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 A COMMISSION DETERMINATION TO EXTEND 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 to extend the target date for completion of the investigation to May 6, 2026.

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. 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 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 ("the '028 patent") (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 June 25, 2025, the ALJ issued Order No. 23 granting, pursuant to Commission Rule 210.18 (19 CFR 210.18), Complainant's motion for summary determination that it has satisfied the economic prong of the domestic industry requirement.

On July 25, 2025, the Commission determined to review Order No. 23. Comm'n Notice at 2 (July 25, 2025).

On September 30, 2025, the ALJ issued the FID, finding a violation of section 337. The FID finds that: (1) claims 1, 3, 5, 8, 17-18, and 20 of the '512 patent and claims 1, 2, 4, 16, 17, and 19-21 of the '028 patent, are directly infringed; (2) claims 8, 17, and 18 of the '512 patent are indirectly infringed via inducement; (3) none of the claims asserted for infringement and/or domestic industry are invalid under 35 U.S.C. §§ 103 and/or 112, ¶ 1; and (4) Complainant has satisfied the technical prong of the domestic industry requirement for both Asserted Patents by practicing claims 1, 2, 4, 5, 8, 19, and 20 of the '512 patent and claims 1, 3, 4, 5, 7, 9, 16-18, and 21 of the '028 patent. The FID also includes the ALJ's recommended determination ("RD") on remedy, the public interest, and bonding, should the Commission find a violation of section 337. Specifically, the RD recommends entry of a limited exclusion order against Respondents' infringing products, entry of a cease and desist orders against each of Respondents, and a bond of zero percent for any importations of infringing products during the period of Presidential review.

On January 28, 2026, the Commission determined to review the FID in part. 91 FR 4630 (Feb. 2, 2026). Specifically, the Commission determined to review: (1) the construction of the claim term "nested hinges" and (2) whether the asserted claims of the Asserted Patents are invalid as obvious. *Id*. The notice also reiterates that Order No. 23 remains under review. *Id.* The Commission did not request briefing on any of the issues under review. The notice also requested submissions on remedy, the public interest, and bonding. *Id*. at 4631.

On February 11, 2026, Complainant and Respondents submitted their respective initial submissions on remedy, the public interest, and bonding. On February 18, 2026, Complainant the parties submitted their respective replies.

On February 24, 2026, Respondents submitted a letter requesting that the Commission take judicial notice of a final written decision ("FWD") issued by the U.S. Patent and Trademark Office Patent Trial and Appeal Board finding claims 1, 2, 4-6, 16, 17, and 19-21 of the '028 patent unpatentable as obvious. On March 5, 2026, the Commission requested additional briefing from the parties on "whether, and to what extent, the FWD should impact the

Commission's determination regarding the validity of the asserted claims of both the '028 patent and the '512 patent." Comm. Not. at 3 (Mar. 5, 2026). On March 12, 2026, the parties submitted their initial responses. On March 19, 2026, the parties submitted their responsive submissions.

The Commission has determined to extend the target date for completion of the investigation to May 6, 2026.

The Commission vote for this determination took place on April 30, 2026.

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 R. Barton
Secretary to the Commission

Issued: April 30, 2026