

Filed on behalf of: Serendia, LLC

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

SERENDIA, LLC,  
Patent Owner.

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Case IPR2024-00842  
Patent 9,480,836

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**DECLARATION OF DANIEL W. VAN DER WEIDE  
IN SUPPORT OF  
PATENT OWNER'S PRELIMINARY RESPONSE**

***PUBLIC VERSION-REDACTED***

## **Table of Contents**

|      |                                                                                                                                                                                                    |    |
|------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|
| I.   | INTRODUCTION AND QUALIFICATIONS .....                                                                                                                                                              | 1  |
| II.  | SUMMARY OF MATERIALS REVIEWED AND CONSIDERED .....                                                                                                                                                 | 5  |
| III. | SUMMARY OF OPINIONS .....                                                                                                                                                                          | 9  |
| IV.  | LEGAL PRINCIPLES .....                                                                                                                                                                             | 9  |
| A.   | Person of Ordinary Skill in the Art .....                                                                                                                                                          | 10 |
| B.   | Claim Construction .....                                                                                                                                                                           | 10 |
| C.   | Validity .....                                                                                                                                                                                     | 13 |
| D.   | Anticipation .....                                                                                                                                                                                 | 14 |
| E.   | Obviousness And Motivations To Combine .....                                                                                                                                                       | 14 |
| V.   | TECHNOLOGY BACKGROUND .....                                                                                                                                                                        | 18 |
| A.   | Overview of RF Technology .....                                                                                                                                                                    | 18 |
| B.   | The “Na Effect” .....                                                                                                                                                                              | 25 |
| C.   | The ’836 Patent .....                                                                                                                                                                              | 26 |
| D.   | The ’836 Patent’s Prosecution History .....                                                                                                                                                        | 41 |
| VI.  | PETITIONER’S GROUNDS FOR REQUESTING <i>INTER PARTES</i><br>REVIEW ARE DEFICIENT .....                                                                                                              | 42 |
| A.   | Grounds I & II: Petitioner Fails To Show That Claims 1-2, 11-<br>15, 23-24, And 26 Would Have Been Obvious Based On Ganz<br>Alone Or In View Of Livneh .....                                       | 43 |
| B.   | Ground III And IV: Petitioner Failed To Demonstrate That<br>Claims 2-10, 15-22, And 25 Would Have Been Obvious Based<br>On Ganz In View Of Hantash, Or Ganz In View Of Livneh And<br>Hantash ..... | 76 |
| C.   | Ground V And VI: Petitioner Failed To Demonstrate That That<br>Claims 27-29 Would Have Been Obvious Based On Ganz In<br>View Of Lee, Or Ganz In View Of Livneh And Lee .....                       | 81 |
| D.   | Objective Indicia Support Non-Obviousness .....                                                                                                                                                    | 81 |
| E.   | Reservations of Rights .....                                                                                                                                                                       | 93 |
| VII. | CONCLUSION .....                                                                                                                                                                                   | 93 |

**I. INTRODUCTION AND QUALIFICATIONS**

1. I have been retained by counsel for Serendia, LLC (“Serendia” or “Patent Owner”) to provide my opinion concerning the validity of U.S. Patent No. 9,480,836 (Ex. 1001).

2. This declaration is based on information available to me to date. If called as an expert witness, I expect to testify regarding my background, qualifications, and experience relevant to the issues in this litigation, the '836 Patent and subject matter thereof, validity of the '836 Patent, and any other matters set forth in this declaration.

3. I obtained a Ph.D. in Electrical Engineering in 1993 from Stanford University. From 1993 to 1995 I was a post-doctoral researcher in the group of Klaus von Klitzing (Nobel Prize winner) at the Max Planck Institut für Festkörperforschung in Stuttgart, Germany.

4. Since my post-doctoral work, I have served as a professor of electrical and computer engineering. I began my teaching career as an Assistant, then Associate Professor of Electrical and Computer Engineering at the University of Delaware, where I taught from 1995-1999. At that time, I was appointed Associate Professor of Electrical Engineering at the University of Wisconsin-Madison, where I was promoted to Full Professor in 2004. I have also received courtesy

appointments in the Radiology, Biomedical Engineering, and Materials Science Departments at the University of Wisconsin-Madison.

5. In addition to being elevated to Fellow of the IEEE, I have received various honors and awards in recognition of my work. I received the Vilas Associate Award, the Alexander Von Humboldt Fellowship, and the PECASE Award from the National Science Foundation. I also received the Young Investigator Program Award from the Office of Naval Research. The DARPA ULTRA Program also awarded me with the Innovation/Technical Achievement Award. I also received the University Research Award from the Ford Motor Company. Additionally, I received the Dean's Merit Increase and the Provost's Special Merit Increase from the University of Delaware. I was also a teaching Fellow at both the National Science Foundation and the University of Delaware.

6. My group at the University of Wisconsin focuses its research on the design and fabrication of microfabricated circuits and transducers for high frequency probes and sensors with an eye toward cross-disciplinary applications. Based on work with infrared and far-infrared imaging and spectroscopy during my PhD and post-doctoral research, I have used and published on scanning techniques for field acquisition and excitation using pulsed lasers combined with scanning probe microscopy. Students in my group have also studied excitation, imaging and

irreversible alteration of biological structures ranging from cell membranes to organs using high-frequency energy, both electromagnetic and acoustic.

7. My work has also led to over 100 journal publications, numerous book sections, and over 100 conference presentations. These publications have focused on topics such as high-frequency energy used for skin treatment,<sup>1</sup> microwave ablation of tissue, imaging of proteins in membranes as well as tumors, nonlinear metamaterials, terahertz radiation, and high-frequency near-field microscopy. These works have been published in well-respected publications. A sample of these publications includes *IEEE Journal of Electromagnetics, RF and Microwaves in Medicine and Biology*, *Optics Express*, *IEEE Transactions on Microwave Theory and Techniques*, *Physical Review*, *Nature Physics*, *Review of Scientific Instruments*,

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<sup>1</sup> Y. Gu, D. Kendig, M. Shakouri and D. W. van der Weide, “Dual Mode Split Ring Resonator Sensing and Hyperthermia Array for Skin,” in *IEEE Journal of Electromagnetics, RF and Microwaves in Medicine and Biology*, doi: 10.1109/JERM.2024.3373537 and D. W. van der Weide, D. Kendig and M. Shakouri, “High-Speed Thermal Imaging Can Resolve Short RF Pulse Effects in Tissue Models,” in *IEEE Journal of Electromagnetics, RF and Microwaves in Medicine and Biology*, doi: 10.1109/JERM.2024.3363906. These are both 2024 “Early Access” publications.

Biosensors and Bioelectronics, Applied Physics Letters, the Journal of Vascular and Interventional Radiology and others.

8. I am an inventor—generally the first named inventor—on nearly 250 patent applications, which have matured into more than 70 issued patents in the U.S. and abroad. A sample of the related topics includes microwave catheters for surgical ablation of blood vessels, energy delivery systems and uses thereof, field scanning probe microscopes for near-field imaging of tissue, pulsed radiation spectrometers, and solid-state quantum dot devices.

9. I co-founded and served on the board of directors of NeuWave Medical, Inc., which was acquired by Johnson & Johnson. At NeuWave, we developed microwave-based systems for percutaneous tissue ablation that provide minimally invasive options for soft tissue lesions in the liver, kidney, and lung; these probes are placed by ultrasound or CT guidance; through this development process I also used RF applicators for tissue ablation, such as systems from ValleyLab. I also co-founded and currently serve on the board of directors of Elucent Medical, Inc., which develops and sells wireless surgical navigation systems. Consistent with my interest in focal tumor ablation, I have been an investor in related startups including Histosonics, which employs HIFU (high-intensity focused ultrasound) to create zones of ablation in organs such as liver without percutaneous probes. Finally, I am a cofounder of Accure Medical, a startup using high-frequency (RF and microwave)

applicators to eradicate finger- and toenail infections; this technology requires careful thermal measurements of the RF/microwave energy deposition in tissue.

10. My opinions are set forth below. I am being compensated for my work on this matter, but my opinions are based on my own views of the patented technology and the prior art. In connection with this matter, I am being compensated at the rate of \$700 per hour for my work performed. I further served as an expert in the 1356 ITC Investigation and was compensated the same for my work in that matter. My compensation is not dependent on and in no way affects the substance of my statements, opinions, or conclusions in this declaration, nor is it dependent on the outcome of these or any other proceedings. A copy of my C.V. is attached to this declaration as Ex. 2072.

