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

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

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

[55] Respondents' citation is to a withdrawn exhibit.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

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

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

iii. Coagulation Limitation

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

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

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

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

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

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

Q. . . . [C]an you tell us about the Ganz reference?

A. So the Ganz reference really is different. Ganz refers to a device for creating a pattern of perforations in tissue. Think of it this way. We cut the skin with a knife. We cut the skin with a scalpel. And I talked about the fact that we get bleeding. Ganz is a device that causes those perforations of the skin but also lessens bleeding.

* * *

Q. Moving on to slide 13, why is Ganz creating perforations in tissue?

A. So, you know, as you can see here, when those perforations are made mechanically, scalpel, knife, rather than with the use of energy, there's a lot of bleeding. We all know that when we cut the skin. So there is a need for a device according to Ganz which creates these perforations, these cuts in the skin, without causing undue bleeding.

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

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

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

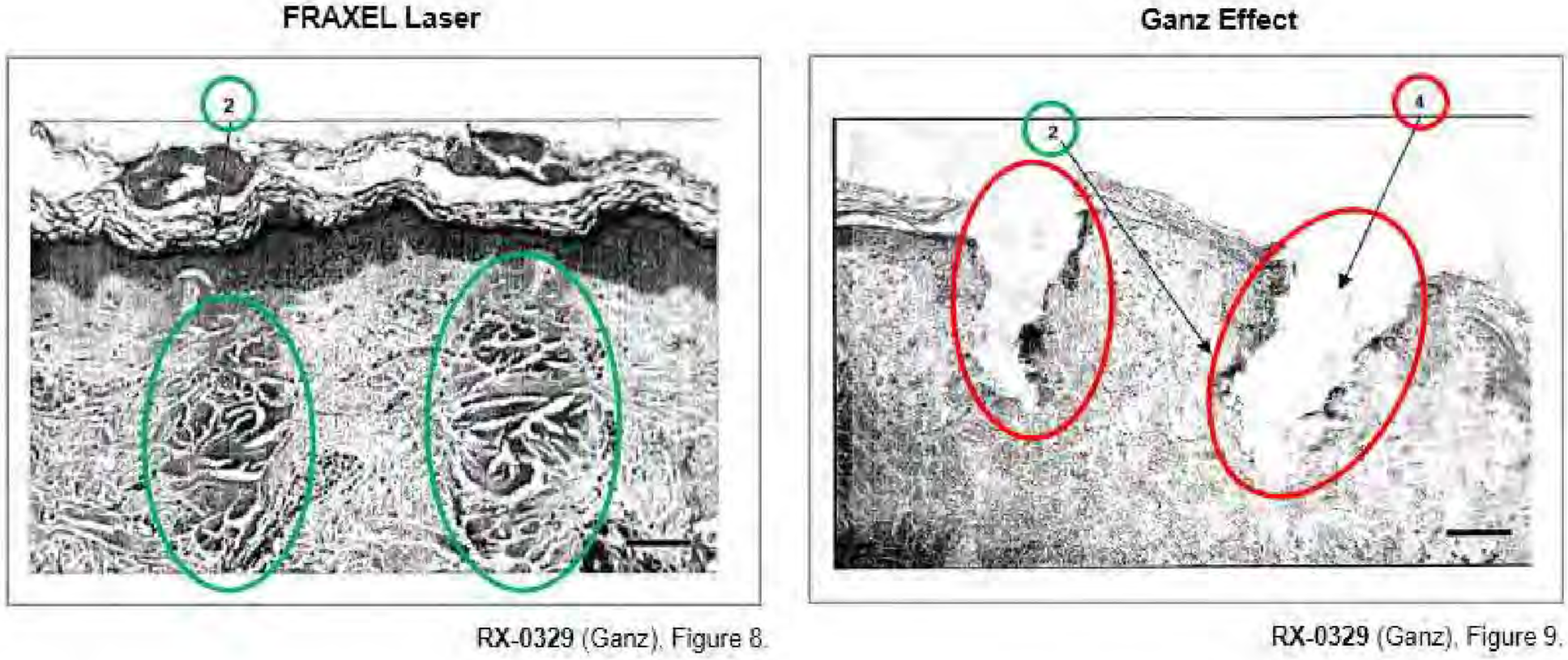
Ganz and the '836 patent expressly distinguish each other's approaches. (Tr. (van der Weide) at 1449:12-16 ("Ganz distinguishes approaches that merely cause coagulation, like the '836 patent, and for its part, . . . the '836 patent distinguishes systems that overheat and burn tissue like Ganz, so they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

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

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

(RX-0329 at [0028].).

