Public Version



UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of **CERTAIN DERMATOLOGICAL TREATMENT DEVICES AND COMPONENTS THEREOF**	**Inv. No. 337-TA-1356**

INITIAL DETERMINATION ON VIOLATION OF SECTION 337 AND RECOMMENDED DETERMINATION ON REMEDY AND BOND

Administrative Law Judge MaryJoan McNamara

(December 19, 2024)

Serendia, LLC
Exhibit 2158
EndyMed v. Serendia
IPR2024-00463

Ex. 2158-001

SELECTED SUMMARY FINDINGS

Pursuant to the Notice of Investigation, 88 Fed. Reg. 20551, dated April 6, 2023, this is the Initial Determination ("ID") of the Investigation in the Matter of Certain Dermatological Treatment Devices and Components Thereof, United States International Trade Commission Investigation No. 337-TA-1356. *See* 19 C.F.R. § 210.42(a).

It is a finding of the ID that Complainant Serendia, LLC ("Complainant" or "Serendia") has proven by a preponderance of evidence that Respondents Jeisys Medical Inc., Cynosure, LLC, EndyMed Medical, Ltd., and EndyMed Medical Inc. (collectively, "Respondents") have violated subsection (b) of Section 337 of the Tariff Act of 1930, in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain dermatological treatment devices and components thereof.[1]

[1] On December 9, 2024, Complainant Serendia, LLC ("Serendia"), and Respondents Jeisys Medical Inc. and Cynosure, LLC (collectively, "Respondents Jeisys and Cynosure," and with Serendia, the "Moving Parties"), filed a joint unopposed motion to suspend remaining Procedural Schedule deadlines in this Investigation ("Motion to Suspend") with respect to them, in view of the Moving Parties' pending motion to terminate Respondents Jeisys and Cynosure from this Investigation due to settlement. (Motion Docket No. 1356-043 (Dec. 9, 2024).). The Motion to Suspend was granted. (*See* Order No. 63 (Dec. 10, 2024).). The Moving Parties stated that they "anticipate filing a joint motion to terminate the Investigation pursuant to Commission Rule 210.21(b) no later than December 23, 2024, pursuant to the terms of the settlement agreement." (Mot. to Suspend at 1.). On December 13, 2024, the Moving Parties filed the motion to terminate Respondents Jeisys and Cynosure due to settlement ("Motion to Terminate"). (Motion Docket No. 1356-044 (Dec. 13, 2024).). The Motion to Terminate was granted. (*See* Order No. 64 (Dec. 18, 2024).). The Moving Parties have known since approximately September 9, 2024, and then were notified again last week, that the ID would be issued by December 20, 2024. The Moving Parties then filed their Motion to Terminate. Given the timing, the Motion to Terminate will not have been addressed by the Commission by the time the ID will be issued. As a result, the analyses and determinations contained in the ID with respect to Respondents Jeisys and Cynosure have not been deleted. Once their Motion to Terminate has been addressed by the Commission, and Respondents Jeisys and Cynosure are no longer parties in this Investigation, Respondents Jeisys and Cynosure's accused products will no longer be at issue in this Investigation and will not be subject to any determinations set forth in the ID, including recommendations on remedy and bond. Respondents EndyMed Medical, Ltd. and EndyMed Medical Inc. are not a party to the settlement agreement and remain as the only respondents in this Investigation. (Mot. to Suspend at 2; Mot. to Terminate at 4-5.). Other named respondents previously settled with Serendia, as noted in the Selected Procedural History of the ID, which will issue following the Notice of Issuance. (*See* Section II.A, *infra*.).

It is a finding of the ID that Respondents have infringed asserted claims 1, 9, and 22 of U.S. Patent No. 9,480,836 ("the '836 patent"). It is also a finding of the ID that the asserted claims of the '836 patent are valid.

It is a finding of the ID that Respondents have infringed asserted claims 11 and 16 of U.S. Patent No. 9,320,536 ("the '536 patent"). It is also a finding of the ID that the asserted claims of the '536 patent are valid.

It is a finding of the ID that Respondents have infringed asserted claim 14 of U.S. Patent No. 9,775,774 ("the '774 patent"). It is also a finding of the ID that the asserted claims of the '774 patent are valid.

It is a finding of the ID that Respondents have infringed asserted claims 5, 13, and 18 of U.S. Patent No. 10,869,812 ("the '812 patent"). It is also a finding of the ID that the asserted claims of the '812 patent are valid.

It is a finding of the ID that one or more of Serendia's domestic industry products have satisfied the technical industry prong of the domestic industry requirement for the '836, '536, '774, and '812 patents. It is also a finding of the ID that Serendia has satisfied the economic prong of the domestic industry requirement under Section 337(a)(3)(B).

Accordingly, the decision recommends: (1) a Limited Exclusion Order with a standard certification provision; (2) Cease and Desist Orders against Cynosure and EndyMed; and (3) that a bond be entered during the Presidential Review Period.

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ABBREVIATIONS

The following shorthand references to the parties, related U.S. agencies, and related proceedings are used in this Initial Determination:

Complainant or Serendia	Complainant Serendia, LLC
SHEnB	Respondent Sung Hwan E&B Co., LTD. d/b/a SHEnB Co. LTD.
ABM	Respondent Aesthetics Biomedical, Inc.
Cartessa	Respondent Cartessa Aesthetics, LLC
Lutronic	Respondents Lutronic Corporation; Lutronic Aesthetics, Inc., also known as Lutronic, Inc.; and Lutronic, LLC
Ilooda	Respondents Ilooda Co., Ltd.
Cutera	Respondent Cutera, Inc.
Jeisys	Respondent Jeisys Medical Inc.
Cynosure	Respondent Cynosure, LLC
Rohrer	Respondents Rohrer Aesthetics, LLC and Rohrer Aesthetics, Inc.
EndyMed	Respondents EndyMed Medical, Ltd. and EndyMed Medical, Inc.
Respondents	Jeisys, Cynosure, and EndyMed, collectively[2]
Staff	Commission Investigative Staff
CBP	U.S. Customs and Border Protection
PTO	U.S. Patent and Trademark Office

[2] Respondents SHEnB, ABM, Cartessa, Lutronic, Ilooda, Cutera, and Rohrer have been terminated from this Investigation. (*See* Section II, *infra*.). As noted in n.1, *supra*, Serendia and Respondents Jeisys and Cynosure filed a motion to terminate Respondents Jeisys and Cynosure due to settlement, which was granted.

The following abbreviations for pleadings, exhibits, briefs, transcripts, and Orders are used in this Initial Determination:

Compl.	Complaint
Jeisys Resp.	Response of Jeisys to the Notice of Investigation and Complaint Under Section 337 of the Tariff Act of 1930, as Amended
Cynosure Resp.	Response of Cynosure to the Notice of Investigation and Complaint Under Section 337 of the Tariff Act of 1930, as Amended
EndyMed Resp.	Response of EndyMed to the Notice of Investigation and Complaint Under Section 337 of the Tariff Act of 1930, as Amended
CX	Complainant's exhibit
CDX	Complainant's demonstrative exhibit
CPX	Complainant's physical exhibit
CPBr.	Complainant's Pre-Hearing Brief
CBr.	Complainant's Initial Post-Hearing Brief
CRBr.	Complainant's Post-Hearing Reply Brief
CPSt.	Complainant's Pre-Hearing Statement
JX	Joint exhibit
RX	Respondents' exhibit
RDX	Respondents' demonstrative exhibit
RPX	Respondents' physical exhibit
RPBr.	Respondents' Pre-Hearing Brief
RBr.	Respondents' Initial Post-Hearing Brief
RRBr.	Respondents' Post-Hearing Reply Brief
RPSt.	Respondents' Pre-Hearing Statement
SX	Staff's exhibit

SDX	Staff's demonstrative exhibit
SPX	Staff's physical exhibit
SPBr.	Staff's Pre-Hearing Brief
SBr.	Staff's Initial Post-Hearing Brief
SPBr.	Staff's Post-Hearing Reply Brief
SPSt.	Staff's Pre-Hearing Statement
Tr.	Evidentiary hearing transcript
Dep. Tr.	Deposition transcript
COMBr.	Complainant's Opening *Markman* Brief
ROMBr.	Respondent's Opening *Markman* Brief
SOMBr.	Staff's Opening *Markman* Brief
Joint CC Chart	Post-Hearing Joint Claim Construction Chart (Doc. ID No. 800737 (July 21, 2023))
***Markman* Order**	Order No. 35 (Oct. 25, 2023)

The following shorthand references to certain products and patents at issue are used in this Initial Determination:

'836 patent	U.S. Patent No. 9,480,836
'379 patent	U.S. Patent No. 10,058,379
'444 patent	U.S. Patent No. 11,406,444
'536 patent	U.S. Patent No. 9,320,536
'774 patent	U.S. Patent No. 9,775,774
'812 patent	U.S. Patent No. 10,869,812
Na Effect Patents or	'836, '379, and '444 patents

Family One Patents	
Needle Assembly Patents or Family Two Patents	’536, ’774, and ’812 patents
Asserted Patents	’836, ’536, ’774, and ’812 patents, collectively[3]
Accused Products	Potenza (Jeisys, Cynosure); and EndyMed Pro and Pure 2.0 with Intensif handpiece (“Intensif”) (EndyMed), collectively
DI Products	Sylfirm X RF microneedling device (“Sylfirm X”), including its handpieces and microneedle tip attachments
Licensed Products	Certain products sold by former Respondents SHEnB, Cartessa, and ABM (e.g., Virtue RF, Vybe RF, Vivace, Vivace Ultra); Ilooda and Cutera (e.g., Secret RF and Secret Pro); and Lutronic (e.g., Genius) that are subject to licenses to the Asserted Patents

[3] The ’379 patent has been terminated from this Investigation. (*See* Section II, *infra*.). During the *Markman* proceedings, the asserted claims of the ’444 patent were found to be indefinite. (*See Markman* Order at 62.). Thus, during the evidentiary hearing, Serendia and Respondents did not present arguments or evidence pertaining to the ’444 patent. (*See, e.g.*, Doc. ID No. 808905 at 1 n.2 (Suppl. Joint Outline of Issues) (Nov. 17, 2023).

I. INITIAL DETERMINATION ON VIOLATION OF SECTION 337, AND RECOMMENDED DETERMINATION ON REMEDY AND BOND

A. Technology Comment

Dr. Jongju Na is the named inventor of the Asserted Patents. By 2008, Dr. Na had invented an approach to treating dermatological tissue, i.e., skin, that involved extending small needles, known as microneedles, into skin, using radio frequency ("RF") signals. (*See, e.g.*, Compl. at ¶ 1.3.). By 2011, Dr. Na had invented an approach that would apply RF signals such that the energy was concentrated around each electrode of a needle that would be inserted into the skin, and that would also thereby cause coagulation around each electrode. (*See id.*). In 2015, Dr. Na published an article in Nature's *Scientific Reports*,[4] an open-access journal from the journal *Nature* that publishes peer-reviewed research. Dr. Na submitted his data that RF-induced coagulation occurred around each microneedle. (*See id.*).

The approach that Dr. Na developed is designed to improve the appearance of skin by activating collagen to smooth out fine lines and wrinkles while lessening the pain and potential scarring for a person who undergoes microneedling treatment. The microneedling technique is also promoted as causing less recovery time for a patient between treatments. (*See id.*). In the article, Dr. Na and the other co-authors proposed calling the new microneedling technique, and the new effect of stimulating collagen through coagulation around each microneedle electrode, a "Na effect," naming it after Dr. Na. (*See id.*). Persons skilled in the field now refer to this "Na effect" in scientific literature. (*See id.*).

[4] CX-0832 (Jongju Na et al., *Electromagnetic Initiation and Propagation of Bipolar Radiofrequency Tissue Reactions via Invasive Non-Insulated Microneedle Electrodes*, NATURE SCIENTIFIC REPORTS, Nov. 13, 2015 (published)).

B. Summary of Findings

A summary of this decision's finding is summarized below.

Table No. 1: Summary of Findings

Product	Patent	Claims	Determination
Accused Products[5]	'836 patent	1, 9, and 22	Violation
	'536 patent	11 and 16	
	'774 patent	14	
	'812 patent	5, 13, and 18	
DI Product[6]	'836 patent	1, 9, and 22	Satisfied
	'536 patent	11 and 16	
	'774 patent	14	
	'812 patent	5, 13, and 18	

II. BACKGROUND

A. Institution and Selected Procedural History

On March 1, 2023, Serendia, LLC ("Complainant" or "Serendia") filed a complaint ("Complaint") under Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, alleging 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 ("the '379 patent"); claims 1-10 of U.S. Patent No. 11,406,444 ("the '444 patent"); claims 1-2, 4-5, 8-9, 11-13, and 16-17 of U.S. Patent No. 9,320,536 ("the '536 patent"); claims 1 and 6-15 of U.S. Patent No.

[5] Potenza and Intensif, collectively.

[6] Sylfirm, including its handpieces and microneedle tip attachments.

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"). (Compl. at ¶ 1.1.).

The Commission instituted this Investigation pursuant to subsection (b) of Section 337 of the Tariff Act of 1930, as amended, on April 6, 2023. 88 Fed. Reg. 20551-53 (Apr. 6, 2023).

The Notice of Investigation ("NOI") names as complainant: Serendia, LLC of Lake Forest, CA ("Serendia" or "Complainant"). *Id*. at 20552. The NOI names as respondents: Sung Hwan E&B Co., LTD., d/b/a SHEnB Co. LTD. of Seoul, Korea ("SHEnB"); Aesthetics Biomedical, Inc. of Phoenix, AZ ("ABM"); Cartessa Aesthetics of Melville, NY ("Cartessa"); Lutronic Corporation of Gyeonggi-do, Korea, Lutronic Aesthetics, Inc. AKA Lutronic, Inc. of Billerica, MA, and Lutronic, LLC of Billerica, MA ("Lutronic"); Ilooda Co., Ltd. of Gyeonggi-do, Korea ("Ilooda"); Cutera, Inc. of Brisbane, CA ("Cutera"); Jeisys Medical Inc. of Seoul, Korea ("Jeisys"); Cynosure, LLC of Westford, MA ("Cynosure"); Rohrer Aesthetics, LLC of Homewood, AL and Rohrer Aesthetics, Inc. of Homewood, AL ("Rohrer"); and EndyMed Medical Ltd. of Caesarea, Israel, EndyMed Medical, Ltd. of New York, NY, and EndyMed Medical Inc. of Freehold, NJ ("EndyMed"). *Id*. Commission Investigative Staff ("Staff," and with Complainant and Respondents, the "Parties") is a party in this Investigation. *Id.*

On May 1, 2023, SHEnB, ABM, Cartessa, Lutronic, Ilooda, Cutera, Jeisys and Cynosure each filed a response to the Complaint and NOI. (Doc. ID Nos. 795225 (Lutronic Resp.), 795237 (ABM Resp.), 795239 (Cartessa Resp.), 795241 (SHEnB Resp.), 795244 (Rohrer Resp.), 795250 (Ilooda Resp.), 795259 (Jeisys and Cynosure Resp.) (May 1, 2023).).[7] On May 2, 2023,

[7] In their Response to the Complaint, Respondents Jeisys and Cynosure asserted a license defense against the Family Two Patents ("License Defense"). (Jeisys and Cynosure Resp. at ¶¶ 54-55 (Sixth Affirmative Defense).). Respondents Jeisys and Cynosure have since withdrawn the License Defense. (Doc. ID No.

EndyMed filed its response to the Complaint and NOI. (Doc. ID No. 795356 (EndyMed Resp.) (May 2, 2023).).

A *Markman* hearing was held on July 13, 2023. (*See* Order No. 17 (July 3, 2023); Doc. ID No. 805543 (Oct. 6, 2023).). On October 25, 2023, a *Markman* Order issued construing the claim terms in dispute.[8] (Order No. 35 ("*Markman* Order") (Oct. 25, 2023).).

Serendia filed two (2) motions *in limine* ("MILs"). (Motion Docket Nos. 1356-023 (Oct. 16, 2023), 1356-024 (Oct. 16, 2023).). Respondents SHEnB, ABM, Lutronic, Ilooda, Cutera, Jeisys, Cynosure, and EndyMed also filed two (2) MILs.[9] (Motion Docket Nos. 1356-025 (Oct. 16, 2023), 1356-026 (Oct. 16, 2023).). On October 31, 2023, Serendia filed a Notice of Withdrawal of MIL No. 2. (Doc. ID No. 807401 (Oct. 31, 2023).). The MILs, and the rulings on these motions, are summarized in Table No. 2 below.

Table No. 2: Private Parties' MILs

MIL No.	Issue	Ruling
Serendia's MIL No. 1 (Motion Docket No.	Motion seeking to exclude evidence and argument about alleged obviousness	Granted in-part and denied in-part. (*See* Order No. 41 (Oct. 31, 2023).). "It appears from Dr. Woloszko's expert

827352 (July 26, 2024).).

[8] The disputed claim term """. . . [causes/to cause] energy to be substantially applied to body segments around each electrode," recited in claim 1 of the '444 patent, was found to be indefinite. (*Markman* Order at 62-67.). On November 7, 2023, Serendia submitted an offer of proof with respect to the '444 patent ("Offer of Proof"). (Doc. ID No. 808008 (Nov. 7, 2023).). In its Offer of Proof, Serendia stated that it was "not moving for reconsideration of this decision" but asserted that "if claim 1 of the '444 Patent were not indefinite, Serendia would have been able to meet its burden of proof for the asserted claims of the '444 Patent (claims 4, 6, and 7), which depend from claim 1." (Offer of Proof at 1.). The filing of the Offer of Proof is accepted but denied on the merits for being contrary to the weight of the intrinsic evidence which supports the finding of indefiniteness with respect to this claim term. (*See Markman* Order at 62-67.). Respondents did not file a Response to Serendia's Offer of Proof.

[9] Respondents labeled the MILs as MIL Nos. 1 and 3. Respondents did not file an MIL No. 2. (*See* Order No. 39 at 2 n.2 (Oct. 31, 2023); Doc. ID No. 806790, Staff's Omnibus Resp. to MILs at 1 n.2 (Oct. 24, 2023).).

MIL No.	Issue	Ruling
1356-023)	for failure to address objective indicia and to articulate motivations to modify/combine	reports and deposition testimony that he did not offer opinions with respect to secondary considerations of non-obviousness. . . . Thus, Dr. Woloszko is precluded from offering testimony/opinions on that topic during the Hearing in accordance with Ground Rule 9.5.6. That part of Serendia's MIL No. 1 is *granted*." (*Id.* at 3 (citations omitted).). "Whether Dr. Woloszko should be precluded from offering an ultimate opinion on obviousness, again, he is limited by Ground Rule 9.5.6. to his opinions (or lack thereof) in his expert reports and deposition testimony. Thus, he is not wholly precluded from offering any such opinion of obviousness, but he is limited by the content of his previous testimony. That part of Serendia's MIL No. 1 is *denied without prejudice*." (*Id.* at 4.). "Based upon a review of Respondents' invalidity contentions (in addition to Dr. Woloszko's expert reports and deposition transcripts), it appears that Respondents presented substantive arguments with respect to secondary considerations of non-obviousness for the first time in this Investigation in their Pre-Hearing Brief at pages 28 and 104. . . . 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. . . . That part of Serendia's MIL No. 1 is *granted*." (*Id.* at 4-5 (citations omitted).). "With respect to Serendia's motion to preclude Dr. Woloszko from

MIL No.	Issue	Ruling
		'backfilling' opinions during the Hearing on the motivations to modify or combine certain prior art references that Respondents assert render obvious certain asserted claims, this aspect of Serendia's MIL No. 1 is *denied*. Based upon a review of Dr. Woloszko's report, it appears he offered opinions in his expert report (Doc. ID NO. 802324) with respect to motivations to modify or combine the prior art references for the claims identified in Serendia's MIL No. 1." (*Id.* at 5 (citation omitted).).
Respondents' MIL No. 1 (Motion Docket No. 1356-025)	Motion seeking to exclude Dr. Daniel W. van der Weide's heat mapping testing and opinions related thereto	Denied. (Order No. 39 (Oct. 31, 2023).).
Respondents' MIL No. 3 (Motion Docket No. 1356-026)	Motion seeking to preclude Serendia from introducing during the Hearing certain economic domestic industry evidence and expert opinions that were not disclosed during fact discovery	Denied. (Order No. 39 (Oct. 31, 2023).).

The evidentiary hearing ("Hearing") was held on November 1-2, 6-7, 2023 and December 11-12, 2023. (*See, e.g.*, Order Nos. 37 (Oct. 25, 2023), 48 (Nov. 29, 2023).).

Serendia filed two (2) post-hearing motions to strike. (Motion Docket Nos. 1356-034 (Nov. 9, 2023), 1356-038 (Dec. 14, 2023).). Respondents Jeisys and Cynosure also filed an unopposed post-hearing motion to strike. (Motion Docket No. 1356-037 (Dec. 14, 2023).). The motions to strike, and their rulings, are summarized in Table No. 3 below.

Table No. 3: Post-Hearing Motions to Strike

MIL No.	Issue	Ruling
Serendia's Motion to Strike (Motion Docket No. 1356-034)	Motion to strike portions of Dr. Woloszko's Hearing testimony and demonstratives with respect to enablement	Granted. (Order No. 46 (Nov. 16, 2023).). "Because Respondents failed to provide an enablement contention with respect to needle insulation for the '836 patent, let alone one 'set forth in detail' in their Pre-Hearing Brief, Dr. Woloszko's Hearing testimony at 913:10-25 and his demonstrative at RDX-0019C.0052-53 are stricken for violating Ground Rules 7.2 and 7.2.1." (*Id.* at 2-3.). "Dr. Woloszko's "new" enablement opinion regarding pulsed versus continuous wave AC RF signals at 915:10-25 and RDX-0019C.0054 are stricken for violating Ground Rules 7.2, 7.2.1, and 9.5.6." (*Id.* at 3.).
Serendia's Motion to Strike (Motion Docket No. 1356-038)	Motion to strike Dr. Bérubé's testimony about the "desired distance" limitation in the Family Two Patents	Serendia, Ilooda, Cutera, and Respondents stated in a joint notice that in view of a settlement agreement among Serendia, Ilooda and Cutera, this motion to strike, Motion Docket No. 1356-0038, is moot and therefore withdrawn. (Doc. ID No. 815977 at 2 (Mar. 12, 2024).).
Respondents Jeisys and Cynosure's Motion to Strike	Unopposed motion to strike certain portions of the evidentiary hearing testimony given by Mr. Peter Crosby[10]	Granted. (Order No. 52 (Dec. 20, 2023).). "[M]r. Crosby attempted, *inter alia*, to provide impermissible legal opinions with respect to certain language

[10] When he testified during the Hearing on November 6, 2023, Mr. Peter Crosby was the CEO and Managing Partner of Biomedical Business Resources LLC, Executive Chairman of ClinNEXUS Inc., Chairman of the Board of Directors of SimTutor, Inc., Member of the Board of Directors of Quench Medical, and Innovation Advisor of the University of California Irvine. (CPSt. at Ex. 1.). Serendia identified Mr. Crosby as an expert to testify about "the state of the art at issue, the skill level of one of ordinary skill in the art, disclosures in the asserted patents and patents or patent applications to which the

MIL No.	Issue	Ruling
		contained in the Korean Patent '581, the U.S. Patent '774 and the so-called 'Family Two' U.S. Patents. (Hr'g Tr. at 1530:2-16, and id. at 1530:25-1531:2.)." (*Id.* at 1.). "[M]r. Crosby's Hearing testimony at Hr'g Tr. at lines 1530:2-16 and 1530:25-1531:2 are stricken." (*Id.* at 1-2.).

As a result of several partial terminations in which certain asserted claims were withdrawn, the following asserted claims remain at issue in this Investigation: (i) claims 1, 9, and 22 of the '836 patent; (ii) claims 11 and 16 of the '536 patent; (iii) claim 14 of the '774 patent; and (iv) claims 5, 13, and 18 of the '812 patent. (*See* Motion Docket Nos. 1356-009 (June 22, 2023), 1356-018 (Sept. 202, 2023), 1356-030 (Nov. 1, 2023); Order No. 16 (June 29, 2023), *unreviewed*, Comm'n Notice, Doc. ID No. 800617 (July 20, 2023); Order No. 27 (Sept. 25, 2023), *unreviewed*, Comm'n Notice, Doc. ID No. 805993 (Oct. 16, 2023); Order No. 43 (Nov. 8, 2023), *unreviewed*, Corrected Comm'n Notice, Doc. ID No. 810217 (Dec. 12, 2023).).

Prior to the Hearing, Respondents Rohrer, ABM, SHEnB, Cartessa, Ilooda, and Cutera were terminated from this Investigation. (*See* Order No. 38 (Rohrer) (Oct. 27, 2023); Order No. 45 (AMB) (Nov. 15, 2023), *unreviewed*, Comm'n Notice, Doc. ID No. 810428 (Dec. 15, 2023); Order No. 47 (SHEnB and Cartessa) (Nov. 20, 2023), *unreviewed*, Comm'n Notice, Doc. ID No. 810429 (Dec. 15, 2023); Order No. 53 (Ilooda and Cutera) (Apr. 11, 2024), *unreviewed*,

asserted patents claim priority, issues relating to claim construction, infringement, validity (including secondary considerations), enforceability of the asserted patents, and the technical prong of domestic industry." (CPSt. at 4.). Mr. Crosby was qualified as an expert without objection to testify about assistance for delivery of electromagnetic radiation energy and RF in medical devices. (Tr. (Crosby) at 570:16-571:2.).

Comm'n Notice, Doc. ID No. 820969 (May 8, 2024).).

On November 2, 2023, the second day of the Hearing, counsel for Serendia informed the Court that it had reached a settlement with Lutronic and would not be presenting any Lutronic evidence. (Tr. at 241:8-25; *see also id.* at 242:24-244:11 (granting Serendia and Lutronic's unopposed oral motion to stay the Procedural Schedule with respect to Lutronic for 45 days); Order No. 51 (Dec. 13, 2023), *unreviewed*, Comm'n Notice, Doc. ID No. 811809 (Jan. 10, 2024).). Thus, the remaining Respondents are Jeisys, Cynosure, and EndyMed (collectively, "Respondents," and with Serendia, the "Private Parties").[11]

On December 26, 2023, Serendia, Respondents, and Staff each filed an Initial Post-Hearing Brief.[12] (Doc. ID No. 810994 (CBr.) (Dec. 26, 2023); Doc. ID No. 810999 (RBr.) (Dec. 26, 2023); Doc. ID No. 810990 (SBr.) (Dec. 26, 2023).). On January 5, 2024, Serendia and Respondents each filed a Reply Post-Hearing Brief. (Doc. ID No. 811579 (CRBr.) (Jan. 5, 2024); Doc. ID No. 811563 (RRBr.) (Jan. 5, 2024).). Staff also filed a Reply Post-Hearing Brief on January 12, 2024. (Doc. ID No. 811809 (SRBr.) (Jan. 12, 2024).).

On August 6, 2024, approximately one (1) month before the due date of this ID (Order No. 55), the U.S. District Court for the District of Columbia issued a Memorandum Opinion and

[11] As discussed in n.1, *supra*, on December 9, 2024, less than two (2) weeks before the due date of the ID, Serendia, Respondent Jeisys, and Respondent Cynosure filed a joint unopposed motion to suspend remaining Procedural Schedule deadlines in this Investigation with respect to them, in view of a pending motion to terminate Respondents Jeisys and Cynosure from this Investigation due to settlement, which was granted. (Motion Docket No. 1356-043 (Dec. 9, 2024); Order No. 63 (Dec. 10, 2024).). The motion to terminate, filed on December 13, 2024, was also granted. (Motion Docket No. 1356-44 (Dec. 13, 2024); Order No. 64 (Dec. 18, 2024).). Because the Commission has not yet addressed Order No. 64, Respondents Jeisys and Cynosure are still parties to this Investigation. (*See* n.1, *supra*.).

[12] On December 18, 2023, Staff submitted a Post-Hearing Notice informing of a change in its pre-hearing position on one sub-issue concerning infringement of the '836 patent. (Doc. ID No. 810525 (Dec. 18, 2023).).

Order ("District Court Opinion and Order"), which granted Respondents' motion to certify to the Commission a request to obtain judicial enforcement of the subpoena *duces tecum* and *ad testificandum* ("Subpoena") issued to non-party Merle W. Richman, III, Esq. ("Motion for Judicial Enforcement"). (*See* Doc. ID No. 828744 at Ex. A (Aug. 6, 2024); Motion Docket No. 1356-006 (May 30, 2023).).[13] The District Court Opinion and Order made several findings and ordered that Mr. Richman make himself available for a deposition. After deposing Mr. Richman on August 25, 2024,[14] Respondents filed a status report with respect to the discovery Mr. Richman had provided that included their concerns about Mr. Richman's responses to certain questions and refusal to provide certain documents, some of which was based upon claimed privilege. ("Status Report"). (Doc. ID No. 830519 (Aug. 26, 2024).). In the Status Report, Respondents reported that, *inter alia*, "Mr. Richman repeatedly refused to respond to questions that bear directly on his conduct during prosecution of the Asserted Patents in this Investigation." (Status Rpt. at 1.). Respondents also indicated that they would be filing a motion "seek[ing] relief and further proceedings in view of the discovery provided by Mr. Richman and, unfortunately, the substantial amount of discovery he refused to provide." (*Id.* at 2.).

On September 3, 2024, Respondents filed a motion to compel additional documentary and testimonial evidence from Mr. Richman ("Motion to Compel") and a memorandum in support of the Motion to Compel ("Memorandum"). (Motion Docket No. 1356-041 (Sept. 3, 2024).). Respondents also requested that the evidentiary hearing record be reopened, and that

[13] The Motion for Judicial Enforcement, Motion Docket No. 1356-006, filed on May 30, 2023, is the re-filed motion of Motion Docket No. 1356-005, filed on May 22, 2023.

[14] On August 15, 2024,4 Respondents moved for leave to reopen discovery for the limited purpose of receiving discovery from, and taking the deposition of, Mr. Richman ("Motion to Reopen Discovery"), which was granted. (Motion Docket No. 1356-040 (Aug. 16, 2024); Order No. 56 (Aug. 20, 2024).).

new Hearing time be committed so that Mr. Richman could testify in person as a witness in an extension of Hearing that was presumed closed. (Mot. to Compel at 1.). On September 6, 2024, one business day before the due date of the ID, Serendia filed an opposition ("Opposition") to Respondents' Motion to Compel, while Mr. Richman also filed a response ("Response"), in which he also opposed Respondents' Motion to Compel. (Doc. ID No. 831677 (Opp'n) (Sept. 6, 2024); Doc. ID No. 831624 (Resp.) (Sept. 6, 2024).).

To assess properly Respondents' Motion to Compel, Serendia's and Mr. Richman's oppositions to the Motion to Compel, and to evaluate Respondents' request to reopen the Hearing and the time that might entail, the Target Date of this Investigation was extended. (*See* Corrected Order No. 57 (Sept. 10, 2024), *unreviewed*, Comm'n Notice, Doc. ID No. 834105 (Oct. 4, 2024).). Subsequently, each of the Private Parties was ordered, *inter alia,* to: (i) identify certain documents that were/were not produced by Mr. Richman during/for his August 25, 2024 deposition; (ii) responses thereto; and (iii) with respect to Serendia, provide a privilege log, as well as submit any documents Mr. Richman did not produce for *in camera* inspection. (*See* Order No. 58 (Sept. 11, 2024).).

In accordance with Order No. 58, the Parties provided the requested information and responses. Mr. Richman submitted a privilege log and more than [redacted] that were listed in the privilege log. After thoroughly reviewing the filings, as well as inspecting *in camera* the documents identified in the privilege log, Respondents' Motion to Compel was denied. (*See* Order No. 60 (Nov. 12, 2024).).

B. The Parties

1. Complainant Serendia, LLC

Serendia, LLC is a California LLC with a principal place of business at 23792 Rockfield

Blvd., Lake Forest, CA 92630. (Compl. at ¶ 2.1.). According to Serendia, its "primary business is developing and distributing dermatological medical technologies." (*Id.*).

2. Respondents

a) Respondent Jeisys Medical Inc.

Jeisys is a corporation organized and existing under the laws of South Korea. (Jeisys and Cynosure Resp. at ¶ 3.15.). It maintains its headquarters at Daeryung Techno Town 8th, Gasang-dong, Room 307, 96 Gamasan-ro, Geumcheon-gu, Seoul 08501, Republic of Korea. (*Id.*). Jeisys "designs, develops, and manufactures healthcare equipment, including RF microneedling dermatological treatment devices such as the accused Potenza products." (*Id.* at ¶ 3.17.).

b) Respondent Cynosure, LLC

Cynosure is a limited liability company organized and existing under the laws of the state of Delaware. (Jeisys and Cynosure Resp. at ¶ 3.16.). It maintains s its headquarters at 5 Carlisle Rd., Westford, MA 01886. (*Id.*). Cynosure "imports into the United States and subsequently sells the accused Potenza products, and . . . sells other medical aesthetic devices in the United States." (*Id.* at ¶ 3.18.).

c) Respondents EndyMed Medical Ltd. (Israel), EndyMed Medical, Ltd. (New York), EndyMed Medical Inc.

EndyMed Medical Ltd. is an Israeli corporation. (EndyMed Resp. at ¶ 3.21.). EndyMed Medical, Inc. is a Delaware corporation and is headquartered at 4400 Route 9 South, Suite #1000, Freehold, NJ 07728. (*Id.*). "EndyMed Medical Ltd., itself and through its subsidiaries and related entities, designs, develops, manufactures, sells for importation, imports into the United States, and/or sells after importation into the United States health care equipment, including RF microneedling dermatological treatment devices and components thereof." (*Id.* at ¶ 3.22.). "[T]his is the primary nature of EndyMed Medical Ltd.'s business." (*Id.*).

