*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

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[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 [redacted].). 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

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[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

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[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);

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[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

(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.

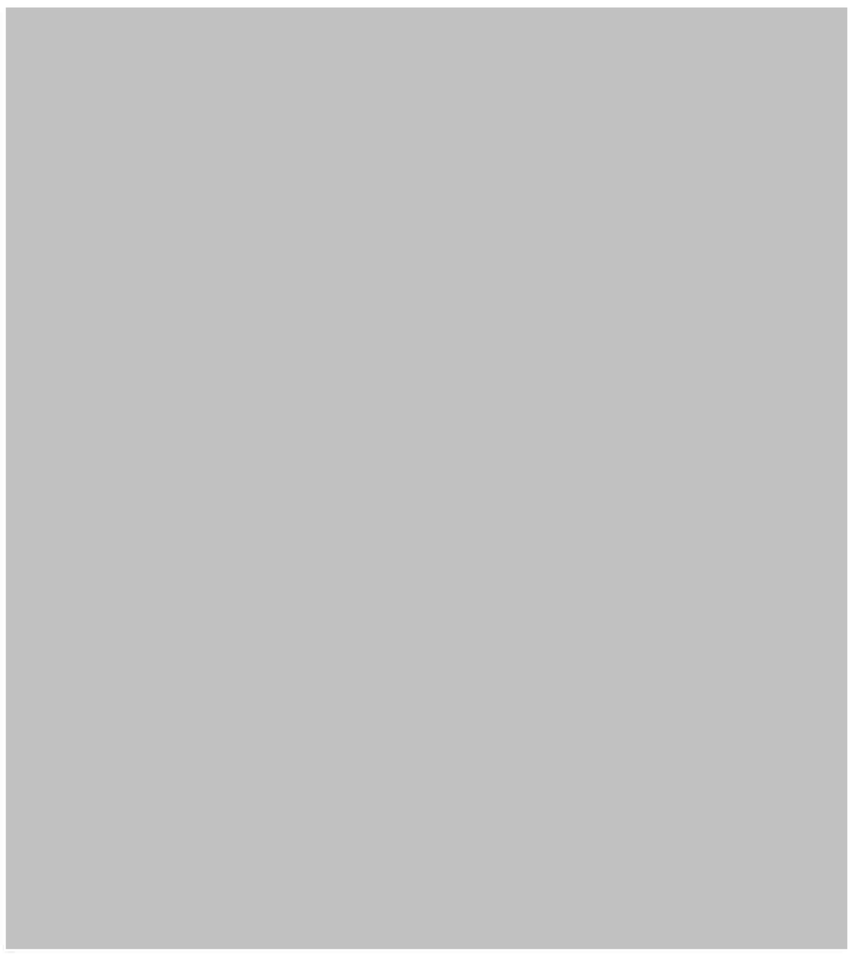
**c) 11[a2]: "the deployable needle assembly mechanically separatably from the proximal end and including a plurality of extendable needles, a plurality of the extendable needles extendable from a deployable needle assembly end surface"**

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]

below, which is the

. (*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.).

