

Filed on behalf of: Serendia, LLC

Entered: November 5, 2024

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

JEISYS MEDICAL INC.,
Petitioner,

v.

SERENDIA, LLC,
Patent Owner.

Case IPR2024-00386
Patent 9,480,836

PATENT OWNER'S RESPONSE

PUBLIC VERSION-REDACTED

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2001	[Proposed] Stipulated Protective Order
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2004	Expert Report of Jean Woloszko, M.D., Ph.D., dated August 14, 2023 (PROTECTIVE ORDER MATERIAL AND REDACTED VERSIONS)
2005	Rebuttal Expert Report of Daniel W. van der Weide, dated August 28, 2023 (PROTECTIVE ORDER MATERIAL)
2006	Rebuttal Expert Report of David Goldberg, M.D., J.D., dated August 28, 2023 (PROTECTIVE ORDER MATERIAL)
2007	Deposition transcript of Jean Woloszko, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C.), taken September 14, 2023 (excerpt)
2008	Deposition transcript of Jean Woloszko, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C.), taken September 15, 2023 (excerpt)
2009	Deposition transcript of Daniel W. van der Weide, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C.), taken August 31, 2023 (excerpt)
2010	Deposition transcript of Daniel W. van der Weide, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C.), taken September 1, 2023 (excerpt)

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2011	Deposition transcript of David J. Goldberg, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C.), taken September 15, 2023 (excerpt)
2012	Hearing transcript, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C.), held November 7, 2023 (Jean Woloszko testimony excerpts) (“Woloszko Hr’g Tr.”)
2013	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) (“VDW Hr’g Tr.”)
2014	Hearing transcript, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C.), held December 11, 2023 (David Goldberg testimony excerpts) (“Goldberg Hr’g Tr.”)
2015	Complainant’s Rebuttal Post-Hearing Brief, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C. Jan. 5, 2024) (PROTECTIVE ORDER MATERIAL)
2016	Complainant’s Public Interest Statement & Complaint of Serendia, LLC, Under Section 337 of the Tariff Action of 1930, as Amended, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C. Mar. 1, 2023)
2017	Parties’ Proposed Procedural Schedule and Notice of USPTO/PTO Proceedings and State and Federal Litigation Pursuant to Order No. 3, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C. Apr. 24, 2023)
2018	Order No. 6: Adopted Procedural Schedule, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C. Apr. 27, 2023)

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2019	Respondents' Joint Reply Post-Hearing Brief, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C. Jan. 5, 2024) (excerpts)
2020	Response of Ilooda to the Complaint and Notice of Investigation, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C. May 1, 2023)
2021	Jeisys Medical Inc.'s and Cynosure, LLC's Response to the Complaint and Notice of Investigation, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C. May 1, 2023)
2022	Letter from Merle W. Richman, CKR Law, to Justin S. Cohen, Thompson & Knight LLP, Cutera, dated March 20, 2018
2023	Letter from Keith K. Im, SynKloud Technologies, LLC, to Todd Tillemans, Cynosure, LLC, dated Nov. 29, 2021
2024	Order No. 33: Granting Parties' Joint Motion to Amend the Amended Procedural Schedule [Motion Docket No. 1356-027], <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C. Oct. 19, 2023)
2025	Exhibit A-02: Invalidity Claim Chart, U.S. Patent No. 9,480,836, Respondents' Invalidity Contentions, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C. May 24, 2023)
2026	U.S. Patent No. 6,766,202 B2
2027	U.S. Patent No. 9,095,358 B2
2028	U.S. Patent No. 8,012,153 B2
2029	RESERVED
2030	Declaration of Daniel W. van der Weide, dated April 23, 2024 ("VDW POPR Decl.") (PROTECTIVE ORDER MATERIAL AND REDACTED VERSIONS)

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2031	Declaration of David J. Goldberg, dated April 20, 2024 (“Goldberg POPR Decl.”) (PROTECTIVE ORDER MATERIAL AND REDACTED VERSIONS)
2032	Jongju Na et al., <i>Electromagnetic Initiation and Propagation of Bipolar Radiofrequency Tissue Reactions via Invasive Non-Insulated Microneedle Electrodes</i> , 5 NATURE SCI. REPS. 16735 (2015)
2033	Hearing transcript, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C.), held December 11, 2023 (Dany Bérubé testimony excerpts) (“Bérubé Hr’g. Tr.”)
2034	U.S. Patent Application Publication No. 2011/0288543 A1 (“Cheng”)
2035	Deposition transcript of Jongju Na, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C.), taken July 24, 2023 (“Na Dep. Tr.”) (excerpts)
2036	Letter from Long H. Chen-S, FDA, to Lisa Pritchard, Galvanize Therapeutics, dated June 17, 2022
2037	Brochure: Sylfirm X Dual Wave RF Microneedling System (2022) (“Brochure”)
2038	ViOL Patent List (Dec. 1, 2023), https://violmedical.com/about/patent
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2042	Kevin A. Wilson, <i>Leading Regenerative Therapies Creating a Paradigm Shift in Aesthetic Medicine</i> , Aesthetic Guide 3–9 (Mar./Apr. 2022)
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2044	ViOL, Sylfirm X Clinical Paper Summary (updated Jan. 2022)
2045	S.B. Cho et al., In Vivo Skin Reactions from Pulsed-Type, Bipolar, Alternating Current Radiofrequency Treatment Using Invasive Noninsulated Electrodes, SKIN RSCH. TECH. 1–8 (2018) (“Cho Study”)
2046	You Jin Jung et al., Therapeutic Effects of a New Invasive Pulsed-Type Bipolar Radiofrequency for Facial Erythema Associated with Acne Vulgaris and Rosacea, J. COSM. LASER THERAPY 1–5 (2021) (“Jung Study”)
2047	Shaun Wootten et al., An Evaluation of Electrocoagulation and Thermal Diffusion Following Radiofrequency Microneedling Using an In Vivo Porcine Skin Model, J. COSM. DERM. 1–7 (2020) (“Wootten Study”)
2048	Yoram Harth et al., <i>Depressed Acne Scars—Effective, Minimal Downtime Treatment with a Novel Smooth Motion Non-Insulated Microneedle Radiofrequency Technology</i> , 4 J. COSM. DERM. SCIS. APPLS. 212 (2014) (“Harth Study”)
2049	U.S. Patent No. 9,510,899 B2 (“Manstein ’899”)
2050	U.S. Patent No. 6,770,071 B2 (“Woloszko ’071”)
2051	U.S. Patent Application Publication No. 2008/0082090 A1 (“Manstein 090”)
2052	Email exchanges between SynKloud and Jeisys, transmitted December 6, 2021 through January 20, 2022, and Certified English Translations thereof (PROTECTIVE ORDER MATERIAL)
2053	Respondents’ Notice of Prior Art, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C. May 24, 2023) (“1356 Investigation NOPA”)

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2054	Complainant's Initial Validity Contentions, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C. June 16, 2023) (PROTECTIVE ORDER MATERIAL)
2055	<i>Curriculum Vitae</i> of David J. Goldberg, M.D., J.D.
2056	Hee Kyung Kim et al., <i>Immediate and Late Effects of Pulse Widths and Cycles on Bipolar, and Gated Radiofrequency-Induced Reactions in In Vivo Rat Skin</i> , 16 CLINICAL COSM. INVESTIGATIONAL DERM. 721 (2023)
2057	S. Tyler Hollmig & Basil M. Hantash, <i>Radiofrequency in Cosmetic Dermatology, Recent & Future Developments</i> , 24 COSM. DERM. 565 (2011)
2058	U.S. Patent No. 8,142,426 B2 ("Knopp '426")
2059	RESERVED
2060	Dany Berube et al., <i>A Predictive Model of Minimally Invasive Bipolar Fractional Radiofrequency Skin Treatment</i> , 41 LASERS SURG. MED. 473–478 (2009)
2061	Exclusive Distribution and License Agreement between ViOL Co., Ltd. and Serendia LLC, dated February 7, 2018 (PROTECTIVE ORDER MATERIAL)
2062	Presentation: Sylfirm X Clinical Training (2021) (PROTECTIVE ORDER MATERIAL)
2063	Sylfirm Video2
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2065	Presentation: Koh Seikoh, <i>Skin Rejuvenation Treatment of Asian Skin Using Pulse Oscillation Needle RF</i> , 38TH ANN. MTG. JAP. SOC'Y AESTHETIC DERM. (Sept. 13, 2020) (PROTECTIVE ORDER MATERIAL)

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2066	Martin Braun, Sylfirm X Revolutionises [sic] the Clinical Applications of RF Microneedling, 12 PRIME INT'L J. AESTHETIC ANTI-AGEING [SIC] MED. 50 (2022)
2067	World-Class Product of Korea 2020, Certificate to ViOL Co., Ltd., dated December 9, 2020 ("Sylfirm X Award")
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2069	Baze Mpinja, <i>A New Filler for Laugh Lines & More Procedures That Are Safe for Dark Skin</i> , ALLURE (Mar. 20, 2023), https://www.allure.com/story/inclusive-skin-procedures
2070	<i>Curriculum Vitae</i> of Vincent A. Thomas
2071	Profit & Loss, January–December 2021 (Accrual Basis) (July 6, 2023, 2:31 PM) (PROTECTIVE ORDER MATERIAL)
2072	<i>Curriculum Vitae</i> of Daniel W. van der Weide
2073	Christopher L. Brace et al., <i>Microwave Ablation with a Triaxial Antenna: Results in Ex Vivo Bovine Liver</i> , 53 IEEE TRANSACTIONS MICROWAVE THEORY TECHS. 215 (2005)
2074	Dieter Haemmerich et al., <i>Finite-Element Analysis of Hepatic Multiple Probe Radio-Frequency Ablation</i> , 49 IEEE TRANSACTIONS BIOMED. ENG'G 836 (2002)
2075	Luca Zilberti, <i>Charge Relaxation in Biological Tissues with Extremely High Permittivity</i> , 7 IEEE MAGNETICS LETTERS 1 (2016)
2076	Int'l Electrotechnical Comm'n Int'l Standard, <i>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</i> (IEC 60601-2-2) (6.0 ed. Mar. 2017)

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2077	Int'l Electrotechnical Comm'n Int'l Standard, <i>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</i> (IEC 60601-2-2:2009 Withdrawn) (5.0 ed. Feb. 2009)
2078	International Standard, <i>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</i> (IEC 60601-2-2:2009 Withdrawn), INT'L ELECTROTECHNICAL COMM'N WEBSTORE (5.0 ed.) (Feb. 23, 2009), https://webstore.iec.ch/publication/2624 (last visited Aug. 25, 2023) (Abstract only)
2079	Sylfirm X (product information), ViOL (2022), https://violmedical.com/for_providers/product?idx=10 (last visited Feb. 25, 2023)
2080	RESERVED
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2082	RESERVED
2083	ViOL, Sylfirm X User Manual (VO-UM-SFX-03), revised April 20, 2022
2084	Sylfirm X, Device Description (PROTECTIVE ORDER MATERIAL)
2085	RESERVED
2086	Sylfirm X Product Photographs
2087	Presentation: D. van der Weide, RF Microneedle Arrays: Thermal Results, dated July 26, 2023
2088	Photographs: Products at Issue Examinations (June–August 2023)
2089	Cirtec Medical System Drawings, Project: AW000083_A GTW RF PCB, including Certificate of Translation (PROTECTIVE ORDER MATERIAL)

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2090	ViOL, Sylfirm X RF Waveform, R&D (May 22, 2023) (PROTECTIVE ORDER MATERIAL)
2091	Product photograph (CX-3378C.1)
2092	Product photograph (CX-3379C.1)
2093	Product photograph (CX-3380C.1)
2094	Product photograph: Bi-Polar Electrodes, Consumable Tip
2095	Jae Min Shin & Jeong Eun Kim, <i>Radiofrequency in Clinical Dermatology</i> , 2 MED. LASERS 49 (2013)
2096	Tae Hwan Ahn & Sung Bun Cho, <i>Invasive Pulse-Type, Bipolar, Alternating Current Radiofrequency Treatment Using Microneedle Electrodes for Nasal Rosacea</i> , 6 MED. LASER 32 (2017)
2097	Sylfirm X Introduction Video 1
2098	Transcript of Exhibit 2097 - Sylfirm X Introduction Video 1
2099	Sylfirm X Introduction Video 2
2100	Transcript of Exhibit 2099 - Sylfirm X Introduction Video 2
2101	Press Release, BENEV Co., Inc., <i>BENEV Launches Sylfirm X Ultimate Edition, a Novel Radiofrequency Micro-needling Device, in the U.S. as the Exclusive Distributor</i> (Apr. 26, 2021, 14:51 ET), https://www.prnewswire.com/news-releases/benev-launches-sylfirm-x-ultimate-edition-a-novel-radiofrequency-micro-needling-device-in-the-us-as-the-exclusive-distributor-301277036.html
2102	Presentation: Jiehoon Kim, ViOL / Sylfirm, <i>Pigmentary and Vascular Treatment with Pulsed RF “Sylfirm,”</i> including Certificate of Translation (PROTECTIVE ORDER MATERIAL)
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2139	Declaration of Vincent A. Thomas, dated April 23, 2024 (“Thomas Decl.”) (PROTECTIVE ORDER MATERIAL AND REDACTED VERSIONS)
2140	Declaration of Charles H. Sanders in Response to Petitioner's Objections to Patent Owner's Evidence [<i>served, not filed</i>]
2141	Declaration of Cecilia Peniza in Support of Patent Owner's Unopposed Motion for <i>Pro Hac Vice</i> Admission Under 37 C.F.R. § 42.10(c)
2142	Declaration of David Goldberg in Support of '836 Patent Owner's Response, dated November 04, 2024 (“Goldberg Decl.”)
2143	Declaration of Daniel van der Weide in Support of '836 Patent Owner's Response, dated November 04, 2024 (“VDW Decl.”) (PROTECTIVE ORDER MATERIAL AND REDACTED VERSIONS)
2144	Deposition transcript of Jean Woloszko, M.D., Ph.D., <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C.), taken September 14, 2023 (excerpts)
2145	Deposition transcript of Jean Woloszko, M.D., Ph.D., <i>Jeisys Medical Inc. v. Serendia, LLC</i> , IPR2024-00386, taken October 10, 2024
2146	Deposition transcript of R. James Koch, M.D., <i>Jeisys Medical Inc. v. Serendia, LLC</i> , IPR2024-00386, taken October 19, 2024
2147	Katarina Kesty & David J. Goldberg, <i>Radiofrequency Microneedling for Acne, Acne Scars, and More</i> , 1 DERMATOLOGICAL REVS. 33 (2020)
2148	Andrew I. Brill, <i>Bipolar Electrosurgery: Convention and Innovation</i> , 51 CLINICAL OBSTETRICS GYNECOLOGY 153 (2008)

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2149	Letter from Long Chen, U.S. Food & Drug Administration letter to Lisa Pritchard, Galvanize Therapeutics, Inc. (June 17, 2022), regarding K212871 (Aliya(TM) System, Aliya(TM) Generator, Aliya(TM) Needle, Aliya(TM) Electrode; Regulation Number: 21 CPR 878.4400; Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories; Regulatory Class: Class II; Product Code: OAB; Dated: September 6, 2021; Received: September 9, 2021) (Ex. CX-2845 to the deposition of Dr. Jean Woloszko, taken October 10, 2024)
2150	R. James Koch MD Inc., Legal & Medical Device Consulting: Stanford-trained, Double Board-Certified Facial Plastic Surgeon, Practice Website (2024) (Ex. 1 to the deposition of Dr. R. James Koch, taken October 19, 2024)
2151	U.S. Patent No. 9,510,899 B2 ("Manstein '899") (Ex. 2 to the deposition of Dr. R. James Koch, taken October 19, 2024)

I. Introduction

Petitioner Jeisys Medical Inc.'s ("Jeisys") petition for *inter partes* review ("IPR") of U.S. Patent No. 9,480,836 ("836 Patent") does not show unpatentability of any challenged claim for three reasons.

First, Petitioner's primary reference, Ganz, is directed to an entirely different treatment approach than the '836 Patent, and both Ganz and the '836 Patent expressly distinguish their respective treatment approaches. Specifically, the '836 Patent is directed to a milder, safer approach to treating tissue by inducing coagulation around treatment electrodes, while minimizing overheating and leaving the treated tissue intact. By contrast, Ganz is directed to aggressively removing tissue to create "ablation holes" and cauterizing the edges of those holes to stop bleeding. None of Petitioner's secondary references address this fundamental difference, and Petitioner does not contend otherwise.

Second, because Ganz and the '836 Patent are directed to contradictory treatment methods, Ganz fails to disclose or teach multiple claim limitations, including "electrodes being bipolar," which are "configured to cause coagulation around each electrode rather than between them," as required by independent claims 1 and 14 of the '836 Patent. Indeed, the evidence Petitioner identifies for these limitations is the same types of evidence that the Board previously rejected during

the prior IPR for the '836 Patent. Petitioner presents no cogent reason why the Board should reach a different conclusion here.

Third, substantial, uncontroverted evidence supports finding that objective indicia of non-obviousness, including commercial success, industry praise, and long-felt need, demonstrate the non-obviousness of the '836 Patent claims and outweigh Petitioner's weak showing. Moreover, despite being aware of Patent Owner's objective indicia evidence since the prior ITC proceedings, Petitioner does not controvert them, and Petitioner cannot — because Petitioner has no valid response to Patent Owner's proffered evidence. Simply put, Petitioner's hindsight obviousness arguments disregard the real-world evidence that the claimed inventions were far from obvious to those skilled in the art.

In short, Petitioner argues that the '836 Patent claims are obvious in view of facially distinguishable prior art and recycled arguments of the same type that have already been rejected by the Board, without addressing any secondary indicia of non-obviousness.

Patent Owner respectfully requests that the Board confirm patentability.

II. Procedural History And Background Of The IPR Petitions

A. Background Of The Denial Of Institution Of The First IPR Petition

On August 6, 2021, Patent Owner sued Sung Hwan E&B Co., Ltd. ("SHEnB") and Cartessa Aesthetics, LLC ("Cartessa") in District Court for infringing Patent

Owner's patents, including the '836 Patent. *SynKloud Techs., LLC v. SHEnB*, No. 6:21-cv-00811 (W.D. Tex. Aug. 6, 2021), ECF No. 1; *SynKloud Techs., LLC v. Cartessa*, No. 2:21-cv-04423 (E.D.N.Y. Aug. 6, 2021), ECF No. 1. On January 4, 2022, Patent Owner also sued Aesthetics Biomedical Incorporated ("ABM") in District Court for infringing the '836 Patent and other patents. *SynKloud Techs., LLC v. ABM*, No. 2:22-cv-00015 (D. Ariz. Jan. 4, 2022), ECF No. 1.

On February 10, 2022, Cartessa and ABM filed the first IPR petition challenging all claims of the '836 Patent. *See Cartessa v. Serendia, LLC*, IPR2022-00594, Paper 1 (P.T.A.B. Feb. 10, 2022) ("*Cartessa IV*"). On May 16, 2022, Patent Owner filed its Patent Owner Preliminary Response. *Id.*, Paper 8. On August 12, 2022, the Board denied institution because petitioners failed to show a reasonable likelihood of prevailing with respect to any of the challenged claims. *Id.*, Paper 9 at 2.

B. The Current And Former Petitioners Fully Litigate The '836 Patent's Validity In The ITC

On March 1, 2023, Patent Owner filed additional complaints alleging infringement of the '836 Patent (and others), against Lutronic Aesthetics, Inc. ("Lutronic"), Rohrer Aesthetics, Inc. ("Rohrer"), EndyMed Medical, Inc. ("EndyMed"), Cynosure, LLC ("Cynosure"), and Cutera, Inc. ("Cutera"). On the same day, Patent Owner filed an ITC complaint alleging infringement of the '836 Patent (and others), against the District Court defendants identified above, as well

as Cynosure's and Cutera's Korean suppliers: Ilooda Co., Ltd. and Jeisys Medical Inc. (the current Petitioner). *In re Certain Dermatological Treatment Devices and Components Thereof*, Inv. No. 337-TA-1356 (U.S.I.T.C. Mar. 1, 2023) ("1356 Investigation").

