

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ENDYMED MEDICAL LTD., ENDYMED MEDICAL, INC.,
Petitioner,

v.

SERENDIA, LLC,
Patent Owner.

Case No. IPR2024-00386

U.S. Patent No. 9,480,836

PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE

PUBLIC VERSION - REDACTED

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EXHIBITS

Exhibit	Description
1001	U.S. Patent No. 9,480,836 (the “’836 Patent”)
1002	File History for U.S. Patent No. 9,480,836
1003	Declaration of Dany Bérubé, Ph.D.
1004	<i>Curriculum Vitae</i> of Dany Bérubé, Ph.D.
1005	U.S. Patent Application Publication No. 2007/0208340 (“Ganz”)
1006	International Publication Number WO 2008/005477 (“Livneh”)
1007	International Publication Number WO 2007/064718 (“Hantash”)
1008	Korean Patent No. 20-0441552 (“Lee”) (translation)
1009	Korean Patent No. 20-0441552 (“Lee”) (original Korean)
1010	Macrene Alexiades-Armenakas et al., <i>Prospective Multicenter Clinical Trial of a Minimally Invasive Temperature-Controlled Bipolar Fractional Radiofrequency System for Rhytids and Laxity Treatment</i> , Dermatol. Surg. 1 (2012)
1011	Barry D. Sudbeck et al., <i>Collagen-stimulated Induction of Keratinocyte Collagenase Is Mediated via Tyrosine Kinase and Protein Kinase C Activities</i> , 269, 47 J. Biol. Chem. 30022 (1994)
1012	Sayaka Kanai et al., <i>Peptide Precursors that Acquire Denatured Collagen- hybridizing Ability by O-to-N acyl Migration at Physiological pH</i> , 18 Org. Biomol. Chem. 2823 (2020)
1013	Kristin M. Kirsch et al., <i>Ultrastructure of Collagen Thermally Denatured by Microsecond Domain Pulsed Carbon Dioxide Laser</i> , 134 Arch. Dermatol 1255 (Oct. 1998)
1014	U.S. Publication No. 2005/0222565 (“Manstein”)

Exhibit	Description
1015	Melissa A. Bogle, <i>Radiofrequency Energy and Hybrid Devices</i> , in NON-SURGICAL SKIN TIGHTENING AND LIFTING 21 (Murad Alam & Jeffrey S. Dover eds., 2009) (“Bogle”)
1016	THE IEEE STANDARD DICTIONARY OF ELECTRICAL AND ELECTRONICS TERMS (6th ed. 1997)
1017	THE ILLUSTRATED DICTIONARY OF ELECTRONICS (8th ed. 2001)
1018	BASIC ELECTRONICS THEORY (1981)
1019	R. James Koch & Brian P. Kim, <i>Radiofrequency Tissue Tightening</i> , in Non-Invasive Cosmetic Procedures 63 (2011)
1020	Heather Woolery-Lloyd & Jenna N. Kammer, <i>Skin Tightening</i> , in BASICS IN DERMATOLOGICAL LASER APPLICATIONS 147 (Inja Bogdan Allemann & David J. Goldberg eds., 2011)
1021	Antois S. Manolis et al., <i>Radiofrequency Catheter Ablation for Cardiac Tachyarrhythmias</i> , 121 Ann Intern Med. 452 (1994)
1022	David E. Haines, <i>Biophysics of Radiofrequency Lesion Formation</i> , in CATHETER ABLATION OF CARDIAC ARRHYTHMIAS 2 (Shoei K. Stephen Huang & Mark A. Wood eds., 2010)
1023	Seong Kuk Yoon, <i>Radiofrequency Ablation of Renal Cell Carcinoma: A Systematic Review</i> , in ADVANCED LAPAROSCOPY 127 (Ali Shamsa ed., 2011)
1024	Diane Irvine Duncan & Michael Kreindel, <i>Basic Radiofrequency: Physics and Safety and Application to Aesthetic Medicine</i> , in RADIOFREQUENCY IN COSMETIC DERMATOLOGY 1 (Moshe Lapidoth & Shlomit Halachmi eds., 2015)
1025	Korean Published Patent App. No. 10-2011-0074842 (translation)
1026	Korean Published Patent App. No. 10-2011-0074842 (original Korean)
1027	U.S. Patent Application Publication No. 2006/0047281 (“Kreindel”)

Exhibit	Description
1028	Order No. 35: Construing Certain Terms of the Asserted Claims, Inv. No. 337-TA-1356.
1029	U.S. Patent Application Publication No. 2010/0262135
1030	International Standard, IEC 60601-2-2, Medical electrical equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
1031	George Hruza et al., <i>Skin Rejuvenation and Wrinkle Reduction Using a Fractional Radiofrequency System</i> , Vol. 8 Issue 3 Journal of Drugs in Dermatology 259 (2009)
1032	Docket Report – Serendia, LLC v. Cutera, Inc., 1:23-cv-00222-RGA (D. Del.)
1033	Docket Report – Serendia, LLC v. Cynosure, LLC, 1:23-cv-00223-RGA (D. Del.)
1034	Birefringence Definition, https://www.merriam-webster.com/dictionary/birefringence
1035	Declaration of R. James Koch, M.D.
1036	<i>Curriculum Vitae</i> of R. James Koch, M.D.
1037	Substitute Declaration of Jean Woloszko, Ph.D
1038	Serendia-Ilooda Settlement Agreement
1039	Excerpt from November 7, 2023 Evidentiary Hearing Transcript from related ITC proceeding
1040	Order No. 3 (Proposed Scheduling Order) from related ITC proceeding
1041	Order No. 2 (Ground Rules) from related ITC proceeding

Exhibit	Description
1042	Goldberg, David, et al., "Prospective Multicenter Clinical Trial of a Minimally Invasive Temperature-Controlled Bipolar Fractional Radiofrequency System for Rhytid and Laxity Treatment," <i>Dermatol. Surg.</i> 2012; 1-11, DOI: 10.1111/dsu.120165 (2012)
1043	Supplemental Declaration of Dr. Jean Woloszko (PROTECTIVE ORDER MATERIAL AND REDACTED VERSIONS)
1044	Deposition Transcript of Dr. David Goldberg in IPR2024-00386, taken April 18, 2025 (PROTECTIVE ORDER MATERIAL AND REDACTED VERSIONS)
1045	Deposition Transcript of Dr. Daniel W. van der Weide in IPR2024-00386, taken April 21, 2025
1046	Prime Journal Media Guide
1047	Hearing transcript, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C.) held December 12, 2023 (Daniel van der Weide testimony excerpts)
1048	Kevin A. Wilson, <i>Leading regenerative Therapies Creating a Paradigm Shift in Aesthetic Medicine</i> , Aesthetic Guide, June 6, 2022, https://www.theaestheticguide.com/regenerative-aesthetics/leading-regenerative-therapies-creating-a-paradigm-shift-in-aesthetic-medicine

Petitioner submits this reply to Serendia, LLC ("Serendia")'s Patent Owner's Response ("POR").

I. GROUNDS I AND II: Claims 1-2, 11-15, 23-24, and 26

A. Ganz Discloses Claim 1[c]: "coagulation *around* each electrode rather than coagulating *between* the electrodes"

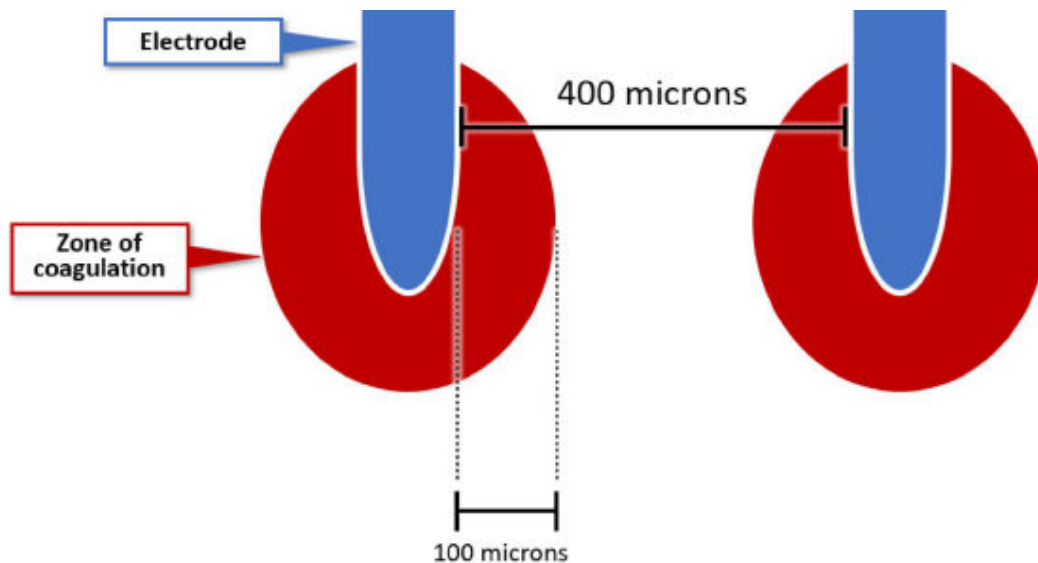
Ganz discloses claim 1[c]: Ganz discloses an "electrode pattern...to create a zone of **coagulative** tissue *surrounding each perforation*"¹ (Ex.1005, ¶48); "Generally, these zones extend into the tissue in all directions originating from the perforation site" (Ex.1005, ¶28). Ganz uses "RF electrodes" to isolate heat around those perforations without heating surrounding tissue:

RF energy is particularly desirable for creating perforations of tissue since it **does not** cause the entire area of tissue being treated to **heat up extensively**. Rather, RF energy can penetrate the body and be absorbed by deeper tissues **without heating up the surrounding tissues**. Thus, a boundary is created between the treated tissue and those tissues surrounding the treated tissues. (Ex.1005, ¶58).