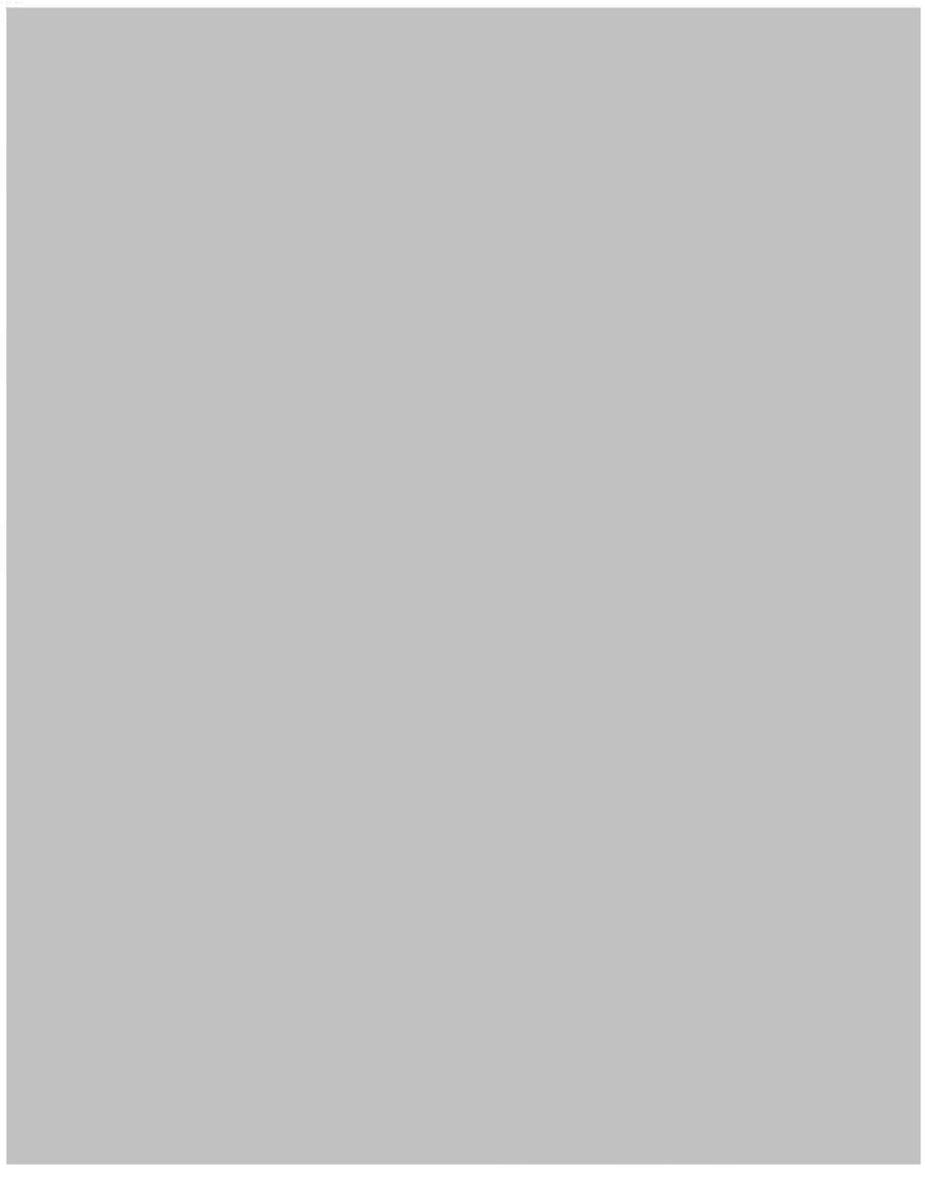
For the reasons discussed above, Serendia has proven by a preponderance of evidence that the Accused Products meet this limitation of claim 11 of the '536 patent.

**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]

[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 [redacted]

[redacted]



