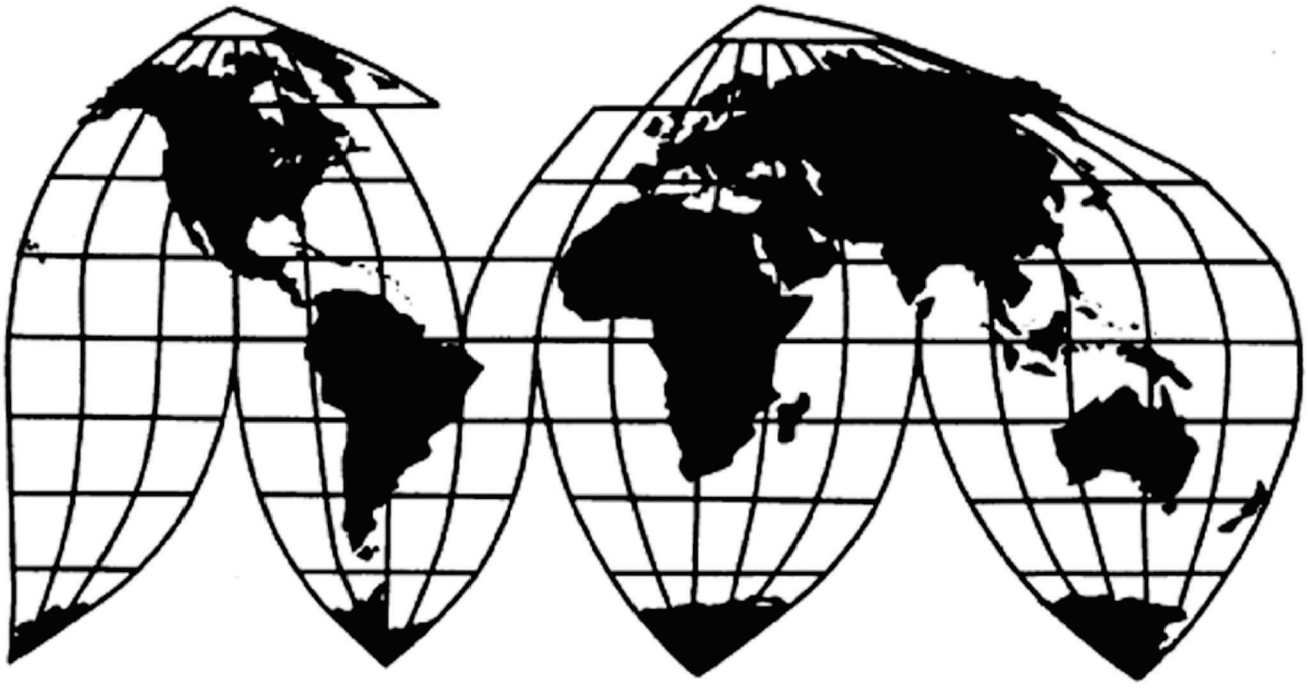
In the Matter of

CERTAIN DENTAL CERAMICS, PRODUCTS THEREOF, AND METHODS OF MAKING THE SAME

Investigation No. 337-TA-1050

Publication 4968 **September 2019**

U.S. International Trade Commission



Washington, DC 20436

U.S. International Trade Commission

COMMISSIONERS

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Irving Williamson, Commissioner
Meredith Broadbent, Commissioner
Rhonda Schmidtlein, Commissioner
Jason Kearns, Commissioner

Address all communications to
Secretary to the Commission
United States International Trade Commission
Washington, DC 20436

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UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of CERTAIN DENTAL CERAMICS, PRODUCTS THEREOF, AND METHODS OF MAKING THE SAME	Investigation No. 337-TA-1050

NOTICE OF A COMMISSION DETERMINATION OF NO VIOLATION OF SECTION 337; TERMINATION OF INVESTIGATION

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has found no violation of section 337 of the Tariff Act of 1930 in the above-captioned investigation. The investigation is terminated.

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

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on April 25, 2017, based on a complaint, as supplemented, filed by Ivoclar Vivadent AG of Schaan, Liechtenstein; Ivoclar Vivadent, Inc. of Amherst, New York; and Ardent, Inc. of Amherst, New York (collectively "Ivoclar"). 82 FR 19081 (Apr. 25, 2017). The complaint, as supplemented, alleged violations of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain dental ceramics, products thereof, and methods of making the same by reason of the infringement of certain claims of four United States patents: U.S. Patent No. 7,452,836 ("the '836 patent"); U.S. Patent No. 6,517,623 ("the '623 patent"); U.S. Patent No. 6,802,894 ("the '894 patent"); and U.S. Patent No. 6,455,451 ("the '451 patent"). The notice of

investigation named as respondents GC Corporation of Tokyo, Japan; and GC America, Inc. of Alsip, Illinois (collectively, "GC"). The Office of Unfair Import Investigations was also named as a party.

Earlier in proceedings, the investigation was terminated as to certain asserted patent claims, including all of the asserted claims of the '623 patent and the '451 patent, based upon withdrawal of the complaint. Order No. 18 (Nov. 21, 2017), *not reviewed*, Notice (Dec. 6, 2017); Order No. 24 (Dec. 19, 2017), *not reviewed*, Notice (Jan. 18, 2017); Order No. 51 (Feb. 22, 2018), *not reviewed*, Notice (Mar. 23, 2018); Order No. 56 (Mar. 28, 2018), *not reviewed*, Notice (Apr. 27, 2018).

On July 23, 2018, the ALJ issued the final initial determination ("ID"). Remaining within the scope of the investigation, as to infringement, domestic industry, or both, were claims 1, 2, 4, 5, 7, 9, 10, 13, 15-19, and 21 of the '836 patent; and claims 1, 2, 4, 16-21, 34, 36 and 38 of the '894 patent. The ID finds, *inter alia*, that Ivoclar failed to demonstrate infringement of the above-referenced claims of the '836 patent. The ID finds, *inter alia*, that claims 36 and 38 ("the '894 flexure strength claims") are invalid as indefinite under 35 U.S.C. § 112 ¶ 2. The ID further finds that Ivoclar failed to demonstrate infringement and failed to meet the technical prong of the domestic industry requirement as to the remaining claims of the '894 patent (claims 1, 2, 4, 5, 7, 9, 10, 13, 15-19, and 21) ("the '894 annealing claims"). The ID finds that some, but not all, of the '894 annealing claims are invalid in view of certain prior art.

After the issuance of the ID, the Commission solicited comments from the public concerning remedy and the public interest. On September 13, 2018, Representative Brian Higgins (R-N.Y.) filed comments in support of his constituent Ivoclar, whose headquarters is in Western New York. Letter from Rep. Brian Higgins to Chairman David S. Johanson at 1 (Sept. 13, 2018). In addition, Ivoclar, GC, and the Commission investigative attorney filed petitions for review and replies to the other parties' petitions.

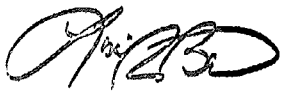
On September 21, 2018, the Commission issued its notice of review. By that notice, the Commission determined not to review the ID with respect to the '836 patent and the '894 flexure strength claims, thereby terminating the investigation as to those patent claims. The Commission determined to review the ID's findings as to the '894 annealing claims and solicited further briefing from the parties on certain issues concerning those patent claims. The Commission also solicited briefing from the parties, interested government agencies, and members of the public on remedy, the public interest, and bonding. No non-parties filed such briefing. On October 5, 2018, the parties filed opening briefs in response to the Commission notice of review, and on October 12, 2018, the parties filed reply briefs.

Having reviewed the record of the investigation, including the final ID, the parties' petitions for review and responses thereto, and the parties' briefing to the Commission, the Commission has determined to affirm, with modified reasoning, the ID's conclusion that Ivoclar failed to demonstrate infringement of the '894 annealing claims. The Commission has also determined to affirm, with modified reasoning, the ID's finding that claims 1, 2, and 34 of the '894 patent are anticipated by U.S. Patent No. 4,189,325 (Barrett) (RX-27). The Commission

has determined to take no position as to whether International Patent Application WO 00/34196 ("WO196") (RX-563) invalidates any of the '894 annealing claims or whether the technical prong of the domestic industry requirement was met for the '894 patent. The Commission has determined to affirm the ID's remaining findings concerning the '894 annealing claims. Accordingly, the Commission terminates the investigation with respect to the '894 annealing claims, and thereby the investigation in its entirety, with a finding of no violation of section 337. The reasons for the Commission's determinations are set forth more fully in the Commission's accompanying opinion.

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

By order of the Commission.



Lisa R. Barton
Secretary to the Commission

Issued: December 18, 2018

CERTAIN DENTAL CERAMICS, PRODUCTS THEREOF, AND METHODS OF MAKING THE SAME **Inv. No. 337-TA-1050**

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **NOTICE** has been served by hand upon the Commission Investigative Attorney, **Todd Taylor, Esq.**, and the following parties as indicated, on **December 18, 2018**.

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

On Behalf of Complainants Ivoclar Vivadent AG, Ivoclar Vivadent, Inc., and Ardent, Inc.:

Kecia J. Reynolds, Esq.
PILLSBURY WINTHROP SHAW PITTMAN LLP
1200 Seventeenth Street, NW
Washington, DC 20036

☐ Via Hand Delivery
☒ Via Express Delivery
☐ Via First Class Mail
☐ Other:_____

On behalf of Respondents GC Corporation and GC America, Inc.:

Jeffrey L. Eichen, Esq.
DRINKER BIDDLE & REATH LLP
222 Delaware Avenue, Suite 1410
Wilmington, DE 19801

☐ Via Hand Delivery
☒ Via Express Delivery
☐ Via First Class Mail
☐ Other:_____

PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, DC

In the Matter of **CERTAIN DENTAL CERAMICS, PRODUCTS THEREOF, AND METHODS OF MAKING THE SAME**	**Inv. No. 337-TA-1050**

COMMISSION OPINION

I. INTRODUCTION

The Commission instituted this investigation on April 25, 2017, based on a complaint, as supplemented, filed by Ivoclar Vivadent AG of Schaan, Liechtenstein; Ivoclar Vivadent, Inc. of Amherst, New York; and Ardent, Inc. of Amherst, New York (collectively "Ivoclar"). 82 Fed. Reg. 19081 (Apr. 25, 2017). The complaint, as supplemented, alleged violations of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain dental ceramics, products thereof, and methods of making the same by reason of the infringement of certain claims of four United States patents: U.S. Patent No. 7,452,836 ("the '836 patent"); U.S. Patent No. 6,517,623 ("the '623 patent"); U.S. Patent No. 6,802,894 ("the '894 patent"); and U.S. Patent No. 6,455,451 ("the '451 patent"). The notice of investigation named as respondents GC Corporation of Tokyo, Japan; and GC America, Inc. of Alsip, Illinois (collectively, "GC"). The Office of Unfair Import Investigations was also named as a party.

Earlier in proceedings, the investigation was terminated as to certain asserted patent claims, including all of the asserted claims of the '623 patent and the '451 patent, based upon withdrawal of the complaint. Order No. 18 (Nov. 21, 2017), *not reviewed*, Notice (Dec. 6,

2017); Order No. 24 (Dec. 19, 2017), *not reviewed*, Notice (Jan. 18, 2017); Order No. 51 (Feb. 22, 2018), *not reviewed*, Notice (Mar. 23, 2018); Order No. 56 (Mar. 28, 2018), *not reviewed*, Notice (Apr. 27, 2018).

On July 23, 2018, the ALJ issued the final initial determination ("ID"). Remaining within the scope of the investigation, as to infringement, domestic industry, or both, were claims 1, 2, 4, 5, 7, 9, 10, 13, 15-19, and 21 of the '836 patent; and claims 1, 2, 4, 16-21, 34, 36 and 38 of the '894 patent. The claims of the '894 patent were divided into two categories: claims 1, 2, 4, 16-21, and 34 are "the '894 annealing claims," whereas claims 36 and 38 are "the '894 flexure strength claims." The ID found, *inter alia*, that Ivoclar failed to demonstrate infringement of the above-referenced claims of the '836 patent. The ID found, *inter alia*, that the '894 flexure strength claims are invalid as indefinite under 35 U.S.C. § 112 ¶ 2. The ID further found that Ivoclar failed to demonstrate infringement and failed to meet the technical prong of the domestic industry requirement as to the '894 annealing claims. The ID found that some, but not all, of the '894 annealing claims are invalid in view of certain prior art.

After the issuance of the ID, the Commission solicited comments from the public concerning remedy and the public interest. On September 13, 2018, Representative Brian Higgins (R-N.Y.) filed comments in support of his constituent Ivoclar, whose headquarters is in Western New York. Letter from Rep. Brian Higgins to Chairman David S. Johanson at 1 (Sept. 13, 2018). In addition, Ivoclar, GC, and the Commission investigative attorney ("IA") filed petitions for review and replies to the other parties' petitions.[1]

[1] Compl'ts Corrected Pet. to Rev. the Final Initial Determination on Violation (Aug. 7, 2018) ("Ivoclar Pet."); Resp'ts Contingent Pet. for Comm'n Rev. (Aug. 6, 2018) ("GC Pet."); Office of Unfair Import Investigations' Pet. for Rev.-in-Part of the Final Initial Determination on Violation (Aug. 6, 2018) ("OUII Pet."); Compl'ts Resp. to Resp'ts Contingent Pet. and Staff's Pet. for Rev.-in-Part (Aug. 14, 2018) ("Ivoclar Pet. Reply"); Resp'ts Resp. to Compl'ts and

On September 21, 2018, the Commission determined to review the ID in part and issued its notice of review. Notice (Sept. 21, 2018) ("Notice of Review"). In particular, the Commission determined not to review the ID with respect to the '836 patent and the '894 flexure strength claims, thereby terminating the investigation as to those patent claims. Notice of Review at 2. The Commission determined to review the ID's findings as to the '894 annealing claims and solicited further briefing from the parties on certain issues concerning those patent claims. *Id.* at 2-4. The Commission also solicited briefing from the parties, interested government agencies, and members of the public on remedy, the public interest, and bonding. *Id.* at 3-4. No non-parties filed such briefing. On October 5, 2018, the parties filed opening briefs in response to the Notice of Review,[2] and on October 12, 2018, the parties filed reply briefs.[3]

On December 18, 2018, the Commission issued a notice finding no violation of section 337. In particular, the Commission affirmed, with modified reasoning, the ID's conclusion that Ivoclar failed to demonstrate infringement of the '894 annealing claims. The Commission also affirmed, with modified reasoning, the ID's finding that claims 1, 2, and 34 of the '894 patent are

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Staff's Pets. for Comm'n Rev. (Aug. 14, 2018) ("GC Pet. Reply"); Resp. of the Office of Unfair Import Investigations to the Pets. for Comm'n Rev. of the Final Initial Determination (Aug. 14, 2018) ("OUII Pet. Reply").

[2] Compl'ts Resp. to the Notice of Comm'n Decision to Review in Part a Final Initial Determination (Oct. 5, 2018) ("Ivoclar Br."); Resp'ts Written Submission in Resp. to the Comm'n Determination to Review in Part an Initial Determination to Review in Part an Initial Determination Finding No Violation of Section 337 (Oct. 5, 2018) ("GC Br."); Office of Unfair Import Investigations' Resp. to the Comm'n Request for Written Submissions on the Issues Under Review and on Remedy, the Public Interest, and Bonding (Oct. 5, 2018) ("OUII Br.").

[3] Compl'ts Reply to Resp'ts and Staff's Resp. to the Notice of Comm'n Decision to Review in Part a Final Initial Determination (Oct. 12, 2018) ("Ivoclar Reply Br."); Resp'ts Reply to Resp'ts and Staff's Resp. to the Notice of Comm'n Decision to Rev. in Part an Initial Determination Finding No Violation of Section 337 (Oct. 12, 2018) ("GC Reply Br."); Office of Unfair Import Investigations' Reply to the Private Parties' Resps. to the Comm'n Request for Written Submissions (Oct. 12, 2018) ("OUII Reply Br.").

anticipated by U.S. Patent No. 4,189,325 ("Barrett") (RX-27). The Commission determined to take no position as to whether International Patent Application WO 00/34196 ("WO196") (RX-563) anticipates any of the '894 annealing claims or whether the technical prong of the domestic industry requirement was met for the '894 patent. The Commission affirmed the ID's remaining findings concerning the '894 annealing claims. Accordingly, the Commission terminated the investigation with respect to the '894 annealing claims, and thereby the investigation in its entirety, with a finding of no violation of section 337. This Opinion sets forth the Commission's reasoning in support of its determinations for the issues under review, which concern violation of section 337 as to the '894 annealing claims.

II. BACKGROUND

The '894 patent is entitled "Lithium Disilicate Glass-Ceramics." The invention of the '894 patent relates generally to "glass-ceramics comprising lithium disilicate and more specifically to glass-ceramics for use in the manufacture of dental restorations and methods of manufacture thereof." '894 patent col. 1 lines 18-21. The accused products are GC's "LiSi Press" products, which are lithium disilicate glass ceramics, in a number of shades. *See, e.g.*, Compl'ts Post-Hearing Br. 3-4, 57-67. The domestic industry products are Ivoclar's "IPS e.max® CAD" products. *Id.* at 1, 4, 81-83. With respect to the claims remaining within the scope of the investigation,[4] Ivoclar alleges infringement of independent claim 1 and dependent

[4] Claims 36 and 38, the flexure-strength claims, were terminated from the investigation when the Commission determined not to review the ALJ's finding that those claims are invalid as indefinite. Notice of Review at 2.

claims 2, 4, 16, and 21. Ivoclar relies upon independent claim 1 and dependent claims 17-20 and 34 to meet the domestic industry requirement of section 337.[5]

A. Claim 1 of the '894 Patent

Claim 1 is directed to a "method of making a lithium disilicate dental product," comprising the following steps:

> melting a starting glass composition at temperatures within the range of about 1200 to about 1600° C.;
>
> forming the molten glass into shaped blanks;
>
> annealing the glass blanks at temperatures in the range of 300° to about 600° C. for a time in the range of about 15 minutes to about 8 hours;
>
> subjecting the glass blanks to one or more heat treatments in the temperature range of from about 400° to about 1100° C. to convert the glass blanks into glass-ceramic blanks.

'894 patent col. 16 lines 16-28. Pursuant to this claim language, there are at least three steps of heating: (1) a *melting* step between 1200-1600° C (of indeterminate time); (2) an *annealing* step between 300-600° C for between 15 minutes to 8 hours; and (3) at least one *heat treatment* between 400-1100° C (of indeterminate time) to convert the glass blanks into glass-ceramic blanks. It is agreed among the parties that "annealing" is a term with a plain and ordinary meaning, which is to reduce the internal stresses in the glass. ID at 44. It is also agreed among the parties that the process of "convert[ing] the glass blanks into glass-ceramic blanks" is a two-step process of nucleation and crystal growth, whereby some of the compounds in the glass crystallize. *See, e.g.*, CX-709C Q/A 13 (Griggs). Although the patent specification explains

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[5] *See Certain Microsphere Adhesives, Process for Making Same, and Products Containing Same, Including Self-Stick Repositionable Notes*, Inv. No. 337-TA-366, Comm'n Op., 1996 WL 1056095, at *7-8 (Jan. 16, 1996) (explaining that the domestic industry requirement is satisfied if the domestic industry practices at least one claim of the patent).

that the nucleation step occurs between 450-700°C (and preferably from 500-650°C), and the crystal growth step occurs between 800-1000°C (and preferably from 830-930°C), '894 patent col. 5 lines 43-50, col. 6 lines 28-34, the patent claim itself calls for a broader combined range of 400-1100° C for the claimed heat treatments in the last limitation of claim 1 of the '894 patent.

B. Relevant Prosecution History

The prosecution history directly relates to the annealing step. The application that issued as the '894 patent was a further continuation-in-part of a continuation-in-part application. JX-5 at .0007. The originally-filed application claim 1 is identical to claim 1 of the issued '894 patent. *Id.* at .0028. After preliminary amendments immaterial to the issue before the Commission, the examiner issued her first office action. She rejected claim 1 and its dependent claims under the written description requirement of 35 U.S.C. § 112. The examiner explained:

> Claims 1-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
>
> There is no teaching of claimed annealing conditions in the specification. While page 14 teaches annealing the blank at 450° for 30 minutes [*see* '894 patent col. 9 lines 44-48], this one teaching does not support the claimed conditions. Therefore the process of claims 1-35 is not supported by the specification, or if they are in the specification, point out where they appear. Pages 4 and 8 and the examples only teach a single heat treatment to convert the glass to a glass-ceramic, which can consist of one or two parts. Thus there is no support [*sic*] claim limitation of "subjecting the glass blank to one or more heat treatments ...".

JX-5 at .0144. In response, the applicant added the following underlined language to the patent specification: "The resulting glass pellets are annealed at temperatures in the range of 300° to

about 600° for a time in the range of about 15 minutes to about 8 hours. Thereafter, the pellets are heat treated to form glass-ceramic pellets using a one or a two-step heat-treatment cycle preferably in the temperature range of about 400° to about 1100°C." *Id.* at .0152. This addition is reflected in the '894 patent at column 5 lines 36-38. The applicant explained that "the specification has been amended to clarify any inconsistencies therein," but asserted that "[n]o new matter has been added." JX-5 at .0171. That amendment was successful to obtain allowance of claim 1. *Id.* at .0904; *see also id.* at .0905 ("The objection to the specification and 35 USC 112, first paragraph rejection are withdrawn due to the amendment to the specification.").

III. ANALYSIS

The parties do not dispute the level of skill in the art for the '894 patent, and we affirm the ID's findings concerning it. ID at 43. Among the ID's claim constructions, GC has contested the construction of "dental product." GC Pet. 55-60. Ivoclar, meanwhile, did not contest any claim construction, but rather contested the application of the claim constructions, in particular to infringement. GC Pet. 34-44. The Commission has determined to adopt the ID's claim constructions, set forth on pages 44-58 of the ID.[6] The Commission's pertinent findings concerning infringement, invalidity, and domestic industry follow.

A. Infringement

The principal infringement dispute in this investigation stems from the fact that the temperature ranges for the annealing and heat treatment steps (reprinted above) substantially overlap: the annealing step is claimed to occur between 300-600° C, but anything between 400-

[6] The Commission thereby affirms and adopts the ID's finding that accused products are "dental products." ID at 54-58, 66; *see* GC Pet. 55-60.

600° C could instead fall within the "convert[ing]" step, the last step of the claim. In order to understand the infringement dispute, it is necessary to understand the claim construction of "annealing," which is not disputed before the Commission. In connection with claim construction, the parties disputed the relationship between the annealing step and the subsequent heat treatments. In particular, GC and the IA contended that no skilled artisan could construe the annealing and heat treatment steps of claim 1 as a single limitation. Respt's Post-Hr'g Br. 54 (Mar. 23, 2018) ("GC Post-Hr'g Br."); Staff's Initial Post-Hr'g Br. 58-59 (Mar. 23, 2018) ("OUII Post-Hr'g Br."). GC's argument was that the annealing could not include nucleation. GC Post-Hr'g Br. 54. The IA's argument was that the annealing could not subsume the subsequent heat treatments. OUII Post-Hr'g Br. 58-59. In response, Ivoclar argued as follows in its post-hearing reply brief:

> Staff's and GC's "separate step" arguments are not the same. GC argues that annealing must be separate from nucleation and crystallization. RIB at 54. However claim 1 does not recite nucleation or crystallization. GC argues this by improperly reading "one or more heat treatments to mean two heat treatments – one for nucleation and one for crystallization." *Id.* at 55.
>
> GC's two heat treatment argument contradicts the claim, which only requires one heat treatment and should be rejected. *See* CIB at 45–50. Thus, GC's requirement that annealing is separate from nucleation and crystallization should also be rejected. *Id.* Staff argues that annealing must be a separate step from the next claim limitation, "one or more heat treatments," and cites to *LizardTech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1342-43 (Fed. Cir. 2005). SIB at 57. ***Ivoclar agrees with the Staff's separate step argument – thatt [sic] annealing is a separate claim limitation from the limitation "one or more heat treatments,"*** which is consistent with case law.

Compl'ts Reply Post-Hr'g Br. 28 (Apr. 13, 2018) ("Ivoclar Post-Hr'g Reply Br.") (emphasis added). In the final ID, the ALJ agreed with, and adopted, Ivoclar's—and the IA's—separate step claim construction requirement. ID at 47-49. Accordingly, the ID finds that "'annealing'

should be given its plain and ordinary meaning, and that as used in claim 1 of the '894 patent, the step 'annealing the glass blanks at temperatures in the range of 300° to about 600 ° C. for a time in the range of about 15 minutes to about 8 hours,' is a separate step from 'subjecting the glass blanks to one or more heat treatments in the temperature range of from about 400° to about 1100° C. to convert the glass blanks into glass-ceramic blanks.'" ID at 49 (emphasis omitted). As noted earlier, Ivoclar has waived any challenge to the claim construction.

To demonstrate infringement, Ivoclar relied substantially upon two charts produced by GC that purport to demonstrate the heating parameters for GC's processes, one from 2015 and one from 2017, CX-364C (2015 process) and CX-363C (2017 process). *See, e.g.*, ID at 68-70. The Commission's notice of review sought briefing on whether "Ivoclar demonstrated, by a preponderance of the evidence, that GC's *methods* practice the 'annealing' limitation of claim 1 of the '894 patent (including time and temperature limitations)." Notice of Review at 3 (emphasis added). In response, Ivoclar provided briefing "that GC's manufacturing *method*"—in the singular—"for the LiSi Press practices the 'annealing' limitation of claim 1. Ivoclar Br. 10 (emphasis added). Ivoclar's briefing fails to argue that the 2015 method infringes. *Id.* at 12-19. The Commission therefore finds that Ivoclar has abandoned any infringement argument concerning GC's 2015 process.

As to the 2017 process, the chart (as translated from Japanese) appears in the "Initial LiSi Press Manufacturing QC Operation Sheet." In particular, at page .0009, the chart shows the heat treatment called for by GC's production process. CX-363C-T; *see also* RX-172C.0020; CX-300C-T.0009. Contrary to GC's and the IA's assertion that Ivoclar should instead have relied on hundreds of actual temperature measurements from each of GC's ovens, OUII Br. 7-8, GC Br. 14, we find that it was reasonable for Ivoclar to use the temperature chart,

which demonstrates GC's parameters for its production process.[7] In particular, GC acknowledges that its furnace is operated according to the profile reflected in the chart. RX-1581C, at Q/A 95.

The chart shows the following process:

[[CHART REDACTED]]

Ivoclar Br. 13 (citing RX-172C and CX-300C-T.0009).

Ivoclar argued that annealing occurred in the middle of the first ramp-up. ID at 68-69; *see* CX-709C Q/A 106; CDX-14C (blue line). In particular, Ivoclar argues that, of the [[REDACTED]] when the LiSi Press glass ingots are heated from [[REDACTED]], the glass ingots are within the temperature range of 300-600° C for about [[REDACTED]]. Ivoclar Br. 14. Of that time spent between 300-600° C, Ivoclar's expert, Dr. Jason Griggs, "testified that annealing occurs for at least about [[REDACTED]] between [[REDACTED]] based on GC's reported glass transition temperature of [[REDACTED]] for its LiSi Press – an offset of

[7] Subsequent versions of CX-363C contain the same chart. *Compare* RX-1041C at .0006 *with, e.g.*, CX-363C-T at .0009. *See generally* GC Reply Br. 14 n.8 (listing versions).

about [[REDACTED]] from the glass transition temperature." Ivoclar Br. 14; *see also* ID at 69 (quoting CX-709C at Q/A 101). As the ID properly recognized, however, Dr. Griggs also testified as follows:

> There are [[REDACTED]] heat treatments shown in the graphs. The [[REDACTED]] heat treatment occurs when the temperature is increased to [[REDACTED]] and held there for [[REDACTED]]. The [[REDACTED]] heat treatment occurs when the temperature is increased to [[REDACTED]] and held there for [[REDACTED]]. The process results in a glass-ceramic ingot.

CX-709C at Q/A 112; *see* ID at 69-70. The Commission affirms the ID's finding that "Dr. Griggs relies on the same single step in the manufacturing process to show that the LiSi Press process practices both the annealing and heat treatment limitations [of] claim 1 of the '894 patent." *Id.* at 70. Further, the Commission affirms the ID's findings that "Complainants attempt, however, to pick a portion of that heat treatment process, namely the portion where the glass ingot is between 300-600°C, to show the presence of an annealing step," *id.*, that Complainants agree that "annealing is subsumed within GC's heat treatment process, *id.* (quoting Ivoclar Post-Hearing Br. 65), and that the annealing "is not a separate step, as required by claim 1," *id.* Accordingly we affirm the ID's finding that Ivoclar failed to demonstrate infringement.

In addition to the ID's findings, however, the Commission further finds that even if a single heat treatment could be divided into portions, one of which is to be attributed to the annealing step, Ivoclar still failed to demonstrate infringement. The proof of infringement in this case is conclusory, and fails to satisfy Ivoclar's burden to demonstrate infringement. The evidence of infringement is presented in the witness statement of Dr. Griggs, Ivoclar's expert. CX-709C, at Q/A 13-20, 79-81, 96-112. In short, Dr. Griggs assumes that any processing at a temperature between [[REDACTED]] should be attributed to the annealing step, and that

temperatures above [[REDACTED]] should be attributed to the conversion step. *Id.* at Q/A 101. His basis for such a conclusion is: "Based on my knowledge and experience, these are the conditions (temperature and heating rate) for annealing a glass object." *Id.* (final sentence of both paragraphs); Hr'g Tr. 228:20-23 (Mar. 6, 2018) ("And as an additional step, I went even further and looked at the length of time in the range *where I think* annealing is actually occurring.") (emphasis added). There is no testing, modeling, or text and treatise support (*i.e.*, the three types of evidence one might expect to see) for these conclusions.

