relevant knowledge and information at his or her disposal, and would be able to predict which parameter settings would result in the claimed coagulation. *See Streck*, 665 F.3d at 1288 ("It is well-established . . . that a specification need not disclose what is well-known in the art."); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986) ("[A] patent need not teach, and preferably omits, what is well known in the art."); *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1244 (Fed. Cir. 2003) ("That is not to say that the specification itself must necessarily describe how to make and use every possible variant of the claimed invention, for the artisan's knowledge of the prior art and routine experimentation can often fill gaps, interpolate between embodiments, and perhaps even extrapolate beyond the disclosed embodiments, depending upon the predictability of the art.").

Specifically, Respondents' experts testified that the state of the art in the area of the invention is well-known and extensive (*see* Tr. (Woloszko) at 1011:2-6), and that a person of ordinary skill would have known or recognized at least the following examples of aspects of the invention:

- Achieving the claimed subject matter of the '836 patent merely requires routine optimization. (*See* Tr. (Woloszko) at 1003:18-24.).
- Controlling the lesion size of an RF microneedling device to be limited to between electrodes to be predictable. (*See* Tr. (Woloszko) at 1004:16-20.).
- What would be a sufficient amount of energy to apply to tissue to cause coagulation. (*See* Tr. (Bérubé) at 1276:4-1277:77.).
- How to select the RF frequency. (*See* Tr. (Woloszko) at 1006:18-20.).
- Frequencies below 100 and 200 kHz are not recommended for electrosurgery. (*See* Tr. (Woloszko) at 1061:14-18.).
- How to adjust the RF energy level to create more or less coagulation. (*See* Tr. (Woloszko) at 1008:16-20.).

- The frequency range of the RF source can be chosen based on the desired effects on various types of tissue and its influence on lesion size and geometry based on the intended application. (*See* Tr. (Woloszko) at 1008:6-11.).

- Energy dissipated in the tissue is a function of the voltage applied and the tissue impedance. (*See* Tr. (Woloszko) at 1009:3-6.).

- There is/was an extensive list of various human tissue impedance including skin over a very broad frequency range. (*See* Tr. (Woloszko) at 1063:20-25.).

- Tissue is a higher impedance at lower frequencies. (*See* Tr. (Woloszko) at 1064:1-4.).

- Coagulation is well-defined in the art (and in the '836 patent), and is very easy to observe. (*See* Tr. (Woloszko) at 1051:11-13, 1053:4-1054:8 ("[y]ou don't even need a microscope").).

- What temperature is needed to achieve coagulation, and that tissue coagulation is induced when tissue reaches a temperature of 60-65 degrees Celsius. (*See* Tr. (Woloszko) at 1009:12-18.).

- Coagulation occurs around the microneedle electrodes where the current density is higher. (*See* Tr. (Woloszko) at 1051:14-17.).

- In a bipolar RF microneedling system, that heating will be higher at and near the surface of the electrodes due to the increased current density, and that "undergraduate level textbooks" provided "both the underlying physical concepts and the appropriate methodologies for estimating the electric field strength surrounding electrodes in a dielectric medium and the associated heating effects." (Tr. (Brennan) 1190:2-20.).

- The experimental methodology to determine whether unconnected coagulation zones were achieved. (*See* Tr. (Woloszko) at 1006:14-17.).

- How to perform histology to determine where coagulation occurred in the tissue. (*See* Tr. (Woloszko) at 1007:18-1008:5.).

- How to model current flow around electrodes using a technique called finite element analysis. (*See* Tr. (Woloszko) at 1010:5-8.).

- How to use a computer model to obtain a very good approximation of how much energy needs to be delivered to achieve a certain amount of heating in the skin. (*See* Tr. (Woloszko) at 1009:19-1010:4.).

- Predict how small changes to bipolar RF microneedling will affect results. (*See* Tr. (Woloszko) at 1010:9-12.).

- How to adjust the distance between the needles to create more isolated coagulation zones. (*See* Tr. (Woloszko) at 1011:7-17.).
- How to adjust the thickness or diameter of the needles to adjust the coagulation zones. (*See* Tr. (Woloszko) at 1012:22-1013:2.).
- How to adjust the needle length or depth to obtain coagulation at the right depth in the dermis. (*See* Tr. (Woloszko) at 1013:6-10.).

Accordingly, Dr. Woloszko's testimony, together with other evidence, demonstrates that the '836 patent's disclosures provide direction and guidance sufficient for a person of ordinary skill to practice the full scope of the coagulation limitation as Respondents' own expert acknowledged. *See Pfizer Inc. v. Teva Pharms. USA, Inc.*, 555 F. App'x 961, 967 (Fed. Cir. 2014) ("In view of the finding that enantiomer separation methods are well-known and routine to a person of ordinary skill, we agree with the district court that the inventors were not required to provide a detailed recipe for preparing every conceivable permutation of the compound they invented to be entitled to a claim covering that compound . . . claim 2 satisfies the requirements under § 112(a) because the '692 application's disclosure, coupled with the methods for synthesis and resolution that were found to be well-known and routine in the art, is sufficiently enabling").

Thus, Respondents' legal contention that "a POSITA would have to make and test every candidate to determine whether it achieves the claimed result" is not supported by the weight of the evidence, including evidence given by their own experts.

Moreover, during his cross-examination, Dr. Woloszko provided equivocated testimony when he was confronted with questions about his testimony that each and every candidate would require testing to determine whether the recited coagulation is achieved. (*See* Tr. (Woloszko) at 1064:14-1066:24 (discussing how changes to the applied AC RF frequency and needle diameter would not necessarily require testing).).

Even if some amount of experimentation might be needed, Respondents did not present clear and convincing evidence that such experimentation would be undue. Dr. Woloszko's testimony on this point was conclusory, lacked factual support, and is thus not persuasive. (*See id.* at 919:24-920:18.). *See Magnetic Tape Cartridges*, Inv. No. 337-TA-1058, Comm'n Op. at 11 (affirming the ID's finding that respondent did not show lack of enablement in part because "we find [respondent's expert] Dr. Wang's analysis consists only of conclusory and wholly unsupported statements").

Furthermore, a patent claim is enabled even if it requires one of ordinary skill to perform "a considerable amount of experimentation," if this experimentation is "routine" and the specification "provides a reasonable amount of guidance." *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1360–61 (Fed. Cir. 1998) (affirming summary judgment of enablement). Here, the evidence supports a finding that the '836 patent's disclosures discussed above, viewed through the lens of a person of ordinary skill—that is, one who would know: (i) the experimental methodology to determine whether unconnected coagulation zones were achieved; (ii) how to perform histology to determine where coagulation occurred in the tissue; (iii) how to predict whether small changes to bipolar RF microneedling will affect results; and (iv) how to use a computer model to obtain a very good approximation of how much energy needs to be delivered to achieve a certain amount of heating in the skin)—would require routine, if any, testing to practice the full scope of the claim. *See Magnetic Tape Cartridges*, Inv. No. 337-TA-1058, Comm'n Op. at 12 (crediting evidence demonstrating that "a person of ordinary skill in the art would recognize how to modify the manufacturing processes and material compositions and sizes for making the claimed magnetic media," and the patent's "disclosures regarding how and to what extent the recited parameters change based on various factors," which "would have

guided a person of ordinary skill in the art's performance of routine experimentation that could be conducted to achieve the full scope of the claim").

Respondents advanced several additional arguments why *Wands* factors 1 and 2 purportedly do not support enablement, none of which are persuasive. For example, Respondents pointed to a statement in the patent that "[d]etermining the parameters to enable the desired energy field according to the present invention required countless trials and errors with insight." (RBr. at 36 (citing JX-0007 at 9:13-16).). During the Hearing, Dr. Na clarified that [redacted] (Tr. (Na) at 127:11-128:4); *see also* Tr. (van der Weide) at 1462:24-1463:9 ("succinctly said, Dr. Na did all that work so that one of skill in the art wouldn't have to").).

Respondents also argued that "Dr. Na testified that [redacted] (RBr. at 36 (citing RX-2546C (Na Dep. Tr.) at 510:4-15).). As Serendia noted, Dr. Na was asked a different question, that is what [redacted]. (RX-2546C (Na Dep. Tr.) at 510:4-15.). As he explained during his deposition, the '836 patent provides the relevant parameters, but it is "impossible" to say in the abstract whether a machine would practice the invention because the "conditions provided are incomplete." (*Id.* at 517:3-17.).

Respondents also argued that the equations in the '836 patent are "gibberish." (RBr. at 36.). Again, Respondents misrepresented both the disclosure of the '836 patent and the relevant testimonial evidence. As both Drs. Na and van der Weide explained, the equations reflect

correlation among the different parameters. (Tr. (van der Weide) at 1460:21-1461:10; RX-2551C (Na Dep. Tr.) at 431:12-16 .).

In addition, Respondents' cited case law is inapposite. Although Respondents string-cited cases purportedly supporting the premise that a claim is not enabled if it encompasses "'thousands' of 'candidate[s]'" and "testing" of each candidate is necessary "to determine which . . . meet [the] claim," Respondents failed to tie any of their cases to the facts of this case. (RBr. at 42.). As Serendia noted, these cases are inapplicable. (CRBr. at 21.). Those cases involved: (i) "new and unpredictable" nucleosides (*Idenix Pharms. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149, 1161 (Fed. Cir. 2019); (ii) "unpredictable" polynucleotide hybridization (*Enzo Life Scis., Inc. v. Roche Molecular Sys., Inc.*, 928 F.3d 1340, 1347 (Fed. Cir. 2019)); (iii) "unpredictable and poorly understood" "synthetic organic chemistry" (*Wyeth and Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380, 1386 (Fed. Cir. 2013)); (iv) a patent providing no guidance other than "to create a wide range of candidate antibodies and then screen them" (*Baxalta Inc. v. Genentech, Inc.*, 8 F.4th 1362, 1366 (Fed. Cir. Sept. 20, 2023); and (v) a case in which the specification could not enable "physically impossible" claims (*Trustees of Boston Univ. v. Everlight Elecs.*, 896 F.3d 1357, 1362 (Fed. Cir. 2018)). Contrary to the state of the art and patents at issue in the cases on which Respondents relied, here, Dr. Woloszko agreed that the relevant art is well-known and extensive (Tr. (Woloszko) at 1011:2-6); that the '836 patent provides substantial guidance as discussed above; and that it is undisputed that achieving the claimed invention is possible.

For the reasons discussed above, given the evidence, the application of *Wands* factors 1 and 2 does not support a finding of lack of enablement.

b) *Wands* Factor 3 (Presence or Absence of Working Examples)

Staff pointed out that "the specification does not provide an example where every parameter has a set value, although it does separately provide parameter ranges (as discussed above), as well as certain test results, including parameters and ranges that were discovered as a result of the inventor's testing." (SBr. at 59 (citing JX-0007 at 6:22-39).). Although this may be the case, as Serendia noted, the Federal Circuit's finding and reasoning in *United Therapeutics Corp. v. Liquidia Technologies, Inc.*, is instructive. (CRBr. at 22 (citing *United Therapeutics Corp. v. Liquidia Techs., Inc.*, 74 F.4th 1360 (Fed. Cir. 2023) ("*United Therapeutics*".).

In *United Therapeutics*, the defendant argued that claims directed to a "therapeutically effective" dose lacked enablement because the specification provided insufficient guidance and no working examples of an appropriate dosage, and thus a person of ordinary skill in the art "would have to engage in undue experimentation to practice the full scope of the claimed invention." *Id.* at 1369. However, the plaintiff pointed out that "claims are not required to carve out all possible inoperative embodiments in a claim in order to avoid that claim being found not to be enabled." *Id.* The Federal Circuit agreed, finding the claims sufficiently enabled because the specification provided information about the administration, concentrations, and dosages of the pharmaceutical, and because expert testimony and record evidence demonstrated that a skilled artisan would understand how to practice the claimed invention without undue experimentation. *Id.* at 1370. The same is true here. As discussed above, the specification provides ample guidance to enable one of ordinary skill to practice the claimed invention without undue experimentation. (Tr. (van der Weide) at 1456:6-1462:23; CDX-0046C.0038-46.).

For the reasons explained, the application of *Wands* factor 3 does not support a finding of lack of enablement.

c) *Wands* Factors 4 (Nature of Invention) and 5 (State of Prior Art)

As Dr. van der Weide testified, the '836 patent claims a ***specific*** type of RF microneedling device, i.e., using AC RF applied to bipolar electrodes, to achieve a ***specific*** result, i.e., coagulation around, rather than between, electrodes. (Tr. (van der Weide) at 1464:2-1465:8.). The '836 patent is an improvement over known RF microneedling systems, such as Hantash, which generated thermal lesions between electrodes, or Ganz, which ablated and destroyed tissue around electrodes.[59] (Tr. (van der Weide) at 1464:2-17.).

Respondents' expert, Dr. Woloszko, also agreed that the state of the art was well-known and extensive.

> Q. . . . In 2011 a person of ordinary skill in the art would have known how to make a skin treatment apparatus with an RF generator that produces alternating current RF signal supplied to bipolar electrodes insertable into skin, right?
>
> A. I have a patent on this, I think, in 2002.
>
> Q. In fact, you believe the state of the art in the area of the invention, as you just referenced, is well known and extensive, correct?
>
> A. To use RF in the skin, yeah, the theory, but it is well-known, yes.

(Tr. (Woloszko) at 1010:22-1011:6.).

Additionally, Dr. Woloszko acknowledged unequivocally that one of ordinary skill would have known the experimental methodology to determine whether unconnected coagulation zones were achieved. (*Id.* at 1006:14-17 ("Q. . . . A person of ordinary skill in the art would have known the experimental methodology to determine whether unconnected coagulation zones were achieved, right? A. Yes.").).

[59] Respondents contended that, *inter alia*, Ganz in view of the knowledge of a personal of ordinary skill or in combination with Hantash render the asserted claims of the '836 patent obvious. For the reasons discussed above in Section VII.D.3, Respondents failed to meet their burden.

In addressing *Wands* factors 4 and 5, Respondents simply reiterated their arguments that the claims are "broad" because they purportedly encompass "endless" devices. (RBr. at 38-39.). Respondents' arguments are not persuasive for the reasons discussed above with respect to *Wands* factors 1 and 2.

Thus, as explained and given the evidence, the application of *Wands* factors 4 and 5 also does not support a finding of lack of enablement.

d) *Wands* Factor 6 (Relative Skill of Those in the Art)

Respondents conceded that a person of ordinary skill has a "high" level of skill. (RBr. at 38.). The level of skill here requires "7-10 years of experience" and a pertinent graduate degree. (*Markman* Order at 15.).

Accordingly, *Wands* factor 6 thus does not support lack of enablement.

e) *Wands* Factor 7 (Predictability or Unpredictability of Art)

Respondents' expert, Dr. Woloszko agreed that the art at issue is predictable, and conceded that one of ordinary skill would be able to use a computer model to obtain a "very good" approximation of how much energy needs to be delivered to achieve a certain amount of coagulation. (Tr. (Woloszko) at 1009:19-1010:12; *see also* Tr. (van der Weide) at 1465:20-1466:8; Tr. (Brennan) at 1190:2-20 (testifying that "undergraduate level textbooks . . . provided . . . the appropriate methodologies for estimating the electric field strength surrounding electrodes").).

Respondents attempted to retreat from Dr. Woloszko's admissions by arguing that "the art is predictable with respect to arriving at a single RF microneedling device that achieves the claimed coagulation result," but that "the art is unpredictable with respect to achieving the ***full scope of devices within the claims***." (RBr. at 39-40 (emphasis in original).). According to

Respondents' attorney argument that deviates from their own expert's opinion is that the art is not predictable with respect to achieving the full scope of the invention because "a POSITA could [not] predict every embodiment" that meets the claims. (*Id.* at 40.). However, the test for enablement is not whether a skilled artisan can predict whether an embodiment will practice the claims in the abstract; instead, the test for enablement is whether undue experimentation is required to practice the claims. The Federal Circuit rejected the conclusory approach Respondents have taken here to try to prove non-enablement by simply pointing out that there are a number of adjustable variables/parameters without any specific evidence that it would have required undue experimentation to practice the claims. *McRO*, 959 F.3d at 1104; *Alcon*, 745 F.3d at 1189-90.

Respondents' inconsistent arguments about predictability undermine the credibility of their arguments. Respondents used belated attorney argument to shore up a position that opposed that of their own expert. Before the Hearing, Respondents contended that "a POSITA would have considered controlling the lesion size of an RF microneedling device to be limited to between electrodes to be predictable." (RPBr. at 25.). After the Hearing, Respondents argued that one of ordinary skill cannot "predict which of the endless candidate devices might practice the claims." (RBr. at 40). Respondents also argued in their Pre-Hearing Brief that "a POSITA cannot predict how even small changes to bipolar RF microneedling devices affect the claimed results" (RPBr. at 31). However, during the Hearing, Respondents' expert, Dr. Woloszko, agreed that a person of ordinary skill in the art could do so (Tr. (Woloszko) at 1010:9-14). Dr. Woloszko's inconsistent testimony reflects Respondents' contradictory positions and attempt to use attorney argument to salvage what they must have known were losing arguments including in view of their own expert's testimony. (*Compare* Tr. (Woloszko) at 1004:16-20 (agreeing that a

person of ordinary skill "would have considered controlling the lesion size of an RF microneedling device to be limited to between electrodes to be predictable") *with id.* at 1005:22-1006:6 (agreeing that "[b]ecause the art is so unpredictable a [POSITA] would have to make and test every candidate to determine whether it achieves the claim result").).

For the reasons explained, the application of *Wands* factor 7 does not support a finding of lack of enablement.

f) *Wands* Factor 8 (Breadth of Claims)

As explained in Sections VII.D.3 (obviousness) and VII.D.6 (patent eligibility), the asserted claims do not broadly cover ***all*** RF microneedling systems causing coagulation in tissue. Rather, the asserted claims are directed to a particular system (or method of using that system) that uses a specific type of signal generator (RF) to send a specific type of signal (AC RF), and a specific type of skin treatment electrodes—bipolar (as opposed to monopolar), through which AC RF signals are applied, to cause the specific type of coagulation claimed (around but not between the electrodes, as opposed to between the electrodes). As explained with respect to *Wands* factors 4 and 5, the claims are an incremental improvement over prior systems and methods.

For the reasons explained, the application of *Wands* factor 8 does not support a finding of lack of enablement.

5. The '836 Patent Is Not Invalid for Lack of Written Description

Respondents argued that the asserted claims of the '836 patent lack written description "for the same reasons they are not enabled." (RBr. at 42.). As in *Alcon*, Respondents' argument is that the claims lack written description because "endless" embodiments may fall within the claims. (RBr. at 34, 38, 40-41.). *Alcon*, 745 F.3d at 1191. That argument fails here, as in *Alcon*,

because the "critical inquiry is whether the patentee has provided a description that 'in a definite way identifies the claimed invention' in sufficient detail that a person of ordinary skill would understand that the inventor was in possession of it at the time of filing." *Id.* at 1190. For the following reasons, the '836 patent provides such description.

Respondents have not clearly and convincingly proven that the asserted claims of the '836 patent lack written description. Here, the asserted claims are directed to a particular system (or method of using that system) that uses a specific type of signal generator (RF) to send a specific type of signal (AC RF), and a specific type of skin treatment electrodes—bipolar (as opposed to monopolar), through which AC RF signals are applied, to cause the specific type of coagulation claimed (***around but not between*** the electrodes, as opposed to ***between*** the electrodes). Dr. Na did not invent RF microneedling systems, or even bipolar RF microneedling systems. (Tr. (Na) at 80:10-18 (testifying that [redacted] (emphasis added).). Nor did he generally invent bipolar microneedling systems that cause coagulation in the skin. During prosecution of the '836 patent, the examiner cited the Manstein reference (asserted by Respondents for obviousness), which, unlike the '836 patent, disclosed (1) a ***monopolar*** RF microneedling system where thermal damage was caused around but not between electrodes (RX-0304 at 6:21-35, Fig. 3);[60] and (2) a bipolar RF microneedling system where thermal damage is generated ***between*** the electrodes (*id.* at 7:13-22, Fig. 4). In contrast, the '836 patent specification explicitly distinguishes monopolar skin treatment systems and treating the areas between (i.e., not just around) the electrodes. (JX-0007 at 2:14-18, 2:28-33, Fig. 2.).

[60] Respondents' expert, Dr. Woloszko, agreed that the thermal damage regions depicted in Figure 3 of Manstein depict the result of using the monopolar configuration. (Tr. (Woloszko) at 1040:8-24.).

Against this backdrop, the evidence demonstrates that the asserted claims, including the coagulation limitation, are supported by an adequate written description.

The specification describes "the effect on the dermis may differ based on the amount of energy applied," and "[t]he present invention improves skin condition by primarily using coagulation" as opposed to, for example, "carbonization [or] vaporization." (JX-0007 at 2:62-66.). The specification makes clear that a particular term "to raise temperature," is used in the specification to mean "applying energy to achieve coagulation." (*Id.* at 3:2-4.). In other words, consistent with how the "present invention" is described, the term "to raise temperature" is narrowly described as coagulation.[61]

The specification also describes that "[i]n 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," and that the heated area is "around each needle," and "not concentrated between needles." (*Id.* at 3:21-29.). For example, Figure 5 depicts concentrated, heated areas around but not between electrodes. As Dr. van der Weide testified, this disclosure teaches ***where*** coagulation occurs, and in contrast to prior art systems. (Tr. (van der Weide) at 1466:15-1468:4 (emphasis added).).

Additionally, the specification identifies the various parameters and settings, and describes the correlation between them such that they can be adjusted. (*See* Section VII.D.4, *supra* (Wands factors 1 and 2).). Accordingly, the '836 patent specification provides sufficient written description for the asserted claims. *See United Therapeutics Corp. v. Liquidia Techs.,*

[61] The Parties' experts agreed that a person of skill would have known what temperature is needed to achieve coagulation, and that tissue coagulation is induced when tissue reaches at 60-65º C. (Tr. (Woloszko) at 1009:12-18; Tr. (Goldberg) at 164:21-24, 1304:24-1305:13.).

Inc., 74 F.4th 1360, 1370-71 (Fed. Cir. 2023) (affirming that the asserted claims are supported by an adequate written description: the '793 patent claims require 'treating pulmonary hypertension comprising administering . . . a therapeutically effective single event dose of a formulation containing treprostinil,' and the specification describes that. In other words, the specification shows possession for the claimed invention[.]") (citation omitted).

Furthermore, because the specification is viewed from the perspective of one of skill in the art, a patentee may rely on information that is "well-known in the art" for purposes of meeting the written description requirement. *Streck*, 665 F.3d at 1285. Respondents' expert, Dr. Brennan, testified that a person of skill would understand that, in a bipolar RF microneedling system, heating will be higher at and near the surface of the electrodes due to the increased current density. (Tr. (Brennan) at 1190:2-20.). Thus, a person of ordinarily skill in the art would understand the '836 patent to adequately disclose the specific type of coagulation using the specific components as claimed. *See Streck*, 665 F.3d 1269, 1287 (affirming summary judgement that the patent was not invalid for lack of writing description: "Given the language in the patents-in-suit, coupled with the well-known use of true reticulocytes in the prior art, a person of ordinary skill would understand the patent to include integrated controls using true reticulocytes.").

Moreover, Respondents' written description argument suffers from several flaws that preclude a finding of invalidity by clear and convincing evidence.

For example. Respondents contended that there is a lack written description because the '836 patent fails to include a working example. (RPBr. at 30; RBr. at 42.). However, the Federal Circuit has "made clear that the written description requirement does not demand either examples or an actual reduction to practice; a constructive reduction to practice that in a definite

way identifies the claimed invention can satisfy the written description requirement." *Ariad Pharms. Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1352 (Fed. Cir. 2010) (en banc); *see also Certain Magnetic Tape Cartridges and Components Thereof*, Inv. No. 337-TA-1058, Comm'n Op. at 14-15 (Apr. 9, 2019) (rejecting respondent's lack of written description defense, which was based on the absence of examples in the specification).

Additionally, like Respondents' enablement defense, Respondents have taken inconsistent and contradictory positions for their Section 112 invalidity defenses on one hand, and their prior art-based invalidity defenses on the other. For example, Respondents argued that "this art is so unpredictable," such that "a POSITA would have to make and test every candidate to determine whether it achieves the claimed result." (RPBr. at 30; *see also* RBr. at 39-40.). In contrast, for their prior art-based invalidity defenses, Respondents contended the opposite: "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); RBr. at 39.). 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. (Tr. (Woloszko) at 1003:1-1006:8.). Thus, Respondents' contradictory positions does not support a finding of clear and convincing evidence of invalidity.

Respondents' cited cases also do not support their argument. Respondents relied on the following cases: *Pernix Ireland Pain DAC v. Alvogen Malta Oper.*, 323 F. Supp. 3d 566 (D. Del.

2018);[62] *ICU Med., Inc. v. Alaris Med. Sys., Inc.*, 558 F.3d 1368 (Fed. Cir. 2009); *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1478–80 (Fed. Cir. 1998); and *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1346-47 (Fed. Cir. 2005). These cases are inapposite because they all involve narrow disclosure of a particular species, without disclosure of the structural features required to practice the broader claims, which encompassed other species that were not described in the specification.[63]

By contrast, as discussed, here the specification does not merely describe a species that falls within the claimed subject matter. The specification describes the structure for obtaining the claimed coagulation—a plurality of bipolar needles and an RF generator that provides an AC RF signal. Additionally, here, unlike in the cases Respondents cited, Respondents did not introduce evidence that supports their argument that certain species are not described. *Hynix Semiconductor Inc. v. Rambus Inc.*, 645 F.3d 1336, 1351-53 (finding the written description requirement met, distinguishing *ICU* and *LizardTech*); *Certain Light-Based Physiological Measurement Devices and Components Thereof*, Inv. No. 337-TA-1276, Comm'n Op. (Nov. 14, 2023) (concluding that written description testimony was conclusory and reversing the ALJ's finding for lack of written description).

Accordingly, Respondents have not met their burden to prove clearly and convincingly

[62] *Pernix* is not controlling authority, and the Federal Circuit declined to reach the written description issue on appeal. *Persion Pharms. v. Alvogen Malta Oper.*, 945 F. 3d 1184, 1185 & n.1 (Fed. Cir. 2019).

[63] *Pernix*, 323 F. Supp. 3d at 623 (only "Example 8" satisfied the claims and there was no disclosure of "structural features" to identify other species that would fall within the claims); *ICU*, 558 F.3d at 1378-79 (specification disclosed only valves with a spike but the claims covered valves without a spike); *Gentry Gallery*, 134 F.3d 1479-80 (specification "identifie[d] the console as the only possible location for the controls" but the claims covered controls elsewhere); *LizardTech*, 424 F.3d at (specification disclosed "a particular method for creating a seamless DWT," criticizing other methods, but the claims covered any way of creating a seamless DWT).

that the asserted claims of the '836 patent are invalid for lack of written description.

6. Patentable Subject Matter

a) *Alice* Step 1: Claims Are Not Directed to an Abstract Idea

Respondents contended that "[t]he claims are directed to an abstract idea of achieving a desired effect/functional result (causing coagulation around but not between needles) without reciting limitations that would be needed to produce the desired effect." (RBr. at 44.). For the following reasons, the evidence does not support Respondents' contention or such a finding.

The asserted claims recite a specific treatment apparatus that applies an AC RF signals to bipolar electrodes to provide a specific effect. (Tr. (van der Weide) at 1470:22-1471:13; *see also* Tr. (Na) at 80:10-18 .). First, the preamble is limiting. (*Markman* Order at 39.). Thus, claim 1 is limited to a specific apparatus to treat skin.[64] (Tr. (van der Weide) at 1470:5-11.). Second, claim 1 requires a plurality of bipolar electrodes insertable into a section of skin to be treated. (Tr. (van der Weide) at 1470:3-13.). Third, claim 1 requires an RF generator configured to apply an AC RF signal to the plurality of electrodes, where the electrodes are configured to cause coagulation around each electrode rather than coagulating between the electrodes. (*Id.*). Claim 1 is thus directed to a ***specific*** treatment apparatus to produce a ***specific*** treatment. (*Id.*).

Respondents improperly overgeneralized the claims in arguing post-hearing that they are directed to "a desired effect/functional result . . . without reciting limitations that would be

[64] Serendia focused its rebuttal to Respondents' unpatentability assertions on claim 1 because Respondents focused their challenge on this claim. (CRBr. at 33 n.14; RBr. at 44.). As Serendia noted, the same reasoning and findings hold for independent claim 14, and the dependent claims add more specific requirements, i.e., the diameter of the electrodes (claim 9), and the frequency range and treatment time (*see, e.g.*, cl. 22). (CRBr. at 33 n.14.).

needed to produce the effect." (RBr. at 44.). As the Federal Circuit has explained, "describing the claims at such a high level of abstraction and untethered from the language of the claims all but ensures that the exceptions to § 101 swallow the rule." *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1337 (Fed. Cir. 2016) (holding claims not abstract). Here, the claims do not cover ***all*** RF microneedling systems, or even ***all*** RF microneedling systems that cause localized coagulation around electrodes. Just as the *Enfish* claims were "not simply directed to any form of storing tabular data," the claims here are not directed to ***any*** way of achieving the claimed coagulation but rather are limited to a treatment apparatus having ***specific*** claimed characteristics.[65] *Enfish*, 822 F.3d at 1337.

Respondents acknowledged that the claims of the '836 patent require "two physical elements," but then disregarded them, without citing any authority, because according to Respondents, those two (2) elements can be found in the prior art. (RBr. at 45.). However, Respondents' position is not legally supported. For example, in *CardioNet, LLC v. InfoBionic, Inc.*, the Federal Circuit explained that "the analysis under *Alice* step one is whether the claims as a whole are 'directed to' an abstract idea, ***regardless*** of whether the prior art demonstrates that the idea or other aspects of the claim are known, unknown, conventional, unconventional, routine, or not routine." *CardioNet, LLC v. InfoBionic, Inc.*, 955 F.3d 1358, 1372 (Fed. Cir. 2020) (emphasis added).

Here, that the known hardware that is claimed "functions differently than conventional" RF treatment devices to provide "an improvement of an existing technology" supports eligibility. *Enfish*, 822 F.3d at 1337. The '836 patent specification explicitly identifies disadvantages of

[65] Notably, the claims do not even cover all bipolar electrode configurations because the INTRAcel configuration is excluded. (*Markman* Order No. 35 at 46-54.).

prior monopolar RF microneedling systems that the invention was designed to overcome. (JX-0007 at 1:53-2:33; *see also* Tr. (van der Weide) at 274:22-275:16; Tr. (Goldberg) at 1302:4-18 (problems with monopolar systems).). The specification also discloses that the invention avoids "side effects" of existing systems that generated "overheating or burning" that could "cause permanent skin damage," such as "scars," consistent with Dr. Goldberg's observations of prior art bipolar systems in practice. (JX-0007 at 4:4-22; Tr. (Goldberg) at 1302:19-1304:4 (with earlier bipolar systems, "we often saw arcing, we saw burns, blistering and a lot of pain."). Here, as in *Enfish*, "the specification's teachings that the claimed invention achieves . . . benefits over conventional" approaches—efficacy with increased safety—supports eligibility. *Enfish*, 822 F.3d at 1337; *see also CardioNet*, 955 F.3d at 1369 (relying on advantages identified in the specification in holding claims eligible).

Moreover, although Respondents referenced Manstein in the context of this argument (RBr. at 45), the fact that during prosecution of the underlying application, the claims at issue were specifically distinguished over Manstein's apparatus based not only on the claimed coagulation but also the characteristics of the claimed treatment apparatus (use of an AC RF signal), further supports the eligibility of these claims. (JX-0008 ('836 patent PH) at 377-381, 391; Tr. (van der Weide) at 1473:19-1474:2.).

Respondents argued that the "Na Effect," a term Dr. Na used to describe the '836 patent, is an "abstract idea." (RBr. at 46.). However, as Serendia pointed out, the asserted claims are not directed to the "Na Effect." (CRBr. at 35.). They are directed to a specific treatment apparatus. (*Id.*). Furthermore, as noted in the *Markman* Order, the claims could not have been distinguished over Manstein based on requiring an AC RF signal if they were generically directed to the "Na Effect." (*Markman* Order at 61 ("the claims were distinguished because

Manstein did not have an embodiment with an AC signal having a radio frequency").). This demonstrates that Respondents' argument that there are not "meaningful technological limitations" to the claims is not supported by the evidence. (RBr. at 46.).

Applicable Federal Circuit precedent confirms that the claims here are patent eligible. Just as the *CardioNet* claims were directed to "an improved medical device" that provided clinically superior "detection of two specific medical conditions," the claims here are directed to an improved skin treatment apparatus that provides clinically superior skin treatment. *CardioNet*, 955 F.3d at 1370. Additionally, like the claims in *National Alternatives International, Inc. v. Creative Compounds, LLC*, the claims here are eligible because they "not only embody [a] discovery," i.e., the Na Effect, but further "require that an infringer actually" construct a treatment device having specific physical properties configured to "administer" this treatment. *Nat'l Alternatives Int'l, Inc. v. Creative Compounds, LLC*, 918 F.3d 1338, 1344 (Fed. Cir. 2019). Claim 1, like the eligible claims in *National Alternatives*, are directed to a "specific" treatment to be administered "to bring about a change in a subject, altering the subject's natural state." *Id.* at 1345. Similarly, in *Rapid Litigation Management Ltd. v. CellzDirect, Inc.*, the "end result" of the claims "is not simply an observation" but rather a practical application to achieve a "new and useful" result, i.e., improved skin treatment. *Rapid Litig. Management Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1048 (Fed. Cir. 2016) (holding claims eligible); *see also Illumina, Inc. v. Ariosa Diagnostics, Inc.*, 967 F.3d 1319, 1328-29 (Fed. Cir. 2020) (eligible claims to application of an observed phenomenon to provide an improved result).

Respondents mainly relied upon *American Axle & Manufacturing, Inc. v. Neapco Holdings LLC*. (RBr. at 46 (citing *Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, 939 F.3d 1355 (Fed. Cir. 2019) ("*American Axle*"). Respondents cited *American Axle* for the proposition

that where claims "prohibit all other persons from making the same thing by any means whatsoever," this supports ineligibility. (*Id.* (quoting *American Axle*, 939 F.3d at 1364).). Respondents' reliance is misplaced. The problem in *American Axle*, and the reason why the Federal Circuit found the subject matter at issue patent ineligible, was that the claims "simply instruct[ed] the reader to tune the liner" without reciting "any physical structure or steps for achieving the claimed result." *Id.* at 1366. The Federal Circuit continued to clarify that "[t]he focus of the claimed advance . . . [wa]s simply the concept of achieving that result, by whatever structures or steps happen to work." *Id.* at 1366. To the contrary, the claims here ***expressly*** require "physical structure," that is, bipolar needles configured in a particular way (not the INTRAcel configuration) and an RF generator to deliver an AC RF signal to them, as discussed above. (Tr. (van der Weide) at 1470:22-1471:13.).