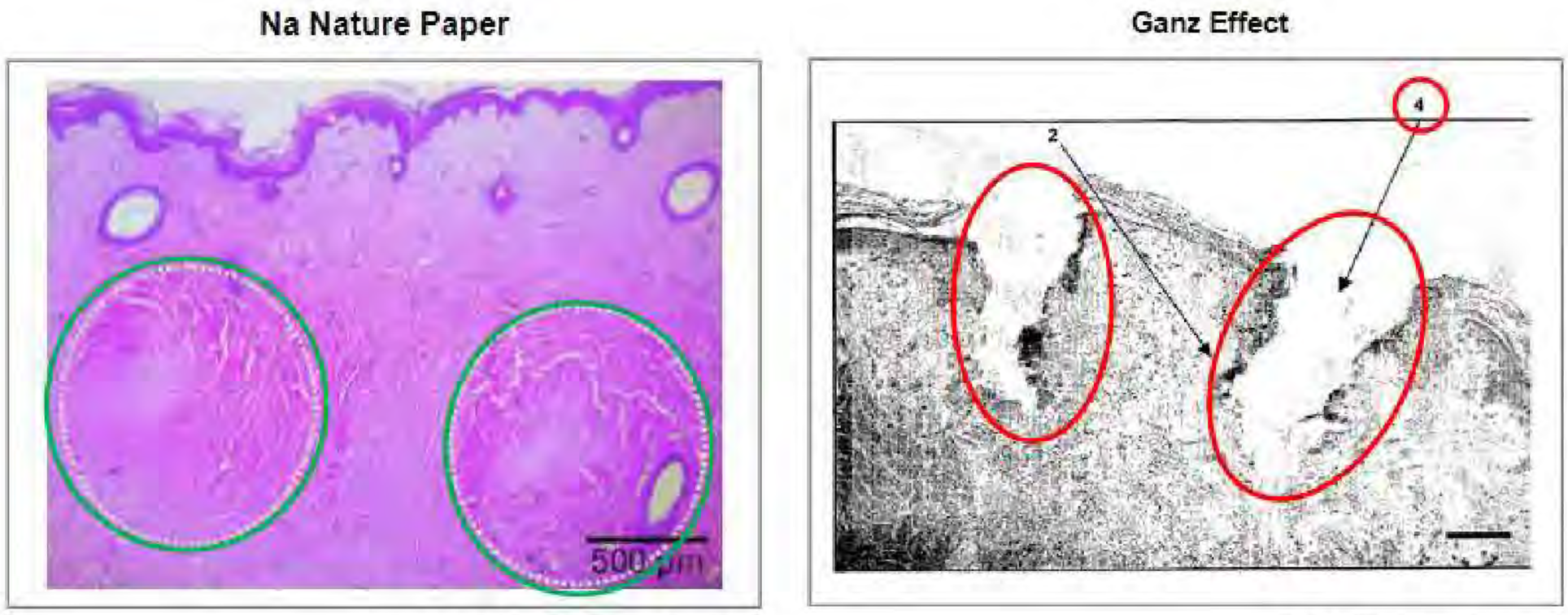
Figure 15: Goldberg Demonstrative Comparing Prior Art Method with Ganz



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

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

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



CX-0832 (Na Nature Article), 3. RX-0329 (Ganz), Figure 9.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Claim 22, which depends from unasserted claim 14, recites: "The method of treating skin of claim 14, wherein the RF is from 0.5 to 10 MHz and the predetermined time interval is from 0.05 to 0.8 seconds." (JX-0007 at cl. 22.). Respondents stated that claim 22 "is essentially directed to a method of treating skin using the device of claim 1," and asserted that claim 22 is rendered obvious for the same reasons as claim 1, and that Hantash discloses claim 22's additional limitation. (RPBr. at 27-28; *see also* RBr. at 22-23.).

