

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of

CERTAIN DERMATOLOGICAL
TREATMENT DEVICES AND
COMPONENTS THEREOF

Investigation No. 337-TA-1356

COMMISSION OPINION

CONTENTS

I. Introduction	3
II. Background.....	3
A. Procedural History.....	3
B. Asserted Patents	8
1. The '536, '774, and '812 Patents (Needle Assembly Patents)	8
2. The '836 and '444 Patents (Na Effect Patents)	12
C. The Accused Products	15
D. Domestic Industry Products	15
III. Commission Review of the ID	15
IV. Analysis	16
A. Statutory Authority.....	16
B. Economic Prong of Domestic Industry	17
C. Contributory Infringement	18
1. Legal Standard.....	19
2. The ID.....	19
3. Commission Determination	20
D. Secondary Considerations for the '536 and '836 Patents	20
1. Legal Standard - 35 U.S.C § 103 (Obviousness).....	21
2. Commission Determination	21
E. Indefiniteness of the Asserted Claims of the '444 Patent	24
1. Legal Standard.....	24
2. Markman Order (Order No. 35)	25

3. Commission Determination	27
V. Remedy	31
A. Limited Exclusion Order	31
1. Legal Standard	31
2. The RD	32
3. Parties' Submissions.....	32
4. Commission Determination	33
B. Cease and Desist Order	35
1. Legal Standard	35
2. The RD	36
3. Parties' Submissions.....	36
4. Commission Determination	36
C. The Public Interest	36
1. Public Health and Welfare.....	38
2. Competitive Conditions in the United States Economy	39
3. Production of Like or Directly Competitive Articles in the United States.....	40
4. United States Consumers.....	40
D. Bond	45
VI. Conclusion	47



I. INTRODUCTION

On February 28, 2025, the Commission determined to review in part the final initial determination (“ID”) issued by the presiding Administrative Law Judge (“ALJ”) on December 19, 2024. 90 Fed. Reg. 11433-36 (Mar. 6, 2023). On review, the Commission has determined to affirm, with modifications, the ID’s finding that there has been a violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 (“section 337”), as to four asserted patents and has determined to remand one patent to the ALJ for further proceedings. Having found a violation of section 337, the Commission has determined to issue a limited exclusion order (“LEO”) and cease and desist orders (“CDO”) as set forth below. The Commission finds that the public interest factors do not preclude the issuance of remedial orders. The Commission has determined that 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 is required for infringing products imported during the period of Presidential review. This opinion sets forth the Commission’s reasoning in support of that determination. The Commission adopts the remainder of the ID that is not inconsistent with this opinion.

II. BACKGROUND

A. Procedural History

On April 6, 2023, the Commission instituted this investigation based on a complaint filed by Serendia, LLC of Lake Forest, California (“Serendia”). 88 FR 20551-52 (Apr. 6, 2023). The complaint alleged violations of section 337 based on the importation into the United States, the sale for importation, or 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 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 (“Sung Hwan”); Aesthetics Biomedical, Inc. of Phoenix, Arizona (“Aesthetics Biomedical”); Cartessa Aesthetics, LLC of Melville, New York (“Cartessa Aesthetics”); Lutronic Corporation of Goyang-si, Republic of Korea (“Lutronic Corporation”); Lutronic Aesthetics, Inc., also known as Lutronic, Inc. of Billerica, Massachusetts (“Lutronic Aesthetics”); Lutronic, LLC of Billerica, Massachusetts (“Lutronic Billerica”); Ilooda, Co., Ltd. of Anyang-si, Republic of Korea (“Ilooda”); Cutera, Inc. of Brisbane, California (“Cutera”); Rohrer Aesthetics, LLC of Homewood, Alabama (“Rohrer LLC”); Rohrer Aesthetics, Inc. of Homewood, Alabama (“Rohrer Inc.”); 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 (collectively, “EndyMed”). *Id.* at 20552. The Office of Unfair Import Investigations (“OUII”) was also named as a party in this investigation. *Id.*

The Commission terminated the investigation as to all claims except claims 4, 6, and 7 of the ’444 patent, 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. Order No. 16 (June 29, 2023), *unreviewed by* Comm’n Notice (July 20, 2023); Order No. 27 (Sept. 20, 2023), *unreviewed by*

Comm’n Notice (Oct. 16, 2023); Order No. 43 (Nov. 8, 2023), *unreviewed by* Comm’n Notice (Dec. 11, 2023).

The Commission terminated the investigation as to all respondents except EndyMed, Jeisys, and Cynosure. Order No. 26 (Sept. 18, 2023), *unreviewed by* Comm’n Notice (Oct. 16, 2023); Order No. 38 (Sept. 18, 2023), *unreviewed by* Comm’n Notice (Nov. 20, 2023); Order No. 45 (Nov. 20, 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. 51 (Dec. 13, 2023), *unreviewed by* Comm’n Notice (Jan. 10, 2024); Order No. 53 (Apr. 10, 2024), *unreviewed by* Comm’n Notice (May 8, 2024).

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 asserted claims of the ’444 patent, claims 4, 6, and 7, invalid for indefiniteness in the *Markman* Order and did not consider those claims in the final ID. *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.

On December 18, 2024, the Commission terminated the investigation as to respondents Jeisys and Cynosure based upon settlement, leaving EndyMed as the only respondent. Order No. 64 (Dec. 18, 2024), *unreviewed by* Comm’n Notice (Jan. 17, 2025).

On December 19, 2024, the ALJ issued the final initial determination (“ID”) finding a violation of section 337 as to the asserted patent claims remaining in the investigation by

respondents EndyMed, Jeisys, and Cynosure.¹ Specifically, the ID found that Serendia 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 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 §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 all but the '444 patent.

The ID included the ALJ's recommended determination on remedy and bonding ("RD"). The RD recommended, should the Commission find a violation, issuance of an LEO and CDOs 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 value of the EndyMed Pure product and 70% of the value of the EndyMed Pro product during the period of Presidential review. *Id.* at 314.

¹ The ID noted that respondents Jeisys and Cynosure have been terminated from the investigation by the ALJ in Order No. 64, but that given the timing of the termination, the analyses pertaining to them contained in the ID would not be deleted. 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 at ii n.1.

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.² On January 10, 2025,³ Serendia and EndyMed filed respective petitions for review of the ID.⁴ On January 21, 2025, the parties, including OUII, filed responses to the petitions.⁵

On February 28, 2025, the Commission determined to review the final ID in part. 90 Fed. Reg. 11433-36 (Mar. 6, 2023). Specifically, the Commission determined to review the final ID's findings on jurisdiction, standing, economic prong of the 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 Fed. Reg. 11435 (Mar. 6, 2023).

² See Respondents Jeisys Medical Inc. and Cynosure, LLC's Petition for Review of Initial Determination on Violation of Section 337 ("Jeisys and Cynosure Pet.").

³ The Chair granted an extension of ten (10) days for the parties to file petitions for review.

⁴ See Complainant Serendia, LLC's Petition for Review of the Final Initial Determination ("Serendia Pet."); EndyMed Respondents' Petition for Commission Review of Initial Determination on Violation of Section 337 ("EndyMed Pet.").

⁵ See EndyMed Respondents' Response to Complainant Serendia, LLC's Petition for Review of the Final Initial Determination ("EndyMed Rep."); Complainant Serendia, LLC's Response to EndyMed's Petition for Review of the Initial Determination ("Serendia Rep."); Response of the Office of Unfair Import Investigations to the Private Parties' Petitions for Review of the Initial Determination on Violation of Section 337 ("OUII Rep.").

On March 14, 2025, the parties filed initial submissions in response to the Commission's request for briefing.⁶ On March 21, 2025, the parties filed reply submissions.⁷

B. Asserted Patents

The Asserted Patents belong to two separate patent families and name the same inventor, Dr. Jongju Na. The '536, '774, and '812 patents share a common specification and are members of one patent family, the so-called "Needle Assembly Patents." *Markman* Order at 8. The '836, and '444 patents share a common specification and are members of another patent family, the so-called "Na Effect Patents." *Id.*

1. The '536, '774, and '812 Patents (Needle Assembly Patents)

The Needle Assembly Patents (or Family Two Patents) relate generally to "treating derma[to]logical tissue." '536 patent at 1:25-27. The patents describe a "derma[to]logical treatment apparatus" that comprises "a user handle 220 coupled to an acupuncture plate 200." *Id.* at 2:51-55, Figs. 1A, 1B (below)). The plate includes "a plurality of acupuncture pins or needles 230." *Id.* at 2:61-67.

⁶ See EndyMed Respondents' Initial Response to the Commission's Notice of Determination to Review in Part the Final Initial Determination ("EndyMed Sub."); Complainant Serendia, LLC's Submission on the Issues Under Review and on Remedy, the Public Interest, and Bonding ("Serendia Sub."); Response of the Office of Unfair Import Investigations to the Commission's Request for Written Submissions on the Issues Under Review and on Remedy, the Public Interest, and Bonding ("OUII Sub.").

⁷ See EndyMed Respondents' Reply Submission in Response to the Commission's Notice of Determination to Review in Part the Final Initial Determination ("EndyMed R.Sub."); Complainant Serendia, LLC's Response to EndyMed Respondents' and OUII's March 14, 2025 Written Submissions on the Issues Under Review and on Remedy, the Public Interest, and Bonding ("Serendia R.Sub."); Reply of the Office of Unfair Import Investigations to the Private Parties' Responses on the Issues Under Review and on Remedy, Bonding, and the Public Interest ("OUII R.Sub.").