On November 1-2, November 6-7, and December 11-12, 2023, evidentiary hearings were held in the ITC. On January 8, 2024, after the validity of the '836 Patent was fully litigated in the ITC, including the submission of all post-hearing briefings, Petitioner Jeisys filed the second IPR petition at issue here. *See Jeisys v. Serendia, LLC*, IPR2024-00386, Paper 1 (P.T.A.B. Jan. 8, 2024). On July 22, 2024, the Board granted institution. *Id.*, Paper 18. Subsequently, on July 31, 2024, EndyMed filed its own IPR petition against the '836 Patent, along with a motion for joinder. *EndyMed v. Serendia, LLC*, IPR2024-00842, Papers 1, 2 (P.T.A.B. July 31, 2024).

III. Technical Background

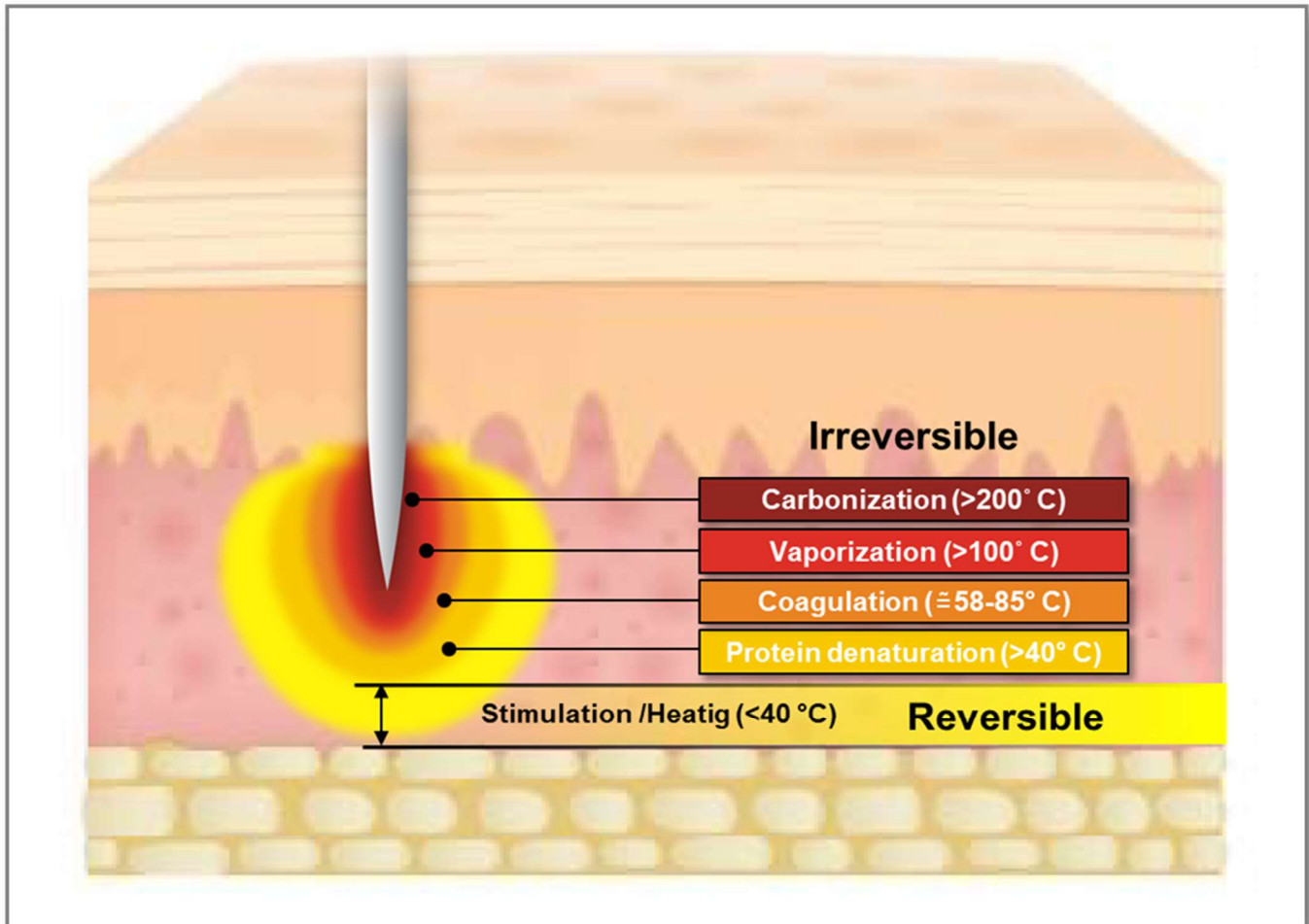
A. RF Microneedling

As discussed in the affidavit of Dr. David Goldberg (a nationally renowned dermatologist who has worked with RF Microneedling devices for decades), radiofrequency ("RF") microneedling is a cosmetic procedure which uses tiny needles and radiofrequency waves to rejuvenate facial skin. Ex.2142 (Goldberg Decl.) ¶14. Microneedling technology, also known as collagen induction therapy,

has been used by physicians since 1995. *Id.* (citing Ex.2147 (Kesty & Goldberg)). RF microneedling is a type of microneedling in which each needle releases a radiofrequency current and creates small zones of neocollagenesis that are termed “radiofrequency thermal zones.” *Id.* During treatment, trauma to the dermis induces neocollagenesis through induction of the wound healing cascade, including growth factors such as transforming growth factor - α (TGF - α), TGF - β , and platelet - derived growth factor. *Id.* Put simply, RF microneedling treatment is a form of controlled skin injury. *Id.* The damage stimulates the growth of healthy new skin, which can benefit common skin issues like acne scars and wrinkles. *Id.*

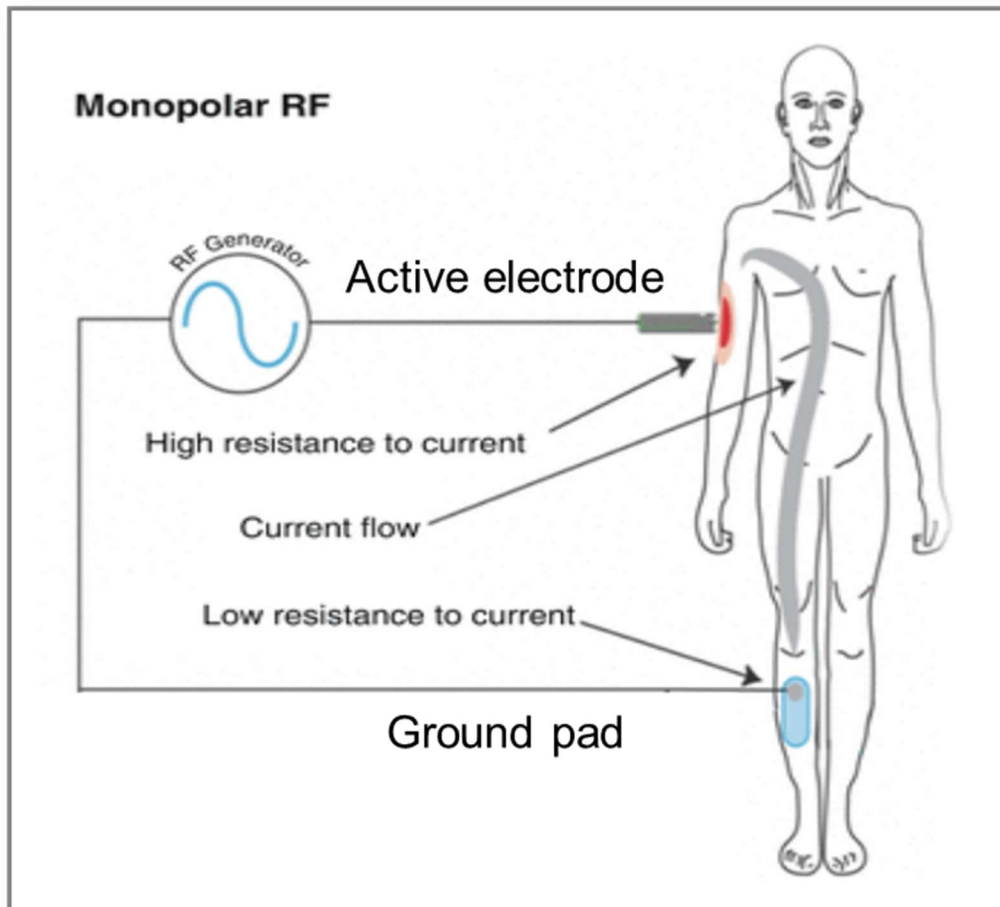
B. The Effects of RF Energy On Tissue

As the RF energy heats the skin, different effects occur to the tissue. Ex.2142 (Goldberg Decl.) ¶15. For example, as illustrated below, at low temperatures (i.e., 40-45°C), reversible cell damage occurs; at temperatures over 60°C, coagulation may occur; and at higher temperatures (i.e., near 100°C), vaporization and carbonization (also known as ablation) of the tissue may occur. *Id.* (citing Ex.2056 (Kim)).

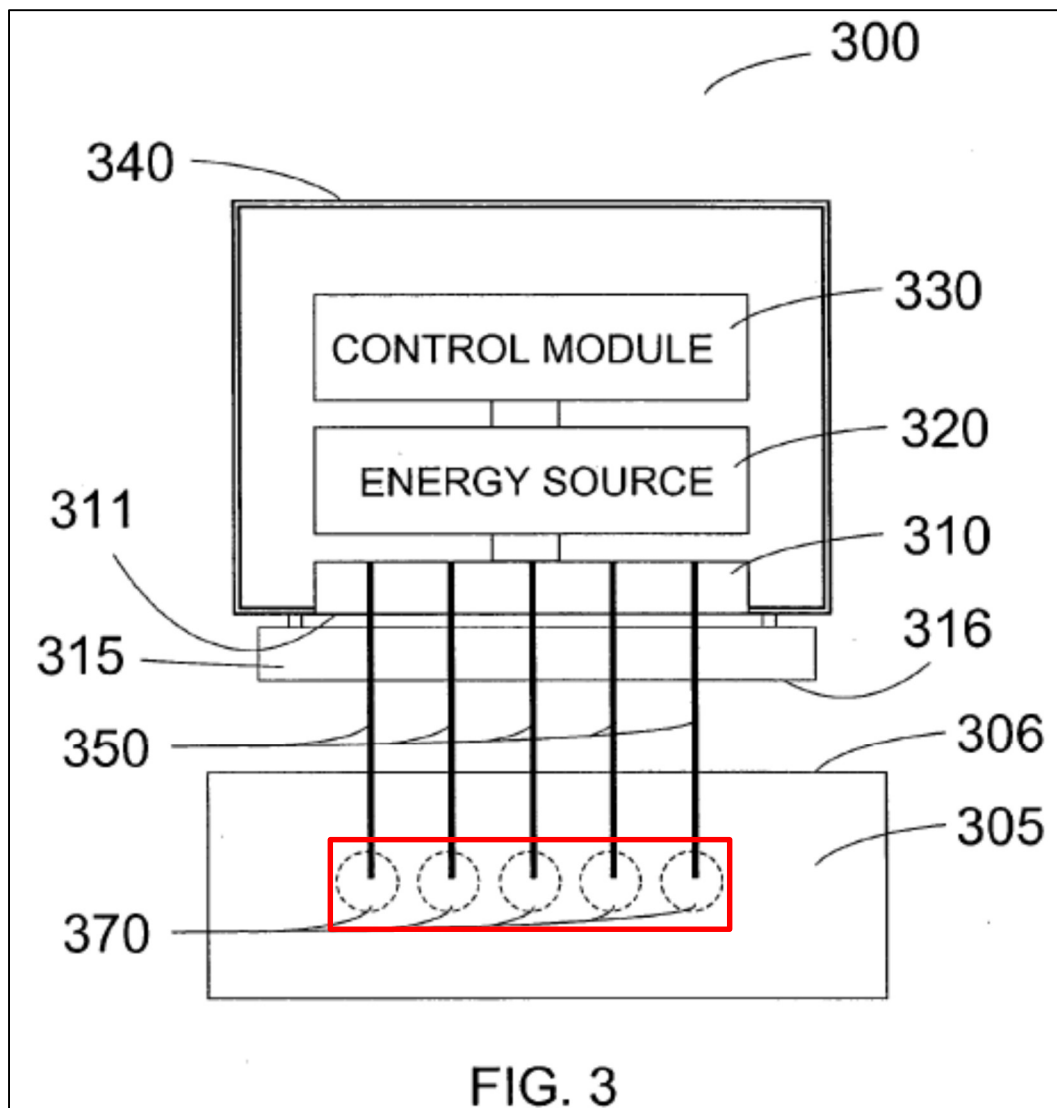


C. Prior Monopolar And Bipolar RF Microneedling

As for how the RF energy is delivered, RF energy can be emitted into the skin via a **monopolar** mode that utilizes an active electrode and a grounded electrode, or via a **bipolar** mode that employs two active electrodes. Ex.2142 (Goldberg Decl.) ¶16 (citing Ex.2032 (Na Nature Paper), 1). As illustrated below, in **monopolar** modes, an electrical circuit, formed by an electron current that flows from the active electrode to the grounded electrode, is generated in the patient's body. *Id.*



Prior monopolar RF microneedling systems had the benefit of causing thermal damage to be localized around just the electrode needles. For example, as discussed in U.S. Patent Application Publication No. 2005/0222565 ("Manstein"), thermal damage is generated around just the tip of electrode needles "from operation of the apparatus in monopolar configuration[.]" Ex.1014, [0037]. This localized thermal damage is illustrated in Figure 3 of Manstein (where each item 370, collectively annotated in red, represents a localized zone of thermal damage around the tip of each needle):



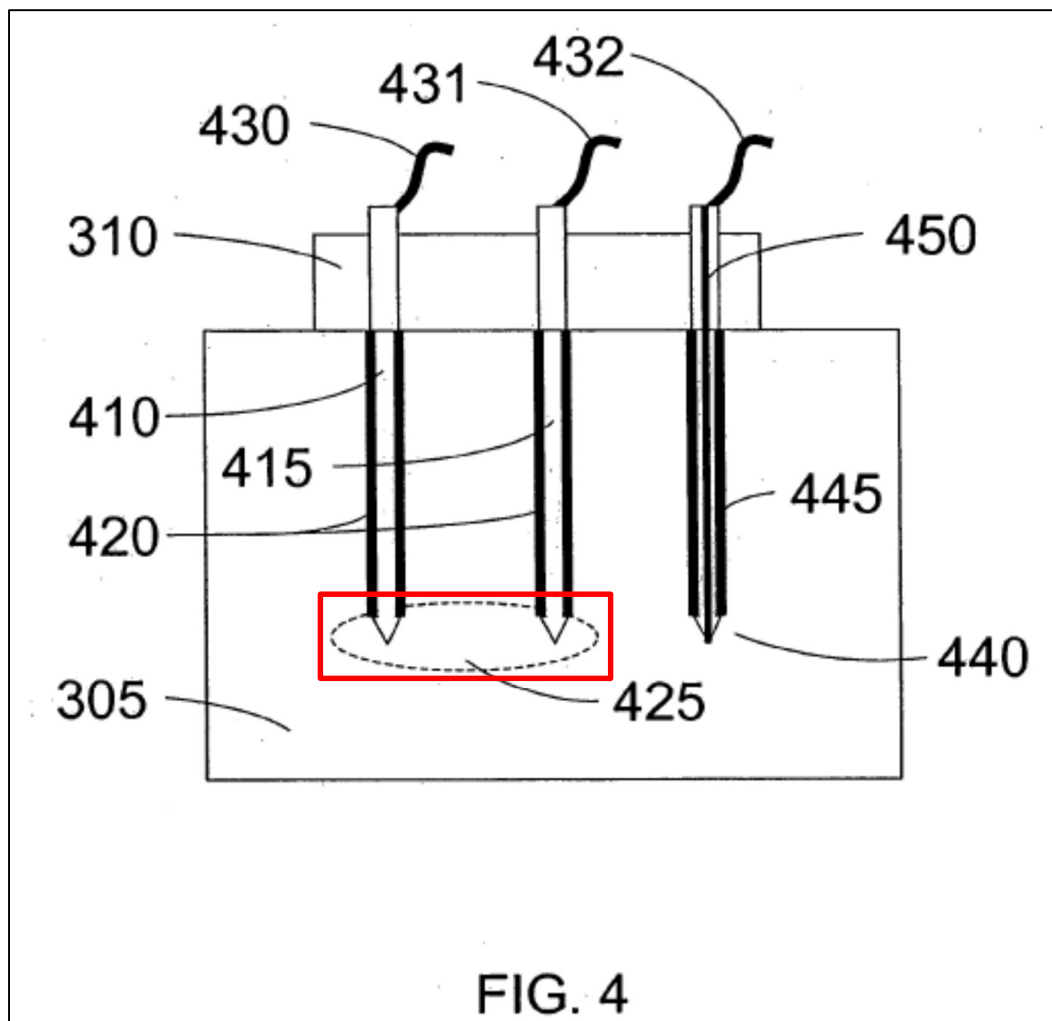
Id., Fig. 3.

While prior monopolar RF microneedling systems allowed for localized thermal damage, these prior systems also carried several risks. Ex.2142 (Goldberg Decl.) ¶16. For example, the first widely accepted aesthetic radiofrequency microneedling technology was a monopolar device call the Thermage device. *Id.* (citing Ex.2057 (Hollmig), 566). Yet “early results with this device were somewhat inconsistent and often were statistically insignificant after photographic analysis.”

Id. And the Thermage was known to cause “***unwanted energy passing to the epidermis***” which “***creates the risk of unwanted collateral damage to the skin.***” *Id.* (citing Ex.2058 (USP 8,142,426), 1:61-2:5).¹

Bipolar systems induce an electrical circuit *between* the two active electrodes. Ex.2142 (Goldberg Decl.) ¶17. Because bipolar electrode configurations induce an electrical circuit *between* two active electrodes, prior RF microneedling devices employing bipolar electrode configurations at first resulted in thermal responses *between* electrodes during treatment. *Id.* (citing Ex.2060 (Berube)). For example, once again looking at the Manstein reference, Manstein explains that when using needles that Manstein states were operating in a “bipolar configuration,” “***the applied current will travel through the tissue between the tips of needles 410 and 415, generating an elongated region of thermal damage 425 around and between the tips of the two needles.***” Ex.1014, [0047]. This is illustrated in Figure 4, shown below (where item 425, in the region annotated in red, represents the elongated region of thermal damage intersecting *between* electrodes):

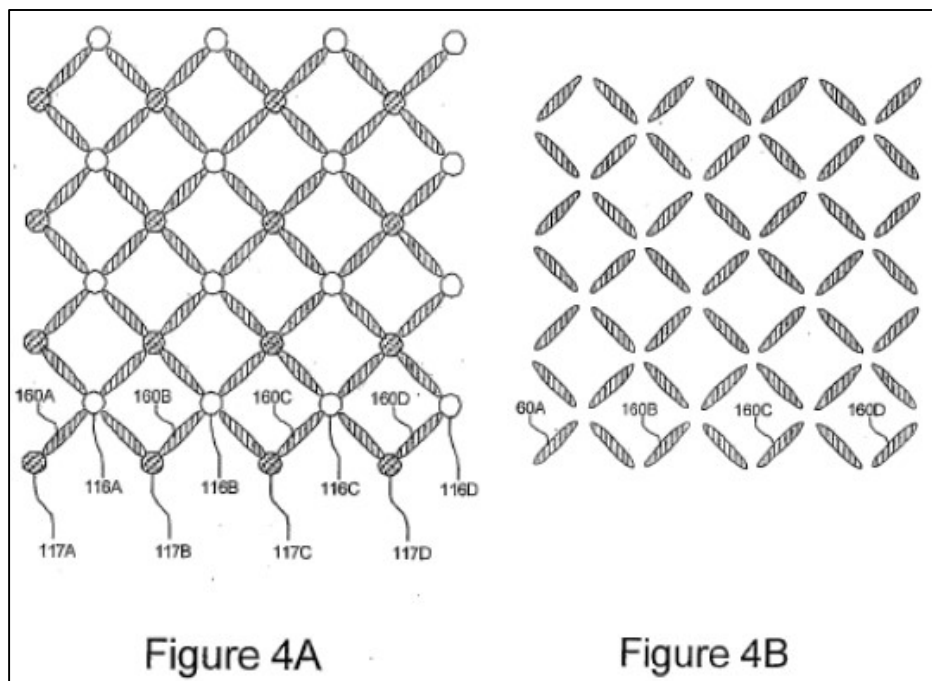
¹ All emphases added unless otherwise noted.