GC and the IA have taken the position that Dr. Griggs should have tested the accused products for annealing, and assert that such testing would be easy to do. OUII Br. 7; GC Br. 6-7. In discovery, GC produced an internal report comparing annealed and non-annealed samples. CX-368C-T; *see also* CX-709C Q/A 18. According to that report, the internal stresses in a product can be seen through polarizing plates: internal stresses create distortion seen through the polarizing plates, and the annealing reduces the distortion that can be seen. Although Ivoclar, through attorney argument, asserts that testing would "mak[e] accurate measurements virtually impossible," Ivoclar Reply Br. 10, Ivoclar's own expert did not go so far as to assert that testing would be virtually impossible, but rather that doing so would have been expensive. Hr'g Tr. 286:3-289:14 (Mar. 6, 2018).

Even if the Commission were to assume, as Ivoclar alleges it demonstrated, Ivoclar Reply Br. 9, that the LiSi Press products have been annealed as part of their processing, that is not enough for Ivoclar to demonstrate infringement: claim 1 does not merely call for "annealing" the glass blanks. Rather it also calls for specific time and temperature ranges for the annealing. Ivoclar's evidence—which consists principally of declaratory statements by its expert—fails to justify carving out a portion of the heat treatment as attributable to annealing,

without any additional support for the expert's choice for what to carve out. Dr. Griggs testified that for the 2017 GC production process, annealing "takes place from at least [[REDACTED]], which is about [[REDACTED]]." CX-709C Q/A 101. If some portion of the time spent near [[REDACTED]] were instead to be attributed to the conversion step, the process would not meet the claim requirement for 15 minutes of annealing. In addition, the record demonstrates certain inconsistencies in Dr. Griggs's analysis of the accused products compared to the domestic industry products that compromise Dr. Griggs's credibility. *See* GC Br. 15-16 (citing CX-709C Q/A 102, 210, 212; Hr'g Tr. 227:23-228:2 (Mar. 6, 2018); *id.* at 230:3-233:10).

The Commission does not impose a requirement that an expert's conclusion of infringement be corroborated. Instead, the Commission has weighed the evidence of record, including assessing Dr. Griggs' credibility, and determined that Dr. Griggs' testimony fails to demonstrate infringement by a preponderance of the evidence. Accordingly, the Commission finds that Ivoclar's evidence is insufficient to demonstrate infringement even if a single heat treatment could be divided and attributed to the separate steps of the patent claim.

B. Invalidity

The ID finds claims 1, 2, and 34 anticipated by Barrett (RX-27) and claims 1, 17, 21, and 34 obvious in view of Beall (RX-44) alone or combined with Petticrew (RX-564). Ivoclar's petition for Commission review argued that none of its claims are invalid. GC's contingent petition argued that Barrett also anticipates claims 4 and 16 of the '894 patent; that claims 1, 2, 4, 16-21 and 34 of the '894 patent are obvious in view of WO196 (RX-563), a parent application to the '894 patent; and that claims 2, 4, 16, and 18-20 are obvious in view of Beall and Petticrew. On review, the Commission has determined to affirm and adopt the ID's findings concerning Beall and Petticrew. ID at 84-92. The Commission's analysis of Barrett and WO196 is set forth below.

1. Barrett

The ID finds that Barrett anticipates claims 1, 2, and 34 of the '894 patent. The ID's findings rely on the '894 patent's own characterization of Barrett. ID at 77-80. In particular, the '894 patent states as follows: "The use of lithium disilicate glass-ceramics for use in dental restorations has been suggested in the prior art. U.S. Pat. No. 4,189,325 to Barrett et al. is directed to a glass-ceramic comprising lithium disilicate for use in dental restorations. . . . Barrett et al. introduced dental restorations made from castable lithium disilicate glass-ceramics in the Li_2O—CaO—Al_2O_3—SiO_2 system nucleated by Pt and NB_2O_5." '894 patent col. 1 lines 24-28. The ALJ found this to be an admission that Barrett teaches lithium disilicates (as opposed to lithium metasilicates) and on that basis found claims 1, 2, and 34 anticipate. ID at 77-80. On petition for review, Ivoclar contended that the '894 patent's statement that Barrett teaches lithium disilicates is plainly wrong based on the temperatures recited in Barrett. Ivoclar Pet. 72-76.

For legal support that it can challenge the '894 patent's representation of Barrett, Ivoclar has cited, *inter alia*, *PharmaStem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342, 1361 (Fed. Cir. 2007). Ivoclar Pet. at 74. Cases such as *PharmaStem*, however, weigh against Ivoclar, and find that a person of ordinary skill is entitled to rely on statements in a patent specification as to the prior art. For example, the Federal Circuit stated in *PharmaStem*:

> PharmaStem's argument that stem cells had not been proved to exist in cord blood prior to the experiments described in the patents is contrary to the representation in the specification that the prior art disclosed stem cells in cord blood. Admissions in the specification regarding the prior art are binding on the patentee for purposes of a later inquiry into obviousness.

PharmaStem, 491 F.3d at 1362. The Commission has determined to affirm and adopt the ID's reasoning as to claims 1, 2 and 34,[8] ID at 77-80, subject to the supplementation below.

In the alternative to the ID's reasoning, to the extent that the admission in the '894 patent as to Barrett is not considered fully binding upon the patentee, Ivoclar may have more appropriately relied upon non-enablement as a potential basis for collateral attack upon that admission. A "claimed invention cannot be anticipated by a prior art reference if the allegedly anticipatory disclosures cited as prior art are not enabled." *Amgen Inc. v. Hoeschst Marion Roussel, Inc.*, 314 F.3d 1313, 1354 (Fed. Cir. 2003). The Commission sought further briefing on the relationship between the '894 patent's admission and the requirement that the prior art provide an enabling disclosure. Notice of Review at 3. The IA's brief discusses the applicable Federal Circuit caselaw. OUII Br. 3-4. As the Federal Circuit has explained:

> [W]hen an accused infringer asserts that a prior art patent anticipates specific patent claims, the infringer enjoys a presumption that the anticipating disclosure also enables the claimed invention. . . . However, the patentee may overcome that presumption with persuasive evidence showing that the prior art patent does not enable the claimed invention.

Impax Labs., Inc. v. Aventis Pharms. Inc., 545 F.3d 1312, 1316 (Fed. Cir. 2008). The IA notes that the test for "persuasive" evidence is unclear.[9] OUII Br. 3-4.

As part of GC's discussion of the burdens, GC alleges that Ivoclar waived the opportunity to demonstrate that Barrett contains a non-enabling disclosure. GC Br. 2-3. We

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[8] The ID places reliance upon an admission in Dr. Kelly's testimony. ID at 79. The Commission would reach the same result even without that admission. In addition, the Commission affirms and adopts the ID's findings that GC failed to demonstrate clearly and convincingly that Barrett anticipates dependent claims 4 and 16. *Id.* at 81-82.

[9] Even if the test is preponderance of the evidence, the lowest threshold for Ivoclar to meet, we find that Ivoclar has not demonstrated that Barrett is non-enabled, for the reasons discussed herein.

agree with Ivoclar, however, that its argument in this case that Barrett fails to teach lithium disilicate subsumes the question whether Barrett's disclosure is enabling. Ivoclar Br. 3-4. In particular, Ivoclar's argument is that the temperatures of Barrett, if practiced, would result in lithium metasilicate, not lithium disilicate.[10] Barrett teaches that the "glass is thermally crystallized by heat treatment at 520° C. for about 4 hours (nucleation) followed by heat treatment at 620° C. for about 0.5 hour to about 2 hours (crystal growth)." Barrett col. 6 line 67 – col. 7 line 3. Changing the components of the mixture can require heating of upwards of "about 15 hours at 620° C." *Id.* col. 7 line 18. In order to demonstrate non-enablement, Ivoclar relies on a recent journal article ("Huang") (CX-482) that purports to explain the heating parameters for making lithium metasilicate versus making lithium disilicate.[11] The article explains:

> At a temperature lower than 770° C and holding time of 20 min, the lithium metasilicate (Li_2SiO_3) phase dominates. On the other hand, when the glass was heated to a higher temperature *or held for a longer time*, the LS2 [lithium disilicate, ($Li_2Si_2O_5$)] phase dominates and some other minor phases such as cristobalite and lithium phosphate emerge.

CX-482 at .0001 (emphasis added).

The Commission finds that Ivoclar failed to demonstrate that Barrett is not enabled. Huang is insufficient to demonstrate that Barrett is not enabled. In particular, Huang's holding

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[10] Barrett purports to teach, *inter alia*, a method for making lithium disilicate glass-ceramics. The parties agree that no person of ordinary skill would use lithium metasilicate for dental restorations, *see, e.g.*, Ivoclar Pet. 20 (citing RX-1586C at Q/A 82 and Hr'g Tr. 407:21-408:3), and Barrett expressly teaches that the glass-ceramic manufactured therein is useful for such restorations, Barrett col. 3 lines 9-10, 18-19, 26-59.

[11] Ivoclar's petition for Commission review also relied upon a statement in certain prior art (a thesis by Dr. Barrett) that was submitted as part of an Information Disclosure Statement to the PTO in the prosecution of the '894 patent. Ivoclar Pet. 75. That statement is even less persuasive than Huang, and Ivoclar fails to rely upon it in its recent briefing to the Commission, thus waiving Ivoclar's reliance upon the thesis.

periods are usually about 20 minutes, and are never more than 2.5 hours. *See* CX-482 at .0002. As discussed above, Barrett's holding period can be as long as 15 hours. Moreover, Ivoclar failed to demonstrate that the specific composition of oxides in Huang would result in the same crystallization characteristics over temperature and time as the different but equally specific composition of oxides in Barrett. *See* GC Reply Br. 8 n.5. We do not speculate whether, had Ivoclar followed Barrett's recipe and ended up with lithium metasilicate, that result, combined with Huang, could have been persuasive evidence that Barrett is not enabled. But, as noted earlier in connection with infringement, Ivoclar's evidence in this investigation was short on testing, relying instead on an expert's conclusions and attorney argument.

In sum, the public notice function of a patent entitles the public to take as true statements in a patent's disclosure, including characterizations of prior art. Under these circumstances, it is appropriate to presume that Barrett discloses what the '894 patent asserts to be Barrett's disclosure. To the extent that Barrett fails to provide an enabling disclosure, and to the extent that such failure is legally relevant, Ivoclar did not meet its burden to so show non-enablement.

2. WO-196

The '894 patent is a continuation-in-part of a continuation-in-part of the application for U.S. Patent No. 6,455,451 ("the '451 patent"). The WO196 reference (RX-563) is the foreign counterpart to the patent application that issued as the '451 patent, and both contain the same disclosure. GC correctly observes that, under the presiding ALJ's ground rules, Ivoclar was required to set forth its arguments for priority, and that Ivoclar never represented that claim 1 of the '894 patent is entitled to the parent's priority date. *See* GC Reply Br. 15. Even now, "Ivoclar does not seek to amend its disclosed priority date for the '894 patent." Ivoclar Reply Br. 14 n.11. Based on that waiver, WO '196 is prior art to the '894 patent.

As discussed earlier, the pertinent difference between the '894 patent and its parent applications is the written description rejection in the prosecution history of the '894 patent, which resulted in the addition of the annealing disclosure to the patent specification. The Commission's question in the notice of review asked "*If the Commission finds that the sequence of steps performed by GC can practice the "annealing" limitation of the '894 annealing claims if annealing were to occur* . . . [w]hether the WO196 patent application (RX-563) can be invalidating prior art, as discussed in Ivoclar's reply to GC's petition, at p. 94." Notice of Review at 3 (emphasis added). As discussed above, the Commission has *not* found that the sequence of steps performed by GC practices the "annealing" limitation of the '894 patent claims if annealing were to occur. That construction moots GC's arguments, *see* ID at 83, and the Commission has determined to take no position on whether WO196 invalidates claim 1 of the '894 patent or any of the '894 annealing claims dependent therefrom.

C. The Technical Prong of the Domestic Industry Requirement

Section 337 requires 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). This is the so-called domestic industry requirement. 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. ITC*, 342 F.3d 1361, 1375 (Fed. Cir. 2003). "The test for the technical prong is whether the domestic products are covered by the asserted claims." *Certain Mobile Device Holders and Components Thereof*, Inv. No. 337-TA-1028, Comm'n Op., 2018 WL 4042764, at *5 (Mar. 22, 2018).

In the present case, it is undisputed that Ivoclar makes metasilicate glass-ceramics in the United States, ID at 97, and sells them in the United States, ID at 97, to dental practitioners who

then, in the United States, heat treat the products to crystallize them into lithium disilicate suitable for clinical use on patients, ID at 74. Indeed, the ID finds that there is "no serious dispute that Complainants' domestic industry products, which are metasilicate blocks, are converted into disilicate dental products by dental practitioners in the United States."[12] *Id.*

The question that the ID addressed was "whether a single entity can be attributed with carrying out all of the steps in the method of claim 1." ID at 74. In short, the ID sought to apply the doctrine of divided infringement, *see Akamai Techs., Inc. v. Limelight Networks*, 797 F.3d 1020, 1022-23 (Fed. Cir. 2015) (en banc), to the existence of domestic industry. In *Akamai*, the Federal Circuit recognized that whether "a single actor directed or controlled the acts of one or more third parties is a question of fact." *Id.* at 1023. The Court also recognized that "other factual scenarios may arise which warrant attributing others' performance of method steps to a single actor" and that "principles of attribution are to be considered in the context of the particular facts presented." *Id.* In connection with infringement, the single-entity test limits who can be liable for direct infringement, including damages. *See Limelight Networks, Inc. v. Akamai Techs., Inc.*, 572 U.S. 915, 919 (2014) ($40 million damages). The parties have not supplied adequate briefing—either to the ALJ or to the Commission—concerning whether and how the single-entity test applies to the statutory domestic industry requirement, which does not impose liability, but ensures that a domestic industry exists for the determination of whether unfair acts

[12] There is also no serious dispute that the Complainants' domestic industry products have no use but for that expected conversion into disilicate dental products by Ivoclar's customers. CX-709C at Q/A 209. Also undisputed is that Ivoclar satisfies the economic prong of the domestic industry requirement. ID at 97. Indeed, the parties so stipulated, meaning that "with respect to the articles protected by the patent . . . concerned," 19 U.S.C. § 1337(a)(3), Ivoclar made significant investment in plant and equipment, *id.* § 1337(a)(3)(A), as well as significant employment of labor or capital, *id.* § 1337(a)(3)(B). ID at 97-100.

have occurred. Accordingly, the Commission does not reach the divided infringement issue—the issue is nondispositive in view of the Commission's earlier findings—in this investigation.[13]

IV. CONCLUSION

For the reasons set forth herein, the Commission finds no violation of section 337 as to the '894 annealing claims. To the extent that any findings in the ID as to the '894 annealing claims are not discussed above, the Commission affirms and adopts those findings. Because the Commission earlier terminated the investigation as to the '836 patent and as to the '894 flexure strength claims, the Commission's findings as to the '894 annealing claims result in termination of the investigation, in its entirety, with a finding of no violation of section 337.

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: February 11, 2019

[13] In addition, in view of the Commission's finding that Ivoclar failed to demonstrate infringement, the Commission finds it unnecessary to reach whether Ivoclar's domestic industry products meet the limitations of claim 1 of the '894 patent, including the "annealing" requirement. *See* GC Pet. 34.

CERTAIN DENTAL CERAMICS, PRODUCTS THEREOF, AND METHODS OF MAKING THE SAME **Inv. No. 337-TA-1050**

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **COMMISSION OPINION** has been served by hand upon the Commission Investigative Attorney, **Todd Taylor, Esq.**, and the following parties as indicated, on **February 11, 2019**.

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

On Behalf of Complainants Ivoclar Vivadent AG, Ivoclar Vivadent, Inc., and Ardent, Inc.:

Kecia J. Reynolds, Esq.
PILLSBURY WINTHROP SHAW PITTMAN LLP
1200 Seventeenth Street, NW
Washington, DC 20036

☐ Via Hand Delivery
☒ Via Express Delivery
☐ Via First Class Mail
☐ Other:_____

On behalf of Respondents GC Corporation and GC America, Inc.:

Jeffrey L. Eichen, Esq.
DRINKER BIDDLE & REATH LLP
222 Delaware Avenue, Suite 1410
Wilmington, DE 19801

☐ Via Hand Delivery
☒ Via Express Delivery
☐ Via First Class Mail
☐ Other:_____

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of CERTAIN DENTAL CERAMICS, PRODUCTS THEREOF, AND METHODS OF MAKING THE SAME	Investigation No. 337-TA-1050

NOTICE OF COMMISSION DECISION TO REVIEW IN PART A FINAL INITIAL DETERMINATION FINDING NO VIOLATION OF SECTION 337; SCHEDULE FOR FILING WRITTTEN SUBMISSIONS ON THE ISSUES UNDER REVIEW AND ON REMEDY, THE PUBLIC INTEREST, AND BONDING; EXTENSION OF TARGET DATE

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review in part the final initial determination ("final ID") issued by the presiding administrative law judge ("ALJ") on July 23, 2018, finding no violation of section 337 of the Tariff Act of 1930, in the above-captioned investigation. The Commission requests certain briefing from the parties on the issues under review, as indicated in this notice. The Commission also requests briefing from the parties, interested persons, and interested government agencies on the issues of remedy, the public interest, and bonding. The Commission has determined to extend the target date for completion of the investigation from November 23, 2018 to November 30, 2018.

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

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on April 25, 2017, based on a complaint, as supplemented, filed by Ivoclar Vivadent AG of Schaan,

Liechtenstein; Ivoclar Vivadent, Inc. of Amherst, New York; and Ardent, Inc. of Amherst, New York (collectively "Ivoclar"). 82 FR 19081 (Apr. 25, 2017). The complaint, as supplemented, alleged violations of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain dental ceramics, products thereof, and methods of making the same by reason of the infringement of certain claims of four United States patents: U.S. Patent No. 7,452,836 ("the '836 patent"); U.S. Patent No. 6,517,623 ("the '623 patent"); U.S. Patent No. 6,802,894 ("the '894 patent"); and U.S. Patent No. 6,455,451 ("the '451 patent"). The notice of investigation named as respondents GC Corporation of Tokyo, Japan; and GC America, Inc. of Alsip, Illinois (collectively, "GC"). The Office of Unfair Import Investigations was also named as a party.

The investigation was previously terminated as to certain asserted patent claims, including all of the asserted claims of the '623 patent and the '451 patent, based upon withdrawal of the complaint. Order No. 18 (Nov. 21, 2017), *not reviewed*, Notice (Dec. 6, 2017); Order No. 24 (Dec. 19, 2017), *not reviewed*, Notice (Jan. 18, 2018); Order No. 51 (Feb. 22, 2018), *not reviewed*, Notice (Mar. 23, 2018); Order No. 56 (Mar. 28, 2018), *not reviewed*, Notice (Apr. 27, 2018). Remaining within the scope of the investigation, as to infringement, domestic industry, or both, are claims 1, 2, 4, 5, 7, 9, 10, 13, 15-19, and 21 of the '836 patent; and claims 1, 2, 4, 16-21, 34, 36 and 38 of the '894 patent.

On July 23, 2018, the ALJ issued the final ID. The ID finds, *inter alia*, that Ivoclar failed to demonstrate infringement of the above-referenced claims of the '836 patent. The ID finds, *inter alia*, that claims 36 and 38 ("the '894 flexure strength claims") are invalid as indefinite under 35 U.S.C. § 112 ¶ 2. The ID further finds that Ivoclar failed to demonstrate infringement and failed to meet the technical prong of the domestic industry requirement as to the remaining claims of the '894 patent (claims 1, 2, 4, 5, 7, 9, 10, 13, 15-19, and 21) ("the '894 annealing claims"). The ID finds that some, but not all, of the '894 annealing claims are invalid in view of certain prior art.

Ivoclar, GC, and the Commission investigative attorney filed petitions for review and replies to the other parties' petitions.

Having reviewed the record of the investigation, including the final ID, as well as the parties' petitions for review and responses thereto, the Commission has determined as follows. The Commission has determined to review the ID's findings as to the '894 annealing claims. The Commission has determined not to review the ID's findings as to the '894 flexure strength claims because the Commission finds that the invalidity of claims 36 and 38 has been shown clearly and convincingly. The Commission has determined not to review the ID's findings for the '836 patent claims. Accordingly, the Commission finds no violation of section 337 as to the '836 patent and as to the '894 flexure strength claims. The Commission has determined not to review the remainder of the ID.

In connection with the Commission's review, the Commission notes that "[a]ny issue not raised in a petition for review will be deemed to have been abandoned by the petitioning party

and may be disregarded by the Commission in reviewing the initial determination." 19 CFR 210.43(b)(2).

The parties are asked to provide additional briefing on the following issues, with reference to the applicable law and the existing evidentiary record. For each argument presented, the parties' submissions should set forth whether and/or how that argument was presented and preserved in the proceedings before the ALJ, in conformity with the ALJ's Ground Rules (Order No. 2), with citations to the record.

1. For purposes of invalidity of the '894 annealing claims, if the Commission were to find that a person of ordinary skill is entitled to rely upon the patentee's representation about the disclosure of Barrett teaching lithium disilicates, *see, e.g., PharmaStem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342, 1362 (Fed. Cir. 2007) ("Admissions in the specification regarding the prior art are binding on the patentee for purposes of a later inquiry into obviousness."), what is the role, if any, of enablement of the prior art, *see, e.g., Hoeschst Marion Roussel, Inc.*, 314 F.3d 1313, 1354 (Fed. Cir. 2003) ("A claimed invention cannot be anticipated by a prior art reference if the allegedly anticipatory disclosures cited as prior art are not enabled.")? Please be certain to identify the appropriate burdens of production and persuasion, and the effect of those burdens in this investigation.
2. If the Commission finds that the sequence of steps performed by GC can practice the "annealing" limitation of the '894 annealing claims if annealing were to occur:
   a. Whether Ivoclar demonstrated, by a preponderance of evidence, that GC's methods practice the "annealing" limitation of claim 1 of the '894 patent (including all time and temperature limitations).
   b. Whether the WO196 patent application (RX-563) can be invalidating prior art, as discussed in Ivoclar's reply to GC's petition, at p. 94.
   c. Whether, to ascertain if GC's products or Ivoclar's products meet the other limitations of claim 1, or the limitations of any claim dependent upon claim 1, a remand to the presiding ALJ is warranted.

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

If the Commission contemplates some form of remedy, it must consider the effects of that remedy upon the public interest. The factors the Commission will consider include the effect

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

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

WRITTEN SUBMISSIONS: The parties to the investigation are requested to file combined written submissions on the issues under review and remedy, the public interest and bonding. Interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such submissions should address the recommended determination by the ALJ on remedy and bonding.

The parties' submissions on the issues under review and on remedy, the public interest, and bonding should not exceed 40 pages. Reply submissions on the issues under review should not exceed 25 pages per side. Parties are encouraged to incorporate by reference any arguments adequately presented in their petitions for review and responses thereto, rather than repeating arguments. The page limits above are exclusive of exhibits, but parties are not to circumvent the page limits by incorporating material by reference from the exhibits or from the record.

The complainants' opening submission is to include proposed remedial orders for the Commission's consideration; the date that the '894 patent expires; the HTSUS numbers under which the accused products are imported; and the names of known importers of the products at issue in this investigation.

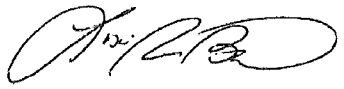
Written submissions by the parties and the public must be filed no later than close of business on Friday, October 5, 2018. Reply submissions by the parties and the public must be filed no later than the close of business on Friday, October 12, 2018. No further submissions will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the investigation number ("Inv. No. 337-TA-1050") in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, https://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf). Persons with questions regarding filing should contact the Secretary (202-205-2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel,[1] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

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

By order of the Commission.



Lisa R. Barton
Secretary to the Commission

Issued: September 21, 2018

[1] All contract personnel will sign appropriate nondisclosure agreements.

CERTAIN DENTAL CERAMICS, PRODUCTS THEREOF, AND METHODS OF MAKING THE SAME **Inv. No. 337-TA-1050**

PUBIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **NOTICE** has been served by hand upon the Commission Investigative Attorney, **Todd Taylor, Esq.**, and the following parties as indicated, on **September 21, 2018.**

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

On Behalf of Complainants Ivoclar Vivadent AG, Ivoclar Vivadent, Inc., and Ardent, Inc.:

Kecia J. Reynolds, Esq.
PILLSBURY WINTHROP SHAW PITTMAN LLP
1200 Seventeenth Street, NW
Washington, DC 20036

☐ Via Hand Delivery
☐ Via Express Delivery
☒ Via First Class Mail
☐ Other:_____

On behalf of Respondents GC Corporation and GC America, Inc.:

Jeffrey L. Eichen, Esq.
DRINKER BIDDLE & REATH LLP
222 Delaware Avenue, Suite 1410
Wilmington, DE 19801

☐ Via Hand Delivery
☐ Via Express Delivery
☒ Via First Class Mail
☐ Other:_____

PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of	
CERTAIN DENTAL CERAMICS, PRODUCTS THEREOF, AND METHODS OF MAKING THE SAME	**INV. NO. 337-TA-1050**

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

Chief Administrative Law Judge Charles E. Bullock

(July 23, 2018)

Appearances:

For the Complainants Ivoclar Vivadent AG; Ivoclar Vivadent, Inc.; and Ardent, Inc.:

Kecia J. Reynolds, Esq., H. Keeto Sabharwal, Esq., Sean M. Weinman, Esq., Alton L. Hare, Esq., Ahmed Abdel-Rahman, Esq. of Pillsbury Winthrop Shaw Pittman LLP of Washington, DC.

Michael K. Heins, Esq. of Pillsbury Winthrop Shaw Pittman LLP of McLean, VA.

Carolyn S. Toto, Esq. of Pillsbury Winthrop Shaw Pittman LLP of Los Angeles, CA.

For the Respondents GC Corporation; and GC America, Inc.:

Jeffrey L. Eichen, Esq. of Drinker Biddle & Reath LLP of Wilmington, DE.

Darren S. Cahr, Esq. of Drinker Biddle & Reath LLP of Chicago, IL.

For the Commission Investigative Staff:

Margaret D. Macdonald, Esq., Director; Jeffrey T. Hsu, Esq., Supervisory Attorney; Todd P. Taylor, Esq., Investigative Attorney of the Office of Unfair Import Investigations, U.S. International Trade Commission, of Washington, DC.

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CX	Complainant's exhibit
Dep.	Deposition
JX	Joint Exhibit
RDX	Respondent's demonstrative exhibit
RIB	Respondent's initial post-hearing brief
RPX	Respondent's physical exhibit
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RRX	Respondent's rebuttal exhibit
RX	Respondent's exhibit
SIB	Staff's initial post-hearing brief
SPB	Staff's Pre-hearing brief
SRB	Staff's reply post-hearing brief
Tr.	Transcript

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Chief Administrative Law Judge Charles E. Bullock

(July 23, 2018)

Pursuant to the Notice of Investigation, 82 *Fed. Reg.* 19081 (Apr. 25, 2017), this is the Initial Determination in the matter of *Certain Dental Ceramics, Products Thereof, and Methods of Making the Same*, Investigation No. 337-TA-1050.

For the reasons stated herein, the undersigned has determined that no violation of section 337 of the Tariff Act of 1930, as amended, has occurred in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain dental ceramics, products thereof, and methods of making the same with respect to U.S. Patents Nos. 7,452,836 and 6,802,894.

I. INTRODUCTION

A. Procedural History

On March 27, 2017, Ivoclar Vivadent AG; Ivoclar Vivadent, Inc.; and Ardent, Inc. ("Ivoclar" or "Complainants") filed a complaint "alleg[ing] violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain dental ceramics, products thereof, and methods of making the same by reason of infringement of certain claims of U.S. Patent No. 7,452,836 (''the '836 patent''); U.S. Patent No. 6,517,623 (''the '623 patent''); U.S. Patent No. 6,802,894 (''the '894 patent''); and U.S. Patent No. 6,455,451 (''the '451 patent'')." 82 *Fed. Reg.* 19081 (Apr. 25, 2017).

On April 25, 2017, the Commission instituted this Investigation to determine:

> whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain dental ceramics, products thereof, and methods of making the same by reason of infringement of one or more of claims 1, 2, 4, 5, 7, 10, 12, 13, 15–19, and 22 of the '836 patent; claim 27 of the '623 patent; claims 1, 2, 4, 12, 16, 21, 23, 38, and 39 of the '894 patent; and claims 3, 4, 17, 18, 19, 30, 52, 53, and 61 of the '451 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337[.]

Id.

The named respondents are GC Corporation of Tokyo, Japan and GC America, Inc. of Alsip, IL ("GC" or "Respondents"). *Id.* The Commission Investigative Staff ("Staff") is also a party to this Investigation. *Id.*

On October 12, 2017, Complainants moved (1050-015) for termination of the investigation as to certain asserted claims. Complainants' motion was granted-in-part and claim 22 of the '836 patent, claim 27 of the '623 patent, and claims 17–19 and 52–53 of the '451 patent

were terminated on November 8, 2017. (Order No. 18; *see also* Notice of Comm'n Decision Not to Review an Initial Determination Terminating the Investigation as to Certain Asserted Patent Claims (Dec. 6, 2017).)

On November 21, 2017, Respondents moved (1050-019) for summary determination of non-infringement as to the asserted claims of the '836 patent. One day later, on November 22, 2017, Complainants moved (1050-020) for summary determination that the economic prong of the domestic industry requirement has been satisfied as to all of the asserted patents based on investments in plant and equipment under 19 U.S.C. § 1337(a)(3)(A). Both motions were denied. (Order No. 21; Order No. 23.)

On December 18, 2017, Complainants moved (1050-022) again for partial termination of the investigation as to certain claims. Complainants' motion was granted on December 19, 2017, and claim 12 of the '894 patent, claims 3 and 30 of the '451 patent, and claim 12 of the '836 patent were terminated from this investigation. (Order No. 24; *see also* Notice of Comm'n Decision Not to Review an Initial Determination Terminating the Investigation as to Certain Asserted Patent Claims (Jan. 18, 2018).)

On January 8, 2018, the target date for this investigation was extended from August 24, 2018, to November 23, 2018. (Order No. 26; *see also* Notice of Commission Decision Not to Review an Initial Determination Extending the Target Date by Three Months (Jan. 26, 2018).)