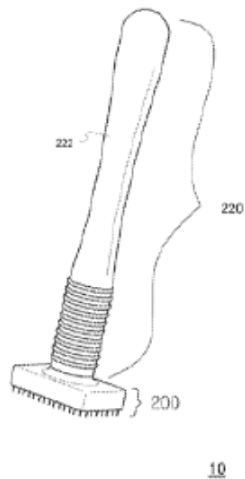


FIGURE 1A

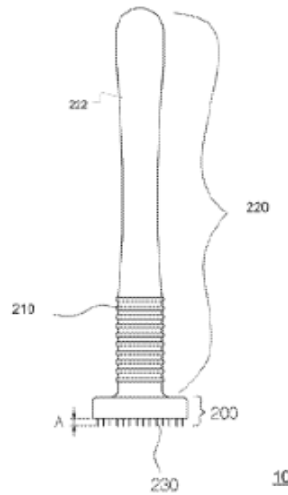


FIGURE 1B

The patent discloses that the apparatus can be used “to create a plurality of micro-wounds or holes in derma[to]logical layers of mammal’s [] skin or dermis” and that creating such micro-wounds or holes in the skin “may improve the absorption or application of one or more chemicals applied on or about the micro-wounds or holes” (*id.* at 3:21-26) and “may increase cellular activity and help heal tissue faster and facilitate the delivery, uptake and use in the cell of the cosmetics, medications, or chemicals [] used” (*id.* at 7:51-54). The patent further discloses that to assist in creating the micro-wounds or holes in the skin, “electrical signal generation system 300 may be electrically coupled to the acupuncture apparatus 320 via one or more wires 300A and to a mammal 20 to be treated via one or more wires 300B” in order to “generate a variety of signals . . . to vibrate one or more pins 351 electrically coupled to system 300.” *Id.* at 3:27- 45, Figs. 2A-2C. Serendia asserts independent claim 11 and dependent claim 16 of the ’536 patent; claim 14 (depending from claims 11 and 12) of the ’774 patent; and claims 5 (depending from claims 1-4), 13 (depending from claim 12), and 18 (depending from claim 12) of the ’812 patent in this investigation. *ID* at 6. The claims recite (asserted claim numbers in bold):

'536 Patent

11. An apparatus for treating dermatological tissue, comprising:

a user holdable device including a proximal end and a releasably couplable deployable needle assembly, the deployable needle assembly mechanically separatably from the proximal end and including a plurality of extendable needles, a plurality of the extendable needles extendable from a deployable needle assembly end surface, one of the proximal end and the deployable needle assembly including at least one electrical conductor and the other including at least one restorably deflectable electrical contact couplable to the one of the proximal end and the deployable needle assembly at least one electrical conductor;

a motor coupled to a plurality of extendable needles that causes the plurality of extendable needles to extend a desired distance from the needle assembly end surface when the motor is energized with a particular signal; and

a signal generator electrically coupled to the plurality of extended needles to energize the plurality of extended needles.

16. The apparatus of claim 11, the wherein at least one restorably deflectable electrical contact includes a depressible pin.

JX-0001 ('536 patent) claims 11, 16).

'774 Patent

11. An apparatus for treating dermatological tissue, comprising:

a device including a plurality of needles one of extending or extendable a desired distance from a surface, the desired distance selected to enable the plurality of needles to penetrate dermatological tissue; and

a signal generator electrically coupled to the plurality of extended needles to produce pulsed radio frequency signals across the plurality of needles to affect dermatological tissue near the plurality of needles.

12. The apparatus of treating dermatological tissue of claim 11, wherein the device includes an end surface configured to be placed on or near dermatological tissue to be treated, the end surface

including a plurality of needles extendable to a desired distance from the end surface.

14. The apparatus for treating dermatological tissue of claim 12, further including a motor coupled to the plurality of extendable needles that may be directed to cause the plurality of the extendable needles to extend a desired distance from the end surface.

JX-0003 ('774 patent) claims 11, 12, 14).

'812 Patent

1. A method of treating dermatological tissue, comprising:

placing a user holdable device releasably couplable deployable needle module end surface on or near dermatological tissue to be treated, the user holdable device including a proximal end and the releasably couplable deployable needle module, the releasably couplable deployable needle module mechanically separatably from the user holdable device proximal end and including a needle assembly including a plurality of needles, the needle assembly movable within the releasably couplable deployable needle module to extend the plurality of needles from the releasably couplable deployable needle assembly end surface while at least one electrical contact of the needle assembly remains electrically coupled to at least one electrical contact of the user holdable device proximal end; and

communicating electrical signals from the user holdable device proximal end to the needle assembly via the electrical contacts.

2. The method of claim 1, further comprising energizing a motor coupled to the needle assembly to cause the plurality of the needles to extend a desired distance from the releasably couplable deployable needle module end surface.

3. The method of claim 2, further comprising energizing the plurality of needles via a signal generator electrically coupled to the user holdable device proximal end.

4. The method of claim 3, wherein the user holdable device proximal end further includes at least one embedded LED therein and further including energizing the at least one embedded LED so the at least embedded LED illuminates the releasably couplable deployable needle module.

5. The method of claim 4, wherein the needle assembly includes a translucent section and further including energizing the least one embedded LED to illuminate the plurality of needles via the needle assembly translucent section.

12. An apparatus for treating dermatological tissue, comprising:

a user holdable device including a proximal end and

a releasably couplable deployable needle module, the releasably couplable deployable needle module mechanically separatably from the user holdable device proximal end and including a needle assembly including a plurality of needles, the needle assembly movable within the releasably couplable deployable needle module to extend the plurality of needles from the releasably couplable deployable needle assembly end surface while at least one electrical contact of the needle assembly remains electrically coupled to at least one electrical contact of the user holdable device proximal end

13. The apparatus of claim 12, further including a motor coupled to the needle assembly to extend the plurality of needles a desired distance from the releasably couplable deployable needle assembly end surface when the motor is energized with a particular signal.

18. The apparatus of claim 12, wherein one of the at least one electrical contacts includes a pin that is extendable in the same direction as the plurality of needles.

JX-0005 ('812 patent) claims 1-5, 12, 13, 18.

2. *The '836 and '444 Patents (Na Effect Patents)*

The Na Effect Patents describe an invention “for medical treatment including skin treatment using electrical energy, especially with the primary purpose for skin treatment for aesthetics, and in some cases, can be used as a direct instrument or Supplement for skin cosmetic surgery.” JXM-0007 ('836 patent) at 1:24-26. The patents describe a “method and apparatus that provides electric stimulation directly to a body region including the dermis via needles” and “revitalizes and regenerates the body region including collagen by wounding the dermis.” *Id.* at 2:37-41). Figure 5 (below), which depicts “a simplified diagram of treatment architecture using

non insulated needles according to an embodiment,” shows “needles 300 with needle tips 302 for generating energy field 909.”

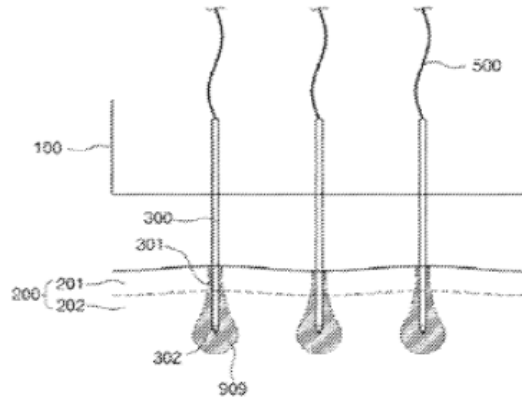


FIGURE 5

The patent states that “[t]he method of the present invention may control electrical factors or distance between needles to control the energy field applied between needles” and “may enable users to control the number of treatments in target areas by controlling the dissipated energy in needles.” *Id.* at 3:31-36. Serendia asserts independent claim 1 with its dependent claim 9, and claim 22 (depending from claim 14) of the ’836 patent and dependent claims 4, 6, and 7 (all depending from claim 1) of the ’444 patent.⁸ The claims recite:

’836 Patent

1. A skin treatment apparatus, comprising:

a plurality of electrodes, the electrodes being bipolar and configured to be insertable into skin to be treated; and

a radio frequency (RF) generation module, the RF generation module electrically coupled to the plurality of electrodes and configured to provide an Alternating Current (AC) RF signal to the plurality of electrodes configured to cause coagulation around each electrode rather than coagulating between the electrodes.

⁸ As discussed above, the ALJ found the asserted claims of the ’444 patent indefinite in the *Markman* Order and did not consider those claims in the final ID. Order No. 35 at 62.

9. The skin treatment apparatus of claim 1, wherein the electrodes are needles and have a diameter from 0.25 mm to 0.30 mm.

14. A method of treating skin, comprising:

inserting a plurality of electrodes, the electrodes being bipolar into a section of skin to be treated; and

applying a Alternating Current (AC) Radio Frequency (RF) signal to the plurality of electrodes configured to cause coagulation around each electrode rather than coagulating between the electrodes.

22. The method of treating skin of claim 14, wherein the RF is from 0.5 to 10 Mhz and the predetermined time interval is from 0.05 to 0.8 seconds.

JX-0007 ('836 patent) claims 1, 9, 14, 22.

'444 Patent

1. A mammalian body treatment apparatus, comprising:

a plurality of electrodes, the nearest electrodes having opposite polarities and the electrodes configured to be deployable into a body segment to be treated; and

a radio frequency (RF) generation module, the RF generation module electrically coupled to the plurality of electrodes and configured to provide an RF signal with oscillating current to the plurality of electrodes that causes energy to be substantially applied to body segments around each electrode.

4. The mammalian body treatment apparatus of claim 1, wherein the electrodes are bipolar

6. The mammalian body treatment apparatus of claim 1, wherein the plurality of electrodes forms a square configuration.

7. The mammalian body treatment apparatus of claim 1, wherein the plurality of electrodes forms a rectangular configuration and their respective polarities form a check board pattern.

JX-0011 ('444 patent) claims 1, 4, 6, 7.

C. The Accused Products

EndyMed's accused products include the EndyMed Pro and Pure 2.0 with Intensif handpiece. ID at 50. EndyMed stipulated that "the EndyMed Pro (when used with the Intensif applicator) and the EndyMed Pure 2.0 (when used with the Intensif applicator), are representative of each other with respect to the Accused Functionality." *Id.*

D. Domestic Industry Products

For domestic industry, Serendia asserts that the "SylfirmX product, its related handpieces, and needles assemblies" practice the Asserted Patents. ID at 52.

