

In the Matter of

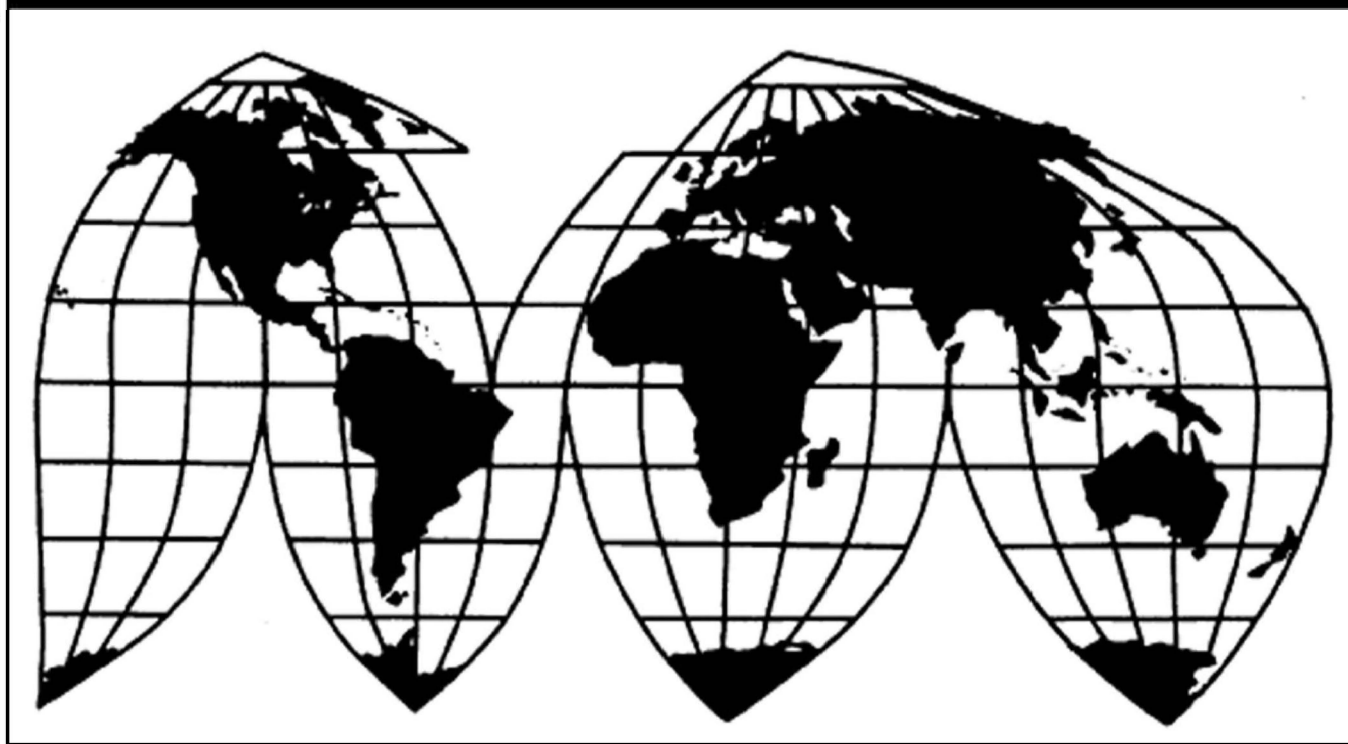
**CERTAIN BONE CEMENTS AND BONE
CEMENT ACCESSORIES**

Investigation No. 337-TA-1175

Publication 5309

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. Schmittlein, 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
www.usitc.gov

In the Matter of

CERTAIN BONE CEMENTS AND BONE CEMENT ACCESSORIES

Investigation No. 337-TA-1175



UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of

**CERTAIN BONE CEMENTS AND BONE
CEMENT ACCESSORIES**

Investigation No. 337-TA-1175

**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 a final initial determination (“FID”) issued by the presiding administrative law judge (“ALJ”) finding that no violation of section 337 has occurred. The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Lynde Herzbach, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-3228. 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, telephone (202) 205-1810.

SUPPLEMENTARY INFORMATION: On September 23, 2019, the Commission instituted this investigation based on a complaint filed on behalf of Zimmer, Inc. and Zimmer US, Inc. both of Warsaw, Indiana (collectively, “Complainants”). 84 FR 49764 (Sept. 23, 2019). The complaint alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 (“section 337”), based on the importation or the sale within the United States of certain bone cements and bone cement accessories by reason of the misappropriation of trade secrets, false advertising, and tortious interference, the threat or effect of which is to destroy or substantially injure an industry in the United States. The complaint also alleges the existence of a domestic industry. The Commission’s notice of investigation names the following as respondents: Heraeus Medical GmbH of Wehrheim, Germany and Heraeus Medical LLC of

Yardley, Pennsylvania (collectively, “Respondents”). *Id.* The Office of Unfair Import Investigations (“OUII”) is named as a party in this investigation. *Id.*

On February 11, 2021, the ALJ issued the FID finding no violation of section 337. More particularly, the FID finds, *inter alia*, that: (1) the Commission has subject matter and personal jurisdiction; (2) Respondents imported or sold within the United States accused bone cements and bone cement accessories; (3) a domestic industry exists under section 337(a)(1)(A)(i) (19 U.S.C. 1337(a)(1)(A)(i)); (4) Complainants own the asserted trade secrets; (5) trade secrets (“TS”) 10, 15, and 28 are protectable, but TS 11 is not protectable; (6) Respondents did not misappropriate any asserted TS; (7) Respondents did not engage in false advertising; (8) Respondents did not tortiously interfere with Complainants’ contracts or prospective business relationships; and (9) Complainants failed to show a substantial injury or threat of injury to their domestic industry.

On February 23, 2021, Complainants filed a petition for review seeking review of most of the FID’s findings. On March 3, 2021, Respondents and OUII filed responses to Complainants’ petition.

On March 15, 2021, Respondents filed a submission on the public interest pursuant to Commission Rule 210.50(a)(4) (19 CFR 210.50(a)(4)). Complainants and OUII did not file a statement on the public interest. The Commission received no submissions in response to its Federal Register notice calling for public interest comments. *See* 86 FR 12029-30 (Mar. 1, 2021).

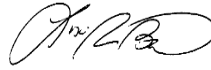
On April 12, 2021, the Commission determined to review the FID in part and requested briefing from the parties on certain issues under review. 86 FR 20200-02 (Apr. 16, 2021). Specifically, the Commission determined to review the FID’s findings and conclusions as to: (1) the alleged misappropriation of TS 10, 15, and 28, including the finding that Respondents independently developed their own data compilation; (2) Respondents’ alleged tortious interference with Complainants’ prospective business advantages; and (3) domestic industry and injury. *Id.* 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 FID, Complainants’ petition 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 affirms, with modified reasoning, the FID’s findings that Respondents did not misappropriate any trade secret, did not engage in false advertising, and did not tortiously interfere with Complainants’ prospective business relationships. The Commission has also determined to take no position regarding the FID’s domestic industry and injury findings. The investigation is hereby terminated.

The Commission vote for this determination took place on June 23, 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.

A handwritten signature in black ink, appearing to read 'LRB', enclosed within a large, loopy oval shape.

Lisa R. Barton
Secretary to the Commission

Issued: June 23, 2021

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **NOTICE** has been served via EDIS upon the Commission Investigative Attorney, **Megan Wantland, Esq.**, and the following parties as indicated, on **June 23, 2021**.



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

On Behalf of Complainants Zimmer, Inc., and Zimmer US, Inc.:

Eric S. Namrow, Esq.
MORGAN, LEWIS & BOCKIUS LLP
1111 Pennsylvania Avenue, NW
Washington, DC 20004
Email: eric.namrow@morganlewis.com

- ☐ Via Hand Delivery
- ☐ Via Express Delivery
- ☐ Via First Class Mail
- ☒ Other: Email Notification
of Availability for Download

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

David A. Caine, Esq.
ARNOLD & PORTER KAYE SCHOLER LLP
3000 El Camino Real, Suite 500
Palo Alto, CA 94306
Email: david.caine@arnoldporter.com

- ☐ Via Hand Delivery
- ☐ Via Express Delivery
- ☐ Via First Class Mail
- ☒ Other: Email Notification
of Availability for Download

PUBLIC VERSION

**UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.**

**In the Matter of
CERTAIN BONE CEMENTS AND
BONE CEMENT ACCESSORIES**

Investigation No. 337-TA-1175

COMMISSION OPINION

The Commission has determined to affirm, with modifications, the presiding administrative law judge's ("ALJ") final initial determination ("FID") 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, false advertising, or tortious interference. The Commission takes no position on the FID's domestic industry and injury findings. This opinion sets forth the Commission's reasoning in support of its determination.

I. BACKGROUND

A. Procedural History

On September 17, 2019, the Commission instituted this investigation based on a complaint filed by Zimmer, Inc. and Zimmer US both of Warsaw, Indiana (collectively, "Zimmer Biomet" or "Complainants"). 84 Fed. Reg. 49764 (Sept. 23, 2019). The complaint accuses the respondents of violating section 337(a)(1)(A)(i) by the importation or sale in the United States of certain bone cements and bone cement accessories by reason of the misappropriation of trade secrets, false advertising, or tortious interference, 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. FID at 1; 19 U.S.C. § 1337(a)(1)(A)(i). The named respondents are Heraeus Medical GmbH of Wehrheim, Germany ("Heraeus Germany") and

PUBLIC VERSION

Heraeus Medical LLC of Yardley, Pennsylvania (“HMUS”) (collectively, “Respondents”).

84 Fed. Reg. 49764. The Office of Unfair Import Investigations (“OUII”) is also named as a party. *Id.*

The ALJ held an evidentiary hearing from October 26-30, 2020. FID at 5.

On February 11, 2021, the presiding ALJ issued the FID finding that Respondents did not violate section 337. The FID finds that the Commission has subject matter, personal, and *in rem* jurisdiction. *Id.* at 22. Specifically, the FID finds that Respondents did not contest that the accused products were imported into the United States. *Id.* at 21. The FID further finds that a domestic industry (“DI”) exists. *Id.* at 95-98. The FID also finds that Zimmer failed to prove substantial injury or threat thereof to an industry in the United States. *Id.* at 98-104.

As to the trade secret misappropriation claim, Complainants asserted various categories of commercial trade secrets, which they presented as TS 10, 11, 15, and 28 at the evidentiary hearing. The FID finds that TS 10, 15, and 28 are trade secrets, but that TS 11 is not a trade secret. *Id.* at 23-43. The FID further finds that Respondents did not misappropriate any trade secret, did not engage in false advertising, and did not tortiously interfere with Complainants’ contracts or prospective business relationships. *Id.* at 43-88.

On February 23, 2021, Complainants petitioned for review of the majority of the FID’s findings.¹ Complainants did not petition for review of the FID’s findings on importation,

¹ Complainants’ Petition for Review of the Initial Determination (Feb. 23, 2021) (“Comp. Pet.”).

PUBLIC VERSION

jurisdiction, and whether TS 11 is a trade secret. On March 3, 2021, Respondents and OUII filed responses to Complainants' Petition.²

On March 15, 2021, Respondents filed a submission on the public interest pursuant to Commission Rule 210.50(a)(4) (19 C.F.R. § 210.50(a)(4)).³ Complainants and OUII did not file a submission on the public interest. The Commission received no filings in response to its Federal Register notice calling for public interest comments. *See* 86 Fed. Reg. 12029-30 (Mar. 1, 2021).

On April 12, 2021, the Commission determined to review the FID in part. 86 Fed. Reg. 20200-2 (Apr. 16, 2021). Specifically, the Commission determined to review the FID's findings and conclusions as to:

- (1) the alleged misappropriation of the asserted trade secrets, including the finding that Respondents independently developed their own data compilation;
- (2) Respondents' alleged tortious interference with Complainants' prospective business advantages; and
- (3) domestic industry and injury.

Id. The Commission determined not to review the remaining findings in the FID, including the FID's findings of no false advertisement. *See* FID at 58-81. The Commission requested briefing regarding several issues, as follows:

- (A) When evaluating the misappropriation of a trade secret, identify and discuss the proper legal standard for wrongful disclosure or use of a trade secret that is a compilation. Please consider whether any particular amount of disclosure or use is required to support a finding of misappropriation, *i.e.*, de minimis, substantial, or the entirety of the trade secret compilation. Discuss whether there are any differences in the application of the

² Respondents' Response to Complainants' Petition for Review of the Initial Determination (March 3, 2021) ("Resp. Reply"); Office of Unfair Import Investigations' Response to Complainants' Petition for Review of the Initial Determination (March 3, 2021) ("OUII Reply").

³ Respondents' Statement on the Public Interest (March 15, 2021).

PUBLIC VERSION

legal standard for disclosure or use if a trade secret compilation includes publicly available information.

(B) Given the legal standard identified in response to (A), please analyze the alleged disclosure and use of TS 10, 15, and 28.

(C) Please discuss and provide a timeline detailing the background and development of Heraeus Medical LLC from 2017 through 2018, including the dates that relevant employees were hired, the relevant employees' positions, the dates of alleged disclosures and/or use of TS 10, 15, and 28, and the dates and relevant facts regarding Respondents' interactions with third parties.

(D) What criteria should the Commission apply to determine whether activities related to meeting FDA requirements constitute activities of a "mere importer"? For example, should one criterion be that the activities are required to be performed in the United States or that the activities differ from those that a wholly domestic company would perform? Please apply the appropriate criteria to the facts of this investigation. Are any of Complainants' FDA-related activities different from what a wholly domestic company would need to undertake? Which, if any, of a Complainants' FDA activities could be conducted abroad?

86 Fed. Reg. at 20201.

On April 30, 2021, the parties filed their opening written submissions on the issues under review and on remedy, public interest, and bonding.⁴ The parties filed replies on May 7, 2021.⁵

B. The Parties

Complainants Zimmer, Inc. and Zimmer U.S., Inc. are related companies and subsidiaries of parent company Zimmer Biomet Holdings, Inc. FID at 7. Zimmer Biomet Holdings, Inc. was created in 2015 as a result of a merger between Zimmer Holdings, Inc. and Biomet, Inc. *Id.*

⁴ Complainants' Brief to the Commission on Issues Under Review, Remedy, and Bonding (Apr. 30, 2021) ("CBr."); Respondents' Opening Brief on Commission's Notice to Review-in-Part the Final Initial Determination (Apr. 30, 2021) ("RBr."); Opening Submission of the Office of Unfair Import Investigations in Response to the Commission's April 12, 2021 Notice (Apr. 30, 2021) ("OUIIBr.>").

⁵ Complainants' Reply Brief to the Commission on Issues Under Review, Remedy, and Bonding (May 7, 2021) ("CBr. Reply"); Respondents' Response to Complainants' and Staff's Briefs on the Commission's Notice to Review-in-Part the Final Initial Determination (May 7, 2021) ("RBr. Reply"); Reply Submission of the Office of Unfair Import Investigations Pursuant to the Commission's April 12, 2021 Notice (May 7, 2021) ("OUIIBr. Reply").

PUBLIC VERSION

Biomet, Inc. was the distributor of Respondents' PALACOS products in the United States from 1996 to 2006, and Zimmer Surgical, Inc. was contracted to distribute the PALACOS products in the United States from 2005 through 2018. *Id.* Complainants are currently responsible for the marketing, distribution, and sales of Zimmer Biomet's bone cements and bone cement mixing and delivery accessories sold in the United States. *Id.* Complainants also manufacture some accessory products, such as Allen Plugs, mixing bowls, mixing systems, centralizers, poly plugs, restrictor plugs, medullary plugs, bone prep kits, curettes, spacer molds, and cement restrictors, in facilities in Warsaw, Indiana and Dover, Ohio. *Id.* at 91-92.

Respondent Heraeus Germany is the successor-in-interest to Heraeus Kulzer GmbH and Kulzer & Co. GmbH, which originally developed Heraeus's bone cements. Heraeus Germany is now responsible for designing, developing, and manufacturing certain PALACOS bone cements and accessory products. *Id.* at 8. HMUS is Heraeus Germany's U.S. affiliate and, since the beginning of 2018, has been responsible for promoting and distributing the PALACOS products in the United States. *Id.* HMUS imports and sells the accused PALACOS bone cements and accessory products in the United States. *Id.*

C. The Asserted Trade Secrets

The three relevant trade secrets are:

Asserted Trade Secret 10 ("TS 10") – Quarterly reports constituting a list of customers, by territory, who purchased Heraeus cements from Zimmer Biomet in that quarter, the full names and delivery addresses of those customers, the types and quantities of the Heraeus cements delivered to those customers, and the prices charged to those customers for the Heraeus cements delivered, as supplied by

PUBLIC VERSION

Zimmer Biomet to Heraeus between October 1, 2015, and December 31, 2018, pursuant to, and during the term of, the 2012 Agreement[.]⁶ [(citations omitted)].

Asserted Trade Secret 15 (“TS 15”) – Customer lists related to the sale of PALACOS or bone cement accessory products constituting a compilation of Zimmer Biomet’s bone cement customer identification information (*see* Columns F, G, or H), customer contact information (*see* Columns I, J, K), and one or more of the following: territory names (*see* Columns C, R), product identification information (*see* Columns P, Q, or Z), product quantity (*see* Column S), actual sales price (*see* Column T), average sales price (calculated from actual sales price and quantity sold), and revenue (*see* Column U). [(citations omitted)].

Asserted Trade Secret 28 (“TS 28”) – The compilation of invoice-level sales data, sourced from Zimmer Biomet’s sales of PALACOS between October 1, 2015[,], and January 1, 2018, that is maintained on, and accessible through, Zimmer Biomet’s PROS system, and exported as [REDACTED] (citations omitted)].

FID at 8-9; JX-309C at 1-2.⁷ The FID notes that TS 15 and 28 include information regarding the Mid-Atlantic region of the United States. *Id.* at 46.

In their prehearing and post-hearing briefs, Complainants combined TS 15 and TS 28 into a single asserted trade secret “compris[ing] customer lists related to the sale of PALACOS or bone cement accessory products, including the Excel file named ‘For Peterson.’” *Id.* at 9. Complainants’ analysis and arguments also discussed TS 15 and TS 28 as though they were a single trade secret. The FID and this opinion, therefore, treat TS 15 and TS 28 as a single asserted trade secret (“TS 15/28”). *Id.*

⁶ The U.S. Distribution and Supply Agreement dated January 1, 2012 (“2012 Agreement”) (*see* JX-204C, Section 2.4(c)), obligated Zimmer to [REDACTED] FID at 23. Under the 2012 Agreement, Zimmer also had to [REDACTED] *Id.*

⁷ As noted above, the FID finds that TS 11 is not a protectable trade secret, and Complainants did not seek review of that finding. FID at 39.

PUBLIC VERSION

D. The Products at Issue

The products at issue are bone cements and bone cement accessory products. Bone cements are used in hip and knee joint surgeries to help anchor the implanted joint prosthesis to the patient's bone. Complaint at ¶ 19. The technical characteristics of bone cements are not at issue in this investigation.

1. Accused Products

Complainants accused the following Heraeus products: PALACOS R, PALACOS R+G, PALACOS FAST R+G, PALACOS LV, PALACOS LV+G, PALACOS MV, PALACOS MV+G, PALACOS R pro 75, PALACOS R+G pro 75, PALACOS Pro nozzle short, PALACOS Pro nozzle medium, PALAMIX uno, PALAMIX duo, PALABOWL, PALAMIX nozzle slim, PALAMIX nozzle medium, PALAMIX nozzle medium, PALAMIX cement gun, PALAMIX vacuum pump, PALAMIX vac hose, and the COPAL exchange G. FID at 10.

2. Zimmer Biomet's Domestic Products

Complainants relied on the following products to satisfy the domestic industry requirement: Biomet Bone Cement R ("BBCR") and Refobacin Bone Cement R ("RBCR") (collectively, "ZB cements"), and a number of accessory products, including plugs, mixing equipment, prep kits, centralizers, and spacer molds. *Id.* As stated above, Zimmer Biomet manufactures some accessory products, such as Allen Plugs, mixing bowls, mixing systems, centralizers, poly plugs, restrictor plugs, medullary plugs, bone prep kits, curettes, spacer molds, and cement restrictors, in the United States. *Id.* at 91-92

II. COMMISSION REVIEW OF THE FINAL ID

When the Commission reviews an initial determination, in whole or in part, it reviews the determination *de novo*. *Certain Soft-Edged Trampolines and Components Thereof*, Inv. No. 337-TA-908, Comm'n Op. at 4 (May 1, 2015). With respect to the issues under review, "the

PUBLIC VERSION

Commission may affirm, reverse, modify, set aside or remand for further proceedings, in whole or in part, the initial determination.” 19 C.F.R. § 210.45(c). The Commission also “may take no position on specific issues or portions of the initial determination,” and “may make any finding or conclusions that in its judgment are proper based on the record in the proceeding.” *Id.*; *see also Beloit Corp. v. Valmet Oy*, 742 F.2d 1421, 1423 (Fed. Cir. 1984).

III. ANALYSIS

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

A. Trade Secret Misappropriation Issues Under Review

The FID finds that TS 10 and TS 15/28 are trade secrets. FID at 23-43. The FID further finds that there was no misappropriation of any of the asserted trade secrets. *Id.* at 54. The Commission determined to review the FID’s trade secret misappropriation findings. 86 Fed. Reg. at 20201. On review, the Commission affirms the FID’s findings that Respondents did not misappropriate TS 10 or TS 15/28, but with the modified analysis below.

1. The FID’s Trade Secret Misappropriation Findings

The FID finds that TS 10 and TS 15/28 are trade secrets. FID at 23-43. The FID further finds that there was no misappropriation. *Id.* at 54.

a. FID’s Findings Regarding TS 10

For TS 10, the FID finds that Complainants shared the Quarterly Reports with Heraeus Germany under Sections 2.4(c) and 3.1 of the 2012 Agreement, which required Complainants to provide Quarterly Reports and forecasts to Heraeus Germany. *Id.* at 45; JX-204C. The FID further finds that Heraeus Germany was required to [REDACTED]

[REDACTED] *Id.*

PUBLIC VERSION

The FID finds that Respondents did not wrongfully disclose TS 10 to third parties. *Id.* at 47. The FID first notes that, because TS 10 is a compilation, “it is the secrecy of the claimed trade secret *as a whole* that is determinative.” *Id.* (quoting Restatement (Third) of Unfair Competition § 39, cmt. f (1995) (emphasis in FID)). The FID finds that “since Complainants relied on a specific ‘comprehensive compilation of customer-specific prices’ to establish the existence of a protectable trade secret, ‘evidence showing anything less than the use of the comprehensive compilation’ is not sufficient for Zimmer Biomet to carry its burden of proving misappropriation.” *Id.* at 47-48 (quoting OUII Post-Hearing Br.⁸ at 37 n.31). The FID further finds that Complainants failed “to present evidence that the entire compilation (or even a majority of information within the compilation) that makes up TS 10 was ever disclosed to any party” and concludes that Respondents did not misappropriate TS 10. *Id.* at 48. In addition, the FID also analyzes why Complainants’ specific allegations fail to show misappropriation of TS 10. *Id.* at 48-52.

b. FID’s Findings Regarding TS 15/28

The FID finds that TS 15/28 was exported when James “Worth” Burns, who was Complainants’ Director of Enterprise Solutions for the Southeastern United States, left Zimmer on December 15, 2017, to become HMUS’s Regional Sales Director of the Mid-Atlantic. *Id.* at 45-46. Mr. Burns exported TS 15/28 and saved the file, named “For Peterson,”⁹ on a USB drive that he took with him when he left Zimmer. *Id.* The FID finds that Mr. Burns violated his employment agreement with Complainants when he took the file. *Id.*

⁸ Commission Investigative Staff’s Initial Post-Trial Brief (Nov. 13, 2020) (“OUII Post-Hearing Br.”).

⁹ A “Mr. Peterson” worked for Zimmer and was responsible for Zimmer’s Mid-Atlantic region. JX-328C (Burns) at 208:7-209:25.

PUBLIC VERSION

The FID, however, rejects Complainants’ allegations that Mr. Burns used the “For Peterson” file to perform his duties for Respondents and that Respondents are “liable for Mr. Burns’ action because he was acting within the scope of his employment.” *Id.* at 46. The FID notes that Complainants did not present any evidence showing that Respondents hired Mr. Burns in order to obtain TS 15/28. *Id.* Rather, the FID finds that the evidence shows Respondents had no knowledge of the “For Peterson” file. *Id.* For example, the FID finds that, although Mr. Burns sought employment with Respondents and had been responsible for PALACOS sales in the southeastern part of the United States while employed by Complainants, Respondents did not become aware of Mr. Burns’ actions regarding the “For Peterson” file until later litigation in Indiana. *Id.* at 46-47.

Accordingly, the FID finds that Complainants’ forensic evidence fails to prove misuse of TS 15/28 by HMUS. *Id.* at 53-54.

c. FID’s Findings Regarding Heraeus’ Independent Development Affirmative Defense

Heraeus asserts as a defense to trade secret misappropriation that they independently developed their customer lists and pricing. *Id.* at 56. The FID agrees and credits the testimony of Heraeus’s witnesses who testified that HMUS spent independent time and effort developing a customer targeting database primarily from the Centers for Medicare & Medicaid Services (“CMS”) data and that HMUS was able to independently develop a targeting database after approximately two weeks of work using less than \$7,000. *Id.* The FID dismisses Complainants’ arguments that the testimony was incredible speculation. *Id.*

2. Complainants’ Petition, Respondents’ Response, and OUII’s Response

a. Complainants’ Petition

Complainants asserted that the FID correctly concludes that TS 10 and 15/28 are

PUBLIC VERSION

protectable trade secrets but errs in finding no misappropriation. Comp. Pet. at 5. Specifically, Complainants asserted that the FID makes two material errors: (i) legal error in applying an incorrect legal standard for misappropriation; and (ii) fact errors, including the FID’s finding that “evidence showing anything less than the use of the ‘comprehensive compilation’ is not sufficient for [Complainants] to carry [their] burden of proving misappropriation” and the finding that Complainants failed to meet the incorrect legal standard. *Id.* at 5-6.

Regarding the legal standard, Complainants argued that the FID allegedly uses a “heightened standard for ‘use’ that departs from the uniform federal standard for misappropriation.” *Id.* at 6. They asserted that there should be a low bar for improper use of a trade secret. *Id.* at 6-7.¹⁰ Complainants further argued that the “[a]cquisition or disclosure of a trade secret alone (without use) can constitute misappropriation.” *Id.* at 7.

Regarding the FID’s alleged factual errors, Complainants argued that the FID should not have considered the compilation nature of the trade secrets and errs in relying on the lack of disclosure of the entire compilation that makes up TS 10. *Id.* at 9 (citing FID at 48). Complainants further argued that the FID also errs in finding that none of Respondents’ uses rose to the level of “use of the entire compilation,” even though the users possessed and manipulated the entire compilation. *Id.* at 10.

Complainants argued there is no dispute that Mr. Burns misappropriated TS 15/28 by improper acquisition, but the FID erroneously finds that Mr. Burns’ misappropriation should not be attributed to HMUS and that there was insufficient evidence of misuse. *Id.* at 26-28 (citing

¹⁰ Complainants cite the following for support: Restatement (Third) of Unfair Competition § 40, cmt. c; 4 Milgrim on Trade Secrets § 15.01(d) (“a trade secret can be unlawfully used in whole or in part or in some variation of the original to benefit the defendant in direct or indirect ways”); and *Crawler Cranes*, Comm’n Op. at 64.

PUBLIC VERSION

FID at 45-46). Complainants also argued that the FID errs in finding there was insufficient evidence that HMUS misappropriated TS 15/28. *Id.* at 28-29; FID at 6.

b. Respondents' Response to Complainants' Petition

Respondents argued that the FID correctly concludes that Complainants did not prove misappropriation. Resp. Reply at 5-32. Respondents asserted that Complainants advocated for a double standard – relying on the compilation of TS 10 to prove it is a trade secret and then arguing there is misappropriation for an “insubstantial portion” of the full compilation. *Id.* at 5-7. Respondents contend that the FID rightly concludes that, “because Zimmer fail[ed] to present evidence that the entire compilation (or even a majority of information within the compilation) that makes up TS 10 was ever disclosed to any party, Zimmer has not shown that TS 10 was misappropriated.” *Id.* (citing FID at 48).

Respondents argued that Complainants are wrong that disclosure of an insubstantial portion of an asserted trade secret constitutes misappropriation. *Id.* Respondents further argued that the FID's findings are supported by the evidence and that the FID uses the correct legal standard. *Id.*

Regarding TS 15/28, Respondents argued that Complainants ignore the large number of findings that support the FID's conclusion that HMUS did not misappropriate TS 15/28. *Id.* at 25 (citing FID at 46-47). Respondents argued that there is no evidence that Mr. Burns used any information in the “For Peterson” file during his employment at HMUS. *Id.* Respondents further argued that the FID correctly finds that there is no evidence any information was transferred to any HMUS file or that the “For Peterson” file was saved onto HMUS's computer

PUBLIC VERSION

systems. *Id.* at 26 (citing FID at 54; Tr. (Vaughn¹¹) at 408:10-15, 409:21-24). Respondents concluded that the FID properly finds that Complainants failed to prove misappropriation of TS 15/28. *Id.* at 27.

c. OUII's Response to Complainants' Petition

OUII argued that the FID applies the correct legal standard and the FID's findings of fact are supported by the record evidence. OUII Reply at 4-14. Regarding the legal standard, OUII noted that Complainants previously acknowledged that determining "improper use of a trade secret is a flexible inquiry." *Id.* at 6 (citing CIB¹² at 50). OUII also noted Complainants' repeated argument that asserted TS 10 should be evaluated "as a whole" when considering whether it meets the requisite value and secrecy requirements for protectability. *Id.* at 7. "Here, Complainants argued and the ALJ agreed that the fact that it is a comprehensive compilation of customer-specific sales data is what sets asserted TS 10 apart from smaller portions of information that are readily available from public sources." *Id.* at 8. Accordingly, OUII concluded that the FID correctly analyzes whether there was disclosure or use of the entire compilation of TS 10 and not just a portion, which might have been readily known or readily ascertainable on its own. *Id.*

OUII argued that Complainants confuse a wrongful taking, which is an element of trade secret misappropriation, with an ultimate finding of trade secret misappropriation. *Id.* at 11-12. OUII further argued that the FID correctly refuses to impute Mr. Burns' wrongful taking of the "For Peterson" file to Respondents. *Id.* at 12. Finally, OUII argued that Complainants cannot

¹¹ James D. Vaughn is Zimmer Biomet's expert witness on computer forensic examination and forensic industry evidence preservation best practices. Comp. Pet. at xi.

¹² Complainants' Post-Hearing Brief (Nov. 13, 2020) ("CIB").

PUBLIC VERSION

establish that Heraeus misappropriated TS 15/28 because there is simply no credible evidence that anyone at Heraeus, including Mr. Burns, actually used the “For Peterson” file. *Id.* OUII concluded that the FID correctly finds that the weight of the evidence indicates Heraeus did not take or use TS 15/28.