Ganz discloses the advantages of "leaving *zones of untreated tissue* in *between* the perforations" is "less scarring and/or pigmentations are visible" (Ex.1005, ¶6). In one embodiment, Ganz discloses coagulating *between* electrodes by forming

¹Petitioner's emphasis throughout unless otherwise indicated.

“perforations...about 100 microns in diameter...spaced apart by...about 400 microns” and “[z]ones of coagulation...extend from the perforation...about 5 microns to about 100 microns” (Ex.1005, ¶¶47-48, 55; Ex.1003, ¶¶109-112; Ex.1035, ¶29). Petitioner's illustration below shows, in this embodiment, coagulation (red) is *around* but not *between* the two electrodes (blue) (Ex.1003, ¶110; Institution Decision, 28-29):



The Board correctly concluded: “This embodiment has about 200 microns of spacing between the two ‘zones of coagulation.’” (Institution Decision, 29)².

²Ganz's coagulation zones are separated by even greater distance when electrode perforations are separated farther by up to “0.5mm” (i.e., 500 microns) or “about 5mm” (i.e., 5000 microns) and/or coagulation zones are narrower between 5-100 microns (Ex.1005, ¶¶47,52; Ex.1003, ¶111; *see also* Ex.2014, 1339:19-23).

Ganz's zones of coagulation are thus entirely separated in this embodiment and do not "**fully extend**[]" from one electrode to another electrode" satisfying the agreed construction of claim 1[c] (Ex.1028, 40). PO's expert agrees that, in an embodiment in Ganz (Ex.1005, ¶¶47-48, 52), "the zones of coagulation in Ganz would not overlap with each other" (Ex.2014, 1339:19-23). Ganz explicitly discloses "*any*...electrode arrangement," which includes "a *bipolar* electrode arrangement," can cause its coagulation dimensions (Ex.1005, ¶¶47-48, 56).

To circumvent Ganz's clear disclosure of claim 1[c]'s agreed construction, PO improperly attempts to narrow its construction to require two additional unclaimed limitations:

- Coagulation "**immediately**"/"**directly**" around the electrode, excluding any space or hole between the coagulation and electrode (POR, 13-14, 40-43, 45-46, 49, 53); and
- "**Only**" coagulation is allowed, **excluding** "**ablation**" (POR, 38-53; *see also* 15-17, 22-28).

Neither requirement however is claimed, nor part of the agreed construction:

1. The Claims Do Not Require Coagulation *Immediately* or *Directly* Around the Electrode

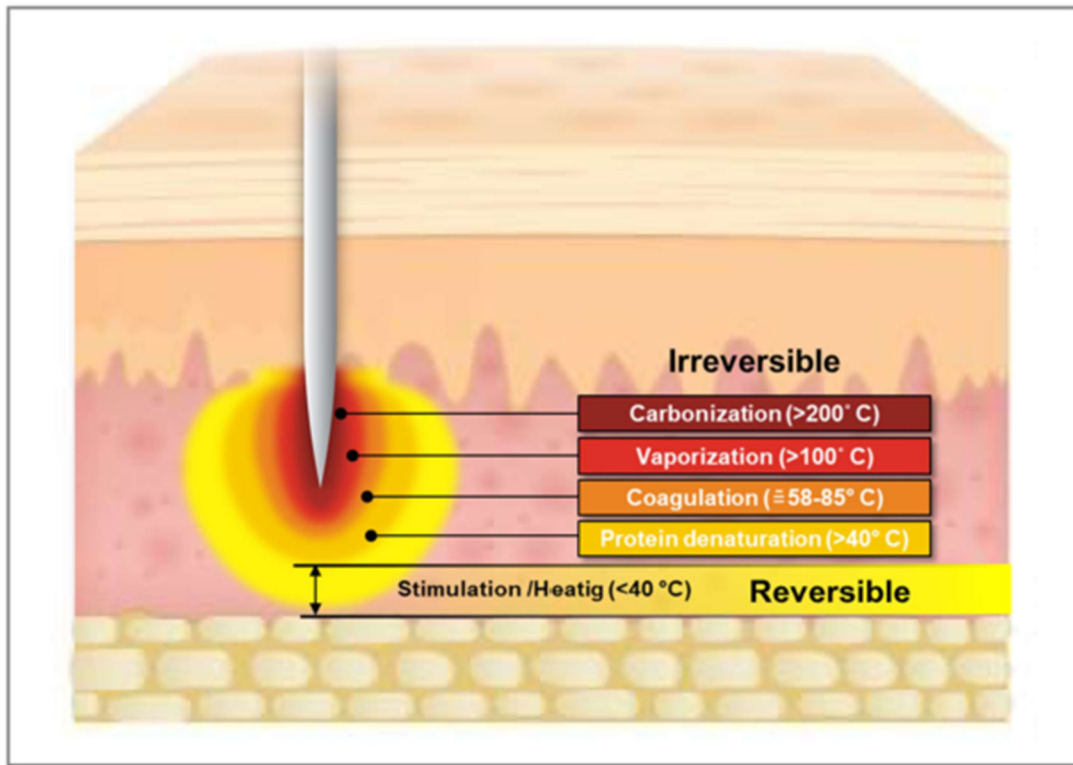
The agreed construction of "*coagulation around each electrode* rather than coagulating between the electrodes" is "two or more electrodes adapted to cause

coagulation around each electrode without such coagulation fully extending from one electrode to another electrode” (Ex.1028, 40).

PO does not dispute Ganz's coagulation does not fully extend from one electrode to another electrode, but instead disputes whether that coagulation is “*around* each electrode” at all (POR, 40-43, 45-46, 49, 53). Because Ganz discloses “[z]ones of coagulation...surrounding each perforation” (Ex.1005, ¶48) and each perforation surrounds the electrode that perforated it (Ex.1005, ¶¶10,51), these zones of coagulation are necessarily around both the perforation and the electrode within that perforation.

PO misrepresents that it “applies” the agreed construction (POR, 21), but instead applies a narrower than agreed construction –that the coagulation is “*immediately* around each electrode” (POR, 45-46) or “*directly* around” the electrode (POR, 13-14). *See also id.*, 40-43, 49, 53. Coagulation immediately or directly around the electrode is narrower than simply “around,” as claimed and required by the agreed construction, because it adds the unclaimed requirement that the coagulation touches the electrode and excludes a space between the coagulation and electrode. Whereas Petitioner uses the plain and ordinary meaning of “around,” as agreed (Ex.1028, 40), not a different claim construction (POR, 46-47 fn.6), PO uses a narrower construction that is contradicted by PO's own expert

testifying: “the illustration [below] shows a variety of different tissue effects *around* the electrode” (Ex.1045, 49:1-50:22):

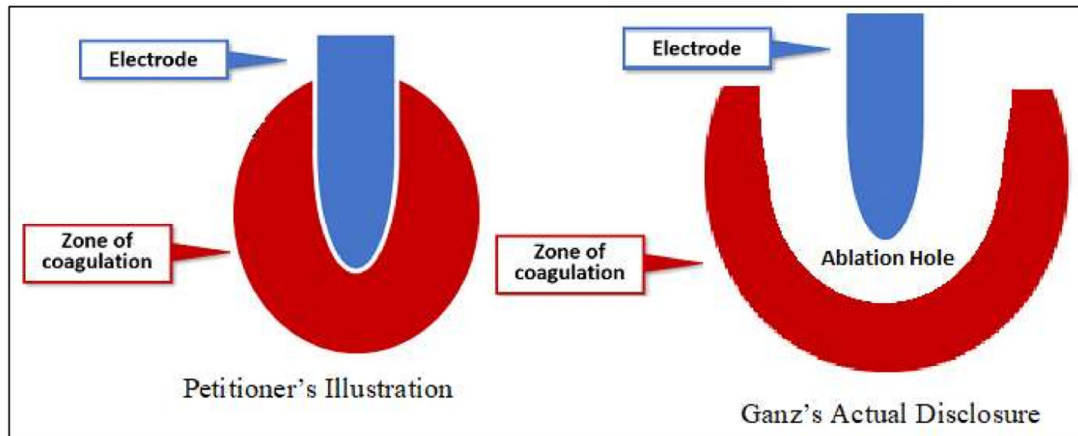


(POR, 6).

This illustration shows the variety of different tissue effects includes “Coagulation,” which is thus “around the electrode,” even though it is separated from the electrode by intermediate tissue effects (“Carbonization” and “Vaporization” equated by PO with “ablation,” POR, 5-6). Consistent with PO’s expert’s use, unlike coagulation immediately/directly around each electrode, “coagulation *around* each electrode” therefore does not require that the

coagulation and electrode touch, allowing separation between the coagulation and electrode.

PO also incorrectly labels an alteration of Petitioner's illustration as "Ganz's Actual Disclosure" (right-below) (POR, 48-50):



PO's illustration, however, references a different embodiment in Ganz (Ex.1005, Figure 9, cited in POR, 49-50) than Petitioner's illustration (based on Ganz ¶¶47-48,53; Petition, 27-29) and so, cannot correct nor negate another distinct embodiment. Further, PO's illustrated dimensions have no basis. While Ganz discloses "the perforation created will be at least the width of the electrode" (Ex1005, ¶53), PO's illustrates an "Ablation Hole" 3-4x wider than the electrode, citing Figure 9 that only depicts a perforation, but not its electrode for relative scale (POR, 49-50). With no basis for its dimensions, PO's illustration cannot be considered "Actual" or "corrected" (POR, 49-50).

