

**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 in a thin black rectangular border.

Lisa R. Barton  
Secretary to the Commission

Issued: May 6, 2026

**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**

**CEASE AND DESIST ORDER**

**IT IS HEREBY ORDERED THAT RESPONDENT** Biofrontera AG of Leverkusen, Germany cease and desist from conducting any of the following activities in the United States: importing, selling, offering for sale, marketing, advertising, distributing, transferring (except for exportation), soliciting United States agents or distributors, and aiding or abetting other entities in the importation, sale for importation, sale after importation, transfer (except for exportation), or distribution of certain photodynamic therapy systems, components thereof, and pharmaceutical products used in combination with the same (as defined in Definition (G) 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”) in violation of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337).

**I.  
Definitions**

As used in this order:

(A) “Commission” shall mean the United States International Trade Commission.

- (B) “Complainant” shall mean Sun Pharmaceutical Industries, Inc. of Princeton, New Jersey.
- (C) “Respondent” shall mean Biofrontera AG of Leverkusen, Germany.
- (D) “Person” shall mean an individual, or any non-governmental partnership, firm, association, corporation, or other legal or business entity other than Respondent or its majority-owned or controlled subsidiaries, successors, or assigns.
- (E) “United States” shall mean the fifty States, the District of Columbia, and Puerto Rico.
- (F) The terms “import” and “importation” refer to importation for entry for consumption under the Customs laws of the United States.
- (G) The term “covered articles” shall mean 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 and claims 1, 2, 4, 16, 17, and 19-21 of U.S. Patent No. 11,697,028. The certain photodynamic therapy systems, components thereof, and pharmaceutical products used in combination with the same subject to this order 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. Covered articles shall not include articles for which a provision of law or license avoids liability for infringement.

## **II. Applicability**

The provisions of this Cease and Desist Order shall apply to Respondent and to any of its principals, stockholders, officers, directors, employees, agents, distributors, controlled (whether by stock ownership or otherwise) and majority-owned business entities, successors, and assigns, and to each of them, insofar as they are engaging in conduct prohibited by section III, *infra*, for, with, or otherwise on behalf of, Respondent.

## **III. Conduct Prohibited**

The following conduct of Respondent in the United States is prohibited by this Order.

For the remaining terms of the Asserted Patents, Respondent shall not:

- (A) import or sell for importation into the United States covered articles;
- (B) market, distribute, sell, offer to sell, or otherwise transfer (except for exportation) in the United States imported covered articles;
- (C) advertise imported covered articles;
- (D) solicit U.S. agents or distributors for imported covered articles; or
- (E) aid or abet other entities in the importation, sale for importation, sale after importation, transfer (except for exportation), or distribution of imported covered articles.

## **IV. Conduct Permitted**

Notwithstanding any other provision of this Order, specific conduct otherwise prohibited by the terms of this Order shall be permitted if:

- (A) in a written instrument, the owner of the Asserted Patents licenses or authorizes such specific conduct;

- (B) such specific conduct is related to the importation or sale of covered articles by or for the United States; or
- (C) such specific conduct is limited to importation, sale, and provision of 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), or limited to importation and provision of 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.

## **V. Reporting**

For purposes of this requirement, the reporting periods shall commence on January 1 of each year and shall end on the subsequent December 31. The first report required under this section shall cover the period from the date of issuance of this order through December 31, 2026. This reporting requirement shall continue in force until such time as Respondent has truthfully reported, in two consecutive timely filed reports, that it has no inventory (whether held in warehouses or at customer sites) of covered articles in the United States.

Within thirty (30) days of the last day of the reporting period, Respondent shall report to the Commission: (a) the quantity in units and the value in dollars of covered articles that it has (i) imported and/or (ii) sold in the United States after importation during the reporting period, and (b) the quantity in units and value in dollars of reported covered articles that remain in inventory in the United States at the end of the reporting period.

When filing written submissions, Respondent must file the original document electronically on or before the deadlines stated above. Submissions should refer to the

investigation number (“Inv. No. 337-TA-1411”) in a prominent place on the cover pages and/or the first page. *See Handbook for Electronic Filing Procedures*, [http://www.usitc.gov/secretary/fed\\_reg\\_notices/rules/handbook\\_on\\_electronic\\_filing.pdf](http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf). Persons with questions regarding filing should contact the Secretary (202-205-2000). If Respondent desires to submit a document to the Commission in confidence, it must file the original and a public version of the original with the Office of the Secretary and must serve a copy of the confidential version on Complainant’s counsel.<sup>1</sup>

Any failure to make the required report or the filing of any false or inaccurate report shall constitute a violation of this Order, and the submission of a false or inaccurate report may be referred to the U.S. Department of Justice as a possible criminal violation of 18 U.S.C. § 1001.

