PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of	
CERTAIN INTRAORAL SCANNERS AND RELATED HARDWARE AND SOFTWARE	**Inv. No. 337-TA-1090**

INITIAL DETERMINATION ON VIOLATION OF SECTION 337; RECOMMENDED DETERMINATION ON REMEDY AND BONDING

Administrative Law Judge Dee Lord

(April 26, 2019)

Appearances:

For Complainant Align Technology Inc.:

Blair M. Jacobs, Esq., Christina A. Ondrick, Esq., John S. Holley, Esq., Mark Consilvio, Esq., and Elizabeth Bernard, Esq. of Paul Hastings LLP in Washington, DC; Thomas A. Counts, Esq. and Grant A. Margeson, Esq. of Paul Hastings LLP in San Francisco, CA; and Raymond W. Stockstill, Esq. of Paul Hastings LLP in Costa Mesa, CA.

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

Goutam Patnaik, Esq., Tuhin Ganguly, Esq., and David J. Shaw, Esq. of Pepper Hamilton LLP in Washington, DC; William D. Belanger, Esq., Gregory D. Len, Esq., Frank D. Liu, Esq., Britanee L. Friedman, Esq., and L. Andrew Tseng, Esq. of Pepper Hamilton LLP in Boston, MA, Charles F. Koch of Pepper Hamilton LLP in Redwood City, CA; S. Lloyd Smith, Esq., Kimberly Coghill, Esq., and Kyle Tsui, Esq. of Buchanan Ingersoll & Rooney PC of Alexandria, VA; and Philip L. Hirschhorn, Esq. of Buchanan Ingersoll & Rooney PC of New York, NY.

PUBLIC VERSION

Pursuant to the Notice of Investigation (Dec. 13, 2017) and Commission Rule 210.42, this is the administrative law judge's final initial determination and recommendation determination on remedy and bonding in the matter of *Certain Intraoral Scanners and Related Hardware and Software*, Commission Investigation No. 337-TA-1090. 19 C.F.R. § 210.42(a)(1)(i).

For the reasons discussed herein, it is my final initial determination that there is no violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, in the importation into the United States, the sale for importation, and/or the sale within the United States after importation of certain intraoral scanners and related hardware and software with respect to U.S. Patent No. 8,638,447 (the "'447 patent"), U.S. Patent No. 8,638,448 (the "'448 patent"), or U.S. Patent No. 9,615,901 (the "'901 patent").

TABLE OF CONTENTS

The following abbreviations may be used in this Initial Determination:

Tr.	Transcript
WS	Witness Statement
DWS	Direct Witness Statement
RWS	Rebuttal Witness Statement
JX	Joint Exhibit
CX	Complainant's exhibit
CPX	Complainant's physical exhibit
CDX	Complainant's demonstrative exhibit
RX	Respondent's exhibit
RPX	Respondent's physical exhibit
RDX	Respondent's demonstrative exhibit
CPHB	Complainant's pre-hearing brief
CIB	Complainant's initial post-hearing brief
CRB	Complainant's reply post-hearing brief
RPHB	Respondent's pre-hearing brief
RIB	Respondent's initial post-hearing brief
RRB	Respondent's reply post-hearing brief

I. BACKGROUND

A. Procedural History

The Commission instituted this investigation in response to a complaint filed by Align Technology, Inc. ("Align") alleging violations of section 337 of the Tariff Act of 1930, as amended, by reason of infringement of certain claims of U.S. Patent No. 9,615,901 ("the '901 patent"), U.S. Patent No. 8,638,448 ("the '448 patent"), U.S. Patent No. 8,638,447 ("the '447 patent"), U.S. Patent No. 6,845,175 ("the '175 patent"), and U.S. Patent No. 6,334,853 ("the '853 patent") by Respondents 3Shape A/S and 3Shape, Inc. The Commission ordered that an investigation be instituted 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 intraoral scanners and related hardware and software by reason of infringement one or more of claims 1-7 and 15-20 of the '901 patent; claims 1-9 and 15-22 of the '448 patent; claims 1-7, 10, 12, and 17-24 of the '447 patent; claims 1-4, 14, 15, and 18-20 of the '175 patent; and claims 1, 3-7, and 9-13 of the '853 patent; and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

Notice of Investigation at 2. The investigation was instituted upon publication of the notice of investigation in the *Federal Register* on Tuesday, December 19, 2017. 82 Fed. Reg. 60215-16 (2017); *see* 19 C.F.R. § 210.10(b). 3Shape A/S and 3Shape, Inc. filed a response to the complaint and notice of investigation on January 8, 2018. On March 7, 2018, the complaint and notice of investigation were amended to add 3Shape Trio A/S as a respondent. Order No. 8, *not reviewed by* Comm'n Notice (Mar. 27, 2018). 3Shape A/S, 3Shape, Inc. and 3Shape Trios A/S (collectively, "3Shape") filed a response to the amended complaint on April 23, 2018.

The investigation was terminated as to the '853 and '175 patents and certain claims of the '447, '448, and '901 patents based on the withdrawal of Align's allegations. Order No. 7 (Mar.

6, 2018) (terminating investigation as to the '853 patent), *not reviewed by* Comm'n Notice (Mar. 27, 2018); Order No. 13 (Apr. 19, 2018) (terminating investigation as to claims 4, 15, 18, and 20 of the '175 patent, claims 21 and 22 of the '447 patent, and claims 7 and 20 of the '901 patent), *not reviewed by* Comm'n Notice (May 17, 2018); Order No. 20 (June 2, 2018) (terminating investigation as to claims 2-9 of the '448 patent), *not reviewed by* Comm'n Notice (July 18, 2018); Order No. 20 (Aug. 14, 2018) (terminating investigation as to the '175 patent, claims 1-7, 10, and 12 of the '447 patent, and claim 1 of the '448 patent), *not reviewed by* Comm'n Notice (Aug. 30, 2018); Order No. 34 (terminating claim 18 of the '447 patent and claims 16, 17, 21, and 22 of the '448 patent), *not reviewed by* Comm'n Notice (Nov. 5, 2018).

A *Markman* hearing was held in this investigation on June 20 2018, and a *Markman* order, issued on September 25, 2018. Order No. 28. The evidentiary hearing was held on November 5-9, 2018. The target date is Monday, August 26, 2019. Order No. 45 (Apr. 3, 2019).

B. The Private Parties

1. Complainants

The complainant is Align Technology, Inc. ("Align"). Notice of Investigation at 2. Align is a Delaware corporation with a principal place of business in San Jose, California. Second Amended Complaint ¶ 13. In 2011, Align acquired Cadent Holdings, Inc. ("Cadent"), an Israeli company that owned the patents asserted in this investigation. *Id.* ¶ 15.

2. Respondents

The respondents are 3Shape A/S, 3Shape, Inc. and 3Shape Trios A/S. Order No. 8 (Mar. 7, 2018). 3Shape A/S is a Danish corporation with its principal place of business in Copenhagen, Denmark. Response to Second Amended Complaint ¶ 17. 3Shape, Inc. is a Delaware corporation with a principal place of business in Warren, New Jersey. *Id.* ¶ 18.

3Shape Trios A/S is a Danish corporation with its principal place of business in Copenhagen, Denmark. *Id.* ¶ 19. 3Shape A/S, 3Shape, Inc. and 3Shape Trios A/S are "sister" corporations that are wholly-owned subsidiaries of 3Shape Holdings A/S. RIB at 8.

C. Products at Issue

The products at issue are intraoral scanner systems. The accused products are scanners made by 3Shape with the brand name Trios 3, and the domestic industry products are scanners made by Align with the brand name iTero Element.

D. Asserted Patents

Through multiple intervening applications, the '447, '448, and '901 patents claim priority to application PCT/IL 99/004431, filed on August 5, 1999. '447 patent at cover; '448 patent at cover; '901 patent at cover.[1] Because of their common ancestry, the patents' specifications are almost identical. Order No. 32 (Sept. 25, 2018) at 5. All three patents identify the same two individuals as inventors, relate to confocal scanning technology, and are entitled "Method and Apparatus for Imaging Three-Dimensional Structure." '447 patent at cover; '448 patent at cover; '901 patent at cover. The '447 and '448 patents issued on January 28, 2014 from applications filed on September 14, 2012 and March 4, 2013, respectively. '447 patent at cover; '448 patent at cover. The '901 patent issued on April 11, 2017, from an application filed on June 18, 2015. '901 patent at cover.

1. Patent Specifications

The asserted patents are directed to methods and apparatuses for imaging three-dimensional structures, such as the surface topology of a "teeth segment." '901 patent, col. 2:28-

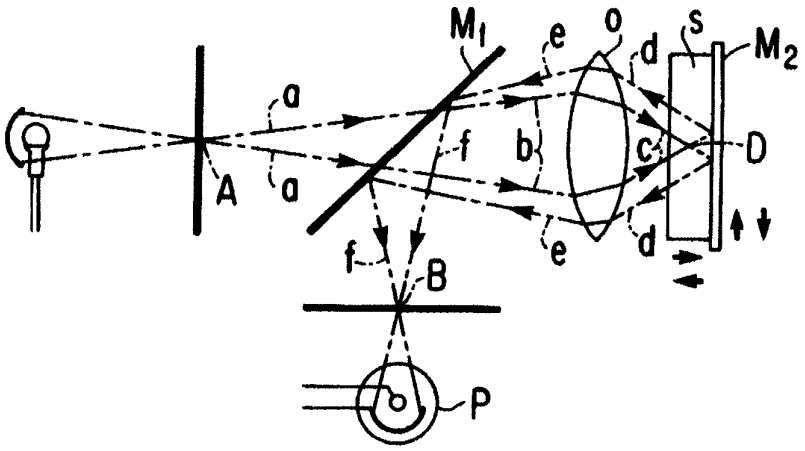
[1] The '447 patent is exhibit JX-0001, the '448 patent is exhibit JX-0002, and the '901 patent is JX-0003.

32. Such imaging allows for "the generation of data for subsequent use in design and manufacture of, for example, prosthesis of one or more teeth for incorporation into said teeth segment." *Id.*, col. 2:32-35.

Prior to the purported invention, a number of methods and apparatuses were used for "direct optical measurement of teeth and the subsequent automatic manufacture of dentures." *Id.* at col. 1:49-51. "Direct optical measurement" involves the "surveying of teeth in the oral cavity of a patient." *Id.*, col. 1:51-53. One such prior art technique used laser triangulation to measure the distance between a tooth and an optical distance probe. *Id.*, col. 1:62-66. According to the patents, data obtained from laser triangulation was often not accurate because the surface of the tooth did not reflect light optimally. *Id.*, col.1:66-col. 2:3. Other prior art techniques required the teeth to be covered with a coating at a specific thickness. *Id.*, col. 2:4-12. Failure to obtain the correct thickness resulted in inaccurate measurements. *Id.*, col. 2:12-14. Another prior art technique involved mapping the teeth by "physical scanning of the surface by a probe and by determining the probe's position, *e.g.* by optical or other remote sensing means." *Id.*, col. 2:15-18. As an example of this technique, the specification discusses U.S. Patent No. 5,372,502, which discloses a method wherein "[v]arious patterns are projected onto the tooth or teeth to be measured and corresponding plurality of distorted patterns are captured by [a] probe," with "[e]ach interaction provid[ing] refinement of the topography." *Id.*, col. 2:19-24. The asserted patents do not criticize this prior art approach.

Two main embodiments of the purported invention are disclosed. Both embodiments "rel[y] on confocal imaging principles." CX-1940C (Ferraro WS) at Q/A 28; *see also* CX-1944C (Ferraro RWS) at Q/A 26 ("The invention disclosed in the Asserted Patents repeatedly references confocal imaging principles. The demonstrative CDX-0007C.4 illustrates an original

schematic of a confocal imaging system from the Minsky patent."); '901 patent, Fig. 1A ("confocal optics 42"), Fig. 4 ("optic unit 162" co-labelled 42). Confocal imaging techniques were first developed in the late 1950s by Marvin Minsky, the inventor of the confocal microscope. Handbook of Biological Confocal Microscopy (Revised Ed. 1990) ("Handbook," CX-1477) at 4. The figure below shows the optical path of one embodiment of Dr. Minsky's microscope.



Id. at 4, Fig. 2. The light from the light source is limited by entrance pinhole A and a reduced image of the pinhole is projected onto on the specimen as spot D by light beam a-b-c. *Id.* Light beam d-e is reflected from the specimen to mirror M_1, which reflects the light beams to exit pinhole B. *Id.* Entrance pinhole A, spot D, and exit pinhole B are confocal to each other, *i.e.*, they have the same focus.[2] *Id.*; Tr. (Christiansen) at 187:3-15; Tr (Zavislan) at 908:22-909:11.

[2] "Confocal" can be used used to describe two or more optical elements that are "optically in the same position," such that they have the same focus. Tr. (Christiansen) at 187:3-15; Tr (Zavislan) at 908:22-909:11. "Confocal," however, can also be used to refer to specific imaging techniques that rely on the principles underpinning Dr. Minsky's confocal microscope. CX-1477.0018. The Handbook's description of "Confocal Imaging" uses "confocal" in both senses. *Id.* First, "confocal" is used in the term "confocal imaging" to refer to Dr. Minsky's confocal microscopy.

While the original application of confocal imaging was in a microscope, the asserted patents apply confocal imaging principles to a scanner determining the three-dimensional topography of an object. CX-1940C (Ferraro WS) at Q/A 29. Instead of illuminating a single spot on the object being scanned, the disclosed invention splits a parent light beam into multiple incident light beams that are projected onto the surface being scanned. *Id.*

2. The Asserted Claims of the '901 Patent

Align is asserting claims '901 patent 1-6 and 15-19 of the '901 patent. Claims 1 and 5 are independent. Claim 1 recites:

> An apparatus for determining surface topology of a portion of a three-dimensional structure, the apparatus comprising:
>
> a probing member;
>
> an illumination unit configured to generate a plurality of incident light beams;
>
> an optical system configured to focus the plurality of incident light beams to a focal plane external to the probing member so as to illuminate the portion of the three-dimensional structure;
>
> a detector unit configured to measure a characteristic of a plurality of returned light beams generated from illuminating the portion of the three-dimensional structure with the plurality of incident light beams; and
>
> a processor coupled to the detector unit and configured to determine a surface topology of the portion of the three-dimensional structure based at least in part on the measured characteristic of the plurality of returned light beams.

Id. ("**CONFOCAL IMAGING** As a young postdoctoral fellow at Harvard University, Marvin Minsky applied for a patent in 1957 for a microscope that uses a stage-scanning confocal optical system. Not only was the conception far sighted, but his insight into the potential application and significance of confocal microscopy was nothing short of remarkable."). In describing the optical path of Dr. Minsky's confocal microscope, the Handbook uses "confocal" to describe the relationship between various optical elements. *Id.* ("Optical path in simple confocal microscope. The condenser lens (C) forms an image of the first pinhole (A) onto a confocal spot (D) in the specimen (S). The objective lens (0) forms an image of (D) onto the second (exit) pinhole (B) which is confocal with (D) and (A).").

'901 patent, col. 8:49-67.

Claims 2 and 3 depend directly from claim 1. Claim 2 requires that the detector unit have "a plurality of sensor elements each configured to measure the characteristic of a corresponding returned light beam in the plurality of returned light beams." *Id.*, col. 9:1-4. Claim 3 requires that the optical system have "a translation mechanism configured to change a position of the focal plane over a range of focal plane positions relative to the probing member." *Id.*, col. 9:5-8. Claim 4 requires that the detector unit of claim 3 "measure the characteristic of the plurality of returned light beams over the range of focal plane positions." *Id.*, col. 9:9-11. Claim 5 requires the processor of claim 4 "determine the surface topology based on the characteristic of the plurality of returned light beams measured by the detector unit over the range of focal plane positions." *Id.*, col. 9:12-17. Claim 6 requires that the translation mechanism of claim 3 "change the position of the focal plane along a direction of propagation of the plurality of incident light beams." *Id.*, col. 9:17-20.

Claim 15 recites:

> A method for imaging a portion of a three-dimensional structure, the method comprising:
>
> providing a probing member;
>
> generating a plurality of incident light beams;
>
> focusing the plurality of incident light beams to a focal plane external to the probing member so as to illuminate the portion of the three-dimensional structure;
>
> measuring a characteristic of a plurality of returned light beams generated from illuminating the portion of the three-dimensional structure with the plurality of incident light beams; and
>
> determining a surface topology of the portion of three-dimensional structure based at least in part on the measured characteristic of the plurality of returned light beams.

Id., col. 10:17-31.

Claim 16 requires the method of claim 15 include a step of "changing a position of the focal plane over a range of focal plane positions relative to the probing member." *Id.*, col. 10:32-34. Claims 17 and 18 depend from claim 16. Claim 17 requires changing "the position of the focal plane of the plurality of incident light beams . . . along a direction of propagation of the plurality of incident light beams." *Id.*, col. 10:35-38. Claim 18 requires the measurement of "the characteristic of the plurality of returned light beams . . . over the range of focal plane positions." *Id.*, col. 10:39-41. Claim 19 depends from claim 17 and requires the surface topology of the three-dimensional structure be "determined based on the characteristic of the plurality of returned light beams measured over the range of focal plane positions." *Id.*, col. 10:42-45.

3. The Asserted Claims of the '447 Patent

Align is asserting claims 17, 19, 20, 23, and 24 of the '447 patent. CIB at 117. Claim 17 is independent and the remaining claims depend directly or indirectly from claim 17. Claim 17 recites:

> An apparatus for determining surface topology of at least a portion of a three-dimensional structure, the apparatus comprising:
>
> a probing member having a sensing face;
>
> an illumination unit configured to transmit a parent light beam along an optical path in the hand-held probe;
>
> a module positioned in the optical path and configured to generate a plurality of incident light beams;
>
> an optical system configured to focus the plurality of incident light beams at a focal plane forward of the sensing face;
>
> a detector unit configured to measure intensities of a plurality of returned light beams that are generated from illuminating the portion of the three-dimensional structure with the plurality of incident light beams; and

> a processor coupled to the detector unit and configured to determine a surface topology of the three-dimensional structure based at least in part on the measured intensities of the plurality of returned light beams.

'447 patent, col. 10:3-20.

Claims 19 and 23 depend directly from claim 17. Claim 19 requires that the optical system have "a translation mechanism configured to change the focal plane of the plurality of incident light beams over a range of focal plane positions." *Id.*, col. 10:25-28. Claim 23 requires that the module be "configured to produce a pattern of the plurality of incident light beams." *Id.*, col. 10:38-40. Claims 20 and 24 depend from claim 19. Claim 20 requires that the translation mechanism of claim 19 "change the focal plane of the plurality of incident light beams while maintaining a fixed distance between the hand-held probe and the three-dimensional structure." *Id.*, col. 10:29-33. Claim 24 requires that the processor "determine the surface topology based on the maximum intensity of each returned light beam measured over the range of focal plane positions," where the "intensities of the plurality of returned light beams depend[] on the position of the focal plane of the plurality of incident light beams." *Id.*, col. 10:41-46.

4. The Asserted Claims of the '448 Patent

Align is asserting claims 15 and 18-20 of the '448 patent. CIB at 117. Claim 15 is independent and the remaining claims depend directly or indirectly from claim 15. Claim 15 recites:

> An apparatus for determining surface topology of at least a portion of a three-dimensional structure, the apparatus comprising:
>
> a probing member comprising a probing end;
>
> an illumination unit configured to generate a plurality of incident light beams for illuminating the portion of the three-dimensional structure;
>
> an optical system configured to focus the plurality of incident light beams at a plurality of focal planes forward of the probing end;

> a detector unit configured to measure intensities of a plurality of returned light beams that are generated from illuminating the portion of the three-dimensional structure with the plurality of incident light beams; and
>
> a processor coupled to the detector unit and configured to determine a surface topology of the three-dimensional structure based at least in part on the measured intensities of the plurality of returned light beams.

'448 patent, col. 10:3-21.

Claims 18 and 19 depend directly from claim 15. Claim 18 requires that "the illumination unit comprise[] a module configured to generate the plurality of incident light beams," so that "the plurality of incident light beams form a pattern of illuminated areas on the portion of the three-dimensional structure." *Id.*, col. 10:29-32. Claim 19 requires that the apparatus have "a translation mechanism configured to change the focal plane of the plurality of incident light beams over a range of focal plane positions." *Id.*, col. 10:33-37. Claim 20 depends from claim 19 and requires that the apparatus be able to change the focal plane of the plurality of incident light beams while a fixed distance maintained between the probing end and the three-dimensional structure." *Id.*, col. 10:38-42. Claim 20 further requires that the "probing end" have a "sensing face."

E. Level of Ordinary Skill in the Art

In the *Markman* order, I adopted Align's proposed definition for the level of ordinary skill in the art: a person of ordinary skill in the art would have "at least a bachelor's degree in electrical engineering, computer engineering, physics or an equivalent field, as well as at least one or two years of experience in optical scanning, at least five years of comparable experience in optical scanning, or an equivalent combination of academic study and work experience." Order No. 32 at 6.

F. Witness Testimony

I received testimonial evidence in this investigation in the form of witness statements, live testimony, and deposition designations.

1. Fact Witnesses

Align began the hearing with the testimony of its chief technology officer and senior vice president Zelko Relic (CX-1938C). Tr. 60-99. Align's second witness was its CEO, Joseph Hogan (CX-1937C). *Id.* 101-154. Align also called its CFO, John Morici (CX-1939C), and its vice president and chief scientist, Avi Kopelman (CX-1936C). *Id.* 210-241, 269-307. Align further called its senior director of global sales and marketing, Kerri Kling (CX-1935C), and its chief marketing officer, Raphael Pascaud (CX-1942C). *Id.* 1013-1103. Align also examined several adverse witnesses from 3Shape, Esben Rosenlund, Mads Broekner Christiansen, and Wendy Cohen. *Id.* 154-208, 1001-1013.

3Shape presented testimony from its vice president of orthodontics, Allan Hyldal (RX-1293C). Tr. 450-493. 3Shape also called its co-founder and co-CEO Tais Clausen (RX-1294C and RX-1569C), Tr. 541-582, and its vice president of sales, Christoffer Melchior (RX-1295C). Tr. 584-611. 3Shape further relied on testimony from its vice president of product strategy, Rune Fisker (RX-1292C and RX-1568C). Tr. 613-642. 3Shape also called its senior director of research and development, Mike Van Der Poel (RX-1565C). Tr. 809-900.

3Shape also examined adverse witness Timothy Mack, the former president and CEO of Cadent. Tr. 502-540. 3Shape further examined adverse witnesses who are Align employees: Michael Sabina, Michael Stubbs, and Yosi Attaya. *Id.* 656-712, 795-808.

2. Expert Witnesses

Align's technical expert is Richard Ferraro, whose testimony was qualified as that of an expert in the fields of scanning technology, three-dimensional graphics, imaging, and image processing. CX-1940C; CX-1944C; Tr. 309-409, 1105-1125; *see id.* at 312 (expert qualification). Align's economic expert is W. Christopher Bakewell, whose testimony was qualified as that of a financial and economic expert. CX-1941C; Tr. 413-448; *see id.* at 416 (expert qualification).

3Shape's technical expert regarding invalidity is David Kessler, whose testimony was qualified as that of an expert in optics and imaging systems. RX-1299; Tr. 643-656; *see id.* at 645 (expert qualification). 3Shape's economic expert is Philip Green, whose testimony was qualified as that of an expert in accounting, finance and valuation issues associated with intellectual property. RX-1566C; Tr. 732-794; *see id.* at 736 (expert qualification). 3Shape's technical expert regarding infringement is James M. Zavislan, whose testimony was qualified as that of an expert in optical engineering and optical imaging systems. RX-1567C; Tr. 901-986; *see id.* 902-03 (expert qualification).

3. Joint Exhibits

The parties submitted numerous joint exhibits, including thirty separate designated deposition transcripts. *See, e.g.,* JX-0043C, JX-0063C, JX-0468.

II. JURISDICTION

In order to have the power to decide a case, a court or agency must have both subject matter jurisdiction and jurisdiction over either the parties or the property involved. 19 U.S.C. § 1337; *Certain Steel Rod Treating Apparatus and Components Thereof*, Inv. No. 337-TA-97, Commission Memorandum Opinion, 215 U.S.P.Q. 229, 231 (1981).

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). The Commission has subject matter jurisdiction over this investigation based on Align's allegation that 3Shape has imported the accused products. *Amgen Inc. v. Int'l Trade Comm'n*, 902 F.2d 1532, 1536 (Fed. Cir. 1990). 3Shape does not dispute that 3Shape Trios A/S imports the accused products and has stipulated to this importation by 3Shape Trios A/S. Joint Stipulation Regarding Importation (Aug. 21, 2018).[3]

B. Personal Jurisdiction

Respondents do not raise any arguments regarding the Commission's personal jurisdiction in their post-hearing briefs. 3Shape answered the Complaint and Notice of Investigation, participated in the investigation, appeared at hearings, and submitted pre- and post-hearing briefs, thus submitting to the personal jurisdiction of the Commission. *See Certain Miniature Hacksaws*, Inv. No. 337-TA-237, USITC Pub. No. 1948, Initial Determination at 4, 1986 WL 379287, *1 (Oct. 15, 1986), *not reviewed in relevant part by* Comm'n Action and Order, 1987 WL 450871 (Jan. 15, 1987).

C. *In Rem* Jurisdiction

The Commission has *in rem* jurisdiction over the accused products by virtue of their

[3] 3Shape argues that two of the named respondents, 3Shape A/S and 3Shape Inc., are not involved in the importation of any accused product. RIB at 10-12; RRB at 6-8. There is no dispute that 3Shape Trios A/S imports the accused products, however, and accordingly, this does not affect the Commission's jurisdiction in this investigation.

importation into the United States. *See Sealed Air Corp. v. U.S. Int'l Trade Comm'n*, 645 F.2d 976, 985-86 (C.C.P.A. 1981) (holding that the ITC's jurisdiction over imported articles is sufficient to exclude such articles).

III. IMPORTATION

A. Legal Standard

Section 337 prohibits "[t]he importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that . . . infringe a valid and enforceable United States patent." 19 U.S.C. § 1337(a)(1)(B). Accordingly, a necessary element for invoking the Commission's jurisdiction under section 337 is proof that the respondent imported, sold for importation, or sold after importation the articles at issue. *Certain Carbon and Alloy Steel Products*, Inv. No. 337-TA-1002, Order No. 103 at 33 (Oct. 2, 2017), *not reviewed by* Comm'n Notice (Nov. 1, 2017). Traditionally, the Commission has viewed its authority under section 337 (a)(1) broadly. "Whether the Commission has jurisdiction over certain activities is a question of law, and the Commission has broadly interpreted its jurisdiction under section 337." *Certain Cigarettes and Packaging Thereof,* Inv. No. 337-TA-643, 2009 WL 6751505 at *4 *("Cigarettes")* (Oct. 1, 2009) (citing *Certain Digital Satellite System (DSS) Receivers and Components Thereof,* Inv. No. 337-TA-392, Notice of Comm'n Decision to Terminate the Investigation and to Vacate Portions of Initial Determination at 14 (Apr. 2001)).

B. Respondents' Activities

Respondents admit that "the importation requirement is satisfied with respect to 3Shape Trios A/S. RIB at 10. Respondents contend, however, that 3Shape A/S and 3Shape Inc. do not satisfy the importation requirement.

The evidence shows that 3Shape A/S and 3Shape Inc. are sister companies of each other and of 3Shape Trios A/S. RX-1294C (Clausen WS) at Q/A 9; Tr. (Cohen) at 1002:1-3. The record reveals no importation or direct sales activities by these respondents, but the evidence does show that 3Shape A/S and 3Shape Inc. participate in selling accused products in the United States. These actions by 3Shape A/S and 3Shape Inc. create the nexus between the two companies and the sale of accused products in the United States that is required to satisfy the importation requirement.

The crux of 3Shape's arguments against a finding of importation by 3Shape A/S and 3Shape Inc. is that 3Shape Inc. uses an "indirect" sales model. RX-1295C (Melchior WS) at Q/A 6.[4] "We don't sell direct, so we sell through distribution. We call them resellers, I believe, or sales partners." Tr. (Clausen) at 560:1-3. "3Shape has a number of resellers in the U.S. 3Shape sells our products to the resellers and the resellers sell the products to end users." *Id.* 3Shape considers the resellers to be its customers. RX-1295C (Melchior WS) at Q/A 7. As discussed below, 3Shape Inc. and 3Shape A/S are closely connected to domestic efforts to develop sales of accused products to resellers as well as end users.

Christoffer Melchior is 3Shape A/S's vice president of global sales and customer care. Tr. (Melchior) at 594:3-5; RX-1295C (Melchior WS) at Q/A 1-3. Among his responsibilities is "to sell the portfolio of 3Shape products" worldwide. Tr. (Melchior) at 594:6-8. Mr. Melchior oversees 3Shape Inc.'s commercial organization, which includes sales, marketing, and business development components. Tr. (Melchior) at 596:18-597:11; RX-1295C (Melchior WS) at Q/A 23. The general manager of 3Shape Inc. reports to Mr. Melchior. *Id.* at Q/A 16. 3Shape Inc.'s

[4] 3Shape Inc. is 3Shape's "U.S. organization." RX-1295C (Melchior WS) at Q/A 13.

functions (which Mr. Melchior ultimately oversees), include supporting resellers "with marketing materials and marketing campaigns that the resellers can use to promote the 3Shape products." *Id.* at Q/A 22, 26. 3Shape Inc. helps "our resellers to sell scanners in America, I think that's fair to say." Tr. (Clausen) at 561:6-7.[5]

When resellers make sales calls on customers, 3Shape Inc. employees accompany them. Tr. (Melchior) at 605:6-19. 3Shape maintains that these visits do not count as sales activities because the 3Shape Inc. employees do not "make the sale," instead, they "help resellers position 3Shape and the 3Shape TRIOS in the right way." Tr. (Melchior) at 606:5-11. Although they may not actually make the sale, however, 3Shape Inc. employees are closely involved in the effort to sell the product.[6]

3Shape A/S and 3Shape Inc. employees participate in trade shows in order to promote sales. If a dentist shows interest in purchasing a 3Shape product, 3Shape Inc. employees will "walk them over to a reseller who would then be trying to make the sale." Tr. (Melchior) at

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[5] Tais Clausen is co-founder and co-CEO of 3Shape A/S. RX-1294C (Clausen WS) at Q/A 3-4. Tr. (Clausen) at 560:4-7.

[6] Under the rubric of "customer care," 3Shape Inc. trains resellers on the technical aspects of 3Shape's products and assists with troubleshooting. *Id.* at Q/A 10. Sales personnel who provide technical expertise to customers nevertheless function as salespeople, and their activities are considered sales under section 337. *See Certain Non-Volatile Memory Devices and Prods. Containing the Same ("Non-Volatile Memory"),* Inv. No. 337-TA-1046, ID at 154-186159-60 ("The Commission has not heretofore distinguished between technical sales and marketing and other types of sales and marketing, nor would it make sense to do so. If a company is importing products from abroad, it needs a sales force in the United States to sell the products. If the company's products are highly technical, the company needs a technically sophisticated cadre of marketers to sell them."), *aff'd* by Commission Op. at 44 (Oct. 26, 2018) ("The Commission has determined to affirm the ID's determination that Macronix failed to establish a domestic industry based on investments in 'customer facing' engineering for the reasons provided in the ID.").

600:8-11. 3Shape Inc. employees thus are closely involved in the effort to sell 3Shape products in the U.S. "The objective of 3Shape's activities at these trade shows is to convince orthodontists to buy 3Shape products." Tr. (Cohen) at 1009:13-15. At a recent trade show in the District of Columbia, more than a dozen 3Shape Inc. employees from Denmark and the U.S. attended. *Id.* at 1008:11-16.

Henrik Brandt, 3Shape A/S senior products manager in the orthodontics group, testifies that he has frequently attended sales meetings in the U.S. with potential customers, other 3Shape employees, and resellers. JX-0045C (Brandt Dep.) at 8:2-4. He reports that in 2017 he was deployed for four and a half months to 3Shape Inc.'s Branchburg, New Jersey facility. *Id.* at 14:21. The purpose of his stint at Branchburg was to make "a new organizational setup in North America, where we employed four what we call ortho territory managers. They divided the United States and Canada between them in four areas and their purpose was to do co-travel with our resellers—we sell indirectly—to basically sell scanners and software." *Id.* at 14:23-15:3. Mr. Brandt trained the ortho territory managers "for best practice on how you conduct a sales meeting with a customer . . . . So I was basically there to train those four ortho territory managers to say the right thing . . . and to help train our resellers." *Id.* at 15:3-9. In this capacity Mr. Brandt attended sales meetings with the ortho territory managers and resellers and visited potential customers. *Id.* at 16:13-13-20, 71:1-74:9.