3. Legal Standard for Misappropriation

The parties mostly agree on the standard for trade secret misappropriation, in particular in the context of this investigation, which concerns compilation trade secrets that include public information in part. Comp. Pet. at 10; Resp. Reply at 5-11; OUII Reply at 6-8. The parties, however, disagree on the amount of disclosure or use required to find misappropriation. *Id.*

Respondents frame the issue in terms of the amount of use or disclosure that is sufficient to show misappropriation by arguing that at least a “substantial” portion of the asserted trade secrets must be used or disclosed to prove misappropriation of the trade secret. RBr. at 6-11. OUII, on the other hand, frames the issue of misappropriation as turning upon what information is found to qualify as a trade secret. In OUII’s view, the question is not what *portion of a* compilation trade secret must be disclosed to constitute misappropriation; rather, the question is if complainant establishes a trade secret based on the entirety of information comprising a compilation, whether it can then establish misappropriation by showing anything less than disclosure of the compilation (which is the entirety of the information comprising the compilation). OUII Br. at 7-8. In the context of the present investigation, OUII points out that Complainants repeatedly argued that TS 10 should be evaluated “as a whole” when considering whether it meets the requisite value and secrecy requirements for protectability as a trade secret (which is not surprising given that portions of the information comprising TS 10 are ascertainable from a variety of sources). In OUII’s view, because Complainants succeeded in arguing that the characteristics of TS 10 (*i.e.*, that it is a comprehensive compilation) shield the

PUBLIC VERSION

asserted trade secret from being publicly known or readily ascertainable, “demonstrating ‘substantial’ use of the trade secret should involve demonstrating that most, if not all, of the compilation trade secret was used.” *Id.* For the reasons stated below, the Commission finds that Complainants must show that Respondents’ use or disclosure of TS 10 and TS 15/28 was substantial to establish a violation of section 337 based on trade secret misappropriation.

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., 2014 WL 7497801, at *4 (Feb. 26, 2014) (“*Rubber Resins*”). The elements of misappropriation of trade secrets are as follows:

- (1) a protectable trade secret exists (*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) the complainant is the owner of the trade secret;
- (3) 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) the respondent has used or disclosed the trade secret causing injury to the complainant.

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 8, 52-55, 2021 WL 141507 (Dec. 16, 2020); *see also Rubber Resins*, 2014 WL 7497801, at *5.

While the Commission has not explicitly articulated whether a complainant must show “any use” or “substantial use” of a trade secret to prevail, prior Commission decisions align with the “substantial use” standard. *See Crawler Cranes*, Comm’n Op. at 61-62 (May 6, 2015) (finding misappropriation despite incomplete “use” of a trade secret where thirteen of the twenty-two features were included in the accused product); *Rubber Resins*, 2014 WL 7497801,

PUBLIC VERSION

at *27 (finding misappropriation where respondents’ “process for manufacturing the accused tackifiers use, *substantially use*, and are substantially derived from Complainant’s trade secret, *i.e.*, the combination of the 17 aspects of Complainant’s process.” (emphasis added)); *Certain DC-DC Controllers and Prods. Containing Same*, Inv. No. 337-TA-698, Enforcement ID at 94-99 (June 8, 2012) (finding overwhelming evidence of the extent of the similarities between the accused products and complainant’s design documents and files), *unreviewed in pertinent part* by Notice (Aug. 9, 2012); *Certain Processes for the Manufacture of Skinless Sausage Casings & Resulting Product*, Inv. No. 337-TA-148/169, ID, 1984 WL 273789, at *101 (July 31, 1984), *unreviewed by* Comm’n Op. (Jan. 1, 1984) (finding, where complainant’s technology was not publicly disclosed or otherwise available, that respondent’s technology “is so close in structural details to that of [Complainant’s] that the conclusion [of misappropriation] is compelled”).

Determining whether there is “substantial” use or disclosure depends on the facts concerning the nature of the trade secret and particularly what information is actually protectable as a trade secret. *See* Restatement (Third) of Unfair Competition § 39, cmt. f (for trade secrets that are compilations, “it is the secrecy of the claimed trade secret as a whole that is determinative”).

In the case of a compilation trade secret that includes in part publicly known or readily ascertainable information, the collected information derives value from keeping the whole compilation secret. *Id.* However, for both compilation and non-compilation trade secrets, the unauthorized use or disclosure of the trade secret must be “substantial” to qualify as misappropriation. *Id.*, § 40, cmt. c (“[U]se of any substantial portion of the secret is sufficient to subject the actor to liability.”); *Penalty Kick Mgmt. Ltd. v. Coca Cola Co.*, 318 F.3d 1284, 1293 (11th Cir. 2003) (finding liability for trade secret misappropriation “if the plaintiff can show that

PUBLIC VERSION

the defendant (1) disclosed information that enabled a third party to learn the trade secret or (2) used a ‘substantial portion’ of the plaintiff’s trade secret to create an improvement or modification that is ‘substantially derived’ from the plaintiff’s trade secret”); 4 Milgrim on Trade Secrets § 15.01(1)(d)(vi) (“Defendant need not appropriate every feature of plaintiff’s trade secret to be a wrongful user, substantial appropriation is actionable (unless it is the result of proven independent development)[.]”).

The FID finds that “since Complainants relied on a specific ‘comprehensive compilation of customer-specific prices’ to establish the existence of a protectable trade secret, ‘evidence showing anything less than the use of the comprehensive compilation’ is not sufficient for Complainants to carry [their] burden of proving misappropriation” and that “because [Zimmer Biomet] fails to present evidence that the entire compilation (or even a majority of information within the compilation) that makes up TS 10 was ever disclosed to any party, [Zimmer Biomet] has not shown that TS 10 was misappropriated.” FID at 48. Complainants disagree with the FID’s finding and allege that case law supports their position that disclosure or use of any portion of TS 10 and TS 15/28 is sufficient to find misappropriation. CBr. at 4-12. However, the cases Complainants cite¹³ either involve circumstances where the court found the entirety of

¹³ As OUII notes, many of Complainants’ cited cases are preliminary injunction decisions, which use a different legal standard than the standard of proof for Complainants to establish a section 337 violation. OUIIBr. Reply at 5, n.2; *compare Farmers Ins. Exch. v. Steele Ins. Agency Inc.*, 2013 WL 2151553, at *10 (E.D. Cal. May 16, 2013) (moving party is “not required to prove that misappropriation actually occurred [but must] only make a clear showing that misappropriation likely occurred”) *with Certain Bone Cements, Components Thereof & Prods. Containing the Same (“Bone Cements (I)”)*, Inv. No. 337-TA-1153, Comm’n Op. at 6-7 (Jan. 12, 2021) (proving misappropriation of trade secrets requires: (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

PUBLIC VERSION

the trade secret had been used or disclosed or where the misappropriation turned on the nature of the protectable trade secret information contained in a customer list or database and the defendants' use of that trade secret information within the list or database. Thus, the cases Complainants cite actually support the requirement that at least "substantial" disclosure or use of the asserted trade secret is necessary for liability and confirm that whether a use or disclosure is "substantial" depends on facts of the case and the actual protectable trade secret.

In *Crawler Cranes*, the Commission determined that the full trade secret (concerning dealer discounts and profit margins for the Manitowoc crawler crane), and not just a portion as Complainants contend, was used to prepare a presentation to respondents' management, to develop a competing product, and to develop the respondent's pricing and dealer discount strategies. *Crawler Cranes*, Comm'n Op. at 65. Further, in *MAI Sys. Corp.*, the Ninth Circuit evaluated misappropriation based on the nature of the trade secret information in a customer database and the defendant's use of that secret information. *MAI Sys. Corp. v. Peak Computer, Inc.*, 991 F.2d 511, 521-22 (9th Cir. 1993). The court found MAI's Customer Database to be a protectable trade secret, which MAI argued was "a valuable collection of data assembled over many years that allows MAI to tailor its service contracts and pricing to the unique needs of its customers[.]" *Id.* at 521. The court affirmed the district court's summary judgment that Peak misappropriated MAI's Customer Database, because Peak solicited new business from MAI's customers using the individual entries of customer information within MAI's Customer

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).

PUBLIC VERSION

Database, which constituted the valuable trade secret information;¹⁴ the court did not hold that use of an insubstantial portion of a trade secret was sufficient for misappropriation. *Id.* at 522 (“The Customer Database has potential economic value because it allows a competitor like Peak to direct its sales efforts to those potential customers that are already using the MAI computer system.”); *see also MAI Sys. Corp. v. Peak Computer, Inc.*, No. 92-1654-R, 1992 WL 159803, at *16 (C.D. Cal. Apr. 14, 1992) (“[T]he evidence strongly suggests that [Peak] has attempted to appropriate for itself the valuable information in [MAI’s] Customer Database,” including that Peak’s customer database is very similar to MAI’s Customer Database, and Peak’s database identified whether the customer is a MAI customer).

Similarly, the Second Circuit in *North Atlantic Instruments* analyzed misappropriation of specific data in a compilation customer list based on the nature of the protectable trade secret information contained in that customer list and the defendants’ use of that secret information. *North Atlantic Instruments v. Haber*, 188 F.3d 38, 44-45 (2d Cir. 1999). The court affirmed the district court’s finding that the identities of individual engineers who purchased North Atlantic’s customized electronic technology and their contact information within North Atlantic’s customer list were trade secrets. *Id.* In contrast to the “needle-in-the-haystack character of the search for the handful of engineers in companies of 100,000 employees who might have a use for one of North Atlantic’s customized products,” the court affirmed the finding that certain other information within the customer list, such as company names, could be readily ascertained from public information and thus was not a protectable trade secret. *Id.* at 44-45. In assessing misappropriation, the court considered the defendants’ use of the entirety of the particular

¹⁴ In *MAI Sys. Corp.*, the identification of and details regarding each customer is valuable, and the value does not come from the entire database as a whole, as Complainants argued and the FID finds, in the present investigation. *Id.* at 511, 521-522.

PUBLIC VERSION

information found to constitute trade secrets, *i.e.*, the individual engineer identities and their contact information, rather than the use of an insubstantial portion of a compilation, as Complainants argue. *Id.* at 47 (considering “whether the defendants’ use of a trade secret – specifically the list of client contacts – was in breach of a duty [not to compete with the former employer].”). Likewise, in *Paz Sys. Inc.*, the court held that the defendant was using Paz’s customer/design database trade secret because the individual pieces of data within the database constituted the protectable trade secret and the defendant was using all of the data. *Paz Sys. Inc. v. Dakota Group Corp.*, 514 F. Supp. 2d 402, 406, 408 (E.D.N.Y. 2007).

Complainants also rely on cases where the actionable misappropriation involved the defendant’s use of specific customer information that was not readily ascertainable and otherwise unknown, which is distinguishable from Complainants’ asserted trade secrets that comprise whole compilations made up in part of publicly-available or readily ascertainable information. *Surgidev Corp. v. Eye Tech., Inc.*, 648 F. Supp. 661, 680-96 (D. Minn. 1986) (finding that certain types of customer information are not readily ascertainable such that the use of that secret information to solicit plaintiff’s customers is sufficient to establish disclosure or intent to disclose the putative trade secrets); *Abernathy-Thomas Eng’g Co. v. Pall Corp.*, 103 F. Supp. 2d 582, 600-601 (E.D.N.Y. 2000) (finding that while “it is unclear on the present record exactly how much of Abernathy’s customer information was supplied to Fluid Flow,” evidence of some disclosure of otherwise unknown customer information, which would have taken substantial time and effort to develop, was sufficient for a jury to find that the trade secrets had been misappropriated). Accordingly, while the Restatement and numerous decisions support that disclosure or use of the trade secret information must be substantial for liability, Complainants’

PUBLIC VERSION

cited cases do not support their argument that an “insubstantial portion” or “slight” use or disclosure is sufficient to demonstrate misappropriation. CBr. at 10, 13.

In sum, both the Restatement (Third) of Unfair Competition and case law require that disclosure or use of the asserted trade secret must be substantial in order to subject the actor to liability, regardless of whether the trade secret is a compilation or not. Here, Complainants successfully urged the ALJ to find that the entirety of Zimmer’s compilations of information contained in TS 10 and TS 15/28 constituted protectable trade secrets owing to the nature of these compilations. FID at 34-35; 40-42. Accordingly, having relied upon the entirety of these compilations as their asserted trade secrets, Complainants were required to show that Heraeus’s use or disclosure of the entirety of these compilations was substantial. The Commission finds that the FID applies the correct legal standard for misappropriation consistent with the Commission’s prior precedents and the court cases discussed above, wherein misappropriation was determined based on whether the unauthorized use or disclosure was substantial given the nature of the protectable trade secrets at issue. *See, e.g.*, FID at 47 (“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.”).

4. Analysis of Alleged Disclosure and Use of TS 10

Complainants alleged that Respondents wrongfully disclosed TS 10 to third parties ([REDACTED]) and to Mr. Devin Childers¹⁵ and HMUS. FID at 45, 47-52. Under the “substantial use” standard discussed above, and with the additional analysis

¹⁵ As explained below, Mr. Childers was hired in September 2017 as Heraeus Germany’s U.S. country manager and he later became HMUS’s general manager.

PUBLIC VERSION

below, the Commission affirms the FID's finding that Complainants failed to show that Respondents misappropriated TS 10.

a. Analysis of Alleged Disclosures of TS 10 to Third Parties

The FID states two independent reasons for finding no misappropriation of TS 10 with respect to third parties [REDACTED]. FID at 47-50. First, the FID finds that "since Complainants relied on a specific 'comprehensive compilation of customer-specific prices' to establish the existence of a protectable trade secret, 'evidence showing anything less than the use of the comprehensive compilation' is not sufficient for Complainants to carry its burden of proving misappropriation" and because Complainants have failed "to present evidence that the entire compilation (or even a majority of information within the compilation) that makes up TS 10 was ever disclosed to any party, Zimmer has not shown that TS 10 was misappropriated." *Id.* at 47-48. Second, the FID finds that Heraeus Germany was entitled to share "Confidential Information" with "[REDACTED]" [REDACTED] *Id.* at 49-50. The FID further finds that the 2012 Agreement permitted the disclosure to the third parties. *Id.* The Commission affirms the FID's findings that the 2012 Agreement authorized Heraeus Germany to share confidential information with its agents and representatives and that the disclosures to third parties were authorized disclosures. The Commission also affirms the FID's findings that Complainants failed to prove misappropriation, with the supplemental analysis described below concerning the first finding.

With respect to the first reason for the FID's finding of no misappropriation (as described above), under the proper legal standard, Complainants needed proof of at least "substantial" use or disclosure of TS 10 to constitute wrongful use or disclosure. *Crawler Cranes*, Comm'n Op. at 61-62; Restatement (Third) of Unfair Competition § 40, cmt. c. TS 10 is comprised of Quarterly

PUBLIC VERSION

Reports, which include spreadsheets of information. FID at 8. The FID found that the compilation of the quarterly reports as a whole is the protectable trade secret and cited testimony of Complainants' witnesses that "emphasized and relied on the fact that the asserted trade secrets are compilations of data, rather than individual data points." *Id.* at 34-35.¹⁶ Here, the Complainants' evidence does not show that Respondents substantially disclosed the TS 10

¹⁶ For example, when opining on the trade secret during direct examination, Complainants' expert, Dr. Blanchard, testified that TS 10 was not readily ascertainable due to its voluminous nature:

Q. How hard would it be for a competitor to properly acquire or duplicate Trade Secret 10 data?

A. Yeah, I think it would be very, very difficult, frankly, if not impossible to recreate the data that's embodied in Trade Secret 10.

Q. Why is that?

A. Well, in order to do that, someone would have to go speak with each and every customer. They would have to speak to each and every surgeon or hospital system in the United States, many of whom aren't Palacos users or wouldn't have been Palacos users, find out if they use Palacos, find out if the Palacos users, how much they were using and how much they were paying for it. So, A, that would take a very, very long time, and a large number of resources to do that, and, B, you would have to make an assumption that they would tell you that information. And I think in most cases they wouldn't, because they are under confidentiality to not provide that information to someone who asks.

Tr. (Blanchard) at 195:10-196:3; *see also id.* at 205:4-11 ("Q. Let's talk about Palacos customers. Could a supplier easily acquire or duplicate a list of Palacos customers from industry sources? A. No, they couldn't. Again, I think the only way you could recreate that list would be to go out and query every hospital that does total joints and expect them to give you their confidential information and give it to you truthfully."). Additionally, Dr. Blanchard also emphasized the customer-specific nature of the compilation when she discounted generic, publicly available bone cement price data because it was not "customer specific." *See id.* at 203:25-204:18 ("... private databases gather their data by, again, having members provide data to them, but they provide that data under the guise that it won't be disclosed according to customer-specific and product-specific information. So they roll the data up and they provide it back to their members or people who pay for the data in an aggregated format, not in a customer-specific format, and it's typically presented back in sort of ranges or percentiles . . .").

PUBLIC VERSION

compilation, which constitutes the trade secret (FID at 34-35), to [REDACTED]
[REDACTED]

Heraeus Germany provided its consultant, [REDACTED], with three charts identifying Heraeus's top twenty customers grouped by "All Palacos," "Palacos R+G/LV+G (Genta Only)," and "Major Total Joint Replacement," categories. The charts also included the customer names and addresses as well as the total sales value, quantity, and average sales price for each customer. CX-1488C, at 2-5; FID at 48-49. In its briefing to the Commission, Complainants argued that through this disclosure of the summary charts to [REDACTED], Heraeus misappropriated TS 10 because these charts were "derived from entire compilations of TS 10 data[.]" CBr. at 13. Complainants argue that the disclosure was substantial because "Heraeus disclosed to [REDACTED] information comprising and derived from the entirety of TS 10." CBr. at 25 (citing Ex. A at 1; CX-1358C; CX-1296C; CX-1594C; CX-1595C). None of these cited documents, however, prove that the chart information was "comprising and derived from the entirety of TS 10" as Complainants contend.¹⁷ Aside from attorney argument, Complainants cite no documentary or testimonial

¹⁷ One portion of Dr. Blanchard's testimony exemplifies the analytical divergence between the subject matter that Complainants claimed as a trade secret and the far narrower subject matter that they relied on in arguing that Respondents misappropriated TS 10:

Q. Well, but for purposes of determining whether misappropriation of a compilation trade secret -- that Trade Secret 10 has occurred, it's your position that Complainants don't need to show use or disclosure of the entire compilation, right?

A. Again, I think it's situational. It's pretty situationally dependent, so I think it depends.

PUBLIC VERSION

evidence to back up their claim that the charts provided to [REDACTED] comprised or were derived from the entire compilation that makes up TS 10. *Id.* at 14.¹⁸ Given Complainants' argument that the charts provided to [REDACTED] were from "the entirety of TS 10," Complainants failed to cite any evidence or expert testimony analyzing data from each of the TS 10 Quarterly Reports, which list thousands of rows of customer and sales information, to prove this point. *See, e.g.,* CX-2093C (containing over 3,700 rows of information). Moreover, the FID notes that Complainants' expert testified that she was unaware of any evidence showing substantial disclosure of TS 10 to any third party. *ID* at 48. Thus, Complainants failed to prove that the charts supplied to [REDACTED] were a substantial unauthorized use or disclosure of TS 10. *Id.*; FID at 48-49.

The information that Heraeus Germany presented to [REDACTED], a surgical supplier, consisted of estimates concerning the number of customers (regardless of the amount of product they purchased) and the number of customers that would make significant purchases (*e.g.*, high-volume purchasers). *See* CX-3261C at slide 8 (indicating that, in 2016, there were "[REDACTED] [REDACTED]" and that "[REDACTED] [REDACTED]"); Tr. (Petermann) at 775:8-18; JX-320C (Williamson) at 158:2-159:1; JX-334C (Petermann) at 98:13-17; *see* FID at 49-50. [REDACTED] received the same statistics

Q. Well, you've opined 30 minutes ago, 45 minutes ago on what you call use of Trade Secret 10 information that only involved little pieces of the information, correct, in terms of the disclosure?

A. It involved pieces of information from the full disclosure that could not have been obtained or would have been useful without using the full dataset.

Tr. (Blanchard) at 253:13-254:1.

¹⁸ For instance, Complainants did not demonstrate that Heraeus improperly disclosed a Quarterly Report file, which might have established wrongful disclosure of the entire secret compilation.

PUBLIC VERSION

provided to [REDACTED]. JX-139C at 16 (“[REDACTED]
[REDACTED],” and that “[REDACTED]”); CIB at 60; *see also*
FID at 49-50. In its briefing to the Commission, Complainants made the same arguments with
respect to [REDACTED] and [REDACTED] as it did for [REDACTED], without supporting evidence to
prove that Heraeus made unauthorized substantial uses or disclosures of TS 10 to [REDACTED]
[REDACTED] as discussed above. CBr. at 13-16. The Commission affirms the FID’s
conclusion that the information given to [REDACTED], Heraeus’ marketing
partner, was neither precise nor substantial enough to “enable[] another to learn the trade secret.”
FID at 50 (citing Restatement (Third) of Unfair Competition § 40, cmt. c). The Commission
affirms the FID’s findings concerning [REDACTED]. *Id.* at 49-50.

In sum, we agree with the FID that Complainants failed to prove that the information
shared with [REDACTED] was a substantial use or disclosure of TS 10.
Accordingly, the Commission has determined to affirm, with the supplemental analysis
discussed above, the FID’s finding that Complainants did not prove that Respondents’ disclosure
to third parties, [REDACTED], amounted to misappropriation of TS
10. Moreover, as noted above, the Commission affirms the FID’s findings that the disclosures
made to third parties were authorized under the 2012 Agreement.

b. Analysis of Alleged Disclosure of TS 10 to Mr. Childers and HMUS

The FID finds that: (1) the transmission of information from TS 10 to Mr. Childers was
allowed under the 2012 Agreement; and (2) Complainants failed to prove that HMUS’s
employees alleged use of TS 10 was either wrongful or substantial use. FID at 50-52.

PUBLIC VERSION

i. Mr. Childers, as U.S. Country Manager, Was Allowed Access to the Quarterly Reports Under the 2012 Agreement

Complainants alleged that information from TS 10 was wrongfully disclosed to Mr. Childers, and allegedly thereby to HMUS, on three occasions in fall 2017. Comp. Pet. at 11 (citing FID at 50-51). Complainants' arguments assume that Mr. Childers was originally hired and served only as the general manager of HMUS, but they fail to consider that Mr. Childers was initially hired for the position of U.S. country manager for Heraeus Germany. CBr. at 27-28; Resp. Reply at 13-14. Complainants do not dispute that Heraeus Germany's U.S. country manager was allowed access to the Quarterly Reports under the 2012 Agreement. *See* Comp. Pet. at 11-14.¹⁹ Thus, the dates on which information from the Quarterly Reports was disclosed and the position that Mr. Childers occupied on those dates are important to the analysis of whether the disclosures to Mr. Childers were unauthorized. In addition, Complainants mischaracterized the FID as finding "that Heraeus was allowed to disclose TS 10 data to HMUS," whereas the FID actually finds that Heraeus Germany was allowed to disclose TS 10 to Mr. Childers, Heraeus Germany's U.S. country manager. *Compare* Comp. Pet. at 11 *with* FID at 50-51.

The FID finds that "when Heraeus Germany sent the Quarterly Reports to Mr. Childers, he was Heraeus Germany's U.S. country manager" but does not state precisely when Mr. Childers transitioned from Heraeus Germany's U.S. country manager to HMUS's general manager. FID at 50-51. For the reasons discussed below, the Commission agrees with the FID that Mr. Childers was first hired in September 2017 as Heraeus Germany's U.S. country manager

¹⁹ Further, Complainants previously sent the Quarterly Reports directly to Mr. Tom Stafford, the U.S. country manager prior to Mr. Childers. *See* CX-1567C.

PUBLIC VERSION

and served in that position through at least December 2017, and thus Mr. Childers was permitted access to the Quarterly Reports in fall 2017 pursuant to the 2012 Agreement. *Id.*

HMUS was incorporated in June 2017. Tr. (Petermann) at 793:25-794:4; FID at 8. Mr. Childers received a formal offer letter from Heraeus Germany on July 27, 2017, and he accepted on July 31, 2017. CX-2142C. Mr. Childers started as Heraeus Germany's U.S. country manager in September 2017. *See* Tr. (Petermann) at 757:4-17; 778:9-17; Tr. (Childers) at 849:6-14, 883:6-9; JX-320C (Williamson) at 41:17-25; JX-311C at 64; JX-311C at 85. Also in September 2017, Respondents made the decision to sell PALACOS directly to customers in the United States, but HMUS was not yet up and running. Tr. (Petermann) at 778:18-779:5, 780:24-781:1.

Ms. Nicole Petermann, Heraeus Germany's Co-President, testified that sending the Quarterly Reports to Mr. Childers in fall 2017 was following Heraeus Germany's practice of sharing the same analyses with Mr. Childers' predecessor as U.S. country manager, Tom Stafford. FID at 51 (citing Tr. (Peterman) at 756:23-757:17). The transmission of the Quarterly Reports to Heraeus Germany's U.S. country manager, including Mr. Childers, was not misuse of the trade secret, but was allowed under the 2012 Agreement. *Id.* (citing JX-204C at 34).

Even in December 2017, Mr. Childers was still the U.S. country manager. Tr. (Childers) at 849:6-14, 886:24-887:10; JX-320C (Williamson) at 41:17-25; *see also* FID at 50-51. HMUS was not yet up and running in September 2017. Tr. (Petermann) at 780:24-781:1. Mr. Childers testified that he did not know the exact date that he transitioned from the U.S. country manager to HMUS's general manager. Tr. (Childers) at 887:2-10. However, Mr. Childers further testified that at least on December 6, 2017, he still had the title of U.S. country manager. *Id.* at 911:24-912:12. His testimony is corroborated by a December 6, 2017 email from Mr. Childers with a signature block, "Devin Childers CFA, Country Manager US, Heraeus Medical"). CX-

PUBLIC VERSION

369C.²⁰ Given that the three disclosures to Mr. Childers occurred during the time period when he was employed as the U.S. country manager for Heraeus Germany, Complainants failed to show that these disclosures were not authorized under the 2012 Agreement.

The Commission affirms, with modified reasoning above, that Complainants failed to show the disclosure of Quarterly Reports to Mr. Childers constituted misappropriation of TS 10.

ii. Complainants' Forensic Evidence Does Not Prove That HMUS Employees Misused TS 10

The FID finds that other alleged misuse of TS 10 by HMUS is not supported by Complainants' forensic evidence, which the FID finds is speculative. FID at 51-52. To prove improper use of TS 10 by HMUS, Zimmer presented forensic evidence that a "PALACOS Customers USA File" was saved on HMUS employees' computers and opened on a number of dates. *Id.* at 51. However, the FID finds that the forensic evidence "shows no more than that certain files were opened, saved, and sent to others." *Id.* Further, the FID credits the testimony of Heraeus employees in finding that they did not rely on data from TS 10 in their work. *Id.* ("By contrast, Heraeus employees testified (both during the evidentiary hearing and by deposition) that they did not rely on information obtained from Zimmer Quarterly Reports."). The FID further credits the testimony of HMUS employees and evidence that HMUS spent considerable time and effort developing its own customer targeting database primarily from CMS data. *Id.* at 52.

Complainants argued that there is ample circumstantial evidence that proves HMUS used TS 10 in 2017 and 2018, and the FID allegedly errs in finding this evidence is speculative. Comp. Pet. at 15-23. According to Complainants, the FID fails to consider forensic evidence

²⁰ The Commission notes that Complainants, who bear the burden on misappropriation, have not shown when Mr. Childers began his tenure as HMUS's general manager.

PUBLIC VERSION

and documents that establish the TS 10 files were purposefully modified, and these modifications show how the data was being used. *Id.* at 16.

The Commission disagrees that the FID failed to consider Complainants' arguments and forensic evidence, as is clear from the FID's findings. FID at 51-52. Further, the Commission agrees with the FID's findings that Complainants' evidence "shows no more than that certain files were opened, saved, and sent to others." *Id.* at 52. With their forensic evidence in hand, Complainants had the opportunity to question the HMUS employees in depositions and at the hearing to ascertain whether HMUS employees wrongfully used TS 10. Complainants failed to elicit testimony to prove their theory of liability, however. The Commission also does not disturb the FID's findings that Heraeus employees credibly testified that they did not rely on information obtained from the Quarterly Reports. *Id.* (citing JX-339C (R. Kolbe Dep.) at 44-47; JX-335C (Cruz Dep.) at 59-60, 80-81; Tr. (Childers) at 870:17-871:4; Tr. (Webb) at 972:10-973:1). Accordingly, the Commission affirms the FID's finding that Complainants' forensic evidence of alleged use of the TS 10 Quarterly Reports by HMUS does not prove misappropriation of TS 10.

5. Analysis of Alleged Disclosure and Use of TS 15/28

The Commission adopts, without modification, the FID's analysis and findings that Complainants did not show that Respondents misappropriated TS 15/28. FID at 45-47, 53-54. Accordingly, the Commission affirms that there was no misappropriation of TS 15/28.

6. Analysis of Respondents' Independent Development of HMUS's Customer Targeting Database

The FID finds that Respondents independently developed their customer lists and pricing, which is an affirmative defense to trade secret misappropriation. FID at 56. The FID credits the testimony of Respondents' witnesses who testified that HMUS spent independent time and effort

PUBLIC VERSION

developing a customer targeting database primarily from CMS data and that HMUS was able to independently develop a targeting database after approximately two weeks of work using less than \$7,000. *Id.* The FID dismisses Complainants' arguments that the testimony was unbelievable speculation. *Id.*

Complainants argued that Mr. Webb, HMUS Vice President of Marketing and Education, who developed HMUS's customer targeting database, had access to files containing TS 10 data. Comp. Pet. at 31. Complainants further argued that the FID mischaracterizes evidence that Mr. Webb received input from others who had access to TS 10 data as mere speculation. *Id.* at 32. Complainants argued that there is "a heavy burden" in proving independent development and a "clean room" approach must be established. *Id.* at 30-32 (citing *Bone Cements (I)*, ID at 53 (May 6, 2020) ("engaging in some independent development is not enough to establish independent development as a legal defense")).

Respondents argued that Complainants do not, and cannot, contradict or rebut Mr. Webb's detailed explanation as to the steps he used to create the customer targeting database without use of information from the TS 10 Quarterly Reports, or any other Zimmer Biomet information. RBr. Reply at 27 (citing Tr. (Webb) at 952:7-981:4). As OUII noted, the phrase "clean room" does not appear in the *Bone Cements (I)* ID, and both OUII and Respondents agreed that the case law does not support requiring proof of a "clean room." OUII Reply at 14-15 (citing *Bone Cements (I)*, ID); Resp. Reply at 32, 39-40.²¹

²¹ As a leading treatise notes, "clean room" development can be "a particularly fact intensive matter." See 1A MILGRIM ON TRADE SECRETS App. 7A: Independent (Clean Room) Development (2021). Here, the evidence Heraeus has presented is sufficient to "withstand scrutiny in the specific circumstances" of this investigation. *Id.*

PUBLIC VERSION

The evidence of record supports the FID's finding that Respondents independently developed their customer targeting database. Mr. Webb, who never worked for Complainants, developed Respondents' customer targeting database. Tr. (Webb) at 952:25-954:15. Mr. Webb developed the database using information from publicly available sources. FID at 56; Tr. (Webb) at 954:7-955:6, 956:6-10; JX-53C (targeting database); JX-52C (cover email attaching targeting database); Tr. (Webb) at 971:22-972:9, 969:7-21. Mr. Webb alone kept and maintained access to the master database. Tr. (Webb) at 970:7-23. Mr. Webb credibly testified that he did not include any information from Complainants or any third party's proprietary information. Tr. (Webb) at 972:10-15. Thus, the evidence of record supports the FID's findings that HMUS's database was not created using TS 10. FID at 56. Based on this evidence, the FID correctly finds that HMUS did not rely on TS 10 in creating its own customer targeting database. *Id.*

Moreover, Complainants failed to analyze the facts under even the stringent "clean room" standard they argued should govern. Comp. Pet. at 30-32. Indeed, Complainants described all the ways the HMUS database is materially different from TS 10. *Id.* at 33-34. As noted in *Bone Cements (I)*, if the independently created improvements or modifications are "substantially derived from the trade secret" then there is liability. *Bone Cements (I)*, ID at 51. Here, however, Complainants appear to admit that the HMUS database is materially different from, and therefore not substantially derived from, TS 10.

