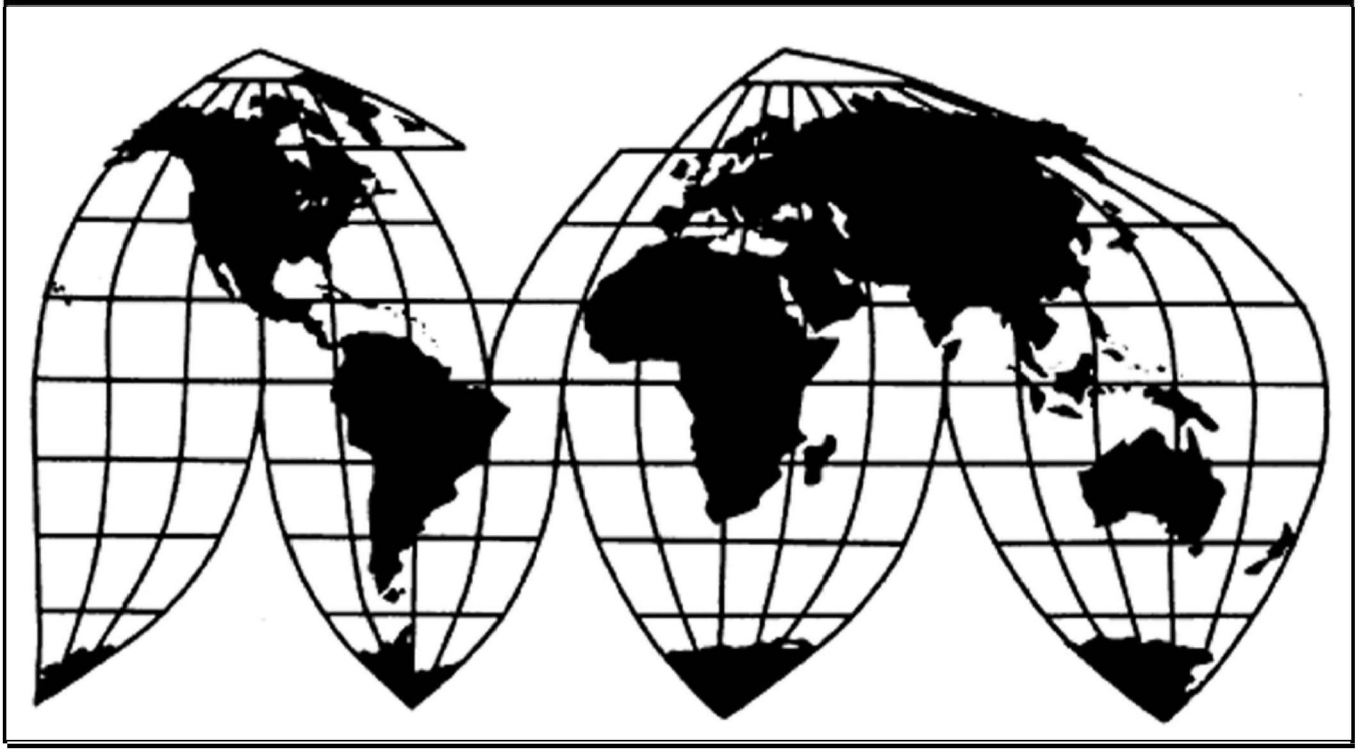
In the Matter of

CERTAIN BONE CEMENTS, COMPONENTS THEREOF AND PRODUCTS CONTAINING THE SAME

Investigation No. 337-TA-1153

Publication 5304 **March 2022**

U.S. International Trade Commission



Washington, DC 20436

U.S. International Trade Commission

COMMISSIONERS

Jason E. Kearns, Chair
Randolph J. Stayin, Vice Chair
***David S. Johanson, Commissioner**
Rhonda K. Schmidtlein, Commissioner
Amy A. Karpel, Commissioner

***Has been recused from investigation.**

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

U.S. International Trade Commission

Washington, DC 20436
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UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of	
CERTAIN BONE CEMENTS, COMPONENTS THEREOF AND PRODUCTS CONTAINING THE SAME	**Investigation No. 337-TA-1153**

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

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission ("Commission") has determined to affirm in part, reverse in part, and vacate in part the final initial determination's ("ID") finding that no violation of section 337 has occurred. The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Ronald A. Traud, Office of the General Counsel, U.S. International Trade Commission, 500 E Street S.W., Washington, DC 20436, telephone (202) 205-3427. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov*. For help accessing EDIS, please email *EDIS3Help@usitc.gov*. General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on April 10, 2019, based on a complaint filed by Heraeus Medical LLC of Yardley, Pennsylvania, and Heraeus Medical GmbH of Wehrheim, Germany (collectively, "Complainants"). 84 FR 14394–95 (Apr. 10, 2019). The complaint alleges a violation of section 337 of the Tariff Act of 1930, as amended, by reason of misappropriation of trade secrets, the threat or effect of which is to destroy or substantially injure an industry in the United States or to prevent the establishment of such an industry. The complaint named the following respondents: Zimmer Biomet Holdings, Inc. of Warsaw, Indiana; Biomet, Inc. of Warsaw, Indiana; Zimmer Orthopaedic Surgical Products, Inc. of Dover, Ohio; Zimmer Surgical, Inc. of Dover, Ohio; Biomet France S.A.R.L. of Valence, France; Biomet Deutschland GmbH of Berlin, Germany; Zimmer Biomet Deutschland GmbH of Freiburg im Breisgau, Germany; Biomet Europe B.V. of Dordrecht, Netherlands; Biomet Global Supply Chain Center B.V. of Dordrecht, Netherlands; Zimmer Biomet Nederland B.V. of Dordrecht, Netherlands; Biomet Orthopedics, LLC of Warsaw,

Indiana; and Biomet Orthopaedics Switzerland GmbH of Dietikon, Switzerland. The Commission's Office of Unfair Import Investigations ("OUII") also was named as a party.

The investigation has terminated as to respondents Zimmer Orthopaedic Surgical Products, Inc. and Biomet Europe B.V., Order No. 10 (May 23, 2019), *unreviewed*, Notice (June 14, 2019), and as to certain accused products, Order No. 30 (Nov. 24, 2019), *unreviewed*, Notice (Dec. 10, 2019). Also, the first amended complaint and notice of investigation were amended to add three entities as respondents: Zimmer US, Inc.; Zimmer, GmbH; and Biomet Manufacturing, LLC. Order No. 18 (June 26, 2019), *unreviewed*, 84 FR 35884–85 (July 25, 2019). The remaining respondents are referred to collectively herein as "Zimmer Biomet."

On May 6, 2020, the presiding administrative law judge ("ALJ") issued the final ID, which found that Zimmer Biomet did not violate section 337. On May 18, 2020, the parties filed petitions for review of the final ID.

On July 13, 2020, the Commission determined to review in part the final ID and requested briefing from the parties on the issues under review. In particular, the Commission determined to review the following: (1) the ALJ's findings and conclusions as to TS 1–35 and 121–23; and (2) the ALJ's domestic industry findings, including whether there has been a substantial injury to the alleged domestic industry. The Commission also sought briefing from the parties, interested government agencies, and any other interested parties on remedy, bonding, and the public interest.

Having examined the record of this investigation, including the final ID, the petitions for review, the responses thereto, and the written submissions in response to the Commission's request for briefing, the Commission finds that no violation of section 337 has occurred. Specifically, the Commission finds that the Complainants did not establish that an industry in the United States exists as required by section 337(a)(1)(A)(i) and therefore did not establish injury to a domestic industry. The investigation is hereby terminated.

The Commission vote for this determination took place on January 12, 2021.

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: January 12, 2021

CERTAIN BONE CEMENT, COMPONENTS THEREOF AND PRODUCTS CONTAINING THE SAME **Inv. No. 337-TA-1153**

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **NOTICE** has been served via EDIS upon the Commission Investigative Attorney, **Monica Bhattacharyya, Esq.**, and the following parties as indicated, on **January 12, 2021.**

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

On Behalf of Complainants Heraeus Medical LLC and Heraeus Medical GmbH:

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On Behalf of Respondents Zimmer Biomet Holdings, Inc., Biomet, Inc., Zimmer Surgical, Inc., Biomet France S.A.R.L., Biomet Deutschland GmbH, Zimmer Biomet Deutschland GmbH, Biomet Global Supply Chain Center B.V., Zimmer Biomet Nederland B.V., Biomet Orthopedics, LLC, and Biomet Orthopaedics Switzerland GmbH:

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PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN BONE CEMENTS, COMPONENTS THEREOF AND PRODUCTS CONTAINING THE SAME**	**Investigation No. 337-TA-1153**

COMMISSION OPINION

I. INTRODUCTION

The Commission has determined to affirm, with modifications, the presiding administrative law judge's ("ALJ") final initial determination ("ID") that there has been no violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, by reason of misappropriation of trade secrets, the threat or effect of which is to destroy or substantially injure an industry in the United States. As explained below, the Commission has determined that Complainants did not establish that they have an "industry in the United States" as required by section 337(a)(1)(A)(i). Therefore, there can be no injury within the meaning of the statute. This opinion sets forth the Commission's reasoning in support of that determination.

II. BACKGROUND

The Commission instituted this investigation on April 10, 2019, based on a complaint filed by Heraeus Medical LLC of Yardley, Pennsylvania ("HMUS") and Heraeus Medical GmbH of Wehrheim, Germany (collectively, "Complainants" or "Heraeus"). 84 Fed. Reg. 14394-95 (Apr. 10, 2019). The complaint alleged a violation of section 337 by reason of misappropriation of Heraeus's trade secrets, the threat or effect of which is to destroy or substantially injure an industry in the United States or to prevent the establishment of such an industry.[1] Heraeus asserted multiple trade secrets, which it designated with "TS" numbers. ID at 9-10. The trade secrets remaining at issue on review are directed to (1) the specifications for the Plex 6612 and Plex 6613 copolymers ("TS 1-35"); and (2) the specifications for the powder and liquid components of two Heraeus products, Refobacin Palacos R and Palacos R bone cements ("TS 121-23"). The alleged domestic industry relates to Heraeus's Palacos bone

[1] Complainants did not pursue their allegations that the threat or effect of the unfair acts is to prevent the establishment of an industry in the United States before the Commission, so they are waived.

cements. *See* Comp. Post-Hrg. Br.[2] at 1; OUIIPet.[3] at 3. The powder component of Heraeus's bone cements includes beads made from two different copolymers (called Plex 6612 and Plex 6613), a zirconium dioxide radio-opaque agent, and a benzoyl peroxide initiator. *See, e.g.*, Tr. (Mays) at 379:17-27, 417:13-17. The liquid component of Heraeus's bone cements uses a chlorophyll-based recipe, which imparts a green color to the hardened bone cement. *See* Tr. (Kluge) at 30:21-31:7.

The respondents include: Zimmer Biomet Holdings, Inc. of Warsaw, Indiana; Biomet, Inc. of Warsaw, Indiana; Zimmer Surgical, Inc. of Dover, Ohio; Biomet France S.A.R.L. of Valence, France; Biomet Deutschland GmbH of Berlin, Germany; Zimmer Biomet Deutschland GmbH of Freiburg im Breisgau, Germany; Biomet Global Supply Chain Center B.V. of Dordrecht, Netherlands; Zimmer Biomet Nederland B.V. of Dordrecht, Netherlands; Biomet Orthopedics, LLC of Warsaw, Indiana; Biomet Orthopaedics Switzerland GmbH of Dietikon, Switzerland; Zimmer US, Inc. of Warsaw, Indiana; Zimmer, GmbH of Winterthur, Switzerland; and Biomet Manufacturing, LLC of Warsaw, Indiana (collectively, "Respondents" or "Zimmer Biomet").[4] Order No. 18 (June 26, 2019), *unreviewed*, 84 Fed. Reg. 35884 (July 25, 2019). The Commission's Office of Unfair Import Investigations ("OUII") also was named as a party.

[2] Complainants' Post-Hearing Brief, EDIS Doc ID 701250 (Feb. 3, 2020) ("Comp. Post-Hrg. Br.").

[3] Petition of the Office of Unfair Import Investigations For Review-in-part of the Initial Determination on Violation of Section 337, EDIS Doc ID 710576 (May 18, 2020) ("OUIIPet.").

[4] The investigation was terminated as to respondents Zimmer Orthopaedic Surgical Products, Inc. of Dover, Ohio, and Biomet Europe B.V. of Dordrecht, Netherlands, Order No. 10 (May 23, 2019), *unreviewed*, Notice (June 14, 2019), and as to certain accused products, Order No. 30 (Nov. 24, 2019), *unreviewed*, Notice (Dec. 10, 2019).

The Accused Products are bone cements designed and manufactured by or for Zimmer Biomet. Heraeus asserts that Zimmer Biomet misappropriated its trade secrets during the development of the original "-1" formulation of Biomet Bone Cement R and Refobacin Bone Cement R in the early 2000s; Heraeus further asserts that the misappropriation bled over into development of Zimmer Biomet's "-3" products. *See* Comp. Post-Hrg. Br. at 1-2.

On May 6, 2020, the ALJ issued the ID, which found that Zimmer Biomet did not violate section 337. ID at 79. Of the asserted trade secrets, the ID found that TS 1-35 are protectable trade secrets, but that TS 121-23, TS 130-34, and TS 145 are not protectable trade secrets. *Id.* The ID further found that Zimmer Biomet misappropriated TS 1-35. *Id*. The ID also found that Heraeus established a domestic industry with respect to Heraeus's education, training, and research and development activities and investments in the United States, but that Heraeus did not show a substantial injury or threat of injury to its domestic industry by Zimmer Biomet's misappropriation of TS 1-35. *Id.*

On July 13, 2020, after considering the parties' petitions and responses thereto, the Commission determined to review the ID in part. Review Notice, 85 Fed. Reg. 43600 (July 17, 2020). Specifically, the Commission determined to review the following issues:

(1) The ID's findings and conclusions as to TS 1-35 and 121-23; and

(2) The ID's domestic industry findings, including whether there has been a substantial injury to the alleged domestic industry.

Id. at 43601. The Commission determined not to review the remainder of the ID. The Commission did not request briefing as to TS 1-35 and TS 121-23; however, the Commission posed several questions relating to domestic industry. *Id.*

On July 27, 2020, the parties filed written submissions on the issues under review and on remedy, public interest, and bonding,[5] and on August 3, 2020, the parties filed replies.[6]

III. THE APPLICABLE LAW

A. The Commission's Standard of Review

When the Commission decides to review an initial determination, it reviews the determination *de novo*. *Certain Polyethylene Terephthalate Yarn & Prods. Containing Same*, Inv. No. 337-TA-457, Comm'n Op. at 9 (June 18, 2002). Upon review, the "Commission has 'all the powers which it would have in making the initial determination,' except where the issues are limited on notice or by rule." *Certain Flash Memory Circuits & Prods. Containing Same*, Inv. No. 337-TA-382, USITC Pub. No. 3046, Comm'n Op. at 9-10 (July 1997) (quoting *Certain Acid-Washed Denim Garments & Accessories*, Inv. No. 337-TA-324, Comm'n Op. at 5 (Nov. 1992)). Commission practice in this regard is consistent with the Administrative Procedure Act. *Certain EPROM, EEPROM, Flash Memory, & Flash Microcontroller Semiconductor Devices & Prods. Containing Same*, Inv. No. 337-TA-395 (Reconsideration), Comm'n Op. at 6 (Dec. 11, 2000); *see also* 5 U.S.C. § 557(b).

[5] Complainant Heraeus's Opening Brief on Commission Review of the Initial Determination, EDIS Doc ID 715745 (July 27, 2020) ("CBr."); Respondents' Brief to the Commission on Issues under Review, Remedy, and Bonding, EDIS Doc ID 715734 (July 27, 2020) ("RBr."); Opening Submission of the Office of Unfair Import Investigations in Response to the Commission's July 13, 2020 Notice, EDIS Doc ID 715727 (July 27, 2020) ("OUIIBr.").

[6] Complainant Heraeus's Reply Brief to Respondents' and OUII's Opening Briefs on Commission Review of the Initial Determination, EDIS Doc ID 716285 (Aug. 3, 2020); Respondents' Responsive Brief to the Commission on Issues under Review, Remedy, and Bonding, EDIS Doc ID 716283 (Aug. 3, 2020); Reply Submission of the Office of Unfair Import Investigations Pursuant to the Commission's July 13, 2020 Notice, EDIS Doc ID 716280 (Aug. 3, 2020).

Upon review, "the Commission may affirm, reverse, modify, set aside or remand for further proceedings, in whole or in part, the initial determination of the administrative law judge." 19 C.F.R. § 210.45. "The Commission may also make any findings or conclusions that in its judgment are proper based on the record in the proceeding." *Id*. This rule reflects the fact that the Commission is not an appellate court but is the body responsible for making the final agency decision. On appeal, only the Commission's final decision is at issue. *See Spansion, Inc. v. Int'l Trade Comm'n,* 629 F.3d 1331, 1349 (Fed. Cir. 2010).

B. Protectable Trade Secrets

"Misappropriation of trade secrets is a method of unfair competition defined by the common law." *Certain Rubber Resins & Processes for Manufacturing Same*, Inv. No. 337-TA-849, Comm'n Op. at 9 (Feb. 26, 2014) ("*Rubber Resins*"). A "single federal standard," rather than the law of a particular state, applies to investigations into trade secret misappropriation under section 337. *TianRui Group Co. v. Int'l Trade Comm'n*, 661 F.3d 1322, 1327 (Fed. Cir. 2011). Sources for this federal standard include the Restatement of Unfair Competition, the Uniform Trade Secrets Act ("UTSA"), the Restatement of Torts, the Defend Trade Secrets Act of 2016 (18 U.S.C. §§ 1831-39), and federal common law. *Rubber Resins* lays out the elements of a trade secret misappropriation claim:

> The elements of misappropriation of trade secrets are as follows: (1) the existence of a process that is protectable as a trade secret (*e.g*., that is (a) of economic value, (b) not generally known or readily ascertainable, and (c) that the complainant has taken reasonable precautions to maintain its secrecy); (2) that the complainant is the owner of the trade secret; (3) that the complainant disclosed the trade secret to respondent while in a confidential relationship or that the respondent wrongfully took the trade secret by unfair means; and (4) that the respondent has used or disclosed the trade secret causing injury to the complainant.

Rubber Resins, Comm'n Op. at 10 (citing *Certain Processes for the Manufacture of Skinless Sausage Casings & Resulting Prod.*, Inv. Nos. 337-TA-148 & 169, ID at 244 (July 31, 1984) (unreviewed in pertinent part) ("*Sausage Casings*"); UTSA, § 1(4)).

The existence of a trade secret is a prerequisite for a trade secret misappropriation claim. *Rubber Resins*, Comm'n Op. at 10 (citing *Sausage Casings*, ID at 244). It is the complainant's burden to show "the existence of a process that is protectable as a trade secret." *Rubber Resins*, Comm'n Op. at 56-59. "The common law does not provide 'precise criteria for determining the existence of a trade secret,' but instead requires 'a comparative evaluation of all the relevant factors, including the value, secrecy, and definiteness of the information as well as the nature of the defendant's misconduct.'" *Certain Activity Tracking Devices, Sys., & Components Thereof*, Inv. Nos. 337-TA-963, ID at 18, (Sept. 22, 2016), *unreviewed*, Notice (Oct. 20, 2016) (quoting Restatement (Third) of Unfair Competition § 39 cmt. d.).

The Commission looks to the following six factors—each of which relates to issues of value and/or secrecy—to help determine whether a trade secret exists:

(1) the extent to which the information is known outside of complainant's business;

(2) the extent to which it is known by employees and others involved in complainant's business;

(3) the extent of measures taken by complainant to guard the secrecy of the information;

(4) the value of the information to complainant and to his competitors;

(5) the amount of effort or money expended by complainant in developing the information; and

(6) the ease or difficulty with which the information could be properly acquired or duplicated by others.

Sausage Casings, ID at 245-46 (citing Restatement of Torts § 757, cmt. b). These factors are "instructive guidelines," not a six-pronged test. *See, e.g.*, *Certain Crawler Cranes & Components Thereof*, Inv. No. 337-TA-887, ID at 24 (July 11, 2014).

Information otherwise eligible for protection as a trade secret may lose that protection, however, if adequate steps are not taken to maintain its secrecy. *Sausage Casings*, ID at 246. The burden is on complainant to establish that reasonable precautions were taken to preserve secrecy to ensure that it would be difficult for others to discover the secret without the use of improper means. *Id.* (citing *Henry Hope X-Ray Prods. Inc. v. Marron Carrell, Inc.*, 674 F.2d 1336, 1340 (9th Cir. 1982)).

C. The Domestic Industry Requirement

Trade secret misappropriation investigations at the Commission are governed by 19 U.S.C. § 1337(a)(1)(A), which declares unlawful—

> Unfair methods of competition and unfair acts in the importation of articles . . . into the United States, or in the sale of such articles by the owner, importer, or consignee, the threat or effect of which is—
>
> (i) to destroy or substantially injure an industry in the United States;
>
> (ii) to prevent the establishment of such an industry; or
>
> (iii) to restrain or monopolize trade and commerce in the United States.

19 U.S.C. § 1337(a)(1)(A). Thus, complainants must show not only that they have an "industry in the United States," but also that the industry has suffered "actual substantial injury or threat of substantial injury." *See, e.g.*, *Rubber Resins*, Comm'n Op. at 10.

In addressing whether an "industry . . . in the United States" exists under section 337(a)(1)(A)(i), the Commission has historically considered the "nature and significance" of the

complainant's activities that allegedly form the domestic industry.[7, 8, 9, 10] For example, in *Certain Miniature, Battery-Operated, All Terrain, Wheeled Vehicles*, Inv. No. 337-TA-122,

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[7] *See, e.g.*, *Certain Modular Structural Sys.*, Inv. No. 337-TA-164, USITC Pub. No. 1668, Comm'n Op. at 13 (June 1984) ("*Modular Systems*") (stating that it is necessary to determine "the nature and significance" of complainant's activities in the United States with respect to the relevant product to determine "whether there is an industry 'in the United States' within the meaning of section 337"); *Certain Cube Puzzles*, Inv. No. 337-TA-112, USITC Pub. 1334, Comm'n Op. at 30 (Jan. 1983) ("*Cube Puzzles*") ("We find that Ideal's domestic activities are of *the appropriate nature and are significant enough* to conclude that their domestic business activities constitute an 'industry . . . in the United States.'") (emphasis added) (footnotes omitted). As discussed below, Commission decisions under section 337(a)(1)(A) after the amendments to Section 337 in the Omnibus Trade and Competitiveness Act of 1988, Pub. L. No. 100-418, have continued to rely upon pre-1988 section 337 precedent. *See Certain Ink Markers & Packaging Thereof*, Inv. No. 337-TA-522, Order No. 30 at 57-58, (July 25, 2005) ("*Ink Markers*") ("The administrative law judge finds that investigations prior to the Omnibus Trade & Competitiveness Act of 1988 (1988 Act) and when injury to a domestic industry had to be established for all unfair acts, including statutory intellectual property based cases, are helpful in determining how to define the industry for the acts relating to the trade dress in issue.") (*unreviewed*, *see* USITC Pub. No. 3971); *see also Certain Cast Steel Railway Wheels, Certain Processes for Manufacturing or Relating to Same & Certain Prods. Containing Same*, Inv. No. 337-TA-655, ID at 78-79 n.38 (Oct. 20, 2009), *unreviewed by* Notice (Dec. 17, 2009) ("*Cast Steel Railway Wheels*") (same).

[8] Whether a complainant's investments in domestic activities must be "substantial" or "significant" is an issue raised by the parties and addressed more fully below. *See, e.g.*, OUIIPet. at 11-16; RPet. at 72-76; OUIIBr. at 21-27; CBr. at 22-26; RBr. at 17-20.

[9] Commissioner Schmidtlein notes that the parties disagreed on the applicable legal standard. In Commissioner Schmidtlein's view, after a complainant presents evidence of its domestic expenditures, the Commission analyzes the nature and extent of those expenditures to determine whether the expenditures are *sufficient* to show that a domestic industry exists. Based on the parties' submissions and her reading of the applicable caselaw, Commissioner Schmidtlein finds that there is no material difference between the Commission's "nature and significance" inquiry and the Federal Circuit's "nature and extent" inquiry. Commissioner Schmidtlein agrees that the legislative history can be read as indicating it was Congress's intent to allow the Commission's pre-1988 "nature and significance" analysis for investigations brought under section 337(a)(1)(A) to persist. This, however, does not mean that Congress intended that a complainant must show its domestic industry expenditures satisfy a "significant" threshold under section 337(a)(1)(A) as the word "significant" does not appear in subparagraph (A). *See TianRui*, 661 F.3d at 1336 ("Because the Senate's proposal did not become law, we cannot rely on the legislative history discussing that proposal to read a strict definition of 'industry' into section 337(a)(1)(A), when the statute itself contains no such definition."). Indeed, requiring a complainant to show that its investments satisfy a "significant" threshold is tantamount to

USITC Pub. No. 1300 (Oct. 1982) ("*Toy Vehicles*"), complainants' toy vehicles were manufactured in Hong Kong, and their claimed domestic industry was based on various business activities that they conducted in the United States. The Commission noted that "[t]he threshold question of the existence of an 'industry . . . in the United States' . . . requires an inquiry into the nature and significance of complainants' business activities in the United States which relate to the STOMPER toy vehicles." *Toy Vehicles*, Comm'n Op. at 6. The Commission considered complainants' business activities involving quality control inspections amounting to "sampling that would be expected of any commercial purchaser," warehousing, and shipping, and noted that the majority of expenditures involved advertising, financing, and licensing fee payments. *Id*. at

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amending the statute rather than simply construing it. *See Burlington N.R.R. Co. v. Okla. Tax Comm'n*, 481 U.S. 454, 463 (1987) ("Respondents' position depends upon the addition of words to a statutory provision which is complete as it stands. Adoption of their view would require amendment rather than construction of the statute, and it must be rejected here."). Thus, in Commissioner Schmidtlein's view, analyzing the nature and extent of a complainant's expenditures fundamentally differs from requiring a complainant to show its investments are significant or substantial. *Compare* 19 U.S.C. § 1337(a)(1)(A) (Congress did not use the word "significant" in subparagraph (A)) *with id.* at § 1337(a)(3)(A)-(B) (Congress used "significant" in subparagraphs (A) and (B)); *see also Certain Hand Dryers and Housing for Hand Dryers,* Inv. No. 337-TA-1015, Comm'n Op. at 4 (Oct. 30, 2017) (the Commission held that "an industry in the United States" under section 337(a)(1)(A)(i) is not limited to the domestic industry definition for statutory IP rights under section 337(a)(3)); *Certain Botulinum Toxin Prods., Processes for Manufacturing or Relating to Same, and Certain Prods. Containing Same*, Inv. No. 337-TA-1145, Comm'n Op. at 50-51 n.37 (Dec. 16, 2020) (Commissioner Schmidtlein's related views) ("*Botulinum Toxin Prods.*"). Accordingly, for investigations brought under subparagraph (a)(1)(A), Commissioner Schmidtlein considers whether a complainant's expenditures are sufficient to constitute an industry in the United States. *See, e.g.*, *Cube Puzzles*, Comm'n Op. at 30 (Jan. 1983) (concluding that the complainant's "domestic activities are of the appropriate nature and *are significant enough* to . . . constitute an 'industry . . . in the United States.'" (emphasis added)). She agrees, however, that minimal domestic investment, is insufficient to satisfy section 337(a)(1)(A). *Accord* n.17, *infra* (discussing "minimal domestic investment"). In this investigation, Commissioner Schmidtlein finds that it is not necessary to parse out the differences between a "sufficient" and "significant" or "substantial" threshold because Heraeus's expenditures do not satisfy the "sufficient" threshold.