Rune Fisker, another 3Shape A/S employee, attended a training session in the U.S. with the reseller Patterson Dental Group ("Patterson") in June 2017. Tr. (Cohen) at 1005:7-1006:25. According to one 3Shape Inc. employee, Mr. Fisker and other 3Shape A/S and 3Shape Inc. employees at this meeting provided training to Patterson to help sell Trios products. *Id.*

Testimony from Wendy Cohen, a 3Shape Inc. account manager, confirms that 3Shape Inc. employees participate in sales activities in the U.S. Tr. (Cohen) at 1001:18-19. 3Shape Inc. is based in Warren, New Jersey, and as of May 2018 employs about 70 people. *Id.* at 1001:20-25. Ms. Cohen confirms that 3Shape Inc. employees work with resellers "so that they can sell TRIOS products in the United States." *Id.* at 1013:3-5. She confirms that 3Shape Inc. employees participate in trade show demonstrations in the U.S. to encourage sales of accused products. Tr. (Cohen) at 1008:18-1009:20. Although they are no longer denominated "sales" managers, the actual work of 3Shape Inc.'s "account managers," is to coordinate with resellers "so that they can sell TRIOS products in the United States." *Id.* at 1012:11-18, 1013:1-6.[7]

Ms. Cohen reports that as of May 2018 3Shape Inc. employed six TRIOS resellers in the U.S. Tr. (Cohen) at 1003:11-1004:1. Ms. Cohen's job is to manage the resellers and prepare them to sell 3Shape products. *Id.* at 1002:15-17. As set forth above, Ms. Cohen testifies that 3Shape Inc.'s activities include providing sales support to U.S. resellers, Tr. at 1004:2-7, training to U.S. resellers, Tr. at 1004:8-10; technical support to U.S. resellers, Tr. at 1004:11-13; and accompanying resellers on visits to potential customers. Tr. (Melchior) at 605:3-14. Resellers also have visited a 3Shape Inc. training facility to receive additional instruction on how to sell 3Shape products. *Id.* at 16:21-17:1.

C. Discussion

The Commission's broad interpretation of the activities that can give rise to liability under section 337 has been consistent over many years and comports with the remedial purpose

[7] According to Mr. Melchior, 20 to 30 employees in the U.S., including three regional business managers, are part of 3Shape Inc.'s sales organization. Tr. (Melchior) 597:12-18, 596-5:15-20.

of the statute. *Suprema, Inc. v. Int'l Trade Comm'n*, 796 F.3d 1338, 1352 (Fed. Cir. 2015). The Commission's authority thus may be extended to parties that do not themselves engage in prohibited acts, but whose activities are so closely entwined with prohibited acts as to bring them within the broad reach of section 337. The Commission's authority extends, in short, to any case in which "some nexus" is found between the activities of the respondent and a jurisdictional element of section 337(a)(1). *Cigarettes,* 2009 WL 6751505 at *4.[8]

3Shape concedes, as it must, that it is "generally involved in training and supporting resellers, managing reseller accounts, attending trade shows and other industry events, and assisting resellers in training end users on 3Shape's products." RIB at 11. Clearly, it engages in activities the purpose and effect of which is to promote the sale in the U.S. of 3Shape's products. In the broadly remedial context of section 337, the dictionary definition of a "sale" does not necessarily limit the Commission's jurisdiction, as 3Shape contends.

This is not a case where no sale or importation actually occurs. This is not a case in which the complainant seeks to pierce the corporate veil to reach a respondent that is not involved in any activity that falls within the Commission's jurisdiction, where the allegation of importation is based merely on corporate consanguinity. In this case, both 3ShapeA/S and 3Shape Inc. themselves participate in the sale to reseller customers or the promotion for sale of accused products to the ultimate consumers and users. Accordingly, the importation requirement is satisfied with respect to these entities.

[8] It is of no moment that *Cigarettes* involves section 337(a)(1)C) instead of (a)(1)(B). Nor does it signify that the issue in *Cigarettes* is importation for sale rather than sale after importation. The principle is the same.

IV. AFFIRMATIVE DEFENSES

3Shape maintains that Align's patents are unenforceable based on the affirmative defenses of equitable estoppel, waiver, acquiescence, license, laches, and unclean hands. RIB at 168-90; RRB at 83-97.

Equity permits a court to grant relief demanded by basic fairness. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1292 (Fed. Cir. 2011). Neither the existence of a violation of equitable principles nor the remedy are subject to inflexible legal analysis. On the contrary, "'[e]quitable relief is not a matter of precise formula.'" *High Point SARL v. Sprint Nextel Corp.*, 817 F.3d 1325, 1331 (Fed. Cir. 2016) (quoting *Aspex Eyewear, Inc. v. Clariti Eyewear, Inc.*, 605 F.3d 1305, 1311 (Fed. Cir. 2010)). Based on careful review of the entire record and the factual findings recited below, I conclude that Align's conduct was misleading, but 3Shape was not misled by it. 3Shape made its own decision to engage in an interoperability arrangement with Align for its own business reasons. 3Shape did not rely on Align's misleading conduct and suffered no harm reasonably attributable to that conduct. The circumstances presented here demand no equitable remedy.

A. Factual background

The story begins at least as far back as 2003-04. At that time Cadent, which is the original source of the scanner patents at issue in this investigation, was a customer of 3Shape. Tr. (Kopelman) at 272:16-21. A relationship between the companies existed for years. *Id.* at 273:5-23; RX-1294C (Clausen WS) at Q/A 37. In the 2005-06 timeframe, Cadent began selling its own intraoral scanner, known as iTero. Tr. (Kopelman) at 272:22-23. Cadent was interested in interfacing its intraoral scan data to 3Shape's software. *Id.* at 273:17-23. iTero "became interoperable with the 3Shape lab software." *Id.* at 273:24-274:9.

In 2011, Align purchased Cadent and its scanner patents. *Id.* at 276:21-23. Several Cadent executives joined Align, among them Avi Kopelman, Cadent's cofounder and chief technical officer. Tr. (Kopelman) 272:2-24); Tr. (Mack) at 508:7-8. Mr. Kopelman's job at Align was "product development," with a focus on the U.S. market. Tr. (Mack) at 508:8-12. As part of his job, Mr. Kopelman would "attend trade shows and look at various competitors' products." *Id.* at 13-15.

[redacted]. *Id.* at 276:8-16, Tr. (Mack) at 513:2-4; 513:20-514:2. These concerns occasionally were expressed to 3Shape's personnel. [redacted], RX-1294C (Clausen WS) at Q/A 39, [redacted]. Tr. (Mack) at 512:22-513:15. [redacted] *Id.* at 513:16-19. [redacted] RX-1294C (Clausen WS) at Q/A 39. [redacted]. Tr. (Mack) at 514:10-14.

Timothy Mack also joined Align after the Cadent acquisition. Tr. (Mack) 502:12-14. He, too, had a history with 3Shape from his time as president and CEO of Cadent. *Id.* at 502:18-20. After Cadent was acquired by Align in 2011, Mr. Mack became vice president of business development and was on the executive management committee of Align (for the first 6 months he was there). *Id.* at 508:19-23. He later took on the role of corporate marketing for both Invisalign and iTero. *Id.* at 510:17-20.

Over the next several years, [redacted], *see generally*, RX-0313C, [redacted]

[redacted] *Id.* at .0020. [redacted]

[redacted] Tr. (Kopelman) at 277:2-278:22. According to Mr. Kopelman, [redacted] *Id.* at 277:16-17. [redacted] *Id.* at 277:13-20-22.

[redacted]

Meanwhile, 3Shape was pressing for an interoperability agreement with Align that would permit 3Shape's Trios scanners to be used with Invisalign clear aligners. "[W]e had an ongoing conversation with Align," Mr. Clausen testifies. RX-1294C (Clausen WS) at Q/A 40. "We were pushing for an interface between 3Shape Trios and Invisalign, and they always rejected it." *Id.*

By 2014 and 2015, Mr. Mack testifies, [redacted] Tr. (Mack) at 516:14-16. However, Mr. Mack states [redacted]

[redacted] *Id.* at 519:14-17.

An internal communication dated June 11, 2014, [redacted] RX-0294C at .0003. [redacted] *Id.*; Tr. (Mack) 518:25-519:6.

Another email chain, dated December 2014, [redacted] RX-310C at .0003. [redacted]

[redacted] *Id.*

In October 2015, Mr. Fisker of 3Shape had a discussion about "patents" with Mr. Kopelman at an event in Canada. RX-1292C (Fisker WS) at Q/A 21-22. "Avi and I both presented at the event, and in a small group discussion afterwards, Mr. Kopelman told me that [redacted]," Mr. Fisker testifies. *Id.* at Q/A 24. Mr. Fisker reports that [redacted] at that time. *Id.* at Q/A 25.

Mr. Mack recalls [redacted]. Tr. at 522:1-7. He testifies consistently [redacted] *Id.* at 523:13-15. Significantly, Mr. Mack testifies that he informed 3Shape that the obstacle to entering into an interoperability agreement was that the legal team was not finished with its analysis of the IP concerns regarding 3Shape's scanner products. "Particularly after—I think exclusively after the public announcement of Invisalign interoperability being available with the 3M scanner and then again with the Sirona scanner in 2015, when I would have these impromptu meetings, and I believe I had a couple of phone calls which I received from Flemming [Flemming Thorup, 3Shape's then-CEO, Tr. (Hogan) at 125:1-2], he would ask what—whether they could start—3Shape could start the interoperability testing. And I repeated the same comments that Avi had these general concerns

and those concerns had been forwarded to the legal department and it was their responsibility to—to do the analysis and reach a conclusion before we could start." *Id.* at 533:19-534:5.[9]

In the fall of 2015, Joseph Hogan, Align's CEO, met with Mr. Thorup to discuss interoperability and spoke with him about the possibility of a lawsuit, or at least, about IP infringement. Tr. (Hogan) at 102:6-8, 124:21-125:2. [redacted] *Id.* at 26:13. Mr. Hogan was asked at hearing [redacted] *Id.* at 127:3-8.

The record reveals no additional exchanges between the parties regarding IP concerns before the interoperability agreement was executed in December 2015. According to Raphael Pascaud, the executive with corporate responsibility for iTero development, [redacted]

[9] Joseph Hogan, Align's CEO, asserts that [redacted] Tr. (Hogan) at 119:16-24.

[redacted] Tr. (Pascaud) at 1064:24-1065:6. [redacted] *Id.* at 1065:7-11.

It is, however, quite clear that in the fall of 2015, Align was holding in reserve the possibility of asserting infringement against 3Shape in the future. Tr. (Pascaud) at 1065:22-1066:2. Mr. Pascaud stated [redacted] *Id.* at 1065:12-23.

This possibility, [redacted] JX-0319C at .0010. [redacted]

[redacted]

Id.

As noted above, there is no evidence of disclosure to 3Shape in the lead-up to the interoperability agreement that Align continued to consider patent litigation against 3Shape's scanners. [redacted] Mr. Pascaud confirmed that [redacted] *Id.* at 1100:11-21. This testimony lends support to [redacted].

In late December 2015, the discussions between the two companies culminated in a "Scanner Agreement" between Align and 3Shape. JX-0163C. The purpose of the Agreement was [redacted] *Id.* at ¶ 1.1. The Scanner Agreement [redacted]

[10] It is plain from this exchange, and consistent with other evidence, that [redacted]. It also is clear, however, that Align gave no indication in these exchanges that it continued to have IP concerns that might result in litigation. On the contrary, the implication in context is that those concerns had been overcome.

[redacted] *Id.* at ¶ 1.9. Align agreed [redacted] *Id.* at ¶ 2.2.

The Scanner Agreement provided that all confidential information disclosed by either party should remain the property of the disclosing party, and conveyed no "[redacted]." *Id.* at ¶ 3.2. It included protections against misuse of confidential information. *Id.* at ¶¶ 3.4-3.6. It provided explicitly: "[redacted]." *Id.* at ¶ 4. The agreement was signed by Mr. Thorup for 3Shape and Mr. Pascaud for Align. *Id.* at ¶ 20.

Details relating to the proposed interoperability were spelled out in Exhibit A. JX-0163C.0007. Among other terms, the parties agreed that if 3Shape's scans were acceptable following [redacted] to determine the scans' technical qualification, they would be used to manufacture aligners using Align's Invisalign system. *Id.* at .0007-.0008. Exhibit B spelled out technical specifications for qualifying the 3Shape scans. *Id.* at .0009.

3Shape's scanners eventually were approved for use with Invisalign as contemplated by the Scanner Agreement, and the result was increased business for both parties. Trios-Invisalign case submissions grew [redacted] from 2016-2017. RIB at 175, JX-0443C, Tr. 1080:22-

1081:23. According to 3Shape, if this rate of growth had continued, Trios scans would have accounted for [redacted] worldwide Invisalign cases by the end of 2018. RIB at 175; JX-0204C; RX-1292C (Fisker WS). 3Shape maintains that, "given this mutual success and Align's continued silence concerning prior IP concerns, 3Shape had a reasonable basis to believe Align's [infringement] allegations were in the past and no longer an issue." RIB at 175. 3Shape's belief is supported by a contemporaneous statement from Mr. Fisker in reaction to the rapid growth in 3Shape submissions to Invisalign: "[redacted]." JX-0204C. This statement shows that 3Shape was aware that [redacted] but that it expected, based on the financial success of the interoperability arrangement, that the agreement would continue. In the absence of any indication from Align that it intended to assert patent rights against 3Shape when it became convenient to do so, 3Shape's expectation was reasonable.

Align filed its complaint under section 337 on November 14, 2017. It filed an amended complaint on December 5, 2017. This investigation was instituted by the Commission on December 14, 2017. Without prior notice to 3Shape, Align on December 20, 2017 announced that it was terminating the three-year Scanner Agreement after only two years, effective January 17, 2018 (the effective date later was extended to January 31, 2018),"due to 3Shape's infringing conduct and the resulting litigation against 3Shape." JX-0165.

B. Equitable estoppel

The first and most likely affirmative defense raised by 3Shape is equitable estoppel.[11]

[11] As noted below, *see infra* at subsection C, the facts will not support any of the other alleged affirmative defenses.

1. Legal standards

"Equitable estoppel serves as an absolute bar to a patentee's infringement action." *John Bean Techs. Corp. v. Morris & Assocs., Inc.*, 887 F.3d 1322, 1327 (Fed. Cir. 2018), *cert. denied,* 2019 WL 113135 (U.S. Jan. 7, 2019) (citing *Scholle Corp. v. Blackhawk Molding Co.,* 133 F.3d 1469, 1471 (Fed. Cir. 1998)). "The defense consists of three elements: (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." *Id.* (citing *Scholle*, 133 F.3d at 1471). "Misleading conduct may include the patentee's 'specific statements, action, inaction, or silence where there was an obligation to speak.'" *Id.* "[E]ven where the three elements of equitable estoppel are established," however, a court must "take into consideration any other evidence and facts respecting the equities of the parties." *Aspex,* 605 F.3d 1313 (quoting *A.C. Aukerman Co. v. R.L. Chaides Constr. Co.,* 960 F.2d 1020, 1043 (Fed. Cir. 1992) (abrogated on other grounds by *SCA Hygiene Prods. v. First Quality Baby Prods.,* LLC, 137 S.Ct. 954 (2017)).

Regarding the first element, the course of dealing between the parties in the particular instance must be "such that the alleged infringer reasonably infers from the patentee's misleading conduct or inaction that the patentee has waived its patent rights." *Scholle* 133 F.3d at 1472. "[T]he conduct by the estopped party need not be affirmative misstatements." *Id.* at 1473. Rather, "'conduct may include specific statements, action, inaction, or silence where there was an obligation to speak.'" *Id.* (quoting *Aukerman,* 960 F.2d at 1028). Vigorous threats of patent infringement followed by silence is not the only way to demonstrate that a patentee's conduct was misleading. Inaction, "combined with other facts respecting the relationship or

contacts between the parties" may give rise to the necessary inference. *Aukerman* 960 F.2d at 1042.[12]

The second element, reliance, requires "a significant change in economic position." *Aspex,* 605 F.3d at 1312. "To show reliance, the infringer must have had a relationship or communication with the plaintiff which lulls the infringer into a sense of security . . . ." *Aukerman,* 960 F.2d at 1043. "To demonstrate substantial reliance . . . [an alleged infringer] must show that it was, in fact, so lulled." *Engineered Prod. Co. v. Donaldson Co., Inc.,* 165 F. Supp. 2d 836, 848-49 (N.D. Iowa 2001). "While the misleading conduct analysis looks mainly to the conduct of the patentee to determine what reasonable inferences flow from its actions, the reliance factor focuses on the conduct and communications of *both* parties in determining whether the infringer substantially relied on the patentee's conduct." *Id.* (citing *ABB Robotics, Inc. v. GMFanuc Robotics Corp.,* 52 F.3d 1062, 1065 (Fed. Cir. 1995)).

Prejudice or harm, the third element, requires a showing of "increased expenditures" that "'were in any way related to actions taken by the patentee.'" *Aspex,* 605 F.3d at 1312 (quoting *ABB,* 52 F.3d at 1065). Specifically, "commercial activities undertaken and expanded during the period of [the patentee's silence]" satisfy the prejudice requirement. *Id.*

The facts leading to equitable estoppel must be "clear, positive, and unequivocal in their implication," but the standard for establishing the defense is a mere preponderance of the evidence. *Aukerman,* 960 F.2d at 1046 (quoting 28 Am.Jur.2d *Estoppel and Waiver* § 148, at 830-31 (1966)).

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[12] In *Scholle*, the patentee's "cooperative behavior, in light of [] previous threats to sue, created a reasonable inference" that the patentee "did not intend to sue." *Scholle,* 133 F.3d at 1472.

2. Align's misleading conduct

The course of dealing over the years between these two adversaries culminated in an agreement predicated on cooperation [redacted]. In the run-up to execution of the Scanner Agreement in December 2015, Align led 3Shape to believe that intellectual property concerns relating to infringement by 3Shape's scanners had been eliminated as an obstacle to interoperability, which was the desired goal of both parties.

While 3Shape could have no reasonable expectation that its cooperative arrangement with Align would continue indefinitely ([redacted]), 3Shape could reasonably believe that Align's previous concerns based on infringement had been overcome. Although Align maintains that its legal reservations were communicated only internally, the record belies this assertion. Mr. Mack, Align's marketing executive, testifies that [redacted]. Tr. at 522-23. Mr. Mack testifies that he made "the same comments" to 3Shape repeatedly—"it had been forwarded to the legal department and it was their responsibility to—to do the analysis and reach a conclusion before we could start." *Id.* at 533-34

3Shape's belief thus was grounded factually on representations from Align officials that Align was awaiting the analysis of its lawyers on the infringement issue before going ahead with interoperability. When Align communicated that it was ready to go forward with the Scanner Agreement, the inescapable inference was that its IP concerns had been analyzed by the Align lawyers and found to constitute no obstacle to a mutually profitable arrangement going forward.

A duty arose in these circumstances to inform 3Shape that the representations by Align were not strictly true. [redacted]

[redacted]. Align was holding in reserve its right to enforce its scanner patents against 3Shape, notwithstanding [redacted]. Align argues that it "never conveyed to [3Shape] that it did not intend to assert its rights." CRB at 92. But in the circumstances, it should have conveyed to 3Shape that it *did* intend to assert its rights, or at least notified 3Shape that it was holding that possibility in reserve. Such disclosures were necessary to correct the impression Align had created by representing that the matter was being analyzed by its lawyers and then agreeing to go forward with interoperability, once the purported obstacle had been removed. Align's conduct falls short of the standard of basic fairness.[13]

As discussed below, however, the evidence does not show that 3Shape's belief in Align's reasonableness and *bona fides* actually were substantial factors in 3Shape's decision to enter into the interoperability agreement.

3. Reliance

3Shape was misled by Align in that the course of conduct outlined above created the impression that patent infringement was no longer an issue in December 2015, when the parties entered into the Scanner Agreement. Mr. Hyldal, 3Shape's vice president of orthodontics,

[13] Align's statements about the activities of its legal department regarding 3Shape's patents seem inconsistent. At a meeting with dissatisfied customers after the Scanner Agreement was terminated, Align's General Counsel, Roger George, announced: "[D]espite the fact that we knew the legal issues were out there, we made a decision to try to have a positive commercial relationship . . . . RX-1290.0004. [redacted]. Align argues that "it did not know that it had a basis for asserting its rights during the time period addressed by Respondents' arguments, as no legal study or analysis had been undertaken." CIB at 178. Yet, as discussed above, Align communicated to 3Shape that IP concerns involving 3shapes scanners were being reviewed by Align's legal department. *See* Tr. (Mack at 517-18, 522-23, 533-34. These statements are borderline dishonest but no more than ordinarily so.

testifies that 3Shape was surprised when, in November 2017, Align filed suit. RX-1293C (Hyldal WS) at Q/A 5, 78-79. He explains why: "[redacted] we were left with the impression that it was not something we should be worried about. And then we had also negotiated and signed the Scanner Agreement and Align was clearly accepting scans from Trios and thereby, accepting of the Trios scanner itself. So from that perspective, it was very surprising." *Id.* at Q/A 80. Mr. Hyldal testifies that 3Shape would not have invested in the interoperability agreement with Align if it had known "what it knows today," Tr. (Hyldal) at 459:10-13, but 3Shape wishes still to "have interoperability reinstated, because [it] can sell more scanners when [it has] interoperability with Invisalign." *Id.* at 459:20-24.

The question is whether 3Shape entered into the interoperability agreement because it was lulled into a sense of security by Align's conduct regarding its IP concerns. The evidence does not support this conclusion. It appears from the record that 3Shape would have agreed to interoperability whether or not it believed that Align might ultimately assert its patents.

Over the course of dealing, 3Shape was the active party seeking interoperability with Align. Align, not 3Shape, raised IP concerns as an obstacle to interoperability. Resolution of those concerns was an issue for Align, not for 3Shape, which neither sought nor received any assurance that Align would forego claims of patent infringement. While the only reasonable inference under the circumstances in December 2015 was that Align had decided not to assert its patents rights and to proceed instead with interoperability, 3Shape had its own business reasons for agreeing to the deal.

According to 3Shape, Align maintains "near-monopoly control of the clear aligner market," RIB at 188, and 3Shape was so eager to enter the U.S. market that it determined to seize the opportunity, regardless of the risk that Align would decide to terminate the agreement and sue for infringement. 3Shape relied not on Align's apparent forbearance regarding its infringement claims, but rather on the prospect that booming sales of 3Shape scanners for use with Invisalign aligners would be so profitable for both companies that termination of the interoperability arrangement would be out of the question. *See* JX-0204C ("[redacted]."). The gamble did not pay off for 3Shape in the long term.[14]

The Scanner Agreement itself could not lull even the most gullible businessperson into a sense of security: [redacted].[15] In negotiating the agreement, 3Shape did not seek to protect itself from the possibility that Align might terminate the agreement when it was convenient, for Align's own business reasons.

To invoke equitable estoppel, the infringer must show that its actions "were in reliance upon supposed actions of [the patentee], rather than a business judgment of its own." *Hemstreet*

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[14] In the short term, 3Shape derived substantial benefit from the Trios interface with Invisalign. Tr. (Clausen) at 565:19-23.

[15] "The general rule is that 'termination for convenience' clauses permit one party to terminate a contract, even in the absence of fault or breach by the other party, without suffering the usual financial consequences of breach of contract." *Harris Corp. v. Giesting & Assocs., Inc.*, 297 F.3d 1270, 1272 (11th Cir. 2002) (citing *Stock Equip. Co. v. Tenn. Valley Auth.*, 906 F.2d 583 (11th Cir.1990)).

v. Computer Entry Sys. Corp., 972 F.2d 1290, 1294-95 (Fed. Cir. 1992). 3Shape's own business interests were decisive in bringing about its agreement to proceed with interoperability; the move was not precipitated by Align's misleading conduct with respect to its intellectual property. For 3Shape, Align's IP concerns were merely an obstacle to achieving interoperability. How those concerns were resolved, or even if they were resolved, was not perceived by 3Shape as an issue. 3Shape simply wanted to get the deal done. 3Shape did not change its position in reliance on Align's misleading statements about patent infringement; it changed its position for business reasons of its own, to expand dramatically its market base in the U.S. by interoperating with Align.

4. Harm

3Shape incurred [redacted] to qualify its scanners for interoperability with Invisalign and to promote the Trios/Invisalign combination. Tr. (Hyldal) at 482:5-24, Tr. (Clausen) at 567:10-19.[16] Possibly, 3Shape also lost opportunities to work with other makers of clear aligners. RX-1294C (Clausen WS) at Q/A 43-45. 3Shape has not quantified such expenditures, but that does not necessarily defeat a claim for equitable estoppel. More importantly, there is no evidence that any loss suffered was caused by 3Shape's reliance on Align's misleading conduct. "'[C]ases in which economic prejudice has been found lacking did not so hold because of a lack of capital investments, but, rather, because the alleged infringer failed to prove that their increased expenditures, *i.e.*, on marketing and development, were in any way related to actions taken by the patentee.'" *Aspex,* 605 F.3d at 1312-13 (quoting *ABB,* 52 F.3d at 1065). Here, the losses suffered by 3Shape were not completely unrelated to Align's

[16] *See* JX-0163C at ¶ 1,1, ¶ 1.9, Ex. A.

actions, but they were not caused by them, either. *See Certain Sortation Systems, Parts Thereof, and Prods. Containing Same,* Inv. No. 337-TA-460. Comm'n Determination, 2003 WL 1712556 at *12 ("[R]eliance and prejudice elements of the equitable estoppel defense are linked because the material prejudice claimed by [the respondent] stems from action taken in purported reliance on [the complainant's] misleading conduct.")

C. Other equitable defenses

The remaining equitable defenses are less plausible in these circumstances than equitable estoppel. They are discussed briefly below.

Acquiescence and waiver, as 3Shape recognizes, require clear and convincing evidence. *See* RIB at 179; *Hynix Semiconductor Inc. v. Rambus, Inc.,* 645 F.3d 1336, 1348 (Fed. Cir. 2011) (quoting *Qualcomm Inc. v. Broadcom Corp.,* 548 F.3d 1004, 1020 (Fed. Cir. 2008)). Since 3Shape cannot prevail on equitable estoppel, which requires only a preponderance of evidence, the record will not support invocation of these other equitable doctrines. Acquiescence, moreover, like equitable estoppel, requires reliance. *Wallpaper Mfrs., Ltd. v. Crown Wallcovering Corp.,* 680 F.2d 755, 762 (Fed. Cir. 1982). As discussed above, 3Shape cannot satisfy this requirement.

Apart from the hurdle presented by the Supreme Court's decision in *SCA Hygiene Products Aktiebolag v. First Quality Baby Products, LLC,* 137 S.Ct. 954, 967 (2017) ("Laches cannot be interposed as a defense against damages where the infringement occurred within the period prescribed by § 286)), laches is unavailable because, as discussed above, any delay by Align in filing suit did not cause material prejudice or injury to 3Shape, as required. *See Gasser Chair Co., Inc. v. Infanti Chair Mfg. Corp.,* 60 F.3d 770, 773 (Fed. Cir. 1995) (citations omitted) (reciting elements of laches). There is no evidence that 3Shape has been prejudiced in its ability

to defend itself against the allegations of patent infringement brought by Align, or that it has otherwise been injured because of Align's delay. Nor do the equities weigh in 3Shape's favor. *See id.* ("The application of the laches defense is discretionary, and as an equitable matter, the district court is to look to all the facts and circumstances of the case and weigh the equities of the parties.") (citing *Aukerman,* 960 F.2d at 1032). The economic harm discussed above results from 3Shape's own business judgment, not from any delay by Align in filing suit.

The facts do not support an allegation of license or implied license. The claim that Align granted an actual license to 3Shape misreads the Scanner Agreement. Nothing in that agreement gives 3Shape a license to practice the Align patents. On the contrary, the Agreement states expressly that: "[redacted]." JX-0163C at ¶ 4. The provisions regarding [redacted] do not alter the express statement that no license is expressly or impliedly granted by the Agreement. *See LG Elecs., Inc. v. Bizcom Elecs., Inc.,* 453 F.3d 1364, 1369 (Fed. Cir. 2006) ("In light of this express disclaimer, no license can be implied."), *rev'd sub nom. Quanta Computer, Inc. v. LG Elecs., Inc.,* 553 U.S. 617, 128 S. Ct. 2109 (2008)).

Unclean hands is "'a self-imposed ordinance that closes the doors of a court of equity to one tainted with inequitableness or bad faith relative to the matter in which he seeks relief, however improper may have been the behavior of the defendant.'" *Romero v. Allstate Ins. Co.*, 158 F. Supp. 3d 369, 374–75 (E.D. Pa. 2016) (quoting *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814 (1945)). The doctrine applies to conduct that involves fraud, deceit, unconscionability, or bad faith. *Id.* (citations omitted). Unclean hands is an

equitable defense within the sound discretion of the trial court. *Princess Cruises, Inc. v. United States,* 397 F.3d 1358, 1369 (Fed. Cir. 2005) ("The trial court has broad discretion under the doctrine of unclean hands."). Evidence of unclean hands must be clear and convincing. *In re Omeprazole Patent Litig.,* 483 F.3d 1364, 1374 (Fed. Cir. 2007).

The facts set forth above concerning Align's misleading conduct do not implicate the doctrine of unclean hands. There is insufficient evidence of deceitful intent, actual dishonesty or reliance by 3Shape on false representations. That Align continues to permit secondary scans of patients whose treatment previously involved Trios scanners does not show bad faith. Align explains that it does not [redacted], and its practice assists patients who are receiving treatment. Tr. (Pascaud) at 1083:6-19. Continued interoperability between Align and 3Shape in other geographical areas also does not show unclean hands under any case law that has been cited by 3Shape. Apparently, Align has business reasons for conducting its operations differently in other areas.[17] I have been directed to no precedent that prohibits a party from asserting its patent rights in these circumstances.[18]

The "basic rule" of patent misuse is "that the patentee may exploit his patent but may not 'use it to acquire a monopoly not embraced in the patent.'" *Princo Corp. v. Int'l Trade Commn.,*

[17] The record indicates, in any event, that [redacted] Tr. (Pascaud) at 1084:10-23 (quoting email between Pascaud and Hogan).

[18] Mr. George, Align's general counsel, in his post-termination meeting with unhappy customers, indicated that Align felt legally constrained to break off the interoperability agreement with 3Shape before alleging in this forum that 3Shape's importation of scanners violates section 337. ""[I]f you have a claim that a product is infringing, you cannot, with clean hands, go to [the ITC] and say, 'We want the product excluded, but meanwhile we're making business from it.' That's their requirement." RX-1290.0004-.0005. *See* Tr. (Pascaud) at 1083:2-6. The Scanner Agreement did not end until several weeks after Align filed its complaint, however.

616 F.3d 1318, 1327 (Fed. Cir. 2010) (quoting *Transparent-Wrap Mach. Corp. v. Stokes & Smith Co.*, 329 U.S. 637, 643 (1947). The "most common form of patent misuse" is "requiring the purchase of an unpatented product as a condition for obtaining a license to the patent." *Id.* The scope of the doctrine is narrow and does not include "a general notion of 'wrongful' use. *Id.* at 1329 (quoting *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1373 (Fed. Cir. 1998)). "[T]he defense of patent misuse is not available to a presumptive infringer simply because a patentee engages in some kind of wrongful commercial conduct, even conduct that may have anticompetitive effects.").

3Shape's allegations of patent misuse turn on the notion that Align may not use its scanner patents to keep competitors out of its clear aligner business. RIB at 187-190. 3Shape claims that Align asserted its scanner patents as a pretext to terminate the Scanner Agreement. But Align needed no such pretext—it was entitled [redacted].

3Shape asserts that Align seeks to protect its clear aligner business by refusing to work with companies that sell to Invisalign competitors. The record belies this assertion but, in any event, 3Shape presents no cogent reason why Align is not within its rights to protect its position in the clear aligner marketplace.

Align does not dispute that it has contacted doctors who had purchased a 3Shape scanner to sell these doctors an iTero scanner made by Align. *See* Tr. (Pascaud) at 1085:8-1086:25. 3Shape asserts that Align's motivation is to extend its scanner patents into the clear aligner realm and derive benefits not attributable to the patents' teachings, but such actions would not constitute classic patent misuse.

The facts disclose no attempt by Align to leverage the patents in issue by imposing conditions for their use that extend the monopoly beyond the grant of the patent itself. Even if the course of dealing between Align and 3Shape were deemed to involve wrongful commercial activity, the doctrine of patent misuse would not necessarily provide a remedy. "[T]he body of misuse law and precedent need not be enlarged into an open-ended pitfall for patent-supported commerce." *Princo*, 616 F.3d at 1332.

Align agreed to interoperability with 3Shape, which it had the right to do, and Align terminated the agreement, which it too had the right to do. Align imposed no improper conditions on the patents in issue in connection with the interoperability arrangement. That Align's course of dealing could have the effect of extending the term of the monopoly granted by its Invisalign patents is beside the point. As stated above, while Align's course of dealing may have had the effect of increasing the marketability of its iTero scanners, there is no evidence that Align used the scanner patents "to obtain economic advantages outside the legitimate scope of the patent grant." *Id.* at 1331. Align used its intellectual property in a way that increased its own fortunes and disfavored a competitor. This occurs in many cases and does not constitute patent misuse.

