UNITED STATES INTERNATIONAL TRADE COMMISSION Washington, D.C.

In the Matter of

CERTAIN DERMATOLOGICAL TREATMENT DEVICES AND COMPONENTS THEREOF

Investigation No. 337-TA-1356

NOTICE OF A COMMISSION DETERMINATION FINDING A VIOLATION OF SECTION 337 AS TO FOUR ASSERTED PATENTS; ISSUANCE OF A LIMITED EXCLUSION ORDER AND CEASE AND DESIST ORDERS; REMAND OF THE INVESTIGATION AS TO ONE ASSERTED PATENT; EXTENSION OF THE TARGET DATE

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has found a violation of section 337 and has determined to issue: (1) a limited exclusion order prohibiting the unlicensed importation of certain dermatological treatment devices and components thereof that infringe one or more of claims 1, 9, and 22 of U.S. Patent No. 9,480,836 ("the '836 patent"); claims 11 and 16 of U.S. Patent No. 9,320,536 ("the '536 patent"); claim 14 of U.S. Patent No. 9,775,774 ("the '774 patent"); and claims 5, 13, and 18 of U.S. Patent No. 10,869,812 ("the '812 patent"); (2) cease and desist orders against Respondents EndyMed Medical Ltd. of Caesarea, Israel; EndyMed Medical, Ltd. of New York, New York; and EndyMed Medical, Inc. of Freehold, New Jersey (collectively, "EndyMed"); and (3) set a bond in the amount of eighty-five percent (85%) of the entered value of the EndyMed Pure, and seventy percent (70%) of the entered value of the EndyMed Pro infringing products imported during the period of Presidential review. The investigation is terminated with respect to these four patents. The Commission has also determined to reverse the presiding administrative law judge's ("ALJ") finding that asserted claims 4, 6, and 7 of U.S. Patent No. 11,406,444 ("the '444 patent") are indefinite, remand the investigation to the ALJ with respect to that patent consistent with the concurrently issued Commission opinion and remand order, and extend the target date for completion of the investigation.

FOR FURTHER INFORMATION CONTACT: Panyin A. Hughes, Office of the General Counsel, U.S. International Trade Commission, 500 E Street S.W., Washington, D.C. 20436, telephone (202) 205-3042. 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

<u>https://www.usitc.gov</u>. 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 April 6, 2023, based on a complaint filed by Serendia, LLC of Lake Forest, California ("Serendia"). 88 FR 20551-52 (Apr. 6, 2023). The complaint, as supplemented, alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain dermatological treatment devices and components thereof by reason of infringement of claims 1, 2, 5, 6, 9-14, 16, 17, 19, and 22 of the '836 patent; claims 1-5, 7-10, and 15 of U.S. Patent No. 10,058,379; claims 1-10 of the '444 patent; claims 1, 2, 4, 5, 8, 9, 11-13, 16, and 17 of the '536 patent; claims 1 and 6-15 of the '774 patent; and claims 1, 5-7, 9, 10, and 12-19 of the '812 patent. Id. at 20551. The complaint further alleges that a domestic industry exists. Id. The Commission's notice of investigation named as respondents Sung Hwan E&B Co., LTD. d/b/a SHEnB Co. LTD of Seoul, Republic of Korea; Aesthetics Biomedical, Inc. of Phoenix, Arizona; Cartessa Aesthetics, LLC of Melville, New York; Lutronic Corporation of Goyang-si, Republic of Korea; Lutronic Aesthetics, Inc., also known as Lutronic, Inc. of Billerica, Massachusetts; Lutronic, LLC of Billerica, Massachusetts; Ilooda, Co., Ltd. of Anyang-si, Republic of Korea; Cutera, Inc. of Brisbane, California; Rohrer Aesthetics, LLC of Homewood, Alabama; Rohrer Aesthetics, Inc. of Homewood, Alabama; Jeisys Medical Inc. of Seoul, Republic of Korea ("Jeisys"); Cynosure, LLC of Westford, Massachusetts ("Cynosure"); and EndyMed. Id. at 20552. The Office of Unfair Import Investigations ("OUII") is also participating in the investigation. Id.