In sum, the asserted claims of the '836 patent are not abstract because they recite a specific treatment apparatus including specific physical components configured to deliver an improved skin treatment, and thus are patent eligible subject matter.

b) *Alice* Step 2: Claim Elements Contain an "Inventive Step"

Because the asserted claims of the '836 patent are drawn to patentable-subject matter, it is not necessary to consider *Alice* step two. *See, e.g.*, *CardioNet*, 955 F.3d at 1371. Even assuming, *arguendo*, that the asserted claims were directed to an abstract idea, they would still be patentable at step two because the elements of the claims contain an "inventive concept" sufficient to "transform the claimed abstract idea into a patent eligible application." *Koninklijke KPN N.V.*, 942 F.3d at 1149. As discussed above with respect to *Alice* step one, the claims recite a specific system with a specific combination of components and functionality to deliver a specific treatment result that constitutes a technical improvement, providing safer, effective skin

treatment. (*See* Tr. (van der Weide) at 1470:3-13, 1470:22-1471:13, 1473:19-1474:2; Tr. (Goldberg) at 1302:19-1304:4; Tr. (Na) at 80:10-18.).

Respondents argued that "[w]hen the Na Effect is stripped out of the claims, all that remains in the independent claims is conventional: an AC RF generator and bipolar needle electrodes, used in a conventional fashion." (RBr. at 51.). However, Respondents failed to demonstrate that RF microneedling devices with AC RF generators and bipolar needle electrodes were "conventional," or introduce evidence of how any such devices were "used in a conventional fashion." Although these individual components existed, "an inventive concept can be found in the nonconventional and non-generic arrangement of known, conventional pieces." *Bascom Glob. Internet Servs., Inc. v. AT&T Mobility LLC*, 827 F.3d 1341, 1350 (Fed. Cir. 2016). That is the case here. As in *Bascom*, while the individual pieces were known, the claims "carve out" a specific use of an AC RF generator combined with bipolar needles that was unconventional at the time. *Id.* at 1352.

As discussed above in Section VII.D.3 with respect to Respondents' obviousness arguments against the '836 patent, Ganz, Manstein, and Hantash, the prior references that Respondents asserted, make evident that there are vastly different ways to implement RF microneedling systems. This includes, for example: (1) different electrode types (i.e., monopolar or bipolar); (2) different electrode configurations (e.g., arrangements like the INTRAcel configuration and in Figure 6 of the '836 patent); and (3) different signal types (e.g., AC or DC RF);[66] (4) to obtain different tissue effects (e.g., coagulation, vaporization, and carbonization);

[66] Respondents also contended that AC RF energy is "entirely conventional" in view of Dr. Woloszko's testimony that the use of DC RF energy would be "illegal" or "dangerous," and further because RF is purportedly inherently AC. (RBr. at 51.). Respondents are wrong for the reasons discussed above with respect to Respondents' obviousness arguments. (*See* Section VII.D.3, *supra*.).

(5) at different locations relative to the electrodes (e.g., between them or localized around them). (*See, e.g.*, Tr. (van der Weide) at 274:22-275:16, 1452:17-1453:6, 1454:1-8, 1473:19-1474:2.). Respondents have not proven which, if any, of these approaches was conventional. Their position that the claims merely require "an AC RF generator and bipolar needle electrodes, used in a conventional fashion" is supported only by Dr. Woloszko's conclusory testimony (Tr. (Woloszko) at 930:16-931:1), which is insufficient. *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1339 (Fec. Cir. 2016) ("[g]eneral and conclusory testimony . . . does not suffice as substantial evidence of invalidity").

In sum, the claimed combination of an unconventional treatment, which was not routine or conventional at the time the '836 patent was filed, and which solved known disadvantages of prior art systems, recites an inventive concept. (*See* Tr. (van der Weide) at 1473:19-1474:2; Tr. (Goldberg) at 1302:19-1304:4.). *See also Bascom*, 827 F.3d, 1341, 1352.

VIII. U.S. PATENT NO. 9,320,536

A. Direct Infringement

1. Infringement Overview

Serendia asserted that the Accused Products directly infringe claims 11 and 16 of the '536 patent. (CBr. at 51.). For the reasons discussed below, Serendia has met its burden and proven that the Accused Products directly infringe claims 11 and 16.

2. The Accused Products Practice Claim 11 of the '536 Patent

a) 11[pre]: "An apparatus for treating dermatological tissue, comprising"

Each Accused Product is "apparatus for treating dermatological tissue," which Respondents did not dispute. (Tr. (Crosby) at 580:10-583:2, 626:10-22; CDX-0001C.0014-16, 89 (Crosby); CX-0166C.0026 (Potenza 510(k)); CX-0164C.0006 (Potenza Manual); CX-

0339C.0041 (Intensif with EndyMed PRO 510(k)); CX-0696.0010, 0014 (EndyMed PRO Manual); CX-0694 (EndyMed PURE Manual).).

Respondents did not contest this in their Pre-Hearing or Post-Hearing Reply Briefs. (RPBr. at 74-94; RRBr. at 48-59.). Thus, 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 the preamble of claim 11 of the '536 patent.

b) 11[a1]: "a user holdable device including a proximal end and a releasably couplable deployable needle assembly"

The Accused Products include "a user holdable device including a proximal end and a releasably couplable deployable needle assembly." Specifically, each Accused Product includes a handpiece with a proximal end. (Tr. (Crosby) at 586:21-587:23, 626:10-22; CDX-0001C.0023; CX-0164C.0029 (Potenza Manual); CX-0696.0019, 0056 (EndyMed Manual).). The Accused Products include a needle assembly, depicted in blue in the portions of Mr. Crosby's demonstrative (CDX-0001C.0022) below for the Potenza Products (within a needle module depicted in green). (Tr. (Crosby) at 584:20-25, 586:4-12, 626:10-22; CX-0170C.0001 (Potenza Tip-49 Drawing); CX-0697C.0023 (EndyMed HP Spec.); CX-0696.0056 (EndyMed Manual); CX-3089C-3158C, CX-3257C-3295C, CPX-0124-0133C, CPX-0140C-0147C (Inspection Photos/Videos); CPX-0162-0183 (physical portions of Accused Products).). Moreover, as Mr. Crosby testified, the photograph below [redacted] (Tr. (Crosby) at 586:13-20.).

Figure 19: Crosby Demonstrative Illustrating the Claimed Needle Assembly



(CDX-0001C.0022.)

The needle assembly in each Accused Product is [redacted] (Tr. (Crosby) at 586:4-587:23, 589:22-591:24, 626:10-22, 627:19-629:1; CDX-0001C.0022-23, 0029-30, 0089, 0092; CX-3089C-3158C, CX-3257C-3295C, CPX-0124-0133C, CPX-0140C-0147C (Inspection Photos/Videos).).

To the extent Respondents attempted to contest this limitation by improperly limiting the needle assembly to only the needles, PCB, and pogo pins, they are incorrect.[67] (Tr. (Crosby) at

[67] Although Respondents did not present any testimony during the Hearing rebutting limitation 11[a1], they disputed that the needle assembly includes a translucent section by improperly limiting the needle assembly. Respondents raised the same argument in their Pre-Hearing Brief for the "releasably couplable needle assembly" portion of limitation 11[a1]. (RPBr. at 78-84.).

1486:10-1487:1.). The Family Two Patents describe and illustrate that the needle assembly is not limited to just those components but rather includes additional components, such as pin cover 924J and drive arm module 924L. (JX-0005 ('812 Patent) at 2:51-56, 13:26-34, Figs. 11B, 11C; CDX-0043.0006; Tr. (Crosby) at 1487:2-24.).

Accordingly, Serendia has proven by a preponderance of evidence that the Accused Products meet this limitation of claim 11 of the '536 patent.

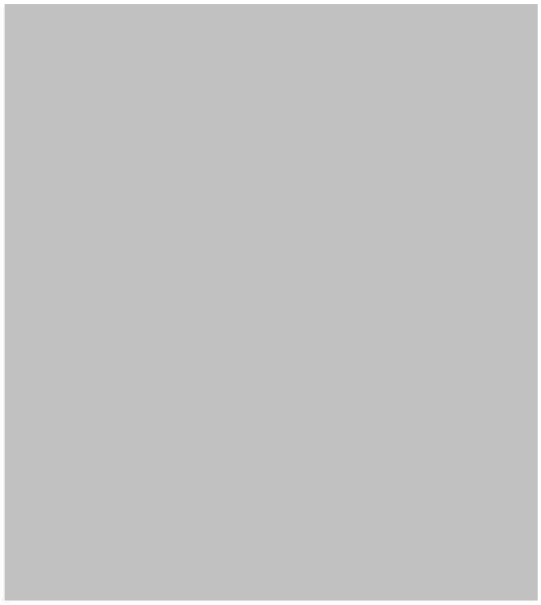
c) 11[a2]: "the deployable needle assembly mechanically separatably from the proximal end and including a plurality of extendable needles, a plurality of the extendable needles extendable from a deployable needle assembly end surface"

The Accused Products include a "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." The claim term "separatably" was construed as "separable," and "the deployable needle assembly is mechanically separably from the proximal end of the user holdable device" was construed as "the deployable needle assembly is mechanically separable from the proximal end of the user holdable device (the deployable needle assembly can be within a needle module that mechanically separates from the proximal end of the user holdable device)." (*Markman* Order at 27, 32, 36.). The "needle assembly end surface" was construed as "the deployable needle assembly end surface is the plane defined by the tips of the needles of the deployable needle assembly when the needles are not extended, the needle assembly can be movable within a needle module that is releasably couplable to the proximal end of a user holdable device." (*Id.* at 26.).

With respect to the first portion of limitation 11[a2], the Accused Products' needle

assemblies are mechanically separable from the proximal end of the handpiece, by themselves or via needle modules, which satisfies the adopted construction, i.e., "the deployable needle assembly can be within a needle module that mechanically separates from the proximal end of the user holdable device." (*Id.* at 32.). Mr. Crosby explained that [redacted] in his demonstrative (CDX-0001C.0092) below. (Tr. (Crosby) at 589:22-591:24, 626:10-22, 627:12-629:1.). Mr. Crosby also explained that the needle module [redacted] (CDX-0001C.0092) below. (Tr. (Crosby) at 589:22-591:24, 626:10-22, 627:12-629:1.).

Figure 20: Crosby Demonstrative Illustrating the Claimed Deployable Needle Assembly



(CDX-0001C.0092 (additional citations omitted).).

With respect to the rest of the claim limitation, Mr. Crosby testified that the needles in the Accused Products [redacted]

[redacted] below, which is the [redacted]. (*Markman* Order at 26; Tr. (Crosby) at 593:6-25, 594:15-595:11, 626:10-22; CDX-0001C.0037, 0089; CX-3089C-3158C, CX-3257C-3295C, CPX-0124-0133C, CPX-0140C-0147C (Inspection Photos/Videos); CPX-0162-0183 (physical portions of Accused Products).).

Figure 21: Crosby Demonstrative Illustrating the Claimed Deployable Needle Assembly End Surface



(CDX-0001C.0037.).

Jeisys/Cynosure argued that the "releasably couplable deployable needle assembly" is not "mechanically separatably" from the proximal end. (RPBr. at 83-84.). First, Jeisys/Cynosure limited the "needle assembly" to the needles, PCB, and pins, which is incorrect for the reasons discussed in Section VIII.A.2(b). Second, their argument that the needle assembly is not mechanically separable from the proximal end fails because Jeisys/Cynosure acknowledged that

the [redacted] (RPBr. at 83), which is sufficient under the adopted construction. (*Markman* Order at 32 ("the deployable needle assembly can be within a needle module that mechanically separates from the proximal end").). As discussed above, the needle assembly itself also mechanically attaches and separates from the handpiece.

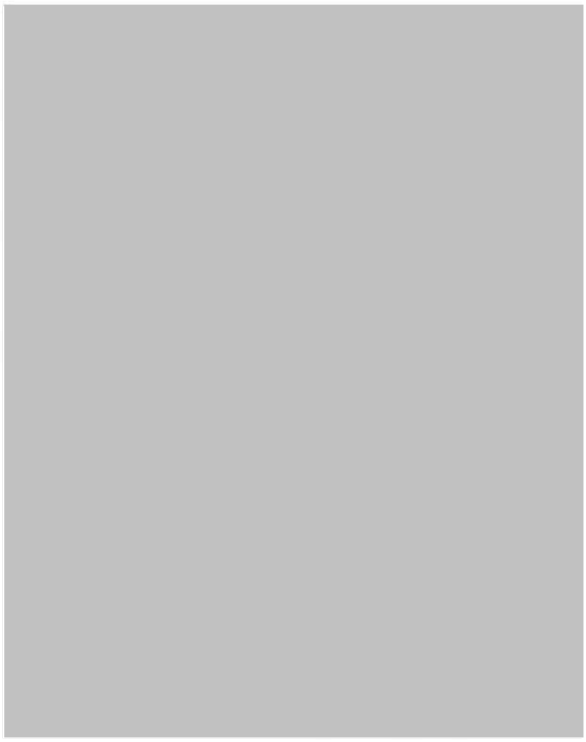
Jeisys and EndyMed contended that, because the needle assembly itself is deployable, their Accused Products do not have "a plurality of needles . . . extendable from a deployable needle assembly end surface." (RPBr. at 89.). However, during the Hearing, they did not present any evidence that would support such an incorrect reading of the claim, which conflicts with the adopted construction that defines the needle assembly end surface as "the plane defined by the tips of the needles of the deployable needle assembly when the needles are not extended." (*Markman* Order at 17.). As Mr. Crosby testified, in all Accused Products, the needles extend from both surfaces. (Tr. (Crosby) at 1489:11-1491:11; CDX-0043C.0008.).

For the reasons discussed above, Serendia has proven by a preponderance of evidence that the Accused Products meet this limitation of claim 11 of the '536 patent.

d) 11[a3]: "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"

In the Accused Products, "one of the proximal end and the deployable needle assembly includ[es] at least one electrical conductor and the other includ[es] 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." As depicted below in Mr. Crosby's demonstrative (CDX-0001C.0040), the Accused Potenza Products [redacted]

Figure 22: Crosby Demonstrative Depicting the Claimed Restorably Deflectable Electrical Contact in Accused Potenza Products



(CDX-0001C.0040.).

As depicted below in Mr. Crosby's demonstrative (CDX-0001C.0094), the



(CDX-0001C.0094; *see also* CX-0716C.0014-16 (Potenza Tips Presentation); CPX-0035 (2nd Gen. Intensif HP Video), 0:13-10:16.).

Mr. Crosby explained that in the Accused Products, (Tr. (Crosby) at 596:5-599:24, 626:10-22, 629:2-630:17, 1492:9-23; CDX-0001C.0040, 0094; CX-0170C.0001 (Potenza Tip-49 Drawing); CX-3146C (Intensif with EndyMed Pure 2.0); CX-3155C (Intensif with EndyMed Pure 2.0); CPX-0124-0133C, CPX-0140C-0147C (Inspection Photos/Videos); CPX-0162-0183 (physical portions of Accused Products).).

During the Hearing, only Jeisys/Cynosure disputed that their Accused Products meet this limitation. Their sole argument was that, . (Tr. (Brennan) at

1162:5-17; RDX-0013C.0018.). Jeisys/Cynosure relied on improperly reading a direct mechanical coupling requirement into the claim. (Tr. (Brennan) at 1186:22-25.). As Serendia's expert, Mr. Crosby, noted, limitation 11[a3] only requires that the claimed electrical conductor couple to the claimed restorably deflectable electrical contact. (Tr. (Crosby) at 1491:12-1492:1.). Jeisys/Cynosure did not identify a basis in the intrinsic record for reading in a direct or mechanical coupling requirement. (*Markman* Order at 32-36 (rejecting a proposed construction for "mechanically separatably" requiring a direct mechanical, structural connection).). *See also Bradford Co, v. ConTeyor N. Am., Inc.*, 603 F.3d 1262, 1270 (Fed. Cir. 2010) ("coupled to" "should be construed broadly so as to allow an indirect attachment"). Moreover, Jeisys/Cynosure did not propose this term for construction and therefore waived any argument under Ground Rule 1.14.1 that the claimed coupling of electrical components is restricted to direct mechanical coupling.

Jeisys/Cynosure did not dispute that the needle assembly includes pogo pins or that the proximal end includes electrical conductors. Serendia's expert, Mr. Crosby, explained that the pogo pins in needle assembly electrically couple to electrical conductors in the proximal end (through an indirect mechanical connection), which meets the claim's requirements. (Tr. (Crosby) at 597:14-23, 1492:9-23.). Jeisys/Cynosure also did not contest that the RF energy generated in the console is delivered to the needles through the handpiece. (Tr. (Brennan) at 1186:2-5, 1186:18-21.). As Mr. Crosby pointed out, that RF energy is delivered from the console to the needles is further evidence that the pogo pins in the needle assembly are electrically coupled to the electrical conductors in the proximal end. (Tr. (Crosby) at 1492:9-23 ("frankly, you wouldn't be able to get any radiofrequency energy to the needles unless there was coupling between the needle assembly and the proximal end").).

For the foregoing reasons, Serendia has proven by a preponderance of evidence that the Accused Products meet this limitation of claim 11 of the ’536 patent.

e) 11[b]: “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”

The Accused Products include “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,” where “a particular signal” was construed to have its plain and ordinary meaning, i.e., an electrical motor control signal. (*Markman* Order at 16). Tr. (Crosby) at 595:1-11, 605:4-609:14; 621:9-622:24, 626:10-22; CDX-0001C.0037, 0048, 0049, 0051, 0075-78, 0089; CX-0233C (Potenza Training) at 57; CX-0171C (Potenza Drawing) at 1; CX-0696 (EndyMed Pro Manual) at 58; CX-0697C (EndyMed HP Spec.) at 23; CX-3089C-3158C, CX-3257C-3295C, CPX-0124-0133C, CPX-0140C-0147C (Inspection Photos/Videos); CPX-0162-0183 (physical portions of Accused Products).).

Respondents did not contest that their Accused Products meet this limitation in either their Pre-Hearing or Post-Hearing Reply Briefs. (RPBr. at 74-94; RRBr. at 48-59.). 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 this limitation of claim 11 of the ’536 patent.

f) 11[c]: “a signal generator electrically coupled to the plurality of extended needles to energize the plurality of extended needles”

It is uncontested that the Accused Products include “a signal generator electrically

coupled to the plurality of extended needles to energize the plurality of extended needles." Each Accused Product [redacted]. (Tr. (Crosby) at 611:17-612:9, 626:10-22; CDX-0001C.0057, 0089; CX-0233C.0014 (Potenza Training); CX-0166C.0028, 0033 (Potenza 510(k)); CPX-0067 (Intensif Video) at 0:44; CX-0339C.0032, 0041-47 (Intensif with EndyMed Pro 510(k)); CX-3089C-3158C, CX-3257C-3295C, CPX-0124-0133C, CPX-0140C-0147C (Inspection Photos/Videos); CPX-0162-0183 (physical portions of Accused Products).).

Respondents did not contest that their Accused Products meet this limitation in either their Pre-Hearing or Post-Hearing Reply Briefs. (RPBr. at 74-94; RRBr. at 48-59.). Thus, 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 11 of the '536 patent.

3. The Accused Products Practice Claim 16 of the '536 Patent

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

It is undisputed that in the Accused Products the "at least one restorably deflectable electrical contact includes a depressible pin." Specifically, the Accused Products [redacted]. (Tr. (Crosby) at 626:10-22; 629:7-630:23; CDX-0001C.0094; CX-3105C (Potenza); CX-0170C.0001 (Potenza Tip-49 Drawing); CX-3146C (Intensif with EndyMed Pure 2.0); CX-3089C-3158C, CX-3257C-3295C, CPX-0124-0133C, CPX-0140C-0147C (Inspection Photos/Videos); CPX-0162-0183 (physical portions of

Accused Products).).

In their Pre-Hearing Brief, Respondents argued that their Accused Products do not meet this limitation for the same reasons as they do not meet claim 11. (RPBr. at 94.). However, Respondents did not raise this argument in their Post-Hearing Reply Brief. Thus, any argument on this issue is deemed abandoned, withdrawn, and/or waived under Ground Rule 10.1.

For the foregoing reasons, Serendia has proven by a preponderance of evidence that the Accused Products meet the additional limitation recited in claim 16 of the '536 patent.

B. Indirect Infringement

1. Indirect Infringement Overview

Serendia alleged that Respondents indirectly infringe by inducing infringement and contributing to the infringement of the asserted claims of the '536, '774, and '812 patents, i.e., Family Two Patents. (CBr. at 88-91.). The following analysis addresses indirect infringement for the three (3) Family Two Patents. For the reasons discussed below, Serendia has proven that Respondents indirectly infringe the asserted claims of the Family Two Patents.

2. Acts of Direct Infringement

Respondents' acts of direct infringement of the Family Two Patents are the same as those for the '836 patent. (*See* Section VII.B.3, *supra*; Tr. (Crosby) at 637:23-638:20.).

3. Respondents Induced and Continues to Induce Users to Infringe the Family Two Patents

a) Knowledge of the Family Two Patents

All Respondents "knew of the existence of the ['536, '774, and '812 patents] because [they] . . . received a cease-and-desist letter concerning it." *Mentor H/S*, 244 F.3d at 1379. Jeisys/Cynosure admitted that they [redacted] (CX-0092C.0012-13 (Jeisys/Cynosure Rog

Resp.); CX-3388C.0001 .). . (CX-0212C.0006, 0008 (*Id.* at 1.). EndyMed (CX-0069C.0009 (EndyMed Rog Resp.); *see also* CX-3069C.0001 . (CX-3072C at 1-2.).

In addition, Respondents indisputably learned of the Asserted Patents when they were served with the Complaint in this Investigation. *Certain Beverage Brewing Capsules*, Comm'n Op. at 19 (service of a Section 337 complaint is sufficient to show knowledge).

b) Respondents' Active Steps to Encourage Infringement

Respondents engaged in active steps to induce infringement for the reasons explained for the '836 patent. (*See* Section VII.B.4, *supra*; Tr. (Crosby) at 637:23-638:20.).

Jeisys and Cynosure also raised a distinct argument against induced infringement of the Family Two Patents, contending they "had a reasonable, good-faith belief that . (RPBr. at 144; RRBr. at 68.). Their argument fails for the following reasons.

First, Cynosure, Jeisys's U.S. distributor,[68] presented no evidence to support any good-

[68] *See* Tr. (Kang) at 836:17-19.

faith belief that [redacted]. "Attorney argument is no substitute for evidence." A Jeisys/Cynosure's unsupported attorney argument that [redacted] cannot negate an inducement finding as a matter of law. *Enzo Biochem., Inc. v. Gen-Probe, Inc.*, 424 F.3d 1276, 1284 (Fed. Cir. 2005) (attorney argument cannot raise "a genuine issue of material fact sufficient to avoid summary judgment").

Second, Jeisys failed to demonstrate it had a genuine good-faith belief that a [redacted]. (Tr. (Kang) at 838:6-17; CX-0212C.0001 (Jeisys-SynKloud Email).). Mr. Kang explained that [redacted] (Tr. (Kang) at 839:1-2.). As Serendia noted, [redacted]. (CBr. at 90.). The only record evidence is [redacted]. (CX-0212C.0006.). Jeisys appears to be seeking an inference [redacted]. However, Mr. Kang's testimony [redacted].

During the Hearing, Mr. Kang [redacted]. He testified that the [redacted]

(Tr. (Kang) at 846:7-10.). As Serendia pointed out, the '836 patent has those as well, which Dr. Woloszko also acknowledged. (Tr. (Woloszko), 1022:8-13 ("Q. Do you agree, Dr. Woloszko, at a high level, the '836 Patent relates to application of electric energy to needles that are in a handpiece that's used for applying the needles into the skin? A. At a high level, we apply some form of electrical signal to needle -- between needles through the skin, yes.").). However, the . (Tr. (Kang) at 854:11-15 .).

If Mr. Kang believed in , he would have offered it during the Hearing. His failure to do so does not support Jeisys and Cynosure's assertion that Jeisys had a good-faith belief it was not infringing the Family Two Patents . *Bio-Rad Labs. V. Int'l Trade Comm'n,* 998 F.3d 1320, 1336 (Fed. Cir. 2021) (affirming an inducement finding based on a finding that Respondent's purported good-faith belief was not credible).

4. Respondents Contributed to and Continue to Contribute to Users' Direct Infringement of the Family Two Patents

As discussed above with respect to induced infringement of the Family Two Patents, Respondents were aware of the Family Two Patents, and they contributorily infringe those patents for the same reasons they contributorily infringe the '836 patent. (*See* Section VII.B.5, *supra*; Tr. (Crosby) at 637:23-638:20.).

Jeisys raised an additional argument specific to claim 14 of the '774 patent based on its argument that "single-pulse mode" does not infringe. (RPBr. at 145' RRBr. at 70.). However, as discussed below in Section IX.A.2(c), that mode has been found to infringe. Moreover, Jeisys

failed to introduce evidence demonstrating that this alleged non-infringing use is substantial. (*See* Section VII.B.5, *supra*.).

C. Technical Prong of Domestic Industry

1. The DI Products Practice Claim 11 of the '536 Patent

a) 11[pre]: "An apparatus for treating dermatological tissue, comprising"

The DI Products practice this limitation. (Tr. (Crosby) at 583:3-20, 626:10-22; CDX-0001C.0017, 0089.). The FDA documents and manuals for the DI Products indicate they treat dermatological (i.e., skin) tissue. (CX-0826C.0002 (Sylfirm X 510(k) Description); CX-0823C.0004 (Sylfirm X Manual); CX-0761C.0002 (Sylfirm X Webpage); CX-0830.0002 (Sylfirm X Brochure); CX-3384 (Sylfirm X 510(k)).).

Respondents did not contest that their Accused Products meet this limitation in either their Pre-Hearing or Post-Hearing Reply Briefs. (RPBr. at 94-96; RRBr. at 59.). Thus, any argument on this issue is deemed abandoned, withdrawn, and/or waived under Ground Rules 7.2 and 10.1.

For the reasons explained, Serendia has proven by a preponderance of evidence that the DI Products meet the preamble of claim 11 of the '536 patent.

b) 11[a1]: "a user holdable device including a proximal end and a releasably couplable deployable needle assembly"

The DI Products practice this limitation because they include a handpiece with a proximal end and a releasably couplable deployable needle assembly. (Tr. (Crosby) at 587:24-588:21, 591:25-592:13, 626:10-22, 627:19-629:1; CDX-0001C.0025, 0031, 0089, 0092; CX-3340C, CX-3326C, CX-3330C (Sylfirm X); CX-0826C.0011 (Sylfirm X 510(k) Description); CX-0760C.0007-10 (DI Photos); CPX-0069 (Sylfirm X Video) at 0:32; CX-0823C.0011, 0012

(Sylfirm X Manual); CX-3384 (Sylfirm X 510(k)); *see also* CX-3321C-3350C (Inspection Photos/Videos); CPX-0160-161 (physical portions of DI Products).).

In their Pre-Hearing Brief, Respondents argued that the needles cannot extend from the needle assembly end surface as construed, i.e., the plane defined by the tips of the needles of the deployable needle assembly when the needles are not extended, because the needles cannot extend from an "imaginary surface." (RPBr. at 95.). However, as Serendia noted, this amounts to rearguing Respondents' rejected construction. (CBr. at 63.). Regardless, Respondents waived argument on this issue under Ground Rule 10.1 because they neither presented any evidence during the Hearing to support it nor specifically raised this contention in their Post-Hearing Reply Brief. (RRBr. at 59.).

Respondents also appear to have argued that the needle assembly end surface itself is not deployable (RPBr. at 95). Respondents' arguments conflict with the adopted construction of "needle assembly end surface," which is the plane defined by the tips of the needles of the deployable needle assembly when the needles are not extended. (*Markman* Order at 26.). The claim requires that the releasably couplable needle assembly be deployable, not that its end surface be deployable.

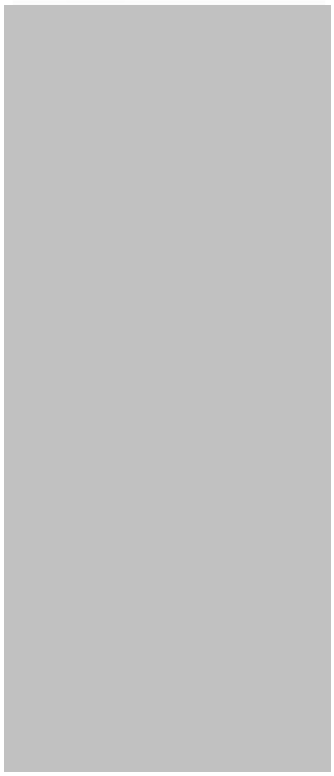
Moreover, Respondents failed to present evidence that would support such an incorrect reading of the claim or raise a specific contention in their Post-Hearing Reply Brief. (RRBr. at 59.). Thus, argument on this issue is deemed waived under Ground Rule 10.1.

For the reasons discussed above, Serendia has proven by a preponderance of evidence that the DI Products meet this limitation of claim 11 of the '536 patent.

c) 11[a2]: "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"

The DI Products practice this limitation because the needle assembly is mechanically separable from the proximal end of the handpiece by itself or via a needle module. Mr. Crosby explained that mechanical elements in the needle assembly enable it to couple and separate from the proximal end of the user holdable device. (Tr. (Crosby) at 626:10-22, 627:12-629:1; CDX-0001C.0092 (red arrow below).). He also explained that the needle module mechanically separates from the proximal end of the user holdable device via mechanical elements. (Tr. (Crosby) at 591:25-592:13, 626:10-22, 627:12-629:1; CDX-0001C.0031, 0089, 0092 (blue arrow below); *see also* CX-0826C.0004, 0006, 0007 (Sylfirm X 510(k) Description); CX-3384 (Sylfirm X 510(k)); CX-3321C-3350C (Inspection Photos/Videos); CPX-0160-161 (physical portions of DI Products).).

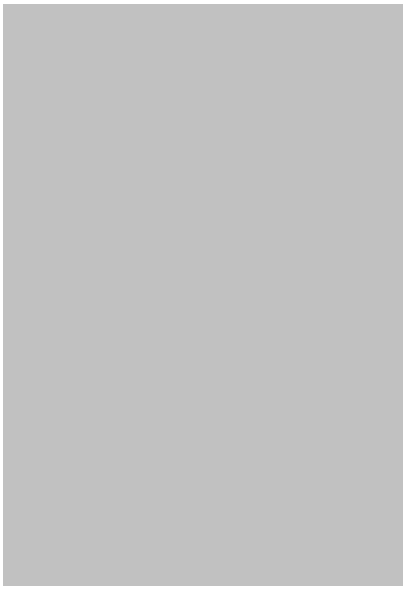
Figure 24: Crosby Demonstrative Illustrating the Claimed Deployable Needle Assembly



(CDX-0001C.0092.).

The needles in the DI Products also extend from the deployable needle assembly end surface (green in CDX-0001C.0038 below), i.e., the plane defined by the tips of the needles of the deployable needle assembly when not extended (*Markman* Order at 26). (*See also* Tr. (Crosby) at 595:12-596:4, 626:10-22; CDX-0001C.0038, 0089; CPX-0152C (Sylfirm X Inspection Video) at 0:00-0:05; CX-3329C, CX-3330C (Sylfirm X).).

Figure 25: Crosby Demonstrative Illustrating the Extended Needle Assembly



(CDX-0001C.0038.).

While Serendia's expert, Mr. Crosby, failed to explain with specificity how or why he considered the Sylfirm X's purported needle assembly to be deployable and mechanically separable from the proximal end, Serendia's documentation more than amply demonstrates this to be the case. (*Supra*.).

Respondents did not contest that the DI Products meet this limitation in their Post-Hearing Reply Brief. (RRBr. at 59.). Thus, any argument on this issue is deemed waived under Ground Rule 10.1.

Accordingly, Serendia has proven by a preponderance of evidence that the DI Products meet this limitation of claim 11 of the '536 patent.

d) 11[a3]: "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"

The DI Products practice this limitation. Mr. Crosby explained that the DI Products

include pogo pins in the needle assembly, which are "restorably deflectable electrical contact[s]" that couple to electrical conductors in the proximal end. (Tr. (Crosby) at 599:25-601:18, 626:10-22, 629:2-630:23; CDX-0001C.0041, 0089, 0094; CX-3326C, CX-3340C (Sylfirm X); CX-0826C.0011 (Sylfirm X 510(k) Description); CX-0759C.0002, 0004 (DI Photos); CX-0760C.0006, 0011 (DI Photos); CX-0823C.0011-13, 0023 (Sylfirm X Manual); CX-2918 (Photo, Sylfirm X tip); CX-2919 (Photo, Sylfirm X tip); CPX-0069 (Video, Sylfirm X) at 0:06; CX-3384 (Sylfirm X 510(k)); CX-3321C-3350C (Inspection Photos/Videos); CPX-0160-161 (physical portions of DI Products).).

Respondents did not contest that the DI Products meet this limitation in either their Pre-Hearing or Post-Hearing Reply Briefs. (RPBr. at 94-95; RRBr. at 59.). Thus, 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 11 of the '536 patent.

e) 11[b]: "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"

The DI Products practice this limitation. Mr. Crosby testified that the DI Products include a motor coupled to the needles that, in response to a particular signal, extends those needles a desired distance from the needle assembly end surface. (Tr. (Crosby) at 595:19-596:4, 609:15-611:7, 620:21-621:8, 622:25-623:8, 626:10-22; CDX-0001C.0038, 0053, 0054, 0075, 0079, 0089; CX-3326C, CX-3329C, CX-3330C, CX-3340C (Sylfirm X); CPX-0152C (Sylfirm X Inspection Video) at 0:00-0:05; CX-0759C.0003 (DI Photos); CX-0823C.0016 (Sylfirm X Manual); CX-0826C.0007, 0015, 0016 (Sylfirm X 510(k) Description); CX-0829C.0003

(Sylfirm X Circuit Drawing); CX-3384 (Sylfirm X 510(k)); CX-3321C-3350C (Inspection Photos/Videos); CPX-0160-161 (physical portions of DI Products).).

In their Pre-Hearing Brief, Respondents made the same arguments noted above as for limitation 11[b]. (RPBr. at 94-95.). They fail for the same reasons discussed above in Section VIII.A.2(b)-(d).

For the foregoing reasons, Serendia has proven by a preponderance of evidence that the DI Products meet this limitation of claim 11 of the '536 patent.

f) 11[c]: "a signal generator electrically coupled to the plurality of extended needles to energize the plurality of extended needles"

The DI Products practice this limitation. As Mr. Crosby explained, the DI Products include an RF generator electrically coupled to the needles that energizes them to deliver RF when the needles are extended so treatment can be delivered. (Tr. (Crosby) at 611:20-612:9, 626:10-22; CDX-0001C.0057, 0089; CX-0823C.00004, 0016, 0017, 0025-27 (Sylfirm X Manual); CX-0830.0002, 0006, 0007 (Sylfirm X Brochure); CX-0826C.0002 (Sylfirm X 510(k) Description); CX-3384 (Sylfirm X 510(k)); CPX-0069 (Sylfirm X Video) at 0:11; CX-3321C-3350C (Inspection Photos/Videos); CPX-0160-161 (physical portions of DI Products).).