V. INFRINGEMENT

Align accuses 3Shape of infringing claims 1-6 and 15-19 of the '901 patent, claims 17, 19, 20, 23, and 24 of the '447 patent, and claims 15 and 18-20 of the '448 patent.[19]

[19] In addition to direct infringement, Align alleges that 3Shape indirectly infringes the asserted claims. In order to prove to indirect infringement, Align must show that there has been an act of direct infringement. *See, e.g., Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F.3d 1263, 1272 (Fed. Cir. 2004) ("Indirect infringement, whether inducement to infringe or contributory infringement, can only arise in the presence of direct infringement . . . ."). For the reasons

A. Legal Standards

Section 337(a)(1)(B)(i) prohibits "the importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that – (i) infringe a valid and enforceable United States patent or a valid and enforceable United States copyright registered under title 17." 19 U.S.C. §1337(a)(1)(B)(i). The Commission has held that the word "infringe" in Section 337(a)(1)(B)(i) "derives its legal meaning from 35 U.S.C. § 271, the section of the Patent Act that defines patent infringement." *Certain Electronic Devices with Image Processing Systems, Components Thereof, and Associated Software*, Inv. No. 337-TA-724, Comm'n Op. at 13-14 (December 21, 2011). Under 35 U.S.C. § 271(a), direct infringement of a patent consists of making, using, offering to sell, or selling the patented invention without consent of the patent owner.

"An infringement analysis entails two steps. The first step is determining the meaning and scope of the patent claims asserted to be infringed. The second step is comparing the properly construed claims to the device accused of infringing." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996) (citation omitted). Infringement must be proven by a preponderance of the evidence. *SmithKline Diagnostics, Inc. v. Helena Labs. Corp.*, 859 F.2d 878, 889 (Fed. Cir. 1988). A preponderance of the evidence standard "requires proving that infringement was more likely than not to have occurred." *Warner-Lambert Co. v. Teva Pharm. USA, Inc.*, 418 F.3d 1326, 1341 n.15 (Fed. Cir. 2005).

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discussed below, the accused products do not infringe the asserted claims and therefore Align has failed to show an act of direct infringement.

A complainant must prove either literal infringement or infringement under the doctrine of equivalents. Literal infringement requires the patentee to prove that the accused device contains each and every limitation of the asserted claim(s). *Frank's Casing Crew & Rental Tools, Inc. v. Weatherford Int'l, Inc.*, 389 F.3d 1370, 1378 (Fed. Cir. 2004). "If even one limitation is missing or not met as claimed, there is no literal infringement." *Elkay Mfg. Co. v. EBCO Mfg. Co.*, 192 F.3d 973, 980 (Fed. Cir. 1999). Literal infringement is a question of fact. *Finisar Corp. v. DirecTV Gr., Inc.*, 523 F.3d 1323, 1332 (Fed. Cir. 2008).

B. Claim Construction

During the *Markman* proceedings, the parties agreed that the term "focal plane," which appears in claims 17, 19, 20 and 24 of the '447 patent, claims 15 and 19-21 of the '448 patent, and claims 1, 3-6, 15-19 of the '901 patent, should be construed to mean "a position where one or more light beams from the optical system are focused." Order No. 32 at 15. The *Markman* order adopted constructions for (1) the "illumination unit" limitations recited in claim 17 of the '447 patent, claims 15 and 18 of the '448 patent, and claim 1 of the '901 patent; (2) the "optical system" limitations recited in claim 17 of the '447 patent, claim 15 of the '448 patent, and claim 1 of the '901 patent; (3) the "processor" limitations recited in claim 17 of the '447 patent, claim 15 of the '448 patent, claims 1 and 5 of the '901 patent; (4) the term "detector unit" recited in claim 17 of the '447 patent, claim 15 of the '448 patent, and claims 1 and 4 of the '901 patent; (5) the "incident light beams" limitations recited in claims 17, 19, 20, 23, and 24 of the '447 patent, claims 15 and 17-21 of the '448 patent and claims 1, 6, 15, and 17 of the '901 patent; (6) the term "returned light beams" recited in claims 17, 18 and 24 of the '447 patent, claims 15, 16, 21 of the '448 patent, and claims 1, 2, 4, 5, 15, 18, and 19 of the '901 patent; and (7) the term "probing member" recited in claim 17 of the '447 patent, claim 15 of the '448 patent, and claims

1, 3, 15, and 16 of the '901 patent. *Id.* at 56-59.

On October 2, 2018, Align filed a motion for reconsideration of the construction of the "optical system" limitations adopted in the *Markman* order. Order No. 39 (Nov. 2, 2018) at 1. The *Markman* order found that the claimed "optical system" is a means-plus-function term subject to 35 U.S.C. § 112, ¶ 6 ("112(6)"). Order No. 32 (Sept. 25, 2018) at 62. The *Markman* order further found that the claimed function of the "optical system" is "to focus the plurality of incident light beams," and that the corresponding structure consists of "a partially transparent mirror or beam splitter, confocal optics operating in a telecentric mode, relay optics, an endoscopic probing member operating as a light guide to ensure total internal reflection, and equivalents thereof." *Id.* In its motion, Align sought reconsideration of the *Markman* order's identification of corresponding structure on the basis that that the "claim construction of the 'optical system' term identifies some but not all of the corresponding structures from the specification for performing the claimed function, thus resulting in an incomplete and unduly restrictive identification of corresponding structures." Order No. 39 (Nov. 2, 2018) at 2 (internal citations omitted). Align's motion for reconsideration was denied. *Id.*

In its post-hearing brief, Align identifies four terms that were construed in the *Markman* order that it contends require additional construction: (1) "illumination unit configured to transmit a parent light beam;" (2) "generating a plurality of incident light beams;" (3) "optical system configured to focus the plurality of incident light beams;" and (4) "processor." CIB at 29-37. With one exception the disputes identified by Align are appropriately addressed in the context of infringement and the technical prong of the domestic industry requirement, not claim construction. The exception relates to the term "illumination unit configured to transmit a parent light beam."

Claim 17 of the '447 patent requires an "illumination unit configured to transmit a parent light beam." '447 patent, col. 10:7-8. During the *Markman* proceedings, the parties disputed whether the term was a means-plus-function term subject to 35 U.S.C. § 112, ¶6 and, if so, the claimed function and corresponding structure. Order No. 32 at 16-17. I found that the term is a means-plus-function term and that the claimed function is "to transmit a parent light beam." *Id.* at 24. With respect to corresponding structure, I found that the following structures are disclosed in the specification as performing the claimed function: illumination unit disclosed at '901 patent, col. 2:63-64; light emitters disclosed at *id.*, col. 4:17-22; semiconductor laser unit 28 disclosed at *id.*, col.5:39-41 and in Figures 1A and 4; and laser emitter 154A-C disclosed at *id.*, col. 8:25-27. *Id.*[20] At issue in the post-hearing briefs is whether the light emitters disclosed at lines 17-22 of column 4 of the '901 patent are lasers. CIB at 29-31.

The specification describes the light emitters accordingly:

> In accordance with one embodiment, the parent light beam is light emitted from a single light emitter. In accordance with another embodiment, the parent light beam is composed of different light components, generated by different light emitters, the different light components differing from one another by at least one detectable parameter.

'901 patent, col. 4:17-22. The references to "one embodiment" and "another embodiment" are clear references to the preferred embodiments described in the "Detailed Description of a Preferred Embodiment" section of the specification. In this section, the specification describes two apparatuses that generate a parent beam from a laser or lasers.

[20] Although the term appears in claim 17 of the '447 patent, the corresponding structure is identified in reference to the '901 patent. As noted above, the asserted patents claim priority to the same application and share a common specification.

The first embodiment is shown in Figure 1A and uses a single semiconductor laser 28 to generate light beam 30.

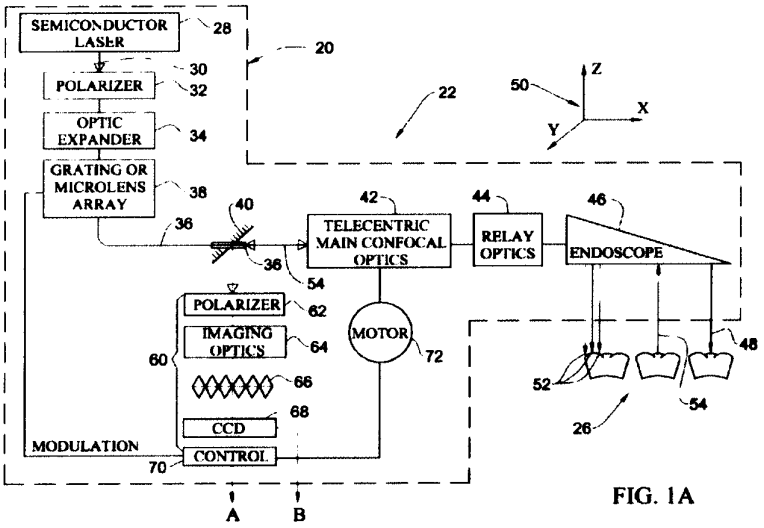


FIG. 1A

See also '901 patent, col. 5:39-49 ("Optical device 22 comprises, in this specific embodiment, a semiconductor laser unit 28 emitting a laser light, as represented by arrow 30 . . . . The light beam 30 then passes through a module 38, which may, for example, be a grating or a micro lens array which splits the parent beam 30 into a plurality of incident light beams 36. . . ."). This first preferred embodiment aligns perfectly with the "one embodiment" discussed in the "Summary of the Invention" section of the specification. *Id.*, col. 4:17-18 ("In accordance with one embodiment, the parent light beam is light emitted from a single light emitter."). Thus, the "single light emitter" referenced in the "Summary of the Invention" section is semiconductor laser 28.

Instead of using a single laser to generate the parent light beam, the embodiment shown in Figure 4 generates parent light beam 152 (co-labeled 30) using three laser light emitters 154A, 154B and 154C.

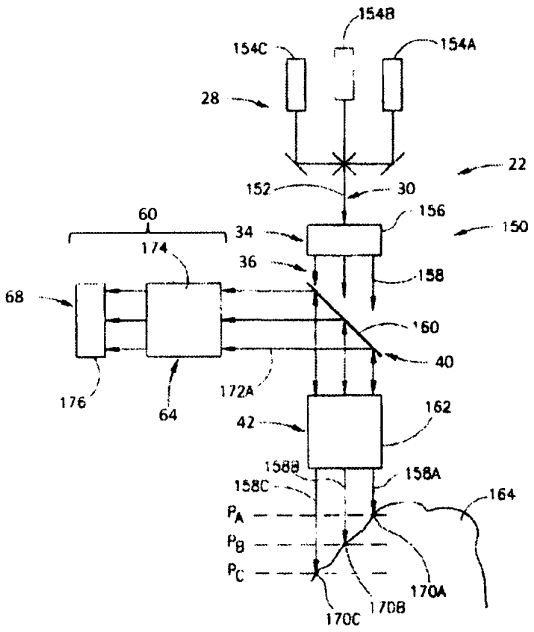


FIG.4

The specification teaches that "the different light components composing parent beam 152 may for example be different wavelengths, a different one transmitted from each of laser emitters 154A-C." '901 patent, col. 8:25-28. The second preferred embodiment aligns perfectly with the "another embodiment" discussed in the "Summary of the Invention" section of the specification. *Id.*, col. 4:19-22 ("In accordance with another embodiment, the parent light beam is composed of different light components, generated by different light emitters, the different light components differing from one another by at least one detectable parameter."). Thus, the "different light emitters" referenced in the "Summary of the Invention" section are laser light emitters 154A, 154B, and 154C.

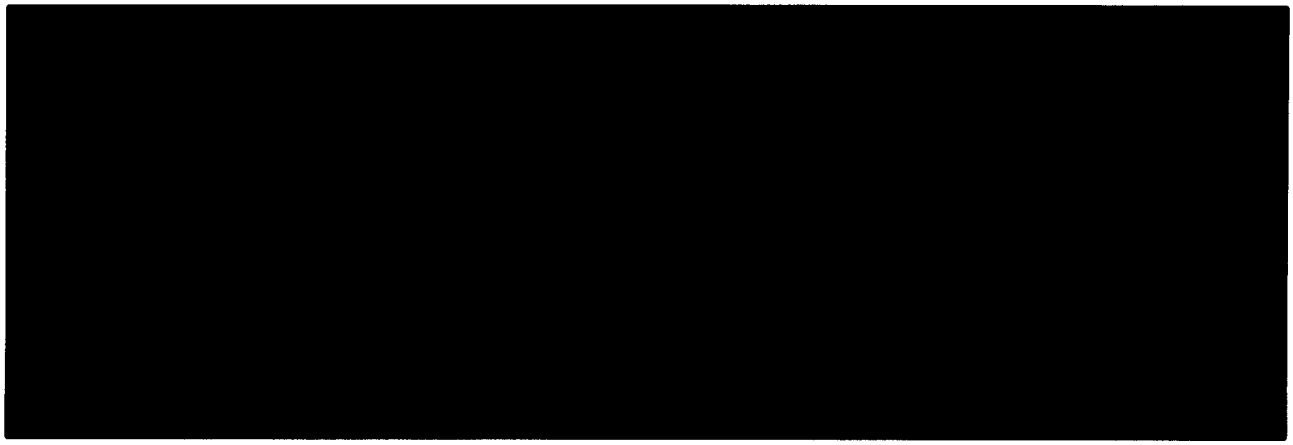
Based on the foregoing, I find that the "Summary of the Invention" section's reference to the "light emitters" of the Figure 1A and the Figure 4 embodiments does not constitute a disclosure of non-laser illumination sources. *See InterDigital Communications, Inc. v. Int'l Trade Comm'n*, 601 Fed. Appx. 972 (Fed. 2015) (non-precedential) ("[W]e do not think that the

summary statements about 'short codes' in the Abstract and Summary of the Invention—where full explanations of the term are not expected—are sufficient to justify a broader reading of short codes.") (citing 37 C.F.R. § 1.72(b)).

C. Accused Products

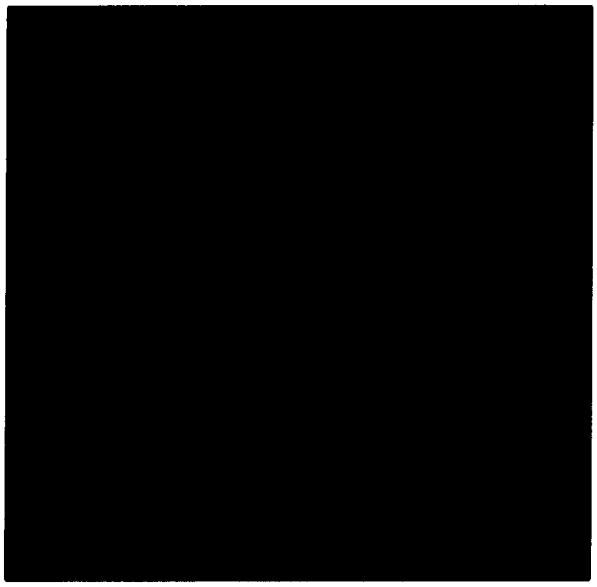
Align alleges that the following models of 3Shape's Trios 3 intraoral scanner systems infringe the asserted claims: T12A, T12P, S1A, S1P, S2A, S2P, S1A, and S2A. CIB at xiii; JX-0265C.0007-.0008. The Trios 3 systems consist of a handheld intraoral scanner connected to a cart. RX-1567C (Zavislan RWS) at Q/A 114. The cart contains an external PC supplied by the customer. *Id.* The systems use one of two types of carts: a regular cart or a "Move" cart. *Id.* The handheld scanner is available in either a handle grip configuration or a pen grip configuration. *Id.* at Q/A 115. Both grip configurations are available as a wired or wireless model. *Id.* With regard to the issues raised by the asserted patents, the software and the hardware of the accused Trios models are either the same or similar enough that each accused model is representative of the other accused models. CX-1940C (Ferraro WS) at Q/A 36, 55; RX-1567C (Zavislan RWS) at Q/A 117.

The structure of a wireless, pen grip Trios 3 scanner is shown below.



CDX-0003C.15 (annotated version of schematic shown in JX-0291); CX-1940C (Ferraro WS) at Q/A 36. The tip of the scanner is designed to be inserted in a patient's mouth. CX-1940C (Ferraro WS) at Q/A 40. The white LED generates light, which is collected by the illumination condenser. *Id.* The collected light passes through [redacted] before passing through the beam splitter. *Id.* The beam splitter directs light to the tip of the scanner and to the image sensor. *Id.* Light directed to the tip of the scanner passes through the translating lens and optic lenses, before passing out of the scanner. *Id.*

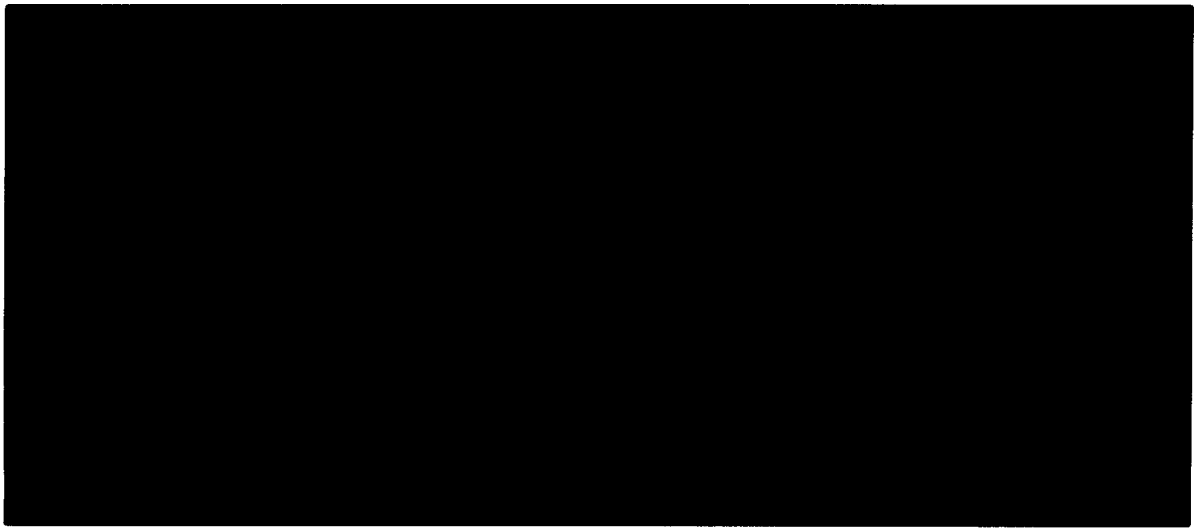
A schematic of [redacted] is shown below.



JX-0295C. [redacted] RX-1099C.0010. When [redacted] is illuminated by the LED, [redacted]. RX-1567C (Zavislan RWS) at Q/A 126. On the portions of the teeth [redacted]. *Id.* at Q/A 126-127; CX-

1940C (Ferraro WS) at Q/A 40. On the portions of the teeth [redacted]. RX-1567C (Zavislan RWS) at Q/A 126-127; CX-1940C (Ferraro WS) at Q/A 40; RX-1099C.0010 ("[redacted]").

Light from the [redacted] and captured by the scanner's image sensor. CX-1940C (Ferraro WS) at Q/A 40; RX-1567C (Zavislan RWS) at Q/A 144. The image sensor consists of a grid of sensor elements called pixels. *Id.* The Trios 3 uses [redacted] to capture the reflected light [redacted]. RX-1565C (van der Poel RWS) at Q/A 49. For illustration purposes, [redacted] is shown below.



RX-01098C.0015; *see also*, RX-1565C (van der Poel RWS) at Q/A 49.

As can be seen, [redacted]. RX-1567C (Zavislan RWS) at Q/A 149. [redacted]. RX-1565C (van der Poel RWS) at Q/A 49; RX-1567C (Zavislan RWS) at Q/A 151. Due to manufacturing tolerances, however, [redacted]. RX-1565C (van der Poel RWS) at Q/A 49; *see also* JX-0260C.0001 ("In the best case, it will be possible to [redacted]."). In order to compensate for the [redacted]. RX-1567C (Zavislan RWS) at Q/A 149, 151; JX-0260C.0001.

To determine whether [redacted], the Trios 3 system uses a [redacted]. RX-1567C (Zavislan RWS) at Q/A 144; *see also* RX-1106C.0001 [redacted]

[redacted]

RX-1567C (Zavislan RWS) at Q/A 151.

To generate a three-dimensional model of the surface topology of the teeth, the Trios 3 products [redacted]. RX-1567C (Zavislan RWS) at Q/A 136. [redacted] *Id.*

[redacted]

RXD-0001.24C; *see also* RX-1567C (Zavislan RWS) at Q/A 136.

D. '901 patent infringement

Align is asserting claims 1-6 and 15-19 of the '901 patent. Claims 15-19 are method claims, while claims 1-6 are apparatus claims. The method claims are addressed first.

1. Claim 15

Claim 15 is an independent claim and consists of a preamble and a five-step method. There is no dispute that the Trios 3 products satisfy the preamble to the extent that it is limiting and the first method step. The Trios 3 products perform a method of "imaging a portion of a three-dimensional structure," as required by the preamble. *See, e.g.,* RX-1567C (Zavislan RWS) at Q/A 136 ("The 3 Shape TRIOS 3 Products perform scanning using an ultrafast optical section technique. The ultrafast optical sectioning technique starts by [redacted] that are later used to generate a three-dimensional model of the scanned object (*e.g.*, teeth)."). In accordance with the first step of the claimed method, the Trios 3 products "provid[e] a probing member" in the form of a tube and tip located on the front of the handheld scanner that can be inserted into a patient's mouth. CX-1940C (Ferraro WS) at Q/A 64; Tr. at 932:22-25 (Zavislan) (testifying that he did not provide an opinion on whether the Trios 3 products provide a probing member). The remaining steps are disputed and are addressed below.

a. "generating a plurality of incident light beams"

The second step of the claimed method requires "generating a plurality of incident light beams." '901 patent, col. 10:20. Align argues that the light transmitted through [redacted] constitute a "plurality of incident light beams," while 3Shape counters that the light transmitted through [redacted] does not form light beams.

Although the term "generating a plurality of incident light beams" was identified during *Markman* proceedings as a term that needed to be construed, the parties did not address the construction of "light beams." During the *Markman* proceedings, 3Shape did not propose a construction of the term "incident light beams"—the term was recited in 3Shape's proposed

construction—but sought to limit the "incident light beams" so that they (1) are generated by a grating or microlens array and (2) "illuminat[e] spatially independent spots on the structure being scanned." Order No. 32 at 49. Align's proposed construction—"generating more than one light beam striking a portion of a three-dimensional structure"—addressed the constructions of "plurality" and "incident," but not "light beams." *Id.* Ultimately, I rejected 3Shape's proposed limitations and found that no further construction of the term "generating a plurality of incident light beams" was necessary at that time. *Id.* at 50.

Although the dispute hinges on the construction of the claim term "light beams," as used in the phrase "incident light beam," the parties do not properly address the term's construction in their post-hearing briefs. Relying on testimony from its expert, Dr. Zavislan, 3Shape argues that the light transmitted through [redacted] does not form a plurality of light beams, because the light is not coherent and is not collimated or focused by [redacted]. RIB at 16. Dr. Zavislan's opinion, however, is based on his comparison of the accused products to the preferred embodiments, not to the claim language. *See, e.g.*, RX-1567C (Zavislan RWS) at Q/A 220 ("[T]he light transmitted through the [redacted] is incoherent and cannot from the light beams described in the '447 patent, which are coherent."). The claim language—not the embodiments—defines the scope of protection. *See, e.g., Dow Chemical Co. v. Sumitomo Chemical Co.*, 257 F.3d 1364, 1378 (Fed. Cir. 2001) ("It is axiomatic that '[c]laims, not the specification embodiments, define the scope of protection.'") (quoting *American Permahedge, Inc. v. Barcana, Inc.*, 105 F.3d 1441, 1444 (Fed. Cir. 1997)). While the specification can limit the scope of a claim term through lexicography or disavowal, *Thorner*, 669 F.3d at 1365-67, 3Shape does not argue that the patentees acted as their own lexicographers or disavowed claim scope.

Although Align addresses the term "generating a plurality of the incident light beams" under the heading "Claim Construction," it does not propose a construction for "light beams," but instead limits itself to criticizing 3Shape's attempt at restricting "incident light beams" to the preferred embodiment. CIB at 31-33. Without addressing the construction of "light beam," Align asserts that the light transmitted through the [redacted] are "light beams." CIB at 19-20 ("Multiple separate light beams are formed as light is transmitted through [redacted]."). In so doing, Align skips the first step of the infringement analysis: "determining the meaning and scope of the patent claims asserted to be infringed." *Duncan Parking Technologies, Inc. v. IPS Group, Inc.*, 914 F.3d 1347, 160 (Fed. Cir. 2019) ("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.") (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (*en banc*) (citations omitted), *aff'd*, 517 U.S. 370 (1996) (internal quotation marks omitted).

Neither party has argued that "light beam" is a term whose "ordinary meaning as understood by a person of skill in the art [is] readily apparent even to lay judges," such that "claim construction . . . involves little more than the application of the widely accepted meaning of commonly understood words." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (*en banc*). In the context of the asserted patents, "light beam" is a technical term, of which people skilled in the art have different understandings. As will be discussed below, Align's expert Mr. Ferraro equates a "light beam" to light that has been "spatially filtered," while 3Shape's invalidity expert equates "light beam" to light that has parallel rays. In addition,

3Shape's witness Dr. van der Poel—who has Ph.D. in physics and has taught courses on optics—"understand[s] a light beam to be a light entity that is propagating along a certain direction, a beam axis, and then it would be confined in space to a limited area and basically surrounded by darkness." Tr. at 879:8-21

The intrinsic evidence does not provide or suggest a definition for "light beams." It is Align's burden to establish that the light transmitted [redacted] constitutes a "plurality of incident light beams." *See Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 571 U.S. 191, 193-94 (2014) ("A patentee ordinarily bears the burden of proving infringement."). Infringement cannot be determined without an adequate evidentiary basis for construing "light beam." See *Baron Services, Inc. v. Media Weather Innovations LLC*, 717 F.3d 907, 914 n. 13 (Fed. Cir. 2013) ("Without construing relevant claim terms, however, . . . the propriety of the parties' positions on infringement . . . cannot be reasonably determined with an appropriate level of clarity."). Although the claims are not limited to the preferred embodiments, Align has not provided any basis for construing "light beam" beyond the "light beams" of the preferred embodiment. On this basis alone, Align's infringement case fails.

Additionally, even if an infringement analysis were conducted without construing "light beam," Align still would not meet its burden of establishing infringement. Align cites to two experts in support of its contention that [redacted][21] These experts—Mr. Ferraro and Dr. Kessler—equate light beams with light having particular characteristics. For the reasons discussed below, Align has not shown by

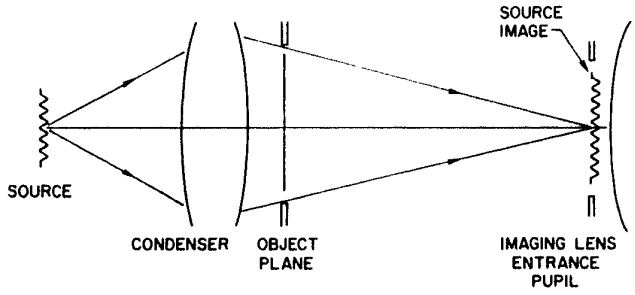
[21] Align also cites to JX-0295C. This exhibit is a single page schematic [redacted] and makes no reference to light beams or spatial filtering.

a preponderance of the evidence that the light transmitted through [redacted] in the Trios 3 products possesses the characteristics identified by Mr. Ferraro and Dr. Kessler.

i. The principles employed in the accused products are fundamentally different than those employed by the disclosed invention.

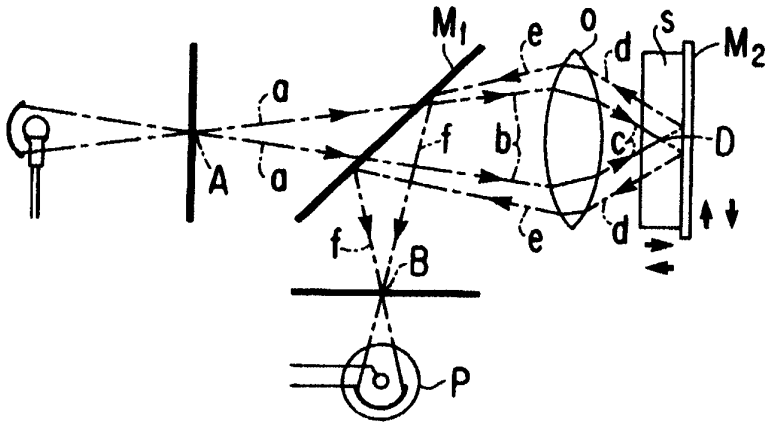
As a preliminary matter, the accused products and the disclosed invention employ different methods of illumination. This differences between the two methods relate directly to the structure of the light that is projected onto the patient's teeth. The accused [redacted]. RX-1567C (Zavislan RWS) at Q/A 121, 130, 222; RX-1565C (van der Poel RWS) at Q/A 48, 84. [redacted] *Id.* at 866:5-18.

The accused products utilize [redacted]. RX-1567C (Zavislan RWS) at Q/A 129-30. In Koehler illumination, light from the light source is focused on the entrance pupil of the objective lens, not on the object being examined. RX-1109.0001 ("Source imaged into entrance pupil."); RX-1567C Zavislan WS) at Q/A 58-63. This results in the light source uniformly illuminating the object. RX-1567C (Zavislan RWS) at Q/A 59; RX-1109.0008 ("Uniformizing effect of Koehler illumination. Each object point is illuminated by many source points. Each source point illuminates the entire object more or less uniformly.").



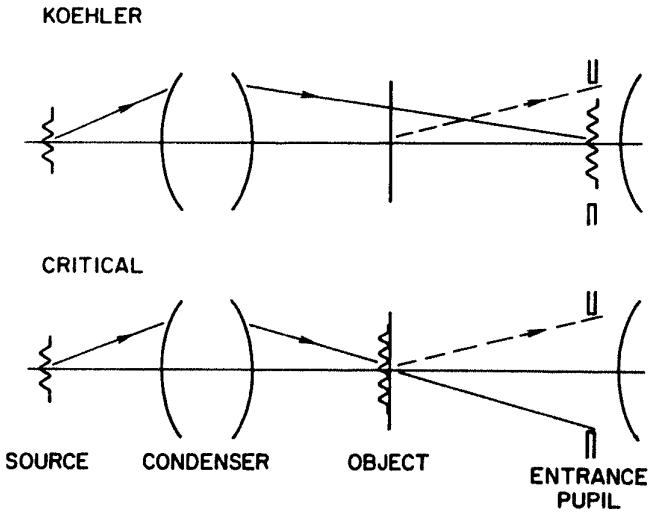
RX-1109.0009

In contrast to the [redacted], the disclosed invention builds upon confocal imaging techniques that were first developed by Dr. Minsky. CX-1940C (Ferraro WS) at Q/A 28-29. Instead of Koehler illumination, confocal imaging techniques utilize "critical illumination." In critical illumination the light source is imaged on the object being examined. RX-1567C (Zavislan RWS) at Q/A 60; RX-1109.0001 ("Source imaged into object plane."). This is shown in the figure below illustrating the optical path of a confocal microscope.



CX-1477 at 4, Fig. 2. As shown in the figure, the illuminating light is limited by entrance pinhole A before being focused on the specimen being examined. The focused light forms spot D on the object, which is an image of the illumination source (the entrance pinhole). *Id.* at 4 ("A reduced image of this pinhole is projected onto the specimen by the 'condenser.'"); *see also* "Real-time three dimensional imaging of macroscopic structures," *Journal of Microscopy*, Vol. 191, Pt. 2, pp. 116-118 (Aug. 1998), by Wilson *et al.* ("Wilson," RX-0202C) at RX-202C.0001 ("The confocal optical system is very simple and merely involves focusing light from a point source onto an object . . . .").

The figure below illustrates the differences between Koehler illumination and critical illumination.



RX-1109.0002 Zavislan WS) at Q/A 59. As shown in the diagram, with Koehler illumination, the source light is not focused on the object but on the entrance pupil of the objective lens resulting in the object being evenly illuminated. RX-1109.0002; RX-1567C (Zavislan RWS) at Q/A 61-62. With critical illumination, the source light is focused on the object itself resulting in only a point on the object being illuminated. RX-1109.0002; RX-1567C (Zavislan RWS) at Q/A

61-62; RX-0202C (confocal imaging "merely probes one point of the object"). Because critical illumination does not provide a uniform distribution of light, it is incompatible [redacted]. RX-1567C (Zavislan RWS) at Q/A 222.