III. COMMISSION REVIEW OF THE ID

When the Commission reviews an initial determination, in whole or in part, it reviews the determination *de novo*. *Certain Soft-Edged Trampolines and Components Thereof*, Inv. No. 337-TA-908, Comm'n Op. at 4 (May 1, 2015). Upon review, the "Commission has 'all the powers which it would have in making the initial determination,' except where the issues are limited on notice or by rule." *Certain Flash Memory Circuits & Prods. Containing Same*, Inv. No. 337-TA-382, USITC Pub. No. 3046, Comm'n Op. at 9–10 (July 1997) (quoting *Certain Acid-Washed Denim Garments & Accessories*, Inv. No. 337-TA-324, Comm'n Op. at 5 (Nov. 1992)). With respect to the issues under review, "the Commission may affirm, reverse, modify, vacate, or remand for further proceedings, in whole or in part, the initial determination of the administrative law judge." 19 C.F.R. § 210.45(c). The Commission also "may take no position on specific issues or portions of the initial determination," and "may make any finding or conclusions that in its judgment are proper based on the record in the proceeding." *Id.*; *see also Beloit Corp. v. Valmet Oy*, 742 F.2d 1421, 1423 (Fed. Cir. 1984).

IV. ANALYSIS

A. Statutory Authority

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 further found that because the accused products have been imported into the United States, the Commission has *in rem* jurisdiction over them. *Id.* The ID also 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.

As discussed more fully in the Commission Opinions recently issued in *Certain Compact Wallets and Components Thereof*, Inv. No. 337-TA-1355, Comm’n Op. at 9-12 (July 29, 2024) and *Certain Liquid Transfer Devices with an Integral Vial Adapter*, Inv. No. 337-TA-1362, Order No. 19, Comm’n Op. at 6-10 (July 26, 2024), the Commission clarifies that the terms “subject matter jurisdiction,” “personal jurisdiction,” and “in rem jurisdiction” are not necessarily appropriate for the Commission’s investigative authority under section 337. The Commission is “a creature of statute.” *Kyocera v. Int’l Trade Comm’n*, 545 F.3d 1340, 1355 (Fed. Cir. 2008). Accordingly, the Commission has statutory authority to investigate an alleged violation of section 337 where a complaint alleges that the named respondents have imported, sold for importation, or sold after importation articles that, *inter alia*, infringe a valid and enforceable U.S. patent. 19 U.S.C. § 1337(a)(1)(B). The Commission likewise has statutory authority over accused products based on their alleged importation, sale for importation, or sale after importation into the United States.

As discussed more fully in the Commission Opinion recently issued in *Certain Active Matrix Organic Light-Emitting Diode Display Panels and Modules for Mobile Devices, and Components Thereof*, Inv. No. 337-TA-1351, Comm’n Op. at 11-16 (May 16, 2024),

constitutional standing does not apply to the Commission's proceedings. Rather, Commission Rule 210.12(a)(7), which implements section 337(a)(1)(B), specifies who may file a complaint with the Commission. "For every intellectual property-based complaint (regardless of the type of intellectual property right involved), include a showing that at least one complainant is the owner or exclusive licensee of the subject intellectual property." 19 C.F.R. § 210.12(a)(7). The Commission has also indicated that it has adopted the standards applied by the Federal Circuit in construing 35 U.S.C. § 281 when interpreting this provision of the Rule. The ALJ, therefore, properly determined that Serendia is the owner of the asserted patents, and the Commission construes the ALJ's use of the term "standing" to refer to Commission Rule 210.12(a)(7) rather than the constitutional principle under Article III.

B. Economic Prong of Domestic Industry

The Commission determined to review the ID's findings that Serendia demonstrated the existence of a domestic industry under 19 U.S.C. § 1337(a)(3)(B) through the activities of its licensee Benev. 90 Fed. Reg. 11434-35 (Mar. 6, 2025); ID at 279-300.

On review, the Commission has determined to affirm the ID's findings.^{9, 10} Thus, the Commission has determined to affirm the ID's ultimate finding that Serendia established the

⁹ Serendia, in response to a question from the Commission, confirmed that the manufacturing costs it presented for ViOL are complete, and that there are no separate contractor costs related to manufacturing. Serendia Sub. at 24; CPX-1056C.

¹⁰ Commissioner Kearns notes that Serendia is relying on a range of activities conducted by Benev with respect to the DI products. He further notes that while *Lashify* appears to require crediting all these activities, at least some of them go beyond the sorts of activities that would be conducted by a mere importer.

existence of a domestic industry under 19 U.S.C. § 1337(a)(3)(B) for the reasons provided in the ID as supplemented herein.¹¹

Serendia, in its submission, seeks to add certain expenditures that it originally excluded as non-cognizable sales and marketing expenses, and now argues should be included in light of the Federal Circuit's decision in *Lashify, Inc. v. Int'l Trade Comm'n*, 130 F.4th 948 (Fed. Cir. 2025). Serendia Sub. at 8. Given the Commission's finding that Serendia has established the existence of a domestic industry on the current record, the Commission finds it unnecessary to consider those additional expenditures. Their inclusion would only further support the Commission's determination that there is a domestic industry.

C. Contributory Infringement

The Commission determined to review the ID's contributory infringement findings for the asserted claims of the '536, '774, '812, and '836 patents. 90 Fed. Reg. 11435 (Mar. 6, 2023). Serendia alleged that EndyMed contributed to infringement by importing and selling the Intensif handpiece, the EndyMed Pro, and EndyMed Pure 2.0 to cause others to domestically combine the Intensif handpiece with either the EndyMed Pro or EndyMed Pure 2.0 to practice the asserted patents.¹² See ID at 102-03.

¹¹ Commissioner Kearns relies on the ID's comparison of qualifying DI product labor and capital investments to ViOL's foreign manufacturing costs to find significance under the statute; he does not rely on the ID's comparison of qualifying DI product labor and capital investments to Benev's total operating expenses. See ID at 295-96.

¹² In addition to contributory infringement, Serendia alleged a violation of section 337 by EndyMed based on induced infringement of the asserted claims of the '536, '774, '812, and '836 patents. It also alleged a violation based on EndyMed's direct infringement of the asserted claims of the '536, '774, '812, and '836 patents. The ID found a violation as to those patents by EndyMed based on induced infringement, contributory infringement, and direct infringement. ID at 70-88, 173-184, 216-225 (direct infringement), 97-104, 185-188 (indirect infringement). The Commission did not review the FID's findings of EndyMed's induced and direct

1. *Legal Standard*

Under 35 U.S.C. § 271(c):

Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination, or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

35 U.S.C. § 271(c). The Federal Circuit has explained that “to prevail on contributory infringement in a Section 337 case, the complainant must show inter alia: (1) there is an act of direct infringement in violation of Section 337; (2) the accused device has no substantial non-infringing uses; and (3) the accused infringer imported, sold for importation, or sold after importation within the United States, the accused components that contributed to another’s direct infringement.” *Spansion, Inc. v. Int’l Trade Comm’n*, 629 F.3d 1331, 1353 (Fed. Cir. 2010).

2. *The ID*

In addressing contributory infringement as to the ’836 patent, the ID found an act of direct infringement and also found that the accused device has no substantial non-infringing uses. ID at 102. Specifically, the ID stated that “[a]lthough the EndyMed Pro and EndyMed Pure 2.0 can provide treatments using handpieces besides the Intensif, these ‘additional separable feature[s]’ are irrelevant to the contributory infringement analysis.” *Id.* at 104 (citing *Ricoh Co. v. Quanta Computer Inc.*, 550 F.3d 1325, 1337 (Fed. Cir. 2008)). The ID found that like in *Ricoh*, “[t]he EndyMed Pro and Pure 2.0 consoles, Intensif handpiece, and consumable tips all constitute material parts of the invention, are specially made or adapted for infringing use, and

infringement and therefore those findings have been adopted by the Commission. 19 C.F.R. § 210.42(h)(2).

work only with each other.” *Id.* at 104 (citing CX-0187C.0018, 0031 (Pure Manual); CX-1055C (Aviram Dep. Tr.) at 26:6-13, 44:1-16).

For the ’536, ’774, and ’812 patents (Family Two Patents), the ID stated that “Respondents were aware of the Family Two Patents, and they contributorily infringe those patents for the same reasons they contributorily infringe the ’836 patent.” ID at 188 (citing Tr. (Crosby) at 637:23-638:20).

3. Commission Determination

EndyMed petitioned for review, arguing that the ID “improperly ignored the undisputed substantial non-infringing uses of the EndyMed Pro and EndyMed Pure 2.0 consoles when used with any number of modular handpieces other than Intensif.” EndyMed Pet. at 47. EndyMed did not, however, petition for review of the ID’s findings that EndyMed itself directly infringes and induces infringement of the asserted claims of the Family Two patents (’536, ’774, and ’812 patents), thereby conceding its infringement of those three patents. *See* 19 C.F.R. § 210.43 (“Any issue not raised in a petition for review will be deemed to have been abandoned by the petitioning party.”); *Broadcom Corp. v. Int’l Trade Comm’n*, 542 F.3d 894, 901 (Fed. Cir. 2008) (citing *Hazani v. Int’l Trade Comm’n*, 126 F.3d 1473, 1476-77 (Fed. Cir. 1997)). Further, the Commission determined not to review the ID’s induced infringement findings and direct infringement by EndyMed as to the ’536, ’774, and ’812, and ’836 patents. Therefore, those infringement finding have been adopted by the Commission. *See* 19 C.F.R. § 210.42(h)(2). Accordingly, the Commission has determined to take no position on the ID’s contributory infringement findings.

D. Secondary Considerations for the ’536 and ’836 Patents

The Commission determined to review the ID’s findings on secondary considerations for the ’536 and ’836 patents. 90 Fed. Reg. 11435 (Mar. 6, 2023).

1. Legal Standard - 35 U.S.C § 103 (Obviousness)

Under 35 U.S.C. § 103, a claim may be found invalid as obvious if “the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” 35 U.S.C. § 103(a).

“Obviousness is a question of law based on underlying questions of fact.” *Scanner Techs. Corp. v. ICOS Vision Sys. Corp. N.V.*, 528 F.3d 1365, 1379 (Fed. Cir. 2008). The underlying factual determinations include the so-called “Graham factors”: (1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between the claimed invention and the prior art, and (4) objective indicia of non-obviousness referred to as “secondary considerations.” *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966).

Secondary considerations include criteria such as “commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.” *Graham*, 338 U.S. at 17-18; *see Merck & Cie v. Gnosis S.P.A.*, 808 F.3d 829, 837 (Fed. Cir. 2015). “[I]n order to accord substantial weight to secondary considerations of nonobviousness, the evidence of secondary considerations must have a ‘nexus’ to the claims, *i.e.*, there must be ‘a legally and factually sufficient connection’ between the evidence and the patented invention.” *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1332 (Fed. Cir. 2019) (internal citations omitted).