On February 16, 2018, Complainants moved (1050-030) to terminate all remaining asserted claims of the '451 patent. Complainants' motion was granted on February 22, 2018, and the '451 patent was terminated from the investigation. (Order No. 51; *see also* Notice of Commission Decision Not to Review an Initial Determination Terminating the Investigation as to One Asserted Patent (Mar. 23, 2018).)

On March 5, 2018, through March 8, 2018, an evidentiary hearing was held at the Commission.

On March 23, 2018, Complainants moved (1050-033) for partial termination of the investigation as to certain claims. Complainants' motion was granted on March 28, 2018, and claims 23 and 39 for the '894 patent were terminated from this investigation. (Order No. 56; *see also* Notice of Commission Decision Not to Review an Initial Determination Terminating the Investigation as to Certain Asserted Patent Claims (Apr. 27, 2018).)

B. The Parties

1. Complainants

a) Ivoclar Vivadent AG ("Ivoclar AG")

Ivoclar Vivadent AG is a privately held corporation organized under the laws of the Principality of Liechtenstein and headquartered in Schaan, Liechtenstein. (Compl. ¶ 3.) Ivoclar AG is the ultimate parent company of both Ivoclar Vivadent Inc. and Ardent Inc. (*See* JX-0015C at 42:16–45:22.) Ivoclar Vivadent AG is the assignee of the '836 patent. (JX-0001 at Cover.)

b) Ivoclar Vivadent, Inc. ("Ivoclar USA")

Ivoclar Vivadent, Inc. is a Delaware corporation with its principal place of business in Amherst, New York. (Compl. ¶ 13.) Ivoclar USA is a subsidiary of Ivoclar AG. (*Id.*) Ivolcar USA is also the parent company of wholly owned subsidiary Ivoclar Vivadent Manufacturing, Inc. ("Ivoclar Somerset"), which is located in Somerset, New Jersey, and of Ardent Inc. (*Id.* at ¶¶ 13-14; JX-0015C at 42:16–45:22.)

c) Ardent, Inc. ("Ardent")

Ardent, Inc. ("Ardent") is a New York corporation with its principal place of business in Amherst, New York. (Complaint. ¶ 14.) Ardent is also a wholly owned subsidiary of Ivoclar USA. (*Id.*) Ardent is the assignee of U.S. Patent No. 6,802,894. (JX-0006 at 24-25.)

2. Respondents

a) GC Corporation

GC Corporation is a Japanese corporation with headquarters located in Tokyo, Japan. (RX-1582C at ¶¶ 9-10.) Through an affiliate, GC Corporation is responsible for the manufacture of the accused Initial LiSi Press products. (*Id.* at ¶ 15.)

b) GC America

GC America is an affiliate of GC Corporation and is an Illinois corporation with its headquarters in Alsip, Illinois. (RX-1582C at ¶¶ 9-10.) GC America sells the accused Initial LiSi Press products in the United States to wholesale distributors, who then sell the products to third parties, such as dental laboratories. (*Id.* at ¶ 15.)

C. Overview of the Technology

The technology at issue in this investigation relates to "ceramic dental material, particularly lithium silicate glass-ceramic, and restorative products made from lithium silicate glass-ceramics of certain formulations and made by specific processes." (Compl. at ¶ 18.) The technology relates both to specific compositions of lithium silicate glass ceramic dental products, as well as methods of manufacturing lithium silicate glass-ceramic. (*Id.* at ¶¶ 18-20.)

D. Asserted Patents

1. U.S. Patent No. 7,452,836

The '836 patent, entitled "Lithium Silicate Glass Ceramic," issued to (i) Elke Apel, (ii) Wolfram Höland, (iii) Marcel Schweiger, (iv) Christian van t'Hoen, (v) Harald Bürke, and (vi) Volker M. Rheinberger as a U.S. Patent on November 28, 2008, from U.S. Patent Application No. 11/348,053 filed February 6, 2006. (JX-0001 at Cover.) The '836 patent is assigned to Ivoclar Vivadent AG (*Id.*) The '836 patent generally relates to "[l]ithium silicate materials . . . which can be easily processed by machining to dental products without undue wear of the tools and which subsequently can be converted into lithium silicate products showing high strength." (*Id.* at Abstract.)

2. U.S. Patent No. 6,802,894

The '894 patent, entitled "Lithium Disilicate Glass-Ceramics" issued to (i) Dmitri Brodkin, (ii) Carlino Panzera, and (iii) Paul Panzera as a U.S. Patent on October 12, 2004, from U.S. Patent Application No. 10/179,881 filed June 25, 2002. (JX-0004 at Cover.) The '894 patent is currently owned by Ardent, Inc., through a series of assignments. (*See* CX-0006.) The '894 patent generally relates to "lithium disilicate ($Li_2Si_2O_5$) based glass-ceramics comprising silica, lithium oxide, alumina, potassium oxide and phosphorus pentoxide." (JX-0004 at Abstract.)

II. JURISDICTION & IMPORTATION

A. Subject Matter Jurisdiction

Section 337 confers subject matter jurisdiction on the Commission to investigate, and if appropriate, to provide a remedy for, unfair acts and unfair methods of competition in the importation, the sale for importation, or the sale after importation of articles into the United

States. *See* 19 U.S.C. §§ 1337(a)(1)(B) and (a)(2). Complainants filed a complaint alleging a violation of this subsection. Accordingly, the Commission has subject matter jurisdiction over this Investigation under section 337 of the Tariff Act of 1930. *See Amgen, Inc. v. U.S. Int'l. Trade Comm'n.*, 902 F.2d 1532, 1536 (Fed. Cir. 1990).

B. Personal Jurisdiction

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

C. *In Rem* Jurisdiction

Respondents have stipulated to the importation of the accused products into the United States. (JX-0010C at ¶ 8.) Accordingly, the Commission has *in rem* jurisdiction over the accused products. *See e.g., Sealed Air Corp. v. United States Int'l Trade Comm'n*, 645 F.2d 976, 985–86 (C.C.P.A. 1981).

D. Importation

As noted above, Respondents have stipulated to the importation of the accused products into the United States. (JX-0010C at ¶ 8.) Accordingly, the importation requirement of section 337 is satisfied.

E. Standing

Complainants are the assignee of both the '836 patent and '894 patent. (*See* JX-0003; JX-0006.) Accordingly, and in the absence of any dispute, Complainants have standing in this investigation. *See* 19 C.F.R. § 210.12(a)(7).

III. LEGAL PRINCIPLES

A. Claim Construction

"An infringement analysis entails two steps. The first step is determining the meaning and scope of the patent claims asserted to be infringed. The second step is comparing the properly construed claims to the device accused of infringing." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (*en banc*) (internal citations omitted), *aff'd*, 517 U.S. 370 (1996). Claim construction is a "matter of law exclusively for the court." *Id.* at 970-71. "The construction of claims is simply a way of elaborating the normally terse claim language in order to understand and explain, but not to change, the scope of the claims." *Embrex, Inc. v. Serv. Eng'g Corp*, 216 F.3d 1343, 1347 (Fed. Cir. 2000).

Claim construction focuses on the intrinsic evidence, which consists of the claims themselves, the specification, and the prosecution history. *See Phillips v. AWH Corp*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (*en banc*); *see also Markman*, 52 F.3d at 979. As the United States Court of Appeals for the Federal Circuit ("Federal Circuit") explained in *Phillips*, courts must analyze each of these components to determine the "ordinary and customary meaning of a claim term" as understood by a person of ordinary skill in the art at the time of the invention. 415 F.3d at 1313. "Such intrinsic evidence is the most significant source of the legally operative meaning of disputed claim language." *Bell Atl. Network Servs., Inc. v. Covad Commc'ns Grp., Inc.*, 262 F.3d 1258, 1267 (Fed. Cir. 2001).

"It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" *Phillips*, 415 F.3d at 1312 (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). "Quite apart from the written description and the prosecution history, the claims themselves provide substantial guidance as to the meaning of particular claims terms." *Id.* at

1314; *see also Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001) ("In construing claims, the analytical focus must begin and remain centered on the language of the claims themselves, for it is that language that the patentee chose to use to 'particularly point[ ] out and distinctly claim[ ] the subject matter which the patentee regards as his invention.'"). The context in which a term is used in an asserted claim can be "highly instructive." *Phillips*, 415 F.3d at 1314. Additionally, other claims in the same patent, asserted or unasserted, may also provide guidance as to the meaning of a claim term. *Id.*

The specification "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Id.* at 1315 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). "[T]he specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Id.* at 1316. "In other cases, the specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor." *Id.* As a general rule, however, the particular examples or embodiments discussed in the specification are not to be read into the claims as limitations. *Id.* at 1323. In the end, "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be . . . the correct construction." *Id.* at 1316 (quoting *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998)).

In addition to the claims and the specification, the prosecution history should be examined, if in evidence. *Id.* at 1317; *see also Liebel-Flarsheim Co. v. Medrad Inc.*, 358 F.3d 898, 913 (Fed. Cir. 2004). The prosecution history can "often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it

would otherwise be." *Phillips*, 415 F.3d at 1317; *see also Chimie v. PPG Indus. Inc.*, 402 F.3d 1371, 1384 (Fed. Cir. 2005) ("The purpose of consulting the prosecution history in construing a claim is to 'exclude any interpretation that was disclaimed during prosecution.'").

When the intrinsic evidence does not establish the meaning of a claim, then extrinsic evidence (*i.e.*, all evidence external to the patent and the prosecution history, including dictionaries, inventor testimony, expert testimony, and learned treatises) may be considered. *Phillips*, 415 F.3d at 1317. Extrinsic evidence is generally viewed as less reliable than the patent itself and its prosecution history in determining how to define claim terms. *Id.* at 1317. "The court may receive extrinsic evidence to educate itself about the invention and the relevant technology, but the court may not use extrinsic evidence to arrive at a claim construction that is clearly at odds with the construction mandated by the intrinsic evidence." *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 977 (Fed. Cir. 1999).

If, after a review of the intrinsic and extrinsic evidence, a claim term remains ambiguous, the claim should be construed so as to maintain its validity. *Phillips*, 415 F.3d at 1327. Claims, however, cannot be judicially rewritten in order to fulfill the axiom of preserving their validity. *See Rhine v. Casio, Inc*, 183 F.3d 1342, 1345 (Fed. Cir. 1999). Thus, "if the only claim construction that is consistent with the claim's language and the written description renders the claim invalid, then the axiom does not apply and the claim is simply invalid." *Id.*

B. Infringement

In a section 337 investigation, the complainant bears the burden of proving infringement of the asserted patent claims by a preponderance of the evidence. *See Spansion, Inc. v. Int'l Trade Comm'n*, 629 F.3d 1331, 1349 (Fed. Cir. 2010). This standard "requires proving that

infringement was more likely than not to have occurred." *Warner-Lambert Co. v. Teva Pharm. USA, Inc.*, 418 F.3d 1326, 1341 n.15 (Fed. Cir. 2005).

1. Literal Infringement

Literal infringement is a question of fact. *Finisar Corp. v. DirecTV Grp., Inc.*, 523 F.3d 1323, 1332 (Fed. Cir. 2008). "Literal infringement requires the patentee to prove that the accused device contains each limitation of the asserted claim(s). If any claim limitation is absent, there is no literal infringement as a matter of law." *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1247 (Fed. Cir. 2000).

2. Doctrine of Equivalents

Where literal infringement is not found, infringement nevertheless can be found under the doctrine of equivalents. Determining infringement under the doctrine of equivalents "requires an intensely factual inquiry." *Vehicular Tech. Corp. v. Titan Wheel Int'l, Inc.*, 212 F.3d 1377, 1381 (Fed. Cir. 2000). The Supreme Court has described the essential inquiry of the doctrine of equivalents analysis in terms of whether the accused product or process contains elements identical or equivalent to each claimed element of the patented invention. *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40 (1997). The Federal Circuit applies two articulations of the test for equivalents, as one phrasing may be more suitable for particular fact patterns or technologies. Under the insubstantial differences test, "[a]n element in the accused device is equivalent to a claim limitation if the only differences between the two are insubstantial." Alternatively, under the function-way-result test, an element in the accused device is equivalent to a claim limitation if it "performs substantially the same function in substantially the same way to obtain substantially the same result." *Voda v. Cordis Corp.*, 536 F.3d 1311, 1326 (Fed. Cir. 2008) (citations omitted). In *Warner-Jenkinson*, the Supreme Court noted that the doctrine of

equivalents is subject to several limitations, including applying the doctrine to individual elements of a claim and not to the invention as a whole. *Warner-Jenkinson,* 520 U.S. at 29.

C. Validity

A patent is presumed valid. 35 U.S.C. § 282; *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2242 (2011). A respondent who has raised patent invalidity as an affirmative defense has the burden of overcoming this presumption by clear and convincing evidence. *See Microsoft,* 131 S. Ct. at 2242. As with an infringement analysis, an analysis of invalidity involves two steps: determining the scope of the claim and comparing the properly construed claim with the prior art to determine whether the claimed invention is anticipated and/or rendered obvious.

1. Anticipation (35 U.S.C. § 102)

Under 35 U.S.C. § 102, a claim is anticipated and therefore invalid when "the four comers of a single, prior art document describe every element of the claimed invention, either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation." *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000), *cert. denied,* 532 U.S. 904 (2001). To be considered anticipatory, the prior art reference must be enabling and describe the applicant's claimed invention sufficiently to have placed it in possession of a person of ordinary skill in the field of the invention. *Helifix Ltd. v. Blok-Lok, Ltd.*, 208 F.3d 1339, 1346 (Fed. Cir. 2000).

2. Obviousness (35 U.S.C. § 103)

Under 35 U.S.C. §103, a patent may be found invalid as obvious if "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. §103(a). Because

obviousness is determined at the time of invention, rather than the date of application or litigation, "[t]he great challenge of the obviousness judgment is proceeding without any hint of hindsight." *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 655 F.3d 1364, 1375 (Fed. Cir. 2011) ("*Star II*").

When a patent is challenged as obvious, the critical inquiry in determining the differences between the claimed invention and the prior art is whether there is an apparent reason to combine the known elements in the fashion claimed by the patent at issue. *See KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 417-418 (2007). The Federal Circuit has since held that when a patent is challenged as obvious, based on a combination of several prior art references, "the burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make the composition or device, or carry out the claimed process, and would have had a reasonable expectation of success in doing so." *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007) (citations omitted).

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

decision on obviousness. For evidence of secondary considerations to be given substantial weight in the obviousness determination, its proponent must establish a nexus between the evidence and the merits of the claimed invention. *See W. Union Co. v. MoneyGram Payment Sys. Inc.*, 626 F.3d 1361, 1372-73 (Fed. Cir. 2010) (citing *In re GPAC Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995)).

3. Written Description (35 U.S.C. § 112, (a)/¶1)

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

4. Indefiniteness (35 U.S.C. § 112, (b)/¶ 2)

A claim must also be definite. Pursuant to 35 U.S.C. § 112, ¶ 2: "The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as the invention." 35 U.S.C. § 112, ¶ 2. In *Nautilus, Inc.* v. *Biosig Instruments, Inc.*, 134 S. Ct. 2120 (2014), the Supreme Court held that § 112, ¶ 2 requires "that a patent's claims, viewed in light of the specification and prosecution history inform those skilled in the art about the scope of the invention with reasonable certainty." *Id.* at 2129. A patent claim that is indefinite is invalid. 35 U.S.C. § 282(b)(3)(A).

D. Domestic Industry

In a patent-based complaint, a violation of section 337 can be found "only if an industry in the United States, relating to the articles protected by the patent . . . concerned, exists or is in the process of being established." 19 U.S.C. § 1337(a)(2). Under Commission precedent, this "domestic industry requirement" of section 337 consists of an economic prong and a technical prong. *See Certain Stringed Musical Instruments and Components Thereof*, Inv. No. 337-TA-586, Comm'n. Op. at 12-14, 2009 WL 5134139 (U.S.I.T.C. Dec. 2009). The complainant bears the burden of establishing that the domestic industry requirement is satisfied. *See Certain Set-Top Boxes and Components Thereof*, Inv. No. 337-TA-454, Final Initial Determination at 294, 2002 WL 31556392 (U.S.I.T.C. June 21, 2002) (unreviewed by Commission in relevant part).

1. Economic Prong

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

> (3) For purposes of paragraph (2), an industry in the United States shall be considered to exist if there is in the United States, with respect to the articles protected by the patent, copyright, trademark, mask work, or design concerned –
>
> (A) significant investment in plant and equipment;
> (B) significant employment of labor or capital; or
> (C) substantial investment in its exploitation, including engineering, research and development, or licensing.

Given that these criteria are listed in the disjunctive, satisfaction of any one of them will be sufficient to meet the economic prong of the domestic industry requirement. *See Certain Integrated Circuit Chipsets and Prods. Containing Same*, Inv. No. 337-TA-428, Order No. 10, Initial Determination (unreviewed) (May 4, 2000).

2. Technical Prong

The technical prong of the domestic industry requirement is satisfied when the complainant in a patent-based section 337 investigation establishes that it is practicing or exploiting the patents at issue. *See* 19 U.S.C. § 1337(a)(2) and (3); *Certain Microsphere Adhesives, Process for Making Same and Prods. Containing Same, Including Self-Stick Repositionable Notes,* Inv. No. 337-TA-366, Comm'n Op. at 8, 1996 WL 1056095 (U.S.I.T.C. Jan. 16, 1996). "The test for satisfying the 'technical prong' of the industry requirement is essentially [the] same as that for infringement, i.e., a comparison of domestic products to the asserted claims." *Alloc, Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361, 1375 (Fed. Cir. 2003). To prevail, the patentee must establish by a preponderance of the evidence that the domestic product practices one or more claims of the patent, either literally or under the doctrine of equivalents. *See Bayer*, 212 F.3d at 1247. It is sufficient to show that the products practice any claim of that patent, not necessarily an asserted claim of that patent. *See Certain Microsphere Adhesives*, Comm'n Op. at 7-16.

IV. U.S. PATENT NO. 7,452,836

A. Overview

1. Asserted Claims

Ivoclar asserts claims 1, 2, 4, 5, 7, 10, 13, and 15–19 of the '836 patent against all shades of the LiSi Press products. (CIB at 11.) Claim 1 is the sole independent asserted claim, while the remaining asserted claims depend from claim 1 directly, or through dependence on another dependent claim. The asserted claims provide as follows:

1. A lithium silicate glass ceramic which comprises the following components:

Component	wt.-%
SiO_2	64.0-75.0
Li_2O	13.0-17.0
K_2O	2.0-5.0
Al_2O_3	0.5-5.0
Nucleating agent	2.0-5.0
Me(II)O	0-3.0
ZrO_2	0.1-4.0

and which comprises less than 0.1 wt. % of ZnO, with Me(II)O being selected from at least one of CaO, BaO, MgO and SrO.

2. Glass ceramic according to claim 1 which is essentially free of ZnO.

* * *

4. Glass ceramic according to claim 1, which comprises 0 to 2.0 wt. % of Me(II)O.

5. Glass ceramic according to claim 1, wherein Me(II)O is selected from at least one of CaO and MgO.

* * *

7. Glass ceramic according to claim 1, wherein the molar ratio of SiO_2:Li_2O is at least 2.2:1.

* * *

10. Glass ceramic according to claim 1, which comprises 70.0 to 73.0 wt. % of SiO_2.

* * *

13. Glass ceramic according to claim 1, wherein the nucleating agent is at least one of P_2O_5 and compounds of the elements Pt, Ag, Cu and W.

* * *

15. Glass ceramic according to claim 1, which is in form of a blank or a dental restoration.

16. Glass ceramic according to claim 15, wherein the dental restoration is an inlay, an onlay, a bridge, an abutment, a facing, a veneer, a facet, a crown, a partial crown, a framework or a coping.

17. Glass ceramic according to claim 1, which comprises 64.0 to 73.0 wt. % SiO_2.

18. Glass ceramic according to claim 4, which comprises 0 to 1.5 wt. % of Me(II)O.

19. Glass ceramic according to claim 7, which comprises a molar ratio of SiO_2:Li_2O of at least 2.3:1.

(JX-0001 at Cls. 1, 2, 4, 5, 7, 10, 13, and 15–19.)

B. Level of Ordinary Skill in the Art

Complainants assert that a person of ordinary skill in the art would have "a Bachelor's or Master's Degree, or its equivalent, in material or chemical science and engineering or a closely related field, and would have had at least two years of experience in making, studying, and/or evaluating glass-ceramic materials." (CIB at 11 (citing CX-0709C at Q/A at 65).) Respondents assert that:

> A POSITA would have had knowledge and experience relating to the design, production and use of glass-ceramic compositions for various applications. Such a person would have been able to design compositions for specific products, taking into account such variables as desired mechanical properties and the application for which the glass-ceramic composition is being used. The POSITA would have had a bachelor's or advanced degree, such as an M.S. or Ph.D. in chemistry, physics, ceramics, materials science and engineering, or chemical engineering, coupled with 2-5 years of academic or industry experience in the area of glass-ceramic research and development or similar work.

(RIB at 20 (citing RX-2331C at Q/A 76; RX-1586C at Q/A 32).) And, Staff asserts that a person of ordinary skill in the art would have "(i) a master's degree in chemistry, physics, ceramics, materials science and engineering, or chemical engineering, and (ii) at least 2 years of academic or industry experience making, studying, evaluating, or using glass-ceramic materials." (SIB at 24.)

The proposed levels of skill offered by the parties are very close in terms of substance. In fact, no party levies any criticisms at any other party's proposal, and no party has identified an issue in dispute where the differences between these proposals will be outcome determinative. While Complainants and Respondents cite to their experts' witness statements to support their positions, the undersigned finds those experts' testimony to be conclusory and of little probative assistance. (*See* CX-0709C at Q/A at 65; RX-2331C at Q/A at 76; RX-1586C at Q/A at 32.) Indeed, Respondents' experts gave verbatim identical descriptions of the level of ordinary skill in the art, which tends to call into question whether those experts used their own knowledge to determine the level of ordinary skill in the art, or instead if they merely parroted back the level of skill given to them by counsel. (*Compare* RX-2331C at Q/A at 76 *with* RX-1586C at Q/A at 32.)

Given the record available, and the absence of any material dispute regarding the level of skill in the art, the undersigned finds Staff's proposal, which appears to define the level of ordinary skill based on the parameters common to both Complainants' and Respondents' proposals, to be most correct. Accordingly, the undersigned finds that the level of ordinary skill in the art for the '836 patent is ***someone with (i) a master's degree in chemistry, physics, ceramics, materials science and engineering, or chemical engineering, and (ii) at least 2 years of academic or industry experience making, studying, evaluating, or using glass-ceramic materials.***

C. Claim Construction

1. "lithium silicate glass ceramic"

The term "lithium silicate glass ceramic" appears in independent claim 1 of the '836 patent. The parties propose the following constructions for this term:

Complainants	Respondents	Staff
Plain and Ordinary Meaning: A glass ceramic which can include lithium metasilicate as the main crystalline phase; lithium disilicate as the main crystalline phase; or a combination of the crystalline phases.	a glass ceramic comprising metastable lithium metasilicate (Li_2SiO_3) as the main crystalline phase (20 to 80% by volume)	a glass ceramic comprising lithium metasilicate (Li_2SiO_3) Alternatively: a glass ceramic comprising lithium metasilicate (Li_2SiO_3) that is essentially free of lithium disilicate

(CIB at 12; RIB at 20; SIB at 26.) The true dispute here is whether prosecution history disclaimer requires restricting "lithium silicate glass ceramic" to glass ceramics with lithium metasilicate as the main crystalline phase. The undersigned finds that it does.

Here, there is no dispute that, absent the prosecution history, a person of ordinary skill in the art would understand the plain and ordinary meaning of this term to include glass ceramics with either lithium metasilicate or lithium disilicate as the main crystalline phase. (*See* RX-1586C at Q/A at 52, 62; CX-0705C at Q/A at 36; CX-0709C at Q/A at 74.) This understanding is supported by the knowledge in the art, (*see id.*), the plain language of the claim in which the term appears, (*see* JX-0001 at Cl. 1), the doctrine of claim differentiation, (*see* JX-0001 at Cl. 3), and the specification, (*see* JX-0001 at 4:58–64; 3:21–24). If claim construction only required consideration of the specification and the claims, then this inquiry would be at an end; but it requires more. The prosecution history of the '836 patent must also be considered.

Following a preliminary amendment on February 6, 2006, the application that matured into the '836 patent consisted of 42 claims. (JX-0002 at 41–48.) Included among them were claims directed to "lithium silicate glass ceramic," "lithium metasilicate glass ceramic," and "lithium disilicate glass ceramic." (*Id.* at 42, 44–45.) Thereafter, on September 4, 2007, the

examiner issued an office action subjecting all 42 claims to a restriction requirement. (*Id.* at 235–240.) Specifically, the examiner stated:

> **Restriction to one of the following inventions is required under 35 U.S.C. 121:**
>
> **I. Claims 1-17,29-37 drawn to a glass ceramic including lithium metasilicate, classified in class 501, subclass 5.**
>
> **II. Claims 19-23,38,39, drawn to a method of making a lithium metasilicate glass ceramic, classified in class 65, subclass 33.1.**
>
> **III. Claims 24,25, drawn to a method of making a lithium disilicate glass ceramic, classified in class 65, subclass 33.1.**
>
> **IV. Claims 1,2,4-14,16-18, drawn to a lithium disilicate glass ceramic, classified in class 501, subclass 5.**
>
> **V. Claims 26-28,40-42, drawn to a glass composition, classified in class 501, subclass 68.**

(*Id.* at 237.) The examiner went on to explain how each of these five inventions was distinct from each other. (*Id.*) Of particular importance here, the examiner explained that:

> **2. Inventions I and IV are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product, and the species are patentably distinct (MPEP § 806.05(j)). In the instant case, the intermediate product (lithium metasilicate) is deemed to be useful as a decorative coating composition and the inventions are deemed patentably distinct because there is nothing on this record to show them to be obvious variants.**

(*Id.*) Thus, the lithium metasilicate glass ceramic of group I and the lithium disilicate glass ceramic of group IV had no overlapping scope for the purposes of the restriction requirement. Further demonstrating this division are the specific claims that the examiner placed in each group. While application claim 1, which recites a "lithium silicate glass ceramic," appears in

groups I and IV, claims 3 and 15, which recite a glass ceramic with lithium metasilicate as the main crystalline phase, appear only in group I. Similarly, claim 18, which recites a glass ceramic with lithium disilicate as the main crystalline phase, appears only in group IV. (*Id.* at 42, 44, 237.) In short, the examiner's restriction requirement was clear and unmistakable in drawing a line between glass ceramics with lithium metasilicate as the main crystalline phase and those with lithium disilicate as the main crystalline phase.

On October 19, 2007, the applicants responded to the restriction requirement by electing group I and cancelling the claims directed to the other non-elected inventions. (*Id.* at 241–46.) The applicants took this action without traverse, and, explicitly indicated a reservation of rights "to file divisional applications directed to the non-elected inventions." (*Id.* at 246.) Thus, the prosecution history also clearly and unmistakably shows that the applicants did not claim that the examiner's restriction requirement was in error, and in fact agreed not to pursue claims covering a lithium glass ceramic with lithium disilicate as the main crystalline phase in this application.

Shortly following the applicants' election of group I for prosecution and the cancellation of claims directed to other inventions, the examiner rejected application claim 1 as anticipated and/or obvious under 35 U.S.C. §§ 102 and 103, and for obviousness-type double patenting in view of U.S. Application No. 10/913,095. (JX-0002 at 255–261.) In response to the examiner's rejection, the applicants argued, *inter alia*, that claim 1 was not obvious in view of the prior art based on its specific composition, which the applicants described as "glass ceramic having metastable lithium metasilicate as a main crystalline phase." (*Id.* at 274.) Specifically, the applicants stated:

> Moreover, the subject matter of newly amended claim 1 is not obvious in view of the cited prior art documents. Claim 1 is directed to a lithium silicate glass ceramic having a very specific composition, which provides a number of unexpected advantages over the prior art.
>
> The specific composition according to claim 1 allows for the production of a glass ceramic having metastable lithium metasilicate as a main crystalline phase. This lithium metasilicate glass ceramic has been surprisingly found to combine a very good machinability and high edge strength with the possibility to be converted by a simple heat treatment involving only very limited shrinkage into lithium disilicate glass ceramics having excellent strength, durability and translucence, all of which are properties useful for the manufacture of dental restorations (see page 4, line 37 to page 5, line 12 and page 16, lines 16 to 24 of the present specification). In particular, the composition according to claim 1 surprisingly allows for the production of glass ceramics having both a very high mechanical strength and excellent optical properties, especially very high translucency.

(*Id.*) The applicants' own characterization of the subject matter of claim 1 being that of a glass ceramic with metastable lithium metasilicate as the main crystalline phase confirms that the applicants shared the examiner's understanding that claim 1 of the '836 patent is limited to lithium metasilicate glass ceramics.

For still further confirmation that the applicants understood lithium disilicate glass ceramics to be a distinct and separate invention from the invention of the '836 patent, the applicants' divisional applications are instructive. Specifically, U.S. application number 12/253,470, which matured into U.S. Patent No. 7,867,931, is a division of the application that matured into the '836 patent. (RX-1068 at Cover.) The '931 patent includes only 1 independent claim, which recites a "lithium silicate glass ceramic which comprises lithium disilicate as the main crystalline phase . . . ." (RX-1068 at Cl. 1.) As the Federal Circuit has noted, "[p]lain common sense dictates that a divisional application filed as a result of a restriction requirement may not contain claims drawn to the invention set forth in the claims elected and prosecuted to patent in the parent application." *Gerber Garment Tech., Inc. v. Lectra Sys., Inc.*, 916 F.2d 683,

687 (Fed. Cir. 1990). Thus, the fact that claim 1 of the '931 patent, which matured from a divisional application, covers glass ceramic with lithium disilicate as the main crystalline phase indicates that its parent application, which matured into the '836 patent, does not.

Based on the foregoing, the undersigned finds that the prosecution history of the '836 patent evinces a clear and unmistakable disavowal of glass ceramics with lithium disilicate as their main crystalline phase. Complainants raise a number of counter-arguments to this conclusion, but none are persuasive.