As of the priority date of the asserted patents, one of ordinary skill in the art would have recognized that [redacted] the confocal imaging techniques used in the disclosed invention were distinct and separate. Wilson describes [redacted] an alternative to confocal imaging. According to Wilson, "[t]he confocal optical system is very simple and merely involves focusing light from a point source onto an object and refocusing the reflected or fluorescent light onto a point detector." RX-0202C.0001. Wilson, however, notes a couple of disadvantages of confocal optical systems. The "optics in a confocal optical system need careful design and usually a telecentric f*θ laser scan lens is used to permit large specimens to be scanned quickly." *Id.* Wilson proposes an alternative method that "permits a simple, cheap, optically sectioning microscope to be built with the minimum modification of existing low-power imaging systems." *Id.* In the alternative method, a "one-dimensional single spatial frequency fringe pattern" is projected onto the object being scanned and the topography of the object is determined by using the in-focus regions of the pattern. *Id.*; *see also* RX-1567C (Zavislan RWS) at Q/A 202. The primary difference between the method disclosed in Wilson and the method used in the Trios 3 products [redacted]. RX-1567C (Zavislan RWS) at Q/A 202.

The distinction between [redacted] confocal imaging techniques is also reflected in the common specification of the asserted patents, which discusses a prior art

method disclosed in U.S. Patent No. 5,372,502 ("'502 patent"). This technique is described in the "Background of the Invention" section of the specification: "Various patterns are projected onto the tooth or teeth to be measured and [a] corresponding plurality of distorted patterns are captured by the probe. Each interaction provides refinement of the topography." '901 patent, col. 2:19-24. Importantly, the specification describes the prior art method as one in which patterns—not light beams—are projected onto a patient's teeth. *Id.*

Align argues that the claims cover the '502 patent's pattern-projection technique. CIB at 52. In support of this argument, Align argues that the specification does not "expressly state that the prior art pattern projection technique is undesirable (like it does for other techniques discussed), nor does it state that the patents claim a different solution than this prior art solution." *Id.* (internal quotation marks and citations omitted). The specification, however, clearly indicates that the '502 patent's pattern-projection method falls outside of the scope of the claims. The description of the '502 patent occurs in the "Background of the Invention" section of the specification, which surveys prior art systems "for direct optical measurement of teeth and the subsequent automatic manufacture of dentures." '901 patent, col. 1:49-51. There is no suggestion in the "Summary of the Invention" and "Description of the Embodiments" sections of the specification that the disclosed invention encompasses one of the described prior art methods or is compatible with the '502 patent's pattern-projection method.

In support of its contention that the disclosed invention encompasses the '502 patent's pattern-projection technique, Align also points to claim 23 of the '447 patent and claim 18 of the '448 patent. These dependent claims require that the plurality of incident light beams form a "pattern" ('447 patent, claim 17, '448 patent, claim 18) and that the "pattern" of incident light beams form a "pattern of illuminated areas" on the patent's teeth ('448 patent, claim 18). CIB at

32. These "patterns" of light beams and illuminated areas are not the projection of an image pattern as disclosed in the '502 patent and Wilson. In the '502 patent and Wilson, the pattern—not the light source—is projected onto the patient's teeth. '901 patent, col. 2:21-23 ("Various patterns are projected onto the tooth or teeth to be measured and [a] corresponding plurality of distorted patterns are captured by the probe.") (describing the '502 patent); RX-0202C.0001 ("A single spatial frequency grid pattern is projected onto an object."). In contrast, in the disclosed invention of the asserted patents, the plurality of light beams—the light source—is organized in a pattern. '901 patent, col. 6:23-28 ("Incident light beams 48 form an array of light beams arranged in an X-Y plane, in the Cartasian frame 50, propagating along the Z axis. As the surface on which the incident light beams hits is an uneven surface, the illuminated spots 52 are displaced from one another along the Z axis, at different (X, Y) locations.").

ii. Align has not shown that [redacted] "spatially filters" light.

In support of its position that [redacted] generates a plurality of incident light beams, Align points to the witness statement of its expert Mr. Ferraro. CIB at 41.[22] In his witness statement, Mr. Ferraro equates "light beams" to light that has been "spatially filtered" opining that [redacted] "generate[s] a plurality of incident of light beams by spatially filtering" the light generated by the Trios 3's white LED. CX-1940C (Ferraro WS) at Q/A 83; *see also id.* at Q/A 84. The only evidence that Mr. Ferraro points to in support of his opinion that [redacted] generates light beams by "spatial filtering"

[22] Although most of Mr. Ferraro's testimony cited by Align is in the context of claim 17 of the '447 patent, *see* CX-1940C (Ferraro WS) at Q/A 72-88, this testimony is applicable to the claims of the '901 patent, which shares a common specification and common claim terms with the '447 patent and the '448 patent.

light is U.S. Patent No. 6,525,828 (CX-1674; the "'828 patent"). *Id.* at Q/A 84. Mr. Ferraro's analysis of this patent is limited to his assertion that lines 18-42 of column 3 of the '828 patent support his opinion that transmitting light through [redacted] "results in generation of a plurality of light beams." CX-1940C (Ferraro WS) at Q/A 84, Q/A 88.

The cited portion of the '828 patent discusses aperture plate 120, which has a grid pattern of holes. The layer, aperture plate 120, is shown in Figure 2b.

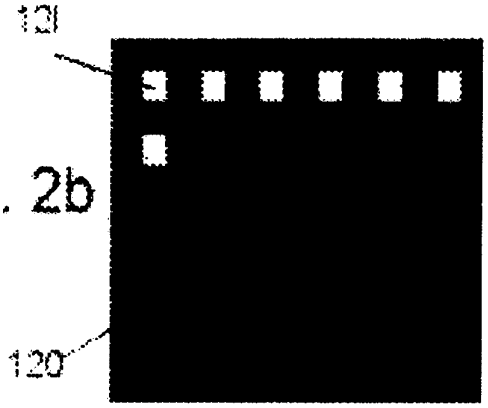


Fig. 2b

The grid pattern generates a plurality of light beams that illuminate the object being examined. '828 patent, col. 3:18-42.

To the extent that Mr. Ferraro's citation to the '828 patent is intended to suggest that the grid pattern of holes in aperture plate 120 is comparable to the accused products' [redacted], Mr. Ferraro fails to acknowledge and address significant differences between the two. Figure 2b of the '828 patent is not to scale. Teaching that the holes in aperture plate 120 are "considerably smaller than their spacing," the '828 patent refers to the holes as "pinholes." *Id.*, col. 2:43-46, Abstract ("the illumination grid being a first aperture plate having a first passive array of pinholes'), col. 5:21-23 (claim 1) ("the illumination grid being a first aperture

plate having a first passive array of pinholes"), col. 6:1-3 (claim 6) ("the first passive array of pinholes has the same dimensions as the second passive array of pinholes"), col. 6:30-32 (claim 8) ("said illumination grid comprising a first aperture plate having a first passive array of pinholes"). The '828 patent also notes that "[i]t is of course obvious that there are in reality many more holes than shown in the example grid with 6 x 6 holes" and that the grids could be 512 x 512 or 256 x 256 holes. '828 patent, col. 2:43-46, col. 3:29-31. As an example, in a 256 x 256 grid of holes, the holes could be dimensioned 4 μm x 4 μm and be spaced 22 μm apart. *Id.*, col. 2:43-49. As shown in Figure 2b, because the holes are "considerably smaller than their spacing," the holes are completely isolated from each other by surrounding opaque regions. *Id.*, col. 2:43-46,

In contrast to the "pinhole" array disclosed in the '828 patent, [redacted]. *See* JX-0295C ("[redacted]"). Moreover, [redacted]. RX-1567C (Zavislan RWS) at Q/A 227; Tr. (Christiansen) at 192:25-193:6.

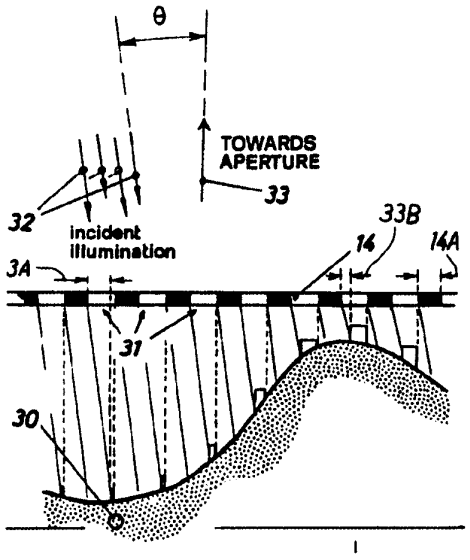
[redacted]

JX-0295C (annotated).

Given the dissimilarity between the "pinhole" array disclosed in the '828 patent and [redacted] in the accused products, Mr. Ferraro's testimony that the Trios 3 "spatially filters" light to create a plurality of light beams is unpersuasive.

iii. Align has not shown that the light rays that pass through the [redacted] are parallel.

In support of its argument that [redacted] generates a plurality of incident light beams, Align also points to the invalidity analysis of 3Shape's expert Dr. Kessler. CIB at 41. In forming his invalidity opinion, Dr. Kessler analyzed U.S. Patent No. 4,575,805 (RX-1330; the "'805 patent"). RX-1299 (Kessler WS) at Q/A 80-82. According to Dr. Kessler, "[t]he '805 Patent is directed to the use of a pattern projection imaging apparatus, which may include a hand-held probe, for determining the three-dimensional structure of objects, including teeth." *Id.* at Q/A 81. The "pattern projection imaging apparatus" transmits light through "a ruling 14 (Edmund Scientific Corp. Barrington, N.J., part #030517)." *Id.*, col. 3:65-67. Ruling 14 consists of series of transparent slits separated by opaque slits.



Id., Fig. 6 (excerpt).

In his expert report, Dr. Kessler opined that "[t]he '805 patent discloses passing the light through a 'ruling,' which results in casting a pattern onto the object wherein the pattern is made up of a plurality of parallel light rays or beams." Tr. (Kessler) at 650:18-651:5; CDX-0019.001. Align argues that Dr. Kessler's opinion that the ruling disclosed in the '828 patent creates light beams supports its argument that [redacted]. CIB at 41. Align's argument is unpersuasive.

The '828 patent explicitly teaches that the "pattern of light and dark stripes" is the result of "essentially parallel light rays 32" passing through the ruling. In his expert report, Dr. Kessler defines light beams in terms of "parallel light rays:" "the pattern is made up of a plurality of parallel light rays or beams." Tr. (Kessler) at 650:18-651:5; CDX-0019.001 (reproducing paragraph 435 of Dr. Kessler's initial expert report). There is no evidence that the rays of light projected onto the teeth by the accused products are parallel to each other. There no evidence showing that [redacted] and the ruling in the '802 patent would have similar effects on light passing through the transparent portions. For instance, there is no evidence comparing the dimensions of slits of the ruling to [redacted] and comparing the ruling's optical properties [redacted]

Based on the foregoing, I find that that the accused products do not generate a plurality of incident light beams as required by claim 15.

b. "focusing the plurality of incident light beams to a focal plane . . ."

The third step of claim 15 requires "focusing the plurality of incident light beams to a focal plane external to the probing member so as to illuminate a portion of the three-dimensional

structure." '901 patent, col. 10:21-23. Because Align has not shown that the Trios 3 products generate "a plurality of incident light beams," it cannot show that the Trios 3 products focus the "plurality of incident light beams." Moreover, even if the light that passes through the [redacted] were deemed to comprise a "plurality of incident light beams," this limitation still would not be satisfied. Instead of focusing the light itself onto the focal plane, the Trios 3 products [redacted]. Tr. (Zavislan) at 939:1-8; JX-0262C.0017 [redacted]; CX-0514C.0001 [redacted]. Tr. (van der Poel) at 864:4-11, 866:5-7; RX-1567C (Zavislan RWS) at Q/A 22 ("[redacted] the light beams described in the Confocal Scanning Patents. [redacted]."). [redacted]. *Id.* at 866:5-18.

Align points to the following figure from a 3Shape Powerpoint and argues that 3Shape's "internal documents created prior to the filing of this Investigation" show that the light projected from the Trios 3 product "[redacted]." CIB at 40.

CX-0112C.0004.[23] The diagram, however, only shows the structure of light from a single point on the tooth. Tr. (Christiansen) at 190:23-194:2. In operation, the [redacted] by the Trios 3 scanner. *Id.*[24]

c. "measuring a characteristic of a plurality of returned light beams . . ."

The fourth step of claim 15 requires "measuring a characteristic of a plurality of returned light beams generated from illuminating the portion of the three-dimensional structure with the plurality of incident light beams." '901 patent, col. 10:24-27. Returned light beams are light beams created "by the reflection of incident light beams from the surface of the three-

[23] The same diagram also appears in CX-01038C.0004 and is relied upon by Align to show that "[t]he TRIOS 3 [redacted] . . . ." CIB at 42

[24] 3Shape argues that Align mischaracterizes the ray trace diagram shown in JX-0208C as showing that the accused products focus light beams on a patient's teeth. RRB at 33-34. Align, however, did not cite the diagram in support of its contention that the light emitted by the Trios 3 products is in the form of light beams, but in support of its contention that "[t]he TRIOS 3 [redacted] . . . ." CIB at 42. The parties' dispute, however, is not whether the Trios 3 [redacted].

dimensional structure." Order No. 32 (Sept. 25, 2018). As discussed above, Align failed to show that the accused products generate a plurality of incident light beams. Because there are no incident light beams to be reflected, there are no "returned light beams" to be measured.

d. "determining a surface topology . . ."

The fifth and final step of claim 15 requires "determining a surface topology of the portion of the three-dimensional structure based at least in part on the measured characteristic of the plurality of returned light beams." '901 patent, col. 10:28-32. As explained with respect to the fourth step of claim 15, the accused Trios 3 products do not measure a characteristic of a plurality of returned light beams. Accordingly, the accused products cannot perform the fifth step of claim 15.

2. Claims 16-19

Claims 16-19 depend from claim 15. Because the Trios 3 products do not infringe claim 15, the products do not infringe its dependents. *Monsanto Co. v. Syngenta Seeds, Inc.*, 503 F.3d 1352, 1359 (Fed. Cir. 2007) ("One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim.") (quoting *Wahpeton Canvas Co., Inc. v. Frontier, Inc.*, 870 F.2d 1546, 1552 (Fed. Cir. 1989) (internal quotation marks omitted).

3. Claim 1

Claim 1 is an apparatus claim and consists of a preamble and five claim elements. There is no dispute that the Trios 3 products satisfy the preamble to the extent that it is limiting and the first claim element. Each accused Trios 3 product is an "apparatus for determining the surface topology of a portion of a three-dimensional structure" as required by the preamble. *See, e.g.*, RX-1567C (Zavislan RWS) at Q/A 136 ("The 3 Shape TRIOS 3 Products perform scanning

using an ultrafast optical section technique. The ultrafast optical sectioning technique starts by [redacted] that are later used to generate a three-dimensional model of the scanned object (*e.g.*, teeth)."). It is undisputed that the Trios 3 products have the first claim limitation: a probing member. CX-1940C (Ferraro WS) at Q/A 64; Tr. at 932:22-25 (Zavislan) (testifying that he did not provide an opinion whether the Trios 3 provides a probing member). The remaining limitations are disputed and are addressed below.

a. "illumination unit"

Claim 1 requires "an illumination unit configured to generate a plurality of incident light beams." '901 patent, col. 8:55-58. "Illumination unit" is a means-plus-function term subject to § 112, ¶ 6. Order No. 32 (Sept. 25, 2018) at 22. The claimed function of "illumination unit" is "to generate a plurality of incident light beams." *Id.* at 24. The following structures are disclosed in the specification as performing the claimed function: illumination unit disclosed at '901 patent, col. 2:63-64; the light emitters and diffraction or refraction optics disclosed at *id.*, col. 4:9-22; semiconductor laser unit 28 disclosed at *id.*, col.5:39-41 and in Figures 1A and 4; module 38 disclosed at *id.*, col. 5:45-51 and in Figures 1A and 4; laser emitter 154A-C disclosed at *id.*, col. 8:25-27; and optics expander 34 disclosed in *id.*, Figures 1A and 4. *Id.* at 24-25. Align argues that the accused products satisfy this limitation because they use an LED and condenser lenses to generate a parent light beam that is [redacted] into a plurality of "incident light beams." CIB at 56. As discussed above with respect to claim 15, however, light beams are not generated [redacted]. *Supra* section V.D.1.a. Because the accused structures do not perform the claimed function, they do not literally satisfy the claim limitation. *Frank's Casing Crew & Rental Tools, Inc. v. Weatherford Int'l, Inc.*, 389 F.3d 1370, 1378 (Fed. Cir. 2004) ("Literal infringement of a § 112, ¶

6 limitation requires that the relevant structure in the accused device perform the identical function recited in the claim and be identical or equivalent to the corresponding structure in the specification.") (quoting *Odetics, Inc. v. Storage Tech. Corp.*, 185 F.3d 1259, 1267 (Fed. Cir. 1999) (internal quotation marks omitted).

b. "optical system"

Claim 1 requires that the apparatus have "an optical system configured to focus the plurality of incident light beams to a focal plane external to the probing member so as to illuminate the portion of the three-dimensional structure." '901 patent, col. 8:55-58. "Optical system" is a means-plus-function term subject to 35 U.S.C. § 112, ¶ 6. Order No. 32 (Sept. 25, 2018) at 27. The claimed function of the "optical system" is "to focus the plurality of incident light beams." *Id.* at 32. The disclosed structure corresponding to the claimed function consists of "a partially transparent mirror or beam splitter, confocal optics operating in a telecentric mode, relay optics, and an endoscopic probing member operating as a light guide to ensure total internal reflection" and equivalents thereof. *Id* at 34. Align argues that the accused products have the corresponding structure in the form of "optics and a lens system that focuses the light beams from [redacted], including a beam splitter and relay optics (in the form of the fixed lenses)." CIB at 57. As discussed above with respect to claim 15, however, the accused products do not focus a plurality of incident light beams. *Supra* section V.D.1.b. Because the accused structures do not perform the claimed function, they do not literally satisfy the claim limitation. *Frank's Casing Crew,* 389 F.3d at 1378.

c. "detector unit"

Claim 1 requires a "detector unit configured to measure a characteristic of a plurality of returned light beams generated from illuminating the portion of the three-dimensional structure with the plurality of light beams." '901 patent, col. 8:59-63. "Detector unit" was construed to mean an "image sensor." Order No. 32 (Sept. 25, 2018) at 48. Although the accused products have an image sensor in the form of a LUX13HSC image sensor by Luxima Technology, Inc., JX-0259C; JX-0419C, the image sensor is not "configured to measure a characteristic of a plurality of returned light beams generated from illuminating the portion of the three-dimensional structure with the plurality of light beams," as required by the claims. As discussed above with respect to claim 15 of the '901 patent, the accused Trios 3 products do not generate "returned light beams." *Supra* section V.D.1.c. Because the accused products do not generate "returned light beams," they cannot "measure a characteristic of a plurality of returned light beams."

d. "processor"

Claim 1 requires "a processor coupled to the detector unit and configured to determine a surface topology of the portion of the three-dimensional structure based at least in part on the measured characteristic of the plurality of returned light beams." '901 patent, col 8:63-67. This limitation is a means-plus-function limitation. Order No. 32 (Sept. 25, 2018) at 42. The claimed function is "determining a surface topology of the portion of the three-dimensional structure." *Id.* at 43-44. The corresponding structure consists of "image capturing module 80" and CPU 82 performing the algorithm described at column 2:53-58, column 3:13-19, 3:24-65, column 4:29-33, column 6:59-63, and column 7:12-20 of the '901 patent and equivalents thereof. *Id.* at 45-46. Although the accused products have processors in the form of an FPGA on the scanner and a

CPU on a host PC, because the Trios 3 systems do not generate returned light beams, these processors do not perform the claimed function of "determining a surface topology of the portion of the three-dimensional structure based at least in part on the measured characteristic of the plurality of returned light beams." Because the accused structures do not perform the claimed function, they do not literally satisfy the claim limitation. *Frank's Casing Crew,* 389 F.3d at 1378.

4. Claims 2-6

Claims 2-6 depend directly or indirectly from claim 1. Because the Trios 3 products do not infringe claim 1, the products do not infringe its dependents. *Monsanto*, 503 F.3d at 1359.

5. Doctrine of Equivalents

To the extent that the Trios 3 products are found not to literally infringe certain claim limitations, Align argues that those are satisfied under the DOE. Align asserts that accused products satisfy the following limitations from claims 1-6 under the DOE: (1) "illumination unit," (2) "optical system," (3) "detector unit," (4) "processor," (5) "translation mechanism," and (6) "characteristic measured over the range." CIB at 64-66. Align also asserts that following limitations from claim 15-19 are satisfied under the DOE: (1) "generating a plurality of light beams," (2) "focusing light beams," (3) "measuring a characteristic," (4) "determining a surface topology," (5) "changing a position of focal plane [over a range/in direction of propagation," and (6) "characteristic measured over the range." *Id.* Even if Align's DOE analysis were accepted, the accused products would still not infringe the claims.

The asserted claims require the generation of a "plurality of incident light beams" and a "plurality of returned light beams." As discussed above, the accused products do not generate either "incident light beams" or "returned light beams" and Align does not raise a DOE argument

with respect to these claim elements. *See* CIB at 64-66. Accordingly, even if Align's DOE arguments were accepted, the accused products would still not satisfy the limitations requiring a "plurality of incident light beams" and a "plurality of returned light beams."

E. '447 patent infringement

Align is asserting claims 17, 19, 20, 23, and 24 of the '447 patent. CIB at 117. All of the asserted claims are apparatus claims. Claim 17 is an independent claim and the remaining asserted claims depend directly or indirectly from it.

1. Claim 17

Claim 17 consists of a preamble and six claim elements. There is no dispute that the Trios 3 products satisfy the preamble to the extent that it is limiting and the first claim element. Each Trios 3 product is an "apparatus for determining surface topology of at least a portion of a three-dimensional structure," as required by the preamble. *See, e.g.,* RX-1567C (Zavislan RWS) at Q/A 136 ("The 3 Shape TRIOS 3 Products perform scanning using an ultrafast optical section technique. The ultrafast optical sectioning technique starts by [redacted] that are later used to generate a three-dimensional model of the scanned object (*e.g.,* teeth)."). As required by the first claim element, the Trios 3 products have a "probing member," in the form of a tube and tip located on the front of the handheld scanner that can be inserted into a patient's mouth. CX-1940C (Ferraro WS) at Q/A 64; Tr. (Zavislan) at 932:22-25. As further required by the first claim element, the probing member has a "sensing face," *i.e.*, an open aperture interface through which returned light will pass, consisting of a front glass and a tip mirror. JX-0418C; CX-0658C, CX-0514C.0001 [redacted]; CX-0891C; Tr. (van der Poel) at 815:6-816:2.

The remaining claim elements are disputed and are addressed below.

a. "illumination unit"

The second element of claim 17 is "an illumination unit configured to transmit a parent light beam along an optical path in the hand-held probe." '447 patent, col. 10:7-8. "Illumination unit" is a means-plus-function term subject to § 112, ¶ 6. Order No. 32 (Sept. 25, 2018) at 22. The term's claimed function is "to transmit a parent light beam," and the disclosed structure corresponding to the claimed function consists of the illumination unit disclosed at '901 patent, col. 2:63-64; the light emitters disclosed at *id.*, col. 4:17-22; semiconductor laser unit 28 disclosed at *id.*, col.5:39-41 and in Figures 1A and 4; and laser emitter 154A-C disclosed at *id.*, col. 8:25-27, and equivalents thereof. Order No. 32 (Sept. 25, 2018) at 24. As discussed above, the light emitters disclosed at lines 17-22 of column 4 of the '901 patent are laser light emitters. *Supra* section V.B.

Align argues that the "illumination unit" limitation is satisfied by the Trios 3 products' "white light emitting diode (*i.e.*, a white LED [redacted]) and two condenser lenses [redacted]." CIB at 39 (citing CX-1940C (Ferraro WS) at Q/A 72-75; JX-0264C; CX-1904C; CX-1907C; CX-0514C.0001). The white light LED in the accused products is different than the structures disclosed in the specification as corresponding to the claimed function. The only structure disclosed in the specification as generating a parent light beam are laser emitters. Under § 112, ¶ 6, however, the corresponding structure includes structural equivalents. 35 U.S.C. § 112, ¶ 6 ("An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.""). The

"inquiry for equivalent structure under § 112, ¶ 6 examines whether 'the assertedly equivalent structure performs the claimed function in substantially the same way to achieve substantially the same result as the corresponding structure described in the specification.'" *Frank's Casing Crew*, 389 F.3d at 1378. In addition to the range of equivalents allowed under § 112, ¶ 6, a patent holder can show equivalence under the DOE. To show equivalence under the DOE, the patent holder must show that the accused structure "perform[s] substantially the same function in substantially the same way with substantially the same results" as the disclosed structure. *Ring & Pinion Service Inc. v. ARB Corp.*, 743 F.3d 831, 835 (Fed. Cir. 2014).

As can be seen, the two tests for equivalence are similar to each other. There are two differences between the tests. The first difference concerns the timing of the equivalence determination. *Ring & Pinion*, 743 F.3d at 835. Under § 112, ¶ 6, equivalence is evaluated as of the issuance date of the patent. *Id.* Under the DOE, equivalence is evaluated at the time of infringement. *Id.* Thus, technology arising after the issuance of the patent will fall outside of the § 112, ¶ 6 equivalence, but can be captured under the DOE. *Id.* The second difference is that to be an equivalent under § 112, ¶ 6, the accused structure must have the same function as the disclosed structure, while the DOE analysis requires only that the accused structure's function be substantially the same as that of the disclosed structure. *Ring & Pinion*, 743 F.3d at 835 ("For literal infringement, the accused structures must perform the function recited in the claim (identical function). The doctrine of equivalents covers accused structures that perform substantially the same function in substantially the same way with substantially the same results.").

The claimed function is to transmit a parent light beam. The white light LED and condenser lenses transmit a parent beam. At his deposition, 3Shape's expert Dr. Zavislan

admitted that the white LED and two condenser lenses generate a "light beam." Tr. (Zavislan) at 922:19-924:14. At the hearing, Dr. Zavislan qualified his opinion that the white LED and condenser lenses generated a "light beam," testifying that the "light beam" generated by the accused products is only a "light beam" with respect to "the general concept of light beam" and is not a "light beam" in the context of the asserted patents. *Id.* at 922:9-13. While Dr. Zavislan did not provide his reasoning for this conclusion at the hearing, in his witness statement he opines that white LED provides incoherent light, while the laser units disclosed in the specification provide coherent light. RX-1567C (Zavislan RWS) at Q/A 205.

The claimed function, however, is "transmitting a parent light beam," not "transmitting a parent light beam of coherent light." Accordingly, it is irrelevant that the light beam produced by the LED is incoherent light, as long as it forms a light beam. Because the white LED and condenser lenses perform the same function as the lasers disclosed in the specification, "the structural equivalence inquiry under § 112 and the structural equivalence portion of the doctrine of equivalents are coextensive." *Ring & Pinion*, 743 F.3d at 835. The remaining questions for both § 112, ¶ 6 equivalency and the DOE are whether the accused structures transmit a parent light beam in substantially the same way and with the substantially the same result as the laser emitters disclosed in the specification.

In support of its contention that the accused structures transmit a parent light beam in substantially the same way and with substantially the same result as the disclosed laser emitters, Align cites its expert's witness statement and two textbooks that are also cited by its expert.[25] Each of the textbooks—"Optics" by Eugene Hecht ("Hecht;" CX-1716) and "Elements of

[25] In addition to the textbooks discussed below, Align and its expert cited a third exhibit (CX-1796), which was not entered into evidence.

Modern Optical Design" by Donald O'Shea ("O'Shea;" CX-0909)—is several hundred pages long. Neither Align nor its expert cite to specific pages or explain how these textbooks support their assertion that the accused structures transmit a parent light beam in substantially the same way and with substantially the same result as the disclosed laser emitters. It is impossible from the blanket citation to determine whether the textbooks in fact support Align's and its expert's position.

With regard to the witness statement of Align's expert, Mr. Ferraro testifies that

> To the extent the Accused Products do not literally infringe this claim element, they infringe under the doctrine of equivalents. For example, any differences between the claim limitation and the Accused Products are insubstantial changes from that which is claimed. Additionally, the Accused Products perform substantially the same function (transmitting a light beam) in substantially the same way (using an illumination unit) to achieve substantially the same result (determining surface topology of at least a portion of a three-dimensional structure) and therefore are equivalent.

CX-1940C (Ferraro WS) at Q/A 79. The only evidence cited in support of this opinion cited by Mr. Ferraro is the citation to Hecht and O'Shea discussed above. Mr. Ferraro's unsupported and conclusory opinion is entitled to no weight. *See Izumi Prods. Co. v. Koninklijke Philips Electronics N.V.*, 140 Fed. Appx. 236, 244 (Fed. Cir. 2005) (non-precedential) (holding the district court did not abuse its discretion in excluding conclusory expert testimony regarding infringement under the doctrine of equivalents where opinion was based solely on expert's subjective belief).

Based on the foregoing, I find that Align has failed to meet its burden of establishing by a preponderance of the evidence that the white LED and condenser lenses in the accused products transmit a parent beam in substantially the same way and with substantially the same result. Accordingly, Align has failed to establish that the accused structures are equivalent to the disclosed structures under either § 112, ¶ 6 or the DOE.

b. "module"

Claim 17 requires a "a module positioned in the optical path and configured to generate a plurality of incident light beams." '447 patent, col. 10:9-10. This term was not construed in the Markman order. Align argues that [redacted] corresponds to the claimed module. CIB at 119. As discussed above with respect to the '901 patent, [redacted] in the accused products does not generate "a plurality of incident light beams." Accordingly, I find that this limitation is not satisfied by the accused products.

c. "optical system"

Claim 17 requires "an optical system configured to focus the plurality of incident light beams at a focal plane forward of the sensing face." '447 patent, col. 10:11-13. The construction of the term "optical system" recited in this limitation is identical to that of the term "optical system" recited in claim 1 of the '901 patent. Order No. 32 (Sept. 25, 2018) at 27, 24-25. Both terms are means-plus-function terms subject to § 112, ¶ 6. Order No. 32 (Sept. 25, 2018) at 22. The terms have identical claimed functions (to focus the plurality of incident light beams) and identical corresponding structure (a partially transparent mirror or beam splitter, confocal optics operating in a telecentric mode, relay optics, and an endoscopic probing member operating as a light guide to ensure total internal reflection). *Id.* at 37, 32, 34. Accordingly, the accused 3Shape products do not satisfy the "optical system" limitation of claim 17 of the '447 patent for the same reasons that they do not satisfy the "optical system" limitation of claim 1 of the '901 patent. *Supra* section V.D.3.b.

d. "detector unit"

Claim 17 requires "a detector unit configured to measure intensities of a plurality of returned light beams that are generated from illuminating the portion of the three-dimensional structure with the plurality of incident light beams." '447 patent, col. 10:13-17. "Detector unit"

was construed to mean an "image sensor." Order No. 32 (Sept. 25, 2018) at 48. Although the accused products have an image sensor in the form of a LUX13HSC image sensor by Luxima Technology, Inc., JX-0259C; JX-0419C, the image sensor is not "configured to measure intensities of a plurality of returned light beams that are generated from illuminating the portion of the three-dimensional structure with the plurality of incident light beams," as required by the claim. As discussed above with respect to claim 15 of the '901 patent, because the accused Trios 3 products do not generate "incident light beams," there are no "returned light beams" to be measured. *Supra* section V.D.1.c.

e. "processor"

Claim 17's final element requires "a processor coupled to the detector unit and configured to determine a surface topology of the three-dimensional structure based at least in part on the measured intensities of the plurality of returned light beams." '447 patent, col. 10:17-20. This limitation is a means-plus-function limitation. Order No. 32 (Sept. 25, 2018) at 42. The claimed function is "a processor coupled to the detector unit and configured to determine a surface topology of the three-dimensional structure based at least in part on the measured intensities of the plurality of returned light beams." *Id.* at 43. The corresponding structure consists of image capturing module 80 and CPU 82 performing the algorithm described at column 2:53-58, column 3:13-19, 3:24-65, column 4:29-33, column 6:59-63, and column 7:12-20 of the '901 patent and equivalents thereof. *Id.* at 45-46. Although the accused products have processors in the form of an FPGA on the scanner and a CPU on a host PC, because the Trios 3 systems do not generate returned light beams, these processors do not perform the claimed function of "determining a surface topology of the three-dimensional structure based at least in part on the measured intensities of the plurality of returned light beams." Because the accused

structures do not perform the claimed function, they do not literally satisfy the claim limitation. *Frank's Casing Crew,* 389 F.3d at 1378.

2. Claims 19, 20, 23, and 24

Claims 19, 20, 23, and 24 depend directly or indirectly from claim 17. Because the Trios 3 products do not infringe claim 17, the products do not infringe its dependents. *Monsanto*, 503 F.3d at 1359.