III. JURISDICTION, IMPORTATION, AND STANDING

A. Jurisdiction and Importation

Serendia filed a complaint alleging a violation Section 337 because of the unauthorized importation into the United States, sale for importation into the United States, and/or sale within the United States after importation of certain dermatological treatment devices and components thereof. (*See* Compl. at ¶ 1.1.). Respondents have appeared and participated in this Investigation. Additionally, Respondents did not contest that the Commission has personal jurisdiction. (RPBr. at 2; RRBr. at 2.). Accordingly, the Commission has personal jurisdiction over Respondents. *See, e.g.*, *Certain Microfluidic Devices* ("*Microfluidic Devices*"), Inv. No. 337-TA-1068, Initial Determination, 2018 WL 5279172, at *16 (Sept. 20, 2018); *Certain Windshield Wiper Devices and Components Thereof* ("*Wiper Devices*"), Inv. No. 337-TA-881, Initial Determination at 5 (May 8, 2014) (unreviewed in relevant-part) (Doc. ID No. 534255).

Respondents also did not contest that the Commission has *in rem* jurisdiction and that the importation requirement is satisfied. (*See* RPBr. at 5; RRBr. at 2.). The Private Parties entered stipulations with respect to the importation of Accused Products wherein each Respondent stipulated that they have imported to the United States, sold for importation into the United States, and/or sold within the United States after importation at least one Accused Product. (*See* JX-0018C (Serendia, Ilooda and Cutera's Joint Stipulation regarding Importation and Inventory); JX-0020C (Serendia, Jeisys, and Cynosure's Joint Stipulation regarding Importation and Inventory); JX-0017C (Serendia and EndyMed's Joint Stipulation Regarding Importation and Inventory).). Evidentiary support is provided in, and attached to, each stipulation (e.g., representative CBP entry documentation and related materials, business records reflecting sales for importation). Accordingly, the Commission has *in rem* jurisdiction over the Accused

Products and the importation requirement is satisfied. *See, e.g.*, *Wiper Devices*, Inv. No. 337-TA-881, Initial Determination at 5 (*in rem* jurisdiction exists when importation requirement is satisfied).

B. Serendia Has Standing in the Commission

1. Legal Standard

Standing to initiate a Section 337 investigation requires that at least one complainant be the owner or exclusive licensee of the intellectual property, or here an asserted patent. 19 C.F.R. § 210.12(a)(7). If a complainant is not the original owner of a patent, the complainant must establish that it has all substantial rights in the patent. *Lone Star Silicon Innovation LLC v. Nanya Tech Corp*., 925 F.3d 1225, 1229 (Fed. Cir. 2019). Whether the provisions of an agreement that confers patent rights transfers all 'substantial rights is a legal question under the law of the U.S. Court of Appeals for the Federal Circuit. *Immunex Corp. v. Sandoz, Inc*., 964 F.3d 1049, 1060 (Fed. Cir. 2020). As the Complainant, Serendia has the burden to prove it has standing. *Certain Communications or Computing Devices*, Inv. No. 337-TA-925, Order No. 34, 2015 WL 41224302 at *2 (May 21, 2015). Serendia has so proven it has standing. Undisputed, certified assignment documents that reflect Serendia's ownership in the Asserted Patents were filed with the Complaint. (*See* CX-0766 ('836 patent), CX-0767 ('379 patent), CX-0768 ('444 patent), CX- 0769 ('536 patent), CX-0770 ('774 patent), and CX-0771 ('812 patent).). Those documents also prove that Serendia has "substantial rights" in the Asserted Patents contrary to Respondents' arguments. *Speedplay, Inc. v. Bebop, Inc.*, 211 F.3d 1245, 1250 (Fed. Cir. 2000). (*See* RPBr. at 3-4; *see also accord* SPBr. at 1, 12-14; SBr. at 1, 12-14.l *see also* Respondents' Motion to Terminate for Lack of Standing and Complainant's Opposition to Termination

Motion.).[15] The certified patent assignments also demonstrate, as Serendia outlines, the chain of

[15] Respondents filed Respondents' Motion to Terminate ("Motion to Terminate") Investigation Pursuant to Commission Rule 210.21(a)(1) for Lack of Standing Because Serendia, LLC Lacks All Substantial Rights in the Asserted Patents, an Adverse Inference Pursuant to Commission Rule 210.33, or, in the Alternative, to Amend the Procedural Schedule and Permit Additional Fact Discovery regarding Standing and Domestic Industry, Motion Docket No. 1356-017 (Sept. 15, 2023). Respondents contended that Serendia is only the "nominal" Complainant. Respondents claimed that Serendia concealed SynKloud Technology, LLC's ("SynKloud") role, and that they did not become aware of SynKloud's role as a patent monetization entity that [redacted] until after the close of fact discovery. (Motion to Terminate at 1.). Based upon their assertions that Serendia did not disclose information to them about SynKloud and [redacted], Respondents asked that: (1) the Investigation be terminated because [redacted] and has substantial rights in the Asserted Patents and the litigation and its outcome (*id.* at 2); and (2) Serendia be sanctioned for violating discovery rules by "actively concealing" [redacted] (*id.* at 25) through an adverse inference that SynKloud has substantial rights in the Asserted Patents (*id*. at 2); and alternatively, (3) that the Procedural Schedule and Target Date be changed to allow Respondents additional time for discovery (*id*.). Specifically, Respondents allege that in addition to concealing SynKloud's role, Serendia failed to answer discovery questions, failed to produce documents such as the Rescission Agreement, and provided incomplete or inaccurate deposition testimony, such as Dr. Na's, in which Dr. Na claimed he did not know [redacted]. (*Id.* at 6.). Respondents submitted some 20 exhibits to support their Motion to Terminate.

On September 27, 2023, Serendia responded by filing Complainant's Opposition to Respondents' Motion to Terminate the Investigation under Commission Rule 210.21(a)(1) for Lack of Standing, an Adverse Inference Pursuant to Commission Rule 210.33, or, in the Alternative, to Amend the Procedural Schedule and Permit Additional Fact Discovery regarding Standing and Domestic Industry ("Opposition to Motion to Terminate"). (Doc. ID No. 804953 (Sept. 27, 2023).). In its Opposition to Motion to Terminate, Serendia addressed and refuted each of Respondents claims about discovery abuse by detailing answers to interrogatories and discovery documents it produced that provide information about SynKloud. (Opp'n to Motion to Terminate at 10 (interrogatory responses); *id.* at 7, 10-11 (documents).). Serendia also noted that Respondents asked every deposition witness from Serendia, ViOL Company, Ltd. ("ViOL"), and Benev about SynKloud. Serendia provided detailed pin cites where that testimony can be found. (*Id.* at 9.). In addition, Serendia noted that Respondents' claims that Serendia withheld information about SynKloud is also false because certain of the Respondents knew the various entities and their involvements with Serendia since 2017 because of several Federal court litigations in which certain of the Respondents were involved. (*Id.* at 13-14.). Additionally, SynKloud was removed as a party from certain Federal litigation [redacted]. (*Id*. at 14.). Based upon the evidence Serendia produced in some 23 exhibits and a timeline, Serendia contended that it did not commit discovery abuse, and Respondents are not entitled to the relief they seek. (*Id.*). Serendia's Timeline is particularly helpful in describing the various agreements at issue. (Appx. A, Opp'n to Motion to Terminate.).

The Parties were given time to argue standing on December 12, 2023, after the formal Hearing testimony had concluded. (Standing Tr. at 1601-1637.).

During oral argument on December 12, 2023, Respondents reasserted their request to take additional

discovery as they had requested in their Motion to Terminate. (*Id.* at 1616:12-14.). Respondents' request was aimed at taking discovery . (CX-3032C . As noted above, Respondents argued that the vested standing in SynKloud, who, Respondents argued, should have been a party to this Investigation. (RPBr. at 3-4; RBr. at 4-6.). In part, Respondents argued that because (RX-0132C, (CX-3031C, is "illusory, and should not be considered[.]" (*See* RPBr. at 3; *see al*so RBr. at 4-5.). Respondents also suggested that raised unanswered questions about SynKloud's relevance to this Investigation that could only be answered by additional discovery. (Standing Tr. at 1605:16-1607:3.).

This decision formally denies Respondents' Motion to Terminate and the relief Respondents requested. It addresses specifically the procedural and substantive reasons why Respondents' request for additional discovery time after the discovery deadline was not granted. First, from a timeline that Serendia submitted and argued, Respondents were aware of SynKloud's existence since before this Investigation was initiated. (*See* Opp'n to Motion to Terminate at 2-6.). Serendia provided a timeline and listed all dates and proceedings dating back to 2020, and all of documents that Serendia provided to Respondents before this Investigation was initiated, and then during discovery, by which Respondents were made aware of various agreements that Serendia had with ViOL, Benev, and SynKloud. All documents reflect dates they became effective or were rescinded. (*Id*.). One of the proceedings that Serendia describes was a parallel Federal District Court litigation from which SynKloud was dropped as a party without opposition. The Private Parties were the same as in this Investigation. (Standing Tr. at 1610: 19-25; Exs. H-6 to Opp'n Motion to Terminate.). Or to state in another way, Respondents knew about SynKloud's existence since at least 2020, and willingly excused that entity from a Federal litigation.

Additionally, in this Investigation, Respondents did not request or serve a deposition subpoena to obtain additional information from SynKloud. (*See* Standing Tr. at 1618:10-14.). Second, Respondents did not request or serve a trial subpoena to obtain SynKloud's testimony for the Hearing in this Investigation. Third, when Dr. Na testified during the Hearing, Respondents did not ask him about the SynKloud relationship with Dr. Na or Benev. (*Id.* at 1618:14-18.). Respondents did not ask Benev's corporate representative (or any other witness, including Dr. Na) during the Hearing about Benev's relationship with SynKloud. (*Id.* at 1618:10-18.).

In sum, Respondents had several opportunities during the normal course of the Investigation to obtain additional information about the Serendia/Benev/ViOL/SynKloud relationship. Respondents chose not to avail themselves of the various opportunities they had either during discovery or during the Hearing, and for at least three (3) years before. Additionally, and perhaps finally, Serendia's counsel represented that Serendia produced the , and (*Id.* at 1617:8-10.). Perhaps most significantly Serendia's counsel "confirmed that Serendia searched for Documents between SynKloud and Dr. Na, Serendia, ViOL, and Benev related to this investigation, related to (*Id.* at 1617:12-16.). Serendia noted and argued, with Staff, *see infra*, that were not relevant to Serendia's domestic industry. (*Id.* at 1616:17-22; *see also* SPBr. at 30-31; SBr. at 13-14.). In other words, Respondents had the opportunity to access all necessary information about SynKloud through discovery in this Investigation and in

title in the Asserted Patents as follows: CX-0766 (assignment of '836 Patent from Dr. Na to ViOL and then to Serendia); CX-0769 (assignment of '536 Patent from Dr. Na to ViOL and then to Serendia); CX-0770 (assignment of application for '774 Patent from Dr. Na to ViOL and then to Serendia); CX-0771 (confirmatory assignment of '812 Patent from Dr. Na to Serendia). (CBr. at 8.). Serendia also noted that the referenced assignments "create[] a presumption of validity as to the assignment and places the burden to rebut such a showing on one challenging the assignment." (*Id*. (citing *SiRF Tech., Inc. v. Int'l Trade Comm'n*, 601 F.3d 1319, 1328 (Fed. Cir. 2010) (affirming that "the Commission's determination that appellants have not sustained their burden is supported by substantial evidence")).). In this instance, Respondents have not rebutted the presumption successfully.

2. The Weight of the Evidence Supports a Finding that Serendia Has Standing Without Including SynKloud as a Party

Since the outset of this Investigation, Respondents have contended that Serendia lacked standing to bring this Investigation. According to Respondents, standing can only be satisfied by the participation of another entity, SynKloud Technologies, LLC ("SynKloud"). (*See* RPBr. at 3.).

Additionally, in support of the standing finding and conclusion, evidence reflects that Benev Co. Inc. ("Benev"): (i) has been impliedly licensed to the Asserted Patents through its exclusive distribution of the Sylfirm X beginning in 2021, pursuant to the terms of the Sole Distribution Agreement dated September 3, 2020 (CX-0763C); and (ii) has been [redacted] (CX-0765C [redacted] *see*

previous litigations. The weight of the evidence does not support Respondents' arguments. Respondents' arguments that Serendia lacks standing have no merit.

also CBr. at 137-138; *accord* SRBr. at 23).[16] Respondents have argued that the Benev License cannot be legitimate because by virtue of the [redacted], Serendia and SynKloud would have been restored to their pre-contract status. (*See* RBr. at 4-5.). The only legal authority that Respondents have cited is a 1996 Fifth Circuit decision that interprets Texas law. (*Id.* at 4.). Staff also has noted that the [redacted] either expressly or impliedly. The [redacted]. (SBr. at 13-14; SRBr. at 23-24.).

Staff and Serendia disagreed with Respondents' interpretations of the various agreements at issue and their arguments, as does this decision.

Nonetheless, Respondents have argued (while Serendia has mostly disputed) that Serendia transferred "all substantial rights" in the Asserted Patents to SynKloud, a patent monetization entity, through [redacted]. (*See* RRBr. at 2-3; RBr. at 4; CX-3028C.). That is an argument to which Serendia agreed. Serendia acknowledged that "SynKloud had 'the exclusive right to license and/or sublicense' the Asserted Patents" [redacted]. (*See* CPBr. at 7-8; Opp'n to Motion to Terminate.). However, on that date, it is apparent from the language of the [redacted], supported by Dr. Na's unrebutted testimony, that any rights SynKloud had in the Asserted Patents

[16] It should be noted that Respondents Jeisys Medical Inc.'s and Cynosure, LLC's Withdrawal of License Defense, Doc. ID No. 827352 (July 26, 2024) ("License Defense Withdrawal") does not pertain to the licenses mentioned in this Section on standing. The License Defense Withdrawal notes that a Korean Court has interpreted a 2012 agreement between the Jeisys Respondents and Dr. Na as not giving the Jeisys Respondents a license to the Family Two Patents. (*See* License Defense Withdrawal at 1.).

themselves were , before this Investigation was filed. (*See* CX-3031C at 1; Tr. (Na) at 90:15- 91:9; Opp'n to Motion to Terminate at 1-3; *see also, e.g.*, Standing Tr. at 1610:12-22.).

Respondents' additional arguments, and the supporting (or negating) documents and arguments that refute their arguments, are explained below.[17] Moreover, well before this Investigation, Respondents were aware that SynKloud had been removed from various Federal court litigations because it lacked standing. (Opp'n to Motion to Terminate at 13; *see also* n.15, *supra*.).

First, as noted above, according to Respondents, SynKloud is the proper party in interest. That SynKloud is a proper party in interest is refuted directly by the (CX-3031C; RX-2576C) [18]

[17] The various agreements that are mentioned in this Section and in other sections of this ID, and that were considered/reviewed, are as follows: (1) (CX-2862C.0001); (2) (CX-0763C) ; (3) (CX-0762C) (certified assignments filed in this Investigation); (4) CX-3028C) (CX-0765C.0001, 0003-4) ; and (6) (CX-3031C). The documents are described in detail in Respondents' Motion to Terminate at 3-8. This decision does not agree with Respondents' interpretations, as explained in this Section.

[18] Respondents noted in their Pre-Hearing Brief that the was produced after the close of fact discovery, yet they relied upon it and made several arguments substantively why it should not be considered. (RPBr. at 3.). Respondents did not move for the exclusion either at the pre-hearing stage or in their Post-Hearing Brief. Therefore, they have waived the right of appeal to argue that the was not in evidence and could not be relied upon, nor should it be allowed in evidence, pursuant to Ground Rules 7.2 and 10.1.

. Specifically, the (CX-3031C.). As Serendia and Staff have argued correctly, any substantial rights SynKloud may have had in the Asserted Patents reverted to Serendia. (CBr. at 8-9; SBr. at 13-14.). Nonetheless, Respondents have criticized the as having no meaning (or as "illusory" and/or as rescinding the Benev Exclusive License). (*See* RPBr. at 3-4; RRBr. at 74-75.).

Respondents also argued that because SynKloud is a patent monetization or "non-practicing entity," which , it has standing. However, SynKloud's has no bearing on standing. (*See* Opp'n to Motion to Terminate at 1, 21, 28-29; 30 (citing *See Fleet Connect Solutions LLC*, 2022 WL 2805132, *2–*3 ("The Court finds that Defendant has failed to show that litigation funding agreements, if any, are relevant to the claims or defenses in this action. Rather, in demanding such documents under the guise of determining ownership of the Asserted Patents, Defendant attempts to engage in a fishing expedition that serves only to shift the burden of establishing proof of standing to Plaintiff prior to any good-faith challenge to standing being put forward by Defendant.")).).

Second, Serendia noted that SynKloud was removed as a co-plaintiff because it lacked standing from Federal litigations through motions and orders of the Federal courts in cases in which EndyMed and Cynosure were parties, along with other Respondents who have been terminated from this Investigation. (CPBr. at 7; Opp'n to Motion to Terminate at 6-7; *see also* Exs. H-J to Opp'n to Motion to Terminate.).

Third, Respondents argued in their Joint Pre-Hearing Brief that Benev and Serendia engaged "in a course of conduct" which "indicates that [redacted] remains effective. For example, in [redacted] (RPBr. at 4 (citing RX-2577C).). However, Respondents did not develop this argument or adduce evidence during the Hearing that would support this argument. Thus, Respondents have waived, rescinded, or surrendered any argument they may try to make about this issue on appeal pursuant to Ground Rule 10.1.

Fourth, [redacted] (*See* Ex. D to Opp'n to Motion to Terminate, [redacted].). [redacted] (Compl. Ex. 66, [redacted].). Serendia also [redacted] The [redacted]. (*See* Opp'n to Motion to Terminate at 13-14; *accord*, SBr. at 13.). As noted in the [redacted] chain of title, this document clearly does not negate Serendia's right to standing.

Fifth, according to Respondents, a [redacted] (RPBr. at 3-4; RBr. at 4; RRBr. at 2-3; Motion to Terminate at 1, 7, 10, 21, 23, 30). In that same vein, Respondents also argued that ViOL has rights in the Asserted Patents because

it had a [redacted]. (RBr. at 4-5). However, the [redacted], which is in evidence contrary to Respondents' argument, [redacted]. (*See* CX-3032C [redacted]; *see also* RRBr. at 4.). As both Serendia and Staff noted, with legal support, the fact that [redacted] has no significance legally and does not confer standing. (CPBr. at 8-9; SBr. at 7-8.). [redacted] is not a substantial right in any Asserted Patent and does not confer standing. (CBr. at 8 (citing *Certain Audio Processing Hardware*, Inv. No. 337-TA-1026, Comm'n Op. at 13-25 (Apr. 2018) ("*Audio Processing*") ("[R]eceive[ing] a portion of the proceeds from litigating or licensing the patent" does not convey standing); *see als*o CX-0762C [redacted]; *Azure Networks, LLC v. CSR PLC*, 771 F.3d 1336, 1347 (Fed. Cir. 2014).).

Sixth, Respondents argued early in the Investigation that "Dr. Na is the alter-ego of Serendia" and controls all enforcement decisions. (*See* CX-0148C (Rog. Resp.). However, Respondents did not adduce evidence during the Hearing on this claim. Consequently, Respondents waived, abandoned, and surrendered any right to raise this argument on appeal pursuant to Ground Rule 10.1. Without more and given that the only legal authority that Respondents relied upon was a distinguishable case that interpreted Texas law, the evidence does not support Respondents' assertion. *Samsung Elecs. Am., Inc.,* 2019 WL 1399927, at *3 (E.D. Tex. Mar. 28, 2019).

Seventh, Respondents argued both in its Motion to Terminate and its Pre-Hearing Brief that Serendia has not retained all substantial rights in the Asserted Patents because of a [redacted]

(CX-3028C)) [redacted] (CX-3031C). (RPBr. at 3-4; Motion to Terminate at 1-2.). As part of that argument, discussed above, Respondents also argued that [redacted] operates an encumbrance on Serendia's rights in the Asserted Patents. (Motion to Terminate at 18; RPBr. at 4.). Whether SynKloud's [redacted] are described as an "encumbrance" on Serendia's patent rights, or as an [redacted] in the Asserted Patents, as noted above, Serendia's standing is not undermined. (*See* SBr. at 14 (citing *e.g., Luminara Worldwide, LLC v. Liown Elecs. Co.*, 814 F.3d 1343, 1351 (Fed. Cir. 2016) (holding that a financial interest in litigation and licensing is not a substantial right) (collecting cases); *WAG Acquisition, LLC v. Multi Media, LLC*, 2019 WL 3804135, at *2 (D.N.J. Aug. 13, 2019) (denying motion to dismiss for lack of standing and rejecting defendants' argument that a litigation funder possessed substantial rights due to plaintiff's inability to pursue litigation without funding).).

Serendia has standing. It has the exclusive rights and ownership in the Asserted Patents. *Active Matrix Organic Light-Emitting Diode Display Panels and Modules for Mobile Devices, and Components Thereof* ("*Display Panels"*), Inv. No. 337-TA-1351, Comm'n Op. at 11 (May 15, 2024).

IV. THE ASSERTED PATENTS

The Asserted Patents share the same named inventor, Dr. Jongju Na, and are members of two (2) patent families. (*See* Compl. at ¶ 1.1, Doc. ID No. 791505 (Mar. 1, 2023).).

The '836, '379, and '444 patents are members of one patent family and share a common specification ("Na Effect Patents" or "Family One Patents") (*see id.*). The '536, '774, and '812 patents are members of another patent family and share a common specification ("Needle

Assembly Patents" or "Family Two Patents") (*see id.*). As discussed above in Section II, only the '836, '536, '774, and '812 patents remain at issue in this Investigation.

According to Serendia, the Na Effect Patents claim priority to U.S. Application No. 14/006,930, filed on June 14, 2012, and Korean Application Nos. 10-2011-0057691 and 10-2011-0057692, both filed on June 14, 2011. (Complainant's Notice of Patent Priority Dates/Dates of Conception at 2-3, Doc. ID No. 795792 (May 5, 2023).). The Needle Assembly Patents all claim priority to U.S. Provisional Application No. 61/449080, filed on March 3, 2011. (*See id.* at 1-2.).

A. Overview of the '836 Patent (Na Effect Patent or Family One Patent)

The Na Effect Patent or Family One Patent describes the claimed invention as being "for medical treatment including skin treatment using electrical energy, especially with the primary purpose for skin treatment for aesthetics[.]" (JX-0007 ('836 patent) at 1:24-26.). The Na Effect Patent describes a "method and apparatus that provides electric stimulation directly to a body region including the dermis via needles. (*Id.* at 2:37-41.). The method purportedly "revitalizes and regenerates the body region including collagen by wounding the dermis." (*Id.* at 2:39-41.).

Figure 5 of the Na Effect Patent depicts a "a simplified diagram of treatment architecture using non insulated needles according to an embodiment[.]" (*Id.* at 4:41-43.). More specifically, Figure 5 depicts needles 300 with needle tips 302 for generating energy field 909. (*See id.* at 7:27-32 (referencing Fig. 6); *see also id.* at 9:25-26.).

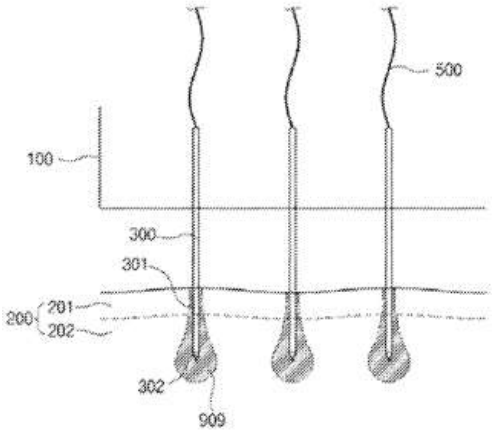


FIGURE 5

(*Id.* at Fig. 5.).

Figure 6 of the Na Effect Patent depicts an embodiment where "adjacent or neighboring needles may be configured to have opposite polarities (+) and (-)[.]" (*Id.* at 4:1-3.).

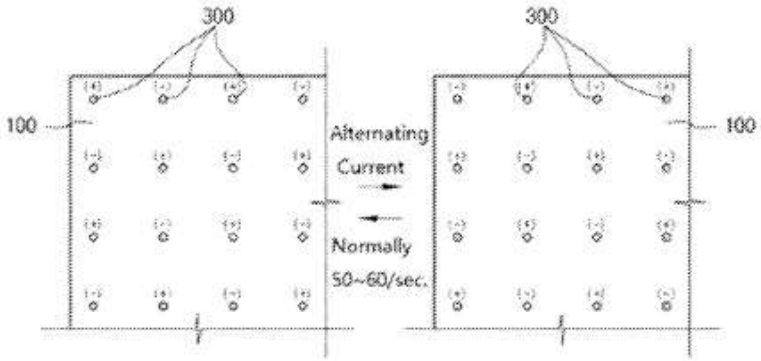


FIGURE 6

(*Id.* at Fig. 6.).

The Na Effect Patent also discloses:

> In an embodiment, the temperature is raised about the tip of each needle, not between needles. The method of the present invention may control electrical factors or distance between needles to control the energy field applied between needles. A method of the present invention may enable users to control the number

of treatments in target areas by controlling the dissipated energy in needles.

(*Id.* at 3:30-36.).

As noted above in Section II, claims 1, 9 and 22 of the '836 patent are at issue. The claims are reproduced below, along with the claims from which they depend.[19]

> **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.
>
> **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.

(*Id.* at cls. 1, 9, 14, 22.).

B. Overview of the '536, '774, and '812 Patents (Needle Assembly Patents or Family Two Patents)

The Needle Assembly Patents or Family Two Patents describe the claimed invention as being "used in treating derma[to]logical tissue." (JX-0001 ('536 patent) at 1:25-27.).[20] The Needle Assembly Patents depict and describe that the "derma[to]logical treatment apparatus"

[19] The asserted patent claim numbers are in bold.

[20] Because the Needle Assembly Patents share a common specification, citations in this ID are to the specification of the '536 patent unless indicated otherwise.

comprises "a user handle 220 coupled to an acupuncture plate 200." (*Id.* at 2:51-55, Figs. 1A, 1B.). The plate includes "a plurality of acupuncture pins or needles 230. (*Id.* at 2:61-67; *see also id.* at Figs. 1B, 1C.).

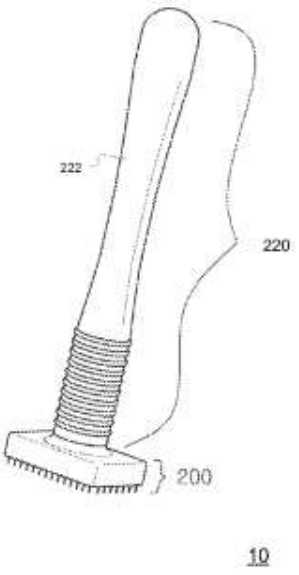


FIGURE 1A

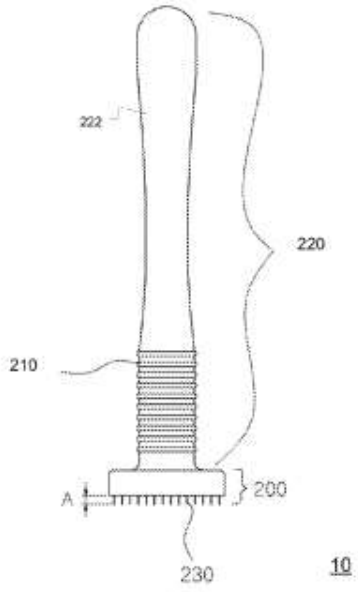


FIGURE 1B

(*Id.* at Figs. 1A, 1B.).

In operation, a user employs the apparatus "to create a plurality of micro-wounds or holes in derma[to]logical layers of mammal's [] skin or dermis." (*Id.* at 3:21-23.). 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 3:23-26) 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).

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" 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.). Additionally, the Needle Assembly Patents depict and describe that the dermatological treatment apparatus may include "a disposable needle module 924 . . . to be removed [from hand module 920] and disposed after one or more treatments or for each patient, client, or user." (*Id.* at 9:26-30, Figs. 9C, 9D.).

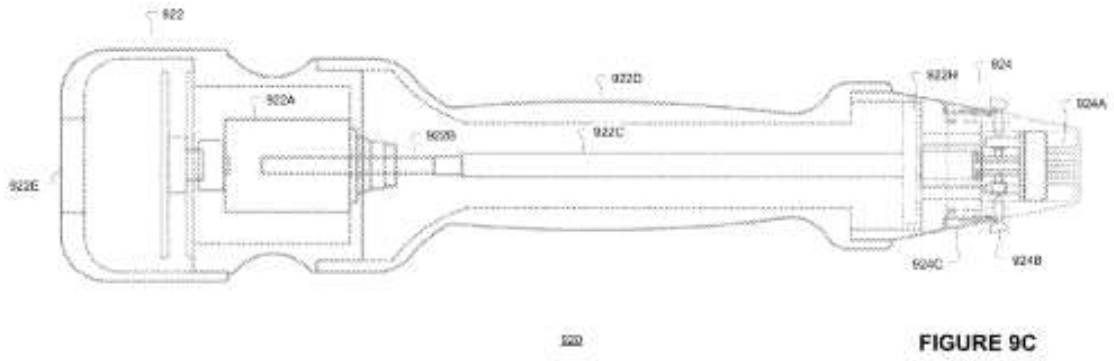


FIGURE 9C

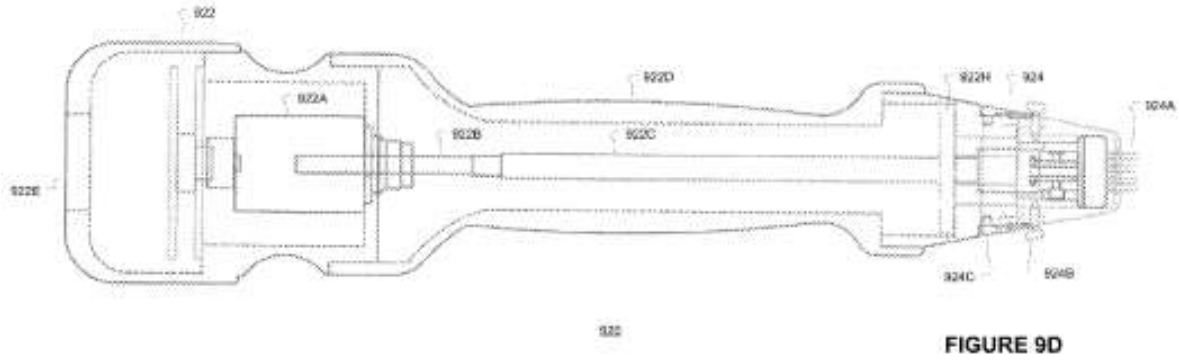


FIGURE 9D

(*Id.* at Figs. 9C, 9D.).

Figures 10A-10D of the Needle Assembly Patents depict how the needle module 924 can be attached and removed from the user handle. Figures 10A and 10C are depicted below.

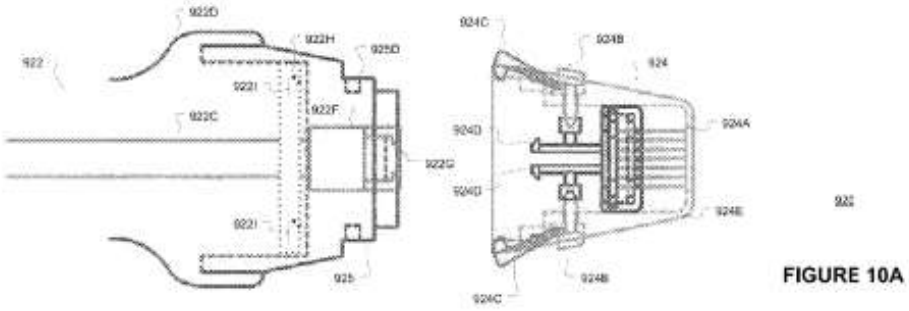


FIGURE 10A

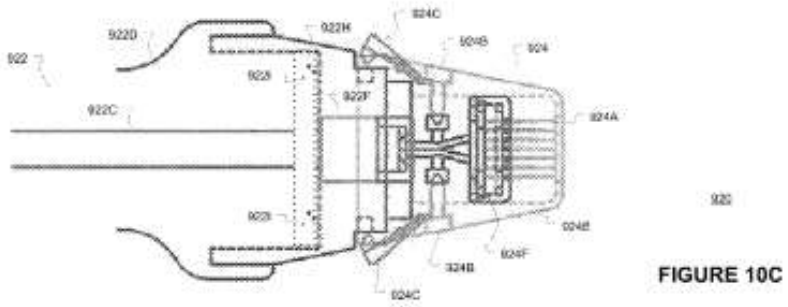


FIGURE 10C

(*Id.* at Figs. 10A, 10C.).

As depicted in Figures 10E and 11A of Needle Assembly Patents, needles 924A can be deployed or extended from the needle module 924. (*See id.* at 2:30-32, 12:18-23, 12:41-43.). Figure 10E is depicted below.

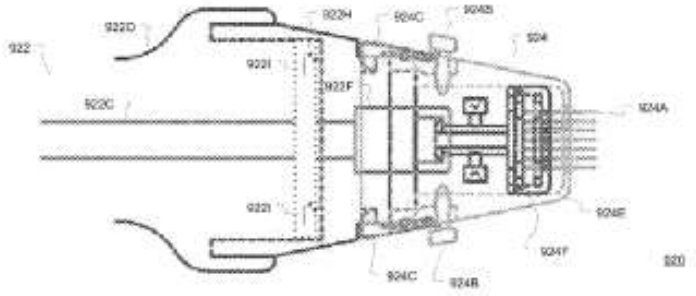


FIGURE 10E

(*Id.* at Fig. 10E.).

As noted above in Section II, a11 and 16 of the ’536 patent; claim 14 of the ’774 patent; and claims 5, 13, and 18 of the ’812 patent are at issue. The claims are reproduced below, along

with the claims from which they depend.[21]

> **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) at cls. 11, 16.).

> 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) at cls. 11-12, 14.).

[21] The asserted patent claim numbers are in bold.

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 suer 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.

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) at cls. 1-5, 13, 18.).

C. Inventorship

1. Respondents Claim That Dr. Na Was Not the Sole Inventor of the '836, '536, and '812 Patents

Respondents attempted to prove that Ilooda's CEO in 2009, Mr. Yonghan Kim, is a co-inventor of the '836 patent (RBr. at 52-62), as well as of the '536 patent and the '812 patent (RBr. at 94-98.). Serendia successfully undermined Respondents' attempt. (CRBr. at 39-45.). Although there is some evidence that Mr. Kim worked with Dr. Na on ideas that eventually became the '836, '536, and '812 patents, the evidence is conflicting as is their testimony about their individual contributions to the ideas that became those patents. Ultimately, the issue is whether Mr. Kim's testimony about his alleged contributions to the inventions is credible and sufficiently corroborated. For the reasons explained below, Respondents have failed to carry their burden to prove by clear and convincing evidence that Mr. Kim is a co-inventor of the '836, '536, and '812 patents.