Accordingly, the Commission adopts and affirms, with the additional analysis above, the FID's findings that Respondents independently developed their own customer targeting database.

B. Tortious Interference With Prospective Business Advantages Issues Under Review

Alleged violations of section 337(a)(1)(A) predicated on non-statutory causes of action, such as tortious interference, may be brought under principles of federal common law. *See*

PUBLIC VERSION

TianRui, 661 F.3d at 1327-28. To prove a claim for tortious interference with a prospective economic advantage, a complainant is required to show “[1] that it had a reasonable expectation of economic advantage, [2] which was lost as a direct result of [the respondent’s] malicious interference, and [3] that it suffered losses thereby.” *Avaya Inc., RP v. Telecom Labs, Inc.*, 838 F.3d 354, 382-83 (3d Cir. 2016).²²

1. Summary of the FID’s Tortious Interference Findings

Before the ALJ, Complainants alleged that Respondents committed tortious interference in two ways: (1) Respondents induced their employees to use Complainants’ confidential and trade secret information to sell PALACOS bone cement in the United States; and (2) Respondents tortiously interfered with Complainants’ prospective economic advantage. FID at 82. The FID finds that Complainants failed to prove either of these allegations. *Id.* at 81-88.

More specifically, Complainants alleged that Respondents interfered with Complainants’ “prospective economic advantage to convert existing customers [to Zimmer’s own bone cement products] in three ways: (i) by refusing to supply [Complainants’] affiliate (Zimmer Surgical, Inc.) with PALACOS in breach of the Distribution Agreement, (ii) by using [Complainants’] trade secret and confidential information, and (iii) by falsely advertising about [Complainants’] right and ability to sell PALACOS and the superiority of PALACOS over RBCR.” *Id.* at 84. The FID notes that Complainants modified their tortious interference allegations from interference with existing contracts to interference with prospective advantage,²³ but under both

²² Because the parties have principally framed their arguments around *Avaya*’s three-factor test, the Commission will use that test to assess Complainants’ allegations.

²³ Under the theory presented in their pre-hearing brief, Complainants argued that Respondents interfered with Complainants’ existing contracts for PALACOS. *See*

theories, Complainants rely on the same three sources of interference: (i); (ii); and (iii). *Id.* at 85.

The FID finds that allegations (ii) and (iii) fail for the same reasons that Complainants’ underlying trade secret and false advertising claims fail, respectively. *Id.* at 84-85; *see also* FID at 58-81 (finding no false advertising). The FID further finds no proof of interference or injury (allegation (i)). *Id.* at 85-88. In particular, the FID finds that Complainants offered no evidence that Respondents knew of any specific contracts that Complainants had with specific customers or any specific contractual details. *Id.* at 86. The FID further finds no proof of interference because Complainants provided no evidence connecting the alleged breach of the 2012 Agreement to any prospective business relationships – “no expert evidence, no internal [Zimmer Biomet] documents or communications, and no customer statements or testimony.” *Id.*

Regarding alleged injury related to allegation (i), the FID finds that Complainants failed to identify any clause in the 2012 Agreement or any evidence that establishes a time for Complainants to introduce their own cements. *Id.* at 87-88. Accordingly, the FID finds that Complainants failed to prove that Respondents’ alleged tortious interference was the proximate cause of any injury. *Id.*

2. Analysis of Alleged Tortious Interference with Prospective Economic Advantage

Because the Commission affirms the FID’s findings that there was no misappropriation or false advertising, Complainants’ allegations (ii) and (iii) fail for the same reasons that those

Complainants’ Pre-Hearing Brief (Sept. 25, 2020) (“CPrHB”) at 134-138. In their post-hearing brief, Complainants argued interference with Complainants’ attempts to convert their current PALACOS customers to Zimmer’s ZB cements customers. CIB at 96-98. Complainants did not preserve their pre-hearing argument regarding the alleged interference with existing PALACOS customer contracts, and that argument is waived. CPrHB at 134-138; CIB at 96-98; Order No. 2 at Ground Rule 13.1 (Sept. 23, 2019).

PUBLIC VERSION

underlying claims fail. FID at 84-85. The Commission also affirms, under a modified analysis explained below, the FID's finding that Complainants failed to prove the tortious interference in allegation (i). *Id.* at 85-88.

A claim of tortious interference with prospective business or economic advantage requires a complainant to prove that the complainant had a reasonable expectation of economic advantage, which is lost as a direct result of the respondent's malicious interference causing the complainant to suffer losses. *Avaya*, 838 F.3d at 382 (explaining "what is actionable is the luring away, by devious, improper and unrighteous means, of the customer of another") (internal quotations and citations omitted). This standard applies to Complainants' allegations of tortious interference with prospective business economic advantages. *Id.*; *see also* FID at 16, 81-82. The parties agree that this is the correct standard. Comp. Pet. at 61; Resp. Reply at 67-68; OUII Reply at 31-32. Thus, while the FID analyzes the existence and knowledge of a contract, analysis of an existing contract is not necessary for allegations of tortious interference with a prospective economic advantage. *See* FID at 86.

For Complainants' allegation (i), they argued that Respondents' refusal to supply PALACOS to Zimmer Biomet after July 2018 was unjustified and qualifies as "wrongful means" and unfair competition because it was allegedly a breach of the 2012 Agreement. CIB at 98-99. Complainants asserted that they had a reasonable expectation of the prospective economic advantage of transitioning a substantial portion of PALACOS customers to purchase their ZB cements after Respondents elected mutual non-exclusivity on January 2, 2018 based on the strength of Complainants' relationships with PALACOS customers and other competitive advantages. *Id.* at 97. Complainants alleged that Respondents' refusal to supply PALACOS to

PUBLIC VERSION

Zimmer Biomet after July 2018 reduced the time agreed to in the 2012 Agreement that Zimmer Biomet had to introduce its own cements to customers. *Id.* at 98-102.

Respondents and OUII argued that Complainants' evidence is insufficient to prove tortious interference because: (1) Complainants did not prove they had a reasonable expectation of transitioning PALACOS customers to its ZB cements; (2) Respondents' alleged withholding of PALACOS supply was not malicious interference; and (3) Complainants failed to prove any losses. Resp. Reply at 66-72; OUII Reply at 31-34. Also, as OUII pointed out, Respondents' decision to withhold PALACOS supplies at the end of 2018 is insufficient to establish a claim for interference with prospective economic advantage. *See, e.g., Cavalieri-Conway v. L. Butterman & Assocs.*, 992 F. Supp. 995, 1012 (N.D. Ill. Jan. 28, 1998) ("It is also well-established that 'the tortious interference allegedly committed by the defendant must be directed toward a third party – not the plaintiff.'" (quoting *Silk v. City of Chicago*, 1997 WL 790598, at *19-20 (N.D. Ill. Dec. 17, 1997))).

The FID's findings of fact support the conclusion that there was no tortious interference with prospective business advantages. FID at 84-88. Specifically, the FID notes that Complainants rely on two pieces of evidence: (1) an email between two Heraeus executives which states that "[i]f [Zimmer Biomet has] more time for conversion, they will convert more customers to [RBCR];" and (2) the testimony of Respondents' expert on Swiss law. *Id.* at 87 (citing CX-1320C at 1; JX-363C (Rohm²⁴ Dep.) at 120:1-9). The FID finds that Complainants failed to explain or provide evidence as to how Respondents' conduct "decreased [Complainants'] time to transition its customers to the ZB Cements" or exactly how that transition time was affected. *Id.* at (citing CPrHB at 98). The FID also finds that the testimony

²⁴ Dr. Patrick Rohn was Respondents' expert on Swiss law. FID at 87.

PUBLIC VERSION

of Respondents' expert on Swiss law, who opined that it was commercially reasonable for Respondents to consider potential loss of market share in deciding to refuse Complainants' firm orders, did not demonstrate tortious interference and actually undermined Complainants' case. *Id.* (citing JX-363C (Rohn Dep.) at 120:1-9). The FID observes that Complainants cite no other evidence connecting the alleged breach of the 2012 Agreement to any prospective business relationships – no expert evidence, no internal Zimmer Biomet documents or communications, and no customer statements or testimony. *Id.*

The FID further finds that Complainants failed to prove that Respondents' alleged tortious interference was the proximate cause of any alleged injury. *Id.* at 88. The FID finds that the email upon which Complainants rely regarding their alleged time frame to introduce their own bone cements does not discuss any "agreed" time that was not met as a result of Respondents' conduct. *Id.* The FID also finds that Complainants failed to provide an injury analysis for tortious interference separate from that of trade secret misappropriation and false advertising. *Id.*

Accordingly, the Commission adopts and affirms the FID's findings that Respondents did not tortiously interfere with Complainants' prospective business relationships, but under *Avaya*'s legal standard for tortious interference with prospective business advantage and with the modified analysis above.

C. Domestic Industry and Injury Issues Under Review

The Commission determined to review the FID's DI and injury findings. 86 Fed. Reg. at 20201. On review, the Commission has determined to take no position on the FID's DI and injury findings. FID at 88-104; *Beloit*, 742 F.2d at 1423. The Commission affirms the FID's findings that there was no misappropriation, no tortious interference, and no false advertising.

PUBLIC VERSION

Because the Commission has affirmed these findings, taking no position on the FID's DI and injury findings does not affect the Commission's finding of no violation of section 337.

IV. CONCLUSION

For the reasons set forth above, the Commission determines that Complainants have not established a violation of section 337 by Respondents by reason of misappropriation of trade secrets, false advertising, or tortious interference. Accordingly, the Commission terminates the investigation with a finding of no violation of section 337.

By order of the Commission.

A handwritten signature in black ink, appearing to read 'Lisa R. Barton', enclosed within a large, loopy oval shape.

Lisa R. Barton
Secretary to the Commission

Issued: July 9, 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, **Megan Wantland, Esq.**, and the following parties as indicated, on **July 9, 2021**.



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

On Behalf of Complainants Zimmer, Inc., and Zimmer US, Inc.:

Eric S. Namrow, Esq.
MORGAN, LEWIS & BOCKIUS LLP
1111 Pennsylvania Avenue, NW
Washington, DC 20004
Email: eric.namrow@morganlewis.com

- ☐ Via Hand Delivery
- ☐ Via Express Delivery
- ☐ Via First Class Mail
- ☒ Other: Email Notification
of Availability for Download

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

David A. Caine, Esq.
ARNOLD & PORTER KAYE SCHOLER LLP
3000 El Camino Real, Suite 500
Palo Alto, CA 94306
Email: david.caine@arnoldporter.com

- ☐ Via Hand Delivery
- ☐ Via Express Delivery
- ☐ Via First Class Mail
- ☒ Other: Email Notification
of Availability for Download

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of

**CERTAIN BONE CEMENTS AND BONE
CEMENT ACCESSORIES**

Investigation No. 337-TA-1175

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

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (“Commission”) has determined to review in part a final initial determination (“FID”) of the presiding administrative law judge (“ALJ”) finding no violation of section 337 of the Tariff Act of 1930, as amended, in the above-captioned investigation. 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: Lynde Herzbach, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-3228. 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, telephone 202-205-1810.

SUPPLEMENTARY INFORMATION: On September 23, 2019, the Commission instituted this investigation based on a complaint filed on behalf of Zimmer, Inc. and Zimmer US, Inc. both of Warsaw, Indiana (collectively, “Complainants”). 84 FR 49764 (Sept. 23, 2019). The complaint alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 (“section 337”), based on the importation into the United States, the sale for importation, and the sale within the United States after importation of certain bone cements and bone cement accessories by reason of the misappropriation of trade secrets, false advertising, and tortious interference, the threat or effect of which is to destroy or substantially injure an industry in the United States. The complaint also alleges the existence of a domestic industry. The Commission’s notice of investigation names the following as respondents: Heraeus Medical

GmbH of Wehrheim, Germany and Heraeus Medical LLC of Yardley, Pennsylvania (collectively, “Respondents”). *Id.* The Office of Unfair Import Investigations (“OUII”) is named as a party in this investigation. *Id.*

On February 11, 2021, the ALJ issued the FID, finding no violation of section 337. More particularly, the FID finds, *inter alia*, that: (1) the Commission has subject matter and personal jurisdiction; (2) Respondents sold for importation into the United States, imported, or sold after importation accused bone cements and bone cement accessories; (3) a domestic industry exists with respect to Complainants’ accessory products under section 337(a)(1)(A)(i) (19 U.S.C. 1337(a)(1)(A)(i)); (4) Complainants own the asserted trade secrets; (5) trade secrets (“TS”) 10, 15, and 28 are protectable, but TS 11 is not protectable; (6) Respondents did not misappropriate any asserted TS; (6) Respondents did not engage in false advertising; (7) Respondents did not tortiously interference with Complainants’ contracts or prospective business relationships; and (6) Complainants failed to show a substantial injury or threat of injury to their domestic industry.

The FID includes the ALJ’s recommended determination (“RD”), which recommends that, if the Commission finds a violation of section 337, the Commission should issue a limited exclusion order and a cease and desist order directed to Respondents. The RD further recommends imposing a bond of five and a half (5.5) percent during the period of Presidential review.

On February 23, 2021, Complainants filed a petition for review that seeks review of most of the FID’s findings. On March 3, 2021, Respondents and OUII filed responses to Complainants’ petition.

On March 15, 2021, Respondents filed a submission on the public interest pursuant to Commission Rule 210.50(a)(4) (19 CFR 210.50(a)(4)). Complainants and OUII did not file a statement on the public interest. The Commission received no filings in response to its Federal Register notice calling for public interest comments. *See* 86 FR 12029.

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

- (1) The FID’s findings and conclusions as to the alleged misappropriation of the asserted trade secrets, including the finding that Respondents independently developed their own data compilation;
- (2) The FID’s findings and conclusions as to Respondents’ alleged tortious interference with Complainants’ prospective business advantages; and
- (3) The FID’s findings on domestic industry and injury.

The Commission has determined not to review the remainder of the FID.

In connection with its review, the Commission requests that the parties brief their positions regarding the following questions with reference to the applicable law and the evidentiary record:

- (A) When evaluating the misappropriation of a trade secret, identify and discuss the proper legal standard for wrongful disclosure or use of a trade secret that is a compilation. Please consider whether any particular amount of disclosure or use is required to support a finding of misappropriation, *i.e.*, de minimis, substantial, or the entirety of the trade secret compilation. Discuss whether there are any differences in the application of the legal standard for disclosure or use if a trade secret compilation includes publicly available information.
- (B) Given the legal standard identified in response to (A), please analyze the alleged disclosure and use of TS 10, 15, and 28.
- (C) Please discuss and provide a timeline detailing the background and development of Heraeus Medical LLC from 2017 through 2018, including the dates that relevant employees were hired, the relevant employees' positions, the dates of alleged disclosures and/or use of TS 10, 15, and 28, and the dates and relevant facts regarding Respondents' interactions with third parties.
- (D) What criteria should the Commission apply to determine whether activities related to meeting FDA requirements constitute activities of a "mere importer"? For example, should one criterion be that the activities are required to be performed in the United States or that the activities differ from those that a wholly domestic company would perform? Please apply the appropriate criteria to the facts of this investigation. Are any of Complainants' FDA-related activities different from what a wholly domestic company would need to undertake? Which, if any, of a Complainants' FDA activities could be conducted abroad?

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 ALJ's RD on remedy and bonding.

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.

Written submissions, including proposed remedial orders must be filed no later than the close of business on **April 30, 2021**. Reply submissions must be filed no later than the close of business on **May 7, 2021**. 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-1175") 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 April 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.

A handwritten signature in black ink, appearing to read 'Lisa R. Barton'.

Lisa R. Barton
Secretary to the Commission

Issued: April 12, 2021

PUBLIC CERTIFICATE OF SERVICE

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



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

On Behalf of Complainants Zimmer, Inc., and Zimmer US, Inc.:

Eric S. Namrow, Esq.
MORGAN, LEWIS & BOCKIUS LLP
1111 Pennsylvania Avenue, NW
Washington, DC 20004
Email: eric.namrow@morganlewis.com

- ☐ Via Hand Delivery
- ☐ Via Express Delivery
- ☐ Via First Class Mail
- ☒ Other: Email Notification
of Availability for Download

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

David A. Caine, Esq.
ARNOLD & PORTER KAYE SCHOLER LLP
3000 El Camino Real, Suite 500
Palo Alto, CA 94306
Email: david.caine@arnoldporter.com

- ☐ Via Hand Delivery
- ☐ Via Express Delivery
- ☐ Via First Class Mail
- ☒ Other: Email Notification
of Availability for Download

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of

**CERTAIN BONE CEMENTS AND BONE
CEMENT ACCESSORIES**

Inv. No. 337-TA-1175

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

Administrative Law Judge Cameron Elliot

(February 11, 2021)

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 And Bone Cement Accessories*, Investigation No. 337-TA-1175.

TABLE OF CONTENTS

I. INTRODUCTION.....	5
A. Procedural Background	5
B. The Parties.....	7
C. The Asserted Trade Secrets	8
D. Products at Issue	10
1. Accused Products	10
2. Zimmer's Domestic Products.....	10
II. STANDARDS OF LAW	11
A. Protectable Trade Secrets	11
B. False and Misleading Advertising	14
C. Tortious Interference.....	16
D. Domestic Industry	17
III. IMPORTATION AND SALE	21
IV. JURISDICTION	22
V. THE ASSERTED TRADE SECRETS.....	23
A. Trade Secret 10	23
1. Extent Trade Secret 10 Was Known Outside Zimmer	23
2. Extent TS 10 Was Known Inside Zimmer	25
3. Extent of Steps Taken By Zimmer to Guard Trade Secret 10.....	27
4. Value of Trade Secret 10 to Zimmer and Competitors	30
5. The Amount of Effort or Money Expended in Development.....	32
6. The Ease or Difficulty of Acquisition or Duplication by Others.....	33
B. Trade Secret 11	35
1. Extent Trade Secret 11 Was Known Outside Zimmer	35
2. Extent Trade Secret 11 Was Known Inside Zimmer	36
3. Extent of Steps Taken by Zimmer to Guard Trade Secret 11	37
4. Value of TS 11 to Zimmer and Competitors	37
5. The Amount of Effort or Money Expended in Development.....	38
6. The Ease or Difficulty of Acquisition or Duplication by Others.....	38
C. The Asserted Trade Secrets 15 and 28	39
1. Extent Trade Secrets 15 and 28 Were Known Outside Zimmer	40
2. Extent Trade Secrets 15/28 Were Known Inside Zimmer	40

3.	Extent of Steps Taken By Zimmer to Guard Trade Secrets 15/28	41
4.	Value of Trade Secrets 15/28 to Zimmer and Competitors.....	41
5.	The Amount of Effort or Money Expended by Zimmer	42
6.	The Ease or Difficulty of Acquisition or Duplication by Others.....	42
VI.	MISAPPROPRIATION OF THE TRADE SECRETS	43
A.	Ownership.....	43
B.	Disclosure or Wrongful Acquisition.....	44
1.	TS 10 and TS 11	45
2.	TS 15/28.....	45
C.	Use of the Asserted Trade Secrets	47
1.	TS 10.....	47
2.	TS 11.....	53
3.	TS 15/28.....	53
D.	Summary.....	54
E.	Harm to Zimmer by Misappropriation.....	54
VII.	HERAEUS' DEFENSES	56
A.	Heraeus Independently Developed its Own Data Compilation	56
B.	Heraeus' Use Was Not Licensed	57
C.	No Prospective Relief for Harm Relating Only to PALACOS Sales	57
D.	Zimmer's Claims Are Not Barred by Unclean Hands or Material Breach	58
VIII.	FALSE AND MISLEADING ADVERTISING.....	58
A.	Statements Regarding Zimmer's Right/Ability to Supply PALACOS	59
1.	Falsity of Statements.....	59
2.	Actual Deception or Tendency to Deceive	67
3.	Materiality	71
4.	Interstate Commerce	72
5.	Likelihood of Injury.....	72
B.	Statements Regarding Product Quality	73
1.	Falsity of Statements.....	73
2.	Actual Deception or Tendency to Deceive	79
3.	Materiality	80
4.	Interstate Commerce	81
5.	Likelihood of Injury.....	81

IX. TORTIOUS INTERFERENCE	81
A. Interference with Confidentiality Agreements with Former Employees	82
1. Existence and Knowledge of Zimmer Employment Contracts	82
2. No Intentional Actions Resulted in Breach of Employment Agreements	83
B. Tortious Interference With Prospective Business Relationships	84
1. Existence of and Knowledge of a Contract	86
2. No Proof of Interference	87
3. No Proof of Injury	87
X. DOMESTIC INDUSTRY	88
A. Characterization Testing and Regulatory Compliance	89
B. Manufacturing Accessories	91
C. Customer Service and Technical Support	93
D. Technical Marketing	94
E. Analysis	95
F. Substantial Injury To Domestic Industry	98
1. Lost sales, Lost Market Share, and Price Erosion of Bone Cements and Accessories	99
2. Reputational Harm and Injury to Goodwill	102
3. Testing, Customer Service and Technical Support/Marketing	103
XI. CONCLUSIONS OF LAW	104
XII. RECOMMENDED DETERMINATION ON REMEDY AND BOND	105
A. Limited Exclusion Order	107
B. Cease and Desist Order	109
C. Bond	109
XIII. INITIAL DETERMINATION AND ORDER	111

TABLE OF ABBREVIATIONS

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

I. INTRODUCTION

A. Procedural Background

Complainants, Zimmer, Inc. and Zimmer US (“Zimmer” or “Complainants”) filed a Complaint with the Commission on August 19, 2019. EDIS Doc. ID 685690 (Aug. 19, 2019). The Commission instituted the investigation on September 17, 2019. 84 Fed. Reg. 49764 (Sept. 23, 2019). The named respondents are Heraeus Medical GmbH and Heraeus Medical LLC (“Heraeus” or “Respondents”).

By publication of a notice in the *Federal Register* on September 23, 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 products identified in paragraph (2) by reason of the misappropriation of trade secrets, false advertising, or tortious interference, 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 products, which defines the scope of the investigation, is "Heraeus' PALACOS® bone cements, including PALACOS® R, PALACOS® R+G, PALACOS® MV, PALACOS® MV+G, PALACOS® LV+G, PALACOS® LV, and other similar bone cements, as well as Heraeus' bone cement accessories, including the PALACOS® All-in-One Fixation Systems, the PALAMIX® vacuum mixing systems, the PALABOWL vacuum mixing bowls, and other similar accessories used for mixing and applying bone cements."

84 *Fed. Reg.* 49764 (Sept. 23, 2019).

On September 4, 2020, Respondents filed a Motion for Summary Determination of No Violation, which was timely opposed by Complainants and Staff. The motion was denied on October 2, 2020. Order No. 9, EDIS Doc. ID 721085.

An evidentiary hearing was held October 26-30, 2020. Following the evidentiary hearing, and pursuant to the procedural schedule, the parties submitted initial and reply post-hearing briefs

[REDACTED]

on November 13, 2020 (EDIS Doc. 725008 (Complainant), EDIS Doc. 725035 (Respondents), EDIS Doc. 725051(Commission Staff)) and December 4, 2020 (EDIS Doc. 727244 (Complainant), EDIS Doc. 727257 (Respondents), EDIS Doc. 727231 (Commission Staff)), respectively.

On October 13, 2020, prior to the evidentiary hearing, Zimmer filed a motion for adverse inferences in view of Heraeus' alleged spoliation of evidence. Mot. 1175-023. Heraeus filed a response ("Resp." EDIS Doc. 722829) as did the Staff ("SResp" EDIS Doc. 723117). Both parties opposed the motion. The motion was held in abeyance until after the hearing so that any relevant evidence could be presented at the hearing.

Zimmer alleges that Heraeus destroyed evidence that it was under an obligation to preserve, thus prejudicing Zimmer. Heraeus allegedly spoliated evidence on two separate occasions: first, when former Zimmer employee James "Worth" Burns destroyed a personal USB device containing a file, the "For Peterson" file, after receiving a litigation hold-style notice letter from Complainants' counsel; and second, when Heraeus had employees' work computers updated pursuant to a global company equipment "refresh" without first forensically imaging the employees' devices. Memorandum in Support of Its Motion for Adverse Interferences In View of Heraeus' Spoliation of Evidence (Memo.) at 2-5.

The Federal Circuit states that "'a party can only be sanctioned for destroying evidence if it had a duty to preserve it.'" *Micron Tech., Inc. v. Rambus Inc.*, 645 F.3d 1311, 1320 (Fed. Cir. 2011)), *aff'd in relevant part by*, Comm'n Op. at 12-19 (Apr. 30, 2015). (quoting *Zubulake v. UBS Warburg LLC*, 220 F.R.D. 212, 216 (S.D.N.Y. 2003)). As will be discussed in more detail later, Zimmer fails to present evidence that Heraeus had knowledge of Mr. Burns' personal USB device, and moreover, did not have control over the USB when it was destroyed. As to Zimmer's second

[REDACTED]

allegation, an Indiana court in a related case issued a preliminary injunction in 2018 enjoining Robert Kolbe, James “Worth” Burns, and Heraeus from, *inter alia*, “possessing, using or disclosing Zimmer Biomet’s Confidential Information.” Resp. at 3, Ex. 2. Complainants did not request that forensic images be taken of these individual’s computers at that time, and the Indiana court did not require it. *See* Resp. at 3 (first request for additional forensic images beyond what was provided in discovery in Indiana was in this Investigation in June 2020); *see also* Resp. at 15, Ex. 14 (the Indiana court order enjoining possession of any Zimmer Biomet confidential information was based on language suggested by Zimmer). And Zimmer cites no support for the proposition that a duty of preservation of evidence must necessarily include forensic images. Later, the computers in question were part of a routine software update and equipment refresh. Zimmer fails to present any evidence that this routine update was done in bad faith, therefore justifying sanctions. *See, e.g., Micron*, 645 F.3d at 1326 (finding “bad faith” requires a showing of purposeful intent to impair the ability of a party to bring its claims).

Accordingly, Zimmer’s motion for adverse inferences (Mot. 1175-023) is denied.

B. The Parties

Complainants Zimmer, Inc. and Zimmer U.S., Inc. are both Delaware corporations with principal places of business in Warsaw, Indiana. Complaint ¶¶ 9, 11. Complainants are subsidiaries of parent company Zimmer Biomet Holdings, Inc., which was created in 2015 as the result of a merger between Zimmer Holdings, Inc. and Biomet, Inc. Complaint ¶ 3. Biomet, Inc. (or a related entity) was the distributor of Heraeus’s PALACOS products in the U.S. from 1996 to 2006. *See* CIB at 7. Zimmer Surgical, Inc. (and/or related entities) was contracted to distribute Heraeus’s PALACOS in the U.S. from 2005 through 2018. CIB at 7, 8; Complaint ¶ 31. Complainants are currently responsible for the marketing, distribution, and sales of Zimmer’s bone

[REDACTED]

cements and bone cement mixing and delivery accessories sold in the United States. CPB at 5 (noting also that Zimmer U.S., Inc. “manages the sales agreements for the [Zimmer Biomet] Cements and bone cement accessories in the United States”). *See* Complaint ¶¶ 9-12.

Respondent Heraeus Medical GmbH is a German company with a principal place of business in Wehrheim, Germany. Heraeus Medical GmbH is the successor-in-interest to Heraeus Kulzer GmbH and Kulzer & Co. GmbH, which developed bone cements originally. Now, Heraeus Medical GmbH is responsible for designing, developing, and manufacturing certain Heraeus PALACOS bone cements and accessory products. RPB at 10.

Heraeus Medical LLC (“HMUS”), a distributor for Heraeus Medical GmbH, is a Delaware limited liability company formed in June 2017 with a principal place of business in Yardley, Pennsylvania. Since the beginning of 2018, HMUS has been responsible for promoting and distributing the PALACOS products in the United States. RPB at 10. HMUS imports and sells the accused PALACOS bone cements and accessory products in the United States. Complaint ¶¶ 9-12. *See* JX-0334 (Petermann Dep.) at 19:20-20:16, 21:14-25.

C. The Asserted Trade Secrets

As set forth in Zimmer’s Fifth Updated Final Identification of Trade Secrets, dated August 12, 2020 (EDIS Doc. ID 717126), the four asserted trade secrets are:

Asserted Trade Secret 10 (“TS 10”) Quarterly reports constituting a list of customers, by territory, who purchased Heraeus cements from Zimmer Biomet in that quarter, the full names and delivery addresses of those customers, the types and quantities of the Heraeus cements delivered to those customers, and the prices charged to those customers for the Heraeus cements delivered, as supplied by Zimmer Biomet to Heraeus between October 1, 2015, and December 31, 2018, pursuant to, and during the term of, the 2012 Distribution Agreement (*see* Appendix A for embodiments of Trade Secret 10, including non-asserted embodiments), and including the data found in Excel files “ZB Analysis” (HERAEUSITC_II_0029774) and “PALACOS Customers USA Fiscal Year 2016”) (HERAEUSITC_II_0013962).

[REDACTED]

Asserted Trade Secret 11. (“TS 11”) Annual rolling forecasts constituting inventory information, inventory forecasts, sales forecasts, sales projections, and binding orders, as supplied by Zimmer Biomet to Heraeus pursuant to Article III, *et seq.*, of the 2012 Distribution Agreement, supplied between October 1, 2015, and December 31, 2018. *See* Appendix A for embodiments of Trade Secret 11.

Asserted Trade Secret 15. (“TS 15”) Customer lists related to the sale of PALACOS or bone cement accessory products constituting a compilation of Zimmer Biomet’s bone cement customer identification information (*see* Columns F, G, or H), customer contact information (*see* Columns I, J, K), and one or more of the following: territory names (*see* Columns C, R), product identification information (*see* Columns P, Q, or Z), product quantity (*see* Column S), actual sales price (*see* Column T), average sales price (calculated from actual sales price and quantity sold), and revenue (*see* Column U). *See* ZBHO-00224488 (10/31/15-12/31/15); ZBHO-00224489 (01/01/16-12/31/16); ZBHO-00224486 (01/01/17-12/31/17); and ZBHO-00224487 (01/01/18-10/31/18); *see also* Appendix A for additional embodiments of Trade Secret 15.

Asserted Trade Secret 28. (“TS 28”) The compilation of invoice-level sales data, sourced from Zimmer Biomet’s sales of PALACOS between October 1, 2015 and January 1, 2018, that is maintained on, and accessible through, Zimmer Biomet’s PROS system, and exported as [REDACTED]
See ZBHO-00224488 (10/31/15-12/31/15); ZBHO-00224489 (01/01/16-12/31/16); ZBHO-00224486 (01/01/17-12/31/17); and ZBHO-00224487 (01/01/18-10/31/18); *see also* Appendix A for additional embodiments of Trade Secret 28.

See JX-0309C.0001-2.

In its Prehearing and Post-Hearing briefs Zimmer collapsed TS 15 and TS 28 into a single asserted trade secret “compris[ing] customer lists related to the sale of PALACOS or bone cement accessory products, including the Excel file named ‘For Peterson.’” *See* CIB at 10 and CPB at 8. Complainants’ analysis and arguments also discuss TS 15 and TS 28 as if they are a single trade secret. Therefore, this Initial Determination will treat asserted TS 15 and TS 28 as a single asserted trade secret (“TS 15/28”).