## **VI. Record-Keeping and Inspection**

- (A) For the purpose of securing compliance with this Order, Respondent shall retain any and all records relating to the sale, marketing, or distribution in the United States of covered articles, made and received in the usual and ordinary course of business, whether in detail or in summary form, for a period of three (3) years from the close of the fiscal year to which they pertain.
- (B) For the purposes of determining or securing compliance with this Order and for no other purpose, subject to any privilege recognized by the federal courts of the United States, and upon reasonable written notice by the Commission or its staff, duly authorized representatives of the Commission shall be permitted access and

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<sup>1</sup> Complainants must file a letter with the Secretary identifying the attorney to receive reports and bond information associated with this Order. The designated attorney must be on the protective order entered in the investigation.

the right to inspect and copy, in Respondent's principal offices during office hours, and in the presence of counsel or other representatives if Respondent so chooses, all books, ledgers, accounts, correspondence, memoranda, and other records and documents, in detail and in summary form, that must be retained under subparagraph VI(A) of this Order.

**VII.  
Service of Cease and Desist Order**

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

Respondent is ordered and directed to:

- (A) Serve, within fifteen (15) days after the effective date of this Order, a copy of this Order upon each of its respective officers, directors, managing agents, agents, and employees who have any responsibility for the importation, marketing, distribution, transfer, or sale of imported covered articles in the United States;
- (B) Serve, within fifteen (15) days after the succession of any persons referred to in subparagraph VII(A) of this order, a copy of the Order upon each successor; and
- (C) Maintain such records as will show the name, title, and address of each person upon whom the Order has been served, as described in subparagraphs VII(A) and VII(B) of this order, together with the date on which service was made.

The obligations set forth in subparagraphs VII(B) and VII(C) shall remain in effect until the expiration of the Asserted Patents.

## **VIII. Confidentiality**

Any request for confidential treatment of information obtained by the Commission pursuant to any section of this order should be made in accordance with section 201.6 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 201.6). For all reports for which confidential treatment is sought, Respondent must provide a public version of such report with confidential information redacted.

## **IX. Enforcement**

Violation of this order may result in any of the actions specified in section 210.75 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.75), including an action for civil penalties under section 337(f) of the Tariff Act of 1930 (19 U.S.C. § 1337(f)), as well as any other action that the Commission deems appropriate. In determining whether Respondent is in violation of this order, the Commission may infer facts adverse to Respondent if it fails to provide adequate or timely information.

## **X. Modification**

The Commission may amend this order on its own motion or in accordance with the procedure described in section 210.76 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.76).

## **XI. Bonding**

The conduct prohibited by section III of this order may be continued during the sixty (60) day period in which this Order is under review by the United States Trade Representative, as delegated by the President (70 Fed. Reg. 43,251 (Jul. 21, 2005)), subject to Respondent's posting

of a bond in the amount of zero percent (0%) of their entered value. This bond provision does not apply to conduct that is otherwise permitted by section IV of this Order. Covered articles imported on or after the date of issuance of this Order are subject to the entry bond as set forth in the exclusion order issued by the Commission and are not subject to this bond provision.

By order of the Commission.

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

Lisa R. Barton  
Secretary to the Commission

Issued: May 6, 2026

**UNITED STATES INTERNATIONAL TRADE COMMISSION  
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SYSTEMS, COMPONENTS THEREOF,  
AND PHARMACEUTICAL PRODUCTS  
USED IN COMBINATION WITH THE  
SAME**

**Investigation No. 337-TA-1411**

**CEASE AND DESIST ORDER**

**IT IS HEREBY ORDERED THAT RESPONDENT** Biofrontera Bioscience GmbH of Leverkusen, Germany cease and desist from conducting any of the following activities in the United States: importing, selling, offering for sale, marketing, advertising, distributing, transferring (except for exportation), soliciting United States agents or distributors, and aiding or abetting other entities in the importation, sale for importation, sale after importation, transfer (except for exportation), or distribution of certain photodynamic therapy systems, components thereof, and pharmaceutical products used in combination with the same (as defined in Definition (G) 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”) in violation of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337).