## II. SUMMARY OF MATERIALS REVIEWED AND CONSIDERED

11. All of the opinions contained in this declaration are based on the documents I reviewed and my knowledge and professional judgment. In forming the opinions expressed in this declaration, while drawing on my experience in the field of Electrical Engineering and the application of energy to tissue, I reviewed the following documents:

| Ex.  | Description                                                                                                                                                                                                       |
|------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2012 | Hearing transcript, <i>In re Certain Dermatological Treatment Devices &amp; Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C.), held November 7, 2023 (Jean Woloszko testimony excerpts) (“Woloszko Hr’g Tr.”) |

| Ex.  | Description                                                                                                                                                                                                                                                                           |
|------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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                                                                                                                                                                                                                                                          |
| 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)                                                                                   |
| 2034 | U.S. Patent Application Publication No. 2011/0288543 A1 (“Cheng”)                                                                                                                                                                                                                     |
| 2035 | Deposition transcript of Jongju Na, <i>In re Certain Dermatological Treatment Devices &amp; 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”)                                                                                                                                                                                                             |
| 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) |

| Ex.  | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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), <a href="https://webstore.iec.ch/publication/2624">https://webstore.iec.ch/publication/2624</a> (last visited Aug. 25, 2023) (Abstract only) |
| 2079 | Sylfirm X (product information), ViOL (2022), <a href="https://violmedical.com/for_providers/product?idx=10">https://violmedical.com/for_providers/product?idx=10</a> (last visited Feb. 25, 2023)                                                                                                                                                                                                                                                                         |
| 2083 | ViOL, Sylfirm X User Manual (VO-UM-SFX-03), revised April 20, 2022                                                                                                                                                                                                                                                                                                                                                                                                         |
| 2084 | Sylfirm X, Device Description (PROTECTIVE ORDER MATERIAL)                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 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)                                                                                                                                                                                                                                                                                                                                           |
| 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)                                                                                                                                                                                                                                                                                                                                                                                                                                            |

| Ex.  | Description                                                                                                                                                                                             |
|------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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                                                                                                                                             |
| 2102 | Presentation: Jiehoon Kim, ViOL / Sylfirm, <i>Pigmentary and Vascular Treatment with Pulsed RF “Sylfirm,”</i> including Certificate of Translation (PROTECTIVE ORDER MATERIAL)                          |
| 2142 | Declaration of David Goldberg in Support of '836 Patent Owner's Preliminary Response, dated November 11, 2024 (“Goldberg Decl.”)                                                                        |
| 2144 | Deposition transcript of Jean Woloszko, M.D., Ph.D., <i>In re Certain Dermatological Treatment Devices &amp; 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                                                                       |
| 2148 | Andrew I. Brill, <i>Bipolar Electrosurgery: Convention and Innovation</i> , 51 CLINICAL OBSTETRICS GYNECOLOGY 153 (2008)                                                                                |

| Ex.  | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2149 | Letter from Long Chen, U.S. Food & Drug Administration 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)                                                                                                                                                                                                                                                                                                        |

### III. SUMMARY OF OPINIONS

12. Based on my analysis, I have arrived at certain opinions set forth throughout this declaration. For example, and without limitation for other opinions set forth in this declaration, I have concluded that the '836 Patent claims are valid over the prior art and combinations of prior art identified in Petitioner's Petition for IPR.

### IV. LEGAL PRINCIPLES

13. I am neither a lawyer nor a patent agent, and I have no formal training in any aspect of the law. However, certain legal principles and standards have been explained to me by Patent Owner's counsel, which I have assumed and applied for purposes of this declaration. Some of these, which form the legal framework for the opinions I am providing, are summarized below.

**A. Person of Ordinary Skill in the Art**

14. I understand that a person having ordinary skill in the art (*i.e.*, a PHOSITA, POSITA or POSA) is a hypothetical person who is presumed to have known the relevant art at the time the invention was made. I understand that the condition “at the time the invention was made” is imposed to rule out impermissible hindsight. I also understand that an expert is to analyze the prior art from the perspective of a person of ordinary skill in the art and not simply to provide his/her own personal conclusions.

15. As Petitioner notes, in the ITC, the Administrative Law Judge (“ALJ”) specified the level of skill of a POSITA for the '836 patent. Pet. at 9. For the purposes of this preliminary response, I understand that Serendia does not dispute the POSITA definition adopted in the ITC and I have applied that definition for purposes of my opinions.

**B. Claim Construction**

16. As Petitioner notes, in the ITC Investigation, Petitioner and Serendia agreed to certain constructions (Ex-1028, 39-40), and the ALJ adopted certain constructions (Ex-1028, 41-62). Petitioner advocates that the Board should apply those constructions, and I likewise apply them for purposes of this preliminary response. For the remaining terms, I have been informed by counsel that claims

should be given their ordinary and customary meaning as understood by a person of ordinary skill in the art (“POSITA”) in the context of the entire patent.

17. I understand that in some instances, the plain and ordinary meaning of claim language is readily apparent and claim construction will involve little more than the application of the widely accepted meaning of commonly understood words. I also understand that in other instances, claim terms have specialized meanings, and it is necessary to determine what a POSITA would have understood particular claim language to mean by analyzing the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, as well as the meaning of technical terms, and the state of the art.

18. I understand the specification is the best guide to the meaning of a disputed term when the meaning of a particular claim term in the context of the patent’s claims is unclear. I also understand the construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be, in the end, the correct construction. I also understand that, generally, the specific examples or embodiments discussed in the specification are not to be read into the claims as limitations.

19. I understand that the claims themselves provide substantial guidance regarding the meaning of particular claim language, and the context in which a term

is used in the asserted claim can be highly instructive. Similarly, I understand that other claims of the patent at issue, whether or not they have been asserted, may show the scope and meaning of particular claim language.

20. I understand that the patent's prosecution history may also inform the meaning of claim language, even though the prosecution history often lacks the clarity of the specification and thus is less useful for claim construction purposes. I have been informed by counsel that the prosecution history includes the entire record of the patent examination proceedings before the U.S. Patent and Trademark Office ("USPTO"), including cited prior art references. I understand the prosecution history may reveal how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.

21. I understand that extrinsic evidence may be used to construe claim language if the intrinsic evidence is inadequate to determine the meaning of particular claim language. It is my understanding that extrinsic evidence may help explain the relevant art and consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises. I understand that extrinsic evidence is less reliable than intrinsic evidence and is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence. I also understand that

extrinsic evidence is considered last, if at all because in cases where the public record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper.

**C. Validity**

22. I have been informed that determining whether a patent is invalid is a two-step process in which the Board must first determine the scope and meaning of the claims, which I understand is called “claim construction,” after which the Board must then determine validity. Once the Board has ruled on the proper construction for contested terms the claims must be considered, using those constructions, from the perspective of a person having ordinary skill in the art at the time of invention.

23. I have been informed that the patent claims themselves – not the written description or the preferred embodiments – define the scope of protection of the patent. I also understand that words in the claim should not be construed in a vacuum, but rather should be construed in the context of the claim as a whole with respect to the entire intrinsic record. Furthermore, the claims should be interpreted from the point of view of a person having ordinary skill in the relevant art at the time of invention.

24. It is my understanding that a patent can be found to be invalid over prior art based on two related but different principles, the first that the claimed invention is anticipated by a specific single piece of prior art and the second that the patent can

be found to have been obvious to a person of ordinary skill in the art at the time of invention in light of prior art.

**D. Anticipation**

25. I am informed that for a claim to be anticipated, every limitation of the claimed invention must be found in a single prior art reference, either expressly or inherently, arranged as in the claim. I understand that the words in a reference are to be construed in light of the relevant surrounding circumstances in each case, and a reference in any event is good only for that which it discloses.

26. I further understand that anticipation cannot be established by multiple, distinct teachings that the artisan might combine to achieve the claimed invention. Additionally, I understand that when a reference does not disclose that the drawings are to scale and is silent as to dimensions, an accused infringer cannot infer dimensions to demonstrate invalidity. Finally, I understand that an element may be inherently disclosed only if it is necessarily present, not merely probably or possibly present, in the prior art.

**E. Obviousness And Motivations To Combine**

27. I understand that even if a patent is not anticipated, it may still be invalid if the differences between the claimed subject matter and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the pertinent art. I

understand that, while obviousness is often based on more than one piece of prior art, only one is required. I understand that it is not sufficient that a collection of prior art references recites the various elements of a challenged patent claim. Rather, I understand it, it must have been obvious to combine those elements in a manner that is consistent with their arrangement or use in the challenged claims.

28. I also understand that an obviousness determination includes several factual inquiries, including (1) determining the scope and content of the prior art; (2) ascertaining the differences between the claimed invention and the prior art; (3) resolving the level of ordinary skill in the pertinent art; and (4) taking into consideration any objective indicia of nonobviousness.