In their Pre-Hearing Brief, Respondents made the same arguments noted above as for limitation 11[c] for "plurality of extended needles." (RPBr. at 95.). They fail for the same reasons discussed above in Section VIII.A.2(c).

Accordingly, Serendia has proven by a preponderance of evidence that the DI Products meet this limitation of claim 11 of the '536 patent.

2. The DI Products Practice Claim 16 of the '536 Patent

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

The DI Products practice this limitation. As Mr. Crosby explained, the DI Products include pogo pins, which are restorably deflectable electrical contacts including a depressible pin. (Tr. (Crosby) at 626:10-22, 629:7-630:21; CDX-0001C.0094; CX-0826C.0011 (Sylfirm X 510(k) Description); CX-0823C.0011-13, 0023 (Sylfirm X Manual); CX-0826C.0011 (Sylfirm X 510(k) Description); CX-0759C.0002, 0004, CX-0760C.0006, CX-2918.0001, CX-2919.0001 (Photos, Sylfirm X); CX-3384 (Sylfirm X 510(k)); CX-3321C-3350C (Inspection Photos/Videos); CPX-0160-161 (physical portions of DI Products).).

Respondents did not contest that the DI Products meet this limitation in either their Pre-Hearing or Post-Hearing Reply Briefs. (RPBr. at 96; RRBr. at 59.). 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 16 of the '536 patent.

D. Invalidity

1. Legal Standard

a) Anticipation

"To anticipate a claim, a prior art reference must disclose each and every element of the claim, either explicitly or inherently." *Adasa Inc. v. Avery Dennison Corp.*, 55 F.4th 900, 910 (Fed. Cir. 2022) (citing *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1375 (Fed. Cir. 2006). "While those elements must be arranged or combined in the same way as in the claim, the reference need not disclose the elements in the very same terms used by the patent." *Id.* (citing *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009) ("[T]he reference need not satisfy

an ipsissimis verbis test." (citing *In re Bond*, 910 F.2d 831, 832-33 (Fed. Cir. 1990))). "The question of what a reference teaches and whether it describes every element of a claim is a question for the finder of fact." *Id.* (citing *Med. Instrumentation & Diagnostics Corp. v. Elekta AB*, 344 F.3d 1205, 1221 (Fed. Cir. 2003)).

As the Federal Circuit further explained in *Net MoneyIN*:

> unless a reference discloses within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. § 102.

Net MoneyIN, Inc. v. VeriSign, Inc., 545 F.3d 1359, 1371 (Fed. Cir. 2008); *see also Verdegaal Bros. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987) ("A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."); *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989) ("The identical invention must be shown in as complete detail as is contained in the . . . claim.").

2. Scope of Prior Art

Respondents asserted that claims 11 and 16 of the '536 patent are anticipated or rendered obvious based on U.S. Patent No. 8,608,737 (RX-0307, "Mehta").[69] (RPBr. at 97, 102; RBr. at 63.). For the reasons discussed below, Mehta does not render obvious claims 11 and 16 of the '536 patent.

a) Mehta (RX-0307)[70]

Mehta discloses a "treatment system 200 [that] generally includes a treatment unit 202

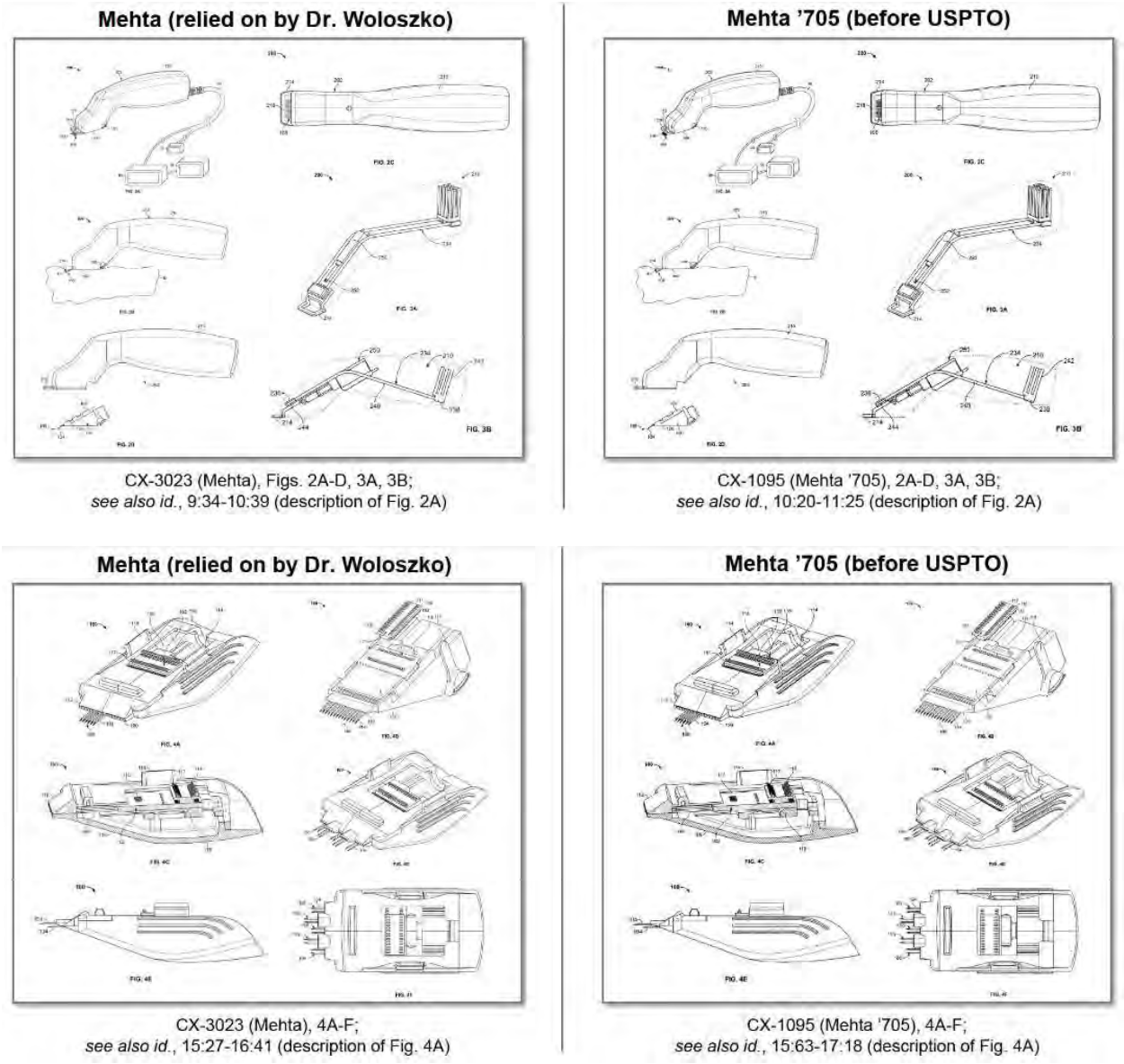
[69] In its Post-Hearing Reply Brief, Serendia cited to Mehta as CX-2023. That exhibit is not a part of the record. All references to Mehta in this ID are to RX-0307, which is in the record. RX-0307 is the same document as CX-2023.

[70] Although this version of Mehta was not considered during prosecution of the '536 patent, the evidence demonstrates that Mehta has the same relevant disclosures as U.S. Pat. No. 8,540,705 ("Mehta '705," CX-1095), which was considered during prosecution of the related '812 patent. (*See* Tr. (Woloszko) at 1043:4-13; Tr. (Crosby) at 1496:17-1499:22.). *Guangdong Alison Hi-Tech*, 936 F.3d at 1365 ("Arguments and references already considered by the Patent Office may carry less weight with the fact finder.").

having a hand-piece or device body 210" with "one or more probes 104" that "[i]n some variations" are "coupled to the body 210 via a removable cartridge 100." (RX-0307 at 9:34-41, Figs. 2A and 2D.

Respondents relied on Mehta for all their anticipation and obviousness arguments for the Family Two Patents. (RBr. at 63-93.). The PTO considered Mehta as U.S. Patent No. 8,540,705 ("Mehta '705") during prosecution of the related '812 patent, which is also at issue in this Investigation. Mehta '705 is on the face of the '812 patent. (JX-0005 at (56).). Additionally, it was uncontested during the Hearing that both Mehta references have the same relevant disclosures. (Tr. (Woloszko) at 1043:4-9; Tr. (Crosby) at 1496:23-1498:6; CDX-0043C.0016; *see also* SBr. at 91-92.). All the figures and associated disclosures regarding the structure and operation of the handpieces and cartridges in Mehta are identical. (*Compare, e.g.*, RX-0307 (Mehta) at Figs. 2-4, 9:34-10:39 (Fig. 2A), 15:27-16:41 (Fig. 4A) *with* CX-1095 (Mehta '705) at Figs. 2-4, 10:20-11:25 (Fig. 2A), 15:63-17:18 (Fig. 4A); Tr. (Crosby) at 1498:7-1499:3; CDX-0043C.0017-18.). A comparison of some of the Figures in the Mehta references are replicated below in Mr. Crosby's demonstrative.

Figure 26: Crosby Demonstratives Comparing Figures in Mehta References



(CDX-0043C.0017-18.).

As Serendia noted, Dr. Woloszko relied on the cited, common disclosures throughout his testimony. (CRBr. at 47.). For example, he relied on Mehta 15:34-42 and 16:34-41 in addressing claim limitations involving extending needles a desired distance (Tr. (Woloszko) at 948:3-949:7, RDX-0010C.0114), which Mr. Crosby pointed out are the same as Mehta '705

16:3-11 and 17:11-18 (Tr. (Crosby) at 1499:5-13; CDX-0043C.0019). Dr. Woloszko also relied on Mehta Fig. 2D, 4:19-34, 11:24-30, and 11:36-39 in addressing claim limitations about an LED in the handpiece (Tr. (Woloszko) at 968:5-969:16, 970:21-973:20; RDX-0010C.0140-141, 144-145), which are substantially the same as Mehta '705 Fig. 2D, 3:23-31, 11:60-66, and 12:5-8 (Tr. (Crosby) at 1499:14-20; CDX-0043C.0019). In addition, Dr. Woloszko relied on Mehta Fig. 4A and its related disclosure, i.e., 15:55-62 and 16:12-18, for the limitations that pertains to a pin extendable in the same direction as the plurality of needles (Tr. (Woloszko) at 976:4-20; RDX-0010C.0150), which are the same as Mehta '705 Fig. 4A, 16:24-31, and 16:56-62.

After failing to adduce testimony about any relevant differences, in their Post-Hearing Brief, Respondents then relied on attorney argument to assert that Mehta '705 "omits key material relevant to at least the disputed 'desired distance' limitations." (RBr. at 63 (citing RX-0307 at 33:21-34).). However, as Serendia clarified, the single disclosure of 13 lines Respondents identified as missing in Mehta '705, describes a "virtual probe array" depiction in a graphical interface, and not about how Mehta's handpiece and cartridges operate. (RX-0307 at 33:21-34.). The disclosures of Mehta and Mehta '705 indicate that the operation of the handpiece and cartridges is the same for both, i.e., the needles extend a fixed distance, and manual adjustment or switching of cartridges is required to reposition the needles. (*See, e.g.*, RX-0307 at 10:2-7, 10:19-25; CX-1095 at 10:55-60, 11:3-11.).

Because Respondents' "primary reference" was in effect "listed on the face of the patents-in-suit" (as Mehta '705), "the examiner is presumed to have considered it" and Respondents thus "ha[ve] the added burden of overcoming the deference that is due to a qualified government agency presumed to have properly done its job, which includes one or more examiners who are assumed to have some expertise in interpreting the references." *Shire*

LLC v. Amneal Pharms., LLC, 802 F.3d 1301, 1307 (Fed. Cir. 2015) (citation omitted); *see also Guangdong Alison Hi-Tech*, 936 F.3d at 1365 ("Arguments and references already considered by the Patent Office may carry less weight with the fact finder.").

3. The Prior Art Reference Does Not Anticipate the Asserted Claims of the '536 Patent[71]

a) Respondents Improperly Relied on Multiple Embodiments Disclosed in Mehta

Respondents failed to point to a single embodiment in Mehta that discloses all the limitations of claims 11 and 16 of the '536 patent, which is legally insufficient to prove anticipation. *Microsoft Corp. v. Biscotti, Inc.*, 878 F.3d 1052, 1069 (Fed. Cir. 2017) ("[A]nticipation is not proven by multiple, distinct teachings that the artisan might somehow combine to achieve the claimed invention.") (internal quotes and citation omitted); *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1371 (Fed. Cir. 2008) ("[U]nless a reference discloses within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it . . . cannot anticipate under 35 U.S.C. § 102.").

Respondents identified Figures 2A, 2D, and 4A of Mehta, which are replicated below, to support their anticipation arguments. (RBr. at 64-65, 67, 71; Tr. (Woloszko) at 939:6-944:4; RDX-0010C.0107-11; *see also* Tr. (Crosby) at 1499:23-1500:7.).

[71] *See* n.54, *supra* (regarding institution of IPRs).

Figure 27: Figures 2A, 2D, and 4A of Mehta

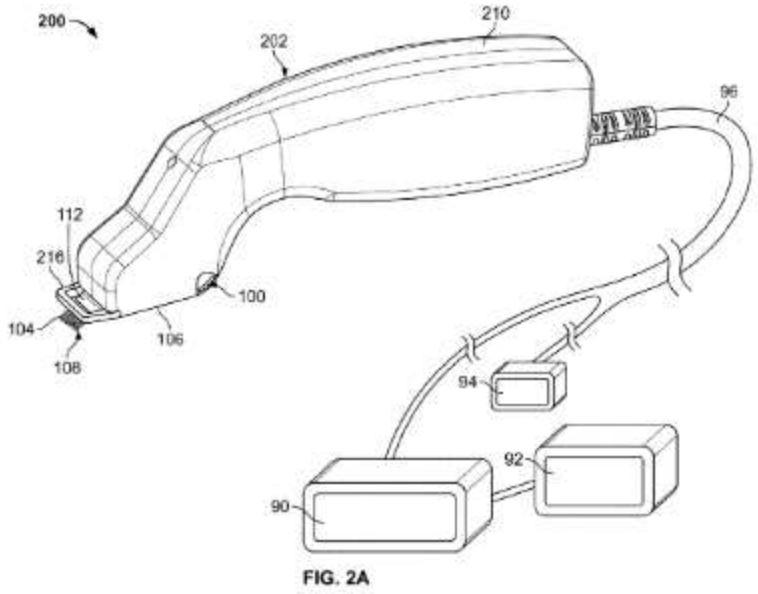


FIG. 2A

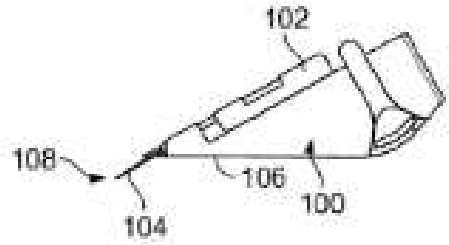


FIG. 2D

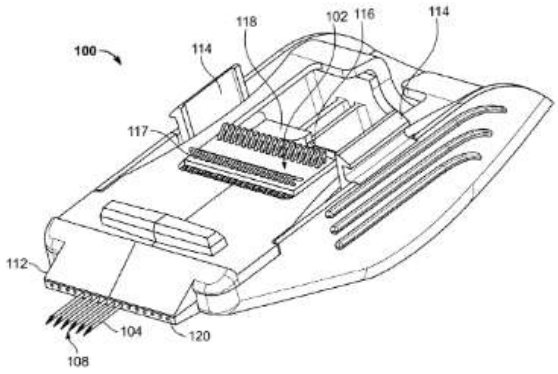


FIG. 4A

(RX-0307 at Figs. 2A, 2D, 4A.).

However, the depicted Figures appear to depict different embodiments. (RX-0307 at 6:30-52 ("FIG. 2A shows a sample variation of a system according to the principles of the invention having probes configured to provide percutaneous energy delivery; . . . FIG. 2D shows the treatment system of FIG. 2A . . . FIGS. 4A and 4B show variations of cartridge bodies for use with variations of the present system[.]"), 15:27-28.). For example, Figure 2D does not depict

the raised contact portions 116, 117 or retention fasteners 114, that are depicted above in Figure 4A. (RX-0307 at Figs. 2D, 4A.). Respondents acknowledged that there are differences between Figure 4A and 2D. (RBr. at 77 n.20 ("Whereas the cartridge in Figure 2D shows tabs for coupling the cartridge to the proximal end, Figure 4A shows slightly different retention fasteners.").). Respondents nonetheless argued that Fig. 4A "depicts in detail" what is depicted in Fig. 2D. (*Id.* at 76-77.). Respondents did not cite evidence to support their assertion.

b) Mehta Does Not Disclose the Desired Distance Limitation

Mehta does not disclose "extend[ing] the [needles] a desired distance."[72]

In the Family Two Patents, the "desired distance" the needles extend is determined based on the depth a user selects for the needle insertion, and an algorithm (i.e., software) executed by the CPU controls the needle deployment accordingly. (JX-0005 at 10:32-37 ("depth" is a "user selected operational parameter"), 10:63-65 ("CPU" can use "algorithm 930 (FIG. 12)"), 13:63-66, 14:12-34 ("In a coagulation operational mode (activity 936A), a user may select . . . needle deployment depth and number of shots per activation (activity 936C)," shown in Fig. 12);[73] Tr. (Crosby) at 1501:15-1502:10; CDX-0043C.0023.). In this way, motor(s) 922A "enable precise needle deployment depth or extension." (JX-0005 at 11:54-61; *see also id.* at 14:3-6 ("motor(s) 922A may enable precise needle extension (effective depth control)"); Tr. (Crosby) at 1500:21-1501:14; CDX-0043C.0022.).

[72] The portions of Mehta Respondents relied upon for the desired distance limitation are identical to disclosures in Mehta '705, which was considered during prosecution of the '812 patent. The asserted claims of the Family Two Patents each contain a "desired distance" limitation, with which Respondents' invalidity expert, Dr. Woloszko, agreed. (Tr. (Woloszko) at 1150:13-23.).

[73] The application that issued as the '812 patent (JX-0005) is a continuation of the application that issued as the '536 patent. (JX-0005 at (63).). Because they share the same specification, reference is only made to the '812 patent for efficiency purposes.

Serendia and Respondents both agreed that the "term 'desired distance' was not subject to claim construction and is to be interpreted according to its plain and ordinary meaning." (RBr. at 67; CRBr. at 50.). Both sides' experts agreed that the plain and ordinary meaning of "desired distance," in the context of extendable needles that "extend a desired distance from" the needle assembly end surface, refers to a distance that can be selected/programmed. Serendia's expert, Mr. Crosby, explained that the user selects the depth in the user interface, and a motor extends the needles a "desired distance" based on the user's selection. (Tr. (Crosby) at 662:4-16, 1502:11-1503:4; CDX-0043C.0022-23.).

Respondents' expert, Dr. Woloszko, testified that, "***[a]s long as you can program the distance***," a motor extending needles to a predetermined distance constitutes extending extendable needles "a desired distance as claimed." (Tr. (Woloszko) at 1151:8-12, 1151:23-1152:3.). Dr. Woloszko's testimony is consistent with the position Cartessa, a former respondent, took in its IPR with respect to the '536 patent. (JXM-0013.0049-50 (arguing that Morris disclosed needles that "extend a desired distance" because the distance is "precisely controlled by the motor by monitoring position sensors," "***varying the depth of penetration***" accordingly) (original emphasis).).

Contrary to their own expert's analysis and opinion, Respondents' attorneys then contended that the "desired distance" need not be selected/programmed, but rather is met by "selection of an appropriate cartridge or selection of an appropriate insertion angle," where the needles extend their full length. (RBr. at 67.). Respondents' newly proposed construction of "desired distance" is unsupported by any intrinsic or extrinsic evidence, and it is deemed waived for failure to request it during claim construction. (G.R. 1.14.1.). Respondents' only "support" for their construction is based on a distortion of the Parties' agreed construction of "needles one

of extending or extendable," which was "needles 'extending' a desired distance from the surface covers non-extendable needles having a fixed length." (RBr. at 68 (citing *Markman* Order at 16).). However, as Serendia pointed out, and as Respondents acknowledged, that was not the construction of "desired distance." (CRBr. at 51.). Respondents cannot twist the Parties' agreement about ***another*** claim term to read the term "extend a desired distance" out of the asserted claims, such that needles that always extend a fixed, unadjustable distance would satisfy the claim. *See, e.g.*, *Callicrate v. Wadsworth Mfg., Inc.*, 427 F.3d 1361, 1369 (Fed. Cir. 2005) (holding that it is improper to read out a limitation clearly required by the claim language).

As Serendia argued, Mehta does not disclose needles extending a "desired distance" from any surface. (CRBr. at 51 (citations omitted).). Instead, Mehta discloses various cartridges that can reach different target regions in skin using different needle lengths and angles, but the needles always extend fully, i.e., they extend a ***fixed*** distance. For example, Mehta's "invention allows a physician to selectively change array configuration by attaching ***different cartridges*** 100." (RX-0307 at 10:2-5 (emphasis added); *see also id.* at 10:5-7 ("Alternatively, variations of the invention contemplate a[] probe assembly that is non-removable from the device body 200."), 10:19-25 ("in those variations . . . the ***length*** of the probes 104 is generally ***selected***") (emphases added), 12:31-34, 16:1-8; Tr. (Crosby) 1502:14-1503:12; 1515:16-24; CDX-0043C.0024.). Mr. Crosby explained that Mehta discloses selecting "the ***length*** of the probes, not the ***distance*** they extend[.]" (Tr. (Crosby) at 1502:14-1503:12, 1507:1-6; CDX-0043C.0024; RX-0307 at 10:19-25.).

Because a user of Mehta's device cannot select a desired distance for the needles to extend, Mehta teaches mechanisms to assess whether the already extended needles have reached the target tissue, so that the user can reposition them or change cartridges if needed. (RX-0307

at 12:1-4, 13:37-45, 24:37-45, 32:46-33:27, 39:33-36.).

Mehta discloses using ultrasound "to assess the penetration depth of the electrodes" (RX-0307 at 12:1-4), "using impedance measurements to precisely determine depth of placement of the active electrode portion" (*id.* at 39:33-36), providing "tissue characteristic indicator[s]" to allow "the user to identify whether placement of the probes is desired," including a "virtual depiction . . . of the depth" (*id.* at 32:46-57) that "can simply show the location of the probe array prior to treatment" (*id.* at 32:63-33:3), and visual observation "to determine the depth of insertion of the probe" (*id.* at 13:37-45). As Mr. Crosby explained, the disclosures in Mehta assessing whether the needles have reached the target tissue after fully extending help physicians and other users determine whether the needles need to be manually repositioned or if a different needle cartridge should be used. (Tr. (Crosby) at 1504:3-16; CDX-0043C.0026.). However, the visualization/measurement system cannot change the distance the needles extend, and does not allow the physician to program the distance, as claimed. (Tr. (Crosby) at 1504:3-1505:2; CDX-0043C.0026-27.).

The only method Mehta discloses to adjust probe placement is to select a different cartridge. (RX-0307 CX-0307 at 10:2-7 ("the target region of tissue drives the array configuration" and "[t]he present invention allows a physician to selectively change array configuration by attaching different cartridges"); Tr. (Crosby) at 1506:2-6.). Thus, Mehta's approach to reaching target tissue (i.e., using different cartridges where probes extend a full distance) is entirely different than the solution claimed in the Family Two Patents of extending the needles a desired distance. (Tr. (Crosby) at 1502:11-1503:12.). Although Mehta discloses various motors and actuators to enable the probe assembly to slide or move within the cartridge (RX-0307) at 15:34-45), as Dr. Woloszko agreed, having a motor does not mean that the motor

controls the desired distance of needle extension. (Tr. (Woloszko) at 1151:23-1152:3.). Rather, the user would have to program the distance (*id.* at 1151:8-12), which Mehta does not disclose. (Tr. (Crosby) at 1506:7-25.).

Respondents identified four (4) disclosures in Mehta that purportedly teach needles extending a desired distance from a surface. For the following reasons, they do not.

The first describes a virtual depth/location depiction that shows needle depth ***after*** insertion and explains that a physician would be informed if further "advancement" is necessary to reach target issue. (RX-0307 at 32:67-33:3, 33:21-34, Fig. 10E; RBr. at 68-69; *see also* CDX-0043C.0028; SBr. at 97.). Respondents also relied on the disclosures about adjusting the system to guide probe placement. (RBr. at 68-69.). However, as explained above, Mehta only discloses repositioning the probes manually or using different cartridges if initial probe advancement was unsuccessful. (Tr. (Crosby) at 1505:11-1506:6; CDX-0043C.0028.). Respondents contended that "further advancement" of the needles would make no sense if needles were already fully extended. (RBr. at 70.). However, Mehta does not disclose that the system advances the needles based on user selection of a "desired distance." Rather, Mehta explains that the virtual depth/location depiction system provides information so "the physician would be ***informed*** that further advancement of the [fixed distance] probes is necessary." (RX-0307 at 33:14-27 (emphasis added).). There is not a disclosure in Mehta which describes that the needles already inserted into the skin would be further extended a desired distance automatically.

A second disclosure describes using a step motor as the actuator 250 to advance the needles. (RX-0307 at 15:34-42; RBr. at 69.). However, the mere fact that the motor disclosed in Mehta can be a "stepping" motor does not mean that Mehta's motor ***controls*** the adjustable distance that needles are extended from the end surface. (Tr. (Crosby) at 1502:24-1503:4

(explaining that, in the Family Two Patents, "the ***software*** energizes the motor properly to extend the needles a desired distance. Mehta provides no explanation of how the needles are extended anything other than full distance.") (emphasis added), 1548:10-1549:10 ("the stepper motor alone is not enough because you need to be able to control that stepper motor to achieve the desired distance . . . it's necessary to have control of the motor, stepper motor, or otherwise to achieve the desired distance."); *see also id.* at 1506:7-1507:6, 1542:18-1543:5; CDX-0043C.0029.). As explained above, Respondents' expert, Dr. Woloszko, agreed that a motor extending needles a predetermined distance only constitutes extending the needles a desired distance as claimed "as long as you can ***program*** the distance." (Tr. (Woloszko) at 1151:8-12 (emphasis added).). He agreed that simply advancing and retracting the needles is not enough to disclose the claimed limitation. (*Id.* at 1151:23-1152:3.). Moreover, Respondents' reliance on control system/energy supply unit 90 that drives the motor is misdirected. (RBr. at 71.). Mehta only discloses controlling the application of energy and measurement of parameters with unit 90. (RX-0307 at 10:57-59.). Neither Dr. Woloszko nor Respondents identified any disclosures in Mehta of how the step motor would be implemented to extend needles a "desired distance."

Respondents attempted to shift ***their*** burden to Serendia, arguing that Mr. Crosby "offers no explanation as to why Mehta would employ a step-motor other than to provide variable extension distance." (RBr. at 71.). However, it is Respondents whose burden was to clearly and convincingly demonstrate why mere disclosure of a step motor is sufficient to disclose the "desired distance" limitation, which they failed to do. Furthermore, Mr. Crosby explained that mere disclosure of a step motor has nothing to do with the claimed desired distance of needle extension. (Tr. (Crosby) at 1506:13-20.).

The third portion describes "intentionally 'over-insert[ing]' and then slightly retract[ing]

prior to initiating the treatment." (RX-0307 at 16:34-41; RBr. at 71.). Mr. Crosby opined that this procedure is not controlling a motor to enable precise needle deployment depth to extend needles a "desired distance," as the claims require. (CDX-0043C.0029; Tr. (Crosby) at 1506:7-1507:6.).

The fourth portion states the treatment devices in Mehta "can include any number of cartridges that can carry various probe configurations." (RX-0307 at 34:25-27; RDX-0010C.0114; RBr. at 70.). As explained above, having different cartridges with various probe configurations is distinct from probes in a particular cartridge extending a desired distance. (Tr. (Crosby) at 1506:7-1507:6; CDX-0043C.0029.). Each cartridge configuration is only set to perform a full extension. (Tr. (Crosby) at 1506:7-1507:6; CDX-0043C.0029.). The penetration depth may change based on the length or angle of the needles in each cartridge, but the needles extend only a fixed distance. (*See, e.g.*, RX-0307 at 10:2-7, 10:19-25, 12:31-34, 16:1-8; *see also* Tr. (Crosby) at 1504:17-1505:4, 1515:16-24; CDX-0043C.0027.).

4. The Prior Art Reference Does Not Render Obvious the Asserted Claims of the '536 Patent

a) Mehta in View of the Knowledge of a Person of Ordinary Skill in the Art (Claims 11 and 16)

i. Respondents Improperly Relied on Multiple Embodiments Disclosed in Mehta

As with anticipation, Respondents relied on multiple embodiments to argue Mehta discloses the limitations of the asserted claims. (*See* Section VIII.D.3(a); Tr. (Crosby) at 1499:23-1500:11.). Respondents failed to explain why one of ordinary skill would mix and match the embodiments of Mehta as they proposed. *In re Stepan Co.*, 868 F.3d 1342, 1346 n.1 (Fed. Cir. 2017).

ii. Mehta Does Not Disclose the Desired Distance Limitation

Additionally, as explained above with respect to anticipation, Mehta does not disclose the desired distance limitation. Although Respondents contended the asserted claims would be obvious in view of Mehta and the knowledge of a person of ordinary skill in the art, they did not identify any such knowledge to fill the gap, and instead relied on generic and conclusory motivations to modify Mehta, as discussed below. (RBr. at 77-80.).

iii. No Motivation to Combine

Moreover, one of ordinary skill would not been motivated with a reasonable expectation of success to modify Mehta or combine its various embodiments to arrive at the claimed invention. Respondents did not provide sufficient reasoning or support for their assertion that a skilled artisan would use his or her knowledge to fill in the gap of the missing "desired distance" limitation. (RBr. at 77-78.). Instead, Respondents relied on an alleged "high degree of similarity between Mehta and the claimed inventions," the predictability of the art, and conclusory assertions that "any alleged differences concern small, basic mechanical design implementations that are not of patentable significance." (RBr. at 77-78.). Respondents' only support is Dr. Woloszko's testimony. However, his testimony is also conclusory and divorced from the requirements of the claims. During the Hearing, he merely provided the following testimony for claim 11.

> Q. . . . Even if Mr. Crosby were correct about anticipation, would the POSITA have nevertheless been motivated to modify Mehta or combine elements of Mehta in light of a POSITA's knowledge and arrive at the asserted claims?
>
> A. Absolutely.
>
> Q. Why?
>
> A. Sorry. You know, this -- those devices, there was a high degree of similarity of Mehta to the device described in the claims. Any difference between what Mehta,

> you know, in terms of this difference of opinion would be a small design implementation that wouldn't be patentable. This is very relevant to the art.
>
> * * *
>
> A. . . . Yes, all limitations are mentioned in basically -- this is about claim 11, yes. I talked about claim 16, but the same thing goes for claim 11, there are a lot of similarities between the Mehta device described and the device mentioned in claim 11.
>
> Q. And would a person of ordinary skill in the art have had a reasonable expectation of success in doing these things?
>
> A. This is basic mechanical design, yes.

(Tr. (Woloszko) at 951:17-952:4, 952:16-24.).

Dr. Woloszko failed to identify specific similarities or provide a basis or explanation for this opinion, other than to say "[t]his is basic mechanical design, yes." (*Id.* at 952:24.). As indicated in his testimony replicated above, Dr. Woloszko did not provide an explanation other than a generic recitation of alleged predictability of the art, routine optimization, and basic design implementation that allegedly lacks patentable significance, which is not persuasive. (Tr. (Woloszko) at 951:17-952:24; *see also* Tr. (Crosby) at 1512:4-10.). His alleged motivations to combine Mehta and the knowledge of one of ordinary skill bear no relationship to any specific combination of claimed elements. As also reflected in his demonstratives, Dr. Woloszko relied on the exact same motivations to modify or combine for all asserted claims of the Family Two Patents even though they include disparate limitations like an LED or desired distance control. (RDX-0010C.0118, 0128, 0151; *see also* Tr. (Crosby) at 1511:16-1512:10; CDX-0043C.0037.).

As discussed above with respect to anticipation by Mehta, Mehta discloses reaching a target tissue by using different cartridges with different probe configurations where the probes extend a fixed distance, as well as mechanisms (e.g., ultrasound, impedance measurements, virtual depth depiction) to assess proper needle placement. (Tr. (Crosby) at 1515:12-1516:9;

CDX-0043C.0044.). That step-motors were known at the time, as Respondents asserted, does not support their argument that one of ordinary skill would have been motivated to program that step motor to arrive at the claimed inventions. (RBr. at 78-79.). *Personal Web Techs.*, 848 F.3d at 994 ("[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.") (original emphasis). Respondents did not provide sufficient evidence of motivation to do so. The mechanisms in Mehta and the Family Two Patents for reaching a target tissue are, as Mr. Crosby described, "apples and oranges." A person of ordinary skill in the art would not been motivated to modify Mehta to arrive at the "desired distance" limitation. (Tr. (Crosby) at 1515:12-1516:9; CDX-0043C.0044.).

For these reasons, Respondents have not met their burden of proving by clear and convincing evidence that Mehta renders the claims obvious. *See, e.g.*, *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1328 (Fed. Cir. 2012) (affirming a JMOL of non-obviousness because Verizon's experts' testimony was "generic and b[ore] no relation to any specific combination of prior art elements" and failed "to explain why a person of ordinary skill in the art would have combined elements from specific references in the way the claimed invention does").

b) Objective Indicia of Non-Obviousness of the Family Two Patents

As noted above in Section VII.D.3(d) with respect to secondary considerations of non-obviousness of the '836 patent, Respondents were precluded from presenting any testimony and evidence by Order No. 41. (*See* Order No. 41 at 3-6.). Nevertheless, as they did with the '836 patent, Respondents attempted to rebut certain of Serendia's objective indicia evidence of

commercial success in their Initial Post-Hearing Brief. (*See* RBr. at 93-94.). Respondents' arguments are deemed abandoned or withdrawn under Ground Rule 7.2. (*See also* Order No. 41.). *See, e.g.*, *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).

For the following reasons, Serendia's objective indicia of commercial success and industry praise weigh in favor of validity and that is the finding.

i. Commercial Success

Serendia presented evidence that the devices that use the inventions claimed in the Family Two Patents have achieved commercial success, at least partially, based on the claimed technology. (Tr. (Crosby) at 1520:15-1521:2.).