The Commission subsequently terminated the investigation as to all asserted patent claims except for claims 1, 9, and 22 of the '836 patent; claims 11 and 16 of the '536 patent; claim 14 of the '774 patent; claims 5, 13, and 18 of the '812 patent; and claims 4, 6, and 7 of the '444 patent. See Order No. 16 (June 29, 2023), unreviewed by Comm'n Notice (July 20, 2023); Order No. 27 (Sept. 25, 2023), unreviewed by Comm'n Notice (Oct. 16, 2023); Order No. 43 (Nov. 8, 2023), unreviewed by Comm'n Notice (Dec. 12, 2023).

The Commission also subsequently terminated the investigation as to all respondents except for EndyMed. *See* Order No. 26 (Sept. 18, 2023), *unreviewed by* Comm'n Notice (Oct. 16, 2023); Order No. 38 (Oct. 27, 2023), *unreviewed by* Comm'n Notice (Nov. 20, 2023); Order No. 45 (Nov. 15, 2023), *unreviewed by* Comm'n Notice (Dec. 15, 2023); Order No. 47 (Nov. 20, 2023), *unreviewed by* Comm'n Notice (Dec. 15, 2023); Order No. 53 (Apr. 11, 2024), *unreviewed by* Comm'n Notice (May 8, 2024); Order No. 51 (Dec. 13, 2023), *unreviewed by* Comm'n Notice (Jan. 10, 2024); Order No. 64 (Dec. 18, 2024), *unreviewed by* Comm'n Notice (Jan. 17, 2025).

The ALJ held a *Markman* hearing on July 13, 2023, and issued a *Markman* Order on October 25, 2023, construing certain disputed claim terms. Order No. 35 (Oct. 25, 2023). The ALJ found the pending claims of the '444 patent, claims 4, 6, and 7, indefinite in the *Markman* Order and did not consider those claims any further in the Investigation. *Markman* (Order No. 35) at 62.

The ALJ held an evidentiary hearing on November 1-2, 6-7, 2023 and December 11-12, 2023, and received post-hearing briefs thereafter. Remaining in the investigation at that time were respondents EndyMed, Jeisys, and Cynosure and claims 1, 9, and 22 of the '836 patent; claims 11 and 16 of the '536 patent; claim 14 of the '774 patent; and claims 5, 13, and 18 of the '812 patent.

On December 19, 2024, the ALJ issued the final initial determination ("ID") in this investigation finding a violation of section 337 as to claims 1, 9, and 22 of the '836 patent; claims 11 and 16 of the '536 patent; claim 14 of the '774 patent; and claims 5, 13, and 18 of the '812 patent by respondents EndyMed, Jeisys, and Cynosure. The ID found that by appearing and participating in the investigation, the parties consented to personal jurisdiction at the Commission. ID at 13. The ID found the importation requirement under 19 U.S.C. 1337(a)(1)(B) satisfied and that the Commission has in rem jurisdiction, noting that "[t]he Private Parties entered stipulations with respect to the importation of Accused Products wherein each Respondent stipulated that they have imported to the United States, sold for importation into the United States, and/or sold within the United States after importation at least one Accused Product." Id. The ID found that Serendia has the exclusive rights and ownership in the Asserted Patents and thus has "standing" to assert the patents in this investigation. Id. at 23. The ID further found that Serendia successfully proved that the accused products directly infringe the Asserted Claims. ID at 70-88, 173-184, 216-225. The ID further found that EndyMed also indirectly infringes the asserted claims of the '836 and '536 patents via inducement and contributory infringement. ID at 97-104, 185-188. The ID found that EndyMed failed to show that the Asserted Claims are invalid for obviousness (ID at 120-145, 209-216, 230-232, 257-267). The ID found that EndyMed also failed to show that the asserted claims of the '536 patent are invalid for anticipation (ID at 196-209) and also failed to prove that the asserted claims of the '836 patent are invalid for lack of enablement (ID at 146-161), lack of written description support (ID at 161-167), or recite unpatentable subject matter under section 101 (ID at 167-173). The ID found the existence of a domestic industry that practices the Asserted Patents as required by 19 U.S.C. 1337(a)(2). ID at 104-110, 189-196, 226-230, 247-256, 267-300. Accordingly, the ID found a violation of section 337 as to four of the remaining five patents.