[10] Vice Chair Stayin is of the view that the application of the "nature and significance" test demonstrates that the Complainant failed to show their U.S. activities were significant enough to constitute a domestic industry in the United States, *see* n.17 below.

10-11. Applying the "nature and significance" test, the Commission determined that these activities were not "sufficient to constitute an 'industry . . . in the United States.'" *Id.*

On appeal, the Federal Circuit affirmed the Commission's approach, stating that "the nature and extent of Schaper's domestic activities (in relation to the total production process of the Stomper toy vehicles) are insufficient to constitute an 'industry . . . in the United States.'" *Schaper Mfg. Co. v. Int'l Trade Comm'n*, 717 F.2d 1368, 1372 (Fed. Cir. 1983). Ultimately, the Court concluded that "[t]here is simply not enough significant value added domestically to the toy vehicles by Schaper's activities in this country (including design, inspection and packaging)." *Id.* at 1373. The Court distinguished qualifying U.S. activities from those that would ordinarily be performed by a mere importer stating that "Schaper has not shown its United States inspection activities to be substantially different from the random sampling and testing that a normal importer would perform upon receipt (and Schaper does no repairs)." *Id.* at 1372. Likewise, the Court found "Schaper's very large expenditures for advertising and promotion cannot be considered part of the production process. Were we to hold otherwise, few importers would fail the test of constituting a domestic industry." *Id.*

Upon establishing an industry in the United States and unfair acts related to the importation and sale of respondents' products, a complainant must show that those unfair acts have substantially injured or threatened to injure the domestic industry. The Commission in *Rubber Resins* explained:

> In determining whether unfair acts have substantially injured the domestic industry, the Commission considers a broad range of indicia, including: the volume of imports and their degree of penetration, complainant's lost sales, underselling by respondents, reductions in complainants' declining production, profitability and sales, and harm to complainant's good will or reputation.

Rubber Resins, Comm'n Op. at 60-61 (citing *Cast Steel Railway Wheels*). In addition, the Commission has recognized the necessity of evidence establishing a causal nexus between the unfair imports and alleged substantial injury. *See, e.g.*, *Certain Drill Point Screws for Drywall Construction*, Inv. No. 337-TA-116, Comm'n Op. at 20-22 (Mar. 3, 1983); *Rubber Resins*, Comm'n Op. at 61.

IV. ANALYSIS

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

A. Existence of Protectable Trade Secrets[11]

As an initial matter, the Commission adopts the ID's findings, conclusions, and analysis as to TS 1-35 in their entirety. Specifically, the Commission affirms the ID's findings that Heraeus has proven that TS 1-35 are protectable trade secrets; Zimmer Biomet misappropriated TS 1-35; and Zimmer Biomet used these trade secrets in the production of its bone cement products. ID at 19-31, 51-55. Thus, as to TS 1-35, the Commission affirms the ID's finding that Heraeus has established an unfair act in the importation and sale of Zimmer Biomet's bone cement products.

The parties dispute whether the confidentiality obligations of an agreement between [ ] Heraeus have expired. Heraeus argues that the obligations have not expired, while

[11] Commissioner Schmidtlein takes no position on the ID's contractual analysis, as it is discussed in Part III.A of this opinion, for reasons of administrative efficiency. *See Beloit Corp. v. Valmet Oy*, 742 F.2d 1421, 1423 (Fed. Cir. 1984) ("The Commission's judicious use of a single dispositive issue approach in issuing final negative § 337 determinations can not only save the parties, the Commission, and this court unnecessary cost and effort, it can greatly ease the burden on a Commission commonly faced with a § 337 proceeding involving numerous complex issues and required by statute to reach its conclusion within rigid time limits.").

Zimmer Biomet argues that they have. *See, e.g.*, CPet.[12] at 54 n.19; RReply[13] at 33-38. This issue relates to whether Heraeus has shown it kept the proprietary information in TS 121-23 confidential, but it does not affect the remainder of the asserted trade secrets.

The Commission agrees with the ID's conclusion that Heraeus failed to take steps to safeguard TS 121-23 in the [ ] its fulfillment of orders, the Biomet Merck Joint Venture, and the Biomet Distribution Arrangement (U.S.). The Commission disagrees, however, that the confidentiality obligations set forth in the [ ] Supply Agreement between [ ] and Heraeus (the "[ ] Supply Agreement" or the "Supply Agreement") (JX-134C) [

]) (JX-25C). ID at 35-38. As discussed further below, this modification does not alter the ID's conclusion that T121-23 are not protectable trade secrets. *See* Restatement (Third) of Unfair Competition § 39 (1995) ("If the information has become readily ascertainable from public sources so that no significant benefit accrues to a person who relies instead on other means of acquisition, the information is in the public domain and no longer protectable under the law of trade secrets.").

Specifically, the Commission finds that the [

]." JX-134C at 50. Zimmer Biomet contends that [ ]

[12] Complainant's Petition for Review of Initial Determination on Violation of Section 337, EDIS Doc ID 710576 (May 18, 2020) ("CPet.").

[13] Respondents' Response to Heraeus' and the Commission Staff's Petitions for Review of the Initial Determination, EDIS Doc ID 711067 (May 26, 2020) ("RReply").

and Heraeus terminated the Supply Agreement through the [ ].[14] *See* JX-25C. The [ ] states that "[

]." JX-25C at 2. The Commission finds that this letter was not an affirmative action taken by the parties to terminate the Supply Agreement with a three-year notice period. Rather, it explained that a portion of the Supply Agreement conflicted with a new regulation in the EU cartel law. JX-25C at 2.

In fact, in accordance with the Supply Agreement's severability clause,[15] the parties continued to comply with the agreement by endeavoring to replace the provisions that had become contrary to law. JX-134C at 53; JX-25C at 2 ("[

]"). In addition, a 2009 submission by [ ] (and multiple Biomet entities) in certain European court proceedings indicated the understanding that the [

]. *See* CX-739C at 65 (HERAEUSITC0328428) (cover page), 68

[14] To the extent Zimmer Biomet attempts to rely on evidence presented by its expert, Dr. Cheryl Blanchard, to show that the [ ] Supply Agreement has terminated, the Commission notes that Dr. Blanchard's testimony is contrary to the text of the agreements themselves (the [ ] Supply Agreement and the [ ]), and as such, this evidence is not persuasive.

[15] [

]. JX-134C at 53.

(HERAEUSITC0328431) (The court filing states: "The Plaintiff has disregarded this still valid jurisdiction agreement between the parties by calling on the District Court of Darmstadt."). Finally, Mr. Schneider, Heraeus's Head of the Legal and Insurance Department, testified that he understood the change in EU law to nullify only *the exclusivity provisions* of the Supply Agreement in Europe. JX-259C (Schneider) at 304:16-306:24. In such circumstances, the Supply Agreement's severability clause provides that all other provisions remain in place. JX-134C at 53. Accordingly, the Commission finds that the Supply Agreement's confidentiality obligations are still in force. JX-134C at 48, 53-54.[16]

This modification to the ID's analysis, however, does not change the ID's conclusion that Heraeus failed to take steps to safeguard TS 121-23 in the [ ] Project, its fulfillment of orders, the Biomet Merck Joint Venture, and the Biomet Distribution Arrangement (U.S.). ID at 33-38. Accordingly, except for the discussion on page 35 of the ID in the section labeled "Heraeus and [ ]," the Commission affirms and adopts the portions of the ID that address TS 121-23 and the conclusion that they are not protectable trade secrets.

B. Failure to Establish an "Industry in the United States"

The Commission next turns to the question of whether Heraeus has proven that it has an "industry in the United States" under section 337(a)(1)(A)(i). The parties dispute whether

[16] [

].

Heraeus's activities are of a nature that qualify under the statute for consideration as "an industry in the United States." The parties further disagree as to whether the statute requires proof of "significant" or "substantial" investments, pertaining to the qualifying activities, to establish that Heraeus has "an industry in the United States." For the reasons provided below, the Commission reverses the ID's conclusion that Heraeus proved the existence of an industry in the United States under section 337(a)(1)(A)(i).

1. The "Nature and Significance" of Domestic Activities and Investments

As noted in Part III.C above, to determine whether an "industry in the United States" exists under section 337(a)(1)(A)(i), the Commission has traditionally considered the "nature and significance" of the complainant's domestic activities. Heraeus argues that there is no statutory requirement that its investments and expenditures in its domestic activities be significant or substantial, but rather only that an industry exists. CBr. at 22. Specifically, Heraeus contends that "[s]ection 337(a)(3), which applies to statutory [intellectual property] investigations, requires proof of domestic investments in specific categories that are 'significant' or 'substantial' to establish a domestic industry[.]" *Id.* Heraeus argues that there is no such requirement in section 337(a)(1)(A)(i). *Id.* Heraeus also argues that "[n]either the legislative history nor precedent support rewriting section 337(a)(1)(A)(i) to require a complainant to prove that the expenditures or investments demonstrating the existence of a domestic industry are 'significant' or 'substantial.'" CBr. at 23.

Respondents and OUII object to this interpretation of the statute and argue that the Commission has consistently held that "a complainant bringing a claim under section 337(a)(1)(A)(i) should demonstrate that its industry in the United States is 'significant'" and does so by analyzing the nature and significance of such activities. OUIIBr. at 21; *see also* RBr.

at 17-20. Moreover, OUII argues that the Commission's pre-1988 precedent continues to provide guidance for investigations instituted under current section 337(a)(1)(A). OUIIBr. at 23-24. As discussed below, the Commission will continue to follow Commission precedent, affirmed by the Federal Circuit, by analyzing the nature and significance of the complainant's domestic activities to determine if they are sufficient to constitute a domestic industry.[17]

To address Heraeus's argument that domestic activities do not need to be "significant," the Commission looks to the language of its governing statute, legislative history, Federal Circuit precedent, and its own historical practice to conclude that the Commission's application of the "nature and significance" test is appropriate. The plain language of section 337(a)(1)(A)(i), quoted above, requires a showing of "an industry in the United States," but does not define that phrase as it is used within the subclause, nor does the language specify the types of activities that would qualify toward establishing a domestic industry.

[17] Vice Chair Stayin is of the view that the statute, relevant legislative history, and Commission precedent discussed herein all show that when evaluating whether a domestic industry exists for purposes of section 337(a)(1)(A), the Commission applies the "nature and significance" of the alleged investments (if manufacture and production occur abroad) to determine if a complainant's industry in the United States is significant. *See also Botulinum Toxin Prods.*, Comm'n Op. at 15, 51, 55 (The Commission, in applying the nature and significance test, found complainants' expenditures in the U.S. to be significant.). A determination without this threshold would otherwise permit a finding of a domestic industry based on any minimal domestic investment. Such a result would be inconsistent with the purposes of section 337. *See, e.g., Certain Computers & Computer Peripheral Devices, & Components Thereof, & Prods. Containing Same*, Inv. No. 337-TA-841, Comm'n Op., Dissenting Views of Commissioner Shara L. Aranoff, at 2 (Jan. 9, 2014) ("Congress intended section 337 to protect American industries and American workers"); *John Mezzalingua Assocs., Inc. v. Int'l Trade Comm'n*, 660 F.3d 1322, 1328 (Fed. Cir. 2011) ("The purpose of the Commission is to adjudicate trade disputes between U.S. industries and those who seek to import goods from abroad." (quoting H.R. Rep. No. 100-40, at 157)). In application of this standard, Vice Chair Stayin is of the view that the Complainant has failed to establish that its activities and investments in the United States are significant enough to constitute a domestic industry, and therefore, he concurs with the majority's finding of no domestic industry.

The term "industry" was originally introduced into law in the predecessor to section 337, section 316 of the Tariff Act of 1922. The statute was re-enacted, with minor changes, in section 337 of the Tariff Act of 1930. The statute provided then, in pertinent part, as follows:

> (a) Unfair Methods of Competition Declared Unlawful.— Unfair methods of competition and unfair acts in the importation of articles into the United States, or in their sale by the owner, importer, consignee, or agent of either, *the effect or tendency of which is to destroy or substantially injure an industry, efficiently and economically operated*, in the United States, or to prevent the establishment of such an industry, or to restrain or monopolize trade and commerce in the United States, are hereby declared unlawful, and when found by the President to exist shall be dealt with, in addition to any other provisions of law, as hereinafter provided.

19 U.S.C. § 1337(a) (1930) (emphasis added).

Prior to 1988, when section 337(a) was last amended to its current form as section 337(a)(1)(A), the Commission's assessment of whether the "industry" requirement was met consisted of considering investments in land, plant, and equipment and to employment of labor and capital, but also more generally to the nature of complainant's claimed business activities in the United States within "the realities of the marketplace." *See TianRui*, 661 F.3d at 1336. This reflects the fact that each industry is unique to its particular facts and circumstances. In many pre-1988 investigations, where the relevant domestic industry product was manufactured abroad and imported, "the Commission traditionally examine[d] the nature and significance of the activities in the United States in order to determine whether a domestic industry exists." *Certain Dynamic Random Access Memories, Components Thereof & Prods. Containing Same*, Inv. No. 337-TA-242, USITC Pub. No. 2034, Comm'n Op. at 67-68 (Sept. 1987), *rev'd in part on other grounds*, *Texas Instruments Inc. v. U.S. Int'l Trade Comm'n*, 871 F.2d 1054 (Fed. Cir. 1989); *see also Toy Vehicles*, Comm'n Op. at 6, *aff'd by Schaper*, 717 F.2d at 1368 ("The threshold question of the existence of an 'industry . . . in the United States' . . . requires an inquiry into the nature and significance of complainants' business activities in the United States which relate to

the STOMPER toy vehicles.").[18] In fact, the Federal Circuit, in affirming the Commission's finding of no industry in the United States in *Toy Vehicles*, where the product was manufactured abroad, looked to the "nature and the extent of [the complainant's] domestic activities (in relation to the total production process of the [domestic industry products]) . . . ." *Schaper*, 717 F.2d at 1372. The Court found that such activities were "insufficient to constitute an industry . . . in the United States," explaining that "[t]here is simply not enough *significant* value added domestically to the toy vehicles by [the complainant's] activities in this country." *Id.* at 1372-73 (emphasis added). The Court in *Schaper* also pointed out that the complainant's inspection activities were not substantially different from those that a "normal importer" would perform, and that crediting its advertising and promotion expenditures would mean "few importers would fail the test of constituting a domestic industry." *Id*.

The term "industry" was retained through the 1988 Amendments, and the legislative history does not indicate that Congress intended to reject the Commission's pre-1988 precedent as it applies to non-statutory intellectual property. Indeed, it supports the contrary. Prior to 1988, section 337(a) covered all unfair methods and acts, including both patent and trade secret claims. *See generally John Mezzalingua*, 660 F.3d at 1327. The 1988 Amendments enacted

[18] *See also Certain Airtight Cast-Iron Stoves*, Inv. No. 337-TA-69, USITC Pub. No. 1126, Comm'n Op. at 11 (Jan. 1981) ("*Cast-Iron Stoves*") (finding that a domestic industry had been shown based on domestic repair, testing, and installation activities because "the value added domestically is significant"); *Cube Puzzles*, Comm'n Op. at 27, 30 (finding domestic activities "significant enough" under a "nature and significance" assessment to establish an industry in the United States where approximately 50 percent of the product's value is added by production activities in the United States); *Modular Systems*, Comm'n Op. at 13-15 (evaluating "the nature and significance" of Complainant's activities in the United States with respect to the relevant product in order to determine "whether there is an industry in the United States within the meaning of section 337" and ultimately finding no industry in the United States, where "inspection and quality control are minimal, and installation and assembly are only sometimes done" (footnote and internal quotation omitted)).

separate domestic industry requirements for statutory-based intellectual property rights, like patents. *See* 19 U.S.C. § 1337(a)(3); *see also* Omnibus Trade and Competitiveness Act of 1988, Pub. L. No. 100-418 (amending section 337). These provisions, including their "significant" language, were intended to codify, for statutory-based intellectual property rights, pre-1988 Commission decisions regarding the domestic industry requirement. *See* S. REP. NO. 100-71, 100th Cong., 1st Sess. at 129 (1987) (noting that the "significant investment in plant and equipment" and "significant employment of labor and capital" factors "have been relied on in prior Commission decisions finding that an industry exists in the United States"). For non-statutory intellectual property claims (*i.e.*, common law trademark or trade secret claims), Congress retained the language of former section 337(a) in section 337(a)(1)(A). The 1988 Amendments removed the "efficiently and economically operated" requirement but retained the term "industry" from former section 337(a) in section 337(a)(1)(A)(i) & (ii). *See* 19 U.S.C. § 1337(a)(1)(A). In light of Congress's decision to retain the term "industry" and the fact that Congress was aware of the Commission's pre-1988 precedent, the pre-1988 precedent continues to provide guidance for investigations instituted under the current version of section 337(a)(1)(A). *See* S. REP. NO. 100-71 at 129; *see also* 2B SUTHERLAND STATUTORY CONSTRUCTION § 49:9 (7th ed.) ("[L]egislative action by amendment or appropriation of some parts of a law which has received a contemporaneous and practical construction may indicate approval of interpretations relating to the unchanged and unaffected parts."); *Lindahl v. Office of Pers. Mgmt.*, 470 U.S. 768, 782-83 (1985) ("Moreover, the fact that Congress amended [the relevant statutory section] in 1980 without explicitly repealing the established [legal] doctrine itself gives rise to a presumption that Congress intended to embody [that doctrine] in the amended version of [that statutory section]. We need not rely on the bare force of this

presumption here, however, because the legislative history . . . demonstrates that Congress was indeed well aware of [the established legal doctrine], amended [the statutory section] on its understanding that [the established legal doctrine] applied to judicial review of disability retirement decisions generally, and intended that [the established legal doctrine] review continue except to the extent augmented by the more exacting standards [added by Congress]." (footnote omitted)).

Heraeus argues that Congress considered whether trade secret misappropriation claims should receive the same treatment as statutory intellectual property claims in the 1988 Amendments, and ultimately did not take that approach. *See, e.g.*, CBr. at 24-26. However, Congress was aware of Commission practice under prior section 337(a) law—including the application of a significance assessment—and yet made no changes to this aspect of subsection 337(a)'s language as it applied to non-statutory intellectual property. Thus, the re-enactment doctrine supports continued application of the Commission's standard. *See Lorillard v. Pons*, 434 U.S. 575, 580-81 (1978) ("Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change . . . where, as here, Congress adopts a new law incorporating sections of a prior law, Congress normally can be presumed to have had knowledge of the interpretation given to the incorporated law, at least insofar as it affects the new statute." (citations omitted)).

Accordingly, to determine whether an "industry" exists in the United States, the Commission has historically considered the nature of the activities in the United States that relate

to the complainant's product and the significance of those activities.[19, 20] The 1988 Amendments did not change that. Thus, the statute, legislative history, Federal Circuit precedent, and Commission precedent support the Commission's continued assessment of the nature and significance of complainants' business activities in the United States that relate to complainants' domestic industry products to determine whether there are sufficient qualifying activities to constitute an industry in the United States or whether complainants' activities are those of a mere importer. *Schaper*, 717 F.2d at 1372-73.

While there is no bright-line rule to determine whether a complainant's domestic activities are distinguishable from those of a mere importer the Commission has often considered some types of activities, such as administrative overhead, inspections, and warehousing costs associated with importation of the domestic industry products as well as sales and marketing of the product, to be indistinguishable from those of a mere importer and has not typically credited them when determining whether a domestic industry exists.[21] *See, e.g.*, *Schaper*, 717 F.2d at

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[19] As explained above, in Commissioner Schmidtlein's view, considering the "nature and significance" of the domestic industry investments to determine whether they are "sufficient" or "significant enough" *per* pre-1988 precedent is not the same as requiring the investments *to be* significant.

[20] *See* views of Vice Chair Stayin, n.17, *supra*, applying nature and significance test to determine if a complainant's domestic activities are significant enough to establish an industry in the United States.

[21] Historically, Commissioner Schmidtlein notes that discrediting "mere importer" activities occurs where the asserted domestic industry lacks domestic manufacturing activity. *See, e.g.*, *Toy Vehicles*, Comm'n Op. at 6, 10-11 (noting that the complainant's manufacturing occurred in Hong Kong, finding that complainant's marketing, financing, and royalty expenses were its largest expenses, and concluding that complainant's activities were not sufficient to constitute an industry in the United States); *Certain Non-Volatile Memory Devices & Prods. Containing Same*, Inv. No. 337-TA-1046, USITC Pub. No. 4965, ID at 159 n.37 (Apr. 27, 2018) ("*Non-Volatile Memory Devices*") (reviewing cases and noting that the Commission has included "ancillary activities," such as sales and marketing expenses, "as part of domestic industry [when the ancillary activity] accompanied actual domestic manufacturing"), *rev'd on other grounds,*

1372-73; *Certain Male Prophylactic Devices*, Inv. No. 337-TA-546, Comm'n Op. at 39 (Aug. 1, 2007) ("*Male Prophylactic Devices*") (examining complainant's U.S. activities to determine whether they are the types of activities that constitute a domestic industry or whether they are the types of activities that a "mere importer" would perform); *Non-Volatile Memory Devices*, ID at 158-60 (noting Commission and Federal Circuit precedents discounting sales and marketing activities as indistinguishable from those of a mere importer).[22, 23]

Comm'n Op. at 44 (Sept. 2019); *Certain Solid State Storage Drives, Stacked Elec. Components, & Prods. Containing Same*, Inv. No. 337-TA-1097, Comm'n Op. at 22 (June 20, 2018) (noting that the Commission "has stated that '[w]hile marketing and sales activity, alone, may not be sufficient to meet the domestic industry test, those activities may be considered as part of the overall evaluation of whether or not a Complainant meets the economic prong.'" (quoting *Certain Printing & Imaging Devices & Components Thereof*, Inv. No. 337-TA-690, Order No. 24 at 34 (Apr. 21, 2010), *rev'd on other grounds*, Comm'n Op. at 30-31 (Feb. 17, 2011) and citing to S. Rep. No. 100-71, at 129 (1987)); *see also Male Prophylactic Devices*, Comm'n Op. at 45 ("[U]nder the statutory domestic industry test, as set forth in the 1988 amendments, actual production is not necessarily required to give a company standing to claim relief under section 337.").

[22] In *Non-Volatile Memory Devices*, the ALJ found that complainant failed to establish a domestic industry in the process of being established, notwithstanding its significant investments in R&D activities, because complainant did not have a commercial product and thus did not meet the "article" requirement under section 337(a)(3). While crediting the R&D investments, the ALJ declined to rely on investments in asserted "customer facing technical work" that were deemed sales and marketing; the ALJ stated that the Commission has not "distinguished between technical sales and marketing and other types of sales and marketing," and added that it would not "make sense to do so. If a company is importing products from abroad, it needs a sales force in the United States to sell the products. If the company's products are highly technical, the company needs a technically sophisticated cadre of marketers to sell them." *See* ID at 160. On review, the Commission rejected the ID's finding that a commercial product is required and found a domestic industry in the process of being established based on significant R&D investments, but affirmed the ID's determination that "Macronix failed to establish a domestic industry based on investments in 'customer facing' engineering for the reasons provided in the ID." Comm'n Op. at 44 (Oct. 26, 2018) (citing ID at 154-186).

[23] Commissioner Schmidtlein notes that in various decisions over the last four decades—and as recently as six months ago—the Commission has credited sales and marketing expenses where the complainant has shown it is more than a mere importer. *See, e.g.*, *Certain Toner Cartridges, Components Thereof, & Sys. Containing Same*, Inv. No. 337-TA-1174, Order No. 40 at 114 n.31

Other types of activities, such as manufacturing in the United States, have traditionally been considered ones that Congress intended to form the basis for a domestic industry and the Commission generally credits them towards a domestic industry. *John Mezzalingua*, 660 F.3d at 1337. Congress, however, in choosing to employ the word "industry" rather than "manufacturing," illustrated that it intended the term "industry" to cover more than just domestic manufacturing. *See Schaper*, 717 F.2d at 1373 (observing that "in proper cases 'industry' may encompass more than the manufacturing of the patented item"). As illustrated in *Toy Vehicles,* when assessing non-manufacturing activities in the United States, the Commission carefully considers the nature of the complainant's activities to determine whether they are the types of activities that qualify toward a domestic industry or whether they are the types of activities that a mere importer would perform. Activities relating to the domestic industry products at issue that go beyond what a mere importer would perform may contribute to a domestic industry, as the *Schaper* Court explained.

(July 23, 2020) (finding that complainant's "marketing and sales expenditures are appropriately considered as part of its domestic industry in light of their relationship to [complainant's] significant investment in manufacturing and servicing products"), *unreviewed by* Comm'n Notice (Sep. 8, 2020); *Certain Integrated Circuits, Processes for Making Same, & Prods. Containing Same*, Inv. No. 337-TA-450, ID at 152-56 (May 6, 2002) (noting that complainants' employees work with customers to customers to ensure complainants' products complied with applicable design rules, rejecting respondents' argument that these activities were "merely sales and marketing activity that cannot form the basis of a domestic industry," and concluding that the complainants satisfied the economic prong "by virtue of their activities and investments which assist customers to design integrated circuits that will be made according to the '345 patented method"), *unreviewed in pertinent part by* Comm'n Notice (June 21, 2002); *Certain Personal Computers & Components Thereof*, Inv. No. 337-TA-140, USITC Pub. No. 1504, Comm'n Op. at 43 (Mar. 1984) (crediting quality control and packaging activities where the complainant also engaged in some domestic production); *see also* H.R. Rep. No. 100-40, Pt. 1, at 157 (1988) ("Marketing and sales in the United States ***alone*** would not, however, be sufficient to meet this test." (emphasis added)).