With respect to the DI Products, marketing and training materials for the Sylfirm X highlight its ability to precisely "adjust[] the needle" for achieve different medical indications such as "melasma, diffuse redness, [and] rosacea." (Tr. (Crosby), 1521:5-12; CX-0830C.0010, 0013 (Brochure); CX-0918.0002 (Press Release); CX-0896.0002, 0015 (Website) (similar); CPX-0158 at 1:06 (Video).). For example, SylfirmX training materials explain that effective treatment of different medical conditions "depends on the ability to have the needles extend a desired distance to deliver the coagulation where it should be." (Tr. (Crosby), 1521:15-21; CX-2673C.0009, 0047 (Training).). The "success of the treatment depends on precise placement of the coagulation in the tissue." (Tr. (Crosby) at 1520:17-18; CX-3384C.1086 (Sylfirm 510(k)).). If the needles are inserted too deeply, the treatment could "dissolve facial fat" and have an adverse consequence. (CX-0858C.0001 (Training Notes).). Thus, "the desired depth" as claimed in the Family Two Patents "allows more indications for these products" to treat more

types of patients and is a "huge factor" in purchasing decisions. (Tr. (Crosby), 1522:4-8.). The technology claimed in the Family Two Patents have significant benefits over the prior art, and these treatment benefits are advertised and linked with the Sylfirm X product and its commercial success. (*Id.* at 1518:22-1522:19; *see also* Section VII.D.3(d), *supra* (Sylfirm X's commercial success).).

Respondents contended that Serendia failed to demonstrate a nexus between the commercial success of the products at issue and the "specific, novel features" of the Family Two Patents. (RBr. at 93-94).). Respondents mischaracterized both Serendia's contention and the evidence.

As explained in above in Section VII.D.3(d), the Sylfirm X practices the asserted claims of the Family Two Patents and the commercial success of that product has been due in large part to the adjustable depth control functionality recited in the desired distance limitations in each of the Family Two Patents. As Mr. Park testified, the [redacted] (Tr. (Park) at 450:11-18.). The marketing materials advertise the adjustable depth control functionality. (*See* CDX-0043C.0046-51 (collecting evidence); CX-0830.0013 (Sylfirm X brochure); CX-0918.0002 (Benev news release); CX-0896.0002, 0015 (Benev Sylfirm X webpage).).

With respect to the Accused and Licensed Products, the weight of the evidence in this Investigation establishes that the Accused Products practice the Family Two Patents. (*See* Section VIII.C, *supra* (tech DI for '536 patent); Sections IX.B and X.B, *infra* (tech DI for '774 and '812 patents).). Likewise, the Licensed Products are "relevant to commercial success." *Certain Radio Frequency Identification (Rfid) Prod. & Components Thereof*, Inv. No. 337-TA-979, Order No. 25 at 13 (July 12, 2016); *Harris Corp. v. Fed. Exp. Corp.*, 502 F. App'x 957, 968

(Fed. Cir. 2013).

The Accused Potenza Products expressly advertise, as a treatment benefit, advancing the needles a desired distance, as taught by the Family Two Patents. (Tr. (Crosby) at 1524:7-1525:6.). The [redacted] advertise the same. (Tr. (Crosby) at 1522:20-1523:11 (SHEnB & ABM), 1523:12-1524:6 (Pixel8 & Genius); CPX-0073 at 0:40-0:49 (Vivace); CPX-0072 at 1:11-1:16 (Vivace ULTRA); CPX-0055 at 0:53; CPX-0064 at 0:45 (Pixel8).). For example, current and former Respondents' marketing materials tout "accurate needle penetration depth control" and the ability to "deliver energy [at the] . . . depth desired." (CPX-0055 at 0:53 (Genius); CPX-0057 at 0:50 (Secret); CPX-0060 at 1:41 (Potenza).). Studies Respondents funded and used for marketing also explain that "coagulation was significantly affected with microneedle depth." (CX-0353C.0005-6 (Wootten Study); CX-2593C.0003 (Oku).). Additionally, Respondents' clinical training and guidance also emphasize the importance of [redacted] and medical indication. (CX-0233C.0007, 0057 (Potenza Training).). Mr. Crosby explained that based on the evidence as described, the Accused and Licensed Products "achieve commercial success due in part to implementation of the Family Two patent inventions." (Tr. (Crosby) at 1525:2-6.). Therefore, there is a nexus between the Family Two Patents and the Accused and Licensed Products' commercial success.

Accordingly, the DI, Accused, and Licensed Products all advertise the benefits of the claimed approach, which is linked to their commercial success. *Gambro Lundia*, 110 F.3d at 1579.

ii. Industry Praise

Extending needles a desired distance and a mechanism for precise needle depth control as

claimed by the Family Two Patents and the products implementing the inventions have received industry praise and recognition. *WBIP*, 829 F.3d at 1334. (*See also* Tr. (Crosby) at 1525:7-1526:3.). Medical providers also have praised the products at issue for their ability to "accurately target and treat[]" at the desired skin depth. (CX-2858C.0003 (Sylfirm X); CX-2591C.0002 (ABM); CX-0316.0002 (Cartessa).). That former Respondents praised the patented technology in their brochures and magazine placements is indicative of non-obviousness. *WBIP*, 829 F.3d at 1334 ("competitors, are not likely to praise an obvious advance over the known art"). Additionally, in 2020, ViOL (the manufacturer of the Sylfirm X) received a world-class product award for the Sylfirm X in Korea. (CX-2859.).

For the reasons explained, the evidence demonstrates that the DI, Accused, and Licensed Products have received industry praise and recognition.

IX. U.S. PATENT NO. 9,775,774

A. Direct Infringement

1. Infringement Overview

Serendia asserted that the Accused Products directly infringe claim 14 of the '774 patent, which depends from unasserted claims 11 and 12. (CBr. at 66.). For the reasons discussed below, Serendia has met its burden and proven that the Accused Products directly infringe claim 14.

2. The Accused Products Practice Claim 11 of the '774 Patent

a) 11[pre]: "An apparatus for treating dermatological tissue, comprising"

Each of the Potenza and Intensif Products is an "apparatus for treating dermatological tissue." (Tr. (Crosby) at 580:10-583:2, 626:10-22;36 CDX-0001C.0014-16, 0089; CX-0166C.0026 (Potenza 510(k)); CX-0164C.0006 (Potenza Manual); CX-0339C.0041 (Intensif

with EndyMed PRO 510(k)); CX-0696.0010, 0014 (EndyMed PRO Manual); CX-0694 (EndyMed PURE Manual).).

Respondents did not contest that the Accused Products meet the preamble in either their Pre-Hearing or Post-Hearing Reply Briefs. (RPBr. at 105; RRBr. at 59-62.). 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 of claim 11 of the '774 patent.

b) 11[a]: "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"

The Accused Products practice this limitation because each is "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." Mr. Crosby explained that the Accused Products have needles that extend a desired distance from a surface, e.g., the needle module end surface, where the distance is selected by a user and enables the needles to penetrate skin. (Tr. (Crosby) at 587:10-23, 605:4-609:14, 633:11-22; CDX-0001C.0024, 0051, 0052, 0102; CPX-0126C (Potenza Inspection Video) at 0:00, 0:01; CX-0171C (Potenza Drawing) at 1; CX-3105C, CX-3108C (Potenza); CX-0233C.0057 (Potenza Training); CX-0166C.0036, 0037, 0039 (Potenza 510(k)); CX-0165C.0005 (Potenza Service Manual); CX-0685C.0083 (Potenza Special 510(k)); CPX-0131C (EndyMed Inspection Video), 0:00, 0:01; CX-0697C.0023 (EndyMed RF HP Spec.); CX-3146C, CX-3155C (Intensif with EndyMed Pure 2.0); CX-0696.0058 (EndyMed Pro Manual); CPX-0812.0003 (Intensif

Brochure); CX-0339C.0047 (Intensif with EndyMed Pro 510(k)); CX-0341.0003, 0007 (Intensif Presentation); CX-0696.0058 (EndyMed PRO Manual); CX-0843C.0002, 0004 (EndyMed Webpage); CPX-0067 (Video, Intensif) at 0:13-0:30, 0:40-0:46; CPX-0068 (Video, Intensif) at 1:34; CX-3089C-3158C, CPX-0124-0133C (Inspection Photos/Videos); CPX-0162-0183 (physical portions of Potenza and Intensif Products).).

Respondents did not contest that the Accused Products meet this limitation in either their Pre-Hearing or Post-Hearing Reply Briefs. (RPBr. at 105; RRBr. at 59-62.). 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 this limitation of claim 11 of the '774 patent.

c) 11[b]: "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"

The Accused Products practice this limitation because they include "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." "Pulsed radio frequency signals" was construed to have its plain and ordinary meaning of "radio frequency signals that are normally off and suddenly on for a period of time (i.e., a rapid, transient change from a baseline to a different amplitude, followed by rapid return to baseline)." (*Markman* Order at 36.).

Based on uncontested evidence, Mr. Crosby testified that the Accused Products

. (Tr. (Crosby) at 611:17-612:13, 633:11-22; CDX-0001C.0057, 0102; CX-0233C.0014 (Potenza Training); CX-0165C (Potenza Service Manual); CX-0166C (Potenza 510(k)); CX-0685C (Potenza Special 510(k)); CX-0717C (Potenza Block Diagram); CX-0803 (Potenza Webpage); CX-0804 (Potenza Brochure); CX-0805 (Potenza Brochure); CPX-0060 (Video, Potenza); CPX-0067 (Intensif Video) at 0:44; CX-0186 (EndyMed Pro Manual, September 2017); CX-0338C (Intensif Drawing); CX-0339C (Intensif with EndyMed Pro 510(k)); CX-0341 (Intensif Presentation) CX-0690C (Intensif Device Description); CX-0696 (EndyMed PRO Manual); CX-0697C (EndyMed RF H/P Spec.); CX-0812 (Intensif Brochure); CX-0813 (Intensif FDA Form).).

Mr. Crosby explained that the (Tr. (Crosby) at 634:4-637:17; CDX-0001C.0106, 0107.). A Jeisys training presentation, replicated below, explains that the . (CX-0233C (Potenza Training) at 57; CX-0165C (Jeisys Service Manual); CPX-0061 (Video, Potenza); CX-0176C (Potenza Review).).

Figure 28: Jeisys Training Discussing Pulsed RF Signals



(CBr. at 68 (citing CX-0233C.0057 (annotated).).

The EndyMed Products also

(CX0339C (Intensif 510(k)) at 32 (emphasis added).). The disclosure from the EndyMed Intensif 510(k) is copied below.



(CX0339C (Intensif 510(k)) at 32; *see also* CX-0843C (EndyMed Webpage); CX-0342C (Intensif Presentation).).

Mr. Crosby's inspections confirm that the

.



(CX-3122C (Potenza Waveform) (left); CPX-0133C (EndyMed Waveform Video) at 0:02 (right).).

Additionally, deposition testimony from Respondents' corporate representative, Mr. An, indicates that the Accused Products include pulsed RF signals. When asked what "pulse" referred to, Mr. An from Jeisys explained:

(CX-1050C (An Dep. Tr.) at 81:15-82:10 (emphasis added).).

(CX-1056C (Witman Dep. Tr.) at 77:2-5 .).

Jeisys/Cynosure only disputed that this limitation is met when the Potenza is in single-pulse mode. (RPBr. at 105, 111; RRBr. at 61-62.). However, as Mr. Crosby explained, even in

this mode, the Potenza is capable of multiple pulses of RF because they can perform more than one single needle extension.

> Q. . . . Dr. Brennan argues that the accused Potenza products don't infringe claim 14 of the '774 patent in the single pulse mode. Do you agree?
>
> A. I do not.
>
> Q. Why not?
>
> A. Well, as I understand it, Dr. Brennan argues that there is not multiple pulses for each needle insertion, but the claims don't require that. The way the Potenza products work in a single pulse, the needles are inserted, a pulse of radiofrequency is delivered, the needles are retracted, they are inserted again, another pulse is delivered, so there is clearly pulse across the needles. And if you read the claims, the claim says pulsed radiofrequency signals across the plurality of needles. It doesn't require there to be for each needle insertion.

(Tr. (Crosby) at 1492:24-1493:14; *see also* CX-0164C (Potenza Manual) at 17, 25.).

Regardless, Jeisys/Cynosure did not contest infringement in any setting other than single-pulse mode. (Tr. (Crosby) at 1493:15-20; CX-0176C (Potenza Review) at 6-8 .). Thus, even if Jeisys/Cynosure's single-pulse mode argument were given any credit, the Potenza still infringes "even though it may be capable of non-infringing modes of operation" because they are also designed to operate in a multiple-pulse mode. *See, e.g.*, *Versata Software, Inc. v. SAP Am., Inc.*, 717 F.3d 1255, 1262 (Fed. Cir. 2013) ("an accused product may be found to infringe if it is reasonably capable of satisfying the claim limitation"); *Hilgraeve Corp. v. Symantec Corp.*, 265 F.3d 1336, 1343 (Fed. Cir. 2001).

For the foregoing reasons, Serendia has proven by a preponderance of evidence that the Accused Products meet this limitation of claim 11 of the '774 patent.

3. The Accused Products Practice Claim 12 of the '774 Patent

a) "The apparatus for treating dermatological tissue of claim 11, wherein the device includes an end surface con-figured to be placed on or near dermatological tissue to be treated, the end surface including a plurality of needles extendable a desired distance from the end surface."

The Accused Products practice this limitation because they include "an end surface configured to be placed on or near dermatological tissue to be treated, the end surface including a plurality of needles extendable a desired distance from the end surface." As Mr. Crosby testified, and as confirmed by the weight of the evidence, in those products, the needle module end surface is placed on or near tissue to be treated, and plurality of needles extend a desired distance from the needle module end surface. (Tr. (Crosby) at 587:10-23, 633:11-22; CDX-0001C.0019, 0024, 0052, 0102; CPX-0126C (Potenza Video) at 0:01 and 0:02; CPX-0059 (Potenza Video) at 0:58; CPX-0060 (Potenza Video); CPX 0063 (Potenza Tiger Tip Video); CX-0165C (Potenza Service Manual); CX-0717C (Potenza Block Diagram); CX-0803 (Potenza Webpage); CX-0804 (Potenza Brochure); CPX-0131C (EndyMed Inspection Video) at 0:00, 0:01; CPX-0068 (Intensif Video) at 2:08; CX-0339C (Intensif with EndyMed Pro 510(k)); CX-0690C (Intensif Device Description); CX-0696 (EndyMed PRO Manual); CX-0697C (EndyMed H/P Spec.); CPX-0035 (Video, Intensif HP); CPX-0067 (Video, Intensif); CPX-0068 (Video, Intensif Treatment); CX-0341 (Intensif Presentation); CX-0812 (Intensif Brochure); CX-0843C (EndyMed Webpage); CX-3089C-3158C, CPX-0124-0133C (Inspection Photos/Videos); CPX-0162-0183 (physical portions of Potenza and Intensif Products).).

Jeisys/Cynosure disputed this limitation, contending that Serendia did not differentiate between a "surface" in claim 11 and an "end surface" in claim 12. (RPBr. at 113-14; RRBr. at 59-60; Tr. (Brennan) at 1162:19-1163:3; RDX-0013C.0019.). However, the claims do not

require different surfaces and here, each claimed "surface" is the needle module end surface. *Powell v. Home Depot U.S.A., Inc.*, 663 F.3d 1221, 1231-32 (Fed. Cir. 2011) (holding the claim terms "cutting box" and "dust collection structure" need not be separate and distinct elements in the accused product); *Certain Three-Dimensional Cinema Sys. and Components Thereof*, Inv. No. 337-TA-939, Comm'n Op. at 21-22 (Aug. 23, 2016); *Certain Cloud-Connected Wood-Pellet Grills & Components Thereof*, Inv. No. 337-TA-1237, ID, 2021 WL 6337517 (Dec. 6, 2021).[74] Respondents' expert, Dr. Woloszko, agreed that the needle module end surface can satisfy both the "surface" in claim 11 and the "end surface" in claim 12. (Tr. (Woloszko) at 1148:22-25.).

During the Hearing, EndyMed did not present any evidence to dispute that its Intensif Products meet this limitation. Nonetheless, in Respondents' Pre-Hearing and Post-Hearing Reply Briefs, EndyMed argued that Serendia failed to identify the claimed end surface or demonstrate how the needles extend from an end surface that is placed on or near dermatological tissue. (RPBr. at 114; RRBr. at 59-60.). That is not so.

As discussed above, Mr. Crosby identified the end surface as the needle module end surface and explained how: (i) it is placed on the dermatological tissue to be treated (Tr. (Crosby) at 587:10-23; CDX-0001C.0024; CPX-0068 (Intensif Treatment) at 2:08; CX-0339C (Intensif, EndyMed Pro 510(k)); CX-0690C (Intensif Description); CX-0696 (EndyMed PRO Manual); CX-0697C (EndyMed H/P Spec.)); and (ii) the needles extend from that surface (Tr.

[74] In their Post-Hearing Reply Brief, Respondents asserted that the cases cited by Serendia and Staff are inapposite. (RRBr. at 60-61 (citing CBr. at 71; SBr. at 108).). Specifically, Respondents contended that the specifications at issue for each of the cited cases "included explicit support for multiple, distinct claim elements being mapped to a single structure, and none of these cases address the situation of using the same word (e.g.,'surface') for multiple antecedents." (*Id.* at 60.). Although these cases may not have addressed the use of the same word of multiple antecedents, as Respondents argued, they also do not squarely support the proposition that a same word categorically cannot cover multiple antecedents without express support in the specification. Accordingly, Respondents' assertion is unsupported.

(Crosby) at 608:12-609:14; CDX-0001C.0052; CPX-0131C (EndyMed Inspection) at 0:00, 0:01; CX-0341 (Intensif Presentation); CX-0690C (Intensif Description); CX-0697C (EndyMed H/P Spec.); CX-0812 (Intensif Brochure); CX-0843C (EndyMed Webpage); CPX-0067 (Video, Intensif); CPX-0068 (Video, Intensif).).

For the reasons explained, Serendia has proven by a preponderance of evidence that the Accused Products meet the additional limitation recited in claim 12 of the '774 patent.

4. The Accused Products Practice Claim 14 of the '774 Patent

a) "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."

The Accused Products include "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." Each of the Accused Products has a motor coupled to the plurality of extendable needles. (Tr. (Crosby) at 595:1-11, 605:4-609:14; 621:9-622:24, 626:10-22; CDX-0001C.0037, 0048, 0049, 0051, 0075-78, 0089; CX-0233C (Potenza Training) at 57; CX-0171C (Potenza Drawing) at 1; CX-0696 (EndyMed Pro Manual) at 58; CX-0697C (EndyMed HP Spec.) at 23; CX-3089C-3158C, CX-3257C-3295C, CPX-0124-0133C, CPX-0140C-0147C (Inspection Photos/Videos); CPX-0162-0183 (physical portions of Accused Products).).

The motor causes the needles to extend a desired distance from the needle module end surface. (Tr. (Crosby) at 587:10-23, 605:4-609:14, 633:11-22; CDX-0001C.0024, 0051, 0052, 102; CPX-0126C (Potenza Inspection Video) at 0:00, 0:01; CX-0171C (Potenza Drawing) at 1; CX-3105C, CX-3108C (Potenza); CX-0233C.0057 (Potenza Training); CX-0166C.0036, 0037, 0039 (Potenza 510(k)); CX-0165C.0005 (Potenza Service Manual); CX-0685C.0083 (Potenza

Special 510(k)); CPX-0131C (EndyMed Inspection Video) at 0:00, 0:01; CX-0697C.0023 (EndyMed RF HP Spec.); CX-3146C, CX-3155C (Intensif with EndyMed Pure 2.0); CX-0696.0058 (EndyMed Pro Manual); CPX-0812.0003 (Intensif Brochure); CX-0339C.0047 (Intensif with EndyMed Pro 510(k)); CX-0341.0003, 0007 (Intensif Presentation); CX-0696.0058 (EndyMed PRO Manual); CX-0843C.0002, 0004 (EndyMed Webpage); CPX-0067 (Video, Intensif) at 0:13-0:30, 0:40-0:46; CPX-0068 (Video, Intensif) at 1:34; CX-3089C-3158C, CPX-0124-0133C (Inspection Photos/Videos); CPX-0162-0183 (physical portions of Potenza and Intensif Products).).

Respondents did not contest that the Accused Products meet this limitation in either their Pre-Hearing or Post-Hearing Reply Briefs. (RPBr. at 105; RRBr. at 59-62.). 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 14 of the ’774 patent.

B. Technical Prong of Domestic Industry

1. The DI Products Practice Claim 11 of the ’774 Patent

a) 11[pre]: “An apparatus for treating dermatological tissue, comprising”

The DI Products are an “apparatus for treating dermatological tissue.” (Tr. (Crosby) at 583:3-15, 626:10-22, 633:11-22; CDX-0001C.0017, 0102; CX-0826C.0002 (Sylfirm X 510(k) Description); CX-0823C.0004 (Sylfirm X Manual); CX-0761C.0002 (Sylfirm X Webpage); CX-0830.0002 (Sylfirm X Brochure); CX-3384 (Sylfirm X 510(k)).).

Respondents did not contest that the DI Products meet the preamble in either their Pre-

Hearing or Post-Hearing Reply Briefs. (RPBr. at 114; RRBr. at 62.). 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 11 of the '774 patent.

b) 11[a]: "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"

The DI Products meet this limitation because they include needles that extend a desired distance from a surface, e.g., the needle module end surface, where the distance is selected by a user and enables the needles to penetrate skin. Specifically, Mr. Crosby testified that the needles extend a desired distance from the needle module end surface. (Tr. (Crosby) at 661:1-662:20, 609:15-611:3; 633:11-22; CDX-0001C.0053-54, 0102.). He explained that this distance correlates to the distance the user selects with the depth setting in the DI Products. (Tr. (Crosby) at 633:11-22, 661:1-662:20; CDX-0001C.0054, 0102; *see also* CX-0826C.0007, 0011 (Sylfirm X 510(k) Description); CX-0760C.0007-10 (DI Product Photos); CPX-0069 (Sylfirm X Video) at 0:32; CPX-0152C (Sylfirm X Inspection Video) at 0:00-0:05; CX-3329C, CX-3330C (Sylfirm X); CX-0823C.0016 (Sylfirm X Manual); *see also* Tr. (Crosby) at 587:24-588:16; CDX-0001C.0025, 0102.).

Respondents did not contest that the DI Products meet this limitation in either their Pre-Hearing or Post-Hearing Reply Briefs. (RPBr. at 114; RRBr. at 62.). 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 this limitation of claim 11 of the '774 patent.

c) 11[b]: "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"

Serendia presented undisputed evidence that the DI Products include an RF generator coupled to the plurality of needles to produce pulsed RF signals across the needles to affect tissue near them. (Tr. (Crosby) at 611:17-612:13, 633:11-22, 635:17-637:17; CDX-0001C.0057, 0102, 0106-07; CPX-0069 (Sylfirm X Video) at 0:11; CPX-0070 (Sylfirm X Video) at 0:38, 1:56-2:00; CX-0823C.0004, 0017 (Sylfirm X Manual); CX-0826C.0008, 0016 (Sylfirm X Device Description); CX-3384 (Sylfirm X 510(k)).). Dr. Na's testimony confirms that the DI Products meet this limitation. (RX-0073C (Na Dep. Tr.) at 205:22-206:5.).

Respondents did not contest that the DI Products meet this limitation in either their Pre-Hearing or Post-Hearing Reply Briefs. (RPBr. at 114; RRBr. at 62.). 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 this limitation of claim 11 of the '774 patent.

2. The DI Products Practice Claim 12 of the '774 Patent

a) "The apparatus for treating dermatological tissue of claim 11, wherein the device includes an end surface con-figured to be placed on or near dermatological tissue to be treated, the end surface including a plurality of needles extendable a desired distance from the end surface."

Serendia presented evidence that the DI Products meet this limitation. The evidence demonstrates that the end surface of the needle module in the DI Products is placed on or near tissue, and the needles extend a desired distance from that surface. (Tr. (Crosby) at 609:15-611:3, 633:11-22, 661:1-662:20; CDX-0001C.0053, 0054, 0102; *see also* CDX-0001C.0025; Tr.

(Crosby) at 587:24-588:10; CX-3329C, CX-3330C (Sylfirm X); CPX-0152C (Sylfirm X Inspection Video) at 0:00-0:05; CX-0826C.0007, 0011 (Sylfirm X 510(k) Description); CX-0760C.0007-10 (Domestic Industry Product Photos); CPX-0069 (Sylfirm X Video) at 0:32; CX-0823C.0016 (Sylfirm X Manual); CX-3384 (Sylfirm X 510(k)).).

Although Respondents did not present evidence during the Hearing to contest this limitation, in their Pre-Hearing Brief, they raised the same arguments as for limitation 11[a2] of the '536 patent for "plurality of needles [that are] extendable . . . from the end surface." (RPBr. at 114.). For the reasons explained in Section VIII.C1 above, Respondents' attorney arguments are neither supported by the evidence nor persuasive.

For the reasons discussed above, Serendia has proven by a preponderance of evidence that the DI Products meet the additional limitation recited in claim 12 of the '774 patent.

3. The DI Products Practice Claim 14 of the '774 Patent

a) "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."

Serendia presented compelling, unrebutted evidence that the DI Products meet this limitation. The evidence demonstrates that the DI Products include a motor coupled to the plurality of extendable needles. (Tr. (Crosby) at 595:19-596:4, 609:15-611:7, 620:21-621:8, 622:25-623:8, 626:10-22; CDX-0001C.38, 53, 54, 75, 79, 89 (Crosby); CX-3326C, CX-3329C, CX-3330C, CX-3340C (Sylfirm X); CPX-0152C (Sylfirm X Inspection Video) at 0:00-0:05; CX-0759C.0003 (DI Photos); CX-0823C.0016 (Sylfirm X Manual); CX-0826C.0007, 0015, 0016 (Sylfirm X 510(k) Description); CX-0829C.0003 (Sylfirm X Circuit Drawing); CX-3384 (Sylfirm X 510(k)); CX-3321C-3350C (Inspection Photos/Videos); CPX-0160-161 (physical

portions of DI Products).). The motor causes the needles to extend a desired distance from the needle module end surface. (Tr. (Crosby) at 661:1-662:20, 609:15-611:3; 633:11-22; CDX-0001C.0053-54, 0102; CX-3326C, CX-3340C (Sylfirm X); CX-0759C.0002-0004 (DI Photos).).

Respondents did not present evidence during the Hearing to contest this limitation. However, in their Pre-Hearing Brief, they raised the same attorney arguments as for limitation 11[a2] of the '536 patent for "plurality of needles [that are] extendable . . . from the end surface." (RPBr. at 114.). For the reasons explained in Section VIII.C.1(c) above, those arguments are neither supported by the evidence nor persuasive.

Accordingly, Serendia has proven by a preponderance of evidence that the DI Products meet the additional limitation recited in claim 14 of the '774 patent.

C. Invalidity

1. The Prior Art Reference Does Not Render Obvious the Asserted Claim of the '774 Patent[75]

a) Mehta in View of the Knowledge of a Person of Ordinary Skill in the Art (Claim 14)

i. Respondents Improperly Relied on Multiple Embodiments Disclosed in Mehta

Like the '536 patent, Respondents improperly relied on multiple embodiments in an attempt to demonstrate that Mehta discloses all claim limitations of asserted claim 14 of the '774 patent.[76] (*See* Section VIII.D.4(a), *supra*; *see also* Tr. (Crosby) at 1499:23-1500:11.). For the same reasons discussed above in Section VIII.D.4 with respect to the '536 patent, Respondents failed to explain why one of ordinary skill would mix and match the embodiments of Mehta as

[75] *See* n.54, *supra* (regarding institution of IPRs).

[76] Asserted claim 14 depends from claims 11 and 12, which are not at issue in this Investigation.

Respondents proposed. *In re Stepan Co.*, 868 F.3d at 1346 n.1.

ii. Mehta Does Not Disclose the Desired Distance Limitation

Additionally, the '774 patent requires that needles extend "a desired distance" from "a surface" (claim 11) and an "end surface" (claim 12). (JX-0003 at cls. 11-12.). As discussed above in Section VIII.D.4(a) with respect to the '536 patent, Mehta does not disclose needles extending a "desired distance" from any surface. Respondents relied on the same analysis for claim 11 of the '536 patent as for overlapping limitations in the '774 patent. (RBr. at 80-82; Tr. (Woloszko) at 957:21-959:14.). Respondents' arguments fail for the same reasons discussed above in Section VIII.D.4(a).

iii. No Motivation to Combine

Moreover, for the reasons explained with respect to the '536 patent, one of ordinary skill would not have had a reasonable expectation of success or would have been motivated to modify Mehta or to combine its various embodiments to arrive at the claimed invention. (*See* Section VIII.D.4(a), *supra*.). As with the '536 patent, Dr. Woloszko's testimony on motivations to modify Mehta are conclusory and divorced from the claim limitations. The entirety of his opinion that a person of ordinary skill would have been motivated to modify Mehta to arrive at claim 14 is replicated below.

> Q. . . . Would the person of ordinary skill in the art have been motivated to modify Mehta or combine the elements of Mehta and arrive at claim 14?
>
> A. Yes, there was -- absolutely. There was a high similarity between the claims and the Mehta, devices described by Mehta. The difference are just small design options, probably not represent any patentable -- not have any patentable significance. This is basic mechanical engineering, so the relevant art is very predictable, and the implementation is obvious and doesn't require much experimentation, you can do some CAD drawing, and routine optimization for manufacturing, production, and so on. So very high level, very high gravity of success expected.

(Tr. (Woloszko) at 959:19-960:6.).

Again, Dr. Woloszko did not identify such similarities or provide a specific basis or explanation for his opinion. He relied on the exact same motivations to modify or combine for all asserted claims of the Family Two Patents even though they include disparate claim limitations like an LED or desired distance control. (RDX-0010C.0118, 0128, 0151; *see also* Tr. (Crosby) at 1511:16-1512:10; CDX-0043C.0037; Tr. (Woloszko) at 959:19-960:6.). That is not sufficient to meet Respondents' burden *of proof*. *See, e.g.*, *ActiveVideo*, 694 F.3d at 1328.

X. U.S. PATENT NO. 10,869,812

A. Direct Infringement

1. Infringement Overview

Serendia asserted that the Accused Products directly infringe claims 5, 13, and 18 of the '812 patent. (CBr. at 74.). Claim 5 depends from unasserted claims 1-4. Claims 13 and 18 depend from unasserted claim 12.

For the reasons discussed below, Serendia has met its burden and proven that the Accused Products directly infringe claims 5, 13, and 18.

2. The Accused Products Practice Claim 1 of the '812 Patent

a) 1[pre]: "A method of treating dermatological tissue, comprising"

The Accused Products practice "[a] method of treating dermatological tissue." (Tr. (Crosby) at 580:10-583:2, 626:10-22;36 CDX-0001C.0014-16, 0089; CX-0166C.0026 (Potenza 510(k)); CX-0164C.0006 (Potenza Manual); CX-0339C.0041 (Intensif with EndyMed PRO 510(k)); CX-0696.0010, 0014 (EndyMed PRO Manual); CX-0694 (EndyMed PURE Manual).).

Respondents did not contest that the Accused Products meet this limitation in either their Pre-Hearing or Post-Hearing Reply Briefs. (RPBr. at 124-25; RRBr. at 63-66.). Thus, any

argument they may make 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 of claim 1 of the ’812 patent.

b) 1[a1]: “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”

Each of the Accused Products includes a method or practice of “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 Accused Products include [redacted]. (Tr. (Crosby) at 586:21-587:23, 626:10-22; CDX-0001C.0023; CX-0164C.0029 (Potenza Manual); CX-0696.0019, 0056 (EndyMed Manual).). This [redacted]

Figure 31: Crosby Demonstrative Illustrating a Releasably Couplable Deployable Needle Module



(CDX.0001C.0022; *see also* Tr. (Crosby) at 583:21-587:23; CDX-0001C.0023, 0024; CX-0164C.0029 (Potenza Manual); CPX-0059 (Potenza Video) at 0:58; CX-0696.0019, 0056 (EndyMed HP Manual); CPX-0068 (Intensif Treatment) at 2:08; CX-3089C-3158C, CX-3257C-3295C, CPX-0124-0133C, CPX-0140C-0147C (Inspection Photos/Videos); CPX-0162-0183 (physical portions of Accused Products).).

Respondents did not contest that the Accused Products meet this limitation in either their Pre-Hearing or Post-Hearing Reply Briefs. (RPBr. at 124-25; RRBr. at 63-66.). Thus, any argument they may make 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 this limitation of claim 1 of the ’812 patent.

c) 1[a2]: "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 Accused Products practice this limitation because "the releasably couplable deployable needle module [is] mechanically separatably from the user holdable device proximal end and including a needle assembly including a plurality." The term "separatably" has been construed to mean "separable." (*Markman* Order at 27.).

The [redacted]. (Tr. (Crosby) at 588:22-591:24; CDX-0001C.0029-30; CX-0170C.0001 (Potenza Tip-49 Drawing); CX-0164C.0029 (Potenza Manual); CX-0339C (Intensif, EndyMed Pro 510(k)); CX-0690C (Intensif Description); CX-0696.0056 (EndyMed PRO Manual); CPX-0035 (Video, Intensif HP) at 0:08-0:40; CX-3089C-3158C, CX-3257C-3295C, CPX-0124-0133C, CPX-0140C-0147C (Inspection Photos/Videos); CPX-0162-0183 (physical portions of Accused Products).). It also [redacted]. (CX-0170C.0001 (Potenza Tip-49 Drawing); CX-0696 (EndyMed PRO Manual); CX-0697C.0023 (EndyMed H/P Spec.).).

Respondents did not contest that the Accused Products meet this limitation in their Post-Hearing Reply Brief. (RRBr. at 63-66.). Thus, any argument they may make on this issue is deemed waived under Ground Rule 10.1.

For the reasons discussed above, Serendia has proven by a preponderance of evidence that the Accused Products meet this limitation of claim 1 of the '812 patent.

d) 1[a3]: "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

The Accused Products practice this limitation because "the needle assembly [is] 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." Mr. Crosby explained that in the Accused Products, the

. (Tr. (Crosby) at 592:14-595:11, 597:2-599:24; CDX-0001C.0036, 0037, 0040; CX-0170C.0001 (Potenza Tip-49 Drawing); CX-3089C-3158C, CX-3257C-3295C, CPX-0124-0133C, CPX-0140C-0147C (Inspection Photos/Videos); CPX-0162-0183 (physical portions of Accused Products).).

In their Pre-Hearing Brief, Respondents summarily raised the same contentions they did for the limitations of claim 11 of the '536 patent regarding a "releasably couplable deployable needle assembly" and "plurality of extendable needles . . . extendable from a deployable needle assembly end surface." (RPBr. at 124-25.). For the same reasons discussed above in Section VIII.A.2, Respondents' arguments contradict the adopted claim construction as well as the evidence presented during the Hearing.

Moreover, Respondents did not raise this argument in their Post-Hearing Reply Brief. (RRBr. at 63-66.). Thus, any argument they may make on this issue is deemed abandoned, withdrawn and/or waived under Ground Rule 10.1.