D. Products at Issue

1. Accused Products

Heraeus imports into and sells the following Accused Products in the United States: PALACOS R, PALACOS R+G, PALACOS FAST R+G, PALACOS LV, PALACOS LV+G, PALACOS MV, PALACOS MV+G, PALACOS R pro 75, PALACOS R+G pro 75, PALACOS Pro nozzle short, PALACOS Pro nozzle medium, PALAMIX uno, PALAMIX duo, PALABOWL, PALAMIX nozzle slim, PALAMIX nozzle medium, PALAMIX nozzle medium, PALAMIX cement gun, PALAMIX vacuum pump, PALAMIX vac hose, and the COPAL exchange G. *See* JX-0311C.0002-3; JX-0334C (Petermann Dep.) at 21:14-18; Tr. (Petermann) at 794:5-796:5.

2. Zimmer's Domestic Products

Zimmer's domestic products at issue in this case are Biomet Bone Cement R ("BBCR") and Refobacin Bone Cement R ("RBCR") (collectively, "ZB cements"), and a number of accessory products, including plugs, mixing equipment, prep kits, centralizers, and spacer molds. *See* CX-3272C.0008-13 (Complainants' 6th Supp. Objects. and Resps. to Staff's 1st Set of Interrogatories) (listing specific product and part numbers/SKUs for each alleged domestic industry product in response, as supplemented, to Interrogatory No. 2). Zimmer also sells other accessory products in the United States, including mixing bowls and spatulas, vacuum mixing systems, cement delivery systems, components used for mixing and applying cement, various types of plugs, nozzles, and other accessories used in cemented joint replacement procedures. CX-3067C; Tr. (Armstrong) at 32:14-33:14; CDX-0008C.4.

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 a trade secret is a prerequisite of a trade secret misappropriation claim. *Certain Rubber Resins*, 2014 WL 749801, at * 5 (citing *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*”). 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

[REDACTED]

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, 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.

Sausage Casings, Inv. No. 337-TA-148/169, Initial Determination, 1984 WL 273789, at *94 (July 31, 1984) (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).



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 1336, 1340 (9th Cir. 1982)). Also, a confidential

[REDACTED]

relationship can exist in the absence of a confidentiality agreement; “an 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. False and Misleading Advertising

The Commission recognizes false advertising as a form of unfair competition under 19 U.S.C. § 1337(a)(1)(A). *See Certain Light-Emitting Diode Prods. and Components Thereof*, Inv. No. 337-TA-947, Initial Determination at 432 (July 29, 2016) (“*Certain LEDs*”). To establish a false advertising claim under the Lanham Act, a complainant must prove that:

- 1.) The [respondent] made false or misleading statements about his own or another person’s product;
- 2.) There is actual deception or at least a tendency to deceive a substantial portion of the intended audience;
- 3.) The deception is material in that it is likely to influence purchasing decisions;
- 4.) The advertised good traveled in interstate commerce; and
- 5.) There is a likelihood of the injury to the complainant in terms of declining sales, loss of good will, etc.

Certain Woven Textile Fabrics and Prods. Containing Same, 337-TA-976, Order No. 21, 2016 WL 7010667, at *5 (Nov. 10, 2016) (“*Woven Textile Fabrics*”); *see also Certain LEDs*, Initial Determination at 430-31. To demonstrate element (1) – a false or misleading statement of fact – a complainant must prove that the statement is either (i) literally false, or (ii) literally true, but ambiguous and likely to mislead, confuse, or deceive consumers. *Woven Textile Fabrics*, 2016 WL 7010667, at *5; *see also Clorox Co. Puerto Rico v. Proctor & Gamble Commercial Co.*, 228

[REDACTED]

F.3d 24, 33 (1st Cir. 2000) (“A plaintiff can succeed on a false advertising claim by proving either that an advertisement is false on its face or that the advertisement is literally true or ambiguous but likely to mislead and confuse consumers.”).

The question of literal falsity is a factual one. *Clorox Co.*, 228 F.3d at 34. The factfinder must first identify the claim that is conveyed by the advertisement, then determine whether that claim is false. *Id.* at 33; *Woven Textile Fabrics*, 2016 WL 7010667, at *6. Literal falsity can be shown based on express claims in advertisements or by demonstrating that the advertisement conveys a falsity by “necessary implication.” *Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1139 (9th Cir. 1997); *see also Clorox Co.*, 228 F.3d at 35 (explaining “[a] claim is conveyed as false by necessary implication when, considering the advertisement in its entirety, the audience would recognize the claim as readily as if it had been explicitly stated.”).

With respect to deception (element 2 above), the Lanham Act does not require proof that consumers were actually deceived if the statement is false. *Id.* In the case of a literally true but misleading statement, however, a complainant must show that the statement deceived a substantial portion of the purchasing public. *United Indus. Corp. v. Clorox Co.*, 140 F.3d 1175, 1182 (8th Cir. 1998). Alternatively, if there is proof that the respondent acted with an intent to deceive, then deception may be presumed. *Certain LEDs*, Initial Determination at 433 (citing *Cashmere & Camel Hair Mfrs. Inst. v. Saks Fifth Ave.*, 284 F.3d 302, 316 (1st Cir. 2002) (*cert. denied* 537 U.S. 1001 (2002))).

With respect to materiality (element 3 above), the false or misleading statement must be material to a substantial part of the relevant audience. That is, “[i]f a significant number of prospective purchasers are likely to attach importance to the representation in determining whether to engage in a proposed transaction, the representation is material.” *See* Restatement (Third)

[REDACTED]

Unfair Competition § 3 cmt. b. The deceptive representation need not be the sole or even the predominant factor influencing the conduct of the prospective purchasers. Nor is it necessary to demonstrate that purchasers would have acted differently in the absence of the representation. It is sufficient if the representation is likely to influence prospective purchasers to some substantial degree. *Id.*

C. Tortious Interference

The Commission recognizes that alleged violations of Section 337(a)(1)(A) predicated on non-statutory causes of action, such as tortious interference, may be brought under principles of federal common law. *See TianRui*, 661 F.3d at 1327-28; *see also Certain Indus. Automation Sys. and Components Thereof Including Control Sys., Controllers, Visualization Hardware, Motion Control Sys., Networking Equip., Safety Devices, and Power Supplies*, Inv. No. 337-TA-1074, Initial Determination at 52 (Oct. 23, 2018) (EDIS Doc. ID 661890) (“*Indus. Automation Sys.*”). To prove a claim of tortious interference, either with a contract or a business relationship, Complainants must prove: (1) there was a contract or existing valid relationship, (2) the respondent knew of it, (3) the respondent’s intentional act was a significant factor in causing breach of contract or interference, (4) the act was without justification, and (5) the act caused injury. *See Indus. Automation Sys.*, Initial Determination at 52 (citing *WaveDivision Holdings, LLC v. Highland Capital Mgmt., L.P.*, 49 A.3d 1168, 1174 (Del. 2012)); *Certain Foodservice Equip. and Components Thereof*, Inv. No. 337-TA-1166, Order No. 23, 2020 WL 2094134, at *1 (Mar. 30, 2020).

To determine whether alleged interference is improper, a number of factors must be examined, including: “(a) the nature of the actor’s conduct, (b) the actor’s motive, (c) the interests of the other with which the actor’s conduct interferes, (d) the interests sought to be advanced by

[REDACTED]

the actor, (e) the social interests in protecting the freedom of action of the actor and the contractual interests of the other, (f) the proximity or remoteness of the actor's conduct to the interference and (g) the relations between the parties." Restatement (Second) of Torts § 767. Because interference with a contract or business relationship is an intentional tort, the actor's motive must be examined to discern whether the actor intended to cause the injury by his or her actions or be substantially certain of the harmful results to be caused by his or her actions. *Id.* at § 767 cmt. b. The Restatement counsels that "[i]ntent alone, however, may not be sufficient to make the interference improper, especially when it is supplied by the actor's knowledge that the interference was a necessary consequence of his conduct rather than by his desire to bring it about." *Id.* at § 767 cmt. d (if the sole motive of the interference was the interference, it "is almost certain" the interference was improper). Therefore, it is important to analyze all the factors in their appropriate context.

In fact, acts may be "proper" where the relationship between the parties is that of competitors:

The relation between the parties is often an important factor in determining whether an interference is proper or improper. In a case where A is the actor, B is the injured party and C is the third party influenced by A's conduct, the significant relationship may be between any two of the three parties. Thus A and B may be competitors, and A's conduct in inducing C to not deal with B may be proper, though it would have been improper if he had not been a competitor.

Restatement at § 767 cmt i; *but see* Restatement at § 768 cmt e ("If the actor employs wrongful means, he is not justified under the rule stated in this Section.").

D. 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),

[REDACTED]

(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 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

[REDACTED]

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 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 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*

[REDACTED]

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 an 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” 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

[REDACTED]

the United States is a significant factor in determining whether the U.S. operation of a foreign corporation is part of the domestic industry”).

In its most recent opinion on the topic, *Certain Bone Cements, Components Thereof, And Products Containing The Same*, Inv. 337-TA-1153 Comm’n Op’n at 17 (January 12, 2021), the Commission further clarified the necessary analysis for determining whether a domestic industry exists when the complainant is a foreign manufacturer. “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.” *Id.* at 21. The first consideration is “the nature of [complainant’s] activities in the United States related to its [domestic industry product],” which is evaluated “to determine whether these activities should be considered for inclusion in an ‘industry’ in the United States.” *Id.* at 27. The investments in these activities are then compared to complainant’s sales of its domestic product to determine if the expenditures in the United States are significant when compared to its sales in the United States. *Id.* at 35-36. “In sum, . . . 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.” *Id.* at 27.

III. IMPORTATION AND SALE

Respondents “do not contest” that the accused products have been imported into the United States. *See* RPB at 19; *see also* JX-0334C (Petermann Dep.) at 19:20-20:16, 21:14-25.

IV. JURISDICTION

The scope of the Commission's *in rem* jurisdiction encompasses articles that are imported into the United States. *See* 19 U.S.C. § 1337(a)(1)(C). In view of the Respondents' statements regarding importation of its accused products, 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)(1)(A), (a)(1)(C), (a)(2). Zimmer 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 Commission.").

Heraeus argues that the Commission lacks subject matter jurisdiction over at least the false advertising and tortious interference allegations, because section 337 provides a remedy for unfair acts and unfair methods of competition, which requires competition. Respondents argue that Zimmer Biomet "no longer competes against Heraeus in selling Palacos." RPB at 8. These are substantive questions of fact, which will be addressed in the ID. Respondents do not, however, contest that the Commission has subject matter jurisdiction over the trade secret misappropriation allegations.

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).

[REDACTED]

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 these factors are relevant, each is discussed below with respect to each of the asserted trade secrets, although the analysis is sometimes the same for all groups.

A. Trade Secret 10

1. Extent Trade Secret 10 Was Known Outside Zimmer

The U.S. Distribution and Supply Agreement dated January 1, 2012 ("2012 Agreement") (see JX-0204C, Section 2.4(c)) obligated Zimmer to [REDACTED]

[REDACTED]
[REDACTED] Under the 2012 Agreement, Zimmer also had to [REDACTED]

[REDACTED]

[REDACTED] JX-0204C.0015. Zimmer asserts that the quarterly reports data that it provided to Heraeus Germany between October 1, 2015 and December 31, 2018 is the data that comprises TS 10. CPB at 12; *see also* Tr. (Armstrong) at 24:10-16; Tr. (Petermann) at 755:3-20

[REDACTED]

[REDACTED] Section 3.1 of the 2012 Agreement obligated Zimmer to [REDACTED]

[REDACTED] JX-0204C.0019-20; *see also* Tr. (Armstrong) at 24:24-25:8.

Zimmer states that for trade secrets that are compilations, such as TS 10, “it is the secrecy of the claimed trade secret as a whole that is determinative.” RIB at 12 (*citing* Restatement (Third) of Unfair Competition § 30, cmt. F (1995)). The evidence shows that the compilations within the 2012 Agreement contained confidentiality provisions that were acknowledged by both Zimmer and Heraeus. *See* JX-0204C.0113-0115; *see also* Tr. (Petermann) at 760:4-10 (“[T]his section made very clear that we had to treat the quarterly report as confidential information under section 8.1.”); Tr. (Armstrong) at 24:17-23 (noting the quarterly reports were [REDACTED])

[REDACTED]¹

Heraeus states that under Section 2.4(c) of the 2012 Agreement, Heraeus was authorized to use the Quarterly Reports “for the purpose of building an internal sales organization for the Products in the Territory or directly . . . selling the Products in the United States or Germany to Zimmer’s customers in the Territory” from January 1, 2019 forward.” *See* Tr. (Blanchard) at

¹ Staff points out that Zimmer customers also were expected to keep the terms of their respective purchase agreements confidential. SPB at 24. While the confidentiality requested by Zimmer of its customers shows that Zimmer intended this information to remain confidential, the individual customers’ information is merely part of, and does not amount to, the compilations that comprise TS 10.

[REDACTED]

213:23-214:2, 350:5-12. Thus, Heraeus argues that the limitation on the duration of the confidentiality of the reports “demonstrates that [Zimmer] did *not* make a reasonable effort to protect its trade secret.” RPB at 14 (emphasis in original). Heraeus further points to Investigation No. 337-TA-1153, where a ten year time limitation on a confidentiality obligation was seen as evidence against a finding that, in that case, the trade secret was not properly protected. *Id.* (citing *Certain Bone Cements, Components Thereof & Prods. Containing the Same*, Inv. No. 337-TA-1153, Hearing Transcript at 871:17-22, 350:13-352:25, 354:21-355:11)).

In this case, however, the TS 10 information (and, as will be discussed later, to an even greater extent TS 11) is ephemeral because the lists of customers and prices change over time. Thus, putting a time limit on this type of sales information is not unreasonable and does not place the trade secrets in jeopardy for the time for which Zimmer protected them. Moreover, TS 10 is defined as quarterly reports “supplied by Zimmer Biomet to Heraeus between October 1, 2015, and December 31, 2018, pursuant to, and *during the term of, the 2012 Distribution Agreement.*” By its own terms, therefore, TS 10 ceased to be a trade secret on January 1, 2019, and the time limit Heraeus criticizes is not especially relevant.

In any event, the evidence shows that TS 10 was treated as confidential by both Zimmer and Heraeus, and not widely known outside of Zimmer during the term of the 2012 Agreement, regardless of the length of that term.

2. Extent TS 10 Was Known Inside Zimmer

The evidence shows that the specific compilations asserted to be TS 10 were not widely known within Zimmer or within the industry at large. In particular, the data contained in the quarterly reports, which is the asserted TS 10, was generated by Zimmer using PALACOS customer sales data captured and stored by Zimmer’s PROS system, which [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] CX-3272C.0106-107 (Complainants' 6th Supp. Response to Staff's First Set of Interrogatories); *see also* Tr. (Smith) at 115:25-116:1 [REDACTED]

[REDACTED] *see, e.g.*, CX-2172C; CX-2094C; Tr. (Armstrong) at 25:25-26:8; Tr. (Smith) at 125:6-8 ("Q: Does Trade Secret 10 comprise data that's available via PROS? A. [REDACTED] [REDACTED]"). Zimmer presented evidence that the PROS system [REDACTED]

[REDACTED] Tr. (Smith) at 116:8-12; JX-0346C (Armstrong Dep.) at 79:4-21. According to Zimmer's team leader responsible for maintaining the PROS system, Mr. Michael Smith, there are currently about [REDACTED] total active users with access to PROS, while Zimmer currently has about 10,000 U.S. employees and independent contractor sales reps. Tr. (Armstrong) at 81:19-82:1. Furthermore, Mr. Smith testified that [REDACTED]

[REDACTED] *Id.* at 119:7-10, 25-120:2. As for the restricted access employees, Zimmer requires that a PROS user must have [REDACTED]

[REDACTED] Tr. (Smith) at 117-120.

Heraeus argues that files exported from PROS are not automatically password protected or marked confidential, thus negating trade secret security. JX-0352C (Kunkelmann Dep.) at 266:11-16, 269:4-21, 270:7-10, 319:15-320:3; JX-0347C (Bezjak Dep.) at 310:15-311:7, 312:5-18, 313:8-17; Tr. (Smith) at 121:23- 122:5, 149:1-19. Heraeus further argues that Zimmer does not police its distributors' protocols, and the distributor witnesses testified that [REDACTED]

[REDACTED] *See, e.g.*, JX-0351C (Fox Dep.) at 47:6-17, 47:20-48:7 ([REDACTED] [REDACTED]); JX-

[REDACTED]

0348C (Ervin Dep.) at 47:1-48:1 [REDACTED]

[REDACTED] JX-0353C (Parker Dep.) at 101:19-102:6, 135:2-4, 135:13-136:18, 153:1-4, 153:9-154:1, 154:7-155:13 [REDACTED]

[REDACTED] RX-0363C; RX-0365C.

Although Zimmer does not dispute these observations, Mr. Smith testified that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Tr. (Smith) at 118:20-25. Moreover, [REDACTED]

[REDACTED] *Id.* at 119:4-6. This limited amount of information is not TS 10, which Zimmer describes as the “[c]ompilation as a whole.” Thus, on balance TS 10 was not widely known within the company.

3. Extent of Steps Taken By Zimmer to Guard Trade Secret 10

Zimmer had physical and contractual measures in place to protect its confidential information internally, some of which have already been discussed. TS 10 was generated by and/or stored within the PROS system, which is [REDACTED]

[REDACTED] Tr (Smith) at 117:20 – 118:1. Mr. Smith testified that [REDACTED]

[REDACTED] Tr. (Smith) at 117:20-118:11 (noting that [REDACTED]

[REDACTED] Mr. Smith further

testified that, as an additional security measure, a record of PROS user activity is [REDACTED]

which allows Zimmer Biomet [REDACTED] Tr. (Smith) at 121:17- 22; *id.* at 165:12-17 [REDACTED]

[REDACTED]

[REDACTED] *see also* JX-0352C (Kunkelmann Dep.) at 274:5-10 [REDACTED]

[REDACTED] *See also* CX-3272C.110-31 (Complainants' 6th Supp. Responses to Staff's 1st Set of Rogs) (noting that, among other measures, [REDACTED])

[REDACTED] And
PROS users receive [REDACTED]

[REDACTED] Tr. (Smith) at 120:5-12;
see also CX-3167C (PROS Training Manual).

Zimmer also maintains a number of internal confidentiality protections, including [REDACTED]

[REDACTED]
[REDACTED] *See* CX- 3272C.0110-31 (Complainants' 6th Supp. Responses to Staff's 1st Set of Interrogatories); JX-0347C (Bezjak Dep.) at 383:3-14 [REDACTED]

[REDACTED] JX-0346C (Armstrong Dep.) at 32:1-33:14
[REDACTED]
[REDACTED]

[REDACTED] *see also* Tr. (Blanchard) at 184:17-185:10 (listing a number of protective measures undertaken by Zimmer). Zimmer has similar confidentiality provisions within its standard agreements with its distributors and independent sales representatives. *See, e.g.,* CX-2716C.0014 (Riccione Orthopedics Inc. Distributorship Agreement); CX-2700C.0012-.0013 (Zimmer Biomet Oregon Distributorship Agreement); CX-2704C.0016-.0018 (Ervin and Associates LLC Distributorship Agreement); *see also* JX-0348C (Ervin Dep.) at 318:20-320:14. Zimmer's distributors also undertake measures to preserve the confidentiality of Zimmer Biomet's sales data. *See, e.g.,* JX-0354C (Young Dep.) at 74:17-75:11 (Zimmer Biomet Southwest Ohio requires [REDACTED])

[REDACTED] JX-0348C (Ervin Dep.) at 320:15-322:3 (tying all of distributor's salespeople to [REDACTED] including

[REDACTED]

[REDACTED] 324:15-22 (information stored in an employee's email account would be [REDACTED])

Zimmer employees testified that Zimmer expected its customers to keep the terms of their respective purchase agreements, including pricing, confidential. *See, e.g.,* CX-2402C.0002; *see also* Tr. (Smith) at 128:22-129:13 (Zimmer fact witness Michael Smith discussing the confidentiality provision included in customer contracts); JX-0352C (Kunkelmann Dep.) at 114:19-115:7 (“So our customers are bound by confidentiality.”), 153:5-16 (explaining the importance of ensuring customers understand pricing information is confidential); Tr. (Senn) at 1074:12-18 (Heraeus’s expert testifying that in the industry vendors typically consider sales and pricing information confidential); JX-0329C (Vulgamott Dep.) at 51:15-21 (Heraeus witness agreeing it is “a common practice” in the bone cement industry to not make customer-specific pricing and quantity information public). And to the extent it reflects internal confidentiality, the 2012 Agreement itself contained confidentiality provisions that were acknowledged by both Zimmer and Heraeus. *See* JX-0204C.0113-0115; *see also* Tr. (Petermann) at 760:4-10 (“[T]his section made very clear that we had to treat the quarterly report as confidential information under section 8.1.”); Tr. (Armstrong) at 24:17-23 (noting the quarterly reports were required to be treated as “confidential for the purposes of section 8.1 [of the 2012 Distribution Agreement]”).

Taken as a whole, Zimmer’s measures to protect its alleged trade secrets meet the required standard of reasonableness. *See Merckle GmbH v. Johnson & Johnson*, 961 F. Supp. 721, 732 (D.N.J. 1997) (“The test is one of reasonable, not absolute, precautions, and the jury will be charged with considering the entire record to determine whether Merckle’s alleged trade secrets were, in fact, secret.”).

[REDACTED]

4. Value of Trade Secret 10 to Zimmer 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 can obtain economic value from its disclosure or use.” Uniform Trade Secrets Act (“UTSA”) §1(4). The compilation of customer and pricing data identified as asserted TS 10 has independent economic value; the data compiled within the PROS system, including the customer name, customer address, quantity of PALACOS purchased, and price(s) paid for PALACOS, which make up TS 10, has competitive value because such information is used “to inform pricing decisions” and provides a “competitive advantage” when responding to customer pricing inquiries. *See* Tr. (Smith) at 116:19-117:13; *see also* Tr. (Childers) at 938:2-939:3 (Heraeus corporate witness testifying that knowing PALACOS usage data is valuable to sales efforts).

Even Heraeus’s witnesses testified to the importance of the TS 10 type of information. Mr. Webb testified that Heraeus’s own targeting data base, which is similar to the PALACOS customer database maintained in the Zimmer PROS system, was valuable in developing Heraeus’ PALACOS sales strategy. *See* Tr. (Webb) at 973:2-973:21; *see also* Tr. (Senn) at 1100:17-22 (Heraeus’ expert acknowledging that [REDACTED]

[REDACTED] Moreover, the data compilations that are asserted as TS 10 (and TS 11, which is discussed later) were required to be reported to Heraeus pursuant to the terms of the 2012 Distribution Agreement. JX-0204C.0015 (2012 Distribution Agreement); *see also* Tr. (Armstrong) at 24:13-16, 25:5-8; Tr. (Petermann) at 755:3-15.

And Heraeus used the data itself to [REDACTED]

[REDACTED] Tr. (Petermann) at 755:3-20; *see also* JX-0334C (Petermann Dep.) at

[REDACTED]

37:8-18 [REDACTED]

[REDACTED] Thus, both Zimmer and Heraeus placed value on the information contained in asserted TS 10 and TS 11.

Heraeus argues that “[c]ourts routinely reject affording trade secret status to information with a short ‘shelf life’ in terms of usefulness and value. *See, e.g., Abrasic 90 Inc. v. Weldcote Metals, Inc.*, 364 F.Supp. 3d 888, 903 (N.D. Ill. 2019).” RPB at 21. Heraeus further submits that “Zimmer admits that the information underlying TS 10 is ‘dynamic in nature, and [is] constantly under development, based on an ever-changing marketplace for the sale of bone cements and bone cement accessories.’ CX-3264C at Complainants’ Resp. to Interrogatory No. 2; *see also* Tr. (Senn) at 1046:6-1047:2.” *Id.*

However, the allegations in this Investigation are of trade secret misappropriation that took place between 2017 and early 2019. During this period, the data of TS 10 was valuable because, as Zimmer notes, “it was customer-specific, detailed, accurate, and allegedly allowed Heraeus to assess its market opportunity in the U.S., identify and prioritize PALACOS customers to target, allegedly giving HMUS a head start on making sales and generating revenue – from both cement and accessories. Tr. (Blanchard) at 208:14-216:8; CDX-0003C.31-39.” CPB at 18; *see also* JX-0320C (Williamson Dep.) at 148:3-149:13 [REDACTED]

[REDACTED] JX-0334C (Petermann Dep.) at 55:8-57:10 [REDACTED]

[REDACTED] JX-0331C (Kiontke Dep.) at 82:3-86:19, 113:15-115:16, 117:18-120:3 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Therefore, TS 10 had independent economic value during the period of the alleged misappropriation.

5. The Amount of Effort or Money Expended in Development

Staff argues that because the alleged trade secrets were not intentionally developed as such, the evidence weighs against a finding that Zimmer actually expended great effort and/or money in developing the alleged trade secrets. SPB at 16. Staff further submits that the compilations comprising the alleged trade secrets were “merely the result of Complainants’ contractual obligations to aggregate and report specific data to Heraeus.” *Id.* at 16-17. While this is technically true, the fact remains that Zimmer expended effort and expense in creating the compilations that are asserted as trade secrets. As Zimmer points out, “in order to generate sales data, Zimmer Biomet must make sales in the first place, and doing so requires a significant amount of time and effort, including establishing price guidelines, responding to RFP requests, negotiating with customers, and making pricing decisions.” CPB at 23, *citing* Tr. (Armstrong) 25:25-26:18; Tr. (Smith) at 108:3-6, 111:5-25, 167:17-23; Tr. (Blanchard) at 192:16-193:5, 193:23-194:9; Tr. (DiGioia) at 442:19-444:11; Tr. (Shapiro) at 1233:24-1234:14.

Although such efforts presumably pale in comparison to, say, bone cement formulation research and development efforts, the type of expenditure here is nonetheless recognized as a legitimate effort in developing a trade secret. Whether the party creates the information to be a trade secret in the first instance, or uses the information created over time to create a compiled set of data that it treats as a trade secret, is of no moment. In *Crawler*, for example, Trade Secret 14 was defined as: “Manitowoc’s pricing of its cranes within the domestic industry targeted by the

[REDACTED]

Sany SCCS500 Crane, including distributor discounts, profit margins, unit and dollar volumes, and manufacturing costs.” *Crawler*, Inv. No. 337-TA-887, Initial Determination, at 174. This was found to be a trade secret, in part because Manitowoc:

spends substantial time and resources setting dealer discount prices. Many factors are determined and analyzed prior to a discount being established, including dealer stocking expectations, typical sales cycle and costs, product support requirements, product development costs and retail purchase price. . . . Manitowoc expends considerable time and effort developing its detailed cost and pricing information by dedicating time during the development of each of its crane models to generating that information. and by working with its dealers several times each year to get feedback on its current pricing.

Id. Zimmer similarly presents evidence of its time, expense, and effort to create its own *Crawler*-type compilations.

Thus, the effort put forth by Zimmer in creating the compilation that makes up TS 10 weighs at least somewhat in favor of finding that TS 10 is a protectable trade secret.

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

Zimmer asserts that TS 10 includes the specific prices and quantities for all PALACOS sold to Zimmer’s PALACOS customers, on a quarterly basis, during the life of the 2012 Agreement. Thus, Zimmer submits that TS 10 is extremely difficult to duplicate because “someone would have to go speak with each and every customer . . . find out if [they are] PALACOS users, how much they were using and how much they were paying for it” Tr. (Blanchard) at 195:10-22.

Heraeus, on the other hand, argues that Zimmer’s bone cement pricing and customer information is not secret because “it is common practice for customers to disclose the prices they paid (including Zimmer’s) to competitors like Heraeus.” RPB at 20. Heraeus further argues that “benchmarking organizations” such as Orthopedic News Network (“ONN”) gather the actual invoice information from hospitals and medical centers and distribute pricing information to its

members. *Id.* at 18, 20 *See also* Tr. (Armstrong) at 61:5-62:7, 68:20-69:14, 70:3-6, 70:14-71:9, 71:12-14; JX-0177C (“2017 Bone Cement Update,” which includes pricing information); RX-0976C (Zimmer marketing strategy, including pricing); Tr. (Childers) at 861:19-862:11, 878:19-883:3; JX-0037C (emails between Heraeus and third parties, including pricing information); Tr. (Senn) at 1015:4-25, 1019:11-16, 1019:24-1020:11, 1028:5-13, 1028:19-1030:10, 1038:17-1040:14; JX-0344C (Mendenhall Dep.) at 19:2-22:17, 24:20-26:11, 36:6-38:7, 39:12-41:1, 41:10-22, 51:21-57:14, 59:11-60:22, 65:3-7, 68:1-14, 69:21-70:6. Finally, Heraeus argues that anyone in the industry can ascertain the identity of Zimmer’s customers by asking a surgeon or hospital what bone cement they currently purchase. RPB at 20; *see also* Tr. (Blanchard) at 258:15-269:3 (during her time at Zimmer she was able to determine which competitors’ bone cements the larger customers were using and noting that surgeons will actually disclose exactly which products they are using), 260:4-21 (agreeing that when a customer engages in all-play pricing, a vendor will know the target price that all vendors must meet), 260:24-261:22 (agreeing that where customers set capitated pricing, vendors competing for that business are aware of the price they must meet to engage with that customer); 262:2-5 (admitting that customers “can, and sometimes they do” share pricing information despite contractual confidentiality obligations).

While the evidence shows that some portions of the asserted TS 10 compilation may have been easily ascertainable, the *entirety* of the specific PALACOS prices and quantities for all customers in a given quarter was not easily ascertainable. Zimmer’s witnesses emphasized and relied on the fact that the asserted trade secrets are compilations of data, rather than individual data points. *See, e.g.,* Tr. (Armstrong) at 27:11-15 (explaining that the “entire compilation of all that data really represents the value of what our entire business is worth”); Tr. (Blanchard) at 252:10-16 (agreeing that asserted TS 10 is a compilation of various data). None of the testimony and

[REDACTED]

evidence showing select pricing and quantity disclosures establishes that the entire compilation claimed to be TS 10 was readily ascertainable from the various industry sources such as benchmarking organizations, IDNS and GPOs, or customers themselves. As Staff points out, none of the examples of industry sources demonstrate that the pricing and usage/quantity information for all health systems using PALACOS in a given quarter (*i.e.*, the compilation of data of asserted TS 10) would have been known to and distributed by a given health system. SPB at 27.

Accordingly, the evidence shows that the compilation asserted as TS 10 is not readily ascertainable. And balancing the evidence relating to all six parameters, Zimmer's Trade Secret 10 is a protectable trade secret.

B. Trade Secret 11

Trade Secret 11 ("TS 11") is defined as:

Annual rolling forecasts constituting inventory information, inventory forecasts, sales forecasts, sales projections, and binding orders, as supplied by Zimmer Biomet to Heraeus pursuant to Article III, *et seq.*, of the 2012 Distribution Agreement, supplied between October 1, 2015, and December 31, 2018.