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

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

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

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

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

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

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

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

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

d) Objective Indicia of Non-Obviousness

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

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

fact, Respondents were precluded from doing so by Order No. 41. (*See* Order No. 41 at 3-6 (Oct. 31, 2023) ("Dr. Woloszko is precluded from offering testimony/opinions on that topic during the Hearing in accordance with Ground Rule 9.5.6. . . . Because Respondents did not offer previous testimony/theories of the same, those portions of pages 28 and 104 of Respondents' Pre-Hearing Brief that reference secondary considerations of non-obviousness are stricken).).

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

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

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

i. Commercial Success

Serendia presented unrebutted evidence of commercial success. When "a product attains a high degree of commercial success, there is a basis for inferring that [attempts to a solution] have been made and have failed." *Merck & Co. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1376 (Fed. Cir. 2005). Serendia's expert, Dr. Goldberg, testified during the Hearing about how the Sylfirm X DI product, the licensed SHEnB, ABM, Lutronic, and Rohrer products, and the Accused Products have experienced commercial success due in large part to the unique characteristics of the claimed invention in the '836 patent, i.e., the application of bipolar RF energy to skin via electrodes to cause coagulation around but not between electrodes. (Tr. (Goldberg) at 1313:19-1317:21, 1320:18-1325:17, 1329:18-1331:18.).

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

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

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

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

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

ii. Industry Praise

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

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

iii. Long-Felt Need

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

Q. Moving on to slide 24, can you explain why it is your opinion that there is a nexus between the benefits of the '836 patent and any commercial success of these products?

A. Well, as I've discussed, I mean, the '836 patent has led to all these devices, which make these treatments more effective, reduce patient pain and downtime, increase the patient compliance, and make us all busier every day.

Q. Are there other factors that may also contribute to selecting an RF microneedling product as a clinician?

A. Sure. I mean, there are things such as how deep the needles penetrate from the skin, how many of these needles are on the handpiece, but at the core we still need the '836 patent.

Q. Moving to slide 25 and starting with the Sylfirm X product, is there any relationship between the Sylfirm X advertisements and the '836 patent specifically?

A. So the Sylfirm X marketing shows that nexus. You can see it right there on the right. They have right on their marketing materials that it is patented, and the patent number is there, '836.

Q. And what are the benefits associated with the '836 patent are described as features of the Sylfirm X?

A. So in the marketing materials, and, frankly, what we see in clinical practice, they are minimally invasive, pretty quick treatment times. Makes it good for us in the office, not a lot of downtime. People don't have to stay away from life every day. Pretty safe and comfortable and sometimes, frankly, even immediate results.

* * *

Q. So moving on to slide 35, and, again, can you remind us of some of the drawbacks of the prior bipolar systems once again?

A. Second generation, now bipolar, so you see two electrodes penetrating into the skin, energy going between those electrodes, arcing between those electrodes, and that arcing and that heat going between the electrodes have the risk of leading to burns and blisters, damaging the skin with pigmentation issues. Certainly more painful, more downtime because of the wounds.

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

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

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

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

a finding of invalidity by clear and convincing evidence.

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

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

Figure 17: Paragraph 65 of Ganz

EXAMPLE

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- How to adjust the distance between the needles to create more isolated coagulation zones. (*See* Tr. (Woloszko) at 1011:7-17.).

- How to adjust the thickness or diameter of the needles to adjust the coagulation zones. (*See* Tr. (Woloszko) at 1012:22-1013:2.).

- How to adjust the needle length or depth to obtain coagulation at the right depth in the dermis. (*See* Tr. (Woloszko) at 1013:6-10.).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

---

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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