2. Legal Standard

The Manual of Patent Examining Procedure ("MPEP"), Section 2109 on Inventorship, states: "The definition of inventorship can be simply stated: 'The threshold question on determining inventorship is who conceived the invention. Unless a person contributes to the conception of the invention, he is not an inventor. . . . Insofar as defining an inventor is concerned, reduction to practice *per se* is irrelevant [except for simultaneous conception and reductio to practice." *Fiers v. Revel*, 984 F.2d 1164, 1168 (Fed Cir. 1993)]."

However, "[t]he burden of proving that an individual should have been added as an inventor to an issued patent is a 'heavy one,' and the 'issuance of a patent creates a presumption that the named inventors are the true and only inventors. Thus, an alleged joint inventor must

prove a claim of joint inventorship by 'clear and convincing evidence.'" *HIP, Inc. v. Hormel Foods Corp.*, 66 F.4th 1346, 1350 (Fed. Cir. 2023), *cert. denied*, 144 S. Ct. 377, 217 L. Ed. 2d 204 (2023) (internal citations omitted).

To meet the clear and convincing burden of proof:

> alleged co-inventors must prove their contribution to the conception with more than their own testimony respecting the facts surrounding a claim of derivation or priority of invention. Whether the inventor's testimony has been sufficiently corroborated is evaluated under a "rule of reason" analysis. Under this analysis, '[a]n evaluation of all pertinent evidence must be made so that a sound determination of the credibility of the [alleged] inventor's story may be reached.' Corroborating evidence may take many forms. Reliable evidence of corroboration preferably comes in the form of physical records that were made contemporaneously with the alleged prior invention. Circumstantial evidence about the inventive process may also corroborate. Additionally, oral testimony of someone other than the alleged inventor may corroborate.

Trovan, Ltd. v. Sokymat SA, Irori, 299 F.3d 1292, 1302–03 (Fed. Cir. 2002) (internal citations omitted).

Additionally, in *Hip, Inc. v. Hormel Foods Corp.*, the Federal Circuit reaffirmed the three-part test from *Pannu v. Iolab Corp.* ("*Pannu*"), that an alleged inventor is one who: (1) contributes in some significant manner to the conception of the invention; (2) contributes to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention; and (3) does more than merely explain to the real inventors well-known concepts and/or the current state of the art. *HIP*, 66 F.4th at 1350 (citing *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1351 (Fed. Cir. 1998) ("*Pannu*"); *see also Plastipak Packaging, Inc. v. Premium Waters, Inc.*, 55 F.4th 1332, 1340 (Fed. Cir. 2022) (reaffirming the three-party inventorship test set forth in *Pannu*); *CardiAQ Valve Techs., Inc. v. Neovasc Inc.*, 708 F. App'x 654, 659-60 (Fed. Cir. 2017) (applying *Pannu*, affirming district court ruling that the patent failed to name two co-inventors, affirming finding that their contributions were more than just

information that existed in the prior art because the prior art reference in which their contribution allegedly was disclosed was not publicly available at the time of the invention); *Tube-Mac Indus., Inc. v. Campbell*, No. 2022-2170, 2024 WL 1132229, at *4 (Fed. Cir. Mar. 15, 2024) (applying *Pannu*, affirming district court ruling that the patent failed to name two co-inventors, affirming finding that the two omitted co-inventors' contribution was significant because, without it, "the invention would not be viable"); *Blue Gentian, LLC v. Tristar Prod., Inc.*, 70 F.4th 1351, 1360 (Fed. Cir. 2023) (applying *Pannu*, contributions of alleged co-inventor were significant because they reflected the subject matter that the patentee had relied on to distinguish the invention from the prior art); *Bio-Rad Labs., Inc. v. Int'l Trade Comm'n*, No. 2020-1785, 2021 WL 1680268, at *1320-22 (Fed. Cir. Apr. 29, 2021) (applying *Pannu*, contributions of alleged co-inventors were not significant because they were publicly known and/or disclosed in the prior art before the time of the invention); *Nartron Corp. v. Schukra U.S.A. Inc.*, 558 F.3d 1352, 1357 (Fed. Cir. 2009) (applying *Pannu*, affirming district court ruling on summary judgment that individual was not an omitted co-inventor, finding that the allegedly omitted co-inventor's contribution was "insignificant when measured against the full dimension of the invention" because the contribution was in the prior art); *Acromed Corp. v. Sofamor Danek Grp., Inc.*, 253 F.3d 1371, 1380 (Fed. Cir. 2001) (applying *Pannu*, affirming the district court's ruling that the patents were not invalid for improper inventorship, affirming the district court's finding that there was insufficient evidence that alleged co-inventor actually contributed the subject matter that he testified he contributed).

3. Mr. Kim's Alleged Contributions to the Claimed Subject Matter

Claims 1, 7, 8, 19, 22, 27, 28, and 29 of the '836 patent each requires "a plurality of electrodes, the electrodes being bipolar," a "radio frequency (RF) generation module," which is

"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." (JX-0007 at 10:48-59, 11:4, 11:7, 11:25-30, 12:5, 12:13, 12:27, 12:30, 12:34.). Claim 27 recites "a drive module to controllably move one or more of the plurality of electrodes into skin to be treated." (*Id.* at 12:27-29.). Respondents argued that Mr. Kim's inventive contributions to the foregoing claims of the '836 patent include: (1) using AC RF and specific frequencies of RF; and (2) a drive module or motor in the handpiece of the RF microneedling device. (RBr. at 55-59.).

Claims 1, 4, 5, 11, 14 and 15 of the '536 patent and claims 1, 2, 4, 5, 12, 13, and 17 of the '812 patent all require "a user holdable device [] releasably couplable deployable needle [assembly or module]." (JX-0001 at 15:17-18, 16:14-15; JX-0005 at 15:47-48, 16:47-48.). Claims 1, 4, 5, 11, 14, and 15 of the '536 patent and claims 2, 4, 5, 13, and 17 of the '812 patent all require "a motor." (JX-0001 at 15:33, 16:26; JX-0005 at 15:67, 16:60.). Claims 4, 5, 14, and 15 of the '536 patent and claims 4, 5, and 17 of the '812 patent all also require an "embedded LED." (JX-0001 at 15:49, 16:41; JX-0005 at 16:7-8, 17:8-9.). Respondents argued that Mr. Kim's inventive contributions to the foregoing claims include: (1) a motor to control the depth of needle insertion; (2) a disposable and detachable needle cartridge; and (3) an embedded LED. (RBr. at 94.).

None of the Parties analyzed the evidence under the three-factor framework provided in *Pannu*.

As detailed below, Dr. Na and Mr. Kim provided conflicting and sometimes diametrically opposing testimony about their respective contributions to the invention.

4. Mr. Kim and Dr. Na Offered Competing Accounts of Their Contributions

Dr. Na, who is the sole named inventor on the face of the '836 patent, met and held discussions with Mr. Kim during the spring and summer of 2009. (Tr. (Kim) at 755:20-756:12). Mr. Kim testified that he met Dr. Na through a mutual acquaintance between the spring and summer of 2009. (Tr. (Kim) at 755:20-756:12.). Mr. Kim testified that their mutual acquaintance informed Mr. Kim that Dr. Na was developing a medical device for skin treatment and was searching for a company to help him. (*Id.*). According to Mr. Kim, at their first meeting, which occurred in person at Ilooda, Dr. Na told Mr. Kim that he wanted to make improvements to his derma stamp device, which is referred to as Dr. Na's microneedling therapy device ("MTS"). (*Id.*at 757:7-12.). However, Dr. Na testified that [redacted] (Tr. (Na) at 98:21-22.). The CEO of Ilooda at the time, Mr. Joon, attended the first meeting between Mr. Kim and Dr. Na. (Tr. (Kim) at 756:21-757:2.). However, Respondents did not call Mr. Joon to testify. As a result, neither Dr. Na's nor Mr. Kim's testimony is corroborated by the testimony of another witness, let alone by clear, documentary evidence.

The MTS consists of a stamp-like structure at the end of a handle. On the stamp-like structure, or derma stamp, there are multiple short needles. (Tr. (Kim) at 761:17-762:5.). According to Mr. Kim, the stamp was used by pressing it against a patient's face so that the needles caused micro damage to the face. (*Id.*). According to Mr. Kim, Dr. Na wanted to add low frequency electrical signals to improve the MTS. These signals were to be the kind of electrical signals that stimulate nerves and muscles and are commonly used in physical therapy devices to reduce pain. (*Id.* at 762:2-14.). In response, Mr. Kim testified that he told Dr. Na

that low frequency signals would not result in skin improvement. (*Id.*). Instead, according to his testimony, Mr. Kim suggested causing limited thermal damage using something like a laser or conductive needles with an RF signal. (*Id.* at 762:15-23.). At that time, and as Dr. Na testified, [redacted]. (Tr. (Kim) at 766:11-16; Tr. (Na) at 114:11-17; RX-2548C (Na Dp. Tr.) at 219:17-220:1 [redacted]). A device that Dr. Na had developed, in 2005, called the "derma stamp device," or the MTS described above, did not use RF. (Tr. (Na) at 75:1-9.). However, in somewhat conflicting testimony, Dr. Na also testified that [redacted]. (*Id.* at 100:23-101:1.). Mr. Kim testified that, during their discussions, Mr. Kim answered questions from Dr. Na and proposed ideas for improving the MTS. (Tr. (Kim) at 762:24-763:2, 764:13-19.).

The foregoing evidence suggests that [redacted]. (Tr. (Na) at 79:18-25, 83:4-13.).

By contrast, according to his unrebutted testimony, Mr. Kim started developing RF surgical devices in 2001 when he joined a Korean company, SomeTech, as a director of its R&D team. (Tr. (Kim) at 751:25-752:7.). As SomeTech's director of R&D, Mr. Kim developed the "Dr. Oppel" and "Thermocon" devices, which used alternating current and had monopolar and bipolar electrodes, including selecting the RF frequencies those devices could use. (*Id.* at 752:8-753:13.). The "Dr. Oppel" device was used for skin treatment, specifically to reduce exposed pores. (*Id.* at 754:4-9.). The "Thermocon" device was used for nerve blocking. (*Id.*). Both devices used disposable electrodes. (*Id.*at 753:17-754:3.). After SomeTech, Mr. Kim joined

Ilooda as its director of R&D. (*Id.* at 754:19-22.). As director of R&D at Ilooda, Mr. Kim developed several RF devices for reducing wrinkles and making skin look younger, that used alternating current. (*Id.* at 754:23-25.). The products that Ilooda developed used both monopolar and bipolar electrodes and included products called: Lunar S, 4sOne, Lunar N, Caresys RF, Qray FRX, CICU-f, and FRAXIS. (*Id.* at 754:23-755:19.).

Mr. Kim testified that the ideas he discussed with Dr. Na are captured by a July 20, 2009 email from Mr. Kim to Dr. Na and its attachment. (*Id.* at 764:13-765:1; CX-0249C.0003 (July 20, 2009 email), CX-0250C (attachment to July 20, 2009 email).). That July 20, 2009 email is reproduced below.

Figure 1: July 20, 2009 Email From Mr. Kim to Dr. Na Regarding Proposed RF MTS Device

Hi there. Director Jong Ju Na!

Sorry for the late reply due to the actuator specification review. The attachment summarizes the simple specifications of RF MTS, etc.

We have conducted 2 internal development reviews in the lab. As for the timeline, the current project will be finalized at the end of August, so we will start from September.
If the contract is signed before then, we plan to proactively start sourcing parts, etc., in advance. We apologize that it is difficult to move up the schedule because the ongoing project is scheduled for a fall release.

We will create a detailed development plan when we go into the actual development, but for now, we will only send you a brief summary of our review findings.
Please cc and reply with any questions you may have. I will respond with answers.

That's all for now.

Yong-han, Kim / Vice President / Research institute

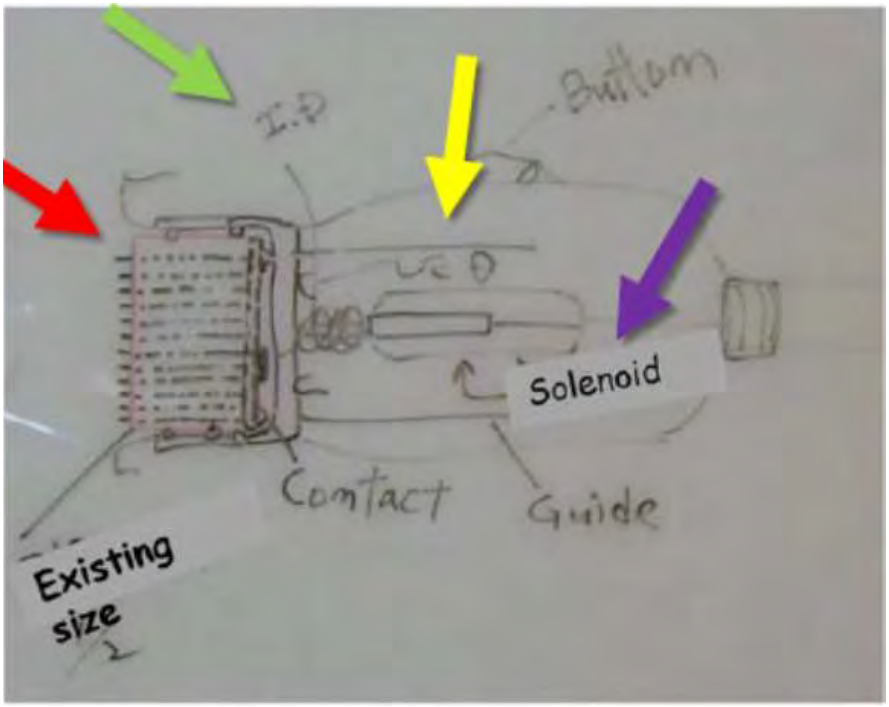
(CX-0249C.0003; Tr. (Kim) at 764:13-765:1.).

A presentation that Mr. Kim said he prepared, titled "Full Automatic RF MTS," is attached to the July 20, 2009 email. (Tr. (Kim) at 764:24-765:16; CX-0250C.0008). That presentation contains a hand drawing of the proposed device. A version of that hand drawing,

with red, green, yellow, and purple arrows that Mr. Kim added as his annotations for the purposes of the present Investigation is reproduced below. The green arrow in Figure 2 below depicts an "ID," which is a memory component that stores information about whether and how many times the needle cartridge has been used. (Tr. (Kim) at 768:24-769:14.). The yellow arrow in Figure 2, below, points to an LED indicator that, when activated, informs the user that RF is being transmitted. (Tr. (Kim) at 769:15-770:13.). This is important because RF electricity must be transmitted at the same time the needles are protruding into the skin. (*Id.*). Dr. Na testified that [redacted]. (Tr. (Na) at 100:20-22.).

The purple arrow in Figure 2 below, indicates a solenoid that controls movement of the needle assembly. (Tr. (Kim) at 770:14-20.).

Figure 2: Hand Drawing of Proposed Fully Automatic RF MTS with Annotations by Mr. Kim



(CX-0250C.0010; Tr. (Kim) at 765:17-767:11; RDX-0008C.0007.).

However, in testimony that somewhat contradicted Mr. Kim's, Dr. Na testified that the [redacted]. (Tr. (Na) at 101:2-10.). Dr. Na also testified consistently during the Hearing and during his deposition, that [redacted]. (Tr. (Na) at 101:15-23; RX-2550C (Na Dep. Tr.) at 138:4-140:12.).

By contrast, Mr. Kim testified that the drawing depicted in Figure 2 above was drawn entirely by him on a whiteboard in a conference room above Ilooda. (Tr. (Kim) at 765:25-767:11.).

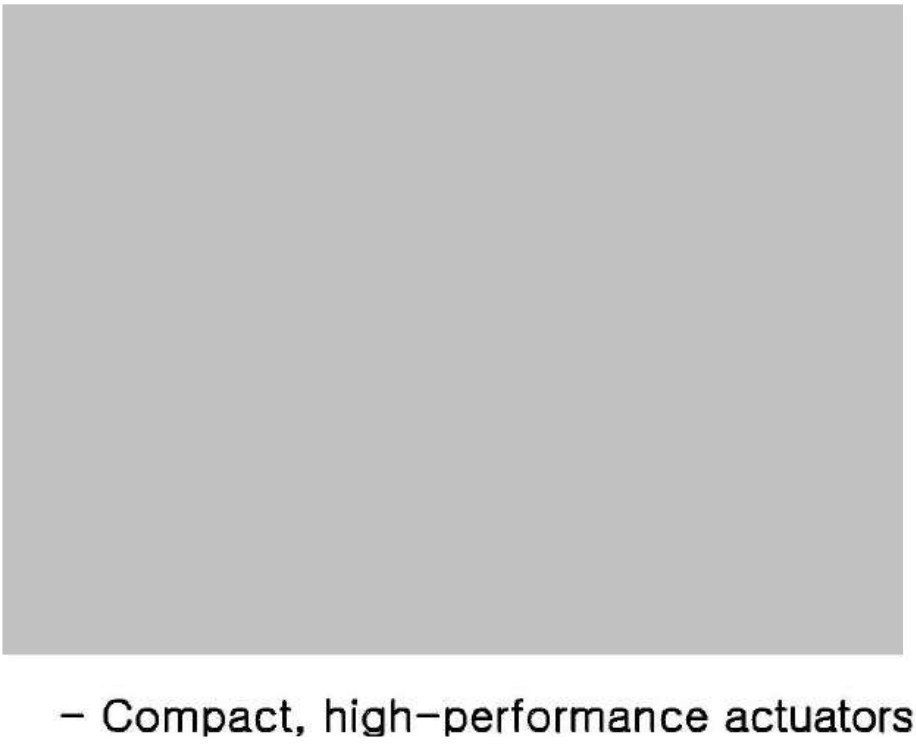
In Figure 2, above, the red arrow points to the needle assembly, the left side of which would face the skin of the patient. (Tr. (Kim) at 767:12-24.). Mr. Kim testified that he proposed to Dr. Na that the needle assembly should be disposable because it must be sterile. He claimed it should be disposable because sterilizing a needle assembly in an autoclave would damage the electrical components. (*Id.* at 767:25-768:8.). However, Dr. Na testified that [redacted]. (Tr. (Na) at 99:16-100:13.).

Mr. Kim testified that he proposed that the needles have a thickness of 350 micrometers because of his experience using lasers with beam diameters of 70 to 350 micrometers. (*Id.* at 768:9-16.). Mr. Kim also testified that he proposed needles (which in the MTS had a length of about 0.25 millimeters), that should have a length of 3 millimeters "to transmit heat to the dermal layer" because "fractional lasers mostly use that length." (*Id.* at 768:17-23.). However, Dr. Na testified that [redacted]. (Tr. (Na) at 100:17-19.). Dr. Na also testified that [redacted]

. (*Id.* at 102:17-24.).

A second picture on the same page of the July 20, 2009 email presentation, depicted below in Figure 3, depicts using actuators to control the movement of the needle assembly:

Figure 3: Depiction of Actuators for Use in Proposed Fully Automatic RF MTS

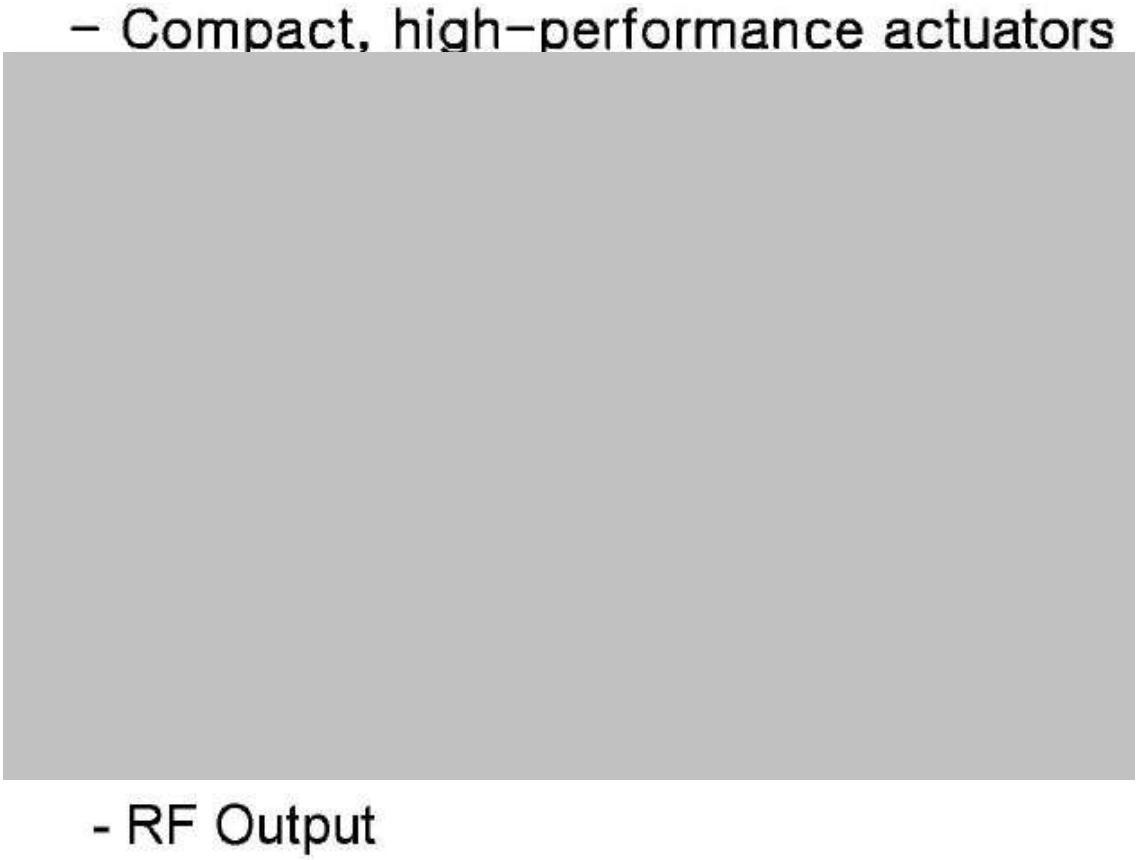


(CX-0250C.0010; Tr. (Kim) at 770:21-771:4.).

Dr. Na testified that . (Tr. (Na) at 100:7-16.).

A third picture on that page of the presentation attached to the July 20, 2009 email, which is depicted below in Figure 4, depicts a 1 MHz RF waveform for use with actuators for the proposed fully automatic RF operated MTS or electrified stamp device.

Figure 4: Depiction of 1 MHz RF Waveform For One of Mr. Kim's RF Devices



(CX-0250C.0010; Tr. (Kim) at 771:10-19.).

Mr. Kim testified that the 1 MHz waveform depicted in Figure 4 above, reflects a measurement taken in 2007 from an actual RF device he developed. (Tr. (Kim) at 771:10-19.). Mr. Kim also testified that he proposed the target specifications for certain components of the proposed fully automatic RF MTS product, including the ID, LED, and RF frequency, which are depicted in Figure 5, below.

Figure 5: Target Specifications for Proposed Fully Automatic RF MTS Product



(Tr. (Kim) at 771:20-772:3; CX-0250C.0009.).

Dr. Na testified that . (Tr. (Na) at 101:11-14.).

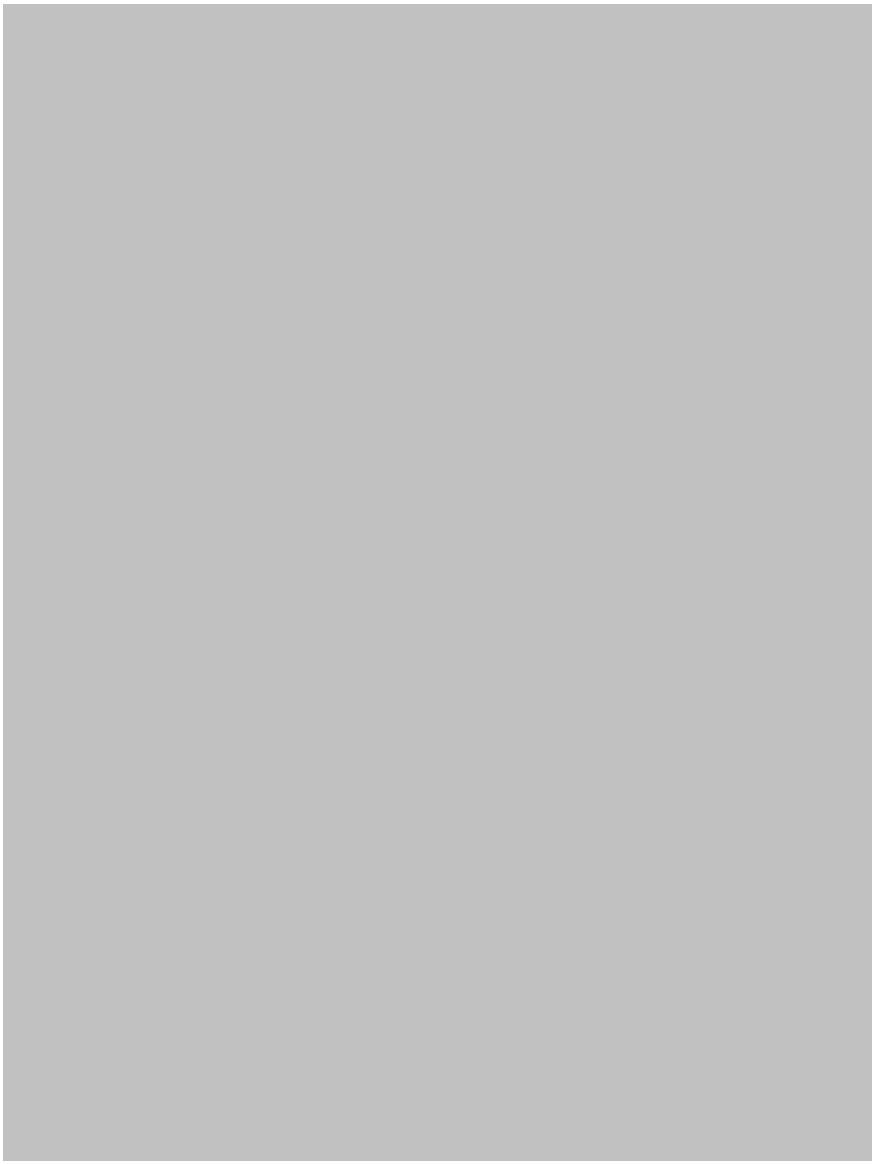
5.

According to Mr. Kim, in August 2009, Mr. Kim sent Dr. Na a draft contract that would have governed their relationship wherein Mr. Kim's company, Ilooda, would handle development and supply of the RF MTS, whereas Dr. Na would handle sales. (Tr. (Kim) at 772:10-773:11; CX-0251C.0001 (August 2009 email sending draft contract); RX-1733C.0002 (translation of August 2009 email sending draft contract); CX-0252C.0001, 0004 (draft contract); RX-0409C.0002, 0005 (translation of draft contract).). After exchanging modifications and revisions, at least according to Mr. Kim, Dr. Na stopped responding. (Tr. (Kim) at 773:13-21.). According to Dr. Na, ultimately, . (Tr. (Na) at 102:25-103:9.). That did not happen.

6. Mr. Kim Was Informed of the ’836 Patent and the ’536 Patent in 2018

In 2018, Serendia sent a letter to Cutera, Ilooda’s distributor, in which Serendia asserted Cutera’s infringement of the ’836 patent and the ’536 patent. (Tr. (Kim) at 786:20-787:2; CX-3067C.). According to his testimony, at that time Mr. Kim consulted U.S. patent lawyers in connection with a response dated April 16, 2018. (Tr. (Kim) at 787:3-13, 790:10-14; CX-3394C.).

Figure 6: Excerpt from Mr. Kim’s Counsel’s Letter to Serendia Responding to Serendia’s Claims of Infringement of the ’836 and ’536 Patents





(Tr. (Kim) at 787:3-13, 790:10-14; CX-3394C.).

As can be seen in the letter dated April 16, 2018, that was sent on Mr. Kim's behalf to Serendia, Mr. Kim's claims of co-inventorship were not asserted even then. (Tr. (Kim) at 787:14-23.).

Mr. Kim testified that he has applied for patents. (Tr. (Kim) at 783:13-784:22.).

7. Respondents Have Not Carried Their Burden of Proof That Mr. Kim is a Co-Inventor

The Federal Circuit's instruction in *Trovan* requires an evaluation of the pertinent evidence, under a rule of reason analysis. *Trovan*, 299 F.3d at 1302-03. Dr. Na and Mr. Kim have competing claims, and often conflicting testimony, about the same ideas and annotations that appear in the July 20, 2020 e-mail and its attachments. (*Compare* Tr. (Kim) at 755:20-756:12 *with* Tr. (Na) at 98:21-22; *compare* Tr. (Kim) at 762:2-23 *with* Tr. (Na) at 100:23-101:1; *compare* Tr. (Kim) at 768:24-770:13 *with* Tr. (Na) at 100:20-101:10; *compare* Tr. (Kim) at 765:25-767:11 *with* Tr. (Na) at 101:15-23, 138:4-140:12; *compare* Tr. (Kim) at 767:12-768:8

with Tr. (Na) at 99:16-100:13; *compare* Tr. (Kim) at 768:9-23 *with* Tr. (Na) at 100:17-19; *compare* Tr. (Kim) at 770:21-771:4 *with* Tr. (Na) at 100:7-16; *compare* Tr. (Kim) at 771:21-772:3 *with* Tr. (Na) at 101:11-14.).). However, neither Serendia nor Respondents provided independent testimonial corroboration of Dr. Na's or Mr. Kim's testimony about their respective contributions.

With respect to credibility, although both men gave what they firmly believed to be their contributions to the asserted patents, Mr. Kim's actions, after he and Dr. Na broke off contact in 2009, do not persuasively support Mr. Kim's claims of inventorship. (*See, e.g.,* Tr. (Kim) at 786:20-788:23; CX-3067.). From Mr. Kim's testimony that he has experience applying for patents and his status as the director of R&D of a medical device company, it can be inferred that he knew something about the necessity of protecting patent rights. However, he allegedly divulged his own ideas to Dr. Na, the Chief Executive Office of another medical device company, about how to improve that other CEO's device. (Tr. (Kim) at 764:13-765:1; CX-0249C.0003, CX-0250C.). When Dr. Na ostensibly stopped responding, Mr. Kim did not investigate whether he should seek patent protection for the automatic RF MTS ideas that he alleged in this Investigation are his. (Tr. (Kim) at 783:13-784:3.). Rather, Mr. Kim waited until this Investigation was filed, ***fourteen years*** after Dr. Na broke off contact (if Mr. Kim is to believed), before asserting his co-inventorship claims. Moreover, despite being informed of the '836 patent and the '536 patent in April 2018, Mr. Kim waited almost ***five years*** until this Investigation was filed in March 2023 to assert his co-inventorship claims.

Mr. Kim's background and expertise with RF medical devices, and [redacted], if considered on its own apart from other evidence, would lend some credibility to Mr. Kim's inventorship testimony that Mr. Kim provided an inventive concept. (Tr. (Kim) at

751:25-753:13, 753:17-754:3, 754:19-755:19, 766:11-16; Tr. (Na) at 75:1-9, 75:18-25, 83:4-13, 114:11-17; RX-2548C (Na Dep. Tr.) at 219:17-220:1.). However, that cited testimony should be read as being undermined by the fact that the use of RF was known in the prior art. (*See* Sections below, which generally discuss prior art for each patent, under Invalidity, but specifically the use of RF.).

However, because of the actions Mr. Kim took after he ceased having contact with Dr. Na, actions which are described more below, it is a finding of this ID that Dr. Na's account, in which [redacted], is persuasive and more supported by the evidence. (Tr. (Na) at 80:5-9, 98:19-94:1, 100:23-101:14.). Consequently, whatever Mr. Kim's contributions to the '836 patent and/or the '536 patent may have been, there is insufficient corroboration, let alone clear and convincing evidence, that would establish that Mr. Kim is entitled to co-inventorship of either the '836 patent or the '536 patent. (*Id.* at 787:25-788:23.). The alleged contributions to the '536 patent are the same as for the '812 patent (RBr. at 94), and so these findings for the '536 patent are equally applicable to the '812 patent.

In addition to the rule of reason analysis of *Troyan*, the Federal Circuit has instructed that a putative inventor's contributions must be analyzed to determine whether those contributions are sufficient for the putative inventor to qualify as a true inventor. *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1351 (Fed. Cir. 1998). Under the three-part inventorship test set forth in *Pannu*, and confirmed by the Federal Circuit (*see, e.g.*, *HIP*, 66 F.4th at 1350), Mr. Kim must have: (1) contributed in some significant manner to the conception of the claimed inventions; (2) made a contribution to the claimed inventions that is not insignificant in quality, when measured against the full dimension of the claimed inventions; and (3) done more than merely explained to Dr. Na

well-known concepts.

Serendia's expert, Mr. Crosby, testified that Mr. Kim's alleged contributions to the '536 patent and the '812 patent were known in the prior art. (Tr. (Crosby) at 1526:25-1527:7.). He testified that the prior art discloses a handpiece that houses a motor, wherein the motor is used for oscillating or reciprocating the needle portion. (*Id.* at 1527:8-1528:2.). He also testified that the prior art discloses embedded LEDs. (*Id.* at 1528:3-9.). Mr. Crosby explained that it is the combination of these elements, not any one individually, that is significant. (*Id.* at 1528:15-1529:7.). According to Mr. Crosby, because Mr. Kim did not claim to conceive of the combination of these elements, he cannot have made a significant contribution to the claimed inventions. (*Id.* at 1529:8-1530:1.).

Respondents' expert, Dr. Woloszko, did not provide contrary testimony to that of Mr. Crosby. (Tr. (Woloszko) at 978:13-991:9.).