2. Commission Determination

The ID found that the cited references failed to render obvious the asserted claims of the ’536 and ’836 patents. *See*, ID at 120-40, 196-213. The Commission determined not to review. The ID also found that, “[e]ven assuming, *arguendo*, that Respondents made a *prima facie* showing of obviousness . . . Serendia adduced sufficient objective evidence of non-obviousness

to rebut Respondents’ *prima facie* showing.” *Id.* at 141, 212-16. The Commission determined to review the finding. 90 Fed. Reg. 11435 (Mar. 6, 2023).

For the ’836 patent, the ID found that “Serendia’s objective indicia of commercial success, industry praise, and long-felt need weigh in favor of validity.” *Id.* at 141-42. Regarding commercial success, the ID stated that “Serendia’s expert, Dr. Goldberg, testified during the Hearing about how the Sylfirm X DI product, the licensed SHEnB, ABM, Lutronic, and Rohrer products, and the Accused Products have experienced commercial success due in large part to the unique characteristics of the claimed invention in the ’836 patent, i.e., the application of bipolar RF energy to skin via electrodes to cause coagulation around but not between electrodes.” *Id.* at 143 (citing Tr. (Goldberg) at 1313:19-1317:21, 1320:18-1325:17, 1329:18-1331:18). That is, the ID implicitly found a nexus between the commercial success and the claimed invention of the ’836 patent. The Commission affirms this finding.

Concerning industry praise, the ID found that “Serendia presented un rebutted evidence that the localized and targeted coagulation claimed by the ’836 patent received industry praise and recognition” and that “[n]umerous medical providers praised the ‘Na Effect,’ and its implementation sets products ‘apart from the pack.’” (Tr. (Goldberg) at 1331:19- 1332:11; (CX-2857C.0001, 0003, 0006 (Aesthetic Guide); CX-2861C (Testimonial)). The ID found that Serendia also “presented un rebutted evidence that the ’836 patent addressed a long-felt need for safer, more effective RF microneedling systems.” ID at 145 (citing CDX-0044C.0034-36 (collecting evidence)). Again, the ID implicitly found a nexus between the industry praise and long-felt need and the invention claimed in the ’836 patent, and the Commission affirms.

For the ’536 patent, the ID found that “Serendia presented evidence that the devices that use the inventions claimed in the Family Two Patents have achieved commercial success, at least

partially, based on the claimed technology.” ID at 213 (citing Tr. (Crosby) at 1520:15-1521:2). Specifically, the ID found that the commercial success of the Sylfirm X domestic industry product “has been due in large part to the adjustable depth control functionality recited in the desired distance limitations in each of the Family Two Patents,” adding that EndyMed’s assertion that Serendia “failed to demonstrate a nexus between the commercial success of the products at issue and the ‘specific, novel features’ of the Family Two Patents,” “mischaracterizes the evidence.” *Id.* at 214. The ID further found that products implementing the Family Two Patent’s claimed element of “extending needles a desired distance and a mechanism for precise needle depth control” have received industry praise and recognition. ID at 216 (citing Tr. (Crosby) at 1525:7-1526:3). The ID noted that “[m]edical providers also have praised the products at issue for their ability to ‘accurately target and treat[]’ at the desired skin depth. *Id.* (citing CX-2858C.0003 (Sylfirm X); CX-2591C.0002 (ABM); CX-0316.0002 (Cartessa)). The Commission affirms the ID’s implicit finding that there is a nexus between the commercial success of the Sylfirm X domestic industry product and the asserted claims.

The ID stated that “Serendia’s objective indicia evidence is un rebutted” and that in Order No. 41, EndyMed was precluded from presenting any substantive discussion of secondary considerations in their Pre-Hearing Brief. *Id.* at 141 (citing Order No. 41 at 3-6 (Oct. 31, 2023) (“Dr. Woloszko is precluded from offering testimony/opinions on that topic during the Hearing in accordance with Ground Rule 9.5.6. . . . Because Respondents did not offer previous testimony/theories of the same, those portions of pages 28 and 104 of Respondents’ Pre-Hearing Brief that reference secondary considerations of non-obviousness are stricken.)).

EndyMed, in its petition for review, argued that the ID “incorrectly found that Respondents waived all arguments to rebut Serendia’s alleged objective indicia evidence of

commercial success, and that, even if Respondents ‘made a prima facie showing of obviousness ... Serendia adduced sufficient objective evidence of nonobviousness to rebut Respondents’ prima facie showing.’” EndyMed Pet. at 63 (citing ID at 141-142). EndyMed then cited to page 28 of its pre-hearing brief and argued that “Dr. Goldberg’s testimony as to nexus, [which] incorrectly attempted to tie commercial success to the ’836 patent as a whole as opposed to a specific, novel feature thereof, Tr (Goldberg) at 1313:19-1335:7, is deficient as a matter of law.” *Id.*

The Commission finds that EndyMed’s assertion above is insufficient to challenge the ID’s detailed findings on commercial success. ID at 143-44. Moreover, EndyMed does not challenge the ID’s findings on “industry praise” or “long felt need” and has abandoned those issues. 19 C.F.R. § 210.43; *Broadcom*, 542 F.3d at 901. Accordingly, the Commission has determined to affirm the ID’s findings. After considering all of the underlying factual findings, including secondary considerations, the Commission finds that EndyMed failed to show that the asserted claims of the ’536 and ’836 patents are obvious.

E. Indefiniteness of the Asserted Claims of the ’444 Patent

The Commission determined to review the ID’s findings that the asserted claims of the ’444 patent are indefinite. 90 Fed. Reg. 11435 (Mar. 6, 2023).

1. Legal Standard

A patent claim must “inform those skilled in the art about the scope of the invention with reasonable certainty” to avoid being indefinite. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 910-11 (2014). The indefiniteness “inquiry trains on the understanding of a skilled artisan at the time of the patent application” and must be conducted in light of the intrinsic evidence. *Id.* at 911, 901. If a person of ordinary skill in the art reading the claim in light of the specification and prosecution history is unable to ascertain with “reasonable certainty” the scope

of the invention, the patent claim is invalid for indefiniteness. *Id.* “Definiteness is a question of law.” *Niazi Licensing Corp. v. St. Jude Med. S.C., Inc.*, 30 F.4th 1339, 1346 (Fed. Cir. 2022).

2. *Markman Order (Order No. 35)*

The claims of the ’444 patent at issue are dependent claims 4, 6, and 7, all of which depend from independent claim 1. Claim 1 recites in relevant part:

a radio frequency (RF) generation module, the RF generation module electrically coupled to the plurality of electrodes and configured to provide an RF signal with oscillating current to the plurality of electrodes that ***causes energy to be substantially applied to body segments around each electrode.***

’444 patent, claim 1 (emphasis added). The *Markman* Order found that the limitation “causes energy to be substantially applied to body segments around each electrode” is indefinite.

Markman Order at 62. The Order stated that “[c]laim 1 is indefinite because the intrinsic evidence does not provide objective boundaries for those of skill in the art as to the scope of energy to be ‘substantially’ applied to body segments around each electrode.” *Id.* The Order noted that “[t]erms of degree are problematic if their baseline is unclear to those of ordinary skill in the art.” *Id.* at 63 (citing *Liberty Ammunition, Inc. v. United States*, 835 F.3d 1388, 1395-96 (Fed. Cir. 2016)).

The Order found that Serendia’s “proposed construction, that this term receive its plain and ordinary meaning, does not define the metes and bounds of ‘substantially applied’ or otherwise provide any explanation of what is meant by substantial application of energy to body segments around each electrode.” *Id.* at 63-64. The Order explained that “the term ‘substantially applied’ does not appear in the specification of the ’444 patent” and that the “specification does not provide any standard for determining how much energy is required for substantially applying energy.” *Id.* at 64. According to the Order, “the specification only describes two energy field formations: (i) embodiments with overlapping or intersecting energy fields (shown in gray), such

as Figure 9A; and (ii) embodiments with non-overlapping or non-intersecting energy fields (shown in gray), such as Figure 9B:

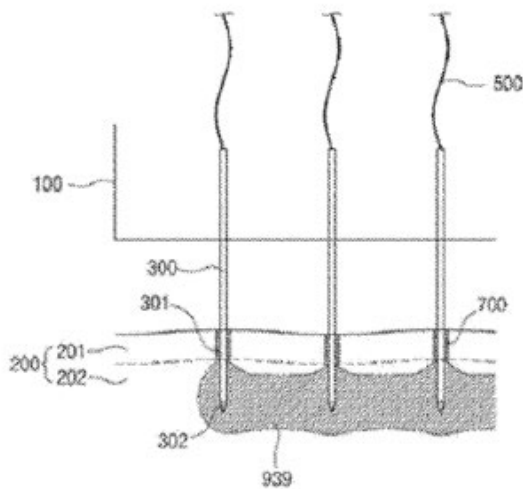


FIGURE 9A

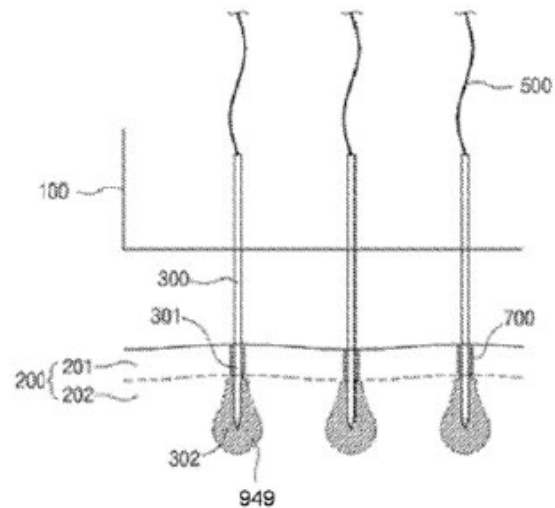


FIGURE 9B

Id. The Order observed that “other than the two (2) embodiments of completely overlapping energy fields and non-overlapping energy fields, no other energy field formation is described in the specification or shown in its drawings that would elucidate the meaning of ‘substantially’ in the context of the claims” and that the patent “examiner allowed the claims because he understood the independent claim to require **no** overlap in energy fields, *i.e.*, that each electrode complete the positive/negative flow path itself.” *Id.* at 65-66 (citing (JXM-0012 (Prosecution History for the ’444 patent) at 429 (emphasis in *Markman* Order)). The Order concluded that “there is no disclosure in the intrinsic record that would help a person of ordinary skill in the art know how much or little overlap is needed to be considered substantial application around an electrode.” *Id.* at 67.

