanner patents share substantially identical specifications and claim priority to the same parent application. *Compare* JX-0003 *with* JX-0004, JX-0005, *and* JX-0006. There is also substantial overlap in the asserted claims of the ’228 patent, the ’456 patent, and the ’207 patent. *Compare* JX-0003 at Cls. 1, 4, 26 *with* JX-0004 at Cls. 1, 15 *and* JX-0005 at Cl. 1.

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Broadly speaking, the asserted claims of the '228 patent are apparatus claims directed to a system for determining the surface topology and associated color of a three dimensional structure. *See* JX-0003 at Cls. 1, 4, 26. The asserted claims of the '456 patent are substantially similar apparatus claims that include language specifying that the three dimensional structure is a “dental structure.” *See* JX-0004 at Cls. 1, 15. The asserted claim of the '207 patent is a method claim that describes a method for determining the surface topology and associated color of a three dimensional dental structure of using the apparatus described in the asserted claims of the '456 patent. *See* JX-0005 at Cl. 1.

The asserted claim of the '433 patent is also an apparatus claim directed to a system for determining the surface topology and associated color of a three dimensional structure. *See* JX-0006 at Cl. 12. The elements of the system recited in the asserted claim of the '433 patent are distinct from those recited in the asserted claims of the other three color scanner patents. *Compare* JX-0006 at Cl. 12 *with* JX-0003 at Cls. 1, 4, 26, JX-0004 at Cls. 1, 15, *and* JX-0005 at Cl. 1.

### **2. The Gingival Deformation Patents**

The parties refer to the '470 and '931 patents collectively as the gingival deformation patents.

United States Patent Number 6,685,470 entitled “Digitally Modeling the Deformation of Gingival Tissue During Orthodontic Treatment,” issued to Chishti et al. on February 3, 2004. JX-0001 at cover page. The patent issued from Application Number 10/280,556 filed on October 24, 2002, and claims priority to U.S. Patent No. 6,514,074, which was filed on May 14, 1999. *Id.* The patent, on its face, is assigned to Align Technology, Inc. *Id.*

United States Patent Number 6,948,931 is also entitled “Digitally Modeling the Deformation of Gingival Tissue During Orthodontic Treatment,” and issued to the same inventors

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on September 27, 2005. JX-0002 at cover page. The patent issued from Application Number 10/691,942 filed on October 22, 2003, and also claims priority to U.S. Patent No. 6,514,074. *Id.* The patent, on its face, is also assigned to Align Technology, Inc. *Id.*

Both of the gingival deformation patents will expire on May 14, 2019. On September 6, 2018, I issued Order Number 34 in this investigation, which denied a motion by 3Shape to terminate this investigation with respect to the gingival deformation patents based on their impending expiration date. At the time of that order, the gingival deformation patents would expire six days prior to the May 20, 2019, target date then in effect for this investigation. I denied 3Shape's motion on the basis that it was still possible for 3Shape to obtain a remedy with respect to the gingival deformation patents if the final initial determination were to issue early, or the Commission were to abbreviate the customary time for its review and consideration of a remedy. Order No. 34 at 1. I expressed no opinion as to the likelihood of either scenario. *Id.*

Since issuing Order Number 34, a lapse in government appropriations caused the Commission to cease regular operations for over a month. As a result of that occurrence, I issued an initial determination extending the target date to July 1, 2019. Order No. 39. The gingival deformation patents will now expire forty-eight (48) days prior to the target date in this investigation. Given this reality, it is a near impossibility that any remedy will issue with respect to the gingival deformation patents. Accordingly, I find that the investigation should be terminated with respect to the gingival deformation patents so as to preserve the resources of the parties and the Commission. *See Certain Graphics Processors and Prods. Containing Same*, Inv. No. 337-TA-1099 ("Graphics Processors") Comm'n Notice at 2 (July 17, 2018). The remainder of this initial determination on violation and recommended determination on remedy will focus exclusively on the color scanner patents.

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### **D. The Technology at Issue**

The technology at issue relates to the determination of both the surface topology and associated color of a three dimensional structure, particularly teeth. *See, e.g.*, JX-0003 at Abstract. The color scanner patents acknowledge that prior to the work of the inventors many methods were known in the art for determining the surface topology of a three dimensional structure and for creating a digital model of that structure. *See id.* at 1:28-48. The creation of such a digital model with accurate color information was difficult, though multiple approaches were known in the art. *See id.* at 1:49-2:43.

The color scanner patents describe an approach to generating a three dimensional model with accurate associated color information. The approach described broadly involves obtaining three dimensional scan data and two dimensional color image data of a structure at nearly identical times. *See id.* at 2:61-4:14. Leveraging the knowledge that the three-dimensional scan data and two dimensional color image data were obtained close in time to each other, the color scanner patents describe obtaining a three-dimensional model of the structure by mapping the two dimensional color image data onto the three dimensional scan data. *See* 3:61-4:32. The color scanner patents disclose a number of variations on this approach. *See* 4:54-12:4.

### **E. The Accused Products**

Align defines the accused products as “TRIOS3 and Accused Software Products.” CIB at x. Align defines “Accused Software Products” as “Respondents’ Ortho and Dental System software.” *Id.* And, Align defines “TRIOS3” as “Respondents’ TRIOS3 scanners identified at JX-0265C at 7-8.” *Id.* at xi. Align accuses Trios scanners of infringing the color scanner patents, and the Accused Software Products of infringing the gingival deformation patents. *See* CIB at 23, 54, 57-58, 73, 83. Because I have terminated this investigation with respect to the gingival

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deformation patents, the Tios scanners are the only remaining accused products in this investigation.

### **F. The Domestic Industry Products**

Align contends that its iTero Element scanners practice the inventions claimed in the color scanner patents in satisfaction of the technical prong of the domestic industry requirement. CIB at 47, 56, 58, 64, 98. Align relies on “Align Software,” which it defines as “Align’s ClinCheck, Treat, and Outcome Simulator software,” to satisfy the technical prong of the domestic industry requirement for the gingival deformation patents. *Id.* at 87, 98. Because I have terminated this investigation with respect to the gingival deformation patents, the iTero Element scanners are the only remaining domestic industry products in this investigation.<sup>1</sup>

## **II. JURISDICTION & IMPORTATION**

### **A. Subject Matter Jurisdiction**

Section 337 confers subject matter jurisdiction on the Commission to investigate, and if appropriate, to provide a remedy for, unfair acts and unfair methods of competition in the importation, the sale for importation, or the sale after importation of articles into the United States. *See* 19 U.S.C. §§ 1337(a)(1)(B) and (a)(2). Align filed a complaint alleging a violation of section 337(a). Accordingly, the Commission has subject matter jurisdiction over this investigation under section 337 of the Tariff Act of 1930. *See Amgen, Inc. v. Int’l. Trade Comm’n*, 902 F.2d 1532, 1536 (Fed. Cir. 1990).

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<sup>1</sup> Align also ambiguously includes the “Invisalign System” as a domestic industry product at various points in its briefing. As I explain in more detail in my analysis of the economic prong of the domestic industry requirement, I do not consider the “Invisalign System” to be a domestic industry product relevant to this investigation.

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### B. Personal Jurisdiction

3Shape has appeared and participated in this investigation. The Commission therefore has personal jurisdiction over 3Shape. *See, e.g., Certain Optical Disk Controller Chips & Chipsets & Prods. Containing Same, Including DVD Players & PC Optical Storage Devices*, Inv. No. 337-TA-506, ID at 4-5 (May 16, 2005) (unreviewed in relevant part).

### C. In Rem Jurisdiction

3Shape does not dispute that the Commission has *in rem* jurisdiction over the accused Trios scanners that have been imported into the United States. *See* RPB at 37 (“3Shape does not dispute that 3Shape Trios A/S sells for importation and imports the Trios 3 Products, and thus does not dispute that the importation requirement for this Investigation is satisfied with respect to 3Shape Trios A/S, as to the Trios 3 Products listed in Appendix A to the parties’ joint stipulation on importation.”); *see also* JX-0389C at ¶ 4, Appendix A. In fact, 3Shape has stipulated to the importation of the accused Trios scanners into the United States. *See* JX-0389C at ¶ 4. Accordingly, the Commission has *in rem* jurisdiction over the accused Trios scanners. *See Sealed Air Corp. v. Int’l Trade Comm’n*, 645 F.2d 976, 985-86 (C.C.P.A. 1981) (noting that the Commission has jurisdiction over imported goods); *Certain Crawler Cranes and Components Thereof*, Inv. No. 337-TA-887, Comm’n Op. at 17 (May 6, 2015) (an article “sold for importation” can confer jurisdiction on the Commission for that article).<sup>2</sup>

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<sup>2</sup> The only dispute briefed by the parties with respect to the Commission’s *in rem* jurisdiction is with respect to the “Accused Software.” *See* RRB at 2. The parties’ dispute with respect to the Commission’s jurisdiction over the “Accused Software” is moot because I have terminated this investigation as to the gingival deformation patents.

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### D. Importation

As noted above, 3Shape has stipulated that 3Shape Trios A/S “sold for importation and imported into the United States at least one unit of each of the models of the 3Shape Trios A/S Products,” listed in appendix A to the parties’ joint stipulation. JX-0389C at ¶ 4, Appendix A. Accordingly, the importation requirement is satisfied as to the accused Trios scanners. The relationship of the various 3Shape entities to this undisputed importation is addressed below in my recommended remedy.

### E. Standing

The evidence of record demonstrates that Align has standing via its ownership by assignment of the asserted patents. *See* JX-0001 at Cover; JX-0002 at Cover; JX-0039 (assignment record); JX-0040 (assignment record); JX-0041 (assignment record). This is undisputed by 3Shape. *See* RPB at 36 (“3Shape does not contest Align’s standing in this Investigation at this time.”). Accordingly, I find that Align has standing in this investigation.

## III. LEGAL PRINCIPLES

### A. Claim Construction

“An infringement analysis entails two steps. The first step is determining the meaning and scope of the patent claims asserted to be infringed. The second step is comparing the properly construed claims to the device accused of infringing.” *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (*en banc*) (internal citations omitted), *aff’d*, 517 U.S. 370 (1996). Claim construction resolves legal disputes between the parties regarding claim scope. *See Eon Corp. IP Holdings v. Silver Spring Networks*, 815 F.3d at 1314, 1319 (Fed. Cir. 2016).

Evidence intrinsic to the application, prosecution, and issuance of a patent is the most significant source of the legally operative meaning of disputed claim language. *See Bell Atl. Network Servs., Inc. v. Covad Commc’ns Grp., Inc.*, 262 F.3d 1258, 1267 (Fed. Cir. 2001). The

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intrinsic evidence includes the claims themselves, the specification, and the prosecution history. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (*en banc*); *see also Markman*, 52 F.3d at 979. As the Federal Circuit explained in *Phillips*, courts must analyze each of these components to determine the “ordinary and customary meaning of a claim term” as understood by a person of ordinary skill in the art at the time of the invention. 415 F.3d at 1313.

“It is a ‘bedrock principle’ of patent law that ‘the claims of a patent define the invention to which the patentee is entitled the right to exclude.’” *Phillips*, 415 F.3d at 1312 (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). “Quite apart from the written description and the prosecution history, the claims themselves provide substantial guidance as to the meaning of particular claims terms.” *Id.* at 1314; *see Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001) (“In construing claims, the analytical focus must begin and remain centered on the language of the claims themselves, for it is that language that the patentee chose to use to ‘particularly point[ ] out and distinctly claim[ ] the subject matter which the patentee regards as his invention.’”). The context in which a term is used in an asserted claim can be “highly instructive.” *Phillips*, 415 F.3d at 1314. Additionally, other claims in the same patent, asserted or unasserted, may also provide guidance as to the meaning of a claim term. *Id.*

The specification “is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.” *Id.* at 1315 (quoting *Vitronics Corp. v. Conceptoronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). “[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.” *Id.* at 1316. “In other cases, the specification may reveal an intentional disclaimer, or disavowal, of claim scope

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by the inventor.” *Id.* 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. In the end, “[t]he construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be . . . the correct construction.” *Id.* at 1316 (quoting *Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998)).

When the intrinsic evidence does not establish the meaning of a claim, then extrinsic evidence (*i.e.*, all evidence external to the patent and the prosecution history, including dictionaries, inventor testimony, expert testimony, and learned treatises) may be considered. *Id.* at 1317. Extrinsic evidence is generally viewed as less reliable than the patent itself and its prosecution history in determining how to define claim terms. *Id.* “The court may receive extrinsic evidence to educate itself about the invention and the relevant technology, but the court may not use extrinsic evidence to arrive at a claim construction that is clearly at odds with the construction mandated by the intrinsic evidence.” *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 977 (Fed. Cir. 1999).

### **B. Infringement**

In a section 337 investigation, the complainant bears the burden of proving infringement of the asserted patent claims by a preponderance of the evidence. *See Spansion*, 629 F.3d at 1349. This standard “requires proving that infringement was more likely than not to have occurred.” *Warner-Lambert Co. v. Teva Pharm. USA, Inc.*, 418 F.3d 1326, 1341 n.15 (Fed. Cir. 2005).

#### **1. Literal Infringement**

Literal infringement is a question of fact. *Finitisar Corp. v. DirecTV Grp., Inc.*, 523 F.3d 1323, 1332 (Fed. Cir. 2008). “Literal infringement requires the patentee to prove that the accused device contains each limitation of the asserted claim(s). If any claim limitation is absent, there is

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no literal infringement as a matter of law.” *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1247 (Fed. Cir. 2000).

### 2. Doctrine of Equivalents

Where literal infringement is not found, infringement nevertheless can be found under the doctrine of equivalents. Determining infringement under the doctrine of equivalents “requires an intensely factual inquiry.” *Vehicular Tech. Corp. v. Titan Wheel Int’l, Inc.*, 212 F.3d 1377, 1381 (Fed. Cir. 2000). 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 Chem. Co.*, 520 U.S. 17, 40 (1997).

The Federal Circuit applies two articulations of the test for equivalents, as one phrasing may be more suitable for particular fact patterns or technologies. Under the insubstantial differences test, “[a]n element in the accused device is equivalent to a claim limitation if the only differences between the two are insubstantial.” Alternatively, under the function-way-result test, an element in the accused device is equivalent to a claim limitation if it “performs substantially the same function in substantially the same way to obtain substantially the same result.” *Voda v. Cordis Corp.*, 536 F.3d 1311, 1326 (Fed. Cir. 2008) (citations omitted).

In *Warner-Jenkinson*, the Supreme Court noted that the doctrine of equivalents is subject to several limitations. *Warner-Jenkinson*, 520 U.S. at 29. The doctrine must be applied to individual elements of a claim and not to the invention as a whole. *Id.*

### 3. Indirect Infringement

Section 271 of the Patent Act defines both direct infringement and the two categories of indirect infringement—active inducement of infringement and contributory infringement.

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35 U.S.C. § 271(a), (b), and (c). There can be no indirect infringement absent direct infringement. *See Limelight Networks, Inc. v. Akamai Technologies, Inc.*, 134 S.Ct. 2111, 2117 (2014); *Aro Manufacturing Co. v. Convertible Top Replacement Co.*, 365 U.S. 341 (1961); *see also Met-Coil Sys. Corp. v. Korners Unltd., Inc.*, 803 F.2d 684, 687 (Fed. Cir. 1986) (“Absent direct infringement of the patent claims, there can be neither contributory infringement . . . nor inducement of infringement.”) (citations omitted).

### *a) Inducement of Infringement*

Section 271(b) of the Patent Act prohibits inducement of infringement: “[w]hoever actively induces infringement of a patent shall be liable as an infringer.” 35 U.S.C. § 271(b). *See DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1305 (Fed. Cir. 2006) (*en banc*) (“To establish liability under section 271(b), a patent holder must prove that once the defendants knew of the patent, they actively and knowingly aided and abetted another's direct infringement.”) (citations omitted). “The mere knowledge of possible infringement by others does not amount to inducement; specific intent and action to induce infringement must be proven.” *Id.* (citations omitted). A violation of section 337 may arise from an act of induced infringement. *Suprema*, 796 F.3d at 1351-52 (*en banc* opinion).

### *b) Contributory Infringement*

Section 271(c) of the Patent Act prohibits contributory infringement. *See* 35 U.S.C. § 271(c). “Under 35 U.S.C. § 271(c), a party who sells a component with knowledge that the component is especially designed for use in a patented invention, and is not a staple article of commerce suitable for substantial noninfringing use, is liable as a contributory infringer.” *Wordtech Sys., Inc. v. Integrated Networks Solutions, Inc.*, 609 F.3d 1308, 1316 (Fed. Cir. 2010). To establish contributory infringement in a section 337 investigation, it must be shown

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that “(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*, 629 F.3d at 1353.

### C. Validity

A patent is presumed valid. *See* 35 U.S.C. § 282; *Microsoft Corp. v. i4i Ltd. P’ship*, 131 S. Ct. 2238, 2242 (2011). A respondent who has raised patent invalidity as an affirmative defense has the burden of overcoming this presumption by clear and convincing evidence. *See Microsoft*, 131 S. Ct. at 2242.

#### 1. Anticipation

Under 35 U.S.C. § 102, a claim is anticipated, and therefore invalid, when “the four corners of a single, prior art document describe every element of the claimed invention, either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation.” *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000). To be considered anticipatory, the prior art reference must be enabling and describe the applicant’s claimed invention sufficiently to have placed it in possession of a person of ordinary skill in the field of the invention. *See Helifix Ltd. v. Blok-Lok, Ltd.*, 208 F.3d 1339, 1346 (Fed. Cir. 2000).

#### 2. Obviousness

Under 35 U.S.C. § 103, a patent may be found invalid as obvious if “the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” 35 U.S.C. § 103(a). Because obviousness is determined at the time of invention, rather than the date of litigation, “[t]he great challenge of the

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obviousness judgment is proceeding without any hint of hindsight.” *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 655 F.3d 1364, 1375 (Fed. Cir. 2011).

When a patent is challenged as obvious, the critical inquiry in determining the differences between the claimed invention and the prior art is whether there is an apparent reason to combine the known elements in the fashion claimed by the patent at issue. See *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398, 417-418 (2007). Thus, 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).

Obviousness is a determination of law based on underlying determinations of fact. *Star Scientific*, 655 F.3d at 1374. The factual determinations behind a finding of obviousness include: (1) the scope and content of the prior art, (2) the level and content of the prior art, (3) the differences between the claimed invention and the prior art, and (4) secondary considerations of non-obviousness. *KSR*, 550 U.S. at 399 (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966)). These factual determinations are referred to collectively as the “*Graham* factors.” Secondary considerations of non-obviousness include commercial success, long felt but unresolved need, and the failure of others. *Id.* When present, secondary considerations “give light to the circumstances surrounding the origin of the subject matter sought to be patented,” but they are not dispositive on the issue of obviousness. *Geo. M. Martin Co. v. Alliance Mach. Sys. Int’l.*, 618 F.3d 1294, 1304-06 (Fed. Cir. 2010). For evidence of secondary considerations to be given substantial weight in the obviousness determination, its proponent must establish a nexus between the evidence and the

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merits of the claimed invention. See *W. Union Co. v. MoneyGram Payment Sys. Inc.*, 626 F.3d 1361, 1372-73 (Fed. Cir. 2010) (citing *In re GPAC Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995)).

### 3. Written Description and Enablement

The hallmark of the written description requirement is the disclosure of the invention. See *Ariad Pharm., Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (*en banc*). The test for determining the sufficiency of the written description in a patent requires “an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. Based on that inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed.” *Id.* Compliance with the written description requirement is a question of fact and “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.” *Id.*

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 “rule” 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.

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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).

### 4. Indefiniteness

A claim must also be definite. Pursuant to 35 U.S.C. § 112, ¶ 2, a patent specification “shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.” 35 U.S.C. § 112, ¶ 2. Section 112, ¶ 2 requires “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.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2129 (2014). A patent claim that is indefinite is invalid. 35 U.S.C. § 282(b)(3)(A).

### D. Domestic Industry

For a patent-based complaint, a violation of section 337 can be found “only if an industry in the United States, relating to the articles protected by the patent . . . concerned, exists or is in the process of being established.” 19 U.S.C. § 1337(a)(2). This domestic industry requirement of section 337 is often described as having an economic prong and a technical prong. *InterDigital Commc’ns, LLC v. Int’l Trade Comm’n*, 707 F.3d 1295, 1298 (Fed. Cir. 2013); *Certain Stringed Musical Instruments and Components Thereof*, Inv. No. 337-TA-586, Comm’n Op. at 12-14, USITC Pub. No. 4120, 2009 WL 5134139 (Dec. 2009). The complainant bears the burden of

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establishing that the domestic industry requirement is satisfied. *See Certain Set-Top Boxes and Components Thereof*, Inv. No. 337-TA-454, ID at 294, 2002 WL 31556392 (June 21, 2002) (unreviewed by Commission in relevant part).

### 1. Economic Prong

Section 337(a)(3) sets forth the following economic criteria for determining the existence of a domestic industry in such investigations:

(3) For purposes of paragraph (2), an industry in the United States shall be considered to exist if there is in the United States, with respect to the articles protected by the patent, copyright, trademark, mask work, or design concerned –

- (A) significant investment in plant and equipment;
- (B) significant employment of labor or capital; or
- (C) substantial investment in its exploitation, including engineering, research and development, or licensing.

Given that the statutory 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. *See Certain Variable Speed Wind Turbines and Components Thereof*, Inv. No. 337-TA-376, Comm'n Op. at 15, USITC Pub. 3003 (Nov. 1996).

### 2. Technical Prong

The technical prong of the domestic industry requirement is satisfied when the complainant in a patent-based section 337 investigation establishes 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, 1996 WL 1056095 (Jan. 16, 1996). “The test for satisfying the ‘technical prong’ of the industry requirement is essentially [the] same as that for infringement, *i.e.*, a comparison of domestic products to the asserted claims.” *Alloc, Inc. v. Int’l Trade Comm’n*, 342

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F.3d 1361, 1375 (Fed. Cir. 2003). To prevail, the patentee must establish by a preponderance of the evidence that the domestic product practices one or more claims of the patent. It is sufficient to show that the products practice any claim of that patent, not necessarily an asserted claim of that patent. *See Certain Male Prophylactic Devices*, Inv. No. 337-TA-546, Comm'n Op. at 38 (Aug. 1, 2007).

### IV. THE COLOR SCANNER PATENTS

#### A. Level of Ordinary Skill in the Art

During the claim construction hearing in this investigation, Align and 3Shape agreed that there was no material distinction between the levels of ordinary skill in the art proposed by each party. Markman Tr. at 4:11-16 (June 6, 2018) (EDIS Doc. 647008). Nothing in the parties' post-hearing briefs suggests that a material distinction has since arisen, and thus I need not resolve which of the two proposals is more correct to resolve the remaining disputes in this investigation. In the context of the color scanner patents, Align proposed that a person of ordinary skill in the art would have:

- at least a bachelor's degree in electrical engineering, computer science, physics or an equivalent field, as well as at least one or two years of industry experience in optical scanning, or
- at least five years of comparable industry experience in optical scanning, or
- an equivalent combination of academic study and work experience.

CIMB at 7. 3Shape proposed that a person of ordinary skill in the art would have:

- a bachelor's degree in electrical engineering, optical engineering, or physics (or equivalent course work) and two to three years of work experience in the areas of optical imaging systems and image processing, or
- 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.

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RIMB at 7. I find that both Align and 3Shape's proposals are suitably indicative of the level of skill in the art with respect to the color scanner patents. *See* CIMB at 6-7; RIMB at 7.

### **B. Claim Construction Disputes**

#### **1. Scanning System**

The parties dispute the meaning of “scanning system,” which appears in claim 1 of the '228, '456, and '207 patents. The nature of the parties' dispute is convoluted, but can be summarized as follows: Align primarily argues that “scanning system” should be given its plain and ordinary meaning. CIB at 11. 3Shape disagrees that “scanning system” should be given its plain and ordinary meaning, and instead advocates for construing the term according to 35 U.S.C. § 112, ¶ 6. RIB at 4. 3Shape advances a construction under § 112, ¶ 6 that would require, among other things, that color and depth data be obtained separately. RRB at 6. In addition to disagreeing that “scanning system” should be construed according to § 112, ¶ 6, Align disagrees with 3Shape's proposed § 112, ¶ 6 construction and provides its own contingent § 112, ¶ 6 construction, which is significantly less restrictive than the construction proposed by 3Shape. CIB at 11. I begin with the question of whether “scanning system” should be given its plain and ordinary meaning, or instead should be construed according to § 112, ¶ 6.

The standard for determining when to construe a claim term according to § 112, ¶ 6 is “whether the words of the claim are understood by persons of ordinary skill in the art to have a sufficiently definite meaning as the name for structure.” *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1349 (Fed. Cir. 2015). “[U]se of the word ‘means’ creates a presumption that § 112, ¶ 6 applies.” *Personalized Media Comm'ns, LLC v. Int'l Trade Comm'n*, 161 F.3d 696, 703 (Fed. Cir. 1998).

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“When a claim term lacks the word ‘means,’ the presumption can be overcome and § 112, para. 6 will apply if the challenger demonstrates that the claim term fails to recite sufficiently definite structure or else recites function without reciting sufficient structure for performing that function.” *Williamson*, 792 F.3d at 1349 (internal quotation marks omitted).

Here, the claim term “scanning system” lacks the word “means,” and therefore a presumption exists that the term should not be construed according to § 112, ¶ 6. Moreover, 3Shape has not demonstrated that “scanning system” fails to recite sufficiently definite structure or recites function without reciting sufficient structure for performing that function. Particularly, I do not find 3Shape’s reliance on its own expert’s conclusory testimony to be particularly persuasive. *See* RIB at 4-5 (citing Tr. at 1061:10-1062:15). I also find 3Shape’s characterization of the testimony from Align’s expert, Dr. Stevenson, to be somewhat misleading. For example, 3Shape argues that Dr. Stevenson’s testimony on whether the term “scanning system” connoted sufficient structure to avoid § 112, ¶ 6 treatment “was undercut by his inability to say what that structure was without reference to the specification (or to his pre-prepared slides).” RIB at 5. However, the hearing testimony 3Shape relies on in support of that assertion reveals that it was 3Shape’s own counsel that focused the testimony on the specification by asking Dr. Stevenson questions about specific figures and elements disclosed in the specification. *See* Tr. at 530:11-534:8 (“So is your opinion today, Doctor, that the scanning system, if I went to the specification to find a scanning system in the ’228 patent, that would be elements 31 and 41 based on this slide?”). Dr. Stevenson did not, as 3Shape’s brief suggests, rely on the specification to define the structure associated with a “scanning system” in response to a straightforward question about the structure associated with that term. Rather, Dr. Stevenson was asked a series of questions about whether certain elements of embodiments disclosed in the specification were part of a scanning

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system, and Dr. Stevenson answered those questions. *See* Tr. at 530:11-534:8. I find no evidence in the portion of the transcript cited by 3Shape to support applying § 112, ¶ 6 treatment to “scanning system” on the basis of Dr. Stevenson’s testimony.

I note also that 3Shape appears to misunderstand the standard for determining whether to apply § 112, ¶ 6 to “scanning system.” Though 3Shape’s briefing frames its argument in terms of “sufficiently definite structure,” much of 3Shape’s argument and questioning at the hearing suggests that in 3Shape’s view, “scanning system” must define a particular structure in order to avoid § 112, ¶ 6 treatment. That approach, however, is incorrect. “Scanning system” need only convey to one knowledgeable in the art a variety of structures encompassed by that phrase. *See Personalized Media Commc’ns*, 161 F.3d at 705 (“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 known as ‘detectors.’ We therefore conclude that the term ‘detector’ is a sufficiently definite structural term to preclude the application of § 112, ¶ 6.”).

3Shape’s briefing also suggests that it is improper to look to the specification to determine whether to apply § 112, ¶ 6. *See, e.g.*, RIB at 5 (“Align’s counsel was likewise unable to identify the components of the “scanning system” at the *Markman* hearing without reference to the specification.”). That suggestion is inconsistent with recent guidance from the Federal Circuit in *Diebold Nixdorf, Inc. v. Int’l Trade Comm’n*, 899 F.3d 1291 (Fed. Cir. 2018). In that case, the court considered whether to apply § 112, ¶ 6 to the term “cheque standby unit.” The court considered whether the written description of the asserted patent provided “any examples of what structures or class of structures fall within the definition of a ‘cheque standby unit.’” *Id.* at 1298. Given that guidance, I do not find fault in Align’s consideration of the specification to determine whether § 112, ¶ 6 should be applied to the term “scanning system.” To the contrary, that approach

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is consistent with *Diebold* and with *Phillips*, which advises that the specification “is always highly relevant to the claim construction analysis. *Phillips*, 415 F.3d at 1315 (quoting *Vitronics*, 90 F.3d at 1582).

Here, as noted by Align’s expert Dr. Stevenson, the color scanner patents include several examples of structures and classes of structures that fall within the definition of “scanning system.” See Tr. at 530:11-534:8. These examples include figures 1 and 4A, reproduced below, and elements 31 and 41 therein.