**I.  
Definitions**

As used in this order:

(A) “Commission” shall mean the United States International Trade Commission.

- (B) “Complainant” shall mean Sun Pharmaceutical Industries, Inc. of Princeton, New Jersey.
- (C) “Respondent” shall mean Biofrontera Bioscience GmbH of Leverkusen, Germany.
- (D) “Person” shall mean an individual, or any non-governmental partnership, firm, association, corporation, or other legal or business entity other than Respondent or its majority-owned or controlled subsidiaries, successors, or assigns.
- (E) “United States” shall mean the fifty States, the District of Columbia, and Puerto Rico.
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- (G) The term “covered articles” shall mean 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 and claims 1, 2, 4, 16, 17, and 19-21 of U.S. Patent No. 11,697,028. The certain photodynamic therapy systems, components thereof, and pharmaceutical products used in combination with the same subject to this order 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. Covered articles shall not include articles for which a provision of law or license avoids liability for infringement.

## **II. Applicability**

The provisions of this Cease and Desist Order shall apply to Respondent and to any of its principals, stockholders, officers, directors, employees, agents, distributors, controlled (whether by stock ownership or otherwise) and majority-owned business entities, successors, and assigns, and to each of them, insofar as they are engaging in conduct prohibited by section III, *infra*, for, with, or otherwise on behalf of, Respondent.

## **III. Conduct Prohibited**

The following conduct of Respondent in the United States is prohibited by this Order.

For the remaining terms of the Asserted Patents, Respondent shall not:

- (A) import or sell for importation into the United States covered articles;
- (B) market, distribute, sell, offer to sell, or otherwise transfer (except for exportation) in the United States imported covered articles;
- (C) advertise imported covered articles;
- (D) solicit U.S. agents or distributors for imported covered articles; or
- (E) aid or abet other entities in the importation, sale for importation, sale after importation, transfer (except for exportation), or distribution of imported covered articles.

## **IV. Conduct Permitted**

Notwithstanding any other provision of this Order, specific conduct otherwise prohibited by the terms of this Order shall be permitted if:

- (A) in a written instrument, the owner of the Asserted Patents licenses or authorizes such specific conduct;

- (B) such specific conduct is related to the importation or sale of covered articles by or for the United States; or
- (C) such specific conduct is limited to importation, sale, and provision of 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), or limited to importation and provision of 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.

## **V. Reporting**

For purposes of this requirement, the reporting periods shall commence on January 1 of each year and shall end on the subsequent December 31. The first report required under this section shall cover the period from the date of issuance of this order through December 31, 2026. This reporting requirement shall continue in force until such time as Respondent has truthfully reported, in two consecutive timely filed reports, that it has no inventory (whether held in warehouses or at customer sites) of covered articles in the United States.

Within thirty (30) days of the last day of the reporting period, Respondent shall report to the Commission: (a) the quantity in units and the value in dollars of covered articles that it has (i) imported and/or (ii) sold in the United States after importation during the reporting period, and (b) the quantity in units and value in dollars of reported covered articles that remain in inventory in the United States at the end of the reporting period.

When filing written submissions, Respondent must file the original document electronically on or before the deadlines stated above. Submissions should refer to the

investigation number (“Inv. No. 337-TA-1411”) in a prominent place on the cover pages and/or the first page. *See Handbook for Electronic Filing Procedures*, [http://www.usitc.gov/secretary/fed\\_reg\\_notices/rules/handbook\\_on\\_electronic\\_filing.pdf](http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf). Persons with questions regarding filing should contact the Secretary (202-205-2000). If Respondent desires to submit a document to the Commission in confidence, it must file the original and a public version of the original with the Office of the Secretary and must serve a copy of the confidential version on Complainant’s counsel.<sup>1</sup>

Any failure to make the required report or the filing of any false or inaccurate report shall constitute a violation of this Order, and the submission of a false or inaccurate report may be referred to the U.S. Department of Justice as a possible criminal violation of 18 U.S.C. § 1001.

