



BILLING CODE 7020-02

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-1411]

Certain Photodynamic Therapy Systems, Components Thereof, and Pharmaceutical Products Used in Combination with the Same; Notice of the Commission's Determination to Lift the Partial Suspension of Enforcement of the Remedial Orders as to U.S. Patent No. 11,697,028

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission ("Commission") has determined to grant a request submitted by Sun Pharmaceutical Industries, Inc. ("Complainant") of Princeton, New Jersey to lift the partial suspension of enforcement of the limited exclusion order ("LEO") and cease and desist orders ("CDOs") as to U.S. Patent No. 11,697,028 ("the '028 patent").

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 Complainant. 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 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 September 30, 2026, the presiding administrative law judge issued a final initial determination (“FID”) finding a violation of section 337 with respect to each of the asserted claims. As relevant to the subject request, the FID finds that the asserted claims of the ’028 patent are not invalid as obvious.

On January 28, 2026, the Commission determined to review the FID in part. 91 FR 4630 (Feb. 2, 2026). As relevant to the current request, the Commission determined to review the FID’s finding that the asserted claims of the ’028 patent are not invalid as obvious.

On February 23, 2026, the Patent Trial and Appeal Board issued a final written decision (“FWD”) finding all asserted claims of the ’028 patent invalid as obvious.

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 25595-96 (May 11, 2026). As relevant to the subject request, the Commission affirmed the FID’s finding that the asserted claims of the ’028 patent are not invalid as obvious and found a violation of section 337 as to the ’028 patent and the ’512 patent. *Id.* at 25596. The Commission determined to issue an LEO and CDOs as to each of Respondents and also set a bond in the amount of zero percent

during the period of Presidential review. *Id.* However, the Commission suspended enforcement of the remedial orders in part upon issuance as to the '028 patent, in light of the FWD. *Id.*

On July 29, 2026, the Director of the United States Patent and Trademark Office issued an order vacating the FWD in its entirety. *See Biofrontera Inc. et al. v. Sun Pharm. Indus. Inc.*, IPR2024-01312, Paper No. 58 (Order) (July 29, 2026).

On July 31, 2026, Complainant submitted a letter requesting that the Commission take judicial notice of the order vacating the FWD and lift the suspension of enforcement of the remedial orders as to the '028 patent.

The Commission, having reviewed the record in this investigation, including Complainant's letter and the Director's order vacating the FWD, has determined to lift the suspension of enforcement of the remedial orders as to the '028 patent.

The Commission vote for this determination took place on September 1, 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.

Issued: September 1, 2026.

Lisa Barton,

Secretary to the Commission.

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