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

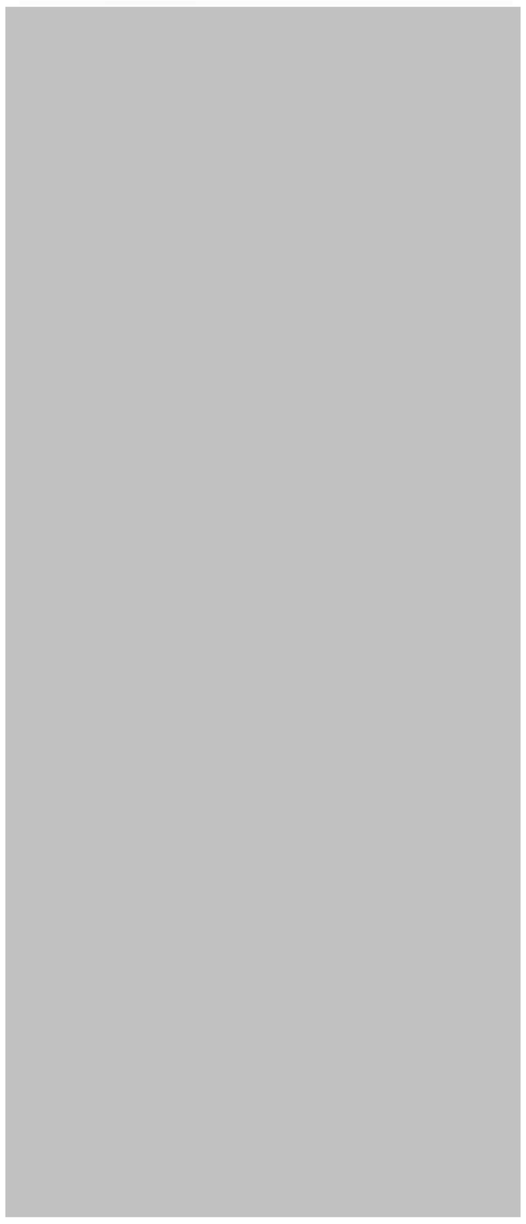
Moreover, Respondents failed to present evidence that would support such an incorrect reading of the claim or raise a specific contention in their Post-Hearing Reply Brief. (RRBr. at 59.). Thus, argument on this issue is deemed waived under Ground Rule 10.1.

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).).

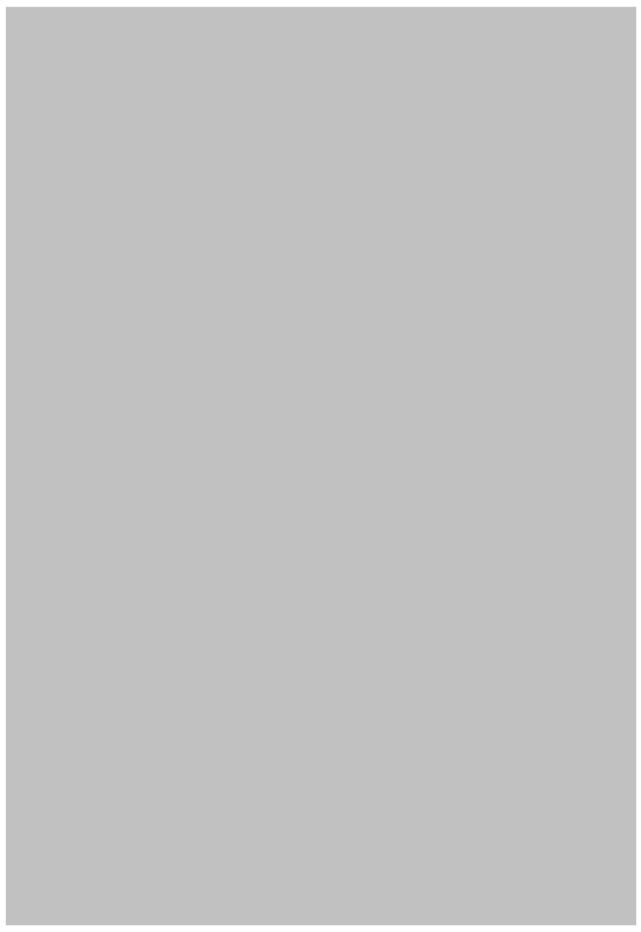
**Figure 24: Crosby Demonstrative Illustrating the Claimed Deployable Needle Assembly**



(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

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[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.