29. It is my understanding that obviousness must be determined as of the date of the invention (*i.e.*, the effective filing date or priority date of the patent). Thus, in considering the reason or motivation to combine references, it is essential to avoid using hindsight. I also understand that the problem examined when considering obviousness may be a problem that would have motivated a POSITA at the time that the invention was made, not the specific problem solved by the invention. I understand that defining the problem in terms of its solution reveals improper hindsight in the selection of the prior art relevant to obviousness. Further, I understand that an overly narrow statement of the problem can represent a form of hindsight, because an inventive contribution may lie in defining the problem in a

new, revelatory way. Similarly, I understand that an assertion that a person of ordinary skill could combine the references, rather than that they would have been motivated to do so, is an impermissible form of hindsight. Moreover, I understand that knowledge of a problem and motivation to solve it are entirely different from reason to combine particular references to reach the particular claimed method.

30. I am informed that the analysis of the reason to combine prior art should be explicit. Additionally, I understand that an obviousness analysis must include articulated reasoning with rational underpinnings to support the conclusion of obviousness. I understand that providing a full explanation of the reason to combine the references and the reasonable expectation of success is a necessary component of the obviousness inquiry, as inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known. However, I understand that conclusory statements fail to adequately explain why a person of ordinary skill would have a motivation to combine the potential prior art references.

31. I am informed that common sense, common wisdom, and common knowledge may be used to support a reason to combine, so long as the use of common sense in the analysis is explained with sufficient reasoning. But I understand that common sense can only be used to supply a limitation missing from the prior art where the technology is unusually simple and straightforward.

32. I am also informed that evidence suggesting reasons to combine cannot be viewed in a vacuum apart from evidence suggesting reasons not to combine. In analyzing motivation, both advantages and disadvantages must be considered. Teaching away, for example, is a statement in the prior art that either (i) discourages one from following the path of the claimed invention, or (ii) encourages one to follow a path that diverges from the path of the claimed invention. The concept of teaching away bears directly on whether there was a reason to combine prior art. Known disadvantages in old devices which would naturally discourage a search for new inventions may also be taken into account in determining obviousness.

33. I am informed that objective indicia of non-obviousness may include (1) a long felt but unsolved need that was satisfied by the claimed invention; (2) commercial success attributable to the claimed invention; (3) unexpected results achieved by the claimed invention; (4) praise by those in the field of the claimed invention; (5) taking of licenses under the patent by others for reasons related to the alleged non-obviousness of the claimed invention; and (6) evidence that competitors in the marketplace are copying the invention instead of using the prior art. I also understand that there must be a relationship, or nexus, between any such secondary indicia and the claimed invention, *i.e.*, objective evidence of non-obviousness must be attributable to the claimed invention. I further understand that near simultaneous invention by two or more equally talented inventors working independently, may or

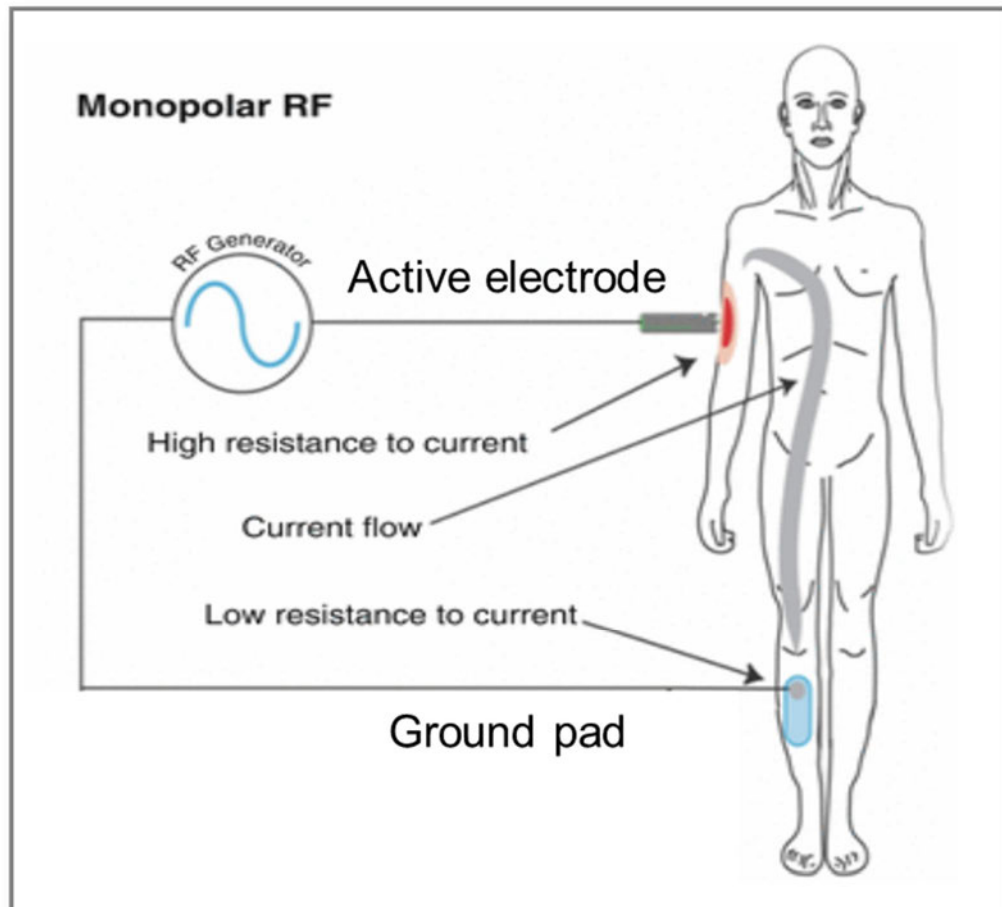
may not be an indication of obviousness when considered in light of all the circumstances.

34. It is further my understanding that to be proper for use in an obviousness analysis, a reference must be analogous art to the claimed invention. Accordingly, I understand that under the correct analysis, any need or problem known in the field of endeavor at the time of the invention and addressed by the claimed invention can provide a reason for combining the elements in the manner claimed.

