INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-1447]

Certain Drug Products Containing C-Type Natriuretic Peptide Variants, and Components Thereof; Notice of a Commission Determination Not to Review an Initial Determination Granting Complainant's Motion to Amend the Complaint and Notice of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission ("Commission") has determined not to review an initial determination ("ID") (Order No. 15) of the presiding Chief administrative law judge ("Chief ALJ") granting Complainant's motion to amend the complaint and notice of investigation.

FOR FURTHER INFORMATION CONTACT: Jonathan D. Link, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street S.W., Washington, D.C. 20436, telephone (202) 205-3103. 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 May 8, 2025, based on a complaint filed by BioMarin Pharmaceutical Inc. of Novato, CA ("Complainant"). 90 FR 19532-33 (May 8, 2025). The complaint, as supplemented, alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain drug products containing C-type natriuretic peptide variants and

components thereof by reason of infringement of claims 15-20, and 31-48 of U.S. Reissue Patent No. 48,267. *Id.* at 19532. The complaint further alleges that a domestic industry exists. *Id.* The Commission's notice of investigation named as respondents: Ascendis Pharma, Inc. of Palo Alto, CA, Ascendis Pharma A/S of Hellerup, Denmark, and Ascendis Pharma Growth Disorders A/S of Hellerup, Denmark (collectively "Ascendis"); and Wacker Biotech GmbH of Jena, Germany. *Id*. at 19533. The Office of Unfair Import Investigations ("OUII") is participating in the investigation. *Id.*

On June 20, 2025, the Commission determined not to review Order No. 5, setting a 17-month target date as October 8, 2026, with any final initial determination to be due no later than June 8, 2026. *See* Order No. 5 (May 27, 2025), *unreviewed by* Comm'n Notice (June 20, 2025).

On June 17, 2025, Complainant filed a motion to amend the complaint and notice of investigation to add Bachem AG ("Bachem") as an additional respondent. Complainant also requested that the Chief ALJ declassify certain discovery responses. On June 27, 2025, Ascendis filed a response in opposition to the motion, while OUII filed a response not opposing the motion. On July 9, Bachem filed a response in opposition to the motion. On July 14, 2025, Complainant filed a reply in support of its motion, and OUII filed a reply maintaining its non-opposition to the motion.

On July 24, 2025, the Chief ALJ issued Order No. 13, granting leave for Complainant to supplement its motion to amend. On July 30, 2025, Complainant filed a supplement to its motion to amend, which included a second proposed amended complaint. On August 1, 2025, OUII filed a response in support of the motion, while Ascendis and Bachem both filed responses continuing to oppose the motion.

On August 14, 2025, the Chief ALJ issued the subject ID (Order No. 15), granting Complainant's motion to amend the complaint and notice of investigation. The subject ID finds that Complainant has demonstrated good cause for the proposed amendments under Commission Rule 210.14(b), 19 CFR 210.14(b). *See* ID at 12-15. The Chief ALJ also granted Complainant's

request to declassify certain discovery responses pursuant to Commission Rule 210.20(a), 19 CFR 210.20(a). *See id.* at 4-7. No party filed a petition for review of the subject ID.

The Commission has determined not to review the subject ID. The complaint and notice of investigation are amended to add Bachem AG of Bubendorf, Switzerland as a respondent.

The Commission vote for this determination took place on September 12, 2025.

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.

Issued: September 12, 2025.

Sharon Bellamy,

Supervisory Hearings and Information Officer.

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