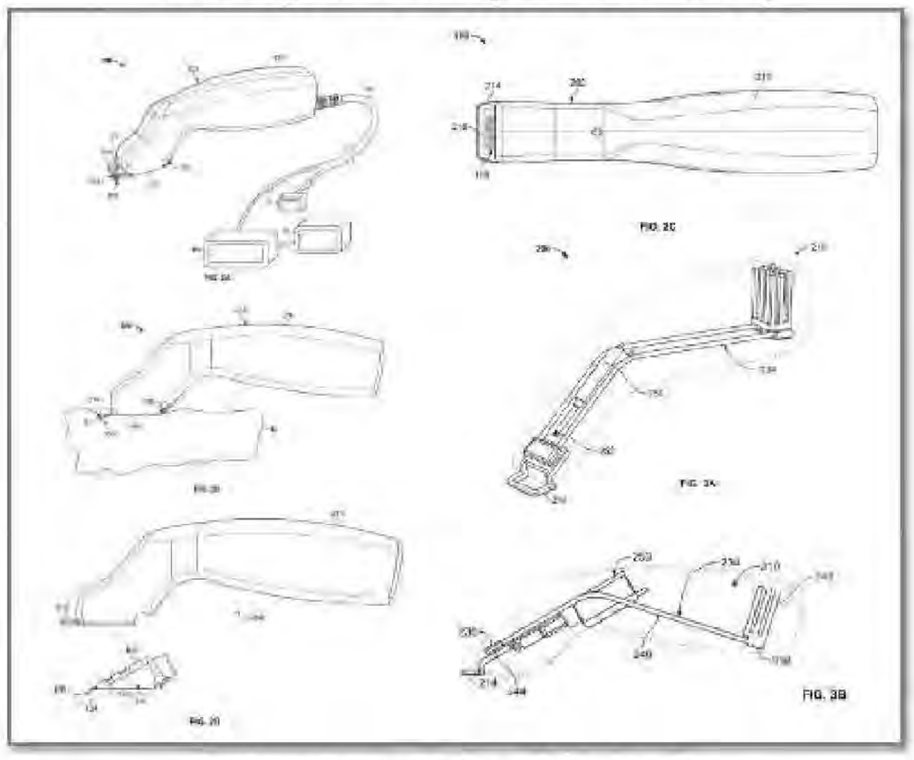
[70] Although this version of Mehta was not considered during prosecution of the '536 patent, the evidence demonstrates that Mehta has the same relevant disclosures as U.S. Pat. No. 8,540,705 ("Mehta '705," CX-1095), which was considered during prosecution of the related '812 patent. (*See* Tr. (Woloszko) 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.

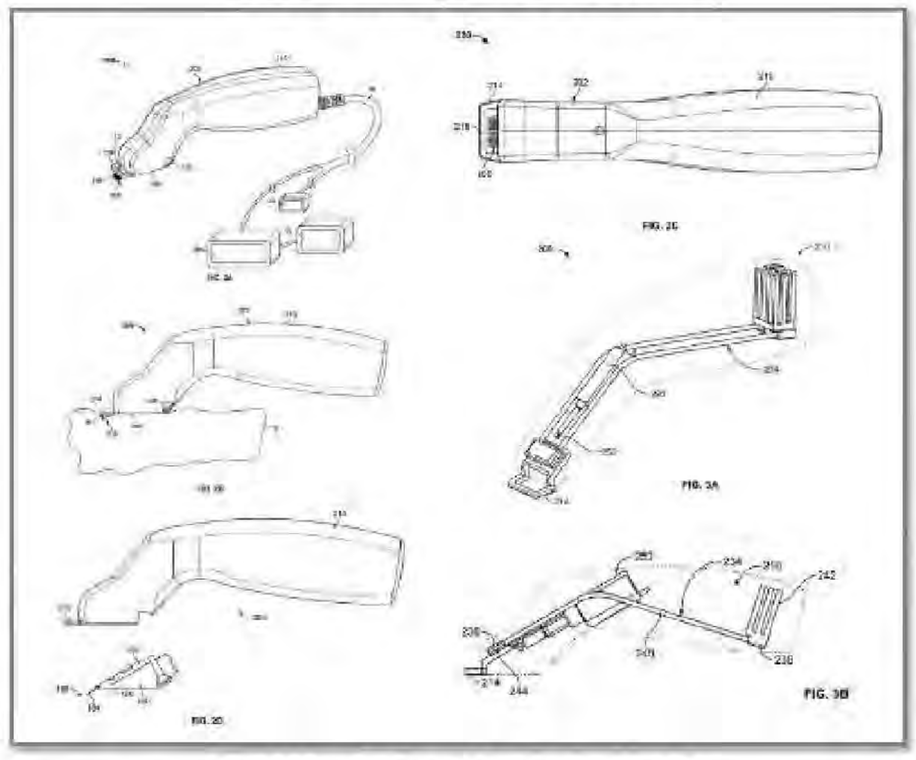
## Figure 26: Crosby Demonstratives Comparing Figures in Mehta References