3. Doctrine of Equivalents

To the extent that the Trios 3 products are found not to literally infringe certain claim limitations, Align argues that those limitations are satisfied under the DOE. Align asserts that the following limitations are met under the DOE: (1) "probing member," (2) "illumination unit," (3) "module," (4) "optical system," (5) "detector unit," (6) "processor," (7) "translation mechanism," and (8) "pattern." CIB at 122-24. The accused products literally satisfy the "probing member" limitation, therefore Align's DOE arguments with respect to this limitation are moot. Align's DOE arguments with respect to "illumination unit" are addressed above. *Supra* subsection 1.a.

The asserted claims require the generation of a "plurality of incident light beams" and a "plurality of returned light beams." As discussed above, the accused products do not generate either "incident light beams" or "returned light beams" and Align does not raise a DOE argument with respect to these claim elements. *See* CIB at 122-24. Accordingly, even if Align's DOE arguments were accepted, the accused products would still not satisfy the limitations requiring a "plurality of incident light beams" and a "plurality of returned light beams."

F. '448 patent infringement

Align is asserting claims 15 and 18-20 of the '448 patent. CIB at 117. Claim 15 is

independent and the remaining claims depend directly or indirectly from claim 15.

1. Claim 15

Claim 15 is an independent claim and consists of a preamble and six claim elements. There is no dispute that the Trios 3 products satisfy the preamble to the extent that it is limiting and the first claim element. Each Trios 3 product is an "apparatus for determining surface topology of at least a portion of a three-dimensional structure," as required by the preamble. *See, e.g.*, RX-1567C (Zavislan RWS) at Q/A 136 ("The 3 Shape TRIOS 3 Products perform scanning using an ultrafast optical section technique. The ultrafast optical sectioning technique starts by [redacted] that are later used to generate a three-dimensional model of the scanned object (*e.g.*, teeth)."). As required by the first claim element, the Trios 3 products have a "probing member," in the form of a tube and tip located on the front of the handheld scanner that can be inserted into a patient's mouth. CX-1940C (Ferraro WS) at Q/A 64; Tr. at 932:22-25 (Zavislan) (testifying that he did not provide an opinion whether the Trios 3 provides a probing member). As further required by the first claim element, the probing member has a "probing end." JX-0418C; CX-0658C, CX-0514C.0001 [redacted]; CX-0891C; Tr. (van der Poel) at 815:6-816:2.

The remaining claim elements are disputed and are addressed below.

a. "illumination unit"

Claim 15 requires "an illumination unit configured to generate a plurality of incident light beams for illuminating the portion of the three-dimensional structure." '448 patent, col. 10:8-10. The construction of the term "illumination unit" recited in this limitation is identical to that of the term "illumination unit" recited in claim 1 of the '901 patent. Order No. 32 (Sept. 25, 2018) at

27, 24-25. Order No. 32 (Sept. 25, 2018) at 22, 24-25. Both terms are means-plus-function terms subject to § 112, ¶ 6. *Id.* at 22. The terms have identical claimed functions (to generate a plurality of incident light beams) and identical corresponding structure (illumination unit disclosed at '901 patent, col. 2:63-64; the light emitters and diffraction or refraction optics disclosed at *id.*, col. 4:9-22; semiconductor laser unit 28 disclosed at *id.*, col.5:39-41 and in Figures 1A and 4; module 38 disclosed at *id.*, col. 5:45-51 and in Figures 1A and 4; laser emitter 154A-C disclosed at *id.*, col. 8:25-27; and optics expander 34 disclosed in *id.*, Figures 1A and 4). *Id.* at 24-25. Accordingly, the accused 3Shape products do not satisfy the "illumination unit" limitation of claim 15 of the '448 patent for the same reasons that they do not satisfy the "illumination unit" limitation of claim 1 of the '901 patent.

b. "optical system"

Claim 15 requires an "optical system configured to focus the plurality of incident light beams at a plurality of focal planes forward of the probing end." '448 patent, col. 10:11-13. The construction of the term "optical system" recited in this limitation is identical to that of the term "optical system" recited in claim 1 of the '901 patent. Order No. 32 (Sept. 25, 2018) at 27, 24-25. Order No. 32 (Sept. 25, 2018) at 27, 24-25. Both terms are means-plus-function terms subject to § 112, ¶ 6. Order No. 32 (Sept. 25, 2018) at 22. The terms have identical claimed functions (to focus the plurality of incident light beams) and identical corresponding structure (a partially transparent mirror or beam splitter, confocal optics operating in a telecentric mode, relay optics, and an endoscopic probing member operating as a light guide to ensure total internal reflection). *Id.* at 37, 32, 34. Accordingly, the accused 3Shape products do not satisfy the "optical system" limitation of claim 15 of the '448 patent for the same reasons that they do not satisfy the "optical system" limitation of claim 1 of the '901 patent.

c. "detector unit"

Claim 15 requires "a detector unit configured to measure intensities of a plurality of returned light beams that are generated from illuminating the portion of the three-dimensional structure with the plurality of incident light beams." '447 patent, col. 10:13-16. This limitation is identical to the "detector unit" limitation of claim 17 of the '447 patent. '447 patent, col. 10:13-17 ("a detector unit configured to measure intensities of a plurality of returned light beams that are generated from illuminating the portion of the three-dimensional structure with the plurality of incident light beams"). Accordingly, the accused 3Shape products do not satisfy the "detector unit" limitation of claim 15 of the '448 patent for the same reasons that they do not satisfy the "detector unit" limitation of claim 17 of the '447 patent.

d. "processor"

Claim 15 requires a "a processor coupled to the detector unit and configured to determine a surface topology of the three-dimensional structure based at least in part on the measured intensities of the plurality of returned light beams." '448 patent, col. 10:17-20. This limitation is identical to the "processor" limitation of claim 17 of the '447 patent. '447 patent, col. 10:17-20 ("a processor coupled to the detector unit and configured to determine a surface topology of the three-dimensional structure based at least in part on the measured intensities of the plurality of returned light beams"). Accordingly, the accused 3Shape products do not satisfy the "processor" limitation of claim 15 of the '448 patent for the same reasons that they do not satisfy the "processor" limitation of claim 17 of the '447 patent.

2. Claims 18-20

Claims 18-20 depend directly or indirectly from claim 1. Because the Trios 3 products do not infringe claim 1, the products do not infringe its dependents. *Monsanto*, 503 F.3d at 1359.

3. Doctrine of Equivalents

To the extent that the Trios 3 products are found not to literally infringe certain claim limitations, Align argues those limitations are satisfied under the DOE. Align asserts that the following limitations are met under the DOE: (1) "probing member," (2) "illumination unit," (3) "optical system," (4) "detector unit," (5) "processor," (6) "translation mechanism," and (6) "pattern." CIB at 122-24. The accused products literally satisfy the "probing member" limitation, therefore Align's DOE arguments with respect to this limitation are moot.

The asserted claims require the generation of a "plurality of incident light beams" and a "plurality of returned light beams." As discussed above, the accused products do not generate either "incident light beams" or "returned light beams" and Align does not raise a DOE argument with respect to these claim elements. *See* CIB at 122-24. Accordingly, even if Align's DOE arguments were accepted, the accused products would still not satisfy the limitations requiring a "plurality of incident light beams" and a "plurality of returned light beams."

VI. INVALIDITY

3Shape contends that the asserted claims are anticipated by Picard (RX-1322). 3Shape further contends that the asserted claims are rendered obvious by (1) Picard in combination with one or more secondary references and (2) Xiao (RX-1324) in combination Gmitro (RX-1325) alone or in further combination with one or more secondary references. The secondary references relied upon by 3Shape are Ishihara (RX-1329) and Watson 1992 (RX-1328). In addition to its prior-art based invalidity contentions, 3Shape contends that the asserted claims of the '901 patent are invalid for failing to comply with the written description requirement.

A. Prior Art Status of References

Through a series of continuations, the asserted patents claim priority to a PCT application

filed on August 5, 1998. '901 patent, cover; '447 patent, cover, '448 patent, cover. There is no dispute that the references relied upon by 3Shape qualify as prior art. Picard is French Patent Application FR2707018 by Picard and was published on December 30, 1994. RX-1322.0001. Xiao is the article "Real-time confocal scanning optical microscope," Appl. Phys. Lett. 53(8):716-18 (1988) by Xiao *et al.* and was published in August, 1998. RX-1324.0001. Gmitro is the article "Confocal microscopy through a fiber-optic imaging bundle," Optics Letters 18(8):565-67 (1993) by Gmitro *et al.* and was published on April 15, 1993. RX-1325.0001. Watson 1992 is the article "In vivo confocal microscopy in clinical dental research: an initial appraisal," J. Dent. 20:352-58 (1992) by Watson *et al.* and was published in 1992. RX-1328.0001. Ishihara is U.S. Patent No. 5,737,084 to Ishihara. RX-1329.0001. Ishihara was filed on September 26, 1996 and issued on April 7, 1998. *Id.* Picard, Xiao, Gmitro, and Watson are prior art under 35 U.S.C. § 102(b) and Ishihara is prior art under 35 U.S.C. § 102(a) and (e).

B. Anticipation

3Shape argues that Picard anticipates the asserted claims. With one exception, 3Shape's anticipation arguments are facially flawed. With the exception of claim 15 of the '901 patent, 3Shape's anticipation arguments are based on Picard in combination with Ishihara ('901 patent, claims 1 and 2; '447 patent, claims 17, 23; '448 patent, claims 15 and 18), Watson 1992 ('901 patent, claims 16-19), or both ('901 patent, claims 3-6; '447 patent, claims 19, 20, and 24; '448 patent, claims 19 and 20). For anticipation, however, 3Shape "must show 'that the four corners of a single, prior art document describe every element of the claimed invention.'" *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008) (quoting *Xerox Corp. v. 3Com Corp.*, 458 F.3d 1310, 1322 (Fed. Cir. 2006)); *see also Therasense, Inc. v. Becton, Dickinson & Co.*, 593 F.3d 1325, 1332 (Fed. Cir. 2010 ("Anticipation requires the presence in a single prior art

disclosure of all elements of a claimed invention arranged as in the claim.") (quoting *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983)) (internal quotation marks omitted). Accordingly, except for claim 15 of the '901 patent, 3Shape's anticipation arguments fail as a matter of law. For claim 15 of the '901 patent, 3Shape relies on the Figure 8 embodiment of Picard, which is a modified version of the Figure 3 embodiment.

1. Picard

Before describing the purported invention, Picard discusses prior art confocal imaging apparatuses. One of these apparatuses is shown in Figure 1. RX-1322.0003.

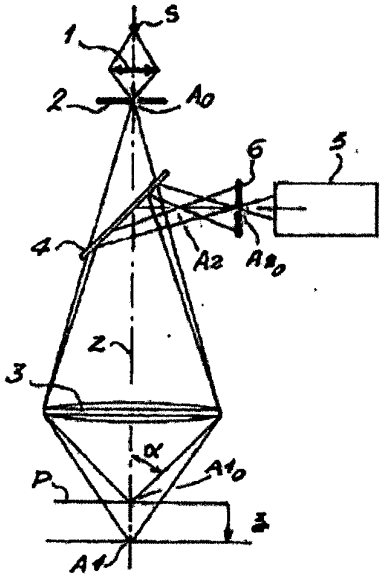


FIG. 1

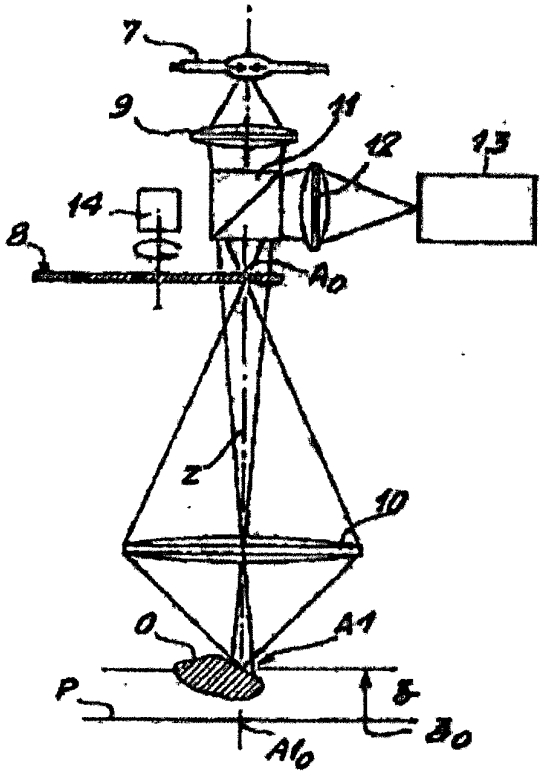
RX-1322.0031. The confocal imaging apparatus shown in Figure 1 generates a point source from light source S. *Id.* at .0003-.0004. The point source is projected as a spot ($A1_0$) onto the

object being examined. *Id.* at 0003-.0004. Light from the spot is reflected to a photodetector (5). *Id.* at RX-1322.0004. By scanning the single light spot ($A1_0$) over the object, the apparatus is able to obtain a two-dimensional image of the object. *Id.*

Picard teaches that implementations of the Figure 1 embodiment either "operate at acquisition rates that are lower than the video rate" or are very "complex and costly." *Id.* One way of obtaining higher acquisition rates without an overly "complex and costly" system is to use a Nipkow disk. *Id.* As explained by Picard,

> A Nipkow disk is a metal disk, for example a chrome mask, which is drilled with tens of thousands of holes a few micrometers in diameter and arranged in spirals . . . .

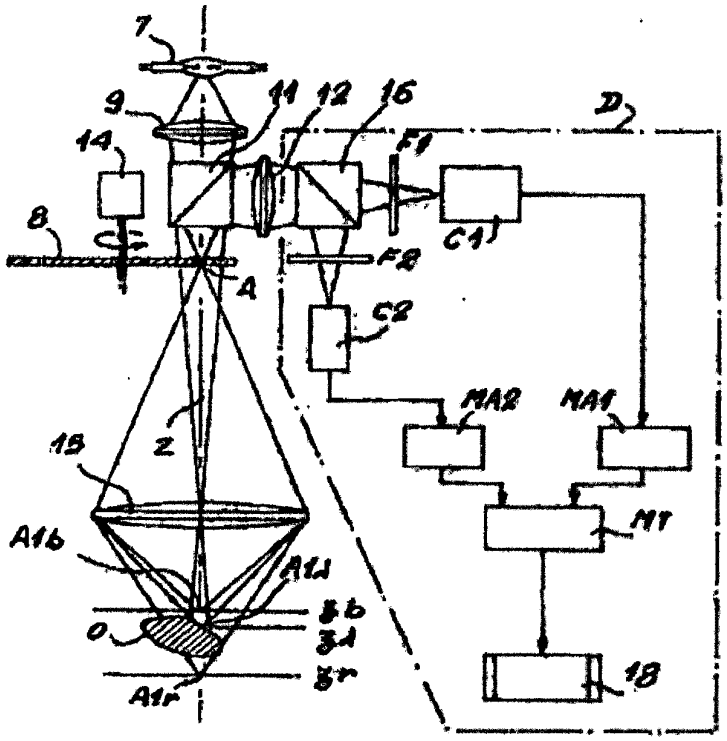
Id. (internal citation omitted). Figure 2 of Picard shows confocal imaging device with a Nipkow disk.



Id. at .0031. In the Figure 2 apparatus, light source 7—which can be a "conventional light source[] such as the arc lamp"—illuminates Nipkow disk 8. *Id.* at .0006. When illuminated, Nipkow disk 8 forms "a set of point light sources." *Id.* at .0007. The point light sources are projected onto object O. *Id.* Light reflected from object O passes through Nipkow disk 8 and is channeled to CCD video camera 13. *Id.* The Figure 2 apparatus can obtain three-dimensional images. *Id.* In order to do so, a set of images are taken as the object is moved to different positions along the z-axis, so that "for each point (x,y), there are N images along the axis Z, and the position z corresponding to the intersection of the object and an axis parallel to the axis Z corresponds to the maximum light intensity." *Id.* at 0008.

In contrast to the Figure 2 apparatus, which captures a set of images in multiple acquisitions in order to generate a three-dimensional image, another prior art device was able to obtain a three-dimensional image in a "single acquisition." *Id.* This prior art device used "a polychromatic light source, *i.e.*, one having at least two different wavelengths," such as "an argon laser whose light contains no more than seven sufficiently intense wavelengths in the visible spectrum." *Id.* at .0009. In a single acquisition, the device was able to capture images in seven planes, wherein each plane corresponds to a wavelength of light. *Id.* While this was "sufficient for use in microscopy, for observation of microelectronic objects such as integrated circuits," it was "unusable for applications requiring a significant longitudinal dynamic." *Id.* The purported invention of Picard—embodiments of which are shown in Figures 3, 7, and 8—essentially seeks to improve upon this device by modifying it to use the "source of broad spectrum light" and Nipkow disk 8 disclosed in the Figure 2 embodiment. *Id.* at .0009-.0010.

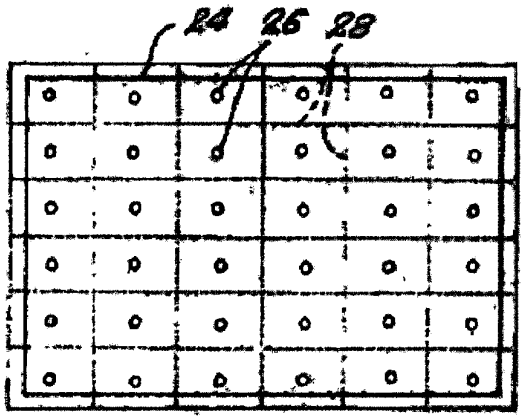
Figure 3 shows one of the embodiments of the purported invention.



Id. at RX-1322.0032. The Figure 3 apparatus uses "broad-spectrum light source 7, for example a xenon arc lamp" and "Nipkow disk 8." *Id.* at .0013. The Figure 3 apparatus has an "objective lens 15 having an axial chromatism," such that it "has as many different focal planes as there are wavelengths present in the incident light beam." *Id.* at .0014. In a single acquisition, the Figure 3 device can take as many images as there are wavelengths in the light. *Id.* at .0014. For each spot projected onto the object, the maximum light intensity of the reflected light is observed for "[t]he wavelength, for which the respective focal plane coincides with the point of the object," while "the other wavelengths are transmitted with decreasing intensities as the distance separating the object from the corresponding focal planes increases." *Id.* at .0015. The intensities of the different wavelengths reflected from the object are analyzed by decoding module D. *Id.* at .0016.

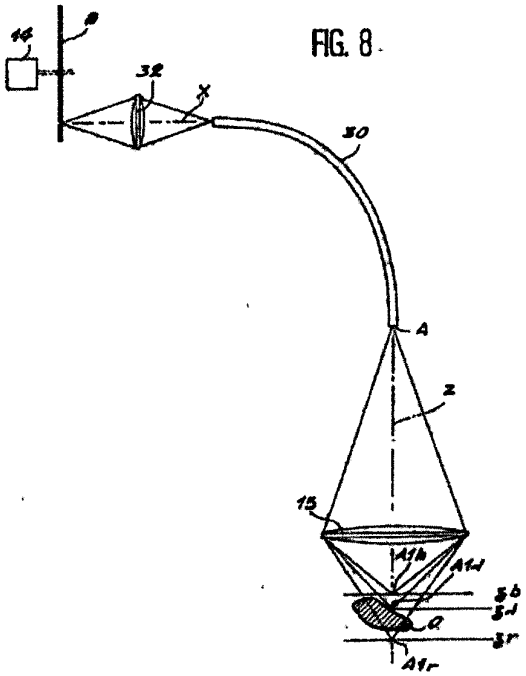
Picard teaches that the Figure 3 apparatus can be modified in two different ways. In one variant, Nipkow disk 8 is replaced by fixed mask 24. Fixed mask 24 "is placed at the same location as the Nipkow disk previously used." *Id.* at .0024. As shown in Figure 7, fixed mask 24 has openings 26.

FIG. 7



Id. at .0035, *see also id.* at .0024. Picard notes that it is advantageous to "replac[e] the mobile Nipkow disk in rotation by a mask that is fixed." *Id.* at .0025.

Another variant of the Figure 3 apparatus has "an ordered fiber-optic bundle 30, which can be a pliable endoscope, between the objective lens 15 and the Nipkow disk 8."



Id. at .0025, .0035.

2. Picard anticipates claim 15 of the '901 patent.

For its anticipation arguments, 3Shape relies on the Figure 8 embodiment, which is a modification of the Figure 3 and Figure 7 embodiments. As a preliminary matter, Align criticizes 3Shape for relying on different embodiments disclosed in Picard for its anticipation arguments. CRB at 42. Align argues that in order to anticipate a claim the prior art reference "'[n]ot only must each claim element be shown in a single reference, the elements must be arranged or combined in the same way as recited in the claims.'" *Id.* (quoting *TF3 Ltd. v. Tre Milano, LLC*, 894 F.3d 1366, 1374 (Fed. Cir. 2018)). As described above, the Figure 7 and Figure 8 embodiments are variations of the Figure 3 embodiment and the Figure 3 embodiment is an improvement on the Figure 2 embodiment. As such, the Figure 3, Figure 7, and Figure 8 embodiments share common components with each other and the Figure 2 embodiment.

Moreover, Picard explicitly discloses the very combinations of features relied upon by 3Shape. The Figure 8 embodiment is explicitly described as a modified version of the Figure 3 embodiment. RX-1322.0025 ("The device according to the invention, which is schematically and partially represented in figure 8, differs from that which is represented in figure 3 by the fact that it further comprises an ordered fiber-optic bundle 30, which can be a pliable endoscope, between the objective lens 15 and the Nipkow disk 8, as can be seen in figure 8). Therefore, the Figure 3 and Figure 8 embodiments must be viewed together. *See CSR, PLC v. Skullcandy, Inc.*, 594 Fed. Appx. 672, 679-80 (Fed. Cir. 2014) (non-precedential) (affirming the PTAB's finding of anticipation based on a combination of two embodiments where "context of the rest of the disclosure" indicated that the embodiments were "not isolated embodiments of the invention").

The Figure 7 embodiment is also described as a modified version of Figure 3. RX-1322.0024 ("In another particular embodiment of the device according to the invention, the Nipkow disk 8 of figure 3 is replaced by a fixed mask 24 (figure 7) . . . ."). In addition, the application claims clearly indicate that the Figure 7 and Figure 8 embodiments can be used together. Application claim 1 is an independent claim directed to a "device for acquisition of three-dimensional images of an object." RX-1322.0028. The device has a means of forming point light sources from the light produced by a broad-spectrum light. *Id.* The application claim expressly indicates by number the structures disclosed in the specification that correspond to the means of forming point light sources. *Id.* Among the structures so indicated are fixed mask 24: "means (8, 14; 20, 22, 24) of forming point light sources from the light produced by this source of broad-spectrum light source." *Id.* Application claim 7 depends indirectly from application claim 1 and requires that the means of forming point light sources be "a fixed mask (24) having openings (26)." *Id.* at .0028-.0029. Application claim 10, which depends from application

claims 1-9, requires that the device of application claim 7 "further comprise[] an ordered fiber-optic bundle (30), placed between the means of forming point light sources and the focusing means (15)." *Id.* at .0030. Accordingly, to the extent it is unclear from rest of the specification, the application claims provide a clear roadmap for integrating Figure 7's fixed mask 24 with the Figure 8 embodiment.

3. Picard discloses each limitation of claim 15.

Claim 15 consists of a preamble and five method steps. There is no dispute that the Figure 8 embodiment of Picard satisfies the preamble to the extent it is limiting and the first method step. In accordance with the preamble, the Figure 8 embodiment of Picard performs a method of "imaging a portion of a three-dimensional structure." *See, e.g,,* RX-1322.0002 ("The present invention concerns a device for acquisition of three-dimensional images."). As required by the first step, the Figure 8 embodiment "provid[es] a probing member" in the form of "an ordered fiber-optic bundle 30, which can be a pliable endoscope." *Id.* at RX-1322.0025. The remaining steps are disputed and are addressed below.

a. "generating a plurality of incident light beams"

The second step of the claimed method requires "generating a plurality of incident light beams." '901 patent, col. 10:20. With respect to the Figure 3 embodiment, 3Shape argues that a plurality of incident light beams is generated when Nipkow disk 8 is illuminated. RIB at 109. Align counters that Picard consistently refers to "light beam," not light beams, being output by the Nipkow disk. CIB at 88.[26] It is clear from the full disclosure of Picard that Nipkow disk 8 in Figure 3 generates a plurality of light beams.

[26]While the parties dispute whether the holes in Nipkow disk 8 are illuminated in sets or one at a time, there is no dispute that when illuminated each hole will generate a light beam. *See, e.g.,*

i. Nipkow Disks and Confocal Imaging

As a preliminary matter, there is no persuasive evidence that Nipkow disks have ever been used in confocal microscopy or confocal imaging to generate a single beam of light. In support of its assertion that a Nipkow disk can be so used, Align points to the witness statement of its expert Mr. Ferraro. Mr. Ferraro asserts that "[t]hough a Nipkow disk may have many pinholes, a scanning system may be arranged such that a single pinhole is illuminated—one at a time." CX-1944C (Ferraro RWS) at Q/A 116, CDX-0007C.14. In support of this assertion, Mr. Ferraro relies on two figures.

The first figure is from the Handbook.

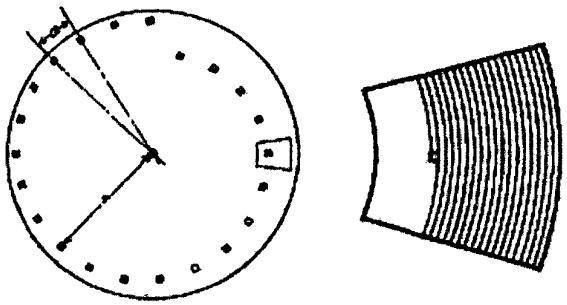


FIG. 3 Nipkow disk. The perforations in the opaque disk (A, which is rotating at a constant velocity), scan the image in a raster pattern as shown in (B). (From Inoué, 1986.)

CX-1477.0019. This figure depicts a Nipkow disk as it was originally developed by Paul Nipkow in 1884. *Id.* In the original Nipkow disk, "successive holes, placed at a constant angle apart around the center of the disk but on a constantly decreasing radius, *i.e.*, arranged as an Archimedes spiral." *Id.* Neither the figure nor the Handbook indicates whether the holes were

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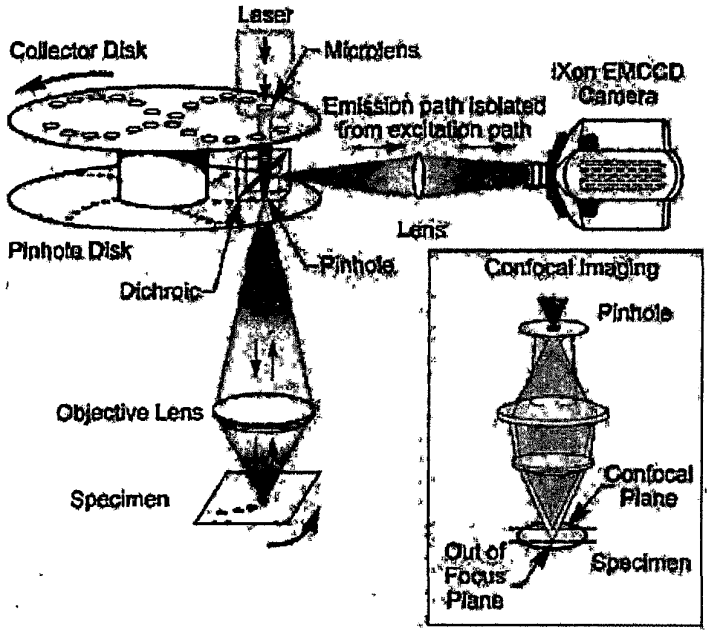
CX-1944C (Ferraro RWS) ("[T]he fiber bundle receives light from one of the holes in the Nipkow disk producing a single beam at a time as the Nipkow disk rotates.") (discussing Nipkow disk 8 in Figure 8).

illuminated one-by-one or in sets in the Nipkow disk's original application: an early attempt at television. *Id.*

The Handbook does indicate, however, that when used in confocal imaging the Nipkow disk's holes are illuminated in sets, not individually. Nipkow disks used in confocal microscopy differ from the original Nipkow disk. Instead of forming a single Archimedes spiral, the holes are arranged in "multiple sets of spirally placed holes." *Id.* This is the type of Nipkow disk that is disclosed in Picard. RX-1322.0006 ("A Nipkow disk is a metal disk, for example a chrome mask, which is drilled with tens of thousands of holes a few micrometers in diameter and arranged in spirals . . . ."). The Handbook confirms that in confocal imaging, Nipkow disks are used to generate a plurality of incident light beams. CX-1477.0019. ("In Petráň's microscope, holes on a portion of the spinning disk placed in front of the light-source collector lens, are imaged onto the specimen by the objective lens. Each point of light, reflected or scattered by the specimen thus illuminated, is focused by the same objective lens onto a centro-symmetric portion of the 'Nipkow disk.' The pinholes at this region exclude the light originating from points in the specimen not illuminated by the first set of pinholes, thus giving rise to confocal illumination.").

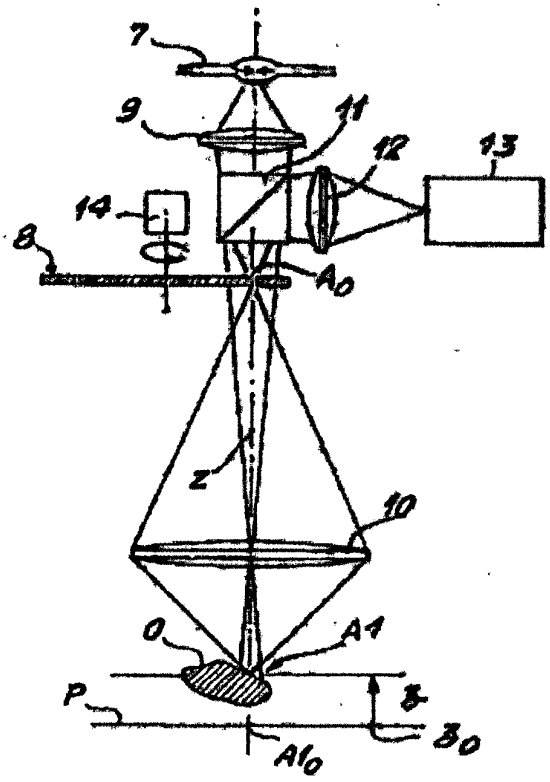
The second figure relied upon by Mr. Ferraro is an article from the website of Oxford Instruments, a company that sells confocal microscopes and imaging apparatuses. CX-1475. The article explains the principles underlying Oxford Instruments's "Dragonfly®'s confocal dual spinning disk technology" and provides the following figure relied upon by Mr. Ferraro.



CX-1475.0003. Although the figure depicts a single laser illuminating a single pinhole in the "pinhole disk," it is clear from the article that in the actual implementation multiple pinholes are illuminated simultaneously by multiple lasers operating in parallel. In particular, the article discusses how confocal scans can be accomplished more quickly through a technique called "parallelism," by using an "array of beams . . .in parallel either by using either a line of pinholes or an array of pinholes." *Id.* at .0004. The "Dragonfly®"—the product depicted in the figure—uses multiple lasers in parallel. *See, e.g., id.* at .0003 ("Low peak power by parallel illumination of ~100's scanning laser points."); .0004 ("In the Andor implementation of the spinning disk, the laser light which enters parallel is focused through an array of micro-lens for each pinhole to ensure good coupling efficiency."). The figure shown in the article depicts a single laser illuminating a single pinhole in order to highlight the "very efficient coupling of the laser to the pinhole" provided by the Dragonfly®'s "patented array of microlens array." *Id.* at .0005.

ii. Nipkow Disk 8

With respect to Picard, Nipkow disk 8 shown in Figures 3 and 8 is clearly used to generate a plurality of incident light beams. As recounted above, before describing embodiments of the purported invention, Picard discusses various prior art confocal imaging apparatuses. In the Figure 1 apparatus, a single point of light was used to scan the object. RX-1322.0003-.0004. Apparatuses implementing the Figure 1 system either "operate at acquisition rates that are lower than the video rate or are very "complex and costly." *Id.* at .0006. A prior art method of achieving higher acquisition rates was to scan the object with multiple points of light generated by a rotating Nipkow disk. *Id.* at .0006-,0007. Such an apparatus is shown in Figure 2.



Id. at .0031. In the Figure 2 apparatus, Nipkow disk 8 is illuminated by lamp 7, while is rotated

by means 14. *Id.* at .0006. Picard teaches that when Nipkow disc 8 is rotated it creates a plurality of incident light beams. *Id.* at .0007 (When the disk 8 is driven in rotation by appropriate means 14, this disk behaves like a set of point light sources and confocal filters . . . which synchronously scan the object to be observed O.").