## **VI. Record-Keeping and Inspection**

- (A) For the purpose of securing compliance with this Order, Respondent shall retain any and all records relating to the sale, marketing, or distribution in the United States of covered articles, made and received in the usual and ordinary course of business, whether in detail or in summary form, for a period of three (3) years from the close of the fiscal year to which they pertain.
- (B) For the purposes of determining or securing compliance with this Order and for no other purpose, subject to any privilege recognized by the federal courts of the United States, and upon reasonable written notice by the Commission or its staff, duly authorized representatives of the Commission shall be permitted access and

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the right to inspect and copy, in Respondent's principal offices during office hours, and in the presence of counsel or other representatives if Respondent so chooses, all books, ledgers, accounts, correspondence, memoranda, and other records and documents, in detail and in summary form, that must be retained under subparagraph VI(A) of this Order.

**VII.**  
**Service of Cease and Desist Order**

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

Respondent is ordered and directed to:

- (A) Serve, within fifteen (15) days after the effective date of this Order, a copy of this Order upon each of its respective officers, directors, managing agents, agents, and employees who have any responsibility for the importation, marketing, distribution, transfer, or sale of imported covered articles in the United States;
- (B) Serve, within fifteen (15) days after the succession of any persons referred to in subparagraph VII(A) of this order, a copy of the Order upon each successor; and
- (C) Maintain such records as will show the name, title, and address of each person upon whom the Order has been served, as described in subparagraphs VII(A) and VII(B) of this order, together with the date on which service was made.

The obligations set forth in subparagraphs VII(B) and VII(C) shall remain in effect until the expiration of the Asserted Patents.

## **VIII. Confidentiality**

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of a bond in the amount of zero percent (0%) of their entered value. This bond provision does not apply to conduct that is otherwise permitted by section IV of this Order. Covered articles imported on or after the date of issuance of this Order are subject to the entry bond as set forth in the exclusion order issued by the Commission and are not subject to this bond provision.

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Lisa R. Barton  
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USED IN COMBINATION WITH THE  
SAME**

**Investigation No. 337-TA-1411**

**CEASE AND DESIST ORDER**

**IT IS HEREBY ORDERED THAT RESPONDENT** Biofrontera Inc. of Woburn, Massachusetts cease and desist from conducting any of the following activities in the United States: importing, selling, offering for sale, marketing, advertising, distributing, transferring (except for exportation), soliciting United States agents or distributors, and aiding or abetting other entities in the importation, sale for importation, sale after importation, transfer (except for exportation), or distribution of certain photodynamic therapy systems, components thereof, and pharmaceutical products used in combination with the same (as defined in Definition (G) 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”) in violation of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337).

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- (D) “Person” shall mean an individual, or any non-governmental partnership, firm, association, corporation, or other legal or business entity other than Respondent or its majority-owned or controlled subsidiaries, successors, or assigns.
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## **II. Applicability**

The provisions of this Cease and Desist Order shall apply to Respondent and to any of its principals, stockholders, officers, directors, employees, agents, distributors, controlled (whether by stock ownership or otherwise) and majority-owned business entities, successors, and assigns, and to each of them, insofar as they are engaging in conduct prohibited by section III, *infra*, for, with, or otherwise on behalf of, Respondent.

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- (C) advertise imported covered articles;
- (D) solicit U.S. agents or distributors for imported covered articles; or
- (E) aid or abet other entities in the importation, sale for importation, sale after importation, transfer (except for exportation), or distribution of imported covered articles.

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- (B) such specific conduct is related to the importation or sale of covered articles by or for the United States; or
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## **V. Reporting**

For purposes of this requirement, the reporting periods shall commence on January 1 of each year and shall end on the subsequent December 31. The first report required under this section shall cover the period from the date of issuance of this order through December 31, 2026. This reporting requirement shall continue in force until such time as Respondent has truthfully reported, in two consecutive timely filed reports, that it has no inventory (whether held in warehouses or at customer sites) of covered articles in the United States.

Within thirty (30) days of the last day of the reporting period, Respondent shall report to the Commission: (a) the quantity in units and the value in dollars of covered articles that it has (i) imported and/or (ii) sold in the United States after importation during the reporting period, and (b) the quantity in units and value in dollars of reported covered articles that remain in inventory in the United States at the end of the reporting period.