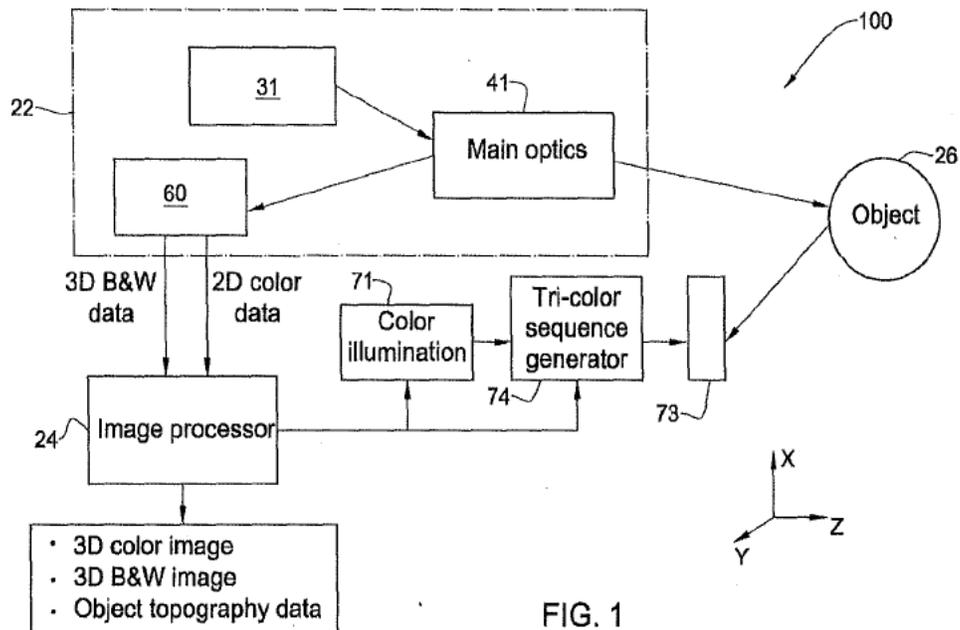


FIG. 1

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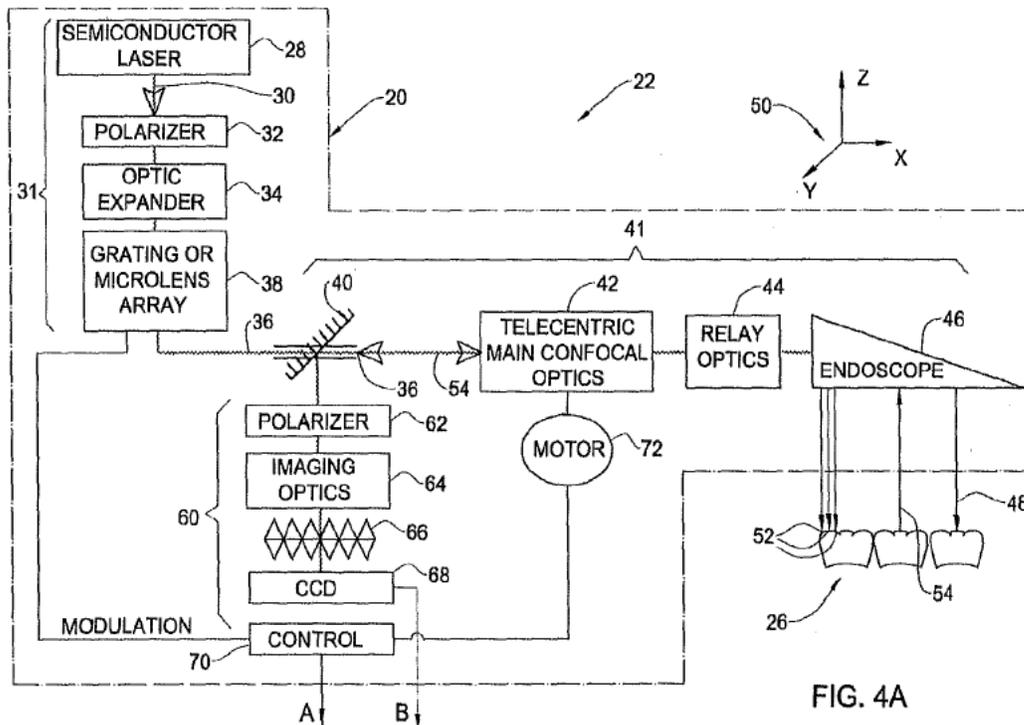


FIG. 4A

See, e.g., JX-0003 at Figs. 1, 4A. These examples of the structure defining a scanning system are markedly more fulsome than the figures in the written description of *Diebold*, which illustrated the disputed “cheque standby unit” as merely “a vertical line indistinguishable from the ‘main transfer path 106a’ that both precedes and follows it and on which it is ‘formed.’” *Diebold*, 899 F.3d at 1298.

At bottom, the absence of the word “means” from the “scanning system” term gives rise to a presumption that “scanning system” should not be construed according to § 112, ¶ 6. For the reasons described above, I find that 3Shape has not rebutted that presumption. Because “scanning system” should not be construed according to § 112, ¶ 6, I need not consider which of Align’s or 3Shape’s proposed § 112, ¶ 6 constructions is more correct.

The next issue with respect to the term “scanning system” is whether the term’s construction should include a requirement that depth data acquired by the scanning system be

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obtained separately from 2D color image data acquired by the imaging system. *See* RRB at 6, 14-19. 3Shape asserts that such a limitation is required based on the claim language, the specification, and prosecution history estoppel. *See id.* at 14-19. I do not agree.

With respect to the claims, 3Shape argues that because “scanning system” and “imaging system” are listed as separate elements in the claim, the depth data and 2D color image data those systems respectively provide must be obtained separately. *See* RRB at 16. First, as a matter of plain language, I am not convinced that the recitation in the claims of the two systems is indicative of how those systems operate from a temporal perspective. The claim language only informs the reader that the invention includes both a scanning system and an imaging system, and that those systems collect depth data and 2D color image data, respectively. *See* JX-0003 at Cl. 1. The claims are silent on the temporal relationship between those systems with respect to data collection.

3Shape relies on *Becton, Dickinson and Co. v. Tyco Healthcare Grp.*, 616 F.3d 1249, 1254 (Fed. Cir. 2010) to argue that because scanning system and imaging system are recited as two different elements in the asserted claims, those structures must obtain depth data and 2D color image data separately. RRB at 16. In *Becton*, the court concluded that the “spring means” and “hinged arm” elements of a claim to a surgical safety needle could not be construed to be the same structure. *See Becton*, 616 F.3d at 1255-54.

The instant dispute about the relationship between “scanning system” and “imaging system” elements is readily distinguishable from *Becton*. First, *Becton*, like other cases questioning the separateness of claim elements, reached its conclusion based on both the language of the claim and on the specification in that case. 616 F.3d at 1254. On different facts, other cases have reached the opposite conclusion of *Becton*. For example, a respondent in *Linear Technology Corp. v. International Trade Commission*, 566 F.3d 1049 (Fed. Cir. 2009), argued that a claim

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having a “second circuit” and “third circuit” required entirely separate and distinct circuits. After reviewing the claims and the specification, the Commission and the Federal Circuit rejected that argument. The Federal Circuit sustained the Commission’s construction, noting that the two circuits “must only perform their stated functions” and could be satisfied by overlapping components. *Id.* at 1055-56.<sup>3</sup>

The dispute here is closer to *Linear Technology* than to *Becton*. As in *Linear Technology*, the dispute here is how two electrical elements perform their respective functions in relation to each other. And as in *Linear Technology*, the specification at issue here discloses embodiments where the “scanning system” and “imaging system” share some components, as 3Shape admits. *Compare* RRB at 18 (acknowledging overlap of components in exemplary embodiments) *and* Tr. at 489:21-491:3 *with Linear Technology*, 566 F.3d at 1055 (specification “expressly disclose[d]” that two claimed element could “share common components.”). To properly resolve the issue here, as in *Becton* and *Linear*, I must thoroughly consider the specification.

3Shape notes that the specification discloses “a two dimensional (2D) color image of the 3D structure that is being scanned” obtained “typically within a short time interval with respect to the 3D scan.” RRB at 6 (quoting JX-0003 at 3:61-64). 3Shape contends this disclosure imposes a requirement that the scanning system and the imaging system obtain their respective data types at different times. But 3Shape fails to acknowledge other passages in the specification that contain broader teachings.

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<sup>3</sup> Other counter-examples to *Becton* abound, especially in the electrical arts. *See, e.g.*, *Gen. Elec. Co. v. Int'l Trade Comm'n*, 685 F.3d 1034, 1045 (Fed. Cir. 2012) (a claimed shunt “circuit coupled with the input of [an] inveter” did not require the circuit and the inverter to be separate); *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1310-11 (Fed.Cir.2005) (claim elements “RF receiver” and “destination processor” could be electrically linked or on the same circuit board). But, like *Becton*, these decisions examined the patent claims and specification to understand the proper resolution of the issue.

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For instance, the specification provides that “operation of the scanning means and the imaging means is substantially or effectively simultaneous in practical terms . . . .” JX-0003 at 4:67-5:2. The following passage makes a similar point:

The device is adapted for providing a time interval between acquisition of said depth data and acquisition of said color image data such that substantially no significant relative movement between said device and said portion occurs. The time interval may be between 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 5:7-15. This passage teaches that the time interval between collection of depth data and color image data can be zero seconds, and in fact, it is more preferable that any time interval be closer and closer to zero. Another passage in the specification expressly states that “one or more color scans may also be taken during the depth scan, and/or at the beginning and at the end of the depth scan.” JX-0003 at 21:46-48. Viewing all of these teachings together, the full scope of disclosure in the specification is that acquisition of depth data and color image data may happen simultaneously, up to about 100 milliseconds apart, or “within a short time interval,” without regard to which acquisition happens first.

Nothing in the language of the claim 1 of each asserted patent limits the invention to less than the full scope of the disclosures above. The claims make no mention of relative timing for the two required data acquisitions. 3Shape’s proposed construction mandating separation in time between the collection of depth data and image data would impose a limitation on the asserted claims without a clear disavowal of claim scope. That would be error. *See Linear Technology*, 566 F.3d at 1055 (finding two limitations should be “accorded their full scope” absent clear disavowal and could be satisfied by overlapping elements).

3Shape also argues a requirement of separate data acquisition arises from disclaimer during prosecution. During prosecution, the patentee made an amendment to claim 1 in response to an

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anticipation rejection based on U.S. Patent No. 7,098,435 (“Mueller”). RRB at 14-15; *see also* RX-0993 (Mueller). Specifically, 3Shape points to the following passage in the prosecution history:

Claim 1 is rejected under 35 U.S.C. § 102(b) as being anticipated by Mueller et al. (US 7,098,435).

While Applicants do not agree with the rejections and do not acquiesce to any reasoning provided in the Office Action, independent claim 1 has been amended to further expedite prosecution. As amended, claim 1 recites in-part:

a hand-held device comprising:

(a) a scanning system configured to provide depth data of said portion, the depth data corresponding to a plurality of data points defined on a plane substantially orthogonal to a depth direction;

(b) an imaging system configured to provide two-dimensional color image data of said portion associated with said plurality of data points; and

(c) a processor configured to associate the depth data with the color image data.

Mueller fails to teach each and every element of claim 1, thereby precluding a *prima facie* case for obviousness. Mueller discloses a system for obtaining a series of two dimensional color images of an object and processing those images to obtain a three dimensional model of the surface of an object. See col. 4, lines 44-47. Mueller, however, fails to at least teach a scanning system configured to provide depth data, an imaging system configured to provide two dimensional color image data, and a processor configured to associate the depth data with the color image data. Thus, Mueller fails to anticipate claim 1. Dependent claims 43-65 are allowable for at least being dependent from claim 1, as well as on their own merits.

Accordingly, for the reasons set forth above, withdrawal of the rejection of claim 1 under 35 U.S.C. § 102(b) is respectfully requested.

JX-0009 at Align-1091\_00003103-04 (underlining in original to show language added in amendment).

In order to impose a “separateness” requirement to the “scanning system” term on the basis of disclaimer, the prosecution history must demonstrate a clear and unmistakable disavowal of an invention that simultaneously obtains depth and 2D color image data. *See Massachusetts Inst. of*

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*Tech. v. Shire Pharm., Inc.*, 839 F.3d 1111, 1119 (Fed. Cir. 2016). The portion of the prosecution history on which 3Shape relies does not demonstrate such a disavowal. It is apparent from the prosecution history that the applicant distinguished Mueller, but it is not clear that the distinction was based on the separate collection of depth and 2D color image data. Indeed, the distinguishing feature may have been the addition of a processor. The applicants' comments submitted with the amendment are silent on whether the imaging system and scanning system can operate concurrently. I cannot discern from that silence a clear and unmistakable disavowal of concurrent collection of depth and 2D color image data.

Faced with a factually analogous situation in *3M Innovative Properties Co. v. Tredegar Corp.*, 725 F.3d 1315 (Fed. Cir. 2013), the Federal Circuit found error in the lower court's application of disclaimer on the basis of an ambiguous amendment. In *3M*, the dispute was whether the term "continuous contact" should be construed to include a "cohesive failure mode of contact." *Id.* at 1324-25. Though the relevant claim had been amended to replace the term "substantially continuous contact" with "continuous contact" in order to distinguish over a prior art reference called Hazelton, the Federal Circuit noted that the accused infringer failed to demonstrate how the amendment was tied to the cohesive failure limitation. *Id.* at 1325. Notably, the court observed "cohesive failure—or a description there-of—is not mentioned in the applicant remarks surrounding either amendment." *Id.* Ultimately, the Federal Circuit concluded that it was "apparent from the prosecution history that the applicant distinguished Hazelton, but there [was] no statement that amounts to a disavowal of cohesive failure." *Id.* at 1326. As such, application of disclaimer to "continuous contact" was inappropriate. *Id.* The facts in this investigation with respect to 3Shape's disclaimer argument and a separateness requirement are similar, and I can discern no reason to depart from the reasoning employed by the court in *3M*. Accordingly, I

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decline to construe “scanning system” in a way that would require separate collection of depth and 2D color image data.

For the sake of completeness, I note that 3Shape’s initial brief also argues that “Align has interpreted the ‘scanning system’ of the ’228, ’456, and ’207 patents to cover systems that use a non-confocal scanning approach,” and that such a construction would result in a lack of enablement under § 112, ¶ 2. RIB at 6-7. 3Shape’s argument is insufficiently complete to prevail. Even assuming that I should construe this term to preserve its validity,<sup>4</sup> 3Shape has failed to establish a lack of enablement under Align’s proposed construction. 3Shape makes no attempt to show that Align’s interpretation would require undue experimentation from persons skilled in the art to practice the full scope of the invention. *See id.* Undue experimentation is the lynchpin of the enablement inquiry, *see In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988), and the absence of any discussion of that topic in 3Shape’s brief precludes adopting a construction for “scanning system” to avoid a supposed enablement concern.

For all of the reasons described above, I decline to construe “scanning system” according to § 112, ¶ 6, and also decline to include a requirement that the scanning system must collect depth data separately from the imaging system’s collection of 2D color image data. “Scanning system” should be given its plain and ordinary meaning, which is “a 3D scanner that scans in the optical axis Z direction to provide depth data.” *See* Tr. at 464:23-465:7.

### 2. Imaging System

The parties’ disputes regarding the term “imaging system” mirror their disputes regarding “scanning system.” Align seeks a plain and ordinary meaning construction, while 3Shape seeks a

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<sup>4</sup> It is not at all clear I should even go down this path. *See Phillips*, 415 F.3d at 1328 (construing claims to preserve their validity is “a doctrine of limited utility”)

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§ 112, ¶ 6 construction and a requirement that the imaging system obtain 2D color image data separately from depth data obtained by the scanning system.

As with “scanning system,” I decline to construe “imaging system” under § 112, ¶ 6. As discussed in the context of “scanning system,” the absence of the word “means” gives rise to a rebuttable presumption that § 112, ¶ 6 does not apply. The “imaging system” term does not use the word “means;” therefore, 3Shape must overcome the presumption against applying § 112, ¶ 6. As noted above, the standard for overcoming the presumption against applying § 112, ¶ 6 requires the challenger to demonstrate “that the claim term fails to recite sufficiently definite structure or else recites function without reciting sufficient structure for performing that function.” *Williamson*, 792 F.3d at 1349 (internal quotation marks omitted).<sup>5</sup>

Notably, unlike 3Shape’s argument regarding “scanning system,” 3Shape cites no testimony—conclusory or otherwise—directed to whether a person of ordinary skill in the art would understand “imaging system” to connote structural meaning. *See* RIB at 7-8; RRB at 7-8. But it is undisputed that the specification discloses at least four examples of imaging system structures. RIB at 7 (citing JX-0003 at 16:37-23:40, 23:41-24:19, 24:20-28, and 24:29-42). Accordingly, this is not a case where “the written description does not include any examples of what structures or class of structures fall within the definition” of an imaging system. *Cf. Diebold*, 899 F.3d at 1298.

Given the absence of the word “means” from the “imaging system” term, as well as the presence of multiple structural examples in the specification of an imaging system configured to

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<sup>5</sup> Rather than engage the standard for overcoming the presumption, 3Shape’s briefing focuses on criticizing Align’s proposed plain and ordinary meaning construction and expert testimony supporting it. *See* RIB at 7-8. But the presumption against applying § 112, ¶ 6 exists no matter Align’s construction. I therefore give little weight to these arguments.

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obtain 2D color image data, I find that “imaging system” should not be construed according to § 112, ¶ 6. Instead, the term should be given its plain and ordinary meaning.

All of the examples in the specification that describe imaging systems include a light source as well as an image sensor. I find that the intrinsic evidence supports the conclusion that the plain and ordinary meaning of “imaging system” is “a system comprising at least an image sensor and a light source.” Because “imaging system” is not subject to construction under § 112, ¶ 6, I need not determine whether Align or 3Shape’s proposed § 112, ¶ 6 construction is more correct.

As with “scanning system,” 3Shape advocates for a construction that the “imaging system” be required to obtain 2D color information separately from the depth information obtained by the “scanning system.” *See* RRB at 8. On this point, 3Shape’s “imaging system” argument raises no contention unique from its arguments about separateness in its “scanning system” construction. Accordingly, for the same reasons stated above with respect to “scanning system,” I decline to construe “imaging system” to include a requirement that imaging system must collect 2D color image data separately from the scanning system’s collection of depth data.

### 3. Processor

The parties’ disputes regarding the term “processor” also mirror their disputes regarding “scanning system” and “imaging system.” Align seeks a plain and ordinary meaning construction, while 3Shape seeks a § 112, ¶ 6 construction. 3Shape also seeks a requirement that the imaging system obtain 2D color image data separately from depth data obtained by the scanning system. With respect to the § 112, ¶ 6 dispute, the specification is replete with examples of processors, which strongly indicates that a person of ordinary skill in the art would understand “processor” in the context of the asserted patents to connote a definite structure. *See, e.g.*, JX-0003 at 5:39, 8:42, 13:13; *see also Diebold*, 899 F.3d at 1298. 3Shape’s argument to the contrary is not persuasive.

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Particularly, 3Shape relies on *Finisar Corp. v. DirecTV Grp., Inc.*, 523 F.3d 1323, 1340 (Fed. Cir. 2008) for the proposition that a processor “programmed” to associate data sets must necessarily be subject to § 112, ¶ 6. *Finisar* simply does not support that proposition. In *Finisar*, the term “database editing means” was presumed to invoke § 112, ¶ 6 because it used the word “means.” The central question, however, was whether the term invalid for indefiniteness because the specification failed to disclose an algorithm for performing the function associated with that term. *See id.* at 1340-41. In other words, *Finisar* is a case about indefiniteness of a term § 112, ¶ 6; it did not establish a rule that a claim to a programmed processor is necessarily presumed to invoke § 112, ¶ 6. *Finisar* is inapposite to the question of when to apply § 112, ¶ 6 to a term that does not use the word “means.”

In the absence of any evidence that a person of ordinary skill in the art would not understand the “processor” in claim 1 to connote a definite structure or class of structures, the presumption that § 112, ¶ 6 should not apply has not been overcome. Therefore, I find “processor” should be construed according to its plain and ordinary meaning. No further construction is required to resolve the parties’ dispute.

#### 4. Confocal Imaging Techniques

The parties’ dispute regarding the term “confocal imaging techniques” is narrow. Both parties agree that the term requires conjugate focal planes. The dispute is whether the term also requires point illumination of a point onto an object to produce an image detected through a point detector. *See CIB* at 19; *RRB* at 9. I find that it does.

As an initial matter, I note that the intrinsic evidence is not sufficient to resolve the parties’ dispute. The intrinsic evidence provides relatively little guidance about what “confocal imaging” means. Indeed, the specification makes it clear that the use of point illumination, imaging, and

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detection is consistent with confocal imaging, but it is not clear from the specification that those elements are required. *See, e.g.*, JX-0003 at 2:61-3:3; 5:18-27, 15:51-65. The single claim in which the term appears provides no guidance. *See id.* at Cl. 4. Because the intrinsic evidence is not sufficient for me to discern the meaning of “confocal imaging” to a person of ordinary skill in the art in the context of the color scanner patents, I find that it is appropriate to consider extrinsic evidence.

Unfortunately, I do not find the expert testimony presented by the parties to be particularly helpful in resolving this dispute. I do find, however, that the documents the experts relied upon for the state of the art are instructive and persuasive. Two academic texts in the record discuss confocal microscopy. The first is “Confocal Microscopy” by Wilson. RX-0741. The second is “Confocal Scanning Optical Microscopy and Related Imaging Systems” by Corle and Kino. RX-1100. A third exhibit is U.S. Patent No. 3,013,467 issued to Minsky. JX-0107. All three of exhibits were created entirely independent of the instant litigation, and thus benefit from a level of impartiality not necessarily present in the carefully curated expert testimony I heard at the hearing.

All three of the exhibits listed above describe confocal microscopy in conjunction with point illumination, imaging, and detection. The Wilson book provides the following figure illustrating different arrangements in optical microscopes:

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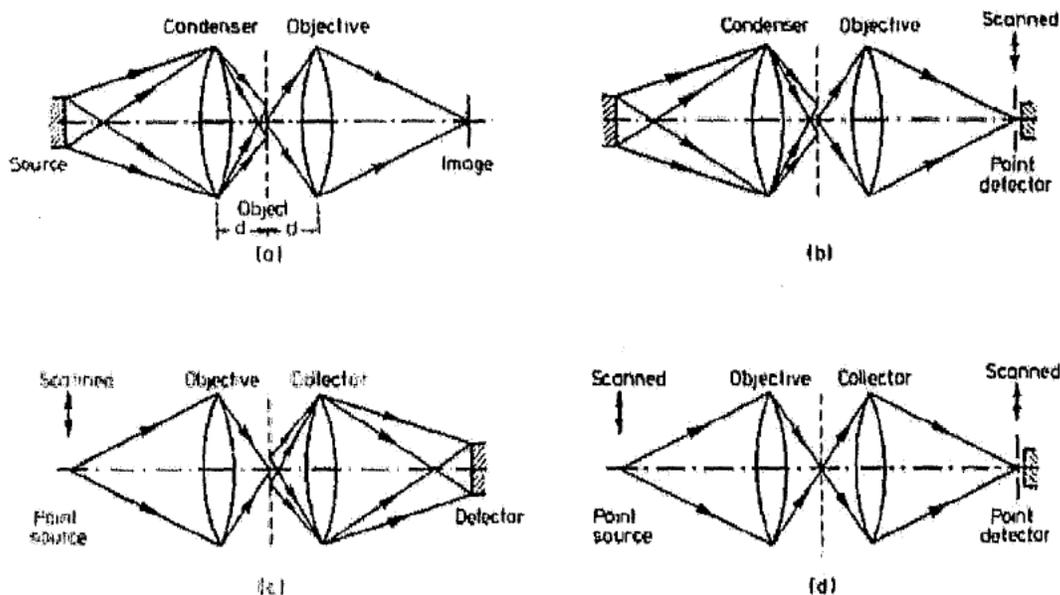
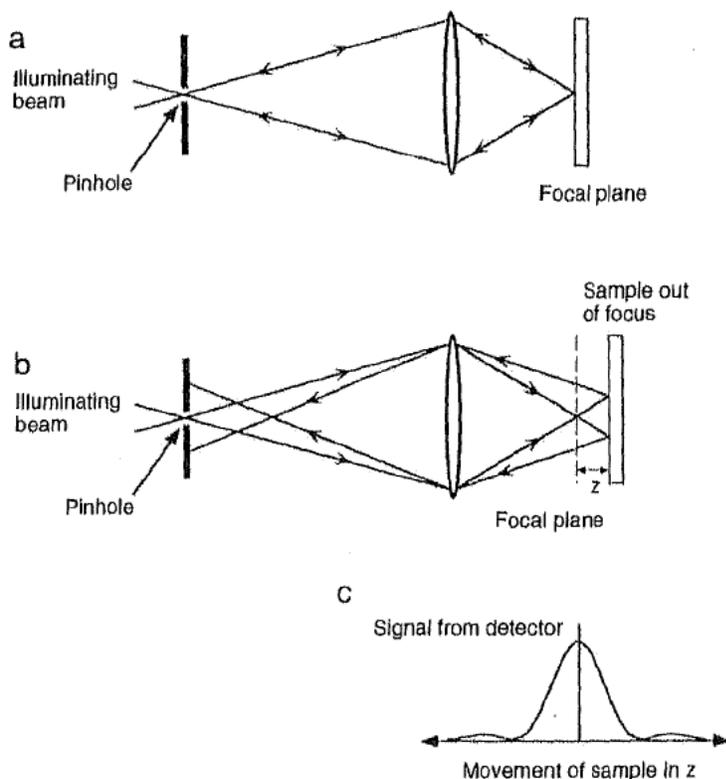


Figure 1.7. The optical arrangement of various forms of scanning optical microscopes. (a) Conventional microscope. (b) A form of conventional scanning microscope. (c) A form of conventional scanning microscope. (d) The confocal optical system.

RX-0741 at .0004. As the caption to the figure states, only configuration “(d),” which utilizes point illumination, point imaging, and point detection is confocal. *See id.* The remainder of the text on the same page further connects point illumination, imaging, and detection to confocal imaging. *See id.* (“In order to make the second lens contribute significantly to the resolution, we need to make it into an *imaging* lens rather than a *collector* lens. We achieve this by using a point detector rather than a large-area one. This is the form of the *confocal* scanning microscope, Figure 1.7(d). Here light from the point source probes a very small region of the object, and the point detector ensures that only light from that same small area is detected.”).

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Next, the Corle and Kino book provides this relevant figure:



**Figure 1.1** Simplified schematic of a confocal scanning optical microscope showing the sample (a) in the focal plane of the objective and (b) out of focus. (c) The form of the signal output from the detector as a function of sample defocus.

RX-1100 at .0006. The text of on that page goes on to state: “**Confocal Microscopy** The basic principle of confocal microscopy, illustrated in Fig. 1.1(a), is to illuminate only one spot on the sample at a time through a pinhole. The light reflected from the sample is imaged by the objective back to the pinhole.” *Id.*; *see also id.* at .0012-.0014.

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The Minsky patent also illustrates the use of point illumination, imaging, and detection in its figure 1:

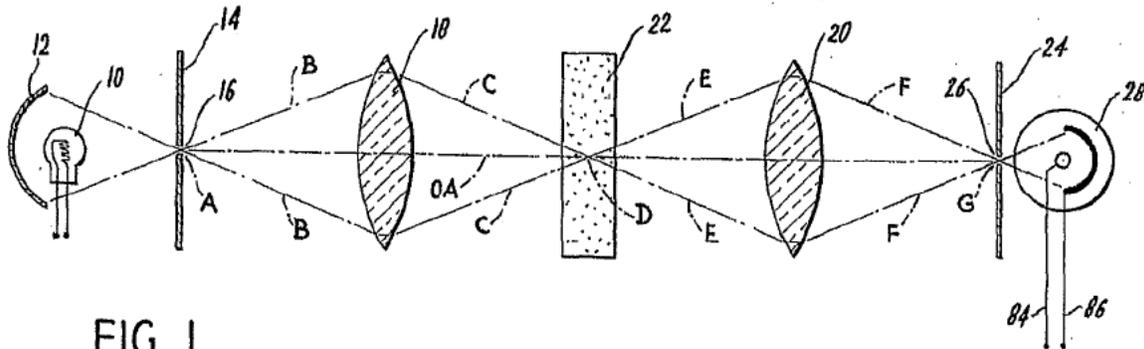


FIG. 1.

JX-0107 at p.1. The written description of the Minsky patent also makes numerous references to a pinhole aperture, an illuminated point, and point sources of light. *See e.g., id.* at 1:10-17 (“According to my invention, I utilize an optical system including a means for producing a point source of light. Light from this point source is focused upon a specimen to be enlarged to illuminate a point observation field included in the specimen. The illuminated point is then focused as an image of the point upon a pinhole aperture, and the light intensity of the image measured by a photosensitive device.”). To summarize, all three of the references identified by the parties as bearing on the meaning of “confocal imaging” tell the same story: A “confocal imaging” system requires conjugate focal planes as well as point illumination, imaging, and detection.

Align’s insistence to the contrary is not persuasive. Align summarily argues, through Dr. Stevenson, that the term “confocal” comes from the idea of creating conjugate focal planes, and therefore all that is required by the term “confocal imaging” in the color scanner patents is conjugate focal planes. *Id.* (citing Tr. at 475:3-15). Align’s argument conflates what is necessary with what is sufficient. There is no dispute from 3Shape that the term “confocal imaging” in the color scanner patents requires conjugate focal planes. Conjugate focal planes on their own, however, are not sufficient to define a “confocal imaging” technique or system within the context

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of the color scanner patents. Nowhere is this clearer than in the text of Corle and Kino, which describes the ambiguity that would follow if conjugate focal planes were the only requirement for confocal imaging:

In summary, the basic requirements for the [confocal scanning optical microscope (“CSOM”)] are point illumination, point detection, a scanned image, and a confocal lens system.

Strictly speaking, the word confocal can apply to both a standard optical microscope and the CSOM. Both instruments can use a high-numerical-aperture lens to illuminate and image the sample; thus both microscopes fit the definition of confocal, two lenses sharing a common focus. The terminology confocal microscope as a synonym for the CSOM is, however, firmly fixed in the literature so we will use it throughout this book.

RX-1100 at .0014. In other words, the Corle and Kino text says that a microscope might literally be “confocal” merely because it has “two lenses” that “share a common focus.” But in the optical arts, that is not how the term is used; it is “firmly fixed in the literature” that a confocal device “require[s]” “point illumination, point detection, a scanned image, and a confocal lens system.” *Id.* Thus, if “confocal imaging” is reduced down to the literal meaning of “confocal,” it would include techniques such as conventional microscopy that those skilled in the art do not consider to be included within the scope of “confocal imaging.”

Remarkably, Align attempts to characterize the Corle and Kino text as *supporting* its argument. Align claims that respondents’ expert, Dr. Zavislan “conceded” that the Corle and Kino text “does not define the basic requirements of ‘confocal’ to include a pinhole.” CIB at 19 (citing Tr. 1146:12-1148:1). A simple review of the transcript portion cited by Align shows no such “concession.” Align’s counsel read a portion of the text in Corle and Kino and then asked Dr. Zavislan to confirm that counsel read it correctly. *See* Tr. at 1147:7-1148:1. Align’s representation of that exchange as a concession is disappointingly misleading and do not support Align’s position.

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I find as a factual matter that the meaning of “confocal imaging” in the relevant art requires both conjugate focal planes and point illumination, imaging, and detection. I decline to follow give “confocal imaging” an overbroad definition that would capture forms of imaging that those in the art would not recognize as confocal imaging.

### **5. Image Gathering Member**

The parties brief a dispute over the meaning of “image gathering member,” which appears in claim 12 of the ’433 patent. *See* CIB at 20-21; RIB at 11-12. However, the parties’ dispute over this term is immaterial to the conclusions in this determination. Accordingly, I need not construe the term further.

### **6. Selectively Map**

The parties dispute the construction of “selectively map the image data to the depth data,” which appears in claim 12 of the ’433 patent. CIB at 22-23; RIB at 12-16. Align proposes this term should be construed to mean “matching image data and depth data based on the plurality of focal lengths and the depth data such that the resulting associated color of the structure portion is in focus relative to the structure portion for a plurality of distances in the depth direction.” CIB at 22. Align contends that its construction is consistent with the plain and ordinary meaning of this term to a person of ordinary skill in the art. 3Shape, by contrast, argues that this term is indefinite. RIB at 12.