The Figure 3 embodiment is presented as an improvement on the prior-art Figure 2 apparatus and shares many of the same structures as the Figure 2 apparatus, including "Nipkow disk 8" and "means for rotation 14." *Id.* at .0013. As discussed above, in the context of the Figure 2 embodiment, Nipkow disk 8 and means for rotation 14 are described as generating a plurality of incident light beams. *Id.* at .0007. There is no suggestion in Picard that these structures perform a different function in the Figure 3 embodiment. The difference between the Figure 2 apparatus and the Figure 3 apparatus is that in addition to using a rotating Nipkow disk to generate a plurality of incident light beams, the Figure 3 apparatus has "an objective lens 15 having an axial chromatism, instead of the objective lens 10" used in the Figure 2 apparatus. *Id.* at .0013, .0016-.0017. To explain the significance of using an objective lens with axial chromatism, Figure 4 of Picard "schematically illustrate[s]" the "effect of axial chromatism[] of objective lens 15." RX-1322.0014. In the context of Figure 4, Picard's explanation of axial chromatism in two instances refers to a "light beam" generated by Nipkow disk 8:

> Such an objective has as many different focal planes as there are wavelengths present in the incident light beam.
>
> Thus, a light source placed at a point A has as many images given by said objective as there are wavelengths present in the light beam.

RX-1322.0014. Align points to the use of the term "light beam" in the singular as evidence that Nipkow disk 8 is used to generate a single light beam . CIB at 88. Align's interpretation of the disclosure is flawed.

The benefits of using Nipkow disk 8 to generate a plurality of incident light beams are explained in the context of the Figure 2 device. The discussion of Figure 4 is intended to explain the benefits of using an objective lens with axial chromatism. That the explanation of Figure 4 uses a representative light beam to explain axial chromatism does not indicate or suggest that Nipkow disk 8 is being used differently in Figure 3 than it is in Figure 2.

To integrate the Figure 3 embodiment with fiber-optic bundle 30 of Figure 8, Picard teaches that lens 32 is used to "inject the light beam from the openings of the disk into said fiber-optic bundle 30." RX-1322.0025. From this description, Align's expert Mr. Ferraro concludes that the "fiber bundle [in Figure 8] receives light from one of the holes in the Nipkow disk producing a single beam at a time as the Nipkow disk rotates." CX-1944C (Ferraro RWS) at Q/A 62. In order to reach his conclusion, however, Mr. Ferraro is forced to rewrite Picard. Picard does not refer to "light from one of the holes in the Nipkow disk," but refers to a "light beam from the openings of the disk," *i.e.*, a single light beam produced by multiple openings of the Nipkow disk. RX-1322.0025. As acknowledged by Mr. Ferraro, however, a single light beam is generated by a single hole in the Nipkow disk, not by multiple holes. CX-1944C (Ferraro RWS) at Q/A 62 ("[T]he fiber bundle receives light from one of the holes in the Nipkow disk producing a single beam at a time as the Nipkow disk rotates . . . . I have created demonstrative CDX-0007C.8 containing Figure 8 of Picard, in which I have highlighted light projecting through a single hole in the Nipkow disk forming a single light beam."). Therefore, Picard's description of a "light beam" being generated by multiple "openings" in the Nipkow disk appears to be poorly worded but is not susceptible to Mr. Ferraro's interpretation.

Mr. Ferraro interprets the sentence as referring to a single light beam produced by a single hole, instead of multiple light beams generated by multiple holes. CX-1944C (Ferraro

RWS) at Q/A 62. Mr. Ferraro does not explain why he interprets Picard to refer to a single hole instead of multiple light beams. While in a vacuum either interpretation may be plausible, in the context of Picard only the latter interpretation is possible. Picard states the Figure 8 embodiment "differs from that which is represented in figure 3 by the fact that it further comprises an ordered fiber-optic bundle 30, which can be a pliable endoscope, between the objective lens 15 and the Nipkow disk 8." RX-1322.0025. Picard does not indicate or suggest that Nipkow disk 8 is used any differently in the Figure 8 embodiment than it is in the Figure 3 embodiment. As discussed above, Nipkow disk 8 is used in the Figure 3 embodiment to generate multiple light beams. Moreover, in the Figure 8 embodiment, as in the Figure 3 embodiment, Nipkow disk 8 is used in conjunction with means for rotation 14.

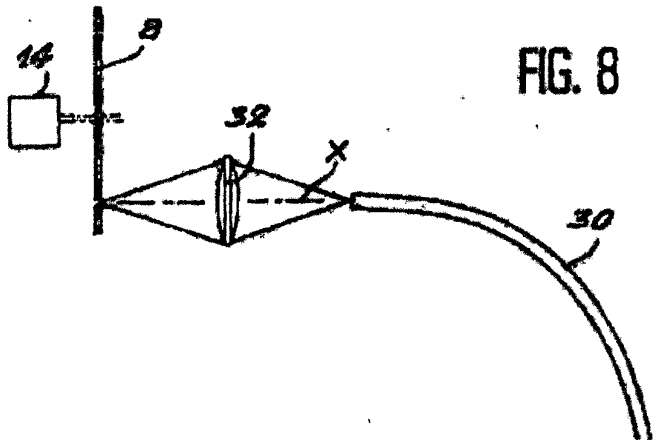


FIG. 8

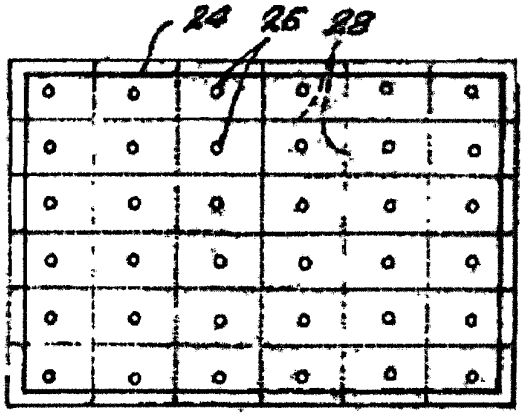
As discussed above, in the context of the Figure 2 embodiment, Picard teaches that when Nipkow 8 is rotated it generates a plurality of incident light beams. RX-1322.0007.

iii. Fixed Mask 24

3Shape also argues that fixed mask 24 shown in Figure 7 generates a plurality of light beams. In the Figure 7 embodiment, "the Nipkow disk 8 of figure 3 is replaced by a fixed mask

24." RX-1322.0024. As shown in Figure 7, fixed mask 24 has openings 26.

FIG. 7



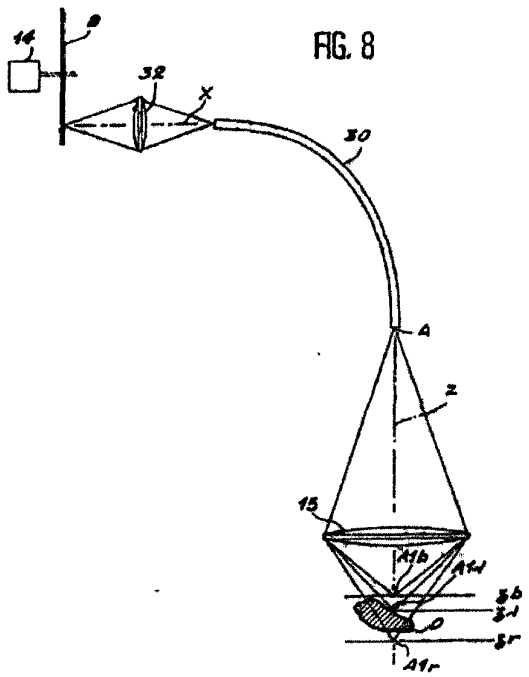
RX-1322.0035, *see also id.* at .0024. When illuminated, fixed mask 24 generates a plurality of light beams. RX-1299 (Kessler WS) at Q/A 177 (". . . Picard discloses the use of a mask (Fig. 7) with multiple holes (Fig. 7 elements 24, 26, and 28) that expands the parent beam in an array of incident light beams."); *see also id.* at Q/A 108, 117, 155, 195, 219.

Align does not dispute that fixed mask 24 generates multiple light beams. Instead, Align argues that ". . . Picard never discloses that the mask of Figure 7 can be used in the embodiment of Figure 8 with the fiber optic bundle." CIB at 89. As discussed above, however, the application claims clearly indicate that mask 24 can be used with the Figure 8 embodiment.

Based on the foregoing, I find that the Figure 8 embodiment using either Nipkow disk 8 and means of rotation 14 shown in Figures 3 and 8 or mask 24 shown in Figure 7 generates a plurality of incident light beams.

b. "focusing the plurality of incident light beams to a focal plane . . ."

The third step of claim 15 requires "focusing the plurality of incident light beams to a focal plane external to the probing member so as to illuminate a portion of the three-dimensional structure." '901 patent, col. 10:21-23. Figure 8 of Picard shows that light beams generated by Nipkow disk 8 are transmitted through the ordered fiber-optic bundle 30 to objective lens 15, which focuses the light beams onto the object being examined (O).



RX-1322.0015 ("[I]f the spectra of the light source 7 and of the object are perfectly white, a colored image is obtained from the object O (which is placed in the focusing area of the objective 15) that is perfectly focused and for which the spectral composition of each point depends only on the axial position of said point relative to the objective lens."), .0035. Picard further teaches that Nipkow disk 8 can be replaced with fixed mask 24. *Id.* at .0024-.0025.

Other than arguing that Picard does not disclose the plurality of incident light beams needed for the focusing step, Align does not dispute this limitation is disclosed.

c. "measuring a characteristic of a plurality of returned light beams . . ."

Picard discloses the fourth step of claim 15, which requires "measuring a characteristic of a plurality of returned light beams generated from illuminating the portion of the three-dimensional structure with the plurality of incident light beams." '901 patent, col. 10:24-27. As discussed above, Nipkow disk 8 and fixed mask 24 generate a plurality of incident light beams. The incident light beams are projected onto the object and are reflected from the object. RX-1322.0006-.0011, 0013-.0014, Fig. 4; RX-1299 (Kessler WS) at Q/A 327. As described with respect to Figure 3 and Figure 7, photosensitive pixels of cameras C1and C2 detect the intensity of the returned light beams. RX-1322.0016, .0025. Other than arguing that Picard does not disclose generating the plurality of incident light beams needed to form the plurality of returned light beams, Align does not dispute that this limitation is disclosed.

d. "determining a surface topology . . ."

The fifth and final step of claim 15 requires "determining a surface topology of the portion of the three-dimensional structure based at least in part on the measured characteristic of the plurality of returned light beams." '901 patent, col. 10:28-32. The Figure 8 device is a three-dimensional imaging device. *See, e.g.,* RX-1322.0008 ("The present invention makes it possible to obtain the three-dimensional image of the object in a single acquisition."). To generate a three-dimensional image, the device detects the intensities of the wavelengths of the light beams reflected from the object being scanned. RX-1322.0006-.0007, .0014-.0016. Using detected intensities, modules MA1 and MA2 calculate the z-axis information for each x,y coordinate. *Id.*

at .0023. The resulting coordinate information is used to generate a three-dimensional image, which can be displayed on a video screen or other "display means." *Id.* at .0016.

In determining the z coordinate for each point from the intensity of the returned light and using that information to derive a three-dimensional image that can be displayed, the operation of the Picard devices mirrors that of the preferred embodiments of the asserted patents:

> Thus, by determining the Z, corresponding to the maximal light intensity or by determining the maximum displacement derivative of the light intensity, for each pixel, the relative position of each light spot along the Z axis can be determined. Thus, data representative of the three-dimensional pattern of a surface in the teeth segment, can be obtained. This three-dimensional representation may be displayed on a display 84 and manipulated for viewing . . . .

'901 patent, col. 7:16-26.

Align argues that 3Shape "fails to explain how finding z coordinates (or height information) of x-y points within an object is a disclosure of determining a surface topology, and one of skill in the art would not understand height information to be surface topology." CIB at 85. Align's assertion that the Picard devices find z-coordinates "within" an object is based solely on the opinion of its expert Mr. Ferraro. CX-1944C (Ferraro RWS) at Q/A 113. Mr. Ferraro opines that "[a]s conventionally-understood, confocal microscopes enable the capture of a series of 2D confocal images that may be taken at different depths to allow for construction of 3D images of thick translucent biological specimens." *Id.* Picard expressly teaches, however, that the disclosed devices are not limited to applications involving the examination of "thick translucent biological samples." Picard explicitly teaches three-dimensional imaging can be used in industrial applications, including "dimensional control," "quality control," and "robot guidance." RX-1322.0002.

Based on the foregoing, I find that Figure 3 embodiment and Figure 7 embodiment, as modified by the Figure 8 embodiment, discloses each limitation of claim 15 of the '901 patent.

C. Obviousness

3Shape asserts that the asserted claims are obvious in view of (1) Picard in combination with Ishihara and/or Watson 1992; (2) Xiao in combination with Gmitro; or (3) the Xiao-Gmitro combination in further combination with Ishihara and/or Watson 1992.

1. The secondary *indicia* of non-obviousness do not weigh against obviousness.

In *Graham v. John Deere Co. of Kansas City*, the Supreme Court held that in determining obviousness "[s]uch secondary considerations as commercial success, long felt but unsolved needs, failure of others, *etc.*, might be utilized" as "*indicia* of obviousness or nonobviousness," 383 U.S. 1, 17-18 (1966). Indeed, "evidence of secondary considerations may often be the most probative and cogent evidence in the record." *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litigation*, 676 F.3d 1063, 1075-76 (Fed. Cir. 2012) (quoting *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538–39 (Fed. Cir. 1983)) (internal quotation marks omitted). Accordingly, such evidence "must always when present be considered *en route* to a determination of obviousness." *Id.* (quoting *Stratoflex,* 713 F.2d at 1538–39) (internal quotation marks omitted). Secondary considerations of non-obviousness "include: commercial success enjoyed by devices practicing the patented invention, industry praise for the patented invention, copying by others, and the existence of a long-felt but unsatisfied need for the invention." *Apple Inc. v. Samsung Electronics Co.*, 839 F.3d 1034, 1052 (Fed. Cir. 2016).

Align identifies four secondary considerations that it alleges weigh against a finding of obviousness. Three of these considerations—solving a long-felt need, commercial success, and

industry praise—relate to powderless scanning, *i.e.*, the ability to scan a patient's teeth without first applying a powder coating to the teeth. Align argues that the inventions of the asserted claims solved the long-felt but unresolved need "to take accurate intraoral scans without coating the teeth with powder." CIB at 113. Align also attributes the commercial success of the iTero scanner to the scanner's ability to perform powderless scanning. *See, e.g.,* CX-1944C (Ferraro RWS) at Q/A 218 (opining that the iTero's "commercial success has a nexus to the Asserted Claims because the inventions of the Asserted Claims permit the taking of accurate intraoral scans without powder"). With regard to industry praise, Align points to praise that the iTero scanner received for its ability to perform powderless scanning. CX-1811.0005 (noting that an advantage of the iTero system is that the system "captures all structures and materials found in the mouth without the need for scanning powders that coat the teeth"); CX-1818C.0002-.0003 (noting that the iTero scanner can "capture[] all elements and materials found in the mouth without the need to apply any materials to the teeth"). *Id.* at .0003.[27]

Align's reliance on secondary considerations relating to powderless scanning is misplaced. The asserted claims are not limited to scanning teeth, much less to powderless scanning of teeth. *See, e.g.,* '901 patent, col. 8:48-51 (claim 1) ("An apparatus for determining surface topology of a portion of a three-dimensional structure, the apparatus comprising. . . ."). Moreover, the asserted patents teach that a method of powderless scanning was already known, as of the filing date of the patents, *viz.*, the method disclosed in U.S. Patent No. 5,372,502. '901

[27] Align cites a number of other exhibits that it contends constitute "unrebutted evidence . . . that the iTero is praised by others in its field." CIB at 114. These exhibits—CX-1794C; CX-1812, CX-1822C, CX-1826, CX-1827C, and CX-1834C—appear to have been authored not by "others" in the field, but by Align, Cadent, distributors of the iTero system, and persons otherwise affiliated with Align and Cadent.

patent, col. 2:19-24 (discussing U.S. Patent No. 5,372,502). Because there is no nexus between the alleged long-felt need, commercial success, and industry praise on one hand and the asserted claims on the other, these factors are not relevant to the obviousness analysis. *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 668 (Fed. Cir. 2000) ("A nexus between the merits of the claimed invention and evidence of secondary considerations . . . in order for the evidence to be given substantial weight in an obviousness decision."); *see also Ormco Corp v. Align Tech., Inc.*, 463 F.3d 1299, 1312-1313 (Fed. Cir. 2006) ("Evidence of commercial success, or other secondary considerations, is only significant if there is a nexus between the claimed invention and the commercial success.").

The remaining secondary consideration relied upon by Align—copying—is unrelated to powderless scanning. Align alleges that 3Shape "explored other methods to make a scanner that produced a surface topology of a patient's teeth" but ultimately was "unsuccessful in implementing any alternative approaches and instead relied on [Align's] patented confocal, powderless solution." CIB at 115-16. In support of this allegation, Align points to testimony from 3Shape witnesses indicating that 3Shape reviewed the asserted patents during development of the Trios 3 scanner. *Id.* As discussed above, the accused 3Shape products do not infringe the asserted claims. Accordingly, there is no nexus between the alleged copying and the asserted claims. *See Ruiz,* 234 F.3d at 668; *Ormco,* 463 F.3d at 1312-13.

Accordingly, Align's evidence of *indicia* of non-obviousness is entitled to little weight, and does not meaningfully affect the obviousness analysis discussed below.

2. Combinations based on Picard

3Shape argues that Picard in combination with Ishihara renders claims 1 and 2 of the '901 patent, claims 17 and 23 of the '447 patent, and claims 15 and 18 of the '448 patent

obvious, and that Picard in combination with Watson 1992 renders claims 16-19 of the '901 patent obvious. 3Shape further argues that the remaining claims—claims 3-6 of the '901 patent, claims 19, 20, and 24 of the '447 patent, and claims 19 and 20 of the '448 patent—are rendered obvious by a combination of all three references. 3Shape's obviousness contentions can be divided into two overlapping groups: combinations that rely on Ishihara and combinations that rely on Watson 1992.

a. Picard and Ishihara

The asserted apparatus claims—claims 1-6 of the '901 patent, claims 17, 19, 20, and 23 of the '447 patent, and claims 15 and 18-20 of the '448 patent—require an "optical system" that has, *inter alia*, "confocal optics operating in a telecentric mode." Order No. 32 (Sept. 25, 2018) at 22. Although Picard discloses confocal optics, 3Shape acknowledges that it "does not explicitly discuss a telecentric confocal system." RIB at 48. Nor does 3Shape contend that Picard inherently discloses a telecentric confocal system. Instead, 3Shape relies on Ishihara to provide the missing structure.

Ishihara discloses "a three-dimensional shape measuring apparatus using a confocal imaging system." RX-1329.0013(col. 1:6-9). The apparatus has "a telecentric objective lens which converges the illuminating light that passes through the pinholes of [a] pinhole array toward an object and converges the reflected light from the object toward the pinhole array." *Id.* at .0015 (col. 5:49-col. 6:2). 3Shape argues that "[o]ne of ordinary skill in the art would have been motivated, with a reasonable expectation of success, to combine Picard and Ishihara to include the telecentric configuration of Ishihara." In support of this contention, 3Shape cites to the witness statement of its expert Dr. Kessler. RIB at 48, 75-76, 102-03.

For claim 17 of the '447 patent, Dr. Kessler opines that

> [Ishihara] discloses a confocal imaging apparatus operating in telecentric mode. As I will discuss in claim 18, it is my opinion that a person of ordinary skill in the art would have been motivated, with a reasonable expectation of success, to combine the teachings of Picard and [Ishihara's] analysis of the motivation combine.

RX-1299 (Kessler WS) at Q/A 120. Thus, for claim 17 of the '447 patent, instead of providing an analysis of the motivation of combine, Dr. Kessler incorporates by reference the analysis he performed for claim 18 of the '447. Dr. Kessler, however, did not perform an analysis of the motivation to combine Ishihara with Picard for claim 18. For claim 18, Dr. Kessler did not propose combining Ishihara with Picard, but instead relied on Ishihara to show that the CCD cameras and detectors disclosed in Picard had "pixels and each pixel is used to measure intensity." RX-1299 (Kessler WS) at Q/A 137.

With respect to the "optical system" limitation of claim 15 of the '448 patent, Dr. Kessler concludes without explanation or evidence that it is his "opinion that a person of ordinary skill in the art would have been motivated, with a reasonable expectation of success, to combine the teachings of Picard and [Ishihara] as they are both directed to confocal scanning systems being used to determine the topology of the scanned object." *Id.* at Q/A 194. Dr. Kessler renders a similar conclusory opinion with respect to the "optical system" limitation of claim 1 of the '901 patent. *Id.* at Q/A 269 ("It is my opinion that a person of ordinary skill in the art would have been motivated, with a reasonable expectation of success, to combine the teachings of Picard and [Ishihara] as each directed to using confocal imaging apparatuses and methods to determine the three-dimensional structure of objects.").[28] Such conclusory statements that one of ordinary skill

[28] For claim 1 of the '901 patent, 3Shape also cited to Q/A 268 of Dr. Kessler's witness statement. RIB at 101-102. In this question and answer, Dr. Kessler offers an opinion

in the art would have been motivated to combine references are not entitled to any weight. *See Whitserve, LLC v. Computer Packages, Inc.*, 694 F.3d 10, 24 (Fed. Cir. 2012) ("General and conclusory testimony . . . does not suffice as substantial evidence of invalidity.") (quoting *Koito Manufacturing Co. v. Turn-Key-Tech, LLC*, 381 F.3d 1142, 1151 (Fed. Cir. 2004) (alterations in original removed; internal quotation marks omitted)); *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1329 (Fed. Cir. 2001).

Accordingly, I find that 3Shape has not shown that one of ordinary skill in the art would have been motivated to modify Picard with Ishihara's telecentric objective lens.

b. Picard and Watson 1992

Claims 16-19 of the '901 patent require a step of "changing a position of the focal plane over a range of focal plane positions relative to the probing member." '901 patent, col. 10:32-45. Claims 3 and 6 of the '901 patent, claims 19, 20, and 24 of the '447 patent, and claims 19 and 20 of the '448 patent require an "optical system" that has "a translation mechanism configured to change a position of the focal plane over a range of focal plane positions." '901 patent, col. 9:5-8, col. 9:17-20; '447 patent, col. 10:25-33, col. 10:41-46; '48 patent, col. 10:34-42. 3Shape does not contend that Picard discloses these limitations, but instead relies upon Watson 1992 to provide the missing limitations.

Watson 1992 discloses the use of "special new objectives" in a tandem confocal microscope, in which "[t]he plane of focus is altered by moving optical components within the microscope objective itself, either manually or with a stepper motor, rather than moving the sample under the lens." RX-1328.0002. With this functionality, the objective lens can be

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concerning the motivation to combine Ishihara with the Xiao-Gmitro combination, but does not address the motivation to combine Ishihara with Picard.

positioned so that it is in close contact with the object being examined. *Id.* at .0002, .0006. So positioned, the objective lens acts as a "steadying surface" and "help[s] to reduce specimen movement." *Id.* at .0006. As explained by Watson 1992, objective lenses in prior systems could not be used as steadying surfaces, because in the earlier systems, the object being examined had to be moved towards or away from the objective lens so that different points on the object could be brought into focus. *Id.* at .0002.

One of ordinary skill in the art would not have been motivated to combine Picard and Watson 1992. Picard is directed to capturing a three-dimensional image in a single acquisition. RX-1322.0008. With this ability, the Picard device can acquire three-dimensional images "'in real time,' *i.e.*, at the video rate (25 images per second)." *Id.* at .0003. Picard contrasts the ability to take a three-dimensional image in a single acquisition to earlier devices that could generate a three-dimensional image only after taking multiple images of an object in different positions along the z-axis. *Id.* at .0006. In contrast to Picard, Watson 1992 does not eliminate the need to take images in multiple acquisitions of in order to derive a single three-dimensional image, but seeks to make the process of taking images in multiple acquisitions more efficient by using a mechanism that "mov[es] optical components within the microscope objective itself, either manually or with a stepper motor," so that the sample can remain stationary. RX-1328.0002. Thus, because the Picard device is able to take three-dimensional images in a single acquisition, it does not need Watson 1992's objective lens.

3Shape's expert Dr. Kessler identifies two reasons that one of ordinary skill in the art would have been motivated to combine Watson 1992 with Picard. According to Dr. Kessler, the Picard apparatus had a limited total depth range (1 mm), and therefore a person of ordinary skill "would have been motivated to move the focal plane of Picard's apparatus in order cover a large

portion, *i.e.*, get more z dimension data, of the scanned object (*e.g.*, tooth)." RX-1299 (Kessler WS) at Q/A 148. The basis for Dr. Kessler's conclusion that the Picard apparatus had a limited depth range appears to be drawn from the description of a preferred embodiment. RX-1322.0020 ("chromatism of the objective = 1 mm in the 0.4-0.8 3m band"). There is no indication and no evidence, however, that the range of depth of the embodiment represents the outermost limit obtainable by an apparatus implementing the principles disclosed in Picard. For instance, Dr. Kessler does not address whether the depth range could be increased by adjusting the optical properties of the components (*e.g.*, the chromatism of the objective lens, the source light's wavelength composition, the objective lens's aperture), so that the device's ability to take a three-dimensional image in a single acquisition is retained.

The second reason for combining Picard and Wilson 1992 proffered by Dr. Kessler is that one of ordinary skill would have been motivated to modify Picard to use Wilson 1992's "internally focusing objectives for imaging teeth" because the resulting apparatus would "avoid[] the need to adjust the sample, increas[e] comfort and ease for the patient or subject, and reduc[e] imaging problems caused by sample movement." RX-1299 (Kessler WS) at 148. Converseely, Dr. Kessler opines that one of ordinary skill would have been motivated to modify Wilson 1992 to incorporate the Picard device "because the number of image acquisitions, and time[] to image teeth[,] would have been greatly reduced using Picard's system of multiple wavelength components at different focal planes at the same time compared to other known systems at the time." *Id.* There is no evidence that it would have been necessary to modify the Picard system in order to gain the benefits of Watson 1992's objective lens. The benefits of Watson 1992's objective lens stem from the lens's ability to obtain three-dimensional without moving the sample. RX-1328.0001 ("The development of a steadying objective (x 240 overall mag.) which

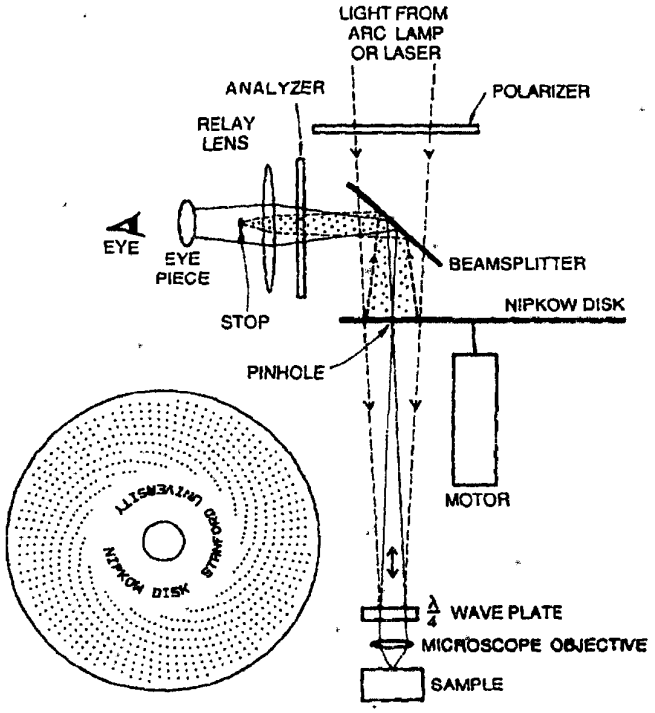
is held against the sample surface and is focused by moving internal elements, avoids the need for fine adjustment of the living sample under the microscope to achieve a change of focus. It is therefore more comfortable and also reduces the problems of movement due to the pulse."). There is no need to move the sample with the Picard system, because it is able to obtain a three-dimensional image in a single acquisition. *See, e.g.*, RX-1322.0006.

Based on the foregoing, I find that 3Shape has not shown that the one of ordinary skill in the art would have been motivated to combine Picard with Watson 1992.

3. Xiao in Combination with Gmitro

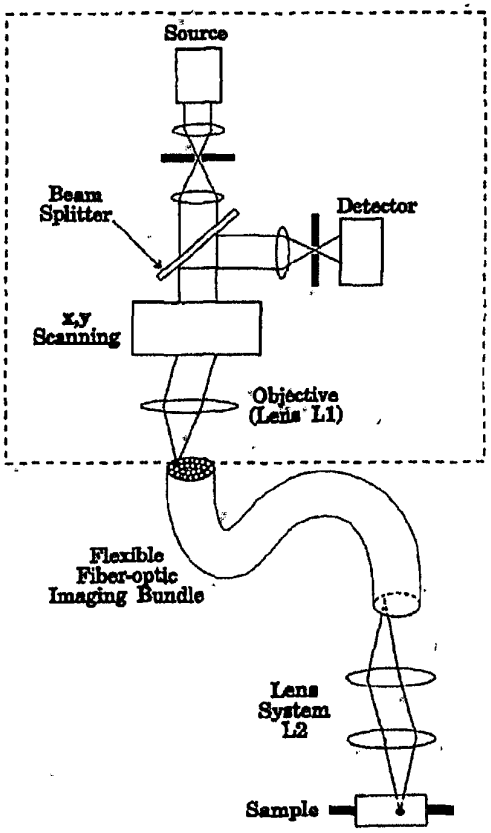
3Shape argues that Xiao in combination with Gmitro renders claims 1-6 and 15-19 of the '901 patent and claims 17, 19, 20, 23, and 24 of the '447 patent obvious. 3Shape further argues that Xiao and Gmitro in further combination with either Ishihara or Watson 1992 renders claims 1, 2, and 15-19 of the '901 patent, claims 17 and 20 of the '447 patent, and claims 15, 18, 19, and 20 of the '448 patent obvious. For claims 3-6 of the '901 patent, claims 19, 20, and 24 of the '447 patent and claims 19 and 20 of the '448 patent, 3Shape relies on an obviousness combination composed of all four prior art references—Xiao, Gmitro, Ishihara, and Watson 1992. All of the prior art combinations rely upon the combination of Xiao and Gmitro. For the reasons discussed below, 3Shape has not shown that one of ordinary skill in the art would have been motivated to combine Xiao and Gmitro and has not shown that one of ordinary skill would have had a reasonable expectation of success in doing so.

Xiao discloses a confocal scanning optical microscope in which "light from either a laser source or arc lamp simultaneously illuminates several thousand pinholes in a rotating disk." RX-1324.0002.



Id. at .0001, Figure 2. The rotating disk is a Nipkow disk that has 200,000 pinholes "arranged in 16 interleaved spirals." *Id.* at .0002. "Each pinhole illuminates a single spot on the object." *Id.* The light reflected from the object passes back through the Nipkow disk's pinholes. *Id.* Xiao teaches that height information of the points on the object illuminated by the light beams can be determined by the change in light intensity as the sample is repositioned along the z-axis. *Id.* The system disclosed in Xiao can generate a "7000-line image at 640 frames per second," as compared to a "typical" confocal scanning optical microscope, which can generate a 512 x 512 image every few seconds. *Id.*

Gmitro discloses a "concept for a new type of confocal microscope with a fiber-optic imaging bundle." RX-1325.0001.



Id., Fig. 1. 3Shape argues that one of ordinary skill in the art would have been motivated to modify the Xiao apparatus with the fiber-optic bundle disclosed in Gmitro. RIB at 54.

In support of this assertion, 3Shape and its expert Dr. Kessler point to Gmitro's teaching that the fiber-optic imaging bundle increases the confocal microscope's flexibility by allowing "[c]onfocal imaging of *in vivo* rather than *in vitro* biological specimens . . . ." RX-1325.0001. In particular, Gmitro notes that the "small size and flexibility of the fiber-optic imaging bundle could even allow confocal imaging of objects that would otherwise be completely inaccessible, such as inside the human body." *Id.* Other statements in Gmitro, however, undercut 3Shape's position. In particular, while Gmitro notes that "[t]his study demonstrates that it is possible to build a confocal microscope with a flexible fiber-optic imaging bundle," it acknowledges that

"[m]uch research remains to characterize fully the imaging properties of this optical system and to develop a practical instrument for specific applications . . . ." RX-1325.0003. Gmitro also acknowledges that "[i]n a practical system, some mechanism will be required to adjust the depth of the in-focus imaging plane within the sample." *Id.* at .0001. No such mechanism is disclosed in Gmitro.[29]

The experimental nature of Gmitro is further demonstrated by the fact that the only implementation disclosed in Gmitro is of the fiber-optic imaging bundle being used with a confocal microscope that projects a single spot on the object being scanned instead of an array of spots. *See, e.g., id.* at .0003 ("With the l0X objective at Ll, the projected diameter of the collection pinhole is ~8 μm . . . .").