Accordingly, Serendia has proven by a preponderance of evidence that the Accused Products meet this limitation of claim 1 of the ’812 patent.

e) 1[b]: “communicating electrical signals from the user holdable device proximal end to the needle assembly via the electrical contacts”

The Accused Products “communicat[e] electrical signals from the user holdable device proximal end to the needle assembly via the electrical contacts.” Mr. Crosby testified that the Accused Products communicate RF, which is an electrical signal, from the proximal end to the needles of the needle assembly through electrical contacts so treatment can be delivered. (Tr. (Crosby) at 601:19-22, 603:14-604:8; CDX-0001C.0044; CX-0233C.0007, 0014 (Potenza Training); CX-0166C.0028, 0033 (Potenza 510(k)); CX-0717C.0004 (Potenza Block Diagram); CPX-0060 (Video, Potenza) at 2:10; CPX-0067 (Intensif Video) at 0:44; CX-0696.0010 (EndyMed PRO Manual); CX-0339C.0032, 0041-47 (Intensif, EndyMed Pro 510(k)); CX-3066C (Intensif HP Spec.); CX-3089C-3158C, CX-3257C-3295C, CPX-0124-0133C, CPX-0140C-0147C (Inspection Photos/Videos); CPX-0162-0183 (physical portions of Accused Products).).

Respondents did not contest that the Accused Products meet this limitation in either their Pre-Hearing or Post-Hearing Reply Briefs. (RPBr. at 124-25; RRBr. at 63-66.). Thus, any argument they may make 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 this limitation of claim 1 of the ’812 patent.

3. The Accused Products Practice Claim 2 of the '812 Patent

a) "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."

The Accused Products "energiz[e] 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." Specifically, the Accused Products include a motor coupled to the plurality of extendable needles. (Tr. (Crosby) at 595:1-11, 605:4-609:14, 621:9-622:24, 626:10-22; CDX-0001C.0037, 0048, 0049, 0051, 0075-78, 0089; CX-0233C (Potenza Training) at 57; CX-0171C (Potenza Drawing) at 1; CX-0696 (EndyMed Pro Manual) at 58; CX-0697C (EndyMed HP Spec.) at 23; CX-3089C-3158C, CX-3257C-3295C, CPX-0124-0133C, CPX-0140C-0147C (Inspection Photos/Videos); CPX-0162-0183 (physical portions of Accused Products).).

Based on evidence adduced in this Investigation, Mr. Crosby opined that the motor causes the needles to extend a desired distance from the needle module end surface. (Tr. (Crosby) at 587:10-23, 605:4-609:14, 633:11-22; CDX-0001C.0024, 0051, 0052, 0102; CPX-0126C (Potenza Inspection Video) at 0:00, 0:01; CX-0171C (Potenza Drawing) at 1; CX-3105C, CX-3108C (Potenza); CX-0233C.0057 (Potenza Training); CX-0166C.0036, 0037, 0039 (Potenza 510(k)); CX-0165C.0005 (Potenza Service Manual); CX-0685C.0083 (Potenza Special 510(k)); CPX-0131C (EndyMed Inspection Video) at 0:00, 0:01; CX-0697C.0023 (EndyMed RF HP Spec.); CX-3146C, CX-3155C (Intensif with EndyMed Pure 2.0); CX-0696.0058 (EndyMed Pro Manual); CPX-0812.0003 (Intensif Brochure); CX-0339C.0047 (Intensif with EndyMed Pro 510(k)); CX-0341.0003, 0007 (Intensif Presentation); CX-0696.0058 (EndyMed PRO Manual);

CX-0843C.0002, 0004 (EndyMed Webpage); CPX-0067 (Video, Intensif) at 0:13-0:30, 0:40-0:46; CPX-0068 (Video, Intensif) at 1:34; CX-3089C-3158C, CPX-0124-0133C (Inspection Photos/Videos); CPX-0162-0183 (physical portions of Potenza and Intensif Products).).

Respondents did not contest that the Accused Products meet this limitation in either their Pre-Hearing or Post-Hearing Reply Briefs. (RPBr. at 124-25; RRBr. at 63-66.). Thus, any argument they may make 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 additional limitation recited in claim 2 of the ’812 patent.

4. The Accused Products Practice Claim 3 of the ’812 Patent

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

The Accused Products “energiz[e] the plurality of needles via a signal generator electrically coupled to the user holdable device proximal end.” (Tr. (Crosby) at 611:17-612:9, 626:10-22; CDX-0001C.0057, 0089; CX-0233C.0014 (Potenza Training); CX-0166C.0028, 0033 (Potenza 510(k)); CPX-0067 (Intensif Video) at 0:44; CX-0339C.0032, 0041-47 (Intensif with EndyMed Pro 510(k)); CX-3089C-3158C, CX-3257C-3295C, CPX-0124-0133C, CPX-0140C-0147C (Inspection Photos/Videos); CPX-0162-0183 (physical portions of Accused Products).).

Respondents did not contest that the Accused Products meet this limitation in either their Pre-Hearing or Post-Hearing Reply Briefs. (RPBr. at 124-25; RRBr. at 63-66.). Thus, any argument they may make 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 3 of the ’812 patent.

5. The Accused Products Practice Claim 4 of the ’812 Patent

a) “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 one embedded LED illuminates the releasably couplable deployable needle module.”

The Accused Products practice this limitation because they include “at least one embedded LED therein and further including energizing the at least one embedded LED so the at least one embedded LED illuminates the releasably couplable deployable needle module.” As Mr. Crosby confirmed, the proximal end of the Accused Products includes at least one embedded LED that illuminates the needle module, which as noted above is releasably couplable to the proximal end and deployable. (Tr. (Crosby) at 612:16-21, 613:13-614:5; CDX-0001C.0061; CPX-0128C (Potenza) at 0:03; CPX-0061 (Video, Potenza); CPX-0063 (Potenza Tiger Tip); CX-0339C (Intensif, EndyMed Pro 510(k)); CPX-0131C (EndyMed Inspection) at 0:01; CX-0186 (EndyMed Pro Manual); CX-0843C (EndyMed Webpage); CX-0338C (Intensif Drawing); CPX-0067 (Video, Intensif); CPX-0068 (Video, Intensif); CX-3089C-3158C, CX-3257C-3295C, CPX-0124-0133C, CPX-0140C-0147C (Inspection Photos/Videos); CPX-0162-0183 (physical portions of Accused Products).).

Respondents did not contest that the Accused Products meet this limitation in either their Pre-Hearing or Post-Hearing Reply Briefs. (RPBr. at 126-28; RRBr. at 63-66.). Thus, any argument they may make 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 4 of the ’812 patent.

6. The Accused Products Practice Claim 5 of the ’812 Patent

a) “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.”

The Accused Products practice this limitation because “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.” The needle assembly in the Potenza Accused Products, depicted below in blue, includes portions that are translucent, illustrated below by pink outlines.

Figure 32: Crosby Demonstrative Depicting Translucent Section of the Needle Assembly



(CDX-0001C.0067; Tr. (Crosby) at 617:10-618:10; *see also* CX-3089C-3158C, CX-3257C-3295C, CPX-0124-0133C, CPX-0140C-0147C (Inspection Photos/Videos); CPX-0162-0183 (physical portions of Accused Products).).

For the Potenza Accused Products, the [redacted]. (Tr. (Crosby) at 617:10-618:10.). The [redacted]. (*Id.*; CPX-0131C (EndyMed Inspection Video) at 0:01.).

The [redacted]. (Tr. (Crosby) at 617:10-618:10; CPX-0128C (Potenza) at 0:03; CPX-0061 (Video, Potenza) at 0:29; CPX-0063 (Potenza Tiger Tip) at 0:30; CX-0164C.0029 (Potenza Manual); CX-0696.0019, 0056 (EndyMed HP Manual); CX-0697C.0023 (EndyMed HP Spec.); CX-0186 (EndyMed Pro Manual); CPX-0067 (Video, Intensif); CPX-0068 (Video, Intensif).).

Jeisys/Cynosure contended through their experts' testimony that their Accused Products do not meet claim 5 by limiting the needle assembly to include only the needles, PCB, and pogo pins—components that they contend are not translucent—and exclude the other components that move as part of the needle assembly within the needle module. (RPBr. at 128; RRBr. at 63-66; RDX-0012C.0011; Tr. (Bérubé) at 1226:23-1228:18; RDX-0013C.0020-21; Tr. (Brennan) at 1163:5-1164:6.). To the contrary, Dr. Brennan's and Dr. Bérubé's interpretations of "needle assembly" contradicts the'812 patent specification, which expressly contemplates that the needle assembly includes more than just the needles, PCB, and pogo pins—it includes the other components that form part of that assembly that moves within the needle module. (JX-0005 at 13:31-34 ("As shown in FIGS. 11B and 11C, the needle assembly 924F may include a pin cover

924J, drive arm module 924L, needles 924A, pins 924G with bases 924H, and needle printed circuit board (PCB) 924K."), Fig. 11C; Tr. (Crosby) at 1486:10-1487:1.).

Although EndyMed did not present evidence during the Hearing to dispute the evidence and Serendia's arguments that EndyMed's Accused Products meet the additional limitations of claim 5, EndyMed incorrectly argued in Respondents' Pre-Hearing Brief that the needles are not illuminated by the LED and that Serendia did not point to a translucent portion of the needle assembly. (RPBr. at 127-28.). That is simply incorrect. As depicted above in Figure 32 (CDX-0001C.0067), the needles are illuminated by the LED. (*See also* CPX-0131C (EndyMed Inspection Video) at 0:00-0:05; CPX-0131C (EndyMed Inspection Video) at 0:00-0:05; CX-3150C; CX-3151C; CPX-0067 (Intensif Video) at 0:15-0:30; CPX-0068 (Video, Intensif) at 2:18, 2:22).). Additionally, the [redacted]. (Tr. (Crosby) at 617:10-618:10; CDX-0001C.0067.). Depicted below are annotated still photos from Mr. Crosby's inspection video, CPX-0131C, which [redacted].



(CBr. at 81.).

For the reasons explained, Serendia has proven by a preponderance of evidence that the Accused Products meet the additional limitations recited in claim 5 of the ’812 patent.

7. The Accused Products Practice Claim 12 of the ’812 Patent

a) 12[pre]: “An apparatus for treating dermatological tissue, comprising”

12[a]: “a user holdable device including a proximal end”

12[b1]: “a releasably couplable deployable needle module”

12[b2]: “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”

12[b3]: “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”

12[b4]: “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”

Claim 12, from which asserted claim 13 depends, is the apparatus claim corresponding to method claim 1. (Tr. (Crosby) at 619:10-25.). There are no elements in claim 12 that are not also part of claim 1. (CDX-0001.0072.).

Thus, for the same reasons noted above for claim 1, Serendia has proven by a preponderance of evidence that the Accused Products meet all the limitations of claim 12 of the '812 patent. (Tr. (Crosby) at 620:1-11; *see also* Section X.A.2, *supra*.).

8. The Accused Products Practice Claim 13 of the '812 Patent

a) "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."

Claim 13 depends on claim 12, which is the apparatus claim corresponding to method claim 1. (Tr. (Crosby) at 619:10-25.). There are no elements in claim 12 that are not also part of claim 1, and for the same reasons discussed above for claim 1, the Accused Products meet all the limitations of claim 12. (CDX-0001.0072; Tr. (Crosby) at 620:1-11.).

The weight of the evidence demonstrates that the Accused Products each includes a motor coupled to the plurality of extendable needles. (*See* Sections X.A.3.). Moreover, the evidence confirms that the motor causes the needles to extend a desired distance from the needle module end surface when energized with a particular signal. (*See id.*).

In their Pre-Hearing Brief, Respondents again summarily raised the same arguments as for the limitations of claim 11 of the '536 patent: a "releasably couplable deployable needle assembly" and "plurality of extendable needles . . . extendable from a deployable needle assembly end surface." (RPBr. at 130.). For the same reasons noted above in Section X.A.3, Respondents' arguments conflict with the adopted claim construction as well as with the

evidence presented during the Hearing.

For the reasons explained, Serendia has proven by a preponderance of evidence that the Accused Products meet the additional limitation recited in claim 13 of the '812 patent.

9. The Accused Products Practice Claim 18 of the '812 Patent

a) "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."

The Accused Products practice the additional limitation of claim 18 because "one of the at least one electrical contacts includes a pin that is extendable in the same direction as the plurality of needles." Specifically, the weight of the evidence demonstrates that the Accused Products include . (Tr. (Crosby) at 623:23-625:5; CX-0170C.0001 (Potenza Tip-49 Drawing); CX-0716C (Potenza Tips Presentation); CX-3146C (Intensif with EndyMed Pure 2.0); CPX-0131C (EndyMed Inspection Video) at 0:01; CX-0701C (Intensif Pin Drawing); CPX-0035 (Video, Intensif HP); CDX-0001C.0083 (Crosby); CX-3089C-3158C, CX-3257C-3295C, CPX-0124-0133C, CPX-0140C-0147C (Inspection Photos/Videos); CPX-0162-0183 (physical portions of Accused Products).

Respondents did not contest that the DI Products meet this limitation in either their Pre-Hearing or Post-Hearing Reply Briefs. (RPBr. at 124-25, 131; RRBr. at 63-66.). Thus, any argument they may make 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 18 of the '812 patent.

B. Technical Prong of Domestic Industry

1. The DI Products Practice Claim 1 of the '812 Patent

a) 1[pre]: "A method of treating dermatological tissue, comprising"

The DI Products practice "[a] method of treating dermatological tissue." (Tr. (Crosby) at 583:3-20; CDX-0001C.0017.). Serendia presented unrebutted evidence demonstrating that the DI Products are described as performing this function. (CX-0826C.0002 (Sylfirm X 510(k) Description); CX-0761C.0002 (Sylfirm X Webpage); CX-0830 (Sylfirm X Brochure) at 2; CX-0827C.0002 (Sylfirm X 510(k) Description).).

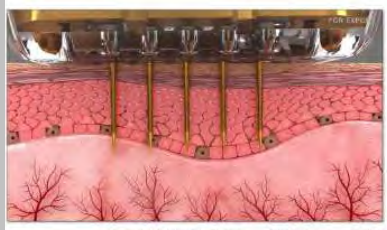
Respondents did not contest that the DI Products meet this limitation in either their Pre-Hearing or Post-Hearing Reply Briefs. (RPBr. at 133; RRBr. at 67-68.). Thus, any argument they may make on this issue is deemed abandoned, withdrawn, and/or waived under Ground Rules 7.2 and 10.1.

For the foregoing reasons, Serendia has proven by a preponderance of evidence that the DI Products meet the preamble of claim 1 of the '812 patent.

b) 1[a1]: "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 DI Products include a handpiece with a proximal end. The handpiece includes a releasably couplable deployable needle module (depicted in green on the left below), where its end surface is placed on the tissue to be treated.

Figure 34: Crosby Demonstrative Showing the Claimed Releasably Couplable Deployable Needle Module



CPX-0069 (Sylfirm X Video), 0:32

(CDX-0001C.0025.).

As depicted in the photos above in Figure 34 and as Mr. Crosby's inspections confirmed, the weight of the evidence is that the needle module is releasably couplable to the proximal end of the handpiece and is deployable, as the needles extend in operation. (Tr. (Crosby) at 587:24-588:16; CX-0826C.0011 (Sylfirm X 510(k) Description); CPX-0069 (Sylfirm X Video) at 0:32 (above); CX-0760C.0007-10 (above), CX-0759C, CX-2915, CX-2916 (DI Product Photos); CPX-0070 (Sylfirm-X Introduction Video); *see also* CX-3340C, CX-3326C, CX-3330C (Sylfirm X); CX-0823C.0011-12 (Sylfirm X Manual); CX-3384 (Sylfirm X 510(k)); CX-3321C-3350C (Inspection Photos/Videos); CPX-0160-161 (physical portions of DI Products).).

Respondents did not contest that the DI Products meet this limitation in their Pre-Hearing Brief. (RPBr. at 133.). Thus, any argument they may make on this issue is deemed abandoned or withdrawn under Ground Rule 7.2.

For the foregoing reasons, Serendia has proven by a preponderance of evidence that the DI Products meet this limitation of claim 1 of the '812 patent.

c) 1[a2]: "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 module in the DI Products includes a needle assembly (as depicted above in blue in Figure 34 (CDX-0001C.0025)) with a plurality of needles. (CX-0826C.0011 (Sylfirm X 510(k) Description); CX-0760C.0007-10 (DI Photos).). The needle module unrebuttedly also includes mechanical elements that engage with mechanical elements in the proximal end of the handpiece, making it releasably couplable and mechanically separable. (Tr. (Crosby) at 591:25-592:13; CDX-0001C.0031; CX-3340C, CX-3326C, CX-3330C (Sylfirm X); CX-0826C.0011 (Sylfirm X 510(k) Description); CX-0760C.0007-10, CX-2915, CX-2916 (DI Photos); CX-0830 (Sylfirm X Brochure); CPX-0069 (Sylfirm X Video) at 0:32; CX-0823C.0011-12 (Sylfirm X Manual); CX-3384 (Sylfirm X 510(k)); *see also* CX-3321C-3350C (Inspection Photos/Videos); CPX-0160-161 (physical portions of DI Products).).

Respondents did not contest that the DI Products meet this limitation in either their Pre-Hearing or Post-Hearing Reply Briefs. (RPBr. at 133; RRBr. at 67-68.). Thus, any argument they may make 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 this limitation of claim 1 of the '812 patent.

d) 1[a3]: "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

The needle assembly moves within the needle module to extend the needles from the

needle assembly end surface, as depicted in Figure 35, in green in the photographs below each other on the right.

Figure 35: Crosby Demonstrative Illustrating Movable Needle Assembly



(CDX-0001C.0038; *see also* CPX-0152C (Sylfirm X Inspection Video) at 0:00-0:05; CX-3329C, CX-3330C (Sylfirm X); Tr. (Crosby) at 595:12-596:4.).

Referring to his demonstrative, as replicated in Figure 36, below, Mr. Crosby explained that the needle assembly includes pogo pins (depicted in gold below in the picture on the far left), which are electrical contacts that maintain electrical contact while the needle assembly moves within the needle module. (Tr. (Crosby) at 599:25-601:18.).

Figure 36: Crosby Demonstrative Illustrating Movable Needle Assembly



(CDX-0001C.0041; *see also* CX-0826C.0011 (Sylfirm X 510(k) Description); CX-0760C.0007-11 (DI Photos); CX-0759C.0002, 0004, CX-0760C.0006, 0011, CX-2915, CX-2916 (DI Photos); CX-0823C.0011-13, 0023 (Sylfirm X Manual); CPX-0069 (Sylfirm X Video) at 0:05-0:11; CX-3384 (Sylfirm X 510(k)); CDX-0001C.0038; CX-3321C-3350C (Inspection Photos/Videos); CPX-0160-161 (physical portions of DI Products).).

Respondents did not specifically contest that the DI Products meet this limitation in either their Pre-Hearing or Post-Hearing Reply Briefs. (RPBr. at 133; RRBr. at 67-68.). Thus, any argument they may make on this issue is deemed abandoned, withdrawn, and/or waived under Ground Rules 7.2 and 10.1.

For the reasons explained, Serendia has proven by a preponderance of evidence that the DI Products meet this limitation of claim 1 of the ’812 patent.

e) 1[b]: “communicating electrical signals from the user holdable device proximal end to the needle assembly via the electrical contacts”

The DI Products communicate RF, an electrical signal, from the proximal end to the needles of the needle assembly through electrical contacts so treatment can be delivered. (Tr. (Crosby) at 604:9-23; CDX-0001C.0045; CPX-0069 (Sylfirm X Video) at 0:11; CX-0823C.0004, 0016, 0017, 0025-27 (Sylfirm X Manual); CX-0830.0002, 0006, 0007 (Sylfirm X

Brochure); *see also* CX-3321C-3350C (Inspection Photos/Videos); CPX-0160-161 (physical portions of DI Products).).

Respondents did not contest that the DI Products meet this limitation in either their Pre-Hearing or Post-Hearing Reply Briefs. (RPBr. at 133; RRBr. at 67-68.). Thus, any argument they may make 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 this limitation of claim 1 of the ’812 patent.

2. The DI Products Practice Claim 2 of the ’812 Patent

a) “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.”

The DI Products include a motor coupled to the plurality of extendable needles. (*See* Section X.B.1, *supra*.). Serendia presented unequivocal, unrebutted evidence that the motor causes the needles to extend a desired distance from the needle module end surface. (Tr. (Crosby) at 609:15-611:7, 661:10-662:20; CDX-0001C.0053-54; CX-3326C, CX-3329C, CX-3330C, CX-3340C (Sylfirm X); CX-0759C.0002-4, CX-0760C.0002 (DI Photos); CX-0823C.0016 (Sylfirm X Manual); CX-0826C.0007, 0015, 0016 (Sylfirm X 510(k) Description); CX-0829C.0003 (Sylfirm X Circuit Drawing); CX-3384 (Sylfirm X 510(k)); *see also* CX-3321C-3350C (Inspection Photos/Videos); CPX-0160-161 (physical portions of DI Products).).

Respondents did not contest that the DI Products meet this limitation in either their Pre-Hearing or Post-Hearing Reply Briefs. (RPBr. at 133; RRBr. at 67-68.). Thus, any argument they may make 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 2 of the ’812 patent.

3. The DI Products Practice Claim 3 of the ’812 Patent

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

The needles in the DI Products are energized via an RF generator electrically coupled to the user holdable device proximal end. (Tr. (Crosby) at 611:17-612:13; CDX-0001C.0057; CPX-0069 (Sylfirm X Video) at 0:11; CX-3321C-3350C (Inspection Photos/Videos); CPX-0160-161 (physical portions of DI Products).).

Respondents did not contest that the DI Products meet this limitation in either their Pre-Hearing or Post-Hearing Reply Briefs. (RPBr. at 133; RRBr. at 67-68.). Thus, any argument they may make 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 the additional limitation recited in claim 3 of the ’812 patent.

4. The DI Products Practice Claim 4 of the ’812 Patent

a) “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 one embedded LED illuminates the releasably couplable deployable needle module.”

The proximal end of the DI Products includes at least one embedded LED that, when energized, illuminates the needle module. (Tr. (Crosby) at 614:6-22; CDX-0001C.0062; CX-3326C, CX-3330C (Sylfirm X); CPX-0081C (Sylfirm X Video) at 3:08-3:14; CX-0826C.0015-

16 (Sylfirm X 510(k) Description); CX-0759C.0002, 0004, CX-0760C.0007-10 (DI Photos); CX-0823C.0027 (Sylfirm X Manual); CX-0829C.0002-3 (Sylfirm X Circuit Drawing); CX-3384 (Sylfirm X 510(k)); CX-3321C-3350C (Inspection Photos/Videos); CPX-0160-161 (physical portions of DI Products).).

Respondents did not contest that the DI Products meet this limitation in either their Pre-Hearing or Post-Hearing Reply Briefs. (RPBr. at 133; RRBr. at 67-68.). Thus, any argument they may make 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 4 of the ’812 patent.

5. The DI Products Practice Claim 5 of the ’812 Patent

a) “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.”

The needle assembly of the DI Products includes a translucent section, and the LED in the proximal end of the handpiece illuminates the needles via that translucent section. (Tr. (Crosby) at 618:11-619:9; CDX-0001C.0068; CX-3330C (Sylfirm X); CX-0826C.0011 (Sylfirm X 510(k) Description); CX-0759C.0002, 0004, CX-0760C.0007-11 (DI Photos); CX-0823C.0027 (Sylfirm X Manual); CX-0829C.0002, 0003 (Sylfirm X Circuit Drawing); CX-3384 (Sylfirm X 510(k)); CX-3321C-3350C (Inspection Photos/Videos); CPX-0160-161 (physical portions of DI Products).).

In their Pre-Hearing Brief, Respondents made the same arguments raised for claim 11 of the ’536 patent. (RPBr. at 133 (citing *id.* at Section VI.B.2).). They fail for the reasons

discussed above in Section VIII.C.1.

Accordingly, Serendia has proven by a preponderance of evidence that the DI Products meet the additional limitation recited in claim 5 of the ’812 patent.

6. The DI Products Practice Claim 12 of the ’812 Patent

a) 12[pre]: “An apparatus for treating dermatological tissue, comprising”

12[a]: “a user holdable device including a proximal end”

12[b1]: “a releasably couplable deployable needle module”

12[b2]: “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”

12[b3]: “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”

12[b4]: “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”

Claim 12, from which asserted claim 13 depends, is the apparatus claim corresponding to method claim 1, addressed above in Section X.B.1. (Tr. (Crosby) at 619:10-620:11.). There are no elements in claim 12 that are not also part of claim 1. (CDX-0001.0072.).

Thus, for the same reasons discussed in Section X.B.1, Serendia has proven by a preponderance of evidence that the DI Products meet claim 12 of the ’812 patent. (Tr. (Crosby) at 620:1-10.).

7. The DI Products Practice Claim 13 of the ’812 Patent

a) “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.”

The DI Products meet the additional limitation of claim 13 because they include a motor coupled to the plurality of extendable needles and energize that motor “with a particular signal” to extend the needles a desired distance from the needle module end surface. (Tr. (Crosby) at 620:21-621:12, 622:25-623:12; CDX-0001C.0075, 0079; CX-0826C.0015-16 (Sylfirm X 510(k) Description); CX 0759C, CX 0760C (DI Product Photos 2); CX-0823C (Sylfirm X Manual); CX 0826C (Sylfirm X 510(k) Device Description); CPX-0069 (Video, Sylfirm X); *see also* Section X.B.6.).

In their Pre-Hearing Brief, Respondents relied on the same arguments they presented for claim 5. (RPBr. at 133.). For the reasons discussed above, the arguments are unpersuasive and not supported by the weight of the evidence.

Accordingly, Serendia has proven by a preponderance of evidence that the DI Products meet the additional limitation recited in claim 13 of the ’812 patent.

8. The DI Products Practice Claim 18 of the ’812 Patent

a) “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.”

The DI Products practice the additional limitation of claim 18 because they include pogo pins extendable in the same direction as the plurality of needles. (Tr. (Crosby) at 625:6-626:4; CDX-0001C.0084; CX-3340C (Sylfirm X); CX-0826C.0011 (Sylfirm X 510(k) Description); CX-0759C.0004, CX-0760C.0007-11 (DI Photos); CX-0823C.0012 (Sylfirm X Manual); CX-

0826C.0006 (Sylfirm X 510(k) Description); CX-2918.0001 (Photo, Sylfirm X tip); CX-2919.0001 (Photo, Sylfirm X tip); CX-3384 (Sylfirm X 510(k)); CX-3321C-3350C (Inspection Photos/Videos); CPX-0160-161 (physical portions of DI Products).).

In their Pre-Hearing Brief, Respondents relied on the same arguments they presented for claim 5. (RPBr. at 133.). For the reasons discussed above, the arguments are unpersuasive and not supported by the evidence.

For these reasons, Serendia has proven by a preponderance of evidence that the DI Products meet the additional limitation recited in claim 18 of the '812 patent.

C. Invalidity

1. Scope of the Prior Art

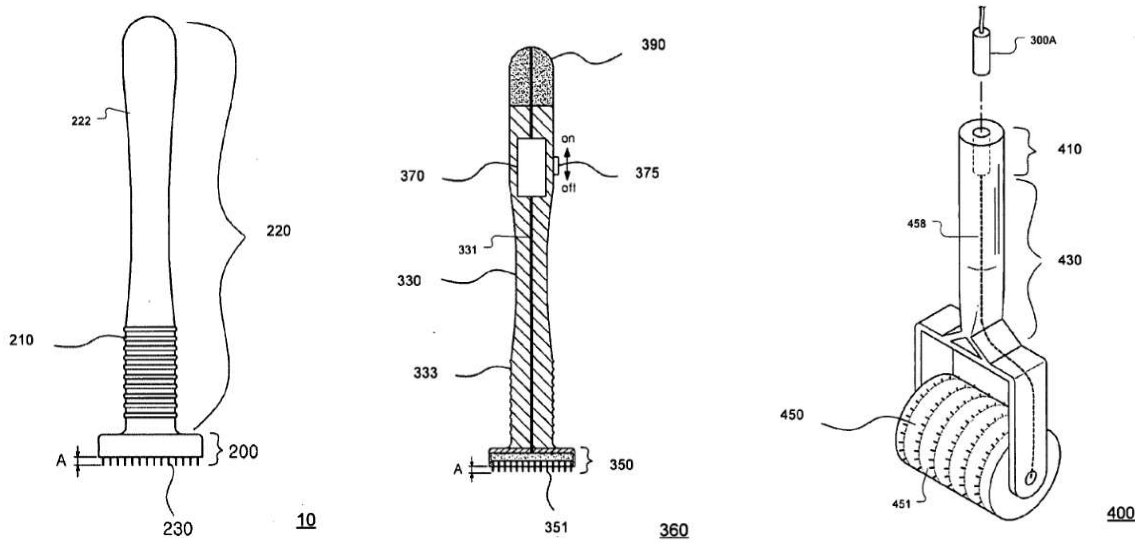
Respondents argued that claims 5, 13, and 18 of the '812 patent are rendered obvious over Mehta in view of the knowledge of a person of ordinary skill in the art.[77] (RPBr. at 134-40; RBr. at 82.). For claim 5 only, Respondents contended that Mehta in view of the knowledge of a person of ordinary skill in the art and in further view of WO 2010/016848 ("Na '848") renders the claim obvious. (RPBr. at 134-40; RBr. at 82.). For the reasons discussed below, these prior art references do not render obvious claims 5, 13, and 18 of the '812 patent.

a) Na '848 (RX-1814)

Na '848 is directed towards an acupuncture-type apparatus with either a plate or roller with pins at the end of a handle. (RX-1814 at ¶¶ 22-38, Figs. 1A-4C; *see also* Tr. (Crosby) at 1512:11-1513:14; CDX-0043C.0038-40, 0042.). The figures below in Figure 37 depict the embodiments in Na '848.

[77] Asserted claim 5 depends from claims 1-4; asserted claims 13 and 18 depend from claim 12. Claims 1-4 and 12 are not at issued in this Investigation.

Figure 37: Figures of Na ’848 Embodiments



(RX-1814 at Figs. 1B (left), 2C (middle), 3A (right).).

The needles in Na ’848 have a fixed length and do not extend. (RX-1814 at ¶¶ 26, 33, Figs. 1A-4C; *see also* Tr. (Crosby) at 1513:10-14; CDX-0043C.0040.). Na ’848 does not disclose RF or supplying RF to needles. (Tr. (Woloszko) at 1046:5-10.). Na ’848 also does not disclose longitudinal movement of the needles to penetrate skin. (*Id.* at 1046:16-22.). Na ’848 also does not have a needle assembly. (*Id.* at 1046:23-1047:2.). Although Na ’848 discloses that the plate or roller can include embedded LEDs, the LEDs are not in the handle. (RX-1814 at ¶¶ 34, 38, Figs. 1A-4C; *see also* Tr. (Crosby) at 1514:5-17; CDX-0043C.0042.).

2. The Prior Art References Do Not Render Obvious the Asserted Claims of the '812 Patent[78]

a) Mehta in View of the Knowledge of a Person of Ordinary Skill in the Art (Claims 5, 13, and 18)

i. Respondents Improperly Relied on Multiple Embodiments Disclosed in Mehta

Like the '536 and '774 patents, Respondents relied on multiple embodiments in an attempt to demonstrate that Mehta discloses all the limitations of the asserted claims of the '812 patent. For the same reasons discussed above in Section VIII.D.4(a) with respect to the '536 patent, Respondents failed to explain why one of ordinary skill would mix and match the embodiments of Mehta as they proposed. *In re Stepan Co.*, 868 F.3d at 1346 n.1. (*See also* Tr. (Crosby) at 1499:23-1500:11.).

ii. Mehta Does Not Disclose the Desired Distance Limitation

Like the '536 and '774 patents, claims 2 and 13 of the '812 patent require needles that extend "a desired distance" from an "end surface." (JX-0005 at cls. 2, 13.). As explained in Sections VIII.D.3 and VIII.D.4 above with respect to the '536 patent, Mehta does not disclose needles that extend a "desired distance" from any surface. Respondents did not point to how the knowledge of a skilled artisan would fill the gaps. (RBr. at 85.). Neither did Dr. Woloszko, because he relied on his same analysis for claim 11 of the '536 patent. (Tr. (Woloszko) at 965:11-966:23.). Respondents' arguments fail for the same reasons discussed above in Section VIII.D.4.

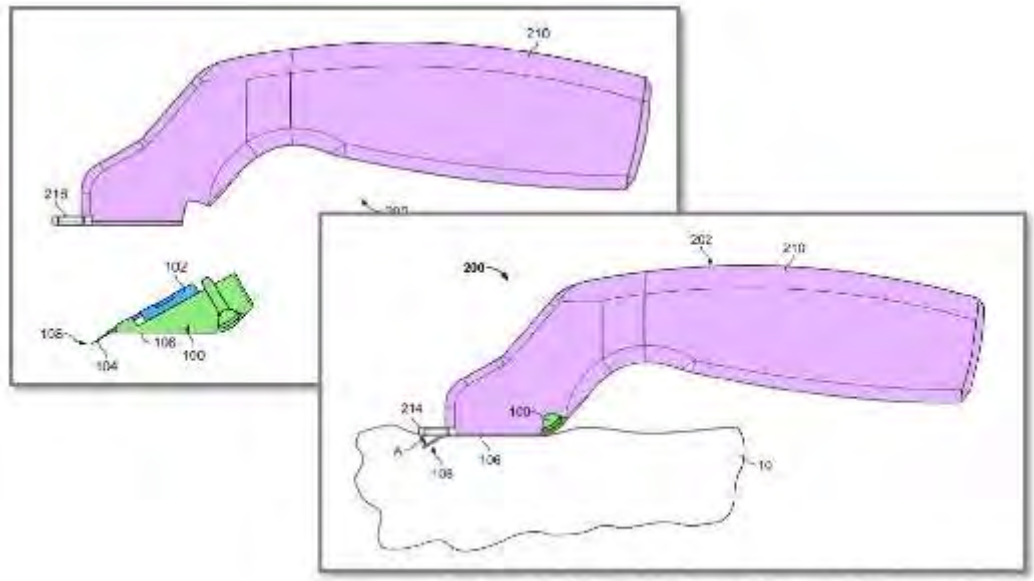
iii. Mehta Does Not Disclose the Embedded LED Limitation

Respondents identified Mehta's electrode assembly 102 as the claimed "needle

[78] *See* n.54, *supra* (regarding institution of IPRs).

assembly." (Tr. (Woloszko) at 939:6-940:16; RDX-0010C.0108; RBr. at 64, 66.). As depicted below in the annotated Figures of Mehta, Mehta discloses that electrode assembly 102 (in blue) is within a removable cartridge 100 (in green), both of which are inserted into the device body 210 (purple).

