INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-1411]

Certain Photodynamic Therapy Systems, Components Thereof, and Pharmaceutical Products Used in Combination with the Same; Notice of the Commission's Final Determination Finding a Violation of Section 337; Issuance of a Limited Exclusion Order and Cease and Desist Orders; Termination 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 found a violation of section 337 in the above-captioned investigation. The Commission has determined to issue a limited exclusion order ("LEO") prohibiting the unlicensed entry of infringing oil vaporizing devices, components thereof, and products containing the same that are manufactured by or on behalf of, or imported by or on behalf of, the respondents and cease and desist orders ("CDOs") against every named respondent. The investigation is terminated.

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 November 17, 2025, Complainant filed a petition for review seeking review of the following findings: (1) that the preamble of each asserted claim is limiting and (2) the RD’s recommendation to set a bond of zero percent for any importations of infringing products during the period of Presidential review. On the same day, Respondents filed a petition for review seeking review of the following findings: (1) that the claim terms “nested hinges” and “higher intensity proximate” are not indefinite; (2) that the asserted claims are not invalid under 35 U.S.C. § 103 for obviousness, or under § 112 ¶ 1 for lack of written description; (3) that certain claims are either directly or indirectly infringed; and (4) that certain declarations from *inter partes* review proceedings are admissible. On November 24, 2025, Complainant and Respondents filed their respective petition responses.

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 ("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.

Having examined the record in this investigation, including the FID, the parties' petitions for review and responses thereto, the parties' submissions regarding the FWD and responses thereto, and the submissions to the Commission regarding remedy, the public interest, and bonding, the Commission has determined to find a violation of section 337 as to both Asserted Patents. As set forth in the simultaneously-issued Commission opinion, the Commission affirms the construction of the claim term "nested hinges" with modified reasoning. The Commission also affirms the FID's findings that none of the asserted claims of the Asserted Patents are invalid as obvious, with modified and additional reasoning. Finally, the Commission affirms Order No. 23's finding that Complainant has satisfied the economic prong of the domestic industry requirement under section 337(a)(3)(B) with modified reasoning.

The Commission has determined that the appropriate form of relief is an LEO prohibiting the unlicensed entry of infringing photodynamic therapy systems, components thereof, and pharmaceutical products used in combination with the same that are manufactured by or on behalf of Respondents or any of their affiliated companies, parents, subsidiaries, or other related business entities, or their successors or assigns. The Commission has also determined to issue CDOs against each of Respondents. The Commission has determined to suspend the orders as to the '028 patent in light of the FWD, pending any further action before the Board and any potential appeals.

The Commission has further determined that the public interest factors enumerated in subsections (d)(l) and (f)(1) (19 U.S.C. 1337(d)(l), (f)(1)) do not preclude issuance of the above-referenced remedial orders. Additionally, the Commission has determined to impose a bond in the amount of zero percent (0%) of the infringing products imported during the period of Presidential review (19 U.S.C. 1337(j)).

The investigation is terminated.

The Commission vote for this determination took place on May 6, 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.

Issued: May 6, 2026.

Lisa Barton,

Secretary to the Commission.

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