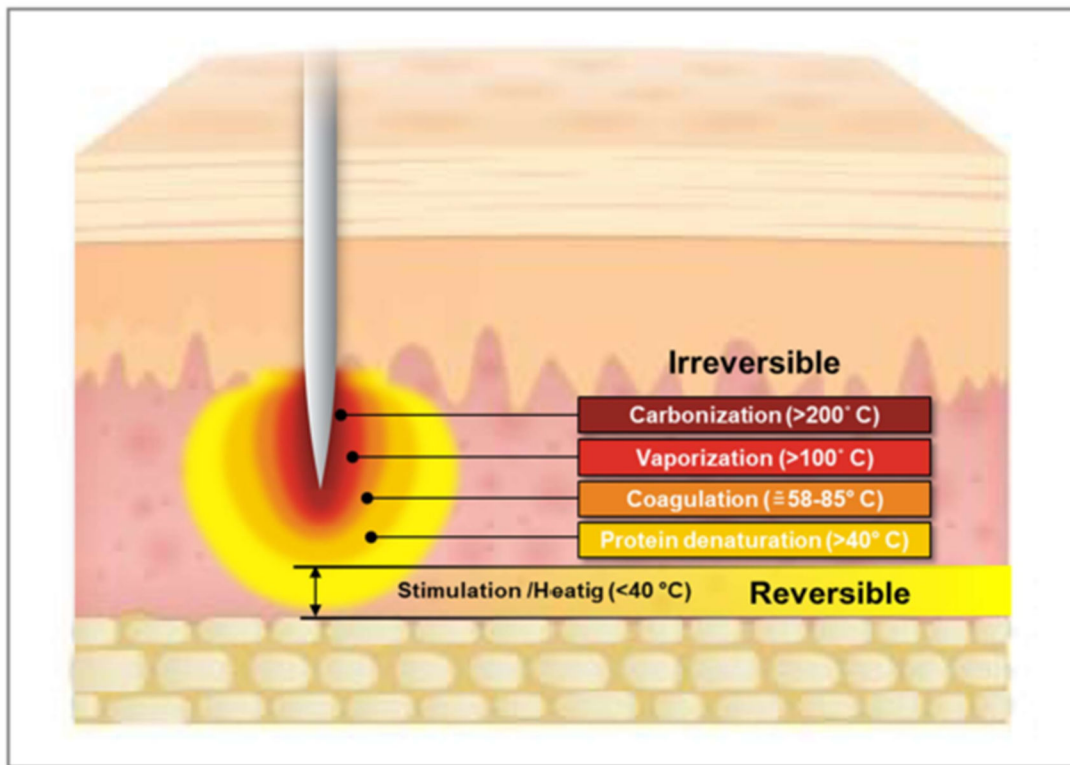
2. The Claims Do Not Require *Only* Coagulation (Excluding Other Treatment Phenomena)

PO unduly limits “the ’836 Patent’s claimed approach” to “*only* cause[] zones of coagulation” (POR, 23, 39) excluding other additional tissue effects, such as, carbonization, vaporization, or ablation (POR, 13-17, 22-28, 38-53; Ex.2143, ¶57; Ex.2142, ¶31). Claims 1 and 14 however recite “**comprising**” that is **inclusive** of providing/applying a signal “configured to cause coagulation,” **not exclusive** of providing/applying other signals or tissue effects. *See Teva Branded Pharm. Prods. v. Amneal Pharms. of N.Y., LLC*, 124 F.4th 898, 913 (Fed. Cir. 2024) (“the potential presence of additional features is the bedrock understanding of a ‘comprising’ claim, which ‘[i]n the patent claim context’ means ‘including but not limited to.’”).

The ‘836 Patent claims and agreed construction contain no negative limitation to exclude other non-coagulative tissue effects (Ex.1028, 39-40). Nor does the specification, which discloses three tissue phenomena –“carbonization, vaporization, and coagulation,” of which coagulation is “*primarily*” used (Ex.1001, 2:62-66). “[P]rimarily using coagulation” indicates these other (non-primary) tissue effects can also be used in conjunction with coagulation (contrary to POR, 15, 17, 22-23). Regardless, “[t]he general rule, of course, is that claims of a patent

are not limited to the preferred embodiment, unless by their own language.” *Prima Tek II, L.L.C. v. Polypap*, 318 F.3d 1143, 1149-51 (Fed. Cir. 2003).

Moreover, PO's expert agreed the “illustration [below] shows a variety of different tissue effects around the electrode,” meaning more than one tissue effect (“Carbonization,” “Vaporization,” “Coagulation”...) can all be around the electrode at the same time (Ex.1045, 49:1-50:22; POR, 6 illustration):



PO repeatedly misrepresents the '836 Patent's aim to prevent “overheating or burning” *entirely* (POR, 17, 22-23, 38-39) omitting this disclosure refers to optional embodiments that “*may prevent or limit overheating **between needles***” (Ex.1001, 4:6-10; *see also* 2:14-16). The '836 Patent raises temperatures higher

along electrodes 302 (shown below) but “control[s] temperature *between needles.*”

(Ex.1001, 4:11-17; *see also* 7:1-6 “as shown in FIGS. 5, 7, 8 and 9B”):

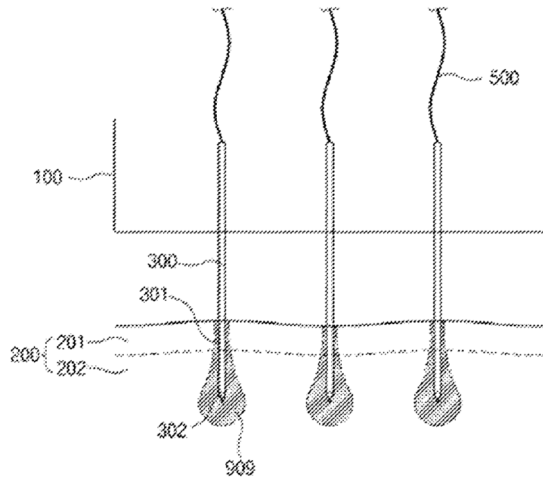


FIGURE 5

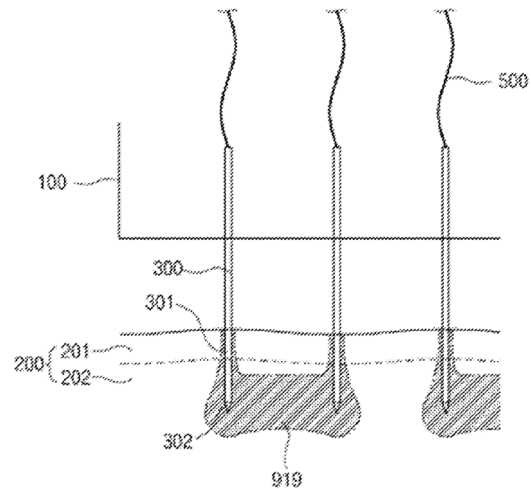
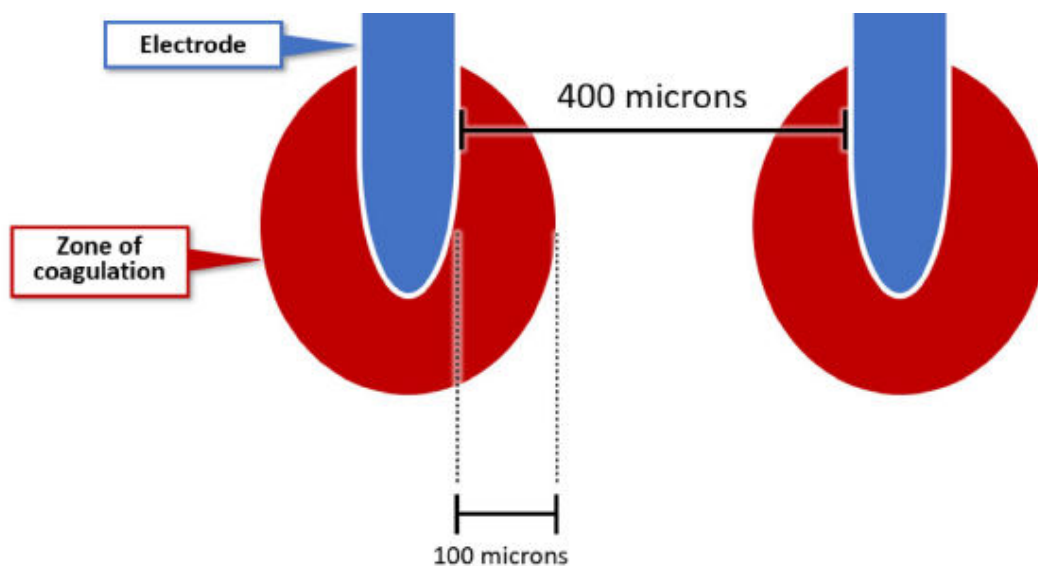


FIGURE 7

Like the '836 Patent, Ganz discloses “leaving zones of untreated tissue *in between* the perforations” and thus *in between* electrodes (Ex.1005, ¶¶6,10) as depicted in Petitioner's illustration (Ex.1005, ¶¶47-48):



(Ex.1003, ¶110; Petition, 27-29).