Complainants' first argument is that claim differentiation requires the phrase "lithium silicate glass ceramic" to be broader than a lithium silicate glass ceramic with lithium metasilicate as its main crystalline phase. (CIB at 14.) The basis for this argument is that claims 3 and 14 of the '836 patent, which depend from claim 1, explicitly recite the presence of lithium metasilicate as additional limitation to claim 1. (*See* JX-0001 at Cls. 3, 14.) Accordingly, absent any other contrary evidence, the doctrine of claim differentiation would suggest that "lithium silicate glass ceramic" should not be limited to ceramics with lithium metasilicate as the main crystalline phase. However "[c]laim differentiation is 'not a hard and fast rule,' but rather a presumption that will be overcome when the specification or prosecution history dictates a contrary construction." *GPNE Corp. v. Apple Inc.*, 830 F.3d 1365, 1371 (Fed. Cir. 2016); *see also Howmedica Osteonics Corp. v. Zimmer, Inc.*, 822 F.3d 1312, 1323 (Fed. Cir. 2016) ("[C]laim differentiation is a rebuttable presumption that may be overcome by a contrary construction dictated by the written description or prosecution history."); *Fenner Invs., Ltd. v. Cellco P'ship*, 778 F.3d 1320, 1327 (Fed. Cir. 2015) ("Although claim differentiation is a useful analytic tool, it cannot enlarge the meaning of a claim beyond that which is supported by the patent documents, or relieve any claim of limitations imposed by the prosecution history.");

Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1480 (Fed. Cir. 1998) ("[T]he doctrine of claim differentiation can not broaden claims beyond their correct scope, determined in light of the specification and the prosecution history and any relevant extrinsic evidence. . . .").

Here, as detailed above, there is ample evidence in the prosecution history to overcome the presumption of claim differentiation. Indeed, because the initial application that matured into the '836 patent covered inventions directed to both lithium disilicate and lithium metasilicate glass ceramics, it is unsurprising that the initial application also included dependent claims covering only one species or the other. Following the applicants' election of the group I invention for prosecution, and the cancellation of claims directed to group IV, which covered lithium disilicate glass ceramics, the dependent claims directed to lithium metasilicate lost some of their interpretive value, at least insomuch as the doctrine of claim differentiation is concerned. Complainants' attempt to recapture a broader scope for claim 1 of the '836 patent through use of the doctrine of claim differentiation with dependent claims 3 and 14 is exactly the type of misuse the Federal Circuit warned against in *Fenner Invs., Ltd.*, 778 F.3d at 1326–27, and *Multiform Desiccants, Inc.*, 133 F.3d at 1480.

Complainants' second argument is based on the specification, which recites preferred embodiments covering both lithium metasilicate and disilicate glass ceramics. (CIB at 15 (citing JX-0001 at 4:58–60, 4:65–67, 7:56–59).) This argument suffers from similar flaws as Complainants' claim differentiation argument. Particularly, though the applicants elected to pursue only the group I invention in the '836 patent, and cancelled the claims directed to lithium disilicate glass ceramics, the applicants did not also amend the specification to remove references to lithium disilicate embodiments. This is consistent with the PTO's regulations, which do not

require an applicant to amend the specification of his application in concert with the cancellation of a claim. *See* 37 C.F.R. § 1.121 ("Manner of making amendments in applications."). Thus, the disclosure of non-elected embodiments may persist in the specification of a patent that was subject to a restriction requirement during prosecution even though no issued claim covers those embodiments. Indeed, considering this very issue, the Federal Circuit explained:

> [The patentee] also argues that the specification includes embodiments, shown in Figures 11 and 13, that are not within the scope of claim 10 as construed by the district court. However, embodiments in which the pin extends through the slot before rotating to locked position were claimed in U.S. Patent No. 5,381,685, not in suit. The '989 patent is a division related to the '685 patent, and was filed in response to a restriction requirement. *See* 35 U.S.C. § 121 ("If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.") The '685 patent contains claims that do not limit pin extension temporally and claims that require that the pin extends into the slot before the slot engagement member is rotated to locked position. Figure 14 was selected "as the illustration of the invention" of the '989 patent. *See* 37 C.F.R. § 1.84(j). ***The presence in the '989 specification of embodiments carried over from the parent application, but claimed in other patents, does not serve to broaden the scope of the '989 claims that were the subject of the divisional application.***

ACCO Brands, Inc. v. Micro Sec. Devices, Inc., 346 F.3d 1075, 1079 (Fed. Cir. 2003) (emphasis added); *see also PSN Illinois, LLC v. Ivoclar Vivadent, Inc.*, 525 F.3d 1159, 1166 (Fed. Cir. 2008) ("cancelled claims may provide 'probative evidence' that an embodiment is not within the scope of an asserted claim."). Complainants' attempt to broaden the scope of claim 1 of the '836 patent in this investigation is no different from that of the patentee in *ACCO Brands, Inc.* As the Federal Circuit found in *Acco Brands, Inc.*, the undersigned also finds here that the '836 specification's disclosure of embodiments included in the initial parent application, but claimed in another patent, does not serve to broaden the scope of the '836 claims that were elected in response to the examiner's restriction requirement.

Third, Complainants argue that the prosecution history supports its construction. (*See* CIB at 16.) This portion of Complainants' argument has multiple subparts. For example,

Complainants argue that by placing application claim 1 in both group I and IV, and by using the word "including" in the description of group I, the examiner evinced an understanding that claim 1 should cover both lithium metasilicate and disilicate glass ceramics. (*Id.* at 17.) However, that the examiner understood application claim 1 to be broad enough to cover two mutually exclusive inventions prior to the applicants' election of a single invention for prosecution does not mean that the claim holds the same scope after the applicants' election of a single invention without traverse. In short, Complainants essentially ask the undersigned to ignore the applicants' election of a single species of invention in interpreting claim 1. The law of claim construction does not allow such an approach. *See Uship Intellectual Props., LLC v. U.S.*, 714 F.3d 1311, 1315 (Fed. Cir. 2013) ("We hold that a patent applicant's response to a restriction requirement may be used to interpret patent claim terms or as a source of disclaimer.").

With respect to the examiner's use of the word "including," in the description of the group 1 invention, the phrasing simply indicates that there may be other elements in the glass ceramic, but that lithium metasilicate is required. The use of the word "including" in no way, however, suggests that the group I invention covered glass ceramics with lithium dislocate as the main crystalline phase, which the examiner unambiguously identified as a mutually exclusive invention covered by invention group IV.

Next, Complainants argue that the examiner's November 2007 office action and the applicants' May 12, 2008, response to that action indicate that claim should be interpreted to include lithium disilicate glass ceramic. The crux of this argument is that the examiner issued an anticipation rejection based on a prior art reference drawn to lithium disilicate glass ceramic, which Complainants assert is evidence that the examiner understood claim 1 to cover lithium disilicate glass ceramics. (CIB at 17.) The applicants' response to this office action, however,

unambiguously forecloses interpreting the prosecution history in the manner Complainants suggest. Specifically, the applicants stated:

> **Moreover, the subject matter of newly amended claim 1 is not obvious in view of the cited prior art documents. Claim 1 is directed to a lithium silicate glass ceramic having a very specific composition, which provides a number of unexpected advantages over the prior art.**
>
> **The specific composition according to claim 1 allows for the production of a glass ceramic having metastable lithium metasilicate as a main crystalline phase. This lithium metasilicate glass ceramic has been surprisingly found to combine a very good machinability and high edge strength with the possibility to be converted by a simple heat treatment involving only very limited shrinkage into lithium disilicate glass ceramics having excellent strength, durability and translucence, all of which are properties useful for the manufacture of dental restorations (see page 4, line 37 to page 5, line 12 and page 16, lines 16 to 24 of the present specification). In particular, the composition according to claim 1 surprisingly allows for the production of glass ceramics having both a very high mechanical strength and excellent optical properties, especially very high translucency.**

(JX-0002 at 274.) Here applicants clearly and unmistakably characterized the glass ceramic of claim 1 as "having metastable lithium metasilicate as a main crystalline phase." (*Id.*) Complainants misrepresent the applicants' response when they assert that the glass ceramic "is 'converted' to lithium disilicate." (CIB at 18.) The applicants' response states only that it is possible to convert the glass ceramic of claim 1 into lithium disilicate glass ceramic with a simple heat treatment. That the applicants acknowledged the fact that glass ceramic of claim 1 could possibly be converted into lithium disilicate through heat treatment does not negate the applicants' characterization of claim 1 as drawn to a glass ceramic with metastable lithium metasilicate as a main crystalline phase. Indeed, the examiner's restriction requirement acknowledged that lithium metasilicate glass ceramics and lithium disilicate glass ceramics are related as intermediate and final products, but nonetheless found them to be mutually exclusive

inventions. Applicants did not dispute the examiner's reasoning, and the applicants' May 12, 2008, response to an office action only confirms the understanding laid out in the examiner's restriction requirement.

Complainants' final prosecution history argument is that because the examiner's final art search included the term "disilicate," the examiner must have understood the '836 patent to cover lithium disilicate glass ceramics. However, the undersigned finds the examiner's search terms to be insufficient evidence to justify ignoring the much clearer statements made by both the examiner and the applicants as to the scope of claim 1 in the '836 patent. For example, the examiner may well have determined to search for "disilicate" references because of the intermediate-final product relationship between metasilicate and disilicate glass ceramics. Further, Complainants fail to acknowledge that the examiner also conducted searches limited only to silicate and metasilicate. (JX-0002 at 253.) In total, Complainants' speculation about the examiner's search strategy is not enough to create ambiguity in the face of clear statements from the examiner and the applicants showing that the invention of the '836 patent does not cover lithium disilicate glass ceramics.

Complainants' final argument is a legal one. Essentially, Complainants attempt to argue that, as a matter of law, a restriction requirement cannot serve as a basis for prosecution history disavowal. This argument is flawed in numerous respects. First, it tries to re-frame this issue as whether the examiner's restriction requirement, in isolation, can serve as a basis for disclaimer. (*See* CIB at 19 ("But as a threshold matter, an examiner's restriction requirement, which is simply an administrative tool, offers limited probative weight during claim construction.").) Even if that proposition were true, here, in addition to the examiner's restriction requirement and the applicants' election of the group I invention, the prosecution history also includes a statement

by the applicants that claim 1 is drawn to lithium metasilicate glass ceramics, and related divisional applications and patents show that the applicants actually did pursue claims directed to lithium disilicate glass ceramics in another application that matured into the '931 patent. Second, the cases Complainants rely on are either nonbinding and unpublished district court cases, *see Bestop, Inc. v. Tuffy Sec. Prods., Inc.*, 2015 WL 470552 (E.D. Mich. Feb. 4, 2015), or focus on the ambiguous character of specific restriction requirements that were at issue, *see Honeywell Int'l, Inc. v. ITT Indus., Inc.*, 452 F.3d 1312, 1319 (Fed. Cir. 2006); *Plantronics, Inc. v. Aliph, Inc.*, 724 F.3d 1343, 1351 (Fed. Cir. 2013). The examiner's restriction requirement for the '836 patent does not suffer from the same type of ambiguity that was present in *Honeywell* and *Plantronics*. Accordingly, those cases do not diminish the interpretive value of the examiner's restriction requirement and the applicants' response thereto with respect to the '836 patent.

The undersigned has reviewed all of Complainants' arguments, including the evidence and cases cited therein, and finds them unpersuasive. The facts of this dispute are that the '836 patent matured from a broad application that was subject, during prosecution, to a restriction requirement that distinguished multiple inventions within the application based on the main crystalline phase of the glass ceramic. The applicants had an opportunity to dispute the examiner's restriction requirement, but did not, and elected to prosecute an invention with lithium metasilicate as the main crystalline phase. Thereafter, the applicants prosecuted a divisional application that eventually matured into a patent covering glass ceramics with lithium disilicate as the main crystalline phase. And, later in prosecution of the '836 patent, the applicants characterized the composition of claim 1 as that of a glass ceramic with lithium metasilicate as the main crystalline phase. While the standard for disavowal is exacting, and

must be clear and unmistakable, here, that standard has been met. A patentee is not entitled to give up subject matter to secure patentability during prosecution only to turn around and reclaim it to enforce the patent.

Accordingly, the undersigned finds that "lithium silicate glass ceramic" should be construed to mean ***"a glass ceramic comprising metastable lithium metasilicate (Li_2SiO_3) as the main crystalline phase."*** Given that no party has indicated that there is a dispute about what is meant by "main crystalline phase," the undersigned declines to include Respondents' parenthetical "(20 to 80% by volume)" in this construction.

2. "dental restoration"

The term "dental restoration" appears in dependent claims 15 and 16 of the '836 patent. The parties propose the following constructions for this term:

Complainants	Respondents	Staff
Plain and ordinary meaning: a material that has been shaped into a form that is suitable for restoring the function, integrity, and morphology of a patient's missing tooth structure	a material that has been shaped for placement into a patient's mouth.	a material that has been shaped into a form ~~that is suitable~~ for restoring the function, integrity, and morphology of a patient's missing tooth structure Original construction: a material that has been shaped for placement into a patient's mouth

(SIB at 38; CIB at 20–21; RIB at 27.) As Staff notes, the parties' constructions and briefing do not present a clear dispute for resolution with respect to the term "dental restoration." (SIB at 38 (citing RX-1586C, Clark WS at Q/A at 140).) Complainants and Respondents appear to dispute whether only a dental appliance created according to a prescription for a particular patient by a

party licensed to install such appliances is a dental restoration. (*See* CRB at 10; RIB at 29.) The point of this dispute is whether generic demonstrative product samples made by Respondents, as opposed to by a licensed dental practitioner for a specific patient, are infringing. (*See* RIB at 27-28; CRB at 10.) However, the constructions offered by the parties only partially address this dispute. Particularly, all proposed constructions include reference to a patient's mouth or tooth structure. Thus, it is unclear why Complainants oppose in their briefing a construction that references a patient, (*see* CRB at 10), when their own proposed construction also includes reference to "patient's missing tooth structure." (CIB at 21.) Adding to the confusion, in their reply briefing, Complainants argue that the plain and ordinary meaning of "dental restoration" is "an inlay, an onlay, a bridge, an abutment, a facing, a veneer, a facet, a crown, a partial crown, a framework, or a coping" based on the specification and dependent claim 16. (CRB at 10; *see also* JX-0001 at 4:54–57, Cl. 16.)[1]

Respondents' construction and briefing present similar issues. While advocating in briefing for a construction of "dental restoration" that would require a licensed dental practitioner to create the restoration for a specific patient, Respondents' proposed construction—"a material that has been shaped for placement into a patient's mouth"— is completely silent about who can make the dental restoration. In short, neither Complainants nor Respondents have presented a construction that actually encompasses the meanings they seek in their briefing.

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[1] Aside from being untimely, this new construction is not persuasive. The specification describes "an inlay, an onlay, a bridge, an abutment, a facing, a veneer, a facet, a crown, a partial crown, a framework, or a coping" as non-limiting examples of a dental restoration, and dependent claim 16 recites these same categories of restoration as additional limitations on the broader term "dental restoration," which appears in claim 15. (JX-0001 at 4:54–57, Cl. 16.) Complainants' belated attempt to turn these species of dental restorations into an exclusive definition of the entire class of dental restorations is unsupported by the evidence they rely on.

Staff, for its part, has adopted the position that there is no claim construction dispute with respect to "dental restoration," and at least suggests that the undersigned need not construe this term. (SIB at 38–39.) To the extent Staff seeks a construction, it proposes a compromise position that incorporates aspects of both Complainants' and Respondents' constructions. (*See id.* at 39.) Staff's construction, like Complainants' and Respondents', incorporates a reference to a patient, but no reference to a requirement that a licensed dental practitioner must create the dental restoration.

Based on the parties' briefing and the intrinsic evidence, the undersigned finds that "dental restoration" should be construed to mean ***"a material that has been shaped into a form for restoring the function, integrity, and morphology of a patient's missing tooth structure."*** This construction incorporates a reference to a patient's tooth structure, based on all parties' proposed constructions, which also included references to a patient's mouth or tooth structure. The construction does not incorporate any requirement that dental restoration be made or fabricated by a particular individual, such as a licensed dental practitioner. Respondents have identified no portion of the intrinsic evidence supporting such a requirement, and the undersigned declines to incorporate that requirement based only on attorney argument and the self-serving testimony of one of Respondents' employees. (*See* RIB at 29 (citing RX-1582C at Q/A at 45-49).)

D. Infringement

1. Claim 1

Claim 1 of the '836 patent includes the preamble: "A lithium silicate glass ceramic which comprises the following components," and then goes on to recite the specific composition ranges by weight. (JX-0001 at Cl. 1.) As, discussed at length in section IV.C.1, the undersigned has

construed the phrase "lithium glass ceramic" to mean "a glass ceramic comprising metastable lithium metasilicate (Li_2SiO_3) as the main crystalline phase." As noted by Staff, "[a]ll of the Accused Products comprise lithium disilicate—not lithium metasilicate." (SIB at 40 (citing CX-0709C at Q/A at 85; RX-2331C at Q/A at 463–64; CX-0708C at Q/A at 46).) Respondents make the same argument. (*See* RIB at 30–31.)

Complainants do not dispute that the accused products in this investigation are lithium disilicate glass ceramics. (*See* CIB at 23 (citing RX-1586C at Q/A at 71 ("And just to be clear, the accused products in this Investigation are lithium disilicates, but the domestic industry products are lithium metasilicates.")).) Instead, Complainants frame this issue as an attempt by Respondents and Staff to argue that the preamble of claim 1 is limiting. (CIB at 23.) The way in which Complainants address this point suggests that they may disagree that the preamble is limiting, but such an assertion is conspicuously absent from Complainants' briefing. Indeed, nowhere in Complainants' briefing on claim construction or infringement do they assert that the preamble is not limiting. The most probative portion of Complainants' briefing on this issue is a single sentence suggesting that Respondents and Staff have failed to carry some burden to establish that the preamble is limiting.[2] (*See* CRB at 2 (citing *Summit 6, LLC v. Samsung Elecs. Co.*, 802 F.3d 1283, 1291-92 (Fed. Cir. 2015)).) The case Complainants rely on, however, *Summit 6*, does not place a burden on any particular party to show that a preamble is limiting. *Summit 6* merely stated that "[g]enerally, a preamble is not limiting," and that "[p]reamble

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[2] Going one step further, a different portion of Complainants' reply brief states that "neither GC nor Staff has contended that the preamble gives meaning to the claim." That assertion is not well-founded or well-taken. A cursory review of Staff's prehearing brief, for instance, shows that the issue of what meaning to give "lithium silicate glass ceramic" was in dispute prior to the evidentiary hearing, and Staff's reliance on its proposed construction to support its noninfringement argument leaves no doubt that Staff contends the preamble is limiting. (SPB at 18, 30-31.)

language that merely states the purpose or intended use of an invention is generally not treated as limiting the scope of the claim." 802 F.3d at 1292. Moreover, *Summit 6* relies on established Federal Circuit precedent that, "[i]n general, a preamble is construed as a limitation if it recites essential structure or steps, or if it is necessary to give life, meaning, and vitality to the claim." *Symantec Corp. v. Computer Assocs. Int'l, Inc.*, 522 F.3d 1279, 1288 (Fed. Cir. 2008) (quotations and citations omitted). Such is the case here, where, without the preamble, claim 1 is little more than a table of chemical compounds by weight percentage. (JX-0001 at Cl. 1.) The preamble is essential to give meaning to that table and to indicate that the basic structure of the claim is a lithium silicate glass-ceramic. (*Id.*) Accordingly, the preamble is limiting. *See Symantec Corp.*, 522 F.3d at 1288.

The evidence of record in this investigation shows that the accused products do not include lithium metasilicate, as required by claim 1. (CX-0709C at Q/A at 85; RX-2331C at Q/A at 463–64; RX-1116C; CX-0708C at Q/A at 46.) Accordingly, the undersigned finds that Complainants have not shown, by a preponderance of the evidence, that the accused products practice each and every limitation of claim 1 of the '836 patent, and thus have not shown that claim 1 of the '836 patent is literally infringed by the accused products. Further, while Complainants make doctrine of equivalents arguments for claim 1, those arguments are not directed to the "lithium silicate glass ceramic" limitation. (*See* CIB at 24–28.) Accordingly, the undersigned also finds that Complainants have not established infringement of claim 1 by the accused products under the doctrine of equivalents.

2. Claims 2, 4, 5, 7, 10, 13, 15–19

"One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim." *Wahpeton Canvas Co. v. Frontier, Inc.*, 870

F.2d 1546, 1552 n. 9 (Fed. Cir. 1989). Given that the undersigned has found that independent claim 1 of the '836 patent is not infringed, dependent claims 2, 4, 5, 7, 10, 13, and 15–19 are also not infringed.

E. Domestic Industry – Technical Prong

Complainant asserts that "the following shades of e.max CAD literally practice each and every element of claim 1: LT-A1, LT-A2, LT-A3, LT-A3.5, LT-A4, LT-B1, LT-B2, LT-B3, LT-B4, LT-C1, LT-C2, LT-C3, LTC4, LT-D2, LT-D3, LT-D4, LT-BL1, LT-BL2, LT-BL3, and LT-BL4. (CIB at 33 (citing CX-0709C, Griggs WS at Q/A at 61; RPHB at 73–74; SPHB at 33–34).) Complainants summarize the evidence supporting that assertion as follows:

Element	**Supporting Evidence**
SiO_2: 64.0-75.0 wt.-%	CX-0709C, Griggs WS at Q237; CX-0198C-T; CX-0712C, Schweiger WS at Q1–68
Li_2O: 13.0-17.0 wt.-%	CX-0709C at Q242; CX-0198C-T; CX-0712C at Q1–68
K_2O: 2.0-5.0 wt.-%	CX-0709C at Q250; CX-0198C-T; CX-0712C at Q1–68
Al_2O_3: 0.5-5.0 wt.-%	CX-0709C at Q245; CX-0198C-T; CX-0712C at Q1–68
Nucleating agent: 2.0-5.0 wt.-%	CX-0709C at Q253; CX-0198C-T; CX-0712C at Q1–68
Me(II)O: 0-3.0 wt.-%.	CX-0709C at Q264; CX-0198C-T; CX-0712C at Q1–68
ZrO_2: 0.1-4.0 wt.-%	CX-0709C at Q255; CX-0198C-T; CX-0712C at Q1–68
Less than 0.1 wt.-% ZnO	CX-0709C at Q260; CX-0198C-T; CX-0712C at Q1–68
Me(II)O is selected from at least one of CaO, BaO, MgO, and SrO	CX-0709C at Q264; CX-0198C-T; CX-0712C at Q1–68

(CIB at 33.) Complainants go on to assert the same shades of e.max CAD practice claims 9, 10, 15, and 21 of the '836 patent. (*Id.* at 33-34.) Both Respondents and Staff concede that the above LT shades of e.max CAD practice these claims and thus satisfy the technical prong of the domestic industry requirement. (RIB at 36-37; SIB at 42-43.)

The evidence of record establishes that the e.max CAD products, as opposed to the accused products, are lithium metasilicate glass ceramics. (RX-2331C at Q/A at 110.) Thus, the

e.max CAD domestic industry products do not suffer from the same difficulty satisfying the claims of the '836 patent as do the accused products, which do not contain lithium metasilicate. Accordingly, and based on the evidence of record, the undersigned finds that Complainants have satisfied the technical prong of the domestic industry requirement for the '836 patent. (CX-0709C at Q/A at 61, 237, 242, 245, 250, 253, 255, 260, 264; CX-0198C-T; CX-0712C at Q/A at 1-41.)

F. Validity

Respondents assert two grounds for invalidity with respect to the '836 patent: (1) anticipation based on U.S. Patent No. 5,968,856 to Schweiger *et al.*; OPC 3G 510(K) (a lithium disilicate ingot created by a company called Jeneric/Pentron); and Great Britain Patent No. 1,467,459; and (2) obviousness based on Schweiger alone or in combination with the '894 Patent; and Beall alone or in combination with Petticrew. (*See* RIB at IV.E) Respondents also argue that there are no secondary considerations of nonobviousness that overcome their assertions of obviousness.

1. Anticipation

a) U.S. Patent No. 5,968,856 to Schweiger et al.

Respondents assert that claims 1, 4, 5, 10, 13, and 15–18 of the '836 patent are anticipated by U.S. Patent No. 5,968,856 to Schweiger *et al.* ("Schweiger" RX-0062) pursuant to 35 U.S.C. § 102(b). Both Complainants and Staff argue that Schweiger does not anticipate the asserted claims of the '836 patent. (*See* CIB at 35–36; SIB at 43–44.) By Respondents' own admission, "Schweiger is directed to 'sinterable lithium disilicate glass ceramic.'" (RIB at 38.) Accordingly, Respondents acknowledge that "Schweiger (and all LiSi Press products) are outside the scope of claim 1 of the '836 patent" under the construction for "lithium silicate glass

ceramic" proposed by Respondents and Staff. (RIB at 38.) As discussed *supra* in section IV.C.1, the undersigned has construed lithium silicate glass ceramic consistently with Respondents' and Staff's proposed constructions. Accordingly, the undersigned finds that Respondents have failed to show, by clear and convincing evidence, that Schweiger discloses the lithium silicate glass ceramic limitation of claim 1. Therefore, Respondents have failed to establish that asserted claim 1 of the '836 patent is anticipated by Schweiger. For the same reason, Respondents also have not shown that any of the remaining asserted claims, all of which depend from claim 1 and incorporate the lithium silicate glass ceramic reference, are anticipated by Schweiger. *See RCA Corp. v. Applied Digital Data Sys., Inc.*, 730 F.2d 1440, 1446 (Fed. Cir. 1984) ("Since claim 3 of the Cole patent is dependent upon claim 2, which is not anticipated, claim 3 cannot be anticipated.").

b) OPC 3G 510(K)

Respondents assert that claims 1, 2, 4, 5, 7, 9-10, 13, 15-17, and 19 of the '836 patent are anticipated by OPC 3G, which is a lithium disilicate ingot made by a company called Jeneric/Pentron. (RIB at 39-40.) More particularly, Respondents point to a document submitted to the U.S. Food and Drug Administration (a "510(k)") that purportedly disclosed the entire OPC 3G formula to the public. (*See id.* at 40 (citing RX-2301 at Q/A at 14-17; RX-1954 (OPC 3G 510(k)); RX1097 (510(k) Summary (May 26, 2000)); RX-1586C at Q/A at 744, 756).) Both Complainants and Staff argue that the OPC 3G 510(k) does not anticipate the asserted claims of the '836 patent because the document is not prior art. (*See* CIB at 36–37; SIB at 44–47.) Here again, Respondents acknowledge that "OPC 3G (and all LiSi Press products) are outside the scope of claim 1 of the '836 patent" because "metasilicates are not disclosed in the OPC 3G 510(k)." (RIB at 40.) As discussed *supra* in section IV.C.1, the undersigned has construed

lithium silicate glass ceramic consistently with Respondents' and Staff's proposed constructions, which require the presence of lithium metasilicate. Accordingly, the undersigned finds that Respondents have failed to show, by clear and convincing evidence, that the OPC 3G 510(k) discloses the lithium silicate glass ceramic limitation of claim 1. Therefore, Respondents have failed to establish that the asserted claim 1 of the '836 patent is anticipated by the OPC 3G 510(k). For the same reason, Respondents also have not shown that any of the remaining asserted claims, all of which depend from claim 1 and incorporate the lithium silicate glass ceramic reference, are anticipated by the OPC 3G 510(k). *See RCA Corp.*, 730 F.2d at 1446.

c) GB 1,467,459

Respondents assert that claims 1, 2, 4, 5, 7, 9, 13, and 17-19 of the '836 patent are anticipated by Great Britain Patent No. 1,467,459 ("GB '459," RX-77) pursuant to 35 U.S.C. § 102(b). (RIB at 43.) Both Complainants and Staff argue that the GB '459 does not anticipate the asserted claims of the '836 patent because the reference lacks one or more elements of the asserted claims. (*See* CIB at 38–39; SIB at 47–48.) Here again, Respondents acknowledge that "GB '459 (and all LiSi Press products) are outside the scope of claim 1 of the '836 patent" because "metasilicates are not disclosed in GB '459." (RIB at 43.) As discussed *supra* in section IV.C.1, the undersigned has construed lithium silicate glass ceramic consistently with Respondents' and Staff's proposed constructions, which require the presence of lithium metasilicate. Accordingly, the undersigned finds that Respondents have failed to show, by clear and convincing evidence, that GB '459 discloses the lithium silicate glass ceramic limitation of claim 1. Therefore, Respondents have failed to establish that the asserted claim 1 of the '836 patent is anticipated by GB '459. For the same reason, Respondents also have not shown that any of the remaining asserted claims, all of which depend from claim 1 and incorporate the

lithium silicate glass ceramic reference, are anticipated by GB '459. *See RCA Corp.*, 730 F.2d at 1446.

2. Obviousness

a) Schweiger, alone or in combination with the '894 patent

Respondents argue that Schweiger alone, or in combination with the '894 patent, renders claims 1, 2, 4, 5, 7, 9-10, 13, 15-19, and 21 of the '836 patent obvious. (RIB at 44.) In support of this assertion, and relying on its anticipation arguments, Respondents submit that "[t]he only element [of claim 1] arguably not present in Example 20 of Schweiger is the amount of ZnO." (*Id.*) However, by Respondents' own admission in their anticipation analysis, Schweiger also does not disclose a lithium metasilicate glass ceramic. (RIB at 38.) Nothing in Respondents' obviousness argument demonstrates, or even suggests, how a person of ordinary skill in the art would understand Schweiger or the '894 patent to disclose that limitation. To the contrary, Respondents affirmatively assert that "both Schweiger and the '894 patents relate to exactly the same area of technology—the use of lithium disilicates to make dental restorations." (RIB at 45.) Accordingly, the undersigned finds that Respondents have failed to establish, by clear and convincing evidence, that Schweiger, alone or in combination with the '894 patent, discloses a lithium silicate glass ceramic as construed in this opinion. Therefore, the undersigned also finds that Respondents have failed to show that the asserted claims of the '836 patent are rendered obvious by those references.

b) Beall, alone or in combination with Petticrew

Respondents argue that claims 1, 2, 4, 5, 7, 9-10, 13, 15-19, and 21 of the '836 patent are obvious in view of U.S. Patent No. 5,219,799 to Beall *et al.* ("Beall," RX-0044), alone or combination with International Application Publication No. WO 95/32678 to Petticrew

("Petticrew," RX-0564). However, as with its other prior art based defenses, Respondents concede that "metasilicates are not disclosed in either Beall or Petticrew," and "[t]herefore, the combination of Beall and Petticrew (and all LiSi Press products) are outside the scope of claim 1 of the '836 patent." (RIB at 47.) Accordingly, the undersigned finds that Respondents have failed to establish, by clear and convincing evidence, that Beall, alone or in combination with Petticrew, discloses a lithium silicate glass ceramic as construed in this opinion. Therefore, the undersigned also finds that Respondents have failed to show that the claims 1, 2, 4, 5, 7, 9-10, 13, 15-19, and 21 of the '836 patent are rendered obvious by those references.