For instance, the Commission has held, depending on the facts and circumstances of the particular investigation, that installation of the domestic industry's product, education and training regarding that product, and corresponding warranty, service, repair, quality control, and packaging activities may be considered. *See, e.g.*, *Cast-Iron Stoves*, Comm'n Op. at 10-11 (finding the existence of a domestic industry of importer-distributors-dealers with respect to wood-burning stoves manufactured abroad based on U.S. repair, testing, and installation activities for those stoves); *Certain Apparatus for the Continuous Prod. of Copper Rod,* Inv. No. 337-TA-52, USITC Pub. 1017, Comm'n Op. at 53-55 (Nov. 1979) (finding a domestic industry related to "SCR systems" based on their development, licensing of related patents and trade secret know-how, related engineering, related start-up operations, and related technical assistance, as well as subcontracted manufacture of related components); *Sleep-Disordered Breathing Treatment Sys. & Components Thereof*, Inv. No. 337-TA-890, ID at 168 (Sept. 16, 2014), *unreviewed in relevant part*, Notice (Oct. 16, 2014) (crediting, in a patent-based investigation brought under 337(a)(3), investments providing for a clinical education group to train medical providers how to "configure ResMed devices and select appropriate masks for patients"); *Certain Road Milling Machines & Components Thereof,* Inv. No. 337-TA-1067, ID at 429-34 (Oct. 1, 2018) (in a patent-based investigation, finding a domestic industry based in part on investments oriented to instructing customers on how to use the domestic industry products), *unreviewed in relevant part by* Comm'n Notice (Apr. 23, 2019); *Cube Puzzles*, Comm'n Op. at 28-30 & n.109-13 (finding a domestic industry based in part on extensive packaging, testing operations, and repair in conjunction with the quality control process, as well as the production of molds and efforts to improve design and materials) (citing *Cast-Iron Stoves*, USITC Pub. No. 1126).

Once the Commission has determined which qualifying activities contribute to the domestic industry, it assesses what investments or expenditures have been made in those activities. The Commission has historically considered relevant investments in plant, equipment, land, labor, and capital, but other investments and expenditures can also be considered. Finally, the Commission considers the extent of all qualifying domestic industry investments and expenditures to determine whether they are sufficient to constitute a domestic industry. *Schaper*, 717 F.2d at 1372 (finding no industry in the United States where "the nature and the extent of Schaper's domestic activities (in relation to the total production process of the Stomper toy vehicles)" were "insufficient").

The Commission has looked to several different contextual indicators to determine if these investments and expenditures are sufficient to constitute a domestic industry. For instance, one methodological approach the Commission has used in both pre- and post-1988 investigations is "comparing complainant's domestic expenditures to its foreign expenditures." *Certain Carburetors & Prods. Containing Such Carburetors*, Inv. No. 337-TA-1123, Comm'n Op. at 9 (Oct. 28, 2019) (finding that "comparing complainant's domestic expenditures to its foreign expenditures is one of the possible factors that the Commission could but . . . is not required to consider") (quoting *Certain Optoelectronic Devices for Fiber Optic Communications*, Inv. No 337-TA-860, Comm'n Op. at 18-19 (May 9, 2014)). Another approach, among others, is to consider "the value added to the article in the United States by the domestic activities." *Id.* at 19. Indeed, Commission decisions have accepted a "value-added" analysis to assess whether an industry in the United States exists. *See Cube Puzzles*, Comm'n Op. at 30 (significance of the domestic operations was shown by the fact that "approximately 50 percent of the value of the cube puzzle" is added in the United States by "Ideal's quality control, packaging and repair

operations"); *Cast-Iron Stoves*, Comm'n Op. at 11 (finding a domestic industry based on repair, testing, and installation activities because "the value added domestically is significant"); *Certain Airless Paint Spray Pumps & Components Thereof*, Inv. No. 337-TA-90, USITC Pub. No. 1199, Comm'n Op. at 10-11 (Nov. 1981) (finding that domestic investments in warranty repairs should be included in the domestic industry "[i]nasmuch as the value added to a product in the United States is a significant factor in determining whether the U.S. operation of a foreign corporation is part of domestic industry"). Moreover, the Federal Circuit in *Schaper* compared the investments in the United States with "the total production process of [the domestic industry products]," and found that there was not "*significant value added*" to the products in the United States. *Schaper*, 717 F.2d at 1372-73 (emphasis added). In sum, as discussed above, the Commission's determination as to the existence of a domestic industry must be assessed according to a highly fact-specific assessment of the "nature and significance" of the complainant's domestic activities.

2. Assessment of Heraeus's Domestic Activities and Investments

To determine whether Heraeus's domestic business activities constitute an "industry in the United States" that merits protection under section 337, "the initial inquiry is what parts of these activities are to be considered[.]" *Schaper*, 717 F.2d at 1370. Consistent with its past practice, the Commission first considers the nature of Heraeus's activities in the United States related to its Palacos bone cements to determine whether these activities should be considered for inclusion in an "industry" in the United States. The Commission finds that, in this investigation, several of Heraeus's activities in the United States do not contribute to an "industry" within the meaning of the statute or Commission precedent. *TianRui*, 661 F.3d at 1337.

Heraeus argues that its claimed activities in the United States relate to its Palacos line of bone cements, which are the products in direct competition with the accused articles.[24] To support its position that it has an industry in the United States, Heraeus relies on expenditures for activities by HMUS and its consultants that can be broadly described as education and training, domestic labor, regulatory, and manufacture of adapters and medical hoses that are used with Heraeus's Palacos bone cements. The Palacos bone cements are manufactured entirely in Germany and imported into the United States. HMUS does not modify or repackage the Palacos units before selling them to customers in the United States. ID at 59; Tr. (Childers) at 187:12-22. Thus, the Commission considers the nature and significance of Heraeus's activities in the United States related to its Palacos bone cements that Heraeus seeks to protect from unfair imports, including whether those activities are those that would be undertaken by a mere importer,[25] to determine whether there is an "industry" in the United States.

The ID credited some of Heraeus's claimed education and training, domestic labor, and regulatory expenditures, in particular those related to the Reduce Revisions Initiative (ID at 60-63), to certain Domestic Labor (ID at 66-68), and to Medical Professionals (ID at 70-71). The ID did not credit other education and training, domestic labor, regulatory, new-contract acquisition, warehousing, or component manufacture expenditures because, in the ID's view, any importer would conduct those activities, they are sales and marketing activities, or they do not sufficiently relate to the Palacos bone cements.

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[24] Heraeus frames its argument as follows: "Once a complainant satisfies the threshold question of whether its domestic industry expenditures are sufficient to establish a domestic industry, the question becomes whether its domestic industry as a whole has been injured. Heraeus is in the bone cement industry. Its education, training and research and development expenditures advance that industry. They are not a separate industry." CPet. at 2.

[25] *See*, *e.g.*, *Male Prophylactic Devices*, Comm'n Op. at 39.

The Commission agrees with the ID that Heraeus's expenditures for Palacademy and the "Other Medical Events and Medical Conferences," trade shows, and conferences are not of the nature of activities that qualify toward establishing an industry under the facts of this investigation because, as the ID found, (a) these activities are largely marketing events, (b) they are the types of activities a mere importer would conduct, and (c) they had an overly attenuated relationship to the Heraeus bone cement products. ID at 60-65. The Commission also affirms and adopts the ID's findings and analysis declining to consider the asserted "Domestic Facility Expenditures," "Domestic Labor Expenditures" (except those credited by the ID), and "Contracting Costs" (except Medical Professionals) as qualifying toward "an industry in the United States."[26] ID at 65-72. The Commission also affirms the ID's findings that four of Heraeus's employees engage in education and training related to the bone cements (totaling $[ ]).[27] ID at 66-68. Accordingly, the Commission affirms and adopts the ID's findings as

[26] For the "Domestic Component Expenditures," the Commission notes that the alleged components—hoses—are actually accessories that connect Heraeus's medical foot pump to compressed air systems in hospital rooms. Comp. Post-Hrg. Br. at 113. They are not a component of the bone cements at issue here. ID at 72. Moreover, even if they were components, the Commission finds that Heraeus relied on the full purchase price of the hoses and did not present evidence of what investments the domestic manufacturer, [ ], made in these hoses. *Cf. Lelo Inc. v. Int'l Trade Comm'n*, 786 F.3d 879, 884 (Fed. Cir. 2015) (in a patent-based investigation, criticizing the complainant for presenting "only generic purchase prices it paid for the off-the-shelf items" as investments). For these reasons, the Commission declines to credit these expenditures. The Commission disagrees, however, that the expenditures for the hoses would necessarily need to be connected to the other domestic activities that Heraeus attempts to rely upon, *i.e.*, education, training, research, and quality control, in order to contribute to a domestic industry. ID at 72.

[27] It is unclear whether all the work of Ms. Ducharme, HMUS's Scientific Quality Affairs Analyst, should be credited toward the domestic industry. ID at 67-68 ("Ms. Ducharme's activity should be considered a non-sales and marketing expense, because, *giving Heraeus the benefit of the doubt*, *at least some of her work* focuses specifically on clinical research studies.") (emphasis added). However, as discussed below, even fully crediting her activities does not result in the Commission finding a domestic industry.

to the nature of those activities and that only the expenses for the four employees qualify toward establishing a domestic industry. The remainder of Heraeus's activities, *i.e.*, (a) the Reduce Revisions Initiative and (b) Heraeus's FDA Activities, are discussed below.

a) The Reduce Revisions Initiative

The Commission finds that the Reduce Revisions Initiative activities do not qualify for consideration as part of the domestic industry. While some education and training expenditures may so qualify under appropriate circumstances, at the very least, the Reduce Revisions activities focus on reducing repeat joint replacements and are not sufficiently related to the Palacos bone cements.[28] As discussed above, in order for the Reduce Revisions Initiative to qualify towards the domestic industry concerning the Palacos bone cements, it must be sufficiently related to the domestic industry that Heraeus seeks to protect from unfair imports. *E.g.*, Comp. Post-Hrg. Br. at 4-5, 85. In particular, the ID observed that the Reduce Revisions Initiative "has no obvious link to Palacos bone cement at all." ID at 63. Rather, the Reduce Revisions Initiative is directed to reducing the number of repeat total joint arthroplasty surgical procedures. Tr. (Prowse) at 545:3-9; CDX-3C at 14-15 ("[

]."). The Commission finds that these activities are not sufficiently related ***to bone cements*** such that they may be considered qualifying activities contributing to the claimed "industry" in the United States. *Id.*

[28] In considering whether to credit education and training expenditures toward a domestic industry, Chair Kearns also considers whether they are of the sort that a mere importer would engage in, and whether they are activities that must by their nature be performed in the United States. Chair Kearns need not resolve these issues for the Reduce Revisions expenditures here, as the Commission finds that they are insufficiently related to the domestic industry product.

Moreover, evidence offered to support the Reduce Revisions Initiative cuts against Heraeus's claim that the program is anything but marketing. Instead, the evidence shows that Heraeus itself treats Reduce Revisions as a sales and marketing effort. Heraeus's financial records classify expenditures related to Reduce Revisions, including [ ], the adverting agency that develops content for the Reduce Revisions website, as "advertising expenses." JX-142C at Rows 823, 825, 13764-13767, 13786-13793, 13890-13893, 15446-15464, 15576-15578, 16905; Tr. (Childers) at 190:18-21. Heraeus hired [ ] for strategy, consulting, and for marketing and selling Heraeus's Palacos brand. *See* Tr. (Childers) at 191:7-14 (Heraeus hired [ ] "for strategy, consulting, marketing, branding."); JX-249C (Childers Dep. Designations) at 182:13-15 ([ ]involved in developing content for Reduce Revisions website); JX-255C (Kolbe Dep. Designations) at 66:11-18 ("Q. And so what does [ ] do? A. They're an ad agency, so marketing stuff."); Tr. (Mulhern) at 906:2-15 ("[ ] provides marketing services to Heraeus of a variety of different types"); RDX-2 at 5; RDX-2 at 6 (summarizing Heraeus testimony regarding [ ]). In short, there is a failure of proof to support Heraeus's claim that the Reduce Revisions expenditures are related to anything but marketing. Accordingly, the Commission finds that Heraeus has not proven that the nature of the Reduce Revisions Initiative qualifies it as an activity that contributes to an "industry" in the United States within the meaning of the statute.[29]

[29] Commissioner Schmidtlein does not join this paragraph. Commissioner Schmidtlein would not dismiss the Reduce Revisions Initiative *as a marketing expense* because the initiative, in her view, is more like an educational symposium. For example, the initiative collects and hosts articles that are published in scholarly journals. *See* CDX-3C at 18. Exemplary articles include [

]. *Id.*

With regard to the medical professionals paid to work on Palacademy and the Reduce Revisions Initiative, the Commission finds that the consulting fees for medical professionals paid to work on those programs do not qualify toward an "industry" in the United States for the same reasons other expenditures for those programs do not. *See, e.g.*, Tr. (Prowse) at 563-64; Tr. (Childers) at 200-01.

b) Heraeus's FDA Activities

The ID held that Heraeus's Food and Drug Administration ("FDA") regulatory activities were no different from the types of activities that a mere importer would engage in. ID at 68-69. Heraeus argues that these expenses should have been included in the total investment of activities in the United States because the Commission has previously included expenditures related to FDA approval and because Heraeus did not have to take on the responsibility for FDA-compliance, but chose to do so. CBr. at 20-22. Zimmer Biomet argues that these activities should not be included because the evidence indicates that some of the expenses are for Heraeus Germany and are not allocated for Heraeus U.S. RBr. at 16-17. The Commission declines to include these expenditures for the reasons discussed below, but holds that, even if these expenditures were included, Heraeus would not have shown the existence of a domestic industry, as discussed *infra* in Part IV.B.2.c.

Commissioner Schmidtlein also notes that Respondents apparently have not rebutted Heraeus's argument by pointing to examples showing that the Reduce Revisions Initiative is a typical marketing activity within the healthcare sector. Further, Commissioner Schmidtlein would not dismiss the initiative as a marketing expense given the Commission's conclusion that the initiative "is not sufficiently related to bone cements." If the initiative is a marketing expense, the Commission's conclusion that it is "not sufficiently related" to Heraeus's products begs the question of what Heraeus was marketing. Additionally, even if the expenses are a marketing expense, the Commission could choose to credit them. *See* n.23, *supra*; *see also Botulinum Toxin Prods.*, Comm'n Op. at 47 n.35 (Commissioner Schmidtlein noting that sales and marketing investments, when combined with other qualifying domestic investments or activities, can be credited in determining whether a domestic industry exists).

The Commission has previously assessed whether expenditures related to FDA compliance may qualify toward an industry based on the facts and evidence of record. *See, e.g.*, *Certain Diltiazem Hydrochloride & Diltiazem Preparations Containing Same*, Inv. No. 337-TA-349, USITC Pub. No. 2902, ID at 142-145 (June 1995) (*unreviewed in relevant part by* Comm'n Notice (Mar. 20, 1995)); *Certain Salinomycin Biomass & Preparations Containing Same*, Inv. No. 337-TA-370, USITC Pub. 2978 (July 1996), ID at 128 (*unreviewed*); *Certain Strontium-Rubidium Radioisotope Infusion Sys., & Components Thereof Including Generators*, Inv. 337-TA-1110, ID at 140-143 (Aug. 13, 2019) *affirmed by* Comm'n Op. at 40-42 (Dec. 11, 2019) ("*Radioisotope Infusion Systems*")).

Heraeus describes its FDA activities as follows: "internal labor for personnel involved in regulatory activities, as well as payments to a third party, [ ], which assists HMUS with its quality systems to ensure that 'products are within a pretty tight band of compliance to manufacturing specifications,' as well as provides general consulting on issues relating to FDA market approval and other government regulations." CBr. at 20 (quoting Tr. (Childers) at 176:2-22). As evidence supporting its expenditures, Heraeus provides several invoices. *E.g.*, CX-144C; CX-145C. In one representative example, the invoice describes the paid-for activities as:

[

]

CX-144C. In a further example, the invoice recites:

[

]

CX-144C. In a third example, the invoice recites: "[

]." CX-145C.

Complainant Heraeus has the burden to show that its U.S. activities are more than those performed by a mere importer. Here, the record is unclear as to the exact nature of Heraeus's FDA activities in the United States, and whether they are distinguishable from activities that a mere importer would perform. Heraeus has not shown, for example, that they are the types of activities, such as research and development, clinical trials, or maintenance of processes and equipment in the United States in accordance with FDA requirements, that the Commission has credited in the past. Thus, Heraeus has failed to prove that its claimed FDA activities qualify for inclusion in the domestic industry.[30] Regardless, even if Heraeus's FDA-related activities were to be credited, Heraeus has not shown the existence of a domestic industry, as discussed *infra*.

[30] Chair Kearns views expenditures on regulatory activities that by their nature can only be performed in the United States as akin to expenditures that a mere importer would have to incur domestically, and thus they may not qualify for inclusion in the domestic industry. *See Radioisotope Infusion Systems,* Comm'n Op. at 42 n.27. While Heraeus argues that it was not "legally required" to undertake the claimed regulatory activities in the United States, CBr. at 21-22, it remains unclear on this record whether some of these expenses, by their nature, could only be performed in the United States, regardless of legal requirements.

c) Sufficiency of Heraeus's Qualifying Activities

As noted above, the Commission finds that only the domestic labor expenditures for four Heraeus employees – whose activities involved education and training related to the alleged domestic industry in Palacos bone cements – are of the nature of activities that contribute to an "industry in the United States" under section 337(a)(1)(A)(i). The parties agree that the domestic labor expenditures for the Heraeus employees' education and training activities related to the Palacos bone cements amount to $[ ]. CBr. at 3-4; RBr. at 3; OUIIBr. at 3-4.

The Commission must determine whether these expenditures are sufficient to establish "an industry in the United States."[31] While Heraeus need not (and indeed does not) manufacture its domestic industry products in the United States in order to have a domestic industry, it does need to provide evidence to demonstrate that its cognizable expenditures in its qualifying U.S. activities are sufficient to constitute "an industry in the United States." Heraeus has provided scant contextual evidence to demonstrate that its cognizable expenditures in qualifying U.S. activities contribute sufficient value to its imported Palacos bone cements to constitute "an industry in the United States."[32] Based on the evidence presented by Heraeus, the Commission concludes that Heraeus's cognizable expenditures in qualifying domestic activities are not significant compared to HMUS's gross sales of the Palacos bone cements in the United States ($[ ]), the only metric that Heraeus relies upon to establish the significance of its

[31] *See* n.17, *supra*.

[32] As the ID noted, in investigations involving a complainant that engages in foreign manufacturing, the Commission often uses a value-added analysis to assess whether an industry in the United states exists. ID at 16-17. In this investigation, complainants did not present evidence of the cost of the imported Palacos products or arguments that would allow a quantitative value-added analysis (for example, there is no evidence of the production cost of the bone cements at issue) or any other similar method by which to assess significance of its alleged domestic activities. *Id.*

domestic industry expenditures.[33] *See* Comp. Post-Hrg. Br. at 114-15 (reporting gross revenues through February 2019, four days before the complaint was filed); Resp. Pre-Hrg. Br.[34] at 151 (noting HMUS was formed in June 2017). In other words, Heraeus's evidence shows that these expenditures are not significant compared to gross sales, ***which is the comparison Heraeus presented*** to show its activities are "significant."[35, 36] *See* Comp. Post-Hrg. Br. at 114-15. Heraeus did not otherwise attempt to show the significance of its investments in cognizable activities in the United States. In sum, the Commission concludes that Heraeus has failed to demonstrate that its qualifying, relevant domestic activities are sufficient to establish the existence of an "industry in the United States."[37]

C. Failure to Demonstrate Substantial Injury to the Claimed Domestic Industry

The parties also dispute whether Heraeus has proven that Zimmer Biomet's importation and sale of its bone cement products that have misappropriated TS 1-35 have the threat or effect of destroying or substantially injuring Heraeus's claimed domestic industry. *See, e.g.*, CPet. at 10-11. To establish a violation under section 337(a)(1)(A)(i), the Complainant must show

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[33] Commissioner Schmidtlein finds that Heraeus's cognizable expenditures are not *sufficient* to constitute a domestic industry when considered in the context of its gross U.S. sales.

[34] Respondents' Pre-Hearing Brief, EDIS Doc ID 697036 (Dec. 11, 2019) ("Resp. Pre-Hrg. Br.").

[35] Qualifying lifetime domestic expenditures ($[ ] divided by lifetime total revenue ($[ ]) is equal to [ ]%. The Commission notes that the expenditures for the [ ] amount to $[ ]. CBr. at 3-4; RBr. at 3; OUIIBr. at 3-4. Even if the Commission were to credit those expenses, the total qualifying lifetime domestic expenditures would be $[ ], which divided by lifetime total revenue is equal to [ ]%. The Commission finds that even if the [ ] expenditures were included, Heraeus has failed to demonstrate that its qualifying relevant domestic activities are sufficient to establish the existence of an "industry in the United States."

[36] *See* n.33, *supra*.

[37] *See* n.17, *supra*.

"substantial injury," or threat thereof, to that industry. However as noted above, the Commission finds that Heraeus did not establish an "industry in the United States." The Commission holds that, without this predicate requirement being met, Heraeus cannot show substantial injury or threat of such injury to the industry. *See* 19 U.S.C. § 1337(a)(1)(A)(i). The Commission therefore vacates the ALJ's injury analysis in its entirety.

V. CONCLUSION

For the reasons set forth above, the Commission determines that Heraeus has not shown that it has an "industry" in the United States in its Palacos bone cement products. Accordingly, the Commission terminates the investigation with a finding of no violation of section 337.

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: January 25, 2021

CERTAIN BONE CEMENT, COMPONENTS THEREOF AND PRODUCTS CONTAINING THE SAME **Inv. No. 337-TA-1153**

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **COMMISSION OPINION** has been served via EDIS upon the Commission Investigative Attorney, **Monica Bhattacharyya, Esq.**, and the following parties as indicated, on **January 25, 2021.**

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

In the Matter of	
CERTAIN BONE CEMENTS, COMPONENTS THEREOF AND PRODUCTS CONTAINING THE SAME	**Investigation No. 337-TA-1153**

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

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 May 6, 2020, finding no violation of section 337 of the Tariff Act of 1930, as amended in connection with the alleged misappropriation of trade secrets. The Commission requests briefing from the parties on certain issues under review, as indicated in this notice. The Commission also requests briefing from the parties, interested government agencies, and interested persons on the issues of remedy, the public interest, and bonding.

FOR FURTHER INFORMATION CONTACT: Ron Traud, Office of the General Counsel, U.S. International Trade Commission, 500 E Street S.W., Washington, DC 20436, telephone (202) 205-3427. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov*. For help accessing EDIS, please email *EDIS3Help@usitc.gov*. General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on April 10, 2019, based on a complaint filed by Heraeus Medical LLC of Yardley, Pennsylvania, and Heraeus Medical GmbH of Wehrheim, Germany (collectively, "Heraeus"). 84 FR 14394–95 (Apr. 10, 2019). The complaint alleges a violation of section 337 by reason of misappropriation of trade secrets, the threat or effect of which is to destroy or substantially injure a domestic industry in the United States or to prevent the establishment of such an industry. The complaint named the following respondents: Zimmer Biomet Holdings, Inc. of Warsaw, Indiana; Biomet, Inc. of Warsaw, Indiana; Zimmer Orthopaedic Surgical Products, Inc. of Dover, Ohio; Zimmer Surgical, Inc. of Dover, Ohio; Biomet France S.A.R.L. of Valence, France; Biomet Deutschland

GmbH of Berlin, Germany; Zimmer Biomet Deutschland GmbH of Freiburg im Breisgau, Germany; Biomet Europe B.V. of Dordrecht, Netherlands; Biomet Global Supply Chain Center B.V. of Dordrecht, Netherlands; Zimmer Biomet Nederland B.V. of Dordrecht, Netherlands; Biomet Orthopedics, LLC of Warsaw, Indiana; and Biomet Orthopaedics Switzerland GmbH of Dietikon, Switzerland. The Commission's Office of Unfair Import Investigations ("OUII") also was named as a party.

The investigation has terminated as to respondents Zimmer Orthopaedic Surgical Products, Inc. and Biomet Europe B.V., Order No. 10 (May 23, 2019), *not reviewed*, Notice (June 14, 2019), and as to certain accused products, Order No. 30 (Nov. 24, 2019), *not reviewed*, Notice (Dec. 10, 2019). Also, the first amended complaint and notice of investigation were amended to add three entities as respondents: Zimmer US, Inc.; Zimmer, GmbH; and Biomet Manufacturing, LLC. Order No. 18 (June 26, 2019), *not reviewed*, 84 FR 35884-85 (July 25, 2019). The remaining respondents are referred to collectively herein as "Zimmer Biomet."

On May 6, 2020, the ALJ issued the final ID, which finds that Zimmer Biomet did not violate section 337. More particularly, the final ID finds, *inter alia,* that: (1) the Commission has subject matter and personal jurisdiction; (2) Zimmer Biomet sold for importation into the United States, imported, or sold after importation the Accused Products; (3) a domestic industry exists with respect to Heraeus's education, training, and research and development and Heraeus owns the asserted trade secrets; (4) trade secrets ("TS") 1–35 are protectable trade secrets, but TS 121–23, 130–34, and 145 are not protectable trade secrets; (5) Zimmer Biomet misappropriated TS 1–35; and (6) Heraeus did not show a substantial injury or threat of injury to its domestic industry by Zimmer Biomet's misappropriation.

The final ID includes the ALJ's Recommended Determination on Remedy and Bond (the "RD"). The RD recommends that, if the Commission finds a violation of section 337, the Commission should issue a limited exclusion order directed to copolymer trade secrets TS 1–35 for five years; a limited exclusion order directed to the other categories of asserted trade secrets for two years or less; and cease and desist orders directed to Zimmer Biomet. The RD further recommends imposing a bond of five percent during the period of Presidential review.

On May 18, 2020, the parties filed petitions for review of the final ID, and on May 26, 2020, the parties filed responses. Issues not raised in the petitions for review are deemed to have been abandoned. 19 CFR 210.43.

Having examined the record in this investigation, including the final ID, the petitions for review, and the responses thereto, the Commission has determined to review the final ID in part. In particular, the Commission has determined to review the following:

(1) The ALJ's findings and conclusions as to TS 1–35 and 121–23; and

(2) The ALJ's domestic industry findings, including whether there has been a substantial injury to the alleged domestic industry.

The Commission has determined to not review the remainder of the final ID.

The parties are requested to brief their positions with reference to the applicable law and the evidentiary record regarding the questions provided below:

(1) For purposes of determining whether Heraeus has established the existence of a domestic industry, if the final ID's findings are modified to exclude expenditures for the Reduce Revisions initiative and contracting costs for medical professionals, but to include the contracting costs for FDA Group: (A) what would be the dollar amount of total qualifying investments, and (B) what evidence and argument was presented to the administrative law judge regarding the nature and significance of those investments?

(2) For purposes of determining whether Heraeus has established the existence of a domestic industry, if the final ID's findings are modified to exclude expenditures for the Reduce Revisions initiative and contracting costs for medical professionals, and the contracting costs for FDA Group were excluded (as the ID did): (A) what would be the dollar amount of total qualifying investments, and (B) what evidence and argument was presented to the administrative law judge regarding the nature and significance of those investments?

(3) For the costs related to education-and-training-related investments (*e.g.*, the Reduce Revisions initiative), discuss: (A) how the Commission and the Federal Circuit have considered education-and-training-related investments in prior investigations, *e.g., Certain Sleep-Disordered Breathing Treatment Systems and Components Thereof*, Inv. No. 337-TA-890, Init. Det. at 168–70 (Aug. 21, 2014), *not reviewed in relevant part*, Notice (Oct. 16, 2014), and (B) how the facts of this investigation should be assessed in light of applicable precedent.

