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 COMMISSION DETERMINATION TO REVIEW IN PART A FINAL INITIAL DETERMINATION FINDING A VIOLATION OF SECTION 337; REQUEST FOR WRITTEN SUBMISSIONS ON THE ISSUES UNDER REVIEW AND ON REMEDY, THE PUBLIC INTEREST, AND BONDING

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that U.S. International Trade Commission ("Commission") has determined to review a final initial determination ("ID") of the presiding administrative law judge ("ALJ"), finding a violation of section 337 as to four asserted patents and no violation as to one asserted patent. The Commission requests written submissions from the parties on the issues under review and submissions from the parties, interested government agencies, and other interested persons on the issues of remedy, the public interest, and bonding, under the schedule set forth below.

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 *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 April 6, 2023, based on a complaint filed by Serendia, LLC of Lake Forest, CA ("Serendia"). 88 FR 20551-52 (Apr. 6, 2023). The complaint, as supplemented, alleged 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 U.S. Patent No. 9,480,836 ("the '836 patent"); claims 1-5, 7-10, and 15 of U.S. Patent No. 10,058,379; claims 1-10 of U.S. Patent No. 11,406,444 ("the '444 patent"); claims 1, 2, 4, 5, 8, 9, 11-13, 16, and 17 of U.S. Patent No. 9,320,536 ("the '536 patent"); claims 1 and 6-15 of U.S. Patent No. 9,775,774 ("the '774 patent'); and claims 1, 5-7,

9, 10, and 12-19 of U.S. Patent No. 10,869,812 ("the '812 patent"). *Id.* at 20551. The complaint further alleged 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 Medical Ltd. of Caesarea, Israel; EndyMed Medical, Ltd. of New York, New York; and EndyMed Medical, Inc. of Freehold, New Jersey (together, "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; and claims 5, 13, and 18 of the '812 patent, which remain pending in this investigation. *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, Jeisys, and Cynosure. *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).

The ALJ held a *Markman* Order 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 *Markman* Order found the asserted claims of the '444 patent indefinite and terminated the investigation as the '444 patent.

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 18, 2024, the ALJ issued an ID granting a motion to terminate the investigation as to respondents Jeisys and Cynosure based upon settlement. Order No. 64 (Dec. 18, 2024), *unreviewed by* Comm'n Notice (Jan. 17, 2025).

On December 19, 2024, the ALJ issued the final ID finding a violation of section 337 as

to the asserted patent claims remaining in the investigation by respondents EndyMed, Jeisys, and Cynosure. Specifically, the ID found that by appearing and participating in the investigation, the parties have 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 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 five patents remaining in the investigation.

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 of 10% for the Accused Potenza Products" but that "if the Commission finds that the 10% royalty rate in the Patent License Agreement is inapplicable to the Accused Potenza Products, then it is recommended that a 5-6% bond rate be entered on value because Respondents conceded that a 5-6% bond is 'economically reasonable.'" *Id.* at 318.

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. The Commission has determined to review and vacate the findings in the ID pertaining to Jeisys and Cynosure due to their termination from the investigation. *See* ID at ii n.1.

On 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.

Having reviewed the record of the investigation, including the final ID, the parties' submissions to the ALJ, the petitions for review, and the responses thereto, the Commission has determined to review the ID in part. Specifically, the Commission has determined to review the

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.

In connection with its review, there is interest in responses to the following questions. The parties are requested to brief their positions with reference to the applicable law and the existing evidentiary record.

(1) Does section 337 allow investments of an implied licensee to count towards the existence of a domestic industry?

(2) Under the terms of the agreement between Serendia and ViOL, could ViOL grant an implied sublicense to Benev?

(3) Under the doctrine of patent exhaustion, did Serendia extinguish its rights to the domestic industry products upon ViOL's sale to Benev? Does it matter whether Benev is an implied licensee?

(4) Provide a breakout of the investments for Benev Personnel, Medical Professionals, and Medical and Scientific Advisor presented in CDX-0003C.48 among the six categories of investments delineated in the ID at 279. Please also provide a breakout of the investments on an annual basis and prior to and after the date of the agreement in CX-0765C.