3. Secondary Considerations

Secondary considerations of nonobviousness may rebut a *prima facie* case of obviousness. Here, where Respondents have not made out a *prima facie* case of obviousness, there is no showing to rebut. Accordingly, the undersigned need not consider any secondary considerations of nonobviousness.

V. U.S. PATENT NO. 6,802,894

A. Overview

1. Asserted Claims

Ivoclar asserts claims 1, 2, 4, 16, 21, and 38 of the '894 patent. (CIB at 44.) Claims 1 and 38 are independent claims, while claims 2, 4, 16, and 21 depend directly or indirectly from claim 1. The asserted claims provide as follows:

1. A method of making a lithium disilicate dental product comprising:

   melting a starting glass composition at temperatures within the range of about 1200 to about 1600° C.;

   forming the molten glass into shaped blanks;

annealing the glass blanks at temperatures in the range of 300° to about 600° C. for a time in the range of about 15 minutes to about 8 hours;

subjecting the glass blanks to one or more heat treatments in the temperature range of from about 400° to about 1100° C. to convert the glass blanks into glass-ceramic blanks.

2. The method of claim 1 wherein the blanks are in the shape of pellets.

* * *

4. The method of claim 2 comprising: pressing the blanks into the dental product.

* * *

16. The method of claim 4 wherein the dental product is selected from the group consisting of orthodontic appliances, bridges, space maintainers, tooth replacement appliances, splints, crowns, partial crowns, dentures, posts, teeth, jackets, inlays, onlays, facing, veneers, facets, implants, abutments, cylinders, and connectors.

* * *

21. The method of claim 1 wherein the glass-ceramic comprises in weight percent:

about 62 to about 85% SiO_2 ;
about 5.1 to about 10 Al_2O_3 ;
about 8 to about 19% Li_2O; and
about 0.5 to about 12 % P_2O_5.

* * *

38. A dental product comprising a glass-ceramic consisting essentially of:

about 62 to about 85% SiO_2 ;
about 5.1 to about 10 Al_2O_3 ;
about 8 to about 19% Li_2O;
about 0.5 to about 12 % P_2O_5.
up to about 7% K_2O;
up to about 1.5% F;
up to about 7% BaO;
up to about 1% SrO;
up to about 5% Cs_2O;

up to about 4.9% B_2O_3 ;
up to about 5% ZnO;
up to about 7% CaO;
up to about 2% MgO;
up to about 5% Na_2O;
up to about 2% TiO_2 ;
up to about 3% ZrO_2 ;
up to about 1% SnO_2 ;
up to about 1% Sb_2O_3 ;
up to about 3% Y_2O_3 ;
up to about 1% CeO_2 ;
up to about 1% Eu_2O_3 ;
up to about 1% Tb_4O_7 ;
up to about 2% Nb_2O_5 ; and
up to about 2% Ta_2O_5 ; and

wherein the 3-point flexure strength is greater than about 370 MPa.

(JX-0004, '894 patent at Cls. 1, 2, 4, 16, 21, and 38.)

B. Level of Ordinary Skill in the Art

Complainants, Respondents, and Staff rely on the same assertions about the level of ordinary skill in the art for the '894 patent as they did for the '836 patent. (CIB at 44; RIB at 52; SIB at 53.) No new arguments or evidence have been presented to suggest that the level of ordinary skill in the art for the '894 patent should differ from that of the '836 patent. Accordingly, the undersigned finds that the level of ordinary skill in the art for the '894 patent is the same as that of the '836 patent, *i.e.*, ***someone with (i) a master's degree in chemistry, physics, ceramics, materials science and engineering, or chemical engineering, and (ii) at least 2 years of academic or industry experience making, studying, evaluating, or using glass-ceramic materials.***

C. Claim Construction

1. "annealing"

The term "annealing" appears in independent claim 1 of the '894 patent. The parties propose the following constructions for this term:

Complainants	Respondents	Staff
Plain and ordinary meaning: the process of slowly heating, slowly cooling, or isothermal maintenance of glass, which relieves internal stresses in the glass	heating in a separate heat treatment step to relieve internal stresses	"annealing" (plain and ordinary meaning) the glass blanks in a separate step

(SIB at 55; CIB at 45; RIB at 53.) Based on the parties' briefing, it does not appear that there is any serious dispute regarding the plain and ordinary meaning of "annealing." The parties may have used different words to describe the plain and ordinary meaning of "annealing," but the basic concept of manipulating the temperature of glass to relieve internal stress in the glass is common to all parties' proposals. Rather, the parties' dispute is over whether "annealing" must be a "separate step." Generally speaking, Respondents and Staff support construing "annealing" as a separate step in the method of claim 1. On this point, Complainants submit that Respondents and Staff each mean something different when they refer to a "separate step." (CRB at 28.) Specifically, Complainants argue that Respondents' proposal requires an annealing step that is separate from nucleation and crystallization, while Staff's proposal requires an annealing step that is separate from the claim limitation that follows annealing: "subjecting the glass blanks to one or more heat treatments . . . ." (*Id.*) Complainants agree with Staff's separate step argument, which they concede "is consistent with case law." (*Id.*)

The undersigned also agrees that Staff's proposal finds support in the law. Particularly, in *Phillips*, the Federal Circuit placed a clear emphasis on using the evidence intrinsic to a patent as the primary source of guidance for claim interpretation. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005). Consistent with that guidance, the undersigned notes that claim 1 of the '894 patent recites, in separate clauses, an annealing step and a heat treatment step. As Staff correctly notes, the law supports the conclusion that these two steps, which encompass two different procedures, and which the inventors recited as separate steps, should not be construed as a single element. *See Kaneka Corp. v. Xiamen Kingdomway Group Co.*, 790 F.3d 1298, 1305–06 (Fed. Cir. 2015); *LizardTech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1342–43 (Fed. Cir. 2005).

The specification also supports the conclusion that the annealing step of claim 1 is separate from the heat treatment step of claim 1. Particularly, example 1[3] from the specification describes annealing cast ingots in one step, and then heat treating the glass in bulk in another step. (JX-0004 at 9:44–53.) The "Description of the Invention" portion of the specification also describes annealing and heat treatment as two separate steps. (*Id.* at 5:36–41.) Accordingly, the intrinsic evidence supports the conclusion that the annealing step of claim 1 of the '894 patent is a separate step from the heat treatment step that converts the glass blanks into glass-ceramic blanks. (*See id.* at Cl. 1.)

Notwithstanding their concession in rebuttal briefing that the annealing and heating steps are separate steps because they are separate claim limitations, (CRB at 28), Complainants raise a

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[3] The '894 patent uses "example" in multiple contexts throughout the specification. Here, the undersigned refers to the heading "EXAMPLE 1" that appears in column 9 of the '894 patent. This should not be confused with "Ex. 1," which appears in Table 2 and refers to a specific composition.

litany of arguments for why Respondents' construction is incorrect. Most of those arguments are straw men, and mischaracterize Respondents' position. For example, Complainants argue that dependent claim 5 of the '894 patent, which recites:

> The method of claim 1 wherein crystallization of lithium disilicate is effected in the glass blanks after annealing when subjected to one or more heat treatments in the temperature range of from about 400° to about 1100°C,

is inconsistent with Respondents' and Staff's proposed constructions due to the doctrine of claim differentiation. (CIB at 46–47.) Specifically, Complainants focus on the word "after" in claim 5 as indicating that claim 1 does not have a temporal limitation on when the annealing and heat treating steps happen in relation to each other. (*Id.*) Complainants are generally correct that, because a dependent claim necessarily includes all the limitations of the claim from which it depends, as well as at least one additional limitation, claim 1 is broader than claim 5. However, in relying on that principle, Complainants mistakenly suggest that Respondents' proposal includes a temporal limitation that would require heat treatment after annealing. It does not. Respondents seek a construction that only requires "heating in a separate heat treatment step to relieve internal stresses." That construction imposes no temporal limitation other than that annealing and heat treatment may not be combined into a single step. Accordingly, Complainants' claim differentiation argument simply fails to address the actual dispute, which is whether the annealing step of claim 1 must be separate from the heat treatment step.

Complainants' arguments regarding the specification are also unpersuasive. First, Complainants' argument that the word "heating" appears nowhere in the specification, and therefore Respondents' construction must be incorrect because it uses the word "heating," is baffling. (CIB at 47-48.) Complainants' own proposed construction for annealing—"the process of slowly heating, slowly cooling, or isothermal maintenance of glass, which relieves internal stresses in the glass"—uses the word "heating." (*Id.* at 45.) The most generous reading of

Complainants' argument is that the process of annealing is not limited to heating materials, but may also encompass controlled cooling of a material. If that is what Complainants intended, they have not clearly said so. Complainants' related argument, that the words "separate step" appear nowhere in the specification is equally unpersuasive. Indeed, if the standard Complainants seek to employ is whether the words of the construction appear verbatim in the specification, they must concede that their own construction is unsupported. Most of the words of Complainants' construction, including "slowly heating," "slowly cooling," "isothermal," and "maintenance" do not appear in the specification. (*Compare* CIB at 45 *with* JX-0004.) As noted above, the specification supports the conclusion that the annealing step of claim 1 is separate from the heat treatment step of claim 1. Complainants' arguments to the contrary are meritless.

With respect to the prosecution history, Complainants again conflate Respondents' and Staff's position that the annealing step must be separate from the heat treatment step with an argument about the order of those steps. (*See* CIB at 49 ("claim 1 is broader [than claim 5] and does not recite "before," "after," or "thereafter," and should not be improperly limited as GC and Staff suggest.").) But the undersigned does not understand Respondents and Staff to be arguing that the annealing and heat treatment steps must happen in a particular order, but rather that they must be separate from each other. In pointing to the specification amendment that added the word "thereafter," Respondents and Staff find support for their position that the annealing step and the heat treatment step are not one in the same. (*See, e.g.*, RIB at 55 (citing JX-0005 at 152).) To the extent Complainants seek to establish that the examiner's rejection, and the response thereto, do not include an explicit discussion of the "separate step" dispute now at issue, the undersigned agrees and notes that this portion of prosecution history would likely not be sufficient to support a construction based on claim scope disavowal. But here, Respondents'

and Staff's construction need not rely on any disavowal argument because the plain language of claim 1 supports reading "annealing" as a separate step from the one or more heat treatments that convert glass to glass-ceramic. The fact that the specification was amended to disclose an example that is consistent with that reading merely bolsters Respondents' and Staff's position.

As for Complainants' arguments directed to the testimony of Respondents' expert, Dr. Rahaman, the undersigned finds that the construction of "annealing" is quite clear in light of the intrinsic evidence, and that extrinsic evidence is not needed for its construction. Accordingly, the undersigned has given no weight to the testimony of the parties' experts in construing this term.

Finally, in its reply brief, Complainants assert that both Respondents and Staff altered their construction after the hearing to require a "slow cooling step after annealing." (CRB at 26–27.) This criticism appears to follow from Respondents' and Staff's citation of Dr. Rahaman's testimony of what a person of ordinary skill in the art would understand "annealing" to mean. (*See* SIB at 56; RIB at 53.) The undersigned agrees that Dr. Rahaman's testimony is not entirely consistent with Respondents' asserted construction, which is "heating in a separate heat treatment step to relieve internal stresses." Staff, however, has always contended that "annealing" should be given its plain and ordinary meaning, (*see* SPB at 47), and Staff has consistently relied on Dr. Rahaman's testimony as an indicator of what the plain and ordinary meaning is. (*Id.*) The undersigned finds no fault in Staff advancing the same position in its post-hearing briefing as in its pre-hearing briefing. Regardless, Complainants' point is moot, because, as indicated *supra*, extrinsic evidence is not needed to construe "annealing," particularly when the only material dispute between the parties is whether the annealing step must be separate from

the heat treatment step of claim 1. On that point, the intrinsic evidence is clear an unambiguous: annealing and heat treatment are separate steps of claim 1.

For the reasons stated herein, the undersigned finds that "annealing" should be given its ***plain and ordinary meaning, and that as used in claim 1 of the '894 patent, the step "annealing the glass blanks at temperatures in the range of 300° to about 600° C. for a time in the range of about 15 minutes to about 8 hours," is a separate step from "subjecting the glass blanks to one or more heat treatments in the temperature range of from about 400° to about 1100° C. to convert the glass blanks into glass-ceramic blanks."***

2. "about"

The term "about" appears in independent claims 1 and 38, and dependent claim 21 of the '894 patent. The parties propose the following constructions for this term:

Complainants	Respondents	Staff
approximately	approximately	approximately

(SIB at 59; CIB at 50; RIB at 55.) As all parties acknowledge, there is no real dispute that where, as here, the term "about" is not given any more precise meaning by the intrinsic evidence, the appropriate construction is "approximately." (CIB at 50 ("There is no dispute that the intrinsic record for the '894 patent does not provide special meaning for the term "about," and thus it should be given its plain and ordinary meaning, i.e. 'approximately.'"); RIB at 55 ("the word *about* should be construed to mean 'approximately,' and there is no additional or more precise definition available anywhere in the intrinsic or extrinsic record."); SIB at 60 ("Because the applicants did not define, explicitly or by implication, 'about' in the specification, the term should be construed according to its plain and ordinary meaning to mean 'approximately.'").)

Notwithstanding this general agreement, Complainants and Staff push for additional construction to place precise limits on the range encompassed by "approximately." Respondents reject that approach and argue that it is inappropriate to give "approximately" precise numerical boundaries when there are none given by the intrinsic evidence. (*See* RIB at 55-56 ("the Commission may not simply invent a definition to add precision to what the patentee chose to leave imprecise, and if this imprecision causes the patentee any difficulty in proving a claim of infringement, that is the correct result as a matter of patent law.").)

The undersigned agrees with Respondents that, here, where the intrinsic evidence gives no additional guidance as to the specific precision that should be afforded "approximately," it is inappropriate to create such precision out of conflicting and conclusory expert testimony. Thus, the undersigned finds that "about" should be construed consistently with its ***plain and ordinary meaning, which is "approximately."*** Contrary to Staff's assertions, Respondents' proposal is not akin to arguing that "about" is indefinite without proof. (*Cf.* SRB at 12.) Respondents have not argued that any claim is indefinite[4] because of the recitation of "about" or "approximately," and the Federal Circuit has construed "about" to mean "approximately" without any apparent

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[4] The undersigned acknowledges that Respondents' assertion in their rebuttal brief that "[t]he Federal Circuit has affirmed the indefiniteness of 'about' . . ." is misleading insomuch as it suggests that Respondents are seeking a ruling that the term "about" is indefinite. (*See* RRB at 16.) Respondents' opening brief, however, does not support that suggestion, and, of course, neither does the case law. *Amgen*, the case that Respondents cite, involved a unique situation where the imprecision that accompanies the word "about" caused a particular problem insomuch as the imprecision could be interpreted to cover anticipatory prior art. *See Amgen, Inc. v. Chugai Pharm Co.*, 927 F.2d 1200, 1218 (Fed. Cir. 1991). Such is not the case here, and the greater weight of authority supports the proposition that terms of degree and approximation, such as "about," are not inherently indefinite, as Respondents' rebuttal brief seems to suggest. *Cf. One-E-Way, Inc. v. Int'l Trade Comm'n*, 859 F.3d 1059, 1063 (Fed. Cir. 2017) (explaining that terms such as "substantial" may be sufficiently definite in context of intrinsic evidence and skill in the art).

indefiniteness problem. *See, e.g., Ferring B.V. v. Watson Labs., Inc.-Fla.,* 764 F.3d 1382, 1389 (Fed. Cir. 2014); *Merck & Co. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1369 (Fed. Cir. 2005). Indeed, in affirming a district court that refused to provide "about" with a more specific construction in the absence of support in the specification, the Federal Circuit has stated:

> We think that the district court did not err in giving the term "about" its ordinary meaning and in refusing to give it a more specific construction. *See also Merck & Co., Inc. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1369–70 (Fed. Cir. 2005) (the term "about" should be given its ordinary and accepted meaning of "approximately" unless the patentee clearly redefines "about" in the specification). We affirm the district court's construction of "about" to mean "approximately," as well as its refusal to construe "about" to represent a particular numerical error rate. Under the circumstances it fell to Ferring, the party with the burden of proof on infringement, to produce evidence that the 2014 ANDA infringed by proposing a 75 percent by weight dissolution rate, under the district court's claim construction. Ferring produced no such evidence and made no claim that the ANDA infringed under the district court's claim construction

Ferring B.V. v. Watson Labs., Inc.-Fla., 764 F.3d 1382, 1389 (Fed. Cir. 2014). Under the guidance of *Ferring*, Complainants bear the burden of proof to establish infringement of the claims reciting "about" as construed according to that term's plan and ordinary meaning, which is "approximately." This is consistent with Respondents' position. (*See* RIB at 57.) Accordingly, the undersigned declines to import additional numerical range limitations into "about" where the parties concede that the intrinsic evidence lacks support for such additional limitations.

3. "glass ceramic"

The term "glass ceramic" appears in asserted independent claims 1 and 38, and asserted dependent claim 21 of the '894 patent. The parties propose the following constructions for this term:

Complainants	Respondents	Staff
Plain and ordinary meaning: a material with an ability to (a) form glass, and (b) control crystallization via nucleation.	lithium disilicate glass-ceramic	lithium disilicate glass-ceramic

(CIB at 54; RIB at 57; SIB at 63.) The root of the parties' dispute here is whether the plain and ordinary meaning of "glass ceramic" should be limited to glass ceramics with lithium disilicate as the main crystalline phase, or if it should retain its broader meaning, which could include glass ceramics with lithium metasilicate as the main crystalline phase. Complainants argue for the broad, plain and ordinary meaning, based on the absence of intrinsic evidence showing that the patentee intended to give "glass ceramic" a narrower meaning. (CIB at 54.) Respondents and Staff argue for the additional lithium disilicate limitation based on the claims and specification, which repeatedly reference lithium disilicate glass ceramics. (RIB at 57-59; SIB at 64.) The undersigned agrees with Respondents' and Staff's positions.

In reading the claims and the specification as a whole, it is impossible to conclude that a person of ordinary skill in the art would interpret the glass ceramics that are the subject of the '894 patent to include glass ceramics with lithium metasilicate as the main crystalline phase. Starting with the first page of the '894 patent, the title is, literally, "Lithium Disilicate Glass-Ceramics." (JX-0004 at Cover); *see also Ruckus Wireless, Inc. v. Innovative Wireless Sols., LLC*, 824 F.3d 999, 1003 (Fed. Cir. 2016) (relying on patent title to determine plain and ordinary meaning of claim term); *UltimatePointer, L.L.C. v. Nintendo Co.*, 816 F.3d 816, 823 (Fed. Cir. 2016) (same); *Exxon Chem. Patents, Inc. v. Lubrizol Corp.*, 64 F.3d 1553, 1557 (Fed. Cir. 1995) (same). The first line of the abstract indicates that "[t]his invention is directed to lithium disilicate ($Li_2Si_2O_5$) based glass-ceramics . . . ." (JX-0004 at Cover.) The field of invention

states that "[t]his invention relates generally to glass-ceramics comprising lithium disilicate . . . ." (*Id.* at 1:16–19.) The background of the invention discusses lithium disilicate glass ceramics exclusively. (*Id.* at 1:23–2:33.) The summary of the invention states that "[t]his invention is directed to lithium disilicate ($Li_2Si_2O_5$) based glass-ceramics . . . ." (*Id.* at 2:35–38.) And, the first line of the description of the invention states that "the present invention provides glass-ceramic compositions comprising a glassy matrix and lithium disilicate ($Li_2Si_2O_5$)." (*Id.* at 3:53–55.)

To be clear, this is not a situation where a single embodiment in the specification deals with lithium disilicate glass ceramics. All of the embodiments described in the specification deal with lithium disilicate glass ceramics. If there is an embodiment directed to lithium metasilicate glass ceramics, which would be covered by Complainants' proposed construction, Complainants have not identified it. (*Cf.* CIB at 54.) In fact, the *only* reference to metasilicate in the specification is as follows: "The best properties are obtained when the lithium metasilicate (Li_2SiO_3) and silica phases are nearly absent, the volume fraction of Li_3PO_4 is less than about 5% and the volume fraction of lithium disilicate ($Li_2Si_2O_5$) is between about 35% and about 60%." (JX-0004 at 8:16–20.) In other words, far from incorporating lithium metasilicate glass ceramics within the scope of the invention, the '894 patent's disclosure teaches persons of ordinary skill in the art that the absence of lithium metasilicate is connected to desirable properties of glass ceramic.

The only evidence adduced by Complainants in support of their position is conclusory expert testimony, which, as matter of law cannot be used to contradict the clear meaning of a claim term as given by the intrinsic evidence. (*See* CIB at 54 (citing CX-0709C at Q/A at 13; *see also* RX-1586C at Q/A at 44); *Phillips*, 415 F.3d at 1318 ("a court should discount any expert

testimony "that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history").) Moreover, the particular expert testimony relied upon by Complainants appears to relate only generally to the meaning of glass ceramics without consideration of evidence intrinsic to the '894 patent. Relying on such testimony, to the exclusion of the intrinsic evidence, would be akin to simply using a dictionary to determine the meaning of "glass ceramic." That approach to claim construction, of course, was expressly rejected in *Phillips*. *See* 415 F.3d at 1318.

The intrinsic evidence in this instance overwhelmingly supports the conclusion that a person of ordinary skill in the art would understand the term "glass ceramic" in the context of the '894 patent to refer lithium disilicate glass ceramics. Complainants have not provided evidence sufficient to support a different conclusion. Accordingly, the undersigned construes "glass ceramic" to mean ***"lithium disilicate glass-ceramic."***

4. "dental product"

The term "dental product" appears in asserted independent claims 1 and 38 of the '894 patent. The parties propose the following constructions for this term:

Complainants	Respondents	Staff
Plain and ordinary meaning: a product that is particularly well-suited for dental applications, such as for making dental restorations	A material that has been shaped for placement into a patient's mouth	a material (including a dental restoration) for placement into a patient's mouth

(CIB at 55; RIB at 60; SIB at 65.) The parties' proposed constructions only partially illustrate the underlying dispute over the meaning of "dental product." The only material dispute with respect to the term "dental product" appears to be whether the meaning of "dental product"

encompasses a glass ceramic blank, prior to machining or pressing, or whether glass ceramic blanks are excluded from the scope of the term "dental product." Complainants argue that the term "dental product" "is easily understood, not highly technical, and neither the claims nor specification suggest the patentee imparted a different definition from the plain and ordinary meaning." (CIB at 55.) Complainants also suggests that Respondents' proposal is based on a patentee as lexicographer approach to claim construction, thus implying that Respondents are asserting something other than the plain and ordinary meaning of "dental product." (*See id.*) Complainants also criticize Respondents' approach as giving "dental product" the same definition as "dental restoration," a result Complainants say is foreclosed by intrinsic evidence. (*Id.*) In terms of affirmative evidence to supports their own construction of "dental product," Complainants rely on the testimony of their expert, Dr. Griggs, (*see* CX-0709C at Q/A at 72–73), a product brochure for Respondents' LiSi Press product, (CX-0301), a portion of the '894 patent specification reciting "dental product or restoration," (JX-0004 at 3:14), and a portion of cross-examination testimony from the evidentiary hearing that reads as follows:

> Q. What kind of dental products does [GC] sell?
> A. A cement....
> Q Hold on a second. So cement is a dental product, but ... LiSi Press is a what?
> A. A laboratory product, it's a fabrication material....
> Q. What other type of dental products does GC make?
> A. I don't have a list in front of me.
> Q. You can't think of any others?
> A. We make, I don't know, glass ionomer restorative.
> Q. Is that a dental restoration?
> A. That's a material that can be used in the fabrication of a dental restoration....
> Q. So that's a dental product, but LiSi Press is not a dental product; is that right?
> A. Correct.

Tr. 323:24–324:7, 326:2–21. Based on this evidence, Complainants seek a construction for "dental product" that includes glass ceramic blanks, such as the LiSi Press products.

By contrast, Respondents seek a construction that "makes clear that the term *dental product* does not include a *blank*." (RIB at 60 (emphasis in original).) In support of their position, Respondents point to dependent claims 4 and 12 as precluding blanks from being dental products under a claim differentiation theory. (*See id.*) Respondents also point to dependent claim 16, which is in the form of a Markush group, as evidence that a dental product must be a material shaped for placement into a patient's mouth. Respondents argue that the specification is also consistent with excluding blanks from the definition of "dental product." (*See id.*) Like Complainants, Respondents also point to expert testimony in support of their construction. (*See id.* (citing RX-2329C at Q/A at 54-78; RX-2331C at Q/A at 219-224; RX-2344 at 1; RX-1586C at Q/A at 144-154).)

Staff's approach is different from the parties'. Particularly, Staff's primary point is that "dental product" should be construed such that it is broader than the term "dental restoration." (*See* SIB at 65–66.) It is unclear whether, under Staff's proposal, a glass ceramic blank would constitute a "dental product."

The preamble of Claim 1 of the '894 patent recites "[a] method of making a lithium disilicate dental product comprising . . ." and then gives a series of steps that form glass blanks as an intermediate product, and glass-ceramic blanks as a final product. (JX-0004 at Cl. 1.) Thus, the plain claim language of claim 1 supports the conclusion that glass-ceramic blank produced by the method is the dental product recited in the preamble. (*See id.*) Dependent claims 4 and 12 provide, however, the additional steps of "pressing the blanks into the dental product," and "machining the glass ceramic blanks into the dental product," respectively. (*See id.* at Cls. 4, 12.) At the same time, the specification acknowledges that glass-ceramic pellets or blanks can be used to form dental products or restorations. (*See id.* at 3:11–16; 6:59–61.) And,

dependent claim 16 is a Markush group where the dental product of the claim is "selected from the group consisting of orthodontic appliances, bridges, space maintainers, tooth replacement appliances, splints, crowns, partial crowns, dentures, posts, teeth, jackets, inlays, onlays, facing, veneers, facets, implants, abutments, cylinders, and connectors," which suggests that the term dental product on its own is broader than the species given in claim 16. (*See id.* at Cl. 16.)

Taken as a whole, the undersigned finds that "dental product" should be construed more broadly than "dental restoration" and should include glass-ceramic blanks, such as those that are the final product of the steps recited in claim 1 of the '894 patent. Respondents' reliance on claims 4 and 12 to establish a contrary result is misplaced. Claims 4 and 12, by virtue of their dependency, must add an additional limitation to the claims upon which they depend. In claim 4, the additional limitation is adding a pressing step, while in claim 12, the additional limitation is adding a machining step. The fact that these additional steps also result in a dental product does not indicate that the steps of claim 1 do not result in a dental product as well. Respondents err in assuming that the additional limitations of claims 4 and 12 are the creation of a dental product. Such a reading is inconsistent with claim 1, which, by its own terms, recites a process for creating a dental product wherein the final product is a glass-ceramic blank. The steps of claim 1 already result in a dental product; claims 4 and 12 simply add a pressing or machining step that is not otherwise required by claim 1.

The extrinsic evidence provided by the parties is largely unhelpful. All of the expert testimony is conclusory, and merely parrots back portions of the claims and specification. Notably absent from the experts' testimony is any discussion of the state of the art with respect to this term, or whether a particular art-specific convention would inform the meaning of "dental product;" these are the types of questions for which expert testimony may actually be helpful.

See Teva Pharm. USA, Inc., 135 S. Ct. at 841 ("[e]xperts may be examined to explain terms of art, and the state of the art, at any given time, but they cannot be used to prove the proper or legal construction of any instrument of writing." (quoting in *Winans v. New York & Erie R. Co.*, 62 U.S. (1859) (internal quotation marks omitted))). What is persuasive, however, is the cross-examination testimony of GC's corporate witness, which tends to support Complainants' assertion that Respondents exclusion of blanks from the definition of "dental product" is not consistent with the knowledge in the art, but rather is contrived for purposes of this litigation. (*See* Tr. 323:24–324:7, 326:2–21.)

For all of these reasons, the undersigned finds that "dental product" should be construed to have its ***plain and ordinary meaning, which does not exclude glass-ceramic blanks.***

5. "wherein the 3-point flexure strength is greater than about 370MPa"

The term "wherein the 3-point flexure strength is greater than about 370MPa" appears in asserted independent claim 38 of the '894 patent. The parties propose the following constructions for this term:

Complainants	Respondents	Staff
Plain and ordinary meaning: the strength of a ceramic as determined by ISO 6872	Indefinite, but if not, then construed as a measurement according to 1995 version of the ISO 6872 standard.	the strength of a ceramic as determined by ISO 6872

(SIB at 67; CIB at 56; RIB at 61, 64.) There is broad agreement that, if not indefinite, "wherein the 3-point flexure strength is greater than about 370MPa" should be construed to require measurement consistent with the ISO 6872 standard. (CIB at 56; RIB at 64; SIB at 67.) Respondents add a level of additional clarity by noting that the ISO 6872 standard has gone through several revisions over time, and that because the 1995 version of the ISO 6872 standard

was the one in effect at the time of both filing and issuance of the '894 patent. (RIB at 62.) However, the parties dispute whether this term is indefinite because the '894 patent specification describes taking 3-point flexure strength measurements from samples that are shaped like bars in some instances and rods in others. (*See* JX-0004 at 10:66–11:2.)