In addition, assuming that one of ordinary skill in the art would have been motivated to use Gitmo's fiber-optic imaging bundle to modify a confocal microscope that generates a plurality of incident light beams, Dr. Kessler does not explain why one of ordinary skill in the art would have looked to Xiao, which uses a Nipkow disk to generate a plurality of incident light beams, instead of a prior art apparatus that uses a fixed mask to generate a plurality of incident light beams. Ishihara teaches that the use of Nipkow disks to generate light beams results in "deviations in scanning and sampling timing [that] cause errors in the XY positions of the

[29] In the context of dependent claims that require a device that is able to change the focal plane of the incident light beams over a range of focal plane positions, 3Shape relies on the statement in Gmitro that "some mechanism will be required to adjust the depth of the in-focus imaging plane within the sample" as a motivation to modify the Xiao-Gmitro combination with Watson 1992. RIB at 59, 86, 120-21, 128. As discussed above, Watson 1992 discloses an objective lens that changes focal planes using internal elements. RX-1328.0002. 3Shape, however, does not address why one of ordinary skill would have looked to Watson 1992 and not Picard. Picard expressly teaches that a fiber-optic bundle—such as the one disclosed in Gmitro—can be used with confocal microscope with a Nipkow disk—such as the one disclosed in Xiao—without the need for Watson 1992's objective lens. *Supra* section VI.C.2.b.

measured points of a confocal image." RX-1329.0013 (col. 2:19-41). In addition, in systems that use a Nipkow disk, the object being scanned must be moved in steps rather than continuously. *Id.* If the object is moved continuously, "the Z positions for various points gradually shift, one after another, by a small distance." *Id.* Because the object cannot be moved continuously along the z axis, more time is required to complete the scan. *Id.* Ishihara teaches that the apparatuses disclosed in Japanese Patent Application Nos. 265918/192 and 181023/1985 could "acquire more accurate confocal images at a higher speed" and were less complex than confocal microscopes using Nipkow disks. *Id.* (col. 2:41-48). Instead of Nipkow disks, these prior art systems generated incident light beams using fixed masks. *Id.* at .0013-.0014 (col. 2:49-col. 3:48). Consistent with Ishihara, Picard also acknowledges that it is advantageous to use a fixed mask instead of a Nipkow disk. RX-1322.0025 ("The device of figure 7 has the advantage of replacing the mobile Nipkow disk in rotation by a mask that is fixed."). These statements indicate that at the time of the invention one of ordinary skill in the art would not have selected Xaio for modification, but would have rather selected a fixed-mask reference for modification. *See Intendis GMBH v. Glenmark Pharm. Inc., USA*, 822 F.3d 1355, 1366 (Fed. Cir. 2016) (affirming district court's finding that claims "would not have been obvious over the previously-marketed Skinoren® cream in combination with" secondary references because "Skinoren®'s formulation had certain undesirable qualities, and that a skilled artisan would consider developing an alternative to Skinoren® in a different dosage form given the market forces and the deficiencies of Skinoren®"); *Insite Vision Inc. v. Sandoz, Inc.*, 783 F.3d 853, 860-61 (Fed. Cir. 2015) (affirming district court's finding that one of ordinary would not have been motivated "to formulate a topical azithromycin formulation for ophthalmic treatment," where other

compounds, such as fluoroquinolones, "were known to be a better option than azithromycin") (internal citation omitted; internal quotation marks and brackets omitted).

Moreover, to establish a *prima facie* case of obviousness, 3Shape not only must show that a person of ordinary skill in the art "would have been motivated to combine references," 3Shape also "must show the artisan 'would have had a reasonable expectation of success from doing so.'" *Artic Cat Inc. v. Bombardier Recreational Products Inc.*, 876 F.3d 1350, 1360-61 (Fed. Cir. 2017) (quoting *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1068 (Fed. Cir. 2012)). 3Shape does not address whether one of ordinary skill in the art would have had a reasonable expectation of success in combining Xiao with Gmitro, other than to assert that its expert Dr. Kessler "opined that a person of skill in the art would have understood how to combine the teachings of Gmitro and Xiao." RRB at 57.

Dr. Kessler's testimony concerning whether one of ordinary skill in the art would have had a reasonable expectation of success in combining Xaio with Gmitro is cursory at best. Other than his conclusory assertions "that a person of ordinary skill in the art would have been motivated, with a reasonable expectation of success to combine the teachings of Xiao and Gmitro," RX-1299 (Kessler WS) at Q/A 119; *see also id.* at Q/A 93 ("It is my opinion that a person of ordinary skill in the art would have been motivated, with a reasonable expectation of success to combine the teachings of Xiao and Gmitro."), Dr. Kessler only addresses reasonable expectation of success in the context of claim 1 of the '901 patent. For the "optical system" limitation of that claim, Dr. Kessler proposes a combination of Xiao, Gmitro, and Ishihara, and opines that one of ordinary skill would have had a reasonable expectation of success in "combin[ing] the teachings of Xiao, Gmitro, and [Ishihara] as each [is] directed to using confocal imaging apparatuses and methods to determine the three-dimensional structure of objects." *Id.* at

Q/A 268. Dr. Kessler does not address the implications of the experimental nature of Gmitro and his conclusory and unsupported opinion is insufficient to meet 3Shape's burden of establishing that there would have been a reasonable expectation of success in combining the references. *See Whitserve,* 694 F.3d at 24; *Telemac,* 247 F.3d at 1329.

Based on the foregoing, I find that 3Shape has not shown that one of ordinary skill in the art would have been motivated to combine Xiao and Gmitro and has not shown that one of ordinary skill in the art would have had a reasonable expectation of success in doing so.

D. Written Description

3Shape argues that the asserted claims of the '901 patent are invalid for failing to comply with the written description requirement. Paragraph 1 of 35 U.S.C § 112 requires that the specification "contain a written description of the invention . . . in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same." This requirement ensures "that the inventor actually invented the invention claimed." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (*en banc*). "[A]n adequate written description requires a precise definition" of the claimed invention. *Id.* at 1350. For a claim to a genus, a "precise definition" of the invention is provided by the disclosure of "a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus." *Id.* If the specification does not demonstrate that "the patentee possessed the full scope of the invention" recited in a claim, the claim is invalid. *LizardTech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1344 (Fed. Cir. 2005).

The asserted apparatus claims of the '901 patent require a means for measuring "a characteristic" of the returned light beams and a means for determining the object's surface

topology using the "measured characteristic." '901 patent, col. 8:59-67 (claim 1). Similarly, the asserted method claims of the '901 patent require a step of measuring "a characteristic" of the returned light beams and a step of determining the object's surface topology using the "measured characteristic." *Id.* at col. 10:24-31 (claim 15). According to 3Shape, if "characteristic" is construed to be broader than "intensity," then the written description of the '901 patent does not support the full-scope of the asserted claims, because the only "characteristic" disclosed in the specification is "intensity." RIB at 131-32.

The construction of the term "characteristic" was not addressed during *Markman* proceedings. Although 3Shape's written description argument turns on the term's construction, 3Shape does not present arguments concerning the construction of "characteristic." 3Shape does not even take the position that "characteristic" is broader than "intensity." Instead, 3Shape tacitly relies on Align's interpretation of the term, one which 3Shape does not endorse. *Id.* at 131 ("Should 'characteristic' be interpreted as anything more than 'intensity,' all Asserted Claims of the '901 patent, which recite a 'characteristic' or depend from a claim which does, lack written description support in the specification and are invalid under 35 U.S.C. § 112 ¶ 1.").

This is not the first time that 3Shape's written description argument has been considered. The argument was presented in a motion for summary determination (Motion Docket No. 1090-033). With regard to "characteristic," 3Shape's motion "relie[d] on Align's proposed construction of the term, but [did] not otherwise address the term's construction." Order No. 41 (Nov. 2, 2018) at 2. Although it indicated that it was not adopting Align's construction, 3Shape did "not provide[] any arguments in support of its claim construction position." *Id.* at 2-3 ("While Align contends that 'characteristic' is broader than 'intensity,' 3Shape does not appear

to share that position."). Because "characteristic" could not be construed on the record as it then existed, 3Shape's motion was denied. *Id.*

In its post-hearing briefing, 3Shape does not attempt to cure the deficiencies of its summary determination motion. 3Shape offers no evidence that "characteristic" means "more than" intensity. Accordingly, 3Shape's written description argument fails.

VII. DOMESTIC INDUSTRY

Align claims a domestic industry in the research and development, design, engineering, sales and marketing of its iTero scanners.

A. Legal Standards

In patent-based proceedings under section 337, a complainant must establish that an industry "relating to the articles protected by the patent . . . exists or is in the process of being established" in the United States. 19 U.S.C. § 1337(a)(2). Under Commission precedent, the domestic industry requirement of section 337 consists of an "economic prong" and a "technical prong." *See, e.g., Alloc, Inc. v. Intl Trade Comm'n,* 342 F.3d 1361, 1375 (Fed. Cir. 2003). To meet the technical prong, the complainant must establish that it practices at least one claim of the asserted patent. *Certain Point of Sale Terminals and Components Thereof,* Inv. No. 337-TA-524, Order No. 40 at 17-18 (Apr. 11, 2005). "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*, 342 F.3d at 1375.

With respect to the "economic prong," subsection (3) of Section 337(a) provides:

> 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.

19 U.S.C. § 1337(a)(3). "Given that these criteria are listed in the disjunctive, satisfaction of any one of them will be sufficient to meet the domestic industry requirement." *Certain Solid State Storage Drives, Stacked Electronics Components, and Products Containing Same* ("*Solid State Storage Drives*"), Inv. No. 337-TA-1097, Comm'n Op. at 7-8 (June 20, 2018) (citing *Certain Variable Speed Wind Turbines & Components Thereof*, Inv. No. 337-TA-376, USITC Pub. No. 3003, Comm'n Op. at 15 (Nov. 1996)). The Commission recently held that "[t]he statutory text of section 337 does not limit sections 337(a)(3)(A) and (B) to investments related to manufacturing or any other type of industry." *Id.* "Moreover, even though subsection (C) expressly identifies 'engineering' and 'research and development' as exemplary investments in the 'exploitation' of the patent, that language does not unambiguously narrow subsections (A) and (B) to exclude those same types of investments." *Id.*

B. Domestic industry products

1. Representativeness

For its technical prong allegations, Align relies on the HDU2.9, the HDU, and "all versions of the iTero Element," including the iTero Element2 and iTero Element Flex. CIB at 16. Align argues that iTero Element is representative of all of the domestic industry products. *Id.* Align's primary support for this contention is the witness of statement of its expert Mr. Ferraro. In his witness statement, Mr. Ferraro opines that with respect to the features that are relevant to the asserted claims [redacted] that the iTero Element, iTero Element 2, and iTero Element Flex [redacted] CX-1940C

(Ferrraro WS) at Q/A 278.30

Mr. Ferraro's opinion is unchallenged and unrebutted, and I find that the iTero Element is representative of the HDU2.9, HDU, iTero Element2, and iTero Element Flex. Align's description of its domestic industry products suggests that there are versions of the iTero Element, other than the iTero Element2 and iTero Element Flex. CIB at 16 ("all versions of the iTero Element, including the iTero Element2 and iTero Element Flex"). With regard to any unidentified versions of the iTero Element, Align has not identified any evidence relating to representativeness. Therefore, my finding that the iTero Element is a representative product is limited to the two versions of the iTero Element specifically identified by Align (iTero Element2 and iTero Element Flex), the HDU2.9, and the HDU.

2. iTero Element

The iTero Element [redacted].

[redacted]

[30] Align also cites the witness statement of Dr. Kopelman in support of its contention that the iTero Element is representative. In his witness statement, Dr. Kopelman testifies that [redacted]. CX-1936C (Kopelman WS) at Q/A 23-24. There is, however, no indication as to what products are encompassed by the term "iTero scanner." Accordingly, it is unclear whether Dr. Kopelman's testimony relates to all of the domestic industry products or a subset thereof.

JX-0090C.0004; *see also* CX-1940C (Ferraro WS) at Q/A 281. [redacted]. CX-1940C (Ferraro WS) at Q/A 301; JX-0388C.0004 [redacted].

[redacted]

JX-0336C.0011; *see also* CX-1940C (Ferraro WS) at Q/A 306; JX-0090C.0004 [redacted].

As the scanner's tip is swept over the patient's dentition, the iTero Element scanner's [redacted]. CX-1940C (Ferraro WS) at Q/A 281. [redacted]

[redacted]. *Id.*

C. Technical Prong

1. '901 patent method claims

There is no dispute that the iTero practices the method claims of the '901 patent (claims 15-19).[31] Claim 15 is an independent claim and consists of a preamble and a five-step method. There is no dispute that the iTero products practice the preamble to the extent that it is limiting and the five claim steps. The iTero products perform a method of "imaging a portion of a three-dimensional structure," as required by the preamble. '901 patent, col. 10:17-18; CX-1940C (Ferraro WS) at Q/A 294; RX-1567C (Zavislan RWS) at Q/A 191-95. As required by the first claim step, the iTero products "provid[e] a probing member" in the form of a single piece probe that can be inserted into the patient's mouth. '901 patent, col. 10:19; CX-1940C (Ferraro WS) at Q/A 295-97.

The iTero products generate a plurality of incident light beams, as required by the second claim step. '901 patent, col. 10:20. Specifically, the iTero products have "[redacted]

[31] For a number of the claim elements, 3Shape takes issue with Align's citation of expert testimony to show that a claim limitation is satisfied by the iTero products because the cited testimony was directed to a different patent. RRB at 47. According to 3Shape, citing to testimony concerning one claim limitation in support of a limitation in another claim in another patent constitutes "unsupported attorney argument [and] should be afforded no weight." *Id.* 3Shape's argument ignores how closely related the patents and claims are. The asserted claims have limitations that are similar, if not identical, in scope to the limitations of claims in other patents. RIB at 67 ("The parties do not dispute that claim 15 of the '448 patent is similar in scope to claim 17 of the '447 patent. As a result, differences between claim 15 of the '448 patent and claim 17 of the '447 patent do not materially affect 3Shape's non-infringement analysis. For this reason, Trios 3 does not meet each and every limitation of claim 15 of the '448 patent for at least the same reasons set forth above with regard to claim 17 of the '447 patent.") (internal citations omitted). Accordingly, I reject 3Shape's argument.

[redacted]." CX-1940C (Ferraro WS) at Q/A 298; JX-0091C. [redacted].[32] 3Shape does not challenge that the [redacted] are "incident light beams." Unlike the light transmitted [redacted] in the accused products, the iTero Element's [redacted] generated by the preferred embodiments. [redacted], the incident light beams in the specification are generated by splitting a laser light beam with a microlens array. See '901 patent, col. 5:39-49 ("Optical device 22 comprises . . .a semiconductor laser unit 28 emitting a laser light, as represented by arrow 30. . . . The light beam 30 then passes through a module 38, which may, for example, be a grating or a microlens array which splits the parent beam 30 into a plurality of incident light beams 36."). Although an explicit construction of "incident light beam" cannot be derived from the current record, any construction of "incident light beam" would encompass the preferred embodiment and would therefore encompass the iTero Element's [redacted]. *See Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583-84 (Fed. Cir. 1996)

[32] In its reply brief, 3Shape argues that Align has not shown that the iTero Element generates a plurality of incident light beams. This argument was not raised in 3Shape's pre-hearing brief and is therefore deemed to have been waived. *See* RPHB at 73 (discussing how the iTero Element [redacted]); Ground Rule 8.2 ("Any contentions not set forth in detail as required herein shall be deemed abandoned or withdrawn . . . .").

(holding that an interpretation that excluded a preferred embodiment "is rarely, if ever, correct and would require highly persuasive evidentiary support").

In accordance with the third step, the iTero products [redacted]. '901 patent, col. 10:21-23; CX-1940C (Ferraro WS) at Q/A 302; RX-1567C (Zavislan RWS) at Q/A 181; CX-1086C. As required by the fourth step, the iTero Element "measur[es] a characteristic of a plurality of returned light beams generated from illuminating the portion of the three-dimensional structure with the plurality of incident light beams focus the incident light beams." '901 patent, col. 10:24-27. The iTero Element performs this step by [redacted]. CX-1940C (Ferraro WS) at Q/A 305; RX-1567C (Zavislan RWS) at Q/A 181; JX-0090C; JX-0091C. In accordance with the fifth step, the iTero Element uses the [redacted] to "determin[e] a surface topology of the portion of the three-dimensional structure based at least in part on the measured characteristic of the plurality of returned light beams." '901 patent, col. 10:28-31; CX-1940C (Ferraro WS) at Q/A 305; RX-1567C (Zavislan RWS) at Q/A 191-95; JX-0100C.

Claims 16-19 depend directly or indirectly from claim 15. Claim 16 depends from claim 15 and requires a step of "changing a position of the focal plane over a range of focal plane positions relative to the probing member." '901 patent, col. 10:32-34. The iTero Element changes the focal plane [redacted]. CX-1940C (Ferraro WS) at Q/A 311. Claim 17 depends from claim 16 and requires a step of changing "the position of the focal plane of the plurality of incident light beams . . . along a direction of propagation of the plurality of incident light

beams." '901 patent, col. 10:35-38. The required change of focal plane position [redacted]. CX-1940C (Ferraro WS) at Q/A 362, 377. As required by claim 18, [redacted] returned light beams "over the range of focal plane positions." *Id.* at Q/A 359; JX-0090C.0004. In accordance with claim 19, the iTero Element uses [redacted] the returned light beams to determine the surface topology of the patient's dentition. CX-1940C (Ferraro WS) at Q/A 305; RX-1567C (Zavislan RWS) at Q/A 191-95; JX-0100C.

2. '901 patent apparatus claims

With the exception of the "optical system" limitation of claim 1, there is no dispute that the iTero products satisfy the limitations of claims 1-6.

a. Undisputed Limitations

Claim 1 is an independent claim and consists of a preamble and five limitations. As required by the preamble to the extent it is limiting, the iTero Element is an "apparatus for determining surface topology of a portion of a three-dimensional structure." '901 patent, col. 8:49-51; CX-1940C (Ferraro WS) at Q/A 294; RX-1567C (Zavislan RWS) at Q/A 191-95. As required by the first limitation, the iTero Element has a probing member in the form of single piece tip that can be inserted into a patient's mouth. CX-1940C (Ferraro WS) at Q/A 295-97. The iTero Element has an "illumination unit" that generates a plurality of incident light beams as required by the second limitation. '901 patent, col. 8:33-34. Specifically, the iTero Element has "[redacted]." CX-1940C (Ferraro WS) at Q/A 298; RX-1567C (Zavislan RWS) at Q/A 181; JX-0090C.0004. [redacted]

[redacted]. CX-1940C (Ferraro WS) at Q/A 300; RX-1567C (Zavislan RWS) at Q/A 181; CX-1086; JX-090C.

The third limitation is the "optical system" limitation and is addressed below. As required by the fourth limitation, the iTero Element has "a detector unit configured to measure a characteristic of a plurality of returned light beams generated from illuminating the portion of the three-dimensional structure with the plurality of incident light beams focus the incident light beams." Specifically, the iTero Element [redacted]. '901 patent, col. 8:59-63; CX-1940C (Ferraro WS) at Q/A 305; RX-1567C (Zavislan RWS) at Q/A 181; JX-0090C; JX-0091C. In accordance with the fifth limitaiton, the iTero Element has "a processor coupled to the detector unit and configured to determine a surface topology of the portion of the three-dimensional structure based at least in part on the measured characteristic of the plurality of returned light beams." CX-1940C (Ferraro WS) at Q/A 305; RX-1567C (Zavislan RWS) at Q/A 191-95; JX-0100C. Specifically, the iTero products [redacted] determine the surface topology of a portion of a three-dimensional structure based on [redacted] the returned light beams. CX-1940C (Ferraro WS) at Q/A 308-309; RX-1567C (Zavislan RWS) at Q/A 188-194.

Claims 2 and 3 depend directly from claim 1. As required by claim 2, the iTero Element's [redacted] has "a plurality of sensor elements each configured to measure the characteristic of a corresponding returned light beam in the plurality of returned light beams" [redacted]. '901 patent, col. 9:1-4; CX-1940C (Ferraro WS) at Q/A 305-306; JX-0090C.0004 [redacted]. As required by claim 3, the iTero Element's [redacted] is "a translation mechanism" that changes the position of the focal plane over a range

of focal plane positions relative to the probing member [redacted]. CX-1940C (Ferraro WS) at Q/A 311; JX-0091C.0018; JX-0091C.0013.

Claims 4 and 6 depend from claim 3, and claim 5 depends from claim 4. As required by claim 4, the iTero Element's [redacted] returned light beams "over the range of focal plane positions." CX-1940C (Ferraro WS) at Q/A 359. In accordance of claim 6, [redacted] changes the focal plane of the incident light beams over a range of focal plane positions along the direction of propagation of the plurality of incident light beams. CX-1940C (Ferraro WS) at Q/A 311, 362; JX-0090C.0003. As required by claim 5, the iTero Element's [redacted] returned light beams measured over the range of focal plane positions to determine the surface topology of the patient's dentition. CX-1940C (Ferraro WS) at Q/A 305; RX-1567C (Zavislan RWS) at Q/A 191-95; JX-0100C.

b. "optical system"

Claim 1 requires that the apparatus have "an optical system configured to focus the plurality of incident light beams to a focal plane external to the probing member so as to illuminate the portion of the three-dimensional structure." '901 patent, col. 8:55-58. "Optical system" is a means-plus-function term subject to 35 U.S.C. § 112, ¶ 6. Order No. 32 (Sept. 25, 2018) at 27. The claimed function of the "optical system" is "to focus the plurality of incident light beams." *Id.* at 32. The structure corresponding to the claimed function consists of "a partially transparent mirror or beam splitter, confocal optics operating in a telecentric mode, relay optics, and an endoscopic probing member operating as a light guide to ensure total internal reflection" and equivalents thereof. *Id* at 34.

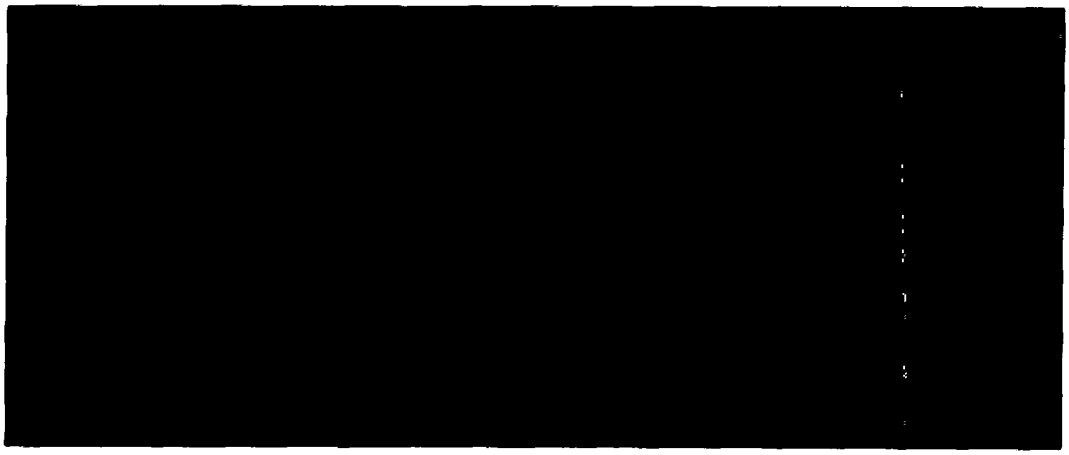
Align argues that the iTero Element satisfies the "optical element" limitation because it focuses a plurality of incident light beams [redacted]

[redacted] CIB at 76. 3Shape does not dispute that the structures identified by Align perform the claimed function of focusing the plurality of incident light beams, but argues that the identified structures are not identical or equivalent to the structures disclosed in the specification. In particular, 3Shape argues [redacted] RIB at 36.

For the reasons set forth below, I find that the iTero Element has "an endoscopic probing member operating as a light guide to ensure total internal reflection," but does not have structures identical to or equivalent to the disclosed "confocal optics operating in a telecentric mode." Because the iTero Element does not have structures comprising "confocal optics operating in a telecentric mode," it does not satisfy the "optical system" limitation.

i. "confocal optics operating in a telecentric mode"

For the "confocal optics operating in a telecentric mode," [redacted]. CIB at 76.



JX-90C.0007. [redacted] CIB at 76-77.

To show that a means-plus-function limitation is satisfied literally, Align must show that the relevant structure in the iTero Element "perform[s] the identical function recited in the claim and be identical or equivalent to the corresponding structure in the specification." *Frank's Casing Crew*, 389 F.3d at 1378 (quoting *Odetics, Inc. v. Storage Tech. Corp.*, 185 F.3d 1259, 1267 (Fed. Cir. 1999)) (internal quotation marks omitted). There does not appear to be a dispute that [redacted]. CX-1940C (Ferraro WS) at Q/A 285. There also does not appear to be any dispute that [redacted]

[redacted]

[redacted] *See* CIB at 77.

[redacted]

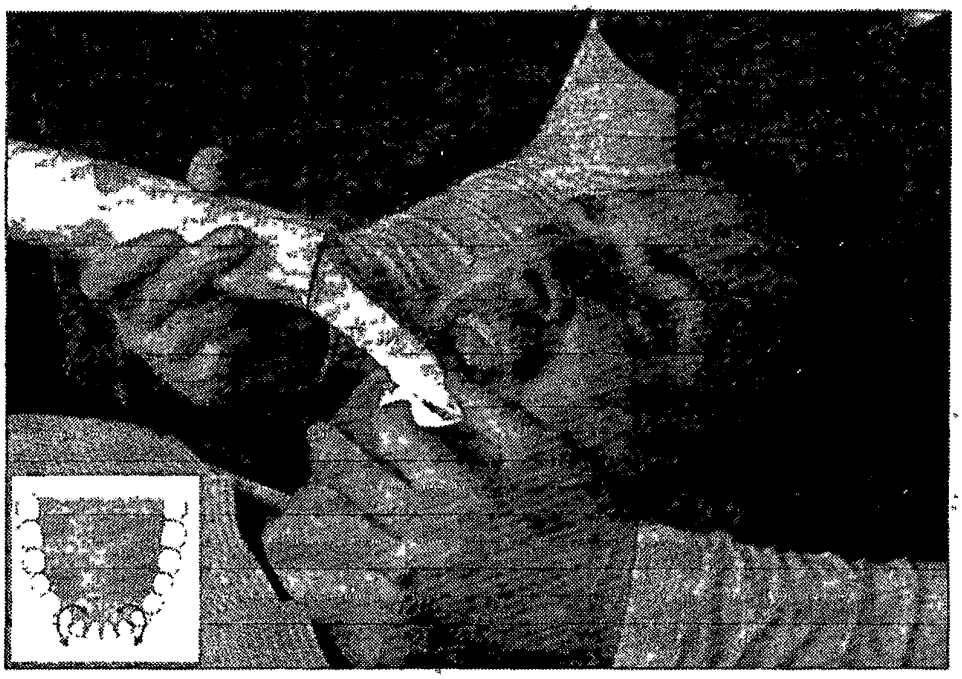
[redacted] To establish equivalency under § 112, ¶ 6, Align must show that the structures in the iTero Element perform the claimed function in "substantially the same way with substantially the same results" as the disclosed structure. *Ring & Pinion*, 743 F.3d at 835. [redacted]

For the "substantially the same way" requirement of the § 112, ¶ 6 equivalence analysis, Align simply asserts—without citation to supporting evidence and without explanation—that the requirement is satisfied: [redacted] CIB at 77. Align cannot meet its burden of establishing § 112, ¶ 6 equivalency through conclusory and unsupported assertions by its attorneys.

[redacted]

ii. "endoscopic probing member operating as a light guide to ensure total internal reflection"

Align argues that the iTero Element's probing member is "an endoscopic probing member" that operates as a "light guide to ensure total internal reflection." CIB at 76.[33] The iTero Element's probing member's tip is designed to be inserted into a patient's mouth and is therefore an endoscopic probe.



[33] Citing pages 293-94 of Align's prehearing brief, 3Shape argues that Align waived the issue of whether the iTero Element's probing member is an "endoscopic probing member operating as a light guide to ensure total internal reflection" by failing to raise it in its pre-hearing brief. RRB at 76. The cited pages address the "optical system" term in the context of claim 1 of the '901 patent and incorporate by reference an earlier discussion of the term in the context of claim 15 of the '448 patent. CPHB at 293. The earlier analysis cites to evidence supporting Align's contention that iTero Element's probing member is an "endoscopic probing member operating as a light guide to ensure total internal reflection." CPHB at 128-30 (citing JX-0091C.0016; CX-1940C (Ferraro WS) at Q/A 302; CX-639C.0035). In view of this analysis, I find that Align has not waived its contention that the iTero Element's probing member is an "endoscopic probing member operating as a light guide to ensure total internal reflection."

CX-0639C.0035. Mr. Ferraro opines that the tip of the probing member acts as a light guide to ensure total internal reflection." CX-1940C (Ferraro WS) at Q/A 303. 3Shape argues that Mr. Ferraro's opinion is conclusory and unsupported by any evidence. RIB at 76. Mr. Ferraro, however, supports his opinion [redacted]

JX-0091C.0016; CX-1940C (Ferraro WS) at Q/A 303 (citing CDX-0003C.0061, which contains an annotated version of the figure). The figure shows [redacted]. Accordingly, I find that Mr. Ferraro's opinion is supported. Because 3Shape has not pointed to any evidence indicating that the tip of the iTero Element's probe acts as something other than "a light guide to ensure total internal reflection," I find that Mr. Ferraro's unrebutted opinion as supported by JX-0091C satisfies Align's burden of proof.

3. '447 patent technical prong

Align asserts that its domestic industry products practice claims 17, 19, 20, 23, and 24 of the '447 patent. CIB at 124-28. All of the asserted claims are apparatus claims. With the exception of the "optical system" limitation of claim 1, there is no dispute that the iTero Element satisfies the limitations of claims 17, 19, 20, 23, and 24.

a. Undisputed Limitations

Claim 17 is an independent claim and consists of a preamble and six claim elements. To the extent the preamble is limiting, the iTero Element is an "apparatus for determining surface topology of at least a portion of a three-dimensional structure," as required by the preamble. CX-1940C (Ferraro WS) at Q/A 294; RX-1567C (Zavislan RWS) at Q/A 191-95. As required by the first limitation, the iTero Element has a "probing member" in the form of single piece tip that can be inserted into a patient's mouth. CX-1940C (Ferraro WS) at Q/A 295-97. The probing member has a "sensing face." *Id.* at Q/A 296; CX-0636C.0009-97. As required by the second limitation, the iTero Element has an "illumination unit" [redacted] CX-1940C (Ferraro WS) at Q/A 298; RX-1567C (Zavislan RWS) at Q/A 181; JX-0090C.0004. As required by the third limitation, [redacted]. CX-1940C (Ferraro WS) at Q/A 300; RX-1567C (Zavislan RWS) at Q/A 181; CX-1086; JX-090C.

The fourth limitation is the "optical system" limitation and is addressed below. As required by the fifth limitation, [redacted]. CX-1940C (Ferraro WS) at Q/A 305; RX-1567C (Zavislan RWS) at Q/A 181; JX-0090C; JX-0091C. In accordance with the sixth limitation, [redacted] determine the surface topology of a portion of a three-dimensional structure based on [redacted] the returned light beams. JX-0100C; CX-1940C (Ferraro WS) at Q/A 305, 308-309; RX-1567C (Zavislan RWS) at Q/A 188-195.

Claims 19 and 23 depend from claim 17, and claims 20 and 24 depend from claim 19. As required by claim 19, [redacted] to change the position of the focal plane over a range of focal plane positions relative to the probing member. CX-1940C (Ferraro WS) at Q/A 311; JX-0091C.0018; JX-0091C.0013. In accordance with claim 20, [redacted] the focal plane of the plurality of incident light beams while a fixed distance is maintained between the hand-held probe and the three-dimensional structure. CX-1940C (Ferraro WS) at Q/A 311; JX-0091C.0018; JX-0091C.0013. As required by claim 23, the plurality of incident light beams form a pattern. CX-1940C (Ferraro WS) at Q/A 300-301, 316; JX-0388C.0004. As required by claim 24, the [redacted] of the returned light beams depend on the position of the focal plane and [redacted] based on [redacted] each returned light beam measured over the range of focal plane positions. CX-1940C (Ferraro WS) at Q/A 318-319; JX-0388C.0004.

b. "optical system"

Claim 17 requires "an optical system configured to focus the plurality of incident light beams at a focal plane forward of the sensing face." '447 patent, col. 10:11-13. The construction of the term "optical system" recited in this limitation is identical to that of the term "optical system" recited in claim 1 of the '901 patent. Order No. 32 (Sept. 25, 2018) at 27, 24-25. Both terms are means-plus-function terms subject to § 112, ¶ 6. Order No. 32 (Sept. 25, 2018) at 22. The terms have identical claimed functions (to focus the plurality of incident light beams) and identical corresponding structure (a partially transparent mirror or beam splitter, confocal optics operating in a telecentric mode, relay optics, and an endoscopic probing member operating as a light guide to ensure total internal reflection). *Id.* at 37, 32, 34. Accordingly, the iTero Element does not

satisfy the "optical system" limitation of claim 17 of the '447 patent for the same reason that it does not satisfy the "optical system" limitation of claim 1 of the '901 patent: it does not have structure that is identical to or equivalent to the disclosed "confocal optics operating in a telecentric mode." Accordingly, the iTero Element does not practice claim 17 or its dependents, claims 19, 20, 23, and 24.