I do not find 3Shape’s indefiniteness argument persuasive. At a high level, 3Shape’s theory of why the “selectively map” limitation is indefinite is far removed from the reasonable certainty standard that governs indefiniteness. Rather, 3Shape lobs a variety of criticisms at what it views to be Align’s interpretation of this term, without explaining how those criticisms lead to indefiniteness. For example, 3Shape argues that the specification fails to disclose any example of

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“selective mapping,” but if true, that point would likely only be evidence of invalidity under § 112, ¶ 1, not § 112, ¶ 2. *See* RIB at 12-13. 3Shape does not appear to assert that claim 12 of the ’433 patent is invalid under § 112, ¶ 1 due to the “selectively map” term.

3Shape also raises a claim differentiation argument with respect to the term “selectively map,” and the term “map,” which appears in other unasserted claims in the ’433 patent. RIB at 13 (citing *CAE Screenplates v. Heinrich Fiedler GmbH*, 224 F.3d 1308, 1317 (Fed. Cir. 2000)). Again, the presumption that different claim terms have different meanings is distinct from the issue of indefiniteness. 3Shape’s point may have some merit inasmuch as the purpose is to argue that a construction that treats “selectively map” and “map” equivalently must be incorrect because it fails to give meaning to the word “selectively.” The point does not, however, support the conclusion that a person of ordinary skill in the art would not understand the metes and bounds of claim 12 with reasonable certainty.

Finally, 3Shape takes aim at the manner Align applies the “selectively map” term to the accused products for the purposes of infringement. RIB at 13. The gist of this argument is that Align conflated the antecedent basis for a related term—“plurality of focal lengths”—such that the term referred to depth data when it should have referred to image data. *See id.* at 13-15. On that basis, 3Shape summarily concludes that the term must be indefinite. *See id.* at 15. Again, 3Shape fails to draw a connection between its argument and the requirements of § 112, ¶ 2. Indeed, 3Shape’s argument appears to sound most readily in noninfringement, which is where the argument appears in 3Shape’s prehearing brief. *See, e.g.*, RPB at 297.

At bottom, 3Shape has failed to present a persuasive argument for why a person of ordinary skill in the art would not understand the scope of the term “selectively map” with reasonable

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certainty. Accordingly, I find that 3Shape has failed to establish, by clear and convincing evidence, that claim 12 of the '433 patent is indefinite due to the “selectively map” term included therein.

I agree with Align that this term should be given its plain and ordinary meaning, and note that Align’s proposed construction largely tracks the language of the claim, except that the words “selectively map” have been replaced with “matching.” *See* CIMB at 32. It is not clear that replacing “selectively map” with “matching” adds any clarity to the claim, and in the absence of compelling evidence to make that substitution, I decline to do it. Accordingly, I find that the “selectively map” term should be given its plain and ordinary meaning, and that no additional construction is needed.

With respect to 3Shape’s concern that “selectively” is being given no meaning under this construction, I disagree. When the “selectively map” term is read in context of the surrounding claim language, instead of looking at only the two words “selectively” and “map” in isolation, it is clear that a person of ordinary skill in the art would understand the term to refer to a correlation of image data to depth data “based on the plurality of focal lengths and the depth data such that the resulting associated color of the structure portion is in locus relative to the structure portion for a plurality of distances in the depth direction.” JX-0006 at Cl. 12. In other words, the claim does not allow any type of mapping, as 3Shape posits, but rather is limited to mapping based on specific criteria delineated in the claim. By contrast, when the patentee used only the term “map,” as in unasserted claims 1 and 7, the claimed mapping is not limited to correlation by specific characteristics. *See id.* at Cls. 1, 7. Thus, the claims themselves makes it clear that “map” refers to a broad class of any possible correlation in claims 1 and 7, while “selectively map” is limited to correlation according to the specific criteria listed in claim 12.

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C. Infringement

Align asserts infringement of the following claims by 3Shape:

'228 Patent	'456 Patent	'207 Patent	'433 Patent
Claims <b>1</b> , 4, 26	Claims <b>1</b> , 15	Claim <b>1</b>	Claim <b>12</b>

Independent claims are emphasized with boldface type. Each claim is addressed in turn herein.

1. '228 Patent

a) Claim 1

Align asserts that 3Shape's Trios systems infringe claim 1 of the '228 patent, which provides as follows:

[P] 1. A system for determining the surface topology and associated color of at least a portion of a three dimensional structure, comprising:

[1] a hand-held device comprising:

[2] (a) a scanning system configured to provide depth data of said portion, the depth data corresponding to a plurality of data points defined on a plane substantially orthogonal to a depth direction;

[3] (b) an imaging system configured to provide two-dimensional color image data of said portion associated with said plurality of data points; and

[4] (c) a processor configured to associate the depth data with the color image data.

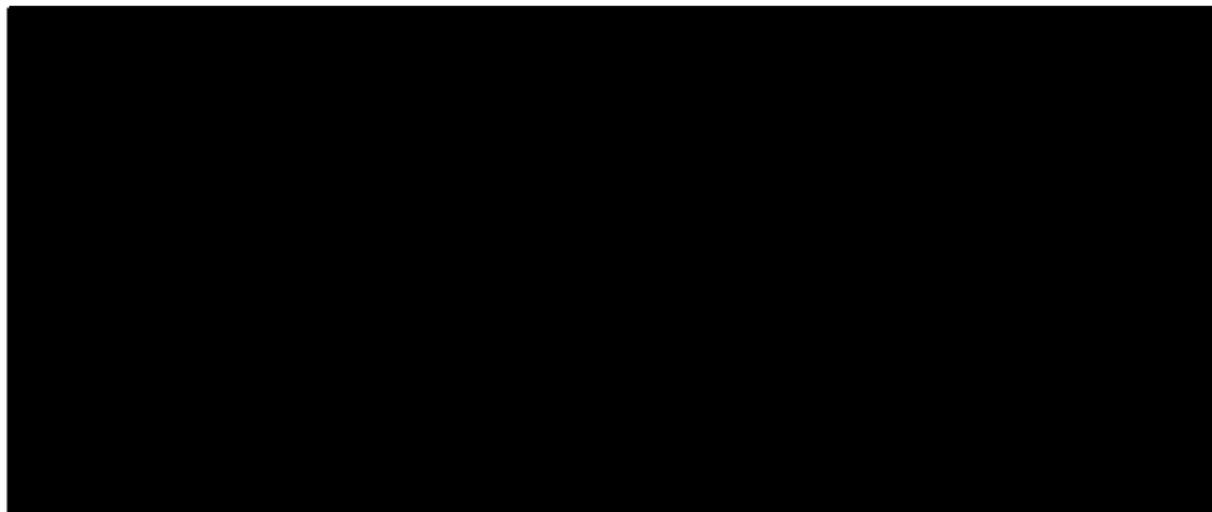
JX-0003 at Cl. 1. Align organizes its argument by breaking the claim into five elements—the preamble labeled [P] above, and four elements labeled [1]-[4] above. I adopt the same convention.

There is no dispute that the Trios scanners satisfy the preamble [P], and I find that Align has produced evidence sufficient to establish as much by a preponderance of the evidence. *See, e.g., CX-1538C at 2; Tr. at 463:12-21.* There is also no dispute that the Trios scanners satisfy

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element [1], and again I find that Align has produced evidence sufficient to establish as much by a preponderance of the evidence. *See* Tr. at 464:8-14.

Turning to element [2], Align points to the following description of components in the Trios scanners as evidence that the products include the structure claimed in element [2]:



CIB at 27 (citing JX-0261C at 8). Align goes on to explain, relying on the testimony of its expert, Dr. Stevenson, that with the aid of a field programmable gate array (FPGA) the scanning system provides depth data through a series of processing steps. *See* Tr. at 457:1-463:4. Align relies on this evidence to show that the Trios products practice element [2] of claim 1. *See* CIB at 26-34.

3Shape provides its own description of how the Trios scanners work, but does not particularly articulate any error in Align's description. *See* RRB at 13-14. Put differently, there does not appear to be any factual dispute about how the scanners operate. Rather, 3Shape emphasizes what it views as a fundamental difference in the way the Trios products operate versus the invention of claim 1. Particularly, 3Shape argues that the Trios products do not have separate systems for providing depth data and color data, nor do they then need a processor to associate depth and color data from those separate systems. RRB at 13-14. As a result, 3Shape argues that

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claim 1 does not read on the Trios scanners because that claim requires separate scanning and imaging systems. *Id.*

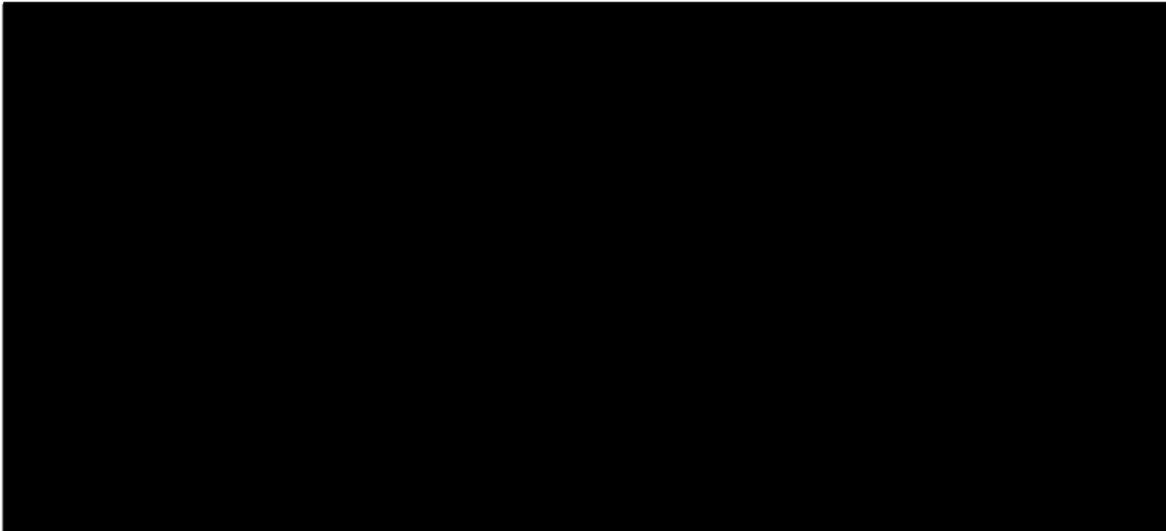
As discussed *supra*, I decline to construe “scanning system” to include a requirement that the depth data referenced in element [2] must be obtained separately from the color data in element [3]. Accordingly, insomuch as 3Shape argues that the Trios scanners do not practice element [2] of claim 1 because those products do not obtain depth data separately from color data, I find 3Shape’s argument unpersuasive. *See* RRB at 14-19.

3Shape also argues in briefing that the Trios scanners do not practice element [2] of claim 1 under 3Shape’s proposed § 112, ¶ 6 construction. *See id.* at 19-20. However, for the reasons explained *supra*, I do not agree that “scanning system” should be construed according to § 112, ¶ 6. Accordingly, whether the Trios products practice claim 1 under 3Shape’s § 112, ¶ 6 construction is immaterial to my determination on infringement.

3Shape makes no other noninfringement arguments with respect to element [2] of claim 1. Accordingly, I find that Align has presented evidence sufficient to establish that the Trios products practice element [2] of claim 1.

Turning to element [3], Align points to a Luxima Z13HSC image sensor (a CCD element) in the Trios products to satisfy the “imaging system” limitation of claim 1. CIB at 38 (citing JX-0291C; JX-0419C; RX-1098C). Align provides the following annotated diagram to further illustrate the location of the CCD in the Trios product:

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*Id.* Align cites hearing testimony to demonstrate that this structure provides 2D color image data in accordance with the claim's requirements. *Id.* (citing Tr. at 468:6-10; 1131:23-1132:6). Additionally, the evidence produced by Align in the context of element [1] shows a common light source used in connection with the Luxima [REDACTED] image sensor. *See* JX-0207C at 1.

3Shape advances no noninfringement arguments with respect to this element that are distinct from the arguments it raised with respect to element [2]. 3Shape maintains its position that depth data and 2D color image data must be obtained separately, and that if construed according to § 112, ¶ 6, the structure identified by Align does not meet 3Shape's own § 112, ¶ 6 construction for "imaging system." *See* RRB at 13-20. As noted *supra*, and as a matter of claim construction, I decline to construe "imaging system" such that 2D color image data obtained thereof must be obtained separately from depth data obtained from the scanning system. Similarly, I have declined to adopt 3Shape's § 112, ¶ 6 construction for "imaging system." Accordingly, all of 3Shape's noninfringement arguments for this term fail. Therefore, I find that Align has established, by a preponderance of the evidence, that the Trios products practice element [3] of claim 1.

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Turning to element [4], Align points to a Field Programmable Gate Array (“FPGA”) in the Trios products to satisfy the “processor” limitation of claim 1. CIB at 39 (citing Tr. at 468:11-24).<sup>6</sup> The disputed question is whether the FPGA associates the depth data and color image data, as required by claim 1. I find that it does.

Align relies on the following testimony from its expert, Dr. Stevenson, to establish that the FPGA associates depth data and color image data:

Q And Dr. Stevenson, the additional exhibits, JX-0299, 0238C, 0240C, 0237C, 0259C, 0260C, 0776C, 0790C, and 0239C, do you have familiarity with these exhibits as well?

A Yes. These are just more internal technical documents that talk about the operation of the FPGA and the PC and are consistent with what I just explained.

Q And when we look here at slide 29, what does this slide show?

A This is trying to get across this idea of what sort of association is going on in regards to the Figure 4. Hopefully just bringing us back to what I talked about ten minutes ago and how the device actually operates. So the data we collected is kind of shown in the bottom, we have the color image data, we have the depth data from the encoder, and then, you know, what I'm showing at the top there is that those kind of processing stage or at least parts of this processing stage to remind you that at the end of the day, we're going to take that depth data and color data for each of those [REDACTED] further use that to build that final model that is displayed on the screen, which is clearly a colored 3D model.

Tr. 469:7-470:5.

Align also relies on the cross-examination testimony of 3Shape’s expert Dr. van der Poel to confirm Dr. Stevenson’s understanding of the way color and depth data are packaged together

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<sup>6</sup> A portion of Align’s brief also suggests that a computer connected to the handheld scanner in the Trios products may satisfy that “processor” limitation. *See* CIB at 39 (“The CPU that is coupled to the wand also contains a processor that implements further association of the color data with depth data to generate a three-dimensional model.”). I reject that suggestion. Element [1] of claim 1 is a “handheld device comprising: . . .” the processor element [3]. A computer that is not part of the handheld device does not satisfy the processor element [3] of claim 1.

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in the wand before being shipped to a separate computer. See CIB at 42 (citing Tr. 958:19-959:4, 967:6-11).

Align finds additional support for its position in the deposition testimony of Drs. Roselund and Hansen, who were designated as corporate representatives for 3Shape. Particularly, Dr. Roselund states:

Q. [REDACTED]

A. [REDACTED]

JX-074C at 79:13-19. And, Dr. Hansen states:

Q. And then how does the color come into the model?

A. [REDACTED]

\* \* \*

Q. [REDACTED]

A. [REDACTED]

Q. Okay.

A. [REDACTED]

Q. [REDACTED]

A. [REDACTED]

Q. [REDACTED]

A. [REDACTED]

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JX-0057 43:7-10; 133:13-134:3. Taken together, these portions of testimony tend to demonstrate that the FPGA associates depth and color image information together before that data is sent to an external computer for additional processing.

3Shape raises two additional arguments with respect to element [4]. First, 3Shape contends that Align is factually wrong in arguing that depth information and color information are sent from the scanner wand to the external computer in a single packet. 3Shape cites additional testimony from Dr. Hansen to support a conclusion that when he mentioned a [REDACTED] the passage above [REDACTED] [REDACTED] RRB at 22-23 (citing Tr. 819:23-821:7, 832:10-22).

3Shape also points to an additional portion of Dr. Roselund's deposition testimony to establish that there are [REDACTED] [REDACTED] [REDACTED] *Id.* (citing JX-0074C 57:20-61:13, 79:13-19).

Having reviewed the evidence 3Shape presents, I still find that Align has established that the Trios products practice element [4] of claim 1. With respect to Dr. Hansen's trial testimony, the most relevant portion appears to contradict the deposition testimony that 3Shape seeks to rely on. *See* Tr. at 819:23-821:7 (testifying that [REDACTED] [REDACTED]). Having reviewed the excerpts of Dr. Hansen's deposition testimony submitted in this investigation, it is not clear that his answers during his deposition were directed to packages received from ScanSuite interface, as 3Shape proposes. Put simply, at best, Dr. Hansen provided testimony at the evidentiary hearing

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that contradicts the portion of his sworn deposition testimony that was admitted into the record. This is not particularly persuasive evidence in 3Shape's favor.

With respect to Dr. Roselund's deposition testimony, the most relevant portions of his testimony appear at JX-0074C, 57:17-58:2 and 60:5-61:13. First, Dr. Roselund acknowledges that the [REDACTED] JX-0074C at 57:17-58:2. Then, speaking about the creation of [REDACTED] Dr. Roselund explains that that FPGA [REDACTED]

[REDACTED] *Id.* at 60:5-60:16. I note that, in the same exchange, Dr. Roselund appears to testify that [REDACTED]

[REDACTED] *See id.* at 60:19-21. Dr. Roselund apparently understood the discrepancy in his answer as he goes on, without prompting, to clarify that the [REDACTED]

[REDACTED] *Id.* at 60:24-61:1. I have reviewed the rest of Dr. Roselund's testimony cited by 3Shape, but it provides little additional clarity.

It appears to me that Dr. Roselund's understanding of what it means for [REDACTED]

[REDACTED] However, I also understand Dr. Roselund's testimony to be

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I do not find the additional portions of Dr. Roselund's deposition testimony to be inconsistent with the conclusion that association of encoder data and image data (*i.e.*, depth and color image data) occurs in the FPGA. The evidence shows that the two types of data are associated [REDACTED]. *Id.* at 57:17-58:2, 60:11-16.

With respect to 3Shape's second argument—that "depth data" should be construed in a way to exclude lens position information [REDACTED]—I find this to be an improper attempt to limit the term "depth data" to a particular embodiment in the specification. *See* RRB at 23-24. I note that it is unclear how 3Shape thinks this term should be construed, as it does not appear in the claim construction sections of 3Shape's briefs, and 3Shape does not offer an affirmative definition of the term in the noninfringement section of its brief. Rather, 3Shape's brief suggests a possible construction whereby depth data must be a Z-coordinate of the structure being scanned. *See id.* I decline to adopt this vague construction because it appears to be a plain request to limit the broad term "depth data" to the types of data obtained in certain exemplary embodiments.

3Shape makes one additional noninfringement argument that is limited only to Trios 3 Mono scanners. Particularly, 3Shape argues that "Trios 3 Mono scanners are configured with different software that ignores the color information and is 'only capable of outputting monochromatic data,'" which is inconsistent with the requirement in claim element [3] for an imaging system configured to obtain color image data. RRB at 24-25 (citing Tr. at 822:7-11; JX-0079C at 50:15-21). 3Shape acknowledges that the Trios 3 Mono scanners can be modified at a 3Shape factory to add color scanning functionality, but argues that "[b]ecause modifications are required to enable to color functionality, [the Trios 3 Mono scanners] cannot be found to infringe." RRB at 25 (citing *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316 (Fed. Cir. 2001))

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(“[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.”)).

There appears to be no response to 3Shape’s Trios Mono argument in any of Align’s briefing, notwithstanding the fact that the argument was included in 3Shape’s prehearing brief. Accordingly, based on the evidence and argument adduced by 3Shape, I find that there are two distinct groups of Trios scanners for the purposes of this determination. One group includes color scanners, which appear to be the focus of Align’s allegations, while the second group includes monochromatic scanners, which 3Shape refers to as the Trios Mono scanners. Based on the unrebutted evidence produced by 3Shape, I find that Align has not established, by a preponderance of the evidence, that the Trios Mono scanners practice element [3] of claim 1, which requires an imaging system configured to provide two-dimensional color image data. *See* Tr. at 822:7-11.

Consistent with reasoning above, I find that Align has established, by a preponderance of the evidence, that claim 1 of the ’228 patent is infringed by the Trios color scanners. I find, however, that Align has not established, by a preponderance of the evidence, that the Trios mono scanners infringe that claim. Because the Trios mono scanners do not infringe independent claim 1 of the ’228 patent, they also cannot infringe claims 4 and 26, which depend from claim 1.

### *b) Claim 4*

Claim 4 of the ’228 patent depends from claim 1 and adds the additional limitation that “operation of the scanning system is based on confocal imaging techniques.” JX-0003 at Cl. 4. As noted above, confocal imaging is construed according to its plain and ordinary meaning, which requires both conjugate focal planes and point illumination, imaging, and detection. Though Align summarily states that “[e]vidence presented at trial confirmed that the TRIOS3 also literally infringe claim 4 of the ’228 patent under either parties’ proposed claim construction,” the evidence

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cited in the post-hearing briefs paints a different picture. CIB at 44. Particularly, Align points to no evidence showing the use of point illumination, imaging, and detection, while 3Shape points to testimony demonstrating that Trios scanners have neither a point illumination source nor point detection. *See id.* at 44-46; RRB at 26 (citing Tr. at 1106:14-20). In the absence of contrary evidence, I find, as factual matter, that the accused Trios scanners do not utilize point illumination or detection. As such, the accused Trios scanners do not practice the “confocal imaging techniques” limitation of claim 4, and thus do not infringe claim 4 of the ’228 patent.

I note that both Align and 3Shape put forward indirect evidence to support their respective positions. Align points to some internal 3Shape documents [REDACTED] [REDACTED] CIB at 45-46 (citing CX-1328C at 11), while 3Shape points to an e-mail sent to Align from a consultant describing 3Shape’s system as [REDACTED] RRB at (citing RX-0201C; RX-0202C). The probative value of this secondary evidence is low, particularly where there appears to be no serious dispute about the components that make up the Trios scanner or how those scanners operate. Direct and un rebutted evidence provided under oath at the evidentiary hearing by a credible witness has established that Trios does not utilize point illumination or detection. Tr. at 1106:14-20. At best, 3Shape’s internal documents and the e-mail to Align might be probative to the meaning of “confocal imaging” to a person of skill in the art, though neither party advanced such an argument. Even then, however, neither document would change my conclusion regarding the construction of “confocal imaging,” given the other highly credible evidence in the record showing an industry-accepted understanding of that term.

In sum, Align has not shown, by a preponderance of the evidence, that Trios scanners practice claim 4 of the ’228 patent.

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*c) Claim 26*

Claim 26 of the '228 patent depends from independent claim 1 and adds the additional limitation that the system of claim 1 "is configured to determine color and surface topology of a portion of a patient's teeth." JX-0003 at Cl. 26. Align has presented evidence showing that Trios scanners are used to scan patient's teeth in a manner consistent with this limitation. CIB at 46-47 (citing Tr. at 478:10-17; JX-0262C; JX-0238C; JX-0265C). 3Shape presents no additional noninfringement argument or evidence with respect to this claim other than arguing that because, in its view, claim 1 is not infringed, claim 26, which depends from claim 1, cannot be infringed. *See* RRB at 27. As noted above, I found that the Trios color scanners infringe claim 1.

Based on the evidence presented, I find that Align has established, by a preponderance of the evidence, that claim 26 of the '228 patent is infringed by the Trios color scanners.

**2. '456 Patent**

*a) Claim 1*

The parties appear to agree that the disputes regarding infringement of claim 1 of the '456 patent are coextensive with the disputes regarding infringement of claim 1 of the '228 patent. Claim 1 of the '456 patent is, in fact, nearly identical to claim 1 of the '228 patent. The differences can be seen highlighted in this chart:

PUBLIC VERSION

Comparison of Claim 1 of '228 and Claim 1 of '456

U.S. Pat. No. 8,363,228	U.S. Pat. No. 8,451,456
1. A system for determining the surface topology and associated color of at least a portion of a three dimensional structure, comprising:	1. A system for determining the surface topology and associated color of at least a portion of a three-dimensional dental structure, comprising:
a hand-held device comprising:	a hand-held device comprising:
(a) a scanning system configured to provide depth data of said portion, the depth data corresponding to a plurality of data points defined on a plane substantially orthogonal to a depth direction;	(a) a scanning system configured to provide depth data of the portion, the depth data corresponding to a plurality of data points defined on a plane substantially orthogonal to a depth direction;
(b) an imaging system configured to provide two-dimensional color image data of said portion associated with said plurality of data points; and	(b) an imaging system configured to provide color image data of the portion associated with said plurality of data points; and
(c) a processor configured to associate the depth data with the color image data.	(c) a processor configured to associate the depth data with the color image data,
	wherein the depth data and the color image data represent the surface topology and the color of the portion of the three-dimensional dental structure.

CDX-0008.41

See CIB at 55. As can be seen, claim 1 the '456 patent additionally requires that the depth data and color image data represent the surface topology and color of a dental structure. Align has produced un rebutted evidence to show that depth data and color image data in the 3Shape Trios scanners represent the surface topology and color of teeth, in accordance with claim 1 of the '456 patent. See CIB at 55 (citing Tr. at 479:4-18; 1129:5-11). Based on the undisputed evidence presented by Align with respect to claim 1 of the '456 patent, and consistent with the evidence and reasoning laid out with respect to claim 1 of the '228 patent, I find that Align has established, by a preponderance of the evidence, that the Trios color scanners practice claim 1 of the '456 patent.

**b) Claim 15**

Claim 15 of the '456 patent depends from claim 1 and adds the additional limitation that “the processor is further configured to conformally map the color image data to the depth data to produce a color, three-dimensional virtual model comprising three-dimensional surface topology data associated with color data..” JX-0004 at Cl. 15. Align points to three sources of evidence to

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establish that Trios scanners practice this additional limitation. *See* CIB at 55-56 (citing Tr. at 481:9-482:24; JX-0079C at 85:15-86:15; CX-1331C). I have reviewed all of the evidence cited by Align and none of it supports the conclusion that Trios scanners infringe claim 15 of the '456 patent.

The first piece of evidence, hearing testimony from Align's expert, Dr. Stevenson, is devoid of any discussion of the FPGA in the scanner, and that is the processor, which, consistent with the plain language of the claim, must be configured to conformally map color image data to depth data to produce a color, three-dimensional virtual model comprising three-dimensional surface topology data associated with color data. *See* Tr. at 481:9-482:24. Instead, Dr. Stevenson focuses on the ultimate output of 3Shape's software, arguing that because the 3D virtual model output by 3Shape's Trios system accurately shows the surface topology, layout, and shape of a patient's teeth, the additional limitation of claim 15 is satisfied. *See id.* It appears that Dr. Stevenson is relying on processing that occurs in an external computer to satisfy this limitation, based on the heavy focus his testimony places on the creation of a 3D model, which no party contends occurs in the FPGA. *See, e.g., id.* at 481:19-23. But the claim requires a handheld device with a processor configured to conformally map color image data to depth data to produce a 3D model. Dr. Stevenson did not identify a handheld device with a processor having the capabilities required in claim 15.

Align's other evidence is no better. The evidence in JX-079C is deposition testimony from 3Shape employee Mike van der Poel. Dr. van der Poel's testimony is not related to the FPGA. It is focused instead on the method of calibrating a Trios scanner. *See* JX-079C at 85:8-17. The testimony has no probative value with respect to establishing that Trios scanners include a processor configured as required by claim 15. The third piece of evidence is similar; it is a draft

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3Shape document about calibration titled “TRIOS Calibration Validation.” See CX-1331C. It also does not identify a processor configured as required by claim 15.

Align has produced no evidence to support a finding that 3Shape’s Trios scanners include a handheld device comprising a processor configured as required by claim 15 of the ’456 patent. Accordingly, I find that Align has failed to establish, by a preponderance of the evidence, that claim 15 of the ’456 patent is infringed by the Trios scanners.

### 3. ’207 Patent

#### a) *Claim 1*

The parties appear to agree that the disputes regarding infringement of claim 1 of the ’207 patent are coextensive with the disputes regarding infringement of claim 1 of the ’228 patent and claim 1 of the ’456 patent. Claim 1 of the ’207 patent is, in fact, nearly identical to claim 1 of the ’228 patent and claim 1 of the ’456 patent, except that it is a claim to a method for using a handheld device instead of a claim to a handheld device itself. The handheld device to be used in the method of claim 1 of the ’207 patent is identical to the handheld device described in claim 1 of the ’456 patent. The differences between claim 1 of the ’207 patent and claim 1 of the ’456 patent can be seen in this chart:

PUBLIC VERSION

Comparison of Claim 1 of '456 and Claim 1 of '207

U.S. Pat. No. 8,451,456	U.S. Pat. No. 8,675,207
1. A system for determining the surface topology and associated color of at least a portion of a three-dimensional dental structure, comprising:	1. A method for determining the surface topology and associated color of at least a portion of a three-dimensional dental structure, comprising:
a hand-held device comprising:	providing a hand-held device comprising:
(a) a scanning system configured to provide depth data of the portion, the depth data corresponding to a plurality of data points defined on a plane substantially orthogonal to a depth direction;	(a) a scanning system configured to provide depth data of the portion, the depth data corresponding to a plurality of data points defined on a plane substantially orthogonal to a depth direction;
(b) an imaging system configured to provide color image data of the portion associated with said plurality of data points; and	(b) an imaging system configured to provide color image data of the portion associated with said plurality of data points; and
(c) a processor configured to associate the depth data with the color image data,	(c) a processor configured to associate the depth data with the color image data,
wherein the depth data and the color image data represent the surface topology and the color of the portion of the three-dimensional dental structure.	wherein the depth data and the color image data represent the surface topology and the color of the portion of the three-dimensional dental structure.
	operating the hand-held device

CDX-0008.45

See CIB at 57.

Align has produced un rebutted evidence to show that 3Shape employees practice the method of claim 1 of the '207 patent with Trios scanners, particularly at trade shows. See CIB at 57-58 (citing Tr. at 483:19-484:14; 807:14-21; 1162:2-15). Align otherwise relies on the evidence and argument presented with respect to claim 1 of the '228 patent and claim 1 of the '456 patent to show that the Trios scanners used by 3Shape meet all the structural limitations in the claim. See CIB at 57.

Based on the evidence presented by Align with respect to claim elements unique to claim 1 of the '207 patent, and consistent with the reasoning laid out with respect to claim 1 of the '228 patent and claim 1 of the '456 patent, I find that Align has established, by a preponderance of the evidence, that the 3Shape infringes claim 1 of the '207 patent when it uses the accused Trios scanners. I also find that 3Shape's resellers infringe claim 1 of the '207 patent when they provide training to others. See, e.g., Tr. at 814:3-9. For example, one of 3Shape's resellers—Patterson

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Dental Holdings, Inc.—used and continues to use 3Shape’s Trios color scanners, and I find that such use infringes claim 1 of the ’207 patent. *See* JX-0192 at ¶ 2. There is also evidence from which I infer that end-user customers like dentists practice the claimed method. Mr. Melchior admitted that 3Shape Inc. employees visit dentists along with resellers to provide expertise on use of the accused scanners. Tr. at 812:3-814:9; *see also* Tr. at 899:18-24.

In sum, the record evidence supports a conclusion that 3Shape, its resellers, and end-user customers practice and infringe the method in claim 1 of the ’207 patent when they use the accused Trios scanners.