Ex.1014, Fig. 4.

This heating of the entire area extending between the needles risked overheating areas of treated tissue, which could cause scarring and limited the practical use of prior bipolar RF microneedling devices. Ex.2142 (Goldberg Decl.) ¶17. For example, prior bipolar systems were “*not always predictable*,” as they could generate “*[u]nwanted thermal injury*,” and could “*carbonize tissue*,” and further cause the thermal damage to “*occur well beyond their confines*.” *Id.* (citing Ex.2148 (Brill)).

Other prior art references discussing bipolar RF microneedling devices likewise described and illustrated how prior bipolar devices resulted in thermal damage zones intersecting *between* electrodes (rather than concentrated around each electrode tip as occurred with use of monopolar devices). For example, Figure 4A of WO 2007/064718 (“Hantash”) (one of Petitioner’s references), shows “treatment zones 160 that are created *between* nearest neighbor needles 115 that are connected to opposite poles of the RF source 110[.]” and Figure 4B “shows the corresponding treatment pattern 161 of FIG. 4A after the needles have been removed from the skin 150[:.]”

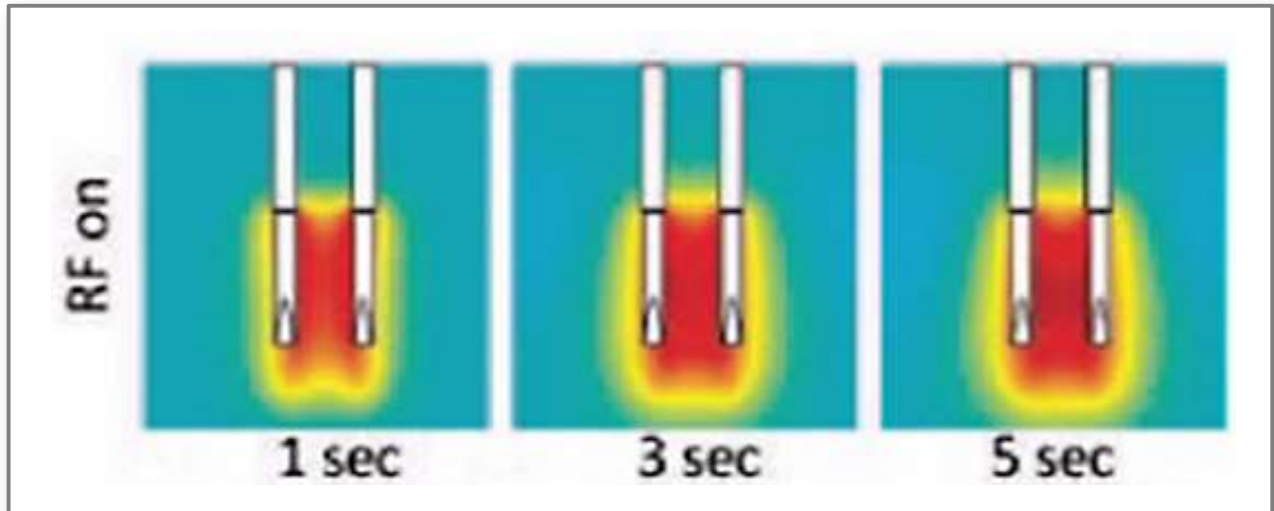


Ex.1007, [0051]; *id.*, Figs. 4A, 4B.

This effect of causing intersecting thermal damage between electrodes was also shown in prior RF devices in the market. For example, the VelaShape device

was an early example of an aesthetic bipolar radiofrequency device with two electrodes attached to the skin. Ex.2142 (Goldberg Decl.) ¶17. The VelaShape would also transmit energy between its two active electrodes, rather than generating localized thermal damage around each electrode like prior monopolar devices. *Id.*

Additionally, Dr. Dany Berube, who initially provided the declaration in support of Petitioner's petition for IPR that was later adopted by Dr. Woloszko, authored a paper discussing the effects of one prior bipolar RF microneedling system, the Miratone™ RF microneedling device. Ex.2060 (Berube). As shown in that paper, the bipolar Miratone™ device resulted in zones of thermal damage *between* each electrode pair:



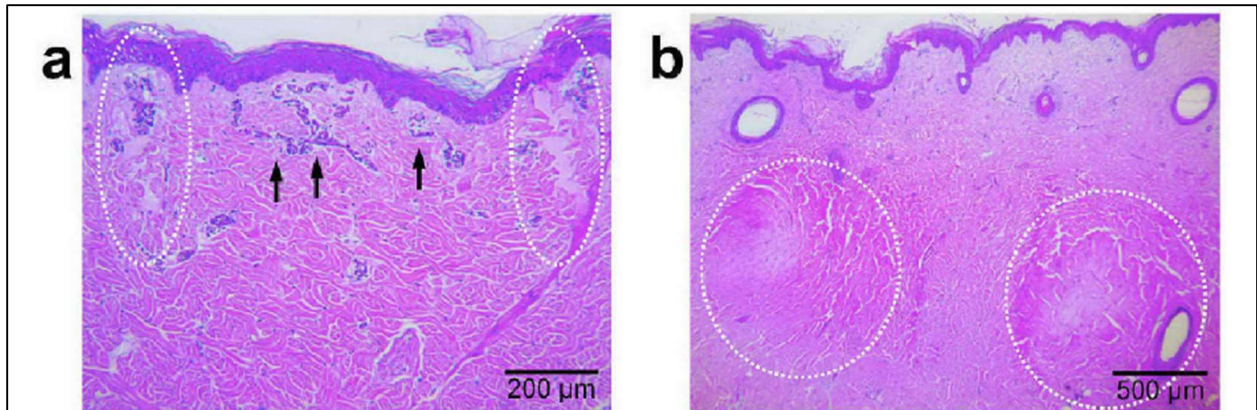
Id., Fig. 5 (excerpted).

In short, physicians were previously forced to choose between utilizing **monopolar** RF microneedling devices that advantageously allowed for precise

localized thermal damage *around* each electrode (but disadvantageously risked collateral damage as the electricity flowed through the body to the grounding pad), or **bipolar** RF microneedling devices that advantageously had less collateral damage (but disadvantageously resulted in thermal damage extending *between* electrodes that risked scarring due to overheating areas of tissue). Ex.2142 (Goldberg Decl.) ¶18.

D. The “Na Effect”

As discussed in the 2015 Nature Article, Dr. Jongju Na, the named inventor of the '836 Patent, demonstrated that under certain parameters, RF microneedling devices with bipolar electrodes can create *ding* coagulation of tissue *around* each needle electrode, rather than *between* the needle electrodes, thereby achieving precise heating of tissue similar to that achieved with monopolar electrodes even while using a bipolar system. Ex.2142 (Goldberg Decl.) ¶19 (citing Ex.2032 (Na Nature Paper)). This approach avoided the disadvantages of each system to provide a “best of both” approach. *Id.* For example, using Dr. Na's technique, “[i]n *ex vivo* bovine liver tissue, the thermal coagulation columns were found to be concentrated maximally around the pointed tips of each electrode” *using bipolar electrodes*. Ex.2032 (Na Nature Paper), 1. This is illustrated in the below histological images (where non-intersecting zones of RF-induced coagulation are shown in the white circles/ovals):



Id., Figs. 1(a), 1(b). As shown in these figures, tissue around each electrode was not ablated to create holes; instead, the benefits of inducing coagulation were achieved *directly* around where each electrode was inserted. Ex.2142 (Goldberg Decl.) ¶19.

This “novel finding of independent tissue coagulation around each electrode” was termed the “Na effect” “to distinguish it from other RF tissue reactions.” Ex.2032 (Na Nature Paper), 7. After Dr. Na’s development of this novel approach to RF microneedling, the use of bipolar RF microneedling devices became more widely adopted by dermatological practices. Ex.2142 (Goldberg Decl.) ¶19. Indeed, countless bipolar RF microneedling procedures are being performed by dermatologists throughout the world because of Dr. Na’s innovation. *Id.*

IV. The ’836 Patent

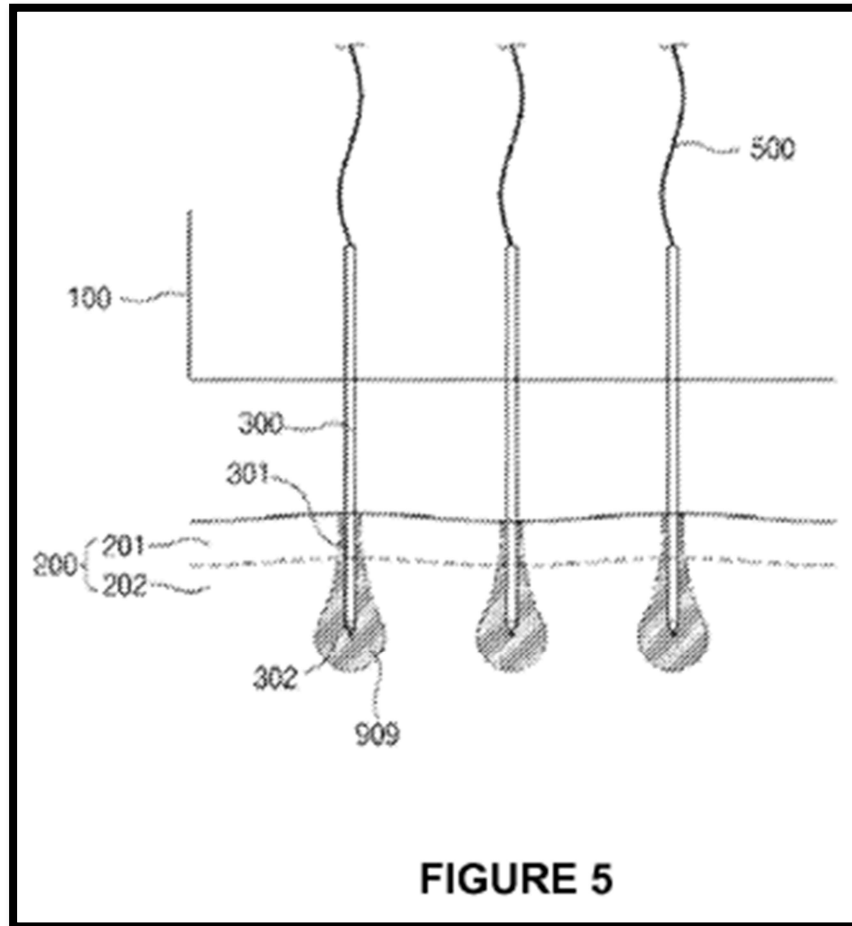
A. Overview

Dr. Na’s pioneering research led to the ’836 Patent. The ’836 Patent generally relates to improved delivery of RF energy to the skin, which reduces side effects of prior systems, such as burning that may cause scarring. Ex.2143 (VDW Decl.) ¶45.

The '836 Patent differentiates between different types of tissue effects that can occur based on the amount of energy supplied, explaining that “[w]hen energy is applied to dermis, the effect on the dermis may differ based on the amount of energy applied and the effect is generally divided into three phenomena: carbonization, vaporization, and coagulation.” Ex.1001, 2:62-65. As discussed above, these different phenomena describe different effects energy has on tissue. At low temperatures (i.e., 40-45°C), reversible cell damage occurs; at temperatures over 60°C, coagulation may occur; and at higher temperatures (i.e., near 100°C), vaporization and carbonization (also known as ablation) of the tissue may occur. Ex.2142 (Goldberg Decl.) ¶15.

The '836 Patent explains that the invention treats tissue through coagulation (i.e., not carbonization or vaporization). Ex.1001, 2:65-3:4 (“The present invention improves skin condition by primarily using coagulation.”). More specifically, in the claimed inventions, the skin treatment is “configured to cause coagulation around each electrode rather than coagulating between the electrodes.” *Id.*, cls. 1, 14. The '836 Patent explains 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 “not be concentrated between needles[.]”—as claimed. *Id.*, 3:20-29. As shown in Figure 5 (copied below), in this treatment method “the heated area[s]” 909 are “around the needle end tips” 302 of the needles 300 in the dermis

202, and accordingly this heat “minimally affect[s] the adjacent epidermis area.” *Id.*; *see also id.*, 5:1-20.



Id., Fig. 5.

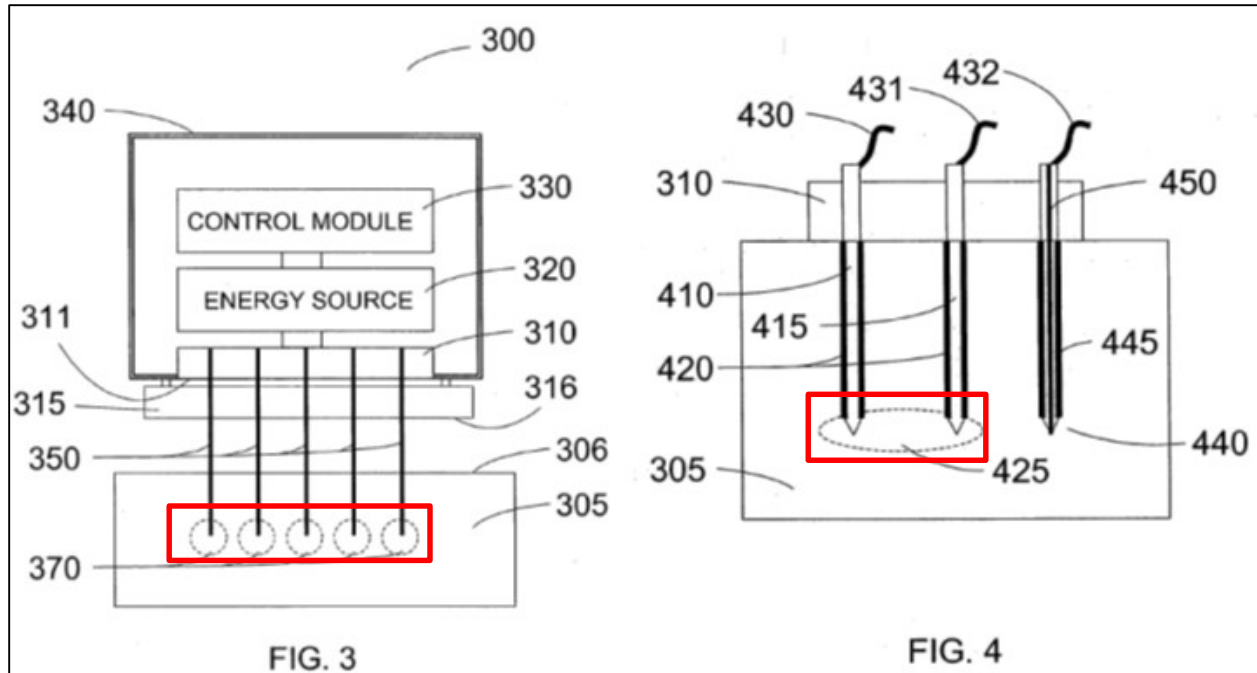
Thus, the treatment claimed in the '836 Patent concentrates energy around each electrode, while limiting the energy applied to ensure that the tissue surrounding each electrode is not carbonized or vaporized (i.e., the tissue surrounding each electrode is not ablated, destroyed, or removed). Ex.2143 (VDW Decl.) ¶57; Ex.2142 (Goldberg Decl.) ¶31.

As the '836 Patent explains, this inventive approach “shown in FIG. 5” can “resolve problems of existing technologies[,]” including the “*serious side effect*” of “*overheating or burning of both dermis and epidermis ..., which may cause permanent skin damage[,]*” e.g., “*scars created in overheated or burned epidermis.*” Ex.1001, 4:4-22. Accordingly, the '836 Patent disparages prior technologies that overheat or burn skin and explains that the claimed treatment overcame this problem. *Id.*; Ex.2143 (VDW Decl.) ¶57; Ex.2142 (Goldberg Decl.) ¶32. A POSITA is thus informed that the prior art approaches for tissue cutting, cauterization, or ablation (involving carbonization and vaporization), are distinct from the '836 Patent's claimed approach that “improves skin condition by primarily using coagulation.” Ex.1001, 2:65-66; Ex.2143 (VDW Decl.) ¶57.

As for how the invention achieves the claimed coagulation around each electrode (rather than coagulating between the electrodes), the specification explains that embodiments of the “invention may employ bipolar needles,” which are driven by a “high frequency” “alternating current (AC)” source. Ex.1001, 3:46-48, 5:58-59. The specification further contemplates the use of “different needle arrangements,” as well as different needle diameters and insulations. *Id.*, 7:24-27, 9:34-48.

B. The '836 Patent's Prosecution History

During prosecution, the '836 Patent claims were initially rejected in view of Manstein (Ex.1014). *See, e.g.*, Ex.1002 ('836 File History), 290-298 (August 4, 2015 Non-Final Rejection, 4-5), 321-328 (January 22, 2016 Final Rejection, 2-3). That said, as the Applicant pointed out, Manstein did not disclose at least: (i) bipolar electrodes configured to cause coagulation around electrodes (rather than between them); and (ii) an RF generator configured to provide AC RF energy. As Applicant noted, while Manstein disclosed bipolar configurations, “Manstein, actually teaches and notes that its bipolar configuration generates *intersecting damage*” *Id.*, 378. For example, as discussed above, *supra* pp. 22-25, Manstein disclosed that its monopolar configurations generated thermal damage around the tip of electrodes, while its bipolar configurations generated larger regions of thermal damage that included damage *between* electrodes:



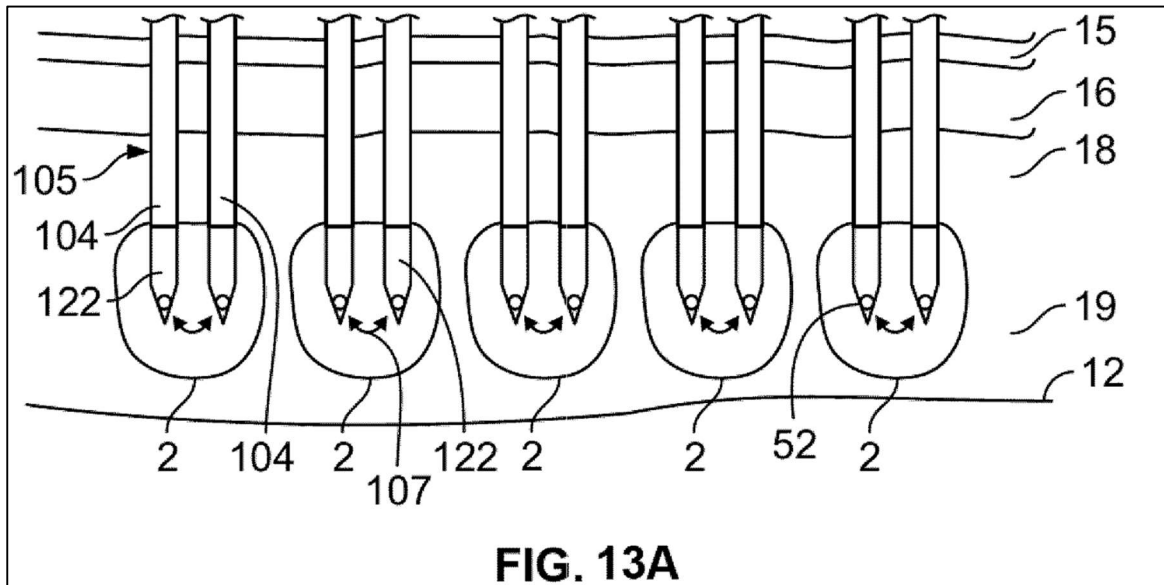
Ex.1014, Figs. 3, 4.

Applicant also noted that “the Manstein reference does not teach applying a high frequency Alternating Current signal to bipolar electrodes.” Ex.1002, 316. For example, as Applicant pointed out, “the RF and AC stimulation are used in different embodiments in the Manstein reference.” *Id.*, 366. The Examiner agreed. *Id.*, 390 (Notice of Allowance, 2).