(4) For the Reduce Revisions initiative costs: (A) are these costs incorporated into Heraeus's general marketing expenses? *See Certain Gas Spring Nailer Products and Components Thereof*, Inv. No. 337-TA-1082, Comm'n Op. at 83 n.20 (Apr. 28, 2020); (B) if the costs are viewed as marketing expenses, is there a basis for concluding the costs are technical marketing costs; and (C) how should technical marketing costs be treated?

(5) For the alleged costs related to FDA and other regulatory approvals and compliance: (A) which of those regulatory efforts had to take place in the United States (for either legal or practical reasons), and which could have been carried out in another country; and (B) does the record permit allocation of costs between those two categories?

(6) Please analyze whether a complainant bringing a claim under section 337(a)(1)(A)(i) must demonstrate that its industry in the United States is "significant" or "substantial." Please include a discussion of the relevant statutory language, any relevant legislative history, any relevant Federal Circuit decisions and any relevant prior Commission determinations.

In connection with the final disposition of this investigation, the statute authorizes issuance of: (1) an exclusion order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) one or more cease and desist orders that could result in the respondents being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or are likely to do so. For background, *see Certain Devices for Connecting Computers via Telephone Lines*, Inv. No. 337-TA-360, USITC Pub. No. 2843, Comm'n Op. at 7–10 (Dec. 1994). In addition, if a party seeks issuance of any cease and desist orders, the written submissions should address that request in the context of recent Commission opinions, including those in *Certain Arrowheads with Deploying Blades and Components Thereof and Packaging Therefor*, Inv. No. 337-TA-977, Comm'n Op. (Apr. 28, 2017) and *Certain Electric Skin Care Devices, Brushes and Chargers Therefor, and Kits Containing the Same*, Inv. No. 337-TA-959, Comm'n Op. (Feb. 13, 2017).

The statute requires the Commission to consider the effects of that remedy upon the public interest. The public interest factors the Commission will consider include the effect that an exclusion order 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, disapprove, or take no action on 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 and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

WRITTEN SUBMISSIONS: The parties to the investigation are requested to file written submissions on the questions identified in this notice. Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such initial written submissions should include views on the RD that issued on May 6, 2020.

In their initial written submission, Complainants are also requested to identify the form of the remedy sought, and Complainants and OUII are requested to submit proposed remedial orders for the Commission's consideration. Complainants are also requested to state the HTSUS subheadings under which the accused articles are imported, and to supply identification information for all known importers of the accused products. Initial written submissions, including proposed remedial orders must be filed no later than the close of business on July 27, 2020. Reply submissions must be filed no later than the close of business on August 3, 2020. No further submissions on these issues will be permitted unless otherwise ordered by the

Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. The Commission's paper filing requirements in 19 CFR 210.4(f) are currently waived. 85 FR 15798 (March 19, 2020). Submissions should refer to the investigation number ("Inv. No. 337-TA-1153") in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf*). Persons with questions regarding filing should contact the Secretary at (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, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All non-confidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

The Commission vote for this determination took place on July 13, 2020.

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

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: July 13, 2020

CERTAIN BONE CEMENT, COMPONENTS THEREOF AND PRODUCTS CONTAINING THE SAME **Inv. No. 337-TA-1153**

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **NOTICE** has been served via EDIS upon the Commission Investigative Attorney, **Monica Bhattacharyya, Esq.**, and the following parties as indicated, on 7/13/2020.

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On Behalf of Respondents Zimmer Biomet Holdings, Inc., Biomet, Inc., Zimmer Surgical, Inc., Biomet France S.A.R.L., Biomet Deutschland GmbH, Zimmer Biomet Deutschland GmbH, Biomet Global Supply Chain Center B.V., Zimmer Biomet Nederland B.V., Biomet Orthopedics, LLC, and Biomet Orthopaedics Switzerland GmbH:

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UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN BONE CEMENTS, COMPONENTS THEREOF, AND PRODUCTS CONTAINING THE SAME**	**Inv. No. 337-TA-1153**

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

Administrative Law Judge Cameron Elliot

(May 6, 2020)

Pursuant to the Notice of Investigation and Rule 210.42(a) of the Rules of Practice and Procedure of the United States International Trade Commission, this is my Initial Determination in the matter of *Certain Bone Cements, Components Thereof, And Products Containing The Same*, Investigation No. 337-TA-1153.

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TABLE OF ABBREVIATIONS

Am. Comp.	Amended Complaint
CDX	Complainant's Demonstrative Exhibit
CIB	Complainant's Initial Post-Hearing Brief
CPB	Complainant's Pre-Hearing Brief
CPX	Complainant's Physical Exhibit
CRB	Complainant's Reply Post-Hearing Brief
CX	Complainant's Exhibit
Dep. Tr.	Deposition Transcript
Hr'g Tr.	Hearing Transcript
JX	Joint Exhibit
RDX	Respondents' Demonstrative Exhibit
RIB	Respondents' Initial Post-Hearing Brief
RPB	Respondents' Pre-Hearing Brief
RPX	Respondents' Physical Exhibit
RRB	Respondents' Reply Post-Hearing Brief
RX	Respondents' Exhibit
SDX	Staff's Demonstrative Exhibit
SIB	Staff's Initial Post-Hearing Brief
SPB	Staff's Pre-Hearing Brief
SPX	Staff's Physical Exhibit
SRB	Staff's Reply Post-Hearing Brief
SX	Staff's Exhibit

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I. INTRODUCTION

A. Procedural Background

Complainants, Heraeus Medical LLC and Heraeus Medical GmbH ("Heraeus" or "Complainants"), filed a Complaint with the Commission on March 5, 2019. 84 Fed. Reg. 13394 (March 5, 2019).[1] On March 20, 2019, proposed Respondents Zimmer Biomet Holdings, Inc., Biomet, Inc., Zimmer Orthopaedic Surgical Products, Inc., Zimmer Surgical, Inc., Biomet France S.A.R.L., Biomet Deutschland GmbH, Zimmer Biomet Deutschland GmbH, Biomet Europe B.V., Biomet Global Supply Chain Center B.V., Zimmer Biomet Nederland B.V., Biomet Orthopedics, LLC, and Biomet Orthopaedics Switzerland GmbH (collectively "Respondents") submitted a letter requesting that the Commission utilize the Early Disposition Program to determine whether Heraeus Medical LLC and Heraeus Medical GmbH satisfy the domestic industry requirement under 19 U.S.C. § l337(a)(3). *See* EDIS Doc. ID 670677. The Request was denied on April 5, 2019. *See* EDIS Doc. ID 672314. The Commission instituted the investigation on April 10, 2019. 84 Fed. Reg. 14394 (April 10, 2019).

By publication of a notice in the *Federal Register* on April 10, 2019, the Commission ordered that:

> 1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(A) of section 337 in the importation into the United States, or in the sale of certain bone cements, components thereof and products containing the same by reason of the misappropriation of trade secrets, the threat or effect of which is to destroy or substantially injure an industry in the United States or to prevent the establishment of such an industry; (2) Pursuant to section 210.1(b)(1) of the Commission's Rules of Practice and Procedure, 19 CFR 210.10(b)(1), the plain language description of the accused products or category of accused

[1]The Commission issued a Notice of Solicitation of Comments Relating to the Public Interest on March 6, 2019, and this Notice was published on March 14, 2019. 84 *Fed. Reg*. 8743. The Commission received public interest comments from the proposed Respondents. *See* Request Not to Institute on Behalf of Proposed Respondents, EDIS Doc. ID 67077 (March 20, 2019).

[redacted]

> products, which defines the scope of the investigation, is "(1) Biomet Bone Cement R, Refobacin® Bone Cement R and other bone cements designed and manufactured by the proposed Respondents; (2) the components of the accused bone cements products, which are the bone cement powder, liquid and the raw materials that comprise the powder and liquid; and (3) the ClearMixTMVacuum Mixing Systems and accessories, the Compact Cement Vacuum Mixing Systems and MillerTM Cement Delivery Systems and accessories, the Optipac® mixing system, mixing bowls, plugs, bone preparation kits, molds, diagnostic kits and other mixing and delivery systems made or sold by the proposed Respondents that contain or are used with the proposed Respondents' bone cements:

84 *Fed. Reg*. 14394 (April 10, 2019).

On May 23, 2018, pursuant to an unopposed motion, I issued an initial determination terminating two of the Respondents—Zimmer Orthopaedic Surgical Products, Inc. and Biomet Europe B.V.—from the investigation. Initial Determination (EDIS Doc. ID 676829); Comm'n Determination Not to Review (EDIS Doc. ID 678704).

On May 28, 2019, Complainants moved for leave to amend the Complaint to add three new respondents identified by the named Respondents in interrogatory responses: Zimmer US, Inc.; Zimmer, GmbH; and Biomet Manufacturing, LLC. EDIS Doc. ID 677185. I denied the motion based on Complainants' failure to serve the proposed new respondents as required by Commission rules. Order No. 15. On June 17, 2019, Complainants renewed their motion. *See* EDIS Doc. ID 678786. I granted Complainants' motion by initial determination on June 26, 2019. Order No. 18 (Initial Determination); Commission Inv. No. 337-TA-1153: Determination Not to Review (EDIS Doc. ID 682349). On November 14, 2019, Complainants withdrew their allegations against the accessory products identified in Paragraph 37 of the Amended Complaint (and set forth in the Notice of Institution of Investigation), including certain mixing and delivery systems. On that same day I entered Order No. 30, which was an Initial Determination Granting Complainants' Unopposed Motion for Partial Termination of the Investigation With Respect to the Accessory

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Products and to Amend the Notice of Investigation. The Commission determined not to review the ID (EDIS Doc. ID 696846) (Dec. 10, 2019).

On November 13, 2019, Respondents filed a Motion for Summary Determination of No Violation, which was timely opposed by Complainants and Staff. The motion was denied on December 14. Order No. 34, EDIS Doc. ID 696276.

An evidentiary hearing was held January 13-17, 2020. Following the evidentiary hearing, and pursuant to the procedural schedule, the parties submitted initial and reply post-hearing briefs on February 3, 2020 (EDIS Doc. 701250 (Complainant), EDIS Doc. 701208 (Respondents), EDIS Doc. 701227 (Commission Staff)) and February 18, 2020 (EDIS Doc. 702860 (Complainant), EDIS Doc. 702856 (Respondents), EDIS Doc. 702853 (Commission Staff)), respectively.

On February 24, 2020, Respondents filed a Motion to Strike Untimely Arguments in Complainants' Post-Hearing Briefs ("Respondents' Motion to Strike") (Motion 1153-050). Complainants and Staff responded to the motion. Respondents allege that Heraeus included numerous new arguments in its Post- Hearing Briefs that were not raised in its Pre-Hearing Brief. Respondents list the following as the new arguments:

- New labor allocations on pages 105, 106, and 107 of the Initial Post-Hearing brief ("Initial PostHB");
- New significance/substantiality contentions on pages 103, 104, 107, 114-115 of the Initial PostHB and pages 53-54 of the reply post-hearing brief ("Reply PostHB");
- New contentions regarding future lost sales and continuing price erosion on pages 116-117, 132-133, 138-139, and 144-145 of the Initial PostHB and page 67 of the Reply PostHB;
- New arguments supporting inclusion of accessory product-related expenditures in domestic industry on page 51-52 of the Reply PostHB; and

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- New arguments regarding the degree of injury required on page 59 of the Reply PostHB.

Respondents' Motion to Strike at 2.

The motion (Motion 1153-050) is denied as moot. All of the alleged new evidence presented relates to Complainants' domestic industry. This evidence has been considered but, as will become apparent, it is irrelevant to the domestic industry findings.

B. The Parties

Complainants Heraeus Medical GmbH and Heraeus Medical LLC are related companies. Heraeus Medical GmbH is a German company with a principal place of business in Wehrheim, Germany. Complaint ¶ 26. Heraeus Medical LLC (HMUS), a subsidiary of Heraeus Medical GmbH, is a Delaware limited liability company formed in June 2017 with a principal place of business in Yardley, Pennsylvania. Complaint ¶ 27; Comp. PHB at 3.

Respondents (collectively, "Zimmer Biomet") are a related group of companies. Zimmer Biomet Holdings, Inc. ("ZBH"), the ultimate parent company, was formed in a 2015 merger between Zimmer Holdings, Inc. and Biomet, Inc. Response to Second Am. Complaint ¶ 28. ZBH maintains its principal place of business at 345 East Main Street, Warsaw, Indiana, 46580. ZBH is the ultimate parent entity to Respondents Biomet, Inc.; Zimmer Surgical, Inc.; Biomet France S.A.R.L.; Biomet Deutschland GmbH; Zimmer Biomet Deutschland GmbH; Biomet Global Supply Chain Center B.V.; Zimmer Biomet Nederland B.V.; Biomet Orthopedics, LLC; and Biomet Orthopaedics Switzerland GmbH. *Id*. at ¶ 28.

Biomet, Inc. is a subsidiary of Zimmer Biomet Holdings, Inc. with a principal place of business at 56 East Bell Drive, Warsaw, Indiana 46582. *Id.* at ¶ 29.

Zimmer Orthopaedic Surgical Products, Inc. changed its name to Zimmer Surgical, Inc. on October 1, 2010, and has a principal place of business at 200 West Ohio Avenue, Dover, Ohio

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44622. Zimmer Surgical, Inc. acted as Heraeus' exclusive U.S. distributor for Heraeus' Palacos bone cement products and related products. *Id.* at ¶ 30.

Biomet France S.A.R.L. has its principal place of business at B.P. 75, Plateau de Lautagne, Valance, France. Biomet France S.A.R.L. manufactures the -3 formulation of Biomet Bone Cement R, Refobacin Bone Cement R, and certain components thereof, and sells for importation into the United States the -3 formulation of Biomet Bone Cement R and Refobacin Bone Cement R through, among others, Biomet Global Supply Chain Center B.V. *Id.* at ¶ 32.

Biomet Deutschland GmbH maintains its principal place of business at Gustav-Krone-Straße 2, Berlin, Germany, 14167. Zimmer Biomet Deutschland GmbH maintains its principal place of business at Merzhauser Str. 112, 79100 Freiburg im Breisgau, Germany. Biomet Deutschland GmbH transferred its bone cement business to Zimmer Biomet Deutschland GmbH, and Zimmer Biomet Deutschland GmbH assists Biomet France S.A.R.L. in the manufacture of Biomet Bone Cement R and Refobacin Bone Cement R. *Id.* at ¶ 33.

Biomet Europe B.V. was formerly known as Biomet Merck B.V. and changed its name to Biomet Europe B.V. in 2004. Biomet Europe B.V. operated as a subsidiary of Biomet, Inc. and the remainder of Biomet Europe B.V. was merged into Zimmer Biomet Nederland B.V. Zimmer Biomet Nederland B.V. maintains its principal place of business at Toermalijnring 600, Dordrecht, 3316 LC, Netherlands. *Id*. at ¶ 34.

Biomet Orthopedics, LLC operates as a subsidiary of Zimmer Biomet Holdings, Inc., and maintains its principal place of business at 56 East Bell Drive, Warsaw, Indiana 46582. *Id.* at ¶ 35.

Zimmer US, Inc. is a subsidiary of ZBH and maintains its principal place of business at 345 East Main Street, Warsaw, IN 46580, United States. Zimmer US purchases the -3

formulations of Biomet Bone Cement R and Refobacin Bone Cement R from Zimmer, Inc., and distributes them to its customers directly or through its distributors. *Id.* at ¶ 37.

Zimmer Switzerland is a subsidiary of ZBH and maintains its principal place of business at Sulzerallee 8, CH-8404 Winterthur, Switzerland. Zimmer Switzerland purchases the -3 formulations of Biomet Bone Cement R and Refobacin Bone Cement R from Biomet France, and then sells them to Biomet Manufacturing. *Id.* at ¶ 38.

Biomet Manufacturing is a subsidiary of ZBH and has a principal place of business at 56 East Bell Drive, Warsaw, IN 46582, United States. Biomet Manufacturing purchases the -3 formulations of Biomet Bone Cement R and Refobacin Bone Cement R from Zimmer Switzerland, and then sells them to Zimmer, Inc. *Id.* at ¶ 39.

C. The Asserted Trade Secrets

The trade secrets in this investigation fall into four general categories; however, the parties assert slightly different trade secret identifications. Complainants identify trade secrets 1-87 as relating to the copolymer specifications, trade secrets 121 and 122-128 as relating to the final powder and liquid specification trade secrets, trade secrets 130-134 as relating to the process for coloring the liquid monomer component, and trade secret 145 as relating to the zirconium dioxide component. CIB. at 6-7. However, as the Staff notes, this list includes certain asserted trade secrets that Complainants withdrew in November. *See* Complainants' Nov. 13, 2019 Letter to ALJ Elliot (EDIS Doc. ID 694252) (providing narrowed list of asserted trade secrets without TS 36-87 and 124-128). Respondents argue that Complainants presented no evidence regarding asserted trade secrets 88, 94-96, 103-105, 112-113, 118-120, 131, 136, 141, 149, and 152 and thus waived any arguments as to those trade secrets. RIB. at 6. Accordingly, Respondents assert that the trade secrets at issue are TS 1-35, TS 121-123, TS 130 and 132-134, and TS 145 and 153.

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Id. In the Staff's view, Dr. Kluge's testimony limited Heraeus's asserted trade secrets to those he identified. Accordingly, the Staff submits that the asserted trade secrets are TS 1-35, TS 121-123, TS 130-134, and TS 145. *See* SRB. at 3.

In view of the hearing testimony, the parties' briefs, and the withdrawn trade secrets, the Staff's list is the most accurate. Therefore, the Asserted Trade Secrets are:

(1) specifications for the Plex 6612 and Plex 6613 copolymers (TS 1-35) ("the Asserted Copolymer Trade Secrets");

(2) specifications for the powder and liquid components of Heraeus's products, Refobacin Palacos R and Palacos R bone cements (TS 121-123) (the "Asserted Powder and Liquid Specifications Trade Secrets");

(3) the recipe and procedure for coloring the liquid component of Heraeus's products, Refobacin Palacos R and Palacos R bone cements (TS 130-134) (the "Asserted Chlorophyll Trade Secrets"); and

(4) the specific part number and distributor of the zirconium dioxide used in Heraeus's products, Refobacin Palacos R and Palacos R bone cement powder component (TS 145) (the "Asserted Zirconium Dioxide Trade Secret").

D. Products at Issue

The accused products are bone cements designed and manufactured by or for Respondents. Complainants assert that their trade secrets were misappropriated during the development of the original "-1" formulation of Biomet Bone Cement R (BBCR) and Refobacin Bone Cement R (RBCR) in the early 2000's, as well as the redesigned "-3" formulation of these products developed after an adverse German court decision in 2014 forced Respondents to halt the sale of the -1 product. *See* Compl. PHB at 1-2; Resp. PHB at 2, 14-15.

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II. STANDARDS OF LAW

A. Protectable Trade Secrets

Misappropriation of trade secrets "is a method of unfair competition defined by the common law." *Certain Rubber Resins and Processes for Manufacturing Same*, Inv. No. 337-TA-849, Comm'n Op., 2014 WL 7497801, at *4 (Feb. 26, 2014) ("*Certain Rubber Resins*"). A "single federal standard," rather than the law of a particular state, applies to investigations into trade secret misappropriation under Section 337. *TianRui Group Co. Ltd. v. ITC*, 661 F.3d 1322, 1327 (Fed. Cir. 2011) ("*TianRui*"). Sources for this federal standard include the Restatement of Unfair Competition, the Uniform Trade Secrets Act, and federal common law as set forth in Commission decisions. *See TianRui* at 1327-28. Although it postdates *TianRui*, the Defend Trade Secrets Act of 2016 is also pertinent. *See* 18 U.S.C. §§ 1831-39. From these references, the Commission developed four elements for establishing misappropriation of a trade secret: (1) a trade secret exists which is not in the public domain; (2) the complainant is the owner of, or possesses a proprietary interest in, the trade secret; (3) the complainant disclosed the trade secret to respondent while in a confidential relationship, or the respondent wrongfully took the trade secret by unfair means; and (4) the respondent has used or disclosed the trade secret, causing injury to the complainant. *Id*.

The existence of trade secrets is a prerequisite of a trade secret misappropriation claim. *Certain Rubber Resins*, 2014 WL 749801, at * 5 (*citing Certain Sausage Casings*, Inv. No. 337-TA-148/169, Initial Determination (July 31, 1984)). It is the complainant's burden to show "the existence of a process that is protectable as a trade secret." *Certain Rubber Resins*, 2014 WL 7497801, at *5. The common law "does not provide 'precise criteria for determining the existence of a trade secret,' but instead requires 'a comparative evaluation of all the relevant factors,

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including the value, secrecy, and definiteness of the information as well as the nature of the defendant's misconduct.'" *Certain Activity Tracking Devices, Systems, and Components Thereof*, Inv. No. 337-TA-963, Initial Determination, 2016 WL 11596099, at *12 (Aug. 23, 2016) ("*Certain Activity Tracking Devices*") (non-reviewed, EDIS Doc. ID 593177 (Oct. 20, 2016)) (*quoting Restatement (Third) of Unfair Competition* § 39 cmt. d.).

The Commission looks to the following six factors—each of which relates to issues of value and/or secrecy—to help determine whether a trade secret exists:

> (1) the extent to which the information is known outside of complainant's business;
>
> (2) the extent to which it is known by employees and others involved in complainant's business;
>
> (3) the extent of measures taken by complainant to guard the secrecy of the information;
>
> (4) the value of the information to complainant and to his competitors;
>
> (5) the amount of effort or money expended by complainant in developing the information; and
>
> (6) the ease or difficulty with which the information could be properly acquired or duplicated by others.

Certain Processes for the Manufacture of Skinless Sausage Casings and Resulting Product, Inv. No. 337-TA-148/169, Initial Determination, 1984 WL 273789, at *94 (July 31, 1984) ("*Sausage Casings*") (*citing Restatement of Torts* § 757, comment b) (unreviewed, *Certain Processes for the Manufacture of Skinless Sausage Casings and Resulting Product*, Inv. No. 337-TA-148/169, Comm'n Op., 1984 WL 273970, at *2 (Jan. 1, 1984)). These factors are "instructive guidelines," not a six-pronged test. *See Certain Crawler Cranes and Components Thereof*, Inv. No. 337-TA-887, Initial Determination, at 24 (July 11, 2014) (EDIS Doc. ID 539295); *Certain Activity Tracking Devices*, 2016 WL 11596099, at *12 (same).

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The Uniform Trade Secrets Act similarly requires an evaluation of value and secrecy, defining a trade secret as information that "(i) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy." Uniform Trade Secrets Act ("UTSA") §1(4); *see also Certain Activity Tracking Devices*, 2016 WL 11596099, at *12 (stating that the UTSA's definition of a trade secret is "consistent with prior Commission decisions"); 18 U.S.C. § 1839(3). Commission decisions have relied on the UTSA's "independent economic value" requirement in determining whether a protectable trade secret exists. *See Certain Rubber Resins*, 2014 WL 749801, at *11, *13; *Certain Activity Tracking Devices*, 2016 WL 11596099, at *12.

A specific embodiment of general concepts or a combination of elements, some or all of which may be known in the industry, may be protectable as a trade secret. *Certain Cast Steel Railway Wheels, Certain Processes for Manufacturing or Relating to Same and Certain Products Containing Same*, Inv. 337-TA-655, Initial Determination at 20 (Oct. 16, 2009) (unreviewed) ("While matters of general knowledge in an industry are not eligible for trade secret protection, a specific embodiment of general concepts or a combination of elements, some or all of which may be known in the industry, may be protectable as a trade secret.").

Information otherwise eligible for protection as a trade secret may lose that protection if adequate steps are not taken to maintain secrecy. *Sausage Casings*, Initial Determination at *95. The burden is on complainant to establish that reasonable precautions were taken to preserve secrecy to ensure that it would be difficult for others to discover the secret without the use of improper means. *Id*. (*citing Henry Hope X-Ray Products. Inc. v .Marron Correll, Inc*. 674 F.2d

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1336, 1340 (9th Cir. 1982)). Also, a confidential relationship can exist in the absence of a confidentiality agreement. "[A]n implied undertaking to abide by the trade's norms of confidentiality" is sufficient to maintain a confidential relationship. *Hicklin Eng'g. L.C. v. Bartell*, 439 F.3d 346, 350 (7th Cir. 2006) (reviewing "trade norm" confidentiality under the UTSA).

B. Domestic Industry

Trade secret misappropriation investigations at the Commission are governed by 19 U.S.C. § 1337(a)(1)(A), which declares unlawful --

> Unfair methods of competition and unfair acts in the importation of articles (other than articles provided for in subparagraphs (B), (C), (D), and (E), into the United States, or in the sale of such articles by the owner, importer, or consignee, the threat or effect of which is--
>
> (i) to destroy or substantially injure an industry in the United States;
>
> (ii) to prevent the establishment of such an industry; or
>
> (iii) to restrain or monopolize trade and commerce in the United States.

19 U.S.C. § 1337(a)(1)(A). Thus, Complainants must show that they have an "industry in the United States," and that the industry has suffered "actual substantial injury, or threat of substantial injury." *See, e.g., Rubber Resins*, Comm'n Op., 2014 WL 7497801, at *5 ("Therefore, there is a requirement not only that the complainant demonstrate the existence of a domestic industry, but also that there be actual substantial injury or the threat of substantial injury to a domestic industry.").

The assessment of whether an "industry . . . in the United States" exists under Section 337(a)(1)(A) requires an inquiry into the "nature and significance" of the complainant's domestic activities. *See Certain Miniature, Battery-Operated, All Terrain, Wheeled Vehicles*, Inv. No. 337-TA-122, USTIC Pub. No. 1300, Comm'n Op. at 6 (Oct. 1982) ("The threshold question of the existence of an 'industry . . . in the United States' . . . requires an inquiry into the nature and

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significance of complainants' business activities in the United States which relate to the STOMPER toy vehicles."), *aff'd* 717 F.2d 1368 (Fed. Cir. 1983); *Certain Modular Structural Systems*, Inv. No. 337-TA-164, USITC Pub. No. 1668, Comm'n Op. at 13 (June 1984) (necessary to determine "the nature and significance" of Complainant's activities in the United States with respect to the relevant product to determine "whether there is an industry 'in the United States' within the meaning of section 337"); *Certain Cube Puzzles*, Inv. No. 337-TA-112, USITC Pub. 1334, Comm'n Op. at 30 (Jan. 1983) ("We find that Ideal's domestic activities are of the appropriate nature and are significant enough to conclude their domestic business activities constitute an 'industry . . . in the United States.'").

Commission decisions assessing the existence of a domestic industry under Section 337(a)(1)(A) (and its pre-1988 predecessor, which concentrated on patent infringement investigations) have focused largely on manufacturing and production related activities. *See, e.g., Schaper Mfg. Co. v. U.S. Intern'l Trade Comm'n*, 717 F.2d 1368, 1372 (Fed. Cir. 1983) ("Both the legislative history of section 337 and past Commission decisions on those section 337 investigations that have been based on claims of patent infringement indicate that, in order to constitute an 'industry . . . in the United States,' the patent must be exploited by production in the United States."). However, the Commission also recognizes that a domestic industry may be established through other types of activities with a close relationship to the products at issue, such as repair and installation activities. *See e.g., Certain Airtight Cast-Iron Stoves*, Inv. No. 337-TA-69, USITC Pub. No. 1126, Comm'n Op. at 11 (Jan. 1981) (finding domestic industry with respect to stoves manufactured abroad based on U.S. repair and installation activities).

