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 [redacted]

. (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.

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[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

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[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 [redacted]. (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