4. '448 patent technical prong

Align asserts that its domestic industry products practice claims 15 and 18-20 of the '448 patent. CIB at 124-28. With the exception of the "optical system" limitation of claim 15, there is no dispute that the iTero Element satisfies the limitations of claims 15 and 18-20.

a. Undisputed Limitations

Claim 15 is an independent claim and consists of a preamble and six claim elements. The preamble of claim 15 of the '447 patent is the same as the preamble of 17 of the '448 patent. To the extent that the preamble of claim 15 of the '447 patent is limiting, it is satisfied by the iTero Element for the same reasons that the product satisfies the preamble of claim 17 of the '448 patent. As required by the first claim element, the iTero Element has a "probing member" that has a "probing end" in the form of single piece tip that can be inserted into a patient's mouth. CX-1940C (Ferraro WS) at Q/A 295-97; CX-0636C.0009-97. The second claim element requires "an illumination unit configured to generate a plurality of incident light beams for illuminating the portion of the three-dimensional structure." '448 patent, col. 10:8-10. The construction of the term "illumination unit" recited in this limitation is identical to that of the term "illumination unit" recited in claim 1 of the '901 patent. Order No. 32 (Sept. 25, 2018) at 27, 24-25. Order No. 32 (Sept. 25, 2018) at 22, 24-25. Both terms are means-plus-function terms subject to § 112, ¶ 6. Order No. 32 (Sept. 25, 2018) at 22. The terms have identical

claimed functions (to generate a plurality of incident light beams) and identical corresponding structure (illumination unit disclosed at '901 patent, col. 2:63-64; the light emitters and diffraction or refraction optics disclosed at *id.*, col. 4:9-22; semiconductor laser unit 28 disclosed at *id.*, col.5:39-41 and in Figures 1A and 4; module 38 disclosed at *id.*, col. 5:45-51 and in Figures 1A and 4; laser emitter 154A-C disclosed at *id.*, col. 8:25-27; and optics expander 34 disclosed in *id.*, Figures 1A and 4). *Id.* at 24-25. Accordingly, the iTero Element satisfies the "illumination unit" limitation of claim 15 of the '448 patent for the same reasons it satisfies the "illumination unit" limitation of claim 1 of the '901 patent.

The third limitation is the "optical system" limitation and is addressed below. The fourth limitation is identical to the "detector unit" limitation of claim 17 of the '447 patent. '447 patent, col. 10:13-17 ("a detector unit configured to measure intensities of a plurality of returned light beams that are generated from illuminating the portion of the three-dimensional structure with the plurality of incident light beams"); '448 patent, col. 10:13-16 (same). Accordingly, the iTero Element satisfies the "detector unit" limitation of claim 15 of the '448 patent for the same reasons that it satisfies the "detector unit" limitation of claim 17 of the '447 patent. The fifth limitation is identical to the "processor" limitation of claim 17 of the '447 patent. '447 patent, col. 10:17-20 ("a processor coupled to the detector unit and configured to determine a surface topology of the three-dimensional structure based at least in part on the measured intensities of the plurality of returned light beams"). Accordingly, the iTero Element satisfies the "processor" limitation of claim 15 of the '448 patent for the same reasons that it satisfies the "processor" limitation of claim 17 of the '447 patent.

Claims 18 and 19 depend from claim 15, and claim 20 depends from claim 19. As required by claim 18, the plurality of incident light beams form a pattern. CX-1940C (Ferraro

WS) at Q/A 300-301, 316; JX-0388C.0004. Claim 19's "translation mechanism" limitation is the same as that of claim 19 of the '448 patent and is satisfied for the same reasons. As required by claim 20, [redacted] the position of the focal plane of the plurality of incident light beams. CX-1940C (Ferraro WS) at Q/A 311; JX-0091C.0018; JX-0091C.0013. As further required by claim 20, the iTero Element's probing end has a "sensing face." CX-1940C (Ferraro WS) at Q/A 295-97; CX-0636C.0009-97.

b. "optical system"

Claim 15 requires an "optical system configured to focus the plurality of incident light beams at a plurality of focal planes forward of the probing end." '448 patent, col. 10:11-13. The construction of the term "optical system" recited in this limitation is identical to that of the term "optical system" recited in claim 1 of the '901 patent. Order No. 32 (Sept. 25, 2018) at 27, 24-25. Order No. 32 (Sept. 25, 2018) at 27, 24-25. Both terms are means-plus-function terms subject to § 112, ¶ 6. Order No. 32 (Sept. 25, 2018) at 22. The terms have identical claimed functions (to focus the plurality of incident light beams) and identical corresponding structure (a partially transparent mirror or beam splitter, confocal optics operating in a telecentric mode, relay optics, and an endoscopic probing member operating as a light guide to ensure total internal reflection). *Id.* at 37, 32, 34. Accordingly, the iTero Element does not satisfy the "optical system" limitation of claim 15 of the '448 patent for the same reasons that it does not satisfy the "optical system" limitation of claim 1 of the '901 patent: It does not have "confocal optics operating in a telecentric mode" or its equivalent. The iTero Element does not practice claim 15 or its dependents, claims 18-20.

D. Economic Prong

Align is a large, international company that makes and markets clear aligners for use in dentistry. CIB at 141, CX-1937C (Hogan WS) at Q/A 5; CX-1941C (Bakewell WS) at Q/A 30; Tr. (Hogan) at 108:13-18; Tr. (Stubbs) at 690:20-24; JX-0087.0062. Its total net revenue in 2017 was $1,473.4 million, and it employed 8,732 people. CX-1941C (Bakewell WS) at Q/A 36. Beginning in 2015, Align began to make and market an oral scanner, the iTero Element. CIB at 141; CX-1941C (Bakewell WS) at Q/A30.[34] Align seeks to demonstrate that it makes significant domestic investments in its iTero scanner under section 337(a)(3) subsections (A) and (B).

It is undisputed that Align invests in no manufacturing of scanners in the U.S. The scanners are made in Israel and [redacted]. RIB at 133; Tr. (Relic) at 77:24-78:1, 80:2-81:7, 81:3-7, 86:13-15; Tr. (Sabina) at 682:17-24; CX-1938C (Relic WS) at Q/A 7. The claimed domestic industry expenditures are for "Research and Development" ("R&D"),[35] "Clinical Education," "Technical Marketing," and "Technical Sales." CX-1941C (Bakewell WS) at Q/A 19, 23.

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[34] The alleged domestic industry product is the Align "iTero color intraoral scanner and related software products, including OrthoCAD and ClinCheck (which is part of OrthoCAD)." CX-0123C (Morici Supp. Declaration) at 7. The alleged DI product is referred to herein as the "iTero" scanner.

[35] R&D is enumerated as a domestic industry activity under subsection (C) of section 337(a)(3), but Align does not rely on that subsection. It does not need to. *Certain Solid State Storage Drives, Stacked Electronics Components, and Products Containing Same* ("*Solid State Storage*"), Inv. No. 337-TA-1097, Comm'n Op. at 14, 2018 WL 4300500 at *8 (Jun. 29, 2018) ("In short, we find that the text of the statute, the legislative history, and Commission precedent do not support narrowing subsections (A) and (B) to exclude non-manufacturing activities, such as investments in engineering and research and development.") Under subsection (C) there is a heightened standard for demonstrating a nexus between domestic industry activities and the patented technology under that subsection. *Certain Marine Sonar Imaging Devices, Including Downscan and Sidescan Devices, Products Containing the Same, and Components Thereof*, Inv. No. 337-TA-921, Comm'n Op. at 65, 2016 WL 10987364 at 42 (Jan. 6, 2016) (expenditures

Align's economic prong contentions are based on the testimony of W. Christopher Bakewell, Align's economic expert. He uses "Align's public financial statements, its Form 10Ks and Form 10Qs, and its ordinary course, or contemporaneous, business records" to carry out his calculations. *Id.* at Q/A 65. To assess the alleged domestic industry, Mr. Bakewell considers a three-year period from January 2015 through March 2018. *Id.* at Q/A 31.

1. Investment in plant and equipment – 337(a)(3)(A)

Mr. Bakewell uses as a starting point the activities at Align's facilities in San Jose, California, and Raleigh, North Carolina. The San Jose facility is Align's corporate headquarters and houses "many groups" including R&D, product development, and "other management." *Id.* at Q/A 20. Starting in the fourth quarter of 2015, Align has conducted R&D in the Raleigh facility, "which is also home to sales and marketing and other general and administrative activities." *Id.*[36]

The "floor plan" analysis is based on Mr. Bakewell's review of the activities of personnel who occupy space in Align's two domestic facilities. *See id.* at Q/A 54. For the current San Jose facility, Mr. Bakewell testifies that "[redacted] . . . is comprised of R&D" "and [redacted] is comprised of sales and marketing." *Id.* at Q/A 56. "In Align's former San Jose facility, R&D comprised [redacted], and the IT team,

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must be "closely related to and enable exploitation of the patented technology.") Under subsections (A) and (B), however, a complainant need show only that its expenditures are related to a product that practices the patent, not to the patented technology itself. *See Solid State Storage*, Comm'n Op. at 13, 2018 WL 4300500 at *8 ("The Commission has not required complainants to show exploitation of the patented technology (as the concept is understood under subsection (C)) to satisfy subsection (A) and (B).").

[36] Mr. Bakewell testifies that he excludes from his domestic industry calculations Align's "executives, its legal team, and other administrative employees." *Id.* at Q/A 26.

[redacted], also occupied [redacted]." *Id.* at Q/A 57.

Mr. Bakewell testifies that he performed "a similar allocation" for the North Carolina facility, *id.* at Q/A 58. He states: "Based on the headcount allocation, Align's employees in Raleigh related to the iTero scanners [redacted] total employees in Raleigh in 2015, 2016, and 2017, respectively. *Id.* at Q/A 59. The result of the floor-plan allocation is investment [redacted] at San Jose and [redacted] in Raleigh, for a total [redacted]. *Id.* at Q/A 60-62.[37] Mr. Bakewell then applies three different allocation methodologies to refine the investment amounts attributable to the iTero scanner. CIB at 147. The first method is the "responsibilities-based allocation." Second is "a revenue-based allocation," and third is "a management-based allocation." *Id.* at Q/A 54.

The responsibilities-based allocation is "related to the floor space allocation in that the people in the responsibilities-based allocation occupy roughly comparable floorspace." Bakewell at Q/A 54-55.

The revenue-based approach "assumes that plant and equipment supporting Align's businesses are used to support iTero scanners pro-rata with sales activities" and "uses actual,

[37] Mr. Bakewell's floorplan and responsibilities allocations are based on the labor headcounts that were made by Align management for the purpose of this litigation. *See* CRB at 81; Tr. (Morici) at 236:23-238:6-25. As discussed below, such allocations are presumed to be reliable under section 337(a)(3) unless their unreliability is persuasively demonstrated by respondents. *Certain Solid State Storage Drives, Stacked Electronics Components, and Products Containing Same,* Inv. No. 337-TA-1097, Comm'n Op. at 21-22, 2018 WL 4300500 at *13 (Jun. 29, 2018) (citation omitted).

accounting-based numbers." *Id.* at Q/A 64. For the revenue-based analysis, Mr. Bakewell uses Align's U.S. sales of scanners, excluding sales of clear aligners and revenue from services related to the scanners. *Id.* at Q/A 68-72. Mr. Bakewell's calculations show that [redacted] Align's total sales are not sales of iTero scanners. *Id.* at Q/A 68. Using [redacted] allocation of Align's revenue to scanners for 2015, [redacted] allocation for 2016, and [redacted] allocation for 2017, Mr. Bakewell allocates [redacted] to expenditures for plant during the pertinent period and [redacted] to equipment. *Id.* at Q/A 74. Mr. Bakewell states that this allocation underestimates Align's actual investment because "these calculations do not reflect the fact that Align's scanning segment also added value to the clear aligner business," and ignores the "business synergies" that "create value through the combination." *Id.* at Q/A 77.

The management-based approach reflects how Align's management runs its business "on a day-to-day basis, as well as strategically." *Id.* at Q/A 78. This analysis relies on the testimony of John F. Morici, Align's chief financial officer, who submitted a declaration that "[redacted] Align's expenses for its domestic facilities are related to the iTero domestic industry products." *Id.* at Q/A 80 (citing CX-0123C ("[redacted] the California facility is devoted to efforts that relate to [sic] associated with the Domestic Industry products."); *see* CX-1939C (Morici WS) at Q/A 23-24; CX-1941C (Bakewell WS) at Q/A 82-83, 85).

The rationale for the management-based allocation is that the combination of the iTero scanner with the Invisalign clear aligner system has been successful and "[redacted]." *Id.* at Q/A 81. According to Mr. Bakewell and Mr. Morici, "the two components of Align's business are complementary [redacted]." *Id.* Consistent with this approach, Align

personnel testify that they "spend [redacted] their time on scanner-related projects. They're working hard to integrate the systems and to capitalize on the scanner investments within the Invisalign system to recognize synergies from combining those businesses together." *Id.* at Q/A 83.

Mr. Bakewell concludes that the responsibilities-based allocation yields a total domestic industry investment from January 2015 through March 2018 [redacted]. *Id.* at Q/A 91. The revenue-based allocation amounts [redacted]. *Id.* at Q/A 61, 89. The management-based approach amounts [redacted]. I find that the amounts of domestic industry investment under subsection (A) under the responsibilities- and management-based models are quantitatively and qualitatively significant in the context Align's operations, as discussed below. Accordingly, the economic prong requirement of subsection 337(a)(3)(A) is satisfied.[38]

2. Significant Employment of Labor and Capital under Subsection (B)

Mr. Bakewell breaks down Align's employees into groups that he characterizes by job function: engineering, product development, clinical education, technical marketing, and technical sales. *Id.* at Q/A 106. With respect to the iTero scanner, [redacted] *Id.* at Q/A 106-107. Mr. Bakewell says he excluded from his calculations under subsection (B) "upper-level management in a general and administrative function, the legal team, employees related to the Invisalign product, and others." *Id.* at Q/A 109. Also excluded are "the inside salespeople and people that do non-technical marketing, such as making product brochures." *Id.* He also excluded "employees characterized under the 'general &

[38] I find that there is insufficient evidence to make a determination on the significance of the [redacted] investment under the revenue-based model.

administrative' and 'manufacturing' designations," as well as temporary employees and contractors. *Id.*

The crucial element of Mr. Bakewell's calculation is the "headcount" information supplied by Align's management. *Id.* at Q/A 110-113, 133. As discussed above, the headcounts satisfy the Commission's requirements: they are "reasonable" "for the purposes of establishing the economic prong of the domestic industry requirement." *Certain Solid State Storage Drives, Stacked Electronics Components, and Products Containing Same ("Solid State Storage"),* Inv. No. 337-TA-1097, Comm'n Op. at 21-22, 2018 WL 4300500 at *13 (Jun. 29, 2018) (citing *Certain NOR and NAND Flash Memory Devices and Products Containing Same,* Inv. No. 337-TA-560, Order No. 37, 2006 WL 3775919, at *2 (Nov. 17, 2006), *not reviewed,* Notice (Dec. 8, 2006)). 3Shape has not persuasively challenged these headcounts, as is their burden. *Id.* ("Respondents have not persuasively rebutted [the complainant's] evidence" that [management's] allocation of [] labor expenses attributable to the [domestic industry product] is reasonable.)

Mr. Bakewell calculates expenditures for the activities of covered employees from 2016-2017. CX-1941C (Bakewell WS) at Q/A 106-113.[39] He uses actual compensation data to

[39] Mr. Bakewell includes some types of employees whose activities may not count as domestic industry expenditures, such as "technical marketing" personnel. His [redacted] allocation to the domestic industry product therefore may be somewhat exaggerated. CX-1941C (Bakewell WS) at Q/A 108-109. The Commission does not recognize the distinction drawn by Mr. Bakewell between "technical" sales activity and other types of sales activity. *See Certain Non-Volatile Memory Devices and Products Containing The Same ("Memory Devices"),* Inv. No. 337-TA-1046, Comm'n Op. at 46, 2018 WL 6012622 at *27 (Oct. 26, 2018), *aff'g in pertinent part,* Final Initial Determination at 158-160, 2018 WL 2734930 at *78-79 (Apr. 27, 2018). As noted in *Solid State Storage,* however, "'[w]hile marketing and sales activity, alone, may not be sufficient to meet the domestic industry test, those activities may be considered as part of the overall evaluation of whether or not a Complainant meets the economic prong.'" 2018 WL 4300500 at *13. The same analysis may be applied to activities in the category of "Clinical Education

compute the amount of investment. *Id.* at Q/A 114-115. He calculates Align's domestic investments in labor and then allocates those amounts to the iTero domestic industry product. Using the revenue-based allocation, the total amount of Align's investments in labor is [redacted]. *Id.* at Q/A 155. Using the management-based allocation, the amount is [redacted]. *Id.* at Q/A 158. Using the responsibilities-based allocation, the amount is [redacted]. *Id.* at Q/A 160.

Mr. Bakewell demonstrates that the domestic employees are among the highest-paid and most valuable in Align's organization. *Id.* at Q/A 164-65. [redacted]. Tr. 92:14-93:13, 1051:14-1052:2; CX-1941C (Bakewell WS) at Q/A 125; CX-1935C (Kling WS) at Q/A 101; CX-1938C (Relic WS) at Q/A 45; CX-1939C (Morici WS) at Q/A 52). As a result, Align's investments in R&D for "the scanner part of the business" are qualitatively as well as quantitatively significant. CX-1941C (Bakewell WS) at Q/A 125.

Respondents' expert, Mr. Philip Green, disputes Mr. Bakewell's analysis on several grounds, principally that Mr. Bakewell improperly allocates many investments to the iTero product that are not attributable to it under strict accounting rules. *See, e.g.,* RX-1566C (Green RWS) at Q/A 97, 129-130, 148, 169. In particular, 3Shape challenges Align's allocations of employee time both to the iTero domestic industry product and to the Invisalign system, which is not a domestic industry product. 3Shape points to Align's reports to the SEC, in which it separates accounting cost centers between the two products. But 3Shape's criticism ignores the

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Marketing." *Id.* at Q/A 138-139. Assisting domestic purchasers to use an imported product might not be enough, on its own, to satisfy the economic prong. *See Memory Devices, supra.*

context in which Align's business operates. Align employees, Mr. Morici states: "[redacted]." CX-1939C at Q/A 27.

The Respondents fail to demonstrate that Mr. Morici's estimates do not reflect work related to the iTero product. As discussed above, I agree with Mr. Green that Mr. Bakewell's calculations may be exaggerated, but I am not persuaded that there is no domestic industry related to the iTero product or that the domestic industry is insignificant.

Mr. Green apparently concedes that, based on the financial information that was available to him, Align has "'allocated [redacted] to iTero R&D in 2017.'" Tr. (Green) at 772:24-773:2. In context, this amount represents a significant investment. This conclusion is buttressed by the importance of the domestic industry product in the overall context of Align's domestic operations. "[redacted]," Mr. Morici testifies. CX-1939C (Morici WS) at Q/A 12. "[redacted]." *Id.*

Accordingly, I find that Align has presented sufficient evidence of significant domestic industry activity under subsection (B) of section 337(a)(3).

VIII. REMEDY AND BONDING

A. Limited Exclusion Order

Align seeks a limited exclusion order ("LEO") pursuant to 19 U.S.C. §1337(d)(1), which states, in pertinent part: "If the Commission determines, as a result of an investigation under this

section, that there is a violation of this section, it shall direct that the articles concerned . . . be excluded from entry into the United States," unless the Commission determines that such exclusion would be contrary to the public interest.[40]

3Shape, relying on the discretion afforded the Commission in selecting the "'form, scope and extent of the remedy,'" suggests a list of "appropriate exemptions" from any LEO. RIB at 191 (quoting *Certain Dental Implants,* Inv. No. 337-TA-934, Comm'n Op. at 43 (May 11, 2016)).

First, without any elaboration or explanation, 3Shape requests an exemption for "products sold to or used by the U.S. government." *Id.* (citing 19 U.S.C. §1337(l)). 3Shape presents no evidence of sales or use by the U.S. government of the accused products.

It is true that "when products resulting from a patented process are imported for the United States, such as by a government contractor, the process patent owner cannot exclude the products from entering the United States." *Zoltek Corp. v. United States,* 672 F.3d 1309, 1321-22 (Fed. Cir. 2012). In the absence of any proffered evidence that the United States or any government contractor imports or uses the accused products, however, the requested exemption should not be granted.

3Shape's second requested exemption would allow continued importation of any model that has been imported into the United States prior to the effective date of the order. Here, 3Shape cites *Certain Baseband Processor Chips and Chipsets, Transmitter and Receiver (Radio) Chips, Power Control Chips, and Prods. Containing Same, Including Cellular Telephone Handsets ("Baseband Processor"),* Inv. No. 337-TA-543, Comm'n Op. at 28, 124, 151-154,

[40] Consideration of the public interest factors articulated in section 337(d)(1) has not been delegated to the ALJ in this investigation. *See Notice of Institution* (Dec. 14, 2017).

2007 WL 9676556 (Jun. 7, 2007). The exemption in *Baseband Processor* was intended to ameliorate possible adverse effects on the public interest. *Id.*, 2007 WL 9676556 at *3. As stated herein, the public interest factors have not been delegated for the ALJ's consideration in the instant case, accordingly, any exemption to ameliorate the effect of an exclusion order in the public interest is outside the scope of my recommendation.

The third requested exemption is for replacement and refurbished parts and devices. 3Shape cites *Certain Automated Mechanical Transmission Sys. for Medium-Duty and Heavy-Duty Trucks and Components Thereof,* Inv. No. 337-TA-503, Comm'n Op. at 4-5, 2005 WL 8152027 at *3 (May 9, 2005), which concerns an exemption granted in the public interest, which falls outside the scope of my recommendation. For the same exemption, 3Shape also cites *Certain Sortation Sys., Parts Thereof, and Prods. Containing Same ("Sortation"),* Inv. No. 337-TA-460, Comm'n Op. at 18-20, 2003 WL 1712556 (Feb. 19, 2003). In that case, the Commission included a certification provision that allowed the respondent to import replacement parts for a warehouse sortation system that had been imported and sold to a third party. *Id.*, 2003 WL 1712556 at *14. The Commission noted that such a provision was appropriate where "it was not readily apparent how the infringing products are to be used and such use is significant." *Id.* In addition, "[t]he Commission has included certification provisions in exclusion orders where the patent(s) that form the basis of the order cover processes for manufacturing goods and Customs is unable readily to determine how goods sought to be imported were made." *Id.* Neither are factors in this case. Moreover, the certification provision in *Sortation* was unopposed. *Id.* at *13.

The fourth requested exemption is for devices earmarked for warranty and repair purposes. 3Shape cites *Certain Mobile Devices, Associated Software, and Components Thereof*

("Mobile Devices"), Inv. No. 337-TA-744, Comm'n Op. (May 18, 2012). RIB 191. Again, the exemption was based on the public interest, consideration of which is not before me. *Mobile Devices,* Comm'n Op. at 21. The facts here show that 3Shape holds a significant number of infringing units in the U.S. that are not limited to non-commercial uses, but are used, *inter alia,* to furnish warranty and replacement parts to customers. JX-0389C at ¶6, App. B.

3Shape also seeks "a carve out provision for any sales of the accused Trios3 that Align has implicitly or explicitly authorized by maintaining the Trios/Invisalign interface for continuing cases. . . ." RIB at 191. There is no citation of authority supporting this request, and no argument to explain it.

3Shape also seeks a certification provision for unaccused products. Align has no objection, and such a certification provision is recommended. Otherwise, 3Shape's requested exceptions and certifications are not recommended.

B. Cease and Desist Order

Align seeks a cease and desist order pursuant to 19 U.S.C. §1337(f)(1). In support, Align maintains that 3Shape maintains a commercially significant inventory of infringing products in the U.S. that could be used to circumvent the effect of any exclusion order. Align points to a stipulation concerning [redacted] 3Shape's Branchburg, New Jersey facility. JX-0389C at ¶6, App. B. Align's expert, Mr. Bakewell, testifies that these units could be used for sales, and that a warranty "is a form of sales." CX-1941C (Bakewell WS) at Q/A 179.

3Shape says the [redacted] in question are not commercially significant because they are not for sale. "Instead, these units are held in the U.S. by 3Shape for technical support, warranty and replacement, and marketing and training demonstrations." RIB at 192 (citing RX-1295C

(Melchior WS) at Q/A 33-35). 3Shape also seeks a "carve-out" from any CDO for service or replacement parts.

There is no persuasive evidence that the number of units in the United States is in itself insignificant or that the units are used solely for non-commercial purposes. *Compare Certain Personal Data and Mobile Communications Devices and Related Software,* Inv. No. 337-TA-710, Comm'n Op., 2011 WL 12488979 at *47-48 (Dec. 29, 2011) ("HTC maintains a small inventory in the United States for testing purposes"). The evidence indicates that at least some of these units are used for replacement of defective products, warranty and repair, RX-1295C (Melchior WS) at Q/A 32-37). Such uses have an impact on the marketplace, *i.e.,* they are commercial.

3Shape cites one decision where the Commission excepted from a CDO "service and replacement parts" on the ground (apart from the public interest) that consumers might otherwise suffer. *See Certain Sys. for Detecting & Removing Viruses or Worms, Components Thereof, & Prod. Containing Same,* Inv. No. 337-TA-510, Comm'n Op. at 6, 2005 WL 8153587 at *3 (Aug. 23, 2005). On this basis, I recommend that an exception from the CDO be granted for the limited purpose of providing service and replacement parts.

Additional "carve outs" to the CDO are not recommended for the same reasons provided above with respect to any LEO.

C. Bond

Commission Rule 210.50(a)(3) specifies that the amount of a bond must be "sufficient to protect the complainant from any injury." 19 C.F.R. § 210.50(a)(3); *see* 19 U.S.C. § 1337(j). ("[A]rticles directed to be excluded from entry under subsection (d) of this section or subject to a cease and desist order under subsection (f) of this section shall, until such determination becomes

final, be entitled to entry under bond prescribed by the Secretary in an amount determined by the Commission to be sufficient to protect the complainant from any injury."). The Commission has set bond amounts based on the price difference between the infringing imports and the domestic industry products or on a reasonable royalty the respondent would otherwise pay to the complainant. *See Certain Inject Ink Supplies And Components Thereof*, Inv. No. 337-TA-691, Comm'n Op. at 15-18 (Nov. 1, 2011). Where the calculation of a price differential is impractical and there is insufficient evidence in the record to determine a reasonable royalty, the Commission has set a bond in the amount of 100% of the entered value of the infringing products. *Certain Marine Sonar Imaging Devices, Including Downscan and Sidescan Devices, Products Containing the Same, and Components Thereof*, Inv. No. 337-TA-921, Comm'n Op. at 83-89 (Jan. 6, 2016). The complainant bears the burden of establishing the need for a bond. *Certain Rubber Antidegradants, Components Thereof, and Products Containing Same*, Inv. No. 337-TA-533, Comm'n Op. at 40 (July 21, 2006).

Align seeks a 100% bond on the ground that a price comparison is not practical because the parties have different business models. Specifically, Mr. Bakewell testifies that calculating a reasonable royalty rate is not possible because 3Shape sells scanners only through distributors while Align sells directly to consumers and "sells its digital ecosystem." CX-1941C (Bakewell WS) at Q/A 184-186.

3Shape argues that Align has not met its burden to establish an appropriate bond. 3Shape points out that Align makes direct sales to customers through at least one distributor, Patterson Dental, and that its negotiations with other distributors could furnish the basis for establishing a bond rate. *See* Tr. (Hogan) at 110:1-3, Tr. (Bakewell) at 435:19-436:14, Tr. (Stubbs) at 694:22-695:1, Tr. (Kling) at 1016:1-22. Although 3Shape asserts that Align has licensing agreements

that were not analyzed to determine if an appropriate bond rate could be determined from those agreements, other than one "internal" agreement that Mr. Bakewell testifies is not an appropriate indication of market conditions, CX-1941C (Bakewell WS) at Q/A 190-193, 3Shape does not point to any licensing agreement that could be used to calculate the rate.

I find that Mr. Bakewell's conclusion that there is no way to calculate an appropriate bond rate is unpersuasive. I find no support in the Commission's precedent for Mr. Bakewell's contention that Align's iTero sales would not be an appropriate basis for determining a bond rate because they do not capture all potential losses. CX-1941C at Q/A 187 ("A bond based on a price differential does not address any later sales of clear aligners that would have been associated with the scanner sale.") The bond rate should be based on a price differential or royalty rate that pertains to the sales of products, rather than on a theory of consequential damages that does not flow from the actual sale of the products at issue in the investigation. The statutory bond covers a narrow period of time, 60 days, and on its face is not fashioned to provide a remedy for complainants who may suffer remote, speculative loss.

In this regard, Align does not refute the testimony of 3Shape's economic expert that [redacted]. RX-1566C (Green RWS) at Q/A 245. Based on this fact, it is difficult to see how Align would suffer any injury during the 60-day review period due to continued sales of 3Shape scanners.

In the absence of evidence of the need for a bond or of an amount of a bond, I recommend that no bond be imposed during the 60-day review period.

X. CONCLUSIONS OF LAW

Based on the foregoing, and the record as a whole, it is my final initial determination that there is no violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, in the importation into the United States, the sale for importation, and/or the sale within the United States after importation of certain intraoral scanners and related hardware and software with respect to U.S. Patent No. 8,638,447 (the "'447 patent"), U.S. Patent No. 8,638,448 (the "'448 patent"), or U.S. Patent No. 9,615,901 (the "'901 patent").

This determination is based on the following conclusions of law:

1. The Commission has subject matter jurisdiction over this investigation, *in personam* jurisdiction over Respondents, and *in rem* jurisdiction over the accused intraoral scanners and related hardware and software.

2. There has been an importation into the United States, sale for importation, or sale within the United States after importation of the accused intraoral scanners and related hardware and software by Respondents.

3. No claims of the '901 patent have been shown to be infringed by the accused products.

4. No claims of the '447 patent have been shown to be infringed by the accused products.

5. No claims of the '448 patent have been shown to be infringed by the accused products.

6. Claim 15 of the '901 patent is invalid for anticipation. No other claims of the '901 patent have been shown to be invalid.

7. No claims of the '447 patent have been shown to be invalid.

8. No claims of the '448 patent have been shown to be invalid.

9. The domestic industry requirement is satisfied with respect to claims 16-19 of the '901 patent.

10. The domestic industry requirement has not been satisfied with respect to any claim of the '447 patent.

11. The domestic industry requirement has not been satisfied with respect to any claim of the '448 patent.

I hereby certify the record in this investigation to the Commission with my final initial determination. Pursuant to Commission Rule 210.38, the record further comprises the Complaint and exhibits thereto filed with the Secretary, the *Markman* order, and the exhibits attached to the parties' summary determination motions and the responses thereto. 19 C.F.R. § 210.38(a).

Pursuant to Commission Rule 210.42(c), this initial determination shall become the determination of the Commission 45 days after the service thereof, unless a party files a petition for review pursuant to Commission Rule 210.43(a), the Commission orders its own review pursuant to Commission Rule 210.44, or the Commission changes the effective date of the initial determination. 19 C.F.R. § 210.42(h)(6).

This initial determination is being issued with a confidential designation pursuant to Commission Rule 210.5 and the protective order in this investigation. Within ten (10) days of the date of this initial determination, each party shall submit to the Administrative Law Judge a statement as to whether or not it seeks to have any portion of this document deleted from the public version. *See* 19 C.F.R. § 210.5(f). A party seeking to have a portion of this document deleted from the public version thereof must attach to its submission a copy of the document with red brackets indicating the portion(s) asserted to contain confidential business information.[41] The parties' submissions under this subsection shall not be filed with the Commission Secretary but shall be submitted by paper copy to the Administrative Law Judge

[41] To avoid depriving the public of the basis for understanding the result and reasoning underlying the decision, redactions should be limited. Parties who submit excessive redactions 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).

and by e-mail to the Administrative Law Judge's attorney advisor.

SO ORDERED.

Dee Lord
Administrative Law Judge

CERTAIN INTRAORAL SCANNERS AND RELATED HARDWARE AND SOFTWARE **Inv. No. 337-TA-1090**

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **INITIAL DETERMINATION** has been served to the following parties as indicated, on **May 24, 2019**

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

On Behalf of Complainants Align Technology, Inc.:

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