It is not necessary for the domestic activities to involve use of the asserted trade secret in Section 337(a)(1)(A) investigations involving trade secret misappropriation. Rather, the domestic

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industry is the industry that is targeted by, or which directly competes with, the unfair imports. *See TianRui*, 661 F.3d 1322, 1337 (Fed. Cir. 2011) (no statutory requirement that the domestic industry use the asserted trade secrets; the fact that the imported wheels directly competed with the complainant's domestically manufactured wheels was sufficient); *see also Cast-Iron Stoves,* Inv. No. 337-TA-69, USITC Pub. 1126, Comm'n Op. at 8 (Jan. 1981) (agreeing with the ALJ that "the domestic industry consists of that segment of the entire coal and wood-burning stove industry which was the target of the unfair acts and practices"); *Certain Apparatus for the Continuous of Copper Rod*, Inv. No. 337-TA-52, USITC Pub. No. 1017, Comm'n Op. at 55 (Nov. 1979) (scope of domestic industry determined by "realities of the marketplace" and including components that were part of the competing system).

While there is no bright-line rule to determine whether a domestic industry exists, it is necessary to distinguish the complainant's domestic activities from those of a mere importer. Sales and marketing expenses do not typically distinguish a domestic industry from a mere importer. *See, e.g., Schaper*, 717 F.2d at 1373 (Fed. Cir. 1983) ("Schaper's very large expenditures for advertising and promotion cannot be considered part of the production process. Were we to hold otherwise, few importers would fail the test of constituting a domestic industry.").

In section 337(a)(1)(A) investigations involving a complainant with foreign manufacturing, Commission decisions have often applied a "value-added" analysis to assess whether an industry in the United States exists. *See Schaper*, 717 F.2d at 1372 (finding no industry in the United States where "the nature and the extent of Schaper's domestic activities (in relation to the total production process of the Stomper toy vehicles)" were insufficient); *Certain Cube Puzzles*, Inv. No. 337-TA-112, USITC Pub. 1334, Comm'n Op. at 30 (Jan. 1983) (significance of domestic operations shown by fact that "approximately 50 percent of the value of the cube puzzle"

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is added in the United States by "Ideal's quality control, packaging and repair operations"); *Certain Airtight Case-Iron Stoves*, Inv. No. 337-TA-69, USITC Pub. No. 1126, Comm'n Op. at 11 (Jan. 1981) (finding domestic industry based on repair, testing, and installation activities because "the value added domestically is significant"); *Certain Airless Paint Spray Pumps and Components Thereof*, Inv. No. 337-TA-90, USITC Pub. No. 1199, Comm'n Op. at 10-11 (Nov. 1981) (domestic investments in warranty repairs should be included in the domestic industry "[i]nasmuch as the value added to a product in the United States is a significant factor in determining whether the U.S. operation of a foreign corporation is part of the domestic industry").

III. IMPORTATION AND SALE

Respondents admit that the -1 and -3 formulations of the Accused Products have been imported in the United States within the meaning of 19 U.S.C. § 1337(a)(1). CX-0643C at 3-3, 12-14.

IV. JURISDICTION

The scope of the Commission's *in rem* jurisdiction is directed to articles that are imported into the United States. *See* 19 U.S.C. § 1337(a)(1)(C). In view of the Respondents' admission of importation of accused products, and the facts identified in the previous section, I find that the Commission has *in rem* 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)(l)(A), (a)(1)(C), (a)(2). Heraeus filed a complaint alleging a violation of Section 337, and the Commission therefore has subject matter jurisdiction. *See Amgen, Inc. v. U.S. Int'l Trade Comm'n*, 902 F.2d 1532, 1535-37 (Fed. Cir. 1990) ("Amgen's complaint alleged that Chugai was importing rEPO and that the rEPO was made by a process covered by the [IP]; thus, on its face the complaint came within the jurisdiction of the

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Commission."). The Respondents appeared through counsel and are participating in this Investigation. Accordingly, the Commission has personal jurisdiction over the Respondents. *See, e.g., Certain Optical Disk Controller Chips*, Inv. No. 337-TA-506, Initial Determination, at 4-5, 2005 WL 1901371, at *5 (May 16, 2005) (unreviewed in relevant part).

V. THE ASSERTED TRADE SECRETS

The first step in an analysis regarding misappropriation of trade secrets is to determine if the trade secrets actually exist, and if Complainants own the trade secrets. Again, in order to establish the existence of the trade secrets, which is the Complainants' burden, Complainants must present evidence concerning:

> (1) the extent to which the information is known outside of complainant's business;
>
> (2) the extent to which it is known by employees and others involved in complainant's business;
>
> (3) the extent of measures taken by complainant to guard the secrecy of the information;
>
> (4) the value of the information to complainant and to his competitors;
>
> (5) the amount of effort or money expended by complainant in developing the information; and
>
> (6) the ease or difficulty with which the information could be properly acquired or duplicated by others.

Skinless Sausage Casings, Inv. No. 337-TA-148/169, Initial Determination, 1984 WL 273789, at *94. To the extent that the factors are relevant, each is discussed below with respect to each group of asserted trade secrets, although the analysis is sometimes the same for all groups.

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A. The Asserted Copolymer Trade Secrets – TS 1-35

1. Extent Trade Secrets 1-35 Were Known Outside Heraeus

TS 1-35 relate to the specifications for Heraeus' Plex 6612 and Plex 6613 copolymers. Tr. (Kluge) at 46:10-14. Each of these alleged trade secrets is a range of values relating to, for example, viscosity, content of benzoyl peroxide, particle size distribution, and water content. CIB at 22, CDX-0004C.003. The range of values is important because while it may be possible to reverse engineer the copolymer and ascertain one value for benzoyl peroxide, according to Complainants' expert Dr. Mays, it is extremely difficult, if not impossible, to ascertain the ranges. Tr. (Mays), 391: 10-17, 475:4-524:23. The evidence shows that these ranges are not publicly known. For example, CX-0292C is an email from Dr. Specht to Dan Smith that was written when the Respondents were attempting to develop bone cement, wherein Dr. Specht states that he was "not so happy" because he "could not find public information concerning particle size, content of BPO (in the beads) and water content" of Heraeus' copolymers. Moreover, Complainants' expert, Dr. Radke, verified at the hearing that Respondents' expert, Dr. Spiegelberg, did not identify any information in the public domain that showed the trade secret ranges in the specifications of Plex copolymers. Tr. (Radke), 1456:17-22. This testimony was not disputed by Respondents.

Respondents argue, however, that samples of Plex 6612 and Plex 6613 could be obtained by third parties directly from the manufacturer Röhm, "at least prior to 2007," and from these samples, the trade secrets could have been discovered. RIB at 53. Respondents cite to a purchase order (JX-0119C) that purportedly shows "the Plex copolymers were sold to and used by other companies." RIB at 54. This exhibit, however, is an exchange between Heraeus and Merck, which was an official distributor of Palacos in 2002 (the date of the document), and the certificate of analysis on the document does not match the trade secret ranges of Plex 6612. CRB at 12.

[redacted]

Moreover, this document does not include any information about Plex 6613 whatsoever. Therefore, the preponderance of the evidence shows that the copolymer trade secrets 1-35 are not generally known outside Heraeus.

2. Extent All Asserted Trade Secrets Were Known Inside Heraeus

Heraeus took reasonable measures to keep its trade secrets secure within the company. Respondents argue that Heraeus did not have adequate internal procedures to protect the trade secrets. Respondents' principal evidence comes from their expert witness, Cheryl Blanchard, who testified that Heraeus failed to meet industry "best practices": She alleged that Heraeus failed to mark the trade secrets as such (Tr. (Blanchard) at 799:21-800:5); failed to maintain documentation of trade secret policies (*id.*); failed to maintain logs of people who accessed the trade secrets (*id.* at 800:3-5); failed to have personnel who were responsible for maintaining the trade secrets (*id.* at 800:13-15); failed to store trade secrets in a secure cabinet (*id.* at 800:6-7); and failed to train employees until the late 1990's on trade secret protection (*id.* at 800:15-19). Dr. Blanchard's conclusions primarily were based upon her review of Mr. Schneider's deposition testimony. *Id.* at 800:3-4.

A fair reading of Mr. Schneider's deposition testimony does not support Dr. Blanchard's conclusions. For example, Mr. Schneider testified that, "[i]f there is already an existing nondisclosure agreement" Heraeus would not mark documents as trade secrets. JX-0258C (Schneider Dep. Tr.) at 36:16-17. Many of the documents cited by Dr. Blanchard were circulated between Heraeus and Merck (or its agent) and these two parties had a nondisclosure agreement; this issue is discussed in further detail below. Mr. Schneider also testified that while there was no one person at Heraeus responsible for making sure the trade secrets remain secret, "all employees had an NDA with their working contract or within their employment agreement." *Id.* at 55:11-22.

[redacted]

Further, Mr. Schneider testified at the hearing that since at least 1980, every employment contract also had an NDA associated with it along with a "work regulations" document, which contains information on what Heraeus considers confidential, what particular secrets the employee is entitled to see, and how to handle the secrets. Tr. (Schneider) at 248:1 – 251:1; CX-113C at HERAEUSITC0008978; CX-118C at HERAEUSITC0008462. Also, German law (UWG Section 710) obligates all employees to keep the company's information confidential. *See* Tr. (Schneider) at 247:15-19; JX-60, Act Against Unfair Competition ("UWG") Sections 17-18; JX-254C (Kohler Dep. Tr.) at 84:1-16; JX-264C (Bornkamm Dep. Tr.) at 55:4-15; *Merckle GmbH v. Johnson & Johnson*, 961 F. Supp. 721, 732 (D.N.J. 1997) (reasonable jury could conclude that European guidelines and German drug laws protected confidentiality). Mr. Schneider further testified there is no need to have a list of people that are approved to see the bone cement trade secrets because each department head instructs new employees on the work space and area, and thus the department is able to keep track of who has access. JX-0258C (Schneider Dep. Tr.) at 58:7 – 60:14; Tr. (Schneider) at 250:2 – 251:1. Moreover, Mr. Schneider testified that HR has the job description of all employees, and thus managers know what trade secrets each employee is entitled to use. JX-0258C (Schneider Dep. Tr.) at 58:7-15.

Presently, with the use of computers, each employee has electronic access to the specific trade secrets needed for the particular job the employee performs. For instance, Mr. Schneider is a lawyer, and thus does not have access to all information on the server. JX-0258C (Schneider Dep. Tr.) at 61:4-13. The trade secrets are stored on a secure server, the trade secret server is not on the internet, so outside access is impossible, and the IT department of Heraeus is able to track access to trade secrets. Tr. (Schneider) at 252:22 – 253:24. Even prior to computer usage, Mr. Schneider testified, all trade secret documentation was locked in cabinets at the end of the day.

[redacted]

JX-0258C (Schneider Dep. Tr.) at 57:8-58:23, 56:16-24, 60:15-61:3; Tr. (Schneider) at 245:1–246:6-12. Therefore, Heraeus has, at all relevant times, taken the appropriate steps to guard all asserted trade secrets within the company.

3. Extent of Steps Taken By Heraeus to Guard Trade Secrets 1-35

Respondents argue that Heraeus disclosed its copolymer trade secrets to third parties without adequate confidentiality agreements in place. Specifically, Respondents submit that Heraeus disclosed these trade secrets to three different entities. First, Heraeus allegedly disclosed its TS 1-35 to Röhm and/or Evonik without reasonable measures in place to secure their secrecy. RIB at 17-20. Respondents state that Heraeus began selling Palacos in the late 1950's and it was purchasing the Plex 6612 and 6613 copolymers from Röhm at that early date. Respondents then argue that "Röhm "must have had access to the claimed copolymer trade secrets since at least the 1950s because Röhm would require the information and the specifications to manufacture the copolymers." *Id.* at 17 (citing Tr. (Blanchard) at 754:22-755:4). Moreover, Respondents assert,

[redacted]

Id. at 11 (citing JX-118C; JX-0233C, Tr. (Blanchard) at 756:20-757:16).

The evidence shows, however, a long-standing [redacted] supply relationship between Heraeus and Röhm. *See* CX-0091C and Specht Dep. Ex. 64, at ZBITC-1748400 (Merck document indicating that Röhm [redacted] delivers Plex 6613 to Kulzer); Tr. (Smith) at 1148:7-1149:9 (testifying that, in early 2000's, after considering the possibility of purchasing Plex 6613 and Plex 6612, Biomet determined that Plex 6612 and Plex 6612 are proprietary products that Röhm could not sell to Biomet); JX-247C (Kühn) at 65:11-13, 66:14-17, 85:22-86:14 (Dr. Kühn understood from predecessors that copolymers were produced [redacted] JX-258C

(Schneider Dep. Tr.) at 78:2-8 JX-118C JX-119C (between Heraeus and Röhm); and JX-37C (between Heraeus and Evonik). Heraeus would not have had such a long-lasting and relationship unless its trade secrets were adequately protected.

Second, Respondents argue that Heraeus disclosed the copolymer trade secrets to Smith & Nephew without having any confidentiality protection in place. RIB at 28. The evidence shows, however, that the disclosures made to Smith & Nephew were secure. Merck signed confidentiality agreements with Heraeus that included non-disclosure requirements. CX-96C JX-134C §§ 9.2,12 Merck appointed Smith & Nephew as its distribution agent in the U.S., and Smith & Nephew's role included obtaining regulatory approval in the U.S. CIB at 51. Moreover, the CIB at 50 (citing JX-0134C; JX-0125C). Moreover,

[redacted] JX-0134C at HERAEUSITC000314, 318. The disclosures to and the relationship of Smith & Nephew with Merck fell under this obligation. Smith & Nephew operated as a licensee of Merck, and thus, Merck was obligated to protect Heraeus's confidential information as it pertained to Smith & Nephew. *See* JX-0032 (product information showing Smith & Nephew as distributor "[u]nder the license of E. Merck"). [redacted] The evidence regarding these disclosures, therefore, illustrates that the trade secrets were sufficiently protected by Heraeus.

Finally, Respondents submit that Heraeus disclosed its trade secrets to [redacted] Respondents allege that [redacted] RIB at 15 (emphasis in original) (citing JX-0135C). However, there is no evidence that any copolymer specifications actually were sent to [redacted] *See* JX-135C; Tr. (Blanchard) at 750:13-753:9 (discussing TS 122, 123, and 145, but not TS 1-35). Therefore, the evidence shows that Heraeus took reasonable precautions to protect trade secrets 1-35, and that these trade secrets were not generally known publicly.

4. Value of Trade Secrets 1-35 to Heraeus and Competitors

A trade secret "derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who

[redacted]

can obtain economic value from its disclosure or use." Uniform Trade Secrets Act ("UTSA") §1(4). Heraeus argues that the copolymer specifications are important to the Palacos cements' handling characteristics. CIB at 16. Respondents, however, argue that the handling properties of Palacos is not evidence that Heraeus' trade secrets have any economic value, because there is no evidence showing that the product has an advantage in the market based on handling properties. Moreover, Respondents argue, there is no evidence that the copolymer trade secrets contribute to the handling properties of Palacos. RIB at 48 and 58.

The evidence shows that the handling characteristics of Palacos is important to users. Tr. (DiGioia) at 1050:19-1051:1. Moreover, Heraeus' bone cement is highly respected in the industry. Tr. (DiGioia) at 1046:6-14 (Palacos and Simplex are gold standard cements in the industry). And as the Staff correctly points out, the evidence shows that the Heraeus copolymer specifications—including the individual specifications for viscosity, BPO, particle size, and water content--add to properties of the resulting bone cement, and thus have value. *See* Tr. (Kluge) at 44:16-45:17 (discussing importance of specifications to the finished bone cement properties); *id.* at 41:6-42:13 (discussing viscosity's relationship to bone cement handling properties); *id.* at 42:14-43:7 (discussing copolymers' benzoyl peroxide specifications and purpose); Tr. (Radke) at 1451:3-10, 1453:3-5 (BPO responsible for speed of reaction, length of polymer chains); Tr. (Kluge) at 43:8-44:1 (discussing particle size specifications for Heraeus); Tr. (Kluge) at 44:2-44:15 (discussing water content specifications); Tr. (Radke) at 1454:14-21 (discussing importance of water content); JX-64 [redacted]

Respondents also argue that the copolymer specifications lack value because [redacted] RRB at 58-59. [redacted]

[redacted]

[redacted] Tr. (Kluge) at 107:6-10, 65:20-69:22. However, the value of a trade secret is not wholly dependent on whether it is used by the trade secret owner. *TianRui,* 661 F.3d at 1335 (no requirement under Section 337 that the domestic industry practice the asserted trade secret). *See also* Restatement (Third) of Unfair Competition § 39, cmt.e ("[u]se by the person asserting rights in the information is not a prerequisite to protection"). And there is plenty of evidence that Respondents and Merck used the trade secret specifications in trying to develop a similar product. *See* Tr. (Mays) at 391:18-411:22 and CX-81C, JX-23C, CX-2052C, CX-82C, CX-546C, CX-272C, CX-552C, CX-87C, JX-24C, CX-83C, CX-91C, CX-1959C (attempts to develop substitutes for Palacos copolymers, using Heraeus copolymer specifications); JX-238C (Specht Dep. Tr.) at 136:7-16 (Dr. Specht acknowledging that he compared samples to specifications when assessing Plex 6612 and Plex 6613 substitutes from multiple companies); CX-307C (Dr. Specht comparing specifications of Plex 6612 and Plex 6613 to Esschem potential copolymer substitutes); *see also* Tr. (Radke) at 1491:1-11 (specifications useful as a target range for development).

5. The Amount of Effort or Money Expended in Development

Respondents argue that there is no evidence showing Heraeus invested money, time, or effort in developing the trade secrets. Thus, according to Respondents, the absence of evidence "on this factor weighs in favor of a conclusion that Heraeus cannot carry its burden to demonstrate protectable trade secrets." RIB at 11. While direct evidence of development of the bone cement is lacking (Tr. (Schneider) at 279:21-280:18, 282:4-7), this does not necessarily prove a lack of protectable trade secrets. First, Heraeus presented general information regarding the development of its copolymers. Tr. (Kluge) 55:18-56:5 (discussion of Heraeus' scientists studying early discovery of MMA polymer, PMMA polymers, and early use by dentist, citing CX-2047C); *id.* at

[redacted]

60:2-61:21 (discussing D. Kühn's work at Heraeus developing Palacos, citing JX-152, Section 3.4, pages 26-27). And as Heraeus points out, first hand witnesses to the development, which most likely occurred in the 1950's, are no longer available as any scientist involved "would be well over 100 today." *See* CRB at 4. And again, this is but one factor that the Commission uses as an "instructive guideline." *Crawler Cranes*, Inv. No. 337-TA-887, Initial Determination, at 24 (July 11, 2014)(EDIS Doc. ID 539295. Thus, the lack of development evidence does not automatically preclude a finding of protectable trade secrets.

6. The Ease or Difficulty of Acquisition or Duplication by Others

Respondents submit that the evidence shows that the copolymer trade secrets can be easily duplicated by others. Respondents allege that the nominal (or measured) values for the viscosity, particle size, water content, and BPO content of the Plex copolymers, which fall within the ranges claimed by Heraeus as trade secrets, were listed on the certificates of analysis provided by Röhm when batches of the Plex copolymers were sold. Respondents also submit these manufacturing specifications could have been used to derive the alleged copolymer trade secrets. JX-0241C (Chisholm Dep. Tr.) at 124:10-124:20. Respondents further argue that these values also can be measured from purchased samples of Plex 6612 and Plex 6613 using known analytical techniques. *See* RIB at 55, citing JX-0119C; JX-0238C (Specht Dep. Tr.) at 85:5-22, 114:9- 117:11; Tr. (Spiegelberg) at 315:13-1316:17, 1319:5-11, 1320:11-1321:20.

Respondents also contend that nominal values of the copolymers can be determined from samples of the Osteopal and Palacos powders. While the powder components of Osteopal and Palacos contain other ingredients, Respondents' expert Dr. Spiegelberg testified that the values for Plex 6613 could be readily and relatively inexpensively measured from a sample of Osteopal (which contains only Plex 6613) using standard analytical techniques. Tr. (Spiegelberg) at 1308:1-

[redacted]

16, 1315:20-1316:17, 1317:2-8; JX-0223; JX-0247C at 236:19-237:13, 238:2-4. He further testified that the values for Plex 6612 could be calculated by performing measurements on a sample of Palacos (which contains both Plex 6612 and Plex 6613) and using mathematical analysis to extract information about Plex 6612 by eliminating known values for Plex 6613 obtained from Osteopal data. Tr. (Spiegelberg) at 1308:1-16, 1317:9-22. Based on this evidence, Respondents take the position that each copolymer nominal value that can be measured falls within the Alleged Trade Secret specifications, and one of skill in the art would be able to estimate or develop a similar manufacturing or quality control range based on the nominal values and knowledge of the industry. Tr. (Spiegelberg) at 1318:3-1319:11.

Respondents' characterization of the evidence is unpersuasive. There is no evidence Plex 6612 or Plex 6613 were publicly sold and/or publicly available; as noted, Röhm/Evonik sold Plex 6612 and Plex 6613 [redacted] to Heraeus. Tr. (Schneider) at 259:6-9; Tr. (Kluge) at 31:21-32:4. Moreover, Heraeus' technical expert Dr. Jimmy Mays testified, without rebuttal, that the trade secret ranges (as opposed to the values in a particular batch) in the specifications of Plex 6612 and Plex 6613 were not generally known or readily ascertainable. Tr. (Mays) at 370:10-16, 371:15-19, 372:20-374:21, 391:10-17, 475:4-524:23. Heraeus' other technical expert, Dr. Wolfgang Radke, also confirmed that the trade secret ranges in the specifications of Plex 6612 and Plex 6613 were never publicly available. CDX-0004C.002; Tr. (Radke) at 1456:17-22.

As the Staff points out, however, Dr. Spiegelberg's testimony regarding determining copolymer ranges is not especially convincing, in light of the lack of any supportive testing data from Dr. Spiegelberg, and the contrary testimony of Dr. Radke. *See* Staff Br. at 14-16. For example, Dr. Spiegelberg testified that to ascertain the copolymer specifications, the steps of: (1) separating Plex 6613 from the rest of the materials in the Osteopal powder (which contains

additional BPO, water, and zirconium dioxide); (2) separating Plex 6612 from the rest of the materials in Palacos R powder (which contains Plex 6613, Plex 6612, [redacted] water, and zirconium dioxide); and (3) determining the trade secret ranges from the nominal viscosity, particle size distribution, BPO content, and water content values of the separated Plex 6612 and Plex 6613 obtained in (1) and (2) would be necessary. Tr. (Spiegelberg) at 1315:20-1316:8, 1317:9-22, 1318:22-1319:4. However, Dr. Spiegelberg admitted at the hearing that he did not perform any such separation, or conduct any other tests, for this investigation. Tr. (Spiegelberg) at 1390:2-15.

Dr. Spiegelberg also testified that isolating Plex 6613 would be comparatively easy because Osteopal contains a single copolymer, Plex 6613, not a combination of Plex 6613 and Plex 6612. Tr. (Spiegelberg) at 1317:2-8. However, Dr. Radke testified that separating Plex 6613 from Osteopal powder would be "difficult," "time-consuming," and "costly" and would be unlikely to re-create the original Plex 6613. Tr. (Radke) at 1456:23-1464:19. Dr. Radke explained that separation using a sieving method, which Dr. Spiegelberg suggested, would either lose small sizes of Plex 6613 or include large sizes of zirconium dioxide [redacted] *See* CDX-0004C at 006; Tr. (Radke) at 1457:3-1460:13. He further testified that separation by a dissolution method would permanently alter the particle size distribution of the original Plex 6613. CDX-0004C at 007; Tr. (Radke) at 1461:16-1462:25.

Dr. Spiegelberg's testimony was further undermined by Dr. Radke's testimony that no known method exists to separate the residual BPO in Plex 6613 from the chemically identical BPO added to the powder, thus precluding the determination of the residual BPO amount in the original Plex 6613. Tr. (Radke) at 1460:14-1461:4, 1463:1-8. Similarly, Dr. Radke testified that no known method exists to [redacted]

[redacted] thus precluding the determination of the water content in the original Plex 6613. Tr. (Radke) at 1461:5-15, 1463:9-14.

Dr. Radke also testified that separating Plex 6612 from Palacos is even more difficult because, in addition to the same difficulties involved in separating Plex 6613 from Osteopal, Plex 6612 and Plex 6613 have [redacted] thus making it impossible to separate Plex 6612 beads from Plex 6613 beads [redacted] CDX 0004C at 010, 011; Tr. (Radke) at 1470-73. Dr. Radke testified that there is no evidence of anyone succeeding in separating Plex 6613 from Osteopal powder or separating Plex 6612 from Palacos. Tr. (Radke) at 1464:1-19; 1473:8-12.

Most importantly, even if one could separate Plex 6612 or Plex 6613 from a package of Palacos and then measure the viscosity, particle size distribution, BPO content, and water content in each copolymer, the results are only a single value, not the trade secret ranges. And according to Dr. Radke, to derive those trade secret ranges, the separation process must be performed using, for example, about 200 batches of Plex 6613. CDX-0004C at 008, 009, 012; Tr. (Radke) at 1464:20-1470:17, 1473:13-1474:21. Moreover, obtaining two hundred different batches of Plex 6613 is difficult because each Plex batch (obtained from Röhm) is divided into numerous individual packages of Osteopal. CDX-0004C at 009; Tr. (Radke) at 1467:6-25. Thus, two hundred different packages of Osteopal powder available commercially (from Heraeus) do not represent the same number of Plex 6613 batches. Tr. (Radke) at 1469:6-25.

Overall, Dr. Spiegelberg's testimony would have been more persuasive had he performed the testing he claims is straightforward and inexpensive. And Dr. Radke's testimony regarding the stumbling blocks to successful separation of the powder components is reasonable. So on

[redacted]

balance, reverse engineering trade secrets 1-35 would be a very difficult, if not impossible, undertaking.

Accordingly, balancing the evidence relating to all six parameters, I find that Heraeus' Trade Secrets 1-35 are protectable trade secrets under the Commission guidelines.

B. The Asserted Powder and Liquid Components – TS 121-123

The asserted trade secrets relating to liquid and powder specifications are:

TS 121: [redacted]

TS 122: Specifications for Palacos R:

[redacted]

TS 123: Specifications for Refobacin-Palacos R:

[redacted]

JX-205C.

1. Extent Trade Secrets 121-123 Were Known Outside Heraeus

The parties presented similar arguments as that above regarding the copolymer trade secrets; namely, Respondents argue that at least nominal values of these trade secrets were publicly disclosed, and one could ascertain the trade secrets by reverse engineering from the values. RIB at 65-66. Complainants again argue that it is nearly impossible to determine the trade secret ranges from nominal values. CIB at 28-30.