Figure 38: Annotated Figures 2B and 2D of Mehta



CX-3023 (Mehta), Figs. 2B and 2D (annotated)

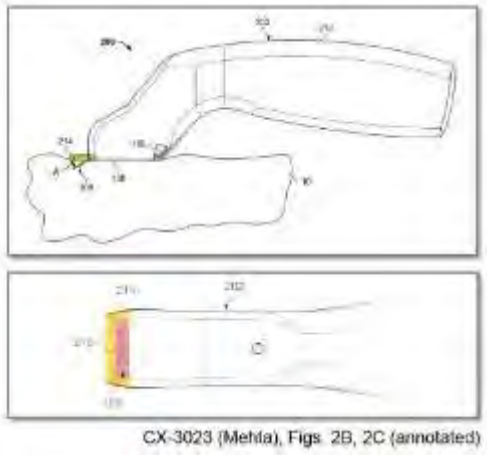
(CDX-0043C.0036 (citing RX-0307 at Figs. 2B and 2D (annotated)).).

As Mr. Crosby explained credibly, Mehta does not describe the electrode assembly 102 or any portion of the removable cartridge 100 as transparent or translucent. (Tr. (Crosby) at 1508:24-1509:12; CDX-0043C.0033.). Rather, the only components Mehta describes as possibly transparent to allow for visualization of the needles are stabilization plate 214 (or cooling surface) and feature 216 (a window or opening). (RX-0307 at 4:19-34, 22:7-10, 13:20-23.).

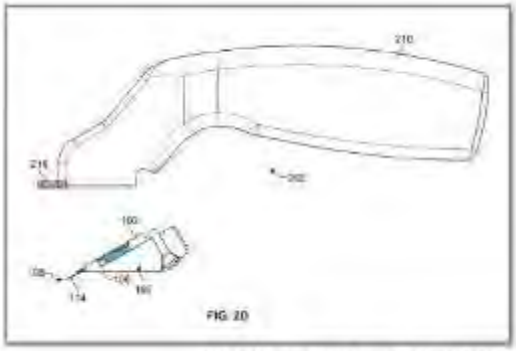
As reflected below in annotated Figures 2B, 2C, and 2D of Mehta, i.e., in Figure 39,

neither the stabilization plate 214 (in yellow) nor feature 216 (in pink) are part of (or exposed to) the electrode assembly 102 (in blue); instead, they are part of device body 210 and separated from the electrode assembly by the device body. (Tr. (Crosby) at 1509:13-1510:18 ("Q. . . . Are the plate 214 or feature 216 part of what Dr. Woloszko relies on for the needle assembly? A. They are not. Q. How do we know that? A. Well, Mehta tells us that. The cartridge and the needle assembly Dr. Woloszko relies on to call the needle assembly is 102 is completely separate from the feature 216 with the stabilization 214, which is attached to the body, not to the cartridge or needle assembly.").).

Figure 39: Annotated Figures 2B-2D of Mehta



CX-3023 (Mehta), Figs. 2B, 2C (annotated)



CX-3023 (Mehta), Figs. 2D (annotated)

(CDX-0043C.0034-35 (citing RX-0307 at Figs. 2B-2D (annotated).).

Even if electrode assembly 102 had a translucent section, Mehta does not disclose an LED illuminating a plurality of needles via any portion of the electrode assembly.

Respondents contended that the LED in Mehta would be around the portion of the device body near feature 216. (RBr. at 86; Tr. (Woloszko) at 968:5-17, 1043:25-1044:12; RDX-0010C.0140).). Mr. Crosby provided persuasive, credible testimony that an LED in that location would not illuminate a plurality of needles via the electrode assembly because the electrode

assembly is encased in the cartridge within device body.

> Q. . . . Would that LED illuminate a plurality of needles via any kind of translucent section in Mehta?
>
> A. No, I don't see how it could.
>
> Q. Why not?
>
> A. Well, the electrode assembly 102, which is the needle assembly, according to Dr. Woloszko, is encased within a cartridge 100, which is the green part, and that's within the device body 210. So any LED in the region of element 216 could not get to the needle assembly even if it had a transparent section and thereby illuminate the needles. There is no light path for that to go.

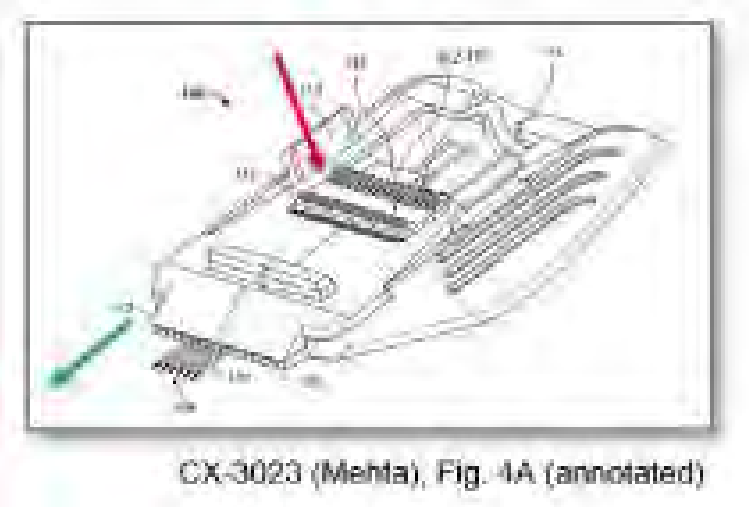
(Tr. (Crosby) at 1510:19-1511:15; CDX-0043C.0036.).

Thus, Mehta fails to disclose any light path from an LED around the region 216 in the device body via the electrode assembly to illuminate the needles.

iv. Mehta Does Not Disclose the Electrical Contacts Limitation

Respondents mapped the claimed electrical contact that includes a pin to Mehta's connection portion 116. (RBr. at 89.). However, as depicted below and as Mr. Crosby explained, the movement of connection portion 116 (in red) is perpendicular to the movement of the probes 104 (in green), and not "in the same direction," as claimed.

Figure 40: Annotated Figure 4A of Mehta



(CDX-0043C.0030 (citing RX-0307 at Fig. 4A (annotated); Tr. (Crosby), 1507:10-1508:3; *see also* RX-0307 at 16:12-18.).

Respondents relied on movement of the printed circuit board, which includes connection portion 116, when probes 104 extend. (RBr. at 89-91; Tr. (Woloszko) at 976:4-20; RDX-0010C.0150.). This fails for two reasons.

First, claim 18 does not recite that the pin ***moves*** in the same direction as the needles, but rather that it ***extends*** in the same direction as the needles. (JX-0005 at cl. 18; *see also* Tr. (Crosby) at 1508:4-16; CDX-0043C.0031.). That is not the case in Mehta.

Second, in their Initial Post-Hearing Brief, Respondents presented a new claim construction argument, in which they attempted to import portions from the construction of the "needle assembly end surface" term into this limitation to argue that "extend" is the same as "move." (RBr. at 90.). That argument is deemed waived for failing to raise it during the claim construction proceedings under Ground Rule 1.14.1 and deemed abandoned or withdrawn because Respondents failed to disclose it in their Pre-Hearing Briefing under Ground Rule 7.2.

Thus, Mehta fails to disclose a pin that is extendable in the same direction as the plurality

of needles.

v. No Motivation to Combine

A person of ordinary skill in the art would not have had a reasonable expectation of success or been motivated to modify Mehta or combine its various embodiments to arrive at the claimed invention. Respondents did not provide adequate reasoning or evidentiary support for their assertion that one of ordinary skill would use his or her knowledge to fill in the gap of the missing limitations above. (RBr. at 88, 91.).

For the "desired distance" limitation, as discussed above in Sections VIII.D.4, Respondents did not prove clearly and convincingly that there would have been a motivation to modify Mehta.

For the LED and pin extendable in the same direction as the needles limitations, Respondents relied on the same alleged motivations to modify Mehta as they did for the "desired distance" limitation. They again argued that the differences between Mehta and the claims are minor; that the art is basic mechanical design and highly predictable; and that the claimed implementation is obvious and easy to optimize. (RBr. at 88, 91.). However, other than Dr. Woloszko's conclusory opinions, Respondents did not provide substantive evidence to support their arguments.

As explained above, Dr. Woloszko's opinions on motivations are deficient because they are generic and conclusory. (Tr. (Woloszko) at 976:21-977:10; RDX-0010C.0118, 0128, 0151; *see also* Tr. (Crosby) at 1511:16-1512:10, 1512:4-10; CDX-0043C.0037.). *See ActiveVideo*, 694 F.3d at 1328.

Moreover, Mehta intrinsically discloses mechanisms to observe proper needle placement, including virtual depiction 350 and a window between the stabilization plate and the tissue

engaging surface. (*See* Section VIII.D.2, *supra*; Tr. (Crosby) at 1516:10-22; CDX-0043C.0044.). Thus, there would be no motivation to modify Mehta to include a translucent section in the needle assembly, much less to illuminate the needles via any such translucent section.

b) Mehta in View of the Knowledge of a Person of Ordinary Skill in the Art and Further in View of Na '848 (Claim 5)[79]

i. Respondents Improperly Relied on Multiple Embodiments Disclosed in Mehta

Respondents again rely on multiple embodiments in Mehta without explanation, which as explained above in Section X.C.2(a)(i), fails to meet their burden. (Tr. (Crosby) at 1499:23-1500:11.).

ii. Mehta Does Not Disclose the Desired Distance Limitation

Mehta does not disclose the "desired distance" limitation as depicted in VIII.D.4(a). Again, Respondents failed to point to knowledge of a person of ordinary skill in the art or Na '848 to fill the gaps. (RBr. at 91-93.). Dr. Woloszko relied on his analysis of Mehta for claim 11 of the '536 patent for this limitation. (Tr. (Woloszko) at 965:11-966:23.). For the same reasons discussed above in Section VIII.D.4(a), his analysis is not supported by the evidence.

iii. Mehta Does Not Disclose the Embedded LED Limitation

As explained above in Section X.C.2(a)(iii), Mehta does not disclose this limitation. The deficiency is not cured by the disclosures of Na '848. Although Na '848 discloses LEDs on plate or roller (RX-1814 at ¶¶ 34, 38, Figs. 1A-4C), those LEDs are not in the handle (*id.* at ¶¶ 34, 38, Figs. 1A-4C; *see also* Tr. (Crosby) at 1514:5-17; CDX-0043C.0042).). Therefore, as Mr. Crosby

[79] Respondents relied on the combination of Mehta and Na '848 solely for the LED limitations in claim 5 and claim 4, on which claim 5 depends. (RBr. at 91-93.).

opined, Na '848 does not disclose an LED embedded in the proximal end of the user holdable device as the claims require. (Tr. (Crosby) at 1514:13-17; CDX-0043C.0042 (Crosby).)

Additionally, although Na '848 explains that certain materials in pin sections 250, 353 can be translucent, it does not disclose a needle assembly at all. (CX-1096 (Na '848) at ¶ 35.). As Respondents' expert, Dr. Woloszko, acknowledged, Na '848 only includes a needle module. (Tr. (Woloszko), 1046:23-1047:2 ("[Na '848] does not have a needle assembly, but it would have a needle module").). However, claim 5 requires that the needle assembly include a translucent section. (JX-0005 at cl. 5.). Dr. Woloszko's testimony that Na '848 meets this portion of the claim is inconsistent with his testimony during cross-examination. Moreover, that the Family Two Patents include some of the same figures as Na '848's acupuncture-type apparatus does not support Respondents' invalidity arguments (RBr. at 92) because the claims of the Family Two Patents are directed to a different invention than Na '848. (Tr (Crosby), 1512:21-24.).

iv. No Motivation to Combine

One of ordinary skill in the art would not have had a reasonable expectation of success or been motivated to modify Mehta or to combine Mehta with Na '848 to arrive at the claimed invention.[80] Respondents failed to provide adequate reasoning or evidentiary support for their assertion that a person of ordinary skill would use his or her knowledge to fill in the gap of the missing limitations. (RBr. at 91-93.). For the "desired distance" limitation, as discussed in Section X.C.2(a), there is no motivation to modify Mehta. For the LED and needle assembly translucent limitation, Respondents relied on the same alleged motivation to modify Mehta for

[80] Respondents did not rely on Na '848 for the desired distance limitation, but only for limitations introduced in claims 4 and 5. (RBr. at 92.).

the "desired distance" limitation as they did for the combination of Mehta and Na '848. (RBr. at 93.).

For the same reasons discussed above in Section X.C.2(a), Dr. Woloszko opinions are conclusory and bear no explicit or specific relationship to the claimed limitations. (Tr. (Woloszko), 977:11-978:2; Tr. (Crosby), 1512:4-10.). Conclusory statements are insufficient for Respondents to meet their burden by clear and convincing evidence. *ActiveVideo*, 694 F.3d at 1328.

There would be no motivation to modify Mehta or combine it with Na '848 to include the claimed LED and needle assembly translucent sections. As discussed above in Section VIII.D.2, Mehta discloses mechanisms to observe proper needle placement, including virtual depiction 350 and a window located between the stabilization plate and the tissue engaging surface. (Tr. (Crosby) at 1516:10-22; CDX-0043C.0044.). As noted above, Na '848 does not disclose an LED in a handpiece (proximal end) or a needle assembly, which further removes a motivation to modify Mehta to include such features. (Tr. (Crosby) at 151:12-1516:22; CDX- 0043C.0044.). Even if the electrode assembly in Mehta were translucent (it is not), a person of ordinary skill in the art would not combine Mehta and Na '848 because the LED is encased within other components, that is, the cartridge and the device body. (*See* Section X.C.2(a), *supra*.). No light from an LED would travel through a translucent section of the needle assembly to illuminate the needles, as the claims require. (*See id.*).

XI. DOMESTIC INDUSTRY REQUIREMENT: ECONOMIC PRONG

A. Legal Standard

The Commission may only find a violation of Section 337 "if an industry in the United States relating to the articles protected by the patent . . . exists or is in the process of being

established." 19 U.S.C. § 1337(a)(2) (emphases added). Typically, a complainant must prove that a domestic industry existed at the time the complaint was filed. *See Motiva LLC v. Int'l Trade Comm'n*, 716 F.3d 596, 601 n.6 (Fed. Cir. 2013).

The domestic industry requirement consists of a "technical prong" and an "economic prong." *See, e.g.*, *Certain Elec. Devices, Including Wireless Commc'n Devices, Portable Music & Data Processing Devices, & Tablet Computs.*, Inv. No. 337-TA-794, Order No. 88, 2012 WL 2484219, at *3 (June 6, 2012); *Certain Unified Commc'ns Sys., Prods. Used with Such Sys., and Components Thereof*, Inv. No. 337-TA-598, Order No. 9 at 2 (Sept. 5, 2007) ("*Communications Systems*"). A complainant satisfies the "technical prong" of the domestic industry requirement when it proves that its activities relate to an article "protected by the patent." *See Communications Systems*, Order No. 9 at 2. A complainant satisfies the "economic prong" of the domestic industry requirement when it demonstrates that the economic activities set forth in subsections (A), (B), and/or (C) of Section 337(a)(3) have taken place or are taking place with respect to the protected articles. *See id.*

Subsection 337(a)(3) states that:

> (3) For purposes of paragraph (2), and industry in the United States shall be considered to exist if there is in the United States, with respect to the articles protected by the patent, copyright, trademark, mask work, or design concerned –
>
> (A) significant investment in plant and equipment;
> (B) significant employment of labor, or capital; or
> (C) substantial investment in its exploitation, including engineering, research and development, or licensing.

19 U.S.C. § 1337(a)(3).

Because the criteria are listed in the disjunctive, satisfaction of any one of them will be sufficient to meet the economic prong of the domestic industry requirement. *Certain Integrated*

Circuits, Chipsets and Prods. Containing Same, Inv. No. 337-TA-428, Order No. 10, Initial Determination (May 4, 2000) ("*Integrated Circuits*") (unreviewed). Establishment of the "economic prong" is not dependent on any "minimum monetary expenditure" and there is no need for a complainant "to define the industry itself in absolute mathematical terms." *Certain Stringed Musical Instruments and Components Thereof*, Inv. No. 337-TA-586, Comm'n Op. at 25-26 (May 16, 2008) ("*Stringed Instruments*"). However, a complainant must substantiate the nature and the significance of its activities with respect to the articles protected by the patent at issue. *Certain Printing and Imaging Devices and Components Thereof*, Inv. No. 337-TA-690, Comm'n Op. at 30 (Feb. 17, 2011) ("*Imaging Devices*").

The Commission has interpreted Sections 337(a)(3)(A) and (B) to concern "investments in plant and equipment and labor and capital with respect to the ***articles*** protected by the patent." *Certain Ground Fault Circuit Interrupters and Prods. Containing Same,* Inv. No. 337-TA-739, 2012 WL 2394435, at *50, Comm'n Op. at 78 (June 8, 2012) ("*Circuit Interrupters*") (emphasis in original) (quoting 19 U.S.C. §§ 1337(a)(3)(A), (B)).

When a complainant proceeds under Section 337(a)(3)(C), it is not sufficient for the "substantial investment" under subsection (C) to merely relate to articles protected by the asserted patents. Rather, "the complainant must establish that there is a nexus between the claimed investment and asserted patent regardless of whether the domestic- industry showing is based on licensing, engineering, research and development." *Certain Integrated Circuit Chips & Prods. Containing*, Inv. No. 337-TA-845, Final Initial Determination, 2013 WL 3463385, at *14 (June 7, 2013).

In addition, the Commission has definitively stated that investments in plant and equipment or labor and capital that relate to engineering and research and development ("R&D")

(that are expressly identified under subsection (C)), are properly considered under subsections (A) and (B):

> The statutory text of section 337 does not limit sections 337(a)(3)(A) and (B) to investments related to manufacturing or any other type of industry. It only requires that the domestic investments in plant and equipment, and employment of labor or capital be "with respect to the articles protected by the patent." 19 U.S.C. § 1337(a)(3). Moreover, even though subsection (C) expressly identifies "engineering" and "research and development" as exemplary investments in the "exploitation" of the patent, that language does not unambiguously narrow subsections (A) and (B) to exclude those same types of investments.

Certain Solid State Storage Drives, Stacked Elecs. Components, and Prods. Containing Same, Inv. No. 337-TA-1097, Comm'n Op. at 8 (June 29, 2018) ("*Storage Drives*"); *see also, e.g.*, *Certain Marine Sonar Imaging Devices, Including Downscan and Sidescan Devices, Prods. Containing the Same, and Components Thereof*, Inv. No. 337-TA-921, Comm'n Op. at 57-64 (Jan. 6, 2016) ("*Sonar Imaging Devices*").

There is no mathematical threshold test or a "rigid formula" for determining whether a domestic industry exists. *Certain Male Prophylactic Devices, Inc*., Inv. No. 337-TA-292, Comm'n Op. at 39, USITC Pub. 2390 (June 1991) ("*Male Prophylactic Devices*"). However, to determine whether investments are "significant" or "substantial," the actual amounts of a complainant's investments or a quantitative analysis must be performed. *Lelo Inc. v. Int'l Trade Comm'n*, 786 F.3d 879, 883-84 (Fed. Cir. 2015). Even after *Lelo*, which requires some quantification of a complainant's investments, there is still no bright line as to a threshold amount that might satisfy an economic industry requirement.

It is the complainant's burden to prove by a preponderance of evidence that each prong of the domestic industry requirement is satisfied. *Certain Prods. Containing Interactive Program Guide and Parental Control Tech.*, Inv. No. 337-TA-845, Final Initial Determination, 2013 WL 3463385, at *14 (June 7, 2013.). Moreover, the Commission makes its determination by "an examination of the facts in each investigation, the article of commerce, and the realities of the

marketplace." *Male Prophylactic Devices*, Comm'n Op. at 39 (quoting *Certain Double Sided-Floppy Disk Drives and Components Thereof*, Inv. No. 337-TA-215, Comm'n Op. at 17, USITC Pub. 1859 (May 1986)).

B. Benev's Domestic Industry

1. Overview of the Sylfirm X DI Products

Serendia's DI Products ("DI Products" or "Sylfirm X"), which entail the Sylfirm X microneedling device and its handpieces and microneedle tip attachments, are manufactured in Korea by one of Serendia's licensees, ViOL. (CX-0823C.0004 (Sylfirm X User Manual) (identifying "Manufacturer – VIOL Co., Ltd.," and "Country of Origin – South Korea"). ViOL, the original assignee of the Asserted Patents from assignor, Dr. Na, was founded in 2009 by Dr. Na. (Tr. (Na) at 75:15-20; CX-0766, CX-0769-0771 (assignment records).). Benev's CFO, Mr. Dan Park,[81] testified that Benev is "ViOL's business partner as well as a distributor for Sylfirm X in the United States," [redacted]. (Tr. (Park) at 445:3-5; CX-0763C [redacted]; *see also* CX-0918 (press release announcing Benev as the exclusive distributor of Sylfirm X); RX-2551C (July 26, 2023 Na Dep. Tr.) at 378:15-379:1 [redacted].).

[81] At the time he testified during the Hearing on November 2, 2023, Mr. Dan Park was Benev's Chief Financial Officer. (CPSt. at 2-3.). Serendia identified Mr. Park as a fact witness to "testify generally as to 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.).

ViOL's CEO, Mr. Sang Jin Lee,[82] testified that [redacted]. (RX-2566C (Lee Dep. Tr.) at 179:13-180:4.). Dr. Na explained that [redacted] (RX-2551C (July 26, 2023 Na Dep. Tr.) at 379:2-380:22.).

Benev is a U.S. company that "sell[s] medical aesthetics products, including medical devices, such as Sylfirm X[.]" (Tr. (Park) at 444:21-24; *see also* CX-0895.0003.). Mr. Park testified that [redacted] (Tr. (Park) at 447:10-20.). He confirmed that Benev operates an approximately 13,000 sq. ft. facility in Mission Viejo, CA, and does not have any facilities outside of the U.S. (*See id.* at 443:18-444:4.). Mr. Park explained that Benev works with several domestic contractors who also work with Sylfirm X, including [redacted] (*Id.* at 447:21-448:18, 456:18-25, 461:24-462:1, 470:10-15; CX-0664C [redacted].).

[82] At the time of his deposition on July 19, 2023, Mr. Sang Jin Lee was ViOL's Chief Executive Officer. (RX-2566C (Lee Dep. Tr.) at 28:7-10; *see also* CPSt. at 3.). Serendia identified Mr. Lee as a fact witness to "testify generally regarding the Domestic Industry Product and ViOL's business operations, including business operations relating to the Domestic Industry Product, and including ViOL's expenses pertaining to the Domestic Industry Product." (*Id.*).

2. Benev Is a Licensee of the Asserted Patents

On [redacted][83] ViOL later [redacted]. (CX-0762C (PAA) at §§ 2(a)-(b); Tr. (Na) at 89:11-20.).[84] The certified assignments reflect ViOL's transfer of the pertinent patents to Serendia. (CX-0766 ('836 patent assignment); CX-0769 ('536 patent assignment); CX-0770 ('774 patent assignment); CX-0771 ('812 patent assignment).). [redacted]. (CX-0762C (PAA) at § 2(c).). Accordingly, as [redacted]. *Genetic Implant Sys., Inc. v. Core-Vent Corp.*, 123 F.3d 1455, 1458–59 (Fed. Cir. 1997) ("The appointment of a distributor to sell a product covered by a patent is analogous to a grant of a patent license . . . [and] conveys an implied license to the distributor."). This is consistent with the Benev's CFO's that [redacted] (Tr. (Park) at 446:15-17; *see also* Tr. (Na) at 88:12-24 (same).).

Commission precedent allows articles that are impliedly licensed to be relied upon for the domestic industry requirement. *See Certain Magnetic Tape Cartridges and Components*

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[83] Benev subsequently [redacted] (Tr. (Park) at 446:21-447:11 (discussing CX-0765C).). Whether Serendia may rely upon Benev's qualifying investments since the date of the [redacted] as opposed to the date of the [redacted] does not impact whether Benev's qualifying investments are significant.

[84] The assignment to Serendia included the [redacted] (CX-0762C (PAA) at §§ 1(a), 2(a).).

Thereof, Inv. No. 337-TA-1058, Comm'n Op. at 41-42 (Mar. 25, 2019) ("*Magnetic Tape Cartridges*"); *Certain Multi-Stage Fuel Vapor Canister Sys. and Activated Carbon Components Thereof*, Inv. No. 337-TA-1140, ID at 116-17 (Jan. 28, 2020) (finding that the complainant could rely on third party for the domestic industry requirement based on implied licenses); *see also Certain Multi-Stage Fuel Vapor Canister Sys.*, Inv. No. 337-TA-1140, Order No. 16 at 3 (Aug. 13, 2019) ("The fact that *Magnetic Tape Cartridges* involved an express, written license, whereas here the claimed license is implied, does not negate the fact that both are a form of authorization; and an overarching principle of section 337 domestic industry is the identification of articles which practice or embody the claims of an asserted patent under authorization from the patent owner."). Here, as Serendia argued. and as Staff agreed, the documents and testimony demonstrate that Benev was authorized to use the Asserted Patents and thus, its investments appropriately can be credited in a domestic industry analysis. (CBr. at 93; SBr. at 137-38.).

Moreover, on [redacted]. (CX-0765C [redacted].). Respondents' assertion that there was no implied license because Benev later entered an express license is unsupported by law, contrary to the evidence, and ignores the realities of the marketplace. (Tr. (Park) at 447:5-11 (testifying that [redacted].).

Additionally, Respondents argued that the [redacted] (CX-3031C) of the [redacted] (CX-3028C [redacted]. (RRBr. at 74-75.). As Serendia has argued correctly, Respondents' argument is

not supported by the evidence. (CBr. at 93.). When the [redacted]. (CX-3028C [redacted]. In the [redacted]. (CX-0765C [redacted]. The [redacted] does not identify the [redacted] as being terminated/rescinded.

Moreover, as Respondents have acknowledged, [redacted] Respondents' Motion to Terminate (Motion Docket No. 1356-017) at 23.). Serendia's and SynKloud's termination rights are limited to terminating [redacted]. (CX-0765C [redacted]; Respondents' Motion to Terminate (Motion Docket No. 1356-017) at 1.). Thus, the [redacted] remains in force, notwithstanding the status of the [redacted]. Respondents have not cited to legal authority for their assertion that [redacted]. Furthermore, Respondents' allegation that [redacted], conflicts with the plain language of the [redacted].

Additionally, Respondents contended that Benev, [redacted], was not impliedly licensed to the Asserted Patents because ViOL did not have the ability to enter into the [redacted]. (RRBr. at 71-72.). Specifically, relying on the [redacted] (CX-2862C [redacted]), Respondents asserted that as of [redacted] Serendia, not ViOL, held the

"exclusive" right to distribute products practicing the Asserted Patents in the U.S. (*Id.* at 72.). As Staff pointed out, Respondents' contention is incorrect and overlooks the fact that Serendia and ViOL authorized Benev's activities with respect to the Sylfirm X. (SRBr. at 24.).

First, Serendia relied only on Benev's domestic investments/activities beginning in 2021. (*See, e.g.*, CBr. at 114; *see also* CDX-0003C.0048 (Thomas demonstrative reflecting labor and capital DI investments during 2021-2023).). The evidence also indicates that Benev did not begin its exclusive distribution of the Sylfirm X until 2021. (*See, e.g.*, CX-0918.0001 (Benev News Release) (announcing on April 21, 2021, that Benev was "launching the Sylfirm X in the U.S. as the exclusive distributor"); Tr. (Thomas) at 1556:19-22 (testifying that the Sylfirm X was first commercially available in the United States in 2021).). Thus, even if Benev did not have rights to distribute the Sylfirm X until after the [redacted], the effective date of the PAA (CX-0762C), as Respondents contended, that two-month gap in 2020 is irrelevant for purposes of the alleged domestic industry. In the PAA, ViOL and Serendia agreed that the [redacted]. (*See* CX-0762C.0001 [redacted].).

The evidence demonstrates that Benev's exclusive distribution of the Sylfirm X (which began in 2021) was understood impliedly to authorize Benev to use the Asserted Patents. (*See* Tr. (Park) at 446:8-17 (testifying that [redacted]).). Serendia, the patent owner and entity that possessed the exclusive distribution rights before Benev, agreed that Benev's exclusive distribution of the Sylfirm X gave Benev [redacted]

(Tr. (Na) at 88:12-24; *see Wang Lab'ys, Inc. v. Mitsubishi Elecs. Am., Inc.*, 103 F.3d 1571, 1580 (Fed. Cir. 1997) ("In patent law, an implied license merely signifies a patentee's waiver of the statutory right to exclude others from making, using, or selling the patented invention."). Thus, the course of conduct between Benev, Serendia, and ViOL supports a finding that Benev was impliedly licensed to the Asserted Patents through its exclusive distribution activities during the relevant period. *See id.* at 1580-82 (Fed. Cir. 1997) (finding that an implied license may arise by conduct or acquiescence, and holding that the "entire course of conduct between the parties . . . led Mitsubishi to infer consent to manufacture and sell the patented products . . . [and thus] properly inferred consent to its use of the invention of Wang's patents."); *Certain Magnetic Tape Cartridges and Components Thereof*, Inv. No. 337-TA-1058, Comm'n Op. at 41-42 (Apr. 9, 2019) (holding that complainant could rely on third party products for purposes of the domestic industry requirement based on "post-litigation correspondence and hearing testimony regarding the understanding of the contracting parties during the time period since the execution of [the agreement at issue.]");[85] *Certain Integrated Repeaters, Switches, Transceivers, and Prods. Containing Same*, Inv. No. 337-TA-435, ID at 177, 190-91 (July 19, 2001) (finding that the select, identified customers of the DI products had implied licenses for purposes of the domestic industry requirement) (not reviewed).

Respondents' additional argument, i.e., that recognizing that Benev had an implied licensee through its exclusive distributorship of the Sylfirm X "would dramatically expand the

[85] As Staff correctly pointed out, Respondents' attempt to distinguish *Magnetic Tape Cartridges* misses the mark. (SRBr. at 25 n.17 (quoting *Certain Multi-Stage Fuel Vapor Canister Sys. & Activated Carbon Components Thereof*, Inv. No. 337-TA-1140, Order No. 16 at 3 (July 1, 2019) (emphasis added) ("The fact that *Magnetic Tape Cartridges* involved an express, written license, whereas here the claimed license is implied, does not negate the fact ***that both are a form of authorization; and an overarching principle of section 337 domestic industry is the identification of articles which practice or embody the claims of an asserted patent under authorization from the patent owner***.").).

universe of parties whose investments and activities are creditable towards a domestic industry," misstates the facts in this Investigation. (RRBr. at 74.). Benev is not a "mere reseller" or a "user," akin to a retailer like Best Buy or Target, Respondents have alleged. (*Id.* at 73-74.). It is undisputed that Benev has been the business partner and sole distributor of the Sylfirm X since 2021. As discussed in detail below in Section XI.B.3, Benev undertook far more activities pertaining to that product than a mere reseller or user could or would. Benev's activities have included research and trials of products, pursuit of additional FDA clearances, and product improvement/development. Thus, Respondents' equation of Benev to a "mere reseller" or "user" is without merit. Respondents' assertion that Benev's implied license would expand the type of entities that can be relied upon for purposes of the domestic industry requirement is unpersuasive.

Respondents' unsupported and conclusory "exhaustion" argument also fails. In just one sentence, Respondents contend that "the patent rights in Sylfirm X exhausted with each sale to Benev." (RPBr. at 167; RRBr. at 73.).

First, Respondents' allegation is conclusory and therefore deemed waived under Ground Rules 7.2 and 10.1. (G.R. 7.2, 10.1; *see also* Order No. 46 at 2 ("conclusory statements are insufficient to preserve an argument").). Second, even if the argument were to be considered on its merits, Respondents are incorrect. As Serendia correctly pointed out, patent exhaustion involves patent rights related to post-sale use, not to patent rights conferred through licensing. *See, e.g.*, *Impression Prods., Inc. v. Lexmark Int'l, Inc.*, 581 U.S. 360, 375-76 (2017) (patent exhaustion is about "passing title to a product" while a license is about "changing the contours of the patentee's monopoly"); *Helferich Pat. Licensing, LLC v. New York Times Co.*, 778 F.3d 1293, 1301 (Fed. Cir. 2015) ("Patent exhaustion . . . eliminates the legal restrictions on what

authorized acquirers 'can do with an article embodying or containing an invention' whose initial sale (or comparable transfer) the patentee authorized."). Accordingly, patent exhaustion is irrelevant to the rights conveyed in Benev License.

3. Benev's Domestic Industry Activities Demonstrate It Is More Than a "Mere Importer"

Serendia demonstrated that Benev, Serendia's domestic industry licensee, has significant employment of labor and capital in the DI Products in the U.S. Benev's investments in the following activities related to the Sylfirm X inlcude: (i) FDA clinical research and trials; (ii) research and development ("R&D") (via product improvement); (iii) post-sale customer training and education; (iv) development of patient care protocols; (v) warranty/repair services; and (vi) installation and delivery.

As Serendia noted, each of those activities has been determined to be a qualifying domestic industry activity. *See, e.g.*, *Certain Strontium-Rubidium Radioisotope Infusion Sys.*, Inv. No. 337-TA-1110, ID at 140-142 (Aug. 1, 2019) (FDA-related expenses); *Certain Bone Cements*, No. 337-TA-1153, Comm'n Op. at 25 (Jan. 25, 2021) (warranty, service, repair, and packaging activities); *Certain Child Carriers*, No. 337-TA-1154, ID at 195 (Mar. 10, 2020) (customer service and support and product training); *Certain Sleep-Disordered Breathing Treatment Sys.*, Inv. No. 337-TA-890, ID at 168 (Sept. 16, 2014) (clinical education to train medical providers); *Certain Airtight Cast-Iron Stoves*, Inv. No. 337-TA-69, Comm'n Op. at 11 (Jan. 1981) (repair, testing, installation activities); *Certain Video Displays*, Inv. No. 337-TA-687, Order No. 20 (ID), 2010 WL 2306671, at *5 (May 20, 2010) (customer support, repairs). Staff agreed that Benev's qualifying activities and investments establish that Benev is more than a mere importer. (SPBr. at 159; SBr. at 138.).

As Mr. Park testified, "other than the actual manufacturing of Sylfirm X, we [Benev] do [redacted] (Tr. (Park), 482:24-483:2.). Each of Benev's qualifying DI activities, listed above in (i)-(vi), are described in more detail below.

a) FDA Clinical Research and Clinical Trials

With respect to FDA research and clinical trials for the Sylfirm X, Mr. Park made clear that [redacted]. (Tr. (Park) at 452:19-453:4; *see also* Tr. (Na) at 92:18-93:5, 94:2-7 (describing Benev's involvement in [redacted] studies, FDA approval, academic seminars, training, and product improvement as well as Dr. Na's Sylfirm X-related consulting work for Benev); RX-2544C (Park Dep. Tr.) at 95:18-24 (testifying that Benev also "contribute[s] a significant amount of time, resources, [] energy, cash to engage in the R&D activities, the clinical trials, specifically in relation to Sylfirm X").). In its Initial Post-Hearing Brief, Serendia stated that "Benev is currently involved in [redacted] clinical trials to [redacted] for the Sylfirm X." (CBr. at 96 (citing CPX-0109C (Benev clinical study summary); CX-1101C).). Dr. Na confirmed that the effort to obtain [redacted] originated with Benev. (Tr. (Na) at 149:15-150:5.).