### 4. ’433 Patent

#### a) *Claim 12*

Align asserts that 3Shape’s Trios scanners infringe claim 12 of the ’228 patent, which provides as follows:

- [P] 12. A system for determining surface topology and associated color of at least a portion of a three-dimensional structure, the system comprising:
- [1] an apparatus comprising an image gathering member to generate depth data of the structure portion corresponding to a two-dimensional reference array substantially orthogonal to a depth direction; and
  - [2] one or more processors configured to cause the system to at least:
    - [3] receive, from the apparatus, the depth data of the structure portion corresponding to the two-dimensional reference array substantially orthogonal to a depth direction;
    - [4] receive, from the apparatus, two-dimensional image data of the structure portion associated with the two-dimensional reference array for each of a plurality of focal lengths relative to the image gathering member; and
    - [5] selectively map the image data to the depth data for the two-dimensional reference array based on the plurality of focal lengths and the depth data such that the resulting associated color of the structure portion is in focus relative to the structure portion for a plurality of distances in the depth direction.

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JX-0006 at Cl. 12.

The crux of the parties' infringement dispute with respect to this term is limited to elements [1] and [5]. For the reasons explained herein, I find that Align has not presented evidence sufficient to show that the Trios products practice element [5]—the “selectively map”—limitation of claim 12 of the '433 patent. Because a showing of infringement requires a showing that each element of a claim is practiced by an accused product, I also find that Align has not established, by a preponderance of the evidence that, 3Shape's Trios products infringe.

With respect to element [5] of claim 12, Align, quite simply, has a failure of proof under any party's construction of “selectively map.” Align relies exclusively on the testimony of its expert, Dr. Stevenson, to show that this element is practiced by the Trios products. *See* CIB at 62-64 (citing only Tr. at 493:19-494:19, 495:1-17). The first portion of that testimony, which deals with Dr. Stevenson's opinions under Align's construction of element [5], is as follows:

Q Do 3Shape's TRIOS 3 scanner systems practice this claim element under Align's proposed construction?

A Yes.

Q And what do you base that opinion on?

A Well, a lot of the same analysis we've already gone through a couple times now. The selective mapping occurs when -- you know, we talked about the fact that we collect all this image data, the one to 200 scans, we've done this analysis where we figured out what is the right focus position, we even do this little extra step of [REDACTED] And then once we select that image and we select that position that we need, we get the depth data from the encoder that tells us physically where the lens is which we can then translate into how far the object is. All that data is what's packaged in the FPGA. It's sent over, and what I'm showing at the bottom there is what they sometimes refer to as a point cloud. At the bottom you can see kind of the reference array associated with the two-dimensional image. [REDACTED]

[REDACTED] So because we're doing a bunch of those, we have a whole bunch of points and associated colors, and that's what they call the point cloud, and that's what you see at the bottom.

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Tr. at 493:19-494:19. On its face, this excerpt of testimony does not demonstrate that the Trios scanners include a processor that receives image data, receives depth data, and selectively maps the received image data “to” the received depth data. JX-0006 at Cl. 12. Instead, Dr. Stevenson’s testimony is that a processor in the Trios scanners [REDACTED]

[REDACTED] See *id.* at 494:5-16 [REDACTED]

[REDACTED] The derivation of color information and depth information is not consistent with the limitation of element [5], which Align construes to require “matching” of depth data and image data. See CIB at 22. Indeed, nowhere in Dr. Stevenson’s testimony does he indicate that a processor in the Trios scanners matches depth data to image data.

The attorney argument in Align’s brief is entirely consistent with this interpretation of Dr. Stevenson’s testimony. See CIB at 63 (“Dr. Stevenson provided evidence that selective mapping occurs when the Trios collects scans of image data, and then analyzes the data to find the focus position [REDACTED] Once the Trios selects the image and position needed, the Trios gets the depth data from the encoder that indicates physically where the lens is, which is then translated. [REDACTED]

[REDACTED] (internal citation omitted)). Thus, Align’s brief does not identify a processor that maps received depth data to received image data in the Trios scanners. Instead, Align describes a process by which depth data is determined or derived *from* image data. Neither Align nor 3Shape has advanced a construction for element [5] that would capture a processor configured to perform that derivation, and, indeed, it is not at all clear that the ’433 patent contemplated such an approach.

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I note that 3Shape advanced no evidence of its own to support its noninfringement position with respect to claim element [5] under Align's construction. *See* RRB at 29-30. Instead, 3Shape argued that Align's proof of infringement was wholly insufficient. *See id.* ("Align recites a series of steps of how it believes Trios 3 generates a point cloud. Align appears to conclude that something in that series of steps meets the 'selectively map' limitation, but provides no explanation of how it is met."). As a general matter, such an approach is often risky, as the standard of proof for infringement is a preponderance of the evidence, which only requires a patentee to show that an accused product more likely than not practices the limitations of a claim. A minimal showing by a patentee can carry the day in the absence of any contrary evidence. Nevertheless, in this particular instance, I believe 3Shape's position is meritorious. Having carefully studied Align's brief and Dr. Stevenson's testimony, I am left to wonder how exactly Dr. Stevenson's testimony is evidence that Trios scanners practice element [5] of claim 12 of the '433 patent. Indeed, it is not even clear whether Align contends that the "selective mapping" occurs in the FPGA, an external computer, or perhaps in both. In this context, it is quite clear that Align has not presented evidence showing that it is more likely than not that 3Shape's Trios scanners practice element [5] of the '433 patent. Accordingly, I find that Align has not established, by a preponderance of the evidence, that 3Shape's Trios scanners literally infringe claim 12 of the '433 patent.

Align also presented an argument of infringement via the doctrine of equivalents under 3Shape's proposed construction. CIB at 64. The primary difference between 3Shape's construction and Align's is a requirement that the image data be monochrome. *See* CIB at 22 (comparing proposed constructions). Align's equivalence argument is directed only to establishing that any difference between mapping color image data and mapping monochrome image data is insubstantial. *See id.* at 64 ("Dr. Stevenson further testified that there is not a substantial difference

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due to the [REDACTED]

[REDACTED] Nothing in that argument remedies the flaw in Align's literal infringement theory. Even if the difference between mapping color image data and mapping monochrome data was insubstantial, Align's equivalents theory still does not show a processor that maps received image data to received depth data. Accordingly, Align's equivalence argument fails for at least the same reasons its literal infringement argument fails.

In sum, Align has not met its burden to show infringement of claim 12 of the '433 patent.

### **D. Indirect Infringement**

#### **1. Contributory Infringement**

Align alleges contributory infringement of the color scanner patents by 3Shape. CIB at 66-67. It appears that Align advances this argument because "whenever a TRIOS3 is imported into the U.S. for 'sales purposes,' it is first sent to Respondents' Branchburg, New Jersey facility, where the Accused Software is 'flashed down,' so that complete scanner systems can then be distributed to resellers for sale to end-users." *Id.* (citing Tr. at 1157:15-22; 1163:16-1164:6). As noted at the beginning of this determination, Align asserted only the gingival deformation patents against the "Accused Software," and no part of Align's infringement evidence relating to the color scanner patents relies on the Accused Software. It is therefore unclear why Align believes the flashing of Accused Software is relevant to establishing contributory infringement of the color scanner patents that have apparatus claims. Contributory infringement may be relevant with respect to method claim 1 of the '207 patent. *See Ricoh Co. v. Quanta Computer Inc.*, 550 F.3d 1325, 1340 (Fed. Cir. 2008) ("contributory infringement may appropriately be found" for sale of a product with "no substantial noninfringing use other than to practice . . . claimed methods"). I will analyze Align's contributory infringement claim for at least that purpose. My analysis may

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also be relevant if a reviewing tribunal finds that whatever is “flushed down” onto the accused Trios scanners in New Jersey is relevant to direct infringement of the color scanner patents.

Align argues that each of four elements required to prove contributory infringement are present in this investigation. *Id.* at 66. Align represents that the four elements are: “1) that there is direct infringement, 2) that the accused infringer had knowledge of the patent, 3) that the component has no substantial non-infringing uses, and 4) that the component is a material part of the invention.” *Id.* (quoting *Fujitsu Ltd. v. Netgear Inc.*, 620 F.3d 1321, 1326 (Fed. 2010)). 3Shape disputes that Align has proven direct infringement of the color scanner patents by the Trios scanners, but does not dispute that any of the other elements of contributory infringement are present. *See* RRB at 33.

As noted *supra*, I have found that 3Shape itself directly infringes claims 1 and 26 of the '228 patent, claim 1 of the '456 patent, and claim 1 of the '207 patent. The evidence also shows that 3Shape's domestic resellers and end-user customers directly infringe those claims when they use the accused Trios scanners. *See* JX-0192 at ¶ 2. Tr. at 812:3-814:9, 899:18-24. Accordingly, I find that Align has established direct infringement of claims 1 and 26 of the '228 patent, claim 1 of the '456 patent, and claim 1 of the '207 patent by 3Shape, its resellers, and end-user customers. Direct infringement has not been established for any other asserted claim of the color scanner patents.

Next, Align asserts that 3Shape has known of the patents asserted in this investigation since at least the filing of parallel actions in Delaware involving the same patents in this investigation.

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CIB at 67; *see also* *Align Tech., Inc. v. 3Shape A/S*, 1:17-cv-01649-LPS-CJB, Compl. at ¶¶ 19-22 (Nov. 14, 2017) (ECF No. 1). This evidence was not rebutted by 3Shape.<sup>7</sup>

I find that 3Shape undeniably had specific knowledge of the color scanner patents at least as of November 14, 2017, the date the complaint was filed in this investigation and the date the complaints were filed in Delaware. The complaint in this investigation was complete with claim charts mapping out infringement allegations. The record contains evidence supporting an inference that 3Shape encouraged resellers to sell and customers to use the accused Trios scanners after that date, at least through May 2018. Tr. 871:13-22 (3Shape actively monitored customer submissions of Trios scans to Invisalign through May 2018). Other testimony and evidence supports an inference of 3Shape's knowledge of the patents even prior to the time the complaints were filed. *See* Tr. at 725:22-726:22, 729:10-731:17, 734:10-737:25; JX-0080C at 325:4-16; JX-0079C at 10:5-6; JX-0201C. Based the forgoing evidence, I find that 3Shape had knowledge of the color scanner patents.

Next, Align asserts that 3Shape imports the Trios scanners into the United States, and that those scanners have no noninfringing uses. CIB at 67 (citing Tr. at 496:8-16). Align asserts that “normal operation of the Trios constitutes an infringing use,” and that 3Shape’s “use and advertisement of the TRIOS3 is limited to intraoral scanning of a patient’s teeth.” *Id.* (citing JX-0079C at 99:1-25; 100:1-18). 3Shape cites no substantial noninfringing uses for the scanner. RRB

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<sup>7</sup> 3Shape did attempt to put some gloss its knowledge of the asserted patents in responding to Align’s allegation of inducement, RRB at 32, but made no mention of the knowledge requirement in its two-sentence rebuttal on contributory infringement. To give 3Shape the benefit of the doubt, I have considered its arguments about knowledge in both contexts. As discussed in my inducement analysis, I find 3Shape had knowledge of the asserted scanner patents sufficient to support findings of contributory infringement and inducement of infringement.

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at 33. I therefore find that the un rebutted evidence presented by Align shows the accused scanners have no substantial noninfringing use. *See* Tr. at 496:8-16.

While the thesis of Align's contributory infringement argument is that all four elements of a contributory infringement claim are present, Align's brief does not specifically address the fourth element—that the component supplied by the contributory infringer is a material part of the invention. *See* CIB at 67. Nonetheless, 3Shape did not dispute the “material component” element of contributory infringement in its responsive brief, arguing instead only that direct infringement had not been established. *See* RRB at 33. I find that the same evidence supporting findings of direct infringement and no substantial noninfringing use demonstrate that the Trios scanners are material components of the inventions claimed in claims 1 and 26 of the '228 patent, claim 1 of the '456 patent, and claim 1 of the '207 patent.<sup>8</sup>

Because all elements of contributory infringement have been proved with respect to claims 1 and 26 of the '228 patent, claim 1 of the '456 patent, and claim 1 of the '207 patent, I find that 3Shape is liable for contributory infringement of those claims. 3Shape is not liable for contributory infringement of any other asserted claims.

### 2. Induced Infringement

Align also alleges that 3Shape induces infringement of the color scanner patents. Specifically, Align argues that 3Shape induced infringement of the color scanner patents by

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<sup>8</sup> I also note that some formulations of the test for proving contributory infringement in a section 337 investigation characterize the test with three elements. *See Spansion*, 629 F.3d at 1353 (“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.”). Align's proofs show contributory infringement under the three-element formulation of contributory infringement in *Spansion* as well.

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“providing the Accused Products to third parties for subsequent distribution, sale, and use in the United States.” CIB at 68. As with its contributory infringement allegations, Align points to direct infringement of the color scanner patents by 3Shape’s domestic distributors and resellers. CIB at 68. 3Shape, relying on its earlier noninfringement arguments, asserts that there is no direct infringement of the color scanner patents by the Trios scanners, and thus there can be no induced infringement. RRB at 32.

As noted *supra*, I have found that 3Shape directly infringes claims 1 and 26 of the ’228 patent, claim 1 of the ’456 patent, and claim 1 of the ’207 patent. I have also found 3Shape resellers and end-user customers directly infringe those same claims. *See, e.g.*, JX-0192 at ¶ 2; Tr. at 812:3-814:9, 899:18-24. Accordingly, I find that Align has established direct infringement of claims 1 and 26 of the ’228 patent, claim 1 of the ’456 patent, and claim 1 of the ’207 patent, but not for any other asserted claim of the color scanning patents.

Next, Align argues that 3Shape “intended to cause the acts that constitute infringement and knew or [was] willfully blind to the fact the induced acts would constitute patent infringement.” CIB at 68. In support of that assertion, Align points to distribution and reseller agreements between 3Shape and third parties as evidence that 3Shape actively encouraged third parties to import and sell Trios scanners in the United States. CIB at 68 (citing JX-0192; JX-0193; JX-0194; CX-0837C). Align also points to evidence that 3Shape provides its resellers with sales, marketing, and training support, which include access to demonstration and training videos. CIB at 68-69 (citing JX-0075C at 23-25; JX-0053C at 70-72; JX-0052C at 81-92, 98:9-15; JX-0214C; JX-0215C; JX-0216C; JX-0392C; Tr. at 1403:22-1404:3; JPX-0014; JPX-0015; JPX-0016). Additionally, Align points to evidence that 3Shape’s employees encouraged sales of the Trios products by 3Shape’s

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resellers at trade shows. CIB at 69 (citing Tr. at 804:13-808:6; 899:14-17; 881:9-24; JX-0045C at 17:2-18:10, 68:3-8).

3Shape's only response to Align's allegation that 3Shape had knowledge of the asserted color scanner patents is a contention that it reasonably believed that the parent patent of the asserted patents, U.S. Patent Number 7,319,529, was "different from 3Shape's approach because it describes taking 2D color data shortly after the 3D image." RRB at 32 (citing Tr. at 952:15-953:14; RX-1266C at .0025.). The unspoken implication of 3Shape's statement is that it lacked the necessary intent to induce infringement because it did not believe its products would infringe any progeny of the parent patent.

While a reasonable belief of noninfringement might in some circumstances rebut the presumption of intent drawn from an accused indirect infringer's knowledge of the patent and their inducing act, *see Ecolab, Inc. v. FMC Corp.*, 569 F.3d 1335, 1350-51 (Fed. Cir. 2009), amended on reh'g in part, 366 F. App'x 154 (Fed. 2009), evidence of such a good faith belief is lacking here. 3Shape relies on a belief relating to the parent of the color scanner patents, and not a belief based on the color scanner patents actually asserted in this investigation. *See* RX-1266C at .0025. Given that the color scanner patents at issue in this investigation have their own unique claims, which were not the subject of 3Shape's patent analysis, I do not find 3Shape's beliefs about the parent patent to be particularly probative evidence of a good faith belief by 3Shape that the Trios scanners would not infringe the color scanner patents asserted in this investigation.

Moreover, the apparent failure of 3Shape to conduct any additional analysis of the color scanner patents in this investigation given its admitted knowledge of the parent patent undercuts a conclusion that 3Shape possessed a reasonable belief of noninfringement with respect to the color

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scanner patents. *Cf. Suprema, Inc. v. Int'l Trade Comm'n*, 626 F. App'x 273, 280 (Fed. Cir. 2015) (non-precedential).

In any event, I find 3Shape undeniably had specific knowledge of the asserted color scanner patents at least as of the filing of the complaint in this investigation on November 14, 2017, and it was served with claim charts mapping out Align's infringement allegations. *See* Complaint (Nov. 14, 2017). Other record evidence supports a conclusion that 3Shape had knowledge of the asserted patents. *See* Tr. at 725:22-726:22, 729:10-731:17, 734:10-737:25; JX-0080C at 325:4-16; JX-0079C at 10:5-6; JX-0201C; RRB at 32; *Align Tech., Inc. v. 3Shape A/S*, 1:17-cv-01649-LPS-CJB, Compl. at ¶¶ 19-22 (Nov. 14, 2017) (ECF No. 1).

I also find that 3Shape encouraged and intended its resellers and distributors to offer for sale, sell, and use its Trios scanners. 3Shape entered into distribution and resellers agreements with its resellers and provided them with sales and marketing support. *See* JX-0192; JX-0193; JX-0194; CX-0837C; Joint Stipulation Regarding 3Shape Inc. at ¶¶ 1-2 (Sep. 21, 2018) (EDIS Doc. 656516). 3Shape instructed its resellers and customers on how to use the accused scanners. JX-0045C at 17:2-18:10, 68:3-8; JX-0052C at 81-92, 98:9-15; JX-0053C at 70-72; JX-0075C at 23-25; JX-0214C; JX-0215C; JX-0216C; JX-0392C; JPX-0014; JPX-0015; JPX-0016; Tr. at 804:13-808:6, 881:9-24, 899:14-17, 1403:22-1404:3. 3Shape continued to actively induce sale and use of the scanners at least through May 2018. Tr. 871:13-22 (3Shape actively monitored customer submissions of Trios scans to Invisalign through May 2018).

Accordingly, based on 3Shape's knowledge of the color scanning patents and evidence of 3Shape's intent to cause others to sell and use the patented inventions therein, I find that 3Shape intended its resellers, distributors, and end-user customers to infringe the color scanner patents. I also find that the evidence cited by 3Shape is not sufficient to conclude 3Shape had a reasonable

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belief of noninfringement of the asserted patents. Consistent with these findings, I find that 3Shape induced resellers and end-user customers to infringe claims 1 and 26 of the '228 patent, claim 1 of the '456 patent, and claim 1 of the '207 patent.

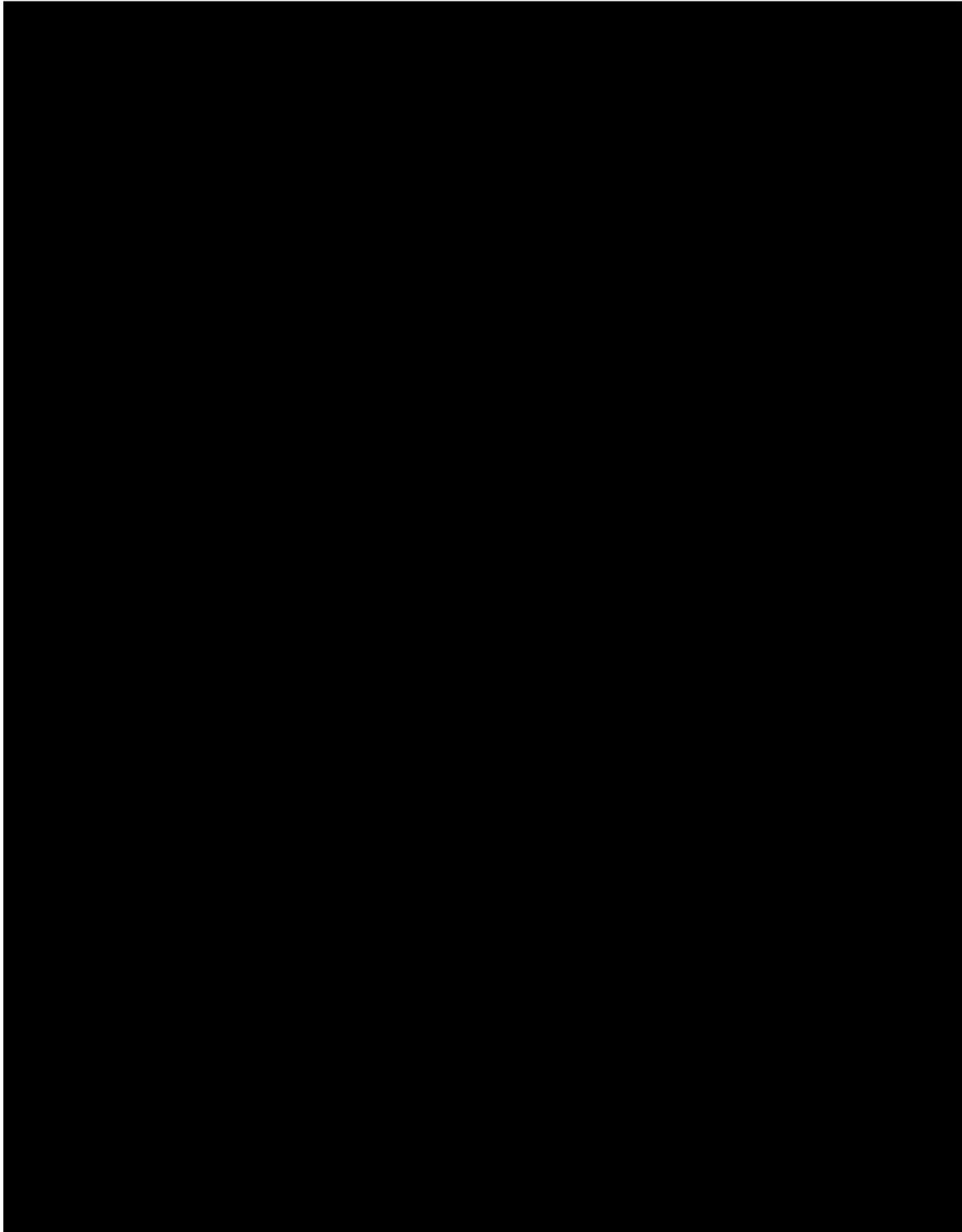
### **E. Domestic Industry – Technical Prong**

Align asserts that its iTero Element, iTero Element 2, and Element Flex scanners all practice claims 1, 4, and 26 of the '228 patent.

#### **1. '228 Patent**

The only dispute with respect to whether Align's iTero Element practices claim 1 of the '228 patent is over element [4], the processor element. Align has presented un rebutted evidence and argument sufficient to demonstrate by a preponderance of the evidence that the iTero Element practices the preamble and elements [P] and [1]-[3] of claim 1. *See* CIB at 47-51 (citing JX-0090C; CX-0916; JX-0091C; JX-100C; CX-1458C; Tr. at 497:8-498:2, 500:8-503:13). As explained herein, however, I find that Align has not established, by a preponderance of the evidence, that the iTero Element practices processor element [4] of claim 1.

To satisfy element [4] of claim 1, Align points to an FPGA in the iTero Element. *See* CIB at 51-52. The following block diagram and text, which are record evidence, describe the operation of the FPGA as follows:



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[REDACTED]

JX-0102C at 00684145-46. While the block diagram is difficult to read in the exhibit, the text describes a process by which the FPGA receives depth and color image data from a scanner, [REDACTED]

[REDACTED]

[REDACTED] *See id.*

Unlike the evidence presented with respect to infringement by the Trios color scanners, which included deposition testimony from a corporate representative from 3Shape that [REDACTED] [REDACTED], *see* JX-0074C at 57:17-58:2, 60:5-61:13, there is no indication in the evidence cited by Align that the iTero Element associates color and depth data as required by the claim. Rather, exhibit JX-0102C

[REDACTED]

[REDACTED]

This evidence does not demonstrate, however, that the two types of data are ever correlated by virtue of those time markings. By contrast, Dr. Roselund's testimony clearly established that in the accused Trios color scanners lens position data (depth data) and color image data [REDACTED]

[REDACTED] *See* JX-0074C at 57:17-58-2. Additionally, JX-0090C, which is an Align document titled "iTero Technical Review," includes a slide explicitly

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dedicated to explaining [REDACTED]. *See* JX-0090C at 12. Conspicuously absent from the description of [REDACTED] is any mention of an operation that could be considered association of color and depth data. *See id.*

Both parties present competing expert testimony regarding whether the FPGA in the iTero Element associates depth data and color image data. CIB at 52 (citing Tr. at 503:14-504:10); RRB at 35 (citing Tr. at 1113:14-1114:3). The testimony of Align's expert, Dr. Stevenson, is exceedingly conclusory on the question of association. Dr. Stevenson merely states, without additional explanation, that when depth data and color data are combined, there is association. *See* Tr. at 503:14-504:10. Given that Dr. Stevenson's testimony was given while referring to JX-0102C described above, which does not demonstrate how any association between color and depth data occurs, it is not surprising that Dr. Stevenson provides no additional elaboration. The relevant portion of the testimony cited by 3Shape provides that in the view of 3Shape's expert, [REDACTED] Tr. at 1113:14-1114:3

Align's evidence in support of finding that the iTero Element practices element [4] of claim is surprisingly thin, particularly given that the iTero scanner is Align's own product and presumably Align knows its inner workings in detail. Nonetheless, Align hangs its hat on a high level block diagram of the FPGA in the iTero and a few lines of conclusory expert testimony. I do not find that this evidence shows that it is more likely than not that the iTero Element practices element [4] of claim 1 of the '228 patent. To find otherwise I would have to construe element [4] so broadly as to remove the association requirement altogether such that merely sending color image data and depth data from the FPGA to a host computer at the same time would suffice to show that the two types of data are associated. I decline to adopt such a broad construction.

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Accordingly, I find that Align has failed to show that its iTero Element products practice element [4] of claim 1 of the '228 patent.

I note that Align also made a cursory argument that its products practice element [4] under the doctrine of equivalents by pointing to the processing that occurs in a computer external to the scanner. This argument is meritless. As 3Shape correctly notes, the requirement of a handheld device with a processor configured to associate depth and color image data was added during prosecution to overcome a prior art rejection. *See* RRB at 36 (citing JX-0009 at Align-1091\_00003096, Align-1091\_00003103-4). Prosecution history estoppel precludes the equivalence argument Align now attempts to make. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739-40 (2002). Align offers no argument why estoppel does not apply, and indeed fails to acknowledge the doctrine at all. As such, I find that Align has also not established that its iTero Element products practices element [4] of claim 1 of the '228 patent under the doctrine of equivalents. Consistent with that finding, I also find that Align has not established, by a preponderance of the evidence, that its iTero element product practices claim 1 of the '228 patent. Because claims 4 and 26 depend from claim 1, I also find that Align has not established, by a preponderance of the evidence, that its iTero element product practices those claims.

Align provided no additional argument or evidence with respect to the iTero Element 2 or the Element Flex products. Rather, it represented that the technical prong analysis for each product is the same in all material respects. *See* CIB at 47 n.4 (citing Tr. at 497:1-7). Accordingly, I find that Align has not established, by a preponderance of the evidence, that its iTero Element 2 and Element Flex products practice claims 1, 4, or 26 of the '228 patent.

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Because Align has failed to establish that any of its domestic industry products practice a claim of the '228 patent, I find that Align has not satisfied the technical prong of the domestic industry requirement with respect to the '228 patent.

### 2. '456 Patent

Align asserts that its iTero products practice claims 1 and 15 of the '456 patent and thus satisfy the technical prong of the domestic industry requirement for the '456 patent. However, Align relies on the same arguments advanced with respect to claim 1 of the '228 patent, including the same arguments regarding the “processor” limitation. *See* CIB at 56. As noted above, the iTero products do not include a handheld device comprising a processor configured to associate depth and color image data. Because that same limitation is present in claims 1 and 15 of the '456 patent and Align has offered no additional evidence or argument demonstrating that the element is present in the iTero products, I find that Align has not established, by a preponderance of the evidence, that the iTero products practice claims 1 or 15 of the '456 patent. Accordingly, I also find that Align has not demonstrated that its iTero products satisfy the technical prong of the domestic industry requirement with respect to the '456 patent.

### 3. '207 Patent

Align asserts that its iTero products practice claim 1 of the '207 patent and thus satisfy the technical prong of the domestic industry requirement for the '207 patent. Unlike its '456 patent arguments, Align does not explicitly state that it is relying on the same evidence it presented earlier, but that appears that is Align's intent and I will consider Align's arguments in that light. *See* CIB at 58. The only evidence Align cites for practicing the '207 patent is directed to the method-specific claim limitations in claim 1 of the '207 patent. *See id.* (citing Tr. at 100:9-20, 518:20-519:1; CX-0916 at 34-36). As noted above, the iTero products do not include a handheld device

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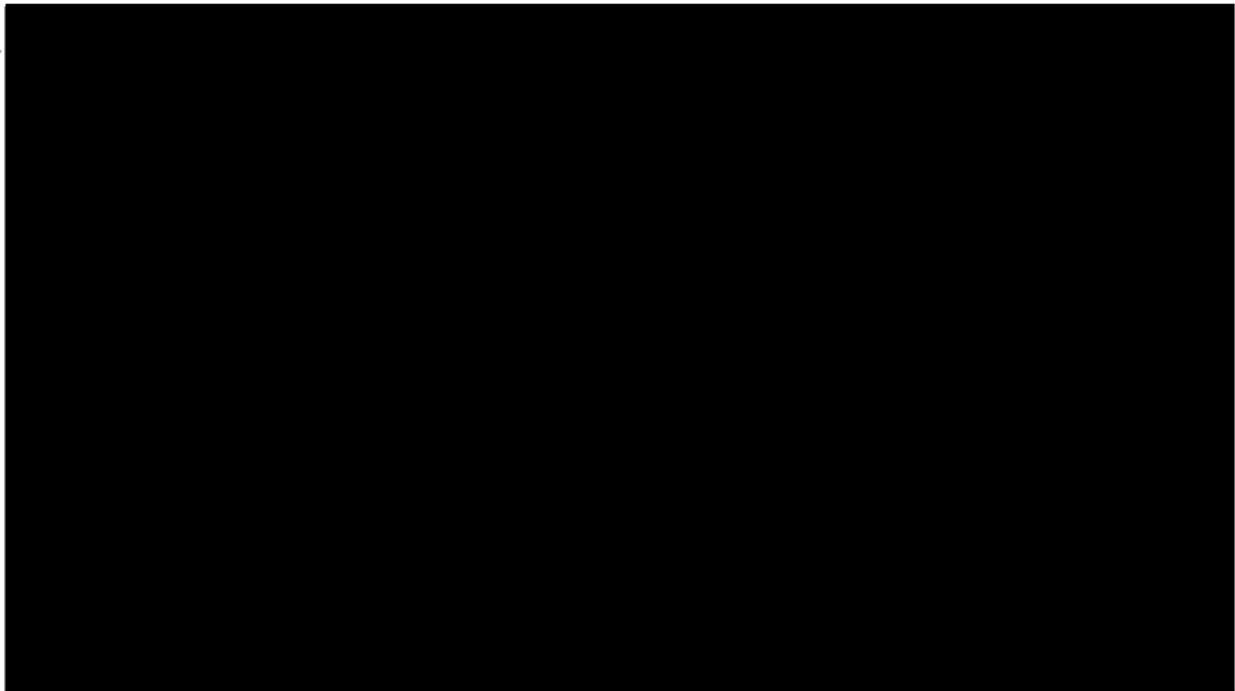
comprising a processor configured to associate depth and color image data. Because that limitation is required by claim 1 of the '207 patent, I find that Align has not established, by a preponderance of the evidence, that the iTero products practice claim 1 of the '207 patent. Accordingly, I also find that Align has not demonstrated that its iTero products satisfy the technical prong of the domestic industry requirement with respect to the '207 patent.

