

Office of the Secretary



UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C. 20436

May 6, 2026

Alaina van Horn, Chief,
Intellectual Property Enforcement Branch/Exclusion Order Enforcement Branch
Jennifer Petelle, Director, Border Security and Trade Compliance
U.S. Customs and Border Protection
Regulations and Rulings – Office of Trade
90 K Street NE – 10th Floor
Washington, DC 20229-1177

Re: Limited exclusion order issued by the U.S. International Trade Commission in
Investigation No. 337-TA-1411, *Certain Photodynamic Therapy Systems,
Components Thereof, and Pharmaceutical Products Used in Combination with the
Same*

Dear Ms. Van Horn:

On May 6, 2026, the United States International Trade Commission issued a limited exclusion order prohibiting Biofrontera Inc. of Woburn, Massachusetts; Biofrontera Pharma GmbH of Leverkusen, Germany; Biofrontera Bioscience GmbH of Leverkusen, Germany; and Biofrontera AG of Leverkusen, Germany from importing into the United States certain photodynamic therapy systems, components thereof, and pharmaceutical products used in combination with the same that infringe one or more of claims 1, 3, 5, 8, 17-18, and 20 of U.S. Patent No. 11,446,512 (“the ’512 patent”) and claims 1, 2, 4, 16, 17, and 19-21 of U.S. Patent No. 11,697,028 (“the ’028 patent”) (collectively, the “subject patents”). The Commission has determined to suspend the order as to the ’028 patent in light of a final written decision from the U.S. Patent and Trademark Office Patent Trial and Appeal Board (“Board”) finding all asserted claims invalid, pending any further action before the Board and any potential appeals.

The owner of the subject patents is Sun Pharmaceutical Industries Inc. of Princeton, New Jersey. Betty Chen (tel. 415-573-1905), of the law firm Desmarais LLP, was counsel for complainant in the proceedings before the Commission.

The products in question are believed to be imported under at least HTSUS Numbers 9018.90.80.00; 9033.00.9000; and 3004.90.9251.

IPR2024-01312
Biofrontera Inc. et al v. Sun Pharmaceutical et al
Sun Pharmaceutical's Exhibit 2101
EX2101, Page 1

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The Commission's order is in effect until the subject patents expire or one or more of its claims are rendered invalid or unenforceable. The expiration date for the '512 patent is January 17, 2037. The expiration date for the '028 patent is October 13, 2036. A copy of each of the subject patents is enclosed. We separately transmitted the limited exclusion order to you, along with the Commission record, on the day of its issuance.

Per the limited exclusion order, the covered products are entitled to entry for consumption into the United States, entry for consumption from foreign trade zone, or withdrawal from a warehouse for consumption under bond from the day after this order is received by the United States Trade Representative, pursuant to subsection (j) of section 337 of the Tariff Act of 1930, as amended, and the Presidential Memorandum of July 21, 2005 (70 FR 43251), until such time as the Representative notifies the Commission of approval or disapproval of this action but, in any event, not later than sixty (60) days after the date of receipt of this action.

Known importers of the infringing products include: Biofrontera Inc. of Woburn, Massachusetts; Biofrontera Pharma GmbH of Leverkusen, Germany; Biofrontera Bioscience GmbH of Leverkusen, Germany; and Biofrontera AG of Leverkusen, Germany.

If you have any questions concerning the limited exclusion order, please feel free to contact B. Rashmi Borah (bornali.borah@usitc.gov; tel: 202-205-2518).

Sincerely,



Lisa R. Barton
Secretary to the Commission

Enclosures

cc: Office of the General Counsel
Office of the United States Trade Representative
600 17th Street, N.W.
Washington, D.C. 20508

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

LIMITED EXCLUSION ORDER

The United States International Trade Commission (“Commission”) has determined that there is a violation of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), in the unlawful importation, sale for importation, or sale within the United States after importation by respondents Biofrontera Inc. of Woburn, Massachusetts; Biofrontera Pharma GmbH of Leverkusen, Germany; Biofrontera Bioscience GmbH of Leverkusen, Germany; and Biofrontera AG of Leverkusen, Germany (collectively, “Respondents”) of certain photodynamic therapy systems, components thereof, and pharmaceutical products used in combination with the same (as defined in paragraph 2 below) that infringe one or more of claims 1, 3, 5, 8, 17-18, and 20 of U.S. Patent No. 11,446,512 and claims 1, 2, 4, 16, 17, and 19-21 of U.S. Patent No. 11,697,028 (“Asserted Patents”).