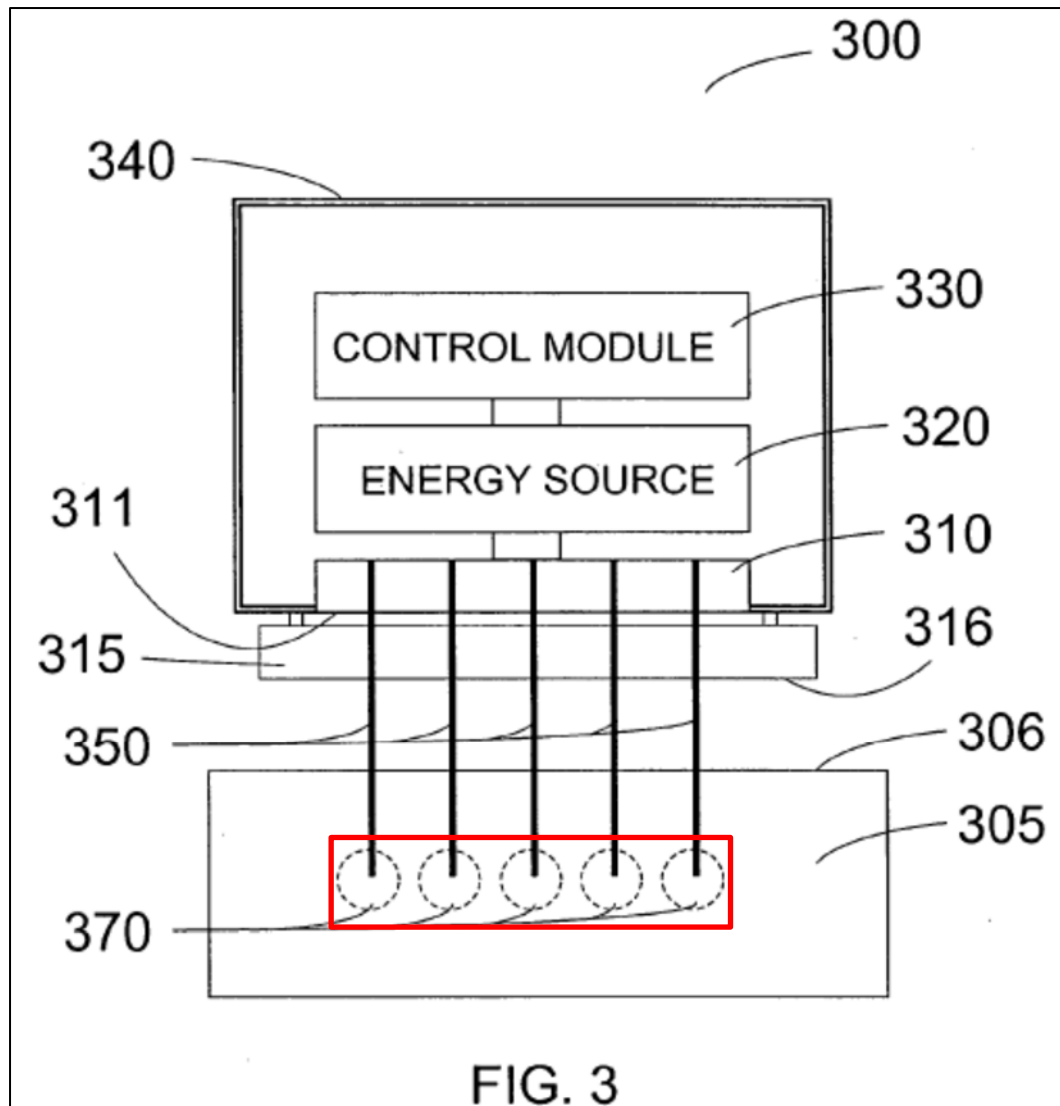
## V. TECHNOLOGY BACKGROUND

### A. Overview of RF Technology

35. 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. *See, e.g.,* Ex. 2032 (Na Nature Paper), 97. 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:



36. Early 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. Pat. Pub. No. 2005/0222565 ("Manstein"), when operating the apparatus in a monopolar configuration, thermal damage is generated around just the tip of electrode needles. 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):



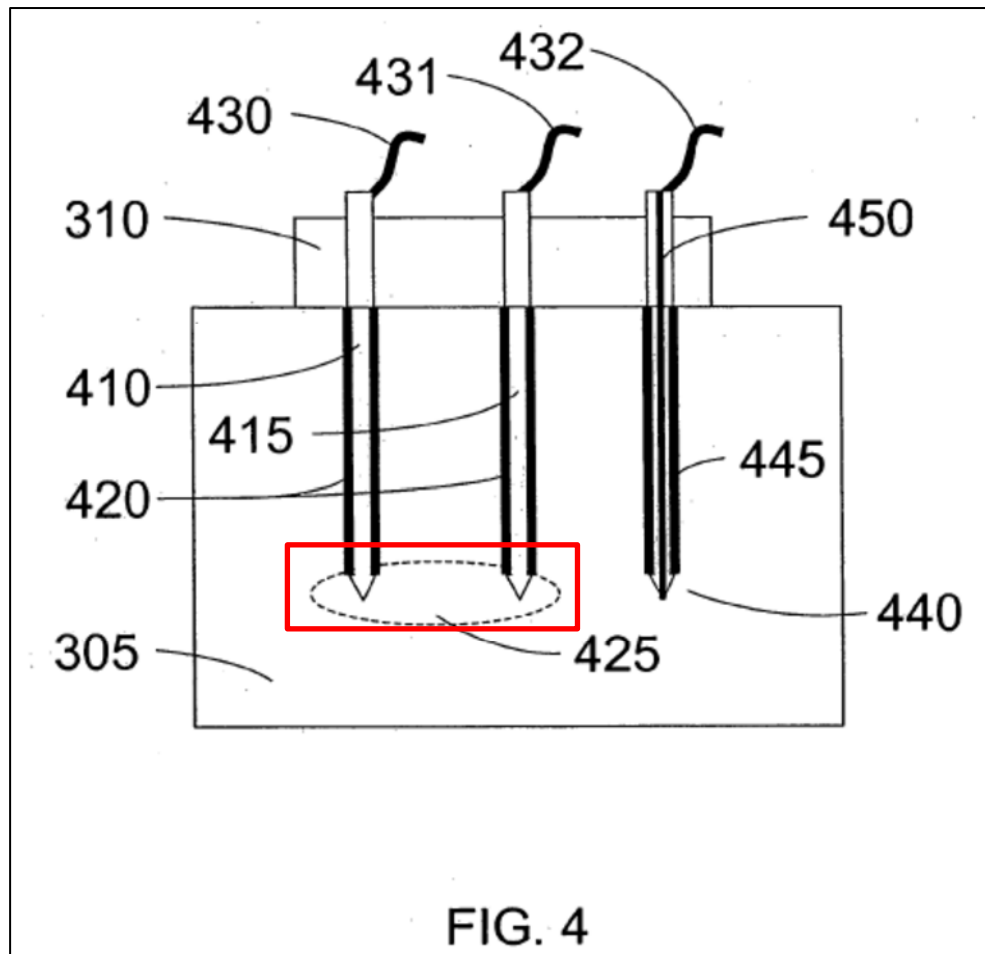
37. However, while these prior monopolar RF microneedling systems allowed for localized thermal damage, these prior systems also carried several risks. Ex. 2142 (Goldberg Decl.), ¶16. For example, the first widely accepted aesthetic radiofrequency microneedling technology was a monopolar device called the Thermage device. *Id.* (citing Ex. 2057 (Hollmig Paper), 769). 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)

38. **Bipolar** systems however, induce an electrical circuit *between* the two active electrodes. And 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. *See, e.g.,* Ex. 2060 (Berube et al.). For example, 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.*”<sup>2</sup> 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):

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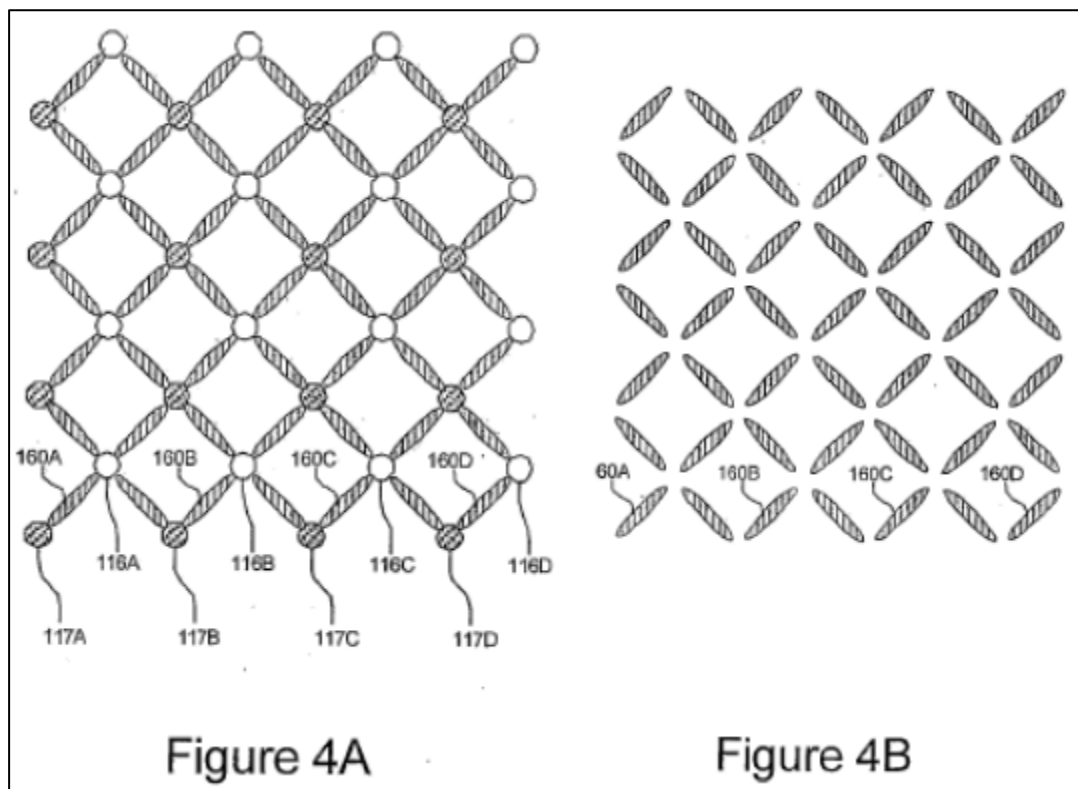
<sup>2</sup> Manstein refers to use of an active electrode and a grounding electrode as “bipolar,” while the ’836 Patent involves use of active electrodes, where sets of electrodes have opposite polarity at any point in time. *Compare* Ex. 1014 (Manstein), [0041] *with* Ex. 1001 (’836 Patent), 7:24-40.



Ex. 1014, Fig. 4.

39. As Dr. Goldberg explains, 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.), ¶¶17-18. 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 *et al.*)).