Although none of the Parties presented an analysis of the *Pannu* factors, the evidence that was presented through Serendia's expert, Mr. Crosby, was not controverted. It is therefore a finding of this ID that, if Mr. Kim contributed anything, his contributions consisted only of subject matter that was already in the prior art, consistent with *Pannu*. Dr. Na credibly testified that [redacted]. (Tr. (Na) at 99:16-100:16, 100:17-22, 101:2-23.). Respondents failed to present clear and convincing evidence that Mr. Kim contributed significantly to the claimed inventions.

Respondents argued that *Ethicon, Inc. v. U.S. Surgical Corp.*, 135 F.3d 1456 (Fed. Cir. 1998) ("*Ethicon*") supports Respondents' arguments that Mr. Kim is a co-inventor. It does not. In *Ethicon*, the Federal Circuit affirmed the Federal district court's holding that Mr. Choi was an omitted co-inventor for two reasons. First, Mr. Choi presented drawings depicting the subject

matter he conceived. *Id.* at 1464. Dr. Yoon needed someone with Mr. Choi's expertise, Dr. Yoon proposed that he and Mr. Choi work together to develop new products, their business relationship was informal, Mr. Choi wasn't paid for his work, Mr. Choi's drawings were very similar to the patent figures, and Mr. Choi described himself as having been a "member' of Dr. Yoon's business. *Id.* at 1464. Second, in *Ethicon*, although the inventor Dr. Yoon claimed that he disclosed the ideas to Mr. Choi before Mr. Choi drew them, Dr. Yoon's testimony and evidence were found by the *Ethicon* court to not be credible. Apparently, Dr. Yoon attempted to rebut Mr. Choi's evidence using an altered drawing that was rejected as unreliable due to how it was altered. The Federal district court found that Dr. Yoon had "altered and backdated documents to make it appear that he had independently invited [the subject matter]." Moreover, the trial court had also found that Dr. Yoon's testimony conflicted with his deposition testimony on key points. *Id.* at 1462.

Here, in contrast with *Ethicon*, it is a finding of this ID that Dr. Na's testimony is credible. Unlike in *Ethicon*, there is no evidence that Dr. Na altered or backdated ***documents*** to create the appearance that he independently developed the invention. There is no evidence of a conflict between Dr. Na's trial testimony and his deposition testimony.

Ultimately, it is a finding of this ID that, under the rule of reason analysis of *Troyan*, as well has under a *Pannu* analysis, that Respondents have failed to prove by clear and convincing evidence that Mr. Kim is a co-inventor of any of the Asserted Patents. Additionally, Mr. Kim's failures to assert any rights in the Asserted Patents for 14 years, as described above, also constitute significant direct and circumstantial evidence that Mr. Kim is not a co-inventor.

V. THE PRODUCTS AT ISSUE

A. Respondents' Accused Products

As defined in the NOI, the accused products in plain language consist of Respondents' "RF microneedling dermatological treatment devices and components thereof[.]" Fed. Reg. 88 at 20552 (Apr. 6, 2023). Below is a table of the Accused Products that identifies each associated Respondent. (*See* CPBr. at 4; CBr. at 6.).

Accused Product(s)	Respondents
Potenza	Jeisys, Cynosure
EndyMed Pro and Pure 2.0 with Intensif handpiece ("Intensif")	EndyMed

EndyMed has multiple Accused Products. It is undisputed that EndyMed's Accused Products are representative of each other for purposes of infringement. 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." (JX-0024C.0002 (EndyMed Rep. Product Stip.), ¶ 3; *see also id.* ¶¶ 4-6.). Serendia also presented unrebutted testimony that the Accused Products "are functionally identical." (Tr. (Daniel van der Weide)[22] at 279:24-280:3.). Additionally, Respondents did not

[22] When he testified as an expert witness during the Hearing on November 2, 2023, Dr. Daniel van der Weide was a Professor of Electrical and Computer Engineering with appointments in Radiology, Biomedical Engineering, and Materials Science. (CPSt. at Ex. 3.). Serendia identified Dr. van der Weide as an expert to testify about, *inter alia*, "the state of the art at issue, the skill level of one of ordinary skill in the art, disclosures in the asserted patents and patents or patent applications to which the asserted patents claim priority, issues relating to claim construction, infringement, validity (including secondary considerations), enforceability of the asserted patents, and the technical prong of domestic industry." (CPSt. at 6.). He was accepted without objection as an expert for the subject matter for which he was called to testify.

challenge the representativeness of the identified EndyMed Accused Products in their Pre-Hearing Brief. (RPBr. at 2.). Thus, any argument on this issue is deemed abandoned or withdrawn under Ground Rule 7.2. (GR 7.2.).

In Respondents' Pre-Hearing Brief, Jeisys contended that its accused needle tip components for the accused Potenza product are not representative of each other for purposes of claims 1 and 14 of the '836 patent's final limitation, "configured to cause coagulation around each electrode rather than coagulating between the electrodes" (the "coagulation" limitation). (RPBr. at 2.). However, Jeisys did not make this argument in its Initial Post-Hearing Brief. Thus, any argument on this issue is deemed waived under Ground Rule 10.1. (G.R. 10.1.). Moreover, Jeisys' contention is not unsupported by the evidence. For example, Jeisys' expert agreed that each of the needle tips identified in the Potenza 510(k) materials are used to coagulate tissue. He also acknowledged that he did not identify any contrary information in the 510(k) submissions (i.e., that would support his attempted Hearing testimony) that would distinguish among needle tips, or with respect to how different needle tips operate with the Potenza product. (Tr. (James F. Brennan III)[23] at 1193:17-1194:2; *see also* CPBr. at 24 (Potenza representativeness).).

Accordingly, Serendia has proven with virtually unrebutted evidence that the Accused Products it analyzed are representative of other Accused Products.

[23] When he testified during the Hearing as an expert witness on December 11, 2023, Dr. James Brennan was a Principal at Exponent, Inc. (RPSt. at App. F.). Respondents identified Dr. Brennan as an expert to testify about, *inter alia*, "the level of ordinary skill in the art, the background technology, the subject matter and file history of the Asserted Patents and related patents, non-infringement of the Potenza product, non-infringing alternatives, and the March 2012 Jeisys cense agreement." (RPSt. at 4.). He was accepted without objection as an expert witness on the subjects for which he was called to testify.

B. Serendia's DI Products

The alleged domestic industry product for all Asserted Patents is the "SylfirmX product, its related handpieces, and needles assemblies" ("Sylfirm X or "DI Product"). (Doc. ID No. 796488 (Disclosure of Domestic Industry Products) (May 15, 2023).).

VI. PERSON OF ORDINARY SKILL IN THE ART[24]

A. Definition of a Person of Ordinary Skill in the Art

Respondents proposed one definition of a person with skill in the art for all Asserted Patents, while Serendia proposed one definition for the Needle Assembly Patents and a somewhat similar definition for the Na Effect Patent.

For the Needle Assembly Patents, the Private Parties proposed similar levels of ordinary skill in the art. The Private Parties' proposed definitions are as follows (material differences identified in bold):

Complainant's Definition	**Respondents' Definition**
"(1) seven to ten years of experience with developing and/or using ***of tissues***, and (2) a related graduate engineering degree or M.D. and may have worked as part of a multidisciplinary team and drawn upon not only his or her own skills, but also would have taken advantage of certain specialized skills of others on the team when solving a technical problem." (CMBr. at 21 (emphasis added).).	"(1) 7-10 years of experience with developing and/or ***using treatment systems for delivery of electromagnetic radiation energy to skin or other tissues***, and (2) a related graduate engineering degree or M.D. The POSA may have worked as part of a multidisciplinary team and drawn upon not only his own skills, but also taken advantage of certain specialized skills of others on the team when solving a technical problem." (SMBr. at 14 (emphasis in original) (citing Ilooda's Supplemental Response to Serendia's Interrogatory No. 14 (June 14, 2023)); *see also* CMBr. at 21-22.).

[24] The legal standard for the level of ordinary skill in the art can be found in the *Markman* Order. (*See Markman* Order at 9-10.).

The Patent and Trial and Appeal Board ("PTAB"), in its decision denying institution of *inter partes review* ("IPR") of the '536 patent, adopted the same definition as the Respondents proposed in this Investigation. (*See* JXM-0016 (IPR2022-00378 Decision Denying Institution of *Inter Partes Review* of the '536 Patent) at 10 (noting that "Serendia does not contest" the proposed definition).). Although there does not appear to be a material difference between the Private Parties' proposals, Respondents' proposed definition for the Needle Assembly Patents has been adopted in view of the PTAB's decision and because Serendia did not dispute that definition during the IPR proceeding.

For the Na Effect Patent, Private Parties proposed substantively identical levels of ordinary skill in the art. The Private Parties' proposed definitions are as follows:

Complainant's Definition	**Respondents' Definition**
"(1) 7-10 years of experience with developing and/or using treatment systems for delivery of electromagnetic radiation energy to skin or other tissues, and (2) a related graduate engineering degree or M.D. and may have worked as part of a multidisciplinary team and drawn upon not only his or her own skills, but also would have taken advantage of certain specialized skills of others on the team when solving a technical problem." (CMBr. at 21.).	"(1) 7-10 years of experience with developing and/or using treatment systems for delivery of electromagnetic radiation energy to skin or other tissues, and (2) a related graduate engineering degree or M.D. The POSA may have worked as part of a multidisciplinary team and drawn upon not only his own skills, but also taken advantage of certain specialized skills of others on the team when solving a technical problem." (SMBr. at 15 (citing Ilooda's Supplemental Response to Serendia's Interrogatory No. 14 (June 14, 2023)); *see also* CMBr. at 21-22.).

The Private Parties' proposed definition for the Na Effect Patent has been adopted as follows: "(1) 7-10 years of experience with developing and/or using treatment systems for delivery of electromagnetic radiation energy to skin or other tissues, and (2) a related graduate engineering degree or M.D. and may have worked as part of a multidisciplinary team and drawn

upon not only his or her own skills, but also would have taken advantage of certain specialized skills of others on the team when solving a technical problem."

VII. U.S. PATENT NO. 9,480,836

A. Direct Infringement

1. Legal Standard: Literal Infringement[25]

"Determination of infringement is a two-step process which consists of determining the scope of the asserted claim (claim construction) and then comparing the accused product . . . to the claim as construed." *Certain Sucralose, Sweeteners Containing Sucralose, and Related Intermediate Compounds Thereof*, Inv. No. 337-TA-604, Comm'n Opinion at 36 (U.S.I.T.C., April 28, 2009) (citing *Litton Sys., Inc. v. Honeywell, Inc*., 140 F.3d 1449, 1454 (Fed. Cir. 1998)).

An accused device literally infringes a patent claim if it contains each limitation recited in the claim exactly. *Litton*, 140 F.3d at 1454. Each patent claim element or limitation is considered material and essential. *London v. Carson Pirie Scott & Co.*, 946 F.2d 1534, 1538 (Fed. Cir. 1991). In a Section 337 investigation, the complainant bears the burden of proving infringement of the asserted patent claims by a preponderance of the evidence. *Enercon GmbH v. Int'l Trade Comm'n,* 151 F.3d 1376, 1384 (Fed. Cir. 1998). If any claim limitation is absent, there is no literal infringement of that claim as a matter of law. *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1247 (Fed. Cir. 2000).

2. FDA Overview

As an initial matter, Serendia's expert, Mr. Crosby, explained in detail the steps ("Steps

[25] Serendia did not assert infringement against any of the Asserted Patent under the doctrine of equivalents.

1-5") of the U.S. Food and Drug Administration's ("FDA") 510(k) clearance process under the Food, Drug and Cosmetic Act. Title 21 U.S.C. § 800 et seq. requires device manufactures, who must register depending upon the program and device, to notify the FDA of their intent to market a medical device at least 90 days in advance.[26] The FDA 510(k) clearance process was required for the devices at issue in this Investigation, which Respondents' experts did not dispute or rebut. The FDA 510(k) clearance process is extensive and complicated. *See* 21 C.F.R. § 807. It involves a comprehensive review of safety and performance data for a given device, which may include submission of designs and labeling and various type of scientific evidence such as clinical tests and/or trials. A 510(k) premarket submission must demonstrate to the FDA that the device to be marketed is safe and effective. Mr. Crosby also described at length his own experience with such clearances, which, again, Respondents' experts did not contest or rebut.

As discussed below, Respondents made ***unequivocal*** representations to the FDA in their 510(k) submissions which demonstrate, again ***unequivocally***, that the Accused Products practice the asserted claims of the '836 patent, namely, the coagulation limitation recited in independent claims 1 (asserted) and 14 (not asserted), from which asserted claims 9 and 22 depend, and which Respondents hotly disputed.[27] Specifically, in

[26] The FDA's 510(k) product pre-clearance guidance required submissions, classification of products, and the FDA review process are described in detail on the FDA website. In addition to the testimony that was provided by witnesses during this Investigation, and the documents that the Parties submitted with respect to their own 510(k) product pre-clearance submissions to the FDA (which included detailed descriptions on clinical testing) with FDA responses thereto, judicial notice is taken here under FRE 602 of the FDA's guidance and information on the 510(k) submission and review process that is contained on the FDA website at https://wwwfda.gov. (*See also* CX-1071 (FDA Premarket Notification 510(k) Guidance).). Microneedling is specifically described in Title 21 CFR 878.4430.

[27] Claim 9 depends from claim 1, which is an apparatus claim. (JX-0007 at cls. 1, 9.). Claim 22 depends from claim 14, a method claim which corresponds to claim 1. (*Id.* at cls. 14, 22.).

[redacted] (CX-0166C (Potenza 510(k)) at 22 [redacted] (emphases added); CX-0339C (Intensif 510(k)) at 23 [redacted] (emphases added).).

For the following reasons, which elaborate on the points made above, Respondents' feeble and un-creditable attempts to discredit the explicit language of the ***certified*** representations they themselves made to the FDA in their 510(k) submissions, to advance their non-infringement arguments in this Investigation, have been found to be neither credible nor persuasive, not to mention disingenuous and potentially ethically questionable.

a) FDA 510(k) Clearance Process

During the Hearing, Mr. Crosby provided the following description of Steps 1-5 of the FDA 510(k) pre-clearance process for electrosurgical medical devices. Mr. Crosby summarized these steps in his demonstratives, which are replicated below in Figures 7 and 8.

> Q. I'd like to move on to another topic and ask you a few questions about the FDA clearance process. I am on slide 110 now.
>
> Can you tell us, at a high level, what does the device development process look like for the FDA?
>
> A. The device development process is governed by Title 21 of the Code of Federal Regulations, which is a lot of language. The FDA helpfully publishes their summary of the device development process on their webpage. And they describe it as having five steps, listed here.
>
> Q. What are they?
>
> A. Step 1 is device discovery and concept, which is research and development for

new device, which begins in the laboratory.

Step 2 is preclinical research usually on a prototype device, where we would subject the device to laboratory testing and engineering testing, perhaps animal, testing to answer basic questions about safety.

Once we have adequate information, we would then do some sort of human testing to make sure they are safe and effective under pathway to clearance step 3. All of that information is assembled and submitted to the Food and Drug Administration for review.

The FDA review teams in step 4 thoroughly examine all that submitted data and make a decision whether or not to provide clearance.

And after the FDA provides clearance to market, the sponsor, the company, has an obligation to comply with the FDA mandated postmarket safety monitoring requirements.

Q. For products that have already been approved but sponsor company is seeking a new indication, what steps would they have to go through for that approval process for the new indication?

A. At least steps 3, 4, and 5. If the new indication requires a modification, perhaps some of the other ones too.

Q. Are these steps regulated by the FDA?

A. They are indeed. The FDA regulates, not only what you have to do, which is listed in this process here, but how you have to do it and who has to do it.

Q. In terms of the who, who is generally involved in the clearance process for devices like the products that we have been discussing in this investigation?

A. The who includes at least the members of the company, the clinical trials people, the R&D people, the quality assurance people. There are often external consultant, there may be regulatory consultants. There may be clinical time frame consultants. There may be engineering consultants. Companies often rely on information and opinions from medical practitioners. They are usually referred to as key opinion leaders. Sometimes they are assembled into a medical advisory board. So the sponsor will utilize multiple external and internal people to support their 510(k) application.

Q. In your experience, is this an involved and expensive process?

A. I've yet to meet to a doctor who works for nothing, so this is very expensive process, yes.

Q. Focusing on step 5 of the device development process, what are some of the activities that companies have to engage in to meet that step?

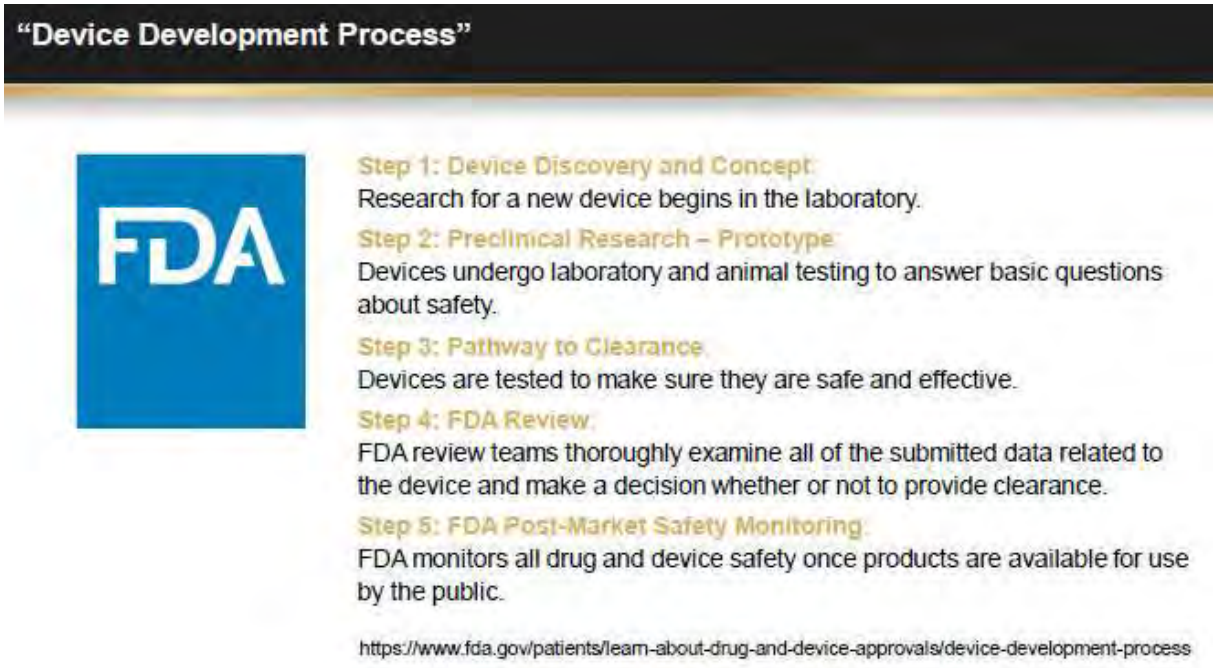
A. The fundamental question here to be answered is, does the real-world performance of a device cleared for market match the performance of the controlled environment of the clinical trial. So monitoring real world performance is one of the key obligations of the sponsor.

And that involves reviewing and responding to complaints and feedback from the field. If there are issues, they need to be reported through the medical device reporting system maintained by the FDA.

The company is required to train users to use their device. You wouldn't want to fly in a plane when the pilot announced it was his first flight. It is necessary to maintain an adequate supply chain and distribution management so you know where your products are, and that they are delivered in a safe manner and installed correctly. And, finally, it's absolutely crucial to maintain traceability. It is an obligation of the sponsor to know where every single product is at every time.

(Tr. (Crosby) at 638:21-641:24.).

Figure 7: Crosby Demonstrative Listing Steps of FDA Device Development Process



(CDX-0001C.0110 (citing FDA web page).).[28]

[28] The contents of CDX-0001C.0110 copy verbatim Steps 5 identified in the cited FDA web page.

Figure 8: Crosby Demonstrative Elaborating on Step 5



(CDX-0001C.0111.).

Mr. Crosby also explained at length his experience with seeking FDA 510(k) clearance for such medical devices.

> Q. . . . [C]an you please describe or highlight an experience or two of yours in which you were involved in seeking FDA 510(k) clearance for a medical device?
>
> A. Sure. At NeoVision, which was a device for three dimensional ultrasound imaging of breasts to enable fine needle biopsy, I collected all the engineering drawings and assembled them. I collected the -- well, we conducted some human clinical trials, and I recorded and collected the data from that.
>
> I assembled the entire collection of information, including additional information about our quality system and submitted it to the FDA and interacted with the FDA until we got 510(k) clearance.
>
> Would you like another example?
>
> Q. One more would be great. Thank you.
>
> A. Sure. So in Ischemia Technology, which is an in vitro diagnosis device, also subject to the 510(k) regulations, we put together the dossier of information, which is probably about a thousand pages, of the way the device is designed, the way it works, the way it's manufactured, the way quality is assured, which is the engineering technical background.
>
> We put together information from a clinical trial that I designed and ran from

multiple patients. We put together information about how the product would be manufactured and the quality of that manufacturing would be maintained, and we submitted that to the FDA.

Ironically, in this case, the FDA changed their mind and said they wanted a PMA, so we had to pivot and redo it as a PMA application, which I did personally. I submitted the first two of three modules of the PMA, and then the FDA changed their mind again and said that it's okay to be a 510(k). So I resubmitted the 510(k), and we eventually got 510(k) clearance.

Q. You used --

JUDGE MCNAMARA: Pardon me. What is the PMA?

THE WITNESS: I beg your pardon?

JUDGE MCNAMARA: Could you define PMA, please?

A. Yes. I beg your pardon. The FDA classifies device according to their risk. PMA stands for premarket approval, and that's a pathway to market, which requires FDA to evaluate the safety and efficacy of a product as opposed to what's called the 510(k) process, which requires the FDA to evaluate substantial equivalence to a product that's already marketed.

Q. Are you familiar with clinical trial protocols for medical devices?

A. Yes. I'm familiar with clinical trial protocols. I've authored multiple clinical trials. I even have a patent on how to run a clinical trial.

Q. What goes into putting together a clinical trial protocol?

A. Are you asking what is my personal experience, how many have I done?

Q. I'm asking, based on your personal experience, what goes into writing a clinical trial protocol?

A. A clinical trial protocol usually involves consultation with multiple external parties, usually potential customers, key opinion leaders, perhaps a medical advisory board. It often involves consultation with regulatory consultants, either external or internal, to figure out the regulatory pathway to market. It often involves consultation with biostatisticians to figure out the numbers required for the clinical trial to prove the hypothesis one way or another.

It involves interacting with an Institutional Review Board or IRB, sometimes called an ethics committee, to get permission to collect data on human patients and perform procedures on human patients. It involves training the people who will be conducting the clinical trial. It involves negotiating clinical trial contracts with

each of the parties. Often the institution and the investigator have separate contracts.

So a clinical trial would involve, say, ten investigators at ten sites will involve 20 contracts. And then to conduct a clinical trial involves following the training and repeat training to ensure the trial is done properly, sending representatives to the clinical trial site to make sure the trial is conducted properly, and then monitoring the data to ensure that it meets the clinical trial requirements.

Q. In your experience in preparing 510(k) submissions for medical devices, did you consult any materials published or provided by the FDA for that process?

A. Some of the material is published by the FDA, if I understand your question correctly. Most of the material submitted by the company to the FDA remains company confidential.

Is that what you're asking?

Q. A slightly different question. My question goes to preparing the materials for submission to the FDA.

A. Yes.

Q. Does the FDA provide any guidance or materials publicly at companies that you've consulted in preparing those submissions?

A. I see. I misunderstood the question. Sorry.

Yes, the FDA publishes multiple guidance documents in multiple fields. There are thousands out there. And it's important to follow the guidance in the documents if you want to get your product cleared.

Q. Why is it important?

A. Because if you don't follow the guidance, the FDA is unlikely to clear it.

Q. I believe you talked about the FDA device development process, the five steps that the FDA provides summarizing that process.

Do you recall that?

A. I do.

Q. In your experience seeking FDA approval for medical devices, did you follow each of the five steps that the FDA publishes for that process?

A. Yes, I did.

Q. Why?

A. Well, the Code of Federal Regulations that governs the FDA mandates certain numbers of these steps to be done, and the guidance that the FDA publishes on their webpages, as I showed in my slide, is a high level list of the steps. There are thousands, if not tens of thousands, of steps within those basic steps. They all have to be done.

Q. The fifth step is FDA postmarket safety monitoring, right?

A. Yes.

Q. For that fifth step, would a company still be undertaking product development on the FDA cleared device?

A. I'm sorry? You'll have to ask me again.

Q. Sure. I'll scoot back over. I apologize. So talking about the fifth step in the FDA device development process, could a company still be undertaking product development on an FDA cleared device when it's in the fifth step of the FDA device development process?

A. I think you're asking could a company undertake product development while a product is cleared for marketing?

Q. Correct.

A. Yes, but it would be difficult to introduce a product with different configuration to the market without getting regulatory clearance, and the FDA provides guidance on how much a company can do without seeking regulatory clearance in advance, and how much has to be done. It's a judgment call.

(Tr. (Crosby) at 663:6-668:22.).

Respondents did not dispute ***any*** aspects of Mr. Crosby's testimony explaining this regulatory clearance process or raise ***any*** arguments about this general procedure. (*See, e.g.*, RPBr. at 16-18; RBRr. at 7-19.). On cross-examination, with respect to the specific issue of the regulatory clearance process, Respondents only asked Mr. Crosby the following questions, none of which were directed to specifically rebutting Mr. Crosby's direct testimony with respect to the same.

Q. . . . Earlier today you testified about the FDA process for approving medical devices, right?

A. Yes.

Q. And you talked about the five steps that are involved in that, correct?

A. This is the FDA's explanation of some of the -- of the five steps as they see it.

Q. Once a device receives a 510 clearance, it can be marketed consistent with that clearance, right?

A. The 510(k) clearance, yes.

Q. And the FDA clearance only regulates how a product can be marketed through its label, right? It doesn't preclude, for example, physicians using a device for off label purposes.

A. The FDA does not regulate the practice of medicine. It regulates the devices that medical practitioners use.

Q. Okay. And so once a product is cleared by FDA, you then move into step 5 on slide CDX 1C.110, right?

A. Yes.

Q. And do you understand that the party that was responsible for getting the domestic industry product, the Sylfirm X, cleared through steps 1 through 4, that was the Korean manufacturer, ER, are you aware of that?

A. I read the 510(k) application. I don't recall who was responsible for all the steps.

Q. You're not giving an opinion today that Benev was the party that was responsible for getting the Sylfirm X cleared in the United States, right?

A. That's not part of my assignment, no.

Q. And then you testified about a bunch of things that can happen after the product is cleared for additional indications under step 5.

Do you remember that?

A. Yes.

Q. You didn't testify today about any of the actual work that Benev has done to secure clearances for those additional indications, right?

MR. MCCRUM: Okay. That's actually all I wanted to confirm, Your Honor.

JUDGE MCNAMARA: Okay. Thank you.

MR. MCCRUM: I have no further questions, Mr. Crosby.

(Tr. (Crosby) at 656:23-658:24.).

b)

Respondents unequivocally . (Tr. (van der Weide) at 292:3-295:19; CDX-0004C.0056-67 (van der Weide demonstratives); CX-0166C.0017 (Potenza 510(k)) (emphasis added), 0022 (Potenza 510(k)); CX-0339C.0013 (Intensif 510(k)) (emphasis added), 0017 (same), 0023 (Intensif 510(k)).).

Figure 9: Respondents' Representations to FDA in 510(k) Submissions with Respect to Intended Use



(CDX-0004C.0057 (excerpting CX-0166C.0017 (Potenza 510(k)) (annotated); CX-0339C.0013 (Intensif 510(k)) (annotated)).).

In their . (Tr. (van der Weide) at 295:20-296:7; CX-0166C.0045 (Potenza 510(k)) (emphasis added); CX-0339C.0048 (Intensif 510(k)) (emphasis added).).

Figure 10: Respondents' Representations to FDA in 510(k) Submissions



(CDX-0004C.0064 (excerpting CX-0166C.0045 (Potenza 510(k)) (annotated); CX-0339C.0048 (Intensif 510(k)) (annotated)).).

Notably, each of the . As depicted

below, [redacted] (Tr. (van der Weide) at 292:3-295:19; CDX-0004C.0056-67; CX-0166C.0017, 0022 (Potenza 510(k)); CX-0339C.0013, 0023 (Intensif 510(k)).).

Figure 11: Verifications of Respondents' 510(k) Submissions





(*See* CDX-0004C.0061 (excerpting CX-0166C.0017, 0022 (Potenza 510(k)) (annotated)); CDX-0004C.0063 (excerpting CX-0339C.0013, 0023 (Intensif 510(k)) (annotated)); *see also* Tr. (van der Weide) at 293:4-294:2 (testifying that Respondents' arguments that their products do not cause coagulation is "at variance" with "sworn representation[s] before the FDA").).

As Staff pointed out, even Respondents' expert, Dr. Brennan, would not go so far as to say that Respondents' FDA submissions and product literature are not truthful or accurate, or that those documents falsely represented the products.





(Tr. (Brennan) at 1191:1-1192:1; *see also id.* at 1192:2-1198:11.).

Moreover, Respondents' expert, Dr. Bérubé, agreed that it is important to avoid misleading the audience (medical professionals and patients) in marketing FDA-approved devices, such as the Accused Products.

> Q. . . . Yes or no, Dr. Berube, you agree that it's important to avoid misleading people in marketing an FDA approved device to the public, right?
>
> A. Yes.
>
> Q. Okay. And you agree that the audience for marketing FDA approved RF microneedling devices includes medical professionals and potential patients, right?
>
> A. Right.

(Tr. (Bérubé) at 1270:1-9.).

Unable to completely dismiss these explicit admissions to the FDA, during the Hearing, Respondents ineffectively attempted to suggest that their sworn representations were potentially ***inaccurate***.

> MR. MCCRUM: I am suggesting, Your Honor, the Respondents submitted 510(k) statements based on a predicate product, and that it is not uncommon that, when you do that, that you are taking portions of that and cutting it into your own.
>
> JUDGE MCNAMARA: On this one, I suggest you move on. I will talk to you about this later. If you have an offer of proof that is somehow relevant and suggests

> that the -- ***what I'm hearing you say is the 510(k) summaries, that the parties themselves submitted to the FDA, are not accurate***. Is that what you are saying?
>
> MR. MCCRUM: ***I am saying there's evidence to suggest that***, Your Honor.
>
> JUDGE MCNAMARA: Well, if that is the case, that's on Respondents, and I think you have to think about what it is they submitted to the FDA and what it is you're saying here.
>
> MR. MCCRUM: Okay.
>
> JUDGE MCNAMARA: I think you have to think through the implications of this.
>
> MR. MCCRUM: Understood, Your Honor.

(Tr. at 438:3-23 (emphases added).).

In what appeared to be another attempt to further undermine their own sworn FDA filings, their expert, Dr. Woloszko (whose direct examination was presented, and thereby endorsed, by all Respondents), resisted answering whether a company would submit misleading information to the FDA.

> Q. . . . You would not give the FDA misleading information, right?
>
> A. You give FDA the information they require in the form that they require.
>
> Q. And you would not give the FDA misleading information, correct?
>
> A. Again, you give FDA the information they ask for. You answer the question.
>
> Q. And when you answer the question, you don't give them misleading information, do you.
>
> A. ***I'm not answering that question***.

(Tr. (Woloszko) at 1024:18-1026:3 (emphasis added).).

Following that response, Dr. Woloszko was impeached with his deposition testimony where he had expressly answered "***definitely not***" in response to the question, "[b]ut you wouldn't give the FDA misleading information, right?"

> Q. Okay. Well, you did answer it at the deposition, so let's take a look at that.

> Can we go to CX 3064 at 35. This is the September 14th deposition, page 264, lines 1 3.
>
> But you wouldn't give the FDA misleading information, right? The answer, "***definitely not***."
>
> A. Yes.
>
> Q. Did I read that correctly?
>
> A. You don't want to on purpose lead the FDA to believe something which would be wrong, yes, true. You would not volunteer information even if it may be in your favor if they don't ask it. That's -- they don't ask for it.
>
> Q. But you understand that the FDA 510(k) submissions are certified to be truthful and accurate, right?
>
> A. Absolutely.
>
> Q. You would not expect that the Respondents would give the FDA misleading information, right?
>
> A. ***You would not lie to FDA, definitely not***.

(Tr. (Woloszko) at 1026:4-23 (emphases added).).

As Staff noted, either Respondents were contending that their documents do ***not*** say what they plainly do, or Respondents were contending that their representations to the federal government and to the public contain ***false*** statements and information. (SBr. at 25.). Either way, Respondents' attempts to dismiss or walk away from how ***they have characterized the Accused Products to the FDA*** are not only unpersuasive, but also, run dangerously close to crossing ethical lines of transparency that were required when making representations to the FDA to obtain regulatory clearance of the Accused Products.

3. Infringement Overview

Serendia asserted that the Accused Products directly infringe claims 1, 9, and 22 of the '836 patent. (CBr. at 11.). For the reasons discussed below, Serendia has met its burden and

proven that the Accused Products directly infringe claims 1, 9, and 22.

4. The Accused Products Practice Claim 1 of the '836 Patent

a) 1[pre]: "A skin treatment apparatus, comprising"

Each Accused Product is a "skin treatment apparatus," which Respondents admitted. (Tr. (van der Weide) at 280:15-25, 281:8-13; CDX-0004C.0024, 0026; CX-0876C.0002-3, 0011 (EndyMed RFA Resp.).).

Respondents did not contest that the Accused Products are skin treatment apparatuses in their Pre-Hearing Brief or Post-Hearing Reply Brief. (RPBr. at 12-19; RRBr. at 4-42.). Thus, any argument on this issue is deemed abandoned, withdrawn, and/or waived under Ground Rules 7.2 and 10.1.

For the foregoing reasons, Serendia has proven by a preponderance of evidence that the Accused Products meet the preamble of claim 1 of the '836 patent.

b) 1[a]: "a plurality of electrodes, the electrodes being bipolar and configured to be insertable into skin to be treated"

The claim term "a plurality of electrodes" was construed to have its plain and ordinary meaning: "two or more electrodes (which can be needles or pins)." (*Markman* Order at 45.). Respondents admitted, and inspections demonstrate, that the Accused Products include "two or more electrodes (which can be needles or pins)." (Tr. (van der Weide) at 281:14-282:11; CDX-0004C.0027-30; CX-0876C.0011-12 (EndyMed RFA Resp.); CX-2939C.0008, 0014-20, 0028-32 (Inspections).). Additionally, Respondents' marketing materials and corporate deposition testimony confirm that the Accused Products meet this limitation. (CPX-0071 (Potenza Video) at 0:08-0:10; CX-1050C (Kyoung Ho An Dep. Tr.)[29] at 45:14-19, 47:20-50:12, 52:1-11, 65:15-

[29]

66:3; CPX-0067 (Intensif Video) at 0:17, 0:45; CX-1056C (Sima Witman Dep. Tr.)[30] at 113:11-114:8.).