#### 4. '443 Patent

Align asserts that its iTero products practice claim 12 of the '433 patent and thus satisfy the technical prong of the domestic industry requirement for the '433 patent. Align offers three citations in support of its argument that iTero practices element [4] of the '433 patent. The first is a portion of testimony from Dr. Stevenson, which reads as follows:

[REDACTED]

Tr. at 520:10-14. The second is a citation generally to the section of its brief dealing with the technical prong of the domestic industry requirement and the '228 patent. *See* CIB at 66 (citing "Domestic Industry – Technical Prong for the '228 patent"). The third is the following image from an iTero Technical Review:



JX-0090C at 14.

3Shape disputes that the iTero products practice element [4] of claim 12 the '433 patent for two reasons. First, 3Shape argues that Align has not presented sufficient evidence to establish that iTero meets all the limitations recited in element [4]. I disagree. Align's evidence is thin, but it is not wholly insufficient. Particularly, as Dr. Stevenson testified, the [REDACTED]



[REDACTED] See Tr. at 520:10-14. Accordingly, I do not agree with 3Shape that Align's evidence fails, "on its face," to establish that the iTero products practice element [4] of claim 12 of the '433 patent.

Second, 3Shape points to evidence in the record that iTero does not "capture color images at a plurality of focal lengths." RRB at 40. That argument appears to rest on a claim construction that 3Shape never before disclosed. Particularly, 3Shape now argues that the two-dimensional

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image data recited in element [4] must relate to color data. RRB at 39. This appears to contradict what 3Shape wrote in its prehearing brief with respect to iTero and element [4]:

“ . . . claim 12 of the '433 patent requires, in part, capturing monochromatic image data at multiple focal lengths to generate a color image. The Align Domestic Industry Products do not capture monochromatic image data at multiple focal lengths to generate a color image. Instead, the evidence shows that the iTero Element uses white illumination to capture two color images at one end of a depth scan at one focal length.”

RPB at 298.

Reviewing the procedural history of 3Shape's argument, I am not convinced that Align had notice of 3Shape's contention that element [4] of claim required receipt of *color* images taken at multiple focal lengths. To criticize Align for not addressing its opening brief an argument that appears for the first time in 3Shape's responsive brief would be unfair.

In any event, the plain language of element [4], and the rest of claim 4, does not require image data to be color image data. *See* JX-0006 at Cl. 12. The other three color scanner patents do include claim language directed to *color* image data, but that language is conspicuously absent from claim 12 of the '433 patent. *Compare* JX-0003 at Cl. 1 *with* JX-0006 at Cl. 12.

I decline to construe element [4] of claim 12 to require receipt of color image data from multiple focal lengths based only on a single embodiment 3Shape points to in the specification. *See* RRB at 40 (citing JX-0006 at 22:3-27). Accordingly, I find that Align's iTero product satisfies element [4] of claim 12 of the '443 patent.

Because Align has presented un rebutted evidence to show that the iTero products practice the remaining elements of claim 12 of the '433 patent, *see* CIB at 64-66 (citing JX-0090C; CX-0916; JX-0091C; JX-100C; JX-0102C; Tr. at 502:8-503:13, 519:7-520:25, 521:16-522:8, I also find that Align has shown, by a preponderance of the evidence, that at least the iTero Element

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practices claim 12 of the '433 patent, and thus Align has satisfied the technical prong of the domestic industry requirement for the '433 patent.

### F. Validity

3Shape raises two primary arguments challenging the validity of the color scanner patents. First, 3Shape contends the asserted claims are invalid as obvious or anticipated in view of the Babayoff WIPO and Yoichi prior art references. Second, 3Shape argues that the “processor” limitation that appears in the '228, '456, and '207 patents lacks written description support in the specification. 3Shape also makes some subsidiary arguments relating to specific patents. With respect to the '207 patent, 3Shape argues (1) that the asserted claim is obvious over an additional Babayoff reference; and (2) that the asserted claim of the '207 patent impermissibly mixes method and system limitations. 3Shape also argues that Yoichi anticipates the '433 patent. Each argument is addressed in turn below.

#### 1. '228 Patent

##### a) *Obviousness in View of the Combination of Babayoff WIPO and Yoichi*

3Shape argues that claims 1, 4, and 26 of the '228 patent are obvious in view of the combination of WIPO Publication No. WO 00/08415 (“Babayoff WIPO”)<sup>9</sup>, JX-0085, and Japanese Patent Application No. 2001 082935 (“Yoichi”), RX-0997. RRB at 17. As an initial matter, I note that the areas of dispute with respect to this argument are (1) whether the “processor” limitation of the asserted claims is disclosed by the prior art; and (2) whether a person of ordinary skill in the art would have been motivated to combine Babayoff WIPO and Yoichi. Aside from

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<sup>9</sup> This WIPO Babayoff reference should not be confused with another reference named Babayoff (U.S. Patent Publication No. 2006/0001379, or “Babayoff '739”) that 3Shape contends is invalidating prior art for other asserted patent claims.

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the processor element of the asserted claims, there appears to be no dispute that Babayoff WIPO and Yoichi disclose every other element of the asserted claims.

**(1) Disclosure of a “processor configured to associate depth data with color data”**

The first substantive dispute between the parties is whether the prior art discloses the “processor” limitation recited in claim 1 of the '228 patent. By way of a reminder, the processor limitation is element [4] in the following claim:

[P] 1. A system for determining the surface topology and associated color of at least a portion of a three dimensional structure, comprising:

[1] a hand-held device comprising:

[2] (a) a scanning system configured to provide depth data of said portion, the depth data corresponding to a plurality of data points defined on a plane substantially orthogonal to a depth direction;

[3] (b) an imaging system configured to provide two-dimensional color image data of said portion associated with said plurality of data points; and

[4] (c) a processor configured to associate the depth data with the color image data.

JX-0003 at Cl. 1.

To avoid later confusion, I note that the processor of element [4] must be part of the hand-held device recited as element [1]. There has been some dispute among the parties about the relationship of the processor to the handheld device. To be clear, element [1], the hand-held device is comprised of elements [2]-[4]. That means the hand-held device must, at a minimum, have all three of those elements, including “a processor configured to associate the depth data with the color image data.” The hand-held device may have any number of other additional elements. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 811 (Fed. Cir. 1999). The overall “system for determining surface topology and associated color of at least a portion of a three dimensional structure” may also have any number of additional elements, including even an additional “processor configured to associate the depth data with the color image data.” *Cf. JX-*

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0003 at Cl. 1. However, only “a processor configured to associate the depth data with the color image data” that is part of the hand-held device will satisfy element [4].

3Shape argues that the processor limitation of the color scanner patents is disclosed by microprocessor 54 in Yoichi. *See* RRB at 28-29 (citing RX-0997 at ¶ 31, 36-37; Tr. at 1294:21-1295:25). 3Shape also appears to argue that the processor disclosed in Babayoff “could be configured” to associate color image data with depth data. *See* RRB at 30 (citing Tr. at 1287:14-1289:2). 3Shape asserts that Yoichi’s microprocessor 54 satisfies the “processor” limitation of the color scanner patents under any party’s construction of that term. *See* RRB at 31. 3Shape acknowledges, however, that Yoichi does not disclose the claimed processor included on a hand held device. *See* RRB at 31. To address the fact that the asserted claims are directed to a processor included in a hand-held device, 3Shape points to two additional references— U.S. Patent No. 6,263,234 (“Engelhardt”), RX-0853, and WIPO Publication No. WO 02/056756 (“Petersen”), RX-1001—for teaching the inclusion of processors in hand-held digital imaging devices. *See* RRB at 31-32.

Align disputes that Yoichi’s microprocessor 54 associates color and depth data as required by the processor limitation of the color scanner patents. *See* CRB at 16-17. Particularly, Align argues that “Yoichi’s microscope does not add color to a 3D model (including depth data) and then render the 3D model. Instead, Yoichi projects a solid model as a set of picture elements (hatched and side wall parts shown in FIG. 3) that are displayed in two dimensions and thus no longer contain height information.” *Id.* In Align’s view “each time Yoichi refers to a ‘color three-dimensional display,[’] [sic] it is actually referring to the colorization of the two-dimensional surface ‘displayed on the monitor screen of display device 47.’” *Id.* at 17.

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The crux of Align's argument appears to be twofold: first, Yoichi does not describe associating color and depth information to form a three-dimensional model because what is actually displayed is a top-down two-dimensional image of color overlaid onto a three-dimensional surface; and second, that overlaying color image data onto the top of a three-dimensional model is not the type of association described in the color scanner patents.

The relevant portions of Yoichi provide as follows:

[0001]

[Technical field of the Invention] The present invention is related to a 3-dimensional measurement device in which the light from the measurement target object is received by photo receptor and based on the light reception information, 3-dimensional surface information that includes the height information of the aforementioned measurement target object is obtained and the aforementioned surface information is displayed 3 dimensionally on the display device.

\* \* \*

[0008]

[Means to solve the issue] A 3-dimensional measurement device of the present invention receives lights from the measurement target object using photo receptor, and obtains 3-dimensional surface shape that includes the height information of the measurement target object based on the light reception information and displays 3 dimensionally surface shape on the display device, and the device comprises color filming means that obtains color of the measurement target object and using the color information for each pixel that is obtained from the color filming means, colors the 3-dimensional display of the surface shape.

\* \* \*

[0025] The distribution or surface heights (surface profile information) that is obtained can be displayed on a monitor screen of a display device 47 by a number of methods. For example, by converting the height data into brightness data, the height data can be displayed as a two-dimensional distribution that elucidates the two-dimensional distribution of surface heights. The surface height distribution can also be displayed as a color distribution by converting the height data into color difference data. In addition, with the confocal microscope of this embodiment, a three-dimensional display can three-dimensionally display the height distribution (surface profile) of the sample.

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[0026] An example of three-dimensional display of a simple solid model M is shown in Fig. 3. As in this example, the solid model M is displayed on a two-dimensional surface as shown in the perspective view drawn by isometric projection. The X axis and Y axis in the drawing correspond to the XY plane that is scanned with the laser light, and the Z axis corresponds to the height direction (optical axis direction) of the sample. This type of three-dimensional display is well known in the field of computer graphics, and by inputting the X coordinate, the Y axis, and the Z coordinate (height) for each picture element, various types of software can be used in order to perform three-dimensional display on a screen.

[0027] In addition, a surface image (black and white image) of the sample w is obtained from brightness signals using the received light quantity for each point (picture element) in the XY scanning range as brightness data. By producing brightness signals using the maximum received light quantity for each picture element as brightness data, focusing has occurred at points with different surface heights, and a confocal image is obtained that has extremely high depth of field.

[0028] Next, a non-confocal optical system 2 will be described. The non-confocal optical system 2 comprises a white light source 20 that illuminates the sample w with white light (illumination light for color imaging), a second collimating lens 21, a first half mirror 22, a second half mirror 23, and a color CCD 24 used as a color information capture sensor. Light receiving elements for each color R, G, and B may be used instead of a color CCD 24. With the non-confocal optical system 2, the objective lens 17 of the confocal optical system 1 is used in conjunction and the optical axes of the two optical systems 1 and 2 coincide.

[0029] A white light lamp, for example, is used for the white light source 20, but natural light or indoor light may be used without providing a particular dedicated light source. The white light that exits the white light source 20 passes through the second collimating lens 21, the light path is bent by the first half mirror 22, and the light is focused by the objective lens 17 on the surface of the sample w that has been placed on the sample stage 30.

[0030] The white light that has been reflected by the sample w passes through the objective lens 17, the first half mirror 22 and the second relay lens 16, is reflected by the second half mirror 23, and is incident on the color CCD 24, where it is imaged. The CCD 24 is provided at a position that is conjugate or nearly conjugate to the pinhole of the pinhole plate PH of the confocal optical system 1. The color image that has been imaged by the color CCD 24 is read by a CCD drive circuit 43, and the analog output signal is provided to a second A/D converter where it is converted to digital values. The color image obtained in this manner is displayed on the monitor screen of the display device 47 as an enlarged color image for observing the sample w.

[0031] Color images obtained with the non-confocal optical system 2 are combined in a three-dimensional display of the surface profile of the sample obtained by the confocal optical system 1 described above, and color three-dimensional display is

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carried out. As a result, portions represented by hatching viewed from above in the Z-axis direction are colored with the colors of a color image in the display model shown in Fig. 3. Picture elements of the hatched portions are imaged in the XY plane and are associated with picture elements of the color image.

[0032] The side wall parts that are not designated by hatching are portions that are not seen from above in the Z axis direction and are therefore not colored. These portions are shaded portions that are represented, for example, by a non-chromatic color such as black, but the representation method can be changed in accordance with the three-dimensional display technique (software). In addition, although the example of Fig. 3 involves three-dimensional display of a solid model, the lines thereof should be colored with colors from the color image in the case where three-dimensional display is carried out with contour lines as with a wire frame model.

\* \* \*

[0036] At the point when scanning in the XY direction over the prescribed Z direction measurement range has been completed, the maximum received light data, the color data at this time, and the height data at this time, are respectively stored in the received light quantity memory 51, the color memory 52, and the height memory 53. The microprocessor 54 then uses these data and generates color three-dimensional display data of the surface profile of the sample which is input to a display memory 55. The color three-dimensional display data is provided to the display device 47 through a D/A converter 56.

[0037] The color three-dimensional display data, as described above, is generated from the height data and color data for each picture element in the XY plane but may also be combined with the maximum received light quantity data. Specifically, by replacing the RGB color data brightness component for each picture element with maximum received light quantity data, a color three-dimensional display image with strong contrast is obtained in comparison to cases where only color data obtained from a non-confocal optical system 2 is used, because the maximum received light quantity for each picture element when in focus is reflected as brightness information in the color data.

\* \* \*

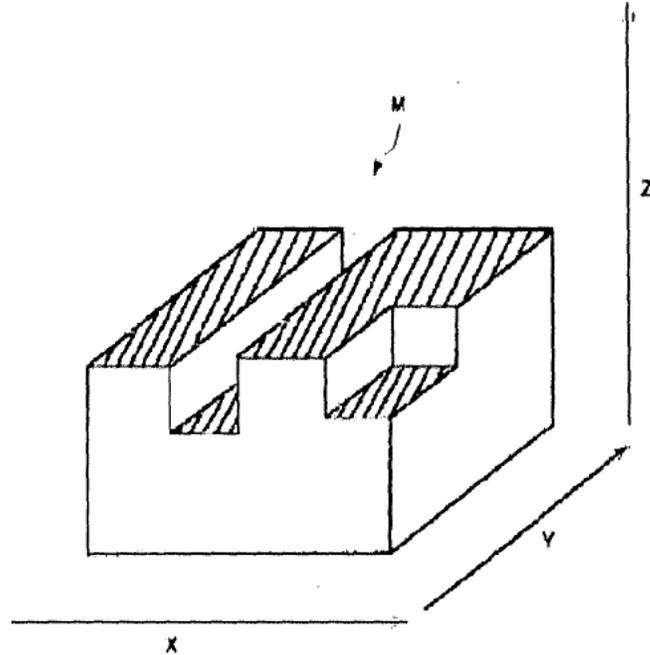
[0046]

[Effect of the Invention] As described above, three-dimensional display of the surface profile is colored with colors that are close to the actual colors of the object to be measured in accordance with the three-dimensional measurement device of the present invention. Therefore, the correspondence between locations on the actual object of measurement and locations on the three-dimensional display of the surface profile that has been displayed on the display will be readily seen.

\* \* \*

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Fig. 3



RX-0997 at ¶¶ 1, 8, 25-32, 36-37, 46, Fig. 3. Based on the disclosure recited above, I find that Yoichi does disclose a processor configured to associate the depth data with the color image data. This follows directly from paragraph 36 of Yoichi, which explains that microprocessor 54 combines height data from height memory 53 and color data from color memory 52, along with other data, to generate color three-dimensional display data. *See id.* at ¶ 36. This process of combining color data and height data meets the broad construction of the processor limitation for which Align advocated in the context of infringement, and which I have adopted over 3Shape's § 112, ¶ 6 proposal. Nothing in the additional paragraphs of Yoichi cited by Align casts any doubt on a conclusion that the processor in paragraph 36 satisfies the processor limitation in the color scanner patents.

Particularly, Align's attempt to distinguish Yoichi's disclosure on the basis that it deals with a two-dimensional display of a three-dimensional model is unpersuasive for several reasons.

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First, the asserted claims of the color scanning patents do not include a limitation directed to creating a three-dimensional model. The preamble, which is the only place the phrase “three-dimensional” is used, requires only “[a] system for determining the surface topology and associated color of at least a portion of a three dimensional structure . . . .” JX-0003 at Cl. 1. With that in mind, Align’s argument that “Yoichi’s microscope does not add color to a 3D model (including depth data) and then render the 3D model,” CRB at 16, is simply irrelevant; the plain language of the claim does not require adding color to a 3D model or rendering a 3D model. *See* JX-0003 at Cl. 1. Align cannot import additional limitations into the asserted claims solely for the purpose of distinguishing the prior art.

Align’s second argument is unavailing for similar reasons. Particularly, inasmuch as Align argues that “Yoichi’s microscope stores the data separately and then creates a 2D image with color on top, which is different than associating the depth and color data to form a color three-dimensional model, as discussed in the Color Scanning Patents,” CRB at 17, that argument appears to be based on the premise that the processor limitation is limited to a certain type of association of depth and color data. Align did not propose any limiting principle for the type of association required by the processor limitation in the color scanner patents, and indeed, Align employed an exceedingly broad interpretation of association in order to show that the FPGA in the accused products associated color data with depth data. *See* CIB at 39-44. It would be error to apply a different, narrower, construction of association in determining whether Yoichi discloses the processor limitation of color scanner patents. Accordingly, based on my construction of the processor limitation, as well as the disclosure of Yoichi, I find that the processor limitation of the color scanner patents is disclosed by Yoichi.

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### (2) Motivation to Combine Babayoff WIPO and Yoichi

The second substantive dispute between the parties is whether a person of ordinary skill in the art would have been motivated to combine Babayoff WIPO, Yoichi, and Engelhardt or Peterson in the manner 3Shape advances. 3Shape asserts that a person of ordinary skill in the art would have been motivated to combine the confocal scanning system in Babayoff WIPO with Yoichi's color imaging capability and processor based on the disclosure in the color scanner patents that acknowledged various methods of associating two-dimensional color image data with three-dimensional scan. RIB at 18 (citing JX-0003 at 1:65-2:39). 3Shape also asserts that the Yoichi reference provides such a motivation for adding a two-dimensional color imaging system to a confocal system and associating that color image data with the 3D data from the confocal scan. *Id.* (citing Tr. 1288:6-1289:2; 1292:16-1295:25; RX-0997 at ¶¶ 0015, 0031). 3Shape further asserts that combining Babayoff WIPO and Yoichi in this manner would have been a straightforward combination with predictable results, and that a person of ordinary skill in the art would have recognized the benefits of such a combination.

In opposition, Align argues that 3Shape has provided nothing more than conclusory statements regarding the teachings of Babayoff WIPO, Yoichi, Engelhardt, and Peterson, without explaining why a person of ordinary skill in the art would have been motivated to combine those references. CRB at 18-19. Elaborating on its position, Align argues first that the prior art cited in the color scanner patents does not disclose associating two dimensional color image data with three dimensional scan data because "none of the cited prior art discloses associating two-dimensional color image data with three-dimensional scan data." CRB at 19. Rather, Align argues that the color scanner patents disclose that associating two-dimensional color image data with three dimensional objects is difficult to do accurately, and that those skilled in the art had attempted to do so without success. *See id.* (citing JX-0003 at 1:49-2:39; RX-0993 at 1:22-2:16). Align next

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argues that the citations to the transcript and prior art on which 3Shape relies to show a motivation to combine “either stand for the proposition that Yoichi’s goal is to associate color data with three-dimensional data (which is factually incorrect) or the proposition that Babayoff [WIPO] discloses three-dimensional data.” *Id.* Put plainly, Align argues that 3Shape’s citations do not support its position. *See id.*

Having reviewed 3Shape’s brief and cited evidence, including testimony from the hearing, I generally agree with Align that the evidence cited does not support the statements in 3Shape’s brief on a motivation to combine. For example, 3Shape points to a portion of its own expert— Dr. Schaafsma’s—hearing testimony as evidence that “one skilled in the art would have been motivated to incorporate Yoichi’s color imaging capability, along with Yoichi’s processor, which associates color image data with three-dimensional surface topology data generated from a confocal scan” with the confocal scanning system of Babayoff WIPO. RIB at 18 (citing Tr. 1288:6-1289:2; 1292:16-1295:25). However, the testimony cited appears to be limited to Dr. Schaafsma describing what is disclosed in Yoichi. *See* Tr. 1288:6-1289:2; 1292:16-1295:25. There is no discussion of Babayoff WIPO at all, much less any testimony about why a person of ordinary skill in the art would combine Yoichi and Babayoff WIPO. To be frank, the final question and answer pair in this citation raises more questions than it answers inasmuch as Dr. Schaafsma appears to suggest that Yoichi “shows you have a confocal device scanning system in a handheld device, and there is a processor to look at the data in the device.” Tr. at 1295:15-25. This is in conflict with the fact that Yoichi does not disclose a handheld device, which 3Shape appears to acknowledge given that it relies on Babayoff WIPO, Engelhard, and Peterson for the disclosure of various elements in a handheld device.

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The frequent disconnect between what 3Shape asserts in its brief and what the cited evidence actually says did not go unnoticed. In addition to the examples noted above, 3Shape asserts that “adding Yoichi’s color imaging and color association to Babayoff WIPO would have a straightforward combination with predictable results.” RIB at 18 (citing Tr. at 1287:3-1289:2). Here again, the hearing testimony cited by 3Shape merely steps through the elements disclosed in Babayoff WIPO and Yoichi. *See* Tr. at 1287:3-1289:2. The testimony is silent on the combination of the two, or any predictable results that would arise from the combination. *See id.* In short, 3Shape has not presented actual evidence of a motivation to combine.

Another problem with 3Shape’s combination is the fact that Yoichi and Babayoff WIPO are directed to different fields of art. Yoichi discloses a stationary benchtop microscope system, *see* Tr. at 1425:1-19, while Babayoff WIPO is directed to a handheld intraoral scanning system that moves relative to the object it is scanning, *see* JX-0085 at 3Shape\_ITC\_00081603. 3Shape must provide some explanation for why a person of ordinary skill in the art would be motivated to combine elements from seemingly dissimilar inventions to achieve to combination 3Shape asserts for obviousness purposes. 3Shape’s brief did not meet that burden. *See* RIB at 18-19.

At bottom, it appears that 3Shape’s case for obviousness based on the combination of Babayoff WIPO and Yoichi amounts to a collection of elements from two different pieces of prior art, without an adequate explanation of why a person of ordinary skill in the art would have been motivated to combine those elements in the manner that they are arranged in the claimed inventions. Put differently, 3Shape’s case for obviousness based on Babayoff WIPO and Yoichi appears to be based on hindsight. Accordingly, I find that 3Shape has not established that claim 1 of the ’228 patent is obvious in view of the combination of Babayoff WIPO and Yoichi.

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I note that the parties also dispute whether a person of ordinary skill in the art would have been motivated to combine Engelhardt and/or Peterson with Babayoff WIPO and Yoichi for the teaching of a processor in a handheld device. Nothing in the Engelhardt or Peterson references supplies the missing motivation to combine Babayoff WIPO and Yoichi. I also find no persuasive evidence of motivation for additional combinations of those references with Engelhardt and Peterson. I reject 3Shape's argument that combinations of those four references would have been obvious.

3Shape also asserts the combination of Babayoff WIPO and Yoichi against claim 4 and 26 of the '228 patent, but provides no additional evidence that would support a finding that a person of ordinary skill in the art would have been motivated to combine those references. *See* RIB at 32-33. Accordingly, I also find that 3Shape has not established, by clear and convincing evidence, that claims 4 and 26 of the '228 patent are invalid as obvious in view of the combination of Babayoff WIPO and Yoichi.

### *b) Written Description*

3Shape asserts that all of the asserted claims of the '228 patent are invalid for a lack of written description. Particularly, 3Shape argues that the '228 patent specification fails to provide written description support for the "hand-held device comprising . . . a processor" limitation recited in claim 1. RIB at 34. In support of its argument, 3Shape points out that the '228 patent specification mentions the term "hand-held" only once, in the following passage:

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The endoscope 46, the illumination unit 31, the main optics 41, color illumination 71 and tri-color sequence generator are preferably included together in a unitary device, typically a hand-held device. The device preferably includes also the detector optics 60, though the latter may be connected to the remainder of the device via a suitable optical link such as a fibre optics cable.

*Id.* at 35 (citing JX-0003 at 24:48-54). 3Shape asserts that none of the references to a processor in the specification suggest that the processor is a component of the hand-held device. *See* RIB at 35-36. 3Shape contends that where the specification discloses a processor, it does so in the context of a personal computer, or PC, external and separate from the hand-held device. *See* RIB at 36 (citing Tr. at 1282:7-16).

Align disputes 3Shape's position and points out that the '228 patent specification, as originally filed, possessed a "hand-held device comprising . . . a processor" as recited in claim 1. CRB at 25. Align raises two arguments in support of its position. The first is that "one of skill in the art would interpret 'comprising' in the claims as not limited to a processor on the hand-held device." *Id.* at 26 (citing Tr. at 464:15-22, 514:6-13; JX-0003 at 25:36-39). This statement by Align is literally correct; but, as discussed below, it does not resolve the dispute at hand.

The phrase "a hand-held device comprising . . ." means that the invention must have a hand-held device that is made-up of the components recited after the word "comprising." *See Vivid Techs., Inc.*, 200 F.3d at 811. In the case of claim 1 of the '228 patent, this means the invention must have a hand-held device made up of at least the scanning system, the imaging system, and the processor recited in the claim. *See* JX-0003 at Cl. 1. The hand-held device may be formed of additional components, but it must have those three that are explicitly recited. *See Vivid Techs., Inc.*, 200 F.3d at 811. Because the preamble also uses the word "comprising" to

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describe the elements of a “system for determining the surface topology and associated color of at least a portion of a three dimensional structure,” it is also true that the overall system of claim 1 may include additional elements beyond the hand-held device. These additional elements could include a personal computer with its own processor. Nothing in the claim prohibits the presence of such an element.

Align’s argument goes astray by suggesting that an additional unrecited element, such as a processor in a personal computer that is not part of the hand-held device, can satisfy the explicit requirement in the claim for a hand-held device with a processor as one of its components. *See* CRB at 26 (“As Dr. Stevenson’s testified, one of skill in the art would interpret ‘comprising’ in the claims as not limited to a processor on the hand-held device. Proving this point, Dr. Schaafsma conceded that the patent discloses a processor on a PC.” (internal citations omitted)). Align cites no legal support for such an aberrant interpretation of claim 1, and I am aware of none that would provide such support. Additionally, the hearing testimony Align relies on offers no support for its position either. *See* CRB at 26 (citing Tr. at 464:15-22, 514:6-13, 1282:5-16).

Align’s second argument is more straightforward. Align asserts that “the specification clearly discloses a processor on the hand-held device.” CRB at 26. In support of its second argument, Align points to a portion of the specification disclosing a processor coupled to a detector, *id.* at 26 (citing JX-0003 at 8:43-49), and a portion of the specification describing a hand-held device that preferably includes detector optics, *id.* (citing JX-0003 at 24:48-54). Align also points to figure 1 of the patent to show disclosure of a processor 24 coupled to detector optics 60 and next to the color illumination 71. *Id.* (citing JX-0003 at Fig. 1). From these portions of the specification, Align contends that a person of ordinary skill in the art “would have understood that the inventor possessed the invention wherein the processor coupled to the detector and shown in

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Figure 1 next to the color illumination 71 *was also included in the hand-held device.*” *Id.* at 27 (emphasis added) (citing Tr. at 1135:18-1136:4). Whether a person of skill in the art would have understood the specification in the manner asserted by Align is the heart of this dispute. I find that such a person would not.

First, as a factual matter, it is true that there is only one reference to a hand-held device in the specification of the '228 patent. That reference is as follows:

The endoscope **46**, the illumination unit **31**, the main optics **41**, color illumination **71** and tri-color sequence generator are preferably included together in a unitary device, typically a hand-held device. The device preferably includes also the detector optics **60**, though the latter may be connected to the remainder of the device via a suitable optical link such as a fibre optics cable.