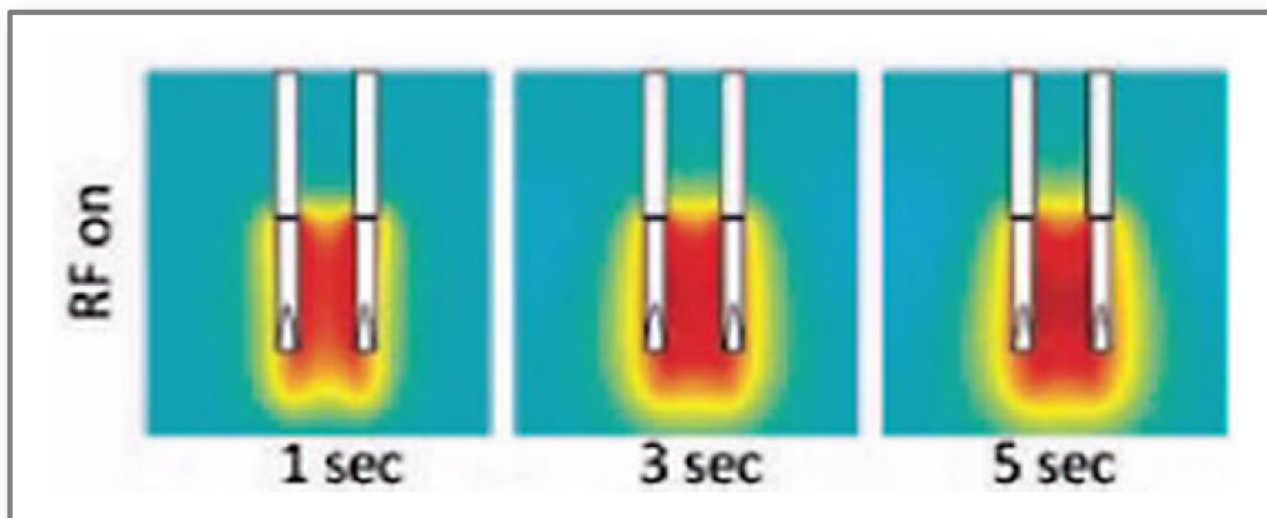
40. As another example if bipolar systems generating thermal damage between electrodes, Figure 4A of WO 2007/064718 (“Hantash”) (one of Petitioner’s references), shows “treatment zones 160 that are created *between* nearest neighbor needles 115 that are connected to opposite poles of the RF source 110,” 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 and 4B.

41. 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 *et al.*). As shown below, the bipolar Miratone™ device resulted in zones of thermal damage *between* each electrode pair:

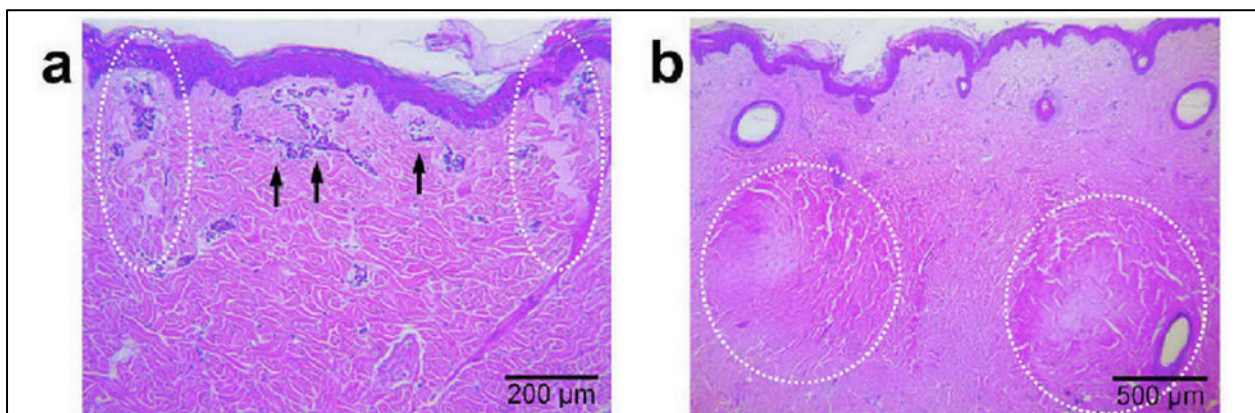


*Id.*, Fig. 5.

42. In short, as Dr. Goldberg explains, 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.

**B. The “Na Effect”**

43. Through innovative clinical testing, Dr. Jongju Na, the named inventor of the '836 Patent, demonstrated that under certain parameters, RF microneedling devices with bipolar electrodes can create thermal responses, including 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) and 1(b).

44. 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.

**C. The '836 Patent**

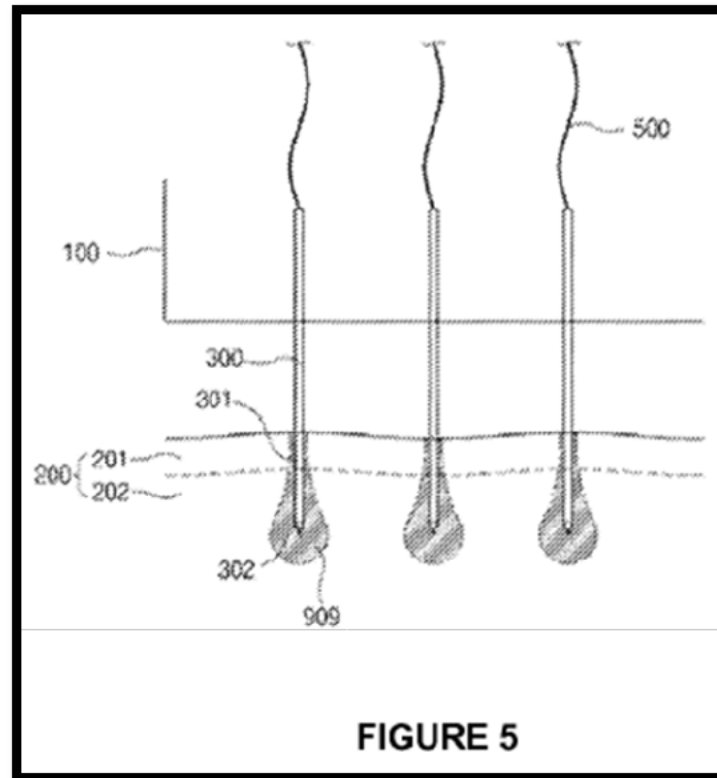
45. The '836 Patent, on which I provide my opinions, generally relates to improved delivery of RF energy to the skin, which reduces side effects such as burning that may cause scarring. This treatment is generally known as “RF microneedling.” As discussed above, the named inventor, Dr. Jongju Na, named the localized effect described in the '836 Patent as a “Na Effect” to distinguish it from other RF-induced tissue reactions.

46. The '836 Patent explains that the “primary purpose” of this patent is “skin treatment for aesthetics.” Ex. 1001 ('836 Pat.) at Abstract. The invention in the '836 Patent relates to methods of improved aesthetic skin treatment, and apparatuses for delivering those treatments, using high frequency energy that minimizes such side effects. In particular, the “invention is a method and apparatus that provides electric stimulation directly to a body region including the dermis via

needles,” where the “method revitalizes and regenerates the body region including collagen by wounding the dermis.” *Id.* at 2:37-41.

47. As the patent explains, the “[d]ermis is the layer beneath epidermis” of the skin. Ex. 1001 ('836 Pat.) at 1:40-51. Within the dermis, “there are two layers: papillary and reticular layer.” *Id.* at 1:43-44. “The [r]eticular layer includes collagen,” which relates to “wrinkle[s].” *Id.* at 1:46-50. Collagen is a protein and, when heated, it undergoes “a physical transformation . . . at a shrinkage temperature.” *Id.* at 2:43-46. The “partial denaturalization of collagen due to shrinkage caused by artificial heat” is a way to perform “[s]oft tissue remodeling” by “offer[ing] a way to aesthetically modify the shape and consistency of soft tissue” (e.g., to “improv[e] skin or reduc[e] wrinkles”) in a relatively rapid manner. *Id.* at 2:46-62. “When 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.” *Id.* at 2:62-65. Here, “[t]he ‘invention improves skin condition by primarily using coagulation,’ *i.e.*, the inventive apparatus can be ‘configured ‘to raise temperature’ by applying energy to achieve coagulation.’” *Id.* at 2:65-3:4. Accordingly, the patent uses the “term ‘to raise temperature’ . . . synonymously with ‘applying energy to achieve coagulation.’” *Id.* at 3:5-8.