In their Pre-Hearing Brief, Respondents only disputed that this aspect of limitation 1[a] was met under Respondents' proposed construction limiting the term to non-insulated electrodes, which was rejected. (RPBr. at 5-6; *Markman* Order at 45.). Thus, Respondents abandoned or withdrew any argument that this aspect of limitation 1[a] is not met under the adopted construction. (*See* G.R. 7.2.). Moreover, Respondents did not contest this aspect of limitation 1[a] in their Post-Hearing Reply Brief. (RRBr. at 4-42.). Accordingly, any argument on this issue is deemed waived under Ground Rule 10.1.

With respect to the claim term "electrodes being bipolar," the term was given its construed to have its plain and ordinary meaning: "electrodes change or alternate between being positive or negative as the current alternates between them (as opposed to a monopolar configuration where current flows from one or more electrodes that deliver current to one or more ground electrodes)." (*Markman* Order at 40.). Respondents represented that [redacted]. (RX-2015C (Potenza 510(k) Summary); CX-0339C (Intensif 510(k)).). As Serendia noted, the FDA defines "bipolar" as "[a]n electrosurgical device in which the current flows between two active electrodes placed in close proximity," consistent with the adopted construction. (CBr. at 12 (citing CX-1071 (FDA Premarket Notification 510(k) Guidance) at 26).).

[redacted] (*See, e.g.*, CX-1050C (An Dep. Tr.) at 13:21-14:17.). [redacted] as a corporate representative. (*Id.* at 11:11-14.). [redacted] also testified in his personal capacity. (*Id.*).

[30] [redacted] (CX-1056C (Witman Dep. Tr.) at 32:19-33:10.). EndyMed designated [redacted] to testify with respect to certain topics on behalf of EndyMed. (*Id.* at 22:9-12.).

Serendia's expert, Dr. van der Weide, testified that he reviewed Respondents' FDA filings, internal documents, and corporate representatives' testimony, and concluded that the Accused Products practice this limitation. (Tr. (van der Weide) at 282:12-285:2, 288:25-289:5; CDX-0004C.0032-34, 44-47; CX-2906C.0004, 0016 (Potenza Histology Presentation); CX-1052C (Lowinn Kibbey Dep. Tr.)[31] at 18:3-5; CX-1050C (An Dep. Tr.) at 97:1-5; CX-0233C.0049 (Potenza Slides); CX-0805.0009 (Potenza Physician Brochure); CX-1056C (Witman Dep. Tr.) at 168:7-170:2, 228:3-5.). He also measured the Accused Products' waveforms and confirmed that they practice this limitation. (Tr. (van der Weide) at 284:18-285:2; CDX-0004C.0034; CX-2939C.0017-20, 0030-32 (Inspections).).

The combined term "a plurality of electrodes, the electrodes being bipolar," was construed to exclude "the Intracel configuration (alternating rows of commonly-polarized electrodes)." (*Markman* Order at 53-54.). Dr. van der Weide testified that he inspected the electrode configurations for Accused Products and determined that they are not the Intracel configuration. (Tr. (van der Weide) at 287:20-289:5; CDX-0004C.0044-47; CX-0064C.0002-3 (EndyMed Rog. Resp.); CX-0233C.0049 (Potenza Slides).). In their Pre-Hearing Brief and Post-Hearing Reply Brief, Respondents did not dispute that the Accused Products practice the "electrodes being bipolar" part of limitation 1[a] and did not contend that any of them have the Intracel configuration. (RPBr. at 6-10; RRBr. at 4-42.). Thus, any argument on this issue is deemed abandoned, withdrawn, and/or waived under Ground Rules 7.2 and 10.1.

Lastly, Serendia demonstrated, and Respondents did not dispute, that the plurality of

[31] [redacted] (CX-1052C (Kibbey Dep. Tr.) at 16:6-9.).

electrodes are "configured to be insertable into skin to be treated."[32] (Tr. (van der Weide) at 289:14-20; CDX-0004C.0048-49; CX-2939C (Inspections).). Accordingly, any argument on this issue is deemed abandoned, withdrawn, and/or waived under Ground Rules 7.2 and 10.1.

For these reasons, Serendia has proven by a preponderance of evidence that the Accused Products meet this limitation of claim 1 of the '836 patent.

c) 1[b]: "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"

The Accused Products have a "radio frequency (RF) generation module, the RF generation module electrically coupled to the plurality of electrodes," which Respondents admitted. (CX-0925C.0012 (Potenza RFA Resp.); CX-0876C.0009 (EndyMed RFA Resp.); Tr. (van der Weide) at 289:21-290:19; CDX-0004C.0050-52.). Respondents did not dispute that the Accused Products meet this aspect of limitation 1[b]. (RPBr. at 6-19; RRBr. at 4-42.). Accordingly, any argument on this issue is deemed abandoned, withdrawn, and/or waived under Ground Rules 7.2 and 10.1.

The term "an Alternating Current (AC) RF signal" was given its plain and ordinary meaning: "an electrical signal with oscillating current (current alternating polarities), and having a radio frequency (measured in MHz)." (*Markman* Order at 62.). As Dr. van der Weide testified, Respondents' admissions, documents, FDA submissions, and corporate testimony demonstrate that the Accused Products practice this aspect of limitation 1[b]. (Tr. (van der

[32] The term "configured to" was construed to have its "[p]lain and ordinary meaning: adapted to." (*Markman* Order at 39.).

Weide) at 290:20-292:2; CDX-0004C.0053-55; CX-0925C.0012 (Potenza RFA Resp.); CX-0233C.0047 (Potenza Slides); CX-0166C.0032-33 (Potenza 510(k)); CX-1050C (An Dep. Tr.) at 56:4-57:18, 58:19-60:1; CX-0876C.0009-10 (EndyMed RFA Resp.); CX-0703C.0034 (EndyMed Rpt.); CX-1056C (Witman Dep. Tr.) at 77:16-19, 81:13-16, 170:4-21; CX-0696.0012, 0058-59 (EndyMed Manual).). Dr. van der Weide also measured the Accused Products' waveforms, confirming that they provide AC RF signals. (Tr. (van der Weide) at 290:20-292:2; CDX-0004C.0053-54; CX-2939C.0010-13, 17-20, 30-32 (Inspections).). Respondents only disputed that the Accused Products practice this limitation under their proposed construction, which was rejected. (RPBr. at 10-12; *Markman* Order at 56-62.). Accordingly, Respondents abandoned or withdrew any argument on this issue under Ground Rule 7.2.

The term "electrodes configured to cause coagulation around each electrode rather than coagulating between the electrodes" (the "coagulation term") was construed to have its plain and ordinary meaning: "two or more electrodes adapted to cause coagulation around each electrode without such coagulation fully extending from one electrode to another electrode." (*Markman* Order at 40.). As discussed below, the evidence, including Respondents' own, verified representations to the FDA in seeking regulatory approval for the Accused Products, Respondents' internal and external product literature, and expert testimony from Dr. Goldberg and Dr. van der Weide, demonstrate that the Accused Products satisfy the coagulation limitation.

As addressed above in Section VII.A.2, Respondents [redacted] (Tr. (van der Weide) at 292:3-295:19; CDX-0004C.0056-67; CX-0166C.0017 [redacted]

(emphasis added), 0022 (Potenza 510(k)); CX-0339C.0013 [redacted] (emphasis added), 0017 (same), 0023 (Intensif 510(k)).). Respondents also [redacted]. (Tr. (van der Weide) at 295:20-296:7; CDX-0004C.0064; CX-0166C.0045 (Potenza 510(k)) [redacted] (emphasis added); CX-0339C.0048 (Intensif 510(k)) [redacted] (emphasis added).). Each of the [redacted] (Tr. (van der Weide) at 292:3-295:19; CDX-0004C.0056-67; CX-0166C.0017, 0022 (Potenza 510(k)); CX-0339C.0013, 0023 (Intensif 510(k)).).

Serendia's expert, Dr. Goldberg, reviewed the evidence and concluded that the Accused Products are configured to cause coagulation around each electrode without such coagulation fully extending between the electrodes.[33] (Tr. (Goldberg) at 173:3-175:25 (Potenza), 179:14-24 (EndyMed); CDX-0002C.0024-30, 0038-40.). For each Accused Product, Dr. Goldberg compared the maximum width of electrocoagulation zones measured during preclinical tests with the minimum distance between needles, which demonstrated that in ***every*** instance the coagulation zones did ***not*** fully extend between neighboring electrodes. (Tr. (Goldberg) at 173:3-175:8, 179:17-20; CDX-0002C.0025-29, 38-40; CX-0172C.0004 (Potenza Performance Rpt.); CX-2907C.0019-20, 0023 (Potenza Eval.); CX-0690C.0007-8 (EndyMed Description).).

[33] Serendia claimed accurately that Dr. Goldberg was the only dermatologist who testified, and the only expert who used the Accused Products in a clinical setting. (CBr. at 16; *see also* SBr. at 36.).

As Dr. Goldberg testified, internal documents and deposition testimony from Respondents' corporate representatives confirm that the Accused Products are configured to cause coagulation around each electrode without such coagulation fully extending between electrodes. (Tr. (Goldberg) at 173:12-22, 179:25-180-13; CDX-0002C.0025, 0039.).

For example, with respect to the [redacted] (CX-0690C.0008) [redacted]. (CX-1056 (Witman Dep. Tr.) at 178:19-179:7.).

Similarly, for the Potenza Products, an internal evaluation concluded that [redacted] (CX-2907C.0023 (Potenza Eval.); *see also id.* at 18 [redacted], 19 (pictures of same).). EndyMed's internal evaluation explained that [redacted] (*Id.* at 18.).

After the Hearing, Jeisys/Cynosure specifically argued that the Potenza "S-49 tip does not produce the claimed coagulation."[34] However, this is directly contrary to: (i) their own test results which reflect and support the opposite conclusion, i.e., that it does (CX.2907.0019); and (ii) how they tell clinicians their "S tips" function (CX-0962.0018 (Potenza Clinical Ref. Guide) (depicting "horizontal areas" of "coagulation" for "S-Tips" around each needle and not between needles)).).

[34] Respondents Jeisys Medical, Inc.'s and Cynosure, LLC's Reply to Staff's Post-Hearing Notice, Doc. ID No. 810861 at 3 (Dec. 21, 2023).

As Dr. Goldberg testified credibly, Jeisys/Cynosure market their products as concentrating energy and/or causing coagulation around needle electrodes, rather than between them, which matches how he understands these products work. (Tr. (Goldberg) at 175:9-25; CDX-0002C.0030 (Goldberg); CPX-0060 (Potenza YouTube) at 1:41.). Dr. Goldberg also credibly testified that the evidence he reviewed (discussed above), aligns with his personal experience with the EndyMed Products in his practice. (Tr. (Goldberg) at 180:21-24.).

Dr. van der Weide similarly reviewed the evidence that Dr. Goldberg reviewed and described and considered the testimony of Drs. Goldberg and Na. Dr. van der Weide concluded that the Accused Products practice this limitation. (Tr. (van der Weide) at 296:10-297:25; CDX-0004C.0066-67, 0083.).

Specifically, EndyMed EndyMed's responses to Serendia's Request for Admission ("RFA") No. 25 is reproduced below.

Figure 12: EndyMed Response to RFA

(CDX-0004C.0066 (citing CX-0876C.0017-18 (EndyMed RFA Resp.)).).

EndyMed's admission is consistent with the weight of other evidence that conclusively reflect how EndyMed's Accused Products operate. (*See, e.g.*, Tr. (Goldberg) at 179:18-180:24,

183:1-9 (EndyMed Accused Devices are configured to cause coagulation around each electrode rather than between electrodes); Tr. (van der Weide) at 295:14- 297:11 (similar).). For example, in Order No. 49, which denied EndyMed's motion to withdraw its response to RFA No. 25, EndyMed's corporate testimony was found to "align[] with EndyMed's admission in its RFA No. 25 Response that the Accused Products have been used to apply energy to cause coagulation around each electrode." (Order No. 49 at 6-7 (Nov. 30, 2023) (citing CX-1056 (Witman Tr.) at 181:8-182:1, 185:8-19).). The admission also [redacted]. (CX-3411.0001, 0003 (EndyMed article); Tr. (Woloszko) at 1028:22-1029:5, 10:29:22-1030:4, 1031:17-22.).

In addition, Dr. van der Weide [redacted]. (Tr. (van der Weide) at 298:1-302:19; CDX-0004C.0069-73; CX-2936C (Heatmapping Tests).). Those [redacted] (Tr. (van der Weide) at 302:6-9; CDX-0004C.0072.). Dr. van der Weide's testing was published as part of a peer-reviewed study and was presented at an IEEE conference in Belgium. (Tr. (van der Weide) at 321:6-24; CX-3055 (IEEE Article).). Moreover, as Dr. van der Weide testified, the [redacted][35] (Tr. (van der Weide) at 302:10-19.).

[35] Serendia represented accurately that its expert, Dr. van der Weide, was the only expert who tested the Accused Products. (CBr. at 19 (citing Tr. (van der Weide) at 299:10-13).).

Respondents contended that none of their Accused Products infringe the coagulation limitation for three (3) reasons: (1) Serendia improperly relied on Respondents' submissions to the FDA and Respondents' product literature to prove infringement, and/or that those documents do not demonstrate the claimed coagulation around (but not between) electrodes; (2) Dr. van der Weide's testing evidence is unreliable and not probative of infringement; and (3) all of their products cause skin temperature to increase between electrodes as the current moves between electrodes such that the recited coagulation necessarily occurs between electrodes. (*See* RPBr. at 12-19.). These arguments are meritless for the following reasons.

First, as discussed above in Section VII.A.2, Respondents' arguments with respect to their own documents are premised on dismissing or walking away from (i.e., ***contradicting***) how ***they have characterized the Accused Products to the FDA***, in their internal documentation, and to the public. As Staff noted, either Respondents are contending that their documents do not say what they plainly do, or Respondents are contending that their representations to the federal government and to the public contain false statements and information. (SBr. at 25.). As noted above in Section VII.A.2, [redacted]. (*See* Fig. 11, *infra*.).

Respondents asserted that "the pre-clinical testing Respondents submitted to the FDA, while consistent with the FDA's guidelines, is not evidence of 'coagulation around each electrode without such coagulation fully extending from one electrode to another electrode' in the skin." (RRBr. at 15.). Dr. Brennan testified that "kidney, liver, and [the] muscle of a cow" used for preclinical testing of the Potenza does not support infringement because it is not "human skin." (Tr. (Brennan) at 1157:9-24.).

The record evidence does not support Respondents' position. Indeed, is directly contrary to Dr. Brennan's testimony. Notably, the FDA accepts testing "performed on ***ex vivo animal tissue***" to clear RF microneedling devices for use on human skin and in fact recommends using "liver, kidney, and muscle tissue," with which Respondents' expert agreed.[36] (CX-1071.0017 (FDA Premarket Notification 510(k) Guidance) ("during testing in *ex vivo* tissue . . ."); *id.* ("during *ex vivo* tissue testing . . ."); Tr. (Woloszko) at 1023:11-14 ("Q. You understand that the FDA accepts histology on animal tissue as part of the information for clearing RF microneedling devices, right? A. Correct."), 1024:9-15; *see also* Tr. (van der Weide) at 330:16-331:2; CDX-0004C.0080.). Dr. Goldberg, Serendia's expert, also confirmed both he and the FDA rely on animal testing as indicative of how a product will function on humans. (Tr. (Goldberg) at 168:6-9.).

[redacted]. (CX-0174C.0005 [redacted]; CX-2907.0020 (Potenza Eval.) (depicting

[36] Respondents argued that the FDA "*ex vivo* animal tissue is ***not*** the same as skin" because in 2020, the FDA "amended its guidance documents to require, for 'specific soft tissue indications,' that 'testing should be performed in tissues relevant to the specific indications for use.'" (RRBr. at 15-16 (citing RX-0512.0016 (FDA Premarket Notification 510(k) Guidance); CX-1071.0016 (FDA Premarket Notification 510(k) Guidance).). Respondents' reading of the quoted language from the FDA Guidelines is not consistent with language on the next page the FDA Guidelines specifically referencing "testing on *ex vivo* tissue" and "*ex vivo* tissue testing," which strongly suggests the contrary. (CX-1071.0017 (FDA Premarket Notification 510(k) Guidance).).

[redacted].).[37]

Serendia also noted that during the Hearing, Dr. Woloszko testified that: (i) the FDA Premarket Notification Guidance distinguishes "coagulation" from "coagulation necrosis"; (ii) the '836 patent is directed to "coagulation necrosis"; and (iii) Respondents' FDA filings do not use that term. (CRBr. at 24.). Dr. Woloszko's testimony to which Serendia cited is reproduced below.

> Q. Does the FDA provide a definition for coagulation?
>
> A. Yes, they do. For FDA coagulation is used for liquid, especially blood, and basically this is very – this is very similar to hemostasis, although it's a different process.
>
> And they say this is considered separate from coagulation necrosis. Coagulation necrosis, as explained on the line below, is when necrosis will affect cells or tissue and convert them into a dry, opaque mass, which is basically what we have discussed over the past several days, as tissue coagulation.
>
> So tissue coagulation, as it says, is a result of protein coagulation. That is what we have discussed all along. We have not discussed so far liquid or blood coagulation.
>
> Q. So there's a difference between coagulation on the one hand and coagulative necrosis on the other?
>
> A. Yes.
>
> Q. And, generally speaking, are the '836 patent family directed to coagulation necrosis as opposed to coagulation?
>
> A. That's what FDA considers as coagulation necrosis.
>
> Q. And are Respondents' products cleared for use as coagulation devices?
>
> A. Yes.
>
> Q. Did the FDA clear the Respondents' products for coagulation necrosis?

[37] Serendia noted that "[i]t is unclear where the study involving human skin was conducted." (CBr. at 31 n.22.). Dr Na testified that he tested animal tissue to develop the invention because testing human tissue is "not ethical." (Tr. (Na) at 82:16-83:3; *see also* Tr. (Goldberg) at 167:20-168:5 (studies are "invariably . . . done on animals" since "FDA would never allow a study to be done on a human").).

A. I have not seen any of these reference in any of the 510(k) I've reviewed. (Tr. (Woloszko) at 997:2-998:7.).

Serendia contended that because Respondents were "[u]nable to dodge their own sworn FDA filings," Respondents "engage[d] in semantics, seeking to differentiate references to 'coagulation' in their FDA filings from the 'coagulation' claimed in the '836 Patent." (CRBr. at 24.). In their own Post-Hearing Reply Brief, Respondents criticized Serendia's contention that Respondents were arguing for a special meaning of coagulation in the context of their FDA submissions, an argument that Serendia alleged was not included in Respondents' Pre-Hearing Brief. (RRBr. at 9 (citing CBr. at 24-26).). Respondents stated that "Dr. Woloszko's testimony that the FDA guidance (RX-0512) defines 'coagulation' and 'coagulation necrosis' in different and particular ways (Tr (Woloszko) 997:2-20; RX-0512.0027) merely emphasizes that the general indication for 'electrocoagulation' provided by the FDA for the Accused Products is broader than just 'coagulation necrosis,' which in turn is broader than the specific result that is claimed by the '836 patent: coagulation necrosis around each electrode, but not between electrodes." (RRBr. at 9-10.).

Dr. Woloszko's supposed clarification of "coagulation" and "coagulation necrosis" does not meaningfully bolster Respondents' non-infringement argument. As Serendia noted, Dr. Woloszko and Respondents attempted to make a false distinction. (CRBr. at 24.). Both Respondents' FDA filings and the '836 patent are about coagulation of tissue, not coagulation of blood. (Tr. (Goldberg) at 1305:14-24.). Serendia pointed out the FDA definition on which Respondents relied explains that the thermal damage zones depicted in Respondents' preclinical tests ***is coagulation necrosis***. (CX-1071.0016 (FDA Premarket Notification 510(k) Guidance) Guidance) ("you should provide a measurement (under magnification) of the size (length, width,

and depth) of the ***thermal damage zone***, i.e***., coagulation necrosis***.").). Dr. Woloszko conceded as much on cross examination. (Tr. (Woloszko) at 1070:11-14 ("Q. Again, in this section, the FDA 510(k) guidance document [CX-1071.0016] refers to thermal damage zone as coagulation necrosis, right? A. Correct.").).

Second, Respondents asserted that Dr. van der Weide's heatmapping tests are "unreliable and not probative of infringement." (RPBr. at 13-16, RRBr. at 7-8, 36-39.). However, as Serendia pointed out, the heatmapping tests, which are just one piece of evidence supporting an infringement finding, are reliable because: (1) they resulted from actual experimentation, not mere theory or simulation; (2) they used the protocol for a peer-reviewed study and were presented at a respected academic conference; (3) the results align with Respondents' own marketing; and (4) the results match the preclinical tests for each Accused Product. (Tr. (van der Weide) at 433:22-25; 421:3-20; CX-3055 (IEEE Article).). *See also Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 580 (1993), which while it does not apply in administrative proceedings, nonetheless provides guidance here (indicators of reliability include: (i) whether the theory has been tested; (ii) whether the theory has been subjected to peer review and publication; (iii) the known or potential error rate, and standards controlling its operation; and (iv) whether the theory has been accepted in the scientific community). As discussed above, the heatmapping tests that Dr. van der Weide performed reflect where the RF energy is applied, that is, it is concentrated around the needle electrodes rather than between them.

Respondents' expert, Dr. Woloszko, testified that the heatmapping tests are unreliable because live human tissue differs from the test specimen. (Tr. (Woloszko) at 994:13-996:5.). On cross-examination, Dr. van der Weide agreed that there are always variations between different samples, even between humans. (Tr. (van der Weide) at 357:25-358:5.). However,

Respondents did not address why testing human tissue would have yielded different results or what material impact, if any, this would make. As noted above, the FDA does ***not*** require human testing to clear RF microneedling devices for electrocoagulation. (CX-1071.0015-17 (FDA Premarket Notification 510(k) Guidance) (requiring testing in animal tissue as part of 510(k) clearance process); *see also* Tr. (Woloszko) at 1024:9-15 ("Q. Just to make sure the record is clear. The FDA accepts testing on liver, kidney, and muscle tissue for a microneedling system for a general indication under its 2020 guidelines, right? A. General indication -- ***general without specific tissue***. So without mentioning skin, that's what general indication is for FDA, yes.") (emphasis added).).[38]

Respondents also contended that operating parameters used in the heatmapping testing can differ from those used in a clinical setting. For example, EndyMed argued that Dr. van der Weide [redacted].[39] (RPBr. at 15; RRBr. at 40-42.). However, as the [redacted]. (CX-2936C.0005, 0008 (Heatmapping Tests).). EndyMed did not explain why using [redacted] would make any difference.

[38] Additionally, Respondents pointed out that Dr. van der Weide used a processed Oscar Mayer turkey lunch meat instead of mammalian tissue. (RPBr. at 13; RRBr. at 37.). Respondents asserted that "lunchmeat is neither 'skin' . . . nor a suitable substitute." (RPBr. at 13; *see also* RRBr. at 37 ("lunch meat is not 'skin'").). That the lunch meat Dr. van der Weide was not "skin" or an appropriate substitute, as Respondents contended, does not materially undermine the validity of his test results. As mentioned above, the results were published as part of a peer-reviewed study and presented at an IEEE conference. (Tr. (van der Weide) at 321:6-24; CX-3055 (IEEE Article).). Dr. van der Weide also confirmed that he did not need to perform the heatmapping tests to reach his conclusions with respect to coagulation and infringement of claim 1 of the '836 patent. (Tr. (van der Weide) at 298:20-8.).

[39] EndyMed did not provide an expert to opine that its Accused Products do not infringe the Asserted Patents. Therefore, Serendia's experts' opinions are unrebutted. EndyMed's arguments amount to little more than attorney argument and are contrary to statements and submissions EndyMed made to the FDA.

Furthermore, during the Hearing, EndyMed [redacted]. (Tr. (Yonay) at 406:19-408:7.). This is yet another example of Respondents contradicting their own documents. As Dr. van der Weide testified, [redacted]. (Tr. (van der Weide) at 431:8-432:2 (discussing CX-0339C (Intensif 510(k))).).

As Dr. van der Weide testified, Respondents failed to produce a single piece of evidence demonstrating that coagulation extends fully between electrodes. (Tr. (van der Weide) at 428:6-10.). Despite having unfettered access to the Accused Products, Respondents' experts did not perform testing to try to support non-infringement arguments. (Tr. (van der Weide) at 299:9-15; Tr. (Woloszko) at 1022:14-21; Tr. (Brennan) at 1174:5-7.).

Third, Respondents argued that their marketing materials do not support a finding of infringement. For example, they contended that their marketing materials are not probative because they are artistic renderings. (Tr. (Brennan) at 1157:25-1158:13.). However, Respondents' corporate representatives testified that they strive to accurately represent the Accused Products' functionality in marketing materials. (*See, e.g.*, CX-1052C (Kibbey Dep. Tr.) at 124:3-125:9.). Even if their marketing materials do not consistently reflect how their products operate, their own preclinical testing, representations to the FDA, and admissions in this Investigation confirm that Respondents' Accused Products infringe. (CX-0172C.0004 [redacted]; CX-2907C.0018-20, 23 [redacted]; CX-0690C.0007-8 (Intensif 510(k) Description); CX-0876C.0017-18 (EndyMed RFA Resp.).).

Respondents' expert, Dr. Brennan, also testified that some marketing materials demonstrate that when needles are applied to skin, there is energy between electrodes. (Tr.

(Brennan) at 1158:1-13.). As Serendia pointed out, Respondents did not identify any ***evidence*** of coagulation between needles. (CBr. at 28.). A device still infringes even if it is sometimes capable of achieving other results. *Broadcom*, 732 F.3d at 1333; *Bell Commc'ns Research*, 55 F.3d at 622-23.

For the foregoing reasons, Serendia has proven by a preponderance of evidence that the Accused Products meet this limitation of claim 1 of the '836 patent.

5. The Accused Products Practice Claim 9 of the '836 Patent

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

It is uncontested that the Accused Products practice claim 9, which additionally requires that "the electrodes are needles and have a diameter from 0.25 mm to 0.30 mm." (Tr. (van der Weide) at 332:10-333:9; CDX-0004C.0084-85, 88; *see also* CX-0805.0009 (Potenza Physician Brochure); CX-1050C (An Dep. Tr.) at 101:5-15; CX-0690C.0006 (Intensif 510(k) Description); CX-0697C.0022 (EndyMed Technical Details); CX-0700C (EndyMed Needle Drawing).).

In their Pre-Hearing Brief and Post-Hearing Reply Brief, Respondents did not dispute that the additional requirement of this claim is practiced. (RPBr. at 20-21; RRBr. at 4-42.). Thus, any argument on this issue is deemed abandoned, withdrawn, and/or waived under Ground Rules 7.2 and 10.1.

Accordingly, Serendia has proven by a preponderance of evidence that the Accused Products meet the additional limitation recited in claim 9 of the '836 patent.

6. The Accused Products Practice Claim 14 of the '836 Patent

a) 14[pre]: "A method of treating skin, comprising"

14[a]: "inserting a plurality of electrodes, the electrodes being bipolar into a section of skin to be treated"

14[b]: "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"

Asserted claim 22 depends from independent claim 14, which is no longer at issued in this Investigation. Claim 14 is a method claim of apparatus claim 1. Because there are no material differences for purposes of this analysis, the Accused Products satisfy claim 14 for the same reasons discussed above for claim 1. (Tr. (van der Weide) at 334:1-5; *see* Section VII.A.4, *supra*.).

Respondents did not make any specific arguments with respect to the limitations recited in claim 14 in either their Pre-Hearing Brief or Post-Hearing Reply Brief nor did they provide rebuttal evidence. (RPBr. at 21; RRBr. at 4-42.). Thus, any argument on this issue is deemed abandoned, withdrawn, and/or waived under Ground Rules 7.2 and 10.1.

Accordingly, Serendia has proven by a preponderance of evidence that the Accused Products meet the preamble and practice the limitations of claim 14 of the '836 patent.

7. The Accused Products Practice Claim 22 of the '836 Patent

a) "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."

It is undisputed that, in the Accused Products, "the RF is from 0.5 to 10 MHz and the predetermined time interval is from 0.05 to 0.8 seconds." (Tr. (van der Weide) at 333:10-334:10; CDX-0004C.0088-90; *see also* CX-0720C.0022 (Potenza 510(k)); CX-0233C.0051, 0054, 0057 (Potenza Clinal Training Slides); CX-0805.0009 (Potenza Physician Brochure); CX-1050C (An Dep. Tr.) at 19:13-15, 61:9-63:20; CX-0339C.0057 (EndyMed 510(k)); CX-1056C (Witman Dep. Tr.) at 228:19-22.).

Other than the disputes they raised with respect to claim 1, Respondents did not dispute that this claim is practiced. (RPBr. at 21; RRBr. at 4-42.). Thus, any argument on this issue is deemed abandoned, withdrawn, and/or waived under Ground Rules 7.2 and 10.1.

For the reasons discussed above, Serendia has proven by a preponderance of evidence that the Accused Products meet the additional limitation recited in claim 22 of the '836 patent.

B. Indirect Infringement

1. Legal Standard

a) Induced Infringement

"Whoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). A patentee who asserts a claim of inducement must prove (i) that there has been direct infringement and (ii) that the alleged infringer "knowingly induced infringement and possessed specific intent to encourage another's infringement." *Minnesota Mining & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1304-05 (Fed. Cir. 2002). With respect to the direct infringement requirement, the patentee "must either point to specific instances of direct infringement or show that the accused device necessarily infringes the patent in suit." *ACCO Brands, Inc. v. ABA Locks Mfrs. Co., Ltd.*, 501 F.3d 1307, 1313 (Fed. Cir. 2007) (citation omitted). This requirement may be satisfied by circumstantial evidence. *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1326 (Fed. Cir. 2009). "[A] finding of infringement can rest on as little as one instance of the claimed method being performed during the pertinent time period." *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1317 (Fed. Cir. 2009); *Toshiba Corp. v. Imation Corp.*, 681 F.3d 1358, 1364 (Fed. Cir. 2012) (citing *Lucent Techs.*, 580 F.3d at 1317).).

The specific intent requirement for inducement necessitates proving that the alleged infringer was aware of the patent, induced direct infringement, and that he knew that his actions

would induce actual direct infringement. *Commil USA, LLC v. Cisco Sys., Inc.*, 720 F.3d 1361, 1367 (Fed. Cir. 2013), *aff'd and vacated in-part on other grounds*, 135 S. Ct. 1920, 1926-28 (2015); *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060, 2068-70 (2011). Specific intent can be proven by, for example: (1) changes in importation practices effectuated to shift infringement liability; (2) the infringer's copying of patented technology; and (3) the infringer's willful blindness of the underlying direct infringement. *Certain Network Devices, Related Software and Components Thereof (I)*, Inv. No. 337-TA-944, Initial Determination at 82; *see also Commil USA, LLC v. Cisco Sys., Inc.*, 135 S. Ct. 1920, 1924-25 (2015) ("It was not only knowledge of the existence of [the asserted] patent that led the Court to affirm the liability finding but also it was the fact that [the accused infringer] copied 'all but the cosmetic features of the [patented product],' demonstrating [the accused infringer] kn[ew] it would be causing customers to infringe [the asserted] patent.") (quoting *Global-Tech*, 131 S. Ct. at 2071).

Willful blindness, which also constitutes "knowledge," has two basic requirements: "(1) the defendant must subjectively believe that there is a high probability that a fact exists"; and "(2) the defendant must take deliberate actions to avoid learning of that fact." *Global-Tech*, 131 S. Ct. at 2070.

The intent to induce infringement may be proven with circumstantial or direct evidence and may be inferred from all the circumstances. *Commil*, 720 F.3d at 1366; *Global-Tech*, 131 S. Ct. 2071-72.ALH

b) Contributory Infringement

35 U.S.C. § 271(c) sets forth the rules for contributory infringement:

> 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).

Specifically with respect to Section 337 investigations, the Federal Circuit has held 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).

"[N]on-infringing uses are substantial when they are not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental." *Vita-Mix*, 581 F.3d at 1327. To determine whether a use is substantial, an Administrative Law Judge may evaluate "the use's frequency, . . . the use's practicality, the invention's intended purpose, and the intended market." *i4i Ltd. Partnership v. Microsoft Corp.*, 598 F.3d 831, 851 (Fed. Cir. 2010). Section 271(c) also requires knowledge of the existence of the patent that is infringed. *Global-Tech*, 131 S. Ct. at 2068.

To satisfy the accused's contributory infringement's knowledge requirement, it is necessary to establish that "the accused contributory infringer knows that its component is included in a combination that is patented and infringing." This requires knowledge of the patent. *Id.* In addition, the Federal Circuit has held that it is not sufficient to know of the patent and the relevant acts, but must also know that "these acts constituted infringement." *Fujitsu Ltd. v. LG Elecs.*, 620 F.3d 1321, 1320 (Fed. Cir. 2010). For purposes of contributory infringement,

such knowledge is inferred where the article at issue has no substantial non-infringing uses. *See Certain Semiconductor Chips with Minimized Chip Package Size and Prods. Containing Same*, Inv. No. 337-TA-605, 2009 WL 8144934, at *28, Comm'n Determination (June 3, 2009).

Where infringement allegations address a "separate and distinct" feature of a product, the contributory infringement analysis (for example, with respect to the existence of non-infringing uses) may address the particular feature in question rather than the product as a whole. *See i4i Partnership v. Microsoft Corp.*, 598 F.3d 831, 849 (Fed. Cir. 2010); *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1320-21 (Fed. Cir. 2009); *Ricoh Co. Ltd. v. Quanta Comput. Inc.*, 550 F.3d 1325, 1338 (Fed. Cir. 2008).

