

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 REQUESTING ADDITIONAL
BRIEFING FROM THE PARTIES; EXTENSION OF THE TARGET DATE**

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (“Commission”) has determined to request additional briefing from the parties regarding the final written decision (“FWD”) issued by the Patent Trial and Appeal Board (“PTAB”) in IPR2024-01312. The Commission has also determined to extend the target date to April 30, 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 presiding administrative law judge (“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). Order No. 23 remains under Commission review. *Id.*

On September 30, 2025, the ALJ issued the final initial determination (“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 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. 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 under 35 U.S.C. § 103 for obviousness. *Id.*

On February 24, 2026, Respondents submitted a letter requesting the Commission to take judicial notice of a FWD issued by the PTAB finding claims 1, 2, 4-6, 16, 17, and 19-21 of the '028 patent unpatentable as obvious.

Having considered the letter from Respondents and the FWD, the Commission directs Complainant and Respondents to provide additional briefing addressing 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. The parties should address at least the following in their response:

1. For motivation to combine and for each claim limitation that the PTAB found satisfied under a preponderance of the evidence standard, explain whether the limitation or issue is satisfied under a clear and convincing evidence standard.
2. With reference to the existing record of this investigation, explain whether any differences in the arguments or evidence presented before the PTAB and the ALJ impacts the weight the Commission should give to the PTAB's findings, if any.

The parties' initial submissions are limited to **25** pages. The parties' responsive submissions are limited to **10** pages. The parties' initial written submissions should be filed by **March 12, 2026**. The parties' responsive written submissions should be filed by **March 19, 2026**. No further submissions on any of these issues will be permitted unless otherwise ordered by the Commission. The Commission also extends the target date in this investigation to April 30, 2026.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above pursuant to 19 CFR 210.4(f). Submissions should refer to the investigation number (**Inv. No. 337-TA-1411**) in a prominent place on the cover page and/or the first page. (See Handbook for Electronic Filing Procedures, https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf). Persons with questions regarding filing should contact the Secretary, (202) 205-2000.

Any person desiring to submit a document to the Commission in confidence must request confidential treatment by marking each document with a header indicating that the document contains confidential information. This marking will be deemed to satisfy the request procedure set forth in Rules 201.6(b) and 210.5(e)(2) (19 CFR 201.6(b) & 210.5(e)(2)). Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. Any non-party wishing to submit comments containing confidential information must serve those comments on the parties to the investigation pursuant to the applicable Administrative Protective Order. A redacted non-confidential version of the document must also be filed with the Commission and served on any parties to the investigation within two business days of any

confidential filing. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection on EDIS.

The Commission vote for this determination took place on March 5, 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.

A handwritten signature in black ink, appearing to read 'Lisa R. Barton', enclosed within a large, loopy oval flourish.

Lisa R. Barton
Secretary to the Commission

Issued: March 5, 2026