48. An “embodiment” of the “invention” “is shown in FIG. 5,” copied below:<sup>3</sup>



49. As shown in the above figure, in this embodiment, heat is “concentrated” around the needles and, thus, it will “not be concentrated between needles.” Ex. 1001 (’836 Pat.) at 3:20-29. The area where the temperature is raised

<sup>3</sup> As discussed during the related IPRs, this embodiment relates to the asserted claims. *See, e.g.*, IPR2022-00594 at Paper 9 (Decision Denying Institution of *Inter Partes* Review) at 556-559. But as the PTAB also found, other embodiments, *e.g.*, Figs. 7-8, do not relate to the asserted claims. *See, e.g., id.*

is shown as 909 around the tip of each needle 300 in the dermis 202 in the above figure. *See id.* at 5:1-20. This inventive approach has the advantage that it can “prevent or limit overheating between needles” and “minimally raise temperature” in the epidermis to address the “serious side effect” caused by treatments that lead to “overheating or burning of both dermis and epidermis located between needles, which may cause permanent skin damage,” including “scars.” *Id.* at 4:6-21. As discussed above, Dr. Na later published a scientific article in a *Nature* journal describing this “independent tissue coagulation around each electrode as a ‘Na effect’ to distinguish it from other RF tissue reactions.” Ex. 2032 (Na, Jongju et al. Electromagnetic Initiation and Propagation of Bipolar Radiofrequency Tissue Reactions via Invasive Non-Insulated Microneedle Electrodes. *Nature Scientific Reports*, vol. 5:16735 (2015)) at 340.

50. It should be noted that, while the patent expresses a preference for non-insulated needles, the patent discloses that the invention can use insulated or non-insulated needles. As the patent explains, at the time of the invention, “[t]o limit epidermis burning,” needles “insulated except at the tip portion” were used so that the portion of the needle in contact with the epidermis 201 in Figure 5 above would be insulated. Ex. 1001 ('836 Pat.) at 2:19-20. Insulated needles, however, “may cause bigger penetration marks” and “pain” because they are thicker because of the insulation, and the “insulation may also fail or come off due to repeated penetration

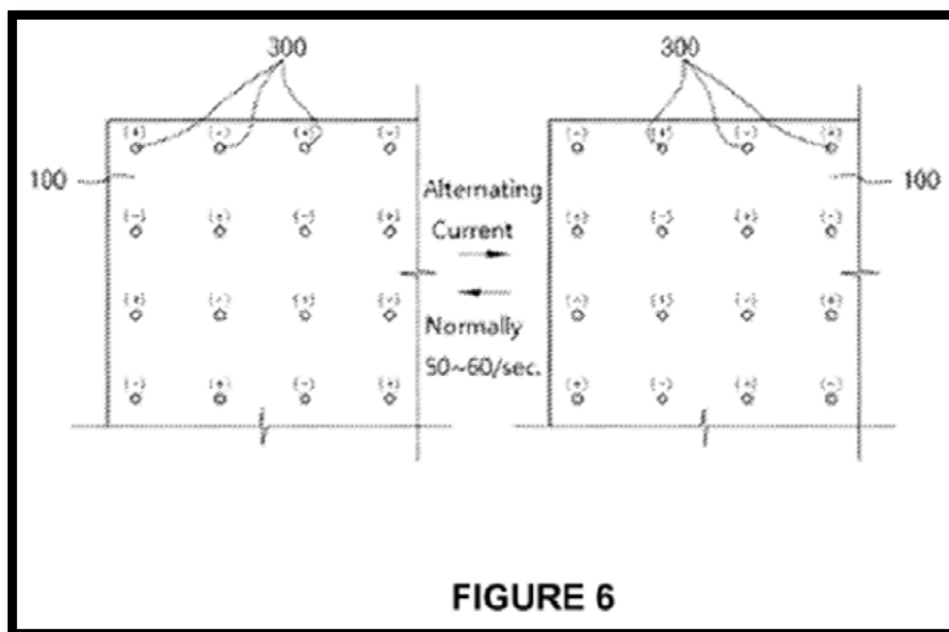
resulting in heating of unintended areas.” *Id.* at 2:21-24. The invention, however, does “not require insulated needles except for special cases.” *Id.* at 3:41-42; *see also id.* at 7:1-6 (“[n]eedle insulation may not be necessary”), 7:12 (“In an embodiment, the needles may not be insulated.”). That is because using the invention provides an “advantage,” allowing “higher temperatures” to “be concentrated in dermis, not epidermis,” which “enable[es] the use of non-insulated needles.” *Id.* at 3:37-40. Thus, the “invention may employ insulating needles in an area where it comes in contact with epidermis,” but “insulation is not required.” *Id.* at 3:42-45. Accordingly, certain embodiments “may use non-insulated needles” while “[o]ther embodiments may use insulated needles,” although this “may[] decrease the effectiveness of treatments.” *Id.* at 3:53-56; *see also id.* at 6:66-7:1 (“In an embodiment, energized needles may be completely electrically insulated, un-insulated, and only insulated near its tip.”), 7:15-18 (the needles “may be insulated while generating a desired energy field about the needle in the dermis.”).

51. The specification further explains that embodiments of the “invention may employ bipolar needles,” and the electrical signals may be of “alternating current (AC)” and have “high frequency.” Ex. 1001 (’836 Pat.) at 3:46-48; *see also id.* at 5:58-59. Use of bipolar needles provided an advantage over existing techniques using “a monopole configuration with a single electrode and a ground on another body location,” which could “require large voltages to conduct enough

energy to generate desired heat” and “impact unintended body parts including the heart.” *Id.* at 2:28-33. Moreover, “alternating current (AC)” “has characteristics that differ from direct current (DC), which flows in one direction and has a constant polarity”—*i.e.*, AC changes “direction periodically.” *Id.* at 6:1-6. The frequency of the AC “may be hundreds of Hz [Hertz] to achieve the desired effect.” *Id.* at 6:9-12. For example, “the AC source may have a frequency above 0.5 MHz and about 2 MHz in another embodiment,” and “[o]ther embodiments may employ an AC signal have a frequency from 0.5 to 10 MHz, 1 to 4 MHz, and 1.5-2.5 MHz.” *Id.* at 6:22-28. This is a much higher frequency than the AC “commonly” “provided by power companies” “worldwide,” which only “alternates polarity at about either 50 Hz or 60 Hz.” *Id.* at 6:6-8. The patent recognizes that “AC signals having frequencies of 2 MHz and 1 MHz” are AC signals in the radiofrequency (RF) range, referring to “RF energy flow or conductance” when a “2 MHz” AC signal is applied to skin. *Id.* at 6:29-39.

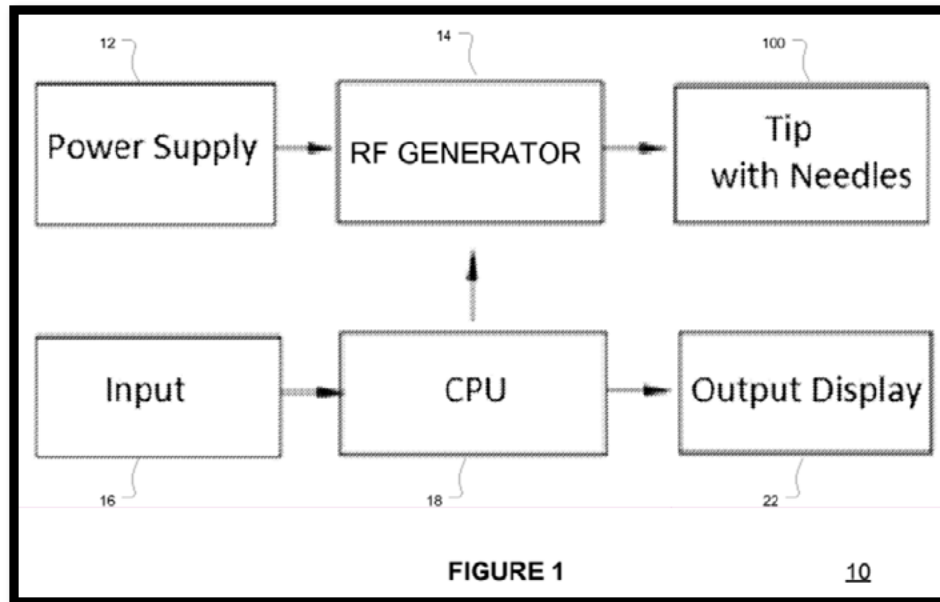
52. The invention also contemplates the use of “different needle arrangements,” including, for example an arrangement where “neighboring or adjacent needles 300” are “configured to have opposite polarities as shown in FIG. 6,” copied below. *Id.* at 7:24-27. In other embodiments, a set of “two or more needles may have the same polarity and then the next set has an opposite polarity.”