C. The Prior IPR

During the prior IPR, the prior Petitioner asserted two primary grounds for invalidity: 1) obviousness over U.S. Patent Application Publication No. 2010/0204695 (“Mehta”) in view of U.S. Patent Application Publication No. 2010/0023003 (“Mulholland”); and 2) obviousness over a video of the prior art “INTRAcel” device in view of Mulholland. *Cartessa IV*, Paper 1, *passim*. But as

the Board explained, Figures 13A and 13B in Mehta, which the prior Petitioner relied on, actually “depict coagulation of tissue that extends continuously *between* electrodes.” *Id.*, Paper 9 at 24. Figure 13A, reproduced below (shows intersecting zones of coagulation around bipolar electrode pairs):



As for the INTRAcel video, while the prior Petitioner pointed to histological results showing coagulation around needle insertion points, as the Board recognized, the INTRAcel video “*does not disclose whether the ‘histology results’ screen capture was taken using electrodes in monopolar or bipolar mode.*” *Cartessa IV*, Paper 9 at 35.

In short, the prior Petitioner failed to demonstrate that any of the identified prior art disclosed results from RF microneedles utilizing a bipolar configuration, where coagulation was generated around each electrode, rather than between them.

V. Person of Ordinary Skill in the Art

As Petitioner notes, in the ITC, the ALJ specified the level of skill of a POSITA for the '836 Patent. Pet. 9. For the purposes of this response, Patent Owner does not dispute the POSITA definition adopted in the ITC.

VI. Claim Construction

As Petitioner notes, in the ITC Investigation, Petitioner and Patent Owner agreed to certain constructions (Ex.1028, 39-40), and the ALJ adopted certain constructions (*id.*, 41-62). Petitioner advocates that the Board should apply those constructions, and Patent Owner likewise applies them for purposes of this response.

VII. The '836 Patent Claims Are Patentable Over Petitioner's Cited Prior Art**A. Grounds I & II: Petitioner Fails To Show That Claims 1-2, 11-15, 23-24, And 26 Would Have Been Obvious Based On Ganz Alone Or In View Of Livneh**

Petitioner's contention that Ganz in view of a POSITA's knowledge, or in view of Livneh, renders obvious claims 1-2, 11-15, 23-24, and 26 fails because Ganz is directed to a completely different treatment method than the '836 Patent, and Ganz alone or in view of Livneh fails to disclose or suggest multiple claim limitations.

1. Ganz Is Directed To A Completely Different Approach Than The '836 Patent

a. The '836 Patent Is Directed To Coagulation Around Electrodes, Rather Than Aggressively Burning Away Tissue Around The Electrodes

As discussed above, the '836 Patent differentiates the types of tissue effects that can occur based on the amount of energy supplied, explaining that “[w]hen energy is applied to dermis, the effect on the dermis may differ based on the amount of energy applied and the effect is generally divided into three phenomena: carbonization, vaporization, and coagulation.” Ex.1001, 2:62-65. The '836 Patent explains that the invention treats tissue through coagulation (i.e., *not* carbonization or vaporization). *Id.*, 2:65-3:4; Ex.2143 (VDW Decl.) ¶57.

As the '836 Patent explains, this inventive approach can “resolve problems of existing technologies[,]” including the “*serious side effect*” of “*overheating or burning of both dermis and epidermis ..., which may cause permanent skin damage[,]*” e.g., “*scars created in overheated or burned epidermis.*” Ex.1001, 4:4-22. Accordingly, the '836 Patent disparages prior technologies that overheat the skin and explains that the claimed treatment overcame this problem. *Id.*; Ex.2143 (VDW Decl.) ¶57; Ex.2142 (Goldberg Decl.) ¶32. A POSITA is thus informed that the prior art approaches for tissue cutting, cauterization, or ablation (involving carbonization and vaporization), are distinct from the '836 Patent's claimed

approach that “improves skin condition by primarily using coagulation.” Ex.1001, 2:65-66; Ex.2143 (VDW Decl.) ¶57.

This inventive approach is embodied in the '836 Patent claims, which require that the electrodes are “configured to cause coagulation”—“around each electrode”—and which excludes heating that would be so intense that it instead carbonizes or vaporizes that tissue around each electrode, or coagulates tissue “between the electrodes.” Ex.1001, cls. 1, 11; Ex.2143 (VDW Decl.) ¶57.

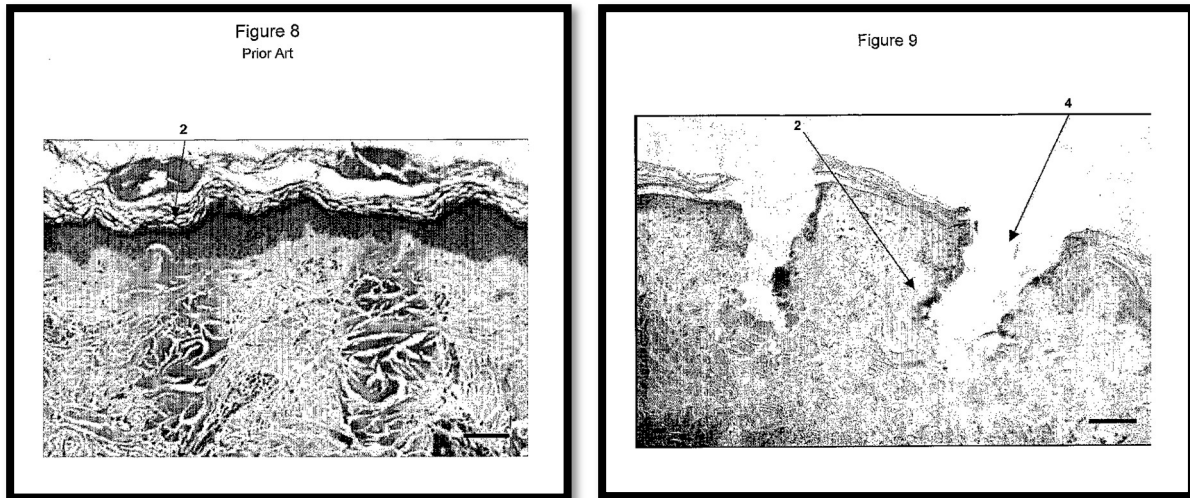
b. Ganz Is Directed To Burning Away Tissue Around Electrodes

U.S. Patent Application Publication No. 2007/0208340 (Ganz), was published in 2007 and never issued as a patent. Ex.1005. Unlike the '836 Patent's claimed skin treatment, Ganz is directed to burning away tissue around each electrode inserted into the skin “to create vertical perforations or *ablation holes* in tissue[]” to “prompt[] an even more aggressive wound healing response.” *Id.*, [0006]; Ex.2143 (VDW Decl.) ¶71; Ex.2142 (Goldberg Decl.) ¶24. Indeed, Ganz expressly distinguishes systems which “*only cause[] zones of coagulation*[],” like the '836 Patent's claimed approach, which Ganz views as a “*drawback*.” Ex.1005, [0006]. Ganz explains that “rather than merely imparting coagulations into the skin[],” Ganz's approach provides for the “creation of actual perforations [which] leads to more aggressive healing responses.” *Id.*, [0032]. Ganz also explains that “the term

‘perforation’” means “vertical areas of thermal damage or **ablation** to the tissue causing tissue necrosis.” *Id.*, [0027].

Thus, rather than teaching coagulation of tissue around treatment electrodes (as in the '836 Patent's claimed approach), Ganz teaches removing the tissue around electrodes to form “**ablation holes**,” i.e., perforations, formed by vaporizing and/or carbonizing the tissue around the electrodes. *Id.*, [0006]; Ex.2143 (VDW Decl.) ¶¶71-72, 92; Ex.2142 (Goldberg Decl.) ¶¶24, 31. Indeed, Petitioner's expert Dr. Koch admits that Ganz teaches removing tissue around electrodes to form ablation holes. Ex.2146 (Koch Oct. 19, 2024 Dep. Tr.), 44:1-3 (“Q. And Ganz discloses creating ablation holes, right? A. **Yes.**”); *id.*, 44:11-13. Ganz discloses creating the perforations by burning away tissue using energy, rather than forming the perforation mechanically because, “when perforations are made mechanically rather than with the use of energy, excess bleeding takes place.” Ex.1005, [0008]-[0009]. In other words, Ganz discloses using energy to cauterize the holes created via Ganz's treatment approach. Ex.2142 (Goldberg Decl.) ¶26.

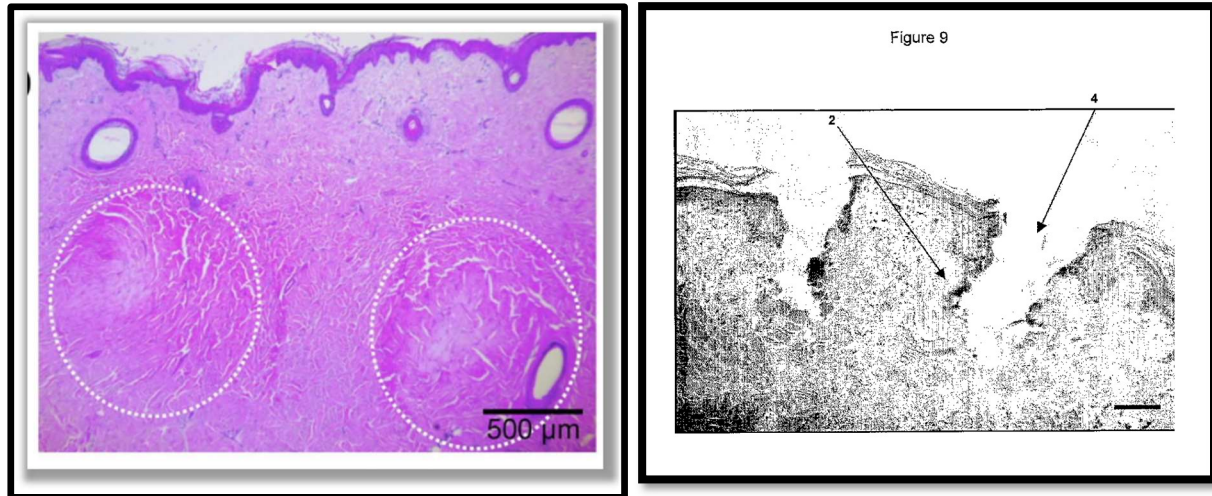
Ganz also illustrates the distinction between treatment approaches that “merely impart[] coagulations into the skin” and the Ganz approach, which burns holes in the skin, using Figures 8 and 9, shown below:



Ex.1005, [0032]; *id.*, Figs. 8-9.

As shown in Figure 8, merely imparting coagulations 2 into the skin (as shown using the prior art FRAXEL laser treatment), leaves the tissue intact. Ex.1005, [0028]. By contrast, as shown in Figure 9, in the Ganz approach, the tissue around each electrode is gone because it has been removed using energy that burned away the tissue, leaving ablation holes (i.e., perforation 4), in the skin. *Id.*; Ex.2142 (Goldberg Decl.) ¶¶28-29. Indeed, as Petitioner's expert Dr. Koch testified, there is no tissue remaining in the Ganz treatment areas because it is "*melted away.*" Ex.2146 (Koch Oct. 19, 2024 Dep. Tr.), 45:7-8; *see id.*, 45:4-6 ("Q. Is there tissue remaining in what's marked as "Treated Area 4" on Figure 9? A. *No.*").

The distinction between the '836 Patent's claimed treatment approach and Ganz's approach is similarly illustrated by comparing histological images of tissue treated using the '836 Patent's claimed approach (on the left below), with Ganz approach (on the right below):



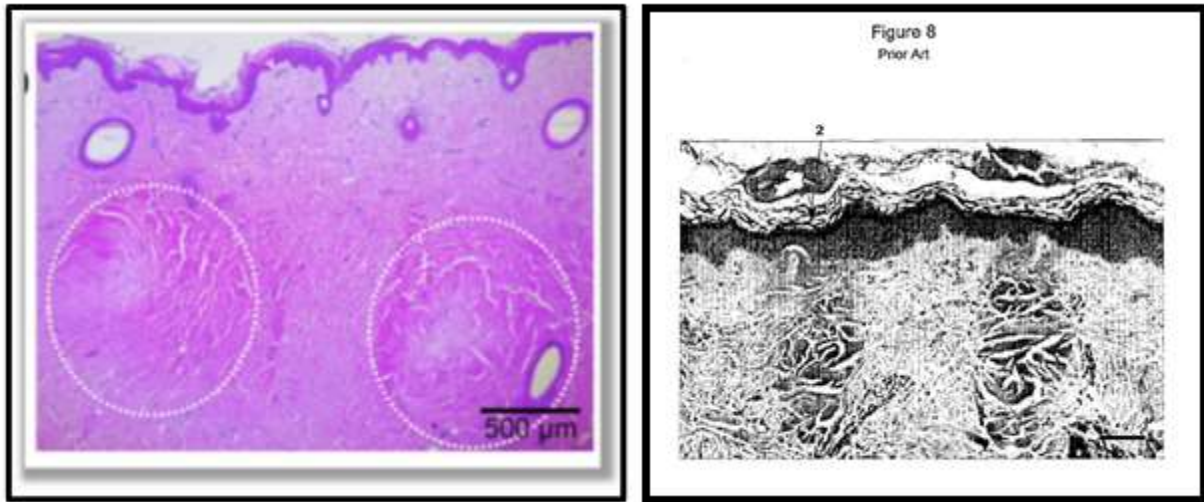
Ex.2032 (Na Nature Paper), Fig. 1b; Ex.1005 (Ganz), Fig. 9.²

As shown in the above images, the '836 Patent's claimed treatment approach creates coagulation around where each electrode was inserted (shown in the dotted lines in the figure on the left)—*while not destroying and removing the tissue*. Ex.2142 (Goldberg Decl.) ¶34. This is contrasted against the Ganz approach, which results in burning away tissue to create ablation holes (shown as item "4" in the figure on the right). *Id.*

The distinction between the '836 Patent's claimed treatment approach and Ganz's approach is further illustrated by comparing the histological images of tissue

² As Dr. Goldberg and Dr. van der Weide explain, the histological images shown in Dr. Na's Nature Paper correspond to treatment results using the '836 Patent's claimed treatment approach. Ex.2142 (Goldberg Decl.) ¶24 n.3; Ex.2143 (VDW Decl.) ¶75 n.5.

treated using the '836 Patent's claimed approach (shown on the left below), with images taken from the prior art FRAXEL approach *that Ganz distinguishes* (shown on the right below):



Ex.2032 (Na Nature Paper), Fig. 1b; Ex.1005 (Ganz), Fig. 8.

As shown in the two above figures, both of these approaches leave the treated tissue intact (rather than ablating and removing the tissue to create large perforations or “ablation holes” like the Ganz treatment approach). Ex.2142 (Goldberg Decl.) ¶36; Ex.2143 (VDW Decl.) ¶¶77-78. Thus, just as Ganz distinguishes its approach as distinct from the prior art FRAXEL approach, Ganz’s approach is similarly distinct from the '836 Patent’s claimed skin treatment. Ex.2143 (VDW Decl.) ¶¶77-79; Ex.2142 (Goldberg Decl.) ¶¶31-36.

Indeed, while Ganz intentionally ablates and removes the tissue to create the desired “ablation holes” (Ex.1005, [0006]), Petitioner’s original (and now

withdrawn) expert, Dr. Dany Bérubé, conceded that the claimed treatment in the '836 Patent “*does not involve ablation*[.]” Ex.2033 (Bérubé Hr'g Tr.), 1268:24-1269:1. Likewise, Petitioner's new expert, Dr. Woloszko, conceded that “*if we define ablation as resection of tissue, [the '836 Patent] does not involve tissue resection.*” Ex.2145 (Woloszko Oct. 10, 2024 Dep. Tr.), 44:1-10.³ Moreover, Dr. Koch, Petitioner's dermatological expert, admitted that the terms “vaporization” and “ablation” can be used interchangeably in the context of RF microneedling, and further that the '836 Patent distinguishes between vaporization and coagulation. Ex.2146 (Koch Oct. 19. 2024 Dep. Tr.), 32:18-33:1; 41:3-9.

Finally, as Dr. Goldberg explains, while he often uses systems applying the '836 Patent's treatment technique in his clinical practice, he would *never* use a system like Ganz that burns away tissue to create holes in the skin because it is dangerous. Ex.2142 ¶41.

³ With respect to “resection of tissue,” Dr. Woloszko explained that “carbonization” (one of the tissue effects the '836 Patent distinguishes), is “one way to describe the effect which is obtained by regular actual surgical cutting or *resection*” of tissue. *Id.*, 39:15-40:8.

2. Because Ganz Is Directed To A Completely Different Approach Than The '836 Patent, It Fails To Disclose Or Render Obvious Multiple Claim Limitations

Because Ganz is directed to a completely different treatment approach than the '836 Patent, it fails to disclose or render obvious multiple claim limitations.

Claim 1 is reproduced below:

1. A skin treatment apparatus, comprising:

a plurality of electrodes, the electrodes being bipolar and configured to be insertable into skin to be treated; and

a radio frequency (RF) generation module, the RF generation module electrically coupled to the plurality of electrodes and configured to provide an Alternating Current (AC) RF signal to the plurality of electrodes configured to cause coagulation around each electrode rather than coagulating between the electrodes.

Ex.1001, c1. 1.

As discussed further below, Ganz fails to disclose or render obvious at least using “bipolar” electrodes that are “configured to cause coagulation around each electrode rather than coagulating between the electrodes” for at least two, independent reasons.⁴ First, Ganz neither discloses nor renders obvious using “bipolar” electrodes to produce the results that Petitioner relies on. Second, the

⁴ While Petitioner's second ground for invalidity relies on combining Ganz with the Livneh reference, Petitioner does not assert that Livneh discloses any limitation other than “Alternating Current RF.” Pet. 22-25.

results that Petitioner relies on do not disclose or suggest “configured to cause coagulation around each electrode rather than coagulating between the electrodes.”

a. Ganz Fails To Disclose Or Render Obvious Using “Bipolar” Electrodes To Produce The Results That Petitioner Relies On

As for the limitation “a plurality of electrodes,” “the electrodes being bipolar,” Petitioner simply points to disclosure of “bipolar electrodes” in Ganz. Pet. 15. But claim 1 requires more than the mere presence of bipolar electrodes—it requires them to be “configured to cause coagulation around each electrode rather than coagulating between the electrodes[.]” Ex.2143 (VDW Decl.) ¶81. Thus, Petitioner needed to show that Ganz discloses or rendered obvious using bipolar electrodes to produce the results that Petitioner relies on as alleged evidence of the claimed coagulation. Petitioner failed to do so. *Id.*

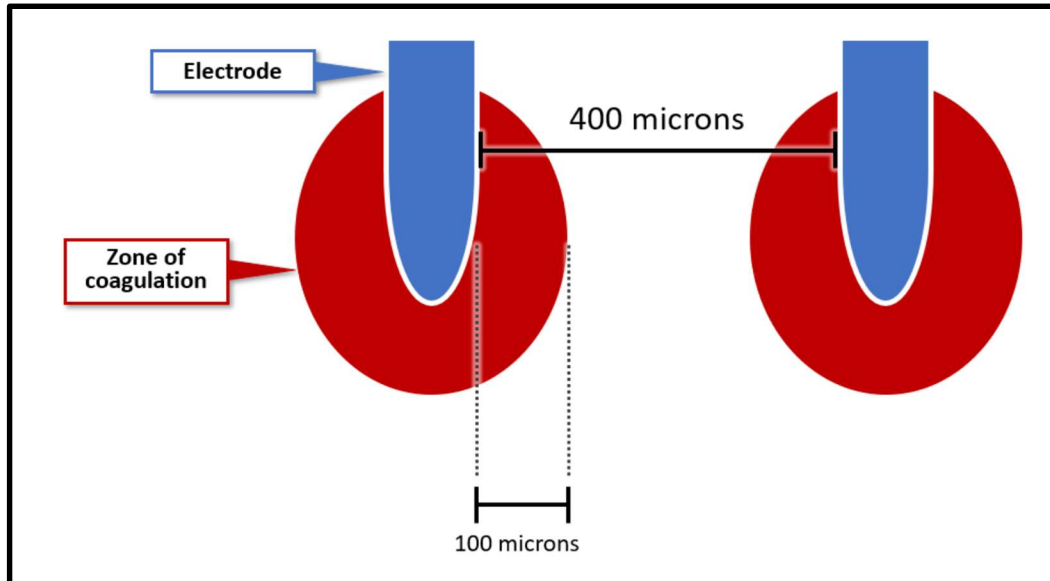
As an initial matter, it is *undisputed* that Ganz does not disclose *any* results using bipolar electrodes, let alone results showing coagulation around each electrode rather than between electrodes. As Dr. van der Weide explains, “[n]o one can identify how Ganz got the results that it produces.” Ex.2143 (VDW Decl.) ¶82. And, Petitioner’s expert Dr. Woloszko agreed that he did not know whether Ganz showed *any* results using bipolar electrodes. Ex.2012 (Woloszko Hr’g. Tr.), 1038:13-15 (“Q. So you don’t know whether Ganz shows any outcome or results using bipolar electrodes, right? A. That’s correct.”). Dr. Woloszko also conceded

that the only example result discussed in Ganz involves a ***monopolar*** configuration. Ex.2145 (Woloszko Oct. 10, 2024 Dep. Tr.), 65:17-20 (“Q. Focusing on that example in paragraph 65, that example involves monopolar, not bipolar, right? A. ***That is correct.***”). Dr. Woloszko also admitted that he did not know whether Figures 9 and 10 of Ganz were generated using a monopolar or bipolar configuration. *Id.*, 65:21-66:2 (“Q. And we don’t know whether Figures 9 and 10 were obtained based on that monopolar example in paragraph 65 or in some other way, right? A. ***That is correct.***”). Likewise, Dr. Koch, Petitioner’s dermatological expert, admitted that “***Ganz does not state whether the images included as Figures 9 or 10 were obtained using bipolar or monopolar electrodes***” Ex.1035 (Koch Decl.) ¶34.