JX-0003 at 24:48-54. This passage clearly discloses a collection of components that the patentee contemplated as part of a hand-held device. *See id.* A processor is not included among that collection of components. Accordingly, I find that the text of the specification does not provide support for a hand-held device with a processor as one of its components. Next I turn to the figures included with the '228 patent, of which I find figures 4A and 4B to be particularly instructive. They are as follows:

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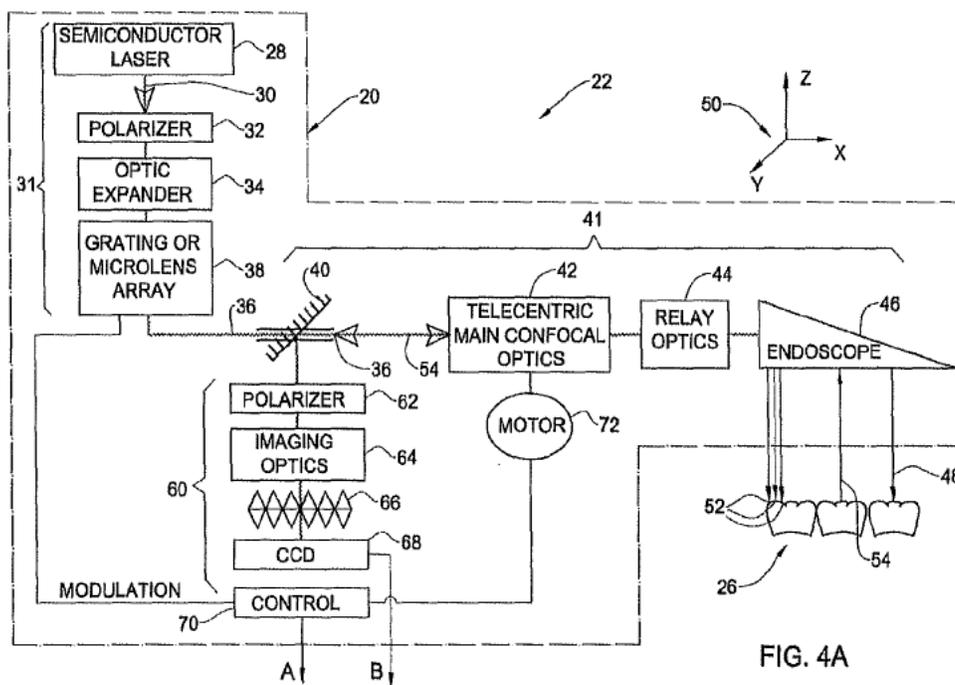


FIG. 4A

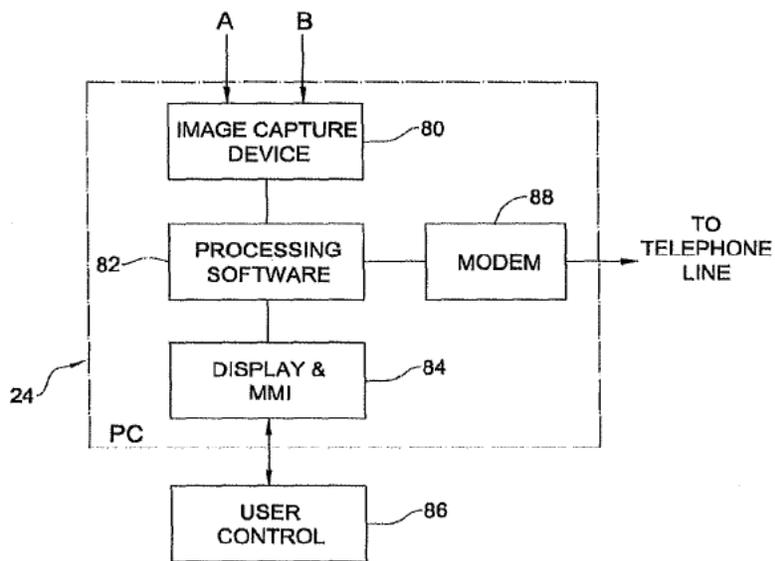


FIG. 4B

JX-0003 at Figs. 4A, 4B.

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Figures 4A and 4B show two distinct groupings of components, each surrounded by a dashed line. In figure 4A, the grouping is labeled both as element 20, which is “the system,” and element 22, which is “an optical device.” JX-0003 at 14:45-46. In figure 4B, the grouping is labeled element 24, which is a “processor,” and is labeled “PC” (for personal computer) in the lower left corner. *See id.* The specification describes the optical device being coupled to the processor. *See id.* Nothing in this description suggests that the processor is a component of the optical device, and in fact, the distinct groupings of the components in the figures tend to suggest the opposite, that the disclosed processor, which appears to be a personal computer, is not a component of the optical device. Given that the optical device includes most of the components described as being within a *unitary* hand-held device, *id.* at 24:48-54, I find that figures 4A and 4B, along with their associated descriptions in the specification, tend to show that the patentee did not contemplate including a processor among the components of the hand-held device. Those figures tend to indicate that the patentee possessed an invention where the processor was a separate, general purpose, personal computer.

My reading of figure 1, which appears below, is similar:

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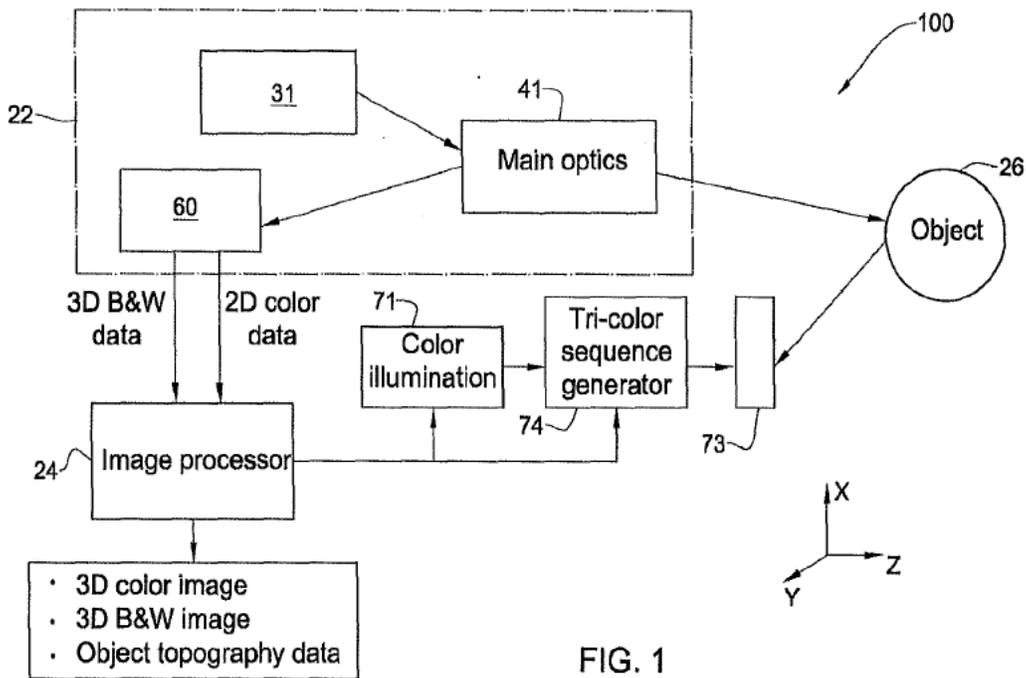


FIG. 1

JX-0003 at Fig. 1.

Figure 1 also shows optical device 22, but with significantly less detail as to its componentry. *See id.* Nonetheless, the figure still makes clear that the processor 24, is not a component of the optical device. Contrary to Align’s assertion, while this figure shows that the processor 24 is coupled to detector optics 60, nothing here suggests that the image processor would be included in a hand-held variant of optical device 22.

I note also that Align criticizes 3Shape’s expert, Dr. Schaafsma, for identifying “every single element shown in Figure 1 but the processor 24 as on the hand-held device, ignoring the disclosure that the processor is coupled to the detector.” CRB at 27 (citing Tr. at 1280:12-1281:12). First of all, Align’s criticism is inaccurate. Dr. Schaafsma identified the elements inside box 22, as well as elements 71, 74, and 73, which correspond to color image gathering, and element 46, which is an unpictured endoscope. Tr. at 1281:10-12. In identifying only those elements, Dr.

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Schaafsma testified consistently with the only portion of the specification that actually describes the elements in a hand-held device. *See* JX-0003 at 24:48-54. I do not find it unreasonable that Dr. Schaafsma did not include processor 24 among the components of the hand-held device given that the specification gives a list of components for the hand-held device, and processor 24 is not among them. I also do not agree with Align’s implied argument that all of the elements in figure 1 must be within the hand-held device because some of them are. Figure 1 is not a diagrammatic representation of the hand-held device; it is an illustration of “the main elements of preferred embodiments of the invention.” *Id.* at 12:12-13.

Based on the evidence and arguments presented, I find, as a matter of fact, that a person of ordinary skill in the art would not conclude from the four corners of the ’228 patent that its inventor actually possessed the invention claimed in claim 1. Particularly, I do not find any disclosure of the “hand-held device comprising . . . a processor” in that claim. Accordingly, I find that 3Shape has established, by clear and convincing evidence, that claim 1 of the ’228 patent is invalid for failure to comply with the written description requirement of § 112, ¶ 1.

Because claims 4 and 26 of the ’228 patent depend from claim 1, and therefore also incorporate the unsupported “hand-held device comprising . . . a processor” limitation, I also find that 3Shape has established, by clear and convincing evidence, that claims 4 and 26 of the ’228 patent are invalid for failure to comply with the written description requirement of § 112, ¶ 1.

### 2. ’456 Patent

#### a) *Obviousness in View of the Combination of Babayoff WIPO and Yoichi*

3Shape asserts the same combination of Babayoff WIPO and Yoichi to argue that claims 1 and 15 of the 56 patent are obvious as it asserted to show that the asserted claims of the ’228 patent are obvious. *See* RIB at 37-38. 3Shape provides no new evidence to demonstrate that a

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person of ordinary skill in the art would have been motivated to combine Babayoff WIPO and Yoichi, however, and therefore, I find that 3Shape has failed to establish that claims 1 and 15 of the '456 patent are invalid as obvious in view of the combination of Babayoff WIPO and Yoichi for the same reasons 3Shape failed to establish that the asserted claims of the '228 patent are obvious.

### *b) Written Description*

The parties' arguments regarding invalidity due to a lack of written description for claims 1 and 15 of the '456 patent are coextensive with their arguments on written description with respect to the asserted claims of the '228 patent. Accordingly, for the same reasons given with respect to the '228 patent, I find that 3Shape has established, by clear and convincing evidence, that claims 1 and 15 of the '456 patent are invalid for failure to comply with the written description requirement of § 112, ¶ 1.

## 3. '207 Patent

### *a) Obviousness in View of the Combination of Babayoff WIPO and Yoichi*

3Shape asserts the same combination of Babayoff WIPO and Yoichi to argue that claim 1 of the '207 patent is obvious as it asserted to show that the asserted claims of the '228 and '456 patents are obvious. *See* RIB at 39. 3Shape provides no new evidence to demonstrate that a person of ordinary skill in the art would have been motivated to combine Babayoff WIPO and Yoichi, however, and therefore, I find that 3Shape has failed to establish that claim 1 of the '207 patent is invalid as obvious in view of the combination of Babayoff WIPO and Yoichi for the same reasons 3Shape failed to establish that the asserted claims of the '228 and '456 patents are obvious.

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### *b) Obviousness in View of the Combination of Babayoff '739 and Engelhardt*

For the '207 patent, 3Shape asserts that claim 1 is obvious in view of the combination of U.S. Patent Publication No. 2006/0001379 (“Babayoff '739”),<sup>10</sup> JX-0029) and Engelhardt. RIB at 39. The crux of 3Shape’s argument is that the “hand-held device comprising...a processor” limitation in claim 1 of the '207 patent lacks written description support in the parent patents and applications to which the '207 patent claims priority, and thus claim 1 of the '207 patent is only entitled to a priority date of April 13, 2013, which is the filing date of the '207 patent. *See id.* at 39-40. Based on that priority date, 3Shape contends that Babayoff '739, which shares a common specification with the '207 patent, is prior art to the '207 patent. 3Shape then asserts that the combination of Babayoff '739 and Engelhardt would render claim 1 of the '739 patent obvious. Align disputes that Babayoff is prior art to claim 1 of the '207 patent, arguing instead that the claim is entitled to a priority date of June 17, 2004. CRB at 29.

As described *supra*, I agree with 3Shape that the only written description support for claim 1 of the '207 patent is found in the claim itself. Accordingly, claim 1 is not entitled to claim priority back to June 17, 2004, because the parent applications and patents coming before the '207 patent lack written description support for the “hand-held device comprising...a processor” limitation in claim 1. *See In re NTP, Inc.*, 654 F.3d 1268, 1276-77 (Fed. Cir. 2011). Claim 1 of the '207 patent is only entitled to a priority date of April 13, 2013, which is the filing date of the '207 patent, based on the fact that the “hand-held device comprising...a processor” limitation was included in original claims filed on that date. *See id.* As such, Babayoff '739, which has a publication date of January 5, 2006, is prior art to claim 1 of the '207 patent.

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<sup>10</sup> Again, this Babayoff reference should not be confused with WIPO Publication No. WO 00/08415 (“Babayoff WIPO”).

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Unlike the combination of Babayoff WIPO and Yoichi, for which 3Shape failed to demonstrate a motivation to combine, here, I find the evidence much more convincing that a person of ordinary skill in the art would have been motivated to modify Babayoff '739 by moving the external processor onto the hand-held scanning device. This follows directly from the teachings of Engelhardt, which discloses:

a device for the confocal measuring of surfaces inside cavities of the body, specially to measure the surface profile (1) of teeth (2) in the mouth cavity. Said device has a probe (3) that can be introduced into the cavity of the body, a light source feeding the probe (3), a detector picking up a light signal (5) and a processor (6) to digitalize the detected signal transforming it into a tridimensional representation.

RX-0853 at Abstract. Unlike the combination of Babayoff and Yoichi—two references from different fields of art—Engelhardt and Babayoff '739 are both directed to devices for intraoral scanning of teeth. *Compare id.* with JX-0029 at Abstract. Moreover, Engelhardt explicitly provides the motivation for miniaturizing the processor disclosed in Babayoff to fit in a hand-held device by stating:

It would also be conceivable to integrate other functional units which are outside the housing in the foregoing description into the housing or to place them within the housing. For instance, the light source and/or the beam splitter and/or-if necessary-the focusing control and/or the detector and/or *the processor could be arranged within the housing by miniaturizing all the functional units. That, correspondingly, would be a compact system needing only connection to the proper power supply.*

RX-0853 at 5:62-6:4 (emphasis added).

Align raises several arguments against combining Engelhardt with Babayoff WIPO, which I understand to be the same as the reasons Align believes Engelhardt should not be combined with Babayoff '739. The first is that “Engelhardt does not disclose a system capable of determining color nor a processor configured to associate color with depth data.” CRB at 24. Align’s point about what Engelhardt discloses is undisputed, but also not particularly probative. A showing of obviousness based on a combination does not require that each reference disclose every element

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of the allegedly obvious claim; were that the case, no combination would be necessary as each reference would independently disclose all the limitations of the claim.

Given the parity between the disclosure in the '207 patent and the disclosure in Babayoff '739, the only thing Engelhardt need disclose is a motivation to modify the processor of Babayoff '739 to reside within the hand-held device, as in claim 1 of the '207 patent. As noted above, Engelhardt explicitly provides that motivation. Align also argues that "Engelhardt provides no explanation of how this miniaturizing could be accomplished and still fit in the oral cavity," CRB at 24, but it is unclear what relevance that observation has to the obviousness combination put forward by 3Shape. At best, the argument suggests Align might believe there to be some kind of enablement problem inherent in Engelhardt, but that is far from clear in its briefing. I also find this argument curious inasmuch as the '207 patent itself provides no explanation of how the processor 24, which is represented as a personal computer, could be modified to fit in a hand-held device that will fit into an oral cavity. Align appears to believe that the disclosure required of prior art references is much more detailed than that required of its own patents.

In any event, I decline to guess at what exactly Align's argument against combining Babayoff '739 with Engelhardt actually is. The evidence before me shows that all of the limitations of claim 1 of the '207 patent except the hand-held processor limitation are present in Babayoff '739, and Englehardt, which also deals with intraoral scanning of teeth provides an explicit motivation to modify the processor of Babayoff '739 to fit on the hand-held device disclosed therein. Accordingly, I find that 3Shape has established, by clear and convincing

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evidence, that claim 1 of the '739 patent is invalid as obvious in view of the combination of Babayoff '739 and Engelhardt.<sup>11</sup>

### c) *Mixed Method Claim*

3Shape argues that claim 1 of the '207 patent is invalid as indefinite because the claim recites both an apparatus and a method of using that apparatus. RIB at 40 (citing *IPXL Holdings, L.L.C. v. Amazon.com, Inc.*, 430 F.3d 1377, 1384 (Fed. Cir. 2005)). In support of this argument, 3Shape cursorily asserts that because “claim 1 of the '207 patent improperly mixes a system and method claim, ‘a manufacturer or seller of the claimed apparatus would not know from the claim whether it might also be liable for contributory infringement because a buyer or user of the apparatus later performs the claimed method of using the apparatus.’” parroting the language of *IPXL Holdings*. *See id.*

3Shape’s argument is not persuasive. Particularly, the application of the rule from *IPXL Holdings* is not as cut and dry as 3Shape suggests. Indeed, in *Microprocessor Enhancement Corp. v. Texas Instruments Inc.*, the Federal Circuit declined to find indefinite a method claim structured very similarly to claim 1 of the '207 patent, *i.e.*, a preamble introducing a method for using a device, followed by structural limitations of the device. *Compare Microprocessor Enhancement Corp. v. Texas Instruments Inc.*, 520 F.3d 1367, 1374 (Fed. Cir. 2008) with JX-0005 at Cl. 1. The court explained that “[m]ethod claim preambles often recite the physical structures of a system in which the claimed method is practiced,” and “[t]he conclusion of *IPXL Holdings* was based on the lack of clarity as to when the mixed subject matter claim would be infringed.” *Microprocessor Enhancement Corp.*, 520 F.3d at 1374. Thus, *IPXL Holdings* does not stand for the proposition

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<sup>11</sup> In reaching this conclusion, analyzed the secondary considerations relating to obviousness proffered by Align, which I address later in this decision. Those secondary considerations do not persuade me that the invention in claim 1 of the '207 patent is not obvious.

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that any combination structural limitations and method steps in a claim renders it indefinite. Indeed, such a rigid rule would likely conflict with the Supreme Court's guidance that the indefiniteness inquiry should focus on whether a person of ordinary skill in the art would understand the metes and bounds of a claim with reasonable certainty. *See Nautilus.*, 134 S. Ct. at 2129.

Here, 3Shape has made no attempt to show why the scope of claim 1 of the '207 patent is uncertain as a result of the combination of structural limitations and method steps. As Align points out, "there is no uncertainty about when direct infringement occurs" with respect to claim 1 of the '207 patent, "it plainly occurs when the [hand-held device] is operated." CRB at 30. Accordingly, I find that Align has failed to show, by clear and convincing evidence, that claim 1 of the '207 patent is invalid as indefinite.

#### 4. '433 Patent

##### a) *Obviousness in View of the Combination of Babayoff WIPO and Yoichi*

3Shape asserts the same combination of Babayoff WIPO and Yoichi to argue that claim 12 of the '433 patent is obvious as it asserted to show that the asserted claims of the '228 patent are obvious. *See RIB* at 41. However, 3Shape provides no new evidence to demonstrate that a person of ordinary skill in the art would have been motivated to combine Babayoff WIPO and Yoichi. For reasons I have already discussed, I find that 3Shape has failed to establish a motivation to combine Babayoff WIPO and Yoichi. Accordingly, 3Shape has not shown clear and convincing evidence that claim 12 of the '433 patent is invalid as obvious in view of the Babayoff WIPO and Yoichi references.

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### *b) Anticipation by Yoichi*

3Shape argues that Yoichi discloses every limitation of claim 12 of the '433 patent if “selectively map” is construed to mean “map,” as Align’s construction suggests. RIB at 41 n.1 (citing Tr. at 1308:14-18), 45.

Align has two responses. First, Align argues that 3Shape’s position “requires reading the word ‘selectively’ out of the claim, which is improper as a matter of law.” CRB at 31. Second, Align argues that the manner in which depth data and color data are associated in Yoichi is “different than creating the 3D model with model with color.” *Id.* at 32. Align argues that the method disclosed in Yoichi is similar to one of the problems the color scanner patents sought to correct, and thus Yoichi cannot be anticipatory.

I agree that Yoichi is not anticipatory, but not for the reasons enumerated by Align. Rather, just as Align had a complete failure of proof with respect to the “selectively map” limitation in its infringement case, so too here does 3Shape fail to prove that Yoichi discloses a processor configured to cause a system to:

selectively map the image data to the depth data for the two-dimensional reference array based on the plurality of focal lengths and the depth data such that the resulting associated color of the structure portion is in focus relative to the structure portion for a plurality of distances in the depth direction.

JX-0006 at Cl. 12. Particularly, 3Shape has essentially ignored the entirety of this limitation after the phrase “selectively map the image data to the depth data.” A review of 3Shape’s proffered evidence demonstrates as much. The entirety of the evidence 3Shape presents to show that Yoichi discloses this limitation is a passage of hearing testimony and two paragraphs from Yoichi. Those sources read as follows:

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Q And how -- in your opinion, how if at all, did his testimony on Tuesday differ from Align's interpretation of selectively map?

A I think that essentially it sounds like Dr. Stevenson equated that with what has been previously referred to as "mapping."

Q And how, if at all, would that affect your opinion related to the art you applied to address claim 12?

A Well, I think if selectively map is interpreted to mean map, then Yoichi essentially reads against the entire claim.

Tr. at 1308:8-18 (testimony of Dr. Schaafsma)

\* \* \*

[0031] Color images obtained with the non-confocal optical system 2 are combined in a three-dimensional display of the surface profile of the sample obtained by the confocal optical system 1 described above, and color three-dimensional display is carried out. As a result, portions represented by hatching viewed from above in the Z-axis direction are colored with the colors of a color image in the display model shown in Fig. 3. Picture elements of the hatched portions are imaged in the XY plane and are associated with picture elements of the color image.

RX-0997 at ¶ 31.

\* \* \*

[0037] The color three-dimensional display data, as described above, is generated from the height data and color data for each picture element in the XY plane but may also be combined with the maximum received light quantity data. Specifically, by replacing the RGB color data brightness component for each picture element with maximum received light quantity data, a color three-dimensional display image with strong contrast is obtained in comparison to cases where only color data obtained from a non-confocal optical system 2 is used, because the maximum received light quantity for each picture element when in focus is reflected as brightness information in the color data.

RX-0997 at ¶ 37.

Nothing in these passages amounts to a showing, by clear and convincing evidence, that Yoichi discloses a processor that maps image and depth data "such that the resulting associated color of the structure portion is in focus relative to the structure portion for a plurality of distances in the

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depth direction.” JX-0006 at Cl. 12. Accordingly, I find that 3Shape has not demonstrated, by clear and convincing evidence, that Yoichi anticipates claim 12 of the ’433 patent.

### **5. Secondary Considerations Bearing on Obviousness**

In connection with its response to 3Shape’s obviousness arguments, Align provides several arguments directed to secondary considerations bearing on the obviousness of the asserted claims. Each category of secondary consideration is addressed in turn herein.

#### ***a) Commercial Success***

Align argues that the commercial success of its iTero Element product is evidence that the asserted claims of the color scanner patents are not obvious. CRB at 35 (citing JX-0220C; Tr. at 412:13-415:17). 3Shape does not dispute that the iTero Element product has achieved commercial success. Consistent with my findings regarding the technical prong of the domestic industry requirement, Align has only shown that the iTero Element practices claim 12 of the ’433 patent. It has not shown that the iTero Element practices any claim of the ’228, ’456, or ’207 patents. Accordingly, there is no nexus between Align’s commercial success evidence and the claims of the ’228, ’456, or ’207 patents. There is, however, evidence of a nexus between the commercial success of the iTero Element and claim 12 of the ’433 patent, and therefore I find that Align’s commercial success evidence tends to support the conclusion that claim 12 of the ’433 patent is not obvious.

#### ***b) Long-felt but Unresolved Need***

Align’s evidence of long-felt but unresolved need largely consists of citations to “Background of the Invention” section in the ’228 patent. CRB at 36 (citing JX-0003 at 1:28-2:43). Align alleges that these passages demonstrate that there was a long-felt but unresolved need for an intraoral scanner that could associate color information with a 3D object. *See id.* Align also

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points to a portion of deposition testimony from 3Shape's employee, Rune Fisker, to show that 3Shape spent between two and three years developing its first monochromatic intraoral scanner, which was launched in 2011. *Id.* (citing JX-0054C at 30:11-15). Here again, 3Shape makes no counter-argument.

I do not find Align's evidence of long-felt but unresolved need particularly persuasive. First, Align's reliance on the specification of the '228 patent to prove the non-obviousness of the color scanner patents is hardly objective evidence, which is the point of including secondary considerations in an obviousness analysis. Second, I do not find Dr. Fisker's testimony to be particularly relevant to showing a long-felt but unresolved need for intraoral scanners that associate color image data with a 3D object. The testimony only shows when 3Shape entered the market with a monochromatic scanner, and roughly how long that scanner was in development. *See* JX-0054C at 30:11-15. To infer from that testimony that 3Shape's development time or date of entry to the market demonstrates a long-felt or unresolved need for the inventions claimed in the color scanning patents would require an unacceptable amount of speculation. Accordingly, I find that Align has not presented persuasive evidence of a long-felt but unresolved need for the inventions claimed in the color scanner patents.

### *c) Praise by Others*

Align presents evidence of others praising its iTero Element product. CRB at 36-37 (citing JX-0080C at 233:23-234:24, 235:12-237:12, 270:14-273:2, 344:8-345:16; JX-0235C at 00101728, 00101721; JX-0048C at 63:1-8, 166:2-8). ). Here again, 3Shape makes no counter-argument.

Having reviewed the evidence cited by Align, I find that the citations in JX-0235C and JX-0048C demonstrate praise by others for the iTero Element, and therefore provide objective evidence tending to support a conclusion that claim 12 of the '433 patent, which is embodied by

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the iTero Element, is not obvious. I do not find a clear nexus between the statements in JX-0080C and any particular claim of the color scanning patent, and thus, I do not find that exhibit to be particularly probative with respect demonstrating praise by others for the asserted claims of the color scanner patents.

### *d) Copying*

Align also argues that there is evidence that 3Shape copied the technology in Align's patents and the iTero Element to create its Trios scanners. CRB at 37 (citing Tr. at 730:9-23, 734:10-737:25; JX-235C; Tr. at 738:1-739:7; 740:1-21; 741:10-742:18; JX-0054C at 23:4-17, 24:2-23, 45:12-24, 60:25-61:13, 81:20-82:24, 190:16-192:8, 196:22-198:8, 246:2-22; JX-0048C at 57:12-58:1, 62:1-63:8, 91:17-24, 110:19-23, 162:9-163:3, 164:10-20; JX-0080C at 255:18-258:12, 273:25-275:20, 297:5-7, 297:14-21, 298:12-299:2, 299:23-301:24, 313:9-317:2, 324:23-327:2; JX-0075C at 155:5-159:3).

3Shape acknowledges that it reviewed the iTero product and the predecessors to the color scanner patents during the time Trios was in development. RRB at 30. However, 3Shape asserts that it "never obtained or opened iTero, prior to fixing Trios's optical design," and once 3Shape did open an iTero, "it did not review the detailed optical system." *Id.* at 31 (citing Tr. at 719:25-721:13). 3Shape characterizes Align's evidence of copying as circumstantial and argues that the main document on which Align relies is merely a competitive intelligence review conducted as part of 3Shape's freedom-to-operate analysis. *Id.* (citing Tr. at 729:10-16, 731:18-733:20; 755:3-8, 952:16-953:14; JX-0235C). 3Shape also argues that a large portion of Align's copying evidence is based on e-mails that I did not admit into the record. *See id.* And, 3Shape points to its own evidence, albeit most of it self-serving, to show that it did not use its competitive analysis for the purpose of copying features or design into the Trios product. *See id.* at 32.

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Having reviewed all of the evidence presented by Align, I agree with 3Shape's characterization of Align's copying argument as circumstantial. What Align has shown is that 3Shape had knowledge of the iTero and of the predecessors to the color scanner patents during the time Trios was being developed. I find Align's evidence lacking, however, with respect to showing that 3Shape used that knowledge to copy the design of the iTero into the Trios. On the record before me, I find 3Shape's explanation of studying iTero scanners for a freedom-to-operate analysis to be credible. *See, e.g.*, Tr. at 731:18-733:20. I decline to infer copying from mere access to the iTero and color scanner patents' predecessors absent more convincing evidence.

### *e) Summary*

In sum, I find that Align has presented evidence of commercial success and praise by others with a nexus to claim 12 of the '433 patent. That evidence supports and is consistent with my conclusion *supra* that claim 12 of the '433 patent is not invalid as obvious. But with respect to claim 1 of the '207 patent, no nexus has been shown between the features of the claimed invention and praise by other or Align's commercial success. Accordingly, my finding that claim 1 of the '207 patent is obvious has appropriately considered secondary considerations of non-obviousness.

## V. 3SHAPE'S EQUITABLE DEFENSES

3Shape advances an assortment of non-statutory equitable doctrines in its defense. *Cf.* 19 U.S.C. § 1337(c) ("All legal and equitable defenses may be presented in all cases."). These doctrines, as grouped by 3Shape, are: (1) equitable estoppel, waiver, and acquiescence; (2) license, (3) unclean hands, and (4) patent misuse. RIB at 68-78. 3Shape primarily argues that Align can no longer assert that 3Shape infringes its patents because Align accused 3Shape of infringing its

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patents as far back as 2011, but then decided to enter into a Scanner Agreement<sup>12</sup> with 3Shape in 2015 instead of suing 3Shape for patent infringement. RIB at 60-68. Under the Scanner Agreement, doctors could use a 3Shape Trios scanner to scan patients' teeth and submit the resulting scans to Align for manufacture of Invisalign clear aligners. See JX-0163C.

Based on the evidence and arguments of the parties set forth in detail in the following subsections, I find that the evidence does not support application of the non-statutory equitable doctrines to bar Align's claims of patent infringement.

### A. Equitable Estoppel, Waiver, and Acquiescence

3Shape asserts that it cannot be held liable for infringing Align's patents under the doctrines of equitable estoppel, acquiescence, and waiver. RIB at 60-72. These are equitable affirmative defenses that may bar Align from receiving relief on its patent infringement claims against 3Shape. See *A.C. Aukerman Co. v. R.L. Chaides Const. Co.*, 960 F.2d 1020, 1028 (Fed. Cir. 1992) (en banc), abrogated on other grounds by *SCA Hygiene Prod. Aktiebolag v. First Quality Baby Prod., LLC*, 137 S. Ct. 954 (2017); cf. *Clark v. Capital Credit & Collection Servs., Inc.*, 460 F.3d 1162, 1170 (9th Cir. 2006) (citations omitted).

The doctrine of equitable estoppel requires that (1) the patentee engages in misleading conduct that leads the accused infringer to reasonably infer that the patentee does not intend to assert its patent against the accused infringer; (2) the accused infringer relies on that conduct; and (3) as a result of that reliance, the accused infringer would be materially prejudiced if the patentee is allowed to proceed with its infringement action. *John Bean Techs. Corp. v. Morris & Assocs., Inc.*, 887 F.3d 1322, 1327 (Fed. Cir. 2018) (citing *Scholle Corp. v. Blackhawk Molding Co.*, 133

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<sup>12</sup> The forum selection clause in this Scanner Agreement was the subject of a motion for summary determination filed by 3Shape. I denied the motion. Order No. 23 (May 18, 2018).

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F.3d 1469, 1471 (Fed. Cir. 1998)). 3Shape must prove by a preponderance of the evidence that the requirements of equitable estoppel are satisfied. *Aukerman*, 960 F.2d at 1046.

Waiver requires (1) “a voluntary or intentional relinquishment of a known right” or (2) conduct that “was so inconsistent with an intent to enforce its rights as to induce a reasonable belief that such right has been relinquished.” *Qualcomm Inc. v. Broadcom Corp.*, 548 F.3d 1004, 1019-20 (Fed. Cir. 2008). 3Shape must prove that the evidence clearly and convincingly satisfies the requirements of waiver. *Hynix Semiconductor Inc. v. Rambus Inc.*, 645 F.3d 1336, 1348 (Fed. Cir. 2011); *Qualcomm Inc. v. Broadcom Corp.*, 548 F.3d 1004, 1019-22 (Fed. Cir. 2008).