*Id.* at 7:60-63. “A variety of needle 300 polarity combinations” can be used. *Id.* at 7:63-67.



53. As the patent explains, and as shown above, AC can “be applied to needles 300 designated (+) and (-).” *Id.* at 7:30-32. Those designations as “(+)” and “(-)” show the relative polarities of the needles to convey that they have opposite polarities; the specification explains that the double arrow reflects that each electrode alternates between “(+)” and “(-)” when driven by an AC signal. Specifically, “[b]ecause of AC signal characteristics, the polarity of each needle may change many times per second (up to 10 Mhz in an embodiment).” *Id.* at 7:33-36.

54. Figure 1, copied below, is a block diagram of a system according to an embodiment of the invention:



55. Using “user input device 16,” a user can input “several parameters that control the energy field 909 generated about needles 300 in the tip or device 100.” *Id.* at 5:35-41.

56. In view of the '836 Patent's claims and specification, a POSITA is informed that the '836 Patent is not merely directed to the general concept of heating tissue or causing coagulation, instead the patent is directed to methods and apparatuses for controlling the application of localized energy around needle electrodes through the configuration of specific treatment parameters, such as the use of bipolar electrodes and AC RF.

57. For example, as discussed above, the '836 Patent explains 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 ('836 Pat.) at 2:62-65. Here, “[t]he invention improves skin condition by primarily using coagulation,” *i.e.*, the inventive apparatus can be “configured ‘to raise temperature’ by applying energy to achieve coagulation.” *Id.* at 2:65-3:4. This is evidenced in the plain language of the '836 Patent claims (which are directed to methods and apparatuses to control where and to what extent coagulation occurs). However, once again, the patent is not directed to just *any* application of energy or temperature to tissue. As discussed above, the '836 Patent disparages the use of prior technologies that overheat the skin and cause scarring, such as general electrosurgical devices that cause carbonization, vaporization, and necrosis of the skin. 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.

58. The specification further discusses specific parameters for controlling where and to what extent energy will form around each electrode:

A user input device 16 may enable a user to set several parameters that control the energy field 909 generated about needles 300 in the tip or device 100 including the voltage, current, and frequency applied to the needles 300, the on time and off time of the RF signal during the cycles, the deployed depth of the needles (to treat a body region including epidermis, dermis, and subcutaneous sections of skin)

*Id.* at 5:35-42; *see also id.* at 8:9-14 (“In order to generate a desired energy field 909 (FIG. 5), 949 (FIG. 9B) about one or more needle 300 tips 302, an embodiment of

the present invention may regulate voltage to be applied to a needle in addition to polarity, pattern, shape, adjacent distance, and frequency.”); *id.* at 6:9-11 (“In an embodiment, actuating needles with AC may be a factor to generate a desired effect or energy field about the each [sic] needle.”); *id.* at 6:40-43 (“In an embodiment a high frequency applied current may create an energy field closer to an electrode or needle than an equivalent energy low frequency current.”); *id.* at 6:59-65 (“as the distance between needles increases, the source frequency value may be decreased to achieve or limit the energy field formation about energized needles or electrodes.”); *id.* at 8:54-57 (“In order to generate a desired energy field 909, 949 about one or more needle 300 tips 302, an embodiment of the present invention may regulate the energy duty cycle.”); *id.* at 9:25-28 (“In order to generate a desired energy field 909, 949 about one or more needle 300 tips 302, an embodiment of the present invention may employ needles with particular lengths and thicknesses.”).

59. In the declaration of Dr. Dany Berube (Ex. 1003), which was adopted by Dr. Jean Woloszko (Ex. 1037), Drs. Berube and Woloszko overlook the teachings of the '836 Patent, as well as the claim language, presenting the '836 Patent as similar to prior art electrosurgical and ablation systems that the '836 Patent expressly distinguishes. Put simply, Drs. Berube and Woloszko misapply concepts from electrosurgery and ablation, which result in tissue charring and vaporization, leading them to opine that the asserted claims are invalid. *Id.* But as noted above, the patent

recognizes “three phenomena: carbonization, vaporization, and coagulation.” Ex. 1001 ('836 Patent) at 2:62-65. One of skill is thus informed that the prior art means of tissue cutting, cauterization or ablation (involving carbonization and vaporization) are not what the patent teaches for “improv[ing] skin condition by primarily using coagulation.” *Id.* at 2:65-66; *see also id.* at 3:3-10. In view of the patent’s categorization of three different types of tissue effects (charring, desiccation, coagulation) and focus on the localized application of energy and coagulation (without overheating or destruction of the tissue), a POSITA would understand that prior art techniques to achieve the first two (such as in electrosurgery and ablation) are in fact teaching away from the desired coagulative effects of claimed inventions. Therefore, the art directed to electrosurgery and ablation cited by Drs. Berube and Woloszko is not only irrelevant, but in fact their citation to it suggests misapprehension of the '836 Patent’s teachings.

60. For example, I cite research results on RF (and microwave) ablation that collaborators and I have published at the University of Wisconsin. In that experiment, focal tumor ablation with RF energy was applied, which causes ionic agitation arising from alternating electrical current which produces frictional heating and subsequent tissue necrosis. Ex. 2073 (C. L. Brace, P. F. Laeseke, D. W. van der Weide, and F. T. Lee, “Microwave ablation with a triaxial antenna: results in ex vivo bovine liver,” IEEE Transactions on Microwave Theory and Techniques, vol. 53,

no. 1, pp. 215-220, 2005). As discussed in the publication describing the experimental results, these types of procedures are further limited by tissue charring (restricting galvanic current flow as conductivity decreases) and electrical interference between multiple activated probes. *Id.*

61. Moreover, as discussed in Haemmerich *et al.*, in bipolar RF ablation, “[w]hen probes are placed close to each other (*e.g.*, to treat a large tumor), the bipolar mode creates the highest temperatures in the region between the two probes, but is limited to the use of two probes simultaneously.” Ex. 2074 (Haemmerich *et al.*, “Finite-element analysis of hepatic multiple probe radio-frequency ablation,” in IEEE Transactions on Biomedical Engineering, vol. 49, no. 8, pp. 836-842, Aug. 2002) (emphasis added). Thus, the skilled artisan is informed that in tissue ablation (involving carbonization and vaporization, not to achieve coagulation), bipolar RF “creates the highest temperatures in the region between the two probes” (emphasis added), which is the opposite of the limitations set forth in the ’836 Patent claims.

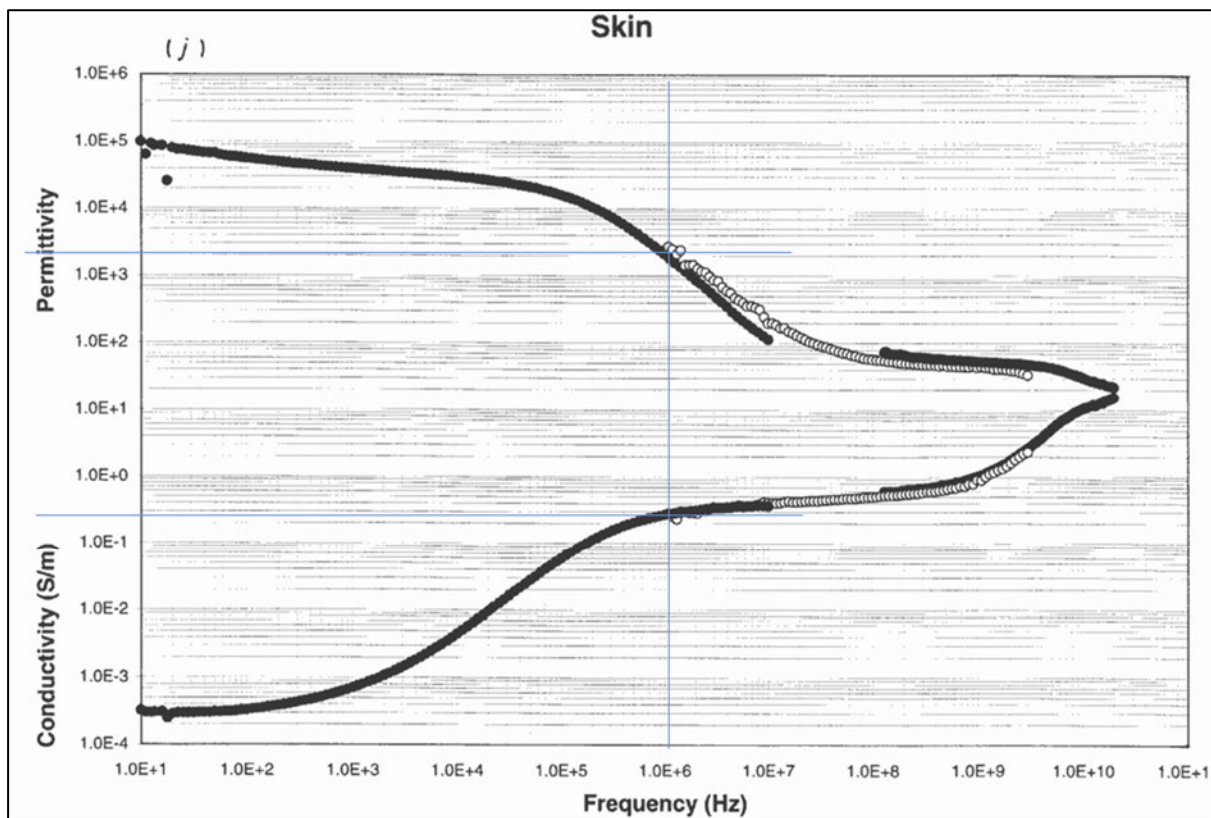
62. Indeed, the specific configuration of electrodes and energy taught and claimed by the patent couples AC RF energy to the tissue in a manner that explicitly avoids the prior-art effects associated with electrosurgery or ablation. This configuration addresses the peculiar dielectric characteristics of human tissue, such as those discussed in Zilberti. *See* Ex. 2075 (L. Zilberti, “Charge Relaxation in Biological Tissues with Extremely High Permittivity,” in IEEE Magnetics Letters,