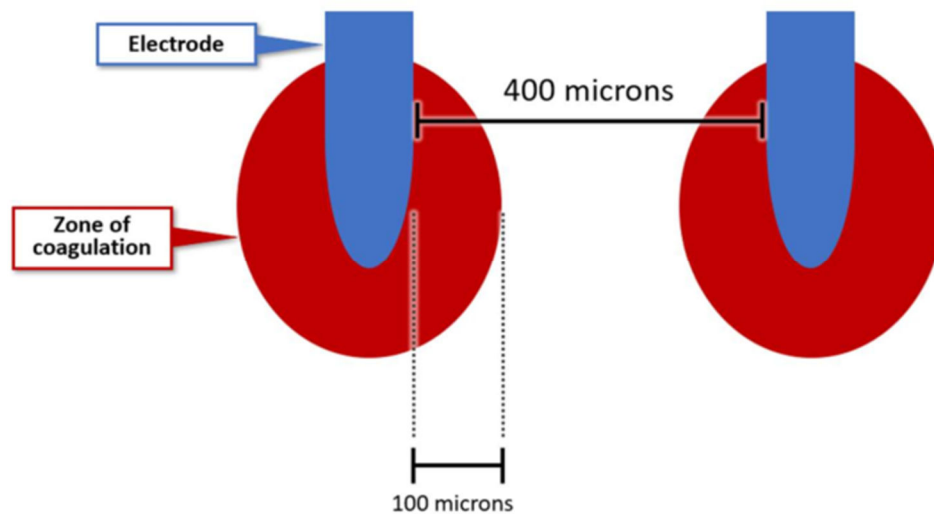
That “the patents in this investigation do not involve ablation,” does not mean the claims **exclude** ablation (POR, 27-28, 40-41). Omission does not constitute disclaimer. *See Novartis Pharms. Corp. v. Accord Healthcare, Inc.*, 38 F.4th 1013, 1017 (Fed. Cir. 2022) (“If it [did], then every later-added negative limitation would be supported so long as the patent makes no mention of it.”). Even if coagulation were the sole embodiment disclosed in the ‘836 Patent, the claims are still not so limited: *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1323 (Fed. Cir. 2005).

Accordingly, the claims “comprising” –i.e., including– coagulation do not exclude other tissue phenomena, such as, “carbonization” and “vaporization” disclosed in the ‘836 Patent (Ex.1001, 2:62-66) and equated with “ablation” in Ganz (Ex.1005, ¶27; POR, 5).

3. Ganz Discloses Coagulation *Immediately/Directly* Around The Electrode

Even though the ‘836 Patent claims do not require coagulation immediately/directly around each electrode, Ganz still discloses this: Ganz discloses “[t]he energy source is configured for powering the electrodes at levels appropriate to provide a **desired diameter** and depth of perforation of tissue” (Ex.1005, ¶59). Although in “many cases” Ganz’s desired diameter of the

perforation is larger than the width of the electrode, it is not always the case: “[t]he width of the perforation created will be **at least** the width of the electrode, and in many cases larger” (Ex.1005, ¶53). Thus, in at least one case, the perforation’s width is the same as the electrode’s width. PO confirms: “the needles used in Ganz are *the same size* or smaller than the perforations” (POR, 56). In the case where the electrodes and perforations are the “same size,” Ganz’s coagulation that surrounds the perforation would also immediately/directly surround the electrode that is the same width, and not fully extend between the electrodes:



(Ex.1003, ¶109).

Regardless, because the spacing between Ganz’s coagulation zones is defined in paragraphs 47-48 relative to the perforations, the distance of that spacing would stay the same, satisfying the claims, whether or not the perforations

are the same size as the electrode (Ex.1003, ¶¶109-110 citing Ex.1005, ¶¶47-48, 53).

Further, Ganz discloses that electrode and coagulation spacing can be adjusted by changing energy and power levels as desired: “[t]he electrodes can also be spaced apart at a desired length so that the perforations in tissue will also be spaced apart at that length” (Ex.1005, ¶52), and “[t]he zone of coagulation can be varied by changes in energy and power levels” (Ex.1005, ¶48; *see* Ex.1003, ¶¶108, 127). While PO criticizes Ganz for not disclosing “what ‘level of energy’ needs to be ‘discharged’ to have coagulation” (POR, 51; Ex.1043, ¶6), that is not claimed, and the ’836 Patent does not disclose *any energy or power values* to cause the claimed coagulation (Ex.1043, ¶6). Those values also cannot be derived from the ’836 Patent’s equations due to unknown variables (e.g., without knowing the “proportional constant,” N, and the “device resistance, needle resistance, and skin resistance values,” Ex.1001, 8:43-53, 10:10-39; Ex.1043, ¶7).

While Ganz discloses there may be “excess bleeding” when holes are made “mechanically” without “the use of energy” (Ex.1005, ¶8), Ganz always uses energy in conjunction with energizing tissue (Ex.1005, ¶27). Contrary to PO’s assertions (POR, 1, 17, 24, 39, 46-47, 49), Ganz also does not disclose to completely stop bleeding, or to cauterize as PO’s expert admitted:

...There is no doubt that [Ganz's] patent, as it delivers energy into the skin, is probably very- there is probably *little bleeding*. That's not the purpose of it; *it's not for cautery*. (Ex.2014, 1338:6-1339:11)

PO's expert also admitted that, in Ganz, "a small amount of coagulation" can "stop the bleeding" (Ex.2013, 1450:4-10), thus, ablation is not required to prevent "excess bleeding" (Ex.1005, ¶8). Indeed, Ganz discloses, in an embodiment, "thermal damage" as an alternative to (i.e., "*or*") ablation (Ex.1005, ¶27). This non-ablative embodiment, e.g., in the case where Ganz's perforation width is the "same size" as the electrode width (*see above*), means no tissue is "ablated" or "burned away" (Ex.1005, ¶53) (contrary to POR, 39-53).

4. Ganz Is Directed To The Claimed Approach

Ganz and the '836 Patent are not directed to "entirely different" or "contradictory" treatment methods (POR, 1-2, 21-28, 38-53; Ex.1035, ¶44; Ex.1003, ¶¶54-57): Like the '836 Patent, Ganz is directed to using "RF" "bipolar electrodes"³ (Ex.1005, ¶11; *compare* Ex.1001, 5:33-35, 5:58-60) to revitalize skin by stimulating coagulation ("coagulation...to revitalize and rejuven[ate] skin," Ex.1005, ¶30; *compare* Ex.1001, 2:37-41), prevent overheating (*see* "without

³Ganz discloses bipolar electrodes arranged in "pairs" (Ex.1005, ¶56), not "a needle that has both polarity" (POR, 34 n.5).

heating up the surrounding tissues,” Ex.1005, ¶58; *compare* Ex.1001, 4:6-10), minimize skin damage (“perforations are so small that they cannot be seen with the naked eye,” Ex.1005, ¶29; *compare* Ex.1001, 4:6-10), and reduce scars (“reduces the chances of scarring,” Ex.1005, ¶32; *compare* Ex.1001, 9:32-33).

PO mischaracterizes the ‘836 Patent as “milder, safer” and Ganz as “aggressively removing tissue” to create “ablation holes” and “cauterizing...to stop bleeding” (POR, 1, *see also* 23-28,38-46). To the contrary, Ganz’s system “is safe to use on tissues in areas near sensitive body parts, e.g., areas of skin near the eyes” (Ex.1005, ¶58). Ganz does not distinguish the “FRAXEL laser” because it causes only coagulation (POR, 24-27, 39), but because it lacks perforations (Ex.1005, ¶6), which is similarly resolved by perforations in both Ganz and the ‘836 Patent.

As discussed above, Ganz’s system does not cauterize (POR, 1, 17, 24, 39, 46-47, 49), which it identifies as a prior art problem it aims to solve (*see* “without causing undue bleeding,” Ex.1005, ¶¶3, 8). *See supra* §I.A.3.

PO’s SylfirmX product literature confirms the claimed needle width of “0.3mm” (claim 9) itself causes “Pin point bleeding” (Ex.2083, 8). In contrast, Ganz discloses, in some embodiments, creating even smaller perforations (e.g., 30-100 micron widths, Ex.1005, ¶10), providing even less scarring using up to ***ten times smaller*** perforations, than the ‘836 Patent (e.g., disclosing electrode/perforation widths of 0.25-0.30mm, Ex.1001, 9:34-36).

Ganz is thus directed to the same approach ***claimed*** by the '836 Patent.

Sylfirm Manual & Na's Paper: Validity compares the claims to prior art.

PO cannot substitute extrinsic research articles –Na's Paper (Ex.2023)– or commercial products –“Sylfirm Manual” (Ex.2083)– for omissions in the '836 Patent (POR, 13-14, 25-27, 42-43, 45, 52-53). *See Vitronics Corp. v. Conceptronic*, 90 F.3d 1576, 1583 (Fed. Cir. 1996); *See Myco Indus., Inc. v. BlephEx, LLC*, 955 F.3d 1, 15 (Fed. Cir. 2020); *L.A. Biomedical Research Inst. at Harbor-UCLA Med. Ctr. v. Eli Lilly & Co.*, 849 F.3d 1049, 1069 (Fed. Cir. 2017). On the contrary, PO's reliance on histological images from Na's Paper published *over four years after* and power levels from the Sylfirm Manual released *over ten years after* the '836 Patent's priority date (Ex.2023, 1; Ex.2083, 43) to show coagulation without ablation (POR, 13-14, 25-27, 42, 45, 47-48, 52) only highlights those omissions in the '836 Patent itself. Na's Paper and the Sylfirm Manual operate at specific parameter ranges not disclosed in, and so not limiting on, the '836 Patent: Na's Paper operates experiments at a maximum voltage of 36.6V –nearly ***three times lower*** than the voltage-limit of 100V in the '836 Patent (Ex.2032, 2,8; Ex.1001, 8:30-34). Absence of ablation at lower-voltages in Na's Paper does not preclude ablation at three times higher-voltage in the '836 Patent (Ex.1043, ¶8). The '836 Patent only imposes an *optional* upper limit that “[i]n **an embodiment**, voltages above 100V...**may** not be recommended” (Ex.1001, 8:34-

37). *Prima Tek*, 318 F.3d at 1149-51 (rejecting limiting claim scope when “[t]he written description only states... ‘may be’ (not must be)” used). Regarding the Sylfirm Manual, its power levels are not disclosed in the ‘836 Patent and so cannot limit the claims (POR, 52; Ex.1043, ¶9).