Acquiescence is a variation of equitable estoppel. *See Mahoning Inv. Co. v. United States*, 3 F. Supp. 622, 630 (Ct. Cl. 1933). The elements of estoppel based on acquiescence are “(1) knowledge of the facts giving rise to the claim; (2) implicit or explicit assurances to the party-opponent; and (3) reliance.” *See Spitz Techs. Corp. v. Nobel Biocare USA LLC*, Case No. 8:17-cv-00660-JVS-JCG, Doc. No. 49, at \*6 (C.D. Cal Sept. 11, 2017).<sup>13</sup>

All three equitable doctrines require, at a minimum, that Align’s conduct misled 3Shape into reasonably believing that 3Shape could, without consequence, infringe the patents Align asserted in this investigation. The evidence proffered by 3Shape to describe the course of conduct between the parties is largely undisputed; the parties do dispute how those facts should be interpreted.

3Shape begins its account of Align’s conduct by alleging that years before the parties entered into the 2015 Scanner Agreement, “Align repeatedly communicated ‘IP concerns’ and ‘IP

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<sup>13</sup> 3Shape cites *Spitz Technologies Corp. v. Nobel Biocare USA LLC*, Case No. 8:17-cv-00660-JVS-JCG, Doc. No. 49 (C.D. Cal Sept. 11, 2017)) for the elements of estoppel based on acquiescence (RIB at 69), and Align does not dispute that *Spitz Technologies* states the correct standard (CRB at 60). Therefore, I will apply the agreed-upon articulation of acquiescence to the evidence of record.

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issues' including that 3Shape infringed Align's scanner patents, with 3Shape seeking ways to resolve those concerns." RIB at 69.

The vice president of orthodontics at 3Shape, Allan Hyldal, testified at the hearing about the history of discussions between 3Shape and Align. Tr. at 834:23-835:10. Mr. Hyldal tells the story of how 3Shape spent several years attempting to reach an agreement with Align that would allow Align's Invisalign system to accept dental scans from 3Shape's oral scanner system, the Trios. Mr. Hyldal testified that the discussions were "called off" at times because of "business reasons" and "legal reasons." Tr. at 845:13-24. Around 2014, Mr. Hyldal was informed by Align's former vice president of business development, Tim Mack, "that there [were] some patent infringement issues that had to be resolved before we could proceed with the agreement." *Id.* As corroborating evidence, 3Shape introduced an email written by Mr. Hyldal to an Align employee from December 2014. Mr. Hyldal wrote that, based on the conversation with Mr. Mack, Mr. Hyldal "[redacted]" regarding integration of the 3Shape and Align systems. RX-0310C at 1.

Six months later, in May 2015, Mr. Hyldal wrote an internal email that conveyed to others at 3Shape rumors he heard at a trade show. JX-0201C. Mr. Hyldal said Align representatives at the event "told customers that Trios will never be integrated with Invisalign because 3Shape is breaking an Align patent." *Id.* He also reported that a "[redacted]" *Id.*

Testimony from Align executive Mr. Mack confirmed Mr. Hyldal's story of the two companies attempting to reach an interoperability agreement over several years. In 2015, Mr. Mack told 3Shape executive Fleming Thorup, Tais Clausen, and Rune Fisker "that Align had concerns around IP and that Align wouldn't begin the validation process for interoperability until

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they addressed those concerns.” Tr. at 282:5-14; *see also id.* at 277:16-280:16, 282:15-21; RX-0294C. He also told them that “the legal team at Align needed to address that question,” but he testified that “[REDACTED]” *Id.* at 283:1-7.

The vice president of products strategy at 3Shape for the Trios product, Rune Fisker, testified that there were “regular rumors from Align employees, who were threatening us with patent infringement.” JX-0054C at 213:2-3. He also testified that, in October 2015, Align’s chief technical officer, Avi Kopelman, “threatened me directly” at a customer event in Canada in which they were both presenting information about scanners. *Id.* at 213:4-18; *see* Tr. at 722:9-21. Mr. Fisker went on to clarify, however, that the “threat[ ]” was actually a “conversational” discussion with Mr. Kopelman and some of their shared customers regarding the technologies in their competing products. JX-0054C at 214:7-215:6; *see* Tr. at 745:17-746:5. According to Mr. Fisker, during this conversation, Mr. Kopelman conveyed “that he had patents,” but he did not “mention[] any patent numbers” or “provide any kind of written analysis, or anything like that.” JX-0054C at 214:7-215:6; *see* Tr. at 745:17-746:5; *see also* Tr. at 746:6-9 (“Q: And he never mentioned any patent numbers to you during that meeting. Fair enough? A: But it was clearly related to the iTero scanner.”); *id.* at 1259:22-1262:4 (Mr. Kopleman testifying that his concerns stemmed from similarities he personally saw between Align’s and 3Shape’s products and not from any legal analysis). Mr. Fisker apparently believed that this conversation was of minimal importance as he did not recall reporting this conversation to anyone at 3Shape, did not “raise[] concerns relating to anything [Mr. Kopelman] said to anybody within 3Shape,” and did not follow up with Mr. Kopelman regarding the substance of the conversation. Tr. at 745:10-747:6; *see* JX-0054C at 216:6-12.

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Align's chief executive officer, Joe Hogan, who joined the company in 2015, testified about his interactions with 3Shape that year. In October 2015 (the same month that Mr. Kopelman and Mr. Fisker had their discussion), Mr. Hogan had lunch with 3Shape's chief executive officer, Fleming Thorup. *See* Tr. at 848:6-14; RX-0114C. The two discussed the possibility of Align accepting images taken by 3Shape scanners for interoperability with the Invisalign system. When Mr. Hogan stood at the end of lunch, he said, "As we go forward, you have to understand, there's some concerns that we have with intellectual property as it relates to, you know, our IP and 3Shape." Tr. at 408:21-409:12; *see id.* at 426:15-20; RX-0115C. Mr. Thorup smiled and replied: "Well, we have some concerns about your infringement of our IP also." Tr. at 408:21-409:12. In Mr. Hogan's contemporaneous account of this conversation to Align colleagues, he stated that he told Mr. Thorup that Align "needed some amount of exclusivity and that we had IP issues that had to be addressed in parallel." RX-0115C. No party in this investigation cites any further communication between the two companies after this meeting but before the signing of the Scanner Agreement. *See* RIB at 64.

This is a good point to pause the narrative and review what we know so far. By October 2015, Align had communicated to 3Shape in multiple ways that it had some generalized concerns about 3Shape's scanners and patent infringement. The record is clear that Align never mentioned any particular Align patent number or even patent family to 3Shape. Align also told 3Shape that Align's legal department needed to evaluate the issue. By October 2015, Align had made no express or implied assurance that Align would not sue 3Shape for patent infringement. To the contrary, Align had warned 3Shape that Align had generalized patent infringement concerns. Importantly, 3 Shape does not argue that any of Align's conduct by October 2015 gave 3Shape a misleading assurance that Align would not assert its patent rights.

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3Shape's brief picks up the narrative about two months after the Hogan-Thorup lunch, when 3Shape and Align sign the Scanner Agreement allowing Trios scans to be integrated into the Invisalign system in December 2015. 3Shape's brief is silent about what transpired between October and December 2015 to lead Align from discussing patent infringement with 3Shape to entering into a business relationship with 3Shape. Nevertheless, 3Shape asserts that when Align agreed to accept Trios scans through the Scanner Agreement, it was "an implicit and explicit acknowledgement" that the "IP concerns" Align had identified several times were addressed to Align's satisfaction. RIB 64. Thus, in 3Shape's view, the Scanner Agreement "evidences Align's acquiescence to Trios scans being sent to both Invisalign and third parties." *Id.*

I find that the facts briefed by 3Shape do not amount to misleading conduct by Align. The only conduct 3Shape identifies that could be misleading is the act of Align entering into the Scanner Agreement. That act is not necessarily inconsistent with assertion of Align's patent rights, however. Just a few weeks before the agreement was ratified, Mr. Hogan put 3Shape on notice that even if the companies were to "go forward" on interoperability, Align "still" had concerns about 3Shape infringing Align's intellectual property. Mr. Hogan also described the 3Shape interoperability deal and Align's intellectual property concerns about 3Shape as "parallel." RX-0115C. Parallel things do not overlap, and one does not come before the other.

There is no indication that the act of entering into the Scanner Agreement was anything but a business decision knowingly entered into by both parties, each with the hope that the arrangement would enrich itself. Both companies were content to leave any intellectual property concerns for another day. *See Tr.* at 427:18-429:15. And the agreement allowed either party to choose that day. The agreement was [REDACTED]

[REDACTED] JX-0163C.

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3Shape decided to move forward under the Scanner Agreement even though the agreement did not expressly state Align's "IP concerns" were resolved. And that decision worked out for a time. 3Shape's Trios sales in the U.S. [REDACTED] during the term of the Scanner Agreement. Tr. at 768:6-11. Trios-Invisalign case submissions [REDACTED] [REDACTED] from 2016 to 2017. JX-0433C; *compare* RX-0815C with RX-0244C. After the Scanner Agreement had been in place for some time, Mr. Fisker at 3Shape wrote in an email to other 3Shape employees that the success of the arrangement [REDACTED] [REDACTED] JX-0204C at 1. I find Mr. Fisker's email shows that even as 3Shape reaped the rewards of the agreement, it knew it was still at risk of Align asserting its patents and closing 3Shape down. But 3Shape thought that the benefits of the arrangement to Align would keep Align sated against patent enforcement, and it accepted that risk. 3Shape might have made a bad bet, but the evidence does not show it was misled by Align.

There is other evidence that belies 3Shape's assertion that it was misled by Align's conduct. In 2017, two years after the parties entered into the Scanner Agreement, Mr. Hyldal wrote an email to an internal patent agent that 3Shape could not make two products, ClinCheck and Simulator, "until 2020." Tr. at 896:18-897:6. He was then asked at the hearing: "If you had a license in 2017 to Align's patents, there would have been no problem with making ClinCheck and Simulator at that point in time . . . , right?" *Id.* at 897:7-13. Mr. Hyldal responded, "Yeah, I would say so." *Id.* Based on that evidence, I find that Mr. Hyldal knew, even after entering into the Scanner Agreement, that Align patents protected certain technology until 2020. If 3Shape had been misled by Align's conduct into believing it could use Align's intellectual property, Mr. Hyldal would not have believed 3Shape needed to wait until certain Align patents had expired to make certain products.

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Another fundamental problem with 3Shape's equitable estoppel argument is the ambiguous scope of the rights Align allegedly lulled 3Shape into believing would not be enforced. The evidence shows that between 2011 and 2015, a few high-level executives from Align (Mr. Kopelman, Mr. Mack, and Mr. Hogan) and a few high-level executives from 3Shape (Mr. Fisker, Mr. Hyldal, and Mr. Thorup) had approximately six conversations relating to the intellectual property concerns of both companies. *E.g.*, Tr. at 283:1-15, 294:14-21, 408:21-409:12; RX-1290 at 4. The discussions about intellectual property rights were mostly general in nature and could have referred to trade secrets, copyrights, or any other intellectual property, although patent rights were mentioned once or twice. Much of communication was also equivocal. *E.g.*, RX-0310C at 1 ("there may be some IP issues").

The necessary implication of 3Shape's argument is that Align forfeited enforcement of its entire intellectual property portfolio against 3Shape when it mentioned "IP concerns" to 3Shape and then failed to enforce all of its intellectual property rights. Align has hundreds of patents. JX-0143 at .0010. Surely Align has not forfeited the right to enforce all patents, copyrights, trademarks, and trade secrets against 3Shape based on the facts in this record. But 3Shape provides no rule to circumscribe the scope of the estoppel it seeks. Indeed, no rule can be equitably fashioned on this record because Align's conduct—even by 3Shape's telling—did not mislead 3Shape about any particular patent, family of patents, or other particular intellectual property right.

3Shape's arguments do not convince me of a contrary conclusion. 3Shape cites many documents and communications that were wholly *internal* to Align to support its claim of misleading conduct. *E.g.*, JX-0338C (Align's Mr. Kopelman discussing [REDACTED] with an Align colleague, in which he stated: [REDACTED]); Tr. at 1247:5-1248:12 (same); RX-201C (an email from a "consultant" to Mr. [REDACTED]);

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Kopelman); JX-0277 (an internal Align email from Mr. Mack to Mr. Kopelman); RX-0294C (in an internal Align email discussing [REDACTED] [REDACTED] stating that “[REDACTED]” and that “[REDACTED]”); RX-0313C at 23 (an internal Align presentation by Mr. Mack, in which [REDACTED] [REDACTED] [REDACTED]).

3Shape similarly relies on testimony that reflected the internal thoughts and beliefs of Align employees that were not known by 3Shape. *E.g.*, JX-0064C at 311:12-17 (Mr. Kopelman testifying that [REDACTED] Tr. at 429:16-20 (Mr. Hogan testifying that [REDACTED] [REDACTED] [REDACTED]). 3Shape fails to explain how these internal communications and personal thoughts, which only came out in this litigation, amount misleading conduct of which 3Shape would have been aware during the relevant time. The evidence does not support such a conclusion. *See Aukerman*, 960 F.2d at 1042 (“The first element of equitable estoppel concerns the statements or conduct of the patentee which must ‘communicate something in a misleading way.’”).

3Shape further relies on evidence of discussions that occurred before 3Shape had even released the Trios. 3Shape cites one such exchange that occurred in 2010, but the Trios did not come out until 2011. *Compare* JX-0050C at 71:25-72:7 (In 2010, Align’s Mr. Mack said 3Shape “violated his patents”) *with* JX-0054C at 30:11-15 (Trios not released until 2011). 3Shape fails to explain how discussions with Align before the Trios was on the market could lead to a reasonable belief that Align would not enforce the asserted patent against the Trios. I find the evidence does

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not support such a conclusion. *See B. Braun Med., Inc. v. Abbott Labs.*, 124 F.3d 1419, 1425 (Fed. Cir. 1997) (equitable estoppel not supported by evidence of patentee's relations with alleged infringer related to different products than those at suit).

3Shape attempts to analogize the evidence in this investigation to two Federal Circuit cases: *High Point SARL v. Sprint Nextel Corp.*, 817 F.3d 1325 (Fed. Cir. 2016) and *Scholle Corp. v. Blackhawk Molding Co.*, 133 F.3d 1469 (Fed. Cir. 1998). But these cases are readily distinguishable. In *High Point SARL*, the licensing activities between the parties' predecessors-in-interest specifically identified the patents-in-suit, 817 F.3d at 1130, but here there is no evidence that the parties discussed the asserted patents prior to the filing of the complaint. And in *Scholle*, the Federal Circuit stated that the patent owner's "cooperative behavior" regarding a design-around to a previously accused product, "in light of [the patent owner's] previous threats to sue, created a reasonable inference that [the patent owner] considered" the design-around to be noninfringing and did not intend to sue. 133 F.3d at 1472. The interaction between 3Shape and Align here is wholly different. There was no threat to sue from Align. Align's conduct "did not follow any communication indicating that it would take immediate action, which if not followed up might indicate that it had dropped the matter." *Hottel Corp. v. Seaman Corp.*, 833 F.2d 1570, 1574 (Fed. Cir. 1987), overruled in part on other grounds, *Aukerman*, 960 F.2d 1020.

In sum, the evidence does not show that Align engaged in misleading conduct that lead 3Shape to reasonably infer that Align does not intend to assert its patent against 3Shape, as required for equitable estoppel. Nor does it show that Align provided implicit or explicit assurances to 3Shape, as required for acquiescence. The evidence also does not show that Align voluntarily or intentionally relinquished its patent rights, or that Align's conduct with so inconsistent with an

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intent to enforce its rights as to induce a reasonable belief that such a right has been relinquished, either of which are required for waiver.

The doctrines of equitable estoppel and acquiescence also require evidence that 3Shape “substantially relied on the misleading conduct of [Align] in connection with taking some action” and, due to that reliance, 3Shape will be materially prejudiced<sup>14</sup> if Align is allowed to proceed with its claims of infringement. *Aukerman*, 960 F.2d at 1042-43.

Importantly, 3Shape marshals no facts from the period leading up to the Scanner Agreement to show reliance. Instead, 3Shape’s reliance arguments focus on the period when the Scanner Agreement was in effect. *See* RIB at 71. The “action” that 3Shape claims it took in reliance on Align’s conduct is as follows. According to 3Shape, it “expend[ed] resources promoting Invisalign to the detriment of its other clear aligner partners, and to further develop and make capital investment in the very products and related software Align now accuses of infringement.” RIB at 71 (citing JX-0163C; Tr. at 877:20-878:10); *see* RIB at 65 (citing RX-0813C; Tr. at 844:11-19). 3Shape also contends, without supporting evidence, that Align’s conduct “fostered [its] confidence in promoting the now accused products” and that it “could have built up . . . alternative clear aligner partnerships” absent Align’s conduct. *Id.*

The evidence shows that 3Shape took its actions due to obligations under the Scanner Agreement it negotiated, not in reliance on Align’s conduct. Section 19 of the Scanner agreement requires that 3Shape “

[REDACTED]

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<sup>14</sup> The legal standard for acquiescence proffered by the parties is ambiguous as to whether 3Shape’s reliance must result in material prejudice.



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sufficiently rebut the presumption of laches because it did not “place the matters of [evidentiary] prejudice and economic prejudice genuinely in issue.” *Lismont*, 2014 WL 4181586, at \*8 (citation omitted). Specifically, the defendant presented un rebutted evidence that it would be prejudiced by its inability to question a key witness due to the patent owner’s delay, that it increased the sales of the accused product, and that it “elected not to pursue non-infringing alternatives based on the fact that they thought the [inventorship] claim had been resolved.” *Id.* at \*8-\*12 (citations omitted). This investigation does not involve the presumption of laches, evidentiary prejudice assertions, or potential noninfringing alternatives. And the evidence as discussed above shows that 3Shape’s increased sales of the accused product was based on its business decisions, not its reliance on Align’s conduct.

Finally, in *Akeso Health Scis., LLC v. Designs for Health, Inc.*, No. 16-cv-07749, 2018 WL 2122644 (C.D. Cal. Apr. 26, 2018), the district court found that the patent owner’s 10-year silence was misleading because the patent owner had sent an adversarial “cease-and-desist letter” to the defendant that identified the patents and referenced another pending lawsuit. *Akeso Health*, 2018 WL 2122644, at \*3-4. The court had also found that the defendant had relied on the patent owner’s misleading silence because the evidence showed that it “would have considered modifying [the accused products] . . . to avoid [the patent owner’s] claims or directing its investment, marketing, production and sales efforts into other products.” *Id.* at \*4. 3Shape does not present similar evidence. *See* RIB at 71 (relying on attorney argument for the assertion that “3Shape could have built up these alternative clear aligner partnerships during the term of the Scanner Agreement”).

Even if the evidence in this record supported the application of the doctrines of equitable estoppel, acquiescence, and waiver in 3Shape’s favor, which I find it does not, these are equitable doctrines, the application of which is committed to my sound discretion. *See Qualcomm Inc. v.*

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*Broadcom Corp.*, 548 F.3d 1004, 1019 (Fed. Cir. 2008) (citing *Aukerman*, 960 F.2d at 1028). I would not exercise my discretion in light of the evidence presented by 3Shape.

3Shape is not without blame here. 3Shape engaged in the same intellectual property posturing as it now labels as misleading conduct by Align. *E.g.*, Tr. at 283:1-15, 294:14-21, 408:21-409:12; RX-1290 at 4. And 3Shape remained silent as to Align’s intellectual property concerns when negotiating the Scanner Agreement although they negotiated other terms [REDACTED]

[REDACTED] See Tr. at 850:15-851:22 (Mr. Hyldal testifying [REDACTED]

[REDACTED]), 853:7-15, 902:2-15, 1384:16-1385:4. To be clear, 3Shape may not have had a duty to raise or resolve the intellectual property concerns during the negotiation process, but under these facts its failure to do so significantly contributed to the situation from which it now requests relief.

In sum, I determine that the facts advanced by 3Shape do not demonstrate that equitable estoppel should bar Align’s patent infringement claims.

**B. License**

Based on the express<sup>15</sup> language of the Scanner Agreement, 3Shape asserts that it “owns all [intellectual property] in and to the process by which Trios [the accused product] scans,” and that “necessarily includes . . . Align’s rights in the Asserted Patents . . . .” RIB at 72-73. 3Shape says “Align transferred, assigned, and agreed never to assert, any and all such rights.” *Id.* In other words, 3Shape appears to open with an argument that it *owns* the patents that Align asserted in this investigation, not that it has a *license* to the patents. This is an inauspicious beginning to a license

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<sup>15</sup> 3Shape provides quotes from case law that include both implied and express license language. RIB at 72. However, 3Shape does not make any argument or assertion that it has an implied license to the patents that Align asserted in this investigation.

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argument. 3Shape does not own the Align patents, as its own witness confirms. *See* Tr. at 904:8-15 (Mr. Hyldal testifying that he did not “understand that ownership of any patents was supposed to change hands because of the agreement.”).

The Scanner Agreement also is not a patent licensing agreement. It is an agreement between Align and 3Shape Trios A/S “[REDACTED]” JX-0163C § 1.1. Regarding the intellectual property of the companies, the agreement explicitly states:

[REDACTED]

*Id.* § 4. 3Shape argues that other provisions the Scanner Agreement specifically set out the intellectual property rights, including rights in the asserted patents, to which a license is granted.

First, 3Shape points to a paragraph of section 4 titled “[REDACTED]” RIB at 72-73. This section states, among other things:

[REDACTED]

*Id.* § 4.

Contrary to 3Shape’s assertions, the only portion of this paragraph that could be interpreted as granting 3Shape a license to the asserted patents is the sentence that starts [REDACTED]



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[REDACTED]

JX-0163C § 4. 3Shape contends, without explanation, that this language contradicts a position that the “[REDACTED]” applies only to intellectual property created under or subsequent to the Scanner Agreement. RIB at 73.

Based on the highlighting in 3Shape’s brief, it appears that 3Shape thinks that the language [REDACTED], modifies “[REDACTED]” *See id.* However, a better parsing of the language shows that “[REDACTED]” instead modifies the phrase that immediately proceeds it: [REDACTED] [REDACTED]” This section therefore specifies that [REDACTED]

Finally, 3Shape points to section 3.6 titled “[REDACTED]” RIB at 74-75. This section states, among other things:

[REDACTED]

JX-0163C § 3.6. 3Shape argues that this section provides “written acknowledgement and authorization of 3Shape’s activities that Align now accuses of infringement with respect to Ortho

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System.” RIB at 75. To the contrary, there are no intellectual property rights specified in this section, and section 1.1 of the agreement specifies that [REDACTED]

[REDACTED] JX-0163C § 1.1.

In view of the foregoing, 3Shape has failed to show that it has a license to the asserted patents.

### C. Unclean Hands

3Shape raises a one-paragraph argument asserting unclean hands, arguing that “Align’s claims are barred by ‘unclean hands’ based on its continued authorization of the allegedly infringing goods Align simultaneously seeks to exclude.” RIB at 75-76. Specifically, 3Shape complains that Align continues to “authorize secondary cases with no intent to stop” and that 3Shape authorized new Invisalign cases sent from Trios scanners up until May 2018, which was after Align filed its complaint in this investigation. In other words, it appears that 3Shape is accusing Align of unclean hands because Align allowed 3Shape to continue to profit from its interoperability with Align’s technology during the pendency of this investigation.

3Shape cites only *Bordeau Bros. v. ITC*, 444 F.3d 1317 (Fed. Cir. 2006) to support its proposition that an unclean hands defense can be “based on [Align’s] continued authorization of the allegedly infringing goods Align simultaneously seeks to exclude.” RIB at 75. *Bordeau*, which pertains to trademark claims, does not support 3Shape’s proposition. Instead, the Federal Circuit simply notes that the respondent argued that the complainant’s claims “were barred by its ‘unclean hands’ as it had permitted its authorized dealers to sell [the accused products] in the United States” and that the ALJ found that respondents “had failed to bear their burden of proving the affirmative defense[] of . . . unclean hands.” *Bordeau*, 444 F.3d at 1326. The Federal Circuit did not state that permitting sales amounted to unclean hands. It instead rearticulated the applicable burdens

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and “remand[ed] this case to the ITC for a determination of whether [the complainant] bore its burden.” *Id.* at 1327.

I find that the secondary cases allowed by Align are follow-up scans taken of patients who started an Invisalign treatment plan with a Trios scan before Align terminated the Scanner Agreement. *See* Tr. at 1392:5-17, 1396:20-1397:9. In considering an unclean hands defense to patent infringement, a tribunal may consider in its equity analysis “the public interest as well as the private interests of the litigants” to “avert[ ] an injury to the public.” *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 815 (1945). Here, allowing follow-up scans reasonably protects patients, who, unlike 3Shape, did not have an intent to infringe the asserted patents. Align receives [REDACTED]

[REDACTED] *Id.* at 1397:6-9. Align should not forfeit its patent rights for allowing a practice that is in the public interest.

I find 3Shape has failed to prove by clear and convincing evidence that Align’s claims should be barred under the equitable doctrine of unclean hands.

### **D. Patent Misuse**

The doctrine of patent misuse prevents a patent owner from “impermissibly broaden[ing] the ‘physical or temporal scope’ of the patent grant with anticompetitive effect.” *Princo Corp. v. Int’l Trade Comm’n*, 616 F.3d 1318, 1328 (Fed. Cir. 2010). “Express conditions accompanying the sale or license of a patented product. . . are generally upheld,” but “[w]hen those contractual conditions violate public policy, . . . the underlying patents become unenforceable . . . .” *Id.* As an initial matter, 3Shape does not identify any sale or license of an Align patented product upon which contractual conditions are attached that might violate public policy. But even ignoring that point, the arguments 3Shape did make have no merit.

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3Shape asserts that “Align is misusing the Asserted Patents to protect its Invisalign clear aligner business.” Unfortunately, 3Shape’s logic supporting that conclusion is difficult to follow. RIB at 76. 3Shape points to evidence that “Align has made clear that its primary focus and concern is Invisalign,” but 3Shape does not explain why this is improper, or whether Align’s primary focus precludes a secondary focus of protecting its innovations by asserting its patents. *Id.* 3Shape next asserts that one way “Align tried to maintain its stranglehold on the clear aligner market was to [REDACTED]” but the evidence shows that 3Shape successfully [REDACTED]. *Id.*; Tr. at 850:15-851:22, 853:7-15, 902:2-15, 1384:16-1385:4.

3Shape next contends that “Align’s motive for bringing this Investigation and terminating the Scanner Agreement stems . . . from its need to stop 3Shape from enabling Invisalign’s strongest competition.” RIB at 77. Even if true, 3Shape presents no reason why inhibiting a competitor is an improper motive for asserting legitimate patent rights. *See USM Corp. v. SPS Technologies, Inc.*, 694 F.2d 505, 510 (7th Cir. 1982) (noting there is nothing inappropriate about a patent owner using patent rights to make money on the patented product).

3Shape also complains about Align’s use of scan data to target doctors who have used a Trios scanner to send scans to Invisalign and market to them. But there is no evidence that the Align marketing program is anything other than “fair and standard business practice,” or that 3Shape could have negotiated a provision in the Scanner Agreement to keep Align from using the data for this purpose. CRB at 75 (citing Tr. at 876:15-21). Instead, as 3Shape acknowledges, Align’s discount marketing plan stemmed from the termination of the Scanner Agreement, which termination 3Shape understood Align could do for any reason. *Id.*; Tr. at 878:23-881:8.

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In sum, 3Shape fails to present any evidence that links 3Shape's business decisions with any misuse of 3Shape's patent rights.

### VI. DOMESTIC INDUSTRY – ECONOMIC PRONG

For the asserted color scanner patents, Align contends that its U.S. investments relating to its iTero Element color scanners constitute a domestic industry under section 337(a)(2). It is undisputed that the iTero scanners are manufactured in Israel, while [REDACTED] [REDACTED] Tr. at 129:20-133:21, 263:8-11. But it is also well established that a domestic industry under sections 337(a)(3)(A) and (B) does not necessarily require domestic investments related to manufacturing. *Certain Solid Slate Storage Drives, Stacked Electronics Components, and Products Containing Same*, Inv. No. 337-TA-1097, Comm'n Op., 2018 WL 4300500 at \*5-8 (June 29, 2018). I must look at the nature and importance of Align's activities to the allegedly patented products in the context of the marketplace or industry in question. *Certain Printing and Imaging Devices and Components Thereof*, Inv. No. 337-TA-690, Comm'n Op. at 31 (Feb. 17, 2011).

Align offers three alternative theories for satisfaction of the economic prong of the domestic industry requirement. First, Align argues that findings from a Commission determination in an investigation initiated in 2012 should apply here. Second, Align contends that all of its domestic expenditures may be attributed to articles alleged to practice the color scanner patents. Third, Align proposes various ways to allocate specific investments with respect to articles alleged to practice the color scanner patents. Of the three theories, only the last one has any merit. But I will still address each theory below.

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### A. Findings from Align's Earlier Investigation

Align's first theory is that "persuasive precedent" has already determined that Align's investments are significant. CIB at 97. In support of this proposition, Align cites an investigation instituted in response to a complaint that Align filed at the Commission in 2012, *Certain Digital Models, Digital Data, and Treatment Plans for Use in Making Incremental Dental Positioning Adjustment Appliances*, Inv. No. 337-TA-833 (*Digital Models*). Align selectively quotes from the administrative law judge's final initial determination, asserting that the ALJ found that Align had "presented a *prima facie* case satisfying the economic prong of the domestic industry requirement." CIB at 97. But Align neglected to mention that the ALJ found that the respondent in that investigation had "waived the right to contest the issue of domestic industry." See *Digital Models*, ID, 2013 WL 3167893 at \*476 (May 6, 2013). After determining to review the ALJ's initial determination entirely, the Commission found the respondent had waived any challenge to the economic prong of the domestic industry requirement. See *Digital Models*, U.S.I.T.C. Pub. No. 4555, Comm'n Op. at 139137 (Nov. 2017). A victory rooted in an opponent's waiver is hardly "persuasive precedent."<sup>16</sup>

Even putting aside the fact that the findings in *Digital Models* originated from a waiver, there are several other reasons I cannot rely on the domestic industry determination in that investigation. First, *Digital Models* examined Align's investments around 2012, the time the complaint was filed in that investigation. Here, the relevant time period is five years later, around the November 2017 filing of the complaint in this investigation. See *Motiva, LLC v. ITC*, 716 F.3d 596, 601 n.6 (Fed. Cir. 2013); *Certain Television Sets, Television Receivers, Television Tuners*,

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<sup>16</sup> Indeed, Align's victory was short-lived. The Federal Circuit eventually vacated it. See *ClearCorrect Operating, LLC v. Int'l Trade Comm'n*, 810 F.3d 1283, 1287 (Fed. Cir. 2015).