1. Extent Trade Secret 11 Was Known Outside Zimmer

TS 11 was created from the [REDACTED]

[REDACTED] Tr. (Armstrong) at 28:4-13; 28:19-22 (TS 11 comprises [REDACTED] that is used to [REDACTED]

[REDACTED] Zimmer was obligated to send this inventory forecast information to Heraeus Germany pursuant to the terms of the 2012 Agreement. Thus, the information always was known to Heraeus Germany, and within that organization, the Customer Service Department provided the reports to Heraeus's Market Intelligence department, who would

[REDACTED]

[REDACTED] See JX-0311C.0091 (Respondents' 8th Supp. Responses to

[REDACTED]

Complainants’ First Set of Interrogatories); Tr. (Petermann) at 822:16-21 (describing Ms. Thiele as the Heraeus employee “responsible for the relationship with Zimmer Surgical”); *see also* JX-0320C (Williamson Dep.) at 247:19-25 [REDACTED]

[REDACTED] JX-0334C (Petermann Dep.) at 36:21-37:25 [REDACTED]

[REDACTED]

[REDACTED]

Zimmer argues, however, that TS 11 was protected as “Confidential Information” under the 2012 Agreement, and thus, the limited number of Heraeus employees were the only outside personnel who had access to this information. RRB at 5; *see* Tr. (Petermann) at 760:4-10 (“[T]his section made very clear that we had to treat the quarterly report as confidential information under section 8.1.”); Tr. (Blanchard) at 356:10-357:1, 358:8-359:1; JX-0204C.15, 33-34. To be sure, as with the discussion regarding TS 10 above, Heraeus presented evidence showing that customer pricing and sales information is readily ascertainable by those in the industry because the customers themselves often share this data and it is published in various industry publications. However, also similar to TS 10, no evidence was presented showing that the specific entire compilations that are claimed as TS 11 are publicly known or known within the wider industry.

Thus, as with TS 10, the evidence shows that TS 11 was not widely known outside of Zimmer.

2. Extent Trade Secret 11 Was Known Inside Zimmer

The discussion of Zimmer’s internal protection of TS 11 is similar to that of TS 10 because the information used for TS 11 also is [REDACTED] As discussed previously, the limited number of employees involved in creating the compilations and the security measures

[REDACTED]

Zimmer uses in granting access to the PROS system illustrate that Asserted TS 11 was not generally known within Zimmer.

3. Extent of Steps Taken by Zimmer to Guard Trade Secret 11

Zimmer asserts that TS 11 was protected “by the general measures Zimmer Biomet undertakes to protect its confidential information discussed above . . . with respect to TS 10.” RRB at 12. The Staff supports this position. SPB at 22-24. Heraeus presented no evidence to the contrary.

Accordingly, the evidence shows that Zimmer took reasonable steps to guards TS 11.

4. Value of TS 11 to Zimmer and Competitors

The forecasts and inventory reports that comprise TS 11 were generated pursuant to the terms of the 2012 Agreement, and the last of the rolling forecasts was provided to Heraeus long before that Agreement terminated. *See* Tr. (Armstrong) at 76:7-10 (indicating the last time an annual rolling forecast was provided to Heraeus was in September 2017 for the following 2018 year). Mr. Armstrong testified that each annual rolling forecast submitted to Heraeus was later replaced by an updated quarterly forecast. Tr. (Armstrong) at 75:11-18. Furthermore, Mr. Armstrong testified that the rolling forecasts did not contain customer identification information, could not be used to target customers, did not include a price list or any pricing information (including historical pricing data), could not be used to determine what price a customer paid or what quantity they purchased, and did not include any Zimmer Biomet sales or marketing strategy information. Tr. (Armstrong) at 76:11-78:4. Finally, Heraeus’ expert Mr. Senn opined that these rolling forecasts have no real value, at least because the forecasts are constantly updated and replaced, rendering the prior forecast obsolete. Tr. (Senn) at 1065:23-1066:3.

[REDACTED]

Zimmer argues that TS 11 was valuable to understand forecasts and to determine its current inventory, and that TS 11 was valuable to Heraeus because Heraeus had no other source of U.S. market information at the time. CPB at 32. However, the fact remains that the information contained within TS 11 became outdated every quarter and was necessarily especially ephemeral.

Thus, TS 11 had little independent economic value to Zimmer and its competitors.

5. The Amount of Effort or Money Expended in Development

Zimmer failed to provide much information or evidence related to its effort expended in developing TS 11. The only statement Zimmer made regarding such effort is that it [REDACTED] [REDACTED] which required tremendous efforts and investments.” CPB at 33. Zimmer relied on and compared the effort it expended in creating TS 10 as translating to effort in developing TS 11. Such a comparison is not especially apt; TS 10 is a relatively comprehensive compilation of data, while TS 11 is a collection of short-lived forecasts. Generating such forecasts may have required considerable effort, but Zimmer provided little evidence of that.

Therefore, this factor does not weigh in favor of finding that TS 11 is a protectable trade secret.

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

The information within TS 11, which was provided by Zimmer to Heraeus pursuant to the 2012 Agreement, was likely not easily ascertainable to the public or to competitors other than Heraeus, because it constituted forecasts and projections. Nonetheless, Zimmer provides no evidence specific to TS 11 regarding this factor (*see* CPB at 35), and it stands to reason that TS 11 could have been readily duplicated by Heraeus. The evidence shows that Heraeus [REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Tr. (Petermann) at 833:21-834:4 [REDACTED]

834:21-23 [REDACTED]

[REDACTED] As Heraeus states, even apart from any Zimmer reports “Heraeus Germany knew how much inventory it sold to Zimmer because Heraeus Germany *manufactured and shipped those exact quantities to Zimmer.*” RPB at 24 (emphasis in original) (citing Tr. (Petermann) at 833:21-834:4, 834:21-23; Tr. (Senn) at 1064:15-1065:3).²

On balance, not all factors weigh against the status of TS 11 as a trade secret. In particular, TS 11 was not known to a great extent either inside or outside of Zimmer, and Zimmer took reasonable steps to keep TS 11 secret. However, Zimmer failed to adequately show how valuable the information of TS 11 was, what effort went into creating the information, and how easy or difficult it was for others to ascertain the information of TS 11. In fact, the evidence shows that Heraeus itself was likely fully capable of generating the same forecasts and projections of TS 11 independently of Zimmer’s input. On balance, therefore, TS 11 is not a protectable trade secret.

C. The Asserted Trade Secrets 15 and 28

In its Post-Hearing Brief, Zimmer defined Trade Secrets 15 and 28 to “comprise compilations of customer and sales data stored in and accessible via the PROS system. The ‘For

² Staff points out that there is some evidence suggesting that Zimmer also readily provided the type of inventory/forecast information alleged to be asserted TS 11 to companies with whom it did not have a confidential business relationship. For example, when trying to sell Palacos R+G cement, Zimmer’s VP for Group Purchasing Organizations [REDACTED]

[REDACTED] SPB at 28, n. 22. Even discounting this evidence, though, this final factor does not weigh in favor of protectability.

[REDACTED]

Peterson’ file is an embodiment of TS 15 and 28.” CPB at 33-34 (*citing* CX-2622C; Tr. (Senn) at 1081:8-15). The evidence shows that the “For Peterson” file was downloaded from the Zimmer PROS system by a former Zimmer employee the evening before his final day at Zimmer. Tr. (Smith) at 123:15-23. Zimmer’s fact witness, Michael Smith, testified that the “For Peterson” file “includes a full customer list for the Mid-Atlantic territory [as well as] a substantial amount of invoice data for that territory related to bone cement and accessories.” Tr. (Smith) at 123:24-124:3; 162:13-18 (the data in the “For Peterson” file is limited to data from 2016 to 2017). Staff further notes that asserted TS 15 includes customer sales data for accessory products (in addition to PALACOS bone cements) while asserted TS 28 is identified as invoice-level PALACOS sales information stored in the PROS system. SPB at 29, n. 23. Naturally, many of the factors considered above for TS 10 and 11 will apply to the alleged TS 15/28 because these also are compilations residing on the PROS system.

1. Extent Trade Secrets 15 and 28 Were Known Outside Zimmer

As noted, the compilations that make up TS 15/28 were stored on the PROS system. Thus, the same precautions that Zimmer took in protecting TS 10 from disclosure are equally applicable with respect to TS 15/28. *See* CPB at 34. However, the customer-specific data related to the accessory product sales that were in the “For Peterson” file was not information that Zimmer was obliged to share with Heraeus under the 2012 Agreement. Tr. (Smith) at 124:4-25; JX-0328C (Burns) at 196-201. Thus, the compilations of TS 15/28 were not known outside Zimmer until the “For Peterson” file was created and removed from Zimmer on a thumb drive.

2. Extent Trade Secrets 15/28 Were Known Inside Zimmer

The in-house protection of Zimmer’s TS 15/28 is the same as its protection of TS 10, because all the information was stored on the PROS system. In fact, the “For Peterson” file itself

[REDACTED]

was technically known only to Mr. Burns, because he logged into PROS and personally generated it. *See* JX-0328C (Burns) at 187:18-188:14, 201:25-202:6, 209:2-14. Thus, TS 15/28 were reasonably protected within Zimmer.

3. Extent of Steps Taken By Zimmer to Guard Trade Secrets 15/28

The same steps taken to protect TS 10 were taken by Zimmer in protecting TS 15/28 because, again, this information resided on the PROS system. Accordingly, Zimmer took reasonable steps to guard TS 15/28.

4. Value of Trade Secrets 15/28 to Zimmer and Competitors

The evidence regarding the value of asserted TS 10 also is generally applicable to the “For Peterson” file, because the “For Peterson” file consists of a compilation of specific customer pricing and usage/quantity data aggregated for bone cement products and accessory products for Zimmer’s customers in its Mid-Atlantic sales region. *See* CX-2622C. Thus, similar to the discussion of asserted TS 10, the data compilation in the “For Peterson” file has competitive value because it may be used to [REDACTED]

[REDACTED] Tr. (Smith) at 125:9-21.

Zimmer argues that the “For Peterson” file actually had additional value over TS 10 data because it [REDACTED]

[REDACTED] CX-2622C; Tr. (Blanchard) at 239:3-10; Tr. (Senn) at 1053:11-17. This stands to reason; the value of TS 15/28 to Heraeus was increased because [REDACTED]

[REDACTED] CPB at 35 (citing JX- 0320C (Williamson Dep.) at 65:8-23). Moreover, for Heraeus such specific information had particular value because [REDACTED]

[REDACTED] *Id.* (citing CX-1727C.0012).

[REDACTED]

Overall, TS 15/28 was valuable to itself and to Heraeus.

5. The Amount of Effort or Money Expended by Zimmer

Zimmer did not present evidence regarding the development of TS 15/28, but instead relied on the evidence related to TS 10. *See* CPB at 35. As pointed out by Staff, Zimmer presented no evidence quantifying its efforts related solely to the development of the “For Peterson” file, nor is there an apportionment of efforts specific to the aggregation of the data in the “For Peterson” file. SPB at 31. In fact, the evidence indicates that the data within the PROS system is [REDACTED] [REDACTED] *See, e.g.,* CX-3272C.0106-107 (describing the many different types of data compiled and stored in PROS [REDACTED] Tr. (Smith) at 164:9-23 (PROS has [REDACTED]” that have been [REDACTED] 165:1-4 (describing how sales data [REDACTED] [REDACTED]

Therefore, the evidence does not indicate that Zimmer expended great effort or money in developing TS 15/28 beyond that of TS 10.

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

Zimmer also did not present evidence regarding ease or difficulty of duplication by others. *See* CPB at 35. Nonetheless, because TS 15/28 contains detailed, customer-level information as a compilation of various sources, it is likely that others (including Heraeus) would have been hard-pressed to duplicate it. *See* JX-0309.0001-2 (Complainants’ Fifth Updated Final Identification of Trade Secrets, defining Asserted TS 15/28 as customer lists that contain detailed customer contact and sales information, including data such as customer identification information, customer contact information, product and quantity sold information, sales price or average sales price,

[REDACTED]

invoice data, and revenue). And no evidence was presented to show that the entire compilation was easily procured. Thus, TS 15/28 was not easy to acquire and/or duplicate by others.

On balance, although not all factors weigh heavily in favor of protectability, more do than with TS 11, and the fact that TS 15/28 essentially did not exist until it was created by one person suggests a confidentiality and value that far exceeds that of TS 11. Therefore, TS 15/28 are protectable trade secrets, largely based on the same analysis as for TS 10.

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)).

Zimmer alleges that it owns the trade secrets because its "personnel, affiliates, agents, and independent contractors" developed the information "for use in carrying out Zimmer Biomet's business." CPB at 35-36 (citing Tr. (Armstrong) at 31:12-22; Tr. (Blanchard) at 223:23-224:9). Respondents dispute that Zimmer actually developed and owns the asserted trade secrets, claiming Zimmer "inherited many legacy customers from Smith & Nephew, a distributor that Heraeus

[REDACTED]

engaged to sell PALACOS in the United States before Biomet and Zimmer Biomet. In fact, Zimmer has not provided any evidence that it initially created the relationships with the customers it claims are trade secrets.” RPB at 25-26 (citing RX-2316C (Krebs Dep.) at 28:21-25, 29:8-10, 45:2-5 [REDACTED])

[REDACTED] This argument is misplaced. The trade secrets are detailed compilations of information gathered over the course of a few, recent years. Even if the Smith & Nephew witness’ testimony is accurate – and the activity referred to occurred almost 25 years ago – there is no direct evidence of specific information that was shared between Zimmer and Smith & Nephew, nor is there sufficient evidence to undermine the conclusion that Zimmer developed, possesses, and uses the trade secrets asserted here (including TS 11, even though it is not protectable).

On balance, therefore, the evidence shows that Complainants possess these secrets and have the right to use them in their business, and have kept the compilations secret such that they own them. *See* Tr. (Armstrong) at 24:13-25:8, 25:25-26:8, 28:4-13 (quarterly reports and rolling forecasts/inventory), 29:11-23, 30:15-21 (“For Peterson” data), 31:12-13 (testifying that Zimmer is the owner of the asserted trade secrets); Tr. (Blanchard) at 223:23-224:9.

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 example, 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 the respondent “wrongfully took Complainant’s trade secrets by unfair means”

[REDACTED]

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).

1. TS 10 and TS 11

The information embodied in TS 10 (and TS 11, to the extent it is found to be a protectable trade secret) was shared by Zimmer with Heraeus Germany under the 2012 Agreement. Specifically, [REDACTED]

[REDACTED] JX-0204C.0015, .0019. Heraeus Germany was required [REDACTED]

[REDACTED] JX-0204C.0033-0034; Tr. (Petermann) at 760:4-10, 761:18-23; Tr. (Blanchard) at 190:16-191:22; JX-0334C (Petermann Dep.) at 36:21-37:5, 40:25-41:133, 46:4-10; JX-0320C (Williamson Dep.) at 40:17-18, 42:1-20, 43:4-6, 47:14-18. Moreover, Heraeus Germany was required [REDACTED]

[REDACTED] JX-0204C.0034, § 8.1(d); Tr. (Blanchard) at 186:2-18; JX-0362C (Hofer Dep.) at 84:11-86:2; JX-0363C (Rohn Dep.) at 53:3-54:9.

Therefore, Respondents obtained TS 10 and TS 11 from Complainants while in a confidential relationship.

2. TS 15/28

The evidence shows that James "Worth" Burns, Zimmer Biomet's Director of Enterprise Solutions for the Southeastern United States, left Zimmer on December 15, 2017 to become Heraeus' Regional Sales Director, Mid-Atlantic. JX-0328C (Burns Dep.) at 177:6-17; CX-0116 (Burns resumé). The night before leaving Zimmer, Mr. Burns exported TS 15 and TS 28,

[REDACTED]

containing bone cement and accessory customer information and sales data from the Mid-Atlantic region from Zimmer's PROS system, saved it on a USB key, naming the file "For Peterson," and took the USB key with him. JX-0328C (Burns Dep.) at 177:6-17, 186:19-195:13, 210:2-5; CX-2278C; Tr. (Senn) at 1081:8-15. The information on the "For Peterson" file included, in addition to some information that was disclosed to Heraeus under the 2012 Agreement, additional customer-specific data concerning accessory products. Tr. (Blanchard) at 184:5-12. This was a violation of his employment agreement with Zimmer Biomet. CX-2268C; *see* Tr. (Armstrong) at 123:15-18 (noting that CX-2622C is the file Mr. Burns downloaded from PROS); Tr. (Blanchard) at 239:3-10. Zimmer alleges that Mr. Burns then used the "For Peterson" file to perform his job duties at Heraeus, which makes Heraeus "liable for Mr. Burns' action because he was acting within the scope of his employment." CPB at 76.

Zimmer's position is not supported by the evidence. Absolutely no evidence was presented that showed that Heraeus hired Mr. Burns in order to obtain the data contained in the "For Peterson" file. Instead, the evidence shows that Heraeus had no knowledge of the "For Peterson" file or its relationship to Mr. Burns. *See* Tr. (Childers) at 851:6-18 (testifying that neither he nor anyone else at HMUS were aware that Mr. Burns had taken information from Zimmer Biomet at the time Mr. Burns joined Heraeus). In fact, Heraeus did not seek Mr. Burns out for employment – Mr. Burns sought employment with Heraeus. JX-0328C (Burns Dep.) at 151:10-152:10. And the "For Peterson" file contained information regarding the Mid-Atlantic region, but while employed with Zimmer, Mr. Burns was responsible for sales activity in the Southeastern part of the United States. *See* JX-0328C (Burns Dep.) at 149:12-18, 49:11-50:20, 177:21-24; *see also* JX-0311.0069 (Resp. 8th Supp. Responses to 1st set of Interrogatories). Mr. Burns would not have

[REDACTED]

been able to use the “For Peterson” file to carry out his duties at Heraeus, and there is no evidence he disclosed the file to anyone who would have been able to do so.

The evidence further shows that Heraeus and Mr. Childers (Mr. Burns’ superior) did not even become aware of Mr. Burns’ actions with respect to “For Peterson” file until the Indiana litigation. Tr. (Childers) at 851:6-18. And finally, Mr. Childers testified that he had never seen the contents of the “For Peterson” file. Tr. (Childers) at 852:6-8.

Therefore, there was no disclosure or wrongful taking by Heraeus of TS 15/28.

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 [it] is relied on to assist or accelerate research or development.” *Certain Crawler Cranes*, Initial Determination, at 26-27 (citing 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. TS 10

Disclosures by Heraeus Germany to Third Parties

Zimmer alleges that Heraeus wrongfully disclosed TS 10 to a number of third parties, and these disclosures amounted to a wrongful use that caused injury to Zimmer. However, the evidence fails to show either wrongful disclosure or injury. As has been discussed throughout this case, Zimmer’s alleged trade secrets are compilations, and “it is the secrecy of the claimed trade secret *as a whole* that is determinative.” Restatement (Third) of Unfair Competition § 30, cmt. F (1995)(emphasis added). The Staff argues that since Complainants relied on a specific “comprehensive compilation of customer-specific prices” to establish the existence of a

[REDACTED]

protectable trade secret, “evidence showing anything less than the use of the ‘comprehensive compilation’ is not sufficient for Zimmer Biomet to carry its burden of proving misappropriation.” SPB at 37, n. 31. In other words, “the very characteristics of a ‘comprehensive compilation’ that were used to shield the asserted trade secret from being deemed publicly known or readily ascertainable cannot then be used as a sword to allege misappropriation with only some partial portion of the compilation.” *Id.* I agree. And because Zimmer fails to present evidence that the entire compilation (or even a majority of information within the compilation) that makes up TS 10 was ever disclosed to any party, Zimmer has not shown that TS 10 was misappropriated. *See* Tr. (Senn) at 1063:15-22 (opining that the entire compilation was not disclosed); *see also* Tr. (Blanchard) at 194:19-23 (Zimmer’s expert agreeing that she had seen no evidence that substantial portions of asserted TS 10 had been shared beyond Zimmer and Heraeus).

Nonetheless, Zimmer’s specific allegations will be addressed. Zimmer contends that Heraeus Germany improperly shared information derived from a Quarterly Report (which, in part, makes up TS 10) with [REDACTED] in May 2017. Tr. (Blanchard) at 205:15-206:13; *see also* Tr. (Senn) at 1054:14-1058:4. [REDACTED] JX-0334C (Petermann Dep.) at 160:22-161:16; 770:21-25; CX-1729C; JX-0320C (Williamson Dep.) at 105:2-19. For that workshop, [REDACTED] asked Heraeus Germany to provide a [REDACTED]

[REDACTED]

[REDACTED] Tr. (Blanchard) at 205:23-206:4; CX-1358C. Zimmer alleges that the information that Heraeus Germany sent to [REDACTED] was “derived from TS 10 data.” CPB at 54. Zimmer, however, does not even allege, much less prove, that [REDACTED] received the whole of TS 10.

[REDACTED]

For its part, Heraeus contends that “the alleged use or disclosure was permitted by the Agreement, which allowed Heraeus Germany to [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] RPB at 31-32, *citing* JX-0204C.0034, § 8.1(b). Heraeus offers evidence that [REDACTED]

[REDACTED]

[REDACTED] Tr. (Petermann) at 771:25-772:6. Moreover, the information was subject to the parties’ NDA, which restricted [REDACTED] use or disclosure of the document. CX-1729C; Tr. (Petermann) at 771:25-772:6; JX-0320C (Williamson Dep.) at 105:2-12. Such evidence rebuts any claim of wrongful taking of TS 10 by Heraeus.

Zimmer also alleges that Heraeus Germany misappropriated TS 10 in 2017 when it gave information, which was derived from a Quarterly Report, to [REDACTED] [REDACTED]

[REDACTED]

[REDACTED] Tr. (Petermann) at 774:21-25; JX-0334C (Petermann Dep.) at 48:3-49:1. Heraeus’ discussions with [REDACTED] took place in May-September 2017 and were subject to an NDA. Tr. (Petermann) at 775:1-776:2; JX-0158C. The information that Heraeus provided [REDACTED] was, as even Zimmer describes, “abridged TS 10 data” and data “derived” from TS 10. CPB at 58, 57. The information consisted of a chart that contained three numbers allegedly derived from a 2016 Quarterly Report: [REDACTED]

[REDACTED] and [REDACTED] CX-3261C. Heraeus Germany also provided data identifying customers as low- to high-volume. Tr.

[REDACTED]

(Petermann) at 775:8-18; JX-0320C (Williamson Dep.) at 158:2-159:1; JX-0334C (Petermann Dep.) at 98:13-17. Therefore, Heraeus did not share with [REDACTED] any of the Quarterly Reports, any pricing, quantities sold, or customer identification information. Tr. (Petermann) at 774:21-778:4, 804:16-21, 805:1-808:8, 809:5-22. As Heraeus points out, “the numbers shared with [REDACTED] cannot constitute a disclosure of Trade Secret 10 because most of the numbers are round-number ‘approximations,’ and the numbers do not correspond with the data in the alleged source document.” RPB at 32, *citing* Tr. (Senn) at 1055:8-1056:3. Thus, the information that was given to [REDACTED] was neither precise nor substantial enough to “enable[] another to learn the trade secret.” Restatement (Third) of Unfair Competition § 40, cmt. (c).

Finally, Zimmer alleges misappropriation of TS 10 when Heraeus Germany sent [REDACTED] a presentation marked “Confidential!” in July 2017. JX-0139C; CX-1496C. According to Zimmer, this presentation included “the same statistics derived from a substantial portion of TS 10 data for 2016 that were shared with [REDACTED] CPB at 60 (citing JX-0139C.0016). As discussed, this type of information does not amount to TS 10 because it is not the entire compilation. Furthermore, Heraeus signed confidentiality agreements with [REDACTED] dated July 31, 2017 (RX-2469C), September 11, 2017 (RX-2470C), and October 10, 2017 (CX-0347C).

Zimmer therefore fails to prove that TS 10 was wrongfully misappropriated by Heraeus’ communications with third parties.

Wrongful Use By HMUS

Zimmer alleges that Heraeus Germany’s transmission of its internal analyses of the Zimmer Quarterly Reports to Mr. Childers was improper. However, when Heraeus Germany sent the Quarterly Reports to Mr. Childers, he was Heraeus Germany’s U.S. country manager. Ms.

[REDACTED]

Petermann testified that sending such files to Mr. Childers at that time was in keeping with its practices of sharing the same analyses with his predecessor as U.S. country manager, Tom Stafford. Tr. (Peterman) at 756:23-757:17. Thus, this type of transmission was not misuse of the trade secret, but was instead allowed under the 2012 Agreement. JX-0204C.0034.

Zimmer also cites a number of specific incidents that it submits proves misuse of TS 10 by Mr. Childers and others at HMUS. However, the evidence that Zimmer offers is speculative. Zimmer used forensic evidence from HMUS employees' computers, but was only able to compare versions of the PALACOS customer USA file that originally was sent from Heraeus Germany to files that were on HMUS employees' computers. CPB at 42-43. According to Zimmer, "Mr. Childers relied extensively on the PALACOS Customers USA File to [REDACTED]

[REDACTED]

[REDACTED]" CPB at 44 (citing, *inter alia*, CDX-0048C.4-5; CDX-0046C, rows 74-75, 80-81, 83-84, 88, 93, 95-98 (indicating file was in an open state on each of Jan. 30-Feb. 2, twice on Feb. 6, on Feb. 8, twice on Feb. 13, on Feb. 14, and twice on Feb. 15, 2018)). Zimmer further alleges that Mr. Childers sent a "modified version of the PALACOS Customers USA File to Robert Kolbe." CPB at 46. Mr. Kolbe allegedly then saved the file and modified it by listing customers in alphabetical order by state, and then in descending order by Sales Amount within each state, and sent his version to National Sales Directors, Paul Cruz and Keith Vulgamott on January 1, 2018. *Id.* at 46-47. Zimmer followed the forensic trail of these files and notes that the PALACOS customers USA File was "in an open state 50 times on 19 separate dates" between Jan 20 and February 15, 2018. *Id.* at 48 (emphasis in original). Zimmer also followed the forensic trail of Mr. Vulgamott's computer and found that Mr. Vulgamott created files containing region-specific folders. *Id.* at 49 (emphasis in original).

[REDACTED]

Zimmer alleges that this forensic evidence proves that HMUS used the TS 10 files in 2017 and 2018 “for purposes of setting up a sales force and making sales, in direct contravention of the Distribution Agreement.” CPB at 52. However, this evidence shows no more than that certain files were opened, saved, and sent to others. By contrast, Heraeus employees testified (both during the evidentiary hearing and by deposition) that they did not rely on information obtained from Zimmer Quarterly Reports. *See, e.g.*, JX-0339C (R. Kolbe Dep.) at 44-47; JX-0335C (Cruz Dep.) at 59-60, 80-81; Tr. (Childers) at 870:17-871:4; Tr. (Webb) at 972:10-973:1. Mr. Vulgamott claimed he did not recall making or using these files. JX-0329C (Vulgamott Dep.) at 107-116 (discussing JX-0154C), at 130-136 (discussing CX-1677C), at 122-123 (discussing JX-0153C), at 123-128 (discussing JX-0155C), 126-138. He also denied using the PALACOS Customers USA File to perform his job duties. *Id.* at 135:1-136:24.9. Mr. Kolbe could not recall why he sent Cruz and Vulgamott the file, or if he discussed it with them. JX-0339C (R. Kolbe Dep.) at 100:9-101:15. Mr. Cruz does not recall opening the “Copy of PALACOS Customers USA FY 2016” file that he received from Mr. Kolbe or discussing the email with Mr. Kolbe. JX-0335C (Cruz Dep.) at 151:13-152:18. He also does not recall seeing the file before, or saving it to his computer, or editing it. JX-0335C (Cruz Dep.) at 170:5-172:7. And Heraeus presented evidence that HMUS spent considerable time and effort developing a customer target database primarily from CMS data. Mr. Webb, HMUS’ Vice President of marketing, testified in detail how HMUS was able to independently develop a targeting database in approximately two weeks of work for less than \$7,000. Tr. (Webb) at 971:12-21, 969:7-14.

So the forensic evidence of use of Zimmer Quarterly Reports by Heraeus does not show misappropriation, and the totality of the record does not support a finding of misappropriation of TS 10 by Heraeus.



2. TS 11

As discussed above, TS 11 is not a valid trade secret. However, to the extent TS 11 is found protectable, the evidence fails to show wrongful use by Heraeus causing injury to Zimmer. Zimmer alleges that, “Heraeus misappropriated TS 11 in 2017 when it used the ‘2018 Forecast and Binding Order’ to evaluate its 2018 market opportunity.” CPB at 61 (citing CX-1307C.0003). Zimmer further alleges that Heraeus “misappropriated TS 11 in mid-2018 when it used the information to decide not to fill Zimmer Biomet’s firm orders and project when Zimmer Biomet would run out of PALACOS.” CPB at 62 (citing JX-0334C (Petermann Dep.) at 135:23-137:8; CX-1319C; CX-1365C; CX-1366C).

Zimmer provides little to no evidence of misappropriation and misuse of TS 11. To the extent Heraeus used the rolling forecasts and inventory information of asserted TS 11, the evidence shows that the use was permitted under the terms of the 2012 Agreement because the use was “in connection with the discharge of [Heraeus’s] obligations.” JX-0204C.0034, § 8.1(b); *see also*, *e.g.*, Tr. (Petermann) at 763:9-764:12; JX-0334 (Petermann Dep. Tr.) at 140:5-141:9. As discussed earlier, Heraeus Germany did not need TS 11 data because it knew how much inventory it sold to Zimmer. RPB at 24 (emphasis in original) (citing Tr. (Petermann) at 833:21-834:4, 834:21-23; Tr. (Senn) at 1064:15-1065:3)). Furthermore, as Staff points out, Complainants’ expert Dr. Blanchard provided no opinion or evidence that asserted TS 11 was misappropriated. Consequently, there is insufficient evidence of misappropriation of TS 11.

3. TS 15/28

As noted, TS 15/28 are valid trade secrets but were not wrongfully taken by Heraeus. Assuming they were, however, Zimmer points to misuse of the “For Peterson” file by HMUS through its forensic expert, Mr. Vaughn. Mr. Vaughn testified that the “For Peterson” file was

[REDACTED]

opened (from a flash drive) on Mr. Burns' Heraeus computer on the same day the "Worth Burns - First 200 Hospitals" list was opened and sent to Mr. Burns by Mr. Webb, the National Sales Director at HMUS. *See, e.g.*, Tr. (Vaughn) at 371:13-23, 391:23-392:12. This evidence fails to prove misuse. First, the fact that these two files may have been open "around the same time" proves nothing, and certainly does not prove that Heraeus misused information on the "For Peterson" file in some way. Moreover, there is no evidence, even from Zimmer's forensic expert, that the files were definitely open at the same time. Tr. (Vaughn) at 371:3-23, 408:23-409:7. Second, there is no evidence that any information was transferred between the files (Tr. (Vaughn) at 409:21-24, 410:23-411:1, 411:24-412:12), or that the "For Peterson" file was ever saved onto HMUS' computer systems, or that any other HMUS employees were aware of or used the file.

Therefore, there is insufficient evidence of misappropriation of TS 15/28 by Heraeus.

D. Summary

In summary, Heraeus did not use or misappropriate protectable trade secrets TS 10 and TS 15/28, and to the extent it is found to be a protectable trade secret, also did not use or misappropriate TS 11.

E. Harm to Zimmer by Misappropriation

The finding that none of the asserted trade secrets were misappropriated used by Heraeus results in a finding that Zimmer did not suffer injury.

Should misappropriation of Zimmer's purported trade secrets be found, however, Zimmer has failed to show that the misappropriation resulted in injury to Zimmer's domestic industry. In brief, Zimmer alleges "lost sales, lost market share, and price erosion," as well as a threat of future injury. CPB at 141-42. However, they offer no evidence connecting that allegation to TS 15/28

[REDACTED]

and do not even allege injury arising from misappropriation of TS 11; they instead focus on TS 10. *See id.* at 119, 134 (“misuse of TS 10, 15, and 28 data”); *see generally id.* at 119-42.