5. Ganz Discloses Using *Bipolar* Electrodes To Generate Its Zones of Coagulation

Contrary to PO's argument (POR 32-33, 37), Ganz links bipolar electrodes to the claimed coagulation: Ganz's paragraphs 47-48, discussed above, and relied on in the Institution Decision, to cause the claimed coagulation around rather than between confirms “*any* desired pattern or *electrode arrangement* is within the scope of the invention” (Ex.1005, ¶47). Ganz then explains that “electrode arrangement” includes “a *bipolar* electrode arrangement” (Ex.1005, ¶56; *see also* ¶55).

PO attempts to divide Ganz into monopolar vs. bipolar embodiments, alleging its bipolar electrodes do not apply to its independent coagulation zones (POR, 30-37, 51). PO's interpretation fails to read Ganz in its entirety: Ganz refers consistently to “***The*** electrodes” –i.e., the same electrodes– as both dimensioned to cause coagulation *around* rather than *between* the electrodes (Ex.1005, ¶¶47-48, *see* Petitioner's illustration above) and “provided as a *bipolar* electrode arrangement” that cause “coagulation” (Ex.1005, ¶56). The only distinction Ganz

discloses between monopolar and bipolar electrodes is the desire for treatment using “individual electrodes” (monopolar) vs “electrode pairs” (bipolar) (Ex.1005, ¶¶55-56). To show the claimed coagulation in Ganz, however, Petitioner relies on Ganz’s dimensions that are not modality-specific, not Ganz’s monopolar “Example,”⁴ nor Figures 9 or 10 (Petition 27-30, citing Ex.1005, ¶¶47-48, 53, POR, 30-34). Ganz explicitly discloses “any...electrode arrangement,” which includes “a *bipolar* electrode arrangement,” can cause its coagulation dimensions (Ex.1005, ¶¶47-48, 56). Generally, when read in its entirety, Ganz consistently discloses monopolar and bipolar electrodes as two options, either of which is configured to cause its coagulation zones, and so would encompass bipolar electrode engineering to achieve that goal (Ex.1005, ¶¶47-48, 55-56).

Unlike *Abbott* (POR, 51-52), Petitioner cites to Ganz’s disclosure as whole and does not “pick and choose isolated elements” from three different prior art references to try to meet a limitation. *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1347-1348 (Fed. Cir. 2008).

⁴While Ganz discloses only one working example, and that happens to be a monopolar configuration (“Example,” Ex.1005, ¶65), absence of a bipolar electrode working example cannot disqualify Ganz where the ‘836 Patent itself discloses no experimental results (POR, 30-31).

Unlike *Cartessa* IPR2022-00594 where petitioner relied on a single “histology result” screen capture of the INTRAcel video not attributed to bipolar (as opposed to monopolar) electrodes (IPR2022-00594, Paper 9, at 35-36), Ganz “links the treatment” generally to using “either monopolar *or bipolar* electrodes” (POR, 31; *see also* 37; Ex.1005, ¶55).

Unlike Manstein, Ganz specifically discloses “the electrodes” as **both** achieving the claimed coagulation (Ex.1005, ¶¶47-48) and being “bipolar” (Ex.1005, ¶56), and links the claimed coagulation pattern any electrode arrangement including bipolar (Ex.1005, ¶¶47-48, 55-56). Manstein showing that monopolar and bipolar electrodes *can* yield different results (POR, 35-36), does not mean they cannot yield the same result, as Ganz discloses, to warrant an inconsistent reading of Ganz for monopolar and bipolar electrodes. Either “monopolar or bipolar” “electrode arrangement” in Ex.1005, ¶¶55-56 *can* and are disclosed to provide Ganz’s coagulation, as “*any...electrode arrangement is within the scope of the invention*” (Ex.1005, ¶47).

PO’s expert admits Ganz “nowhere describes one zone of coagulation overlapping with another zone of coagulation” (Ex.2014, 1339:19-1340:2). Because Ganz discloses monopolar and bipolar with the same level of specificity and as the only two options to achieve its coagulation patterns (Ex.1005, ¶¶55-56), it is inconsistent and makes no sense to read Ganz as selectively disclosing the

isolated coagulation zones for only monopolar electrodes, and overlapping coagulation zones for bipolar electrodes.

II. GROUNDS III AND IV: CLAIMS 2-10, 15-22, AND 25

A. A POSA Would Have Been Motivated To Combine Ganz And Hantash

Ganz discloses varying parameters including electrode “diameter” (Ex.1005, ¶53; Ex.1001, claim 9), “treatment time” and “RF” “power setting” (Ex.1005, ¶59; Ex.1001, claim 22), thereby motivating a POSA to consider literature in the same field, such as Hantash, to select optimal values for those parameters (Petition, 54, 58; Ex.1003, ¶229).

Both Ganz and Hantash are directed to the same goals of using bipolar RF electrodes (“RF” “bipolar electrodes,” Ex.1005, ¶11; “bipolar RF,” Ex.1007, ¶77) to revitalize skin by stimulating coagulation (“coagulation...to revitalize and rejuven[]ate skin,” Ex.1005, ¶30; “revitalizing aging skin,” “coagulate collagen...to stimulate the wound healing response,” Ex.1007, Abstract, ¶79), prevent overheating (“without heating up the surrounding tissues,” Ex.1005, ¶58; “avoiding overheating of the treated zones,” Ex.1007, ¶18), minimize skin damage (“perforations are so small that they cannot be seen with the naked eye,” Ex.1005, ¶29; “smaller treatment zones,” Ex.1007, ¶79), and reduce scars (“reduces the chances of scarring,” Ex.1005, ¶32; “reduce[] the incidence of scarring,” Ex.1007,

¶58). Ganz and Hantash have overlapping objectives: *See e.g.*, Ex.1005, ¶10 (“create a zone of **coagulative** tissue surrounding each **perforation**”); Ex.1007, ¶79 (“These parameters can be used to **coagulate**...and to **kill or injure** cells to stimulate the wound healing response in surrounding healthy tissue”).

Contrary to PO, Hantash does not cause coagulation **between** electrodes (POR, 11, 57-58, citing treatment patterns of Figs. 4A-9). Hantash's treatment pattern 164 between electrodes 116 and 117 are **not** zones of **coagulation** as claimed, but zones of collagen/protein “**denaturation**” (Ex.1007, ¶60; *see also* Ex.1045, 47:5-48:18):

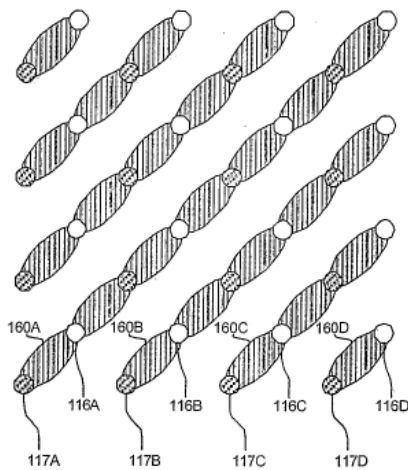


Figure 7A

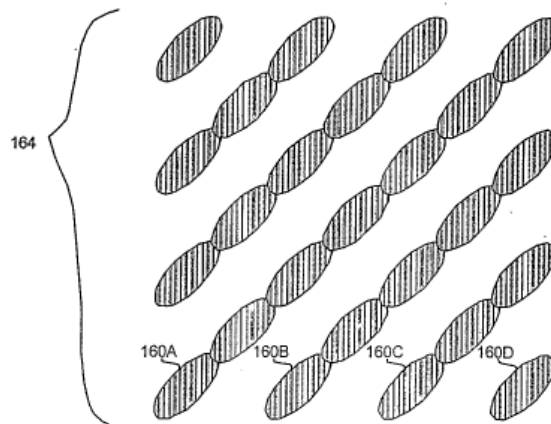


Figure 7B

PO agrees protein “denaturation” occurs at lower-temperatures than, and is distinct from, coagulation (POR, 5-6; Ex.2142, ¶15). Thus, while Hantash causes coagulation around needles 116 and 117 (Ex.1007, ¶79), which is the area of highest heat (Ex. 1002, 344, POR, 5-6), Hantash only causes “denaturation” –**not**

coagulation— between the needles (Ex.1003, ¶231). This does not constitute “conflicting objectives” or render Ganz unable to achieve its intended purpose (POR, 58-59; *see also* 56-57)⁵.

Consistent with Ganz, Hantash thereby avoids overheating *between* electrodes (only heating up to “denaturation” temperatures, Ex.1007, ¶60), while allowing the higher heat around electrodes to reach coagulation temperatures (Ex.1007, ¶79; Ex.1005, ¶10).

1. Claim 9: Electrode Needle Diameter Of 0.25mm-0.30mm

The ‘836 Patent admits claim 9’s dimensions are *not critical* to the invention: “a needle may have a diameter or outer profile of about 0.25 mm and 0.30 mm but is *not critical* to achieve desired energy fields 909, 949.” (Ex.1001, 9:34-36).

Ganz discloses example perforation widths “about 30 to about 100 microns” (i.e., 0.03-0.1mm) and “no more than...about 0.5mm” (i.e., $\leq 0.5\text{mm}$) (Ex.1005, ¶47). Ganz discloses “[t]he width of the perforation created will be at least the width of the electrode” (¶53), yielding electrode widths in the same range or

⁵Ganz also discloses “leaving zones of untreated tissue in between the perforations” where treatment in Ganz refers to coagulation and perforation (Ex.1005, ¶6, 28), not denaturation.

smaller between 0.03-0.5mm –i.e., containing claim 9's 0.25mm-0.30mm range (POR, 55). Ganz discloses “[t]he width or diameter of each electrode pin can also be varied to provide a perforation having a desired width,” directing a POSA to consider analogous art, like Hantash, to select a preferred electrode width (Ex.1005, ¶53; Petition, 58; Ex.1003, ¶¶195-199).