When filing written submissions, Respondent must file the original document electronically on or before the deadlines stated above. Submissions should refer to the

investigation number (“Inv. No. 337-TA-1411”) in a prominent place on the cover pages and/or the first page. *See Handbook for Electronic Filing Procedures*, [http://www.usitc.gov/secretary/fed\\_reg\\_notices/rules/handbook\\_on\\_electronic\\_filing.pdf](http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf). Persons with questions regarding filing should contact the Secretary (202-205-2000). If Respondent desires to submit a document to the Commission in confidence, it must file the original and a public version of the original with the Office of the Secretary and must serve a copy of the confidential version on Complainant’s counsel.<sup>1</sup>

Any failure to make the required report or the filing of any false or inaccurate report shall constitute a violation of this Order, and the submission of a false or inaccurate report may be referred to the U.S. Department of Justice as a possible criminal violation of 18 U.S.C. § 1001.

## **VI. Record-Keeping and Inspection**

- (A) For the purpose of securing compliance with this Order, Respondent shall retain any and all records relating to the sale, marketing, or distribution in the United States of covered articles, made and received in the usual and ordinary course of business, whether in detail or in summary form, for a period of three (3) years from the close of the fiscal year to which they pertain.
- (B) For the purposes of determining or securing compliance with this Order and for no other purpose, subject to any privilege recognized by the federal courts of the United States, and upon reasonable written notice by the Commission or its staff, duly authorized representatives of the Commission shall be permitted access and

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<sup>1</sup> Complainants must file a letter with the Secretary identifying the attorney to receive reports and bond information associated with this Order. The designated attorney must be on the protective order entered in the investigation.

the right to inspect and copy, in Respondent's principal offices during office hours, and in the presence of counsel or other representatives if Respondent so chooses, all books, ledgers, accounts, correspondence, memoranda, and other records and documents, in detail and in summary form, that must be retained under subparagraph VI(A) of this Order.

**VII.  
Service of Cease and Desist Order**

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

Respondent is ordered and directed to:

- (A) Serve, within fifteen (15) days after the effective date of this Order, a copy of this Order upon each of its respective officers, directors, managing agents, agents, and employees who have any responsibility for the importation, marketing, distribution, transfer, or sale of imported covered articles in the United States;
- (B) Serve, within fifteen (15) days after the succession of any persons referred to in subparagraph VII(A) of this order, a copy of the Order upon each successor; and
- (C) Maintain such records as will show the name, title, and address of each person upon whom the Order has been served, as described in subparagraphs VII(A) and VII(B) of this order, together with the date on which service was made.

The obligations set forth in subparagraphs VII(B) and VII(C) shall remain in effect until the expiration of the Asserted Patents.

## **VIII. Confidentiality**

Any request for confidential treatment of information obtained by the Commission pursuant to any section of this order should be made in accordance with section 201.6 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 201.6). For all reports for which confidential treatment is sought, Respondent must provide a public version of such report with confidential information redacted.

## **IX. Enforcement**

Violation of this order may result in any of the actions specified in section 210.75 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.75), including an action for civil penalties under section 337(f) of the Tariff Act of 1930 (19 U.S.C. § 1337(f)), as well as any other action that the Commission deems appropriate. In determining whether Respondent is in violation of this order, the Commission may infer facts adverse to Respondent if it fails to provide adequate or timely information.

## **X. Modification**

The Commission may amend this order on its own motion or in accordance with the procedure described in section 210.76 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.76).

## **XI. Bonding**

The conduct prohibited by section III of this order may be continued during the sixty (60) day period in which this Order is under review by the United States Trade Representative, as delegated by the President (70 Fed. Reg. 43,251 (Jul. 21, 2005)), subject to Respondent's posting

of a bond in the amount of zero percent (0%) of their entered value. This bond provision does not apply to conduct that is otherwise permitted by section IV of this Order. Covered articles imported on or after the date of issuance of this Order are subject to the entry bond as set forth in the exclusion order issued by the Commission and are not subject to this bond provision.

By order of the Commission.

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

Lisa R. Barton  
Secretary to the Commission

Issued: May 6, 2026

**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**

**CEASE AND DESIST ORDER**

**IT IS HEREBY ORDERED THAT RESPONDENT** Biofrontera Pharma GmbH of Leverkusen, Germany cease and desist from conducting any of the following activities in the United States: importing, selling, offering for sale, marketing, advertising, distributing, transferring (except for exportation), soliciting United States agents or distributors, and aiding or abetting other entities in the importation, sale for importation, sale after importation, transfer (except for exportation), or distribution of certain photodynamic therapy systems, components thereof, and pharmaceutical products used in combination with the same (as defined in Definition (G) 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”) in violation of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337).