Complainants and Staff both assert that the specification explicitly defines 3-point flexure strength as measured by ISO 6872, and therefore based on the measurement of bars, not rods. (SIB at 67; CIB at 56.) Having reviewed the citations to the specification provided by Complainants and Staff, the undersigned cannot agree. Complainants point to the following portion of the specification as defining "3-point flexure strength" in accordance with ISO 6872:

> Results of the 3-pt flexure tests for glass-ceramic pellets fabricated by three alternative processes described above for glass-ceramic compositions of Examples 6 and 8 are summarized in the Table 4 below.
>
> TABLE 4
>
Glass-Ceramic Composition Pellet type	Example 6			Example 8		
	CAST-CRYSTAL-LIZED	SINTERED	POWDER-CRYSTAL-LIZED	CAST-CRYSTAL-LIZED	SINTERED	POWDER-CRYSTAL-LIZED
3-pt Flexure Strength per ISO 6872, MPa	420 ± 60	290 ± 40	250 ± 30	440 ± 60		
As-Pressed Rod (D = ⅛") 3-pt Flexure Strength, MPa	370 ± 40	320 ± 20	260 ± 20	370 ± 30	270 ± 40	300 ± 20
>
> Comparing the strength values obtained for the various types of pellets, the cast-crystallized pellets exhibited the highest flexure strength compared to the other two types of pellets and were fabricated with the least number of processing steps involved, The noticeable decrease in strength for the sintered and powder-crystallized pellets was attributed to accumulation of processing flaws introduced during the extra processing steps, especially the vacuum sintering step required to produce these types of pellets. The cast crystallized pellets herein generally have a 3-point flexure strength exceeding about 350 MPa and preferrably [sic] equal to or greater than about 370.

(JX-0004 at 12:5-37.) There is only a single reference to ISO 6872 in this portion of the specification, and it does not define 3-point flexure strength as being measured by that standard.

To the contrary, to the extent Table 4 says anything "explicitly" about measuring 3-point flexure strength, it explicitly demonstrates that the inventors utilized two methods for measuring 3-point flexure strength—one method based on ISO 6872, and one method based on as-pressed rods. According to the specification, these two methods produce different results, with different error ranges. (JX-0004 at Table 4.) To the extent this portion of the specification expresses any preference for one method over the other, it may disclose a preference for the as-pressed rod measurement method given that the specification states that "[t]he cast crystallized pellets herein generally have a 3-point flexure strength exceeding about 350 MPa and preferrably [sic] equal to or greater than about 370," and the 370 MPa value appears in Table 4 for the as-pressed rod 3-point flexure measurements, not the ISO 6872 3-point flexure strength measurements. (*Id.* at 12:35-38.) Accordingly, the undersigned does not agree that the portion of the specification relied on by Complainants to construe this term dictates that 3-point flexure strength must be measured according to ISO 6872.

Staff relies on a different portion of the specification to argue that 3-point flexure strength must be measured according to ISO 6872. (SIB at 68 (citing JX-0004 at 10:66–11:2).) Specifically, the portion of the specification Staff relies on provides:

> These three types of pellets were used to make rectangular bars (23x4x2 mm) and rods (23 mm lengthx3.2 mm diameter) for measuring flexural strength in a standard 3-pt bending fixture described in ISO 6872 specification.

(JX-0004 at 10:66–11:2.) Here again, rather than suggesting strict adherence to ISO 6872, which would require testing only of bars, this portion of the specification explicitly recites two different testing methods: one with rectangular bars and one with rods. (*Id.*) The reference to ISO 6872 is limited to describing the 3-point bending fixture used for both of these methods. (*Id.*) No part of this portion of the specification expresses a preference for measuring rectangular bars over rods. (*Id.*)

The only other evidence relied on by Complainants or Staff to support construing the 3-point flexure strength to require measurement according to ISO 6872 is a single question from the witness statement of Complainants' expert, Dr. Griggs. (*See* CIB at 56 (citing CX-0709C at Q/A at 76).) That question and answer reads as follows:

> Q76. Dr. Griggs, in conducting your analysis of infringement and domestic industry for this investigation, did you form an opinion about the plain and ordinary meaning of the claim term "3-point flexure strength?"
>
> A76. Yes. I reviewed the patents and prosecution histories and determined that a POSITA in the field of dental glass-ceramics would understand from reading the patents that the term "3-point flexure strength" has its plain and ordinary meaning, which is: the strength of a ceramic as determined by ISO 6872, and as described in the patent specification. This is because ISO 6872 is an international standard developed specifically for dental ceramic materials, and it is the standard recited in the specification for measuring 3-point flexure strength.

(CX-0709C at Q/A at 76.) Dr. Grigg's testimony is conclusory, and also unhelpful insomuch as it fails to address, or even acknowledge, that the '894 patent discloses two methods of measuring flexure strength, one using rectangular bars and the other using as-pressed rods. Moreover, as detailed above, the '894 patent does not recite measuring 3-point flexure strength according to ISO 6872, and therefore Dr. Grigg's statement that ISO 6872 "is the standard recited in the specification for measuring 3-point flexure strength" is simply wrong. It is well-settled that an expert's testimony cannot be used to contradict the intrinsic evidence for claim construction purposes. *See, e.g.*, *SkinMedica, Inc. v. Histogen Inc.*, 727 F.3d 1187, 1210 (Fed. Cir. 2013) ("In whole, [the expert's] opinions are unhelpful to our analysis here. They are conclusory and incomplete; they lack any substantive explanation tied to the intrinsic record; and they appear to conflict with the plain language of the written description."). Here, the specification simply does not say what Complainants and Staff say it does, and Dr. Grigg's testimony cannot, as a matter of law, re-write the specification so that it does.

Respondents seize on the fact that the '894 patent recites two different methods for measuring 3-point flexure strength—one based on rectangular bars and one based on rods—to argue that the claims reciting a 3-point flexure limitation are indefinite. (*See* RIB at 111.) Respondents review and interpret the disclosure of the specification in a manner largely consistent with the undersigned's interpretation *supra*. (*Id.* at 111-113.) Respondents also point to a portion expert testimony from their expert, Dr. Clark, to support their indefiniteness argument. (*See* RX-1586C at Q/A at 597-613.) Portions of Dr. Clark's testimony, like Dr. Grigg's testimony, are conclusory and drawn to legal questions, which testimony is generally unhelpful to the undersigned. However, Dr. Clark does provide some helpful testimony with respect to understanding the feasibility of testing cylindrical rods with the three-point bending fixture described in ISO 6872. Particularly, Dr. Clark explains the structure of the 3-point bending fixture described in ISO 6872. (*Id.* at Q/A at 603.) He explains that cylindrical rods can in fact be tested for flexure strength with the 3-point bending fixture of ISO 6872. (*Id.* at Q/A at 604–606.) He explains that the formula for determining flexure strength of a cylindrical rod is known to persons of ordinary skill in the art, and available in ASTM 1684. (*Id.* at Q/A at 607.) And, he explains that there is no compatibility obstacle to using that formula with the raw data generated from the 3-point bending fixture of ISO 6872 to determine flexure strength for cylindrical rods. (*Id.* at Q/A/ at 608.) In sum, Dr. Clark's testimony supports the conclusion that the '894 patent's reference to the use of the bending fixture from ISO 6872 does not dictate that 3-point flexure strength, as used in the patent, only refers to the measurement of rectangular bars.

Complainants' first argument in response to Respondents' indefiniteness assertions is that Dr. Clark used the wrong legal standard in forming his opinions on indefiniteness, *i.e.*, Dr. Clark applied the pre-*Nautilus* insolubly ambiguous standard instead of the post-*Nautilus* reasonable

certainty standard. (CIB at 103.) Complainants posit, on that basis, that none of Dr. Clark's opinions on indefiniteness should be given any weight. (*Id.* at 103–04.) As the undersigned explained at the hearing, to the extent any expert strays into offering opinions on legal issues, that testimony shall be given no weight. However, as detailed above, significant portions of Dr. Clark's testimony are not legal in nature, and are relevant and probative with respect to what was known in the art regarding ISO 6872 and flexure testing. The legal standard for indefiniteness is inapposite to determining the value of those portions of Dr. Clark's testimony.

Next, Complainants argue that counsel for Respondents conceded during opening statements "that the '894 patent does disclose which shape of the specimen should be tested through its recitation of the ISO 6872 standard." (CIB at 104 (citing Eichen, Tr. at 92:9–11).) Complainants' representation of this portion of the transcript is extremely misleading. During opening statements, counsel for Respondents walked through the portions of the '894 patent specification dealing with 3-point flexure strength measurements, and correctly indicated that there were two lines of results in Table 4, one of which reported results for 3-point flexure measurements taken from rectangular bars according to ISO 6872, and the other reporting 3-point flexure strength measurements taken from as-pressed rods. (Eichen, Tr. at 91:19–92:15.) Respondents' counsel did not concede that the recitation of ISO 6872, in one row of Table 4, dictated that every flexure strength measurement performed in the context of the '894 patent should employ rectangular bars, particularly when the very next row of Table 4 indicates otherwise. Complainants' assertion of a dispositive concession is inaccurate.

Next, Complainants attempt to rebut Respondents' infringement argument with the testimony of another of its expert witness, Dr. Kelly. (*See* CIB at 105 (citing CX-0705C at Q/A at 608, 612, 614, 615).) Dr. Kelly's answers are unhelpful to Complainants, however, because

they presume that the '894 patent specification directs flexure strength testing to be completed according to ISO 6872, which it does not. (*See, e.g.,* CX-0705C at Q/A at 612.) Further some of Dr. Kelly's explanation restricting flexure strength testing to rectangular bars is based on his belief that the term "dental product," which appears in the preamble of the claims reciting the flexure strength limitation, is limited to "finished and polished" glass ceramic dental products. (*See id.* at Q/A at 614.) No party, including Complainants, argued that "dental product" should be construed to require finishing and polishing, and Dr. Kelly gives no explanation for importing those requirements into the construction of "dental product." Accordingly, Dr. Kelly's exclusion of rods from flexure strength testing because they are unpolished is unpersuasive.

Finally, Complainants argue that, when taking into account the margins of error recited in Table 4, the as-pressed rods "fall outside of the claims." (CIB at 105.) Basic arithmetic shows that assertion to be false. Considering example 6 from Table 4 as illustrative, the recited value for 3-point flexure strength of cast-crystallized rectangular bars is 420 ± 60 MPa, and the value for cast-crystallized as-pressed rods in 370 ± 40 MPa. Thus, taking the margins for error into account, the measured value for rectangular bars ranges from 360 to 480 MPa, and the measured value for as-pressed rods ranges from 330 to 410 MPa. In other words, a flexure strength greater than about 370 MPa is within the margin of error reported for the measurement of as-pressed rods in the '894 patent. To the extent Complainants are arguing that, because a portion of the margin for error for the as-pressed rod measurement extends below 370 MPa, the measurement is outside the scope of the claims, the same thing is true of the reported rectangular bar measurement, which also extends below 370 MPa. At best, this line of reasoning is inapposite for Complainants.

Since the Supreme Court decided *Nautilus*, the Federal Circuit has further clarified the application of the reasonable certainty standard to claim limitations that are subject to multiple measurement methods.[5] Specifically, in *Dow Chemical*, the Federal Circuit framed the relevant indefiniteness inquiry as "whether the existence of multiple methods leading to different results without guidance in the patent or the prosecution history as to which method should be used renders the claims indefinite." *Dow Chem. Co. v. Nova Chemicals Corp. (Canada)*, 803 F.3d 620, 634 (Fed. Cir. 2015). Here, the intrinsic evidence discloses two methods for measuring 3-point flexure strength—one using rectangular bars, and one using as-pressed cylindrical rods. The intrinsic evidence also discloses that these two measurement methods lead to different results. And, the intrinsic evidence is silent on which of these two methods should be used to determine flexure strength with respect to the claims in which that term appears. The undersigned is not persuaded, either, that the knowledge in the art provides any guidance to an ordinary artisan that would resolve the question of which measurement method to employ. For all of these reasons, the undersigned finds that Respondents have established, by clear and convincing evidence, that the claims reciting the limitation: "wherein the 3-point flexure strength is greater than about 370MPa," are invalid as indefinite. Therefore, independent claims 36 and 38 are indefinite.

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[5] Staff relies on two cases for the proposition that "the mere possibility of different results from different measurement techniques does not render the claim indefinite." (SIB at 79 (citing *PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1563 Fed.Cir.1996); *Takeda Pharm. Co. Ltd. v. Zydus Pharms. USA, Inc.*, 743 F.3d 1359, 1367 (Fed. Cir. 2014)).) These cases were decided prior to *Nautilus*, and portions of their discussion of the standards for adjudicating indefiniteness are likely no longer good law. *Cf., e.g., A. Schulman, Inc. v. Polyone Corp., Inc.*, No. 1:15 CV 1760, 2017 WL 2805857, at *7 (N.D. Ohio Apr. 27, 2017), *aff'd sub nom. A. Schulman, Inc. v. Polyone Corp.*, 712 F. App'x 1007 (Fed. Cir. 2018). Regardless, those cases, which dealt with theoretical differences between measurement methods, are inapposite here where the '894 patent specification explicitly reports that the two disclosed methods of measurement produce different results.

D. Infringement

1. Claim 1

There are only two disputes with respect to whether the accused products infringe this claim. The first is whether the preamble is satisfied with respect to the term "dental product." The second is whether the "annealing" step is practiced by the method used to make the accused products. In light of the construction given to "dental product," (*see* supra V.C.4), Respondents' non-infringement argument with respect to that term must fail. Specifically, Respondents argue that, "[t]he LiSi Press products are, in fact, *blanks* and as such are not shaped for placement into a patient's mouth," and thus are not "dental products." (RIB at 64.) However, as explained *supra*, the term "dental product," as used in the '894 patent includes lithium disilicate glass ceramic blanks such as the LiSi Press blanks. Accordingly, the undersigned finds that the preamble of claim 1 is satisfied by the method for manufacturing LiSi Press products.

The second dispute regarding infringement of this claim is whether Respondents practice a separate annealing step in creating the LiSi Press products. Complainants assert that they do, while Respondents and Staff assert there is no separate annealing step.

To show that the annealing limitation is satisfied, Complainants first argue that [redacted]. (*See* CIB at 60–62.) Complainants then argue that [redacted]." (*Id.* at 62–63.) Next, Complainants argue that the specific annealing conditions are met because [redacted]. (*See id.* at 63–64.) Finally, with respect to whether annealing is a separate step from heat treatment in the LiSi Press manufacturing process, Complainants argue that annealing [redacted]

[redacted] (CIB at 65.)

By contrast, Respondents argue that "GC's manufacturing process does not include a separate annealing step" because the process [redacted] (RIB at 66.) Additionally, Respondents argue that, even if there was no requirement that annealing happen in a separate step from heat treatment, Complainants have not presented evidence sufficient to carry their burden on infringement for the annealing limitation. (*See id.* at 67–69.) The basis of this second argument really appears to be that Respondents believe Complainants can only meet their burden to prove infringement with direct testing evidence. (*See id.* at 67 ("instead of actually examining samples and taking measurements, Ivoclar's proof of *annealing* here is actually a grab bag of GC documents that somewhere mention the word or idea of annealing.").)

Staff effectively joins both of Respondents' arguments, relying on Respondents' expert to argue that "[t]he evidence shows that the Accused Products are not made according to the method of claim 1, which includes the separate step of annealing the glass blanks at temperatures in the range of 300° to about 600° C. for a time in the range of about 15 minutes to about 8 hours." (SIB at 68 (internal quotation marks omitted).) And, also arguing that "Ivoclar has not come forward with any competent evidence, including testing results, showing that the Accused Products were annealed." (*Id.*)

As an initial matter, the undersigned notes that the annealing limitation has been construed as a separate step from the heat treatment step recited in claim 1. (*See* supra § V.C.1.) Accordingly, Complainants must show, by a preponderance of the evidence, that the LiSi Press

manufacturing process includes an annealing step, according to the conditions recited in claim 1, that is separate from the heat treatment steps recited in that claim. Here, Complainants have not made that showing.

Strangely, in their opening brief, Complainants appear to admit that, "annealing is subsumed within GC's heat treatment process." (CIB at 65.) That admission is consistent with the testimony of Complainants' expert, Dr. Griggs, who points to the same evidence to satisfy both the annealing and heat treatment limitations of claim 1. (*Compare* CX-709C at Q/A at 100–101 *with* Q/A at 111–112.) Specifically, Dr. Griggs relies on two documents produced by Respondents that are flow charts that purport to show the LiSi Press manufacturing process in 2015 and 2017. (*Id.*; *see also* CX-0364C (2015 process), CX-0363C (2017 process).) In the 2015 process flow chart, Dr. Griggs points to step 14, which is named "Heat Treatment" to show that the LiSi Press process practices both limitations. (*See* CX-709C at Q/A at 101, 112). Specifically Dr. Griggs first states for the annealing step:

[redacted]

(*Id.* at Q/A at 101 (emphasis added).) Then, for the heat treatment step, Dr. Griggs states:

[redacted]

[redacted]

(*Id.* at Q/A at 112 (emphasis added).) In short, Dr. Griggs relies on a single process to satisfy both the annealing and heat treatment limitations of claim 1. As discussed *supra*, this is not what is recited in claim 1 of the '894 patent, and is therefore not sufficient to show infringement by the LiSi Press process. Dr. Griggs's analysis of the 2017 process is similar. For the annealing step, he states:

[redacted]

(*Id.* at Q/A at 101 (emphasis added).) And then for the heat treatment step he states:

[redacted]

(*Id.* at Q/A at 112 (emphasis added).) Here again, Dr. Griggs relies on the same single step in the manufacturing process to show that the LiSi Press process practices both the annealing and heat treatment limitations claim 1 of the '894 patent.

The underlying disagreement here is an extension of the parties' claim construction dispute. The evidence upon which Complainants rely makes it quite clear that the LiSi Press manufacturing process includes a heat treatment step wherein [redacted]. (CX-0364C (2015 process), CX-0363C (2017 process).) That step satisfies the heat treatment limitation of claim, which Respondents and Staff do not dispute. Complainants attempt, however, to pick a portion of that heat treatment process, namely, the portion where the glass ingot is between 300–600°C, to show the presence of an annealing step. As Complainants admit, "annealing is subsumed within GC's heat treatment process." (CIB at 65.) It is not a separate step, as required by claim 1.

Complainants' theory of infringement with respect to the annealing step is similar to the one rejected by the Federal Circuit in *Kaneka Corp. v. Xiamen Kingdomway Grp. Co.*, 790 F.3d 1298, 1305 (Fed. Cir. 2015). There, discussing whether an "oxidation" step had to be active or passive, the Federal Circuit explained that:

> A process is defined as an act, or a series of acts, and thus because the claims affirmatively recite the step of "oxidizing," "oxidizing" cannot be interpreted as doing nothing, or to simply allow oxidation to occur on its own. ***Nor can the other recited claim steps, such as culturing or disrupting, suffice as the active step resulting in oxidation. If those other steps qualify as the oxidation step, the patentee's inclusion of a separate oxidation step would have no significance.***

Id. (internal quotations omitted) (emphasis added). Here, Complainants attempt to show the annealing step of claim 1 by arguing that internal stress is relieved during the heat treatment

steps. As noted in *Kaneka Corp.*, such an interpretation gives no significance to the fact that the patentee of the '894 patent included annealing as a separate step.

For the reasons set forth above, the undersigned finds that Complainants have not shown, by a preponderance of the evidence, that the LiSi Press manufacturing process satisfies the "annealing" limitation of claim 1 of the '894 patent. Given that every limitation of an asserted claim must be present in an accused device to establish infringement, the undersigned also finds that the accused products do not infringe independent claim 1 of the '894 patent.

2. Claims 2, 4, 16, and 21

"One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim." *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n. 9 (Fed. Cir. 1989). Given that the undersigned has found that independent claim l of the '894 patent is not infringed, claims 2, 4, 16, and 21, which depend from claim 1, are also not infringed for the same reasons.

3. Claim 38

As discussed above, the undersigned has found that claim 38 of '894 patent is invalid as indefinite based on the 3-point flexure strength limitation recited therein. (*See* supra § V.C.5.) Because an invalid claim cannot be infringed, *Richdel, Inc. v. Sunspool Corp.*, 714 F.2d 1573, 1580 (Fed. Cir. 1983) ("The claim being invalid there is nothing to be infringed."), the undersigned also finds that the LiSi Press products do not infringe claim 38 of the '894.

E. Domestic Industry – Technical Prong

1. Claim 1

a) "lithium disilicate dental product"

Complainants argue that their e.max CAD products are lithium disilicate dental products based on the testimony of their expert, Dr. Griggs. (CIB at 81 (citing CX-0709C, Griggs WS at Q/A at 202; CX-0471 at 4).) Dr. Grigg's testimony confirms, however, that e.max CAD blocks do not contain lithium disilicate until dental practitioners temper "the product to make a lithium disilicate dental restoration." (CX-0709C at Q/A at 202.) Complainants submit, however, that "Ivoclar has been making dental restorations from e.max CAD and using them for clinical trials for over ten years," and therefore have practice this limitation of claim 1. (CIB at 82 (citing JX-0027C at 246:19–247:8).) The evidence Complainants rely on for that assertion, however, is not persuasive. The only arguably relevant portion of the deposition transcript Complainants cite states: "We have over ten years of clinical trials." (JX-0027C at 247:3–4.) That isolated statement, which says nothing of the state of crystallization, disilicates versus metasilicates, tempering, or heat treatments, simply is not enough to conclude that Complainants themselves directly practice this limitation.

Complainants alternatively argue that they indirectly practice this limitation because purchasers of e.max CAD mill the block and then temper it into a lithium disilicate restoration. (CIB at 82–83.) Complainants are effectively relying on a theory of joint, induced, or contributory domestic industry, albeit without disclosing which one, or the legal basis in support thereof. (*See id.*) Assuming for the moment that there is legal support for the proposition that the technical prong of the domestic industry requirement can be satisfied with a showing of infringement under 35 U.S.C. § 271 (b) or (c), Complainants would still need to show direct infringement of claim 1 of the '894 patent. *See AIDS Healthcare Found., Inc. v. Gilead Scis.,*

Inc., 890 F.3d 986, 992 (Fed. Cir. 2018) ("Liability for induced infringement requires that some other entity is directly infringing the patent."); *Fujitsu Ltd. v. Netgear Inc.*, 620 F.3d 1321, 1326 (Fed. Cir. 2010) ("To establish contributory infringement, the patent owner must show the following elements relevant to this appeal: 1) that there is direct infringement, 2) that the accused infringer had knowledge of the patent, 3) that the component has no substantial noninfringing uses, and 4) that the component is a material part of the invention.").

The Federal Circuit, sitting *en banc*, recently explained that:

> Direct infringement under § 271(a) occurs where all steps of a claimed method are performed by or attributable to a single entity. Where more than one actor is involved in practicing the steps, a court must determine whether the acts of one are attributable to the other such that a single entity is responsible for the infringement. We will hold an entity responsible for others' performance of method steps in two sets of circumstances: (1) where that entity directs or controls others' performance, and (2) where the actors form a joint enterprise.

Akamai Techs., Inc. v. Limelight Networks, Inc., 797 F.3d 1020, 1022 (Fed. Cir. 2015) (internal citations omitted). The *Akamai* court went on to indicate that whether an entity directs or controls the acts of another should be analyzed under general principles of vicarious liability, while a joint enterprise requires proof of the following four elements:

(1) an agreement, express or implied, among the members of the group;
(2) a common purpose to be carried out by the group;
(3) a community of pecuniary interest in that purpose, among the members; and
(4) an equal right to a voice in the direction of the enterprise, which gives an equal right of control.

Id. at 1022–23. Thus, to satisfy the technical prong of the domestic industry requirement via reliance on a combination of Complainants' own acts and the acts of downstream purchasers, *i.e.*, through divided infringement, Complainants must show that they or a downstream purchaser—dental practitioners most likely—direct or control the other's performance, or that they have formed a joint enterprise. The evidence cited by Complainants does not make either showing.

First, Complainants cite to the witness statement of Marcel Schweiger, Director of Inorganic Chemistry R&D for Ivoclar Vivadent AG, for the proposition that Ivoclar "manufactures and sells e.max CAD as a partially crystallized lithium disilicate dental product in the metasilicate state." (CIB at 82; CX-0712C at Q/A at 13, 70–71.) However, Mr. Schweiger actually resists characterizing e.max CAD blocks as lithium disilicate, and acknowledges that the blocks are metasilicate that only become disilicate after an additional crystallization step. (CX-0712 at Q/A at 70–71.) Upon review of Mr. Schweiger's witness statement, the undersigned finds no discussion of what entity performs that final crystallization step, and no discussion bearing on whether Complainants direct or control the entity performing the final crystallization step, or are in a joint enterprise with the entity performing the final crystallization step.

Second, Complainants cite to e.max CAD instructions to show that "e.max CAD is sold with instructions for use, which includes milling the partially crystallized e.max CAD block to form a fully crystallized lithium disilicate dental restoration." (CIB at 82 (citing CX-0573 at 10–22).) The e.max CAD instructions do in fact show a crystallization step, and show particular firing parameters for achieving crystallization. (*See* CX-0573 at 21, 50.) There is, however, no serious dispute that Complainants' domestic industry products, which are metasilicate blocks, are converted into disilicate dental products by dental practitioners in the United States. The question is whether a single entity can be attributed with carrying out all of the steps in the method of claim 1. The undersigned is not aware of any precedent that would support finding that Complainants direct and control the dental practitioners who perform the crystallization step of claim 1 simply because Complainants provided instructions on how to perform the crystallization process. To the contrary, since deciding *Akamai*, the Federal Circuit appears to have acknowledged a distinction between merely guiding or instructing another to perform one

or more steps of a claim, and conditioning the receipt of a particular benefit by another on that person's performance of those claim steps. *See Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*, 845 F.3d 1357, 1366 (Fed. Cir. 2017) ("But the evidence regarding the critical nature of folic acid pretreatment and physicians' practices support a finding that physicians cross the line from merely guiding or instructing patients to take folic acid to conditioning pemetrexed treatment on their administration of folic acid."). Mere guidance or instruction are not hallmarks of direction and control, but conditioning a benefit on performance is. *See id.*

Complainants rely on a document titled "Scientific Documentation IPS e.max CAD" for a similar purpose to the e.max CAD instructions. (CIB at 82; CX-0471 at 4–5.) Here again though, the document establishes only that metasilicate e.max CAD blocks can be converted to disilicate dental products through additional processing. The document is simply inapposite on the question of whether Complainants direct and control the actions of another with respect to the additional processing. In a similar vein, Complainants rely on the testimony of two experts, Drs. Kelly and Griggs, to establish that both have made disilicate dental products from metasilicate e.max CAD blocks. (CIB at 82 (citing CX-0704C at Q/A at 104–07; Tr., Griggs, at 245:4–11).) Neither expert's testimony demonstrates direction or control by Complainants. None of the other evidence cited by Complainants in support of their indirect practice argument fares any better. (*See* CIB at 82–83 (citing CX-0707C at Q/A at 13; CX-0688C; CX-0471; CX-0121C; CX-0573; Tr., Clark, at 407:21–408:3).) At bottom, Complainants misunderstand what they must prove to establish divided infringement of claim 1 of the '894 patent, and concordantly satisfaction of the technical prong of the domestic industry requirement. Complainants' focus has been on showing that "lithium disilicate dental restorations are made [from e.max CAD] by dental labs and dentists in the United States." (CIB at 83.) Such a showing is surely necessary

to establish practice of claim 1, but it is not sufficient on its own. Complainants must also show that the infringing acts, in this case the practice of the method steps recited in claim 1, are attributable to a single entity. Complainants have not addressed that point, and the evidence cited by Complainants is not sufficient for the undersigned to reach that conclusion *sua sponte*. Accordingly, the undersigned finds Complainants have not shown that they practice all the steps of claim 1 of the '894 patent, and thus cannot satisfy the technical prong of the domestic industry requirement through that claim.

2. Claims 17–20 and 34

Each of claims 17–20 and 34 depend from claim 1 of the '894 patent, and therefore incorporate the lithium disilicate limitation from the preamble of claim 1. As discussed *supra*, Complainants have not shown that their e.max CAD blocks are lithium disilicate dental products, nor have Complainants shown that they direct and control, or are in a joint venture with, the dental practitioners who do convert e.max CAD blocks to lithium disilicate dental products. Accordingly, the undersigned finds Complainants have not shown that they practice all the steps of claims 17–20 or 34 of the '894 patent, and thus cannot satisfy the technical prong of the domestic industry requirement through those claims.

3. Claim 36

Claim 36 includes the 3-point flexure strength limitation the undersigned has found to be indefinite. (*See* supra § V.C.5.) Because Complainants "cannot satisfy the technical prong of the domestic industry requirement by practicing an invalid claim," *Certain Beverage Brewing Capsules, Components Thereof, and Products Containing the Same*, Inv. No. 337-TA-929, Comm'n Op. at 81 (Apr. 5, 2016) (Public Version), the undersigned finds that Complainants cannot satisfy the technical prong of the domestic industry requirement through claim 36.

4. Conclusion

For the reasons described in this section, the undersigned finds that Complainants have not satisfied the technical prong of the domestic industry requirement for the '894 patent.

F. Validity

Respondents assert three grounds for invalidity with respect to the '894 patent: (1) anticipation based on U.S. Patent No. 4,189,325 to Barrett *et al.*; and International Patent Application Publication No. WO 00/34196 to Brodkin *et al.*; (2) obviousness based on Beall alone or in combination with Petticrew; and obviousness based on International Patent Application Publication No. WO 00/34196 to Brodkin *et al.*; and (3) lack of written description or indefiniteness under 35 U.S.C. § 112. (*See* RIB at V.E) Respondents also argue that there are no secondary considerations of nonobviousness that overcome their assertions of obviousness.

1. Anticipation

a) U.S. Patent No. 4,189,325 to Barrett et al.

(1) Claim 1

Respondents argue that claims 1, 2, 4, 16, and 34 of the '894 patent are anticipated by U.S. Patent No. 4,189,325 to Barrett *et al.* ("Barrett," RX-0027). (RIB at 93.) Complainants assert that Barrett does not anticipate any of these claims because "Barrett does not disclose the 'method of making a lithium disilicate dental product' limitation of claim 1." (CIB at 96.) More specifically, Complainants assert that Barret does not disclose glass that is a lithium disilicate as opposed to lithium metasilicate. (*See id.* at 97.) Whether Barrett discloses a lithium disilicate glass ceramic is the only element in dispute with respect to anticipation of claim 1, and also the only disputed element common to anticipation of claims 2, 4, 16, and 34 of the '894 patent.