**Mehta (relied on by Dr. Woloszko)**



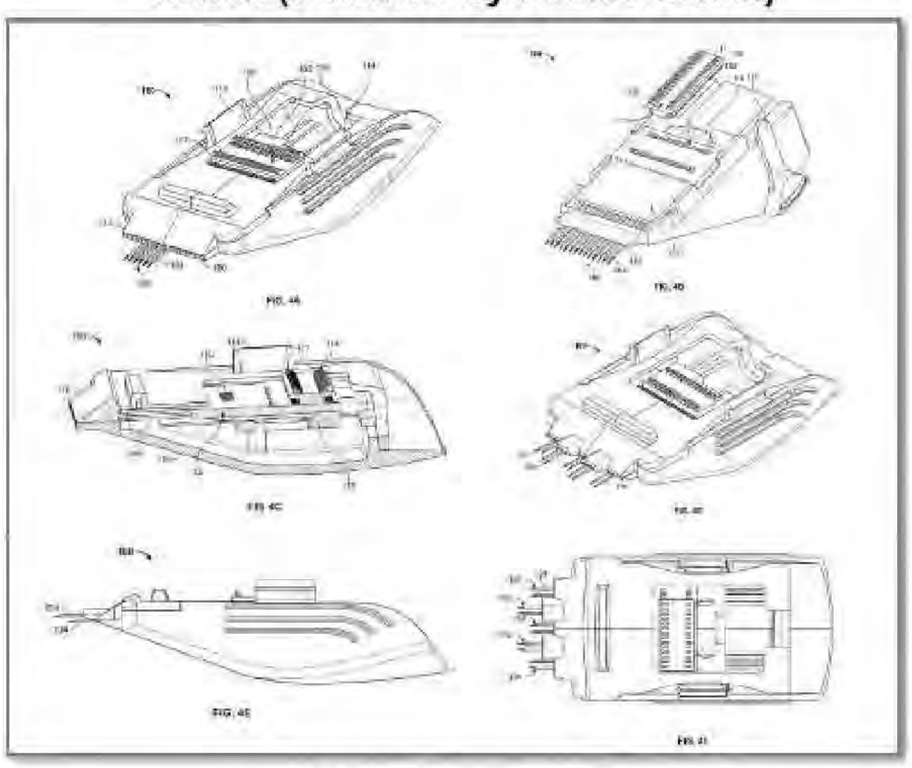
CX-3023 (Mehta), Figs. 2A-D, 3A, 3B;
*see also id.*, 9:34-10:39 (description of Fig. 2A)