The evidence shows public disclosure of all these trade secrets. The Staff prepared a comprehensive list of them, based on the testimony of Dr. Spiegelberg and a small collection of exhibits:

[redacted]

• With respect to TS 121 (relating to the monomer liquid), public information relating to Palacos provides several points within the alleged trade secret range of [redacted] and several points within the alleged trade secret range of [redacted]

• With respect to TS 122 (relating to the powder component of Palacos R), the same public information provides ranges of copolymer content within the alleged trade secret range of [redacted] multiple points within the alleged zirconium trade secret range of [redacted] and the exact BPO range of [redacted]

• With respect to TS 123 (relating to the powder component of Refobacin Palacos), public information provides a copolymer content within the alleged trade secret range of [redacted] a zirconium dioxide content within the alleged trade secret range of [redacted] and a BPO content value within the alleged trade secret range of [redacted]

SIB at 20-21.

Respondents cite to additional evidence that these trade secrets were disclosed publicly. For example, [redacted]

Complainants do not rebut this evidence in either their initial or reply post-hearing briefs. Accordingly, TS 121-123 were publicly disclosed.

[redacted]

2. Extent Trade Secrets 121-123 Were Known Inside Heraeus

The discussion of Heraeus' in-house protection of all of its trade secrets is discussed above and applies with equal force to TS 121-23.

3. Extent of Steps Taken by Heraeus to Guard Trade Secrets 121-123

Trade secrets 121-123 were disclosed by Heraeus on a number of occasions.

[redacted] **Product**:

[redacted] *See Union Pacific R. Co. v. Mower*, 219 F.3d 1069, 1075-76 (9th Cir. 2000) (holding that nondisclosure requirements no longer apply after expiration of time limitation); *ECT Intern., Inc. v. Zwerlein*, 597 N.W.2d 479, 485 (Wis. 1999) ("[b]y limiting the period in which an employee agreed not to divulge trade secrets ECTI manifested its intent that after one year there was no need to maintain the secrecy of any sensitive and confidential information"); *Structured Capital Solutions, LLC v.*

[redacted]

Commerzbank AG, 177 F. Supp. 3d 816, 836 (S.D.N.Y. 2016) ("[o]nce a third party's confidentiality obligation . . . expires, so does the trade secret protection").

Complainants argue that this fax does not demonstrate a lack of reasonable measures to protect the powder trade secrets, because despite the document itself indicating that it was sent to all three parties, and included the certificates of analysis, "no evidence concerning the contents of the certificates has been presented. And, nothing suggests that the certificates of analysis were also to be sent to [redacted] CIB at 46-47. But the document speaks for itself, and clearly lists the recipients and the contents. [redacted] CIB at 48. But actual use is not the test for whether safeguards were reasonable. Rather, the touchstone is Heraeus' actual protection of its purported trade secrets, and [redacted] This disclosure under the [redacted] project indicates a lack of reasonable precautions to protect secrecy.

Heraeus/Merck/Biomet

The rather complicated evidence surrounding the various relationships between Heraeus and Merck, the Biomet Merck Joint Venture, and Heraeus/Biomet agreements, further illustrate Heraeus' lax behavior regarding its TS 121-123. As a precursor, and of particular relevance, is the evidence establishing that whenever an order of Heraeus' bone cement was delivered, Heraeus provided certificates of analysis with the order, and the certificates of analysis included the TS 121-123 information. Tr. (Schneider) at 353:21-354:6 (standard part of process when Heraeus is distributing product through another entity is to include a certificate of analysis, including to

[redacted]

Biomet or the Biomet joint venture); JX-259C (Schneider Dep. Tr.) at 241:18-242:5 ("[t]here would always be a certificate with a batch of the product delivery"); Tr. (Kluge) at 128:20-130:24 and RX-262C (certificates of analysis for finished powder and liquid batches include the asserted powder and liquid trade secrets); Tr. (Schneider) at 354:7-356:9; (testifying regarding certificates of analysis sent to Biomet Deutschland GmbH for Refobacin Palacos R in JX-126C with values corresponding to TS 121 and TS 123); JX-126C, at HERAEUSITC 327287, 327289, and 327290 (certificates of analysis showing lack of confidentiality labels at time of transmission on August 24, 2005); Tr. (Blanchard) at 775:25-776:8 and RX-498C.0049. RX-498C.0114 (cover letter showing that certificate of analysis for Refobacin Palacos R40 was sent from Heraeus to Biomet Merck on October 20, 2004). This standard practice, too, shows a lack of reasonable precautions.

Heraeus and Merck

[redacted]

Biomet Merck Joint Venture

[redacted]

[redacted]

The record is similarly lacking in [redacted] JX-0237C at 348. Illustrating one such order fulfillment is JX- 0126C -048 to -053, which is a fax from Heraeus to the Biomet Merck Joint Venture that shows a shipment from Heraeus of Palacos bone cement accompanied by the certificates of analysis for Refobacin Palacos. The certificates of analysis disclosed the copolymer content, zirconium dioxide content, and BPO content specified in alleged trade secret 122 and MMA and DMPT content specified in alleged trade secret 121. *See also* RX-0146C (fax to Biomet Merck in January 2003 containing certificates of analysis for Palacos R powder and

[redacted]

liquid containing the information claimed in TS 121 and 123). These shipments and certificates of analysis were not subject to any confidentiality requirement at the time the information was sent to the Biomet Merck Joint Venture. Thus, Heraeus did not take reasonable precautions to protect its TS 121 and 123 in its dealings with the Biomet Merck Joint Venture.

Biomet Distribution Arrangement (U.S.)

[redacted] RX-0625C. [redacted]

[redacted] illustrates Heraeus' failure to take reasonable precautions to protect trade secrets 121-123.

4. Value of Trade Secrets to Heraeus and Competitors

In discussing the value of its TS 121-123, Heraeus presents similar arguments as related to the copolymer trade secrets. These arguments relate to "the importance of the copolymer specifications and powder and liquid specifications to the Palacos cements' handling characteristics." CIB at 15-16. These arguments are addressed above and need not be repeated; suffice it to say that to the extent that TS 121-123 contribute to Palacos' handling characteristics, they are valuable because the handling characteristics of Palacos is important to users. Tr. (DiGioia) at 1046:9-13, 1050:19-1051:1.

5. The Amount of Effort or Money Expended in Development

As discussed above, there is not much evidence showing how any of the asserted trade secrets were developed. However, this lack of evidence is not necessarily determinative of the existence or absence of trade secret protection, including of TS 121-123.

6. The Ease or Difficulty of Acquisition or Duplication by Others

Respondents make a similar argument regarding TS 121-123 as was made with TS 1-35: the nominal values for the various elements of these trade secrets are either published or can be

[redacted]

easily measured. RIB at 66. With the nominal values, the argument goes, one skilled in the art can establish ranges "using these approximations [in] materially the same [method] as the alleged copolymer trade secrets." *Id.* at 67 (citing Tr. (Spiegelberg) at 1335:10-1338:7 and RDX3-33).

For essentially the same reasons as given in the discussion of TS 1-35, the ranges of the powder and liquid specifications are not readily determinable. Complainants' expert explained that in order to discover the ranges, a large number of batches of Palacos R powder and liquid components would have to be evaluated, which would be expensive and time consuming. Tr. (Radke) at 1476:2-1478:6. However, as noted, these trade secrets were disclosed publicly, so reverse engineering would be unnecessary. *See, e.g.,* [redacted]

On balance, not all factors weigh against the status of TS 121-123 as actual trade secrets. In particular, their independent economic value weighs in favor of trade secret status, notwithstanding the peculiarity that their full range appears to be impossible to practice: [redacted] *See* RIB at 67, SIB at 22. But the weightiest factor by far is that they were not adequately protected by Heraeus and were disclosed under circumstances that nullified their trade secret status. Complainants essentially ignore this clearly significant consideration in their post-hearing reply brief. On balance, therefore, TS 121-123 are not protectable trade secrets.

C. The Asserted Chlorophyll Recipe and Procedure – TS 130-134

TS 130-134 relate to Heraeus' procedure for coloring the liquid monomer component of its Palacos R products green. CIB at 31. Specifically:

[redacted]

TS 130: [redacted]

TS 131: [redacted]

TS 132: [redacted]

TS 133: [redacted]

TS 134: [redacted]

JX-205C.

1. Extent Trade Secrets 130-134 Were Known Outside Heraeus

TS 132, which calls for the use of a [redacted] was generally known. In 1983, the FDA exempted the use of a 5% copper-based chlorophyll solution in a mixture of palm oil, peanut oil, and hydrogenated peanut oil for coloring PMMA bone cements. JX-207C (21 C.F.R. § 73.3110, effective in 1983); Tr. (Spiegelberg) at 1341:2-20. Complainants argue that the C.F.R. provision

[redacted]

does not disclose [redacted] used in Palacos R products. CIB at 31-32. Complainants also state that "the evidence about what Biomet knew and did not know belies any claim that the trade secret was generally known." *Id.* However, there is no record evidence that [redacted] adds any particular value, or that it could not have been readily reverse engineered. The use of [redacted] is irrelevant because the asserted trade secrets do not specify [redacted] *See* CIB at 31-32. Finally, the use of a 5% final chlorophyll concentrate is clearly listed in the C.F.R. provision and is therefore public knowledge. JX-207C.

Further, Heraeus's own patents and patent applications disclose the use of a chlorophyll solution and refined peanut oil (including Biskin oil) to color the monomer component of Heraeus's bone cements. CX-237C at col. 1:45-50 (U.S. Patent No. 7,569,621) ("In the case of the polymethyl methacrylate bone cements from Heraeus Kulzer GmbH, the chlorophyllin is dissolved in the liquid monomer component by means of refined peanut oil (Biskin) as solubiliser."); *see also* Tr. (Spiegelberg) at 1341:6-1341:17; Tr. (Kluge) at 103:3-5 (publicly known that peanut oil can be used as a solvent in chlorophyll solutions). Finally, the use of chlorophyll in Palacos and the final concentration of chlorophyll in the liquid component were published in Dr. Kühn's textbook. JX-0103C at 110 and 213. Complainants do not offer evidence that contradicts this information.

Therefore, given that the details of TS 132 are publicly disclosed in the Federal Register, in Heraeus' patents, and Dr. Kühn's text, TS 132 was known outside of Heraeus. *See* Restatement (Third) of Unfair Competition § 39 cmt. f ("information that is disclosed in a patent or contained

[redacted]

in published materials reasonably accessible to competitors does not qualify for protection"); *Mobile Medical Intern'l Corp. v. United States*, 95 Fed. Cl. 706, 734 (Fed. Cl. 2010) ("As a general proposition and according to Comment to section 1 of the Uniform Trade Secrets Act,' information is readily ascertainable if it is available in trade journals, reference books, or published materials.'") (*quoting* Uniform Trade Secrets Act §1 cmt., 14 U.L.A. 437). However, as for the other trade secrets in this group, 130, 131, 133, and 134, which generally pertain to chlorophyll mixing recipes, there is no evidence that they are publicly known, and Respondents do not even argue that they are. *See* RIB at 69-70.

2. Extent Trade Secrets 130-134 Were Known Inside Heraeus

The discussion of Heraeus' in-house protection all of its trade secrets above applies to TS 130-34.

3. Extent of Steps Taken By Heraeus to Guard Trade Secrets 130-134

As noted, TS 132 was not protected by Heraeus, because it was disclosed in Heraeus' patents and in Dr. Kühn's textbook. With respect to TS 130, 131, 133, and 134, the evidence shows that a Heraeus employee, Dr. Gopp, provided Heraeus's detailed chlorophyll recipe to Dr. Specht in response to a request for chlorophyll samples that was to be provided to an outside, third-party dermatologist. *See* JX-231C. This letter contained no confidentiality markings. *See id.*; *see also* JX-251C (Gopp Dep. Tr.) at 50:6-24; JX-225C (Gopp Dep. Tr.) at 296:12-307:23 (Dr. Gopp's testimony regarding this issue, including admission that the recipe was not marked confidential). Complainants argue that Heraeus sent only the chlorophyll sample to Dr. Specht to be given to the dermatologist, and that the later email containing the information about the chlorophyll was sent only to Dr. Specht. JX-231 at HERAEUSITC0323693. Whether the dermatologist received the later sent email with information is not relevant to the issue, however. Dr. Gopp admitted, and the

[redacted]

documents themselves illustrate, that the sample and information were sent without any type of confidential indicia. At the time the information was sent, Dr. Specht was not a Merck employee (and thus arguably under a confidentiality agreement) but rather he was employed by the Merck-Biomet Joint Venture, which did not have a confidentiality agreement with Heraeus during the 2002 time frame. Accordingly, Heraeus did not reasonably protect TS 130-134.

4. Value of Trade Secrets to Heraeus and Competitors

Heraeus argues that the green color of Palacos is a "signature" characteristic that provides a "clear contrast to bone and tissue during surgery," and is obtained by adding chlorophyll to the liquid monomer (as well as the powder component). CIB at 18 and n.7. The Code of Federal Regulations, however, has disclosed a method of coloring bone cement using a 5% chlorophyll solution for decades. *See* JX-207C (21 C.F.R. § 73.3110). Moreover, Heraeus's own patents and patent applications disclosed the use of chlorophyll to color Heraeus's products, including that it is dissolved in peanut oil as a solvent.

Nor is there any record evidence that the particular methods of coloring bone cement described in the asserted trade secrets provide a competitive advantage over the publicly known C.F.R. procedure. Complainants' experts did not compare the C.F.R. provision to the asserted chlorophyll trade secrets, so there is no expert evidence on the issue. Tr. (Mays) at 521:13-523:3. In particular, there is no evidence that [redacted] adds any particular value over [redacted] *See* CIB 31-32; JX-207C (C.F.R. provision indicating that chlorophyll should be "diluted to a 5 percent concentration"). Nor is there evidence that following the "comprehensive flow chart" referenced in TS 131 has any economic value. *See* CRB at 10 n.5.

Therefore, Complainants have not established value for TS 130-134.

[redacted]

5. The Amount of Effort or Money Expended by Heraeus in Developing

As discussed earlier, there is not much evidence showing how any of the trade secrets were developed. Again, however, the lack of evidence is not necessarily determinative of the existence or absence of trade secret protection of TS 130-134.

6. The Ease or Difficulty of Acquisition or Duplication by Others

As discussed, the FDA issued exemptions for bone cement colorants in which use of 5% chlorophyll solution in vegetable oil was described, and Heraeus' patents described how to dilute the chlorophyll solution into a final concentration. [redacted] Tr. (Spiegelberg) at 1341:25-1342:12; Tr. (Sobolewski) at 1188:16-25, 1205:2-15. [redacted] Complainants did not present any evidence to the contrary. Thus, TS 130-134 are relatively easy to acquire and/or duplicate by others.

Therefore, on balance Heraeus' claimed TS 130-134 are not protectable trade secrets.

D. The Asserted Zirconium Dioxide Trade Secret - TS 145

According to Complainants, the "supplier and part number of the zirconium dioxide used in the Palacos R products comprise" TS 145. CIB at 30. Specifically, the zirconium dioxide has a [redacted] and is supplied by [redacted] with particular article numbers, originally under the trademark [redacted] *See id.*; CX-0002C. This product was allegedly sold only to Heraeus for use in Palacos R bone cements. *See* CIB at 30.

[redacted]

1. Extent Trade Secret 145 Was Known Outside Heraeus

As with TS 121-125, during the [redacted] project Heraeus disclosed [redacted] as the zirconium dioxide product it used. [redacted] As the Staff points out, there is no evidence that there is more than one [redacted] brand of zirconium dioxide. *See* SIB at 33. [redacted]

Heraeus originally purchased zirconium dioxide ZrO2 from [redacted] and only later purchased it from [redacted] JX-258C (Schneider Dep. Tr.) at 267:13-268:4. [redacted] Tr. (Smith) at 1073:25-1074:2 (Biomet previously used zirconium dioxide from [redacted] in its Boneloc cement). The [redacted] Tr. (Smith) at 1106:21-1107:3 [redacted] Thus, the [redacted] zirconium dioxide was likely readily identifiable to people in the industry. There is no evidence of a confidential supply arrangement between Heraeus and [redacted] *See* Tr. (Schneider) at 347:20-348:11 (not aware of any agreement with confidentiality provision between [redacted] and Heraeus during the time when [redacted] supplied zirconium dioxide to Heraeus).

The record does not specifically show when Heraeus began purchasing its zirconium dioxide from [redacted] however, when it began, [redacted] supplied zirconium dioxide to Heraeus through individual purchase orders, not pursuant to a supply agreement. *See* JX-0259C (Schneider Dep. Tr.) at 214:19-216:17, 264:7-266:23; JX-0248C. The purchase orders of record, which do

[redacted]

not have a confidentiality marking, identify the zirconium dioxide purchased from [redacted] *See* JX-0259C (Schneider Dep. Tr.) at 216:11-17, 266:16-268:7; Tr. (Blanchard) at 760:25-761:21; 762:19-763:3; RX-291C at HERAEUSITC025740.

At some point, Heraeus discontinued purchasing [redacted] and/or [redacted] from [redacted] and began purchasing the same chemical substance (with a different brand name and part number) from [redacted] Tr. (Blanchard) at 761:22-762:1. [redacted] RX-0289C. [redacted]

Furthermore, the record includes a 2011 scientific publication suggesting that Heraeus supplied a researcher with [redacted] zirconium dioxide for an experiment that involved a comparison with Palacos. Tr. (Spiegelberg) at 1343:5-25 and JX-209 at ESSCHEM0117290. An online search for [redacted] shows [redacted] as the supplier and the [redacted] part number claimed as a trade secret. Tr. (Spiegelberg) at 1344:4-13; RX-765. Lastly, the bone cement textbook by Dr. Kühn (published in 2000) also shows zirconium dioxide used in Heraeus' product, [redacted] *See* JX-103C at Fig. 8a, ZBITC-1758458.

The lack of confidentiality of an [redacted] indicates that Heraeus did not originally intend to protect the confidentiality of this information. Moreover, the evidence shows a lack of reasonable precautions to protect secrecy in Heraeus's purchase orders from, at minimum, [redacted] which did not contain confidentiality provisions. And the scientific publications discuss TS 145, as well. So TS 145 was known outside Heraeus.

[redacted]

2. Extent Trade Secret 145 Was Known Inside Heraeus

Again, the discussion of Heraeus' in-house protection all of its trade secrets is discussed above.

3. Extent of Steps Taken By Heraeus To Guard Trade Secret 145

As noted, Heraeus disclosed TS 145 to [redacted] zirconium dioxide in a textbook dated 2000, by Heraeus employee Dr. Kühn. Finally, Heraeus disclosed its use of [redacted] to a researcher in 2011. Accordingly, Heraeus did not take reasonable measures to protect the confidentiality of its source and specific product name.

4. Value of TS 145 to Heraeus and Competitors

Heraeus' particular choice of zirconium dioxide provided a "non-neglectable influence on the properties of the cement" due to its [redacted] and [redacted] JX-204C at ZBITC-0009041; *see also* JX-238C (Specht Dep. Tr.) at 206:20-208:1. Therefore, TS 145 did have some value both to Heraeus and its competitors.

5. The Amount of Effort or Money Expended in Developing TS 145

Heraeus did not develop this product, it simply bought it from a supplier, and this factor weighs against finding a protectable trade secret.

6. The Ease or Difficulty of Acquisition or Duplication by Others

In view of Heraeus' disclosures, as described above, it stands to reason that TS 145 could be very easily acquired or duplicated by others.

Considering all the relevant factors, although TS 145 does have some value to Heraeus, it was disclosed on a multitude of occasions to various third parties, was generally known in the

[redacted]

industry, is easily reverse engineered, and Heraeus spent no effort developing it. On balance, therefore, TS 145 is not a protectable trade secret.

VI. MISAPPROPRIATION OF THE TRADE SECRETS

The next analytical step is determining whether there has been misappropriation of Heraeus' asserted trade secrets. This involves consideration of three issues: ownership, confidential disclosure or wrongful acquisition, and use. *Certain Rubber Resins*, 2014 WL 7497801, at *5 (*citing Certain Sausage Casings,* Inv. No. 337-TA-148/169, Initial Determination (July 31, 1984)).

A. Ownership

"[O]ne 'owns' a trade secret when one knows of it, as long as it remains a secret." *Crawler Cranes*, Inv. No. 337-TA-887, Initial Determination at 134, n. 41. A trade secret may be transferred; however, "its continuing secrecy provides the value, and any general disclosure destroys the value." *Id.* (citing *DTM Research, LLC v. AT&T Corp.,* 245 F.3d 327, 331 (4th Cir. 2001)). Heraeus asserts that it owns a propriety interest in all of the asserted trade secrets because it developed them and has consistently used them over the decades. CIB at 9-14. Respondents dispute that Heraeus actually developed the asserted trade secrets, and as noted, the evidence on this is sparse. However, the evidence does show that Heraeus used and is using the asserted trade secrets. Tr. (Kluge) at 40:24-46:1, 61:22-69:24 and CDX-0001C.008, JX-01C, CX-1032C, CX-1034C, CX-1035C, JX-167C (copolymer specifications 1-35); Tr. (KIuge) at 47:2-52:15; CX-13C; JX-5C (powder and liquid specifications 121-124); Tr. (Kluge) at 52:16-54:10 (chlorophyll asserted trade secrets 130-134); Tr. (Kluge) at 54:11-55:3 (zirconium dioxide trade secret 145). Respondents do not effectively dispute this.

[redacted]

On the other hand, as explained above a number of the asserted trade secrets have not remained secret. *See* discussion relating to TS 121-124, 130-134, and 145. Therefore, Heraeus owns only TS 1-35, because these are the only ones that remain secret. Additionally, of course, they are the only trade secrets that remain protectable.

B. Disclosure or Wrongful Acquisition

Misappropriation requires evidence that the "complainant disclosed the trade secret to respondent while in a confidential relationship or that the respondent wrongfully took the trade secret by unfair means." *Certain Rubber* Resins, 2014 WL 7497801, at *5. A taking is wrongful if, for instance, the respondent used a trade secret acquired by an employee under circumstances giving rise to a secrecy obligation. *See Certain Rubber Resins*, Comm'n Op., at *19-20 (affirming ID's reasoning that Respondent "wrongfully took Complainant's trade secrets by unfair means" through copying information obtained by Complainant's former employees under confidentiality agreements); *Certain Rubber Resins*, Initial Determination, 2013 WL 4495127, at * 136-*140 (June 17, 2013).

Here, there was misappropriation by a Merck employee who originally was under an obligation to keep Heraeus' trade secrets confidential. Dr. Specht[2] worked in the Merck laboratory for bone cement starting in 1991. JX-238C (Specht Dep. Tr.) at 27:2-13. During this time, [redacted] *See* JX-125C; JX-134C. Technical confidential information about the Palacos and Refobacin-Palacos bone cements were given to Dr. Specht during his tenure at Merck. JX-

[2] Complainants argue that Respondents wrongfully secured Dr. Specht's absence from the evidentiary hearing, and that this weighs in favor of a finding of misappropriation. *See* CIB at 54-55. Although the circumstances of Dr. Specht's absence are suggestive, they do not warrant an adverse inference or otherwise support a finding of misappropriation.

[redacted]

238C (Specht Dep. Tr.) at 28:15-30:21. Dr. Specht then joined the Biomet Merck Joint Venture, and around 2002, this Joint Venture began working on "Project Galapagos," an effort to develop a Palacos-like cement. Tr. (Mays) at 391:18-392:4; JX-238C (Specht Dep. Tr.) at 76:8-21. The project was headed by Roger Van Broeck, who had never been a Merck employee, and he chose the name Galapagos because "it sounds [similar] to 'Palacos.'" JX-0238C (Specht Dep. Tr.) at 76:8-21. Dr. Specht and others at Zimmer Biomet, including Dan Smith, knew that Dr. Specht possessed non-public Heraeus technical information about Palacos, and knew that such information was being used for the Galapagos bone cement development project. *See, e.g.,* CX-307C (email from R. Specht to D. Smith comparing potential copolymers to Plex 6612 and Plex 6613 specifications); JX-204C (email from R. Specht to D. Smith discussing zirconium dioxide source and indicating this was not public information).

Although Respondents characterize this evidence as a "theory," and note, as described above, that some of the asserted trade secrets were not subject to lasting confidentiality agreements, they do not expressly dispute that Dr. Specht learned the trade secrets during the course of his employment with Merck. *See* RRB at 36-38. Therefore, Dr. Specht had knowledge of Heraeus' confidential information, which he originally obtained while a secrecy obligation was in effect. As discussed below, Respondents used this confidential information for the development of what ultimately became Zimmer Biomet's -1 and -3 formulations of Biomet Bone Cement R and Refobacin Bone Cement R.

C. Use of the Asserted Trade Secrets

"Use" of a trade secret occurs "when goods that embody a trade secret are marketed, the trade secret is employed in manufacturing or production, or is relied on to assist or accelerate research or development." *Certain Crawler Cranes*, Initial Determination, at 26-27 (citing

[redacted]

Restatement (Third) of Unfair Competition § 40, comment c). "An actor is liable for using the trade secret with independently created improvements or modifications if the result is substantially derived from the trade secret." *Id.*

1. The Asserted Copolymer Trade Secrets TS 1-35

Respondents' -1 Products

Biomet sought to create a bone cement [redacted] CX-514C at ZBITC-1696367, is a May 8, 2003 email chain among personnel of the Biomet Merck Joint Venture and Biomet, Inc., stating, [redacted] CX-515C at ZBITC-1696371 is another Biomet email regarding "Priority List for Bone Cement Projects," including an entry for a [redacted] *See also* CX-563, at ZBITC-1753934 (August 25, 2005 presentation on "Background and quality of Biomet Bone Cement") ("Target for production: Make the cements as close as possible to the existing ones . . . Use of same raw materials if possible or Use of materials with the same specifications.").

Biomet contracted with Esschem, the same copolymer manufacturer the Biomet Merck Joint Venture had used, and consequently Esschem already knew of at least one Palacos copolymer specification. *See* JX-238C (Specht Dep. Tr.) at 112:14-113:6, 115:16-20 (Mr. Norquist at Esschem received at least one copolymer specification from Biomet-Merck); JX-24C; Tr. (Sobolewski) at 1209:11-1211:6; JX-20C. For example, in June 2004, when evaluating copolymer candidates from Esschem, Dr. Specht compared the copolymers against the Heraeus specifications for Plex 6612 and Plex 6613, to "see where we are in comparison with the 'original' material."

[redacted]

CX-307C at ZBITC-0009027. Dr. Specht specifically identified [redacted] *See id*. at ZBITC-0009022; *see also* JX-239C (Specht Dep. Tr.) at 235:22-242:13; JX-238C (Specht Dep. Tr.) at 120:4-122:22, 136:7-16, 158:16-161:7 (Dr. Specht admits comparing tests on copolymer samples to [redacted] JX-0023C; CX-0082C: CX 272C: CX-83C; CX-87C. [redacted] Tr. (Mays) at 421:3- 422:8 and CX-38 (discussing change in [redacted] in next iteration of samples).