3. *Commission Determination*

The Commission finds that the intrinsic evidence provides sufficient guidance for a person of ordinary skill to understand the claim limitation “[causes/to cause] energy to be substantially applied to body segments around each electrode” with reasonable certainty. Although the specification does not use the words “substantially applied,” it discloses that the “heat may be concentrated at an area in [the] dermis by the needle(s)” and explains that the “applied energy field” is what generates those heated areas. ’444 patent at 3:29-33, 6:5-13. The specification also explains that, when heat is concentrated “around each needle” (because that is where the energy has been substantially applied), it is “not [] concentrated between [the] needles” and will “minimally affect” adjacent areas. *Id.* at 3:33-38. The specification discloses that:

In the present invention the temperature may be raised and the heat may be concentrated at an area in dermis by the needle(s) to cause coagulation. The heat generated by the present invention may minimally affect the adjacent epidermis area. Also, the heated area around the needle end tips may be oval or tear shaped as shown in FIG. 5. In an embodiment, heat may not be concentrated between needles. In an embodiment, the heated area may be around each needle.

’444 patent, col.3:30-38. That is, the “heated area may be around each needle,” such that “heat may not be concentrated between needles” and “may minimally affect the adjacent epidermis area.” FIG 5 illustrates this embodiment and shows temperature is raised 909 around each needle 300”:

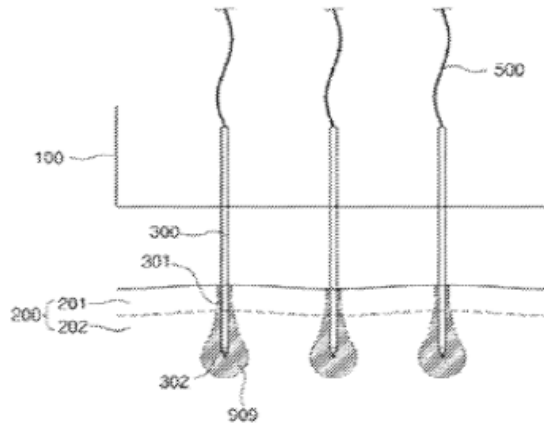


FIGURE 5

'444 patent FIG 5. Consistent with the specification, the invention allows a person of ordinary skill in the art “to control temperature between needles” to avoid the “overheating or burning of both dermis and epidermis located between needles” that can occur with existing technologies. *See* '444 patent at 4:15-29.

As Serendia notes, the patent examiner distinguished Figures 5 and 9B in the '444 patent, which practice the claims, from Figure 13 in the Mehta reference (U.S. Patent No. 8,608,737 (RX-0307)), which shows energy applied between and around pairs of needles to form lesions around those pairs and does not practice the claims. *See* Serendia Pet. at 20 (citing JX-0012.429; RX-0307 (US 8,608,737) at RX-0307.37 (Fig. 13), 37:25-41, 39:24-27). The Commission agrees that “this evidence of the Examiner’s ability to understand and apply the claims, differentiating between what is covered by the claims (as shown in the specification) and what is not covered by the claims (as shown in the prior art) supports definiteness.” *Id.* Indeed, as the ID found, the patent “examiner allowed the claims because he understood the independent claim to require **no** overlap in energy fields, *i.e.*, that each electrode complete the positive/negative flow path itself.” *Markman* Order at 65-66 (citing (JXM-0012 (Prosecution History for the '444

patent) at 429 (emphasis in *Markman* Order)). This demonstrates that the scope of the limitation can be ascertained with reasonable certainty.

Moreover, the expert testimony adduced during the hearing in connection with the related '836 patent suggests that the claim limitation is definite. Dr. Woloszko testified that a skilled artisan would have known how to predict the energy distribution around electrodes and to control it. *See, e.g.*, Tr. (Woloszko) at 1009:19-1010:4 (“Q. In 2011 a person of ordinary skill in the art would have been able to use computer model to obtain a very good approximation of how much energy needs to be delivered to achieve a certain amount of heating in the skin, right? ... A. Yes.”); *id.* at 1010:5-8 (“Q. Indeed, modeling of current flow around electrodes has been performed for decades using a technique called finite element analysis, correct? A. Yes.”).

As Serendia argues, “[u]sing the term of degree ‘substantially’ to describe the application of energy ‘to body segments around each electrode’ renders the ’444 Patent claims no less definite than the many claims using the same term of degree that the Federal Circuit has held to be definite.” Serendia Pet. at 13; *Ironburg Inventions Ltd. v. Valve Corp.*, 64 F.4th 1274, 1281 (Fed. Cir. 2023) (“substantially the full distance”); *Exmark Mfg. Co. v. Briggs & Stratton Power Prods. Grp., LLC*, 879 F.3d 1332, 1347 (Fed. Cir. 2018) (“substantially straight”); *Deere & Co. v. Bush Hog, LLC*, 703 F.3d 1349, 1359 (“substantially planar”); *Enzo Biochem, Inc. v. Applera Corp.*, 599 F.3d 1325, 1336 (Fed. Cir. 2010) (“not interfering substantially”); *Andrew Corp. v. Gabriel Elecs., Inc.*, 847 F.2d 819, 821 (“substantially equal”).

The Commission agrees with Serendia that the ’444 patent specification provides at least as firm a foundation for definiteness as the specification in *Exmark*. Serendia Pet. 15. In *Exmark*, the Federal Circuit found that identification of where the “elongated and substantially straight” baffle portion was located supported definiteness. Similarly, here the claims’

identification of where energy is “substantially applied,” *i.e.*, “around each electrode,” also supports definiteness. *Exmark*, 879 F.3d at 1345; ’444 patent at claims 1. The Commission notes that in *One-E-Way, Inc. v. Int’l Trade Comm’n*, 859 F.3d 1059 (Fed. Cir. 2017), some claims recited “free from interference” and others recited “virtually free from interference.” *One-E-Way*, 859 F.3d at 1066. The Federal Circuit reversed the Commission’s indefiniteness finding, stating that “[a]udio ‘free from interference’ will be a bit better than audio ‘virtually free from interference,’ in the same way something ‘free from defects’ will be a bit better than something ‘substantially’ or ‘virtually free from defects.’” *Id.* at 1066-67. Similarly, the ’444 patent specification discloses that the applied energy can be “concentrated” around each electrode, rather than concentrated between them, and “minimally affect” adjacent areas. ’444 patent at 3:29-38. That is, the specification provides adequate guidance as to where the energy is “substantially applied.”

EndyMed argues that if the Commission finds that the claims of the ’444 patent are not invalid for indefiniteness, it should be given an opportunity to present the rest of its invalidity grounds for the ’444 patent before any finding on whether the patent is valid and enforceable. EndyMed Sub. at 15. Serendia states that in the interests of efficiency and conserving the Commission’s resources, the Commission need not remand to the ALJ if it finds that the claims of the ’444 patent are not indefinite because the Commission can simply address the issues raised by the ’444 patent claims in its final determination. Serendia Sub. at 26. OUII states that “there would be little benefit to remanding the investigation to the ALJ if the Commission were to reverse the ALJ’s well-reasoned finding that the asserted claims are indefinite because an exclusion order naming the ’444 Patent would not cover any additional products than those already covered by the ’836 Patent.” OUII Sub. at 20.

As noted above, the ALJ did not consider the '444 patent during the evidentiary hearing. The Commission, therefore, has determined to remand to the ALJ to consider issues pertaining to the '444 patent in the first instance. While the '444 and '836 patents are related, they recite different limitations. Notably, the asserted claims of the '444 patent do not include the coagulation limitation and are broader in scope than the asserted claims of the '836 patent. Thus, the scope of any remedial relief that might issue could be impacted by the difference in claim scope and the Commission cannot simply extend the findings on the '836 patent to the '444 patent as the parties did not contend before the ALJ that the patents must be treated as representatives of each other. Because the ALJ effectively terminated the '444 patent from the investigation after the *Markman* Order issued, Serendia and EndyMed did not have an opportunity to present arguments or evidence pertaining to the '444 patent during the evidentiary hearing. *See* Order 35 at 68; ID at xxi, n.3. Therefore, the record lacks findings related to the '444 patent. Thus, the Commission remands for the ALJ to consider issues pertaining to the '444 patent in the first instance.

V. REMEDY

Where a violation of section 337 has been found, the Commission must consider the issues of remedy, the public interest, and bonding. The Commission has “broad discretion in selecting the form, scope, and extent of the remedy.” *Philip Morris Products S.A. v. Int’l Trade Comm’n*, 63 F.4th 1328, 1339-1340 (Fed. Cir. 2023); *Viscofan, S.A. v. U.S. Int’l Trade Comm’n*, 787 F.2d 544, 548 (Fed. Cir. 1986).

A. Limited Exclusion Order

1. Legal Standard

Section 337(d)(1) provides that “[i]f the Commission determines, as a result of an investigation under this section, that there is a violation of this section, it shall direct that the

articles concerned, imported by any person violating the provision of this section, be excluded from entry into the United States, unless, after considering the [public interest], it finds that such articles should not be excluded from entry.” 19 U.S.C. § 1337(d)(1); *see also Spansion, Inc. v. Int’l Trade Comm’n*, 629 F.3d 1331, 1358 (Fed. Cir. 2010) (“[T]he Commission is required to issue an exclusion order upon the finding of a Section 337 violation absent a finding that the effects of one of the statutorily-enumerated public interest factors counsel otherwise.”).

2. The RD

As noted above, the ID included the ALJ’s recommended determination on remedy and bonding. ID/RD at 302-11. The ALJ recommended that, in the event the Commission finds a violation of section 337, an LEO should issue against EndyMed. *Id.* at 303-304. The ALJ further recommended that the LEO include the Commission’s standard certification provision. *Id.* at 304. The ALJ, however, recommended that the LEO not include an exception for importation of parts for service, repair, and replacement because the EndyMed respondents provided no evidence to support their request for a LEO with such an exemption and that a record should be developed regarding EndyMed’s proposal. *Id.* at 304.