Mr. Park explained that ongoing product trials are supported by Benev's expenditures in labor and capital (including R&D equipment), made through the activities of Benev's: MAB and KOL consultants; with the assistance of Dr. Na; with the assistance of Benev personnel who support the studies involved; and with the help of Benev's consultants who have worked on studies. (Tr. (Park) at 453:21-455:19.). Serendia's evidence supports findings that: Benev's MAB/KOLs have participated in clinical trials; have [redacted], have

published their results; have provided before-and-after pictures; have given presentations on their research; and have assisted with clinical implementations. (CX-0360C.0007 (MAB Agmt.); CPX-0109C; CX-0652C, CX-0504C, and CX-0503C (MAB Agmts.); CX-1099C, CX-1100C, CX-1101C, CX-2539C, CX-2545C, and CX-2552C (clinical trial files).). Documentary and testimonial evidence also reflect that Dr. Na has participated in the required FDA clinical trials of the DI Products. (CPX-0109C; RX-2551C (July 26, 2023, Na Dep. Tr) at 367:16-371:17; Tr. (Park) at 454:18-25.). Mr. Park testified that Benev's CEO, CFO, and the customer support team have supported clinical trials by collaborating with the MABs/KOLs, working directly with the teams running the clinical trials, and . (Tr. (Park) at 453:25-455:14; *see also* CX-0464C, CX-0465C, CX-0467C, CX-0469C, and CX-1015C .).

In addition to its labor investments, Serendia presented evidence that (CPX-0016C .). Moreover, Serendia provided evidence that . (Tr. (Park) at 456:20-457:8; CX-0478C to CX-0496C, CX-0498C to CX-0502C, and CX-1010C (thereof); CPX-0109C.).

Additionally, invoices also reflect that . (CX-0464C, CX-0465C, CX-0467C, CX-0469C, and CX-1015C ; CX-0877.). Mr. Park explained that . (Tr. (Park) at 455:15-19.).

b) R&D (via Product Improvement)

As Mr. Park testified, Benev has engaged in Sylfirm X product improvement through its MABs/KOLs, its personnel, Dr. Na, and [redacted] as discussed above. (Tr. (Park) at 457:16-460:10.). Testimonial and documentary evidence demonstrate unrefutedly that Benev's MABs/KOLs also made additional improvements to the product that are significant, including the [redacted]. (Tr. (Park) at 458:14-460:4; RX-2551C (July 26, 2023, Na Dep. Tr.) at 389:5-15; RX-2549C (Aug. 9, 2023, Na Dep. Tr.) at 76:12-79:16; CX-2901C, CX-2902C, and CX-0667C [redacted]; CX-0459C [redacted].).

For example, Dr. Na testified that Benev's CEO developed improvements, as his "idea was that if [redacted] (RX-2551C (July 26, 2023, Na Dep. Tr.) at 396:2-397:3; *see also* Tr. (Park) at 458:24-459:4.). Additionally, Mr. Park testified that Benev's MABs/KOLs and personnel monitored for additional product improvements. They consulted with doctors and others in the field about potential product improvements. (Tr. (Park) at 460:5-14; *see also* Tr. (Thomas Vander Veen)[86] at 1406:17-21 (***Respondents'*** economic expert agreeing that monitoring for product

[86] When he testified during the Hearing on December 12, 2023, Dr. Thomas Vander Veen was a Managing Director at Epsilon Economics. (RPSt. at 2.). Respondents identified Dr. Vander Veen as an expert to testify about "the economic prong of Serendia's claimed domestic industry and the appropriate bond during any 60-day Presidential Review Period." (*Id.* at 3.). He was accepted without objection as an expert on the subject matter for which he was called to testify.

improvements could qualify as a domestic industry activity).). Notably, part of the MABs/KOLs' express scope of work was to [redacted] (CX-0360C.0007 (MAB Agmt.).

c) Post-Sale Customer Training and Education

Mr. Park explained that Benev provides post-sale customer training on how to use the Sylfirm X device through its MABs/KOLs, Dr. Na, Independent Sales Reps ("ISRs"), contractor nurse trainers, and its own personnel who supported the training. (Tr. (Park) at 460:16-463:14.). Mr. Park also testified that Benev worked with the Clearskin Institute to train its trainers. (*Id.* at 463:15-21.).

Additionally, relying on documentary evidence, Mr. Park also testified that Benev's MABs/KOLs provide training to trainers, customers, and participated in education lectures, including at the X-Class Aesthetic Elite Summit, which is limited only to existing Benev customers. (*Id.* at 461:25-462:5, 464:4-465:2; CX-0895 (X-class announcement); CPX-0104C (X-class expenses); CX-1005C-CX-1008C (Thomas Schedules).). Mr. Park also confirmed, along with Dr. Na, that Dr. Na has developed protocols for training programs, and has provided workshops and training sessions directly to customers. (Tr. (Park) at 462:6-10; RX-2551C (July 26, 2023, Na Dep. Tr.) at 370:7-374:18; CX-0664C (Benev Na Agmt.).). Benev's ISRs also provided post-sale training to customers. (CPX-0108C (ISR comp.); *see also* Tr. (Park) at 462:11-17.).

In addition, Mr. Park testified that Benev worked and continues to work with contractor nurses to provide onsite training of the operation of the Sylfirm X to customers. (Tr. (Park) at 462:18-25; CX-1018C and CX-1019C (Thomas Schedules) (identifying, for example, Jungah ("Sarah") Oh, RN; Shawn Lea Carter, RN; Daniel Lee, RN; Jin Woo, RN; and Trong Bae

Nguyen, RN, as some of the contractor nurses).). Mr. Park explained that Ms. Oh, the head trainer, coordinated Benev's training for its customers and worked directly with the CEO, MABs/KOLs, and Dr. Na to develop training protocols for the Sylfirm X. (Tr. (Park) at 462:18-463:14.). Mr. Park also testified that Benev is "[redacted] in training and educating the customers to use [Benev's] products efficiently and safely" and that Benev [redacted] for these Sylfirm X trainings, which is reflected in the training documents and invoices upon which Serendia relied. (*Id.* at 460:22-24, 465:12-17; CPX-0107C (training); CPX-0112C (Benev expenses); CX-0611C - CX-0636C, CX-0638C - CX-0642C, CX-0644C - CX-0647C, CX-0649C, CX-0650C, RX-1225C, RX-1234C, and RX-2346C (training invoices); RX-0157C (training); CX-1018C and CX-1019C (Thomas Schedules).).

d) Development of Patient Care Protocols

Mr. Park testified that Dr. Na, Mr. Min, and Benev's MABs/KOLs all have contributed to the development and refinement of Sylfirm X patient care protocols. (Tr. (Park) at 465:23-469:6; RX-2544C (Park Dep. Tr.) at 183:6-186:14; CX-2901C, CX-2902C, and CX-0667C (patient care protocols); CX-0664C (Benev Na Agmt.).). These individuals have observed how the DI Product is used and the resulting effects, and then conferred with ViOL [redacted]. (Tr. (Park) at 465:23-466:4, 469:2-6 (testifying that [redacted].). As Mr. Park indicated, the [redacted]. (Tr. (Park) at 467:1-469:8.). Dr. Na specifically testified that [redacted]. (Tr. (Na) at 97:16-22.).

e) Warranty/Repair Services

Mr. Park explained that Benev has engaged in Sylfirm X warranty and repair services through its engineering contractor, Mr. McDaniel of West Coast Laser Services, and Benev's personnel who troubleshoot, coordinate repairs, and arrange for the devices to be returned to Benev for repair and then shipped back to customers once repaired. (Tr. (Park) at 469:8-472:13.). According to Mr. Park, Mr. McDaniel received special training to repair the Sylfirm X and performs repairs at Benev's facility, in its warehouse. (*Id.* at 469:17-21; RX-2544C (Park Dep. Tr.) at 51:4-21; CPX-0015C (West Coast Laser).). Mr. Park also testified that Benev stored replacement parts at its facility so repairs can be quickly completed. (Tr. (Park) at 472:8-13; RX-2544C (Park Dep. Tr.) at 158:16-159:12.). He clarified that to support these repairs, Benev's CEO and CFO set up the warranty and repair program for the U.S. (Tr. (Park) at 471:21-472:7.). Additionally, Mr. Park explained that Benev's customer service team have provided technical support by troubleshooting problems with customers and assists with warranty and repair claims that require escalation. Benev's ISRs communicate with customers about needed repairs, and Benev's delivery service (Trump Card) picks up devices to be repaired and deliveres loaner devices. (Tr. (Park) at 470:14-471:20; 475:6-14; CPX-0105C, CPX-0106C, CX-0609C, and CX-0591C (Trump Card).).

f) Installation and Delivery

Mr. Park testified that Benev provides white glove delivery service of the Sylfirm X product through its contractor, Trump Card. (Tr. (Park) at 475:14-477:15; CX-0609C, CPX-0105C, and CPX-0106C (Trump Card); CX-1016C (Thomas Schedule).). Trump Card "specializes in delivery, transportation, setting up, [and the] installation of medical devices, including Sylfirm X." RX-2544C (Park Dep. Tr.) at 16:10-13.). As described above, Trump

Card also provides pick-up and delivery services for devices that require repair, and then provides loaner devices. (Tr. (Park) at 476:16-20.). [redacted]. (*Id.* at 476:21-477:5.).

g) Respondents' Expert's Acknowledgement of Benev's Domestic Industry Activities

Respondents' economic expert, Dr. Vander Veen, acknowledged that the activities Serendia included in its domestic industry analysis are appropriate. For every one of Benev's activities that Mr. Thomas included in his domestic industry analysis, Dr. Vander Veen confirmed that the activity: (i) could be a qualifying domestic industry activity, (ii) has previously been credited by the Commission as a qualifying domestic industry activity, (iii) was credited by Dr. Vander Veen in this Investigation as a qualifying domestic industry activity, or (iv) all the above. Dr. Vander Veen's testimony is quoted below.

> Q. Dr. Vander Veen, I'm asking: You previously have included customer service investments in your domestic industry analyses, right?
>
> A. In certain context, yes.
>
> * * *
>
> Q. . . . You have previously opined that product quality improvement or utilization are qualifying domestic industry activities, right?
>
> A. Yes.
>
> * * *
>
> Q. And you agree that activities in relation to developing patient care protocols may be a cognizable domestic industry activity, right?
>
> A. Yes, I think it could be.

* * *

Q. Okay. Now you agree that if MABs or KOLs, that's key opinion leaders, are monitoring for product improvements, that could qualify as a domestic industry activity, right?

A. That's correct.

* * *

Q. And you recognize that clinical research and trial expenses could be qualifying DI expenses?

A. Could be, yes.

Q. In fact, here in your analysis you actually credit some of Benev's clinical trial investments in your adjusted calculations, right?

A. Yes, as for the reasons discussed yesterday.

* * *

Q. Okay. And you agree that warranty and repair work is a category of investment that the Commission has previously credited towards the domestic industry analysis, right?

A. That's correct.

Q. And, in fact, in your analysis before Judge McNamara you credited Benev's service warranty and repair expenses, right?

A. Yes, I included an amount.

Q. You actually credited the same amount as Mr. Thomas.

There's no dispute with warranty and repair expenses between you and Mr. Thomas, right?

A. Not for this. Not for this number. There were other disputes, some of those investments Mr. Thomas isn't asserting.

Q. I'm talking about warranty and repair expenses, Dr. Vander Veen.

You credit to your analysis the same amount for warranty and repair that Mr. Thomas credits for his analysis; is that fair?

A. Yes, under this prong B calculation. I said there were other investments that he

is no longer asserting that we had disputes about.

* * *

Q. Let's talk about the next category, FDA regulatory consultants.

Now you agree that FDA regulatory expenses, like the other categories, have previously been credited by the Commission in a domestic industry analysis, right?

A. That's correct.

Q. And in your analysis before Judge McNamara you actually credit some of Benev's FDA regulatory expenses as qualifying DI expenses, right?

A. Yes.

* * *

Q. All right. Then let's move on to the next category, delivery and installation.

You agree that delivery and installation could be a qualifying domestic industry activity?

A. In certain contexts.

Q. Is that yes?

A. I said yes, in certain contexts.

* * *

Q. All right. Let's move on to the last category, then, of DI investments, post-sale customer training and education.

Now you agree that the Commission has in the past credited some investments in post-sale customer training and education towards the DI analysis?

A. Yes, in certain contexts.

Q. And, in fact, you actually credit in your analysis for Judge McNamara some of Benev's investments in post-sale customer training and education, right?

A. That's correct.

Q. But you limit those credited investments to those you found in just one document. It's Bates number Benev 977, which is now RX 1226C, right?

A. I believe that's correct. I didn't memorize the exhibit numbers, but yes.

Q. Okay. Now that's because, according to you, Mr. Park testified at deposition that that document, which is now RX 1226C, provided an accurate representation for Benev's training expenses, right?

A. Yes, for the time period of that document.

Q. All right. But Mr. Park did not testify at his deposition that that document, RX 1226C, was a complete accounting of Benev's cost for post-sale customer training and education, right?

A. No. Again, as I said, it's for the time period that he was discussing.

Q. So you agree that Mr. Park didn't testify that that document was a complete accounting of Benev's costs for post-sale customer training and education, right?

A. Yes.

Q. Okay. In fact, he testified at his deposition that , right?

A. I believe that's correct, yes.

Q. But still the only post-sale training and education expenses you credit are just from that one document, right?

A. I, again, I was relying on the -- on expenses I could see in the documents, and so that's what I relied upon.

Q. And so I'm right, the only expenses you credited are from that one document?

A. Yes. Again, my exercise was to determine expenses that I could identify in the documents, and that's what I relied upon.

Q. And because the only expenses you credited are from that one document, you don't include in your analysis any Benev post-sale training and education expenses that aren't included in just that one document, right?

A. That's correct.

(Tr. (Vander Veen) at 1401:2-5 (customer service), 1403:9-13 (product quality improvement/ utilization), 1405:25-1406:3 (developing patient care protocols), 1406:7-16 (customer training and education), 1406:17-21 (monitoring for product improvements), 1407:24-1408:5 (FDA clinical research and trials), 1411:6-1412:4 (service, warranty, and repair), 1412:5-14 (FDA regulatory consulting); 1412:15-21 (delivery and installation), 1415:9-1417:9 (post-sale customer training and education).).

h) Conclusion

As Serendia pointed out, the described activities in which Serendia, through Benev, and others engage, demonstrate, and the evidence confirms, that Benev is more than a "mere importer." (CBr. at 101.). That Benev's U.S. competitors, including those that are no longer a party to this Investigation, ***largely forego*** these activities also confirms that Benev is more than a "mere importer." (CX-1048C (Jonathan Banks Dep. Tr.)[87] at 85:14-88:16; CX-1042C (Andrew Storrs Dep. Tr.)[88] at 27:5-16, 31:11-19, 37:6-20, 217:10-16; CX-1054C (Mark Rohrer Dep. Tr.)[89] at 163:6-9; CX-1044C (Bradley Renton Dep. Tr.)[90] at 37:10-38:18, 57, 146:1-24, 225:17-21, 229:1-234:25; CX-1052C (Kibbey Dep. Tr.) at 45:9-12, 65:1-20, 97:2-98:20, 101:4-11; CX-1056C (Witman Dep. Tr.) at 57:11-19; CX-1055C (Aviram Dep. Tr.) at 73:6-74:4, 150:11-151:1; CX-1049C (James Bartholomeusz Dep. Tr.)[91] at 17:20-22.). Accordingly, in view of the realities of the marketplace when compared to Respondents' activities, Benev is more than a "mere importer." *Certain Male Prophylactic Devices*, Inv. No. 337-TA-546, Comm'n Op., 39 (Aug. 1, 2007) (domestic industry evaluated in view of "the facts in each investigation, the article of commerce, and the realities of the marketplace").

[87] When he was deposed on June 28, 2023, Mr. Jonathan Banks was the Chief Financial Officer of Cartessa. (CX-1048C (Banks Dep. Tr.) at 18:17-20.).

[88] When he was deposed on June 29, 2023, Mr. Andrew Storms was the Chief Operating Officer of Cartessa. CX-1042C (Storrs Dep. Tr.) at 21:22-22:4.).

[89] When he was deposed on June 27, 2023, Mr. Mark Rohrer was the founder of Rohrer Aesthetics, LLC. (CX-1054C (Rohrer Dep. Tr.) at 12:11-12.).

[90] When he was deposed on July 7, 2023, Dr. Bradley Renton was an employee of Cutera. (CX-1044C (Renton Dep. Tr.) at 19:4-20:20.).

[91] When he was deposed on July 26, 2023, Mr. James Bartholomeusz was the Chief Technology Officer of Lutronic. (CX-1049C (Bartholomeusz Dep. Tr) at 11:2-3, 7-8.).

C. Benev's Significant Investment in Labor and Capital

1. Mr. Thomas' Allocations Are Reasonable

As Benev's CFO, Mr. Park, explained, Benev [redacted]. (Tr. (Park) at 452:5-18.). Rather, to isolate Benev's investments that are both cognizable and specific to the Sylfirm X, Serendia's expert, Mr. Vincent Thomas,[92] performed two (2) types of calculations.

First, for Benev's employees (CEO, CFO, and two customer service employees), MABs and KOLs, and ISRs, Mr. Thomas performed a time-based allocation to exclude time that those employees *did not spend* on qualifying activities with respect to the Sylfirm X, such as to exclude time spent on "sales and marketing." (Tr. (Thomas) at 689:6-15; CDX-0003C.0010 (identifying the time-based allocations and supporting documentation).). Mr. Park provided the specific time-based allocations. (Tr. (Park) at 478:23-479:8 [redacted], 479:9-23 [redacted], 479:24-480:13 [redacted], 480:14-481:2 [redacted], 481:3-12 [redacted].).

The evidence demonstrates that Mr. Park's time estimates are reliable and sufficient under Commission precedent. Mr. Park provided his time estimates based on his personal knowledge, experience, and observations from his day-to-day job responsibilities, and in view of instructions from Mr. Thomas to only include time spent on qualifying activities (i.e., the

[92] When he testified during the Hearing on November 6, 2023, Mr. Vincent Thomas was a Senior Managing Director of FTI Consulting. (CPSt. at Ex. 5.). Serendia identified Mr. Thomas as an expert to "testify regarding matters relating to the economic prong of the domestic industry; importation issues; secondary indicia of non-obviousness; the remedy and bond sought by Serendia in the Investigation; and/or other economic issues within the scope of his expert report or deposition." (CPSt. at 7.).

activities discussed above in Section XI.B.3) and exclude time spent on non-Sylfirm X products or non-qualifying activities such as sales and marketing. (Tr. (Park) at 477:25-478:17 (describing instructions from Mr. Thomas regarding providing approximate time estimates and to be "very conservative in terms of my estimation"), 481:19-482:20 (describing the bases and accuracy of his time estimates), 485:13-19 (testifying that it took a [redacted] to come up with his time estimates).).

As Staff noted, Mr. Park's time estimates, and Mr. Thomas' allocations based thereon, are reasonable in view of the available evidence and circumstances of the alleged domestic industry. *See, e.g.*, *Certain Solid State Storage Drives*, Inv. No. 337-TA-1097, Comm'n Op. at 17-21, 32 (June 29, 2018) (relying on the DI licensee's president's "general recollection" to make a "reasonable, good faith estimate" for allocations of square footage and employee time and rejecting contention that the time estimates were unreliable due to a lack of documentary corroboration).[93]

[93] Respondents filed a notice of supplemental authority ("NSA") with respect to the Federal Circuit's opinion in *Zircon Corp. v. Int'l Trade Comm'n*, 2024 WL 2037162, Case No. 2022-1649 (Fed. Cir. May 8, 2024). (Doc. ID No. 821353 (May 13, 2024).). In the NSA, Respondents argued that the Federal Circuit affirmed in *Zircon* "a finding that testimony attributing a portion of overall research and development investments to the domestic industry product was unreliable because it lacked documentary support and an explanation for how the corporate witness arrived at the recited portion," and that this ruling is relevant to arguments in this Investigation regarding the economic prong." (NSA at 1 (citing *Zircon*, 2024 WL 2037162, at *8-9).

Serendia and Staff each filed a response to Respondents' NSA. (Doc. ID No. 821664 (Serendia Resp.) (May 16, 2024); Doc. ID No. 821689 (Staff Resp.) (May 16, 2024).). Both Serendia and Staff argued that Respondents are mistaken. (Serendia Resp. at 1; Staff Resp. at 1.). For the following reasons, it is a finding of this ID that *Zircon* is not applicable here. If anything, *Zircon* reaffirms the principles that support finding a domestic industry in this Investigation.

Zircon does not support Respondents' arguments concerning: (1) Mr. Park's (Benev's CFO) detailed and credible testimony concerning how much time certain Benev employees (including himself) and domestic contractors, including Benev's MABs and KOLs, devote to qualifying, non-sales and marketing activities for the Sylfirm X; and (2) the documentary support for certain of the alleged domestic industry activities.

Mr. Thomas also performed a revenue-based allocation. He took Benev's sales of the DI Products and "divided that into the total sales for Benev, which included, not only the sale of the Sylfirm X, but all the products that Benev sells," to "isolat[e] the impact of Sylfirm X and remov[e] the effect of other products." (Tr. (Thomas) at 687:24-689:5; CDX-0003C.0010

As Staff noted, the portions of *Zircon* to which Respondents cited did not change the law, but in fact, credited the Commission's decisions (including the precedent discussed in Staff's briefs) on the issue of sworn witness testimony directed to the domestic industry requirement. *See Zircon*, 2024 WL 2037162, at *9 (discussing *Certain Solid State Storage Drives, Stacked Elecs. Components, and Prods. Containing Same* ("*Solid State Storage Drives*"), Inv. No. 337-TA-1097, Comm'n Op., 2018 WL 4300500, at *13 (June 29, 2018); *Certain LED Lighting Devices, LED Power Supplies, & Components Thereof* ("*LED Lighting Devices*"), Inv. No. 337-TA-1081, ID, 2018 WL 7350925, at *91, 93 (Dec. 19, 2018)). Thus, Respondents' cited portion of *Zircon* does not alter the basic principle that "there is no Commission requirement that sworn witness testimony directed to the domestic industry requirement cannot be credited without further corroboration by underlying documentation. Instead, all that is required is the use of reasonable allocations for the purposes of establishing the economic prong of the domestic industry requirement." *Solid State Storage Drives*, Inv. No. 337-TA-1097, Comm'n Op. at 21-22 (internal citations omitted); *see also Certain Raised Garden Beds*, Inv. No. 337-TA-1334, Comm'n Op. at 44-45 (Apr. 1, 2024) (quoting *Solid State Storage Drives* in (1) crediting a corporate officer's "estimates of employee time" attributable to cognizable activities, and (2) dismissing Respondents' argument that the estimates were "'self-serving' and 'not supported by any record or evidence.'").

Moreover, the relevant facts in *Zircon* are distinguishable from the evidence/facts here. The Federal Circuit noted that, unlike in *LED Lighting Devices* where "the witness in question ***explained*** how he derived his estimate," the *Zircon* witness "provided ***no explanation*** of how he reached the particular figure in his witness statement," and thus the Federal Circuit declined to "override" "[t]he ALJ's credibility determinations and weighing of the evidence [which] are entitled to great weight[.]" *Id.* (emphases added). Here, as in *LED Lighting Devices*, Mr. Park ***credibly explained*** the bases for each of his time estimates. (*See* Tr. (Park) at 477:18-482:20; *see also* SBr. at 156-58.).

To the extent that Respondents cite *Zircon* for their argument that certain of the labor investments lack corroborating documentary support and should therefore be disregarded or reduced, Respondents' reliance is misplaced. First, *Zircon* does not support Respondents' argument. The cited portion of *Zircon* concerned a witness' conclusory, "unelaborated" estimate of the amount of "[R&D] funds that were devoted to developing the chip," and not whether or how much documentary evidence is required to corroborate that labor activities were performed. *Zircon*, 2024 WL 2037162, at *8-9. Second, there is no "absence of documentary evidence that these activities are occurring at all." (RRBr. at 82.). As discussed above, there is documentary and credible testimonial evidence demonstrating that each category of labor activity was undertaken. (*See* Section XI.B.; *see also* SBr. at 138-58; SRBr. at 27-28.).

In sum, *Zircon* does not support Respondents' domestic industry arguments. The relevant law cited in the Staff's and Serendia's briefs was credited by the Federal Circuit, and unlike in *Zircon*, the testimony at issue in this Investigation is credible and supported by detailed explanations. Here, there is documentary and testimonial evidence supporting each category of cognizable labor activities.

(identifying the revenue-based allocation percentages and supporting documentation). The sales-based allocation resulted in a ***further*** reduction to Benev's claimed DI investments for the Benev personal, medical professionals, and post-sale customer support, labor categories. (*See* Tr. (Thomas) at 696:8-19; CDX-0003.0019 (Benev personnel), 0027 (medical professionals), 0042 (post-sale customer support).). For example, Mr. Thomas' two-part allocation resulted in crediting only [redacted] of Benev's total payments to ISRs. (*See* Tr. (Thomas) at 709:19-710:14.).

Thus, Mr. Thomas' revenue-based allocation is reasonable in view of the available evidence and circumstances of the alleged domestic industry. *See, e.g.*, *Certain High-Density Fiber Optic Equipment and Components Thereof*, Inv. No. 337-TA-1194, Comm'n Op. at 64 (Aug. 3, 2021) (agreeing that a "sales-based allocation method" was reasonable because it "eliminate[d] non-DI related investments"); *Certain Collapsible Sockets for Mobile Elec. Devices and Components Thereof*, Inv. No. 337-TA-1056, Comm'n Op. (July 9, 2018) (finding a sales-based allocation appropriate).

Respondents contended that the time allocations are "unreliable" and "not credible" because "Benev cannot actually track the time or effort any employee spends on the Sylfirm X." (RPBr. at 154, 166.). Respondents effectively seek to impose a requirement that any company alleging a domestic industry must track its expenditures on a product-by-product basis, and its employee's time on a product- and category-specific basis. However, the Commission has repeatedly made clear that "a precise accounting is not necessary, as most people do not document their daily affairs in contemplation of possible litigation." *Certain Stringed Musical Instruments and Components Thereof*, Inv. No. 337-TA-586, Comm'n Op. at 26 (May 16, 2008); *see also Certain Movable Barrier Operator Sys. and Components Thereof*, Inv. No. 337-TA-1118, Comm'n Op. at 28 (Jan. 21, 2021) ("[C]omplainants do not need to provide a 'precise

accounting' of their expenditures[.]"). That labor hours are not tracked for a particular product or activity in the ordinary course of business is not at all unusual, nor does it preclude a knowledgeable employee from making reasonable estimates as to how much time employees spend performing certain types of activities (as opposed to time spent on other, non-qualifying activities, or non-DI products). "All that is required it the use of reasonable allocations for the purposes of establishing the economic prong of the domestic industry requirement." *Certain Solid State Storage Drives, Stacked Elec. Components, and Prods. Containing Same*, Inv. No. 337-TA-1097, Comm'n Op. at 21-22 (June 20, 2018). It is a finding that Mr. Thomas' allocations are reasonable.

In sum, the evidence demonstrates that Mr. Thomas' allocation methodologies are reasonable and reliable. They sufficiently identify the specific, cognizable investments in the DI Products.

2. Benev's Investments in Labor and Capital Are Quantitatively and Qualitatively Significant

The evidence demonstrates that Benev's cognizable, allocated labor and capital expenditures are quantitatively and qualitatively significant because they are necessary to support ongoing innovation and product development for the Sylfirm X. Moreover, Benev's investment of [redacted] is significant in the context of Benev's business and ViOL's total manufacturing costs for the Sylfirm X.

Mr. Thomas presented two (2) alternative contextual analyses: (1) comparing Benev's qualifying labor and capital investments to Benev's total operating expenses from its financial statements (i.e., not just limited to Benev's total labor and capital expenses); and (2) comparing Benev's qualifying labor and capital investments to ViOL's manufacturing costs for the Sylfirm

X products in Korea converted to U.S. dollars.[94] (Tr. (Thomas) at 717:19-720:16.).

As demonstrated below in Mr. Thomas' demonstratives, the evidence establishes that Benev's domestic industry investments are ***quantitatively*** significant under either contextual metric, with which Staff agreed. (SBr. at 159.).

Figure 41: Thomas Demonstratives Illustrating Quantitative Significance of Labor and Capital



(CDX-0003C.0058 (citing CX-0999C; CX-1001C; CX-1004C; CX-3401C.0002; CX-0359C; CX-0666C; CX-0665C); *see also* Tr. (Thomas) at 717:19-718:21.).



(CDX-0003C.0059 (citing CX-0999C; CX-1001C; CX-1004C; CX-3401C.0002; RX-2566C; CPX-0156C; CX-3382C); *see also* Tr. (Thomas) at 718:22-720:16.).

Respondents contended that using ViOL's manufacturing data as a comparator is "improper" because ViOL did not produce "any underlying business records to support" its

[94] Respondents' economic expert, Dr. Vander Veen, did not offer rebuttal to Mr. Thomas' quantitative significance analysis. (Tr. (Vander Veen) at 1347:23-1367:21.). Thus, Mr. Thomas' opinion that the domestic industry investments are ***quantitatively*** significant is ***unrebutted***. (Tr. (Thomas) at 717:19-720:13; CDX-0003C.0058-59.).

manufacturing costs. (RPBr. at 163; *see also* RRBr. at 82 (quoting Vander Veen's testimony, Respondents asserted that "there is a 'striking' absence of documentary evidence that these activities are occurring at all").). However, the evidence indicates that ViOL's summary document was created for this Investigation from data kept in the ordinary course of business, and that ViOL's CEO, Mr. Lee, was deposed by Respondents' counsel about the document. (*See* RX-2566C (Lee Dep. Tr.) at 118:18-119:18 (testifying that [redacted]). The document itself contains a [redacted]. (CPX-0156C (tab 2); *see also* Tr. (Thomas) at 745:9:17 (describing the [redacted].). Accordingly, Respondents' criticism is without merit. *See Certain Wet Dry Surface Cleaning Devices* ("*Wet Dry Surface Cleaning Devices*"), Inv. No. 337-TA-1304, ID at 233-34 (Mar. 24, 2023) (rejecting contention that a summary domestic industry document created for the investigation was unreliable); *Elec. Digital Media*, Inv. No. 337-TA-796, ID at 451 (Oct. 24, 2012) ("I find no basis to dispute the authenticity or accuracy of the data in Exhibit CX-19C. Samsung's expert ***Dr. Vander Veen insinuates the data was created for litigation purposes and is unreliable. I find his assertion to be unfounded speculation that is not supported by the record evidence.***") (emphasis added). That is the finding here, also.

The respondents in *Wet Dry Surface Cleaning Devices* made a similar argument as Respondents did here, specifically that a spreadsheet that was prepared for the investigation and was the primary piece of evidence for the alleged labor expenses was unsupported by corroborating evidence. The Commission found that the respondents "overstated their case when

they argued that there is no evidence to support" the quantification of the identified labor expenses because multiple witnesses, including the complainants' economic expert, and its corporate witness (Vice President for Financial Planning) "testified about the document, how it was created, and why it is accurate, reliable, and credible." *Wet Dry Surface Cleaning Devices*, Inv. No. 337-TA-1304, Comm'n Op. at 83 (Dec. 18, 2023); *see also id.* at 83 n.24 (noting that "[a]lthough Respondents do not have the burden of proof on this issue, Respondents provided no contrary evidence, beyond opinion and conjecture that [the data used to calculate the asserted domestic industry investments] is inaccurate or unreliable"). Here, too, Respondents have "overstated their case."

In this Investigation, there is ample documentary and testimonial evidence for the identified labor and capital investments, including testimony from Serendia's economic expert (Mr. Thomas), Benev's CFO (Mr. Park), and ViOL's CEO (Mr. Lee).

The weight of the evidence also demonstrates and supports a finding that the Benev's allocated domestic labor and capital investments are ***qualitatively*** significant. Staff agrees. (SBr. at 160.). Specifically, Benev's investments in labor and capital are qualitatively significant because: (i) the DI Products are important to Benev and add value to Serendia/Benev DI Products; (ii) Benev's qualifying activities rise above those of a "mere importer;" and (iii) the DI Products are important to Benev's customers and patients. (Tr. (Thomas) at 715:11-717:18; CDX-0003C.0054-57; CX-0918, CX-0896, CX-0887, and CX-0912 (customer/patient praise).).[95] The investments are important to Benev because the

[95] Respondents' economic expert, Dr. Vander Veen, did not offer a rebuttal to Mr. Thomas' qualitative significance analysis. (Tr. (Vander Veen) at 1347:23-1367:21.). Thus, Mr. Thomas' opinion that the domestic industry investments are qualitatively significant is unrebutted. (Tr. (Thomas) at 715:11-717:18; CDX-0003C.0054-57.).

[redacted] (Tr. (Park) at 450:9-16.). The [redacted]. (*Id.*; Tr. (Thomas) at 715:11-16; CDX-0003C.0054; RX-2544C (Park Dep. Tr.) at 85:2-17; CX-1021C (Thomas Schedule).).

Additionally, Benev's domestic activities and investments in labor and capital add value to the DI Products because they relate directly to the FDA development and clearance process, clinical research and trials, quality assurance and product safety tracking, technical customer support, warranty returns and repairs, post-sale training and education, product improvements, development of patient care protocols, and professional installation. (Tr. (Thomas), at715:17-716:15; CDX-0003C.0055; RX-2544C (Park Dep. Tr.) at 73:8-79:24, 85:2-17, 92:15-93:22, 95:18- 99:18, 101:11-103:24, 108:8-22, 126:6-128:25, 158:2-159:12, 183:2-184:6, 220:3-221:3; RX-2551C (July 26, 2023 Na Dep. Tr.) at 367:7-371:8, 379:2-380:22, 389:5-15; RX-2549C (Aug. 9, 2023 Na Dep. Tr.) 76:12-79:16; RX-2566C (Lee Dep. Tr.) at 88:7-89:19, 97:3-98:21, 150:1-6, 183:6-184:1; CPX-0109C; CX-2901C; CX-2902C; CX-1099C; CX-1100C; CX-1101C; CX-2539C; CX-2545C; CX-2552C; CX-0360C; CX-0652C; CX-0504C; CX-0503C; CX-0667C; CX-0459C; CX-0037C; CX-0103C; CX-0068C; CX-0085C; CX-0918; CX-0896; CX-0887; CX-0912; CX-0915; CX-0916; CX-0917; CX-0900; CX-0901; CX-0902; CX-0914; CPX-0117C; CX-0895; CX-0877; CX-0670C.).