As with the prior IPR, Petitioner’s failure to link the treatment results it relies on to the use of bipolar electrodes is fatal to its arguments. *See supra* pp. 32-34 (citing *Cartessa IV*, Paper 9 at 35 (rejecting Petitioner’s invalidity grounds because the cited material “***does not disclose whether the ‘histology results’ screen capture was taken using electrodes in monopolar or bipolar mode***”)).

Petitioner’s arguments as to why this limitation is met lack merit. For example, Petitioner argues that Ganz discloses “perforations created by electrodes are spaced apart by about 400 microns and zones of coagulation extend from the perforations into the tissue ‘in all directions’ to about 100 microns.” Pet. 26-27 (citing Ex.1005,

[0028], [0047]-[0048]). Petitioner relies on the following illustration of this text that Petitioner generated:



Pet. 27-28.

But Petitioner fails to show that the disclosure in Ganz that Petitioner relies on to create the illustration above was produced using *bipolar* electrodes. None of the portions of Ganz Petitioner cites—paragraphs [0028] and [0047]-[0048]—disclose that perforations or coagulation within these ranges were generated. Ex.2143 (VDW Decl.) ¶84.

For example, Paragraph [0028] describes Ganz's Figures 9 and 10, but does not specify what electrode configuration was used. Ex.1005, [0028]. Indeed, Petitioner's expert, Dr. Woloszko, testified in his prior deposition in the 1356 ITC Investigation that Figure 9 of Ganz showed the results of a *monopolar* configuration. Ex.2144 (Woloszko Sept. 14, 2023 Dep. Tr.), 243:4-13. Dr. Woloszko then changed

his testimony during his deposition for this IPR proceeding, testifying that he simply cannot not tell whether the results in Figures 9 and 10 were created using monopolar electrodes or in some other way. Ex.2145 (Woloszko Oct. 10, 2024 Dep. Tr.), 65:21-66:1 (“Q. And we don’t know whether Figures 9 and 10 were obtained based on that monopolar example in paragraph 65 or in some other way, right? A. *That is correct.*”). As discussed above, Dr. van der Weide agrees that it is impossible to tell whether the results in those figures were created with bipolar or monopolar electrodes. Ex.2143 (VDW Decl.) ¶82.

Likewise, paragraphs [0047] to [0048] do not specify what electrode configuration was used either. Ex.1005, [0047], [0048]. Petitioner relies on the statement in paragraph 48 that “[t]he zones [of coagulation] can extend from the perforation site into the tissue for a length ranging from about 5 microns to about 100 microns” (Pet. 27 (citing Ex.1005, [0048])), but nothing in Ganz indicates that this was achieved with *bipolar* electrodes. Ex.2143 (VDW Decl.) ¶86. Indeed, as discussed above, Dr. Woloszko admitted that he cannot tell whether Ganz discloses *any* results using bipolar electrodes. Ex.2012 (Woloszko Hr’g. Tr.), 1038:13-15 .

Notably, the only discussion of “bipolar electrodes” in Ganz is where Ganz states that “either monopolar or bipolar electrodes” can be used. Ex.1005, [0011], [0055], [0056]. But nothing in these paragraphs explains how each configuration would affect the treated tissue. *Id.* Moreover, Ganz’s only specific “[e]xample” of

inserting electrodes into skin involves use of a “*monopolar* electrode array,” as Dr. Woloszko admits. *Id.*, [0065]; Ex.2145 (Woloszko Oct. 10, 2024 Dep. Tr.), 65:17-20 (“Q. Focusing on that example in paragraph 65, that example involves *monopolar*, *not bipolar*, right? A. *That is correct.*”).⁵

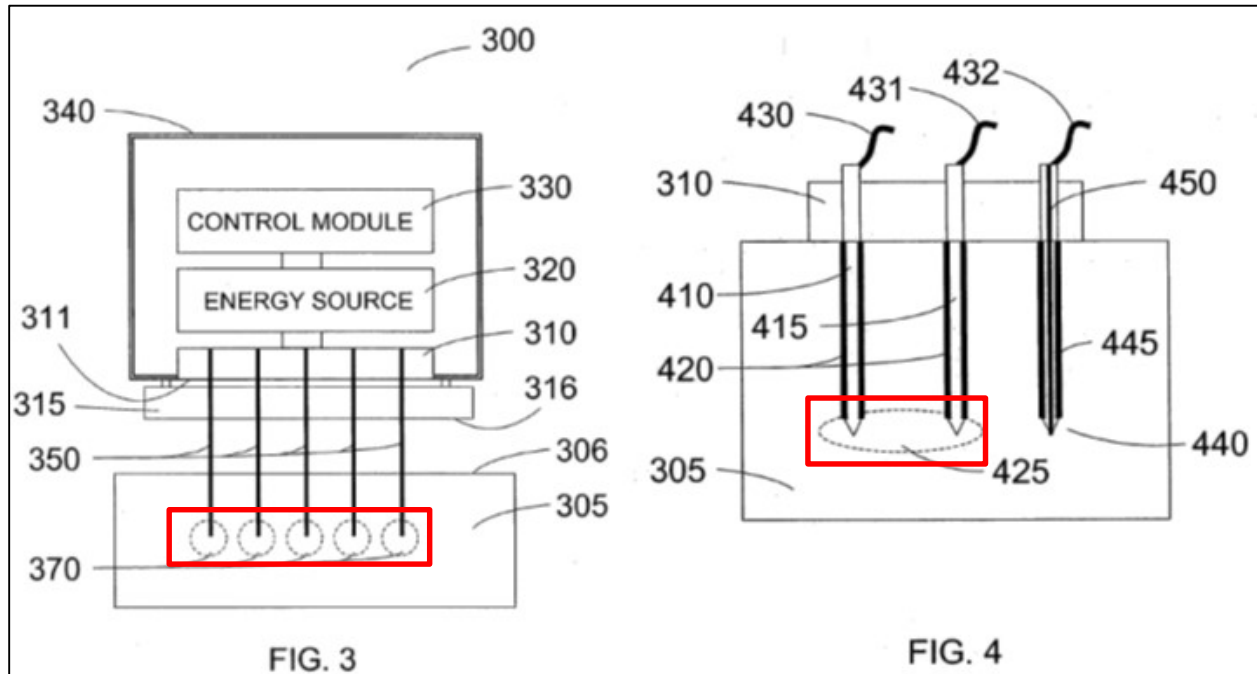
Recognizing this glaring deficiency, Petitioner tries to fill the gap in Ganz's disclosure with its expert Dr. Koch's *ipse dixit* assertion that a POSITA would expect to see the same output results “using either modality.” Ex.1035 (Koch Decl.) ¶34. Dr. Koch's conclusory, unsupported assertion is entitled to no weight. *See In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016) (“To satisfy its

⁵ Notably, Petitioner's experts cannot even identify whether Ganz discloses the type of “bipolar” electrodes that the '836 Patent claims require. For example, Dr. Woloszko testified that he believes that “bipolar” electrodes actually refer to electrodes that have “both pol[arities] on the same needle” and that the “bipolar” electrodes discussed in the '836 Patent are actually “monopolar” needles arranged in a bipolar configuration. Ex.2004 (Woloszko ITC Report), 146 n.19; Ex.2145 (Woloszko Oct. 10, 2024 Dep. Tr.), 44:19-45:7; Ex.2146 (Koch Oct. 19, 2024 Dep. Tr.), 18:15-19:1 (explaining that there are “two general configurations” for bipolar needles, i.e., “a needle that has both polarity” and “a pair that is ... positive and the other is negative”).

burden of proving obviousness, a petitioner cannot employ mere conclusory statements.”). His testimony on this issue further merits no weight because it is outside his area of expertise—he is neither an engineer nor a physics expert, nor has he identified any evidence of ever comparing results achieved using monopolar versus bipolar electrodes. *Compare* Ex.1035 (Koch Decl.) ¶34 (concluding that “in my opinion” the results of Ganz “could be obtained using either modality”), *with* Ex.2146 (Koch Oct. 19, 2024 Dep. Tr.), 10:20-21 (“Q. You are not an engineer, correct? A. ***That’s correct.***”). As the Federal Circuit has explained, “[t]estimony proffered by a witness lacking the relevant technical expertise fails the standard of admissibility under Fed. R. Evid. 702.” *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1363 (Fed. Cir. 2008) (holding that it was an abuse of discretion to allow an expert to testify on issues outside of their area of expertise).

The record evidence also shows that Dr. Koch’s unsupported assertion is not credible. ***Every*** other expert on both sides in this proceeding has opined that monopolar and bipolar configurations yield different treatment results. Ex.2142 (Goldberg Decl.) ¶¶16-17; Ex.2143 (VDW Decl.) ¶¶33-42; Ex.2004 (Woloszko ITC Invalidity Rpt.) ¶¶73-88 (explaining the background of monopolar and bipolar RF microneedling systems). As discussed above, *supra* pp. 19-27, prior art systems yielded starkly different results depending on whether they were using monopolar or bipolar configurations. This is reflected, for example, in Manstein, which

distinguishes the thermal damage produced using a monopolar configuration and the thermal damage produced using his bipolar configuration:



Ex.1014, Figs. 3, 4.

The overwhelming weight of the evidence thus shows that POSITAs would have recognized the significant differences between monopolar and bipolar electrodes, and would have understood that one method could not be simply substituted for the other. Petitioner's illustration based on paragraphs [0028] and [0047]-[0048] of Ganz is thus meaningless because Petitioner fails to establish that the results described in those paragraphs would have been obtained using a bipolar electrode configuration, which the claims require, rather than a monopolar electrode configuration, which the claims exclude.

Petitioner's arguments here thus fail for reasons that are similar to those that the Board applied in rejecting institution of the first IPR petition against the '836 Patent—i.e., because Petitioner fails to support the illustration that Petitioner relies on. As discussed above, *supra* pp. 33-34, the prior Petitioner relied on a video of a prior art device (the "INTRAcel" device), pointing to histological results showing coagulation around needle insertion points rather than extending between the needles. *Cartessa IV*, Paper 9 at 35. But the Board rejected Petitioner's reliance on those results, explaining that the INTRAcel video "***does not disclose whether the 'histology results' screen capture was taken using electrodes in monopolar or bipolar mode.***" *Id.* That finding applies with equal force here. Petitioner cannot show that Ganz teaches any results obtained using a bipolar modality (rather than a monopolar modality), because as its own expert admits, Ganz simply leaves a POSITA guessing. Ex.2012 (Woloszko Hr'g. Tr.), 1038:13-15 ("Q. ***So you don't know whether Ganz shows any outcome or results using bipolar electrodes***, right? ***A. That's correct.***"); Ex.2143 (VDW Decl.) ¶82 ("[N]o one can identify how Ganz got the results that it produces.").

In short, as the Board concluded last time, it is of no matter whether Petitioner can identify disclosure of coagulation localized around each electrode in the prior art, unless Petitioner can ***also*** demonstrate that said localized coagulation is achieved using ***bipolar*** electrodes. Petitioner fails to do that here.

**b. Ganz Fails To Disclose Or Render Obvious
“configured to cause coagulation around each
electrode rather than coagulating between the
electrodes”**

Even if Petitioner did show that the treatment effects disclosed in Ganz resulted from using bipolar electrodes—*and it did not*—Petitioner has not shown that Ganz discloses or renders obvious a device “configured to cause coagulation around each electrode rather than coagulation between electrodes.” Ex.2143 (VDW Decl.) ¶¶78, 81, 86-87, 92. Ganz fails to disclose “coagulation around each electrode” because Ganz instead discloses carbonization / vaporization and **removal** of tissue around each electrode, i.e., the creation of “**ablation holes.**” *Id.* ¶¶75, 92; Ex.2142 (Goldberg Decl.) ¶¶39-40. As Dr. Goldberg explains, “**there’s no coagulation around the microneedles because the tissue is gone.**” Ex.2142 (Goldberg Decl.) ¶39; *see also* Ex.2146 (Koch Oct. 19, 2024 Dep. Tr.), 45:4-6 (“Q. Is there tissue remaining in what’s marked as “Treated Area 4” on Figure 9? A. **No.**”); *id.*, 45:7-8 (“Q. What happened to that tissue? A. “**It melted away.**”).

As discussed above, the ’836 Patent and Ganz expressly distinguish each other’s approaches. *Supra* Section V(A)(1). While Ganz discloses burning away the epidermis and dermis around the electrode to form “ablation holes,” the ’836 Patent discloses and claims achieving coagulation around each electrode to “resolve problems of existing technologies[,]” including the “**serious side effect**” of “**overheating or burning of both dermis and epidermis ..., which may cause**

permanent skin damage[.]” e.g., “*scars created in overheated or burned epidermis.*”

Ex.1001, 4:4-22. Indeed, the '836 Patent distinguishes the claimed effect of “coagulation” from the other tissue effects—“carbonization” and “vaporization”—used by Ganz to remove the tissue around the electrodes. *Id.*, 2:62-3:10; Ex.2143 (VDW Decl.) ¶91 (“Ganz is actually overheating and burning the epidermis in order to create its perforations.”); Ex.2142 (Goldberg Decl.) ¶40 (“Ganz is directed to ablating and removal tissue, i.e., cauterizing the tissue surrounding the puncture sites.”).

On the other hand, Ganz distinguishes systems which “*only cause[] zones of coagulation[.]*” like the '836 Patent's claimed approach, which Ganz views as a “*drawback.*” Ex.1005, [0006]. Ganz explains that “rather than merely imparting coagulations into the skin” around electrodes as claimed in the '836 Patent, Ganz's approach provides for the “creation of actual perforations” around the electrodes to achieve a “more aggressive healing responses.” *Id.*, [0032]. In short, Ganz's approach of creating “ablation holes” (*id.*, [0006]), stands in contrast to the '836 Patent which, as Petitioner's original expert here, Dr. Bérubé admitted, “*does not involve ablation[.]*” Ex.2033 (Bérubé Hr'g. Tr.), 1268:24-1269:1.

Accordingly, Ganz fails to disclose or suggest the electrodes “configured to cause *coagulation* around each electrode,” as the claims require. Ex.1001, cls. 1, 11. In contrast to the '836 Patent claims, which require electrodes “configured to cause

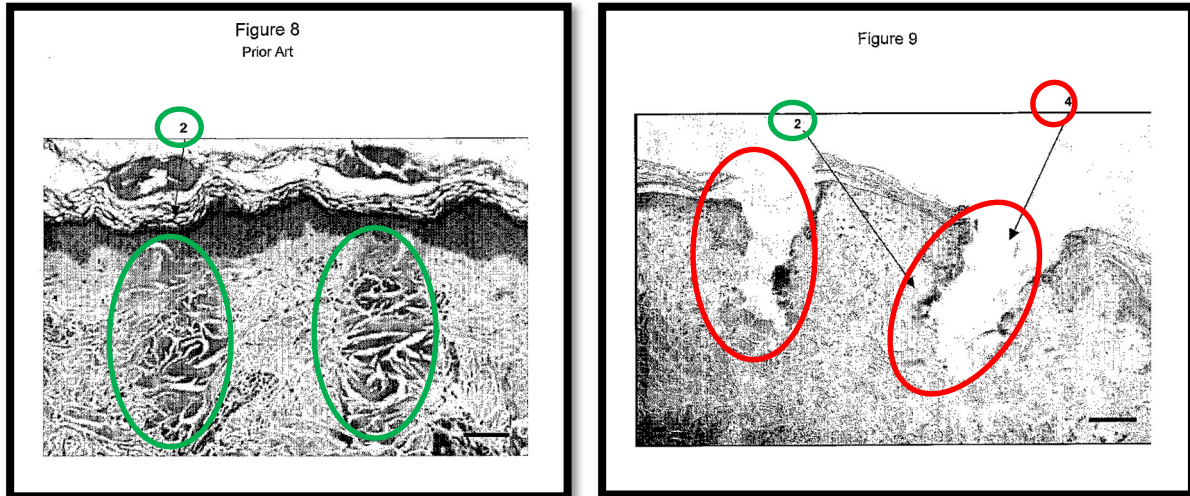
coagulation” in the region where Petitioner and its expert admit “the heat is most intense”—*i.e.*, “around each electrode” (Pet. 43-44, 56; Ex.1003 (Bérubé Decl.) ¶¶172, 231)—Ganz *ablates* that tissue to create “*ablation holes*” around where the electrodes are inserted. *Id.*, [0006]; Ex.2146 (Koch Oct. 19, 2024 Dep. Tr.), 44:1-3 (“Q. And Ganz discloses creating ablation holes, right? A. “*Yes.*”); *id.*, 44:11-13 (“Q. Are ablation holes shown in Ganz’s figures? A. *Yes.*”).

While Petitioner points to disclosure in Ganz that some coagulation occurs during treatment, Ganz actually discloses that its coagulation does not occur around each electrode, but instead occurs around the *ablation holes* in the tissue. *See, e.g.*, Ex.1005, [0028] (“zones of coagulation are seen on areas of the skin surface *surrounding the perforation*”). This is because the tissue “around each electrode” has been overheated (*i.e.* carbonized / vaporized), so it is no longer there, which is directly contrary to what is disclosed and claimed in the ’836 Patent. Ex.1001, 4:4-22, cls. 1, 11; Ex.2142 (Goldberg Decl.) ¶¶9, 39-41; Ex.2143 (VDW Decl.) ¶105.

These facts are uncontested. Petitioner’s experts admit that Ganz only discloses creating coagulation around the edges of the holes its electrodes create in the tissue via the “use of energy.” Ex.1035 (Koch Decl.) ¶40 (explaining that zones of coagulation in Ganz occur “surrounding each perforation”); Ex.2145 (Woloszko Oct. 10, 2024 Dep. Tr.), 51:22-52:4 (“Q. So the coagulation disclosed in Ganz begins at the edge of the perforations that was created during treatment, right? A.

That's how we – he measures that here. Correct. Yes.”). Likewise, it is undisputed that the claimed invention in the '836 Patent is ***not*** about electrodes configured to ***overheat*** tissue (i.e., creating ablation holes with mere incidental coagulation around the edges of each ablation hole). Ex.2033 (Bérubé Hr'g Tr.), 1268:24-1269:1 (the '836 Patent “***does not involve ablation***”); Ex.2145 (Woloszko Oct. 10, 2024 Dep. Tr.), 44:1-10 (“***if we define ablation as resection of tissue, [the '836 Patent] does not involve tissue resection***”); Ex.2143 (VDW Decl.) ¶¶105-106; Ex.2142 (Goldberg Decl.) ¶¶31-33.