3. Parties’ Submissions

Serendia and OUII agree with the ALJ’s recommendation. Serendia Sub. at 29-34; OUII Sub. at 24. EndyMed argues that any remedial orders should be expressly limited to EndyMed’s Intensif handpiece because that is the only device found to infringe. EndyMed Sub. at 16. According to EndyMed, the EndyMed Pro and Pure 2.0 consoles should not be subject to the remedial orders. *Id.* EndyMed also contends that remedial orders should include an exemption for service and repair of EndyMed consoles and handpieces already sold to U.S. customers, “in light of EndyMed’s contractual warranty obligations to all such customers.” *Id.* at 16-17, 19. EndyMed further seeks an exemption to continue importing and selling replacement tips for

Intensif handpieces. *Id.* at 17. According to EndyMed, such tailoring is warranted on account of the statutory public-interest factors. *Id.*

4. ***Commission Determination***

The Commission has determined to issue an LEO that includes the Commission's standard certification provision. EndyMed argues that any remedial orders should be expressly limited to EndyMed's Intensif handpiece because that is the only device found to infringe. EndyMed Sub. at 16. While Commission remedial orders are directed to only products that infringe the asserted claims, they are not limited to current model numbers or versions or to the specific products adjudicated in the investigation. *See, e.g., Certain Graphics Systems, Components Thereof, and Digital Televisions Containing The Same* (Reconsideration), Inv. No. 337-TA-1318, Comm'n Op. at 14-16 (May 22, 2024) (explaining the Commission's "well-established practice ... that the Commission does not limit remedial orders to cover only those specific products that were adjudicated to infringe in the underlying investigation" but instead the remedial orders extend to "***all products within the scope of the investigation*** that are covered by the patent claims as to which a violation has been found"); *Certain Fitness Devices, Streaming Components Thereof, and Systems Containing Same*, Inv. No. 337-TA-1265, Comm'n Op. at 74 (Mar. 23, 2023) (same). The Commission sees no reason to deviate from its standard practice.

Moreover, the adjudicated infringing products in this investigation include the combination of (1) the Pro or Pure 2.0 console; (2) the Intensif handpiece; and (3) consumable (*i.e.*, needle) tips. ID at 50-51 (accused and representative products), 96-97 (direct infringement), 98-101 (induced infringement) ("Respondents provide the Accused Products with handpieces, consumable tips, and user manuals, and encourage the assembly and use of the products in an infringing manner," and "supply the medical providers with the components of the

Accused Products and instruct them to assemble and use the Accused Products in an infringing manner.”). Thus, the exclusion order covers the combined products found to infringe. The ID also found that EndyMed, by supplying the Intensif handpiece, induces the infringement of the asserted claims when used together with either the EndyMed Pro or Pure 2.0 consoles. ID at 50-51 (accused and representative products), ID at 70-88, 173-184, 216-225 (direct infringement), 97-104, 185-188 (indirect infringement). Therefore, the order also covers the Intensif handpieces. While the ID found that the EndyMed Pro and EndyMed Pure 2.0 consoles can provide treatments using handpieces besides the Intensif, there is no finding of non-infringement with regard to the Pro or Pure 2.0 consoles.¹³ The Commission therefore finds no basis to allow EndyMed to exempt the Pro and Pure 2.0 consoles from the remedial orders. *See Certain Marine Sonar Imaging Devices, Including Downscan and Sidescan Devices, Products Containing the Same*, Inv. No. 337-TA-921, Comm’n Op. (Modification) at 2, 10 (Aug. 29, 2016) (carve-out provision of LEO exempted standalone components that the Commission specifically found did not infringe the subject claims). Ancillary proceedings at the Commission may be requested, as appropriate, to adjudicate EndyMed Pro and Pure 2.0 consoles that are to be used with handpieces other than the Intensif handpiece. *See* 19 C.F.R. §§ 210.76, 210.79.

The Commission notes that EndyMed proposes to exempt certain alleged redesigns or configurations as non-infringing. *See* EndyMed Sub. at 16, 26-27 (“The PRO and PURE 2.0 consoles should not be subject to remedial orders, particularly if their programming is adjusted...”). These alleged redesigns, which were not disclosed during the investigation and thus not considered by the ALJ or the Commission, cannot be exempted from the remedial orders

¹³ The record contains no evidence that the Intensif handpiece has any non-infringing uses. ID at 104.

because they have not been adjudicated. *See Certain Robotic Vacuum Cleaning Devices and Components Thereof Such as Spare Parts*, Inv. No. 337-TA-1057, Comm’n Op. at 56-58 (Feb. 1, 2019) (declining to exempt products from a remedial order that were not adjudicated); *Certain Road Construction Machines and Components Thereof*, Inv. No. 337-TA-1088, Comm’n Op. at 10 (Sept. 14, 2020) (“The Commission does not adjudicate hypothetical redesigned products but instead requires that any redesigns be ‘fixed in design, ... imported, and ... sufficiently disclosed by respondents during discovery.’”).¹⁴ Ancillary proceedings at the Commission may be requested, as appropriate, to address the scope of the remedial orders pertaining to redesigned products

B. Cease and Desist Order

1. Legal Standard

Section 337(f)(1) provides that in addition to, or in lieu of, the issuance of an exclusion order, the Commission may issue a cease and desist order (“CDO”) as a remedy for violation of section 337. *See* 19 U.S.C. § 1337(f)(1). CDOs are generally issued when, with respect to the imported infringing products, respondents maintain commercially significant inventories in the United States or have significant domestic operations that could undercut the remedy provided by an exclusion order. *See, e.g., Certain Tobacco Heating Articles and Components Thereof*, Inv. No. 337-TA-1199, Comm’n Op. at 49 (Sept. 29, 2021), *aff’d*, *Philip Morris Products S.A.*, 63 F.4th at 1332; *Certain Audio Players and Controllers, Components Thereof, and Products*

¹⁴ As to EndyMed’s arguments regarding an exemption for service and repair, while such exemptions may be considered as part of the Commission’s remedy determination, we address this issue in our consideration of the effect of remedy on U.S. consumers. *See, e.g., Certain Icemaking Machines and Components Thereof*, Inv. No. 337-TA-1369, Comm’n Op. at 6 (Feb. 27, 2025) (“Although warranty exemptions may be considered as part of the Commission’s remedy determination, we address this dispute as part of the Commission’s consideration of the effect the LEO will have on U.S. Consumers.”); *Wearable Electronic Devices*, Inv. No. 337-TA-1266, Comm’n Op. at 80-81; *Fitness Devices*, Inv. No. 337-TA-1265, Comm’n Op. at 89-92).

Containing Same, Inv. No. 337-TA-1191, Comm’n Op. at 26 (Jan. 6, 2022), *aff’d*, *Sonos, Inc. v. Int’l Trade Comm’n*, 2024 WL 1507605 (Fed. Cir. Apr. 8, 2024). Complainants bear the burden on this issue. “A complainant seeking a cease and desist order must demonstrate, based on the record, that this remedy is necessary to address the violation found in the investigation so as to not undercut the relief provided by the exclusion order.” *Tobacco Heating Articles*, Comm’n Op. at 49-50 (citations omitted); *Audio Players*, Comm’n Op. at 26-27 (citations omitted); *see also* H.R. REP. No. 100-40, at 160 (1987).

2. The RD

The ALJ recommended that the Commission issue CDOs against EndyMed. ID/RD at 311. EndyMed stipulated that it and Cynosure together and separately control a “commercially significant inventory of the Accused Products.” ID/RD at 309 (citing JX-0017C.0002, ¶ 6; JX-0020C.0002-0003, ¶ 6).

3. Parties’ Submissions

Serendia and OUII agree with the ALJ that CDOs are warranted in this investigation. Serendia Sub. at 35; OUII Sub. at 25-26. EndyMed does not argue against issuance of CDOs.

4. Commission Determination

In light of the undisputed evidence of significant domestic inventory, the Commission has determined to heed the ALJ’s advice and issue CDOs directed against each of the EndyMed respondents. *See* JX-0017C (Joint Stipulation Regarding Importation and Inventory).

C. The Public Interest

Section 337 requires the Commission, upon finding a violation of section 337, to issue an LEO “unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles

should not be excluded from entry.” 19 U.S.C. § 1337(d)(1). Similarly, the Commission must consider these public interest factors before issuing a CDO. 19 U.S.C. § 1337(f)(1).

The statute requires the Commission to consider and make findings on the public interest in every case in which a violation is found regardless of the quality or quantity of public interest information supplied by the parties. 19 U.S.C. §§ 1337(d)(1), (f)(1). Thus, the Commission publishes a notice inviting the parties as well as interested members of the public and interested government agencies to gather and present evidence on the public interest at multiple junctures in the proceeding. 19 U.S.C. §§ 1337(d)(1) & (f)(1).

Serendia and EndyMed submitted public interest comments.^{15, 16} Serendia states that the ID’s recommended remedies do not implicate any compelling public interest. Serendia Public Interest Statement at 1. Specifically, Serendia asserts that:

(1) the Accused Products are cosmetic or aesthetic devices that are not important to any public health, safety, or welfare issue; (2) third parties, including licensed former respondents, manufacture and sell products that directly compete with, and are substitutes for, the Accused Products in the United States; (3) third parties could fill any void in the market created by exclusion of the Accused Products within a commercially reasonable time and indeed are already available in the market; and (4) the requested remedies would not adversely impact U.S. consumers.

Id. at 2. According to Serendia, “[a]bsent these concerns, the public interest favors protecting Complainant’s intellectual property rights by excluding the Accused Products.” *Id.* EndyMed argues that “the scope of remedies proposed in the Recommended Determination (“RD”) is incommensurate with the findings of infringement” because “[i]t is undisputed that Serendia has

¹⁵ See Complainant’s Public Interest Statement (“Serendia Public Interest Statement”).

¹⁶ See EndyMed Respondents’ Statement on the Public Interest (“EndyMed Public Interest Statement”).

not accused EndyMed's PRO or PURE consoles of infringement, either on their own or even when used with handpieces other than the accused Intensif handpiece." EndyMed Public Interest Statement at 1. EndyMed contends that it should be able to continue importing and selling those unaccused consoles. *Id.* As noted above, EndyMed also argues that any remedial orders should include exemptions for service and repair for products under warranty and to continue selling replacement tips for the Intensif handpiece.