Respondents argued that, with respect to significance, Mr. Thomas, "fails to account for Benev's activities that do not relate to the Asserted DI Products - i.e., cosmeceutical products and the 'compounding' or 'cooking,' labeling, and packaging of its products." (RPBr. at 163-64.). However, Benev has not relied upon the so-called cosmeceutical products for purposes of the domestic industry requirement, and thus Benev's activities with respect to non-DI Products

does not negate the significance of its investments with respect to the Sylfirm X. *See Certain Fitness Devices, Streaming Components Thereof, and Sys. Containing Same*, Inv. No. 337-TA-1265, ID at 253 (Sept. 9, 2022) ("[T]he total size of a company relative to its investments in the articles protected by the patent does not negate the possibility that those investments are still 'significant' and 'substantial.'") (citing and quoting *Certain Carburetors and Prods. Containing Such Carburetors*, Comm'n Op. at 28 (Oct. 28, 2019) ("Significance is based on the marketplace conditions regarding the articles protected by the Asserted Patents. The fact that a complainant may have substantial sales of other products is not pertinent to this analysis.")) (unreviewed).

In any event, as explained above, Mr. Thomas did compare Benev's qualifying labor and capital investments with respect to the Sylfirm X to Benev's total operating expenses, i.e., Benev's operating expenses pertaining to all its products. (Tr. (Thomas) at 717:19-718:12 ("[T]he comparative that I'm using is total operating expenses. It [redacted]. So I'm being, I think, very conservative in that regard. As you can see, over this period, the expenditures that I've identified amounted to [redacted] of the total operating expenses, which, again, is very conservative, in light of the fact that the denominator or total operating expenses [redacted]); *id.* at 746:23-747:17 (discussing comparative analysis).).

For the foregoing reasons, the weight of the evidence adduced demonstrates and supports findings that Benev's qualifying investments are both quantitively and qualitatively significant.

XII. RECOMMENDATION ON REMEDY AND BOND

A. Legal Standard

1. A Limited Exclusion Order Is Standard

Pursuant to Commission Rule 210.42, an administrative law judge ("ALJ') must issue a

recommended determination on: (i) an appropriate remedy if the Commission finds a violation of Section 337, and (ii) an amount, if any, of the bond to be posted. 19 C.F.R. § 210.42(a)(1)(ii). When a Section 337 violation has been found, as here, "the Commission has the authority to enter an exclusion order, a cease and desist order, or both." *Certain Flash Memory Circuits and Prods. Containing the Same*, Inv. No. 337-TA-382, Comm'n Opinion on the Issues Under Review and on Remedy, the Public Interest and Bonding, at 26 (June 9, 1997).

Additionally, upon a finding of infringement, 19 U.S.C. § 1337(d) provides for a Limited Exclusion Order ("LEO"), directed to the products of named respondents, excluding any articles that infringe one or more claims of the asserted patents. 19 U.S.C. § 1337(d). A Cease and Desist Order ("CDO") is also appropriate where the evidence demonstrates the presence of commercially significant inventory in the United States. 19 U.S.C. § 1337(f); *see also Certain Crystalline Cefadroxil Monohydrate*, Inv. No. 337-TA-293, Comm'n Opinion, USITC Pub. No. 2391, 1991 WL 790061 at *30-32 (June 1991). Infringing articles may enter upon the payment of a bond during the sixty-day Presidential Review Period. 19 U.S.C. § 1337(j)(3). The bond is to be set at a level sufficient to "offset any competitive advantage resulting from the unfair method of competition or unfair act enjoyed by persons benefiting from the importation." *Certain Dynamic Random Access Memories, Components Thereof and Prods. Containing Same*, Inv. No. 337- TA-242, Comm'n Opinion, 1987 WL 450856 at 37 (Sept. 21, 1987).

2. Exceptions for Warranty Repairs Are Often Considered to be in The Public Interest When There is Evidence to Support the Same

If the Commission determines there has been a violation, it "shall direct that the articles concerned, imported by any person violating the provision of this section, be excluded from entry into the United States unless, after considering the effect of such exclusion upon the public

health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles should not be excluded from entry." 19 U.S.C. § 1337(d)(1). The Commission has determined previously that the public interest weighs in favor of exempting service, repair, and replacement parts from the scope of an LEO for devices sold before issuance of the LEO. *Certain Mobile Devices* at 22; *Certain Liquid Crystal Display Devices* at 27. In addition, the Commission has determined that, to mitigate harm to U.S. consumers, any repair and service exemption may extend until the expiration of the Presidential review period. *Certain Fitness Devices* at 3.

B. A Limited Exclusion Order with a Standard Certification Provision Is Warranted

If there is a finding of violation of Section 337, Serendia has requested that the Commission issue a Limited Exclusion Order ("LEO") "directed to named Respondents and their agents, subsidiaries, affiliates, importers of record, and suppliers excluding from entry into the U.S. products manufactured by or on behalf of named Respondents that infringe any claim of the Asserted Patents." (CBr. at 118.).

Respondents agreed that, if a violation of Section 337 is found, then a LEO is the appropriate form of relief. (RBr. at 104.). However, Respondents have argued that a LEO should include "a certification provision permitting importers to certify that their products do not contain the accused functionality and are thus not subject to exclusion." (*Id.* (citing *Certain Laser Bar Code Scanners and Scan Engines, Components Thereof and Products Containing Same*, Inv. No. 337-TA-551, Comm'n Op. (June 14, 2007)).).

1. Service, Repair, and Replacement

Respondents have argued that a LEO should "include an exception to allow for continued service, repair, or replacement of any products sold by Respondents before the expiration of the Presidential review period." (RBr. at 104 (citing *Certain Fitness Devices, Streaming Components Thereof, and Systems Containing Same*, Inv. No. 337-TA-1265, Reconsideration Notice (May 5, 2023) ("*Certain Fitness Devices*")).). Respondents argued that the LEO exception for service, repair, or replacement should "include replacement parts, such as disposable cartridge tips, so that the utility of the products is not impaired and any warranties can be honored." (RBr. at 104 (citing *Certain Liquid Crystal Display Devices*, Inv. No. 337-TA-631, Comm'n Op. at 27 (July 14, 2009) ("*Certain Liquid Crystal Display Devices*"); *Certain Mobile Devices, Associated Software, and Components Thereof*, Inv. No. 337-TA-744, Comm'n Op., 2012 WL 3715788, at *14 (June 5, 2012) ("*Certain Mobile Devices*").). Here, the service, repair and replacement provision would include exemptions for "replacement parts, such as disposable cartridge tips, so that the utility of products is not impaired and any warranties can be honored." (RBr. at 104.).

Serendia argued that it would not have opposed Respondents' request for an exception for service, warranty, and repair if Respondents had provided evidence that Respondents have existing warranty obligations and that the service, warranty, and repair exemption were limited to articles purchased by U.S. consumers prior to issuance of remedial orders. (CBr. at 118 (citing *Certain Movable Barrier Operators*, Inv. No. 337-TA-1209, LEO, ¶ 1 (Feb. 9, 2022)).). Respondents did not provide evidence during the Hearing to justify the remedial orders that Respondents have requested, even if such an exception is often granted and may be in the public interest here.

Staff's view is that Respondents' requested service, warranty, and repair exception is a public interest issue that falls outside the scope of this proceeding, (SBr. at 168.). To the extent such an exception is recommended, then Staff argued that it should cover infringing products sold through the end of the Presidential Review period. (*Id.* at n.67).

Because neither Jeisys/Cynosure nor EndyMed provided evidence to support their request for a LEO with an exception for importation of parts for service, repair, and replacement, it is not recommended that the Commission adopt Respondents' proposal. A record should be developed that would support Respondents' proposal.

2. No Exemption for Products Capable of Being Operated in a Non-Infringing Manner

Respondents argued that a LEO should not prohibit importation of Accused Products or components thereof that are "not found to infringe or are beyond the scope of this Investigation." (RBr. at 105.).

According to Jeisys/Cynosure, its Accused Potenza System "can be operated in monopolar mode, can be operated using a handpiece and tips that include only a single microneedle, and can be operated using a handpiece and tips that do not include microneedles." (*Id.*). According to Dr. van der Weide's testimony, these three (3) modes of operation are not infringing. (Tr. (van der Weide) at 331:22-332:5 ("the monopolar modality or single or noninvasive tips are not within the asserted claims" of the '836 patent.")). Moreover, Respondents argued that a LEO should not prohibit importation of the Jeisys/Cynosure Accused Potenza System for use in a non-infringing manner. (RBr. at 105-106.).

With respect to Respondent EndyMed, Serendia has not accused EndyMed's PRO and PURE consoles of infringement on their own or when used with handpieces other than the

accused Intensif handpiece. (RBr. at 106.). Dr. Goldberg testified that his infringement opinion was limited to the EndyMed consoles with the Intensif handpiece. (Tr. (Goldberg) at 214:1-3.). Dr. van der Weide also testified that he did not provide an opinion that the EndyMed PRO or PURE consoles infringe on their own or with any handpiece other than the accused Intensif handpiece. (Tr. (van der Weide) at 390:6-13.). Therefore, Respondents argued that a LEO should "exclude EndyMed's PRO and PURE consoles." (RBr. at 106.).

Serendia argued that Respondents' requested carveouts for both would "eviscerate any remedial relief for their violation of Section 337." (CBr. at 119.). Serendia cited Commission precedent which states that the scope of a remedial order generally is not limited to the products that were adjudicated to infringe. (*Id.* (citing *Certain Audio Players and Controllers, Components Thereof, and Products Containing the Same*, Inv. No. 337-TA-1191, Comm'n Op. at 24 (Feb. 1, 2022) ("*Certain Audio Players*"); *Certain Human Milk Oligosaccharides & Methods of Producing Same*, Inv. No. 337-TA-1120, Comm'n Op. at 19-20 (June 20, 2020) ("*Certain Human Milk Oligosaccharides*").).

Staff's view is that it is "black letter Commission law that exclusion orders are not limited to products that were actually adjudicated to infringe the Asserted Patents." (SBr. at 166 (citing *Certain Audio Players* at 24; *Certain Human Milk Oligosaccharides* at 19-20).). According to Staff, the type of carveout that Respondents have requested, i.e., a carveout for importation of products capable of being used in a non-infringing manner, "is only appropriate if a specific product has been adjudicated and explicitly found not to infringe." (SBr. at 167.). Therefore, Staff has recommended that the scope of products subject to any remedial order "are those products specified in the Notice of Institution of Investigation, *i.e.*, "RF microneedling dermatologic treatment devices and components thereof." (SBr. at 166.).

Serendia and Staff both correctly rely on the Commission's decisions in *Certain Audio Players* and *Certain Human Milk Oligosaccharides*. Both of those decisions stand for the proposition that the scope of a remedial order is not limited by the products adjudicated as infringing in this Investigation. Respondents did not identify contrary authority. Therefore, it is not recommended that the Commission include the exemption or carveouts for infringing Accused Products that also have non-infringing uses as Respondents have requested.

3. No Delay for Respondents to Develop Alternative, Non-Infringing Products

Respondents argued that a remedy should be delayed to permit Respondents "an opportunity to develop alternative, non-infringing products in order to mitigate the significant unwarranted impact on consumers, the Respondents, and the economy." (RBr. at 107.).

Respondents asserted that "an economically reasonable adjustment period is 12-24 months, given the technical nature of the products and potentially required FDA review." (*Id.* (citing *Certain LTE- and 3G-Compliant Cellular Communications Devices*, Inv. No. 337-TA-1138, RD at 3, 31-33 (Apr. 3, 2020) ("*Cellular Communications Devices*"); *Certain UMTS and LTE Cellular Communication Modules and Products Containing the Same*, Inv. No. 337-TA-1240, RD (Apr. 15, 2022) ("*Cellular Communication Modules*"); *Certain Chemical Mechanical Planarization Slurries and Components Thereof*, Inv. No. 337-TA-1204, Comm'n Op. at 42-43 (Jan. 6, 2022)).).

Serendia argued that Respondents failed to elicit evidence during the Hearing about the development process for their proposed, alternative, non-infringing products, or how the 12-24 month figure for the delay of remedial orders was calculated. (CBr. at 119.). According to Serendia, Respondents have "wholly failed to justify why such continuing infringement should

be authorized." (*Id.*).

Staff's view is that Respondents' requested delayed implementation is based on public interest grounds. (SBr. at 168.). Since public interest was not delegated to the ALJ, Staff considers Respondents' requested delayed implementation to be beyond the scope of the present proceeding. (*Id.*).

There have been instances in which implementation of a remedy has been justified by public-interest related evidence. For example, in *Cellular Communications Devices*, the respondents argued that entry of the LEO should be delayed 12-24 months "to provide sufficient time for Respondents to implement a potential design-around or negotiate a FRAND royalty with INVT, given that INVT claims its patents are SEPs." *Cellular Communications Devices* at 31-32. However, there was evidence to support that recommendation. (*Id.* at 32-33.).

In *Cellular Communications Modules*, the ALJ found that certification of a new non-infringing communication module could take "up to 19 months, and re-design and re-certification of a downstream device to transition for a new module from a different supplier can take 8 to 24 months. The evidence shows that a delay of less than 12 months [for entry of the exclusion order] would be insufficient, and would further exacerbate the worldwide semiconductor shortage already affecting Philips, respondents, and respondents' downstream customers." *Cellular Communications Modules* at 32. Therefore, the ALJ found that "a delay of 12 months in entry of any exclusion order will be required to mitigate the effects on third parties." *Id.* at 32-33.

However, neither *Cellular Communications Devices* nor *Cellular Communications Modules* applies here. There is no evidence to support delay consistent with the four (4) public interest factors. 19 U.S.C. § 1337(d)(1). Indeed, public interest fact-finding was not delegated;

and thus there is no evidence of the same in the record. Moreover, Respondents did not offer an evidence -based justification why such a delay is warranted. The Accused Products are largely used for cosmetic or "aesthetic" purposes even though the devices themselves may require medical clearance by the FDA. (*See infra*.). Indeed, the Accused Products, like the DI Products, concern devices that are largely used for elective treatment. Therefore, it is the recommendation here that the Commission not delay implementation of remedial orders. Currently, there is no evidentiary basis for making such a recommendation.

C. A Cease and Desist Order Is Warranted

In the event of a finding of violation of Section 337, Serendia has also requested that the Commission issue a permanent cease and desist order ("CDO") that would prohibit Respondents from, *inter alia*, importing, selling for importation, marketing, advertising, offering for sale, offering for lease, selling, leasing, distributing, licensing, using, or otherwise transferring the infringing products within the United States. (CBr. at 120.).

The Commission has held that a CDO should issue when "with respect to the imported infringing products, respondents maintain commercially significant inventories in the United States or have significant domestic operations that could undercut the remedy provided by an exclusion order." *Certain Air Mattress Systems, Components Thereof, and Methods of Using the Same*, Inv. No. 337-TA-971, Comm'n Op. at 49 (June 20, 2017).

Serendia argued that a CDO should issue because Respondents have "stipulated to the amount of inventory held in the U.S., and that they either '(i) keep, store, hold, warehouse, maintain, or control a ***commercially significant inventory***,' or (ii) ***would not contest the commercial significance*** of their inventory." (CBr. at 120 (citing JX-0017C (EndyMed Importation and Inventory Stipulation ("EndyMed Stipulation")); JX-0020C (Jeisys and

Cynosure Importation and Inventory Stipulation ("Potenza Respondents Stipulation")) (emphasis in original).). According to the [redacted]. (JX-0017C.0002, ¶ 6.).

According to the [redacted]. (JX-0020C.0002-0003, ¶ 6.). According to [redacted] (JX-0017C.0002, ¶ 6; JX-0020C.0002-0003, ¶ 6.).

With respect to Respondent Jeisys, Serendia argued that a CDO should issue because [redacted] (CBr. at 121 (citing CX-1047C (Kang Deposition Transcript)[96] at 127:16-129:14) (emphasis in original).).

Respondents argued that "Serendia has not shown that any Respondent currently maintains a commercially significant inventory of infringing products. In addition, Serendia has not compared importation or inventory information to any reliable metric and therefore fails to show commercial significance." (RBr. at 107 (citing *Certain Wireless Consumer Electronics Devices and Components Thereof*, Inv. No. 337-TA-853, 2013 WL 5821012, at *208 (Sep. 6, 2013)) ("*Wireless Consumer Electronics Devices*".).

[96] Mr. Don Hwan Kang is Jeisys's CEO and corporate designee.

Respondents are correct that the Commission has traditionally issued a CDO if there is evidence of either a commercially significant inventory in the United States or significant domestic operations[97] "that would undercut the remedy provided by an exclusion order." *See, e.g., Certain Automated Put Walls and Automated Storage and Retrieval Systems, Associated Vehicles, Associated Control Software, and Component Parts Thereof*, Inv. No. 337-TA-1293, Comm'n Op. at 33-34 (August 17, 2023). However, Section 337(f)(1) does not list any requirements for issuance of a CDO, except that a CDO should not issue if the four public interest factors weigh against it. 19 U.S.C. § 1337(f)(1); *see also Certain Tobacco Heating Articles and Components Thereof*, Inv. No. 337-TA-1199 ("*Tobacco Heating*"), Comm'n Op. at 49-54 (Oct. 19, 2021) (Commissioner Schmidtlein expressing her view that neither the inventory nor domestic operations need to be "commercially significant" for a CDO to issue, rather the presence of some infringing domestic inventory or domestic operations, regardless of commercial significance, provides the basis to issue a CDO).

Staff's view is that Respondents failed to identify in their Pre-Hearing Brief which of the named Respondents do not have commercially significant inventory of infringing product, in violation of Ground Rule 7.2, and so Respondents' contention may be deemed waived, abandoned, or withdrawn. (SBr. at 163.). Therefore, Staff recommends that the Commission issue a CDO directed to each of the named Respondents, except Jeisys. (*Id.* at 164.).

With respect to Jeisys, Staff's view is that, because the Potenza Respondents Stipulation says Cynosure controls a commercially significant inventory and contains inventory data only for Cynosure, not Jeisys, Serendia "has not provided evidence that Jeisys maintains any domestic

[97] None of the Parties have argued that any of the Respondents have "significant domestic operations."

inventory, or has significant domestic operations." (*Id.*). Staff argued that a CDO against Jeisys would not address Serendia's concern that Jeisys would circumvent the LEO by finding another (non-Respondent) U.S. distributor, because "CDO's do not prohibit a foreign entity from conducting activities ***outside*** of the United States." (SBr. at 165 (emphasis in original).).

Staff also argued that Respondents acknowledged that a LEO would prevent it from making sales for importations of infringing products. (SBr. at 165.). Therefore, because there is no evidence that Jeisys maintains inventory of the Accused Products or has significant domestic operations, and because a LEO would prohibit Jeisys from selling infringing products for importation to any new, non-Respondent distributor, Staff would not recommend a CDO issue against Jeisys.

The recommendation here is that a CDO should not issue against Jeisys. However, a CDO should issue against Cynosure and EndyMed. With respect to Jeisys, it seems clear that Jeisys itself does not maintain inventory of the Accused Products in the United States, let alone that it has operations in the United States. Serendia relied on the Respondents' Stipulations to support its contention that Respondents have a commercially significant inventory of the Accused Products.[98] With respect to Serendia's concern that Jeisys may attempt to circumvent the LEO by finding a new U.S. distributor, a LEO would address that concern because Jeisys would be prohibited from selling for importation to the new U.S. distributor any infringing product. For the foregoing reasons, a CDO is recommended against Respondents Cynosure and EndyMed.

[98] In the *Wireless Consumer Electronics Devices* decision cited by Respondents, the stipulations at issue were not sufficient evidence because they did not represent that inventory in the U.S. was commercially significant. *Wireless Consumer Electronics Devices* at *208. That is not the situation here with respect to EndyMed or Cynosure.

D. Bond During the Presidential Review Period Is Warranted

Upon issuance of a LEO or CDO, articles excluded from entry by the LEO or subject to the CDO are entitled to entry during the Presidential Review Period ("PRP") under bond in an amount the Commission determines to be sufficient to protect the complainant from injury. 19 U.S.C. § 1337(j)(3).

The Commission frequently sets the bond based on the difference in sales prices between the patented domestic product and the infringing product. *See, e.g., Certain Microsphere Adhesives, Process for Making Same, and Prods. Containing Same, Including Self-Stick Repositionable Notes*, Inv. No. 337-TA-366, USITC Pub. No. 3949, Comm'n Opinion at 24 (Jan. 1996). In other instances where a direct comparison between a patentee's product and the accused product is not possible, the Commission has set the bond at a reasonable royalty rate. *See, e.g., Certain Integrated Circuit Telecommunication Chips and Prods. Containing Same, Including Dialing Apparatus*, Inv. No. 337-TA-337, Comm. Opinion at 41-43 (Aug. 3, 1993). Commission precedent allows for a 100 percent bond when it is not practical or possible to set the bond based on price differential. *Certain Voltage Regulators, Components Thereof and Prods. Containing Same*, Inv. No. 337-TA-564, Comm'n Opinion at 79 (Public Version Oct. 19, 2007). The purpose of the bond is to protect the complainant from any injury. 19 U.S.C. § 1337(j)(3); 19 C.F.R. §§ 210.42(a)(1)(ii), 210.50(a)(3).

Complainants bear the burden of establishing the need for a bond, including the amount of bond. *See, e.g.*, *Certain Rubber Antidegradants, Components Thereof & Prods. Containing Same*, USITC Pub. No. 3975, Inv. No. 337-TA-533, Comm'n Opinion at 40 (April 2008); *Certain Coenzyme Q10 Products and Methods of Making Same*, Inv. No. 337-TA-790, Initial and Recommended Determination (Sept. 27, 2012) (recommending Commission not impose a

bond because complainant failed in its burden to demonstrate the appropriate bond amount); *Certain Mobile Telephones and Wireless Communication Devices Featuring Digital Cameras, and Components Thereof*, Inv. No. 337-TA-703, Recommended Determination (Jan. 24, 2011) (recommending no bond because complainant did not meet its burden in providing evidence on the necessity of a bond); *Certain Liquid Crystal Display Devices and Prods. Containing the Same*, Inv. No. 337-TA-631, Comm'n Opinion at 27-28 (July 14, 2009) (setting zero bond because complainant "simply claimed that it was impossible to conduct a price differential analysis" and "should not benefit from a lack of any effort to identify" relevant pricing information, particularly that which is in its possession).

1. EndyMed Pure and EndyMed Pro

Serendia claimed that there is no dispute that it would be injured if sales of infringing articles were continued during the PRP, and so there is no dispute that a bond is warranted. (CBr. at 122.). According to Serendia, the only dispute is over how to calculate the amount of the bond. (*Id.*). Serendia requested the following bond amounts for the indicated Accused Products: [redacted]. (*Id.*). Serendia's support for the proposed bond amounts consists of the analysis and opinions of its expert, Mr. Vincent Thomas, who calculated a price differential between Serendia's Sylfirm X DI Product and each of the EndyMed Pure product and the EndyMed Pro product. (*Id.*).

Mr. Thomas testified that [redacted]. (Tr. (Thomas) at 722:1-723:5; CX-1023C [redacted]; CX-0608C [redacted]; CX-0062C (EndyMed's

interrogatory responses including its July 25, 2023 Second Supplemental Response to Interrogatory No. 4, which provides pricing information for EndyMed Pure and EndyMed Pro).).

According to Mr. Thomas's testimony, based on his comparison analysis between Serendia's Slyfirm X DI Products and the EndyMed products,

Serendia contended that Respondents' expert, Dr. Vander Veen, did not offer a contrary analysis or opinion. (Tr. (Vander Veen) at 1420:21-1421:1, 1421:25-1422:3.).

Respondents argued that Mr. Thomas's price comparison is unhelpful because it fails to account for "any differences in features or complementary services that may account for price differences." (RBr. at 108-109.).

Staff's view is that the price differentials that Mr. Thomas calculated are appropriate bond amounts for the EndyMed Pro and EndyMed Pure products. (SBr. at 169.).

Respondents' argument that special features or complimentary services may explain the price differential between Sylfirm X and the EndyMed products is unsupported attorney argument. Neither Respondents nor Dr. Vander Veen identified special features of, or services for, the EndyMed products that would support the price differential between Sylfirm X and EndyMed Pure or EndyMed Pro so as to disregard let alone undermine the product comparison and bond analysis that Mr. Thomas conducted. Therefore, it is recommended that the Commission enter a bond .

2. Accused Potenza Product

Serendia conceded that the [redacted]. Therefore, Serendia also conceded that calculating the bond amount based on a price differential analysis would not be appropriate. (CBr. at 122-123.). Accordingly, Serendia argued that the amount of the bond for the Potenza Product should [redacted] based on a reasonable royalty rate analysis. (*Id.* (citing *Certain Integrated Circuit Telecommunication Chips*, Inv. No. 337-TA-337, Comm'n Op. at 41 (1995)).).

The source of Serendia's proposed [redacted] bond on the Jeisys/Cynosure accused product is a patent licensing agreement between [redacted] that was executed in February 2022, (CX-0765C, "Patent License Agreement") in which [redacted]. (CX-0765C; Tr. (Thomas) at 723:6-724:5.). The [redacted] royalty rate [redacted] (CX-0765C.0005, § 3.1 ("Royalties").). Respondents' expert Dr. Vander Veen acknowledged that, because Serendia had to bring this lawsuit against Respondents, the royalty rate discount based on [redacted] would not apply to Respondents. (Tr. (Vander Veen) at 1422:25-1423:10.). Dr. Vander Veen also acknowledged that several other entities have been licensed to the Asserted Patents, and so [redacted] (*Id.* at 1423:11-1425:2.).

Respondents agreed in principle that a bond should be based on a reasonable royalty rate. (RBr. at 109; RRBr. at 90.). However, according to Respondents, the appropriate bond rate is no more than [redacted] because the patent licensing agreement with Benev "did not result from an arm's-length transaction, suggesting that the license agreement was unnecessary and

litigation-driven." (RBr. at 109; *see also* Tr. (Vander Veen) at 1366:15-1367:30.).

Specifically, relying on Dr. Vander Veen's testimony, Respondents argued that, at the time that Serendia and Benev executed their patent licensing agreement for the Serendia Sylfirm X DI Product, Benev already had an implied license to the Asserted Patents arising out of its distribution agreement with the prior owner of the Asserted Patents. (Tr. (Vander Veen) at 1367:4-8 [redacted] CX-0763C [redacted].).

Respondents also argued that Serendia "has made it impossible for Respondents to determine the arms-length royalty rate paid by competitors to license the Asserted Patents by moving to shield agreements made with Respondents in this Investigation from discovery or examination. Having made that choice, Serendia should not be allowed to rely on less reliable evidence to advance its bond arguments." (RBr. at 109.).

It is true that other respondents have been terminated from this Investigation pursuant to settlement agreements. *See, e.g.,* Order Nos. 51, 53. However, Respondents did not cite to evidence that Serendia attempted to shield those settlement agreements from Respondents for the purpose of obfuscating a bond analysis. Similarly, Respondents did not provide legal authority that a complainant's failure to present its prior settlement agreements with terminated respondents means the Commission should reject that complainant's bond arguments. Respondents' argument is not supported legally.

Serendia responded that Respondents' argument about the terminated Respondents' licenses should be disregarded because "[a]ll Respondents consented to limited service of those licenses, and none of them objected to limited service on the grounds that those licenses could be relevant to bond." (CBr. at 123 n.56 (citing Tr. (Vander Veen) at 1425:24-1426:17).). Serendia has a point that Respondents did not, before their Post-Hearing Brief, raise the issue of the relevance of the terminated respondents' settlement agreements to bond.

Staff's view is that the royalty rate in the Patent License Agreement is not useful for setting a bond rate because "Benev is selling the DI Product—not a competing product." (SBr. at 170.). Since Respondents Jeisys, Cynosure, and EndyMed conceded that a [redacted] bond is "economically reasonable," Staff suggests that a [redacted] bond is warranted for the Potenza products. (*Id.* (citing RPrHB at 173, Tr. (Vander Veen) at 1366:18-20, 1531:11-17).).

Staff's argument that the [redacted] royalty rate from the Patent License Agreement is not applicable because it is for the Sylfirm X DI Product, not a competing product, is not fully supported either. The Sylfirm X DI Product and the Accused Potenza Product both practice the Asserted Patents. They are presumably comparable absent evidence to the contrary. There is no evidence, and Respondents presented none, that the Jeysis/Cynosure Accused Potenza Product is different from the Sylfirm X DI Product such that it would result in the Accused Potenza Product being subject to a lower reasonable royalty rate than the Sylfirm X DI Product.

Respondents' argument that the [redacted] royalty rate from the Patent License Agreement is not applicable because it did not result from an arm's-length transaction is also unpersuasive. Benev's distribution agreement with VIOL Co., Ltd. ("VIOL"), executed in September 2020, (CX-0763C, "Distribution Agreement") with the prior owners of the Asserted Patents, out of which Benev's implied license arises, [redacted]

. (CX-0763C.0003, § 6.1, CX-0763C.0008.). Moreover, the (CX-0763C.0003, § 6.4.). In other words, in February 2022 when the Patent License Agreement was executed, Benev was free to either . Instead, Serendia chose to . (CX-0765C.0003, § 1.5.). In return, Benev chose to pay a royalty. (*Id.*, § 3.1.). The negotiations between Benev and ViOL were negotiated with each obtaining certain commercial rights. The negotiations appear to be arms-length. Even if arguably not so, there is no other license agreement against which to compare a reasonable royalty rate.

With respect to Respondents' argument that Serendia cannot rely on the Patent License Agreement with Benev, that is not so. The 2020 Distribution Agreement, (CX-0763C), and the 2022 patent licensing agreement, (CX-0765C), are both in evidence and have been considered. In the absence of other evidence of a reasonable royalty rate, the royalty rate set in the 2022 patent licensing agreement is relevant and reasonable. Therefore, it is recommended that the Commission enter a bond of for the Accused Potenza Products. Alternatively, if the Commission finds that the royalty rate in the Patent License Agreement is inapplicable to the Accused Potenza Products, then it is recommended that a bond rate be entered on value because Respondents conceded that a bond is "economically reasonable." (RBr. at 109.).

XIII. WAIVER OR WITHDRAWAL OF RESPONDENT'S DEFENSES

Jeisys and Cynosure did not raise in Respondents' Pre-Hearing Brief or offer any evidence during the Hearing to support their: (i) Fifth Affirmative Defense of Inequitable Conduct and Unclean Hands (Jeisys and Cynosure Resp. at ¶¶ 8-53); (ii) Seventh Affirmative Defense of Patent Exhaustion and/or First Sale Doctrine (*id.* at ¶ 56); (iii) Eighth Affirmative Defense of Prosecution History Estoppel (*id.* at ¶ 57); (iv) Ninth Affirmative Defense of Prosecution Laches (*id.* at ¶ 58); (v) Eleventh Affirmative Defense of Waiver and/or Estoppel (*id.* at ¶ 60); (vi) Thirteenth Affirmative Defense of Relief Sought Not in the Public Interest (*id.* at ¶ 62); and (vii) Fourteenth Affirmative Defense of Ensnarement of Prior Art (*id.* at ¶ 63). As noted above in Section II.A, Jeisys and Cynosure withdrew their Sixth Affirmative Defense of Express or Implied License.

EndyMed did not raise in Respondents' Pre-Hearing Brief or offer any evidence during the Hearing to support their: (i) Third Affirmative Defense of No Import Violation (EndyMed Resp. at ¶¶ 12.14, 12.15); (ii) Fifth Affirmative Defense of Inequitable Conduct (*id.* at ¶¶ 12.18-12.31); and (iii) Sixth Affirmative Defense of No Priority Claim (*id.* at ¶¶ 12.32, 12.33).

Consequently, it is a finding of this decision that Respondents have withdrawn, waived and/or abandoned these Affirmative Defense consistent with Ground Rules 7.2 and 10.1. *Kinik Co. v. Int'l Trade Comm'n*, 362 F.3d 1359, 1367 (Fed. Cir. 2004).

XIV. CONCLUSIONS OF FACT OR LAW: THIS INITIAL DETERMINATION FINDS A SECTION 337 VIOLATION BASED UPON INFRINGEMENT OF U.S. PATENT NO. 10,618,951

1. Jurisdiction and standing requirements are satisfied.

2. Claims 1, 9, and 22 of U.S. Patent No. 9,480,836; claims 11 and 16 of U.S. Patent No. 9,320,536; claim 14 of U.S. Patent No. 9,775,774; and claims 5, 13, and 18 of U.S. Patent

No. 10,869,812 have been found to be directly and indirectly infringed.

3. Serendia's DI Products have been found to practice one or more claims of the Asserted Patents.

4. The Asserted Patents are valid and specifically have not been found to be invalid.

5. Serendia's domestic activities with respect to their DI Products have been found to satisfy the economic prong of the domestic industry requirement under 19 U.S.C. § 337(a)(3(B).

6. A Limited Exclusion Order and Cease and Desist Orders are recommended based upon the evidence and findings of infringement.

7. A Bond is recommended.

The lack of discussion of any matter raised by the Parties, or any portion of the record, does not indicate that it has not been considered. Rather, any such matter(s) or portion(s) of the record has/have been determined to be irrelevant, immaterial, or meritless. Arguments made on briefs, which were otherwise unsupported by record evidence or legal precedent, have been accorded no weight.

XV. CONCLUSION AND ORDER

This Initial Determination on Violation of Section 337 of the Tariff Act of 1930 is certified to the Commission. All orders and documents, filed with the Secretary, including the exhibit lists enumerating the exhibits received into evidence in this Investigation, that are part of the record, as defined in 19 C.F.R. § 210.38(a), are not certified, since they are already in the Commission's possession in accordance with Commission Rules. *See* 19 C.F.R. § 210.38(a). In accordance with 19 C.F.R. § 210.39(c), all material found to be confidential under 19 C.F.R. § 210.5 is to be given *in camera* treatment.

After the Parties have provided proposed redactions of confidential business information ("CBI") that have been evaluated and accepted, the Secretary shall serve a public version of this ID upon all parties of record. The Secretary shall serve a confidential version upon counsel who are signatories to the Protective Order (Order No. 1) issued in this Investigation.

Pursuant to 19 C.F.R. § 210.42(h), this Initial Determination shall become the determination of the Commission unless a party files a petition for review pursuant to 19 C.F.R. § 210.43(a) or the Commission, pursuant to 19 C.F.R. § 210.44, orders on its own motion a review of the Initial Determination or certain issues therein.

Within fourteen (14) days of the date of this document, the Parties shall submit to the Office of Administrative Law Judges a joint statement whether they seek to have any portion of this document deleted from the public version. The Parties' submission must include a copy of this ID with yellow highlighting, with or without red brackets, that indicate words, phrases, sentences, or paragraphs that they assert contain CBI and that they ask to be deleted from the public version. The Parties' submission shall also include an index identifying the pages of this document where proposed redactions are located. The Parties' submission concerning the public version of this document need not be filed with the Commission Secretary.

SO ORDERED.

MaryJoan McNamara
Administrative Law Judge

CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the parties listed have entered an appearance in the above captioned investigation, and a copy of the PUBLIC CERTIFICATE OF SERVICE was served upon the following parties via first class mail and air mail where necessary.

Document	Security	Document Type	Official Rec'd	Title
840954	Public	ID/RD - Final on Violation	01/13/2025 03:22 PM	Initial Determination on Violation of Section 337 and Recommended Determination on Remedy and Bond

Service Date: January 13, 2025

/s

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