Respondents' guidance to Esschem involved at least three other features of the -1 product. First, Dr. Specht proposed a [redacted] in the R262 and R263 copolymer beads, an element of the Plex 6612 and Plex 6613 specifications, but [redacted] *See* Tr. (Mays) at 423:25-424:17; CX-38C (discussing specifications for [redacted] JX-0061C at ZBITC-0001397 (proposing specifications including [redacted] for R262 and R263); JX-239C (Specht Dep. Tr.) at 264:12-265:8. Second, he proposed a particular [redacted] that was an element of the asserted copolymer trade secret specifications. *See* JX-61, at ZBITC-0001397 (April 19, 2005 email from R. Specht to E. Sobolewski re "Specifications for 262 and 263"). Third, Respondents used the [redacted] *See* Tr. (Mays) at 427:17-431:9 and CX-1888, "Table 42-58" (showing [redacted] and "Table 6-94" (showing [redacted]

Therefore, Respondents' guidance to Esschem, especially by Dr. Specht, confirms that Biomet made significant use of the asserted copolymer trade secret specifications in developing

[redacted]

the -1 product. *See* Tr. (Mays) at 431:10-21; *cf. Computer Assoc. Int'l v. Quest Software*, 333 F. Supp. 2d 688, at 696-697 (N.D. Ill. 2004) (finding strong likelihood of misappropriation where employees were "assigned to tasks that were nearly identical" to former employment and "repeatedly accessed" the asserted trade secret during development). To be sure, Respondents also engaged in their own research and development, both by themselves and via Esschem. *See generally* RIB at 80-92. For instance, the R262 and R263 copolymers have an additional specification, [redacted] which is not a feature of the asserted trade secrets, and the eventual [redacted] of R262 and R263 are somewhat different from the asserted trade secrets. *See* Tr. (Spiegelberg) at 1357:1-1358:16; JX-0205C at TS 35; JX-0229. But engaging in some independent development is not enough to establish independent development as a legal defense; the relevant efforts must actually be "independent." *See Sausage Casings*, 1984 WL 273789, at *95 ("it is not enough to assert that a secret process could have been developed independently, without access to the confidential source of information"). The development of Respondents' -1 product copolymers was clearly not independent in any meaningful sense.

The -3 Products

The same is true of the -3 product copolymers. In June 2014, a German court found Biomet had misappropriated Heraeus' trade secrets in developing its -1 product and enjoined the production of -1 in Germany. *See* CIB at 55; RRB at 45. Biomet started developing a different product, which was ultimately named the -3 product. Dr. Specht and Dan Smith, who were involved in misappropriating trade secrets for the -1 cements, [redacted] *See* CX-643C at 59 (Zimmer Biomet's Responses to

[redacted]

Interrogatories) (describing [redacted] Tr. (Smith) at 1164:7-25.

Dr. Specht [redacted] with the goal of [redacted] *See* Tr. (Mays) at 432:21-433:4 [redacted] which were derived using Heraeus's specifications). The selection of the -3 copolymers involved comparing [redacted] to the specification for R262 (which was developed through comparison to Heraeus's Plex 6613). *See* Tr. (Mays) at 437:11-440:6; CX-482 at ZBITC-1191765 (Biomet December 2014 Validation Master Plan comparing specifications of [redacted] CX-541C (March 2, 2015 email from Axel Steiof to D. Smith and R. Specht stating the plan [redacted] had already been chosen as an alternative to R263 in connection with the -1 products, and Biomet determined to use [redacted] as the R263 substitute for -3 products, as well. *See* Tr. (Spiegelberg) at 1421:7-16; CX-468 at ZBITC-0080291 (technical report for -3 formulation indicating that R263 [redacted] CX-530C at 375. Biomet's work with [redacted] for the -1 products included a comparison to the Plex 6612 and Plex 6613 particle size specifications. *See* Tr. (Mays) at 427:21-431:9; CX-1888 at "Table 42-58" (showing Heraeus Plex 6612 particle size specification and comparison [redacted] and "Table 6-94" (showing Plex 6613 particle size specification). And Respondents considered a candidate copolymer [redacted] although it was ultimately rejected after comparison with Plex 6613. JX-0239C (Specht Dep. Tr.)

[redacted]

at 323:20-324:7; *see* CX-0463C (2014 email containing comparison of R262, Plex 6613, and [redacted]

Respondents argue that there is no evidence showing that any "alleged technical information obtained by Dr. Specht was provided by Heraeus subject to confidentiality agreements between Heraeus and Merck" because the [redacted] RRB at 36. Even assuming this point applies to the copolymer trade secrets, however, the [redacted] long after the misappropriation took place. Respondents also argue that the -3 copolymers were developed independently. *See* RIB at 94. [redacted] *See* CIB at 81-82. [redacted] *See* Tr. (Mays) at 436:25-444:6; CX-0482C at 764-65; JX-0101C at 651 [redacted]

As with the -1 product, therefore, the development of Respondents' -3 product copolymers was clearly not independent in any meaningful sense and was instead the product of misappropriation of Heraeus' trade secrets. So Respondents misappropriated and used Heraeus' TS 1-35 in the development of their -1 and -3 bone cements.

[redacted]

2. The Asserted Powder and Liquid Specification Trade Secrets

As discussed above, TS 121-123 are not valid trade secrets. However, to the extent TS 121-123 are found to be protectable trade secrets, the evidence shows that they were used to gain regulatory approval for the -1 and -3 products. *See generally* JX-0076C. As one example, when seeking regulatory approval for Refobacin Bone Cement R in 2017, Respondents represented to the FDA that the "bone cement powder and monomer materials used for the different sizes of Refobacin Bone Cement R are the same as the materials used in [Refobacin Palacos R]," except for the green colorant. *Id*. at 66. That is, Respondents represented that their powder and liquid ingredients were the same as the powder and liquid ingredients in Refobacin Palacos R, except for the chlorophyll.

Respondents make little effort to dispute this. *See generally* RIB at 108-09. Mr. Smith testified that the -3 product's liquid and powder components were developed independently, by starting with target nominal values and developing specification ranges consistent with ISO protocols. *See* Tr. (Smith) at 1114:13-1116:14. There is reason to doubt this, given [redacted] *See* JX-0215C; Tr. (Smith) at 1166:17-1167:12. But even accepting Mr. Smith's testimony on this point, his additional testimony that the words "the materials used . . . are the same as" in Respondents' FDA application really meant "the types of material are the same" is facially unbelievable. Tr. (Smith) at 1118:23-1119:8. It is also uncorroborated by Dr. Spiegelberg, because FDA applications for other bone cements claim substantial equivalency but not identical ingredients, except where the application is for a product made by the same manufacturer. *See* Tr. (Spiegelberg) at 1359:1-1360:5 (citing RDX-0003.51); RX-0737.0002 (application for a Tecres bone cement where the "bone cement formulation is identical" to a previous Tecres bone cement) (emphasis in original). Respondents bluntly

represented that the -3 product's ingredients were "the same as" the ingredients in Refobacin Palacos R, and they could only have made that representation if they knew both sets of ingredients, that is, if they knew TS 121-23 and determined to use it in their FDA application. And Respondents similarly employed TS 121-23 in connection with the European regulatory filings for the -1 product. *See* JX-0228C at 84-87. Therefore, Respondents misappropriated TS 121-23 in relation to the -1 and -3 products.

3. The Asserted Chlorophyll Trade Secrets

As discussed above, TS 130-134 are not valid trade secrets. Moreover, to the extent that they are found to be protectable, they were not used by Respondents. TS 130-32 all require [redacted] but the -1 product used an [redacted] and the -3 product uses a [redacted] *See* Tr. (Mays) at 473:3-474:12 (discussing JX-0228C at 85). TS 133 and 134 require [redacted] (TS 133), and [redacted] (TS 134). The record appears to be silent on whether either of these steps occurred in coloring the -1 product, and the record affirmatively demonstrates that the [redacted] *See* RX-0438C.0015; JX-0076C at 66 (chlorophyll "is present in the monomer"). Therefore, even though Dr. Specht had informed Mr. Smith that [redacted] and Respondents use chlorophyll as a colorant, Respondents did not misappropriate TS 130-134 in developing the accused bone cement products because they did not use the specific asserted trade secrets.

[redacted]

4. The Asserted Zirconium Dioxide Trade Secret

TS 145, pertaining to zirconium dioxide, is not a valid trade secret, but to the extent it is found to be, the evidence shows it was misappropriated. Admittedly, there is no evidence Respondents practice TS 145, because they do not obtain their zirconium dioxide from [redacted] under the relevant brand names and part numbers. *See* Tr. (Smith) at 1106:7-1107:8; JX-0205C at 26 (reciting the particulars of TS 145). In fact, Respondents did not even select the zirconium dioxide for their bone cements; that selection was made by a contractor. *See* Tr. (Smith) at 1106:7-15. Nonetheless, both Dr. Specht and Mr. Smith were aware no later than 2004 that Heraeus used [redacted] *See generally* CX-0518C. Although Mr. Smith's testimony suggests that uncovering the identity of that vendor [redacted] would not have been difficult, because [redacted] Respondents represented to the FDA and to European regulators that the materials used for both the -1 product and the -3 product "are the same as the materials used" in Refobacin Palacos R. JX-0076 at 66; *see* Tr. (Smith) at 1106:16-1107:8; JX-0228C at 83 ("The supplier of the zirconium dioxide remains the same."). As with the asserted powder and liquid trade secrets, this representation "ease[d] the regulatory process" and was made possible by Respondents' knowledge of the asserted zirconium dioxide trade secret. Tr. (Mays) at 466:7-16. This constitutes misappropriation as to both the -1 product and the -3 product.

D. Summary

In summary, Respondents used and misappropriated protectable trade secrets relating to the copolymer specifications (TS 1-35), and to the extent they are found to be protectable trade secrets, the powder and liquid specifications (TS 121-123) and zirconium dioxide source (TS 145).

[redacted]

The evidence does not support a finding of use or misappropriation for the asserted trade secrets relating to chlorophyll (TS 130-134).

E. Harm to Heraeus by Respondents' Misappropriation

This issue is intertwined with the domestic industry discussion and is addressed below.

VII. DOMESTIC INDUSTRY

In a case like this where Complainants' product is manufactured outside the U.S., a domestic industry may be established through activities having a close relationship to the products at issue – in this case bone cement. *Cast-Iron Stoves*, Inv. No. 337-TA-69, USITC Pub. No. 1126, Comm'n Op. at 11 (Jan. 1981) Moreover, the domestic industry need not involve use of the asserted trade secrets at issue; however, the domestic industry must be the industry that is targeted by, or that directly competes with, the unfair imports. *TianRui*, 661 F.3d at 1337. While there is no bright-line rule to determine whether a domestic industry exists, it is necessary to distinguish Complainants' domestic activities from those of a mere importer. *See Schaper*, 717 F.2d at 1373.

As noted, one approach to evaluating domestic industry in this situation is a "value-added" analysis, where domestic activities that add value to a product are scrutinized. *E.g.*, *Certain Cube Puzzles*, Comm'n Op. at 30 (quality control, packaging, and repair operations added "approximately 50 percent of the value of the cube puzzle"). As the Staff observes, however, Complainants have not pursued this approach. *See* SIB at 69; Tr. (Prowse) at 592:19-23. Another method is to consider activities that do not necessarily add value to a product, but are connected to the product in some concrete way, such as repair and installation work. *E.g.*, *Certain Airtight Cast-Iron Stoves*, Comm'n Op. at 11. Complainants have not pursued this method, either.

Instead, Complainants assert that a domestic industry exists under Section 337(a)(1) "through its investments in education, training, domestic support, research and development,

[redacted]

quality control, domestic component manufacturing, distribution, marketing, and sale of Heraeus' bone cement products and related mixing systems." CIB at 85 (citing *Schaper*, 717 F.2d at 1373). Complainants provide a brief history of the alleged domestic industry, explaining that Zimmer Biomet distributed Palacos before HMUS was established, and once HMUS was established, Complainants decided to [redacted] CIB at 92 (citing Tr. (Childers) at 151:19-22). But most of Complainants' investments have been in areas that any mere importer would also invest in, including "sales, marketing, regulatory compliance and research." Tr. (Prowse) at 592:3-8. And investments that might be analyzed under a "value-added" or repair/installation rubric have been withdrawn (as with mixing and delivery systems). *See* Order No. 30 (Nov. 19, 2019).

So of the various categories of investments Heraeus relies on for its domestic industry, several do not qualify. The qualifying categories include education, training, research and development, and quality control. *See* CIB at 85. With this background in mind, Heraeus' specific domestic activities can be analyzed to determine whether they qualify as legitimate "domestic industry expenses." *See id*. at 91-114.

A. Training and Education

The first activity that Heraeus alleges makes up its domestic industry is training and education, and the expenditures for this involve a number of different events. One event is the Heraeus sponsored "Reduce Revisions" initiative, which is a program to reduce "total joint arthroplasty" (TJA) revisions (i.e., multiple surgeries to replace the same joint). Tr. (Prowse) at 545:3-9; CDX-0003.14. Heraeus presented evidence that Reduce Revisions includes a website, roundtable discussions, an annual survey, live symposia, and live web seminars that are managed by an editorial board of surgeons. CIB at 95. JX-0141C; Tr. (Childers) at 166:10-15; Tr. (Prowse)

[redacted]

at 546:22-547:8. Heraeus further alleges that its Reduce Revisions initiative is "not focused on the sale of Palacos bone cement products, but [is] instead geared towards providing an educational platform and resource relevant to existing Palacos users, as well as other health care professionals using bone cements in performing TJA's." CIB at 94-95 (footnote omitted) (citing Tr. (Childers) at 165:10-21; Tr. (Prowse) at 547:23-548:7). Heraeus alleges that it invested [redacted] in support of the various Reduce Revisions programs, excluding labor and prior to the filing of the complaint. CIB at 97, citing Tr. (Prowse) at 550:9-24; JX-0140C; JX-0175C; CX-1276C, CX-1277C, CX-1278C, CX-1279C, CX-1280C, CX-1281C, CX-1283C, CX-1284C, CX-1285C, CX-1286C, CX-1287C, CX-1288C, CX-1289C, CX-1290C, CX-1291C; CX-1380C; CX-1385C; CX-1471C; CX-1534C; CX-1536C; CX-1598C.

Another aspect of the alleged training and education expenditures is Heraeus' "Palacademy," which it describes as a "Heraeus-conducted Product Training and Education institution." CIB at 98, citing Tr. (Childers) at 156:7-15, 162:24-163:6; Tr. (Prowse) at 550:25-551:11; JX-0040C at 518. Heraeus submits that the purpose of the Palacademy is "to make training and education (e.g. hands on training, lectures and presentations) on [Heraeus'] products and Medical Technologies available to [Healthcare Professionals]." CIB at 98-99 (citing JX-0040C; Tr. (Childers) at 156:7-12). CIB at 98-99. Before March 2019 (the filing date of the complaint), Heraeus put on two major Palacademy events and many local regional Palacademy events. *See* Tr. (Childers) at 158:7-10, 207:23-208:6 ("So there have been several national and then there's been many local and regional and they take many different forms from in servicing at a hospital on how to use products, doing grand rounds or journal club, different forms."). Heraeus further asserts that the Palacademy events are highly technical and educational in nature, because the events contract with medical professionals to author and present lectures, and the majority of

[redacted]

attendees are users of Palacos. *See* Tr. (Childers) at 156:20-157:5; 159:12-160:9, 161:18-162:13; Tr. (Prowse) at 551:12-552:1.

Heraeus alleges that it invested [redacted] in conducting the Palacademy events in the United States, excluding labor, prior to the filing of the complaint in this Investigation. *See* Tr. (Prowse) at 554:5-18; JX-0139C; JX-0140C; JX-0175C; JX-232C; CX-1054C; CX-1276C— CX-1292C; CX-1437C; CX-1444C; CX-1469C; CX-1482C; CX-1524C; CX-1549C; CX-1556C; CX-1559C; CX-1565C; CX-1577C; CX-1587C—CX-1589C. Invoices related to associated speaker costs, such as travel, lodging, the speakers' time, and meals, are, according to Heraeus' Code of Conduct, "modest in value and subordinate in time and focus to the training and/or educational purpose of the meeting." CIB at101, citing JX-0040C at 519.

Heraeus further alleges that "Other Educational Events and Medical Conferences" also are part of the training and education section of its domestic industry. Heraeus includes costs for exhibition booths and costs to sponsor education events and medical conferences in this category. *See* CIB at 56-58. Heraeus alleges that it spent [redacted] in sponsoring and participating in these other conferences. *Id.* at 103. Heraeus contends that it plays "an important role in enhancing the learning experience for attendees." *Id.* at 103 (quoting RX-0694, which is the 2019 Association of Hip and Knee Surgeon Annual Meeting website).

On balance, the Reduce Revisions initiative is fairly characterized as an educational tool. The Reduce Revisions "Project Plan" document states that the goal is to "Reduce total joint arthroplasty (TJA) revisions by," for example, having clinicians communicate, collaborate, and share information "in a way that improves the quality of patient care." JX-0141C at 4. The Staff argues against finding the Reduce Revisions to be educational, noting that the company that develops content for the Reduce Revisions website, [redacted] is a marketing and advertising

[redacted]

company. *See* SIB at 55 (citing Tr. (Childers) at 191:7-14 (Heraeus hired [redacted] "for strategy, consulting, marketing, branding")). And another goal of the program is to "Associate the Heraeus brand" with the initiative (*id.*), however, the website and seminars actually do contain educational content relating to total joint replacement (JX-106). The site has a number of articles related to TJA, which appear to be aimed at medical professionals, and do not relate to HMUS' Palacos. *See* JX-106. In fact, the initiative has no obvious link to Palacos bone cement at all, especially when considering the goal of the initiative is to reduce the number of TJAs. Thus, Complainants' assertion that the Reduce.revisions.org website is "not a vehicle to convey marketing material to tout Heraeus' product" is reasonably accurate. CPB at 138. Overall, the Reduce Revisions is somewhat related to bone cement and joint replacement, and thus, does contribute to Complainants' education and domestic industry.

However, Respondents and the Staff are correct that the Palacademy events are primarily marketing activities. Heraeus' sales reps attend the Palacademy events, and Heraeus holds them at expensive restaurants and hotels, including five star properties in Las Vegas (the Green Valley Ranch Resort and the Aria Resort), and tourist attractions such as the Greenbrier (an event which included a tour of a distillery and a presentation on the Impact of War and Bourbon on the Evolution of Orthopedics). *See* RIB at 122 (citing JX-0249C (Childers Dep. Tr.) at 151:9-13, 162:14-19; CX-1394C; CX-1434C; CX-1438C; JX-49C). The Staff notes that Heraeus generally pays travel and lodging costs for attendees, and many attendees are not presently Heraeus customers. *See* SIB at 56-57 (*citing* JX-249C (Childers Dep. Tr.) at 147:17-19, 148:3-9 (invitations may be sent out to "all the members of a society or a congress"); JX-249C (Childers Dep. Tr.) at 155:15-156:18 (generally Palacademy attendees' food and hotel costs are paid for); Tr. (Childers) at 211:24-212:4 (Heraeus will pay for airfare for health professionals and food at

[redacted]

the events); Tr. (Prowse) at 602:23-603:14 (evidence indicates that one-third of attendees at 2018 Palacademy event were not customers); *id*. at 617:2-13 (for May 2019 Palacademy event, evidence indicates that more than half of attendees were not customers)). Further, Nicole Petermann, President of Heraeus Medical, testified that Palacademy events are "part of the marketing budget" in the United States. *See* JX-256C (Petermann Dep. Tr.) at 37:18-19, 84:4-7. Thus, the location of the events, the paid travel and lodging costs for attendees, and the majority of non-related topics covered in the programs all indicate that the events are marketing activities.

Moreover, the Palacademy has only an attenuated relationship to Heraeus' bone cement product. For example, the Staff points to the presentation "Why Revisions Matter" (CX-0154C), which was highlighted by Heraeus's Country Manager as "typical." Tr. (Childers) at 159:12-160:24. But this presentation had little to no information on bone cements. *See generally* CX-0154C. Similarly, another Palacademy presentation entitled "Healthcare Change Management" contained little or no information on bone cements. *See* CX-151C; Tr. (Childers) at 209:7-211:17 (identifying CX-151C as a Palacademy presentation). And although some Palacademy activities appear to relate to bone cement use, as the Staff points out, these activities were not separately accounted for. *See* SIB at 57-58 (citing Tr. (Prouse) at 596, 671).

Respondents and the Staff are also correct that HMUS' spending for attendance and participation at trade shows and conferences are clearly marketing and sales expenses that any importer incurs. The Staff identifies numerous examples of Heraeus' trade show booths where marketing material is displayed. *See generally* SIB at 58-59; Tr. (Mulhern) at 914:21-915:22; RDX-0002C.10; JX-249C (Childers Dep. Tr.) at 171:4-172:3; JX-250C (Cruz Dep. Tr.) at 140:5-15, (trade shows are "part of the marketing effort by Heraeus with respect to cements"); JX-255C (Kolbe Dep. Tr.) at 67:20-68:13 (stating that at industry events such as the Association of

[redacted]

Operating Room Nurses meeting, "[w]e have the sales collateral available, we have banners, there might be an advertisement in a periodical that's associated with the event, we have a booth at the event"); JX-256C (Petermann Dep. Tr.) at 83:9-84:13 ("we do a lot of . . . congresses and trade fairs in the United States . . . we are present there, represent our products, and are there with sales reps explaining the products, and too are very active in – in marketing our products"). Thus, these expenses are not part of Complainants' education and training domestic industry.

B. Domestic Facility Expenditures

Heraeus asserts that it had rent and lease expenditures of [redacted] for office and storage facilities that should be seen as part of its education and training domestic industry. *See* CIB at 104 (citing Tr. (Prowse) at 563:8-16). Specifically, Heraeus claims that it rents an office facility in Yardley, Pennsylvania, "where [Heraeus] house[s] [its] Human Resources, Analysis, Customer Service, and Operations functions." Tr. (Childers) at 152:20-22; JX-0249C (Childers Dep. Tr.) at 24:19-22. Heraeus alleges that the rent and lease expenses for this office facility were [redacted] in 2017 and [redacted] in 2018. Tr. (Prowse) at 563:3-16; CX-0146C; CX-0173C. Heraeus further claims a storage unit in Nashville, Tennessee, rented from Extra Space Storage, as a domestic industry expense. The storage space holds literature and samples of Heraeus' bone cement products and accessories for use at various training and education events. *See* JX-0249C (Childers Dep. Tr.) at 40:21-22; CX-0180C. The rent for this storage facility, prefiling, was [redacted] Tr. (Prowse) at 563:8-16; CX-1450C.

Similar to the expenses incurred by Complainants at marketing events, discussed above, the expenses incurred in renting the office and storage space are marketing expenses and do not contribute to Complainants' domestic industry. The Pennsylvania office supports primarily sales and marketing functions (SIB at 67 (citing Tr. (Mulhern) at 911:10-912:2)) and the Nashville

[redacted]

facility stores literature used at sales and marketing conferences (*id.* (*citing* Tr. (Mulhern) at 912:7-12. RIB at 131-132)).

C. Domestic Labor Expenditures

Heraeus claims that it paid [redacted] for 76 employees' salaries in the United States, and these employees are involved in "activities pertaining to Palacos bone cement products and their delivery and mixing system. CIB at 104. The main employees are:

(1) President and Country/General Manager, Devin Childers, whose job responsibilities include regulatory, research and development, clinical education, operations, marketing, and finance functions. *See* Tr. (Childers) at 149:5-11, 171:11-172:9; 180:16-181:1. Heraeus submits that Mr. Childers spends approximately 45% of his time on training and education, regulatory, quality affairs, and research and development functions, and on that basis Heraeus claims it spent [redacted] for his services through the filing of the complaint. CIB at 105 (citing Tr. (Childers) at 172:10-14; CDX-003C.00040; JX-0161C—JX-0163C; CX- 0193C; CX-1615C).[3]

(2) Vice President of Marketing and Education, Baxter (William) Webb, who performs activities relating to Heraeus' education and training programs and oversees other members of the marketing and education department at Heraeus. Mr. Webb allegedly spends approximately 45-55% of his time on either clinical training and education, regulatory affairs, or research and development, and Heraeus claims it spent between [redacted] and [redacted] through the filing of the complaint. *See* CIB at 106 (citing Tr. (Childers) at 174:18-23; CDX-003C.00040; JX-0161C-JX-0163C; CX-0193C; CX-1615C).

(3) HMUS' Scientific Quality Affairs Analyst, Carly Ducharme, had two main responsibilities: regulatory (e.g., she "maintain[ed] the US system for FDA compliance" (JX-

[3] Heraeus' evidence related to time percentages of Mr. Childers and Mr. Webb are the allegedly new evidence that is the subject of Respondents' motion to strike.

[redacted]

0052C; Tr. (Childers) at 173:3-10)), and scientific affairs (e.g., she "work[ed] with the Head of Marketing to plan, get approval, contract and manage US-based research studies" (JX-0052C)). In addition, Ms. Ducharme allegedly supported HMUS' educational efforts. *See* Tr. (Childers) at 154:12-21. Ms. Ducharme spent almost 100% of her time on these functions, and Heraeus submits that it expended [redacted] for her services through the filing of the Complaint. CIB at 106 (citing CDX-003C.00040; JX-0161C-JX-0163C; CX-0193C; CX-1615C).

(4) Clinical education employees, responsible for educating nurses, doctors, physician assistants, scrub technicians, and other clinical personnel, and Heraeus' internal team, on the treatment of patients using the Palacos bone cement products and their delivery and mixing systems. *See* Tr. (Childers) at 172:15-173:3; CX-0170C (internal anatomy presentation); CX-0192C (internal total joint arthroplasty presentation). Heraeus states it expended [redacted] for the clinical education team's services through the filing of the Complaint. CIB at107 (citing CDX-003C.00040; JX-0161C-JX-0163C; CX- 0193C; CX-1615C).

Heraeus alleges that these salaries (totaling [redacted] represent between [redacted] and [redacted] of its gross sales of Palacos through the filing of the Complaint. CIB at 107 (citing CDX-003C.00040; JX-0161C-JX-0163C; CX-0193C; CX-1615C; JX-0047C).[4] The Staff's assessment of this aspect of Complainants' domestic industry allegations is correct. *See* SIB at 60-61. Only three clinical education employees and one quality affairs employee should be considered as qualifying expenses related to Heraeus' education and training domestic industry; in particular, three clinical education employees [redacted] "appear to conduct and oversee training related to the bone cements." SIB at 60-61. These salaries were [redacted] CDX-0003C.0040 (listing "Clinical Education Subtotal"). Furthermore, Ms.

[4] The percent of gross sales evidence, too, is part of Respondents' motion to strike.

[redacted]

Ducharme's activity should be considered a non-sales and marketing expense, because, giving Heraeus the benefit of the doubt, at least some of her work focuses specifically on clinical research studies. Thus, salaries totaling [redacted] fairly comprise a part of Complainants' claimed domestic industry. The other employees (Mr. Childers and Mr. Webb), who are quite senior, likely do engage in some educational, training, research, and quality control-related activities, particularly of an administrative and supervisory nature. However, aside from Mssrs. Childers and Webb, only four of Heraeus' 76 domestic employees engage in its domestic industry, accounting for only [redacted] out of a total payroll of [redacted] It is therefore implausible that Mr. Childers and Mr. Webb (who, as noted, is responsible for both marketing and education) spend 45% or more of their time on the domestic industry. It is much more likely that they are focused on activities that any importer would typically incur, rather than education, training, research, and quality control, and their contribution to legitimate payroll expenses is at best de minimis.