**Mehta '705 (before USPTO)**



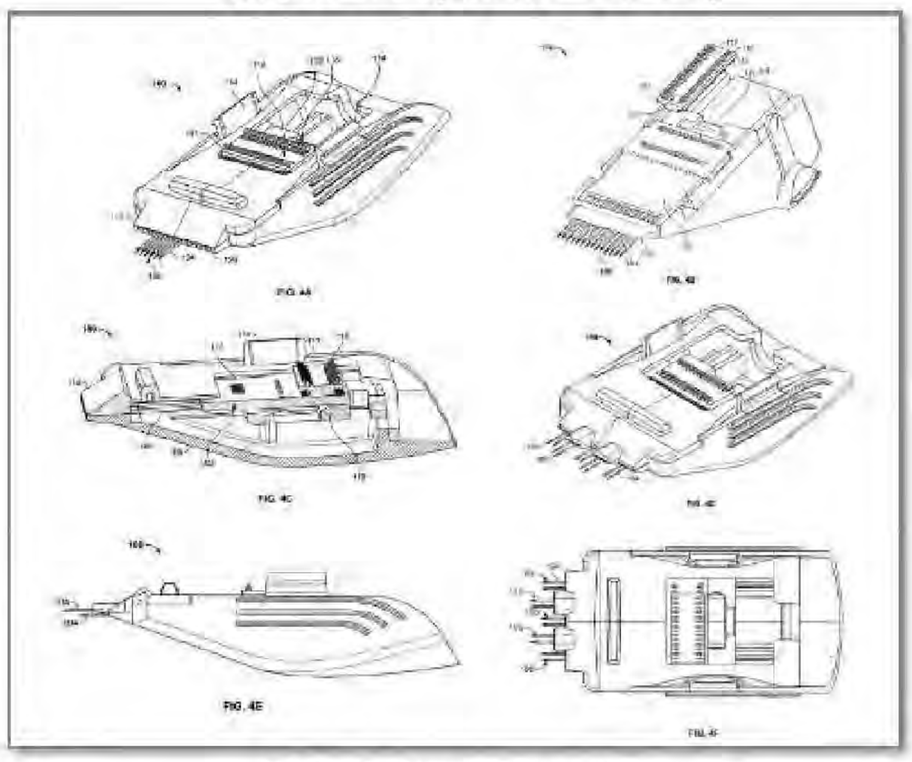
CX-1095 (Mehta '705), 2A-D, 3A, 3B;
*see also id.*, 10:20-11:25 (description of Fig. 2A)

**Mehta (relied on by Dr. Woloszko)**



CX-3023 (Mehta), 4A-F;
*see also id.*, 15:27-16:41 (description of Fig. 4A)

**Mehta '705 (before USPTO)**



CX-1095 (Mehta '705), 4A-F;
*see also id.*, 15:63-17:18 (description of Fig. 4A)

(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.).