2. Indirect Infringement Overview

Serendia alleged that Respondents indirectly infringe by inducing infringement and contributing to the infringement of the asserted claims of the '836 patent. (CBr. at 37-51.). For the reasons discussed below, Serendia has proven that Respondents indirectly infringe the asserted claims of the '836 patent.

3. Acts of Direct Infringement

a) Jeisys and Cynosure

Jeisys/Cynosure, and their customers have directly infringed the apparatus and method claims of the '836 patent by using the Potenza in the United States. For example, Cynosure [redacted]. (CX-0093C.0024 (Cynosure Rog Resp.) [redacted]. Similarly, Jeisys [redacted]. (CX-0722C (GLP Rpt.).). *Centillion Data Sys., LLC*

v. Qwest Comm'ns Int'l, Inc., 631 F.3d 1279, 1284 (Fed. Cir. 2011). CX-0686C and CX-0174C [redacted]. (CX-0686C.0001, 0004, 0021 [redacted]; CX-0174C.0014 [redacted].). In the [redacted]. Likewise, CX-0174C [redacted]. (CX-0174C.0014 [redacted].). [redacted]. (CX-1052C (Kibbey Dep. Tr.) at 88:8-11.).

Additionally, Jeisys' and Cynosure's customers directly infringe by using the Potenza in the United States. (CX-0925C.0004 (Jeisys, Cynosure RFA Resp.) [redacted] (emphasis added).). For example, CX-0750C [redacted]. (CX-0750C [redacted]; CX-1060C ([redacted] Dep. Tr.)[41] at 24:7-10.).

[40] *See, e.g.*, Tr. (Dan Park) at 448:5-8 ("Q. What are KOLs? A. They are key opinion leaders . . . they are the doctors who actually use Sylfirm X and give us feedback and suggestions.").).

When he testified during the Hearing on November 2, 2023, Mr. Dan Park was the Chief Financial Officer of Benev. (CPSt. at 2-3.). Serendia identified Mr. Park as a fact witness to testify about "Benev's business operations in the United States, including business operations relating to the Domestic Industry Product, investments pertaining to its domestic industry, including its facilities and domestic operations in the United States." (*Id.* at 3.).

[41] [redacted]

Respondents argued that "Cynosure does not perform any acts of direct infringement at the time of importation or at the time of sale to its customers in the U.S. because the accused Potenza products are imported and sold in an unassembled form where the tips are not attached to the handpiece." (RPBr. at 59.). Respondents' argument is "legally meritless" because there is no "at time of importation" requirement. *Certain Audio Players and Controllers, Components Thereof, and Prods. Containing the Same*, Inv. No. 337-TA-1191, Comm'n Op. at 18-22 (Feb. 1, 2022); *Certain Blood Cholesterol Testing Strips*, Inv. No. 337-TA-1116, Comm'n Op. at 25-26 (May 1, 2020) ("[Respondent's] argument that no violation exists because its products are not 'articles that infringe' at the time of importation has twice been rejected by the United States Court of Appeals for the Federal Circuit.").

Jeisys and Cynosure "cannot avoid liability" because the Potenza tips are imported unattached to the handpiece. *Certain Blood Cholesterol Testing Strips*, Comm'n Op. at 31 ("[respondent] cannot avoid liability based on the application of fluid to the test strips [after importation] in the United States"). Cynosure simply attaches the needle tips after importation and uses the assembled Potenza devices, which is sufficient to directly infringe both the asserted apparatus (claims 1 and 9 of the '836 patent) and method claim (claim 22 of the '836 patent). *See id.* at 29-31. As part of its [redacted] (CX-0686C.0005, 0008, 0009-10 (Clinical Report) [redacted]; *see also* CX-

[redacted]. (CPSt. at 4.). Serendia identified [redacted] as a fact witness to testify generally about the "usage of certain Accused Products, including the . . . Potenza devices, and infringing acts of certain Respondents." (*Id.*).

0234C.0028, 0031 (Potenza Manual) (instructing the user to [redacted]; CX-0174C.0014 [redacted].).

Jeisys and Cynosure also argued that "[t]o the extent that Jeisys may sponsor studies performed in the U.S., this does not constitute an act of direct infringement." (RPBr. at 59 n.25.). However, Jeisys did not explain why studies sponsored, approved, and directed by Jeisys in the United States would not constitute direct infringement. *Georgetown Rail Equip. Co. v. Holland L.P.*, 867 F.3d 1229, 1240 (Fed. Cir. 2017) (finding direct infringement where infringer "put the invention into service, i.e., control[s] the system as a whole and obtain benefit from it"). Even if Jeisys were correct, it still meets the requirements of Section 337 and there is direct infringement by its distributor and by customers, as discussed above.

Additionally, Jeisys and Cynosure contended that Serendia has not established that use by Cynosure and its third-party customers is "infringing use (as opposed to non-infringing use)." (RPBr. at 59-60 n.25.). This argument only pertains to dependent claim 22 of the '836 patent, which depends from independent method claim 14, because importation and sale after importation are acts of direct infringement of independent apparatus claim 1 and dependent claim 9. 35 U.S.C. § 271(a). In any event, this argument fails on the merits for the following reasons.

Jeisys and Cynosure asserted that "the accused Potenza console can be operated in a monopolar manner using the I-, S-, CP-21, and single-needle tips," and that the "main body/console is also configured to work with other components such as single-needle tips and noninvasive, needleless tips that are not accused." (RPBr. at 63.). However, as Serendia pointed out, the [redacted] CX-0174C [redacted].

(CX-0174C.0014 .). A Potenza customer, ,[42] also explained that he . (CX-1060C (Dep. Tr.) at 59:19, 60:16-21.). That . (*Id.* at 72:11-73:21, 93:3-5; CX-0234C.0006, 0020 (Potenza Manual).). This "sale of disassembled products" suffices "to demonstrate direct infringement by customers" because "there is no indication that the products can be combined into a non-infringing configuration." *Certain Beverage Dispensing Sys. and Components Thereof*, Inv. No. 337-TA-1130, Comm'n Op. at 12 (Mar. 26, 2020).). As Serendia noted, although not every possible use of the Potenza infringes, there is ample evidence that the Potenza products are used in an infringing manner. (CBr. at 41.).

b) EndyMed

EndyMed and its customers directly infringe because they use the EndyMed Pro and EndyMed Pure 2 with the Intensif handpiece in the United States. EndyMed (CX-0876C.0002-3 (EndyMed RFA Resp.); *see also* CPX-0075 (treatment in the United States with the Intensif handpiece)[43].). EndyMed also

[42] *See* n.41, *supra*.

[43] EndyMed did not challenge that the treatments depicted in CPX-0075 took place in the United States. According to Serendia, EndyMed's public YouTube channel states the treatments look place in Los Angeles, California. (CBr. at 42 n.29 (citing https://www.youtube.com/watch?v=Ei7AOlVtnvw).).

(CX-1055C (Rami Aviram Dep. Tr.)[44] at 136:6-12, 57:5-6; CX-1056C (Witman Dep. Tr.) at 76:8-10.). Additionally, Dr. Goldberg personally used the Intensif handpiece in his New York-based practice, and that the evidence of infringement he reviewed is "in line with what we see clinically when I've used the product." (Tr. (Goldberg) at 175:17-24, 158:23-25.).

4. Respondents Induce and Continue to Induce Users to Infringe the '836 Patent

a) Knowledge of the '836 Patent

Respondents "knew of the existence of the ['836 Patent] because [they] . . . received a cease-and-desist letter concerning it" and did not have a license. *Mentor H/S, Inc. v. Med. Device All., Inc.*, 244 F.3d 1365, 1379 (Fed. Cir. 2001).[45] Respondents Cynosure and Jeisys admitted that they (CX-0092C.0012-13 (Jeisys/Cynosure Rog Resp.); *see also* CX-3388C.0001). EndyMed (CX-0069C.0009 (EndyMed Rog Resp.); *see also* CX-3069C.0001 ; CX-3072C at 1-2.). Respondents also indisputably learned of the Asserted Patents when served with the Complaint. *See e.g.*, *Certain Beverage Brewing Capsules, Components Thereof, and Products Containing the Same*, Inv. No. 337-TA-929, Comm'n Op. at 19 (Apr. 5, 2016) (service of a

[44] (CX-1055C (Aviram Dep. Tr.) at 24:16-19.).

[45] To the extent Respondents disputed that Serendia has proven Respondents had the requisite knowledge, Respondents at minimum were willfully blind because, by receiving cease and desist letters, they knew there was a "high probability" that their products infringed, and deliberately turned a blind eye. *Info-Hold, Inc. v. Muzak LLC*, 783 F.3d 1365, 1373 (Fed. Cir. 2015).

Section 337 complaint is sufficient to show knowledge).

b) Respondents' Active Steps to Encourage Infringement

Inducement can rest on "[e]vidence of active steps taken to encourage direct infringement," such as "advertising an infringing use or instructing how to engage in an infringing use."[46] *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 936 (2005). Here, Respondents' advertising, training, instructional, and operational material demonstrate that they promote "active steps taken to encourage" (*id.*) the direct infringement discussed above in Section VII.A. The record evidence listed below establishes that Respondents provide training and instruction on how the Accused Products can be used in an infringing manner.

- Jeisys and Cynosure: CX-0234C.0005 (Potenza Manual) CX-0100C (Cynosure Rog Resp.) at 4 (emphasis added); CX-1052C (Kibbey Dep. Tr.) at 28:14-16, 45:13-46:11, 48:1-3, 94:11-20 , 95:22-10; CX-0233C.0073, 0078 (Potenza Clinal Training Slides) ; CX-0962C.0030, 0032, 0033, 0061, 0062 (Potenza Clinical Ref. Guide) ; CX-1060C (Dep. Tr.) at 41:7-42:12.
- EndyMed: CX-0187C.0005-6 (Pure Manual) CX-1055C (Aviram Dep. Tr.) at 55:22-57:8, 74:20-75:20, 135:5-136:11, 146:12-147:21; CX-0185C (EndyMed Webpage); CX-1056C (Witman Dep. Tr.) at 73:22-74:2; CX-2903C.0007-8, 0043 (EndyMed Training) ; CPX-0068 (Instructional

[46] Respondents argued that their infringing instructions and training to customers "does not establish the specific intent required for induced infringement." (RPBr. at 60 (citing *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1329 (Fed. Cir. 2009)).). However, in *Vita-Mix*, the accused infringer changed its instruction manual to "teach an undisputedly non-infringing use." *Id.* Here, by contrast, Respondents made no such change; their training and user manuals all teach an infringing use of their Accused Products.

Video).

Respondents contended that "the purpose of the 'clinical training' is not to teach medical practitioners to practice the asserted claims" and that "medical practitioners set the treatment parameters based on their own experience and assessments of the patients." (RPBr. at 60-62.).[47]

However, according to , one of the Serendia's fact witnesses and himself a user of certain Accused Products, the (CX-1060C (Dep. Tr.) at 56:17-22.). That testimony, even without more, and there is much more evidence, is sufficient to prove inducement. *Barry v. Medtronic, Inc.*, 914 F.3d 1310, 1336 (Fed. Cir. 2019) ("[T]the Medtronic sales force was constantly teaching surgeons the nuances of and techniques for using the devices… On the evidence of record, we conclude, the jury could permissibly find inducement.").

In addition, 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.

- Jeisys and Cynosure: CX-0234C.0006, 0025-37 (Manual) , 43 ; CX-0100C.0004 (Cynosure Rog Resp.)

[47] EndyMed argued that "'[m]erely 'describ[ing],' an infringing mode is not the same as 'recommend[ing],' 'encourag[ing],' or 'promot[ing],' an infringing use." (RPBr. at 61 (citing *Memory Integrity, LLC v. Intel Corp.*, 144 F. Supp. 3d 1185, 1195, 1197 (D. Or. 2015)).). However, in *Memory Integrity*, unlike in this case, the instructions and advertising at issue did not "closely track the claimed features and benefits of the asserted patents" as EndyMed's instructions and advertising do here. *Id.* at 1197. For example, EndyMed's training specifically touts the benefits of "fractional" heating zones. (CX-2903C.0007-8, 0043 (EndyMed Training).). EndyMed's advertising also touts the benefits of "controlled energy to the depth of the dermis" compared to traditional bipolar systems. (CX-0812.0005 (Intensif Brochure); *see id.* at 3 (touting benefits of precise motor-controlled needle insertion).).

; CX-1052C (Kibbey Dep. Tr.) at 27:15-28:1; CX-1047C (Dong Hwan Kang Dep. Tr.)[48] at 31:17-32:12; CX-1050C (An Dep. Tr.) at 45:14-19; CX-1060C (Dep. Tr.) at 46:1-10.

- EndyMed: CX-0187C.0030-34 (EndyMed Pure Manual) 0019 ; CX-1055C (Aviram Dep. Tr.) at 74:11-17, 84:8-17, 153:13-18.

The evidence described above supports a factual and a legal finding of inducement. *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 843 F.3d 1315, 1335 (Fed. Cir. 2016) ("[W]e have affirmed induced infringement verdicts based on circumstantial evidence of inducement (e.g., advertisements, user manuals) directed to a class of direct infringers (e.g., customers, end users) without requiring hard proof that any individual third-party direct infringer was actually persuaded to infringe by that material."); *Certain High-Density Fiber Optic Equipment and Components Thereof*, Inv. No. 337-TA-1194, Comm'n Op. at 33-36, 46, 50 (Aug. 23, 2021) (circumstantial evidence including instructions on how to assemble the accused product supported an inducement findings).

Respondents induce infringement by medical providers because they 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. *Arthrocare Corp. v. Smith & Nephew, Inc.*, 406 F.3d 1365, 1377 (Fed. Cir. 2005). Medical providers provide treatments with the Accused Products and instructions in the user manuals.[49] (CX-1060C (Dep. Tr.) at 44:21-45:6). Respondents also provide suggested treatment guidelines,

[48] (CX-1047C (Kang Dep. Tr.) at 20:11-14, 21:4-5.).

[49] Respondents caution not to use the Accused Products differently than as instructed in their manuals. (CX-0234C.0007 (Potenza Manual); CX-0187C.0006 (EndyMed Pure Manual).).

which include the identification and description of specific settings for an infringing use of the Accused Products. (CX-1052C (Kibbey Dep. Tr.) at 94:11-20 ; CX-0962C.0030, 0033, 0061, 0062 (Potenza Clinical Ref. Guide) ; CX-2903C.0007-8, 0043 (EndyMed Training) (benefits of heating zones).).

Respondents also induce providers to infringe by encouraging their use of marketing to promote the product uses, including an infringing use. (CX-1052C (Kibbey Dep. Tr.) at 28:17-30:5, 49:19-51:3; CPX-0061 (Cynosure Video), 0:51-1:13 (touting coagulation around the needles); CPX-0060 (Video), 1:04 (similar); CX-0805.0007 (Potenza Brochure) (similar and advertising adjustable depth control); CX-1055C (Aviram Dep. Tr.) at 143:4-144:8, 132:2-20; CPX-0067 (Video), 0:19 (advertising smooth gliding needle insertion using Intensif), 0:48 (advertising coagulation around the needle of the Intensif); CX-0812.0005 (Intensif Brochure) (touting fractional heating using the Intensif); *see also id.* at 0003 (touting the benefits of precise motor-controlled needle insertion for the Intensif).).

To the extent Respondents argue that sponsoring and conducting studies is not direct infringement, nonetheless, that activity demonstrates Respondents' active encouragement of infringing conduct. (CX-0174C.0014 ; CX-0093C.0024 (Cynosure Rog Resp.) ; CX-0686C at 485; CX-0175C ; CX-1052C (Kibbey Dep. Tr.) at 70:21-71:3; CX-0722C

[redacted][50].).

Jeisys and Cynosure argued that the Potenza has a monopolar mode (RPBr. at 61). That is irrelevant because, as discussed, they encourage infringing use of the bipolar mode. *See Sanofi v. Watson Labs., Inc.*, 875 F.3d 636, 646 (Fed. Cir. 2017) ("a person can be liable for inducing an infringing use of a product even if the product has substantial noninfringing uses" and "factual inferences about intended effects" can "rest on circumstantial evidence"); *Certain Digital Video Receivers and Hardware and Software Components Thereof*, 337-TA-1001, Comm'n Op. at 21 (Dec. 6, 2017) ("Because the concept of substantial non-infringing uses is applicable only in the context of contributory infringement, it plays no role in the analysis of the direct and induced infringement . . . ."), *aff'd Comcast Corp. v. Int'l Trade Comm'n*, 951 F.3d 1301 (Mar. 2, 2020).

5. Respondents Contributed to and Continue to Contribute to Users' Direct Infringement of the '836 Patent

"[C]ontributory infringement in a Section 337 case is established where (1) there is an act of direct infringement in violation of Section 337; (2) the accused device has no substantial noninfringing 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*, 629 F.3d at 1353. The first prong is met because, as discussed above, there have been acts of direct infringement. The second prong is met because, as explained below, the Accused Products have no substantial non-infringing use. The third prong is met because Respondents have imported, sold for importation, or sold after importation within the United States components of the Accused Products that contribute to another's direct infringement. The knowledge requirement of § 271(c) is the same as § 271(b), therefore, it is

[50] GLP stand for Good Laboratory Practice. (*See, e.g.*, CX-0722C.0004.).

met for the same reasons. (*See* Section VII.B.4, *supra*.). *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 765 (2011).

a) Jeisys and Cynosure

The Potenza user manual explains that it [redacted] and describes this operation in an infringing manner. (CX-0234C.0015-38 (Potenza Manual).). The consoles, bipolar handpiece, and consumable tips of the Potenza Products all constitute material parts of the invention, are specially made or adapted for infringing use, and work only with each other. (CX-0234C.0009, 0046 (Potenza Manual) [redacted].

Jeisys and Cynosure contended that the Potenza can work with single-needle tips, needleless tips, and a monopolar configuration, and thus the Accused Potenza has a non-infringing use. (RPBr. at 63.). However, Jeisys and Cynosure are incorrect as a matter of law that a product that has a non-infringing use that also has an infringing use is exempt from a finding of infringement. In *Ricoh Co. v. Quanta Computer Inc.*, the accused optical disc drives were capable of performing a patented data recording method and were also able to "read discs in a noninfringing manner." *Ricoh Co. v. Quanta Computer Inc.*, 550 F.3d 1325, 1336 (Fed. Cir. 2008). The Federal Circuit noted that the accused "drives contain at least some distinct and separate components used only to perform the allegedly infringing write methods," and that an infringer cannot "escape liability as a contributory infringer merely by embedding [a] microcontroller in a larger product with some additional, separable feature before importing and selling it." *Id.* at 1337.

As in *Ricoh*, the single-needle tips, needleless tips, and a monopolar configuration for the

Potenza [redacted] to operate and are, therefore, "additional separable feature[s]" that are irrelevant to the contributory infringement analysis. *Id.*; CX-0234C.0015 (Potenza Manual) [redacted], 0018-19 [redacted]. Additionally, [redacted], which is another reason that they do not constitute a substantial non-infringing use. (CX-1060C ([redacted] Dep. Tr.) at 56:17-22, 59:17-19 [redacted].).

b) EndyMed

Although 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. *Ricoh*, 550 F.3d at 1337. The EndyMed Pro and Pure 2.0 consoles, Intensif handpiece, and consumable tips all constitute materials part of the invention, are specially made or adapted for infringing use, and work only with each other. (CX-0187C.0018, 0031 (Pure Manual); CX-1055C (Aviram Dep. Tr.) at 26:6-13, 44:1-16.).

C. Technical Prong of Domestic Industry

1. Legal Standard

A complainant in a patent-based Section 337 investigation must demonstrate that it is practicing or exploiting the patents at issue. *See* 19 U.S.C. § 1337(a)(2) and (3); *Certain Microsphere Adhesives, Process for Making Same, and Prods. Containing Same, Including Self-Stick Repositionable Notes*, Inv. No. 337-TA-366, Comm'n Op. at 8, Pub. No. 2949 (U.S.I.T.C. Jan. 16, 1996) ("*Microsphere Adhesives*"). "In order to satisfy the technical prong of the domestic industry requirement, it is sufficient to show that the domestic industry practices any

claim of that patent, not necessarily an asserted claim of that patent." *Certain Ammonium Octamolybdate Isomers* ("*Certain Isomers*"), Inv. No. 337-TA-477, Comm'n Op. at 55 (U.S.I.T.C. Jan. 5, 2004).

The test for claim coverage for the purposes of the technical prong of the domestic industry requirement is the same as that for infringement. *Certain Doxorubicin and Preparations Containing Same*, Inv. No. 337-TA-300, Initial Determination at 109, 1990 WL 710463 (U.S.I.T.C. May 21, 1990), *aff'd*, Views of the Commission at 22 (October 31, 1990) ("*Doxorubicin*"). "First, the claims of the patent are construed. Second, the complainant's article or process is examined to determine whether it falls within the scope of the claims." *Id.* The technical prong of the domestic industry can be satisfied either literally or under the doctrine of equivalents. *Certain Dynamic Sequential Gradient Devices and Component Parts Thereof*, Inv. No. 337-TA-335, Initial Determination at 44, Pub. No. 2575 (U.S.I.T.C. Nov. 1992).

2. The DI Products Practice Claim 1 of the '836 Patent

a) 1[pre]: "A skin treatment apparatus, comprising"

It is undisputed that the DI Products are a "skin treatment apparatus." (Tr. (van der Weide) at 281:1-13; CDX-0004C.0025-26; CX-0823C.0001, 0004 (Sylfirm X Manual).). Respondents did not dispute this. (RPBr. at 22; RRBr. at 42-43.). Thus, any argument on this issue is deemed abandoned, withdrawn, and/or waived under Ground Rules 7.2 and 10.1.

For the foregoing reasons, Serendia has proven by a preponderance of evidence that the DI Products meet the preamble of claim 1 of the '836 patent.

b) 1[a]: "a plurality of electrodes, the electrodes being bipolar and configured to be insertable into skin to be treated"

Serendia presented evidence that the DI Products have "a plurality of electrodes." (Tr.

(van der Weide) at 281:23-282:11; CDX-0004C.0029-30; CX-2939C (Product Inspections); CX-0830.0008-11 (Sylfirm X brochure); CX-0760C.0009 (DI Photos); CPX-0069 (Serendia instructional video).).

Serendia also provided evidence that the DI Products meet the limitation "electrodes being bipolar." (Tr. (van der Weide) at 286:25-289:5; CDX-0004C.0043-44; CX-0826C.0006 (Sylfirm X Device Description); CX-2939C.0039 (Product Inspections); CX-0862C.0005-6 (Sylfirm X Elec. Schematic); CX-0833C.0003-4 (Sylfirm X Waveform); Tr. (Na) at 87:19-20.). Dr. van der Weide confirmed that the electrodes used with the DI Product are connected in a zigzag pattern, and not as "alternating rows of commonly-polarized electrodes" as in the disclaimed Intracel configuration. (Tr. (van der Weide) at 288:15-24; CDX-0004C.0046; *see also* CX-2942C (Sylfirm X Array).).

Moreover, Dr. van der Weide testified that the plurality of electrodes of the DI Products also are "configured to be insertable into skin to be treated." (Tr. (van der Weide) at 289:6-20; CDX-0004C.0048-49.).

Respondents did not dispute that the DI Products practice any of these claim limitations in their Pre-Hearing Brief or or Post-Hearing Reply Brief. (RPBr. at 22; RRBr. at 42-43.). Accordingly, any argument on this issue is deemed abandoned, withdrawn, and/or waived under Ground Rules 7.2 and 10.1.

For these reasons, Serendia has proven by a preponderance of evidence that the DI Products meet this limitation of claim 1 of the '836 patent.

c) 1[b]: "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"

Serendia presented uncontroverted evidence that the DI Products have a "radio frequency (RF) generation module, the RF generation module electrically coupled to the plurality of electrodes." (Tr. (van der Weide) at 290:4-19; CDX-0004C.0051-52; CX-0830.0002 (Sylfirm X Brochure); CX-0826C.0005-6, 0015 (Sylfirm X Device Description); Tr. (Na) at 87:21-23.). Respondents did not dispute this aspect of limitation 1[b] in their Pre-Hearing Brief or Post-Hearing Reply Brief. (RPBr. at 22; RRBr. at 42-43.). Thus, any argument on this issue is deemed abandoned, withdrawn, and/or waived under Ground Rules 7.2 and 10.1.

Additionally, Drs. Na and van der Weide testified that the DI Products use "an Alternating Current (AC) RF signal." (Tr. (Na) at 87:21-23; Tr. (van der Weide) at 290:20-292:2; CDX-0004C.0053-55.). Dr. van der Weide measured the DI Products' waveforms and confirmed that they have an AC RF signal. (Tr. (van der Weide) at 290:20-292:2; CDX-0004C.0053-55; CX-2939C (Product Inspections).).

Furthermore, Drs. Na, Goldberg, and van der Weide explained that the DI Products practice the limitation "electrodes configured to cause coagulation around each electrode rather than coagulating between the electrodes." (Tr. (Na) at 87:24-88:1; Tr. (Goldberg) at 180:25-181:25; CDX-0002C.0041-42; Tr. (van der Weide) at 297:12-302:19, 321:8-25, 332:2-9; CDX-0004C.0068-73, 0083.). The DI Products are marketed as having this functionality. (CPX-0069, CPX-0070 (Sylfirm X Videos); CX-0830.0002,000 4 (Sylfirm X Brochure); CX-2944C.0025 (Sylfirm X Presentation).).

Respondents argued that the DI Products do not practice this limitation for the same reasons they argued the Accused Products do not practice this limitation. (RPBr. at 22-23.). As discussed above in Section VII.A.4, Respondents' arguments are not supported by the evidence, and thus lack merit.

Accordingly, Serendia has proven by a preponderance of evidence that the DI Products meet this limitation of claim 1 of the '836 patent.

3. The DI Products Practice Claim 9 of the '836 Patent

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

It is uncontested that the DI Products satisfy claim 9 because the electrodes are needles that have a 0.30-mm diameter. (Tr. (van der Weide) at 332:24-333:9; CDX-0004, 0087-88; CX-0826 (Sylfirm X Device Description) at 11.). Respondents did not dispute this in their Pre-Hearing Brief or Post-Hearing Reply Brief. (RPBr. at 23; RRBr. at 42-43.). Thus, any argument on this issue is deemed abandoned, withdrawn, and/or waived under Ground Rules 7.2 and 10.1.

For the foregoing reasons, Serendia has proven by a preponderance of evidence that the DI Products meet the additional limitation recited in claim 9 of the '836 patent.

4. The DI Products Practice Claim 14 of the '836 Patent

a) 14[pre]: "A method of treating skin, comprising"

14[a]: "inserting a plurality of electrodes, the electrodes being bipolar into a section of skin to be treated"

14[b]: "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"

As explained above in the infringement analysis of independent claims 1 and 14, claim

14, from which asserted claim 22 depends, is a method claim of apparatus claim 1, and contains no material differences from claim 1. (Tr. (van der Weide) at 334:1-5; *see* Sections VII.A.4, VII.6, *supra*.). For the same reasons discussed above for claim 1, the DI Products practice claim 14.

Respondents did not make any specific arguments with respect to the limitations recited in claim 14 in either their Pre-Hearing Brief or Post-Hearing Reply Brief. (RPBr. at 23; RRBr. at RRBr. at 42-43.). Thus, any argument on this issue is deemed abandoned, withdrawn, and/or waived under Ground Rules 7.2 and 10.1.

Accordingly, Serendia has proven by a preponderance of evidence that the DI Products meet the preamble and practice the limitations of claim 14 of the ’836 patent.

5. The DI Products Practice Claim 22 of the ’836 Patent

a) “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.”

It is undisputed the DI Products practice this claim because the RF frequency of the DI Product is 2.0 MHz, which is “from 0.5 to 10 Mhz,” and the user can select a “predetermined time interval is from 0.05 to 0.8 seconds.” (Tr. (van der Weide) at 333:10-334:10; CDX-0004C.0089-90; CX-0823C.0027 (Manual); CX-0760C.0002-3 (Photos).). Respondents did not dispute this in their Pre-Hearing Brief or Post-Hearing Reply Brief. (RPBr. at 23; RRBr. at 42-43.). Thus, any argument on this issue is deemed abandoned, withdrawn, and/or waived under Ground Rules 7.2 and 10.1.

For the reasons discussed above, Serendia has proven by a preponderance of evidence that the DI Products meet the additional limitation recited in claim 22 of the ’836 patent.

D. Invalidity

1. Legal Standards

a) Obviousness

Under 35 U.S.C. § 103(a), a patent is valid unless "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. 35 U.S.C. § 103(a). The ultimate question of obviousness is a question of law, but "it is well understood that there are factual issues underlying the ultimate obviousness decision." *Richardson-Vicks*, 122 F.3d 1476, 1479 (Fed. Cir. 1997) (citing *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17 (1966)).

After claim construction, "[t]he second step in an obviousness inquiry is to determine whether the claimed invention would have been obvious as a legal matter, based on underlying factual inquiries including: (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) secondary considerations of non-obviousness." *Smiths Indus. Med. Sys., Inc. v. Vital Signs, Inc.*, 183 F.3d 1347, 1354 (Fed. Cir. 1999) (citing *Graham*, 383 U.S. at 17). The existence of secondary considerations of non-obviousness does not control the obviousness determination; a court must consider "the totality of the evidence" before reaching a decision on obviousness. *Richardson-Vicks*, 122 F.3d at 1483.

The Supreme Court clarified the obviousness inquiry in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 389 (2007). The Supreme Court said:

> When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars

> its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. *Sakraida* and *Anderson's-Black Rock* are illustrative–a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions.
>
> Following these principles may be more difficult in other cases than it is here because the claimed subject matter may involve more than the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for the improvement. Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit.
>
> * * *
>
> The obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents. The diversity of inventive pursuits and of modern technology counsels against limiting the analysis in this way. In many fields it may be that there is little discussion of obvious techniques or combinations, and it often may be the case that market demand, rather than scientific literature, will drive design trends. Granting patent protection to advances that would occur in the ordinary course without real innovation retards progress and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility.

KSR, 550 U.S. at 417-19.

The Federal Circuit has since held that when a patent challenger contends that a patent is invalid for obviousness based on a combination of several prior art references, "the burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make the composition or device, or carry out the claimed process, and would have had a reasonable expectation of success in doing so." *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007) (citations omitted).

> The TSM[51] test, flexibly applied, merely assures that the obviousness test proceeds on the basis of evidence--teachings, suggestions (a tellingly broad term), or motivations (an equally broad term)--that arise before the time of invention as the statute requires. As *KSR* requires, those teachings, suggestions, or motivations need not always be written references but may be found within the knowledge and creativity of ordinarily skilled artisans.

Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc., 520 F.3d 1358, 1365 (Fed. Cir. 2008).

b) Enablement

> Section 112 provides the statutory basis for the enablement requirement:
>
> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same.

35 U.S.C. § 112, ¶ 1 (Pre-AIA).

The enablement requirement ensures that "any person skilled in the art" can "make and use" the invention upon reading the patent. The standard for enablement is whether a person skilled in the art can "make and use" the invention "without undue experimentation." *In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988) (finding enablement where the disclosure provided considerable direction and guidance, working examples, in combination with a high level of skill and that methods to practice the invention were well-known).

The Federal Circuit interprets 35 U.S.C. 112, first paragraph, as providing a written description requirement that is separate from the enablement requirement. *Ariad*, 595 F.3d at 1344, 1351 (citing *Vas-Cath*, 935 F.2d at 1562-63). Unlike the written description requirement, which is a question of fact, the enablement requirement is a question of law. *Ariad*, 595 F.3d at 1351; *Amgen Inc. v. Sanofi, Aventisub LLC*, 987 F.3d 1080, 1084 (Fed. Cir. 2021) ("*Amgen*"),

[51] TSM is an acronym that stands for teaching, suggestion, motivation.

cert. granted in part sub nom. Amgen Inc. v. Sanofi, 143 S. Ct. 399 (2022) (denying certiorari as to whether enablement is a question of law; granting certiorari as to whether the full scope of the claimed embodiments must be enabled).

"Sufficiently routine" experimentation that would be reasonable to the skilled artisan to carry out does not preclude a finding of enablement. *Amgen*, 987 F.3d at 1085. Lack of enablement requires finding "undue" experimentation to make and use the invention. Factual considerations, now known as the *Wands* factors, guide the inquiry as to whether a person skilled in the art would require "undue" experimentation to make and use the invention. *Amgen*, 987 F.3d at 1084. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." *Wands*, 858 F.2d at 737.

The *Wands f*actors are:

(1) the quantity of experimentation necessary,
(2) the amount of direction or guidance presented,
(3) the presence or absence of working examples,
(4) the nature of the invention,
(5) the state of the prior art,
(6) the relative skill of those in the art,
(7) the predictability or unpredictability of the art, and
(8) the breadth of the claims.

Id.

The *Wands* factors "are illustrative, not mandatory" and there is no requirement to consider all the *Wands* factors. *Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1288 (Fed. Cir. 2012) ("*Streck*") (quoting *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991)). In *Streck*, true reticulocytes and analogs worked in the same way and were virtually indistinguishable, and experimentation was not undue to make and use the

invention. *Id.* at 1290-91. A *Wands* analysis usually considers identification of embodiments that are asserted to not be enabled "so that breadth is shown concretely and not just as an abstract possibility, and how much experimentation a skilled artisan would have to undertake to make and use those products or processes." *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 959 F.3d 1091, 1100 (Fed. Cir. 2020) ("*McRO II*") (citations omitted). In *McRO II*, the novel aspect of the invention was related to a set of rules to output mouth shapes. *Id*. at 1102. Lack of enablement required a finding that the challenger "identify specifics that are or may be within the claim but are not enabled." *Id*. at 1104.

A patent is presumed to be valid. 35 U.S.C. § 282. Therefore, lack of enablement requires clear and convincing evidence. *Streck*, 665 F.3d at 1288. "Enablement is determined from the viewpoint of persons of skill in the field of the invention at the time the patent application was filed." *Ajinomoto Co., Inc. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345 (Fed. Cir. 2000) (finding enablement of claims to bacterial strains where methods to practice the invention were conventional and used well-known genetic engineering techniques). A specification does not need to "describe how to make and use every possible variant of the claimed invention," but "when a range is claimed, there must be reasonable enablement of the scope of the range." *Amgen*, 987 F.3d at 1084-85 (quoting *McRO II*, 959 F.3d at 1100).