Hantash discloses such a “preferred” needle diameter range of “50 to 300µm,” i.e., 0.05-0.3mm, encompassing claim 9's entire 0.25mm-0.30mm range (Ex.1007, ¶39). Hantash motivated this “preferred” range to provide electrode needles “at least 50µm” to be thick enough for the strength required “to reduce breakage” and “less than 300µm” to be thin enough “to allow close packing of the needles 115 and to reduce disruption” (Ex.1007, ¶39; Petition, 58; Ex.1003, ¶235).

PO's argument that Hantash's diameter range would “create much larger areas of ablation” (POR, 56) ignores Ganz's embodiment of a larger needle diameter of “about 0.5mm” (Ex.1005, ¶47). Modifying Ganz's needle diameter from 0.5mm to Hantash's 0.3mm would create *smaller* less-visible perforations. Additionally, Ganz discloses increasing needle length for “deeper perforation” and varying width accordingly “based on the desired treatment,” thereby motivating a POSA to increase electrode/perforation diameter up to “0.5mm” for the strength required “to reduce breakage” when penetrating “deeper into the tissue layers” (Ex.1005, ¶51; Ex.1007, ¶39).

Hantash's diameter range will not "result in unacceptable damage to the skin" (POR, 56). Hantash's **widest** diameter ("300 μ m," Ex.1007, ¶39) is the same used in Na's Paper ("diameter of 300 $\pm$ 10 μ m," Ex.2032, 8) in which PO confirms "no holes are visible in the histological images" (POR, 48). Ganz's needle diameter so modified thus still "cannot be seen with the naked eye" (Ex.1005, ¶29).

2. Claim 22: RF From 0.5 To 10Mhz And Predetermined Time Interval From 0.05 To 0.8 Seconds

"[P]redetermined time interval": PO does not dispute obviousness of this limitation (POR, 59).

"RF" Range: Ganz provides no specific values for its "radio frequency energy," motivating a POSA to consider literature in the same field, such as Hantash, to select optimal RF values (Ex.1005, ¶57; Petition, 58; Ex.1003, ¶¶229-230, 234). Ganz and Hantash are not directed to different objectives (POR, 59), but the same objectives and treatment types, including revitalizing skin by stimulating coagulation, preventing overheating between electrodes, minimizing skin damage, and reducing scars (see above). Hantash provides the benefit (POR, 59) of using its "preferred" RF range to achieve a "desired treatment zone profile" for those aligned treatment objectives in Ganz (Ex.1007, ¶40).

A POSA would have a reasonable expectation of success (Petition, 59-60): the '836 Patent identifies no unexpected result from the claimed RF range

(Ex.1003, ¶223), frequencies in the range of 0.2-6MHz (containing Hantash's RF range) are the most common in medicine and so were routinely used and understood by POSAs (Ex.1024, 3; Ex.1007, ¶40; Ex.1003, ¶223) and PO's expert testified: "there are no ranges of these parameters [including RF frequency and time ranges] in which one would get unexpected results" (Ex.1047, 1457:19-1459:2; Ex.2013, 1474:23-1475:5).

A POSA would thereby have been motivated, and have reasonable expectation of success, to use Hantash's RF range 0.1-10MHz for Ganz's treatment, which encompasses claim 22's entire 0.5-10MHz RF range (Ex.1007, ¶40; Petition, 53,58; Ex.1003, ¶¶221-223, 234).

III. GROUNDS V AND VI: CLAIMS 27-29

PO's only arguments regarding claims 27-29 in Grounds V-VI incorporate arguments for claim 1 in Grounds I-II (POR, 60). PO is incorrect for the reasons above. *See supra* §I.

IV. SECONDARY CONSIDERATIONS

PO's attributes its evidence to other patents and modes prohibited by the claims, as shown below, rendering no presumption nor showing of nexus between its claims and evidence. *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373

(Fed. Cir. 2019); *Volvo Penta of the Americas, LLC v. Brunswick Corp.*, 81 F.4th 1202, 1210 (Fed. Cir. 2023).⁶

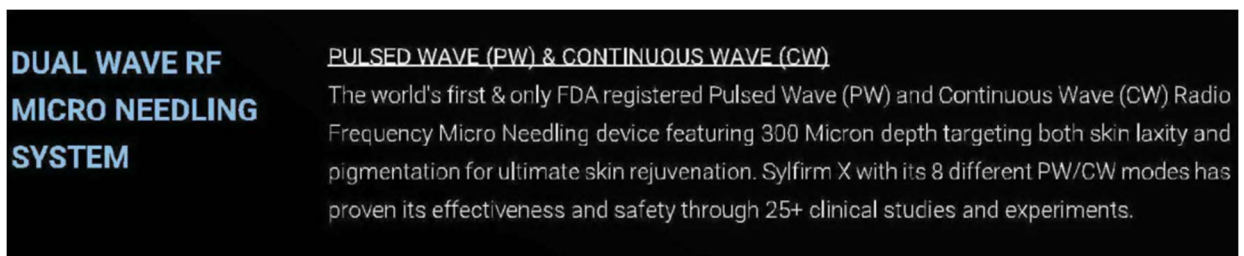
A. Commercial Success

PO's nexus showing is insufficient because, as per the Board: PO attributed the "success of the SylfirmX device...only 'at least partially' due to the '836 Patent claims" and also due "to a different, unrelated invention...[directed to] a *desired distance*, not claimed in the '836 Patent." (Institution Decision, 37-38). *See also* IPR2024-00383, Paper 26, 50, 53-54 (PO asserts "[t]here is a strong nexus between the commercial success of the Sylfirm X and the claimed invention" of

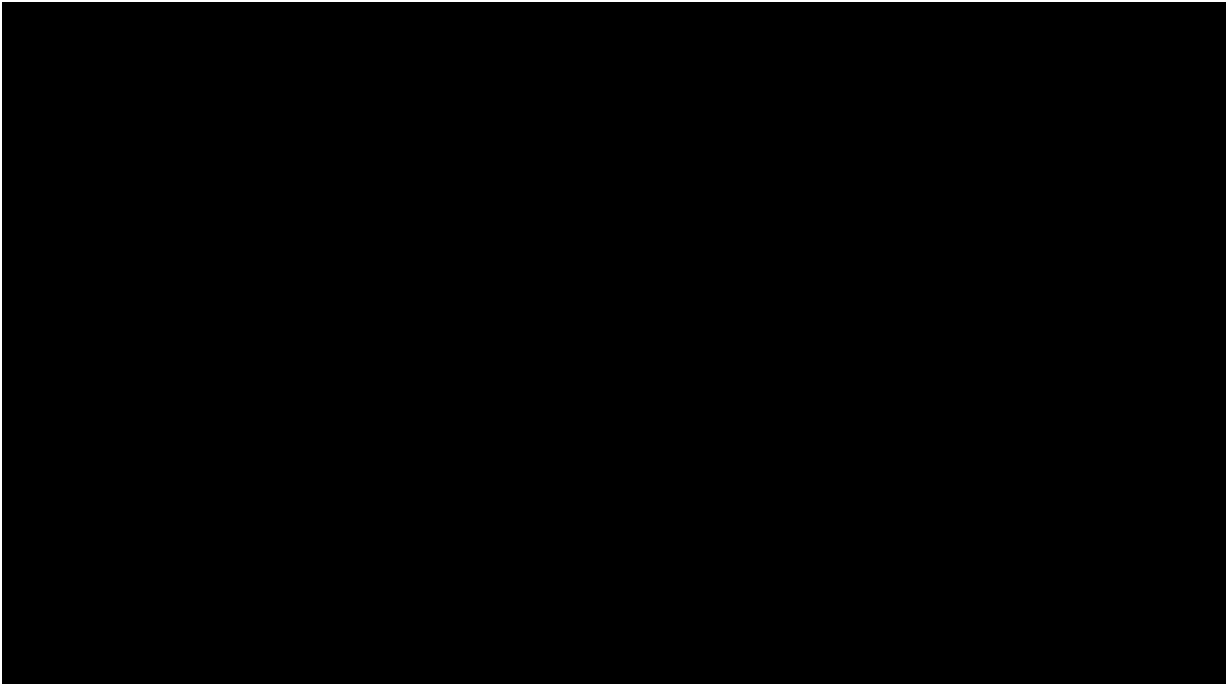
⁶PO's citations at POR 62-64 are irrelevant as relating to not instituting IPRs where (1) petitioner's obviousness arguments were not "persuasive[]," and petitioner did not address "very strong" secondary considerations evidence; and (2) where petitioner did not address "unexpected results" that were "part of the public prosecution" that the Examiner relied on to allow the patent. *See e.g., Robert Bosch Tool Corp. v. SD3, LLC*, IPR2016-01753, Paper 15, pp.26-28; *Gilead Scis., Inc. v. United States.*, IPR2019-01455, Paper 16, pp.50-53. Neither is the case here. In contrast, "[t]he weak evidence of secondary considerations presented here simply cannot overcome the strong showing of obviousness." *ZUP, LLC v. Nash Mfg.*, 896 F.3d 1365, 1375 (Fed. Cir. 2018).

U.S. Patent 9,775,774). PO erred by submitting “the *same evidence* as providing evidence of nonobviousness for *four different patents*” including the ‘836 Patent (Institution Decision in joined IPR2024-00842, 11, Board’s emphasis) without “proving the degree to which evidence of secondary considerations tied to a product is attributable to a particular claimed invention.” *Fox Factory*, 944 F.3d at 1377-78. As the Board correctly found, “PO has failed to explain ‘how its evidence of commercial success is the direct result of the claimed invention here, as opposed to the claimed invention at the heart of [PO]’s other patent.’” (Institution Decision, 38).

