



7020-02

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-1153]

**Certain Bone Cements, Components Thereof and Products Containing the Same;
Commission Determination to Review in Part a Final Initial Determination Finding a
Violation of Section 337; Schedule for Filing Written Submissions on the Issues Under
Review and on Remedy, the Public Interest, and Bonding**

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review in part the final initial determination (“final ID”) issued by the presiding administrative law judge (“ALJ”) on May 6, 2020, finding no violation of section 337 of the Tariff Act of 1930, as amended, in connection with the alleged misappropriation of trade secrets. The Commission requests briefing from the parties on certain issues under review, as indicated in this notice. The Commission also requests briefing from the parties, interested government agencies, and interested persons on the issues of remedy, the public interest, and bonding.

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

<https://www.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

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

The investigation has terminated as to respondents Zimmer Orthopaedic Surgical Products, Inc. and Biomet Europe B.V., Order No. 10 (May 23, 2019), *not reviewed*, Notice (June 14, 2019), and as to certain accused products, Order No. 30 (Nov. 24, 2019), *not reviewed*, Notice (Dec. 10, 2019). Also, the first amended complaint and notice of investigation were amended to add three entities as respondents: Zimmer US, Inc.; Zimmer, GmbH; and Biomet

Manufacturing, LLC. Order No. 18 (June 26, 2019), *not reviewed*, 84 FR 35884-85 (July 25, 2019). The remaining respondents are referred to collectively herein as “Zimmer Biomet.”

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

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

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

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

- (1) The ALJ's findings and conclusions as to TS 1–35 and 121–23;
and
- (2) The ALJ's domestic industry findings, including whether there has
been a substantial injury to the alleged domestic industry.

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

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

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

- (3) For the costs related to education-and-training-related investments (*e.g.*, the Reduce Revisions initiative), discuss: (A) how the Commission and the Federal Circuit have considered education-and-training-related investments in prior investigations, *e.g.*, *Certain Sleep-Disordered Breathing Treatment Systems and Components Thereof*, Inv. No. 337-TA-890, Init. Det. at 168–70 (Aug. 21, 2014), *not reviewed in relevant part*, Notice (Oct. 16, 2014), and (B) how the facts of this investigation should be assessed in light of applicable precedent.
- (4) For the Reduce Revisions initiative costs: (A) are these costs incorporated into Heraeus’s general marketing expenses? *See Certain Gas Spring Nailer Products and Components Thereof*, Inv. No. 337-TA-1082, Comm’n Op. at 83 n.20 (Apr. 28, 2020); (B) if the costs are viewed as marketing expenses, is there a basis for concluding the costs are technical marketing costs; and (C) how should technical marketing costs be treated?
- (5) For the alleged costs related to FDA and other regulatory approvals and compliance: (A) which of those regulatory efforts had to take place in the United States (for either legal or practical reasons), and which could have been carried out in another country; and (B) does the record permit allocation of costs between those two categories?
- (6) Please analyze whether a complainant bringing a claim under section 337(a)(1)(A)(i) must demonstrate that its industry in the United States is “significant” or “substantial.” Please include a discussion of the relevant

statutory language, any relevant legislative history, any relevant Federal Circuit decisions and any relevant prior Commission determinations.

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

The statute requires the Commission to consider the effects of that remedy upon the public interest. The public interest factors the Commission will consider include the effect that an exclusion order and/or cease and desist orders would have on: (1) The public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers.

The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve, disapprove, or take no action on the Commission's action. *See* Presidential Memorandum of July 21, 2005, 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

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

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

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. The Commission's paper filing requirements in 19 CFR 210.4(f) are currently waived. 85 FR 15798 (March 19, 2020). Submissions should refer to the investigation number ("Inv. No. 337-TA-1153") in a prominent place on the cover page and/or the first page. (See Handbook for Electronic Filing Procedures, https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf). Persons with questions regarding filing should contact the Secretary at (202) 205-2000.

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

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

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

By order of the Commission.

Lisa Barton,

Secretary to the Commission.

Issued: July 13, 2020.

[FR Doc. 2020-15459 Filed: 7/16/2020 8:45 am; Publication Date: 7/17/2020]