While the written description requirement and enablement requirement may rise and fall together, they need not always do so. *Ariad*, 598 F.3d at 1352. Unlike written description, which is an objective inquiry into what the specification describes, the enablement analysis may rely on the knowledge of a person skilled in the art. For example, claims may be present that do not require undue experimentation, but an invention that has not yet been invented, cannot be described. *Id*. (citing *In re DiLeone*, 436 F.2d 1404, 1405 (C.C.P.A Feb. 11, 1971)

("*DiLeone*")). The Federal Circuit explained in *DiLeone* that an invention may be enabled as broadly claimed, but not describe the invention. *DiLeone*, 436 F.2d at 1405. As an example, "consider the case where the specification discusses only compound A and contains no broadening language of any kind. This might very well enable one skilled in the art to make and use compounds B and C; yet the class consisting of A, B and C has not been described."). *Id*. at n.1.

"It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement." *Idenix Pharm. LLC v. Gilead Scis., Inc*., 941 F.3d 1149, 1159 (Fed. Cir. 2019) ("*Idenix*") (finding non-enablement where the need to screen thousands of molecules for HCV efficacy required a large quantity of experimentation and rejecting that a POSA's knowledge would guide testing to a predictable group of compounds).

c) Written Description

In pertinent part, 35 U.S.C. § 112, states the written description requirement:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112 (Pre-AIA).

A patent's specification satisfies the written description requirement when it "reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Novartis Pharms. Corp. v. Accord Healthcare, Inc.*, 38 F.4th 1013, 1016 (Fed. Cir. 2022) ("*Novartis*") (quoting *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (citations omitted) ("*Ariad*")). In *Novartis*, the Federal Circuit held that

the written description requirement was not met because the specification did not support that a "skilled artisan would understand a negative limitation to necessarily be present in [the] disclosure." *Novartis*, 38 F. 4th at 1020.

The written description analysis into whether there is "possession as shown in the disclosure" in the patent at issue is "an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art." *Ariad*, 598 F.3d at 1351. The analysis varies depending on context. *Id*.

> [T]he level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology. For generic claims, we have set forth a number of factors for evaluating the adequacy of the disclosure, including "the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science of technology, [and] the predictability of the aspect at issue"

Ariad, 598 F.3d at 1351 (citations omitted); *see also Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F. 4th 1330, 1335 (Fed. Cir. 2021) ("What is required to meet the written description requirement 'varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence.'").

The written description requirement is separate from the enablement requirement. *Ariad*, 598 F.3d at 1344. In *Ariad*, the inventors had over "years of hard work, great skill and extraordinary creativity" discovered, named, and described "previously unknown cellular components as a necessary predicate for their inventions" in a field of invention that was particularly unpredictable. *Id*. at 1354. The patent failed to meet the written description where it disclosed the use of three classes of molecules, but failed to sufficiently disclose molecules capable of the claimed function of reducing NF-eB activity. *Id*. at 1354-55.

Compliance with the written description requirement is a question of fact. *Id*. at 1354-55; *see also Enzo Biochem, Inc. v. Gen-Probe, Inc*., 323 F.3d 956, 963 (Fed. Cir. 2002) ("*Enzo*

Biochem") ("Compliance with the written description requirement is essentially a fact-based inquiry that will 'necessarily vary depending on the nature of the invention claimed.'" (quoting *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991) ("*Vas-Cath*")).

The written description requirement does not require examples or an actual reduction to practice. *Ariad*, 598 F.3d at 1352. Filing of a patent application, i.e., a constructive reduction to practice, that "in a definite way identifies the claimed invention can satisfy the written description requirement." *Id*. The written description need not use the same words as the claimed invention, but a description that only renders the claimed invention obvious is also not adequate. *Id*.

Evidence of possession of the claimed invention may include "'disclosure of sufficiently detailed, relevant identifying characteristics . . . *i.e.,* complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure*,* or some combination of such characteristics.'" *Enzo Biochem*, 323 F.3d at 954 (quoting and adopting PTO's standard for compliance with written description requirement; Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, 1, "Written Description" Requirement, 66 Fed. Reg. 1099, 1106 (Jan. 5, 2001) ("PTO Guidelines") (emphasis deleted)).

The written description requires a comparison between the claimed invention and the disclosure, as explained below in the PTO Guidelines.

> The analysis of whether the specification complies with the written description requirement calls for the examiner to ***compare the scope of the claim with the scope of the description*** to determine whether applicant has demonstrated possession of the claimed invention. Such a review is conducted from the standpoint of one of skill in the art at the time the application was filed and should include a determination of the field of the invention and the level of skill and knowledge in the art. Generally, there is an inverse correlation between the level

> of skill and knowledge in the art and the specificity of disclosure necessary to satisfy the written description requirement. Information which is well known in the art need not be described in detail in the specification.

(*See* PTO Guidelines, 66 Fed. Reg. at 1105 (citations omitted); Manual of Patent Examining Procedure § 2163(II)(A)(2) ("MPEP") (June 2020) (emphasis added); *see also Indivior UK Ltd. v. Dr. Reddy's Lab'ys S.A.*, 18 F.4th 1323, 1328 (Fed. Cir. 2021) ("*Invidior*") (describing that claims in a parent application can provide written description support for ranges in a child application); *Ariad*, 598 F.3d at 1351 ("the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed").

The purpose of the "written description" requirement is to "convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." *Vas-Cath*, 935 F.2d at 1563-64 (emphasis in original). In other words, the specification must describe the claimed invention.

> To comply with the written description requirement of **…** pre-AIA 35 U.S.C. 112, first paragraph, or to be entitled to an earlier priority date or filing date under … [35 U.S.C.] 120…, each claim limitation must be expressly, implicitly, or inherently supported in the originally filed disclosure. When an explicit limitation in a claim "is not present in the written description whose benefit is sought it must be shown that a person of ordinary skill would have understood, at the time the patent application was filed, that the description requires that limitation." *Hyatt v. Boone,* 146 F.3d 1348, 1353, 47 USPQ2d 1128, 1131 (Fed. Cir. 1998); see also ... *Yeda Research and Dev. Co. v. Abbott GMBH & Co.,* 837 F.3d 1341, 120 USPQ2d 1299 (Fed. Cir. 2016) ("Under the doctrine of inherent disclosure, when a specification describes an invention that has certain undisclosed yet inherent properties, that specification serves as adequate written description to support a subsequent patent application that explicitly recites the invention's inherent properties.") (citing *Kennecott Corp. v. Kyocera Int'l, Inc.,* 835 F.2d 1419, 1423 (Fed. Cir. 1987)).

(MPEP § 2163 II(A)(3)(b); *see also Novartis*, 38 F.4th at 1016 ("possession must be 'shown in the disclosure'").).

"It is not enough that a claimed invention is 'an obvious variant of that which is disclosed in the specification.' Disclosure is essential; it is 'the ***quid pro quo*** of the right to exclude.'"

Novartis, 38 F.4th at 1016 (emphasis in original) (citations omitted)); *Nuvo Pharms. (Ireland) Designated Activity Co. v. Dr. Reddy's Lab'ys Inc.*, 923 F.3d 1368, 1376-77 (Fed. Cir. 2019) ("*Nuvo*") ("The essence of the written description requirement is that a patent applicant, as part of the bargain with the public, must describe his or her invention so that the public will know what it is and that he or she has truly made the claimed invention.") (quoting *AbbVie Deutschland GmbH & Co. v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1298 (Fed. Cir. 2014)).

A patent is presumed to have adequate written description. *Novartis*, 38 F.4th at 1019. Clear and convincing evidence overcomes the presumption of validity. *Ariad*, 598 F.3d at 1354.

d) Patent Eligibility

Section 101 limits patent eligible subject matter to "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." 35 U.S.C. § 101. Under Supreme Court precedent, "applications" of abstract concepts "to a new and useful end" remain patent eligible. *Alice Corp. Pty. v. CLS Bank Intern.*, 573 U.S. 208, 217 (2014) ("*Alice*") (citation omitted). Determining whether a claim is invalid for being directed to a patent-ineligible abstract idea involves a two-step analysis. The court first determines whether the claim is "directed to" an abstract idea, and second determines "whether the claim nonetheless includes an 'inventive concept' sufficient to '"transform the nature of the claim" into a patent-eligible application.'" *Yu v. Apple Inc.*, 1 F.4th 1040 (Fed. Cir. 2021) ("*Yu*") (citations omitted). "[F]eatures that are not claimed are *irrelevant* as to step 1 or step 2 of the *Mayo/Alice* analysis." *Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, 967 F.3d 1285, 1293 (Fed. Cir. 2020) ("*American Axle*") (emphasis added) (collecting cases).

2. Scope of the Prior Art[52]

Respondents asserted that claims 1, 9, and 22 of the '836 patent are rendered obvious based on U.S. Patent Application Pub. No. 2007/208340 to Ganz et al. (RX-0329, "Ganz") alone and/or in combination with U.S. Patent No. 7,824,394 to Manstein (RX-0304, "Manstein"), and WO 2007/064718 to Hantash et al. (CX-1089, "Hantash"). (RPBr. at 23; RBr. at 7.). For the reasons discussed below, these prior art references do not render obvious claims 1, 9, and 22 of the '836 patent.

a) Ganz (RX-0329)

Ganz's approach to skin treatment appears to be fundamentally different in its methods and/or objectives and outcomes from that which claim 1 of the '836 patent requires. As Dr. Goldberg testified, "Ganz is directed to cauterizing and removing tissue," which is "very different" from the skin treatment "claimed in the '836 Patent" that involves "causing coagulation localized around each needle electrode." (Tr. (Goldberg) at 1313:12-18.).

Ganz's device "imparts perforations into the skin, rather than merely imparting coagulations into the skin." (RX-0329 (Ganz) at [0032]; *see also* Tr. (Goldberg) at 1309:22-1311:17; CDX-0044C.0016-18.). Ganz explains that these "perforations" are "vertical areas of thermal damage or ablation to the tissue causing tissue necrosis." (RX-0329 (Ganz) at [0027].). Ganz viewed "only caus[ing] zones of coagulation" as a "drawback" of the prior art. It distinguishes zones of coagulation from his approach of ablating and removing tissue to "create perforations or vertical holes in the tissue." (RX-0329 (Ganz) at [0006]; *see also* Tr. (Goldberg) at 1308:1-1309:21; Tr. (Van der Wiede) at 1448:23-1451:3.).

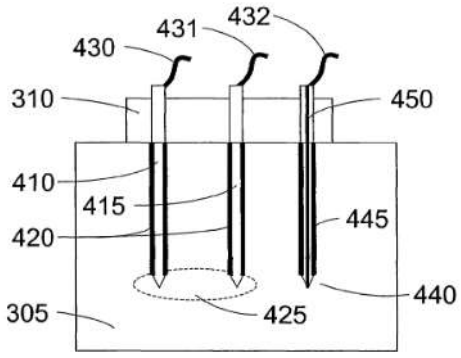
[52] There is no dispute that the asserted claims of the '836 patent are entitled to an effective U.S. filing date of June 14, 2012, and an effective foreign filing date of June 14, 2011. (RBr. at 6; SBr. at 32; Tr. (Woloszko) at 868:7-11.). Thus, the '836 patent is properly analyzed under pre-AIA laws. (*Id.*).

According to Ganz, there was "a need for a device and method which imparts actual perforations into the skin, thereby promoting more aggressive healing" than approaches that create "zones of coagulated tissue" without "creat[ing] vertical perforations or ablation holes." (RX-0329 (Ganz) at [0006].). Thus, Ganz created "ablation holes," in contrast to the '836 patent, which, as Respondents' expert, Dr. Bérubé, admitted, "does not involve ablation." (Tr. (Bérubé) at 1268:24-1269:1.).

b) Manstein (RX-0304)[53]

Manstein describes generating intersecting thermal damage zones between electrodes, which is the opposite of that which the asserted claims of the '836 patent require. (RX-0304 (Manstein) at 7:19-22 ("In this configuration the applied current will travel through the tissue between the tips of needles 410 and 415, generating an elongated region of thermal damage 425 around and ***between*** the tips of the two needles.") (emphasis added).). The zone of thermal damage 425 is clearly depicted in Figure 4 of Manstein, which is copied below.

Figure 13: Figure 4 of Manstein Depicting Thermal Damage Between Needle Tips



(*Id.* at Fig. 4.).

[53] The published application that issued as RX-0304 (Manstein) was considered during prosecution. *See generally*, *Guangdong Alison Hi-Tech Co. v. Int'l Trade Comm'n*, 936 F.3d 1353, 1365 (Fed. Cir. 2019) ("Arguments and references already considered by the Patent Office may carry less weight with the fact finder.") (citing *Sciele Pharma Inc. v. Lupin Ltd.*, 684 F.3d 1253, 1260 (Fed. Cir. 2012)).

Moreover, during prosecution of the application that issued as the ’836 patent, in response to a Final Office Action, the applicant stated that the claims at issue were amended “to note the apparatus may be configured to provide and the method may provide an alternating current (AC) RF signal to a plurality of electrodes (that are bipolar) to coagulate around each electrode rather than coagulating between the electrodes.” (JX-0008.0377-381, 0391 (’836 Pat. Pros. Hist.).). The patent examiner allowed the claims, with a minor modification. (*Id.* at JX-0391 (adding the following examiner’s amendment: replacing “signal to the plurality of electrodes to coagulate around each electrode” with “signal to the plurality of electrodes configured to cause coagulation around each electrode”).).

c) Hantash (CX-1089)

Like Manstein, Hantash describes generating intersecting thermal damage zones between electrodes—the opposite of that which the asserted claims of the ’836 patent require. (CX-1089 (Hantash) at [0023]-[0027], Figs. 4-9; Tr. (van der Weide) at 1454:1-14; CDX-0046C-0031.).

3. The Prior Art References Do Not Render Obvious the Asserted Claims of the ’836 Patent[54]

a) Ganz in View of the Knowledge of a Person of Ordinary Skill (Claim 1)

The evidence does not clearly and convincingly prove that Ganz in view of the general

[54] On July 26, 2024, Respondents submitted a notice regarding the PTAB’s decision to institute IPR proceedings for the ’836, ’536, and ’774 patents (“Notice of IPR”). (Doc. ID No. 827354 at Exs. A-C (July 26, 2024).). With respect to the ’836 patent, the PTAB found that “[p]etitioner has shown a reasonable likelihood that claim 1 would have been obvious based on Ganz in view of a POSITA’s knowledge.” (Notice of IPR, Ex. A (’836 patent institution) at 29.). The PTAB also found that petitioner has demonstrated a reasonable likelihood that claims 9 and 22 would have been obvious over, *inter alia*, Ganz in view of Hantash. (*Id.* at 35.). With respect to the ’536 and ’774 patents, the PTAB found that petitioner has shown a reasonably likelihood that Mehta anticipates and/or renders obvious, *inter alia*, claims 11 and 16 of the ’536 patent, and claim 14 of the ’774 patent. (*Id.*, Ex. C (’536 patent institution) at 16-18; *id.*, Ex. B (’774 patent institution) at 17.). Respondents subsequently filed a supplemental

knowledge of a person of ordinary skill renders obvious claim 1 of the '836 patent.

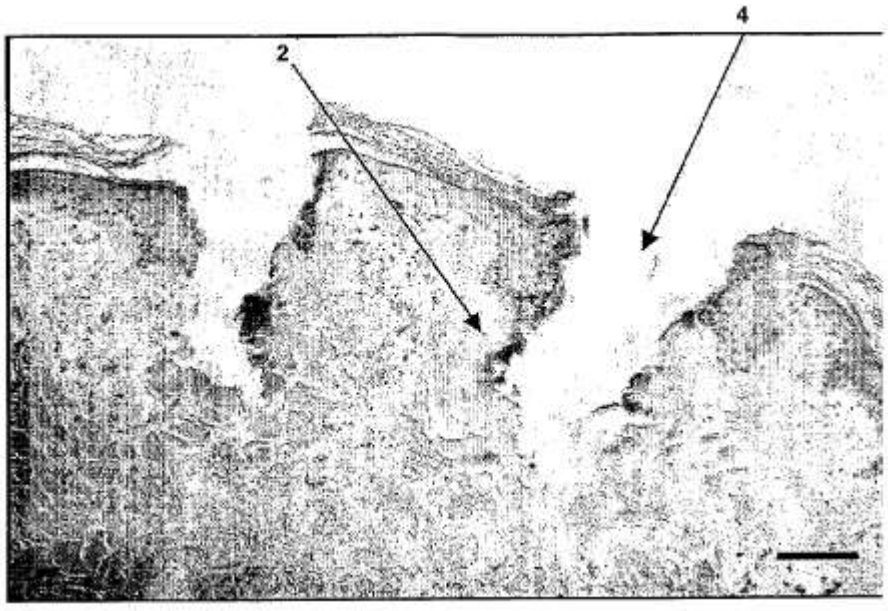
As an initial matter, the scope and content of Ganz are fundamentally different than that of the '836 patent. Ganz discloses "[a] device for creating a pattern of perforations in a tissue." (RX-0329 at [Abstract].). Ganz's invention is directed to improving on "cumbersome" prior art methods of "create[ing] vertical ***perforations or ablation holes*** in tissue," such prior art methods including using a "simple knife, needle or other device" that would be "subjected to the skill of the operator" to create precise "depth, width, and pattern of perforation," and cause "excess bleeding." (*Id.* at [0006], [0008] (emphasis added).). Ganz defines the term "perforation" to explicitly refer to ablating tissue: "[a]s used herein, the term 'perforation' means ***vertical areas of thermal damage or ablation to the tissue*** causing tissue necrosis." (*Id.* at [0027] (emphasis added).). Figure 9 of Ganz, replicated below, "illustrates a skin area treated in accordance with the invention," i.e., creating vertical ablation holes.

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notice with respect the institution of IPR of the '812 patent ("Supplemental Notice of IPR"). (Doc. ID No. 830443 at Ex. D (Aug. 23, 2024).). With respect to the '812 patent, the PTAB found that Mehta anticipates and/or renders obvious, *inter alia*, claims 5, 13, and 18. (Suppl. Notice of IPR, Ex. D at 20.).

As Serendia pointed out in its responses to Respondents' Notice of IPR ("Response to Notice of IPR") and Supplemental Notice of IPR ("Response to Supplemental Notice of IPR"), "Respondents cited no authority to support their contention that the PTAB's preliminary, non-final institution decisions on . . . [the] asserted patents 'should be given significant weight here.'" (Doc. ID No. 828242 (Resp. to Notice of IPR) at 1 (Aug. 2, 2024); Doc. ID No. 830694 (Resp. to Suppl. Notice of IPR) at 1 (Aug. 27, 2024).). The Commission has confirmed that "non-final IPR proceedings have no bearing on Commission investigations." *Certain Magnetic Data Storage Tapes and Cartridges Containing the Same*, Inv. No. 337-TA-1012, Comm'n Op. at 49 n.26 (Apr. 2, 2018) (emphasis added).). Moreover, the Commission has explained that PTAB proceedings and Commission proceedings concerning invalidity are distinct. *See, e.g.*, *Certain Network Devices, Related Software and Components Thereof (II)*, Inv. No. 337-TA-945, Comm'n Op. at 12 (Aug. 16, 2017) (citing *Novartis AG v. Noven Pharm., Inc.*, 853 F.3d 1289, 1294 (Fed. Cir. 2017) ("[E]ven if the record were the same" before a trial court and the PTAB, "the PTAB properly may reach a different conclusion based on the same evidence."). Accordingly, validity in this Investigation have been assessed based on the evidentiary record and higher burden of proof that applies here.

Figure 14: Figure 9 of Ganz Depicting Vertical Ablation Holes



(*Id.* at Fig. 9, [0028].).

As Staff correctly noted, Ganz's inventive method: (i) caused tissue to be removed (i.e., ablation) surrounding the electrodes; and (ii) the areas surrounding those ablation holes/perforations were coagulated: "The treated area 4 is clearly a perforation, which extends vertically into the skin. Areas or zones of coagulation 2 can also be seen in the areas surrounding the perforation 4." (*Id.* at [0028].). Ganz's invention, therefore, is a result of the "Applicant['s] [] discover[y] that it is desirable to create vertical perforations or ablation holes in tissue, as this prompts an even more aggressive wound healing response than is currently seen." (*Id.* at [0006].).

In view of the scope and content of Ganz, and notwithstanding the IPR filings, the evidence in this Investigation does not clearly and convincingly demonstrate that Ganz renders obvious every limitation of claim 1 of the '836 patent. For the additional reasons discussed below, Ganz does not render obvious the following claim limitations: (i) "a plurality of

electrodes, the electrodes being bipolar" (plurality of electrodes being bipolar limitation); (ii) "provid[ing] an Alternating Current (AC) RF signal to the plurality of electrodes" (alternating current (RF) signal limitation); and (iii) "configured to cause coagulation around each electrode rather than coagulating between the electrodes" (coagulation limitation).

i. Plurality of Electrodes Being Bipolar Limitation

As Dr. van der Weide opined, Ganz fails to disclose a plurality of "bipolar" electrodes "configured to cause coagulation around each electrode rather than coagulating between the electrodes." (Tr. (van der Weide) at 1442:11-1445:4; CDX-0046C.0007-12.). Respondents pointed to Ganz's disclosure that "[t]he electrodes can be either monopolar or bipolar." (RBr. at 9 (citing RX-0329 (Ganz) at [0055].). However, as Serendia noted, claim 1 of the '836 patent requires more than the mere presence of bipolar electrodes. (CRBr. at 4.). Claim 1 also requires the electrodes to be configured to cause the claimed coagulation. (*Id.*).

Respondents relied on the "embodiment[s]" described in Ganz's paragraph [0047] and Figures 9 and 10 to contend that Ganz discloses the claimed coagulation. (RBr. at 16-17.). However, as explained below, Ganz does not disclose the claimed coagulation of the '836 patent. Moreover, Respondents failed to demonstrate that these embodiments in Ganz use bipolar electrodes.

Notably, Respondents' expert, Dr. Woloszko, confirmed that he did not know whether any of the "outcome[s] or results" depicted and described in Ganz were obtained using bipolar electrodes. (Tr. (Woloszko) at 1038:13-15 ("Q. So you don't know whether Ganz shows any outcome or results using bipolar electrodes, right? A. That's correct."); *see also* Tr. (van der Weide) at 1442:24-1443:10 ("no one can identify how Ganz got the results that it produces"), 1443:21-23, 1444:14-20; CDX-0046C.0009-11.). Dr. Woloszko also conceded that he did not

know whether Figures 9-10 of Ganz were obtained using bipolar electrodes. (Tr. (Woloszko) at 1038:9-12 ("Q. Okay. Just to make sure I understand your testimony clearly today, you don't know whether Figs. 9 and 10 in Ganz are monopolar or bipolar. Do I have that right? A. Correct."); *see also* Tr. (van der Weide) at 1444:9-13 ("neither I nor Dr. Woloszko . . . could identify such information").).

Additionally, Respondents did not contest that Ganz fails to disclose using bipolar electrodes configured according to the adopted construction, which "excludes the INTRAcel configuration (alternating rows of commonly-polarized electrodes)." (*Markman* Order at 46.). Respondents acknowledged that Ganz's disclosure encompasses the INTRAcel configuration and expressly argued that "Ganz discloses an arrangement of bipolar electrodes that is broader than, and not limited to, the INTRAcel configuration." (RBr. at 11.). Respondents neither contended that it would have been obvious to select a configuration excluding the INTRAcel configuration (*see id.*) nor adduced any evidence to support such a contention. In fact, Dr. Woloszko merely testified that Ganz is not limited to the INTRAcel configuration (Tr. (Woloszko) at 877:1-20). However, he did not offer an opinion that it would have been obvious to use some other configuration in any embodiment on which he relies. (Tr. (van der Weide) at 1444:21-1445:4; CDX-0046C.0012).).

The only case Respondents cited to support their disclosure position, *Upsher-Smith Lab'ys, Inc. v. Pamlab, L.L.C.*, 412 F.3d 1319 (Fed. Cir. 2005), is inapposite. (RBr. at 11.). As Respondents described, that case held that disclosure of "both a composition with antioxidants and a composition without antioxidants anticipated claims that required a composition without antioxidants." (*Id.* (citing *Upsher-Smith*, 412 F.3d at 1322).). Here, while Ganz discloses bipolar electrodes generally as an option, Respondents failed to demonstrate that Ganz discloses

a bipolar configuration that is not the INTRAcel configuration that is used to produce the results on which they rely (e.g., Ganz's Figures 9-10). Respondents also have not argued that it would have been obvious to modify Ganz to do so. In fact, Respondents failed to present evidence that one of ordinary skill would have been motivated to pick such a configuration, as required. *See, e.g.*, *Personal Web Techs., LLC v. Apple, Inc.*, 848 F.3d 987, 994 (Fed. Cir. 2017) ("[O]bviousness concerns whether a skilled artisan not only ***could have made*** but ***would have been motivated to make*** the combinations or modifications of prior art to arrive at the claimed invention.") (emphasis in original).

Accordingly, the evidence does not clearly and convincingly demonstrate that the plurality of electrodes being bipolar limitation would have been obvious.

ii. Alternating Current (RF) Signal Limitation

Claim 1 of the '836 patent recites a skin treatment device comprised of bipolar, insertable electrodes, and a RF generation module configured to provide an alternating current RF signal to the electrodes. (JX-0007 at cl. 1.). The plain language of this element requires that the RF signal be specifically of ***alternating*** current (as opposed to direct current).

Respondents did not dispute that Ganz does not explicitly disclose an alternating current RF signal, but instead argued that a person of skill would have known "that a radio-frequency is a high frequency AC, [and] a POSITA would have recognized that Ganz's RF energy provides AC/RF." (RPBr. at 24-25; RBr. at 12-15.). For the following reasons, Respondents have not clearly and convincingly demonstrated that this claim element is obvious.

As Serendia pointed out, Ganz does not mention alternating (or oscillating) current at any point in its claims or specification. (CRBr. at 6.). Moreover, the evidence, including Dr. Woloszko's own patents, indicate that one of ordinary skill understood both non-AC and AC RF

could be used, and would refer to AC RF specifically when that is what they meant to use or specify. Dr. van der Weide explained that there are "at least two . . . categories of radiofrequency energy that can be supplied to electrodes"—non-AC "voltage pulses" applied at a frequency in the RF range or AC RF. (Tr. (van der Weide) at1446:13-21; *see also* RX-2545C (Na Dep. Tr.) at 44:5-8 .). Dr. Woloszko's own prior art patent, U.S. Pat. No. 6,766,202, confirms that either non-AC or AC RF can be used, disclosing that "high frequency (RF) electrical energy" "is usually delivered in a series of voltage pulses or alternating current." (RX-0303 (U.S. Patent No. 6,766,202) at 5:31-34, 6:42-52; Tr. (van der Weide) at 1446:22-1447:17.).

Serendia provided other patents (including Dr. Woloszko's own) that similarly distinguish between non-AC RF and AC RF. (CX-2653 (US 2011/0288543) at [0017], [0035], [0036]; CX-3024 (U.S. Patent No. 9,095,358 to Woloszko) at 4:7-11, 6:28-34; Tr. (van der Weide) at 1446:22-1448:3.). Notably, Dr. Woloszko specifically claimed "radiofrequency alternating-current" when he meant AC RF—just as the '836 patent does—and in contrast to Ganz's disclosure. (CX-1092.0032 (U.S. Patent No. 8,012,153) at cl. 37.). Thus, as Dr. van der Weide testified, Ganz's generic reference to RF would not inform a person or ordinary skill in the art that AC RF was used. (Tr. (van der Weide) at 1448:4-8.).

Respondents attempted to explain away Dr. Woloszko's patents referencing "voltage pulses or alternating current" by contending that this means that they are "synonyms," and that the "or" should be interpreted as "i.e.": "voltage pulses [i.e.] alternating current." (RBr. at 15.). Respondents' argument is not persuasive because it conflicts with the patents' plain language. Furthermore, Dr. Woloszko's support of this incorrect reading (Tr. (Woloszko) at 904:1-11) undermines his credibility. Respondents also failed to address the fact that Dr. Woloszko

expressly claimed "radio frequency alternating-current" in his own patent, which, as Serendia noted, would be redundant if RF on its own meant AC RF. (CRBr. at 7 (citing CX-1092.0032 (U.S. Patent 8,012,153) at cl. 37).).

Additionally, Respondents argued that one of ordinary skill would have understood the RF in Ganz to be AC RF because: (i) an Annals of Internal Medicine article about "catheter ablation for cardiac" use (CX-2657.0001) states that RF energy is generated from alternating current; (ii) Dr. Na purportedly stated that RF is AC in an unrelated Korean patent application (RX-0125);[55] and (iii) using DC for skin treatment would be "dangerous" and "illegal" (Tr (Woloszko) at 882:6-12). (*See* RBr. at 13-15.). Even if Respondents' arguments were given some credit, at most, they would establish that there is conflicting evidence, thereby leading to some uncertainty whether a skilled artisan would have viewed Ganz's disclosure of RF as referring to AC RF. However, that falls far short of meeting Respondents' burden to establish by clear and convincing evidence that this is how a person of ordinary skill would interpret Ganz. Furthermore, for the reasons discussed below, Respondents' positions lack merit.

First, Respondents single article in the Annals of Internal Medicine, is in a much different field, i.e., "radiofrequency ablation for cardiac tachyarrhythmias." (CX-2657.0001.). Second, a statement purportedly made in a Korean patent application not of record merely demonstrates that RF ***can*** refer to AC RF. This does not demonstrate that one of ordinary skill in the art would have understood ***Ganz's*** references to RF to refer to AC RF. Notably, all the witnesses (from both Parties) who addressed the issue agreed that RF can be AC or DC. (Tr. (Woloszko) at

[55] Respondents' citation is to a withdrawn exhibit. (Doc ID No. 811000 (Respondents' Final Exhibit List) at 5 (Dec. 26, 2023).).

880:15-881:3 (referring to "what people would call (DC) RF"); Tr. (van der Weide) at 1446:13-1448:7 ("at least two . . . categories of" RF); RX-2545C (Na Dep. Tr.) at 44:5-8 [redacted].). Third, Respondents contended that a person of ordinary skill would have interpreted Ganz's references to RF as meaning AC RF because using DC RF would have been "illegal" and have "detrimental effects." (RBr. at 13-14.). However, as Serendia pointed out, Ganz is just a published patent application, and not an issued patent or a commercial device that would need to meet alleged safety standards.[56] (CRBr. at 8.).

Accordingly, the evidence does not clearly and convincingly prove that the alternating current (RF) signal limitation would have been obvious.

iii. Coagulation Limitation

Claim 1 recites a skin treatment apparatus comprised of bipolar, insertable electrodes, and a RF generation module configured to provide an AC RF signal to the electrodes "configured to cause coagulation around each electrode rather than coagulating between the electrodes." (JX-0007 at cl. 1.). The treatment disclosed in the '836 patent causes "coagulation around each electrode rather than coagulating between the electrodes" by applying sufficient AC RF energy to skin treatment regions around (but not between) bipolar electrodes. (*Id.* at 2:63-3:10; 3:21-23 ("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 '836 patent distinguishes the "effect on the dermis" from energy applied to cause the recited "coagulation" versus "carbonization" and "vaporization." (*Id.* at 2:63-66; *see also* Tr. (Goldberg) at 1304:16-1306:13

[56] Dr. Woloszko's own patents about "electrosurgical systems," including devices "to treat a patient's skin," disclose using RF composed of "either voltage pulses or alternating current." (RX-0303 (U.S. Patent No. 6,766,202 to Woloszko et al.) at 1:44-48, 5:31-34, 6:42-52; CX-3024 (U.S. Patent No. 9,095,358 to Woloszko et al.) at 1:43-44, 4:7-11, 6:28-34.).

(explaining the distinctions between coagulation, carbonization, and vaporization, and the dermatological applications of each).).

Respondents argued that Ganz "discloses this limitation" but failed to prove by clear and convincing evidence that Ganz "caus[es] coagulation around each electrode rather than between the electrodes" for several reasons. (RBr. at 15.).

A fundamental reason that also explains a critical difference is that Ganz fails to disclose "coagulation around each electrode." Rather, Ganz "removes tissue around each electrode" to create vertical perforations or ablation holes in tissue. (Tr. (van der Weide) at 1448:23-1449:16; RX-0329 at [0006] ("One drawback with the [prior art procedure] is that the laser does not create perforations or vertical holes in the tissue, but only causes zones of coagulation. Applicant has discovered that it is desirable to create vertical perforations or ablation holes in issue . . . ."); CDX.0046C.0021 *see also* Tr. (Goldberg) at 1311:7-10 ("there's no coagulation around the microneedles because the tissue is gone"); Tr. (van der Weide) at 1450:11-13.).

Ganz discloses using "energy," rather than "a simple knife," to create "perforations without causing undue bleeding." (RX-0329 at [0008].).

> Q. . . . [C]an you tell us about the Ganz reference?
>
> A. So the Ganz reference really is different. Ganz refers to a device for creating a pattern of perforations in tissue. Think of it this way. We cut the skin with a knife. We cut the skin with a scalpel. And I talked about the fact that we get bleeding. Ganz is a device that causes those perforations of the skin but also lessens bleeding.
>
> * * *
>
> Q. Moving on to slide 13, why is Ganz creating perforations in tissue?
>
> A. So, you know, as you can see here, when those perforations are made mechanically, scalpel, knife, rather than with the use of energy, there's a lot of bleeding. We all know that when we cut the skin. So there is a need for a device according to Ganz which creates these perforations, these cuts in the skin, without causing undue bleeding.

> Q. How does Ganz create perforations without causing undue bleeding?
>
> A. Well, it creates these perforations because it ablates, vaporizes, it carbonizes tissue.

(Tr. (Goldberg) at 1307:11-18, 1308:1-8.).

As Dr. Goldberg credibly testified, with experience, Ganz's approach of "cauterizing and removing tissue" is "very different than the types of treatments . . . claimed in the '836 patent, which are causing coagulation localized around each needle electrode." (Tr. (Goldberg) at 1313:12-18; *see also id.* at 1300:21-42.). Respondents' expert, Dr. Woloszko, agreed that Ganz teaches removing tissue to create holes in the skin. (Tr. (Woloszko) at 1034:19-23.).