(5) To the extent not already briefed, to what extent are any of the six categories of investments delineated in the ID at 279 of the sort that a mere importer would engage in, including by addressing if they are activities that must by their nature be performed in the United States as a legal or a practical matter, such that they might not be distinguishable from the activities of a mere importer?

(6) Address if there is any distinction or legal requirement under the statute or legislative history of Section 337 or by Commission or Federal Circuit precedent that certain activities are only cognizable if (1) the activities must be performed in the United States or (2) if the activities are chosen to be performed in the United States?

(7) What costs for contractors (both types of services and amounts) are not included in the data provided for ViOL's manufacturing costs (*see, e.g.,* RX-2566C at 119:1-11, CPX-0156C)? Please provide a breakout prior to and after the date of the agreement in CX-0765C.

(8) Regarding the '444 patent, if the Commission finds that the claims are not indefinite, what benefit is there in remanding to the ALJ? Would an exclusion order naming the'444 patent cover products that the asserted claims of the '836 patent would not cover?

The parties are invited to brief only the discrete issues requested above. The parties are not to brief other issues on review, which are adequately presented in the parties' existing filings.

In connection with the final disposition of this investigation, the statute authorizes issuance of, *inter alia,* (1) an exclusion order that could result in the exclusion of the subject articles from entry into the United States; and/or (2) cease and desist orders that could result in the respondents being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, see *Certain Devices for Connecting Computers via Telephone Lines*, Inv. No. 337-TA-360, USITC Pub. No. 2843, Comm'n Op. at 7-10 (Dec. 1994).

The statute requires the Commission to consider the effects of that remedy upon the public interest. The public interest factors the Commission will consider include the effect that an exclusion order and cease and desist orders would have on: (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If any respondents are requesting that remedial orders contain an exemption related to service and/or repair, parties are invited to address the following issues, as appropriate.

(1) What is the rationale for providing an exemption, either under the Commission's broad remedial discretion or under the public interest factors? Please provide available factual evidence in support, including any not currently on the record.

(2) What are the warranty terms, if any, for the merchandise in question?

(3) Should the exemption apply only to merchandise under warranty, or to all needed service and repair?

(4) Should the exemption cover only parts for service/repair, or should it also allow complete replacement of merchandise?

(5) What should the temporal cutoff be for the exemption, *e.g.*, should the operative date be the issuance of the Commission's final determination or the end of the Presidential review period, and should it apply to merchandise sold prior to such date or imported prior to such date?

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve, disapprove, or take no action on the Commission's determination. *See* Presidential Memorandum of July 21, 2005, 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

WRITTEN SUBMISSIONS: The parties to the investigation are requested to file written submissions on the issues identified in this notice. Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such submissions should address the recommended determination by the ALJ on remedy and bonding.

In its initial submission, Complainant is also requested to identify the remedy sought and Complainant and OUII are requested to submit proposed remedial orders for the Commission's consideration. Complainant is further requested to provide the HTSUS subheadings under which the accused products are imported, and to supply the identification information for all known importers of the products at issue in this investigation. The initial written submissions and proposed remedial orders must be filed no later than close of business on **March 14, 2025**. Reply submissions must be filed no later than the close of business on **March 21, 2025**. Opening submissions are limited to **60** pages. Reply submissions are limited to **30** pages. No further submissions on any of these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above pursuant to 19 CFR 210.4(f). Submissions should refer to the investigation number (Inv. No. 337-TA-1356) in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf*). Persons with questions regarding filing should contact the Secretary, (202) 205-2000.

Any person desiring to submit a document to the Commission in confidence must request confidential treatment by marking each document with a header indicating that the document contains confidential information. This marking will be deemed to satisfy the request procedure set forth in Rules 201.6(b) and 210.5(e)(2) (19 CFR 201.6(b) & 210.5(e)(2)). Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. Any non-party wishing to submit comments containing confidential information must serve those comments on the parties to the investigation pursuant to the applicable Administrative Protective Order. A redacted non-confidential version of the document must also be filed with the Commission and served on any parties to the investigation within two business days of any confidential filing. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection on EDIS.

The Commission vote for this determination took place on February 28, 2025.

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: February 28, 2025