

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,

PUBLIC VERSION

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

PUBLIC VERSION

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

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.”).

PUBLIC VERSION

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.

PUBLIC VERSION

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

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).

PUBLIC VERSION

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

PUBLIC VERSION

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.

PUBLIC VERSION

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’

PUBLIC VERSION

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,

PUBLIC VERSION

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).

PUBLIC VERSION

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

PUBLIC VERSION

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,

PUBLIC VERSION

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 $\text{Li}_2\text{O}-\text{CaO}-\text{Al}_2\text{O}_3-\text{SiO}_2$ 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.

PUBLIC VERSION

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

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.

PUBLIC VERSION

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, ($\text{Li}_2\text{Si}_2\text{O}_5$)] 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

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.

PUBLIC VERSION

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.

PUBLIC VERSION

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

PUBLIC VERSION

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.

PUBLIC VERSION

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.

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: _____