Zimmer has not sufficiently shown that any of the disclosures of TS 10 to third parties resulted in injury. As to [REDACTED] for instance, Zimmer asserts that Heraeus relied on the data and advice [REDACTED] provided to [REDACTED] giving Heraeus a head start to unfairly compete with Zimmer. *See* CPB at 123. But Heraeus’ engagement of [REDACTED] *See* Tr. (Petermann) at 770:17-20; JX-0334C (Petermann Dep.) at 161:2-16. Zimmer does not show a sufficient nexus between such limited interactions with [REDACTED] and a loss of customers or other harm in 2018. As to [REDACTED] Zimmer fails to show any connection between any disclosure to [REDACTED] and injury to Zimmer. *See* CPB at 121. In fact, Heraeus Germany ultimately did not [REDACTED] [REDACTED] Tr. (Petermann) at 777:16-778:4. And as to [REDACTED] although there is evidence [REDACTED] Zimmer does not even attempt to link that work to any harm Zimmer suffered. *See* JX-0325C (Wilemon Dep.) at 32:9-33:4; 69:9-70:2; *see generally* CPB at 119-42.

Similarly, Zimmer’s evidence of injury arising from HMUS’ use of TS 10 is speculative and lacks a nexus between the trade secret – which, again, is a compilation, not bits and pieces of data – and the injury alleged. *See* CPB at 122-24. Lastly, Zimmer fails to provide any evidence that Mr. Burn’s creation and taking of the “For Peterson” file resulted in any particular injury to Zimmer. *See* CPB at 119. As noted, there is insufficient evidence Mr. Burns or anyone at Heraeus ever even used the data within the file. *See, e.g.,* Tr. (Vaughn) at 370:24-371:23 and CDX-0006C.6 (finding only a single instance in which the USB drive with the “For Peterson” file was connected to Mr. Burns’ Heraeus work computer).

[REDACTED]

Thus, Zimmer cannot prove injury based on trade secret misappropriation.

VII. HERAEUS' DEFENSES

Heraeus raises five affirmative defenses: (1) Heraeus independently developed its own customer target lists and pricing; (2) Heraeus' purported use and disclosure was licensed; (3) Zimmer cannot obtain prospective relief for past harm; (4) Zimmer's claims are barred by its unclean hands; and (5) Zimmer's claims are barred by its prior material breaches. RPB at 46-52.

A. Heraeus Independently Developed its Own Data Compilation

Heraeus alleges that it independently developed the customer target lists and pricing that it used when it began selling PALACOS in the United States. RPB at 66-70. As discussed previously, Heraeus presented witnesses who testified that HMUS spent independent time and effort developing a customer target database primarily from CMS data. Mr. Webb, HMUS' Vice President of marketing, testified in detail how HMUS was able to independently develop a targeting database in approximately two weeks of work using less than \$7,000. Tr. (Webb) at 971:12-21, 969:7-14. Moreover, the record shows that customer and pricing information is readily available from a number of sources, including customers and industry organizations and publications.

Zimmer's critique of this evidence, in sum, is that the testimony of Messrs. Webb and Childers is not credible in light of the evidence that they had access to TS 10 while developing Heraeus' own data compilation. *See* CRB at 18-22. But speculation cannot replace hard evidence, and as noted, Heraeus' witnesses testified that they did not rely on TS 10 in creating their own work product. Thus, Heraeus proved that it independently developed its customer lists and pricing.

[REDACTED]

B. Heraeus' Use Was Not Licensed

Heraeus argues that it cannot have misappropriated Zimmer's alleged trade secrets because the 2012 Agreement provided Heraeus with license to use and disclose them. *See* JX-0204C.0034, § 8.1(b); *see also* Tr. (Petermann) at 760:13-18, 762:5-11; JX-0363C (Rohn Dep.) at 56:15-57:23. Heraeus further argues that the 2012 Agreement expanded Heraeus' right to use the Zimmer Quarterly Reports after January 1, 2019. *See* JX-0204C.0015, § 2.4(c); Tr. (Blanchard) at 213:23-214:2, 350:5-12; JX-0362C (Hofer Dep.) at 88:1-4. Zimmer makes little effort to refute these points other than speculation regarding Heraeus' actions and earlier statements. *See, e.g.*, CRB at 23. Nonetheless, Heraeus presents no evidence of a license agreement separate from its evidence that the 2012 Agreement permitted it to use the data contained in TS 10 and TS 11, and it does not even address TS 15/28. *See* RPB at 51. Staff is therefore correct that insufficient evidence has been presented to support this defense. *See* SRB at 20.

C. No Prospective Relief for Harm Relating Only to PALACOS Sales

Heraeus asserts that Zimmer cannot obtain relief for the asserted trade secret misappropriation because the purported misappropriation ceased, and any alleged injury also ceased before the initiation of this Investigation. RPB at 71. To the extent that Zimmer's claims for relief arise from rights to sell PALACOS, such claims are, in fact, moot, because Zimmer no longer possesses such rights. *See, e.g., Certain Elec. Fireplaces, Components Thereof, Manuals for Same, Certain Processes for Mfg. or Relating to Same and Certain Prods. Containing Same*, Inv. No. 337-TA-791/826, Comm'n Op. at 9 (May 1, 2013) (EDIS Doc. ID 510087) ("*Electric Fireplaces*") (vacating as moot a finding of violation to the extent it was based on expired contract provisions); *see also Certain Lighting Control Devices Including Dimmer Switches and Parts Thereof*, Inv. No. 337-TA-776, Comm'n Notice, 77 *Fed. Reg.* 43612-14 (July 25, 2012) (vacating

[REDACTED]

in pertinent part an initial determination finding a section 337 violation based on infringement of a patent that expired during the course of the investigation); *Tessera, Inc. v. Int’l Trade Comm’n*, 646 F.3d 1357, 1371 (Fed. Cir. 2011) (vacating as moot Commission determinations relating to expired patents). However, Heraeus’ arguments on this defense are otherwise sketchy, and do not even address, for example, alleged ongoing lost market share for Zimmer’s products, so Respondents have not otherwise met their burden to show that relief is entirely unwarranted. *See* RPB at 51-52.

D. Zimmer’s Claims Are Not Barred by Unclean Hands or Material Breach

Heraeus asserts that it cannot be found liable because Zimmer misappropriated Heraeus’ trade secrets pertaining to PALACOS in its development of BBCR and RBCR, which constitutes unclean hands and a material breach of the parties’ 2012 Agreement. *See* RPB at 52. Heraeus barely presents its case on these two defenses at all, and Staff is correct that there is insufficient evidence to support them. *See id.*; SRB at 20.

VIII. FALSE AND MISLEADING ADVERTISING

As stated earlier, to establish a false advertising claim under the Lanham Act, a complainant must prove that: 1) The [respondent] made false or misleading statements about his own or another person’s product; 2) There is actual deception or at least a tendency to deceive a substantial portion of the intended audience; 3) The deception is material in that it is likely to influence purchasing decisions; 4) The advertised good traveled in interstate commerce; and 5) There is a likelihood of injury to the complainant in terms of declining sales, loss of good will, and similar harm. *Certain Woven Textile Fabrics*, 2016 WL 7010667, at *5 (Nov. 20, 2016) (“*Woven Textile Fabrics*”); *see also Certain LEDs*, Initial Determination at 430-31. To demonstrate element (1) – a false or misleading statement of fact – a complainant must prove that the statement is either

[REDACTED]

(i) literally false, or (ii) literally true, but ambiguous and likely to mislead, confuse, or deceive consumers. *Woven Textile Fabrics*, 2016 WL 7010667, at *5.

Zimmer presents two categories of allegedly false or misleading statements made by Heraeus about their own or Zimmer's products: (1) statements concerning Zimmer's right and/or ability to supply PALACOS, and (2) statements about the relative quality or superiority of PALACOS compared to Zimmer's bone cement products. Complaint, ¶¶ 78-86; CIB at 79.

A. Statements Regarding Zimmer's Right/Ability to Supply PALACOS

1. Falsity of Statements

a) Statements Regarding Zimmer's Right to Supply PALACOS

The first category of alleged false advertising relates to Zimmer's right to supply PALACOS to customers in the U.S. In 2018, after Heraeus elected non-exclusivity, Heraeus and Zimmer each had the right to, and did, distribute PALACOS in the U.S. JX-0204C.0008, .0013; JX-0362C (Hofer Dep.) at 29:1-8, 211:3-212:6. Following the co-distribution period, Zimmer had the right to [REDACTED] JX-0204C.0040; JX-0362C (Hofer Dep.) at 211:3-212:6; JX-0363C (Rohn Dep.) at 73:14-74:13. Zimmer alleges that false statements "were widely distributed to PALACOS customers in the U.S. beginning in early 2018 at the start of the co-distribution period." CPB at 66. Zimmer alleges that the alleged false or misleading statements concerning Complainants' "ongoing right and ability to sell PALACOS" fall within four sub-categories:

- Widely distributed letters, form emails, and pamphlets that are non-specific about the timing of Zimmer Biomet's right to distribute (*see e.g.*, JX-0068C);
- Individual communications that are non-specific about the timing of Zimmer Biomet's right to distribute (*see e.g.*, CX-0494C);
- Individual communications that misidentify the timing of Zimmer Biomet's right to distribute (*see e.g.*, CX-2057.0005); and

-
- Individual communications that misstate Zimmer Biomet’s inability to distribute PALACOS due to the alleged insufficiency of Zimmer Biomet’s PALACOS supply (*see e.g.*, CX-1927C).

CIB at 85-86; *see also* CDX-0005C.16, CDX-0005C.22, CDX-0005C.26, CDX-0005C.31.

As a preliminary matter, the evidence shows that the specific statements at issue in each of the above categories qualify as “commercial advertising or promotion.” *See, e.g., Proctor & Gamble Co. v. Haugen*, 222 F.3d 1262, 1273 (10th Cir. 2000) (citing *Gordon & Breach Science Publishers, S.A. v. American Institute of Physics*, 859 F. Supp. 1521, 1535-36 (S.D.N.Y. 1994)). The statements at issue are speech by Heraeus for the purpose of persuading its customers or potential customers to purchase its bone cement products, and are, therefore, commercial. *See id.* (setting forth the test for what constitutes “commercial advertising or promotion” under the Lanham Act); *see, e.g., JX-0326* (Childers Dep.) at 538:11-539:8.

As for the statements, a Heraeus customer letter (among other similar communications) was sent in February 2018³ to supply chain contacts at hospitals across the U.S. Tr. (Webb) at 1000:5-8. The letter stated:

Heraeus Medical — the inventor and exclusive manufacturer of PALACOS® — is proud to announce that it is transitioning to become its sole provider. Heraeus Medical is committed to easily and seamlessly transitioning our customers from our United States distributor Zimmer Biomet to Heraeus, ensuring immediate and continuous access to the PALACOS® portfolio of high-quality cements.

...

In order to provide you with the bone cement you know and trust, simply fill out the attached form to continue to receive your PALACOS® products, now from Heraeus Medical, or visit www.Heraeus-Medical-USA.com and fill out the Contact Us form.

JX-0068C.0001

³ Shortly thereafter, Heraeus sent a mass email with similar language. CX-1061C; CX-0511C. An “AAOS Mailer” containing nearly identical language was sent to the list of attendees of the American Academy of Orthopedic Surgeons in early 2018. Tr. (Webb) at 999:12-24; CX-0486C.

[REDACTED]

In August 2018, Heraeus distributed a “Second Customer Letter” with slightly different language:

As you know, Heraeus Medical has manufactured the industry-leading PALACOS® line of Bone Cement for many years. Heraeus had distributed those products in the United States through Zimmer (now known as Zimmer Biomet Holdings) Effective January 1, 2019, Heraeus and its network of distributors will be the only parties authorized to purchase authentic PALACOS bone cement products from the manufacturer and resell them in the United States.... If you wish to continue to receive the premier PALACOS line after January 1, 2019, directly from our distributor, please contact 1-833-PALACOS or HMEUSA@Heraeus.com.

CX-0737C.

“Literal falsity can be found based either on the face of the advertisement or by necessary implication.” *Castrol Inc. v. Pennzoil Co.*, 987 F.2d 939, 943, 946 (3d Cir. 1993). Further, a “literally false message” can be either (i) explicit or (ii) ‘conveyed by necessary implication when, considering the advertisement in its entirety, the audience would recognize the claim as readily as if it had been explicitly stated.’” *Woven Textile Fabrics*, 2016 WL 7010667 at 5 (citing *Groupe SEB USA, Inc. v. Euro-Pro Operating LLC*, 774 F.3d 192, 198 (3d Cir. 2014)). Zimmer argues that, in view of the standard, each of the above letters is literally false.

Zimmer’s expert, Dr. DiGioia, opines that statements “such as ‘transitioning from’ and ‘sole provider,’ ‘transitioning our customers for our United States distributor to Heraeus’ [is] just not true, because at this point Zimmer Biomet had the right to [REDACTED]

[REDACTED] Tr. (DiGioia) at 466:9-19 (discussing February 2018 letter (JX-0068C)). He argues that this language generates a “sense of urgency . . . when Zimmer [REDACTED]

[REDACTED] Tr. (DiGioia) at 466:15-19, 24-467:5. Dr. DiGioia further states that by failing to also state that Zimmer was a co-distributor during the transition period and because they gave no specific date for the transition, the statements falsely imply that customers must immediately order from Heraeus. *See* Tr. (DiGioia) at 467:15-21, 468:2-11. Dr. DiGioia further opines that even

[REDACTED]

if the letter is not false, it is misleading because it “impl[ies] that Zimmer Biomet cannot sell or distribute during this time frame.” *Id.* at 468:12-21.

Dr. DiGioia also takes issue with the August 2018 letter because the letter does not properly reflect the full scope of the parties’ relationship during the transition. Specifically, Dr. DiGioia argues that the letter’s use of the past tense to describe that Heraeus “had distributed” PALACOS in the United States through Zimmer does not properly reflect that as of August 2018, “Zimmer could still continue to distribute.” Tr. (DiGioia) at 470:9-471:1. He contends that the second letter’s statement that “[e]ffective January 1, 2019, Heraeus and its network of distributors will be the only parties authorized to purchase authentic PALACOS bone cement products from the manufacturer and resell them in the United States,” is misleading because it implies that “Zimmer could not sell any PALACOS [in 2019], which, is not true.” *Id.*

Zimmer’s points are not well taken. When the statements are read as a whole, which they must be, the communications explain that the transition to being the sole provider is an ongoing process rather than an immediate event. *See, e.g., Castrol Inc. v. Pennzoil Co.*, 987 F.2d 939, 946 (3d Cir. 1993) (determination of whether an advertising claim is literally false – whether explicitly on its face or by necessary implication – requires that the claim be analyzed in its full context). As the Staff points out, the Heraeus’ “communications not only introduce existing PALACOS customers to the manufacturer of PALACOS, but also introduce those customers to the idea that, following a transition period, Heraeus would be the sole provider of PALACOS.” SPB at 49 (citing Tr. (DiGioia) at 529:2-8 (agreeing the customer letter did not explicitly or implicitly give a time)). Similarly, the statement “[e]ffective January 1, 2019, Heraeus and its network of distributors will be the only parties authorized to purchase authentic PALACOS bone cement products from the manufacturer and resell them in the United States” is not false or misleading. By focusing on only part of the statement, *i.e.*, the “resell” portion, Zimmer argues that the statement is false because Zimmer still had the right to resell any

[REDACTED]

additional PALACOS it had. *See* Tr. (DiGioia) at 470:19-471:1. However, when the statement is read as a whole, it says that Heraeus and its distributors would be the only parties authorized to do two things: both purchase PALACOS and resell that PALACOS. [REDACTED]

[REDACTED]

[REDACTED] *See* JX-0204C.0039 (2012 Agreement).

The statement, read as a whole, is not false or misleading.

b) Heraeus Statements Distributed by Its Sales Agents

The second allegedly false statements include similar language as the first category, but the statements allegedly were distributed by Heraeus' sales agents to individual purchasers in early 2018:

“Attached is the letter announcing Heraeus as the sole provider of PALACOS.” CX-0494C (Feb. 2018 email to Northwell) .

“Heraeus Medical, the inventor and manufacturer of PALACOS bone cement, is becoming the sole provider of the product.” JX-0032C (Feb. 2018 email to Baptist Healthcare) (emphasis added).

These statements also qualify as advertising even though some of the statements can be characterized as “individual communications” with customers. *See Seven-Up Co. v. Coca-Cola Co.*, 86 F.3d 1379, 1385 (5th Cir. 1996) (discussing that “both the required level of circulation and the relevant ‘consuming’ or ‘purchasing’ public . . . will vary according to the specifics of the industry”). This is because, as the evidence shows, sales representatives in the bone cement industry used directed communications to customers and potential customers to sell bone cement products. *See, e.g.*, CX-1328C.0010 (market entry strategy deck discussing need to build “direct, proprietary communication channel to surgeons, techs, and administrators”); JX-0326C (Childers Dep.) at 245:17-246:5, 538:11-539:8; JX-0341C (Lyon Dep.) at 132:6-133:10; JX-0333C (Bair Dep.) at 77:1-6.

Zimmer alleges that the first document listed above, CX-0494C, is evidence of the sales training information being disseminated to customers. However, CX-0494C actually is an internal

[REDACTED]

communication from Heraeus to one of its independent distributors/sales representatives. Tr. (DiGioia) at 476:6-17 (noting that the communication is between Heraeus and its sales agent). While Dr. DiGioia opines that the letter “leads the customer to believe that PALACOS can only be provided by Heraeus” (*id.* at 476:12-23), Dr. DiGioia offers no evidence that this internal communication describing the announcement of “Heraeus as the sole provider of PALACOS” was distributed to customers or anyone beyond the recipient of the email at CX-0494C. Moreover, the statement is literally true (that is, the description of the letter’s contents is literally true, and Heraeus had announced that it was transitioning to being the sole provider of PALACOS), and Zimmer offers no evidence that anyone was misled by the statement. *See* CPB at 73-74.

The second example given above is a February 16, 2018 email from Heraeus employee Sara Dorsey to [REDACTED]. The statement that “Heraeus Medical, the inventor and manufacturer of PALACOS bone cement, is becoming the sole provider of the product” is true. JX-0032C. Zimmer points to no evidence contradicting this conclusion, or that the statement is misleading. *See* CPB at 70, 73-74.

c) Sales Agents Told Customers That Zimmer Could Not Sell PALACOS After 2018

Zimmer alleges the following statements made by Heraeus or its sales agents amount to false advertising:

“PALACOS had been distributed by Zimmer Biomet Holdings for the previous 10 years. Recently that relationship has been terminated.” CX-2057C.0005 (April 2018 email to [REDACTED]). *See also* JX-0213C; CX-1912C; CX-1429C; CX-1852C; CX-1856C; CX-1855C; CX-1870C.

“As of the end of 2018, Zimmer will no longer have the right to buy/distribute PALACOS bone cement.” CX-1193C (June 2018 email to [REDACTED]). *See also* CX-1817C; CX-1811C; CX- 1813C; RX-1026C; CX-1919C; CX-1932C; CX-1939C; CX-1920C; CX-1927C; CX-1929C; CX-1935C; CX-1937C; CX-1938C; CX-1940C; CX-1941C; CX-1945C; CX-1114C; CX-0578C; CX-1804C; CX-1144C; CX-0776C; CX-1870C; CX-1863C; CX-1829C; CX-1825C.

[REDACTED]

CPB at 74. These statements qualify as commercial advertising for the same reasons discussed earlier.

Zimmer presents the April 2018 message (the first statement given above) that HMUS distributor Synergy Surgical Products LLC sent to “at least six bone cement customers, including the [REDACTED] system” as representative of the messages at issue. CPB at 74 (citing JX-0213C.0009-14). Zimmer argues that these types of messages to customers amount to false advertising because they misidentify the time period in which Zimmer had the right to distribute PALACOS and/or when the relationship was terminated. CPB at 74-75.

The statement is literally true. “[T]hat relationship,” as it had existed between Zimmer and Heraeus Germany, in which Zimmer was the exclusive distributor of PALACOS in the United States, ceased to exist as of [REDACTED]. See JX-0203C (election of mutual non-exclusivity); JX-0240 (2012 Agreement). Nothing in the communication states or necessarily implies that PALACOS is exclusively available from Heraeus at that specific time. Admittedly, counsel for Synergy stated that the company would “be sending e-mails in which it will rescind and correct the misstatements,” but counsel provided little explanation for why they believed the Zimmer/Heraeus relationship had not been terminated. JX-0213C.

Moreover, these emails were not authorized by Heraeus or the principals at Synergy Surgical. JX-0213C.0001; Tr. (Shapiro) at 1247:16-1248:10. Thus, Heraeus cannot be held accountable for the statements in any event.

To be sure, the statement “[a]s of the end of 2018, Zimmer will no longer have right to buy/distribute PALACOS bone cement,” does have arguably ambiguous “buy/distribute” language. However, the statement as a whole is not misleading. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] See JX- 0204C. And Zimmer’s right to sell PALACOS was indeed limited. See JX-0204C.0039; see also JX-0346C (Armstrong Dep.) at 462:16-22

[REDACTED]

d) Statements Regarding Zimmer’s PALACOS Inventory

The final communications that Zimmer alleges are false or misleading are statements made by Heraeus’ sales agents and distributors to customers that allegedly misrepresented Zimmer’s ability to supply PALACOS (the level of its inventory or stock), as opposed to Zimmer’s contractual right to supply PALACOS. CPB at 75-76 (citing CX-1927C (June 17, 2018 email stating, “Again, ZB can sell PALACOS until the end of the year, but they have an allotted amount which may run out before then.”)). These statements also qualify as commercial advertising for the same reasons discussed earlier.

Dr. DiGioia asserts that the statement made in the June 17, 2018 email is false because when the statement was made “it was clear that Zimmer could both purchase PALACOS from Heraeus as well as distribute it.” Tr. (DiGioia) at 483:8-19. Dr. DiGioia further asserts that if the statement is not false outright, it is misleading because the statement implies a lack of supply during a time in which “Zimmer could both purchase and distribute [PALACOS].” Tr. (DiGioia) at 483:8-484:3.

The statement in the email was literally false. The assertion that “they have an allotted amount which may run out before then” was not true at the time, because it was not until the following month that Heraeus stopped fulfilling Zimmer’s purchase orders. See CX-2335C.0003. As of June 2018, when the statement at issue was made, Zimmer did not have an “allotted amount which may run out before [the end of the year],” because Heraeus was still selling Zimmer PALACOS on an as-needed basis. In fact, on July 12, 2018 Heraeus sent an email to Zimmer

[REDACTED]

asking for an “update” on “Firm orders for Q4 2018,” which suggests that as of July 2018 Heraeus was still willing to sell Zimmer an undetermined – *i.e.*, unallotted – quantity of PALACOS. CX-2335C.0007.

2. Actual Deception or Tendency to Deceive

Zimmer states that because Heraeus’ statements regarding Zimmer’s right and ability to supply PALACOS are literally false, the actual effect on the buying public need not be shown. CPB at 76. However, the statements in question are true (except the one statement noted above). Zimmer argues in the alternative that even if the statements are true, they are misleading. Again, the evidence shows that the statements are not misleading. Nonetheless, in the event that the Commission finds the statements to be misleading, Zimmer states that “the evidence shows actual deception by Heraeus via: (i) Heraeus’ intent to deceive customers into believing that they had to immediately transition PALACOS supply contracts to Heraeus, and (ii) actual customer responses to Heraeus’ marketing messages demonstrating that a substantial number of customers were actually deceived.” *Id.* at 77.

Zimmer must prove either that Heraeus acted with an intent to deceive, and thus the deception may be presumed (*See Certain LEDs Inv. No. 337-TA-947*, Initial Determination at 433) (*citing Cashmere & Camel Hair Mfrs. Inst. v. Saks Fifth Ave.*, 284 F.3d 302, 316 (1st Cir. 2002))); or that the challenged statements deceived a substantial portion of the purchasing public. *United Indus.*, 140 F.3d at 1182. In “proving actual deception, the complainant must show that the statement ‘conveys a misleading message to the viewing public’ and must show ‘how consumers actually reacted to the challenged advertisement rather than merely demonstrating how they could have reacted.’” *Woven Textile Fabrics*, 2016 WL 7010667, at *6 (*quoting Clorox Co.*, 228 F.3d at 33); *see also Certain Cigarettes and Packaging Thereof*, Inv. No. 337-TA- 424, Initial

[REDACTED]

Determination, 2000 WL 1726827 at *38 (Oct. 16, 2000) (unreviewed by Commission) (“As set forth above, when making a claim based on misleading implication or context, a party cannot rely on its own intuitive reaction to an advertisement, or on the intuitive reaction of the finder of fact, but must introduce evidence that the relevant recipients of the advertisement find it misleading”) (citing *United Indus.*, 140 F.3d at 1182); *Johnson & Johnson Merck Consumer Pharm. Co. v. Smithkline Beecham Corp.*, 960 F.2d 294, 297-98 (2d Cir. 1992) (in the absence of finding literal falsity, “[i]t is not for the judge to determine, based solely upon his or her own intuitive reaction, whether the advertisement is deceptive,” rather, “the success of a plaintiff’s claim usually turns on the persuasiveness of a consumer survey”). Zimmer failed to prove either that Heraeus intended to deceive or that Heraeus’ statements actually deceived a substantial portion of the purchasing public.

Zimmer first argues that Heraeus intended to deceive consumers into believing that Zimmer’s right and ability to supply PALACOS was ending immediately. CPB at 77-78. Zimmer cites Heraeus’ marketing materials and internal belief [REDACTED]

[REDACTED] *Id.* Complainants also argue that Heraeus’ failure to discuss Zimmer’s part in selling PALACOS and failure to provide an “exact timepoint” in its communications with PALACOS customers proves that Heraeus purposefully chose to deceive customers about the timing of the transition to PALACOS. *Id.*, citing CX-1053C. These examples do not prove an intent to deceive. *See Phone-Poulenc Rorer*, 19 F.3d at 131-32 (declining to find an intent to deceive where there was no evidence of “deliberate conduct” that is of an “egregious nature”). The internal discussions with Heraeus’s marketing partner [REDACTED] and the internal FAQs demonstrate Heraeus was only trying to communicate the fact of the distribution transition, and

[REDACTED]

further that Heraeus wanted customers to reach out for more details depending on their respective circumstances and needs, so that each customer received accurate information. *See, e.g.*, JX-0326 (Childers Dep.) at 185:10-24; 539:17-540:23; JX-0146C (“I don’t have an exact date”); RX-1026C (“We want to make sure we have the story straight . . . and not create or add to any confusion”).

In the alternative, Zimmer argues that a substantial portion of customers were actually deceived regarding Zimmer Biomet’s ability to continue to distribute PALACOS. CPB at 78. However, Dr. DiGioia testified that he did not identify what percentage of the purchasing public constitutes a substantial portion of customers. Tr. (DiGioia) at 522:6-18; *id.* at 525:9-13 (admitting that in rendering his opinions he did not assess the number of customers that received the challenged statements and discarded or did not rely on the statement). Only two instances of “customer reactions” purportedly showed that the customers were being misled. Dr. DiGioia explained that the first such “reaction” was from a supply chain manager, who stated that he believed that Heraeus’ August 2018 letter meant that “Zimmer Biomet will no longer distribute PALACOS cement.” Tr. (DiGioia) at 471:16-24 (discussing CX-1068C). This is at best ambiguous; there is no evidence (such as customer testimony) that this customer understood the August 2018 letter to require an immediate transition to Heraeus or that Zimmer Biomet would immediately not be able to distribute PALACOS. *See* Tr. (DiGioia) at 522:19-23 (agreeing that he relied only on his personal experience to render his opinions), 523:12-15 (agreeing that he did not analyze or apportion how the purchasing public would have relied on each challenged statement). As Staff points out, a review of the entire communication indicates that the customer knew that PALACOS was still available from Zimmer Biomet. SPB at 50 (citing Tr. (DiGioia) at 531:2-14 (discussing response at CX-1068C.002 and admitting that someone within the

[REDACTED]

purchasing organization of the health center was aware that PALACOS would still be available from Zimmer Biomet)).

The second customer reaction also fails. The customer writes that [REDACTED]

[REDACTED]

[REDACTED] JX-0003C.0001; *see* Tr. (DiGioia) at 472:6-21. Whether this one (unnamed) customer was misled is a matter of speculation, again principally because we have no direct testimony from that customer. Moreover, even Zimmer was [REDACTED]

[REDACTED] *See, e.g.*, JX-0001C at p.6 (email from a Zimmer distributor to [REDACTED]

[REDACTED] *see also* Tr (DiGioia) at 534:16-535:23 (admitting that a Zimmer Biomet distributor was [REDACTED]

[REDACTED] 539:7-11 (admitting that Heraeus was telling the truth when it informed [REDACTED]

[REDACTED] In fact, there is considerable evidence that customers did not think the need to transfer business to Heraeus was immediate, and instead simply wondered when the transition would take place. *See, e.g.*, JX-0047C.0001 [REDACTED]

[REDACTED]

[REDACTED] JX-0118C [REDACTED]

[REDACTED]

[REDACTED] JX-0146C.0001 [REDACTED]

[REDACTED]

Not only do the cited communications fail to support Zimmer's assertion (*see* Staff Br. at 56-57 (citing customer questions that indicate customers were not deceived)), but there were no

[REDACTED]

customer surveys to evaluate how the challenged statements actually were understood by the purchasing public. Tr. (DiGioia) at 522:19-21. Instead, Dr. DiGioia used only his personal experience when offering his opinions. Tr. (DiGioia) at 522:19-21. Although such evidence is probative, and customer-oriented evidence is not necessarily an absolute requirement, two examples supported only by an expert's subjective views is not sufficient. *See Aviva Sports, Inc. v. Fingerhut Direct Mktg., Inc.*, 829 F. Supp. 2d 802, 813-14 (D. Minn. 2011) ("Unless a claim is literally false, or a trier of fact has determined that a competitor acted willfully with intent to deceive in bad faith, a party seeking relief under this section of the Lanham Act bears the ultimate burden of proving actual deception by using reliable consumer or market research.") (quoting *United Indus. Corp.*, 140 F.3d at 1183) (internal quotations omitted).

Thus, the evidence fails to show that Heraeus had an intent to deceive customers or that any customer was actually deceived by Heraeus' letters.

3. Materiality

Zimmer asserts that Heraeus' statements relating to the supply of PALACOS are material "because a significant number of purchasers are likely to attach importance to the representations in determining whether to engage in a proposed transaction." CPB at 79. Respondents and Staff criticize Zimmer's evidence because, among other things, no customer surveys were performed. *See* RPB at 70-71; SPB at 58. Certainly such surveys, and similar evidence, would have strengthened the case for materiality, but the materiality threshold is low. *See Woven Textile Fabrics*, 2016 WL 7010667, at *5 ("likely to influence purchasing decisions"). It stands to reason that the reliability of product supply is important to purchasers, particularly sophisticated purchasers such as those working for medical organizations. And Dr. DiGioia, who has "personal experience as a user, purchasing committee member, and thought leader with exposure to a

[REDACTED]

national audience on issues relating to medical device purchasing,” explicitly opined that these messages were material. CPB at 79; *see* Tr. (DiGioia) at 489:8-490:1; *see generally* Tr. (DiGioia) at 441-445. Such evidence is sufficient to establish materiality.

4. Interstate Commerce

Respondents do not dispute that PALACOS traveled in interstate commerce. *See* RPB at 19.

