

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 REVIEW IN PART
A FINAL INITIAL DETERMINATION FINDING A VIOLATION OF SECTION 337;
REQUEST FOR WRITTEN SUBMISSIONS ON REMEDY, THE PUBLIC INTEREST,
AND BONDING**

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (“Commission”) has determined to review in part a final initial determination (“FID”) of the presiding administrative law judge (“ALJ”), finding a violation of section 337 of the Tariff Act of 1930, as amended. The Commission requests written submissions from the parties, interested government agencies, and other interested persons on the issues of remedy, the public interest, and bonding, under the schedule set forth below.

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 (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 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.

Having reviewed the record of the investigation, including the FID, and the parties' submissions, the Commission has determined to review the FID in part. Specifically, the Commission has 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. The Commission has determined not to review the remainder of the FID. Order No. 23 remains under Commission review. Comm'n Notice at 2 (July 25, 2025). The Commission will consider the reviewed issues identified above as well as any issues concerning Order No. 23 and the RD in connection with the final disposition of this Investigation.

In connection with the final disposition of this investigation, the statute authorizes issuance of, *inter alia*, (1) an exclusion order that could result in the exclusion of the subject articles from entry into the United States; and/or (2) cease and desist orders that could result in the respondents being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, see *Certain Devices for Connecting Computers via Telephone Lines*, Inv. No. 337-TA-360, USITC Pub. No. 2843, Comm'n Op. at 7-10 (Dec. 1994).

The statute requires the Commission to consider the effects of that remedy upon the public interest. The public interest factors the Commission will consider include the effect that an exclusion order and cease and desist orders would have on: (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve, disapprove, or take no action on the Commission's determination. See Presidential Memorandum of July 21, 2005, 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

WRITTEN SUBMISSIONS: The parties to the investigation are requested to file written submissions on the issues identified in this notice. Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such submissions should address the recommended determination by the ALJ on remedy and bonding.

In its initial submission, Complainant is also requested to identify the remedy sought and Complainant is requested to submit proposed remedial orders for the Commission's consideration. Complainant is further requested to state the dates that the Asserted Patents expire, to provide the HTSUS subheadings under which the accused products are imported, and to supply the identification information for all known importers of the products at issue in this investigation. All initial written submissions, from the parties and/or third parties/interested government agencies, and proposed remedial orders from the parties must be filed no later than close of business on **February 11, 2026**. All reply submissions must be filed no later than the close of business on **February 18, 2026**. Opening submissions from the parties are limited to **25** pages. Reply submissions from the parties are limited to **15** pages. All submission from third parties and/or interested government agencies are limited to **10** pages. No further submissions on any of these issues will be permitted unless otherwise ordered by the Commission.

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 January 28, 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 shape.

Lisa R. Barton
Secretary to the Commission

Issued: January 28, 2026