No public interest comments were received from the public pursuant to the Commission's solicitation of public interest comments. *See* 89 FR 106577-78 (Dec. 30, 2024).

1. Public Health and Welfare

Nothing in the record indicates or suggests that issuance of remedial orders in this investigation will harm the public health and welfare. EndyMed's main argument is that the Commission should tailor any remedial orders to only apply to the Intensif handpiece (discussed above) and to include a warranty service and repair exemption (discussed below). *See* EndyMed Sub. at 16-17. OUII states that it "is not aware of any information that would indicate that issuance of remedial orders would be contrary to the public health and welfare." OUII Sub. at 30. OUII explains that "the products at issue, RF microneedling dermatological treatment devices and components thereof, are devices used for aesthetic treatments" and "are not the types of articles that are likely to raise public health and welfare concerns." *Id.* at 30-31 (citing *Certain Coin-Operated Audio-Visual Games and Components Thereof*, Inv. No. 337-TA-87, Comm'n Op. at 30, USITC Pub. 1160 (June 1981) ("Because of the nature of the articles involved (audio-visual games), it is unlikely that [an exclusion order] would have a detrimental impact on the public health and welfare.")). Serendia contends that remedial orders would not implicate any particular public health, safety, or welfare concerns. Serendia Sub. at 36. Serendia notes that the accused products "are used for cosmetic treatments, e.g., to reduce facial wrinkles

to promote youthful-looking skin, which does not raise the type of health, safety, or welfare issues that the Commission has found may implicate the public interest.” *Id.* Serendia states that the Commission has previously determined there to be no public health, safety, or welfare concerns in excluding other cosmetic skin care products. *Id.* at 36-37 (citing *Certain Elec. Skin Care Devices, Brushes & Chargers Therefor & Kits Containing the Same*, Inv. No. 337-TA-959, Comm’n Op. at 35, 2017 WL 8683854, at *19 (Feb. 13, 2017) (exclusion of skin cleansing products relating to the treatment of acne, a non-life-threatening and largely cosmetic skin condition, did not raise any public interest concerns)).

The Commission agrees with Serendia and OUII that the record evidence contains no indication or suggestion that issuance of remedial orders in this investigation will harm the public health and welfare.

2. *Competitive Conditions in the United States Economy*

Serendia asserts that third parties including respondents terminated from the investigation, such as Sung Hwan E&B Co., LTD. d/b/a SHEnB Co. LTD; Aesthetics Biomedical, Inc.; Lutronic Corporation; Lutronic Aesthetics, Inc., also known as Lutronic, Inc.; Lutronic, LLC; Ilooda Co., Ltd.; Jeisys Medical Inc.; Rohrer Aesthetics, LLC; and Rohrer Aesthetics, Inc., are authorized to distribute their competing devices in the United States. Serendia Sub. at 37-38. Serendia adds that other third parties, including Candela, Goldskin, Sano-Laser, MicroDerma, Benev, Hironic, Lumenis, and more, make like and directly competitive articles that can replace the Accused Products if they are excluded from the United States. *Id.* at 37. OUII states that an exclusion order would have no significant impact on competitive conditions in the United States economy due to “the availability of licensed and other RF microneedling dermatological treatment devices (including those supplied by former respondents SHEnB, Lutronic, Ilooda, Jeisys, and Rohrer—all of which were terminated based

on license and settlement agreements).” OUII Sub. at 31 (citing Complainant’s Public Interest Statement at 3-4 (citing evidence)).

The Commission agrees with Serendia and OUII that the record evidence shows that an exclusion order will not harm competitive conditions in the United States as there are numerous third parties (licensed by Serendia and others) that supply the market with microneedling devices. As Serendia notes, “the Accused EndyMed Products accounted for [REDACTED] of sales of RF microneedling devices in the U.S.” Serendia Sub. at 37-38 (citing CDX-0045C.4 (*citing* CPX-0036C)) (emphasis omitted).

3. *Production of Like or Directly Competitive Articles in the United States*

OUII contends that remedial orders are unlikely to have significant adverse effect on the production of like or directly competitive articles in the United States because there is no evidence of domestic manufacturing by EndyMed. OUII Sub. at 31. The Commission agrees. The record evidence shows that remedial orders will have no impact on production of like or directly competitive articles in the United States. As noted above, the Commission finds that the evidence confirms there are numerous third parties that make like or directly competitive articles who can replace the accused EndyMed Products.

4. *United States Consumers*

EndyMed argues for an exemption for warranty service and repair to avoid adversely impacting U.S. consumers. EndyMed Sub. at 17-18. It states that the Commission has previously found that the public interest weighs in favor of exempting service, repair, and replacement parts from the scope of an LEO for devices sold before issuance of the LEO. *Id.* at 18 (citing ID at 302). EndyMed also argues for an exemption to continue importing and selling replacement tips for Intensif handpieces. *Id.* at 17. EndyMed notes Serendia’s argument that “it would not have opposed Respondents’ request for an exception for service, warranty, and repair

if Respondents had provided evidence that Respondents have existing warranty obligations and that the service, warranty, and repair exemption were limited to articles purchase[d] by U.S. consumers prior to issuance of remedial orders.” *Id.* (citing ID at 303). EndyMed argues that fact finding on public interest was not delegated to the ALJ in this investigation and so “there was no need or relevance for EndyMed to submit such evidence during the course of the case.” *Id.* EndyMed states that “[w]ith this brief, and as invited by the Commission’s Notice of February 28, EndyMed provides information pertinent to the remedy and public-interest analysis that is not currently in the record.” *Id.* (citing Notice at 5).

Serendia responds that EndyMed has “failed to provide any evidence to identify its ‘contractual warranty obligations’ at any point in this Investigation, including in its submission before the Commission” and that “this failure alone is dispositive.” Serendia R.Sub. at 20 (citing ID at 303-304) (emphasis omitted). Serendia states that “[t]o the extent that EndyMed submits, for the first time, actual evidence of existing warranty or repair obligations on reply, EndyMed will have wholly deprived Serendia or Staff from addressing that evidence by not presenting it in its March 14 initial submission.” *Id.* at 21.

OUII contends that “EndyMed failed to provide any factual support regarding its requested exemptions in its initial submission.” OUII Sub. at 23 (citing EndyMed Sub. at 17-19). As an example, OUII contends that “EndyMed did not provide any evidence of consumer expectations regarding service, repair, or replacement, including with respect to the replacement needle tips” and “did not even provide the warranty agreement that is allegedly provided with its products.” *Id.*

The ALJ recommended that remedial orders not include an exemption for importation of parts for service, repair, and replacement because EndyMed provided no evidence to support

their request for a LEO with such an exemption. ID/RD at 304. The Commission then asked the parties about a potential service and/or repair exemption including “to provide available factual evidence in support, including any not currently on the record.” 90 Fed. Reg. 11435 (Mar. 6, 2025). In response to the Commission’s inquiry, EndyMed provided no evidence to substantiate its request for an exemption related to service and repair of EndyMed consoles already sold to U.S. customers, despite arguing that remedial orders should include an exemption due to EndyMed’s alleged contractual warranty obligations to all such customers (EndyMed Sub. at 16-17). EndyMed waited until its final Reply submission to the Commission to present evidence of its contractual warranty obligation despite an explicit request from the Commission to present such evidence in its initial submission and despite the ALJ’s admonition that a record needs to be developed to support such an exemption. *See* ID/RD at 304. Moreover, EndyMed did not sufficiently provide answers to the questions explicitly asked by the Commission in the review notice.

Reply submissions are for responding to arguments made in initial submissions and not for introducing new evidence. EndyMed does not explain why it waited until the very last filing in this investigation to provide such evidence. The Commission agrees with OUII that “EndyMed’s attempt to provide evidentiary support in its reply brief to [the] Commission is untimely, prejudicial to OUII and Complainant (who would not have any opportunity to respond), and should be rejected.”¹⁷ OUII R.Sub. at 23 n.9; *Certain Magnetic Data Storage Tapes and Cartridges Containing the Same (II)*, Inv. No. 337-TA-1076, Comm’n Op. at 59-62

¹⁷ As explained in footnote 19 below, Chair Karpel would consider the evidence and grant exemptions for service, repair and replacement. While she agrees EndyMed’s submission of evidence is untimely and deprived Serendia of an opportunity to respond, she does not think that evidence addressing the remedy’s impact on the public interest can be ignored. She also notes that Serendia has indicated that it would not object to such exemptions if support was provided.

(June 20, 2019) (rejecting respondent's untimely submission of documents, including warranty agreements, and declining to include respondent's requested warranty provision in the remedial orders); *Certain Cloud-Connected Wood-Pellet Grills & Components Thereof*, Inv. No. 337-TA-1237, Comm'n Op. at 11-13 (May 24, 2022) (declining to include exemption for service and repair in remedial orders because respondent failed to provide record evidence necessary to justify the exemption); *Certain Light-Emitting Diode Prods., Fixtures, & Components Thereof*, Inv. No. 337-TA-1213, Comm'n Op. at 13 (Jan. 14, 2022) (declining to include a warranty exception to the remedial orders because of respondent's failure to show any record evidence of "previous warranty service imports or customer use of the warranty replacement provision" and failure to present public interest arguments or provide record evidence of harm to U.S. consumers).

The Commission takes seriously its statutory obligation to consider the public interest, which is why it provided several opportunities for parties and members of the public to provide information to assist the Commission in its analysis. Parties may and often do comment on public interest issues even at the institution stage. However, in this investigation, EndyMed waited until its reply submission on review to provide critical information regarding its requested exemption (and even this information did not fully answer the Commission's questions).¹⁸ The Commission also notes that it can consider such exemptions as part of its remedy analysis and not just as part of its public interest analysis. *See, e.g., Icemaking Machines*, Comm'n Op. at 6. Thus, EndyMed could and should have developed a record before the ALJ on this issue.

¹⁸ For example, EndyMed did not clearly indicate the extent to which servicing or repair requires imported parts, rather than parts that can be obtained domestically, and did not adequately address the Commission's question regarding whether an exemption should allow complete replacement of merchandise, nor its question regarding the appropriate temporal cutoff.