5. Likelihood of Injury

Zimmer asserts that in order to prove injury due to false advertising it “need only prove that it has ‘a reasonable basis for the belief that it is likely to be damaged as a result of the false advertising,’ either in terms of lost sales (or other economic injury) or lost goodwill.” CPB at 81 (*quoting Certain LEDs*, ID at 480). The case on which *Certain LEDs* relies, however, does not set forth a subjective, “reasonable belief” test. *See Certain LEDs*, ID at 480 (citing *Johnson & Johnson v. Carter-Wallace, Inc.*, 631 F.2d 186, 190 (2d Cir. 1980)). Instead, it clarifies that “[t]he correct standard is whether it is likely that [the allegedly false] advertising has caused or will cause a loss of [Complainants’] sales,” which requires a “likelihood of injury and causation” to “be demonstrated.” 631 F.2d at 190. Under this standard, the “causation” element is conspicuously missing, because the complained-of statements all pertain to Zimmer’s distribution of PALACOS, rather than its own products. Heraeus makes this point succinctly – “Zimmer Biomet cannot be injured in the future because it can no longer sell PALACOS” – and Zimmer makes no effort to rebut it. RPB at 72; *see* CRB at 46. Furthermore, even if Zimmer was injured in 2018 and 2019 from the alleged false statements, such injury is alone insufficient because Zimmer is not entitled to prospective relief for purely past harm. *See Electric Fireplaces*, Comm’n Op. at 9. Therefore, even assuming that Zimmer proved all the other elements of false advertising with respect to

[REDACTED]

statements regarding its right and ability to supply PALACOS, it has not proven the element of injury.

B. Statements Regarding Product Quality

1. Falsity of Statements

a) Statements About MAUDE Quality Events

Zimmer alleges that Heraeus falsely claimed, in its sales training materials, that according to the MAUDE database, “Refobacin has 2.5 times as many global quality events as PALACOS.” JX-0066C.0005; *see also* JX-0070C (“Refobacin has significantly more quality events reported (~210) than PALACOS (~80) . . . (so if you were to calculate a rate of quality complaints Refobacin would have 8 times the complaints of PALACOS.)”); JX-0182C (“[Q]uality issues with Refobacin are likely increasing.”); JX-0013C; CX-0201C; CX-0218; CX-1751C; CX-1893C; CX-1897C; CX-1913C; CX-1908C; CX-1909C; CX-1910C.A

“MAUDE” stands for “Manufacturer and User Facility Device Experience” and is an FDA database that “is a repository of medical device reports or MDRs (Managed Detection and Response) that [document] device problems or failures.” Tr. (Spiegelberg) at 557:14-17. The reports submitted to MAUDE – either voluntary or mandatory – are used “to monitor device performance, detect potential device-related safety issues and contribute to benefit-risk assessments of these products.” *See* JX-0283 (MAUDE web homepage printout); *see also* Tr. (Mays) at 1176:20-24 (discussing JX-0283).

The statements concerning the MAUDE database are [REDACTED]

[REDACTED] *See* JX-0066C (flashcards); JX-0070C (email). The parties do not question whether these statements actually qualify as advertising. Given that the statements were conveyed to Heraeus sales agents being

[REDACTED]

trained to interact and use the information with customers, it is reasonable to believe that the sales agents, in turn, communicated the information to customers. Thus, the statements qualify as advertising.

Zimmer argues that it need not prove Refobacin actually does not have 2.5 times more global quality events, but rather it need only “demonstrate that the data on which Heraeus relies does not support its statement.” CPB at 82 (citing *McNeil-P.C.C.*, 938 F.2d at 1549 (finding an advertisement literally false when the underlying data is “not sufficiently reliable to permit one to conclude with reasonable certainty that they established the claim made”)). Specifically, Zimmer argues that Heraeus’ statements may not be accurate because there is a potential that MAUDE *may* contain possible instances of double reporting, non-relevant mentions of a product, or misreporting. As Staff states, “Dr. Spiegelberg [Zimmer’s expert] offers only reasons to potentially mistrust the challenged statement, and no evidence showing the challenged statement is actually false.” SPB at 61. In fact, Dr. Spiegelberg does not even assert that the statement “2.5 times more” is inaccurate, but rather that the phrase “global quality events” *may* be misleading. Tr. (Spiegelberg) at 611:17-22; *see also* Tr. (Mays) at 1176:2-8; 1177:16-20 (“the dispute is not about the numbers, but it’s about the term ‘global quality events’”). And while “every MAUDE report relates to a quality event,” the number of reports submitted to MAUDE *may* not accurately reflect the number of quality events. Tr. (Spiegelberg) at 611:23-25; 563:12-17 (a single quality event may result in multiple MAUDE reports). Finally, Dr. Spiegelberg explains that MAUDE data *may* be unreliable because a product *may* have a MAUDE report when the product was not the cause of the reported quality event, and also because not all companies report events to MAUDE at the same rate, due to different internal reporting procedures. Tr. (Spiegelberg) at 563:23-564:1.

[REDACTED]

Dr. Spiegelberg's testimony regarding MAUDE is speculative, and does not prove that Heraeus' statements were false or misleading. He admits that he did not find actual evidence of underreporting of PALACOS MAUDE entries. Tr. (Spiegelberg) at 612:7-9. He also does not identify any instances of more than one report per quality event in MAUDE, or reporting having nothing to do with a global quality event for either Zimmer's bone cements or PALACOS. Tr. (Spiegelberg) at 613:2-16. Therefore, Zimmer has failed to show that Heraeus' statements related to MAUDE data are either false or misleading.

b) Statements About Product Recalls

Zimmer next asserts that Heraeus made false statements to U.S. consumers by telling them that versions of Refobacin have been recalled three times in other countries while PALACOS has had zero "safety or quality recalls." CPB at 84 (citing JX-0066C.0005; JX-0013; JX-0168C; JX-0174C; JX-0182C; JX-0187C; JX-0241C; CX-0186; CX-1908C; CX-1909C; CX-1910C; CX-1959C). These statements are part of the sales agents' training material as well as emails to customers, and thus, qualify as advertising.

Zimmer alleges that the statements regarding Refobacin are false because "there have been no recalls of the ZB Cements sold in the U.S." CPB at 84 (citing Tr. (Spiegelberg) at 570:20-571:2; Tr. (Mays) at 1215:2-8; Tr. (Shapiro) at 1296:14-1297:4)). Zimmer asserts that the statements were false because the statements were made to U.S. customers and "there's only one version of Refobacin bone cement that's sold in the U.S. market and it's never been recalled." Tr. (Spiegelberg) at 570:20-25. However, the two statements which Dr. Spiegelberg cites make clear that the recalls were for Refobacin, or "versions of Refobacin," sold in other countries, including Canada and the U.K., and the recalled products contain Refobacin and have "Refobacin" in their names. CPB at 84; Tr. (Spiegelberg) at 569-74 (citing JX-0066C, JX-0187C)). The statements

[REDACTED]

are therefore not false, either literally or by necessary implication. Furthermore, they are not misleading, and Zimmer in any event fails to present any evidence that customers were actually misled. *See, e.g.*, Tr. (Spiegelberg) at 630:12-14 (he did not conduct a consumer survey), 631:7-11 (he did not communicate with any bone cement consumers or purchasers for the purposes of this Investigation). The evidence thus shows that Heraeus' statements regarding Refobacin recalls are not false or misleading.

Heraeus' statements that PALACOS has had "zero safety or quality" recalls raise a question of interpretation. The evidence shows that there have been at least two U.S. PALACOS recalls related to packing and labelling issues, which are Class 2 recalls. Tr. (Spiegelberg) at 593:5-595:12. The FDA defines a Class 2 recall as one which "may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote." CX-2096. Thus, Zimmer's expert argues that a Class 2 recall is based on a "risk to health," and as such, the PALACOS Class 2 recalls amount to safety recalls. Tr. (Mays) at 1219:25-1220:22; Tr. (Spiegelberg) at 594:5-7.

However, the Class 2 recall definition states that the product "may" cause health issues, so the recall does not necessarily relate to safety. *See* RPB at 129-130. Moreover, Heraeus' expert, Dr. Mays, testified that one PALACOS recall related to possible mislabeling and the other related to packaging, and Dr. Mays testified that neither of these are "safety" issues. Tr. (Mays) at 1188:13-1189:24. And although the use of "may" in the FDA definition makes the statements somewhat ambiguous, that ambiguity itself rules out the possibility of outright falsity.

To establish that the statements are misleading, Zimmer must prove both that the statements convey a misleading message and how consumers reacted to the message. *Woven Textile Fabrics*, 2016 WL 7010667, at *6. But Zimmer conducted no surveys related to the

[REDACTED]

statements, and presented no evidence of actual consumer confusion. Tr. (Spiegelberg) at 617:18-20 (admitting he had no evidence showing how recipients of the statements understood or reacted to those statements). Accordingly, the evidence is insufficient to prove that Heraeus' statements regarding recalls are either false or misleading.

c) Statements About PALACOS Consistency and Time On the Market

Zimmer asserts that the statements (1) "PALACOS® was introduced in 1957, has been unchanged for 30 years . . .:" (2) "PALACOS® . . . has been unchanged for 60 years;" and (3) "PALACOS hasn't changed or reformulated in over 50 years" are false. Statement (1) appears in Heraeus' training flashcards (JX-0066C.0008); statement (2) comes from a competitive comparison argument manual (JX-0170C); and statement (3) comes from a Heraeus distributor email (JX-0182C). Tr. (Spiegelberg) at 597:12-16, 598:1-7. For the same reasons as discussed above, these statements qualify as advertising.

Zimmer argues that these statements are false because "PALACOS has undergone three changes over its lifetime," [REDACTED]

[REDACTED] Tr. (Spiegelberg) at 598:15-599:2. Zimmer's contention that the statements are false is based on a reading of the statements to mean that [REDACTED]

[REDACTED].

Tr. (Spiegelberg) at 598:13-599:2. However, even Zimmer's expert admits that each statement refers to the original PALACOS R, and not all versions of PALACOS products. Tr. (Spiegelberg) at 622:9-12; 623:18-21. But Zimmer did not present evidence on what aspect of the original PALACOS R had changed and when and why the statements that PALACOS R "has been unchanged for 30 [or 60] years" was purportedly false. Tr. (Spiegelberg) at 598:13-599:2.

[REDACTED]

Moreover, Zimmer's expert admitted that each statement refers to the composition of PALACOS R being unchanged, and "composition" is defined as a "description of ingredients that make up the cement." Tr. (Spiegelberg) at 622:12-18, 623:22-24; *see also* Tr. (Mays) at 1194:21-23 ("Composition is what a material is made of. It's basically the ingredients that are used to make the cement in this case."); 1195:1-2 ("Composition would include a list of ingredients."). The experts for both Zimmer and Heraeus testified that the composition of the product does not include the amounts of ingredients, properties of ingredients, or source of the ingredients, which are the features that Zimmer contends create the false statements. Tr. (Mays) at 1195:1-16, 1226:19-1227:20; Tr. (Spiegelberg) at 622:19-25 (Physical properties are separate things from the description of ingredients.). Thus, the [REDACTED] in PALACOS about which Dr. Spiegelberg testified, even if they applied to PALACOS R, would not have constituted changes to the composition. As for the change in [REDACTED] Heraeus presents evidence showing that a 2013 bone cement book discussed the composition of PALACOS R, and stated that the composition had not changed because [REDACTED]

[REDACTED] Tr. (Mays) at 1194:6-19 (citing JX-0161, a text book on cements); 1196:25-1197:20 (citing JX-0161 at -716). Thus, the composition of PALACOS R did not change because the [REDACTED]

[REDACTED] Tr. (Mays) at 1196:12-15.

Accordingly, the statements are not literally false. Dr. Spiegelberg testified that the statements "mislead purchasers into believing that they can rely on the long clinical history of PALACOS with the assumption that the formulation hasn't changed over the entire lifetime." Tr. (Spiegelberg) at 600:4-8. However, Zimmer did not perform consumer surveys regarding this

[REDACTED]

issue, nor did Dr. Spiegelberg speak with customers about these statements. *See* Tr. (Spiegelberg) at 630:12-14 (no consumer surveys), 631:7-11 (no discussions with consumers). Thus, Zimmer failed to present evidence of customers being misled by any of Heraeus' statements.

Accordingly, the statements regarding the composition of PALACOS are neither literally false nor misleading.

2. Actual Deception or Tendency to Deceive

Zimmer states that since Heraeus' statements regarding product quality are literally false, it need not show actual deception. CPB at 88. However, the statements in question are true. Zimmer also argues that it proved deception in two ways: first, Heraeus intended to deceive customers into believing that Zimmer's cements are inferior to PALACOS, and second, that customers expressed concern about the quality of Zimmer's cement due to Heraeus' advertising. *Id* at 89.

As for the first point, Zimmer offers evidence only that Heraeus was internally discussing ways to distinguish PALACOS from the Zimmer Biomet cements, and training its sales team [REDACTED]

[REDACTED] CPB at 81 (citing JX-0138C.0040); *see* Tr. (Spiegelberg) at 604:8-605:2 (citing an internal guidance document at JX-0140C); *see also* CIB at 121. And Heraeus presented evidence illustrating that it intended to be truthful in its advertising. *See* Tr. (Mays) at 1178:6-21 [REDACTED]

[REDACTED] Moreover, as discussed, the statements at issue are not false or misleading. Without further evidence, Zimmer fails to prove Heraeus had an intent to deceive customers.

[REDACTED]

As for the second point, Zimmer states that it “and its sales force received numerous communications from customers expressing concern about the quality of RBCR and BBCR due to Heraeus’ advertising.” *See* JX-0350C (Fenton Dep.) at 233:16-235:20, 259:4-13, 261:19-262:9, 354:10-357:4; Tr. (Spiegelberg) at 607:25-609:6. However, all of the citations listed as purportedly showing “numerous communications” refer to the same instance of customer confusion – a surgeon who “expressed concerns about information he received about Refobacin bone cement recalls and needed information about what was going on with the recall.” Tr. (Spiegelberg) at 607:25-608:17. Without further evidence, Zimmer fails to prove that a significant or “substantial” portion of the consuming public” was deceived. *United Indus. Corp. v. Clorox Co.*, 140 F.3d 1175, 1182 (8th Cir. 1998).

3. Materiality

Materiality is not presumed when the statements at issue are not found to be literally false. Accordingly, Complainants must demonstrate that the statements are “likely to influence prospective purchasers to some substantial degree.” *Certain LEDs*, Initial Determination at 433-34 (quoting Restatement (Third) Unfair Competition § 3 cmt. b).

Zimmer presents evidence that purchasers generally find the safety and quality of bone cements important when making purchasing decisions. *See, e.g.*, Tr. (DiGioia) at 451:13-17 (discussing factors that are import in selecting a bone cement, factors include “quality and safety of the cements themselves”), 497:1-2 (stating “quality is very important to the decision of purchasers”). Heraeus witnesses also testified that product quality and safety are generally relevant to purchasing decisions. *See, e.g.*, JX-0341C (Lyon Dep.) at 83:3-20; JX-0333C (Bair Dep.) at 96:14-24; JX-0324C (Rupp Dep.) at 119:14-123:9. The materiality element is therefore satisfied.



4. Interstate Commerce

Again, Respondents do not dispute that PALACOS traveled in interstate commerce. *See* RPB at 19.

5. Likelihood of Injury

In contrast to the alleged false statements regarding PALACOS, the alleged false statements regarding product quality, if otherwise proven, might satisfy the “likelihood of injury” element. *See* CPB at 91-92. Nevertheless, this category of false statements suffers from the same problem as the other category – lack of proof of causation. Zimmer’s expert candidly admitted that she had not “disentangled” false advertising from all the other alleged violations that could have caused the various forms of injury Zimmer asserts. Tr. (Mulhern) at 709:9-710:3. Zimmer therefore has not met its burden of showing that it was injured from any false advertising, even assuming that Heraeus’ advertising was, in fact, false.

In summary, Zimmer failed to prove its false advertising case.

IX. TORTIOUS INTERFERENCE

As noted, to prove a claim of tortious interference — either with a contract or a business relationship — Zimmer must prove: (1) there was a contract or existing valid relationship, (2) the respondent knew of it, (3) the respondent performed an intentional act that was a significant factor in causing breach of contract or interference, (4) the act was without justification, and (5) it caused injury. *See Indus. Automation Sys.*, Initial Determination at 52 (citing *WaveDivision Holdings, LLC v. Highland Capital Mgmt., L.P.*, 49 A.3d 1168, 1174 (Del. 2012)); *Certain Foodservice Equip. and Components Thereof*, Inv. No. 337-TA-1166, Order No. 23, 2020 WL 2094134, at *1 (Mar. 30, 2020).

[REDACTED]

Zimmer asserts that Heraeus tortiously interfered with Zimmer’s business opportunities in two ways. First, Heraeus induced its employees to use Zimmer’s confidential and trade secret information to sell PALACOS bone cement in the United States. Second, Heraeus tortiously interfered with Zimmer’s prospective economic advantage by refusing to provide a contractual supply of PALACOS, using Zimmer’s confidential and trade secret information to convert customers to Heraeus, and falsely advertising to the detriment of Zimmer. *See* CPB at 92.

A. Interference with Confidentiality Agreements with Former Employees

Zimmer argues that Heraeus hired “a number of employees away from Zimmer Biomet,” and then induced these former employees to breach their respective agreements by setting up HMUS and having its employees directly compete with Zimmer Biomet. CPB at 94-95. Zimmer specifically identifies D. Childers, R. Kolbe, P. Cruz and W. Burns. *See id.* For example, Zimmer points to Devin Childers, the former National Commercialization Director, Biologics at Zimmer, who was hired by Heraeus to lead its U.S. bone cement sales force while having never hired sales agents, prepared a bone cement business plan, or otherwise obtained appropriate experience. *See* CPB at 94. Zimmer asserts that Heraeus induced each of these former Zimmer employees, who had signed confidentiality, non-competition, and non-solicitation agreements with Zimmer, to violate the Agreements and to use Zimmer’s trade secret information during their “employment duties at Heraeus.” *Id.* at 95. Zimmer’s assertions are unsubstantiated.

1. Existence and Knowledge of Zimmer Employment Contracts

Each of the former Zimmer employees (Messrs. D. Childers, R. Kolbe, P. Cruz and W. Burns) signed a confidentiality, non-competition, and non-solicitation agreement (“Employee Agreement”) with Zimmer. The Employee Agreements required the employees to [REDACTED]

[REDACTED] CX-

[REDACTED]

1028C; CX-2270C: RX-2392C; CX-2268C. Heraeus knew of the Employee Agreements that these individuals had with Zimmer because Heraeus' legal department reviewed the agreements when each of the employees were hired. JX-0326C (Childers Dep.) at 546:19-457.5.

2. No Intentional Actions Resulted in Breach of Employment Agreements

However, with the exception of Mr. Burns, discussed earlier, Zimmer fails to provide any evidence to show that these employees breached their respective Employee Agreement. Moreover, Zimmer fails to provide evidence that Heraeus "intentionally and without justification" induced any of the former Zimmer employees, including Mr. Burns, to breach their contracts. Zimmer argues that Heraeus' market entry was such that Heraeus must have intentionally induced the former employees to use Zimmer confidential and/or trade secret information to the benefit of Heraeus. *See* CIB at 131-32. Zimmer Biomet reasons that "Heraeus gave HMUS the unrealistic goals of simultaneously minimizing price erosion while converting as many customers as quickly as possible to preserve its long-term revenue trajectory." CPB at 95 (citing CX-1576C.0006; CX-1320). "HMUS was a new U.S. market entrant. It is highly unlikely that, as a new market entrant, HMUS could achieve these diametrically opposed goals through normal competition with Zimmer Biomet." CPB at 95.

Zimmer provides no evidence to prove this allegation, however. Zimmer does not cite any evidence demonstrating that the actions of Heraeus in setting sales goals and hiring former Zimmer employees were intended to cause those former Zimmer employees to breach their agreements. *See* CPB at 94-96. Mr. Childers testified at length to the contrary, describing how he hired personnel and created the sales and marketing plan. *See* JX-0326C (Childers Dep.) at 34:14-35:18; 36:14-24; 38:18-41:24; 45:6-25; 88:11-89:8 (collectively showing Mr. Childers's experience); *id.* (Childers Dep.) at 149:1-4 (explaining Mr. Childers hired individuals like Baxter Webb who were

[REDACTED]

“incredibly adapt at harvesting data” because of prior experience in startups). Moreover, the evidence shows that Heraeus did not approach the former employees with offers of employment with the intention of having those employees breach their respective agreements; rather, the former employees sought out employment opportunities with Heraeus. *See, e.g.*, JX-0326C (Childers Dep.) at 61:16-63:11; JX-0339C (R. Kolbe Dep.) at 17:1-6; JX-0335C (Cruz Dep.) at 85:4-88:18; JX-0328C (Burns Dep.) at 151:10-152:10.

Zimmer also argues that these former employees breached their employment agreements with Zimmer by failing to notify Zimmer “of any circumstances which may constitute unauthorized disclosure, transfer, or use.” CPB at 96. Heraeus is correct that this argument is new, and Zimmer therefore waived this theory of tortious interference. RPB at 44. Moreover, Zimmer failed to identify or prove any “unauthorized disclosure, transfer, or use” of its “Confidential Information” by the former employees in question, and did not prove any participation in a possible breach by Heraeus. *See* CPB at 96.

Accordingly, Zimmer’s first allegation of tortious interference fails.

B. Tortious Interference With Prospective Business Relationships

Zimmer also alleges that Heraeus interfered with Zimmer’s “prospective economic advantage to convert existing customers in three ways: (i) by refusing to supply Zimmer Biomet’s affiliate (Zimmer Surgical, Inc.) with PALACOS in breach of the Distribution Agreement, (ii) by using Zimmer Biomet’s trade secret and confidential information, and (iii) by falsely advertising about Zimmer Biomet’s right and ability to sell PALACOS and the superiority of PALACOS over RBCR.” CPB at 96-97. Zimmer’s allegation (ii), which is tortious interference through misuse or disclosure of Zimmer asserted trade secrets, fails for the same reasons that Zimmer’s underlying

[REDACTED]

trade secret claims fail. Similarly, Zimmer’s allegation (iii), which is tortious interference through false advertising, fails for the same reasons that Zimmer’s underlying false advertising claims fail.

Staff correctly notes that Zimmer’s tortious interference allegations have been revised from their original position. *See* SRB at 32-33. Zimmer originally focused on existing customer contracts as the relevant “prospective business relationships” (*see* CIB at 134-38), but now focuses on the impact of Heraeus’s actions on Zimmer’s ability to convert PALACOS into BBCR and RBCR customers (*see* CPB at 96-98). Under both theories, however, Zimmer advances three specific sources of interference, and as noted, the second and third lack merit for the same reasons Zimmer’s trade secret misappropriation and false advertising claims lack merit. For its part, Heraeus contends that Zimmer never even disclosed the second and third sources of interference until Zimmer’s prehearing brief. *See* RPB at 95-96. Again, though, these two positions lack merit, and it is unnecessary to find waiver. *See id.*

This leaves only Zimmer’s allegation of interference with its prospective economic advantage caused by Heraeus’ refusal to supply PALACOS to Zimmer Surgical, Inc. starting in July 2018, pursuant to the 2012 Agreement. Zimmer argues that “Heraeus’ refusal to supply PALACOS was unjustified and qualifies as ‘wrongful means’ and unfair competition because it was a breach of the Distribution Agreement.” CPB at 98-99 (citing *Conoco, Inc. v. Inman Oil Company, Inc.*, 774 F.2d 895, 907 (8th Cir. 1985)).

Article 3 of the 2012 Distribution Agreement defines how [REDACTED]

[REDACTED]

[REDACTED] JX-0204C.0019-20; JX-0362C (Hofer Dep.) at 204:5-206:7. Specifically, every September, Zimmer Surgical was [REDACTED]

[REDACTED]

JX-

[REDACTED]

0204C.0019, .0022 (Sections 3.1(b) and 3.4(b)). Heraeus Germany was then to [REDACTED]
[REDACTED] *Id.* at .0020 (Section 3.3(b)).

[REDACTED] *See id.* at .0019, .0039 (Sections 3.1(a), 11.1(a)). [REDACTED]
[REDACTED] JX-0232C; JX-0363C (Rohn Dep.) at 114:17-22; JX-0362C (Hofer Dep.) at 204:3-206:7. In response, however, Heraeus Germany refused to deliver PALACOS products to Zimmer Surgical for the remainder of 2018. See CX-2335C. Zimmer now asserts that this refusal amounts to tortious interference with its ability to convert existing customers to its own products. *See* CPB at 98-102.

1. Existence of and Knowledge of a Contract

Zimmer offers no evidence that Heraeus knew of any specific contracts Zimmer had with specific customers or any specific contractual details that might have a bearing on conversion to Zimmer's own products. The evidence does show, of course, that Zimmer had customer contracts for PALACOS bone cements in 2018 when HMUS became a co-distributor of PALACOS in the U.S., and that Heraeus knew of some of these Zimmer customers as a result of its own efforts to acquire customers. *See, e.g.*, CX-0574C.0001 (discussing companies they learned have contracts with Zimmer beyond 2018); JX-0065C (same); CX-1804C (same). However, Zimmer provides no evidence that Heraeus knew the specific contractual details of any of these customer contracts. More to the point, Zimmer offers no evidence that Heraeus knew that Zimmer intended to transition any specific customer contract to Zimmer's own products, or that any particular prospective business relationship would be affected by Heraeus' actions.



2. No Proof of Interference

The bulk of Zimmer’s discussion of whether Heraeus interfered with prospective business relationships by tortiously refusing to supply it with PALACOS pertains to allegations of breach of the 2012 Agreement. *See* CPB at 98-102. Very little pertains to how that breach, assuming it occurred, interfered with Zimmer’s effort to convert PALACOS customers into Refobacin customers, and in fact, only two items of evidence even reference such conversion. The first is an email between two Heraeus executives which states that “[i]f [Zimmer has] more time for conversion, they will convert more customers to Refo.” CX-1320C.0001. Although this is not inconsistent with Zimmer’s basic theory that Heraeus’ conduct “decreased Zimmer Biomet’s time to transition its customers to the ZB Cements,” Zimmer does not otherwise provide specifics on exactly how that transition time was affected. CPB at 98. The second is the testimony of Heraeus’ expert on Swiss law,⁴ Dr. Patrick Rohn, who apparently opines that it was commercially reasonable for Heraeus to consider potential loss of market share in deciding to refuse Zimmer’s firm orders. JX-0363C (Rohn Dep.) at 120:1-9. Here, too, Zimmer does not explain how that demonstrates tortious interference; indeed, it would seem to undermine Zimmer’s case. Zimmer cites no other evidence connecting the alleged breach of the 2012 Agreement to any prospective business relationships – no expert evidence, no internal Zimmer documents or communications, and no customer statements or testimony.

3. No Proof of Injury

Zimmer argues that “Heraeus’ unjustified intentional actions caused Zimmer Biomet to lose its prospective business advantage, because each of the actions decreased Zimmer Biomet’s time to transition its customers to the ZB Cements.” CPB at 98. Specifically, Zimmer argues that

⁴ The 2012 Agreement specifies that the laws of Switzerland govern the contract. JX-0204C.0041.

[REDACTED]

“Heraeus’ refusal to supply PALACOS to Zimmer Biomet after July 2018 reduced the time agreed in the 2012 Distribution Agreement that Zimmer Biomet had to introduce its own cements to customers.” *Id.* (citing CX-1320C). But CX-1320C is an email between two Heraeus executives, with no apparent discussion of any “agreed” time, and Zimmer fails to point to any clause in the 2012 Agreement that establishes such an understanding. And as both Heraeus and Staff point out, Zimmer failed to provide an injury analysis for tortious interference separate from that of trade secret misappropriation and false advertising. RPB at 48; SPB at 78; *see also* Tr. (Mulhern) at 709:14-710:3. Zimmer therefore fails to prove that Heraeus’ alleged tortious interference (which Zimmer also failed to prove) was the proximate cause of any injury alleged by Zimmer Biomet.

On balance, therefore, Zimmer’s tortious interference claim is unproven.

X. DOMESTIC INDUSTRY

Where a product is manufactured outside the U.S., a domestic industry may be established through activities having a close relationship to the products at issue. *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, but 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. And 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. Thus, the nature and significance of Zimmer’s business activities in the United States that relate to its bone cement and accessories must be assessed to determine whether there are sufficient qualifying activities to constitute an industry in the United States, or whether its activities are those of a mere importer. *Certain Bone Cements*, Inv. 337-TA-1153, Comm’n Opp’n at 21.

[REDACTED]

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”). With an important exception – the accessories themselves – these types of activities are what Zimmer contends establishes its domestic industry. Zimmer asserts that it has made investments in facilities, labor, and capital related to its characterization testing, regulatory compliance, manufacturing, customer service, technical support, and technical marketing activities for the bone cements and bone cement accessories that are sold in the United States (Zimmer refers to these as “ZB Products”). Zimmer’s specific domestic activities will thus be analyzed to determine whether they qualify as legitimate “domestic industry expenses.”

A. Characterization Testing and Regulatory Compliance

The first activity that Zimmer alleges makes up its domestic industry is characterization and regulatory compliance. Zimmer contends that its [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] CPB at 106-107 (citing JX-0346C (Armstrong Dep.) at 567:12-568:8; Tr. (Armstrong) at 35:25-36:15, 41:14-23; CDX-0008C.0005). Zimmer further states that its characterization tests are part of [REDACTED]

[REDACTED]

[REDACTED] *Id.*

Zimmer further contends that other activities related to regulatory compliance of the ZB Products performed in the United States are part of its domestic industry. CPB at 107.

[REDACTED]

Specifically, Zimmer states that its United States personnel [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] CPB at 107 (citing JX-0346C (Armstrong Dep.) at 488:16-22; Tr. (Armstrong) 38:16-25; CDX-0008C.0006). Zimmer further asserts that between April 2017 and August 2019, it operated the [REDACTED]

[REDACTED]

Id. [REDACTED]

[REDACTED]

[REDACTED] Tr.

(Armstrong) at 39:15-40:7.

Zimmer asserts that the expenses associated with facilities used for characterization testing and regulatory compliance are approximately [REDACTED] Tr. (Mulhern) at 649:20-650:2; CDX-0001C.5. Zimmer's expert, Ms. Mulhern, explained that this investment was calculated by allocating a portion of the investments in office space used by the testing and compliance employees as well as a portion of the investments in a number of specialized laboratories. Tr. (Mulhern) at 650:3-19; CDX-0001C.5-6. Zimmer also claims that it invested approximately [REDACTED] in labor associated with its characterization testing and regulatory compliance activities. Tr. (Mulhern) at 650:21-651:4; CDX-0001C.7. Ms. Mulhern calculated this investment by adjusting the share of time employees allegedly spent on the bone cements and accessory products at issue during the period of 2017 to August 2019 and also including the compensation of two Regulatory Affairs Specialists, who allegedly spent [REDACTED] of their time on regulatory and compliance activities. Tr. (Mulhern) 650:20-651:4; CDX-0001C.7. Zimmer alleges that its

[REDACTED]

investment in contract labor and supplies for the [REDACTED] that are allocable to the bone cement accessories is approximately [REDACTED] Tr. (Mulhern) at 651:8-652:9.