To support its assertion that Barrett discloses a lithium disilicate glass ceramic, Respondents point to the abstract of Barrett and the testimony of its expert, Dr. Clark. (RIB at 93 (citing RX-0027 at Abstract; RX-1586C at Q/A at 382).) Dr. Clark explains that while Barrett does not use the phrase "lithium disilicate glass-ceramic," it does recite Li_2—Al_2O_3—CaO—SiO_2, which Dr. Clark submits may be abbreviated as "LACS" glass-ceramic, and "is widely known and understood in the field that this Li2O—Al2O3—CaO—SiO2 or LACS glass-ceramic in the proportions described in Barrett is lithium disilicate." (RX-1586C at Q/A at 382.)

Respondents also assert that according to "Ivoclar's expert, Dr. Kelly, the glass-ceramic compositions disclosed in Barrett are lithium disilicate glass-ceramic compositions." (RIB at 93 (citing Kelly, Tr. at 447:25-448:9).) This portion of testimony from the hearing is impeachment where counsel for Respondents played a portion of Dr. Kelly's deposition testimony, where, when asked whether the LACS glass ceramic disclosed in Barrett is lithium disilicate, Dr., Kelly stated: "It probably is, yes." (*See* Tr., Kelly, 447:25-448:9.) This statement stands in contrast to Dr. Kelly's witness statement and hearing testimony, in which Dr. Kelly indicated that Barrett did not disclose a lithium disilicate. (Kelly, Tr. at 446:20–447:21; CX-0705C at Q/A at 233.)

Finally, Respondents rely on the '894 patent's description of Barrett, which states that "Barret [sic] et al. is directed to a glass-ceramic comprising lithium disilicate for use in dental restorations." (JX-0004 at 1:26–29.)

In opposition, Complainants rely on their expert, Dr. Kelly's, testimony. (CIB at 96-97 (citing CX-0705C at Q/A at 230-237).) The principal point of the cited testimony from Dr. Kelly is that Barrett does not disclose lithium disilicate because the disclosed crystallization temperature of 700°C is not high enough to produce lithium disilicate. (CX-0705C at Q/A at 232-237.) Complainants also assert that Respondents' expert, Dr. Clark, "simply assumed that

the disclosed Li_2O-Al_2O_3-CaO-SiO_2 ("LACS") glass system in Barrett was a lithium disilicate." (CIB at 97 (citing Tr., Clark at 406:1-18).)

Staff joins Respondents and asserts that Barrett discloses a lithium disilicate dental restoration. Staff relies on the description of Barrett in the '894 patent and on a portion of *Constant v. Advanced Micro Devices, Inc.*, 848 F.2d 1560, 1570 (Fed. Cir. 1988) that states that a "statement in the patent that something is in the prior art is binding on the applicant and patentee for determinations of anticipation and obviousness." (SIB at 75-76.)

The undersigned finds that Barrett discloses a lithium disilicate dental product. That conclusion is supported by the hearing testimony of Dr. Clark and the description of Barrett in the '894 patent itself. (*See* RX-1586C at 382; JX-0004 at 1:26-29.) Complainant's affirmative evidence to the contrary comes from the testimony of Dr. Kelly. However, Dr. Kelly's credibility on this issue is undermined by his inconsistent answers between his deposition and his witness statement. And, though counsel for Complainants attempted to address the inconsistencies on redirect examination, Dr. Kelly did not offer a persuasive explanation for the discrepancy in his testimony. (*See* Kelly, Tr. at 496:6-497:25.) Indeed, Dr. Kelly attempted to explain the discrepancy by suggesting that the predicate question during his deposition was ambiguous as to the term "glass." (*Id.* at 497:20-21.) However, the question at Dr. Kelly's deposition was fairly specific, directing Dr. Kelly to lines 25 through 32 of column 5 in Barrett, and asking if the glass being described there is lithium disilicate. (*Id.* at 447:25-448:4.) There appears to be nothing confusing in the question, and Dr. Kelly's response indicating that the glass would be lithium disilicate was immediate and unremarkable.

At base, what is disclosed by Barrett is a question of fact, and the undersigned finds that, considering all the evidence presented, that Respondents have shown by clear and convincing evidence that Barrett discloses a lithium disilicate dental product.

In addition to the lithium disilicate limitation, Respondents assert that all of the remaining elements of claim 1 of the '894 patent are disclosed by Barrett. (RIB at 93-95.) Neither Complainants nor Staff dispute that the other limitations of claim 1 are disclosed by Barrett. Accordingly, and in view of the evidence presented by Respondents, the undersigned finds that all of the remaining elements of claim 1 of the '894 patent are disclosed by Barrett. (*See* RX-0027; RX-1586C at Q/A at 382-386 (comparing Barrett to elements of claim 1 of the '894 patent).) Because Barrett discloses every element of claim 1 of the '894 patent, the undersigned finds that claim 1 of the '894 patent is anticipated by Barrett.

(2) Claim 2

Dependent claim 2 incorporates the additional limitation: "The method of claim 1 wherein the blanks are in the shape of pellets." (JX-0004 at Cls., 2, 4, 16.) Respondents assert that Barrett discloses this limitation by reciting: "the ultimate user may be provided with intermediate glass ingots of simple shape (cubes, spheres or, preferably, cylinders) and sufficient volume so that one ingot can be processed into one final glass-ceramic article (e.g. a single dental restoration)." (RIB at 95 (citing RX-0027 at 4:33-37; RX-1586C at Q/A at 391).) Complainants counter that "Barrett does not disclose forming glass-ceramic blanks 'in the shape of pellets', as required by claim 2; rather, Barrett, to the extent it discloses a blank, discloses a glass blank that can be in the shape of pellets. (CIB at 97 (citing CX-0705C at Q/A at 239).) Complainants' counter argument is not persuasive. Particularly, the distinction Complainants rely on is not supported by the language of claim 2, *i.e.*, the claim recites only a "blank," without

indicating a glass blank or a glass-ceramic blank. Complainants cannot distinguish Barrett on the basis of an additional unrecited limitation in claim 2. Accordingly, the undersigned finds that Barrett discloses the additional limitation of dependent claim 2, and therefore Barrett anticipates claim 2 of the '894 patent. (*See* RX-0027 at 4:33-37; RX-1586C at Q/A at 391.)

(3) Claim 4

Dependent claim 4 incorporates the additional limitation: "The method of claim 2 comprising: pressing the blanks into the dental product." (JX-0004 at Cl. 4.) Respondents assert that Barrett discloses this limitation because it states that "[c]ommercially available investment dental laboratory molds, e.g. Ceramigold and Bio-Vest molds, may be used in the manufacture of the dental restorations of this invention, i.e., the same type of molds currently found in dental laboratories for use in making cast alloy dental restorations." (RIB at 95 (citing RX-0027 at 7:45-50; RX-1586C at Q/A at 394).) Complainants counter that this limitation is not disclosed "because in Barrett the glass blanks are melted into molten glass that are then shaped into a dental restoration using an investment mold (i.e., not pressed), and then crystallized to form a glass ceramic." CX-0705C at Q/A at 240. Respondents' only response to Complainants' criticism is that the portion of Barret Respondents rely on states otherwise. (RRB at 49.)

On the record available and in view of the evidence cited by the parties, the undersigned finds that Barrett does not disclose the additional limitation of claim 4. Specifically, the portion of Barrett that Respondents rely on says nothing of pressing. (*See* RX-0027 at 7:45-50.) To the extent Respondents assert that a person of ordinary skill in the art would interpret the cited portion of Barrett as disclosing pressing based on their expert's testimony, Complainants have adduced contrary evidence from its own expert. Given the dispute between the experts, and the absence of clear disclosure of pressing in Barrett, the undersigned cannot conclude that

Respondents have met their burden to show that Barrett discloses the additional limitation of claim 4 by clear and convincing evidence.

(4) Claim 16

Claim 16 depends from claim 4, and thus incorporates all the limitations of claim 4. Accordingly, the undersigned finds that Barrett does not anticipate claim 16 for at least the reasons that Barrett does not anticipate claim 4. *See RCA Corp.*, 730 F.2d at 1446 ("Since claim 3 of the Cole patent is dependent upon claim 2, which is not anticipated, claim 3 cannot be anticipated.")

(5) Claim 34

Claim 34 depends from independent claim 1, and includes the additional limitation: "The method of claim 1 wherein the shaped blanks are formed by: pouring the glass into molds to form the blanks; and removing the glass blanks from the molds after the blanks have hardened." (JX-0004 at Cl. 34.) Respondents assert that Barret discloses this limitation because "Barrett discloses '[t]he melt is then cast into a preheated dental laboratory investment mold and allowed to cool (air quench) into a glass article of the final desired shape.'" (RIB at 96 (citing RX-0027 8:11-13; RX-1586C at Q/A at 418).) Respondents add that a "POSITA would understand that the 'glass article of the final desired shape' described in Barret include glass blank [sic] because, as noted above, Barrett discloses that the glass ingots may be of any simple shape, such as cubes, spheres or cylinders." (RIB at 96 (citing RX-0027 at 4:33-37).) Complainants counter that "Barrett does not disclose pouring the glass melt into a mold shaped as a blank because Barrett pours the glass melt into the shape of the dental restoration – not into the shape of a blank." (CIB at 98 (citing CX-0705C at Q/A at 239; RX-0027 at 5).)

The evidence cited by Complainants is not persuasive. Particularly, the citation appears to have been made in error. Dr. Kelly's opinion on whether Barrett anticipates claim 34 is found in Q/A pair 243, and states only that claim 34 cannot be anticipated for the same reasons claim 1 cannot be anticipated. (CX-0705C at Q/A at 243.) No additional opinions specific to claim 34 are given. (*Id.*) By contrast, the portion of Barrett identified by Respondents—lines 11 through 13 of column 8—discloses casting of melted glass into a mold that could take various shapes, including that of a blank. (*See* RX-1586C at Q/A at 418).) Accordingly, the undersigned finds that Barrett discloses the additional limitation of claim 34, and therefore claim 34 is anticipated by Barrett.

b) WO '196

Respondents assert that International Patent Application Publication No. WO 00/34196 to Brodkin *et al.* ("WO '196," RX-0563) anticipates claims 1, 2, 4, 16-21, 34, 36, and 38 of the '894 patent.

(1) Claim 1

While Respondents submit WO '196 anticipates claim 1 of the '894 patent, Respondents' assertion is contingent on the adoption of a construction for the term "annealing" that would allow the annealing limitation of claim 1 to be subsumed within the heat treatment limitation of claim 1. (*See* RIB at 98 ("if the Commission were somehow to adopt Ivoclar's construction that annealing is not a separate heating step, then WO '196 clearly anticipates this limitation.").) Because the undersigned has construed the annealing limitation of claim 1 to be a separate step from the heat treatment limitation, and because Respondents provide no evidence or analysis to show anticipation by WO '196 under such a construction, the undersigned finds that

Respondents have failed to show, by clear and convincing evidence, that WO '196 anticipates claim 1 of the '894 patent.

(2) Claims 2, 4, 16-21, and 34

Claims 2, 4, 16-21, and 34 of the '894 all depend in some way from independent claim 1. Accordingly, each of those claims includes the annealing limitation of claim. Because Respondents have not shown that the annealing limitation of claim 1 is disclosed in WO '196, the undersigned finds that Respondents have not shown, by clear and convincing evidence, that WO '196 anticipates claims 2, 4, 16-21, or 34 of the '894 patent. *See RCA Corp.*, 730 F.2d at 1446.

(3) Claims 36 and 38

Claims 36 and 38 both include the "wherein the 3-point flexure strength is greater than about 370MPa" limitation, which the undersigned has found to be indefinite, and which therefore renders claims 36 and 38 indefinite. (*See* supra § V.C.5.) Respondents acknowledge that their anticipation arguments with respect to these claims and WO '196 are contingent on the failure of their indefiniteness arguments. (RRB at 50.) Accordingly, given that the undersigned has found that claims 36 and 38 are indefinite, the undersigned also finds that Respondents have not established that those claims are anticipated by WO '196.

2. Obviousness

a) Beall, alone or in combination with Petticrew

Respondents assert that Beall, alone or in combination with Petticrew, renders obvious claims 1, 2, 4, 16-21, 34, 36, and 38 of the '894 patent. (RIB at 102.)

(1) Claim 1

The only substantive dispute regarding whether the combination of Beall and Petticrew render claim 1 obvious is whether that combination "would meet the 'lithium disilicate dental product' limitation of claim 1." (CIB at 100.) Respondents assert that Beall discloses lithium disilicate glass-ceramics, and "Petticrew expressly teaches that lithium disilicate glass-ceramic materials disclosed in both Petticrew and Beall can be used to produce dental products." (RIB at 102 (citing RX-1586C at Q/A at 815; RX-0564 at 23:19-21).) Respondents therefore conclude that "it would have been obvious for a POSITA to combine the teachings of Beall and Petticrew to arrive at a *lithium disilicate dental product*, as required by claim 1." (RIB at 102 (emphasis in original).) Complainants counter that "Petticrew teaches away from the use of the compositions in Beall as suitable dental restorations." (CIB at 100 (citing CIB § IV.E.2.b; CX-0705C at Q/A at 339-342; Kelly, Tr. at 470:12-24, 499:9-501:10).) Staff joins Respondents and argues that "Petticrew explicitly directs one of ordinary skill in the art to Beall," and therefore "the evidence shows that a person of ordinary skill in the art would have been motivated to combine the teachings of the prior art references to achieve the inventions of claims 1, 2, 4, and 16, and would have had a reasonable expectation of success in doing so." (SIB at 78 (citing RX-1586C at Q/A at 425–439, 443–445).)

At bottom, the parties' dispute is about whether Respondents have established a motivation to combine the Beall and Petticrew prior art references. Petticrew is titled "Method for Molding Dental Restorations and Related Apparatus," and the invention therein is described as "a process for the formation of dental restorations from glass-ceramic materials and the resulting dental restorations." (RX-0564 at Cover.) There can be no serious dispute that Petticrew discloses both a dental product and a method of making a dental product. (*See id.*)

Petticrew goes on to indicate that the "preferred glass-ceramic materials for use in this invention are lithium disilicate glass-ceramic materials." (*Id.* at 23.) Petticrew then goes on to indicate that "[o]ther lithium disilicate glass-ceramic materials which may be used in this invention are disclosed in U.S. patent 5,219,799," which is Beall. (*Id.*; *see also* RX-0044 at Cover (Beall).) It is difficult to conceive of a clearer motivation to combine two references than the explicit statement found in Petticrew. Petticrew, quite literally, instructs the reader to look to Beall for other lithium disilicate glass-ceramics that can be used in the dental product invention of Petticrew. (RX-0564 at 23.) The undersigned disagrees with Complainants that Petticrew teaches away from using the compositions in Beall. Particularly, Complainants, and their expert, mistakenly focus on the fact that Beall is directed to tableware, and not a dental product. But Respondents do not rely on Beall for the disclosure of a dental product. Rather, Respondents rightly rely on Petticrew for the disclosure of a lithium disilicate glass-ceramic dental product, and rely on Beall for the more specific limitations directed to how to create that glass-ceramic and its compositional characteristics. Based on the clear disclosures of Petticrew and Beall, the undersigned finds that a person of ordinary skill in the art would have been motivated to combine the teachings of the two references to create a lithium-disilicate dental product, as recited in the preamble of claim 1 of the '894 patent.

As there are no other substantive[6] disputes regarding whether claim 1 of the '894 patent is rendered obvious by the combinations of Petticrew and Beall, and given that Respondents

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[6] Complainants contend that that Respondents are "precluded from contending that claim 1 of the '894 patent (from which all other asserted dependent method claims depend) is rendered obvious over Beall in combination with Petticrew," in view of the undersigned's ruling on Complainants' motion *in limine* no. 3. (CIB at 100.) Respondents disagree, and argue that Complainants' motion in *limine* was limited to certain question and answer pairs in the witness statement of Respondents' invalidity expert. (RRB at 52.) Thus, Respondents assert that they

have produced evidence sufficient to show that the combination of those references includes every limitation of claim 1 of the '894 patent, (*see* RX-1586C at Q/A at 428-431), the undersigned finds that Respondents have established that claim 1 of the '894 patent is invalid as obvious in view of the combination of Petticrew and Beall.

(2) Claim 2

Respondents assert that the combination of Beall and Petticrew would render obvious the additional limitation of claim 2—*wherein the blanks are in the shape of pellets*—because "Petticrew discloses the desirability of pellets of lithium disilicate glass-ceramics," and "Petticrew also discloses blanks of lithium disilicate material in the shape of pellets (but uses the term 'buttons' for these pieces)." (RIB at 103 (citing RX-1586C at Q/A 435-436; RX-0564 at 16-17).) Complainants counter that the combination of Beall and Petticrew "does not teach blanks in the shape in pellets," but "instead, Beall teaches casting molten glass into slabs having specific dimensions." (CIB at 100-101 (citing RX-0044 at 9:10–13; CX-0705C at Q/A at 343–345).)

Beall and Petticrew disclose forming glass blanks into different shapes. Beall discloses forming the molten glass into slabs, (RX-0044 at 9:10–13), while Petticrew discloses glass-ceramic material in the form of buttons, (RX-0564 at 16). Respondents do not explain why the disclosure of Beall and Petticrew are interchangeable with respect to the shapes of the glass

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are free to argue the combination of Beall and Petticrew for claim 1 as long as they do not rely on the stricken question and answer pairs. (*Id.*) The undersigned agrees with Respondents. Complainants' motion *in limine*, by its own terms, is directed to certain expert testimony. (*See* Mot. Dkt. No. 1050-026.) Complainants' did not request, and the undersigned did not issue, an order prohibiting Respondents from relying on the combination of Beall and Petticrew to establish the obviousness of claim 1. Rather, the undersigned's order excluded certain expert testimony, which Respondents have not cited or relied on. The undersigned finds no fault in Respondents' compliance with the undersigned's ruling on Complainants' motion *in limine* no. 3.

blanks. While Petticrew definitely indicates that the lithium disilicates of Beall can be used to create dental products such as those disclosed in Petticrew, it does not go so far as to suggest that portions of the method for creating lithium disilicates disclosed in Beall can be swapped with portions of the method disclosed in Petticrew. The undersigned is not persuaded that the testimony of Respondents' expert, who summarily states that "Beall teaches forming a slab and one would have had a reasonable expectation of success pouring the molten glass into other forms, such as pellets," is sufficient to show, by clear and convincing evidence, that a person of ordinary skill in the art would have been motivated to combine Beall and Petticrew in the way Respondents suggest. (*Cf.* RX-1586C at Q/A at 436.) Accordingly, the undersigned finds that Respondents have not shown that claim 2 of the '894 patent is invalid as obvious in view of the combination of Beall and Petticrew.

(3) Claims 4 and 16

Claims 4 and 16 depend from claim 2. Accordingly, the undersigned finds that claim 4 and 16 of the '894 patent, which incorporate all the limitations of claim 2, are not rendered obvious by the combination of Beall and Petticrew for at least the same reasons that claim 2 is not rendered obvious by that combination.

(4) Claim 17

Respondents assert that dependent claim 17, which depends from claim 1, and which includes additional compositional limitations, is rendered obvious by the combination of Beall and Petticrew because "Example 3 of Beall (RX-0044 at Table I) contains 74.2% SiO_2, 3.54% Al_2O_3, 15.4% Li_2O, 3.25% K_2O and 3.37% P_2O_5, all within the ranges recited in claim 17." (RIB at 104 (citing RX-1586C at Q/A at 447-449; RX-0044 at Table I).) Complainants counter that Respondents have failed "to provide any explanation for why a POSITA would select Beall

Example 3 to render obvious [claim 17]." (CIB at 101.) Complainants' argument ignores the fact that Petticrew explicitly directs readers to look to the lithium disilicate compositions of Beall for use in creating the dental products of Petticrew. Such direction is entirely consistent with what was required in *In re Fine*, which Complainants erroneously assert supports their argument. *See* 837 F.2d 1071, 1075 ("Obviousness is tested by "what the combined teachings of the references would have suggested to those of ordinary skill in the art. But it cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination." (internal citations omitted)).

Accordingly, and considering the evidence submitted by Respondents, (RX-1586C at Q/A at 447-449; RX-0044 at Table I), the undersigned finds that claim 17 of the '894 patent is obvious in view of the combination of Beall and Petticrew.

(5) Claim 18

Respondents assert that claim 18, which depends from claim 17, and which includes additional compositional limitations as well as a molar ratio limitation, is rendered obvious by the combination of Petticrew and Beall. (RIB at 104.) Respondents' argument has two features: (1) that all of the additional compositional limitations are preceded by the phrase "up to about" and thus any disclosure that lacks those elements completely satisfies the limitations; and (2) that "it would have been obvious for a POSITA to adjust the relative amounts of each of the components." (*Id.*) Complainants counter that Respondents have failed "to provide any explanation for why a POSITA would select Beall Example 3 to render obvious [claim 17]," (CIB at 101), and that Beall Example 3 also fails to satisfy the "wherein the molar ratio of (Na2O + K2O + CaO + SrO + BaO) / (Al2O3 + ZnO) ≥ 1.3" limitation as the ratio of Beall Example 3 is only 0.994." (CIB at 101.)

For the reasons described previously, the undersigned finds Complainants' first argument unpersuasive given Petticrew's explicit instructions to look to Beall for the composition of a lithium disilicate glass-ceramic. However, the undersigned agrees with Complainants that Example 3 of Beall does not disclose the molar ratio required by claim 18. (*See* RX-0044 at Table 1.) The undersigned also finds that the single conclusory sentence from Respondents' expert stating: "As for the molar ratio, it would have been obvious to a person of skill in the art to adjust the relative amounts of each of the components," falls well short of the clear and convincing evidence required to establish obviousness. (*See* RX-1586C at Q/A at 452.) Accordingly, the undersigned finds that Respondents have not shown that claim 18 of the '894 patent is invalid as obvious in view of the combination of Beall and Petticrew.

(6) Claim 19

Respondents assert that claim 19, which depends from claim 1, and which includes certain compositional ranges, is rendered obvious in view of the combination of Beall and Petticrew because "Beall discloses broad ranges matching the components recited in claim 19." (RIB at 105 (citing RX-0044 at 2:3-12).) Complainants counter that Respondents have not shown why a person of ordinary skill in the art would select "the appropriate amounts of the claimed oxides for claims 19-20 after reviewing broad generic ranges for such oxides in Beall." (CIB at 101 (citing CX-0705C at Q/A at 346-47).)

The undersigned agrees with Complainants that Respondents have not shown why a person of ordinary skill in the art would have been motivated to select the particular compositional ranges recited in claim 19 from the broad ranges recited in the specification of Beall. Respondents appear to have relied on hindsight, *i.e.*, using claim 19 itself as a guide to interpret Beall, which is impermissible to establish obviousness. (*See* CX-0705C at Q/A at 350.)

Accordingly, the undersigned finds that Respondents have not shown that claim 19 of the '894 patent is invalid as obvious in view of the combination of Beall and Petticrew.

(7) Claim 20

Claim 20 depends from claim 19. Accordingly, the undersigned finds that claim 20 of the '894 patent, which incorporates all the limitations of claim 19, is not rendered obvious by the combination of Beall and Petticrew for at least the same reasons that claim 19 is not rendered obvious by that combination.

(8) Claim 21

Respondents assert that claim 21, which depends from claim 1, and which includes certain compositional ranges, is rendered obvious in view of the combination of Beall and Petticrew because "Example 7 of Beall (RX-0044 at Table I) contains 71.7% SiO_2, 9.49% Al_2O_3, 9.47% Li_2O and 5.48% P_2O_5, all within the oxide ranges of claim 21." (RIB at 105.) Complainants counter that Respondents have failed "to provide any explanation for why a POSITA would select . . . Beall Example 7 to render obvious claim 21." (CIB at 101 (citing CX-0705C at Q/A at 346–347).) Complainants' argument ignores the fact that Petticrew explicitly directs readers to look to the lithium disilicate compositions of Beall for use in creating the dental products of Petticrew. Such direction is entirely consistent with what was required in *In re Fine*, which Complainants erroneously assert supports their argument. *See* 837 F.2d 1071, 1075 ("Obviousness is tested by what the combined teachings of the references would have suggested to those of ordinary skill in the art. But it cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination." (internal citations omitted)).

Accordingly, and considering the evidence submitted by Respondents, (RX-1586C at Q/A at 460-461; RX-0044 at Table I), the undersigned finds that claim 21 of the '894 patent is obvious in view of the combination of Beall and Petticrew.

(9) Claim 34

Respondents assert that claim 34, which depends from claim 1, and which further requires pouring the molten glass into molds and removing the glass blanks from the molds, is rendered obvious in view of the combination of Beall and Petticrew because Beall discloses "forming the molten glass into shaped blanks," further discloses "[a]fter the glass slabs were removed from the annealer, samples for testing purposes were cut from each . . . and those test samples plus the remainder of the slabs subjected to the heat treatments reported in Table II," and because a person of ordinary skill "would understand that, in order to cut samples from the formed slab (i.e. blank), the slab must be removed from the mold." (RIB at 105-106.) Complainants do not specifically address the obviousness of claim 34.

Considering the evidence submitted by Respondents, (RX-1586C at Q/A at 429, 467-468; RX-0044 at 10:9-13), the undersigned finds that claim 34 of the '894 patent is obvious in view of the combination of Beall and Petticrew.

(10) Claims 36 and 38

Both claims 36 and 38 of the '894 patent include the 3-point flexure strength limitation the undersigned found to be indefinite *supra*. (*See* supra § V.C.5.) Because a determination of obviousness necessarily requires a comparison of the prior art to the limitations of the claim, but here the 3-point flexure strength limitation is indefinite, the undersigned cannot determine that claims 36 and 38 of the '894 patent are obvious in view of the combination of Beall and Petticrew.

b) WO '196

Respondents assert that WO '196 renders obvious claims 1, 2, 4, 16-21, 34, 36 and 38 of the '894 patent. (RIB at 107.) The thrust of Respondents' argument appears to be that the only potentially missing element from the disclosure of WO '196 is the annealing step of the listed claims. (RIB at 107.) As with anticipation though, Respondents' condition their argument on a claim construction that the undersigned has not adopted. Particularly, Respondents explain that "if the Commission were to adopt Ivoclar's definition for *annealing*, then *annealing* as defined by Ivoclar is also occurring during the heat treatment steps disclosed in WO '196, even without being explicitly mentioned." (*Id.* at 107-108.) Because the undersigned has not adopted the construction for annealing Respondents rely on to argue obviousness over WO '196, Respondents' obviousness arguments with respect to claims 1, 2, 4, 16-21 and 34 must fail.

With respect to claims 36 and 38, as noted above, both claims are indefinite by virtue of their recitation of the 3-point flexure strength limitation. (*See* supra § V.C.5.) Accordingly, the undersigned cannot determine that claims 36 and 38 of the '894 patent are obvious in view of WO '196 because it is not possible to compare the 3-point flexure strength limitation of the claims to the prior art, which is a required step in any obviousness analysis.

3. Secondary Considerations

Complainants offer two categories of secondary considerations to rebut Respondents' obviousness assertions: (1) unexpected results; and (2) commercial success. (CIB at 102–103.)

a) Unexpected Results

Complainants assert that the inventors of the '894 patent "discovered that a lithium disilicate glass ceramic with superior strength, solubility, translucency, chemical durability, and formability could be achieved without key components used by the prior art," and therefore

obtained unexpected results. (CIB at 103.) Particularly, Complainants assert that "the inventors of the '894 patent found that lithium disilicate dental glass ceramics could exclude La_2O_3 (which according to Schweiger (RX-0062) was critical to providing good chemical stability)." (CIB at 103.) Respondents counter that Complainants La_2O_3 "argument is incorrect, because the omission of La_2O_3 was not a difference over prior art glass-ceramics, and Dr. Kelly fails to cite any evidence showing that the glass ceramics without La_2O_3 have superior properties over those that include it." (RIB at 108-109.)

Complainants', and Complainants' expert's, generic assertions of unexpected results are not particularly helpful. (*See, e.g.*, CX-0705C at Q/A at 589–590.) With respect to Complainants' La_2O_3 argument, the undersigned notes that Schweiger, the prior art Complainants rely on to establish the existence of a belief in the art that La_2O_3 was a critical component of lithium disilicate glass ceramics, does not support Complainants' position. The portion of Schweiger relied on by Complainants and their expert states:

> Surprisingly, these two properties are obtained with the glass ceramic according to the present invention by the use of La_2O_3 and Al_2O_3 in the specified quantities. It is very surprising that the glass ceramic blank is free flowing and can be pressed in the plastic state, although it is already a glass ceramic material.

(RX-0062 at 7:23–28.) This portion of Schweiger does not evince a belief in the art that La_2O_3 was a critical component to achieve certain properties. To the contrary, the excerpt appears to establish that in the late 1990s, when Schweiger was being prosecuted, the attribution of beneficial properties to the presence of La_2O_3 was surprising. (*See id.*) That point is very different from establishing that those of skill in the art understood La_2O_3 to be a critical component for achieving certain properties in glass-ceramics. Accordingly, the undersigned finds that Complainants have not established that the invention of the '894 patent produced unexpected results.

b) Commercial Success

Complainants assert that their "IPS e.max CAD products are commercially successful" and that "[t]he commercial success of e.max CAD is tied to the invention in the '894 patent – the method of making and the composition claimed, which impart superior strength, solubility, translucency, chemical durability, and formability to e.max CAD." (CIB at 103 (citing CX-0705C at Q/A at 591, 593).) Given the undersigned's finding that none of Complainants' domestic industry claims are practiced by it e.max CAD products, and the absence of any evidence showing that the e.max CAD products practice any other claim of the '894 patent, Complainants' reliance on their e.max CAD products to show commercial success of the invention claimed in the '894 patent is unpersuasive. *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1130 (Fed. Cir. 2000) ("A nexus between commercial success and the claimed features is required."). Accordingly, the undersigned finds that Complainants have not established that the invention claimed in the '894 patent has enjoyed commercial success.

c) Conclusion

Consistent with the reasoning above, the undersigned finds that secondary considerations of nonobviousness do not rebut the *prima facie* showings of obviousness made by Respondents, as discussed in section V.F.2 above.