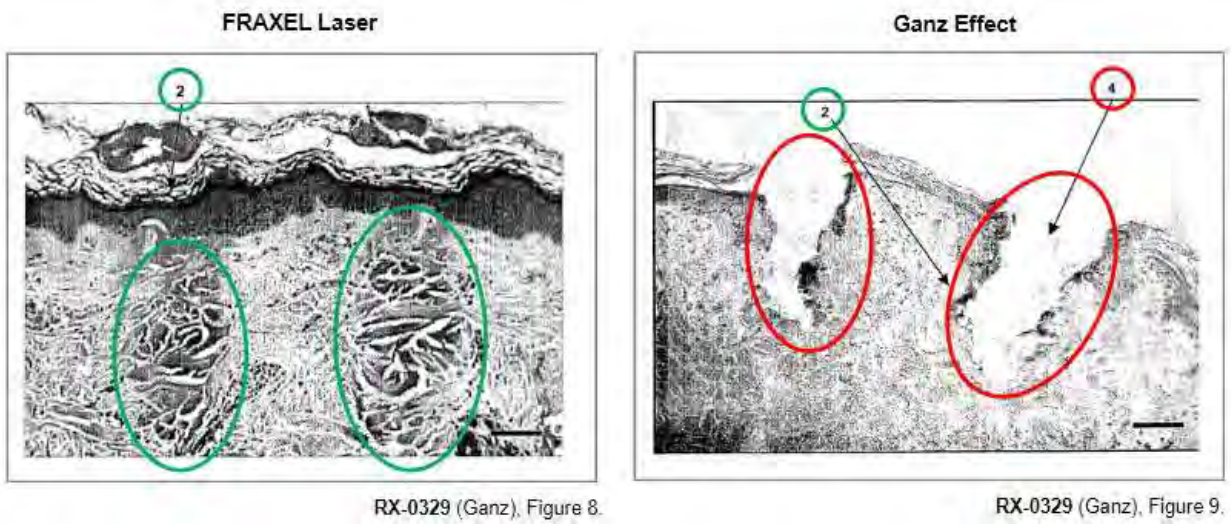
Ganz and the '836 patent expressly distinguish each other's approaches. (Tr. (van der Weide) at 1449:12-16 ("Ganz distinguishes approaches that merely cause coagulation, like the '836 patent, and for its part, . . . the '836 patent distinguishes systems that overheat and burn tissue like Ganz, so they are really distinct.").). Ganz explains that his device "imparts perforations into the skin, rather than merely imparting coagulations into the skin." (RX-0329 at [0032]; *see also* Tr. (Goldberg) at 1309:22-1311:6.). Ganz views producing "zones of coagulation," without "creat[ing] perforations or vertical holes in the tissues," as a "drawback," because it is not "aggressive" enough. (RX-0329 at [0006]; *see also* Tr. (Goldberg) at 1309:7-1310:7; Tr. (VDW) at 1449:17-1450:3.).

As depicted below in Dr. Goldberg's demonstrative, Ganz illustrates the distinction between "caus[ing] coagulation, indicated at reference number 2" (green below) using a "prior art" laser in Figure 8 and his approach in Figure 9 of creating a "treated area 4 [that] is clearly a perforation, which extends vertically into the skin" (red below), with "coagulation 2" only at the edges, which Ganz describes as follows:

> FIG. 8 illustrates a skin area treated in accordance with a prior method. The skin area in FIG. 8 has been treated using a FRAXEL infrared scanning laser. The laser causes coagulation, indicated at reference number 2. A perforation is not created at area 2, which is treated by the laser. On the other hand, FIG. 9 illustrates a skin area treated in accordance with the invention. The treated area 4 is clearly a perforation, which extends vertically into the skin. Areas or zones of coagulation 2 can also be seen in the areas surrounding the perforation 4.

(RX-0329 at [0028].).

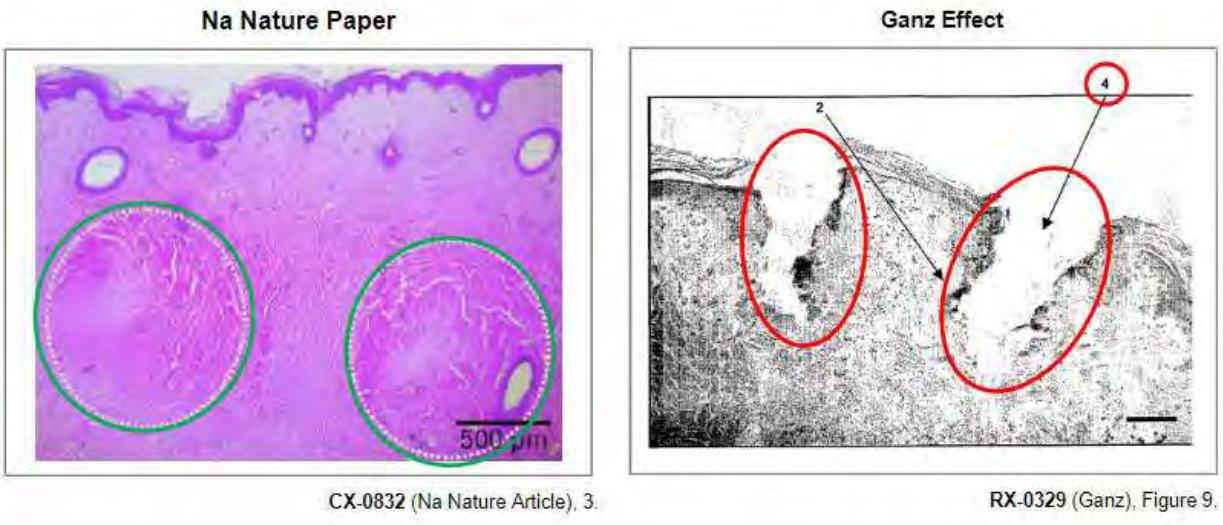
Figure 15: Goldberg Demonstrative Comparing Prior Art Method with Ganz



(CDX-0044C.0018; RX-039 at Figs. 8-9; *see also* Tr. (Goldberg) at 1310:8-1312:3; Tr. (van der Weide) at 1449:17-1450:3.).

Additionally, a comparison of other histological images of coagulation around needle insertion sites produced using RF microneedling devices to Ganz's approach, depicted below, confirms that Ganz teaches a different approach than claimed in the '836 patent.

Figure 16: Histological Images Illustrating Distinction Between Na Effect and Ganz Effect



(CDX-0044C.0019-20; CX-0832.0003 (Na Nature Article) (left above); RX-0329 at Fig. 9 (right above); Tr. (Goldberg) at 1312:7-1313:11.).

The '836 patent similarly distinguishes approaches like the one taught in Ganz. The '836 patent differentiates "coagulation" from other tissue effects—"carbonization" and "vaporization"—that occur when more energy is applied. (JX-0007 at 2:62-3:10; *see also* Tr. (Goldberg) at 1304:16-1305:13 ("As we get to somewhere around 60 degrees, we coagulate tissue. That leads to healthy new tissue, and that's what we need for antiaging and for acne scarring, skin tightening. What we don't want to do is get to 100 and 200 degrees. That's vaporization, that's carbonization, that's ablation. That destroys tissue. That leads to scars.").).

Critically, the '836 patent discloses that applying energy beyond that needed to coagulate tissue has the side effect of "overheating or burning of both [the] dermis and epidermis," which "may cause permanent skin damage"; in other words, using this "[e]xisting technology may create scars." (JX-0007 at 4:4-19; *see also* Tr. (Goldberg) at 1306:25-1307:10.). Ganz is an example of an existing system that the '836 patent distinguished because Ganz "creates

perforations because it ablates, vaporizes, . . . carbonizes tissue." (Tr. (Goldberg) at 1308:9-12; *see also* Tr. (van der Weide) at 1450:14-1451:8 ("Ganz is actually overheating and burning [the] epidermis in order to create its perforation").). Thus, Ganz's approach of creating "ablation holes" (RX-0329 at [0006]), stands in contrast to the '836 patent which, as Respondents' expert, Dr. Bérubé, confirmed, "does not involve ablation." (Tr. (Bérubé) at 1268:24-1269:1 ("Q. . . . The patent, the '836 patent investigation, does not involve ablation, correct? A. That's correct."); *see also* Tr. (van der Weide) at 1451:4-8 (testifying that Ganz and the '836 patent involve "completely distinct teachings").).

Respondents argued that Ganz discloses the claimed "coagulation around each electrode" because Ganz discloses "[z]ones of coagulation" in "tissue surrounding each perforation," i.e., coagulation "at the 'edges' of the perforations." (RBr. at 15-16 (citations omitted).). However, as Serendia noted, this is not "coagulation ***around each electrode***"—it is coagulation around the edge of the "holes" that Ganz created by "remov[ing] tissue around each electrode." (CRBr. at 12; Tr. (van der Weide) at 1448:23-1450:13, RX-0329 at [0006], [0027].). Dr. Goldberg explained that Ganz does not cause "coagulation around each electrode" because the tissue that had been around each electrode "is gone." (Tr. (Goldberg) at 1311:7-10.). Respondents unpersuasively contended that Serendia seeks to read in a requirement that coagulation be "'immediately' around each electrode." (RBr. at 18.). By its plain language and under the agreed construction, the claim requires "coagulation ***around each electrode***"—not coagulation at the edges of holes created around each electrode. (*Markman* Order at 40.). Thus, Ganz's ablation treatment leaving "zones of coagulation" around the perforation holes that are created because of ablating the tissue falls outside the scope of the claim 1's recited "coagulation around each electrode rather than coagulating between the electrodes."

Accordingly, the evidence does not clearly and convincingly prove that the coagulation limitation would have been obvious.

b) Ganz in View of the Knowledge of a Person of Ordinary Skill and Further in View of Manstein (Claim 9)

Claim 9, which depends from claim 1, recites: "The skin treatment apparatus of claim 1, wherein the electrodes are needles and have a diameter from 0.25 mm to 0.30 mm." (JX-0007 at cl. 9). Respondents relied on the combination of Ganz and Manstein to demonstrate that the limitation recited in dependent claim 9 is obvious. (*See* RPBr. at 25-27; RBr. at 18-21.).

As an initial matter, because claim 9 depends on claim 1, Ganz does not render claim 9 obvious for the same reasons. *See Mylan Pharms. Inc. v. Research Corp. Techs., Inc.*, 914 F.3d 1366, 1376 (Fed. Cir. 2019) ("Dependent claims, with added limitations, are generally not obvious when their parent claims are not.") (citation omitted).

Additionally, Ganz in view of Manstein does not render obvious that "the electrodes are needles and have a diameter from 0.25 mm to 0.30 mm," as recited in claim 9. As Staff noted, Ganz does not disclose any particular ***electrode/needle*** diameter. (SBr. at 38.). Respondents cited to paragraphs [0051] and [0053] in Ganz. (RPBr. at 26; RBr. at 19.). However, those paragraphs only generally describe that "[t]he length and width of the electrode pins are ***variable***," and that "[t]he width or diameter of each electrode pin can also be ***varied*** to provide a perforation having a desired width." (RX-0329 at [0051], [0053].). These paragraphs in Ganz do not disclose any specific diameters of its electrodes, let alone needles having "a diameter from 0.25 mm to 0.30 mm," as required by claim 9.

In view of Ganz's sparse disclosure, Respondents attempted to gap-fill by arguing that "[a] POSITA would have recognized that to achieve these perforations a needle diameter of 0.25

to 0.30 mm is necessary and deduce that the diameter of Ganz's needles is 0.25-0.30 mm." (RPBr. at 26 (citing RX-0329 at [0065]; *see also* RBr. at 19-20.).

As Staff also pointed out, paragraph [0065] in Ganz discloses diameter ranges of the perforations/ablation it causes in tissue. (RX-0329 at [0065]; *see also id.* at [0047], cl. 4.). Respondents' attempt to extrapolate specific needle diameters based on Ganz's general disclosure of perforations/ablation hole diameter does not amount to clear and convincing evidence. *See In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1073 (Fed. Cir. 2012) ("where the prior art, at best, gives only general guidance as to the particular form of the claimed invention or how to achieve it, relying on an obvious-to-try theory to support an obviousness finding is impermissible") (internal citations and quotation marks omitted). Moreover, paragraph [0065] Respondents cited pertains to a ***monopolar*** electrode configuration. (RX-0329 at [0065] ("A monopolar electrode array was placed upon the skin.").). However, as Respondents' expert, Dr. Woloszko admitted, the '836 patent claims require ***bipolar*** electrodes, and that he was relying only of Ganz's disclosures concerning its bipolar configuration. (Tr. (Woloszko) at 1140:12-1141:2.).

In view of Ganz's shortcomings, Respondents contended that combining Ganz with Manstein would render claim 9 obvious. (RPBr. at 26-27; RBr. at 19-21.). The evidence is that Manstein also fails to disclose claim 9's recited diameter of 0.25 mm to 0.30 mm. Manstein discloses needles with larger widths. (RX-0304 at 7:41-45 ("practicing the methods and apparatus of the present invention, the needles can have a width ***of about 500-1000 um or preferably about 700-800 µm***.") (emphasis added).). Respondents relied on Manstein's general disclosure that electrodes less than 500 um in diameter can be used "they are mechanically strong enough." (RPBr. at 26.). This is insufficient to meet the clear and convincing standard.

See In re Cyclobenzaprine, 676 F.3d at 1073.

Furthermore, Respondents have failed to present evidence that demonstrates a motivation to combine Ganz with Manstein. Respondents argued that needles of the claimed diameter were known elsewhere in the art, that both Ganz and Manstein are about "dermatological treatment," that both involve "inserting needles into skin" and "using RF energy," and that the "combination would have required a simple substitution." (RBr. at 20-21.). Even crediting all those arguments, they would only demonstrate that one of ordinary skill ***could*** have used needles of the claimed diameter, but not why one of ordinary skill ***would have been motivated*** to do so. Respondents thus failed to meet their burden to support obviousness. *Personal Web Techs.*, 848 F.3d at 993 (noting that it "is not enough" to demonstrate that two references "***could*** be combined," instead, there must be "a motivation to pick out those two references and combine them to arrive at the claimed invention") (emphasis in original) (citation omitted).

Additionally, Respondents did not address how Ganz and Manstein are compatible, whether and why the combination would have yielded predictable results, or whether it would have been obvious to try with some expectation for success. *See Orexo AB v. Actavis Elizabeth LLC*, 903 F.3d 1265, 1273 (Fed. Cir. 2018) ("The question is not whether the various references separately taught components of the [claimed invention], but whether the prior art suggested the selection and combination achieved by the [ ] inventors."). For example, there are fundamental differences between Ganz's perforation/ablation skin treatment and Manstein's skin treatment where thermal damage is caused between two (2) adjacent needles in bipolar configuration. (RX-0304 at 7:19-22, Fig. 4 (describing and depicting "thermal damage 425 around ***and between the tips*** of the two needles") (emphasis added).). Moreover, according to Serendia's expert, Dr. van der Weide, a person of skill would not have been motivated to combine Ganz with Manstein,

including specifically for the purposes of using a needle diameter within the scope of claim 9. (Tr. (van der Weide) at 1452:9-1453:9.). *See Arctic Cat Inc. v. Bombardier Recreational Prods. Inc.*, 876 F.3d 1350, 1363 (Fed. Cir. 2017) ("Evidence suggesting reasons to combine cannot be viewed in a vacuum apart from evidence suggesting reasons not to combine.").).

Moreover, Respondents' expert, Dr. Woloszko, offered only "conclusory and unsupported expert testimony" about why a person of ordinary skill in the art would allegedly have been motivated to modify Ganz in view of Manstein, which is "impermissible." (Tr. (Woloszko) at 897:8-898:1; RBr. at 20.). *TQ Delta, LLC v. CISCO Sys., Inc.*, 942 F.3d 1352, 1361 (Fed. Cir. 2019). Respondents, therefore, failed to provide a sufficient motivation to combine Ganz with Manstein.

For the reasons discussed above, Respondents have failed to prove by clear and convincing evidence that claim 9 would have been rendered obvious by Ganz in view of the knowledge of one of ordinary skill in the art in further view of Manstein.

c) Ganz in View of the Knowledge of a Person of Ordinary Skill and Further in View of Hantash (Claim 22)

Claim 22, which depends from unasserted claim 14, recites: "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 at cl. 22.). Respondents stated that claim 22 "is essentially directed to a method of treating skin using the device of claim 1," and asserted that claim 22 is rendered obvious for the same reasons as claim 1, and that Hantash discloses claim 22's additional limitation. (RPBr. at 27-28; *see also* RBr. at 22-23.).

As an initial matter, claim 22 depends from claim 14 (which tracks claim 1), and thus claim 22 is not obvious over Ganz in view of Hantash for the same reasons Ganz does not render

claim 1 obvious. (Tr. (van der Weide) at 1453:18-25.).

Additionally, Ganz in view of Hantash does not render obvious "the RF is from 0.5 to 10 Mhz" and "the predetermined time interval is from 0.05 to 0.8 seconds" requirements of claim 22. As Respondents acknowledged, "Ganz does ***not*** provide any express limitation for the frequency range of the RF" and "does ***not*** explicitly disclose time intervals over which the RF energy is applied." (RBr. at 23; *see also* Tr. (van der Weide) at 1454:15-24.).

Moreover, as Dr. van der Weide explained, one of ordinary skill in the art would not have been motivated to combine Ganz with Hantash because Ganz teaches "removal of tissue" to create holes around electrodes and leaving regions between them untouched (as discussed above in Section VII.D.3(c)), while Hantash teaches causing thermal damage "between electrodes." (Tr. (van der Weide) at 1454:25-1455:9.).

Respondents made the same generic arguments for claim 22 as they did for claim 9 to try to support a motivation to combine: the references are about "dermatological treatment," involve "inserting needles into skin" and "using RF energy," and combining them "would have required a simple substitution." (RBr. at 24.). Again, even crediting those arguments, Respondents failed to meet their burden because they only demonstrated that a person of ordinary skill ***could*** have combined Ganz and Hantash, but failed to explain why a person of ordinary skill ***would have been motivated*** to combine them to achieve the claim requirements. *Personal Web Techs.*, 848 F.3d at 993.

Respondents also failed to explain how or why one would combine Ganz with Hantash. Other than a general contention that both Ganz and Hantash "disclose RF microneedling devices and provide alternate solutions to using lasers," Respondents did not address how these two references are compatible, whether the combination would have yielded predictable results, or

whether it would have been obvious to try with some expectation for success. (RPBr. at 27.). For example, Respondents did not explain why a person of ordinary skill would combine Ganz's perforation/ablation skin treatment with Hantash's skin treatment where thermal damage is caused between needles. (CX-1089 at Figs. 8A-9B.). Indeed, "knowledge of a problem and motivation to solve it are entirely different from motivation to combine particular references." *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1373 (Fed. Cir. 2008).

In addition, Dr. Woloszko again offered only "conclusory and unsupported expert testimony" about why one of ordinary skill would purportedly have been motivated to modify Ganz in view of Hantash), which is "impermissible." (Tr. (Woloszko) at 902:13-903:1; RBr. at 24.). *TQ Delta*, 942 F.3d at 1361. Thus, Respondents failed to provide a sufficient motivation to combine Ganz with Hantash.

For the reasons explained, Respondents have failed to prove by clear and convincing evidence that claim 22 would have been rendered obvious by Ganz in view of the knowledge of one of ordinary skill in the art in further view of Hantash.

d) Objective Indicia of Non-Obviousness

Even assuming, *arguendo*, that Respondents made a *prima facie* showing of obviousness or that a person of ordinary skill in the art would have been motivated to combine or modify the prior art and would have had a reasonable expectation of success in doing so, Serendia adduced sufficient objective evidence of non-obviousness to rebut Respondents' *prima facie* showing. *Certain Soft Projectile Launching Devices, Components Thereof, Ammunition, and Prods. Containing Same*, Inv. No. 337-TA-1325, ID at 70, 90 (Oct. 25, 2023).

Moreover, Serendia's objective indicia evidence is unrebutted. Respondents did not present any substantive discussion of secondary considerations in their Pre-Hearing Brief. In

fact, Respondents were precluded from doing so by Order No. 41. (*See* 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).).

Nevertheless, Respondents attempted to rebut certain of Serendia's objective indicia evidence of commercial success in their Initial Post-Hearing Brief. (*See* RBr. at 31-32, 93-94.). Respondents' arguments are deemed abandoned or withdrawn under Ground Rule 7.2. (*See also* Order No. 41.). *See, e.g.*, *Certain Robotic Vacuum Cleaning Devices and Components Thereof Such as Spare Parts*, Inv. No. 337-TA-1057, Comm'n Op. at 51-52 (Feb. 1, 2019) (finding that Respondents waived an invalidity contention "by not raising the argument in their pre-hearing brief."); *Fitness Devices*, Inv. No. 337-TA-1265, Comm'n Op. at 19-23 (reversing ID and finding theory not included in pre-hearing brief was waived under the ALJ's Ground Rules); *Computer Network Security Equipment and Sys.*, Inv. No. 337-TA-1314, ID at 51, 88, 89, 111, 152-53, 256-57 (finding arguments not raised in pre-hearing briefs waived pursuant to GR 7.2).[57]

For the following reasons, Serendia's objective indicia of commercial success, industry praise, and long-felt need weigh in favor of validity.

[57] Respondents asserted that even though "Order No. 41 struck . . . Respondents' pre-hearing brief with respect to objective indicia, Respondents may nonetheless contest the sufficiency of Serendia's evidence." (RBr. at 31.). Respondents cited three (3) Final Initial Determinations that other administrative law judges issued to support their argument. (*Id.*). However, as Serendia pointed out, none of them involved a previous order to strike, and Respondents cannot use "failure of proof" as an excuse for failing to disclose their positions. *See Certain Digital Cameras, Software, and Components Thereof*, Inv. No. 337-TA-1059, Order No. 53 at 2 (Feb. 20, 2018) ("Respondents may not rely upon cross-examination to argue a 'failure of proof' when they did not submit their own affirmative contentions that might have rebutted Dr. Schonfeld's expert report, or the testimony that he may be giving during the evidentiary hearing.").).

i. Commercial Success

Serendia presented unrebutted evidence of commercial success. When "a product attains a high degree of commercial success, there is a basis for inferring that [attempts to a solution] have been made and have failed." *Merck & Co. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1376 (Fed. Cir. 2005). 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. (Tr. (Goldberg) at 1313:19-1317:21, 1320:18-1325:17, 1329:18-1331:18.).

Dr. Goldberg's testimony is supported by more than a preponderance of evidence, including marketing materials that prominently advertise the unique characteristics of the claimed invention in the '836 patent. (CDX-0004C.0025-32 (collecting evidence).). *Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573, 1579 (Fed. Cir. 1997) ("The prominence of the patented technology in Baxter's advertising creates an inference that links the Gambro invention to this success.").

For example, marketing materials tout features of the Sylfirm X that are unique characteristics of the claimed inventions, such as applying bipolar RF energy to skin via electrodes to cause coagulation around but not between electrodes, which "maximizes the thermal effect on the target with little to no epidermal damage, enabling effective and safe treatments." (CX-0830.0004; *see also* CX-0830.0007 (advertising that the product "creates wide, independent coagulation around each electrode"); CX-0830.0012 (advertising "the achievement of independent tissue coagulation around each micro-needle electrode."); CX-

0896.0012 (Benev website) (advertising that the product causes "[c]omplete coagulation in total dermal layer," and depicts such coagulation only around the electrodes.); CX-2858C.0003 (physician testimonial describing that the Na effect "provide(s) safe effective treatment because the tear drop shaped thermal effect minimizes heat damage to the epidermis and maximizes the therapeutic effect at the target"); CX-0918.0002 (Benev news release) ("Undoubtedly the most profound advantage seen with the Sylfirm X Ultimate Edition is the 'Na Effect.'").).

Indeed, Mr. Park, Benev's CFO, testified that [redacted]. (Tr. (Park) at 450:9-16.). *Certain Automated Put Walls and Automated Storage and Retrieval Sys., Associated Vehicles, Associated Control Software, and Component Parts Thereof*, Inv. No. 337-TA-1293, ID at 136-41 (Mar. 31, 2023) (holding that the objective indicia of commercial success supports nonobviousness, because, inter alia, "[t]he OPEX Domestic Industry Products are a cornerstone of OPEX's business and the appeal of those products in the marketplace is . . . achieved via the patented technology.") (unreviewed in relevant part).

Additionally, Serendia's economic expert, Mr. Thomas, analyzed sales data for the Sylfirm X DI product, the licensed SHEnB, ABM, Lutronic, and Rohrer products, and the Accused Products. He testified, that [redacted]. (Tr. (Thomas) at 1556:6-1559:9; CDX-0045C.0002-4 (collecting sales data).).

ii. Industry Praise

Serendia presented unrebutted evidence that the localized and targeted coagulation claimed by the '836 patent received industry praise and recognition. (Tr. (Goldberg) at 1331:19-

1332:11.). Numerous medical providers praised the "Na Effect," and its implementation sets products "apart from the pack." (CX-2857C.0001, 0003, 0006 (Aesthetic Guide); CX-2861C (Testimonial).). Many industry studies also recognized the advancements claimed in the '836 patent, (CX-2855 (Paper Summary); CX-2853 (Cho Study); CX-2854 (You Study))—including ones conducted by Respondents (CX-0353C.0001-3 (Wootten Study); CX-2590C.0005-6 (Harth Study). *See Gambro Lundia*, 110 F.3d at 1579; *WBIP*, 829 F.3d at 1334 (Fed. Cir. 2016) ("competitors, are not likely to praise an obvious advance over the known art").

iii. Long-Felt Need

Serendia presented unrebutted evidence that the '836 patent addressed a long-felt need for safer, more effective RF microneedling systems. (*See* CDX-0044C.0034-36 (collecting evidence).). "Evidence of a long felt but unresolved need tends to show nonobviousness because it is reasonable to infer that the need would have not persisted had the solution been obvious." *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1331 (Fed. Cir. 2016). Dr. Goldberg testified that'836 patent inventions have enabled products that practice the patent to provide safer and more effective treatments due to the specific type of coagulation caused (around but not between needles), particularly in comparison to prior generation RF microneedling systems.

> Q. Moving on to slide 24, can you explain why it is your opinion that there is a nexus between the benefits of the '836 patent and any commercial success of these products?
>
> A. Well, as I've discussed, I mean, the '836 patent has led to all these devices, which make these treatments more effective, reduce patient pain and downtime, increase the patient compliance, and make us all busier every day.
>
> Q. Are there other factors that may also contribute to selecting an RF microneedling product as a clinician?
>
> A. Sure. I mean, there are things such as how deep the needles penetrate from the skin, how many of these needles are on the handpiece, but at the core we still need the '836 patent.

> Q. Moving to slide 25 and starting with the Sylfirm X product, is there any relationship between the Sylfirm X advertisements and the '836 patent specifically?
>
> A. So the Sylfirm X marketing shows that nexus. You can see it right there on the right. They have right on their marketing materials that it is patented, and the patent number is there, '836.
>
> Q. And what are the benefits associated with the '836 patent are described as features of the Sylfirm X?
>
> A. So in the marketing materials, and, frankly, what we see in clinical practice, they are minimally invasive, pretty quick treatment times. Makes it good for us in the office, not a lot of downtime. People don't have to stay away from life every day. Pretty safe and comfortable and sometimes, frankly, even immediate results.
>
> * * *
>
> Q. So moving on to slide 35, and, again, can you remind us of some of the drawbacks of the prior bipolar systems once again?
>
> A. Second generation, now bipolar, so you see two electrodes penetrating into the skin, energy going between those electrodes, arcing between those electrodes, and that arcing and that heat going between the electrodes have the risk of leading to burns and blisters, damaging the skin with pigmentation issues. Certainly more painful, more downtime because of the wounds.

(Tr. (Goldberg) at 1314:15-1315:18, 1333:6-15; *see also* CX-0209C.0008 (describing challenges with 1st generation monopolar systems and prior bipolar RF microneedling systems); JX-0007 at 4:4-19 (describing how the present invention overcomes problems caused by prior technologies that cause overheating or burning).).

4. The '836 Patent Is Not Invalid for Lack of Enablement

Respondents contended that there is no disclosure in the '836 patent that would enable one of ordinary skill in the art to make or use the full scope of invention set forth in the asserted claims of the '836 patent, specifically with respect to the "coagulation" limitation. (RPBr. at 31-37; RBr. at 32-42.). For the reasons discussed below, every *Wands* factor weighs against a finding of invalidity.

As an initial matter, similar to Respondents' written description defense discussed below in Section VII.D.5, Respondents' enablement arguments suffer from several flaws that preclude

a finding of invalidity by clear and convincing evidence.

Specifically, Respondents asserted certain arguments for their enablement defense on one hand and presented inconsistent and contradictory positions with respect to their prior art-based invalidity defenses on the other. For example, Respondents contended that with respect to their Section 112 invalidity defenses (i.e., lack of enablement and written description), "the field is ***unpredictable***," and that "a POSITA ***cannot predict*** which of the endless candidates might practice the claims. (RPBr. at 32, 37 (emphases added).). In contrast, for their prior art-based invalidity defenses (i.e., obviousness), Respondents stated that the opposite is true, that is, "[a] POSITA would have recognized that the relevant art is ***predictable***," and "requires merely routine optimization." (RPBr. at 54 (emphasis added); *see also id.* at 25 ("a POSITA would have considered controlling the lesion size of an RF microneedling device to be limited to between electrodes to be ***predictable***") (emphasis added).).

Respondents' invalidity expert, Dr. Woloszko, provided the same inconsistent and contradictory testimony during the Hearing—that the art is ***unpredictable*** for purposes of his Section 112 opinions, but ***predictable*** for purposes of his obviousness opinions. (*See* Tr. (Woloszko) at 1003:1-1006:8.). Dr. Woloszko testified that, unlike and in contrast to the '836 patent, the Ganz reference (the primary reference on which he relied for obviousness) is enabled because it identified a working "example" in paragraph 65 of the specification. (Tr. (Woloszko) at 1139:7-11:40:5.). Notably, paragraph 65 of Ganz, which is quoted below, describes an example of a ***monopolar*** electrode configuration.

Figure 17: Paragraph 65 of Ganz

EXAMPLE

[0065] A freshly exercised pig skin was obtained. A monopolar electrode array was placed upon the skin. The array consisted of two 0.3 mm length needles placed in a row 500 microns apart. The array was hooked up to an electrical generator. A power of 50 watts and an energy of 1 joule were delivered to the electrode array. A 4 mm punch biopsy was taken and process for routine light microscopy. Upon examination of the tissue, both the epidermis and dermis were perforated by two equivalent vertical perforations. The perforations were widest at the top (50 to 100 microns in diameter) and tapered to a point at a depth of 250-300 microns. Throughout the edge of the injury, a 10-50 micron zone of coagulation was also seen.

(RX-0329 at [0065] (annotated and copied from SBr. at 53).).

As he expressly clarified during the Hearing, Dr. Woloszko's obviousness opinions are limited to Ganz's ***bipolar*** electrode configuration.

> Q. . . . Now, Dr. Woloszko, you agree that the Ganz reference discloses multiple electrode configurations, right?
>
> A. Yes.
>
> Q. Bipolar configurations on one hand and monopolar configurations on the other, right?
>
> A. Correct.
>
> Q. And you are relying on Ganz' ***bipolar*** configuration for your invalidity opinions, right?
>
> A. Correct.
>
> Q. The example disclosed in paragraph 65 in Ganz only describes an example of a ***monopolar*** electrode, right?
>
> A. That's correct.
>
> Q. All asserted claims of the '836 patent require ***bipolar*** electrodes, right?
>
> A. Correct.

> Q. And paragraph 65 in the Ganz reference does not contain an example for a ***bipolar*** electrode configuration, right?
>
> A. ***Correct***.

(Tr. (Woloszko) at 1140:8-1141:2 (emphases added).).

Thus, paragraph [0065] of Ganz does not provide support for Dr. Woloszko's opinion that Ganz is enabled with respect to bipolar electrodes.

In addition to Respondents' and their expert's contradictory arguments and testimony, which as an initial matter precludes a finding of clear and convincing evidence of invalidity, for the reasons discussed below, each of the *Wands* factors weighs against a finding of invalidity of the '836 patent.

a) *Wands* Factors 1 (Quantity of Experimentation Necessary) and 2 (Amount of Direction or Guidance Needed)

The evidence supports a finding that the specification provides sufficient direction and guidance for the coagulation limitation, and that the quantity of experimentation necessary would not be undue. Specifically, the '836 patent specification identifies the various parameters that a user can adjust in the claimed apparatuses/methods. (*See, e.g.*, JX-0007 at 5:35-41 (identifying relevant parameters to control energy field generated around the needles, including voltage, current, and frequency applied to the needles, the on time and off time of the RF signal during cycles, and the deployed depth of the needles), 8:9-14 (identifying parameters of voltage, polarity, pattern, shape, adjacent distance, and frequency), 8:54-57 (identifying duty cycle parameter), 9:25-28 (identifying needle length and thickness parameter). The specification provides one of ordinary skill with information about the relevant parameters, including parameter settings/ranges, which are depicted below in Dr. van der Weide's demonstrative.

Figure 18: Van Der Weide Demonstrative Listing Parameter Ranges and Examples Disclosed in the '836 Patent



(CDX-0046C.0040; Tr. (van der Weide) at 1457:19-1458:1 (discussing CDX-0046C.0040 and evidence cited therein).).[58]

Moreover, the '836 patent specification discusses the correlation among various parameters that can be adjusted in claimed apparatuses/methods, and discloses parameter settings, outer boundaries, and how adjusting certain parameters will affect other parameters. (JX-0007 at 10:10-39 (describing the correlation of various parameters), 10:19-39 (describing the correlation of various parameters), 6:52-57 (describing how decreasing distance between needles can allow increasing the frequency, and vice versa).).

Respondents contended that "in order to determine which bipolar RF microneedling devices among the endless options achieve the claimed result and which do not, a POSITA would have to make and test each and every one of them." (RPBr. at 30; RBr. at 40.). However, as discussed below with respect to *Wands* factors 5 and 7, Respondents' own experts testified that a person of ordinary skill in the art reviewing the '836 patent would have a wealth of

[58] Additionally, the types of bipolar electrode configurations within the scope of the claims exclude the Intracel bipolar configuration of alternating rows of commonly-polarized electrodes. (*Markman* Order at 46-54.).