

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

**In the Matter of**

**CERTAIN PHOTODYNAMIC THERAPY  
SYSTEMS, COMPONENTS THEREOF,  
AND PHARMACEUTICAL PRODUCTS  
USED IN COMBINATION WITH THE  
SAME**

**Investigation No. 337-TA-1411**

**NOTICE OF COMMISSION DETERMINATION TO REVIEW AN INITIAL  
DETERMINATION GRANTING SUMMARY DETERMINATION THAT  
COMPLAINANT HAS SATISFIED THE ECONOMIC PRONG OF THE DOMESTIC  
INDUSTRY REQUIREMENT**

**AGENCY:** U.S. International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the U.S. International Trade Commission has determined to review an initial determination (“ID”) (Order No. 23) of the presiding administrative law judge (“ALJ”) issued in the above-captioned investigation, granting complainant’s motion for summary determination that it has satisfied the economic prong of the domestic industry requirement.

**FOR FURTHER INFORMATION CONTACT:** B. Rashmi Borah, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-2518. 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](mailto: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:** The Commission instituted this investigation on August 1, 2024, based on a complaint filed by Sun Pharmaceutical Industries, Inc. (“Complainant”) of Princeton, New Jersey. 89 FR 62790 (Aug. 1, 2024). The complaint, as supplemented, alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, based on the importation into the United States, the sale for importation, and the sale within the United States after importation of certain photodynamic therapy systems, components thereof, and pharmaceutical products used in combination with the same by reason of infringement of certain claims of the U.S. Patent Nos. 11,446,512 (“the ’512 patent”) and 11,697,028 (collectively, “the Asserted Patents”). *Id.* The complaint further alleges that a domestic industry exists or is in the process of being established. *Id.* The notice of investigation

names four respondents: (1) Biofrontera Inc. of Woburn, Massachusetts; (2) Biofrontera Pharma GmbH of Leverkusen, Germany; (3) Biofrontera Bioscience GmbH of Leverkusen, Germany; and (4) Biofrontera AG of Leverkusen, Germany (collectively, “Respondents”). *Id.* The Office of Unfair Import Investigations is not a party to this investigation. *Id.*

On November 20, 2024, the Commission amended the complaint and notice of investigation to add infringement allegations as to claims 17 and 18 of the ’512 patent. Order No. 8 (Oct. 22, 2024), *unreviewed by Comm’n Notice* (Nov. 20, 2024).

On May 2, 2025, Complainant moved for summary determination that it has satisfied the economic prong of the domestic industry requirement under subsections 337(a)(3)(B) and (C), or, in the alternative, that it has a domestic industry in the process of being established. On May 16, 2025, Respondents filed their opposition to Complainant’s motion for summary determination.

On June 25, 2025, the ALJ issued the subject ID (Order No. 23) granting Complainant’s motion pursuant to Commission Rule 210.18 (19 C.F.R. § 210.18). The ID finds that Complainant has satisfied the economic prong of the domestic industry requirement.

On June 26, 2025, Complainant submitted a letter to the ALJ, explaining that the ID inadvertently relies on an incorrect investment-to-revenue percentage that has since been corrected.

On July 3, 2025, Respondents filed a petition for review of the ID, arguing that Complainant’s investments are not cognizable for several reasons and are not significant or substantial. On July 11, 2025, Complainant filed a response to Respondents’ petition for review.

Having examined the record in this investigation, including the subject ID, petition for review, and the response thereto, the Commission has determined to review the ID.

The Commission vote for this determination took place on July 25, 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 rectangular box.

Lisa R. Barton  
Secretary to the Commission

Issued: July 25, 2025