Having reviewed the record in this investigation, including the written submissions of the parties, the Commission has made its determinations on the issues of remedy, the public interest, and bonding. The Commission has determined that the appropriate form of relief is a limited exclusion order prohibiting the unlicensed entry of infringing photodynamic therapy systems, components thereof, and pharmaceutical products used in combination with the same, manufactured by or on behalf of Respondents or any of their affiliated companies, parents,

subsidiaries, agents, or other related business entities, or its successors or assigns.

The Commission has also determined that the public interest factors enumerated in 19 U.S.C. § 1337(d) do not preclude the issuance of the limited exclusion order, and that the bond during the period of Presidential review shall be in the amount of zero percent (0%) of the entered value of the articles subject to this Order.

Accordingly, the Commission hereby **ORDERS** that:

1. Certain photodynamic therapy systems, components thereof, and pharmaceutical products used in combination with the same that infringe one or more of claims 1, 3, 5, 8, 17-18, and 20 of U.S. Patent No. 11,446,512 or claims 1, 2, 4, 16, 17, and 19-21 of U.S. Patent No. 11,697,028 and are manufactured abroad by, or on behalf of, or imported by or on behalf of Respondents or any of their affiliated companies, parents, subsidiaries, agents, or other related business entities, or its successors or assigns, are excluded from entry for consumption into the United States, entry for consumption from a foreign-trade zone, or withdrawal from a warehouse for consumption, for the remaining terms of the Asserted Patents, except under license from, or with the permission of, the patent owner or as provided by law; and except for parts necessary to service and repair covered articles purchased by consumers prior to the date this Order becomes final within the meaning of 19 U.S.C. § 1337(j)(4), and except for covered articles that are replacements for covered articles purchased by consumers prior to the date this Order becomes final within the meaning of 19 U.S.C. § 1337(j)(4), provided that replacement is pursuant to a warranty for the replaced article.

2. The certain photodynamic therapy systems, components thereof, and pharmaceutical products used in combination with the same subject to this exclusion order (*i.e.*, “covered articles”) are as follows: illuminators for photodynamic therapy with light sources on

at least five panels, assembled or disassembled, replacement parts, and 5-aminolevulinic acid used in combination with the illuminators for photodynamic therapy.

3. Notwithstanding paragraph 1 of this Order, covered articles are entitled to entry into the United States for consumption, entry for consumption from a foreign trade zone, or withdrawal from a warehouse for consumption, under bond in the amount of zero percent (0%) of their entered value, pursuant to subsection (j) of section 337 (19 U.S.C. § 1337(j)) and the Presidential Memorandum for the United States Trade Representative of July 21, 2005 (70 Fed. Reg. 43,251), from the day after this Order is received by the United States Trade Representative until such time as the United States Trade Representative notifies the Commission that this Order is approved or disapproved but, in any event, not later than sixty (60) days after the receipt of this Order. All entries of covered articles made pursuant to this paragraph are to be reported to U.S. Customs and Border Protection (“CBP”), in advance of the date of the entry, pursuant to procedures CBP establishes.

4. At the discretion of CBP and pursuant to the procedures it establishes, persons seeking to import articles may be required to certify that they are familiar with the terms of this Order, that they have made appropriate inquiry, and thereupon state that, to the best of their knowledge and belief, the products being imported are not excluded from entry under paragraph 1 of this Order. At its discretion, CBP may require persons who have provided the certification described in this paragraph to furnish such records or analyses as are necessary to substantiate the certification.

5. In accordance with 19 U.S.C. § 1337(l), the provisions of this Order shall not apply to covered articles that are imported by and for the use of the United States, or imported for and to be used for, the United States with the authorization or consent of the Government.

6. The Commission may modify this Order in accordance with the procedures described in Rule 210.76 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.76).

7. The Secretary shall serve copies of this Order upon each party of record in this investigation and upon CBP.

8. Notice of this Order shall be published in the Federal Register.

By order of the Commission.

A handwritten signature in black ink, appearing to read "Lisa R. Barton", enclosed within a thin black rectangular border.

Lisa R. Barton
Secretary to the Commission

Issued: May 6, 2026