4. Written Description & Definiteness

a) Claims 2, 4, and 16

Respondents assert that claims 2, 4, and 16 are invalid as indefinite or lacking written description due to the phrase "the blanks," which appears in the additional limitations of claims 2 and 4 (and which is incorporated into claim 16 via its dependence on claim 4). (RIB at 110–

111.) The thrust of Respondents' argument is that "the blanks" lacks an antecedent basis, and is therefore invalid under 35 U.S.C. § 112. (*See id.*) Respondents do not identify which portion of § 112 forms the basis of their invalidity argument for this claim, despite the fact that written description and definiteness are distinct requirements to patentability that require separate and distinct proofs to establish invalidity. *See* Manual of Patent Examining Procedure § 2174 (Jan. 2018) ("The requirements of 35 U.S.C. 112(a) and (b) or the first and second paragraphs of pre-AIA 35 U.S.C. 112 are separate and distinct.") With the exception of the three claims themselves, Respondents cite no evidence in support of their invalidity argument, and instead simply argue that the claims are "invalid under Section 112 as a matter of law," without any additional citation.

Respondents bear the burden of establishing invalidity by clear and convincing evidence. Here, where even the legal basis for Respondents' invalidity argument is unclear, Respondents have not met that burden. Accordingly, the undersigned finds that Respondents have failed to show, by clear and convincing evidence, that claims 2, 4, or 16 of the '894 patent are invalid for failure to comply with 35 U.S.C. § 112.

b) Claims 36 and 38

Respondents assert that claims 36 and 38 of the '894 patent are invalid as indefinite due to their recitation of the 3-point flexure strength limitation discussed *supra*. (*See* supra § V.C.5.; RIB at 111-115.) The undersigned addressed this issue a length in the section of this determination dealing with the construction of the 3-point flexure strength limitation, and found that the limitation is indefinite, as are claims 36 and 38, which recite the limitation. (*See* supra § V.C.5.)

VI. DOMESTIC INDUSTRY – ECONOMIC PRONG

Pursuant to a stipulation among the parties, there is no dispute that Complainants satisfy the economic prong of the domestic industry requirement. (JX-0029 (Domestic Industry Stipulation).) Staff also agrees that Complainants have satisfied the economic prong of the domestic industry requirement. In its post-hearing briefing, Complainants assert that they satisfy the economic prong of the domestic industry requirement through domestic investments in plant and equipment, and domestic investments in labor and capital.

A. Significant Investments in Plant and Equipment

1. Investments in Plant

Complainants rely on two facilities in Somerset, NJ—the "Pierce" and "Memorial" facilities—to establish their domestic industry investments in plant. (CIB at 106.) Complainants assert that '[redacted].'" (*Id.* (citing CX-0710C at Q/A at 121; JX-0023C at 107:18–109:10).) Complainants submit that the Pierce plant expenses total $[redacted] for the time period [redacted], (CX-0410C; CX-0441C; CDX-0001C at 6). Complainants submit that the '[redacted].'" (CIB at 106 (citing CX-0710C at Q/A at 120, 127; JX-0023C at 107:18–109:10).) Complainants also submit that [redacted] and that from [redacted] the Memorial plants expenses related to e.max CAD totaled over $[redacted]. (CIB at 107 (citing CX-0710C at Q/A at 120, 127; JX-0023C at 107:18-109:10, 252:14-254:5; CX0053C; CDX-0001C at 8).)

Complainants assert that they used two different allocation methodologies to capture their investments in plant. For the Memorial facility, Complainants employed a sales-based

allocation, which showed that [redacted] of the Memorial facility's plant expenses should be allocated to e.max CAD sales between [redacted]. (CIB at 107 (citing CX-0710 at Q/A at 99-102; CDX-0001C at 1; CX-0417).) For the Pierce facility, Complainants employed a production-based allocation and assert that [redacted] of their investments in the Pierce facility should be allocated to e.max CAD products. (CIB at 108 (citing CX-0710C at Q/A at 111-114; CX-0420; CDX-0001C at 3; CX-0420C).) Complainants also assert that [redacted] and thus, "[redacted]" (CIB at 108 (citing CX-0710C at Q/A at 106).) Complainants apply a [redacted] allocation factor to these plant investments based on the fact that e.max CAD products account for [redacted] "of all intercompany sales made from [redacted] (CIB at 108 (citing CX-0710C at Q/A at 106; CX-0420C; CDX-0001C at 2).)

Based on its allocation methodologies, Complainants submit that [redacted] of their investments in the Pierce plant, and [redacted] of its investments in the Memorial plant, should be allocated to e.max CAD products, for a total of [redacted] of plant investment allocated to Complainants' domestic industry products. (CIB at 109 (citing CX-0710C at Q/A at 126, 131-132, 140; CDX-0001C at 7, 9, 11).)

2. Investments in Equipment

With respect to equipment, Complainants rely only on the equipment investments used exclusively for e.max CAD, and therefore assert that no allocation is required. (CIB at 109.) Complainants submit that their "expenditures that are exclusive to e.max CAD between [redacted]

[redacted] (CIB at 109-110 (citing CDX-0001C at 15-16; CX-0710C at Q/A at 151-52; CX-0419C).)

3. Conclusion

Having reviewed the evidence presented by Complainants, the undersigned finds that Complainants' allocation methodologies are reasonable and that Complainants have demonstrated that its domestic plant and equipment investments for e.max CAD total [redacted]. (CX-0710C at Q/A at 140, 151-152; CDX-0001C at 11, 15-16 (citing CX-0419C).)

B. Significant Investments in Labor and Capital

Complainants break the investments in labor and capital into two groups: (1) investment in labor exclusively related to e.max CAD; and (2) investments in labor at the Somerset facilities partially related to e.max CAD.

1. Investments in Labor Exclusively Related to e.max CAD

Complainants assert that [redacted] and that [redacted] ((CIB at 110 (citing CX-0424C; CX-0710C at Q/A 161–163; CDX-0001C at 20).) Complainants assert that no allocation of these expenses is necessary because the employees work exclusively with e.max CAD.

2. Investments in Labor at the Somerset Facilities Partially Related to e.max CAD

With respect to Complainants' employees at the Somerset facilities whose work is partially related to e.max CAD, Complainants assert that [redacted]

[redacted]." (CIB at 110–111 (citing CX-0424C; CX-0710C at Q/A at 165-167).) To allocate these labor expenses to e.max CAD products, Complainants employed the same [redacted] allocation factor based on Somerset intercompany sales. (CIB at 111 (citing CX-0710C at Q/A at 167; CX-0420).) Applying that allocation factor to [redacted] that can be allocated to the e.max CAD products. (CIB at 111 (citing CX-0710C at Q/A at 167; CX-0424; CDX-0001 at 22).)

3. Conclusion

Having reviewed the evidence presented by Complainants, the undersigned finds that Complainants' allocation methodologies are reasonable and that Complainants have demonstrated that their domestic labor investments for e.max CAD total [redacted]. (*See* CX-0424C; CX-0710C at Q/A 161–163, 167; CDX-0001C at 20, 22).)

C. Shade by Shade Allocation Methods

Because the domestic industry products come in various shades, and only some shades practice certain domestic industry claims, Complainants provide shade by shade allocation information. (CIB at 111-113.) Given that the undersigned has not found that any of the domestic industry products practice the asserted patents, a shade by shade allocation is not necessary to the undersigned's ultimate conclusion. Nonetheless, such an allocation is discussed here should the Commission determine that one or more of Complainants' domestic industry products practice either or both of the asserted patents.

For the '836 patent, Complainants assert that [redacted] of exclusive investments in plant and equipment, and [redacted] of exclusive investments in labor can be allocated to the LT shades of e.max CAD, which Complainants assert practice all of the domestic industry claims of the '836 patent. (CIB at 112 (citing CDX-0001C at 28-29, 37).) For the '894 patent, Complainants

assert that [ ] of exclusive investments in plant and equipment, and [ ] of exclusive investments in labor can be allocated to all shades of e.max CAD, should the Commission find that all shades practice the '894 patent. (*Id.*) Alternatively, Complainants assert that [ ] of exclusive investments in plant and equipment, and [ ] of exclusive investments in labor can be allocated to the shades of e.max CAD that practice claim 20, which Complainants describe as the lowest allocation. (*Id.*)

Complainants perform a similar allocation for their total allocable Somerset investments, which produces the following breakdown:

For the '836 patent (highest and lowest claim allocation – all and only LT shades):

[redacted]

For the '894 patent (highest allocation – all shades):

[redacted]

For the '894 patent (lowest allocation – shades practicing claim 20):

[redacted]

(CIB at 112–113 (citing CDX-0001C at 29, 37).)

The undersigned finds Complainants' shade-based allocation methodologies to be reasonable and supported by the evidence. (CDX-0001C at 28-29, 37; CX-0573C; CX-0419C; CX-0417C; CX-0420C; CX-0415; CX-0423; CX-0441C.)

D. Quantitative and Qualitative Significance of Complainants' Domestic Investments

Complainants assert that their domestic investments in e.max CAD are quantitatively and qualitatively significant. Particularly, Complainants assert that their domestic sales of e.max CAD account for [ ] of their total net domestic sales. (CIB at 113 (citing CX-0417; CX-0710C at Q/A at 100-101, 178).) Complainants assert that their investments are [redacted]

[redacted]" (CIB at 113 (citing JX-0015C at 229:1-11).) Complainants further assert that they produce over [redacted] of their worldwide e.max CAD products in the United States. (CIB at 113 (citing CX-0710C at Q/A at 184; CX-0418C).) And, Complainants assert that amount of their investments in equipment and labor that is exclusively related to e.max CAD products is significant as compared to the total investments in those categories at its Somerset, NJ facilities. (CIB at 113 (citing CX-0710C at Q/A at 185-186; CDX-0001C at 26; CX-0419C; CX-0424C).) Staff agrees that Complainants' domestic investments are significant. (SIB at 83-84.)

Based on the evidence provided by Complainants, the undersigned finds that Complainants' domestic industry investments in plant and equipment and in labor are significant within the meaning of section 337. Accordingly, and consistent with the reasoning *supra*, the undersigned finds that Complainants have presented evidence sufficient to satisfy the economic prong of the domestic industry requirement for both the '836 and '894 patents.

VII. CONCLUSIONS OF LAW

1. The Commission has personal jurisdiction over the parties, and subject-matter jurisdiction over the accused products.
2. The importation or sale requirement of section 337 is satisfied as to all Respondents.
3. Respondents do not infringe any valid asserted claim of U.S. Patents Nos. 7,452,836 and 6,802,894.
4. The asserted and domestic industry claims of U.S. Patent No. 7,452,836 are not invalid under 35 U.S.C. § 102 as anticipated.
5. The asserted and domestic industry claims of U.S. Patent No. 7,452,836 are not invalid under 35 U.S.C. § 103 as obvious.
6. Claims 1, 2, and 34 of U.S. Patent No. 6,802,894 are invalid under 35 U.S.C. § 102 as anticipated.

7. Claims 1, 17, 21, and 34 of U.S. Patent No. 6,802,894 are invalid under 35 U.S.C. § 103 as obvious.

8. Claims 36 and 38 of U.S. Patent No. 6,802,894 are invalid under 35 U.S.C. § 112 as indefinite.

9. The technical prong of the domestic industry requirement for U.S. Patent No. 7,452,836 has been satisfied.

10. The technical prong of the domestic industry requirement for U.S. Patent No. 6,802,894 has not been satisfied.

11. The economic prong of the domestic industry requirement for U.S. Patent No. 7,452,836 has been satisfied.

12. The economic prong of the domestic industry requirement for U.S. Patent No. 6,802,894 has been satisfied.

VIII. RECOMMENDED DETERMINATION ON REMEDY & BOND

The Commission's Rules provide that the administrative law judge shall issue a recommended determination concerning the appropriate remedy in the event that the Commission finds a violation of section 337, and the amount of bond to be posted by respondents during Presidential review of the Commission action under section 337(j). *See* 19 C.F.R. § 210.42(a)(l)(ii).

A. Limited Exclusion Order

Under section 337(d), the Commission may issue a limited exclusion order ("LEO") directed to a respondent's infringing products. 19 U.S.C. §1337(d). A limited exclusion order instructs the U.S. Customs Service to exclude from entry all articles that are covered by the patent at issue that originate from a named respondent in the investigation. *See Fuji Photo Film Co. Ltd. v. Int'l Trade Comm'n*, 474 F.3d 1281, 1286 (2007).

Should the Commission find a violation, Complainants seek an LEO "directed to LiSi Press and methods of making the same." (CIB at 114.) Respondents do not disagree that an LEO is appropriate if a violation is found, but argue that any LEO "should only cover the exact shades that have been found by the Commission to have infringed the asserted patents." (RIB at 116.) Staff also agrees that an LEO "will be appropriate if the Commission finds a violation of Section 337 in this investigation." (SIB at 84.)

In the event the Commission finds a violation, the undersigned recommends that a limited exclusion order issue prohibiting the importation of all the accused products found to infringe the asserted patents.

B. Cease and Desist Order

Under section 337(f)(1), the Commission may issue a cease and desist order ("CDO") in addition to, or instead of, an exclusion order. 19 U.S.C. § 1337(f)(1). The Commission generally issues a cease and desist order directed to a domestic respondent when there is a "commercially significant" amount of infringing, imported product in the United States that could be sold, thereby undercutting the remedy provided by an exclusion order. *See Certain Crystalline Cefadroxil Monohydrate,* Inv. No. 337-TA-293 USITC Pub. 2391, Comm'n Op. on Remedy, the Public Interest and Bonding at 37-42 (June 1991); *Certain Condensers, Parts Thereof and Prods. Containing Same, Including Air Conditioners for Automobiles,* Inv. No. 337-TA-334 (Remand), Comm'n Op. at 26-28, 1997 WL 817767, at *11-12 (U.S.I.T.C. Sept. 10, 1997).

Complainants seek a cease and desist order. (*See* CIB at 114–115.) Complainants argue that such an order is justified because Respondents "maintain commercially significant inventory of LiSi Press in the United States." (*Id.* at 115.) More specifically, Complainants assert that "[a]s of August 16, 2017, [redacted] units of LiSi Press were in inventory in the U.S.," and that

Respondents have "stipulated that about [redacted] units of LiSi Press are expected to be in inventory as of the target date in this Investigation." (*Id.* (citing JX-0010C at 3-4; CX-0240).) Complainants assert that this amount of inventory would allow Respondents to continue selling accused products for [redacted], and that their assertion holds true for each shade of the accused LiSi Press products. (CIB at 115 (citing CX-0706C at Q/A at 144; CX-0240).) Complainants argue that the domestic inventory is worth approximately [redacted], and therefore the value of the domestic inventory [redacted]. (CIB at 115 (citing CX-0706C at Q/A at 63-64, 90; RX-2332C at Q/A at 90).) Complainants also argue that even if Respondents' actual sales of LiSi Press were small, Respondents' presence in the market would harm Complainants, and thus "[t]his competitive threat is commercially significant, *per se*." (CIB at 115–116 (citing CX-0706C at Q/A at 139-147).)

Respondents argue that no cease and desist order should issue. Respondents assert first that Complainants' evidence of commercially significant inventory is insufficient because it does not break down inventory by shade of LiSi Press products. (RIB at 119 (citing JX-0010C at 3).) Second Respondents argue that its domestic inventory is not commercially significant, [redacted]." (RIB at 117 (citing JX-0010C at ¶ 11; RX-2332C at Q/A at 93).) Finally, Respondents argue that Complainants have not demonstrated that they have encountered any harm from competing against Respondents' LiSi Press products. (RIB at 118 (citing RX-2332C at Q/A at 93, 94, 96).)

Reviewing the same evidence presented by Complainants and Respondents, Staff submits that "the evidence supports a finding that GC maintains a commercially significant inventory of the accused products in the United States," and that a cease and desist order would be appropriate even if the Commission only found a violation based on claim 38 of the '894 patent, which would implicate only [redacted] shades of the LiSi Press products. (SIB at 84-85 (citing CX-0706C at Q/A at 143-147; CX-0240).)

As an initial matter, the undersigned notes that Respondents' argument that Complainants' evidence of commercially significant inventory is insufficient because it does not break down shade-by-shade was never mentioned in its pre-hearing brief, and thus is waived. (RPB at 330-331.) Moreover, CX-0240C actually does disclose inventory of LiSi Press products on a shade-by-shade basis as of August 16, 2017. That breakdown shows that the inventory per shade ranged from as low as [redacted] units to as high as [redacted] units at that time. (CX-0240C.) If Respondents have, in the last year, liquidated their entire inventory of any particular shade, they were free to come forward with evidence establishing as much. Respondents did not do so. On consideration of the evidence actually produced, the undersigned finds that Respondents maintain a commercially significant inventory of accused products, based at least on the fact that the value of Respondents' inventory of domestic industry products as of August 2017 actually [redacted]. Accordingly, should the Commission find a violation of section 337, the undersigned recommends that a cease and desist order issue to Respondents with respect to the specific accused products that form the basis of the Commission's violation finding.

C. Bond During Presidential Review

Pursuant to section 337(j)(3), the Administrative Law Judge and the Commission must determine the amount of bond to be required of a respondent during the 60-day Presidential review period following the issuance of permanent relief, in the event that the Commission determines to issue a remedy. *See* 19 U.S.C. §1337(j)(3). The purpose of the bond is to protect the complainant from any injury. *See* 19 C.F.R. § 210.42(a)(1)(ii), § 210.50(a)(3).

When reliable price information is available, the Commission has often set the bond by eliminating the differential between the domestic product and the imported, infringing product. *See Microsphere Adhesives, Processes for Making Same, and Prods. Containing Same, Including Self-Stick Repositionable Notes*, Inv. No. 337-TA-366, USITC Pub. 2949, Comm'n. Op. at 24 (Dec. 8, 1995). In other cases, the Commission has turned to alternative approaches, especially when the level of a reasonable royalty rate could be ascertained. *See, e.g., Certain Integrated Circuit Telecomm. Chips and Prods. Containing Same, Including Dialing Apparatus*, Inv. No. 337-TA-337, Comm'n. Op. at 41, 1993 WL 13033517, at *24 (U.S.I.T.C. June 22, 1993). A 100 percent bond has been required when no effective alternative existed. *See, e.g., Certain Flash Memory Circuits and Prods. Containing Same*, Inv. No. 337-TA-382, USITC Pub. No. 3046, Comm'n. Op. at 26-27 (July 1997) (imposing a 100% bond when price comparison was not practical because the parties sold products at different levels of commerce, and the proposed royalty rate appeared to be *de minimus* and without adequate support in the record).

Complainants argue that the bond should be set at [redacted]. (CIB at 117 (citing CX-0706C at Q/A at 159).) Complainants' bond rate is based on the wholesale price difference between its e.max Press products and the accused LiSi Press products. (*Id.* (citing CX-0706C at Q/A at 156–158).) Complainants offer an alternative bond rate of [redacted] based on the wholesale price difference between its domestic industry products—e.max CAD—and the accused LiSi Press

products. (*Id.*) Complainants argue that wholesale, as opposed to retail, prices are appropriate for comparison because "wholesale prices reflect the actual price sold from Ivoclar and GC to distributors or other consumers," whereas "[r]etail prices are recommended prices that reflect the prices for sales from distributors and middlemen. (*Id.* (citing CX-0706C at Q/A at 157; Kerr, Tr. 692:21–693, 695:15–19).) Further, Complainants argue that a retail price differential would not accurately reflect the harm to Complainants or benefit to Respondents from the presence of the LiSi Press products on the market. (CIB at 117.) And, Complainants argue that Respondents "do[] not have a reliable retail price as [they] merely suggest[] a retail price based on a percentage of [their] set wholesale price." (*Id.* (citing Kerr, Tr. at 693:3-5; JX-0013 at 25:8-20).)

Respondents first argue that no bond is appropriate at all because "Ivoclar has presented no evidence that the introduction of the Initial LiSi Press products had any impact on Ivoclar (whether in a reduction of sales or price erosion) or on the market." (RIB at 118 (citing RX-2332C at Q/A at 82).) Respondents argue that no such showing of harm is possible because their share of the pressable ceramics market is minimal. (*Id.*) If a bond is warranted, Respondents argue that "it should not exceed [ ]," which value is "calculated based on the retail price differential between GC's LiSi Press products ([ ]) and Ivoclar's e.max Press products ([ ]),"[redacted] and which amounts to a [ ] price difference. (*Id.* (citing RX-2332C at Q/A at 85, 87-89; JX-0010C at ¶¶ 6, 10).)

Respondents criticize Complainants' bond calculation as being inappropriately based on the revenues received from the sales of LiSi Press and e.max Press products, as opposed to those products' retail prices. (RIB at 118-119 (citing RX-2332C at Q/A at 84).) Moreover, Respondents criticize Complainants' calculation insomuch as Complainants "calculated the e.max Press average revenue per unit (which [they] call[] the average wholesale price of

[redacted]) . . . based on sales Ivoclar make [sic] directly to dental laboratories," while Complainants calculate the average wholesale price of the LiSi Press products based on "the price paid by the distributor to GC and not the laboratory." (RIB at 119 (citing Putnam, Tr. at 133:23-134:1, 139:22-24, 140:7-18; RX-1582C at Q/A at 73).) In short, Respondents argue that Complainants bond calculation is based on an apples to oranges comparison.

Staff relies on Complainants' wholesale calculations and concludes that a [ ] bond rate is appropriate based on a comparison of e.max Press products to LiSi Press products. Staff appears to prefer that comparison, as opposed to a comparison with e.max CAD, because there is evidence in the record that e.max Press and LiSi Press are actually competing products. (SIB at 86–87 (citing CX-0706C at Q/A at 76, 83, 147, 154).)

As an initial matter, the undersigned notes that there is broad agreement that, if a bond is required, it should be based on a price-differential calculated between Complainants' e.max Press products and Respondents' LiSi Press products. No party has suggested that reliable pricing information is wholly unavailable, and thus no party has suggested imposing a 100% bond rate. The undersigned also disagrees with Respondents that the relatively small presence of LiSi Press in the marketplace should dictate the absence of any bond at all. The statutory language authorizing the Commission to require a bond directs that the bond should be "sufficient to protect the complainant from ***any*** injury." 19 U.S.C. § 1337(j)(3) (emphasis added). The use of the word "any" forecloses the argument that a quantitatively or qualitatively small injury to Complainants requires no bond. Accordingly, given that e.max Press and LiSi Press are competing products, the undersigned finds that a bond is appropriate. The only question remaining is how to calculate the price differential.

There is a fundamental problem with Complainants' and Staff's reliance on a wholesale price comparison: Complainants do not have a wholesale price for their products. In order to remedy this problem, Complainants' expert based his price differential calculations on the average revenue per unit that Complainants' realize through the sale of their products. Though Complainants argue that "[t]he average revenue per unit is equivalent to the average wholesale price" for its products, the evidence it cites in support of that position is not persuasive. (*See* CX-0706C at Q/A at 55-61.) In the absence of actual evidence that an average revenue per unit is equivalent to a theoretical wholesale price, the undersigned cannot recommend imposition of a bond based on that calculation.

By contrast, Respondents' proposed calculation, which compares the prices that dental laboratories pay for LiSi Press and e.max Press, appears to be a more reliable approach. While the undersigned acknowledges Complainants' criticism that Respondents only suggest the price that its distributors charge to dental laboratories, Complainants point to no evidence in the record that the suggested price is significantly different than the price distributors actually charge to laboratories. The record shows that Respondents suggest a price of $[redacted] per unit for LiSi Press to laboratories while Complainants sell e.max Press to laboratories at a price of $[redacted]. (RX-2332C at Q/A at 85.) Thus, the price differential between the two is $[redacted]. (*Id.*) Accordingly, should the Commission find a violation, the undersigned recommends imposition of a [redacted] bond.

IX. PUBLIC INTEREST

In connection with this Recommended Determination, and pursuant to Commission Rule 210.50(b)(1), 19 C.F.R. § 210.50(b)(1), the Commission ordered that the presiding administrative law judge:

> [S]hall take evidence or other information and hear arguments from the parties and other interested persons with respect to the public interest in this investigation, as appropriate, and provide the Commission with findings of fact and a recommended determination on this issue, which shall be limited to the statutory public interest factors set forth in 19 U.S.C. §§ 1337(e)(1), (f)(1), (g)(1).

82 *Fed. Reg.* 19,081 (Apr. 25, 2017).

Before issuing a remedy for a violation of section 337, the Commission must consider the effect of the remedy on the following public interest factors: (1) the public health and welfare; (2) competitive conditions in the U.S. economy; (3) the U.S. production of articles that are like or directly competitive with those that are the subject of the investigation; and (4) U.S. consumers. *See* 19 U.S.C. §§ 1337(d)(1), (f)(1). The Commission begins this analysis with the understanding that the public interest favors the protection of intellectual property rights by excluding infringing products. *See, e.g., Certain Two-Handle Centerset Faucets & Escutcheons & Components Thereof,* Inc. No. 337-TA-422, Comm'n Op. at 9 (July 21, 2000). It is rare for the Commission to determine that the public interest considerations outweigh the patent holder's rights. *See Spansion Inc. v. Int'l Trade Comm'n,* 629 F.3d 1331, 1360 (Fed. Cir. 2010). The Commission can, however, tailor the remedy to minimize the impact on the public interest. *See e.g., Certain Personal Data and Mobile Commc'ns Devices & Related Software,* Inv. No. 337-TA-710, Comm'n Op. at 83 (delaying the effective date of an exclusion order based on competitive conditions in the U.S. economy).

Here, no party has made any significant argument that the public interest should preclude imposition of remedial orders. Respondents summarily argue that "[t]he LiSi Press products at issue are FDA-licensed medical devices ultimately used to make dental restorations such as crowns, bridges, inlays, veneers and implants for the public," and therefore "[t]he public interest weighs against an exclusion of the LiSi Press products because, as described herein, exclusion would be contrary to the merits of U.S. patent law, is unsupported by the evidence, and would thus deny available treatment options for U.S. dental patients in the absence of a violation of 19

U.S.C. § 1337." (RIB at 119 (citing Bradshaw, Tr. at 312:5-10).) As Complainants correctly point out, however, "absent other factors, the Commission regularly excludes medical products." (CRB at 59-60 (citing investigations).) Staff also submits that "without any record evidence of the potential harm any remedy would have on the public health and welfare, the Staff is of the view that the statutory public interest factors do not weigh against entering the Staff's proposed remedy." (SIB at 88.)

Based on the parties' arguments, the undersigned finds that there is no evidence that the statutory public interest factors weigh against imposition of remedial orders should the Commission find a violation.

X. INITIAL DETERMINATION

Based on the foregoing, it is the Initial Determination of the undersigned that Respondents do not infringe any asserted claim of U.S. Patents Nos. 7,452,836 and 6,802,894. The undersigned further determines that the asserted and domestic industry claims of U.S. Patent No. 7,452,836 are not invalid, that claims 1, 2, 17, 21, 34, 36, and 38 of U.S. Patent No. 6,802,894 are invalid, and that the domestic industry requirement has been satisfied for U.S. Patent No. 7,452,836, but not for U.S. Patent No. 6,802,894.

The undersigned hereby CERTIFIES to the Commission this Initial Determination and the Recommended Determination. The parties' briefs, which include the final exhibits lists, are not certified as they are already in the Commission's possession in accordance with Commission rules. *See* 19 C.F.R. § 210.38(a).

The Secretary shall serve the confidential version of this Initial Determination upon counsel who are signatories to the Protective Order (Order No. 1) issued in this Investigation. A public version will be served at a later date upon all parties of record.

Pursuant to 19 C.F.R. § 210.42(h), this Initial Determination shall become the determination of the Commission unless a party files a petition for review pursuant to 19 C.F.R. § 210.43(a) or the Commission, pursuant to 19 C.F.R. § 210.44, orders on its own motion a review of the Initial Determination or certain issues therein.

Within ten days of the date of this document, the parties shall submit to the Office of Administrative Law Judges a joint statement regarding whether or not they seek to have any portion of this document deleted from the public version. The parties' submission shall be made by hard copy and must include a copy of this Initial Determination with red brackets indicating any portion asserted to contain confidential business information to be deleted from the public version.[7] The parties' submission shall include an index identifying the pages of this document where proposed redactions are located. The parties' submission concerning the public version of this document need not be filed with the Commission Secretary.

SO ORDERED.

Charles E. Bullock
Chief Administrative Law Judge

[7] If the parties submit excessive redactions, they may be required to provide an additional written statement, supported by declarations from individuals with personal knowledge, justifying each proposed redaction and specifically explaining why the information sought to be redacted meets the definition for confidential business information set forth in Commission Rule 201.6(a). 19 C.F.R. § 201.6(a).

CERTAIN DENTAL CERAMICS, PRODUCTS THEREOF, AND METHODS OF MAKING THE SAME **Inv. No. 337-TA-1050**

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **Initial Determination on Violation of Section 337 and Recommended Determination on Remedy and Bond** has been served by hand upon the Commission Investigative Attorney, Todd P. Taylor, Esq., and the following parties as indicated, on **August 28, 2018.**

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

On Behalf of Complainants Ivoclar Vivadent AG, Ivoclar Vivadent, Inc., and Ardent, Inc.:

Kecia J. Reynolds, Esq.
PILLSBURY WINTHROP SHAW PITTMAN LLP
1200 Seventeenth Street, NW
Washington, DC 20036

- ☐ Via Hand Delivery
- ☒ Via Express Delivery
- ☐ Via First Class Mail
- ☐ Other:_____

On Behalf of Respondents GC America, Inc. and GC Corporation:

Jeffrey L. Eichen, Esq.
DRINKER BIDDLE & REATH LLP
222 Delaware Avenue, Suite 1410
Wilmington, DE 19801

- ☐ Via Hand Delivery
- ☒ Via Express Delivery
- ☐ Via First Class Mail
- ☐ Other:_____