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*and Components Thereof*, Inv. No. 337-TA-910, Comm'n Op. at 56-57 (Oct. 30, 2015). Align has made no showing that its investments remained static during the five years between 2012 and 2017. To the contrary, Align put forward evidence that its business has fluctuated. *See, e.g.*, JX-0093 at Align-1091\_00577151 (“Because our business is evolving, it is difficult to predict our future operating results or levels of growth, and we have in the past not been and may in the future not be able to sustain our historical growth rates. . . . Our operating results have fluctuated in the past and we expect our future quarterly and annual operating results to fluctuate as we focus on increasing doctor and consumer demand for our products.”); *see also* JX-0141; ;JX-0146.

Then there is the fact that all of the patents Align asserted in the *Digital Models* investigation expired before Align filed its complaint in the present investigation. *See Digital Models*, Align’s Written Submission on Issues Under Review at 20 (Aug. 8, 2013) (EDIS Doc. 515629). The expiration of these patents was so significant to Align’s business that Align drew special attention to their expiration in its SEC filings. JX-0143 at .0010. There are no “articles protected by” an expired patent. *Cf.* 19 U.S.C. § 1337(a)(3). Thus, even if Align had a domestic industry with relation to the patents it asserted in the *Digital Models* investigation in 2012, Align must still prove up in this investigation its current investments with respect to articles protected by unexpired patents. *See id.*

At least four of the six patents Align asserts in this investigation—the color scanner patents—do not expire imminently. But those patents relate to color scanners, not the Invisalign orthodontic trays Align relied on in the *Digital Models* investigation. *See Digital Models*, Final Initial Determination at 768 (June 14, 2013) (“Invisalign is the commercial embodiment of Align’s asserted patents”). Align specifically admits that the purported domestic industry products at issue here are *not* clear aligner trays. CIB at 98 (“Align’s iTero Element Scanners are the domestic

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industry product for the Color Scanner Patents”; it “has never been Align’s contention” that the domestic industry products in this investigation are clear aligners.). For any of the foregoing reasons, Align’s reliance on determinations in the *Digital Models* investigation is inadequate to carry its burden in this investigation.

### **B. The “All Expenditures” Theory**

Align’s second theory is that “all of Align’s expenditures” in the United States may be attributed to the color scanner patents “given Align’s end-to-end digital ecosystem and the realities of the marketplace.” CIB at 99. But Align’s own brief undercuts this proposition. Align admits that “Align’s iTero Element Scanners are the domestic industry product for the Color Scanner Patents” and that it “has never been Align’s contention” that the domestic industry products in this investigation include clear aligners. CIB at 98. Align must be held to the domestic industry products it identified for 3Shape during discovery. For the color scanner patents, those products are the iTero Element scanners, nothing else.

Beyond Align’s disclaimer of any domestic industry product beyond scanners, the “realities of the marketplace” indicate that not all of Align’s expenditures are necessary to exploit its color scanner patents. If there is any reality in the marketplace, it is in SEC filings, where misleading statements have serious consequences. In SEC filings, Align reports its business based on how its internal leadership “views and evaluates [Align’s] operations as well as allocation of resources.” JX-0093 at Align-1091\_00577224. And those SEC filings “group [Align’s] operations into two reportable segments: Clear Aligner segment and Scanner segment.” JX-0146 at .0065; JX-0093 at Align-1091\_00577135; JX-0141 at 0033. Align executive Mr. Morici confirmed that reporting about the business in these two segments is “a reflection of how management thinks about managing the business,” tr. at 236:14-17, and 3Shape’s expert, Mr. Green, agrees that Align executives manage the company by “looking at it from the point of view

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of iTero on the one hand, and Invisalign, on the other,” tr. at 1176:16-22. Align has reported on its scanner business separately from its clear aligner business since at least 2006. Tr. at 235:20-236:9. Those are the realities of the marketplace, not litigation-inspired accounting.

Other evidence corroborates a conclusion that Align’s color scanner investments are not linked to its clear aligner investments. Align’s scanners and clear aligners are sold separately. Tr. at 101:2-9, 203:25-204:2. They can also be used separately: iTero scans can be used for non-Invisalign treatments and Invisalign cases can be started with traditional impressions or non-iTero scanners. Tr. at 101:6-22, 102:5-16, 136:5-10, 192:25-193:5, 193:12-194:8, 203:25-204:2, 213:3-6, 254:14-17. [REDACTED]

[REDACTED] Tr. at 193:12-194:8, 253:2-254:17; RX-0244C. Based on this evidence, I find, as a factual matter, that the marketplace does not require Align to invest in its clear aligner business in order to exploit its color scanner patents. The reverse is also true: Align’s clear aligner business does not require Align to invest in scanner development and sales.

It is true that in some circumstances the Commission will consider additional components beyond the patented articles in a domestic industry analysis. For example, where additional products enable exploitation of the claimed subject matter, investments relating to non-patented components may be relevant. *See, e.g., Certain Video Game Systems and Wireless Controllers and Components Thereof*, Inv. No. 337-TA-770, Comm’n Op. at 68, 70 (Oct. 28, 2013). An “important” factor in making that determination is whether the alleged domestic activities “have a direct relationship to exploitation of the patented technology.” *Id.* at 67. Activities “far removed from the technology protected by the patent” should not be included. *Id.*; *see also Certain*

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*Integrated Circuit Chips and Products Containing The Same*, Inv. No. 337-TA-859, Comm'n Op. at 36 (Aug. 22, 2014).

Align's attempt to link its clear aligner investments to its color scanner patents fails when compared to the Commission's guidance in *Video Game Systems* and other decisions. As noted above, doctors and patients can obtain Invisalign trays without using Align's iTero scanner, and doctors can use the iTero scanner to produce teeth aligners from providers other than Align. The two products are managed and accounted for separately inside Align's business, reported separately to the market place, and sold separately. Neither is necessary to exploit the other. For the foregoing reasons, I reject Align's all-expenditures theory.

**C. Investments Related to the Color Scanner Patents**

Align's last theory differs from its two previous theories by distinguishing specific investments relating to the color scanner patents from other investments (recall the other two theories lump all Align investments together). In this theory, Align relies upon the analysis of its retained economics expert, W. Christopher Bakewell, who utilized a three-step method. First, Mr. Bakewell identified Align's U.S. investments; second, he allocated these investments to the color scanners products; and third, he considered the context of these investments to evaluate their qualitative and quantitative significance. Tr. at 615:25-616:7. I analyze each step below.

With respect to Mr. Bakewell's first step—identifying U.S. investments—there is no serious dispute. While 3Shape repeatedly urges me to consider the fact that Align has investments in other countries, 3Shape does not dispute the domestic investments identified by Mr. Bakewell in his first step were actually made in the United States. For instance, 3Shape does not dispute that Align recently purchased a facility in San Jose, California, for “about \$45 million,” and put “about \$30 million of additional capital into it” to turn it into Align's headquarters. Tr. at 239:18-22. Align also has a major U.S. facility in Raleigh, North Carolina. Tr. at 240:23-241:1. 3Shape

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does not dispute that Align pays employees at both of those facilities. Tr. at 239:23-240:22, 147:20-148:1, 241:2-5. In fact, 3Shape's brief "does not dispute that Align is a large company with U.S. facilities and employees." RRB at 51.

Mr. Bakewell's second step—the allocation step—is more disputed. Mr. Bakewell testified about three different ways that Align's domestic expenditures could be allocated to the color scanner patents. An examination of only one of Mr. Bakewell's methods—his sales allocation method—is sufficient to resolve the dispute.

In his sales allocation method, Mr. Bakewell allocated Align's expenditures proportionally to sales of Align's two main products: clear aligners and scanners. To calculate the appropriate proportions, Mr. Bakewell relied upon Align's internal sales data and Align's public financial statements submitted to the SEC, including JX-0141, JX-0144, JX-0145, JX-0142, JX-0092, CPX-0216C and CPX-0214C. Align's U.S. clear aligner sales for this period ranged from [REDACTED] of Align's total U.S. sales, and its U.S. scanner sales ranged from [REDACTED] of Align's total U.S. sales. Tr. at 641:6-642:22; CX-1549C; CX-1550C; CX-1551C; CX-1552C.

Mr. Bakewell's sales allocation methodology has indicia of reliability because it generally comports with other descriptions of Align's business in the record. Align describes its business to the SEC as being divided along the same line as Mr. Bakewell's sales allocation, with the clear aligner segment on one side and the scanner segment on the other. JX-0146 at .0065; JX-0093 at Align-1091\_00577135; JX-0141 at 0033. 3Shape admits that Align's SEC filings are reliable. RRB at 56. 3Shape's expert Mr. Green studied those filings and calculated that, after general corporate expenses are excluded, "[REDACTED] of the allocated expenses are Scanners." RRB at 60. Mr. Bakewell's sales allocation percentages are on the same order of magnitude as Mr. Bakewell's, and if anything Align's calculations are more conservative than 3Shape's.

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With respect to plant and equipment under section 337(a)(3)(A), Mr. Bakewell calculated Align's plant and equipment acquisition costs, rents, and depreciation for its San Jose and Raleigh facilities for 2015, 2016, 2017, and the first quarter of 2018. Mr. Bakewell then prorated the plant and equipment investments Align made each year or quarter proportionally to the percentage of Align's domestic sales revenue derived from U.S. scanner sales during the same period. Tr. at 641:6-642:22. This resulted in a proportional plant and equipment investment of about [REDACTED] for the total period. CX-1543C. I find this calculation to be a reasonable reflection of the proportion of Align's domestic plant and equipment investments attributable to the color scanner patents.

With respect to labor under section 337(a)(3)(B), Mr. Bakewell identified Align payroll expenditures for a set of U.S. employees in 2015, 2016, 2017, and the first quarter of 2018. Tr. at 657:4-660:20; JPX-0001C. Mr. Bakewell excluded non-technical sales and marketing personnel and part-time employees from this tabulation. Tr. at 187:2-16; 611:12-612:3, 658:1-8. Mr. Bakewell then prorated the payroll expenditures Align made each year or quarter proportionally to the percentage of Align's domestic sales revenue derived from U.S. scanner sales during the same period. Tr. at 660:24-663:2. This resulted in a proportional labor expenditure of nearly [REDACTED] [REDACTED] for the total period. *Id.*; CX-1543C; CX 1547C. More than a quarter of those labor costs ([REDACTED]) were for U.S. employees involved in research and development. *Id.* I find this calculation to be a reasonable reflection of the proportion of Align's domestic labor expenditures attributable to the color scanner patents.

Mr. Bakewell offered two other methods for apportioning investments to the color scanner patents in his second step. He calls these methods "management-based" allocation and "responsibilities-based" allocation. 3Shape devotes the bulk of its economic prong arguments to

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attacking these allocation methods. I need not dwell on Align's arguments based on Mr. Bakewell's other allocation methods because his sales-based allocation method is sufficiently reliable. Importantly, 3Shape raises no specific criticism of Mr. Bakewell's sales allocation methodology in its brief. *See* RRB at 51-55. The sales allocation method applied by Mr. Bakewell has been widely accepted at the Commission. *See, e.g., Certain Ground Fault Circuit Interrupters and Products Containing Same*, Inv. No. 337-TA-739, Comm'n Op. at 77 (June 8, 2012); *Certain Digital Televisions and Certain Products Containing the Same*, Inv. No. 337-TA-617, Final Initial Determination at 159 (Nov. 17, 2008) (unreviewed in relevant part).

The last step in Mr. Bakewell's analysis was consideration of the "significance" of Align's investments. 3Shape disputes this analysis. RRB at 70-75. As explained below, I find that a preponderance of the evidence in the record demonstrates that Align's investments are significant.

As to the quantitative significance of Align's investments, 3Shape's expert Mr. Green admitted that the financial data show that Align spent [REDACTED] on domestic R&D payroll attributable to color scanners in 2017 alone. Tr. at 1237:11-20. The actual number is about [REDACTED] Tr. at 661:19-662:3; CX-1543C. I find that amount alone is quantitatively significant. The domestic R&D payroll attributable to scanners for the whole 2015-2018 period is more than [REDACTED] CX-1543C. I find that amount is quantitatively significant. And I find Align's domestic plant and equipment investment of about [REDACTED] attributable to scanners in the 2015-2018 period to be quantitatively significant. CX-1543C.

As to the qualitative significance of Align's investments, I have compared Align's domestic R&D payroll investments to Align's total R&D expense worldwide. In the first quarter of 2018, for example, Align spent nearly [REDACTED] on domestic R&D labor attributable to its scanners, and worldwide it spent \$29.5 million on R&D in the same quarter. CX-1543C,

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CX-1584C. Thus, I find that about [REDACTED] of Align's total R&D expense (which includes payroll and non-payroll expenses for all products in all countries) was spent paying U.S. employees for R&D work related to scanners during that quarter. That is significant. Did Align make bigger R&D investments in other countries? Clearly it did. But it cannot be denied that Align expended [REDACTED] to pay U.S. employees for R&D work related to scanners during the 2015-2018 time period. CX-1543C.

I also find that the record data shows—independently from any expert opinion—that Align's domestic labor costs per person are much higher than its average labor costs per person worldwide. Tr. at 671:4-18; JX-0140 (2010 Form 10-K); JX-0097 (2011 Form 10-K); JX-0096 (2012 Form 10-K); JX-0141 (2013 Form 10-K); JX-0144 (2014 Form 10-K); JX-0145 (2015 Form 10-K); JX-0142 (2016 Form 10-K); JX-0143 (2017 Form 10-K); CPX-0104C (payroll expenses). Based on that data, I find that the Align employees adding the most value to Align's scanners are the employees working on scanner activities in the United States. *See also* Tr. at 671:4-18. That makes sense because Align's top executives work in the United States. Tr. at 239:23-240:22. These are the people driving high-level decisions about product features and R&D priorities. *Id.*; *see also* Tr. at 147:20-148:1. The sales-based allocation method I approved above credits a proportion of the payroll expenses and plant space for these high-value-adding employees. The qualitative nature of their work and the investments that fund that work are significant.

In sum, I find that Align has shown a significant investment in plant and equipment and a significant employment of labor in relation to articles alleged to be protected by the color scanner patents, in satisfaction of the economic prong of 19 U.S.C. § 1337(a)(3)(A) and (B).

## VII. CONCLUSIONS OF LAW

1. The Commission has personal jurisdiction over the parties, subject-matter jurisdiction over the investigation, and *in rem* jurisdiction over the accused Trios scanners.

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2. The importation or sale requirement of section 337 is satisfied as to 3Shape Trios A/S and the Trios scanners.
3. 3Shape infringes claims 1 and 26 of U.S. Patent No. 8,363,228.
4. Claims 1, 4, and 26 of U.S. Patent No. 8,363,228 are not invalid as obvious.
5. Claims 1, 4, and 26 of U.S. Patent No. 8,363,228 are invalid for lacking written description support.
6. The technical prong of the domestic industry requirement for U.S. Patent No. 8,363,228 has not been satisfied.
7. The economic prong of the domestic industry requirement for U.S. Patent No. 8,363,228 has been satisfied.
8. 3Shape infringes claim 1 of U.S. Patent No. 8,451,456.
9. Claims 1 and 15 of U.S. Patent No. 8,451,456 are not invalid as obvious.
10. Claims 1 and 15 of U.S. Patent No. 8,451,456 are invalid for lacking written description support.
11. The technical prong of the domestic industry requirement for U.S. Patent No. 8,451,456 has not been satisfied.
12. The economic prong of the domestic industry requirement for U.S. Patent No. 8,451,456 has been satisfied.
13. 3Shape infringes claim 1 of U.S. Patent No. 8,675,207.
14. Claim 1 of U.S. Patent No. 8,675,207 is invalid as obvious.
15. Claim 1 of U.S. Patent No. 8,675,207 is not invalid as indefinite.
16. The technical prong of the domestic industry requirement for U.S. Patent No. 8,675,207 has not been satisfied.
17. The economic prong of the domestic industry requirement for U.S. Patent No. 8,675,207 has been satisfied.
18. 3Shape does not infringe claim 12 of U.S. Patent No. 9,101,433.
19. Claim 12 of U.S. Patent No. 9,101,433 is not invalid as obvious.
20. Claim 12 of U.S. Patent No. 9,101,433 is not invalid as anticipated.
21. Claim 12 of U.S. Patent No. 9,101,433 is not invalid as indefinite.

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22. The technical prong of the domestic industry requirement for U.S. Patent No. 9,101,433 has been satisfied.
23. The economic prong of the domestic industry requirement for U.S. Patent No. 9,101,433 has been satisfied.
24. 3Shape induced infringement of the '228, '456, and '207 patents.
25. 3Shape contributorily infringed the '228, '456, and '207 patents.
26. U.S. Patent No. 6,948,931 and U.S. Patent No. 6,685,470, which expire 48 days prior to the target date for this investigation, are terminated from this investigation.
27. 3Shape's equitable defenses fail.
28. The investigation should be terminated with respect to articles alleged to infringe the '931 patent without a finding of violation.
29. The investigation should be terminated with respect to articles alleged to infringe the '470 patent without a finding of violation.

### VIII. RECOMMENDED DETERMINATION ON REMEDY & BOND

The Commission's Rules provide that the administrative law judge shall issue a recommended determination concerning the appropriate remedy in the event that the Commission finds a violation of section 337, and the amount of bond to be posted by respondents during Presidential review of the Commission action under section 337(j). *See* 19 C.F.R. § 210.42(a)(1)(ii).

#### A. Findings of Fact Relevant to Remedy and Bond

As noted *supra*, I have found that 3Shape Trios A/S imported the accused Trios scanners into the United States. *See supra* § II.D. I also find, as a factual matter, that 3Shape Trios A/S, 3Shape A/S, and 3Shape Inc., are so closely related that any remedial orders the Commission ultimately issues on the basis of that importation should be directed to all three entities, all of whom appeared and were represented in this investigation. This follows from a number of observations. First, 3Shape's own briefing makes no distinction between actions taken by the three

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3Shape entities in the context of acts alleged to be patent infringement. RRB 12-33. No corporate distinction is made in 3Shape's briefing on remedy and bonding either. *See, e.g.*, RRB at 76-79. Second, 3Shape acknowledges in its prehearing brief that "3Shape A/S, 3Shape Trios A/S, and 3Shape Inc. are 'sister' corporations that are wholly-owned subsidiaries of 3Shape Holdings A/S." RPB at 13. Third, earlier in this investigation, in the context of a motion for summary determination of no violation with respect to 3Shape Inc., 3Shape presented a declaration to establish that 3Shape Inc. was not a subsidiary of any other respondent in this investigation, but that declaration was signed by senior legal counsel for 3Shape A/S, further demonstrating the close relationship between 3Shape's "sister companies." Mot. No. 1091-006, Ex. 7 (Feb. 20, 2018) (EDIS Doc. 636822).

The Commission routinely crafts its remedial orders such that they apply to "Respondents or any of their affiliated companies, parents, subsidiaries, or other related business entities." *E.g.*, *Certain Insulated Beverage Containers, Components, Labels, and Packaging Materials Thereof*, Inv. No. 337-TA-1084, Transmittal of Limited Exclusion Order, LEO at ¶ 1 (Feb. 8, 2019). There is no reason to depart from that practice in this investigation, particularly where the record shows that the three 3Shape respondents are closely related entities. Accordingly, any remedial orders that issue in this investigation should be directed to all three 3Shape respondents.

### **B. Limited Exclusion Order**

Under section 337(d), the Commission may issue a limited exclusion order directed to a respondent's infringing products. *See* 19 U.S.C. § 1337(d). A limited exclusion order instructs the U.S. Customs Service to exclude from entry all articles that are covered by the patent at issue that originate from a named respondent in the investigation. *See Fuji Photo Film Co. Ltd. v. Int'l Trade Comm'n*, 474 F.3d 1281, 1286 (2007).

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There is no dispute that, should the Commission find a violation, a limited exclusion order directed to the infringing articles upon which such a violation is predicated should issue. *See* CIB at 113; RRB at 76. Accordingly, should the Commission find a violation, I recommend that an appropriate limited exclusion order issue.

I note that in its brief, Align asserted that “the public interest factors enumerated in 19 U.S.C. §1337(d) do not preclude the issuance of the limited exclusion order.” CIB at 113. I take no position on Align’s statement as the Commission did not delegate to me responsibility to make factual findings on the public interest in this investigation. I also note that 3Shape, in its brief, requested that any limited exclusion order “include the carveouts identified in 3Shape’s Pre-Hearing Brief and a certification provision.” RRB at 76. 3Shape’s reliance on its pre-hearing brief is an obvious end-run around the word limits placed on post-hearing briefs in my ground rules. *See* Order No. 16 at G.R. 14. Accordingly, I take no position on whether the Commission should include any carveouts or certification provision based on 3Shape’s briefing prehearing briefing.

### **C. Cease and Desist Order**

Under section 337(f)(1), the Commission may issue a cease and desist order in addition to, or instead of, an exclusion order. *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, thereby undercutting the remedy provided by an exclusion order. *See Certain Crystalline Cefadroxil Monohydrate*, Inv. No. 337-TA-293, USITC Pub. 2391, Comm’n Op. on Remedy, the Public Interest and Bonding at 37-42 (June 1991); *Certain Condensers, Parts Thereof and Prods. Containing Same, Including Air Conditioners for Automobiles*, Inv. No. 337-TA-334 (Remand), Comm’n Op. at 26-28, 1997 WL 817767, at \*11-12 (U.S.I.T.C. Sept. 10, 1997).



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*Certain Integrated Repeaters, Switches, Transceivers and Prods. Containing Same*, Inv. No. 337-TA-435, Comm'n Op. at 27 (Aug. 16, 2002); Tr. at 1160:6-14, 1161:5-10, 1162:2-7, 1221:9-20). As a factual matter, 3Shape also makes the distinction that the stipulation on which Align relies to show inventory of Trios scanners does not “represent the number of fully assembled Trios units in the U.S., but [rather] components such as wands and carts.” *Id.* at 77 (citing JX-0389C at Appendix B).

I find, based on the importation stipulation between the parties, that 3Shape maintains a commercially significant inventory of Trios scanners in the United States, and therefore recommend that a cease and desist order issue in this investigation to preclude any 3Shape entity from selling or offering to sell Trios scanners in the United States, should the Commission find a violation of section 337. *See* JX-0389C at ¶ 6, Appendix B. I note that 3Shape’s primary contention—that 3Shape’s professed lack of intent to sell its domestic inventory precludes that inventory from being commercially significant—is without legal support. The relevant inquiry is whether there is a commercially significant inventory that could be sold, thus allowing 3Shape to undercut the remedy provided by an exclusion order. *See Certain Condensers, Parts Thereof and Prods. Containing Same, Including Air Conditioners for Automobiles*, Inv. No. 337-TA-334 (Remand), Comm’n Op. at 26-28, 1997 WL 817767, at \*11-12 (U.S.I.T.C. Sept. 10, 1997) (“The well-established purpose of cease and desist orders is to ensure complete relief to complainants when infringing goods are held in inventory in the United States and, therefore, beyond the reach of an exclusion order.”). I also am cognizant of the fact that each line in Appendix B to the importation stipulation on which Align relies does not necessarily equate to a whole assembled Trios scanner. *See* JX-0389C at Appendix B. Nonetheless, the Appendix includes line after line of entries for items such as “3Shape Trios Scanner with Pen Grip,” “3Shape Trios Scanner with

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Handle,” and “3Shape Trios Scanner,” among other components. *See id.* Even if some of these components would have to be combined to form a fully assembled Trios scanner, Appendix B would still provide ample evidence of a commercially significant inventory.

Finally, I note that 3Shape requests any cease and desist order include a carveout for warranty and repair units of the Trios scanners. RRB at 77. Should the Commission determine to issue a cease and desist order, I also recommend that a carveout for warranty and repair activities be included, both because such a carveout is consistent with the Commission’s determinations in prior investigations, *see, e.g., Certain Sys. 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), and because the record supports the finding that 3Shape maintains domestic inventory of Trios scanners for such purposes. *See Tr.* at 1160:6-1161:4.

### **D. Bond During Presidential Review**

Pursuant to section 337(j)(3), the Administrative Law Judge and the Commission must determine the amount of bond to be required of a respondent during the 60-day Presidential review period following the issuance of permanent relief, in the event that the Commission determines to issue a remedy. *See* 19 U.S.C. §1337(j)(3). The purpose of the bond is to protect the complainant from any injury. *See* 19 C.F.R. § 210.42(a)(1)(ii), § 210.50(a)(3).

When reliable price information is available, the Commission has often set the bond by eliminating the differential between the domestic product and the imported, infringing product. *See Microsphere Adhesives, Processes for Making Same, and Prods. Containing Same, Including Self-Stick Repositionable Notes*, Inv. No. 337-TA-366, USITC Pub. 2949, Comm’n Op. at 24 (Dec. 8, 1995). In other cases, the Commission has turned to alternative approaches, especially when the level of a reasonable royalty rate could be ascertained. *See, e.g., Certain Integrated Circuit Telecomm. Chips and Prods. Containing Same, Including Dialing Apparatus*, Inv. No. 337-TA-

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337, Comm'n Op. at 41, 1993 WL 13033517, at \*24 (U.S.I.T.C. June 22, 1993). A 100 percent bond has been required when no effective alternative existed. *See, e.g., Certain Flash Memory Circuits and Prods. Containing Same*, Inv. No. 337-TA-382, USITC Pub. No. 3046, Comm'n Op. at 26-27 (July 1997) (imposing a 100% bond when price comparison was not practical because the parties sold products at different levels of commerce, and the proposed royalty rate appeared to be *de minimus* and without adequate support in the record).

Here, Align asserts that a 100% bond rate is required because its expert, Mr. Bakewell, was “unable to find reliable product comparison information,” and because he also “found no evidence that would permit a reasonable royalty analysis.” CIB at 116 (citing Tr. at 677:6-678:15). 3Shape counters that a price comparison was practical based on the fact at least one reseller sold both Trios scanners and iTero scanners. RRB at 78 (citing Tr. at 421:25-422:5). 3Shape argues that this is not a situation where it was impractical to calculate a price differential; it is a situation where Align did not attempt to calculate a price differential. *See id.*

When a complainant “fail[s] to satisfy [its] burden to support a 100% bond or to properly explain why a reasonable royalty or price differential would be impractical,” the Commission has set a zero bond during the Presidential review period. *Certain L-Tryptophan, L-Tryptophan Products, and their Methods of Production*, Inv. No. 337-TA-1005, Comm'n Op. at 53 (Jan. 11, 2018) (public version). Such a result follows from the fact that “[t]he complainant has the burden of supporting any bond amount it proposes.” *Id.* at 52 (citing *Certain Rubber Antidegradants, Components Thereof and Products Containing Same*, Inv. No. 337-TA-533, Comm'n Op. at 40 (July 21, 2006)). Here, Align points only to a few lines of conclusory testimony from its expert that it would be impractical to calculate a price differential between the iTero Element scanner and the Trios scanner because Align is a direct sale company and 3Shape sells through distributors.

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See Tr. at 677:6-678:2. Align makes no attempt to explain why its expert could not calculate a price differential based on a comparison of the sale price charged to end-users of each scanner. Indeed, the record indicates that one reseller—Patterson Dental—sells both iTero and Trios scanners, making the absence of such a comparison particularly suspect. See Tr. at 421:25-422:5; JX-0192 at ¶ 2. I also note that in other investigations, differences in distribution models have not prevented experts from conducting price comparisons based on retail prices. See *Certain Dental Ceramics, Products Thereof, and Methods of Making the Same*, Inv. No. 337-TA-1050, Initial Determination on Violation of Section 337 and Recommended Determination on Remedy and Bond at 107-110 (Aug. 28, 2018) (summarizing the parties' competing price differential calculations where complainants and respondents used different distribution models).

Align has not demonstrated that it would impractical to calculate a bond rate based on the retail price differential between the iTero and Trios scanners. Rather, the evidence suggests that Align simply did not attempt to calculate a price differential, even though the record reveals at least one distributor that sells both products to end users. See Tr. at 421:25-422:5; JX-0192 at ¶ 2. Because Align bears the burden to support the 100% bond rate it has proposed, but has not carried that burden, I recommend that the Commission enter a bond rate of 0% should it find a violation.

### IX. INITIAL DETERMINATION

Based on the foregoing, I have determined that no violation of section 337 of the Tariff Act of 1930, as amended, has occurred in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain color intraoral scanners and related hardware and software with respect to U.S. Patent No. 8,363,228; U.S. Patent No. 8,451,456; U.S. Patent No. 8,675,207; or U.S. Patent No. 9,101,433. I have further determined

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the investigation should be terminated with respect to articles alleged to infringe U.S. Patent No. 6,948,931 and U.S. Patent No. 6,685,470 without a finding of violation.

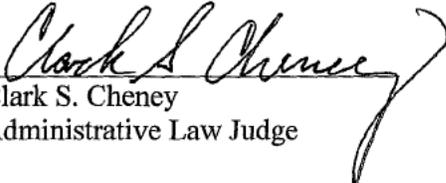
I hereby certify to the Commission this Initial Determination and the Recommended Determination.

The Secretary shall serve the confidential version of this Initial Determination upon counsel who are signatories to the Protective Order (Order No. 1) issued in this investigation. A public version will be served at a later date upon all parties of record.

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 seven days of the date of this document, each party shall submit a statement to Cheney337@ustic.gov stating whether or not it seeks to have any portion of this document redacted from the public version. Any party seeking to have any portion of this document redacted from the public version thereof shall attach a copy of this document with red brackets indicating any portion asserted to contain confidential business information.<sup>17</sup> The parties' submissions concerning the public version of this document should not be filed with the Commission Secretary.

**SO ORDERED.**

  
Clark S. Cheney  
Administrative Law Judge

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<sup>17</sup> If the parties submit excessive redactions, they may be required to provide an additional written statement, supported by declarations from individuals with personal knowledge, justifying each proposed redaction and specifically explaining why the information sought to be redacted meets the definition for confidential business information set forth in Commission Rule 201.6(a). 19 C.F.R. § 201.6(a).

**PUBLIC CERTIFICATE OF SERVICE**

I, Lisa R. Barton, hereby certify that the attached **INITIAL DETERMINATION ON VIOLATION OF SECTION 337 AND RECOMMENDED DETERMINATION ON REMEDY AND BOND** has been served by hand upon the following parties as indicated, on **July 15, 2019**



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.:**

Blair M. Jacobs, Esq.  
**PAUL HASTINGS LLP**  
875 15<sup>th</sup> Street, N.W.  
Washington, DC 20005

- Via Hand Delivery
- Via Express Delivery
- Via First Class Mail
- Other: \_\_\_\_\_

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

Goutam Patnaik, Esq.  
**PEPPER HAMILTON LLP**  
2000 K Street, N.W.  
Suite 600  
Washington, DC 20006-1865

- Via Hand Delivery
- Via Express Delivery
- Via First Class Mail
- Other: \_\_\_\_\_