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

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

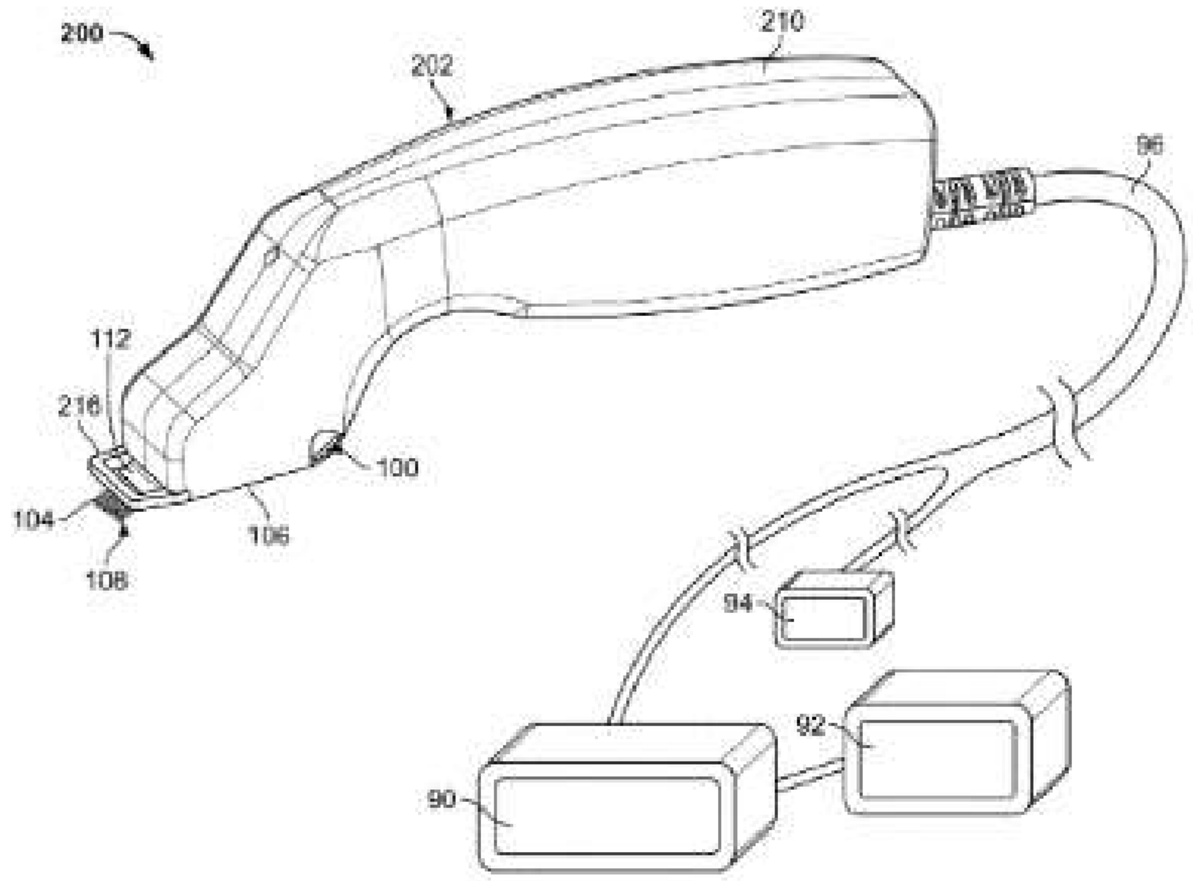



FIG. 2A

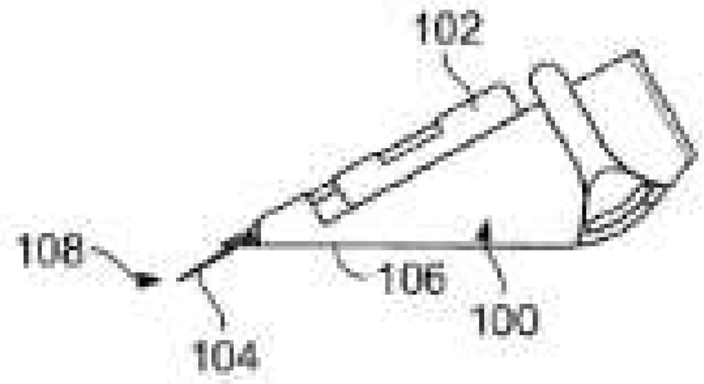



FIG. 2D

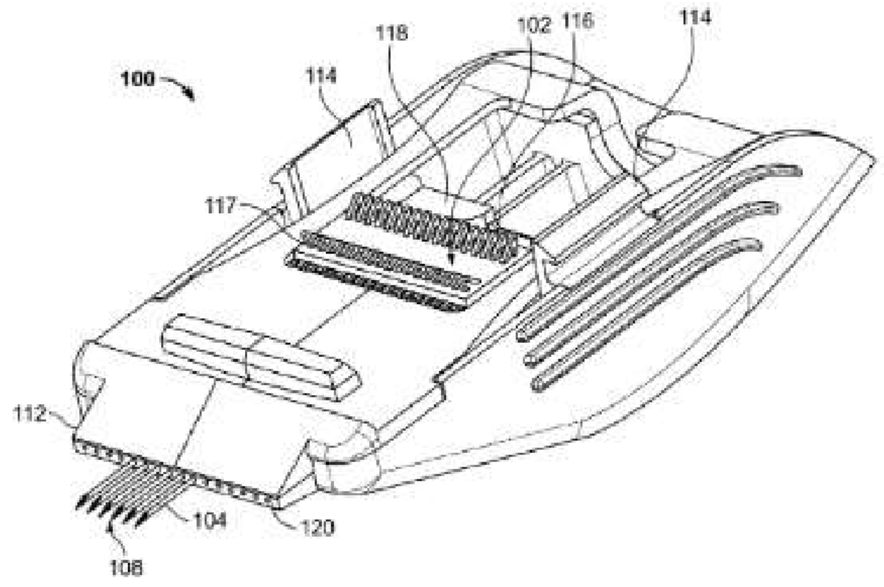



FIG. 4A

(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.).

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[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.