

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 COMMISSION DETERMINATION NOT TO REVIEW AN INITIAL
DETERMINATION GRANTING IN PART COMPLAINANT'S MOTION TO AMEND
THE COMPLAINT AND NOTICE OF INVESTIGATION**

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination ("ID") (Order No. 8) of the presiding administrative law judge ("ALJ") issued in the above-captioned investigation, granting in part complainant's motion to amend the complaint and notice of investigation ("NOI") to add infringement allegations as to claims 17 and 18 of U.S. Patent No. 11,446,512 ("the '512 patent").

FOR FURTHER INFORMATION CONTACT: Richard P. Hadorn, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-3179. 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, telephone (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on August 1, 2024, based on a complaint filed by Sun Pharmaceutical Industries, Inc. ("Sun Pharma") 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 '512 patent and U.S. Patent No. 11,697,028 ("the '028 patent"). *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, “Biofrontera”). *Id.* The Office of Unfair Import Investigations is not a party to this investigation. *Id.*

On October 7, 2024, Sun Pharma filed a motion to amend the complaint and NOI to add infringement allegations as to claims 9, 11, 17, and 18 of the ’512 patent and claims 10 and 12 of the ’028 patent. On October 17, 2024, Biofrontera filed a response opposing-in-part the motion. Specifically, Biofrontera did not oppose the motion with respect to adding infringement allegations as to claims 17 and 18 of the ’512 patent, but opposed the remainder of the motion.

On October 22, 2024, the ALJ issued the subject ID granting the motion in part. The ID finds that, in accordance with Commission Rule 210.14(b) (19 CFR 210.14(b)), good cause exists for amending the complaint and NOI to add infringement allegations as to claims 17 and 18 of the ’512 patent, noting that “Biofrontera agrees that Sun Pharma’s allegations with respect to these claims are based on information obtained through discovery.” ID at 3. The ALJ, however, found that Sun Pharma has not shown the requisite good cause to amend the complaint and NOI to add infringement allegations as to claims 9 and 11 of the ’512 patent and claims 10 and 12 of the ’028 patent because “Sun Pharma failed to demonstrate why it was unable to bring the allegations [of those claims] in the complaint.” *Id.* at 3-5. No petitions for review of the subject ID were filed.

The Commission has determined not to review the subject ID. The complaint and NOI are amended to add infringement allegations as to claims 17 and 18 of the ’512 patent.

The Commission vote for this determination took place on November 20, 2024.

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.



Lisa R. Barton
Secretary to the Commission

Issued: November 20, 2024