The Staff and Respondents dispute these allegations, primarily because Zimmer failed to accurately allocate expenses to the relevant activities that make up the domestic industry. *See, e.g.*, SPB at 88; RPB at 109. Staff argues that Zimmer’s calculations “appear inflated based on the inclusion of activities that were not related” to Zimmer’s domestic bone cement products, such as the [REDACTED] which includes “activities wholly unrelated to the development of the domestic industry bone cements.” SPB at 88 (citing Tr. (Armstrong) at 40:8-41:13). Respondents argue that characterization testing done by Zimmer was “performed for the benefit of the entire Cement Business Unit” and not just its bone cement products. RPB at 108. Thus, Heraeus also argues that Zimmer’s allocation is inflated. Heraeus further points out that the characterization testing was used in Zimmer’s marketing, because the data generated through the characterization testing was included in Zimmer’s product brochures. *Id.* Accordingly, Heraeus submits that Zimmer’s claimed expenditures for characterization testing should be rejected. *Id.* at 109.

B. Manufacturing Accessories

Zimmer further claims investments in the domestic manufacturing of certain accessory products in the United States as part of its domestic industry. Zimmer states that it manufactures some of its accessory products, such as Allen Plugs, mixing bowls, mixing systems, centralizers, poly plugs, restrictor plugs, medullary plugs, bone prep kits, curettes, spacer molds, and cement restrictors, in facilities in [REDACTED] CPB at 111 (citing JX-0346C (Armstrong Dep.) at 486:2-13; Tr. (Armstrong) at 43:6-44:6; CDX-0008C.0008). The evidence shows that Zimmer manufactures Allen Plugs, centralizers, poly plugs, and cement restrictors in the [REDACTED] JX-0346C (Armstrong Dep.) at 485:7-490:2. Injection molding

[REDACTED]

also is done there, in a [REDACTED] sq. ft. area of the facility. *Id.* Zimmer alleges that this area “is entirely dedicated to the manufacturing of the accessory products.” CPB at 111 (citing CX-2436C; CDX-0008C.0008; Tr. (Armstrong) at 43:5-21). Zimmer claims an average annual expenditure of [REDACTED] per sq. ft. for its Indiana Warsaw facilities. CX-2428C; Tr. (Armstrong) at 43:19-44:1. Zimmer further claims that it “invested approximately [REDACTED] for rent, maintenance, overhead, and utilities” for Warsaw Building 5 for the period from January 2017 to August 19, 2019. *Id.* (citing CX-3011C; CDX-0001C.0011; Tr. (Mulhern) at 653:12-654:2).

Zimmer further alleges that it manufactures mixing bowls, spatulas, mixing systems, quick use curettes, bone prep kits, cartridge kits, and plugs and inserters in [REDACTED] JX-0346C (Armstrong Dep.) at 485:7-490:2; CDX-0008C.0008; Tr. (Armstrong) at 24:6-9; 44:2-6. [REDACTED] CDX-0008C.0008; CDX-0001C.0011; Tr. (Armstrong) at 44:7-17. Zimmer states that the bone cement accessories comprise [REDACTED] of the value of production at the Dover facility; and by allocating the net book value of the Dover facility (alleged to be [REDACTED]) to the manufacturing space (based on the square footage), and then allocating the manufacturing space to the accessory (by share of value of the production), Zimmer invested [REDACTED] in its accessory products. CBP at 111-112 (citing CDX-0008C.0008; CDX-0001C.0011; Tr. (Armstrong) at 44:7-17; CX-3012C; CDX-0001C.11; Tr. (Mulhern) at 654:3-19).

Zimmer also claims labor costs of [REDACTED] associated with the accessory products manufactured in [REDACTED] per unit sold in the United States from 2017 to August 2019. Tr. (Mulhern) at 654:22-655:6; CDX-0001C.12. The labor costs associated with the employees at the Dover, Ohio facility are alleged to be approximately [REDACTED] based on the average hourly rate of the manufacturing activities,

[REDACTED]

including molding, extrusion, and assembly activities, at that facility. Tr. (Mulhern) at 655:7-14; CDX-0001C.12.

Staff and Heraeus argue that Zimmer is not entitled to include its manufacture of accessories as part of its domestic industry. Heraeus asserts that under § 1337(a)(1)(A) the proper scope of a complainant's domestic industry "is defined in terms of 'the target of the unfair acts and practices.'" RPB at 104 (citing *Rubber Resins*, ID, 2013 WL 4495127, at *216 ("[19 U.S.C. § 1337(a)(1)(A)] requires that a complainant prove that a domestic industry exists that is subject to injury as a result of unfair acts, i.e., the target of the unfair acts and practices.")). And, Heraeus argues, Zimmer's accessory products are not the target of the alleged unfair acts.

C. Customer Service and Technical Support

Zimmer claims [REDACTED] of investments in customer service and support activities as domestic industry investments. Tr. (Mulhern) at 658:8-13 (CDX-0001C.17 provides summary of calculations for the customer service). Zimmer's expert, Ms. Mulhern, calculated this amount because approximately [REDACTED] in facilities expenses (located in Warsaw, Indiana, Building 4) and [REDACTED] 0 in labor costs (one director who [REDACTED] [REDACTED])⁵ are attributable to customer service and technical support functions associated with both the bone cements and the accessories. See Tr. (Mulhern) at 656:14-658:13; CDX-0001C.15-.17. Ms. Mulhern used an allocation factor of [REDACTED] percent, which is a "sales-based allocation that takes into account the share of total sales associated with the Zimmer Biomet bone cements and accessories at issue." Tr. (Mulhern) at 656:24-657:8, 657:24-658:7.

⁵ [REDACTED]

[REDACTED] JX-0244C; CX-3272C.0016-17; Tr. (Armstrong) at 45:1-23.

[REDACTED]

Heraeus and Staff assert that these activities are not part of the domestic industry because they include activities directed to products that are not the domestic industry products. However, as discussed below, accessory products are properly included in assessing Zimmer’s domestic industry. Heraeus further argues that the customer service and technical support are sales and marketing expenditures, and “[a]t least a portion of Zimmer Biomet’s ‘411 Product Services’ team’s activities are sales and marketing.” RPB at 109-110. But although customer service and technical support can certainly be used for marketing, overall they are more akin to repair services, which qualify as domestic industry. *See Case-Iron Stoves*, Comm’n Op. at 11 (finding domestic industry based in part on repair activities). So this category, with expenditures of approximately [REDACTED] counts toward Zimmer’s domestic industry.

D. Technical Marketing

Finally, Zimmer asserts that approximately [REDACTED] in investments in “technical marketing” activities are qualifying domestic industry expenses. Tr. (Mulhern) at 659:13-660:25; CDX-0001C.18-.22. Included in this are [REDACTED] Tr. (Mulhern) at 659:13-20. Zimmer claims these marketing activities are “technical,” but Zimmer itself defines these teams as primarily marketing. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] CPB at 115.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] *Id.* [REDACTED]

[REDACTED]

[REDACTED] *See, e.g.,* Tr. (Armstrong) at 82:18-23 [REDACTED]

[REDACTED]

83:8-84:2 ([REDACTED]).

E. Analysis

Zimmer has the burden to show that its U.S. activities are more than those performed by a mere importer. The record is unclear, however, as to whether Zimmer’s Characterization Testing and Regulatory Compliance Practice engages in activities distinguishable from activities that a mere importer would perform. The Commission has credited investments to obtain FDA approval as part of the domestic industry in the past, but only after robust analysis of detailed evidence. For example, in *Certain Salinomycin Biomass and Preparations Containing Same*, Inv. No. 337-TA-370, USITC Pub. 2978 (July 1996), Initial Determination at 128 (not reviewed), a domestic industry was found in part based on findings that (1) many employees of the patent owner’s licensee spent time on “regulatory activities” (*id.* at 128); (2) the licensee had an FDA-approved plant for making the chemical (*id.* at 299); (3) the complainant had “a consultant in the United States that it uses in connection with FDA matters related to” the chemical (*id.* at 296), and (4) the licensee had “plans to submit elements of the package seeking FDA approval” for use of the chemical in animals (*id.* at 301). Similarly, in *Certain Diltiazem Hydrochloride and Diltiazem Preparations Containing Same*, Inv. No. 337-TA-348, USITC Pub. 2902 (June 1995), Initial Determination at 120-28 (unreviewed in relevant part), a domestic industry was found in part based on findings that the complainant (1) “conducts research and development . . . in order to comply with FDA requirements” (ID at 142, 323, *see also id.* at 144); (2) maintains processes and

[REDACTED]

equipment in accordance with “FDA requirements” (*id.* at 143, 323); (3) spent an amount on the order of at least \$1 million “on research and development including FDA approval, clinical trials, formulation research,” and other activities (*id.* at 324); (4) employed personnel “responsible for the research and development activities relating to FDA-required clinical testing from development phase 1 through phase 3” (*id.* at 325-26); and (5) employed other personnel responsible for research on “products for which FDA approval is pending (phase 3B) and for those products which have already been approved” (*id.* at 326).

In the present case, however, Zimmer has not shown, for example, that its Characterization Testing and Regulatory Compliance Practice involves these 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. *See* CPB at 106-07. Zimmer states that it has specialized laboratories, but it does not assert that these laboratories actually are used and maintained in accordance with FDA requirements. *See id.* And Zimmer does not allege that any type of research and development takes place in the U.S. Instead, Zimmer’s identified activities are seemingly no more specialized than those of any mere importer seeking FDA compliance. The same is true of the [REDACTED] expenditures. *See* CPB at 107.

Zimmer’s accessory manufacturing costs, however, are part of its domestic industry, because Heraeus’ acts were directed to both cements and accessories. As Zimmer points out, TS 15 includes sales data on Zimmer’s accessory products (CX-2622C; JX-0309C) and Trade Secrets 10 and 28 include data on Zimmer customers who purchased both cements and accessories. CRB at 51 (citing CX-2172C; CX-2499C). Moreover, the scope of the investigation, as defined in the Notice of Investigation, is for both bone cements and accessories. 84 Fed. Reg. 49764 (Sept. 23, 2019); *see, e.g., Certain Wireless Comm’n Devices, Components Thereof, and Prods. Containing*

[REDACTED]

the Same, Inv. No. 337-TA-583, Order No. 6 at 3 (Dec. 15, 2006) (“[N]otice of investigation determines the scope of the investigation”). Accordingly, Zimmer’s investments in the manufacture of its accessory products in the United States is properly part of its domestic industry

Investments for customer service and technical support and technical marketing are primarily sales and marketing activities, which are not cognizable as domestic industry activities. However, as Heraeus recognizes, “[a]t least a portion of the ‘411 Product Services’ are sales and marketing,” and thus, another portion may be technical. RPB at 110. Zimmer’s expert realized that and allocated only [REDACTED] of the investments as going to the domestic industry. This is reasonable in light of the evidence that at least some activity is not sales-related, but is, in fact, technical assistance. The remainder of Zimmer’s claimed activities of technical marketing “are not of the nature of activities that qualify toward establishing an industry.” *Certain Bone Cements*, Inv. 337-TA-1152, Commission Op. at 29. They are largely marketing activities that a mere importer conducts.

Thus, Zimmer’s activities and expenditures that make up its domestic industry are its investments in accessory manufacturing (a combined [REDACTED] for facilities and [REDACTED] for labor at two sites), and a portion [REDACTED] of its customer service and technical support. Unsurprisingly, the more important of these is the accessory manufacturing, because an investment of almost [REDACTED] [REDACTED] although not automatically or even presumptively sufficient, certainly merits close attention, and because the investment is in domestic manufacturing. That is, Zimmer may well be a mere importer with respect to its bone cements (and discounting accessory manufacture, a domestic industry investment of only [REDACTED] in customer service and technical support likely would be insufficient), but it is not an importer with respect to a portion of its accessory manufacturing.

[REDACTED]

To be sure, Zimmer’s domestic accessory manufacturing is [REDACTED]

[REDACTED] As Dr. Vander Veen, Heraeus’ expert, notes, the number of full-time equivalent employees who Ms. Mulhern attributes to Zimmer’s domestic industry is [REDACTED]

[REDACTED] See Tr. (Vander Veen) at 1328:4-13; RDX-0003C.29. But Zimmer’s domestic accessory manufacturing business overall is nonetheless significant. Between January 2017 and August 2019, Zimmer’s U.S. employees spent over [REDACTED] performing [REDACTED] [REDACTED] at its two U.S. sites. CPB at 112; Tr. (Mulhern) at 655:7-14; CX-3015C. Between 2017 and April 2020, this domestic manufacturing accounted for [REDACTED] of Zimmer worldwide accessory sales on a unit basis. See CX-3028C. And it is seemingly highly profitable: again including the period ending in April 2020, its U.S. accessory manufacturing resulted in over [REDACTED] in net sales revenue, which was [REDACTED] of worldwide accessory net sales revenue, compared to labor costs of less than [REDACTED]. Id; CX-3015C. Lastly, although Dr. Vander Veen criticizes Zimmer’s analysis of its accessories business, the record readily permits a specific identification of accessory manufacturing labor and facilities costs, unit sales, and net revenues, and it is clear that the accessories business is significant. Compare, e.g., CX-3028C (breaking down sales and revenues by year and region) with Tr. (Vander Veen) at 1326:14-1327:10 (criticizing Ms. Mulhern’s analysis for lack of “context”).

Therefore, Zimmer has demonstrated the existence of a domestic industry under section 337(a)(1)(A)(i).

F. Substantial Injury To Domestic Industry

In addition to proving that a domestic industry exists, Zimmer must “demonstrate . . . that there [is] actual substantial injury or the threat of substantial injury” to it. See *Rubber Resins*,

[REDACTED]

Comm’n Op., 2014 WL 7497801, *5. In addition, “[w]hen the complainant alleges actual injury, there must be a causal nexus between the unfair acts of the respondents and the injury.” *Id.* at *30.

Zimmer fails to provide sufficient evidence that any actions by Heraeus caused or threatened substantial injury to its domestic industry. Instead, the majority of Zimmer’s arguments and evidence of injury relate to its sales of bone cement. This is not Zimmer’s domestic industry, and thus, this evidence is not relevant to the analysis. Nonetheless, the following analysis will address the various theories of injury.

1. Lost sales, Lost Market Share, and Price Erosion of Bone Cements and Accessories

Zimmer asserts that Heraeus’ misappropriation of trade secrets enabled it to undercut Zimmer Biomet’s historic pricing for PALACOS with those customers. No misappropriation has been proven; however, should misappropriation of Zimmer’s purported trade secrets be found, Zimmer fails to show that the misappropriation resulted in injury to Zimmer’s domestic industry. In brief, Zimmer asserts that the alleged misappropriation of TS 10 and alleged wrongful disclosure to [REDACTED] injured Zimmer because Heraeus relied on the data and advice [REDACTED] provided to guide its development of its operations in 2017 and market entry in 2018, giving Heraeus a head start to unfairly compete with Zimmer Biomet. However, the evidence shows that Heraeus’ engagement of [REDACTED] *See* Tr. (Petermann) at 770:17-20; JX-0334C (Petermann Dep.) at 161:2-16. Zimmer did not provide any evidence that such limited interactions with [REDACTED] resulted in a loss of customers or other harm in 2018. Similarly, Zimmer fails to provide evidence showing that the alleged disclosure to [REDACTED] caused any injury. In fact, Heraeus Germany ultimately did not engage [REDACTED] Tr. (Petermann) at 777:16-778:4. Accordingly, Zimmer cannot link Heraeus’ preliminary discussions with [REDACTED] to the loss of any customers or other harm in 2018. Finally, Zimmer alleges

[REDACTED]

that the sharing of trade secrets with [REDACTED] injured Zimmer because [REDACTED] used the information to guide HMUS' marketing strategy and execute targeting of Zimmer's customers. JX-0325C (Wilemon Dep.) at 32:9-33:4; 69:9-70:2. However, Zimmer presented no evidence connecting the alleged early and limited disclosures to [REDACTED] to any customer loss or other harm.

Similarly, Zimmer failed to provide any evidence that Mr. Burns' creation and taking of the "For Peterson" file resulted in any injury to Zimmer. No evidence was provided to show that Mr. Burns or anyone at Heraeus ever used the data within the file. *See, e.g.*, Tr. (Vaughn) at 370:24-371:2; CDX-0006C.6 (finding only a single instance in which the USB drive with the "For Peterson" file was connected to Mr. Burns' Heraeus work computer).

Nonetheless, Zimmer presents evidence purportedly showing that Heraeus' actions caused lost sales of bone cement and accessory products. For example, Zimmer claims that in [REDACTED]

[REDACTED]

[REDACTED] CX-3036C. [REDACTED] *Id.*; Tr. (Mulhern) at 666:7-20; CDX-0001C.27. According to Zimmer, its bone cement sales totaled [REDACTED] units. CX-3022C; CX-3064C; Tr. (Mulhern) at 667:3-21; CDX-0001C.30. But by 2019, Zimmer Biomet's annual sales of bone cements [REDACTED]

[REDACTED] *Id.* Zimmer further argues this loss occurred while the bone cement market was growing. CX-3000C. On a revenue basis, Zimmer argues that its sales decline is even greater. In 2017, Zimmer Biomet's bone cement revenues totaled [REDACTED] and [REDACTED] [REDACTED] in 2019, which amounts to a [REDACTED] CX-3023C; Tr. (Mulhern) at 667:21-668:7; CDX-0001C.20.

[REDACTED]

Zimmer's figures are misleading, however, because they include Zimmer's historic sales of PALACOS, which of course would decrease because of the termination of the 2012 Distribution Agreement. *See* RPB at 122. As Staff points out, Heraeus made sales of approximately [REDACTED] of the accused PALACOS bone cement products in 2018 and approximately [REDACTED] in sales in 2019. SPB at 95-96 (citing CX- 3030C). Zimmer made sales of approximately [REDACTED] in U.S. sales from its own BBCR and RBCR products in 2018 and [REDACTED] in 2019. CX- 3023. These numbers illustrate that Zimmer did not suffer injury in its sales of its own bone cement products, even assuming they are part of its domestic industry.

With respect to Zimmer's sales of bone cement accessories, which actually is part of its domestic industry, Zimmer fails to present evidence that it lost sales due to Heraeus' actions. Zimmer often does not focus on these alleged lost sales in detail, but instead generally lumps the accessory sales together with bone cement sales. *See, e.g.,* CPB at 126 ("Zimmer Biomet's cement sales and accessory sales to [REDACTED] members have each declined since 2018. Tr. (Smith) at 133:24-134:4").

And even when Zimmer does disaggregate accessories from bone cements, its evidence does not establish a nexus with Heraeus' actions. For instance:

In 2018, Zimmer Biomet's sales of products competitive with HMUS' accessory products totaled [REDACTED] units accounting for [REDACTED] in revenue. CX-3025C; CX-3026C. In 2019, Zimmer Biomet's sales of these same products [REDACTED] units [REDACTED] and [REDACTED] in revenue [REDACTED]. Tr. (Mulhern) at 672:15-673:13; CDX-0001C.36-37; CX-3025C; CX-3026C. This includes a decline in revenue from the sales of accessories to [REDACTED] Tr. (Smith) at 133:24-134:4, 135:10-16. While the absolute percentage of [REDACTED] and is expected to continue growing, thus showing injury. Tr. (Mulhern) at 673:4-13; CX-3001C; CX-3002C.

CPB at 135. Such trends are not necessarily attributable to Heraeus' unfair acts; certainly the evidence cited does not clearly point to that conclusion. As another example, Zimmer asserts that

[REDACTED]

it lost sales of accessories because “Heraeus’ unfair acts also led customers to turn to third-parties, such as Stryker or DePuy, who can supply a full line of products.” *Id.* (citing Tr. (Mulhern) at 687:17-689:12). However, Zimmer offers no more evidence of the injury beyond this statement. By contrast, Staff presents a chart that Zimmer’s expert offered, that shows Zimmer’s market share of “Cement Delivery and Mixing Systems” in 2016 was [REDACTED] and in 2019 it was [REDACTED] and at the same time Stryker’s market share [REDACTED] while “other” entities’ share [REDACTED], and Heraeus showed no market share at all in 2019. SRB at 48. Such evidence undermines Zimmer’s case.

The only reference to Zimmer’s alleged injury to its accessory domestic industry due to price erosion relates to a contract negotiation it had with [REDACTED]. According to Zimmer, the “evidence demonstrates that [REDACTED] leveraged Heraeus’ low proposed prices in negotiations with Zimmer Biomet.” CPB at 139. In fact, the evidence actually shows that [REDACTED] issued a Request for Proposal to multiple companies, and Heraeus ultimately lost the bid after submitting a second response at the request of [REDACTED] to lower its prices. Tr. (Smith) at 134:12-135:3; CX-2043C.0005. This is insufficient to prove that Zimmer suffered price erosion due to actions by Heraeus.

2. Reputational Harm and Injury to Goodwill

Zimmer also asserts that it suffered injury in the form of “harm to reputation and brand” as a result of Heraeus’s alleged violations. Tr. (Mulhern) at 680:2-22; CDX-0001C.45. Zimmer fails to provide evidence to support this, however. As Staff and Heraeus argue, Zimmer’s expert Dr. DiGioia agreed that Zimmer has “a very good national reputation as a medical device company” and has held this reputation “consistently from late 2017 to the present.” Tr. (DiGioia) at 516:8-14, 510:8-10 (testifying that Zimmer’s reputation for safety and quality is very high);

[REDACTED]

see also Tr. (Shapiro) at 1242:17-20 (opining that “if any injury was caused, I think that in terms of reputation that Zimmer hurt their own reputation”). In other words, Zimmer’s reputation has not suffered as a result of Heraeus’ actions. Moreover, Complainants’ experts have not provided any analysis of injury specific to loss of goodwill or reputation, or to show a nexus between these allegations and the domestic industry.

3. Testing, Customer Service and Technical Support/Marketing

Zimmer states that its [REDACTED]

[REDACTED] CRB at 70. However, Zimmer fails to link these changes to Heraeus’ alleged misappropriations of trade secrets, tortious interference, or false advertising, as opposed to lost sales of PALACOS. Moreover, these changes in Zimmer’s personnel and business structure are a natural progression of the nature of the business. As Heraeus points out, Zimmer’s bone cements were approved by the FDA, and thus, Zimmer no longer needs employees dedicated to seeking regulatory approval, and Zimmer has identified no other types of regulatory expenditures that it had or lost due to Heraeus’ alleged violations. RRB at 72-73 (citing Tr. (Vander Veen), 1321:6-10 (“Now, that [regulatory affairs team] would for the [510(k)] submissions occurred in 2016 and 2017. And after the time it was submitted, I don’t see evidence of what post-submission work was occurring.”)). Zimmer admits that “the majority of the characterization testing of the DI Bone Cement Products occurred in [REDACTED] which were filed in 2016 and 2017. CX-3270.0009; Tr. (Spiegelberg), 556:22-557:1 (“A lot of the regulatory submissions involve 510(k) submissions.”); CX-0559C (Apr. 27, 2016 FDA 510(k) for Refobacin Bone Cement R); CX-2935C (May 23, 2017, Zimmer’s 510(k) for Refobacin Bone Cement R); JX-0301C (510(k) for Biomet Bone Cement R from Aug. 1, 2017).

[REDACTED]

Zimmer further explains that its [REDACTED]

[REDACTED] and this caused injury to its alleged domestic industry. However, Zimmer fails to show that the elimination of these positions is the result of any of the unfair acts. Heraeus notes that in its interrogatory responses, Zimmer stated that it “engages in the sale and distribution of BBCR and RBCR through its vast network of direct territories and independent distributors, including nearly [REDACTED] sales representatives[.]” RRB at 74 (citing CX-3272C.0025-0026). The [REDACTED] members of Zimmer’s [REDACTED] role always had been to assist other employees in making sales. *Id.* (citing CX-3272C.0026 [REDACTED])

[REDACTED]

[REDACTED]

[REDACTED] No further evidence was presented related to the elimination of these positions. Thus, Zimmer fails to show that Heraeus’ alleged acts are related at all to Zimmer’s testing, customer service, and technical support and marketing.

Therefore, Zimmer has failed to prove injury or threat of substantial injury to its domestic industry.

XI. CONCLUSIONS OF LAW

1. The Commission has jurisdiction to conduct this Investigation.
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.
3. Zimmer owns the asserted Trade Secrets.
4. TS 10 is a protectable trade secret.
5. TS 11 is not a protectable trade secret.

-
6. TS 15/28 are protectable trade secrets.
 7. Respondents did not misappropriate any Trade Secret.
 8. Respondents did not engage in false advertising.
 9. Respondents did not tortiously interfere with Zimmer Biomet's contracts or prospective business relationships.
 10. Zimmer has established a domestic industry.
 11. There is not and has not been a substantial injury or threat of injury to Zimmer's domestic industry by Heraeus' actions.
 12. There is no violation of Section 337 on any asserted basis.

XII. 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's 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 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

[REDACTED]

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

[REDACTED]

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.* 49764 (September 23, 2019).

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. For the accused PALACOS bone cements, these entities include Respondents Heraeus Medical GmbH and Heraeus Medical LLC. In addition, any affiliated companies, parties, subsidiaries, and others, including certification provisions, are included.

“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.”). With respect to a violation involving asserted trade secrets 10, 15, and/or 28, Zimmer’s corporate witness Mr. Armstrong testified that the typical development time is approximately [REDACTED] [REDACTED] and the development time for asserted trade secret 11 would take no more than [REDACTED] [REDACTED] to develop. Tr. (Armstrong) at 26:9-11, 28:14-16, 29:14-30:1, 30:22-24. Zimmer’s expert Ms. Mulhern agreed with these time frames. Tr. (Mulhern) at 690:15-25 and CDX-0001C.56.

[REDACTED]

On the other hand, Heraeus' expert Mr. Senn testified that the asserted trade secrets would have taken no more than two weeks to independently develop. Tr. (Senn) at 1048:1-14 (explaining that the [REDACTED] of development for asserted TS 10 proposed by Zimmer Biomet reflects the normal course of sales efforts, not development of the asserted trade secret); RDX-0006C. Dr. Vander Veen further testified that "as of January of 2019 . . . Heraeus [was] permitted to make use of the trade secrets" to sell PALACOS, and any exclusion order that goes into effect in 2020 or later risks restricting legitimate competition. Tr. (Vander Veen) at 1356:24-1357:6; RDX-0003C.073.

Zimmer seeks to exclude Heraeus' bone cement and accessories, which are not manufactured or tested using any of the asserted trade secrets. Thus, I agree with Staff that the appropriate measure of duration for an exclusion order is the time advantage in marketing that Heraeus allegedly gained as a result of the alleged misappropriation. SPB at 102. Heraeus did not have use of the data in the Trade Secrets asserted TS 10 and TS 11 (and, thus, most of TS 15/28 to the extent of overlap) from the time Heraeus gave notice of its mutual election of non-exclusivity until the 2012 Agreement terminated at the end of 2018, *i.e.*, roughly a year. JX-0204C.0015.

With respect to false advertising, Commission remedial orders simply prohibit the respondent from importing falsely advertised products, so no time limitation is warranted. *See, e.g., Woven Textile Fabrics*, General Exclusion Order, ¶ 1 (EDIS Doc. ID 605891). With respect to tortious interference, Zimmer's allegations are based in large part on the same arguments as its claims of trade secret misappropriation and false advertising and should be subject to the same limitations. Inasmuch as Zimmer's tortious interference allegations are based on failure to supply PALACOS according to the 2012 Agreement, Biomet's right to distribute PALACOS has

[REDACTED]

unquestionably expired at this point, so any remedy on that basis would be inappropriate. *See Electric Fireplaces*, Comm’n Op. at 9 (vacating finding of violation based on expired contract).

Accordingly, to the extent trade secret misappropriation or tortious interference based on such misappropriation is found, a limited exclusion order of one year is appropriate. To the extent false advertising or tortious interference based on such false advertising is found, a limited exclusion order with no time limit is appropriate. Zimmer does not seek a general exclusion order, nor does the record support imposing one. *See* CPB at 147.

B. Cease and Desist Order

If a violation of Section 337 is found, a cease and desist order is appropriate because Heraeus maintains a significant inventory of PALACOS bone cement and accessories in domestic inventory. *See* Tr. (Mulhern) at 691:1-16; CDX-0001C.57 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] CX-1734C; CX-1735C.

Heraeus seemingly does not dispute that it maintains a substantial inventory. *See* RPB at 150. 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, the affected articles are entitled to entry or sale under bond during the 60-day Presidential review period. The Commission often sets the bond based on price differential or on a reasonable royalty. *See, e.g., Certain Microsphere Adhesives, Processes for Making Same, and Products Containing Same, Including Self-Stick Repositionable Notes*, Inv. No. 337-TA-366, Comm’n Op. at 24, USITC Pub. 2949 (Jan. 1996) (“the Commission typically has considered the differential in sales price

[REDACTED]

between the patented product made by the domestic industry and the lower price of the infringing imported product, and has set a bond amount sufficient to eliminate that difference”); *Certain Plastic Encapsulated Integrated Circuits*, Inv. No. 337-TA-315, USITC Pub. 2574, Comm’n Op. at 45 (Nov. 1992) (setting the bond based on a reasonable royalty).

Zimmer’s expert testified that calculation of a price differential is “impractical in this investigation” because the bone cement products and accessories are sold at varying prices, often separately negotiated with individual customers. Tr. (Mulhern) at 691:25-692:4. Instead, she asserted that industry royalty rates can be used to set an appropriate bond rate. Tr. (Mulhern) at 692:5-8 and CDX-0001C.58 (noting industry royalty rates in the medical and health products industry range from 2.5 percent to 7.0 percent, with an average of 6.0 percent and a median of 4.5 percent, while bone cement royalty rates range from 2.5 percent to 10 percent, with a median of 5 percent); *see also, e.g.*, CX-2834; CX-2816. Accordingly, Zimmer’s expert stated that a bond of 6% is reasonable. Tr. (Mulhern) at 692:5-8; CDX-0001C.58.

On the other hand, Heraeus’ expert Dr. Vander Veen testified that bond should be set at no more than 5%, which is the amount the Administrative Law Judge found to be economically reasonable in the 1153 Investigation. Tr. (Vander Veen) at 1358:4-10 (explaining that as Ms. Mulhern’s opinions appear to be consistent with those presented in the 1153 investigation, and lacking any reason to otherwise distinguish this investigation from the previous investigation, there is “no reason to increase the bond beyond the 5 percent” established by the ALJ in the 1153 investigation); RDX-0003C.075. Both experts’ positions are reasonable; the record supports a bond that is halfway between them, or 5.5%.



XIII. 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 bone cement accessories. Respondents did not engage in trade secret misappropriation, false advertising, or tortious interference with prospective business relationships. A domestic industry in the United States exists, but was not injured or subject to threat of injury by virtue of any violations.

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 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

[REDACTED]

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.

A handwritten signature in cursive script, appearing to read "C. Elliot", written in black ink.

Cameron Elliot
Administrative Law Judge

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, **Megan Wantland, Esq.**, and the following parties as indicated, on **February 23, 2021**.



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

On Behalf of Complainants Zimmer, Inc., and Zimmer US, Inc.:

Eric S. Namrow, Esq.
MORGAN, LEWIS & BOCKIUS LLP
1111 Pennsylvania Avenue, NW
Washington, DC 20004
Email: eric.namrow@morganlewis.com

- ☐ Via Hand Delivery
- ☐ Via Express Delivery
- ☐ Via First Class Mail
- ☒ Other: Email Notification
of Availability for Download

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

David A. Caine, Esq.
ARNOLD & PORTER KAYE SCHOLER LLP
3000 El Camino Real, Suite 500
Palo Alto, CA 94306
Email: david.caine@arnoldporter.com

- ☐ Via Hand Delivery
- ☐ Via Express Delivery
- ☐ Via First Class Mail
- ☒ Other: Email Notification
of Availability for Download