That Ganz fails to disclose “coagulation around each electrode” is reinforced by comparing Figures 8 and 9 of Ganz, copied below.

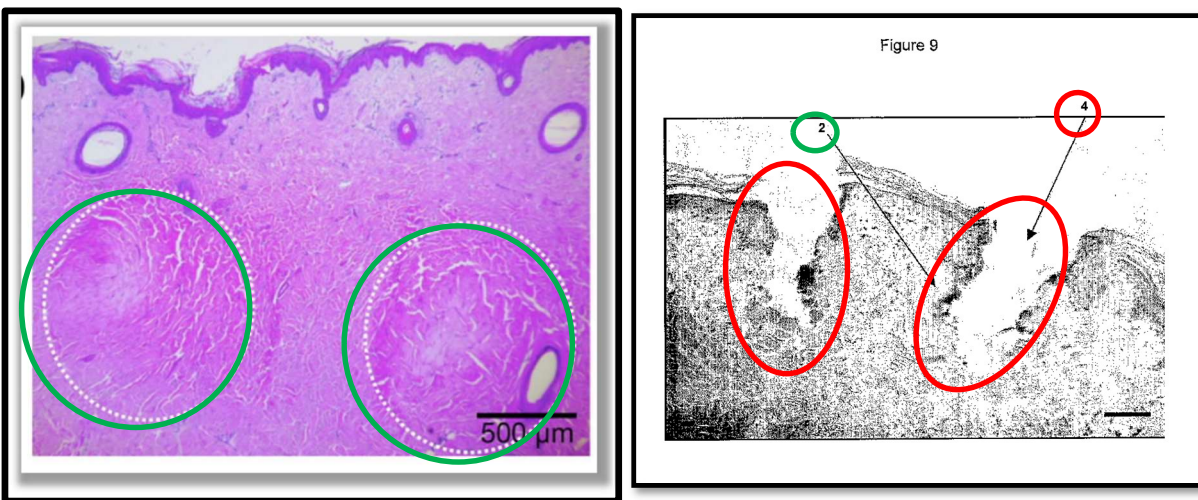


Compare Ex.1005 (Ganz), Fig. 8 (annotated), with *id.*, Fig. 9 (annotated).

As shown above on the left in Figure 8, the FRAXEL laser imparts zones of coagulation in the tissue being treated (labeled as No. 2, annotated in green); conversely, the Ganz approach ablates and removes tissue, leaving only small

residual zones of coagulation around the edges of the perforated holes (labeled as No. 4, annotated in red). Ex.1035 (Koch Decl.) ¶40; Ex.2145 (Woloszko Oct. 10, 2024 Dep. Tr.), 51:22-52:4; Ex.2143 (VDW Decl.) ¶¶92-94; Ex.2142 (Goldberg Decl.) ¶¶24, 31.

Comparing histological images of coagulation around needle insertion sites produced using the '836 Patent's claimed approach (shown below on the left), with Ganz's approach (shown below on the right), similarly confirms that Ganz teaches an entirely different approach than claimed in the '836 Patent:



Compare Ex.2032 (Na Nature Paper), Fig. 1b (showing “RF-induced coagulation columns” which are “generated separately around each microneedle electrode,” annotated in green), *with* Ex.1005 (Ganz), Fig. 9 (showing only residual coagulation around the “ablation holes,” annotated in red). Again, it is apparent that what Ganz produces is **not** coagulation around each inserted electrode, as shown on the left, but

rather coagulation around the edges of the ablation holes that each electrode created. Ex.2142 (Goldberg Decl.) ¶¶37-38.

Moreover, further confirming that Ganz's treatment approach is directed to the ablation of tissue, paragraph 31 of Ganz explains that one treatment use for its device is "to treat conductive abnormalities of the heart" "by **ablating** multiple foci of aberrant electrical paths." Ex.1005, [0031].

Indeed, there is no genuine dispute that Ganz ablates and thus removes the tissue around each electrode, as both sides' experts agree that Ganz's approach results in ablation—i.e., carbonization and/or vaporization—and **removal** of the tissue that was around each electrode. Ex.2142 (Goldberg Decl.) ¶¶39-40; Ex.2143 (VDW Decl.) ¶¶71-78; Ex.2146 (Koch Oct. 19, 2024 Dep. Tr.), 44:1-3, 44:11-13, 45:4-8. Petitioner's expert Dr. Woloszko also admitted during his prior deposition in the 1356 ITC Investigation that Ganz "**does teach removing ... some tissue**," and further that he analogized Ganz's approach to a "**chemical etching process**," which he agreed "**etches away some of the tissue**." Ex.2144 (Woloszko Sept. 14, 2023 Dep. Tr.), 236:9-14, 241:9-11, 241:17-19; *id.*, 242:21-243:3 ("Q. So would you agree that Ganz distinguishes the approach of only creating coagulation from his approach of creating perforations of vertical holes in the skin? A. **I agree**.").

Notably, Dr. Woloszko tried to backtrack from his prior testimony during his deposition for this IPR proceeding, now conceding that he simply does not know

whether Ganz's results show ablation and removal of tissue surrounding the electrodes. For example, when Dr. Woloszko was asked whether he believes the perforations in Ganz are "ablation holes," Dr. Woloszko responded that "*I don't know what ablation holes means really,*" but that "*it's possible that the – that some tissue is removed.*" Ex.2145 (Woloszko Oct. 10, 2024 Dep. Tr.), 50:10-19. Indeed, when confronted with Ganz's disclosure, Dr. Woloszko now contends that he cannot tell whether the perforations in Ganz involves ablation and the removal of tissue. *Id.*, 51:3-7. ("Q. Is it correct that you're unable to tell from Ganz's disclosure whether the perforations that he describes involve removal of tissue? A. *I – yes.*"). Dr. Woloszko's backtracking bears on the credibility of his testimony. In any event, it was **Petitioner's** burden to prove what Ganz discloses and how that renders the claims obvious, and Dr. Woloszko's newfound inability to tell what Ganz discloses only reinforces that Petitioner cannot meet its burden.

Petitioner's other expert, Dr. Koch, likewise admits that Ganz discloses ablation. Ex.2146 (Koch Oct. 19, 2024 Dep. Tr.), 44:1-13. Indeed, Dr. Koch's obviousness opinions turn on his mistaken assumption that **all** RF microneedling devices result in the same type of ablative thermal damage. Ex.1035 (Koch Decl.) ¶36. But that is plainly wrong, as that assumption conflicts with the admissions of Petitioner's own experts that the '836 Patent does **not** involve ablation / recitation of tissue. Ex.2033 (Bérubé Hr'g Tr.), 1268:24-1269:1 (the '836 Patent "**does not**

involve ablation”); Ex.2145 (Woloszko Oct. 10, 2024 Dep. Tr.), 44:1-10 (“*if we define ablation as resection of tissue, [the ’836 Patent] does not involve tissue resection*”); *see also* Ex.2143 (VWD Decl.) ¶¶88, 91; Ex.2142 (Goldberg Decl.) ¶¶31-32.

Tellingly, Dr. Koch had not seen histological results obtained using the ’836 Patent’s approach and, when confronted with those histological images at his deposition, he admitted that they did **not** show ablation holes. Ex.2146 (Koch Oct. 19, 2024 Dep. Tr.), 65:1-66:20. And while Dr. Koch speculated that those histological images may have been taken much later (after the wounds had healed) (*id.*), Dr. Na’s paper states that the histological examination occurred within **one hour** after treatment (Ex.2032, 8 (“At one hour after treatment, biopsy specimens of full thickness from the *in vivo* micropig skin study and *ex vivo* bovine liver tissue study were obtained for histologic evaluation.”)).

Petitioner’s arguments as to why Ganz discloses the claimed “coagulation around each electrode” lack merit. For example, Petitioner argues 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. Pet. 25-27. But this is not “coagulation **around each electrode**” as claimed—it is coagulation around the edge of the “ablation holes” that Ganz created by removing tissue around each electrode. Ex.2143 (VWD Decl.)

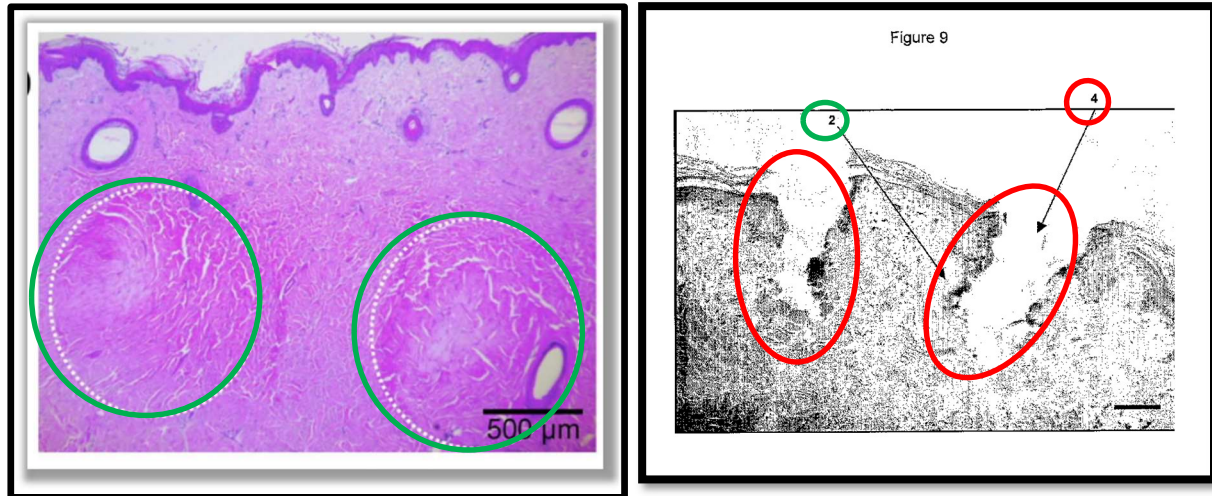
¶¶75, 94. Indeed, as Dr. Woloszko concedes, “Ganz describes creating perforations of certain sizes and zones of coagulation *surrounding those perforations* having certain sizes.” Ex.2145 (Woloszko Oct. 10, 2024 Dep. Tr.), 57:4-8. Thus, as Dr. Goldberg explains, “*there’s no coagulation around the microneedles because the tissue is gone.*” Ex.2142 ¶39.

To try to pre-but this argument, Petitioner asserts that “the claim limitation merely requires that coagulation be formed ‘around each electrode,’ not ‘immediately around each electrode.’” Pet. 29 (emphasis omitted). But by its plain language the claim requires configuration to cause “coagulation *around each electrode*”—not coagulation at the edges of ablation holes created near where electrodes were inserted. As shown above, cauterizing the edges of a hole created by inserting an electrode that applies energy to remove tissue, as in Ganz, is entirely different from inserting an electrode to cause coagulation around it in tissue that remains intact. Ex.2142 (Goldberg Decl.) ¶¶9, 39-41; Ex.2143 (VWD Decl.) ¶94.⁶

⁶ Petitioner also had an opportunity to argue that this claim term should be construed to cover situations where coagulation does *not* actually occur around each electrode (to cover cases where the tissue around each electrode is actually destroyed and removed). But Petitioner declined to make that affirmative claim construction

Petitioner also tries to equate Ganz's and the '836 Patent's distinct treatment methods by arguing that *any* needle electrodes will cause perforations in the skin. Pet. 26. But Ganz expressly distinguishes his approach from merely making holes “mechanically” through “needle” insertion, explaining that his approach creates holes “with the use of energy.” Ex.1005, [0008]. Ganz thus is *not* simply creating holes by mechanically inserting needles, but rather using energy to ablate the tissue to create holes. Ex.2146 (Koch Oct. 19, 2024 Dep. Tr.), 43:20-22 (“Q. Ganz discloses making that perforation through use of energy, correct? A. *Yes.*”). Indeed, Ganz's holes are much larger than those that mechanical needle insertion would create. Ex.2142 (Goldberg Decl.) ¶40 (“While any microneedling device creates mechanical punctures, Ganz goes further and burns away tissue to cauterize the area....”). Again, one need only compare the histological images of the '836 Patent treatment method with those of Ganz's treatment method to see that Petitioner's argument about all microneedling devices creating similar perforations lacks merit:

argument—likely because that would directly conflict with both the plain claim language and the '836 Patent's teachings.

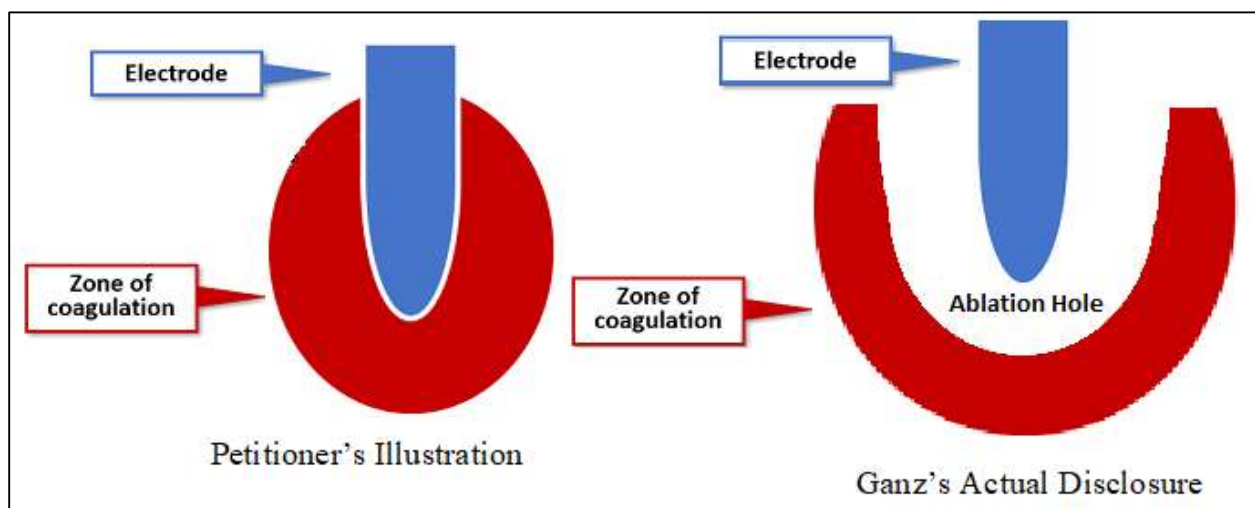


Ex.2032 (Na Nature Paper), Fig. 1b; Ex.1005, Fig. 9.

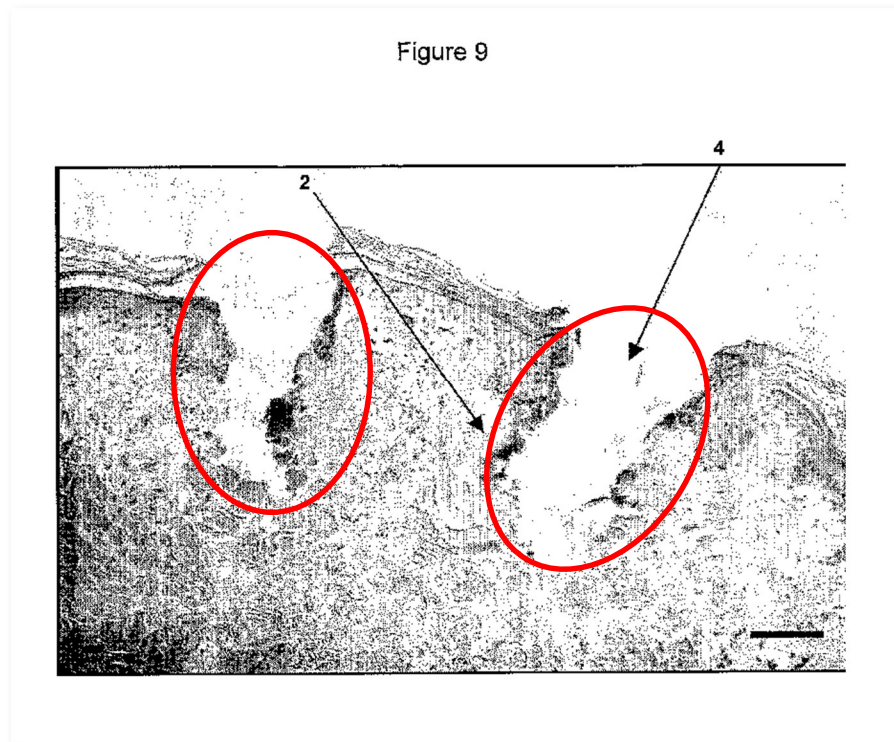
And as shown in the above images, while both treatment methods used needles to puncture the skin, the Ganz treatment method (shown on the right) left gaping holes where the electrode needles were inserted, resulting from the ablation and removal of tissue, while the '836 Patent treatment method (shown on the left) kept this tissue intact. Ex.2142 (Goldberg Decl.) ¶¶33-40; Ex.2143 (VDW Decl.) ¶105. Petitioner's expert Dr. Koch admitted as much, confirming that the holes in Ganz (created around where needles were inserted) are shown in Figure 9 and labeled "4", while no holes are visible in the histological images from the Na Nature Paper. Ex.2146 (Koch Oct. 19, 2024 Dep. Tr.), 44:1-13, 65:1-66:20. Simply put, the Ganz approach does not result in mere incidental perforations caused by the mechanical insertion of electrode needles, it intentionally overheats the tissue surrounding each electrode so that the tissue is removed—the *very effect the '836 Patent is trying to avoid*. Ex.2143 (VDW Decl.) ¶105; Ex.2142 (Goldberg Decl.)

¶¶33-40. As Dr. Goldberg explains, “Ganz thus discloses cauterizing and removing tissue, which is very different than the types of treatments claimed in the ’836 Patent, which cause coagulation localized around each needle electrode.” Ex.2142 ¶39.

Considering Ganz’s *actual* disclosure, Petitioner’s “illustration” (shown on the left below), does not accurately reflect Ganz’s treatment results. Instead, Ganz’s treatment results are more accurately represented by the illustration on the right:



Indeed, the *corrected* illustration (shown above on the right), is more in line with the histological images Ganz includes to demonstrate its treatment approach (i.e., creating “ablation holes” where the electrodes were inserted):



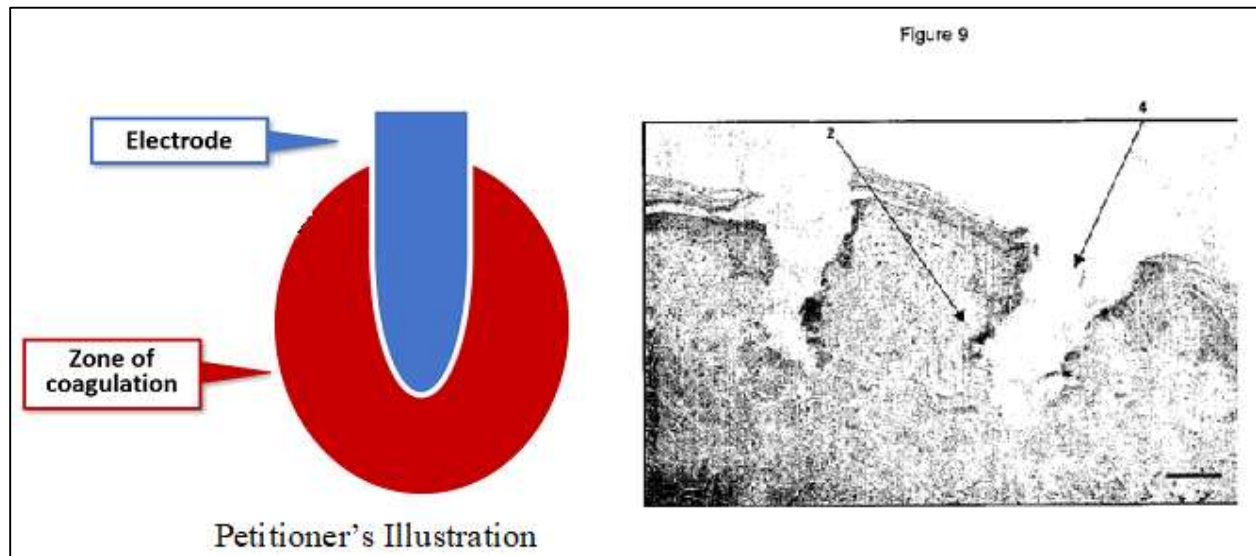
Ex.1005, Fig. 9 (showing large areas of ablated tissue around where the electrodes were inserted, annotated in red).