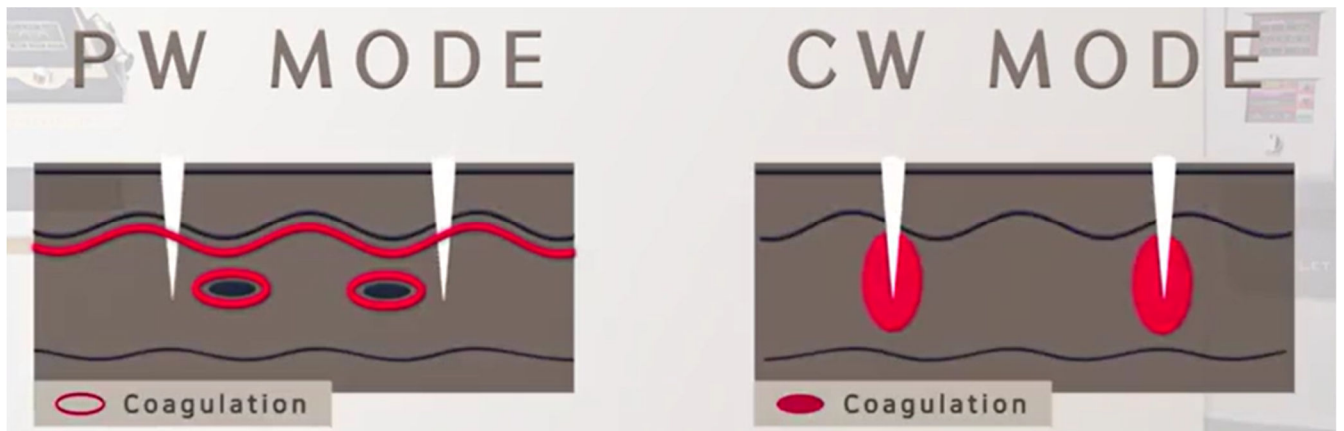
Additionally, PO’s advertisements prominently tout the SylfirmX’s unclaimed features: its “Dual Wave” technology, and particularly its “PW” (“Pulsed Wave”) modes (*see e.g.*, Ex.2037, 2 (“The world’s first and only FDA registered Pulsed Wave (PW) and Continuous Wave (CW) Radio Frequency Micro Needling device”); *see also* [REDACTED]; Ex.2101, 1).



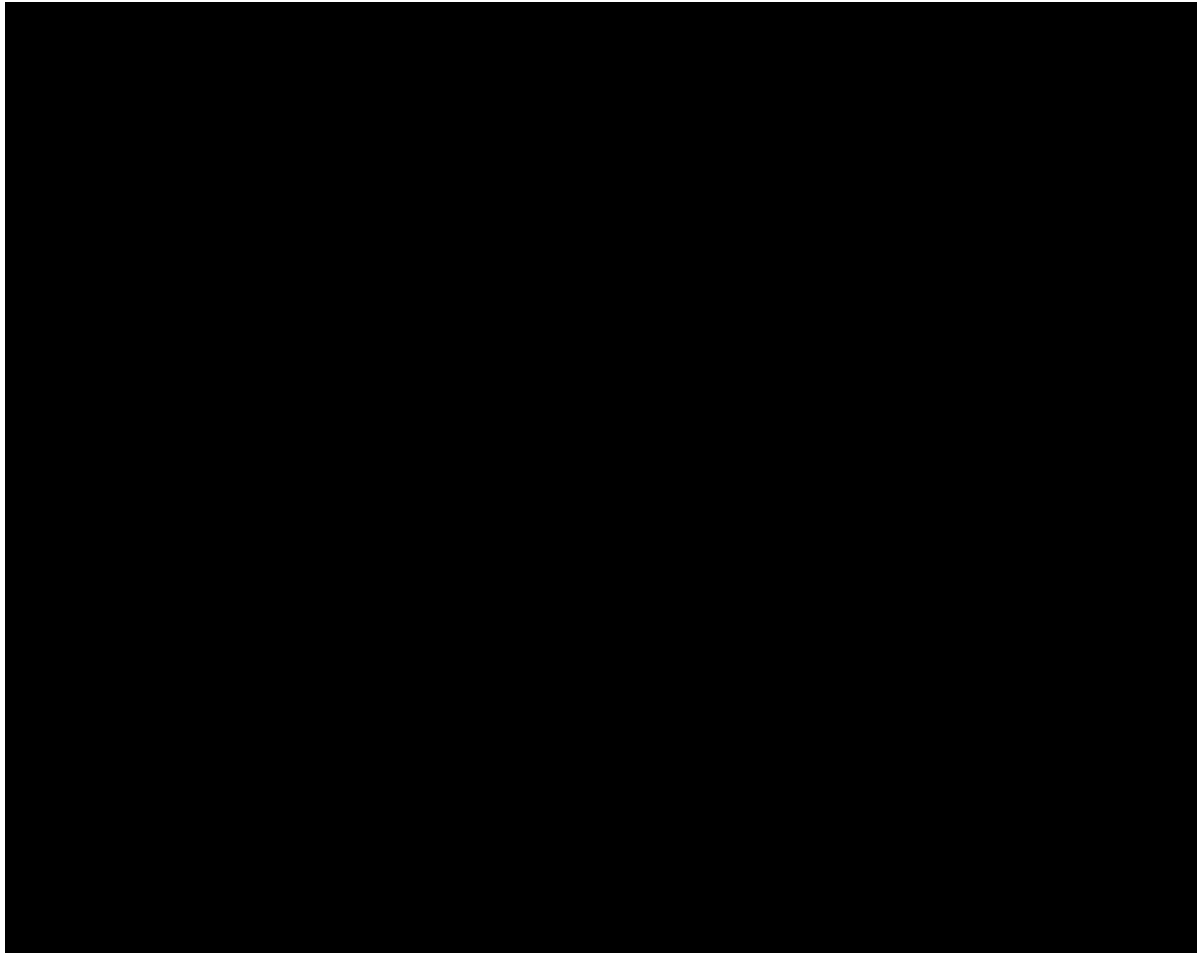
(Ex.2037, 2).



Sylfirm X's "PW mode" (left-image below) is advertised to cause coagulation illustrated by the *red wave* that is "*fully extending* from one electrode to another electrode" (*see e.g.*, Ex.2099, 0:59-1:08; Ex.2097, 0:33-0:40; Ex. 1045, 65:21-67:12), which is prohibited by the agreed claim construction (Ex.1028, 40; Ex.1043, ¶11-12):

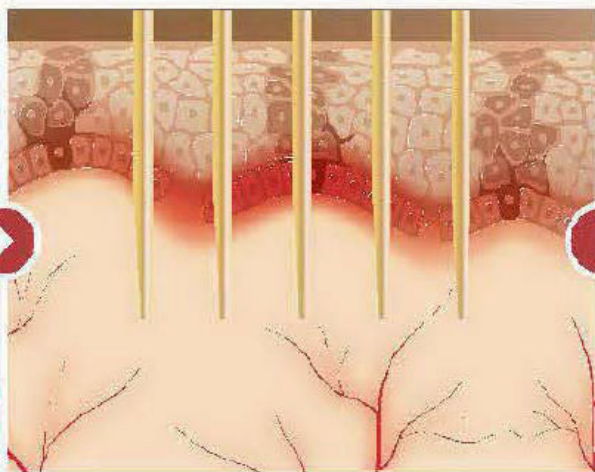


(Ex.2099, 1:00: PW coagulation in red fully extends between electrodes in white).

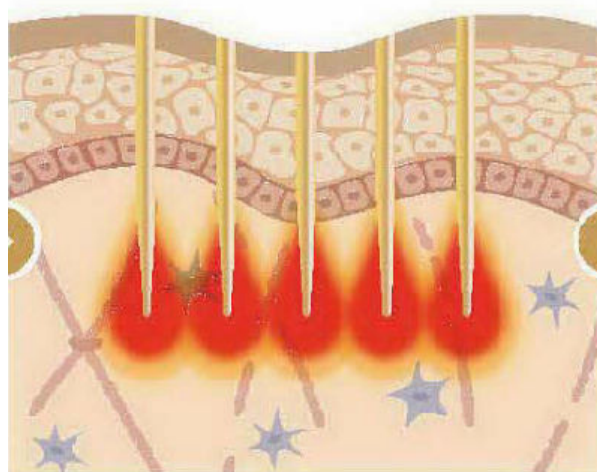


([REDACTED]).

