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 THE COMMISSION'S DETERMINATION TO DENY RESPONDENTS' PETITION FOR RECONSIDERATION

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission ("Commission") has determined to deny a petition for reconsideration filed by respondents Biofrontera Inc. of Woburn, Massachusetts; Biofrontera Pharma GmbH of Leverkusen, Germany; Biofrontera AG of Leverkusen, Germany; and Biofrontera Bioscience GmbH of Leverkusen, Germany (collectively, "Respondents") in the above-captioned investigation.

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 and 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 Respondents as respondents. *Id*. The Office of Unfair Import Investigations was not a party to this investigation. *Id*.

On May 6, 2026, the Commission issued a final determination finding a violation of section 337 by Respondents with respect to all remaining asserted claims. 91 FR 22595-96 (May 11, 2026). The Commission determined to issue a limited exclusion order ("LEO") and a cease and desist order ("CDO") to each of Respondents and also set a bond of zero percent during the period of Presidential review. *Id.* at 22596. The Commission suspended the remedial orders as to the '028 patent in light of a final written decision from the United States Patent Trial and Appeal Board finding the asserted claims of the '028 patent invalid as obvious. *Id.* The LEO and CDOs include within their scope "Ameluz intended for use with RhodoLED XL." Comm'n Op. at 52, 54 (May 6, 2026). The Commission also determined to issue an exemption to both the LEO and CDOs to "allow the importation of infringing devices and components necessary for service and repair functions, as well as replacements covered by warranty, for devices that have been purchased by U.S. consumers before the expiration of the period of Presidential review of the orders." *Id.* at 52.

On September 1, 2026, the Commission determined to lift the partial suspension of enforcement of the remedial orders as to the '028 patent. Comm'n Notice (Sept. 1, 2026).

On May 20, 2026, Respondents filed the subject petition for reconsideration, pursuant to Commission Rule 210.47, 19 CFR 210.47, arguing that the Commission's determinations to include Ameluz within the scope of the LEO and CDOs and to include a service and repair exemption "created a paradox" because " by prohibiting the sale of Ameluz to customers who have already purchased the RhodoLED XL lamp, the Commission has created a situation where all RhodoLED XL lamps will no longer be able to be used for their sole approved use." Respondents' Petition for Reconsideration at 3. Respondents argue in the alternative that the Commission should delay enforcement of the remedial orders by an additional 60 days beyond the end of the period of Presidential review. *Id.* at 13-14. On May 28, 2026, Complainant filed its response opposing the petition.

The Commission, having reviewed the record in this investigation, including the Commission's final determination and opinion, Respondents' petition, and Complainant's response thereto, has determined to deny Respondents' petition for reconsideration. The Commission issues an order herewith setting forth its determination.

The Commission vote for this determination took place on September 9, 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.

Lisa R. Barton
Secretary to the Commission

Issued: September 9, 2026