Faced with clear disclosure in Ganz that the coagulation does *not* occur around electrodes, but rather around the *perforations* caused by Ganz's ablation, Petitioner posits a hypothetical example "where the width of the perforation is the same as the width of the electrode." Pet. 28. But while Ganz discloses that the width of the perforations will be "*at least the width of the electrode[s]*," Ganz further discloses that the perforations will be "*in many cases larger*." Ex.1005, [0053]. Ganz adds that the width of each perforation depends on "the level of energy discharged [from] the electrode" and that "[w]hen more energy is discharged from the electrode, a larger perforation width and depth is created." *Id.* Here, neither Petitioner, nor its

experts, identify any results in Ganz showing perforations the same size as its electrodes. Ex.2143 (VDW Decl.) ¶87. Nor does Petitioner, or its experts, identify any disclosure in Ganz that perforations the same size as its electrodes could be created using *bipolar* electrodes (or when utilizing Alternating Current RF energy). *Id.* Nor does Petitioner, or its experts, identify any disclosure in Ganz of where coagulation (if any), would be located in such a hypothetical. *Id.* Ganz also does not say, e.g., what “level of energy” needs to be “discharged” to have coagulation, and what the width of the perforation would be in those cases. *Id.* That is because it is the '836 Patent—not Ganz—that discloses coagulation around each electrode, and Petitioner's attempt to cobble together a hypothetical that meets the claims is infected with hindsight. *Abbott Laboratories v. Sandoz, Inc.*, 544 F.3d 1341, 1348 (Fed. Cir. 2008) (refusing to reverse the district court's validity finding, stating, “in addressing the question of obviousness a judge must not pick and choose isolated elements from the prior art and combine them so as to yield the invention in question if such a combination would not have been obvious at the time of the invention”) (quoting *Dennison Mfg. Co. v. Panduit Corp.*, 475 U.S. 809, 810 (1986) (per curiam)).

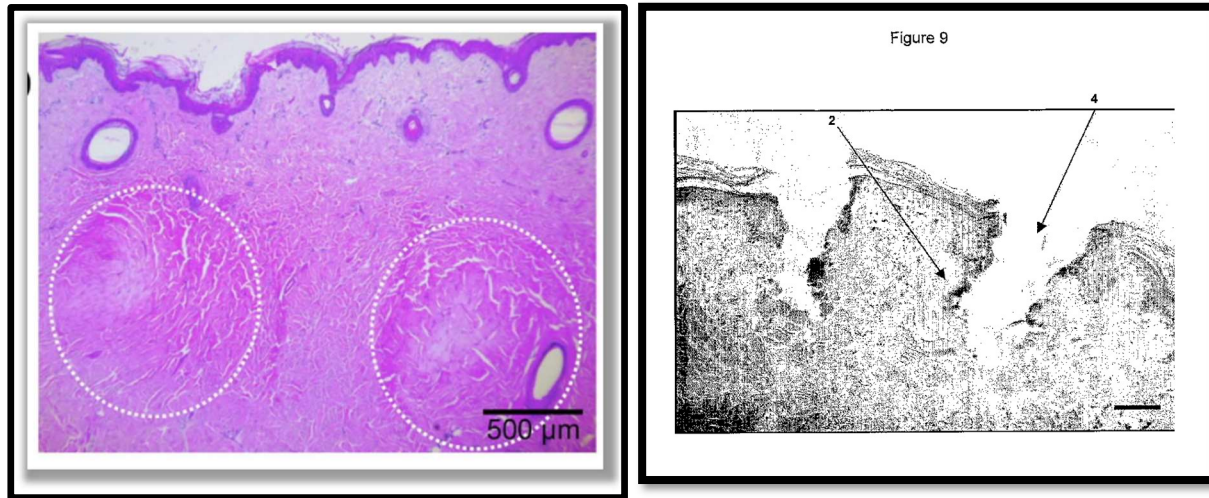
In short, Petitioner's cartoon illustration cobbles together disparate disclosures in Ganz without any factual foundation. Indeed, Petitioner must create

a cartoon because the results Ganz actually discloses are nothing like the '836 Patent—and nothing like Petitioner's cartoon, as shown below:



Indeed, as Dr. van der Weide explains, Ganz discloses output powers that would almost certainly result in ablation and recitation of tissue surrounding where electrodes were inserted. Ex.2143 (VDW Decl.) ¶108. For example, Ganz discloses that its electrodes “are configured to provide power in the range of about **50 to about 200 watts per square centimeter**” (or “energy of at least about 1 joules per square centimeter”). Ex.1005, [0057]. To put these power ranges in perspective, the Sylfirm X RF microneedling product (which practices the '836 Patent, as discussed below, *infra* pp. 78-80), operates at a “Max” output power of just **16 watts**. Ex.2083 (Sylfirm Manual), 25.

Given these vastly different power ranges, it is unsurprising that histological images of tissue treated with the '836 Patent's approach, look vastly different than images of tissue treated with the Ganz approach:



Ex.2032, Fig. 1b; Ex.1005, Fig. 9.

In sum, Petitioner has failed to show that Ganz discloses “caus[ing] coagulation around each electrode rather than coagulating between the electrodes” because Ganz is directed to removing tissue around the electrodes to create “ablation holes”—*so the tissue around each electrode is gone*—and only creating coagulation around the edges of the holes rather than around the electrodes themselves. Ex.2142 (Goldberg Decl.) ¶¶26, 39.

3. Ganz Alone, Or In View of Livneh, Fails To Disclose Or Render Obvious Claims 2, 11-15, 23-24, And 26

Claims 2 and 11-13 depend on claim 1, and thus Petitioner has failed to demonstrate that Ganz in view of a POSITA's knowledge, and/or in further view of

Livneh, discloses or renders obvious these claims for the same reasons discussed with respect to claim 1 of the '836 Patent. Ex.2143 (VWD Decl.) ¶¶99-100. Independent claim 14 of the '836 Patent is the method version of claim 1's system claim, and as Petitioner points to the same evidence for claim 14 as for claim 1, Petitioner similarly has failed to demonstrate that independent claim 14 is invalid under these grounds. *Id.* Likewise, because claims 15, 23-24, and 26 depend upon claim 14 of the '836 Patent, Petitioner has failed to demonstrate the prior art discloses or renders obvious these claims for the same reasons discussed with respect to claim 1 of the '836 Patent. *Id.*

B. Ground III And IV: Petitioner Failed To Demonstrate That Claims 2-10, 15-22, And 25 Would Have Been Obvious Based On Ganz In View Of Hantash, Or Ganz In View Of Livneh And Hantash

Claims 2-10 depend on claim 1, and thus Petitioner has failed to demonstrate that Ganz in view of a POSITA's knowledge, and/or in further view of Livneh or Hantash, discloses or renders obvious these claims for the same reasons discussed with respect to claim 1 of the '836 Patent. *Id.* ¶101. Additionally, as discussed above, independent claim 14 of the '836 Patent is the method version of claim 1's system claim, and claims 15-22 and 25 depend upon independent claim 14. Thus, Petitioner has failed to demonstrate that Ganz in view of a POSITA's knowledge, and/or in further view of Livneh or Hantash, discloses or renders obvious claims 15-

22 and 25 for the same reasons discussed with respect to claim 1 of the '836 Patent. *Id.*

Moreover, as discussed below, Petitioner failed to demonstrate that the cited prior art discloses or renders obvious additional limitations of the '836 Patent's dependent claims.

1. Petitioner Failed To Demonstrate That The Additional Limitations Of Claim 9 Would Have Been Obvious

Claim 9 of the '836 Patent requires that “the electrodes are needles and have a diameter from 0.25 mm to 0.30 mm.” Ex.1001, cl. 9. Ganz does not teach needles with a diameter from 0.25 mm to 0.30 mm. Ex.2143 (VWD Decl.) ¶131. Indeed, Ganz is silent as to the diameter of the needles used to create the perforations. *Id.* Instead, Ganz states that “[t]he width or diameter of each electrode pin can also be varied to provide a perforation having a desired width.” Ex.1005, [0053]. As for the perforations, Ganz discloses perforations that are “widest at the top (50 to 100 microns in diameter).” *Id.*, [0065]. But this is the width of the perforations, not the electrodes, and 50 to 100 microns is 0.05 to 0.1 mm, which is not within the claimed range. Moreover, Ganz explains that the “width of the perforation created will be at least the width of the electrode, *and in many cases larger.*” *Id.* (citing Ex.1005, [0053]). Therefore, a perforation of between 0.05 to 0.1 mm is likely caused by a needle smaller than (at most) 0.1 mm and, therefore, again not within the claimed range. *Id.*

Recognizing that Ganz does not disclose the claimed needle diameter range, Petitioner argues that Hantash discloses needles with a diameter between 0.05 mm to 0.30 mm, and that “a POSITA would have been motivated to use Hantash’s needle diameter for Ganz’s electrodes.” Pet. 49. But a POSITA would not be motivated to use the needles of Hantash, which are many times larger, because the larger needles of Hantash would create much larger areas of ablation. Ex.2143 (VDW Decl.) ¶132. As discussed above, the needles used in Ganz are the same size or *smaller* than the perforations, which are 0.050-0.100 mm. *Id.* Indeed, Ganz expressly states that its perforations should be “so small that they cannot be seen with the naked eye.” *Id.* (citing Ex.1005, [0029]). Petitioner’s experts do not explain why using Hantash’s much larger needles would not result in unacceptable damage to the skin. *Id.* In short, because Ganz removes the tissue around each needle, a POSITA would have been discouraged from using the much larger needles of Hantash because that would result in much wider areas of tissue removal. *Id.*

Additionally, a POSITA would be discouraged from combining Ganz with Hantash because they have different objectives. *Id.* ¶133. As discussed above, Ganz teaches creating “*ablation holes*” around each electrode to generate a more aggressive healing response. *Supra* pp. 37-42. In contrast, Hantash teaches the use of a controller with specialized “algorithms” to limit the energy delivered, thereby “*avoiding overheating* of the treated zones” *Id.* (citing (Ex.1007, [0018])). Thus,

Ganz is about “overheating” to remove tissue, while Hantash is about avoiding this. *Id.*; see also *Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1069 (Fed. Cir. 2018) (a reference’s “statements regarding preferences are relevant to a finding regarding whether a skilled artisan would be motivated to combine that reference with another reference”) (citation omitted).

Ganz also teaches causing ablation and necrosis **around** each electrode to remove the tissue around each electrode. *Supra* pp. 37-42. On the other hand, Hantash teaches away from causing thermal damage around the needles, instead focusing on causing thermal damage between them. For example, Figures 4 through 9 of Hantash show treatment patterns which extend **between** the treatment electrodes:

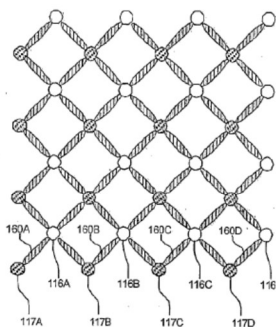


Figure 4A

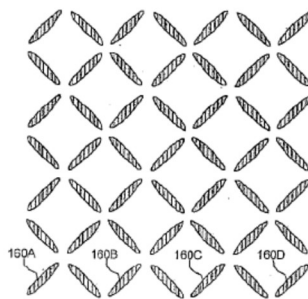


Figure 4B

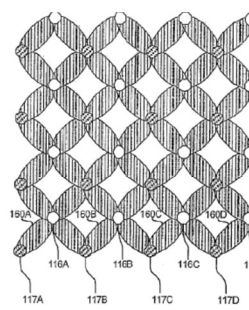


Figure 5A

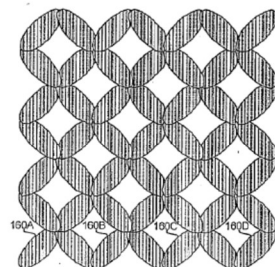


Figure 5B

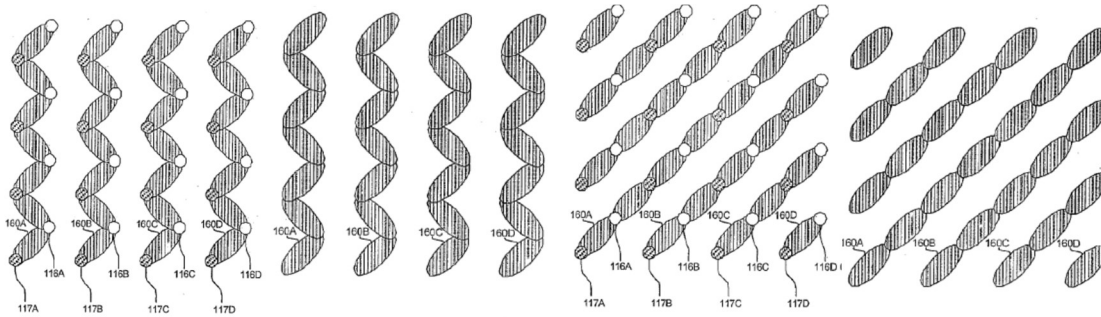


Figure 6A

Figure 6B

Figure 7A

Figure 7B

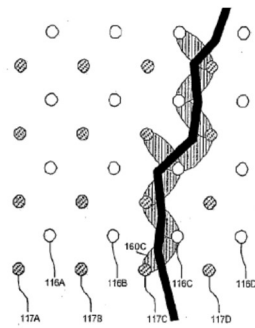


Figure 8A



Figure 8B

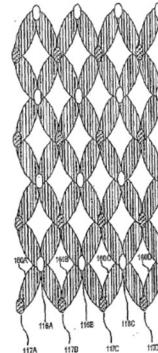


Figure 9A

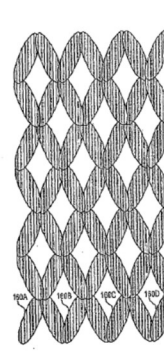


Figure 9B

Ex.1007, Figs. 4A-9B.

Neither Petitioner, nor its experts, explain how a POSITA would determine which patterns and parameters from Hantash, if any, could be safely used with an ablation system such as Ganz, and a POSITA would not have a reasonable expectation of success when combining Ganz with Hantash due to their conflicting objectives. Ex.2143 (VDW Decl.) ¶135. Likewise, a POSITA would not modify Ganz in view of Hantash such that Ganz would no longer achieve its intended purpose of overheating tissue around each electrode. *Id.*

2. Petitioner Failed To Demonstrate That The Additional Limitations Of Claim 22 Would Have Been Obvious

Claim 22 of the '836 Patent requires “[t]he 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.” Ex.1001, cl. 22. Ganz does not disclose the claimed frequency range; Petitioner does not contend otherwise. Ex.2143 (VDW Decl.) ¶136.

Instead, Petitioner asserts that Hantash discloses a frequency range of “0.1 to 10 MHz,” and that “a POSITA would have been motivated to use Hantash’s RF range for Ganz’s device” because Hantash discloses that “[t]he frequency range of the RF source can be chosen based on the desired treatment zone profile.” Pet. 53, 58. But as discussed above, a POSITA would not be motivated to combine Ganz and Hantash because they have different objectives. Petitioner also fails to identify any disclosure in Hantash regarding the benefits of using the disclosed frequency range, and thus Petitioner fails to explain *why* a POSITA would use Hantash’s disclosed ranges. Ex.2143 (VDW Decl.) ¶137. Additionally, Petitioner fails to explain how using Hantash’s frequency ranges would affect Ganz’s ablation technique, or why a POSITA would have a reasonable expectation of success given Ganz’s and Hantash’s conflicting objectives. *Id.*

C. Ground V And VI: Petitioner Failed To Demonstrate That Claims 27-29 Would Have Been Obvious Based On Ganz In View Of Lee, Or Ganz In View Of Livneh And Lee

Petitioner has further failed to show that Ganz in view of a POSITA's knowledge, and/or in further view of Lee and Livneh, discloses or renders obvious the limitations of claims 27-29. Ex.2143 (VDW Decl.) ¶138. As discussed above, independent claim 14 of the '836 Patent is the method version of claim 1's system claim, and each other claim depends upon these two independent claims. Thus, Petitioner has failed to demonstrate that Ganz in view of a POSITA's knowledge, and/or in further view of Lee and Livneh, discloses or renders obvious these claims for the same reasons discussed with respect to claim 1 of the '836 Patent. *Id.*

D. Objective Indicia Support Non-Obviousness

Objective evidence of a patented invention's non-obviousness—such as commercial success, industry praise, and long felt need—“may often be the most probative and cogent evidence in the record[]” and “must be considered in *every* case.” *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1328-37 (Fed. Cir. 2016) (original emphasis) (citing cases); *see also, e.g., Polaris Indus.*, 882 F.3d at 1071-72. Such evidence serves “to ‘guard against slipping into use of hindsight’ ... and to resist the temptation to read into the prior art the teachings of the invention.” *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 36 (1966) (citation omitted).

Here, Petitioner's (and Petitioner's experts') failure to address secondary considerations of non-obviousness render their obviousness arguments insufficient and incomplete as a matter of law. This omission is particularly glaring where, as here, significant objective indicia support non-obviousness. As discussed above, the '836 Patent revolutionized the field of RF microneedling. Specifically, after Dr. Na's development of this novel approach to RF microneedling, the use of bipolar RF microneedling devices became more widely adopted by dermatological practices. Ex.2142 (Goldberg Decl.) ¶20. Indeed, countless bipolar RF microneedling procedures are being performed by dermatologists throughout the world because of Dr. Na's innovation. *Id.* Thus, it is no surprise that, as discussed below, the products practicing the patented invention garnered significant commercial success and industry praise, and addressed a long felt need. This evidence confirms that the '836 Patent was far from obvious.

1. Petitioner's Failure To Address Secondary Considerations Of Non-Obviousness Render Its Obviousness Arguments Insufficient As A Matter Of Law

Whether patent claims would have been obvious to a POSITA is a legal question that is assessed based on underlying factual findings, known as the *Graham* factors: (1) the level of ordinary skill in the pertinent art; (2) the scope and content of the prior art; (3) the differences between the prior art and the claims at issue; and (4) secondary considerations of non-obviousness such as commercial success, long-

felt but unsolved needs, failure of others, etc. *See generally KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The Federal Circuit has “repeatedly emphasized that an obviousness inquiry requires examination of ***all four Graham*** factors and that an obviousness determination can be made only after consideration of each factor.” *Nike, Inc. v. Adidas AG*, 812 F.3d 1326, 1335 (Fed. Cir. 2016) (citations omitted), *aff'd*, No. 2021-1903, 2022 WL 4002668 (Fed. Cir. Sept. 1, 2022). And, “when secondary considerations are present ... it is error not to consider them.” *Id.* at 1339 (original alteration) (citation omitted).

Here, evidence of secondary considerations is present, and Petitioner has been on notice of that evidence since at least June 16, 2023, when Patent Owner served its initial validity contentions in the 1356 ITC Investigation. Ex.2054 (June 16, 2023 Initial Validity Contentions). Indeed, because Petitioner waited until after the evidentiary hearing in the ITC and post-hearing briefing to file their Petition, Petitioner filed its Petition with knowledge of the full evidentiary record on secondary considerations that was developed in the ITC. *See, e.g.,* Ex.2145 (Woloszko Oct. 10, 2024 Dep. Tr.), 18:20-19:11 (Dr. Woloszko admitting that he saw Serendia's presentation of evidence regarding secondary considerations of non-obviousness at the ITC evidentiary hearing). Yet Respondents failed to address Patent Owner's evidence of secondary considerations at all in the ITC, and Petitioner's obviousness arguments suffer from the same glaring omission here. *See,*

e.g., id., 17:6-18:14 (Dr. Woloszko admitting that he, once again, did not address secondary considerations).