D. Contracting Costs

Finally, Heraeus submits that its contracts with other professionals and companies for assistance related to quality assurance, customer service, and education should be viewed as domestic industry expenditures. Heraeus lists the following:

(1) [redacted] which assists Heraeus "with its quality systems to ensure that" products are in compliance with manufacturing specifications and provides consulting on FDA market approval and other government regulations. CIB at 109 (citing Tr. (Childers) at 176:2-22; CX-0616). Heraeus alleges that it spent [redacted] in fees paid to the [redacted] CIB at 109. On the one hand, the Staff is correct that the work done by the [redacted] is "not sales and marketing expenses." SIB at 63-64. On the other hand, Respondents are correct that the activities of the

[redacted] "are no different than those undertaken by a 'mere importer,' and therefore, are not relevant to the domestic industry inquiry." RIB at 128.

(2) [redacted] was hired by Heraeus for three different tasks: to provide assistance with licensure to enable shipping to all 50 states, to advise on aspects of commercializing Palacos in the U.S., and to provide information for the manufacture of Heraeus' mixing system components. *See* CIB at 109-11 (citing CX-0140C). Heraeus claims expenses of [redacted] for these three tasks. *See* Tr. (Prowse) at 563-64. As the Staff notes, however, the [redacted] website defines its role as "support to marketing, sales and distribution activities." *See* SIB at 64 (citing RX-734); *see also* Tr. (Mulhern) at 904:22-906. Complainants' retained this company to aid Complainants' marketing strategy, and thus, the associated expenses are not part of Complainants' education and training domestic industry.

(3) [redacted] is a consulting agency that Heraeus hired to provide "medical education" services, along with a range of marketing planning and support initiatives. CIB at 110. Heraeus contends that its expert, Dr. Prowse, separated out the educational work from the marketing work before presenting his opinions of domestic industry expenditures. Heraeus accordingly alleges that it spent [redacted] on educational assistance from [redacted] activities include creation of a website for the Reduce Revisions initiative, website strategy for the Palacademy initiative, and unspecified services related to other educational events and medical conferences. *See* CIB at 110-111. As the Staff and Respondents both contend, however, [redacted] is principally a marketing firm engaged to help Heraeus with brand development. *See* SIB at 64-65; RIB at 127. Numerous facts point to this conclusion: the firm holds itself out as providing [redacted] (RX-0881.0001); it promotes the idea that [redacted]

[redacted] (RX-0882.0002); it advocates use of [redacted] (*id.*); [redacted] (JX-0139C at 1); and the testimony of even Heraeus' witnesses suggests that [redacted] services were primarily marketing-oriented (*see* Tr. (Childers) at 190-91; JX-0255C (Kolbe Dep. Tr.) at 66 [redacted] is "an ad agency"); Tr. (Prowse) at 623:10-624:17). Although Dr. Prowse did not count the entirety of Heraeus' payments to [redacted] in forming his opinion, because he recognized that some payments were for marketing, the basis for his allocation is to a large extent either not well-founded or not entirely clear. *See* Tr. (Prowse) at 559:6-560:2. Specifically, he included [redacted] work related to Palacademy (which, as discussed above, is more marketing than education) and he lumped a number of [redacted] activities into the catch-all category "Other Education and Training," which is unduly vague, particularly given [redacted] conflation of marketing and education in its own marketing materials, and which may refer to the other education and conferences found above to be non-qualifying. *See id*. (citing CDX-0003C.0037); CIB at 56-58. So the preponderance of the evidence does not show that [redacted] expenses contribute to Complainants' education and training domestic industry.

(4) Medical professionals who Heraeus hired to give lectures and lead training and educational sessions at, for example, Palacademy and Reduce Revisions events. Heraeus states it invested [redacted] in fees for these medical professionals. Tr. (Prowse) at 563-64. Because they contend that Palacademy and Reduce Revisions events are sales events, the Staff and Respondents assert that these expenses are primarily sales and marketing investments and should not be part of the domestic industry expenditures. *See* SIB at 66; RIB at 126. To be sure, it is not clear to what

[redacted]

extent these professionals worked only on the Reduce Revisions initiative (which counts toward the domestic industry) or Palacademy (which does not), or both, or neither. *See generally* CIB at 111-12. Nonetheless, giving Complainants the benefit of the doubt, the entirety of this category of expenses will be counted, so the lecturers and participants in Complainants' education and training endeavors are part of Complainants' education and training domestic industry.

(5) [redacted] is a warehouse in which Heraeus rents about 4,000 sq. ft. for "warehousing and distribution, as well [as] establishing and maintaining 'a device complaint record system,' complying 'with its Medical Device Reporting (MDR) obligations,' and maintaining 'regulatory compliance,' customer support, and more." CIB at 112 (citing JX-0039C; Tr. (Childers) at 203:15-22; Tr. (Prowse) at 564:19-22). Heraeus alleges that it spent [redacted] in fees paid to [redacted] for these services. CIB at 112. But rental of storage space is a typical expense for any importer of products into the United States, and these expenses are not part of Heraeus' claimed domestic industry. *See Certain Portable Electronic Calculators, Inv*. No. 337-TA-198, Initial Determination, 1985 WL 303607, at *51 (April 18, 1985) ("warehousing is considered an activity of the type typically engaged in by importers and also will not be considered part of the domestic industry").

(6) [redacted] allegedly assists Heraeus with "sales management to gain and maintain new contracts through [relationships] with a targeted group." CIB at 113 (citing JX-005C; Tr. (Prowse) at 564:18-19). Heraeus states it paid [redacted] in fees to [redacted] CIB at 113. As with [redacted] above, Complainants' own characterization of this entity as an aid to sales management clearly portrays it as a marketing relationship and not part of the domestic industry.

[redacted]

(7) Domestic Component Expenditures includes adapters and medical hoses that are used with Heraeus' Palacos bone cements and are purchased from a company named [redacted] *See* CIB at 113. The hoses allegedly are custom fabricated through direction from Heraeus. *See* Tr. (Childers) at 177:13-22; Tr. (Prowse) at 565:4-17. Heraeus states it invested [redacted] towards the manufacture of these components. CIB at 113. But these components are not part of this investigation, and they also have no connection to the claimed education, training, research, and quality control domestic industry.[5]

E. Analysis

Complainants' activities in the U.S., beyond those activities of a "mere importer," revolve around education and training related to total joint replacements and to a lesser degree to bone cement usage, as well as research and development; there is little evidence, however, that quality control is part of the claimed industry. The investments in these categories of activities include [redacted] for the Reduce Revisions initiative, [redacted] for payroll, and [redacted] for medical professionals. The amount of expenditures is not necessarily even relevant to the analysis, because in trade secret investigations the significant/substantial requirement of Section 337(a)(3) does not expressly apply. *See* CIB at 88-89 (citing 19 U.S.C. § 1337(a)(3)). But even if Complainants were required to make a showing of significance or substantiality, they have done so.

F. Substantial Injury To Domestic Industry

So understood, however, the domestic industry is disconnected from Complainants' bone cement product to a degree that it is simply not "subject to injury or destruction as a result of respondents' unfair acts." CIB at 90 (quoting *Steel Railway Wheels*, ID at 79-80). There are two particular problems.

[5] This evidence also was part of Respondents' motion to strike.

[redacted]

First, the domestic industry is not really an industry as that term is conventionally understood, because it does not turn a profit. Although Complainants' sales revenues are not entirely of Palacos products – for instance, they include other goods such as "Palabowl" – there is no record evidence that the domestic industry generates any revenues at all. *See* JX-0047C (sales spreadsheet). It is not required to, of course; as Complainants explain, it is sufficient but not necessary for the existence of a domestic industry if Section 337(a)(3) is satisfied, and Section 337(a)(3) focuses entirely on expenses rather than revenues. *See* CIB at 88-89; 19 U.S.C. § 1337(a)(3). But an industry that consists entirely of expenditures on education, training, and research and development, with no concomitant revenues, is an industry that is wholly insulated from competition. The domestic industry proven here could conceivably continue even if Respondents captured the entirety of the domestic bone cement market.

Second, even assuming that the domestic industry generates some revenues, its nature is such that it is not subject to injury as a result of Respondents' importation of bone cement. *See Rubber Resins*, Comm'n Op., 2014 WL 7497801, at *5 ("Therefore, there is a requirement not only that the complainant demonstrate the existence of a domestic industry, but also that there be actual injury or the threat of substantial injury to a domestic industry."). The question is whether the unfair imports have, or threaten to have, a substantial adverse effect on the domestic industry. 19 U.S.C. § 1337(a)(1)(A)(i). The domestic industry is education, training, and research and development. But Complainants fail to provide any evidence that the importation of Respondents' bone cement causes harm or threatens to cause harm to Complainants' education, training, and research and development activities. Respondents do not argue this point, but rather focus on the alleged injury to the sale of Heraeus' bone cement. *See* RIB at 132-47. The Staff, on the other hand, recognizes the problem and correctly notes that "Complainants have provided

[redacted]

no expert testimony indicating that the alleged unfair imports have affected Heraeus' investments in education and training, compliance costs, or clinical education employee salaries." SIB at 79; *see Certain Activity Tracking Devices*, Inv. 337-TA-963, Initial Determination, 2016 WL 11596099, at *43 (finding failure to show substantial injury due, inter alia, to the lack of evidence "connecting [Complainant's] sales to the alleged domestic industry in research and development").

These two considerations are fatal to Complainants' case. Complainants' domestic industry is not capable of being injured by Respondents' unfair acts, and, assuming it is, Complainants fail to meet their burden of proving harm to their domestic industry as a result of Respondents' unfair acts. So the evidence does not support a finding of substantial injury or a threat of substantial injury to the Complainants' domestic industry, as required by Section 337(a)(1)(A)(i).

Nonetheless, to the extent that a domestic industry is found to exist with respect to Heraeus' bone cement – and this is the focus of the parties' briefing on the subject – Heraeus similarly failed to establish injury, as explained below.

G. Customer Confusion

Heraeus alleges that Respondents "sewed customer confusion" in an effort to sell the accused products instead of Palacos. CIB at 125. Heraeus presents evidence that once Respondents had the Accused Products available to sell in the U.S., they began to sell off their remaining Palacos bone cement and told customers that the Accused Products were similar to or the same as Palacos and "were replacements for Palacos." *Id.* at 125-128. Complainants call this strategy Zimmer Biomet's "conversion program." CIB at 117. Heraeus alleges that this strategy

[redacted]

ultimately resulted in lost sales of Palacos (i*d.* at 128), significant future lost sales (*id.* at 129), and price erosion (*id.* at 139).

With respect to the lost sales allegations, Complainants present market share evidence that purportedly shows a loss to Heraeus. Complainants allege that in 2017, Zimmer Biomet sold approximately [redacted] and in 2018, when Respondents introduced their own products and HMUS started selling Palacos in the U.S. directly, [redacted] *See* CIB at 130 (*citing* Tr. Prowse at 676:10-677:23). They further allege that "[n]early that entire revenue shortfall was made up by Zimmer Biomet's sales of the Accused Products [redacted] and HMUS' sales of Palacos [redacted] CIB at 130. Thus, Complainants argue, the presence of Accused Products resulted in less sales of Palacos by Respondents. However, the evidence also shows an increase in market share by Heraeus' own sales of its Palacos product in 2018, which occurred because that was the first year HMUS directly sold its own product in the United States. Thus, Complainants own allegations fail to show lost market share. If any loss occurred, it actually was Respondents' loss of market share of sale of Palacos. This loss is not an injury to Complainants' domestic industry.

Complainants further contend that the above evidence of Respondents' lower sales of Palacos illustrates that HMUS would have had substantially greater sales in 2018 were it not for Zimmer Biomet selling their own products. *Id.* at 131 ("The only logical conclusion from the fact that the two companies are direct competitors is that some portion of Zimmer Biomet's sales would have gone to HMUS had the Accused product not been on the market."). But the relevant market is not a two-party market; there are at least three other significant (and non-accused) similar bone cement products for sale – products by Stryker (the market leader), DePuy, and DJO Surgical. *See* Tr. (Mulhern) at 945:11-946:10; RDX-2C.15-16 (a summary of deposition testimony regarding

[redacted]

Heraeus' competitors). And because this is a multi-party market, Complainants simply did not prove that but for Respondents' products, Heraeus would have made a sale. Moreover, as the Staff points out, other considerations go into a buyer's decision making, such as whether the bone cement supplier also can supply other articles, such as the implants, whether the seller offers volume discounts, and surgeon preferences. *See* SIB at 74 (citing Tr. (Mulhern) at 951-55).

While Heraeus argues that Palacos and the Accused Products are almost identical, and thus, all sales of the Accused Products would have gone to Heraeus' sales of Palacos, the record evidence does not support this because of the similarities between all competing bone cements. *See, e.g.*, Tr. (DiGioia) at 1038:25-1039:3, 1039:22-1040:9, and 1041:16-1043:3. Dr. DiGioia testified that he used Palacos, the Accused Products, Stryker's Simplex High Viscosity, and BBCR in surgery. *See id*. Dr. DiGioia further testified that Stryker products Simplex HV and BBCR were similar to Palacos, and that neither were identical in terms of usability or handling. *Id.* at 1021:14-20, 1041:12-1042:10. Dr. DiGioia also testified that in his experience, bone cements within a viscosity class are interchangeable with each other. *Id.* at 1042:11-1043:3. Thus, sales of Respondents' products would not necessarily have been sales of Palacos.

Complainants further contend the importation and sale of the Accused Products have eroded Palacos prices. Heraeus presents evidence that Respondents charged lower prices for its accused bone cement than what it charged for Palacos. *See* Tr. (Prowse) at 588:2-6. Complainants further present evidence that Respondents "undercut Palacos on price [of its own product]" in order to gain sales and still make profits. *See id*. at 583:25-583:4-24. Complaints present a number of instances when Respondents set the price of its product to be [redacted] below that of Palacos. *See, e.g.,* CX-0424C at 222 [redacted]

[redacted]

[redacted] JX-0245C (Armstrong Dep. Tr.) at 193:23-194:11; CDX-0003C.00066; Tr (Prowse) at 587:3-587:16. [redacted] JX-0102C; CX-0212C; CDX-0003C.00067; Tr. (Prowse) at 587:17-588:6, 677:24-678:15. Dr. Prowse's testimony regarding price erosion relied primarily on instances of Zimmer Biomet charging lower prices for the accused bone cement products than for Zimmer Biomet's Palacos products. *See* Tr. (Prowse) at 588:2-6 (discussing Zimmer Biomet's sales of the accused product at lower prices than Zimmer Biomet was selling Palacos). According to Dr. Prowse, the "natural effect" of this pricing strategy produced a downward pressure on the amounts that HMUS could charge for its Palacos products "because Heraeus's PALACOS has got to compete with the accused products." Tr. (Prowse) at 583:16-24. Thus, according to Complainants, the pricing strategy forced HUMUS to lower the price of Palacos. *See* CIB at 142.

As with lost sales, Complainants' price erosion fails to account for a competitive market involving multiple bone cement suppliers and non-accused bone cement products. Complainants do not take into consideration any of the other competitors in the bone cement industry, even though Dr. Prowse acknowledged that the target price set by hospitals is "usually put together based on their knowledge of market conditions, which would include what all the other companies are selling their products for." Tr. (Prowse) at 641:18-23; 655:11-17 (price pressure from Stryker could affect Heraeus's prices). In fact, Stryker's Simplex product dropped in price between 2017 and 2018. *See* Tr. (Prowse) at 643:23-647:11; RX-775, at 20; CX-668 at 1. Thus, the record evidence is insufficient to reach any meaningful conclusions about the causes behind any bone cement seller's pricing decisions and price fluctuations.

[redacted]

Moreover, Complainants' evidence all relates to the price of Palacos that Respondents charged, not the price that Heraeus charged for its own product. Dr. Mulhern, Respondents' expert, testified that a comparison of the accused bone cements to Palacos shows "no systematic undercutting" of HMUS's prices by Zimmer Biomet's accused products. Tr. (Mulhern) at 957:10-958:6; RDX-2C.19; *see also* Tr. (Prowse) at 657:6-18 (prices charged by HMUS for Palacos when compared with Zimmer Biomet's prices for the accused products were "fairly close" and "it's hard to get a conclusive determination"). Other evidence showed significant other sources of price pressure in the marketplace, including an industry trend towards cost containment, and price competition from third party competitors and non-accused products. *See* Tr. (Mulhern) at 943:2-947:6, 958:7-25, 985:10-13, 990:12-991:25; RX-703; RDX-2C.15; JX-0087C at ZBITC-0412951. And there is evidence of aggressive pricing by Stryker and others. *See* Tr. (Mulhern) at 947:7-22; JX-255C (Kolbe) at 81:8-13, 82:8-11, 82:17-20, 82:25-83:4 [redacted] Tr. (Childers) at 203:23-207:6; RX-234C (testifying about email from HMUS customer who identified Stryker, Smith & Nephew, and Dupuy—but not Zimmer Biomet—as having "more cost effective options for the antibiotic cement" than HMUS).

Therefore, Complainants failed to prove injury or threat of substantial injury to their domestic industry – be that the education, training, and research and development or sale of Palacos bone cement.

VIII. CONCLUSIONS OF LAW

1. The Commission has subject matter and personal jurisdiction over the Accused Products.

2. Respondents have sold for importation into the United States, imported or sold after importation accused products, and thus, the importation or sale requirement of Section 337 is satisfied.

[redacted]

3. A domestic industry exists with respect to Complainants' education, training, and research and development.

4. Complainants own the asserted Trade Secrets.

5. TS 1-35 are protectable trade secrets

6. TS 121-123 are not protectable trade secrets

7. TS 130-134 are not protectable trade secrets

8. TS 145 is not a protectable trade secret

9. Respondents misappropriated TS 1-35.

10. There is not and has not been a substantial injury or threat of injury to the Complainants' domestic industry by Respondents' misappropriation of TS 1-35.

11. There is no violation of Section 337 with respect to the Complainants' trade secrets.

IX. RECOMMENDED DETERMINATION ON REMEDY AND BOND

The Commission's Rules provide that subsequent to an initial determination on the question of violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, 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 respondent during Presidential review of the Commission action under section 337(j). *See* 19 C.F.R. § 210.42(a)(1)(ii).

The Commission has broad discretion in selecting the form, scope, and extent of the remedy in a section 337 proceeding. *Viscofan, S.A. v. Int'l Trade Comm'n*, 787 F.2d 544, 548 (Fed. Cir. 1986). Under Section 337(d)(1), if the Commission determines as a result of an investigation that there is a violation of section 337, the Commission is authorized to enter either a limited or a general exclusion order. 19 U.S.C. § 1337(d)(1). A limited exclusion order instructs

[redacted]

the U.S. Customs and Border Protection ("CBP") to exclude from entry all articles that are covered by the trade secrets at issue and that originate from a named respondent in the investigation. A general exclusion order instructs the CBP to exclude from entry all articles that are covered by the trade secrets at issue, without regard to source. *Certain Purple Protective Gloves*, Inv. No. 337-TA-500, Comm'n Op. at 5 (Dec. 22, 2004). Under section 337(f)(1), the Commission may issue a cease and desist order 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. August 20, 1997).

Additionally, during the 60-day period of Presidential review under 19 U.S.C. § 1337(j), "articles directed to be excluded from entry under subsection (d) . . . shall . . . be entitled to entry under bond prescribed by the Secretary in an amount determined by the Commission to be sufficient to protect the complainant from any injury." *See* 19 U.S.C. § 1337(j)(3). "The Commission typically sets the bond based on the price differential between the imported infringing product and the domestic industry article or based on a reasonable royalty. However, where the available pricing or royalty information is inadequate, the bond may be set at one hundred (100) percent of the entered value of the infringing product." *Certain Industrial Automation Systems and Components Thereof Including Control Systems, Controllers, Visualization Hardware, Motion and Motor Control Systems, Networking Equipment, Safety Devices, and Power Supplies*,

[redacted]

Inv. No. 337-TA-1074, Comm'n Op. at 13 (Apr. 23, 2019) ("Automation Systems") (public version) (citation omitted).

Although Section 337 also mandates consideration of the effect of exclusion on (1) 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 the articles subject to the investigation; and (4) U.S. consumers, the public interest inquiry was not delegated to me. *See* 84 Fed. Reg. 14394 (April 10, 2019); 19 U.S.C. § 1337(d)(1).

A. Limited Exclusion Order

Section 337 has not been violated. However, should a violation be found, the evidence supports a limited exclusion order as to those entities involved in the sale for importation, importation, and sale after importation of the accused products for which a violation is found. The evidence shows that Respondents' -1 products have not and will not be imported in significant amounts, and thus these products are not part of the order.

"The duration of an [exclusion] order in a trade secret misappropriation case is set as the time it would have taken to independently develop the trade secrets." *Certain Rubber Resins*, Comm'n Op., 2014 WL7497801, at *43; *see also Certain Sausage Casings*, Comm'n Op, 1984 WL 273970, at *11 ("The facts of this investigation, particularly the fact that the misappropriation involved an actual theft of trade secrets, support the conclusion that Viscofan should not be credited with the time between the misappropriation and the entry of the Commission's remedial order."). The copolymer trade secrets, TS 1-35, are protectable, and Dr. Spiegelberg testified that the typical time frame for a bone cement development project is two to three years. *See* Tr. (Spiegelberg) at 1295:11-16. Heraeus's witness, Dr. Kühn, likewise testified that developing a bone cement (apart from regulatory timing) would take "one to two to three years." *See* JX-247C

[redacted]

(Kühn Dep. Tr.), at 260:15-24, 261:2-14. Dr. Kühn also testified that it would take longer to develop a new bone cement that has the same characteristics as Palacos. *See* JX-247C (Kühn Dep. Tr.) at 262:1-14. [redacted] Complainants argue that any limited exclusion order should be "perpetual" because Zimmer Biomet failed to develop a successful bone cement. In view of the evidence, however, a limited exclusion order of 5 years is reasonable.

With respect to the other categories of asserted trade secrets, a limited exclusion order with a duration of approximately 2 years or less is reasonable. *See* Trial Tr. (Giffard) at 1281:13-20 (a second round of testing zirconium dioxide would require "anywhere from several months to two years").

B. Cease and Desist Order

If a violation of Section 337 is found, a cease and desist order is appropriate because Respondents maintain a significant inventory of the -3 products in domestic inventory. Tr. (Prowse) at 588:19-589:9; CDX-3C.00068 (indicating [redacted] units of the -3 formulation of BBCR and [redacted] units of the -3 formulation of RBCR in domestic inventory as of August 2019, with an approximate value of [redacted] and [redacted] respectively); CX-643C at 38-40 and Appendix 2 attached thereto). Respondents do not dispute that they hold significant domestic inventory. *See* Resp. PHB at 187. Therefore, a cease and desist is appropriate in the event of a violation.

C. Bond

If the Commission determines to enter an exclusion order and/or a cease and desist order in this investigation, the affected articles are entitled to entry or sale under bond during the 60-day

[redacted]

Presidential review period. Complainants' expert testified that a bond of 100% is reasonable because "a price comparison is not feasible" (Tr. (Prowse) at 539:24-540:2) and because "a hundred percent bond rate from an economic perspective would be appropriate" given Heraeus' and Zimmer Biomet's status as direct competitors (*id.* at 540:4-8, 589:10-19). But Complainants did not provide a price differential analysis, and Complainants' argument that a 100 percent bond is appropriate simply because Heraeus and Zimmer are competitors is not consistent with Commission precedent. *See, e.g., Certain Graphics Systems, Components Thereof, and Consumer Products Containing the Same*, Inv. No. 337-TA-1044, Comm'n Op., 2018 WL 8648378, at *43 (Sept. 18, 2018) (setting zero percent bond where complainant "failed to show why a bond based on price differential or royalty rate would be inadequate to protect Complainants from any injury, particularly in view of Complainants' contention that Respondents' accused products compete directly with Complainants' and their licensees' products"). Moreover, while the parties are competitors, they are not alone in this market.

On the other hand, Respondents' expert, Dr. Mulhern, provided evidence regarding royalty rates in the medical field or involving health care products generally showing a range between 2.5 and 7 percent, and license agreements relating to bone cement technology with a range of 2.5 to 10 percent. *See* Tr. (Mulhern) at 966:9-967:15; RX-836.

Accordingly, to the extent a violation is found, the evidence supports a bond near the middle of these ranges, or 5% of entered value.

D. Public Interest

None of the parties address the statutory public interest factors, and there is no evidence that the requested relief would meaningfully impact public health and welfare, competitive conditions, domestic production of articles, or U.S. consumers. Accordingly, it is my

[redacted]

recommended determination that issuance of a remedial order in this investigation would not be contrary to the public interest.

X. INITIAL DETERMINATION AND ORDER

Based on the foregoing, it is my Initial Determination that there is no violation of Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, in the importation into the United States, the sale for importation, or the sale within the United States after importation of bone cements, and products containing the same, in connection with the Complainants' trade secrets. Furthermore, it is my determination that a domestic industry in the United States does not exist that practices or exploits the trade secrets.

I certify to the Commission this Initial Determination, together with the Record of the hearing in this Investigation consisting of the following: the transcript of the evidentiary hearing, with appropriate corrections as may hereafter be ordered; and the exhibits accepted into evidence in this Investigation, as listed by the parties, attached herein as Appendix A with appropriate corrections as may hereafter be ordered. The pleadings of the parties filed with the Secretary need not be certified as they are already in the Commission's possession in accordance with Commission rules.

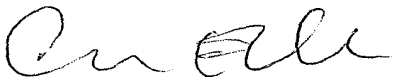
Pursuant to 19 C.F.R. § 210.42(h), this Initial Determination shall become the determination of the Commission unless a party files a petition for review pursuant to 19 C.F.R. § 210.43(a) or the Commission, pursuant to 19 C.F.R. § 210.44, orders on its own motion a review of the Initial Determination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

This Initial Determination is being issued as confidential, and a public version will be issued pursuant to Commission Rule 210.5(f). Within seven (7) days of the date of this Initial

[redacted]

Determination, the parties shall jointly submit: (1) a proposed public version of this opinion with any proposed redactions bracketed in red; and (2) a written justification for any proposed redactions specifically explaining why the piece of information sought to be redacted is confidential and why disclosure of the information would be likely to cause substantial harm or likely to have the effect of impairing the Commission's ability to obtain such information as is necessary to perform its statutory functions.

SO ORDERED.



Cameron Elliot
Administrative Law Judge

CERTAIN BONE CEMENT, COMPONENTS THEREOF AND PRODUCTS CONTAINING THE SAME **Inv. No. 337-TA-1153**

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **INITIAL DETERMINATION** has been served via EDIS upon the Commission Investigative Attorney, **Monica Bhattacharyya, Esq.**, and the following parties as indicated, on 5/19/2020.

Lisa R. Barton, Secretary
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