**I.  
Definitions**

As used in this order:

(A) “Commission” shall mean the United States International Trade Commission.

- (B) “Complainant” shall mean Sun Pharmaceutical Industries, Inc. of Princeton, New Jersey.
- (C) “Respondent” shall mean Biofrontera Pharma GmbH of Leverkusen, Germany.
- (D) “Person” shall mean an individual, or any non-governmental partnership, firm, association, corporation, or other legal or business entity other than Respondent or its majority-owned or controlled subsidiaries, successors, or assigns.
- (E) “United States” shall mean the fifty States, the District of Columbia, and Puerto Rico.
- (F) The terms “import” and “importation” refer to importation for entry for consumption under the Customs laws of the United States.
- (G) The term “covered articles” shall mean 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 and claims 1, 2, 4, 16, 17, and 19-21 of U.S. Patent No. 11,697,028. The certain photodynamic therapy systems, components thereof, and pharmaceutical products used in combination with the same subject to this order 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. Covered articles shall not include articles for which a provision of law or license avoids liability for infringement.

## **II. Applicability**

The provisions of this Cease and Desist Order shall apply to Respondent and to any of its principals, stockholders, officers, directors, employees, agents, distributors, controlled (whether by stock ownership or otherwise) and majority-owned business entities, successors, and assigns, and to each of them, insofar as they are engaging in conduct prohibited by section III, *infra*, for, with, or otherwise on behalf of, Respondent.

## **III. Conduct Prohibited**

The following conduct of Respondent in the United States is prohibited by this Order.

For the remaining terms of the Asserted Patents, Respondent shall not:

- (A) import or sell for importation into the United States covered articles;
- (B) market, distribute, sell, offer to sell, or otherwise transfer (except for exportation) in the United States imported covered articles;
- (C) advertise imported covered articles;
- (D) solicit U.S. agents or distributors for imported covered articles; or
- (E) aid or abet other entities in the importation, sale for importation, sale after importation, transfer (except for exportation), or distribution of imported covered articles.

## **IV. Conduct Permitted**

Notwithstanding any other provision of this Order, specific conduct otherwise prohibited by the terms of this Order shall be permitted if:

- (A) in a written instrument, the owner of the Asserted Patents licenses or authorizes such specific conduct;

- (B) such specific conduct is related to the importation or sale of covered articles by or for the United States; or
- (C) such specific conduct is limited to importation, sale, and provision of 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), or limited to importation and provision of 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.

## **V. Reporting**

For purposes of this requirement, the reporting periods shall commence on January 1 of each year and shall end on the subsequent December 31. The first report required under this section shall cover the period from the date of issuance of this order through December 31, 2026. This reporting requirement shall continue in force until such time as Respondent has truthfully reported, in two consecutive timely filed reports, that it has no inventory (whether held in warehouses or at customer sites) of covered articles in the United States.

Within thirty (30) days of the last day of the reporting period, Respondent shall report to the Commission: (a) the quantity in units and the value in dollars of covered articles that it has (i) imported and/or (ii) sold in the United States after importation during the reporting period, and (b) the quantity in units and value in dollars of reported covered articles that remain in inventory in the United States at the end of the reporting period.

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## **VI. Record-Keeping and Inspection**

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- (B) For the purposes of determining or securing compliance with this Order and for no other purpose, subject to any privilege recognized by the federal courts of the United States, and upon reasonable written notice by the Commission or its staff, duly authorized representatives of the Commission shall be permitted access and

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**VII.**  
**Service of Cease and Desist Order**

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

Respondent is ordered and directed to:

- (A) Serve, within fifteen (15) days after the effective date of this Order, a copy of this Order upon each of its respective officers, directors, managing agents, agents, and employees who have any responsibility for the importation, marketing, distribution, transfer, or sale of imported covered articles in the United States;
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- (C) Maintain such records as will show the name, title, and address of each person upon whom the Order has been served, as described in subparagraphs VII(A) and VII(B) of this order, together with the date on which service was made.

The obligations set forth in subparagraphs VII(B) and VII(C) shall remain in effect until the expiration of the Asserted Patents.

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Lisa R. Barton  
Secretary to the Commission

Issued: May 6, 2026