In short, despite being aware of the substantial evidence of secondary considerations, Petitioner and its experts disregard it. This alone is sufficient to reject Petitioner's invalidity arguments. *See, e.g., Robert Bosch Tool Corp. v. SD3, LLC*, IPR2016-01753, 2017 WL 1096548, at *12, 16 (P.T.A.B. Mar. 22, 2017) (finding that "the evidence of secondary considerations weighs decisively toward nonobviousne[ss]"); *id.* ("Although we are mindful that at this stage of a proceeding a petitioner may be unaware of a patent owner's potential objective indicia of nonobviousness, in the case before us Patent Owner relies upon evidence that was introduced during the related ITC proceeding against Petitioner."); *see also Gilead Scis., Inc. v. United States ex rel. Sec'y of the Dep't of Health & Hum. Servs.*, IPR2019-01455, 2020 WL 582380, at *8, 21 (P.T.A.B. Feb. 5, 2020) (finding that Petitioner's failure to address known secondary considerations of non-obviousness "means Petitioner falls short of its burden to establish a reasonable likelihood of success in prevailing on its challenge"); *In re Nat. Alts., LLC*, 659 F. App'x 608, 614-15 (Fed. Cir. 2016) (explaining that evidence of objective indicia "must always when present be considered en route to a determination of obviousness") (citation omitted).

Indeed, as the Federal Circuit has explained, when, as here, an expert “fail[s] to account for objective evidence of nonobviousness, [his or her] analysis [i]s incomplete, and ultimately insufficient to establish obviousness,” and thus, the expert cannot offer an “ultimate question of obviousness” because the “expert must consider all factors relevant to that ultimate question” to render an opinion on it. *InTouch Techs., Inc. v. VGO Commc'ns, Inc.*, 751 F.3d 1327, 1352 & n.8 (Fed. Cir. 2014). Petitioner's expert was properly informed that he needed to consider evidence of secondary considerations (Ex.1003 (Bérubé Decl.) ¶21), but he failed to do so. Because Petitioner's expert failed to consider all four *Graham* factors, his analysis is incomplete and his opinion on the ultimate issue of obviousness is not competent. *InTouch Techs.*, 751 F.3d at 1352 & n.8; *see also Inline Plastics Corp. v. Lacerta Grp., LLC*, No. 2022-1954, 2024 WL 1292741 (Fed. Cir. Mar. 27, 2024).

2. The Claimed Invention Has Been Commercially Successful

a. The Sylfirm X Practices The Claimed Invention

The Sylfirm X was designed by the inventor of the '836 Patent, Dr. Jongju Na, who discovered how to utilize bipolar AC RF energy to generate localized coagulation around microneedle electrodes, a phenomenon he called the “Na Effect.” Ex.2037 (Sylfirm X Brochure), 4. And as Dr. van der Weide explains, the Sylfirm X RF Microneedling Device practices the claimed invention. Ex.2143 (VDW Decl.) ¶¶134-156. For example, the Sylfirm X is “[a] skin treatment apparatus[.]” Ex.1001,

cl. 1[pre]; Ex.2143 (VDW Decl.) ¶¶135-136. The Sylfirm X User Manual shows that the Sylfirm X is an RF microneedling system used to treat skin. Ex.2083 (Sylfirm X User Manual), 1; Ex.2084 (Sylfirm X Device Description), 1-20; Ex.2079 (Sylfirm X webpage), 3; Ex.2037 (Sylfirm X Brochure), 2.

The Sylfirm X also includes a “plurality of electrodes, the electrodes being bipolar and configured to be insertable into skin to be treated[.]” Ex.1001, cl. 1[a]; Ex.2143 (VDW Decl.) ¶¶137-145. For example, the Sylfirm X utilizes an array of electrode needles in a bipolar configuration. Ex.2037 (Sylfirm X Brochure); Ex.2086 (Domestic Industry Photos), 9; Ex.2088 (Product Inspection Photos), 37-39; Ex.2084 (Device Description), 5-6; Ex.2037 (Sylfirm X Brochure), 2; Ex.2089 (Electrical Schematic), 6; Ex.2090 (Waveform), 3-4. And as discussed above, the plurality of electrodes of the Sylfirm X are configured to be insertable into the skin to be treated.

The Sylfirm X also includes “a radio frequency (RF) generation module, the RF generation module electrically coupled to the plurality of electrodes and configured to provide an Alternating Current (AC) RF signal to the plurality of electrodes configured to cause coagulation around each electrode rather than coagulating between the electrodes.” Ex.1001, cl. 1[b]; Ex.2143 (VDW Decl.) ¶¶146-156. For example, Sylfirm technical documents confirm that the Sylfirm X includes a radio frequency (RF) generation module electrically coupled to the

plurality of electrodes, and that said generator produces AC / RF output. Ex.2037 (Sylfirm X Brochure), 2; Ex.2084 (Device Description), 14-15; Ex.2083 (Sylfirm X User Manual), 25; Ex.2096 (Invasive Pulse-Type), 33-35; Ex.2088 (Product Inspection Photos), 39; Ex.2090 (Waveform), 3-4.

Patent Owner's documents further confirm that in the Sylfirm X, the RF generation module along with the plurality of electrodes are configured to cause coagulation around each electrode rather than coagulating between the electrodes. *See* Ex.2097 (Sylfirm X video 1); Ex.2099 (Sylfirm X video 2); Ex.2037 (Sylfirm X Brochure), 2, 4; Ex.2102 (Sylfirm X presentation), 25. Additionally, Dr. van der Weide performed heatmapping tests using the electrode array of the Sylfirm X and confirmed that heat is substantially focused around each needle electrode during treatment. Ex.2087 (Heatmapping Tests), 4.

Thus, the Sylfirm X practices the '836 Patent.

b. The Sylfirm X Has Been Commercially Successful

Moreover, as Patent Owner's economic expert, Mr. Thomas explains, the Sylfirm X has been commercially successful. Ex.2139 (Thomas Decl.) ¶¶13-14. For example, its sales "have grown significantly" each year. *Id.* ¶14. In its first year on the market (2021), sales were [REDACTED]; the next year (2022), sales [REDACTED]. *Id.* In just the first quarter of 2023, Sylfirm X made [REDACTED] in sales, which annualizes to [REDACTED]. *Id.*

c. There Is A Strong Nexus Between The Commercial Success Of The Sylfirm X And The Claimed Invention

There is a strong nexus between the commercial success of the Sylfirm X and the claimed invention. For objective evidence of secondary considerations to be relevant, there must be a nexus between the merits of the claimed invention and the objective evidence. *Volvo Penta of the Ams., LLC v. Brunswick Corp.*, 81 F.4th 1202, 1210 (Fed. Cir. 2023) (citing *In re GPAC*, 57 F.3d 1573, 1580 (Fed. Cir. 1995)). A showing of nexus can be made in two ways: (1) via a presumption of nexus, or (2) via a showing that the evidence is a direct result of the unique characteristics of the claimed invention. *Id.* A patent owner is entitled to a presumption of nexus when it shows that the asserted objective evidence is tied to a specific product that “embodies the claimed features, and is coextensive with them.” *Id.* (quoting *Brown & Williamson Tobacco Corp. v. Philip Morris, Inc.*, 229 F.3d 1120, 1130 (Fed. Cir. 2000)). Yet even absent a presumption of nexus, “the patent owner is still afforded an opportunity to prove nexus by showing that the evidence of secondary considerations is the ‘direct result of the unique characteristics of the claimed invention.’” *Id.* (citing *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373-74 (Fed. Cir. 2019) (quoting *In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996))).

Importantly, a nexus analysis need not be limited to a discussion of only novel features. *Id.* at 1212 (citing *WBIP*, 829 F.3d at 1330) (stating that “proof of nexus is not limited to only when objective evidence is tied to the supposedly ‘new’

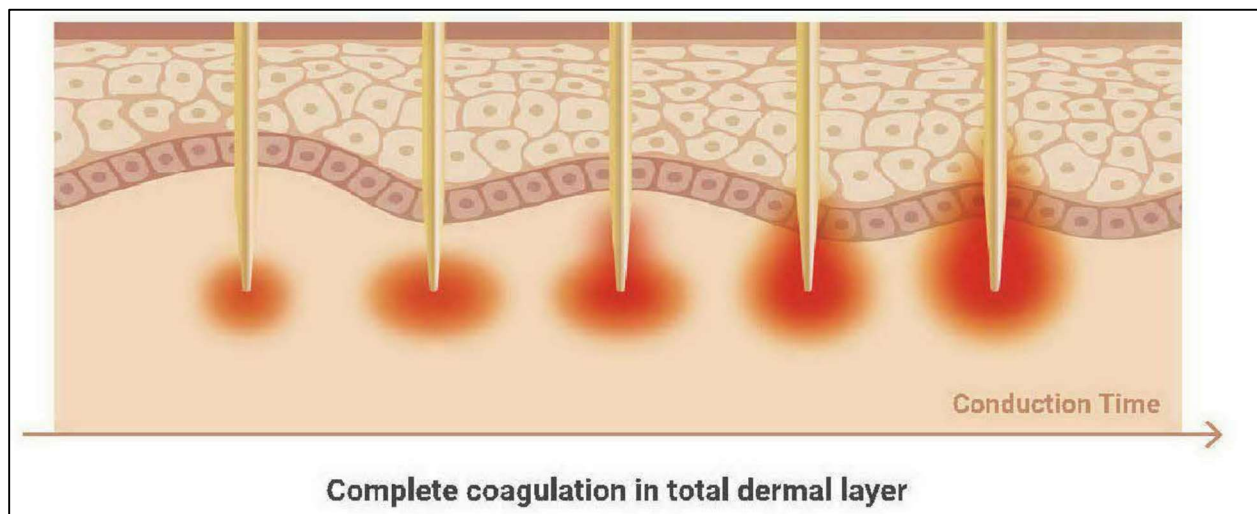
feature(s)"). Instead, it is important to consider "the invention as a whole," rather than on a "limitation-by-limitation" basis. *Id.* (quoting *Chemours Co. FC, LLC v. Daikin Indus., Ltd.*, 4 F.4th 1370, 1377 (Fed. Cir. 2021)); *Yita LLC v. MacNeil IP LLC*, 69 F.4th 1356, 1364 (Fed. Cir. 2023) (discussing *WBIP*).

The evidence shows that the "inventive combination" of features drove the commercial success of the Sylfirm X. *Chemours*, 4 F.4th at 1378 (citation omitted). As discussed above, Dr. Na pioneered the use of alternating current RF energy through bipolar electrodes to achieve thermal coagulation around each electrode (rather than between the electrodes), which was termed the "Na Effect." *Supra* pp. 27-28. Dr. Na further patented his invention, and then worked to develop the Sylfirm X RF microneedling product. *See, e.g.*, Ex.1001, cl. 1 (claiming a skin treatment apparatus comprising bipolar electrodes driven by AC RF energy to achieve localized coagulation around each electrode); Ex.2037 (Sylfirm X Brochure), 4 (discussing how the Sylfirm X results in "[m]inimal downtime " and "[l]ittle to no pain" due to the "Na Effect").

As Dr. Goldberg explains, the introduction of the technology claimed in the '836 Patent "radically revolutionized the way practitioners use RF microneedling devices and made treatments more effective, reduced patient pain and downtime, and increased the patient compliance." Ex.2142 ¶43. Thus, products utilizing the

inventions have achieved commercial success from incorporating the '836 Patent's technology. *Id.* ¶37 (“The benefits of the '836 Patent make us all busier every day.”).

Advertisements for the Sylfirm X tout the benefit of the '836 Patent technology. For example, the Sylfirm X brochure discusses how, “[i]n 2015, ViOL's founder, Dr. Jung Ju Na, conducted a clinical study to observe the skin response to ***alternating current bipolar RF energy***.” Ex.2037 4. As the brochure explains, “[w]hen bipolar RF energy” is released through a microneedle, “tissue coagulation begins at each end of the microneedle electrode, and then forms a droplet or cocoon shape as conduction time increases, showing less thermal effect on the epidermis.” *Id.* The brochure emphasizes the '836 Patent's effect:



Id.

As Sylfirm X's marketing materials explain, “[t]he primary takeaway of the ‘Na effect’ is that it maximizes the thermal effect on the target with little to no epidermal damage, enabling effective and safe treatment.” *Id.*; see also Ex.2039

(Video), 0:52; Ex.2142 (Goldberg Decl.) ¶44. Other marketing and training materials likewise focus on the treatment benefits associated with implementing the technology claimed in the '836 Patent. Ex.2142 (Goldberg Decl.) ¶46; Ex.2101 (press release), 2 (“*Undoubtedly the most profound advantage seen with Sylfirm X Ultimate Edition is the ‘Na Effect[.]’*”). The '836 Patent is also directly cited in the Sylfirm X marketing materials and in the exclusive distribution and license agreement between VIOL and Serendia. Ex.2061 (Distribution and License Agreement), 5; Ex.2079 (Product Webpage); Ex.2038 (Patent List).

Moreover, removing any doubt that the '836 Patent's claimed invention is directly tied to the commercial success of the Sylfirm X, the Sylfirm X brochure explains that the “Na effect is the *key method* for the safest and most effective RF treatment” and further that “[t]he *distinguishing factor* of this phenomenon is the achievement of independent tissue coagulation around each micro-needle electrode.” Ex.2037, 12. “Th[is] prominence of the patented technology in ... advertising creates an inference that links the ... invention to this success.” *Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573, 1579 (Fed. Cir. 1997).

In short, the evidence establishes that the claimed invention is a “distinguishing factor” in selecting RF microneedling devices, and that the inventive combination of features, such as applying AC RF energy through bipolar electrodes to achieve localized coagulation, drove the commercial success and widespread use

of the Sylfirm X. Ex.2142 (Goldberg Decl.) ¶¶47, 56. Thus, there is a strong nexus between the '836 Patent and Sylfirm X's commercial success.

3. The Claimed Invention Has Also Received Industry Praise And Recognition

The localized and targeted coagulation claimed by the '836 Patent has also received industry praise and recognition, and thus supports a finding of non-obviousness. Ex.2142 (Goldberg Decl.) ¶¶57-64; *WBIP*, 829 F.3d at 1334. For example, many medical providers have praised the “Na Effect,” and its implementation sets products “apart from the pack.” Ex.2142 (Goldberg Decl.) ¶54; Ex.2042 (Aesthetic Guide), 1, 3, 6; Ex.2043 (Testimonials). Many industry studies also recognize the advancements claimed in the '836 Patent. Ex.2142 (Goldberg Decl.) ¶¶60-63; Ex.2044 (Paper Summary); Ex.2045 (Cho Study); Ex.2046 (Jung Study); Ex.2047 (Wootten Study), 1-3; Ex.2048 (Harth Study), 5-6.

Thus, the technology claimed in the '836 Patent has become widely recognized and praised, and “[r]ecognition of the importance of this advance is relevant to a determination of nonobviousness.” *Gambro Lundia*, 110 F.3d at 1579 (citation omitted); *WBIP*, 829 F.3d at 1334 (“competitors, are not likely to praise an obvious advance over the known art”).

4. The Claimed Invention Also Addressed A Long-Felt Need

The '836 Patent's approach also overcame drawbacks associated with the prior art systems, addressing a long-felt but unsolved need in the industry.

Millennium Pharms., Inc. v. Sandoz Inc., 862 F.3d 1356, 1369 (Fed. Cir. 2017). As Dr. Goldberg explains, prior art treatments were known to cause burns, blisters, scarring, longer downtime, and pain. Ex.2142 ¶¶66-67; *see also* Ex.2049 (Manstein '899), 3:31-59; Ex.2050 (Woloszko '071), 2:35-50; Ex.2051 (Manstein 090), [0040]. The technology claimed in the '836 Patent addressed these long-felt issues and “radically revolutionized the way we use these devices for skin tightening, acne scarring, aging skin, a whole different variety of entities and all different skin types and colors.” Ex.2142 (Goldberg Decl.) ¶71; *see also* Ex.1001, 4:4-19.

5. The Board's Institution Decision

In its Institution Decision, the Board concluded that Patent Owner's Preliminary Response “fails to explain sufficiently how the evidence of objective indicia correlates to the recited features such as bipolar electrodes or alternating current.” ID 38-39 (emphasis omitted). To begin with, as demonstrated above, Patent Owner has provided additional citations and explanation of the evidence to address the Board's concern. As discussed above, the Sylfirm X marketing materials explicitly highlight the use of “***alternating current bipolar RF energy***,” explaining that “[w]hen bipolar RF energy” is released through a microneedle, “tissue coagulation begins at each end of the microneedle electrode, and then forms a droplet or cocoon shape as conduction time increases, showing less thermal effect on the epidermis.” Ex.2037 (Sylfirm X Brochure), 4.

Moreover, as the Federal Circuit has explained, it is important to consider “the invention as a whole,” rather than on a “limitation-by-limitation” basis. *Volvo*, 81 F.4th at 1212 (citing *Chemours*, 4 F.4th at 1377). For example, in *Volvo*, the Board determined that the patent owner did not demonstrate a nexus to certain objective indicia. *Id.* The Federal Circuit disagreed however, finding that the Board’s determination was not supported by substantial evidence. *Id.* As the Federal Circuit explained, the Patent Owner cited documents demonstrating a connection between claimed elements of the invention and the objective evidence of non-obviousness. *Id.* This included evidence highlighting what made aspects of the claimed invention valuable and useful. *Id.* This further included evidence that “[t]he inventive combination of [claimed elements] provided certain benefits praised in the industry and not achieved ... in the prior art,” as well as evidence that potential customers “strongly desired” the claimed features. *Id.* (first alteration in original). Thus, the Federal Circuit concluded that “[t]here is therefore a nexus between the unique features of the claimed invention ... and the evidence of secondary considerations.” *Id.*

Here, as discussed above, there is substantial evidence directly linking the claimed invention and the evidence of secondary considerations. This includes evidence demonstrating what makes aspects of the claimed invention valuable and useful, such as how the “Na Effect” “maximizes the thermal effect on the target with

little to no epidermal damage, enabling effective and safe treatment.” Ex.2037 (Sylfirm X Brochure), 4; Ex.2039 (Video), 0:52; Ex.2142 (Goldberg Decl.) ¶44. As the Sylfirm X brochure explains, the “Na effect is the *key method* for the safest and most effective RF treatment” and further that “[t]he *distinguishing factor* of this phenomenon is the achievement of independent tissue coagulation around each micro-needle electrode.” Ex.2037, 12.

This further includes evidence that many medical providers have praised the “Na Effect,” and that industry studies have also recognized the advancements claimed in the ’836 Patent. Ex.2142 (Goldberg Decl.) ¶¶57-64; Ex.2042 (Aesthetic Guide), 1, 3, 6; Ex.2043 (Testimonials); Ex.2044 (Paper Summary); Ex.2045 (Cho Study); Ex.2046 (Jung Study); Ex.2047 (Wootten Study), 1-3; Ex.2048 (Harth Study), 5-6.

This further includes evidence demonstrating how the claimed invention addressed the long-felt issues such as prior art treatment devices causing “burns, blisters, scarring, longer downtime, and pain” via its inventive combination of elements, and thus “radically revolutionized the way [surgeons] use these devices for skin tightening, acne scarring, aging skin, a whole different variety of entities and all different skin types and colors.” Ex.2142 (Goldberg Decl.) ¶¶65-71; Ex.1001, 4:4-19; Ex.2049 (Manstein ’899), 3:31-59; Ex.2050 (Woloszko ’071), 2:35-50; Ex.2051 (Manstein 090), [0040].

In short, here, just as in *Volvo*, “[t]here is therefore a nexus between the unique features of the claimed invention ... and the evidence of secondary considerations.”

Volvo, 81 F.4th at 1212.

VIII. Conclusion

For the reasons set forth above, the Board should confirm the patentability of all challenged claims.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH 37 C.F.R. § 42.24

I hereby certify that this Patent Owner's Response complies with the word count limitation of 37 C.F.R. § 42.24(b)(2) because the Patent Owner's Response contains 13,947 words using Microsoft Word's counting feature, excluding the cover page, signature block, and the parts of the Patent Owner's Response exempted by 37 C.F.R. § 42.24(b)(2).

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that on this 5th day of November, 2024, a true and correct copy of the foregoing **Patent Owner's Response and all Exhibits** were served by electronic mail on Petitioner's lead and backup counsel at the following email addresses:

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