

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of

**CERTAIN DRUG PRODUCTS
CONTAINING C-TYPE NATRIURETIC
PEPTIDE VARIANTS, AND
COMPONENTS THEREOF**

Investigation No. 337-TA-1447

**NOTICE OF A COMMISSION DETERMINATION NOT TO REVIEW
AN INITIAL DETERMINATION EXTENDING THE TARGET DATE FOR
COMPLETION 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 not to review an initial determination (“ID”) (Order No. 17) of the presiding Chief administrative law judge (“Chief ALJ”) extending the target date for completion of the above-captioned investigation until November 30, 2026.

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. 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.* 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; Ascendis Pharma Growth Disorders A/S of Hellerup,

Denmark (collectively “Ascendis”); and Wacker Biotech GmbH of Jena, Germany. *Id.* 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. On June 27, 2025, Ascendis filed an opposition to the motion, while OUII filed a response not opposing the motion. On July 9, 2025, Bachem filed an opposition to the motion. On July 14, 2025, Complainant filed a reply in support of its motion, and OUII filed a reply continuing not to oppose 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 supporting the motion, while Ascendis and Bachem both filed responses continuing to oppose the motion.

On August 14, 2025, the Chief ALJ issued Order No. 15, granting Complainant’s motion to amend the complaint and notice of investigation. As part of Order No. 15, the Chief ALJ ordered Complainant, Respondents, Bachem, and OUII to meet and confer regarding the procedural schedule, including whether the target date needed to be extended. No party filed a petition for review of Order No. 15. On September 12, 2025, the Commission determined not to review Order No. 15. *See* Order No. 15 (Aug. 14, 2025), *unreviewed by* Comm’n Notice (Sept. 12, 2025).

On August 21, 2025, Complainant, Respondents, Bachem, and OUII filed a Joint Submission of Proposed Revised Procedural Schedule and Target Date, setting forth the proposed schedule and target dates proposed by Complainant, Respondents and Bachem, and OUII.

On August 25, 2025, the Chief ALJ issued the subject ID (Order No. 17) extending the deadline for issuing the final initial determination of violation to July 30, 2026, and the target date for completion of the investigation to November 30, 2026. Order No. 17 at 8. The ID finds good cause to extend the target date to allow Bachem and all parties to address claim construction and discovery issues arising from the new allegations raised against Bachem. *Id.* at 2. No petitions for review of Order No. 17 were filed.

The Commission has determined not to review the subject ID. The target date for completion of the investigation is extended to November 30, 2026, and the new deadline for issuing the final initial determination on violation is July 30, 2026.

The Commission vote for this determination took place on September 15, 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.

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: September 15, 2025