Moreover, the Commission has set forth the kind of information it has found useful in considering such an exemption in notices in other recent investigations, which should have informed EndyMed in developing a record on the issue. *See, e.g.*, 19 Fed. Reg. 32245 (May 19, 2023) (soliciting information on a service and repair exemption in *Certain Light-Based Physiological Measurement Devices and Components Thereof*, Inv. No. 337-TA-1276).

EndyMed's dilatory approach to the issue; the fact that no EndyMed product purchaser or patient filed comments in support of an exemption; and the type of device at issue here as discussed above in relation to public health and welfare, do not suggest there is a sufficient consumer interest in an exemption to overcome the need for fair, probative, and timely adjudication.

The Commission has therefore determined to reject the affidavit from Mr. Bill Scott, EndyMed's president, and exhibits as untimely as the record is bereft of any explanation as to why the documents could not have been submitted earlier. To do otherwise would reward EndyMed for its delay and could encourage parties in other investigations to behave similarly. Because the record is not sufficient to support EndyMed's request for exemptions for service and repair, nor to determine what the terms of such any such exemption should be, the Commission has determined not to include such exemptions.¹⁹

¹⁹ Chair Karpel would exempt from the remedial orders EndyMed's importation and use of Pure and Pro 2.0 consoles and Intensif handpieces, including any components, for service, repair and replacement of devices currently in the hands of U.S. consumers under the terms of existing warranties. She would also exempt EndyMed's importation and sale of replacement tips for the Intensif handpieces currently possessed by U.S. consumers.

She finds that these exemptions are supported by the record and are necessary to mitigate harm to U.S. consumers. *See Fitness Devices*, Inv. No. 337-TA-1265, Comm'n Op. at 89-92; *Certain Robotic Floor Cleaning Devices and Components Thereof*, Inv. No. 337-TA-1252, Comm'n Op. at 77-79 (April 13, 2023); *Certain Variable Speed Wind Turbine Generators and Components Thereof*, Inv. No. 337-TA-1218, Corrected Comm'n Op. at 23-25, 46-48 (April 8, 2022). Specifically, the evidence shows that EndyMed is contractually obligated to provide service, repair, and replacement support to its U.S. customers under warranty agreements that accompany

Accordingly, the Commission finds that the public interest factors do not compel declining to issue remedial orders in this investigation and do not compel including exemptions for service and repair.

D. Bond

If the Commission enters an exclusion order or a cease and desist order, a respondent may continue to import and sell its products during the 60-day period of Presidential review under a bond in an amount determined by the Commission to be “sufficient to protect the complainant from any injury.” 19 U.S.C. § 1337(j)(3); *see also*, 19 C.F.R. § 210.50(a)(3). When reliable price information is available in the record, the Commission has often set the bond in an amount that would eliminate the price differential between the domestic product and the

the sale or lease of its Pro and Pure consoles and Intensif handpieces. *See* Exhibit A (Declaration of Bill Scott) to EndyMed Reply Sub. at ¶ 11. This includes supplying replacement Intensif handpieces and consoles under warranty to U.S. customers if those devices fail during normal use. *Id.* Moreover, because the Intensif handpieces are expensive devices representing a substantial investment on the part of the customer (Exhibit A to EndyMed Reply Sub. at ¶ 2; Exhibit 2), and cannot be used without sterile disposable needle tips, which must be discarded after a single treatment session, customers have the expectation that they will be able access replacement tips for continued operation of the devices already in the field. Exhibit A to EndyMed Reply Sub. at ¶ 5.

While she does not condone EndyMed waiting until its reply remedy brief to supply evidence in support of its request for exemptions, and shares the majority’s concerns in this regard, Chair Karpel is of the view that the evidence should not be set aside due to EndyMed’s late raising of the evidence. The statute requires the Commission to consider and make findings on the impact of the remedial orders on the public interest factors in every case in which a violation is found. *See* 19 U.S.C. § 1337(d)(1), (f)(1); S. Rep. No. 93-1298, at 193 (1974) (“[T]he public interest must be paramount in the administration of this statute.”). While rejecting EndyMed’s requested exemption is an appropriate consequence to impose on EndyMed for its late submission of supporting evidence, U.S. consumers would bear the brunt of that consequence as they are left with expensive devices that are inoperable without sterile disposable needle tips or if they breakdown and need to be replaced or repaired. Because Chair Karpel finds that the evidence submitted shows that the remedial orders without the requested exemptions would adversely impact U.S. consumers, she would grant the exemptions in this case.

imported, infringing product. *See Streaming Players*, Comm’n Op. at 41-42 (citations omitted); *Tobacco Heating Articles*, Comm’n Op. at 77 (citations omitted). The Commission also has used a reasonable royalty rate to set the bond amount where a reasonable royalty rate could be ascertained from the evidence in the record. *See, e.g., id.* Where the record establishes that the calculation of a price differential is impractical or there is insufficient evidence in the record to determine a reasonable royalty, the Commission has imposed a one hundred percent (100%) bond. *See, e.g., id.*

The ALJ found that Serendia relied on price differential calculation from its expert, Mr. Vincent Thomas, between Serendia’s Sylfirm X DI Product and each of the EndyMed Pure and the EndyMed Pro products to support its bond request. ID/RD at 313. “Mr. Thomas testified that he calculated the product price differentials by comparing the average pricing of Serendia’s Sylfirm X DI Product to average pricing for the EndyMed Accused Products for the first two months of 2023.” *Id.* at 313-14 (citing Tr. (Thomas) at 722:1-723:5; CX-1023C (Mr. Thomas’s “Schedule 18 – Price Analysis” listing Sylfirm X price and Accused Products prices); CX-0608C (Sylfirm X order package with pricing information); CX-0062C (EndyMed’s interrogatory responses including its July 25, 2023 Second Supplemental Response to Interrogatory No. 4, which provides pricing information for EndyMed Pure and EndyMed Pro)). Based on that analysis, the ALJ recommended that the Commission enter a bond in the amount of eighty-five percent (85%) of the entered value of the EndyMed Pure, and seventy percent (70%) of the value of the EndyMed Pro product imported during the period of Presidential review. *Id.* at 314.

Serendia and OUII support the ID’s bond amount and contend that EndyMed’s “economic expert Dr. Vander Veen does not opine that a price differential is not practicable or appropriate, and does not perform his own price differential analysis for the EndyMed accused

devices.” Serendia Sub. at 39 (citing Vander Veen Tr. at 1420:21-1421:1, 1421:25-1422:3).

Serendia states that thus, “Mr. Thomas’ price differential analysis is unrebutted.” *Id.* (emphasis omitted).

EndyMed argues that any bond should be based on the value of the Intensif handpiece as that is the infringing device and that because the PRO and PURE 2.0 consoles do not infringe, “[i]t would make no sense to calculate a bond based on the value of products that, themselves, do not infringe and which should not be subject to exclusion.” EndyMed R.Sub. at 17-18.

The Commission has determined to set the 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 products imported during the period of Presidential review. EndyMed’s argument that the bond should be based only on the Intensif handpiece is unpersuasive. Direct infringement occurs when the Intensif handpiece is used in conjunction with the EndyMed Pure or EndyMed Pro products. Moreover, EndyMed induces infringement of the asserted claims by providing the whole system, including consoles and handpieces, to customers and instructs them to use them together in an infringing manner. ID at 96-101. EndyMed does not contest this finding and did not petition the Commission to review it. Thus, it is appropriate to base the bond amount on the infringing products which comprise the handpiece in conjunction with the EndyMed Pure or EndyMed Pro products. The Commission also found that EndyMed in supplying the Intensif handpiece induces the infringement of the asserted claims (ID at 100), so when imported separately, they are subject to the same bond rate as the EndyMed Pure or EndyMed Pro system for which they are being imported.

VI. CONCLUSION

The Commission has determined to affirm the ID’s finding of a violation of section 337. Regarding the issues under review, the Commission has determined to (1) provide the

modification above 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 with the additional discussion above, (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 with the additional discussion above, and (5) reverse and remand the ID's indefiniteness finding of the asserted claims of the '444 patent.

For remedy, the Commission has determined to: (1) issue a LEO prohibiting the unlicensed importation of dermatological treatment devices and components thereof that infringe one or more of 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 that are manufactured abroad by or on behalf of, or imported by or on behalf of, Respondents or any of their affiliated companies, parents, subsidiaries, or other related business entities, or their successors or assigns for the remaining terms of the patents, except under license of, or with the permission of, the patent owner or as provided by law; (2) issue CDOs directing that Respondents EndyMed Medical Ltd. of Caesarea, Israel; EndyMed Medical, Ltd. of New York, New York; and EndyMed Medical, Inc. of Freehold, New Jersey, cease and desist from conducting any of the following activities in the United States: importing, selling, offering for sale, marketing, advertising, distributing, transferring (except for exportation), soliciting United States agents or distributors, and aiding or abetting other entities in the importation, sale for importation, sale after importation, transfer (except for exportation), or distribution of dermatological treatment devices and components thereof that infringe one or more of 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; (3) find that the public interest factors do not preclude the issuance of the



proposed remedial orders; and (4) set a bond in the amount of 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.

By order of the Commission.

A handwritten signature in black ink, appearing to read 'L.R. Barton', enclosed within a thin black rectangular border.

Lisa R. Barton
Secretary to the Commission

Issued: June 3, 2025

CONFIDENTIAL CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **COMMISSION OPINION** has been served via EDIS upon the Commission Investigative Attorney, **Aaron D. Rauh**, and the following parties as indicated, on **June 3, 2025**.



Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112
Washington, DC 20436

On Behalf of Complainant Serendia, LLC:

Kevin C. Wheeler, Esq.
LATHAN & WATKINS LLP
555 11th Street, NW, Suite 1000
Washington, DC 20004-1304
Email: kevin.wheeler@lw.com

- ☐ Via Hand Delivery
- ☐ Via Express Delivery
- ☐ Via First Class Mail
- ☒ Other: Email Notification
of Availability for Download

**On Behalf of Respondents EndyMed Medical Ltd. and
EndyMed Medical Inc.:**

Guy Yonay, Esq.
PEARL COHEN ZEDEK LATZER BARATZ LLP
7 Times Square, 19th Fl.
New York, NY 10036
Email: GYonay@PearlCohen.com

- ☐ Via Hand Delivery
- ☐ Via Express Delivery
- ☐ Via First Class Mail
- ☒ Other: Email Notification
of Availability for Download