The ID included the ALJ's recommended determination on remedy and bonding ("RD"). The RD recommended, should the Commission find a violation, issuance of a limited exclusion order and cease and desist orders against EndyMed. ID/RD at 302-111. Regarding the amount of bond to be imposed during the period of Presidential review, the ID recommended that "the Commission enter a bond in the amount of 85% of the price of value EndyMed Pure product and 70% of the value of the EndyMed Pro product during the PRP [period of Presidential review]." *Id.* at 314.

Regarding Jeisys and Cynosure, the ID noted that they have been terminated from the investigation by the ALJ, but that given the timing of the termination, the analyses pertaining to them contained in the ID would not be deleted. ID at ii n.1. The ID stated that once the Commission addresses the ID terminating them, "Jeisys and Cynosure are no longer parties in this Investigation," and their "accused products will no longer be at issue in this Investigation

and will not be subject to any determinations set forth in the ID." *Id.*; Order No. 64 (Dec. 18, 2024) (terminating Jeisys and Cynosure from the investigation), *unreviewed by* Comm'n Notice (Jan. 17, 2025).

On January 2, 2025, Jeisys and Cynosure filed a petition for review, asking the Commission to set aside the findings in the ID pertaining to them because of their termination from the investigation.

January 10, 2025, Serendia and EndyMed filed respective petitions for review of the ID. On January 21, 2025, the parties, including OUII, filed responses to the petitions.

On February 28, 2025, the Commission determined to review the final ID in part. 90 FR 11433-36 (Mar. 6, 2023). Specifically, the Commission determined to review the final ID's findings on jurisdiction, standing, economic prong of domestic industry for all five patents, contributory infringement for the asserted claims of the '536, '774, '812, and '836 patents, secondary considerations for the '536 and '836 patents, and indefiniteness of the asserted claims of the '444 patent. The Commission requested briefing on certain issues under review and on remedy, the public interest, and bonding. *Id*.

In its notice of review, the Commission vacated the findings in the ID pertaining to Jeisys and Cynosure due to their termination from the investigation. 90 FR 11435 (Mar. 6, 2023).

On March 14, 2025, the parties filed initial submissions in response to the Commission's request for briefing. On March 21, 2025, the parties filed reply submissions.

Upon review of the parties' submissions, the ID, the RD, evidence of record, and the public interest, the Commission has determined that EndyMed violated section 337 by reason of importation and sale of articles that infringe asserted claims 1, 9, and 22 of the '836 patent; claims 11 and 16 of the '536 patent; claim 14 of the '774 patent; and claims 5, 13, and 18 of the '812 patent. Regarding the issues under review, the Commission has determined to (1) provide the modification in the accompanying Commission opinion for the ID's findings on jurisdiction and standing, (2) affirm the ID's findings on the economic prong of domestic industry for the reasons provided in the ID as supplemented in the opinion, (3) take no position on the ID's contributory infringement finding, (4) affirm the ID's findings on secondary considerations for the reasons provided in the ID, and (5) reverse and remand the ID's indefiniteness finding of the asserted claims of the '444 patent.

For the '444 patent, the Commission has determined to remand to the ALJ for further proceedings consistent with the Commission's opinion and remand order. The target date is extended to July 8, 2025. For remedy, the Commission has determined to issue a limited exclusion order prohibiting further importation of infringing products and cease and desist orders against EndyMed. The Commission has also determined that the public interest factors enumerated in paragraphs 337(d)(1) and (f)(1) (19 U.S.C. 1337(d)(1), (f)(1)) do not preclude the issuance of these remedial orders. The Commission has determined to set a bond in the amount

of eighty-five percent (85%) of the entered value of the EndyMed Pure, and seventy percent (70%) of the entered value of the EndyMed Pro, for infringing products imported during the period of Presidential review pursuant to 19 U.S.C. 1337(j). The Commission's orders were delivered to the President and to the United States Trade Representative on the day of their issuance.

The Commission vote for this determination took place on June 3, 2025. The investigation is hereby terminated with respect to the '836, '536, '774, and '812 patents. The '444 patent is remanded to the ALJ.

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: June 3, 2025