

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

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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.

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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).

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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.*

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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).

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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.

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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).

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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

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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,

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

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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

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 Schmidlein’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 Schmidlein’s related views) (“*Botulinum Toxin Prods.*”). Accordingly, for investigations brought under subparagraph (a)(1)(A), Commissioner Schmidlein 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 Schmidlein 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.

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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.

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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 Secrets¹¹

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 Schmidlein 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.").

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Zimmer Biomet argues that they have. *See, e.g.*, CPet.¹² at 54 n.19; RReply¹³ 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”).

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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.

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(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 [

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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.

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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.

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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

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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)).

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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

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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

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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

¹⁹ As explained above, in Commissioner Schmidlein'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 Schmidlein 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*,

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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 Schmidlein 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

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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 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)).

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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).

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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

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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.

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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.

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.

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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.

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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.

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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 advertising 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 Schmidlein does not join this paragraph. Commissioner Schmidlein 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.*

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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 Schmidlein 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 Schmidlein 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 Schmidlein 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).

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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:

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[

]

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.

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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.*

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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

³³ Commissioner Schmidlein 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*.

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“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

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**.



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