PW Mode



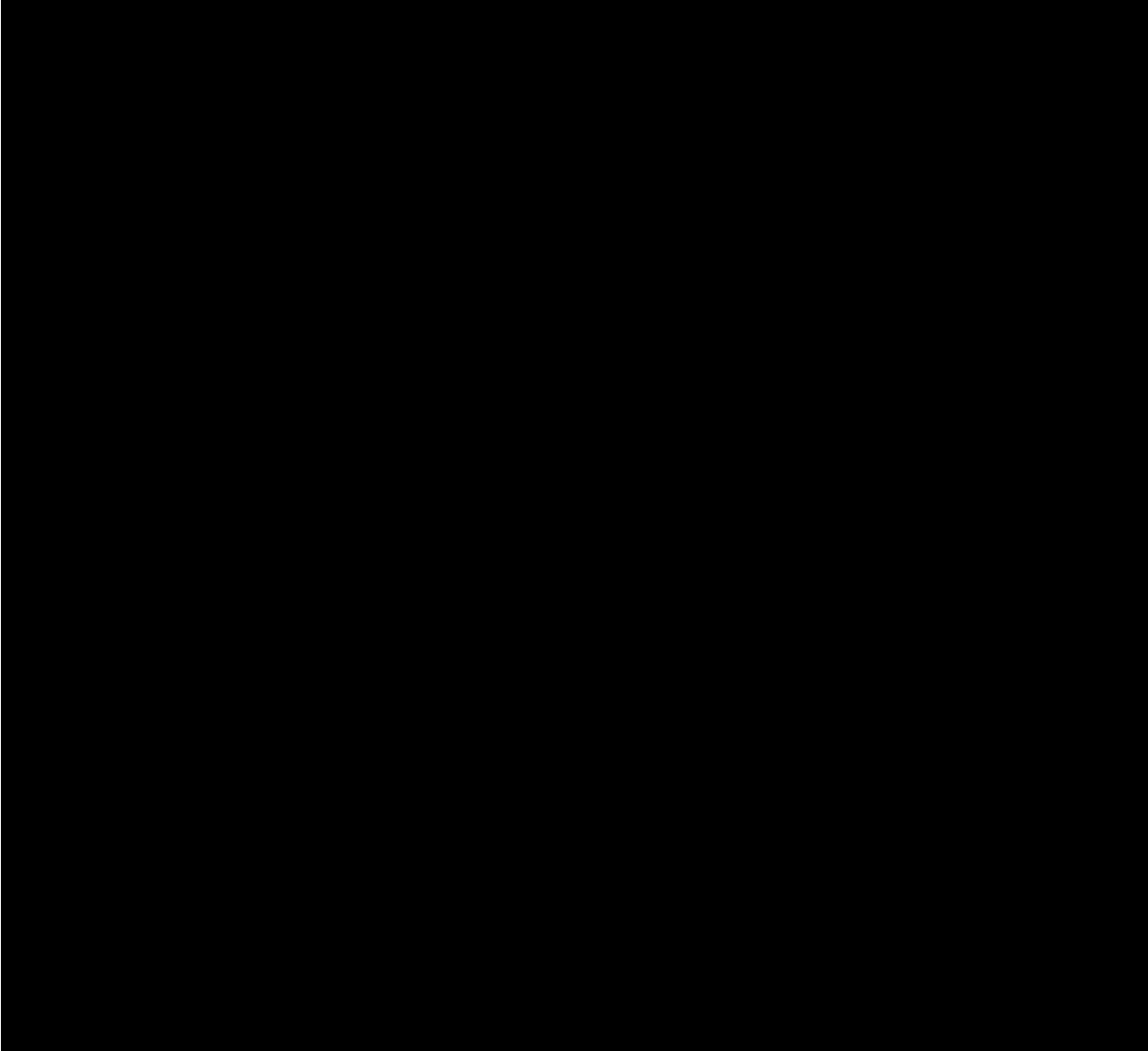
CW Mode



(Ex.2037, 6-7, annotated: PW coagulation fully extending across all electrodes).

PO's expert confirmed Sylfirm X literature shows coagulation in PW mode that “*extends continuously* between the electrodes” (Ex.1044, 68:15-69:3, 72:16-73:9).

Dr. van der Weide confirmed his opinions, which Dr. Goldberg relied on, that “the Sylfirm X practices the claim limitations...is limited to the Sylfirm X's CW mode.” (Ex.1045, 67:13-19, 68:18-69:9; *see also* Ex.2142, ¶45).



([REDACTED] see also Ex.1044, 61:18-64:1).

Because PO provides no evidence attributing commercial success specifically to the '836 Patent's claimed coagulation around rather than between electrodes (as distinct from its unclaimed PW mode), PO's evidence of alleged success cannot be attributed to the '836 Patent claims. The Federal Circuit made clear, "if the commercial success is due to an unclaimed feature of the device, the commercial success is irrelevant." *Ormco Corp. v. Align Technology, Inc.*, 463 F.3d 1299, 1312 (Fed. Cir. 2006).

Accordingly, PO's showing alleging nexus between commercial success and the '836 Patent claims is insufficient (POR, 64-71; Ex.2142, ¶¶46-55).

B. Industry Praise and Peer Recognition

PO has "failed to connect the evidence of industry praise to the novel elements of the claims." *S. Ala. Med. Sci. Found. v. Gnosis S.p.A.*, 808 F.3d 823, 827 (Fed. Cir. 2015). Initially, nearly all evidence PO and PO's expert rely on to allege industry praise or peer recognition (Exs.2032, 2043-2045, 2047, cited in POR, 71; Ex.2142, ¶¶58-63) appears to have been written by or paid for by patent owner, the named inventor, Sylfirm X's distributor Benev, original patent owner Viol, or other interested parties, and so, amounts to self-promotion rather than objective praise (*See* Ex.1043, ¶¶18, 21-22). For instance, PO's Ex.2042 submitted as evidence that "many medical providers" praise the Na Effect as setting the

Sylfirm X “apart from the pack” (POR, 71)⁷ is admitted “[m]arketing of the Sylfirm X” (Ex.2142, ¶54) that is a paid promotional material, “Sponsored By BENEV,” the Sylfirm X’s US distributor (Ex.1043, ¶18, citing Ex.1048).

Likewise, “Prime” magazine article (Ex.2066) is also “[m]arketing of the Sylfirm X” (Ex.2142, ¶¶54-55) that is paid “PRIME Promotion” (Ex.2066, 1; Ex.1043, ¶18, citing Ex.1046). Additional articles cited by PO (POR, 71) are self-praise by either PO and/or named inventor (Exs.2044-2045, 2032)⁸.

Additionally, all evidence of industry praise or peer recognition is immaterial to the ‘836 Patent claims: PO’s expert admitted Ex.2043 does not mention anything related to the claims (Ex.1044, 97:21-99:1, 100:7-102:5); Ex.2067 omits any mention related to any claim limitation; and Exs.2044-2048 praise unclaimed features (*See e.g.*, Ex.2044, 15 (“pulsed-type delivery of RF signal” contrasted with “the Na effect”); Ex.2045, 1-2 (“pulsed-type” technology); Ex.2046, 4, 6 (“pulsed-type RF” distinguishing the “Na effect” caused by

⁷This quote, however, discusses an indistinguishable combination of features including “adjustable depths” (attributed to U.S. Patent 9,775,774) and “PW mode” (excluded) (Ex.2042, 3, 6).

⁸*Bayer Healthcare Pharms., Inc. v. Watson Pharms., Inc.*, 713 F.3d 1369, 1377 (Fed. Cir. 2013).

“continuous-type RF”); Ex.2048, 6 (“unique smooth needle motorized insertion”); Ex.2047, 2, 5 (absence of epidermal damage)⁹) (Ex.1043, ¶¶17, 19-20, 22-25; *see also* Ex.1044, 114:4-8; 120:3-121:19, 124:4-8).

All evidence PO's expert relies on for industry praise or peer recognition thus amounts to self-praise and/or is irrelevant to the '836 Patent claims (Ex.1043, ¶¶17-26).

C. Long-Felt But Unmet Need

PO alleges drawbacks of “burns, blisters, scarring, longer downtime, and pain” (POR, 71-72), but PO “fails to show that these drawbacks constituted a long-felt, unmet need alleviated by the patent.” *Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1332-1333 (Fed. Cir. 2009). PO has “provided no evidence to explain how long [the alleged] need was felt, or when the problem first arose,” nor did PO provide any evidence of “efforts to solve that problem.” (*Id.*, at 1332-1333; *see also* 37 C.F.R. §42.6(a)(3)). Dr. Goldberg's declaration cites Ex.2044 and Ex.2037 (Ex.2142, ¶¶66-67, 71), both of which were created **by PO** only *after* the '836 Patent's priority date, and so cannot inform a need of its past (*compare* Ex.1001 June 14, 2011 priority with Ex.2044, 2 “Updated in Jan 2022”; Ex.2037,

⁹PO attributed absence of epidermal damage (“skin surface”) to depth control claimed in a different patent (IPR2024-00383, Paper 11, 61-62).

16 (“2022”). PO’s other exhibits cite problems already solved in the prior art (“monopolar” problems solved by prior art bipolar devices (Exs.2049-2051; Ex.2142, ¶70; Ex.1044, 10:15-11:17, 16:7-17:4); absence of epidermal damage (Ex.2047, 2, 5; Ex.2048, 2) already solved (*see* Ex.1043, ¶28) and unrelated to any claim limitation). (*id.*). Regardless, as discussed above, Ganz discloses the claimed invention, and, thus, “it cannot be said that any long-felt need was unsolved.” *See ZUP*, 896 F.3d at 1374.

PO does not show a need “**unmet**”: Issues of “overheating” and “scarring” (Ex.2142, ¶¶66-67) where already solved in the prior art –*See* PO admitting: “Hantash teaches...‘avoiding overheating...” (POR, 56-57, citing Ex.1007, ¶18; *see also* “reduces...scarring” *id.* 58). Ganz also solved these problems. *See supra* §I.A.2-3, §II.A.

Thus, PO does not overcome the strong *prima facie* case of obviousness in Grounds 1-VI. *ZUP*, 896 F.3d at 1375.

II. CONCLUSION

In view of the foregoing, Petitioner respectfully requests the Board find claims 1-29 of the ‘836 Patent unpatentable.

Respectfully submitted,

Date: April 29, 2025

/ Guy Yonay /
Guy Yonay
Registration No. 52,388

CERTIFICATE OF WORD COUNT COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), I hereby certify that Petitioner's Reply to Patent Owner's Response complies with the type-volume limits of 37 C.F.R. § 42.24(c)(1) requiring this reply to not exceed 5,600 words. As calculated by the word count feature of the word-processing system used to prepare this reply, it contains 5,558 words, excluding the parts of this reply that are exempted by 37 C.F.R. § 42.24(c).

Date: April 29, 2025

/ Guy Yonay /
Guy Yonay
Registration No. 52,388

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e)(1), the parties have agreed that service may be made electronically. I hereby certify that, pursuant to 37 C.F.R. § 42.6(e), a complete copy of the attached Petitioner's Reply to Patent Owner's Response for U.S. Patent No. 9,480,836 and supporting Exhibits, is being served via electronic mail, on April 29, 2025, the same day as the filing of the above-identified document in the USPTO with the Patent Trial and Appeal Board, to lead and back-up counsel of record for Patent Owner, pursuant to its November 25, 2024 Updated Mandatory Notices, as follows:

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