vol. 7, pp. 1-5, 2016, Art no. 1504105, doi: 10.1109/LMAG.2016.2572038) (“Zilberti”). For example, while mentioning some uncertainty in the permittivity and conductivity values obtained by researchers including “Gabriel 1996b,” Zilberti acknowledges that “extrapolations obtained through dispersion models (that fit very well the more accurate measurements in the radio-frequency band) are consistent with the experiments [Gabriel 1996b].” Zilberti addresses the special dielectric characteristics of human tissue by reminding the skilled artisan that:

It is well known that charge separation occurs in conductors placed within an external electric field  $\mathbf{E}_0$ . In this case, free charges rearrange themselves over the surface of the body, giving rise to surface charge densities and creating a Coulombian field  $\mathbf{E}_Q$  that tries to counteract  $\mathbf{E}_0$ . For good conductors, like copper, this charge relaxation process requires a time interval on the order of 10 fs [Ashby 1975, Ohanian 1983, Gauthier 1985, Bochove 1990, Elliott 1993]. Thus, if  $\mathbf{E}_0$  is static or quasi-stationary, a complete screening (with a net field  $\mathbf{E}_N = 0$  inside the body) is obtained in a time that, for many practical purposes, is negligible. In case of perfect dielectrics, the material polarizes and the dielectric dipoles oppose to  $\mathbf{E}_0$  their own polarization field  $\mathbf{E}_p$ . So, depending on the relative permittivity  $\epsilon_r$ , a partial shielding is obtained ( $\mathbf{E}_N \neq 0$ ). Since most dielectrics exhibit a dispersive behavior with frequency, the screening capability depends on the rate of change of the applied field. The slower the dynamic is, the more the polarization mechanisms develop [Elliott 1993, Martinsen 2002]. ***Between these two extremes, we find lossy dielectrics, where the relaxation process occurs with a time constant  $\tau$  given by the ratio between the absolute permittivity  $\epsilon$  and the electrical conductivity  $\sigma$  of the material [Ohanian 1983].*** A special case for these materials is given by biological tissues, to which, at very low frequency (around 1 Hz), an extremely high permittivity (EHP)  $\epsilon_r \approx 50 \times 10^6$  has been assigned [Polk 1996, Gabriel 1996a, 1996b, 1996c, Kuang 1998, Martinsen 2002, Stoneman 2010, Cundin 2011]. [. . .] Thus, even if due caution must be adopted before trusting such EHP, this feature becomes of interest when studying human exposure to electromagnetic fields . . .

*Zilberti* at 2.

63. Thus, as *Zilberti* explains, one must consider the “relaxation process” which occurs as electric fields are applied. And as the skilled artisan understands, “[s]ince most dielectrics exhibit a dispersive behavior with frequency, the screening capability depends on the rate of change of the applied field.” *Id.* For example, as shown below *Gabriel et al.* plots the permittivity and conductivity of skin as follows:

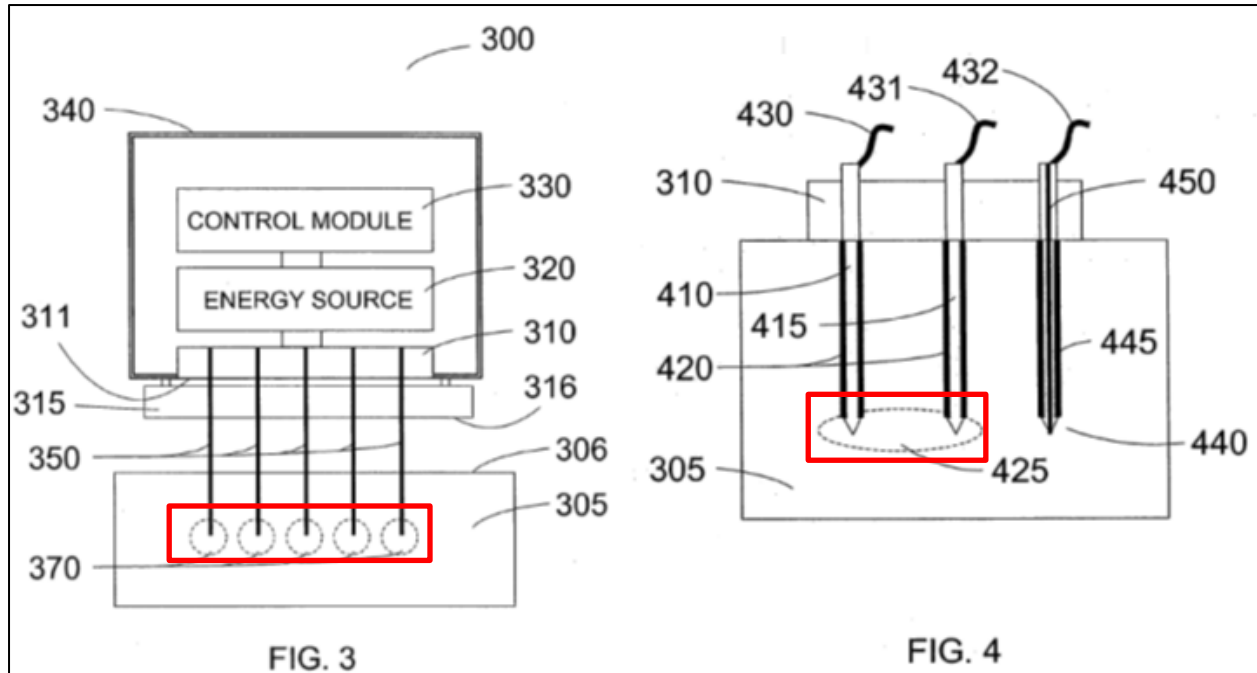


64. Note that in the above figure from *Gabriel et al.* I have superimposed thin blue lines to estimate both relative permittivity ( $\sim 2 \times 10^3$ ) and conductivity ( $\sim 3 \times 10^{-1}$  S/m) at 1 MHz. Applying the principles of *Gabriel et al.* with the principles of *Zilberti*, we see that the dielectric relaxation “time constant  $\tau$  given by the ratio

between the absolute permittivity  $\epsilon$  and the electrical conductivity  $\sigma$  of the material” of skin using Gabriel’s data above yields  $\tau \approx 60$  ns. Since it takes  $\sim 5$  time constants for a single-time-constant system to reach  $>99\%$  of its final value, this would yield a  $\tau$  value of approximately  $0.3 \mu\text{s}$ , which is comparable to the half-period of a 1 MHz excitation. In fact, the duration of a sinusoidal voltage waveform during which it is above 70.7% of its peak value (corresponding to its 50% power threshold) is  $1/3$  of its period, which is equivalent to  $0.3 \mu\text{s}$  for a 1 MHz sinusoid. *Id.* Put another way, the particular RF frequency range in which the Na Effect is observed is consistent with the (nearly complete) dielectric relaxation time of the tissue under treatment; *i.e.*, the particular configuration of frequency range and skin dielectric properties achieves “complete screening (with a net field  $E_N = 0$  inside the body)” during a time remarkably comparable to the duration of the RF excitation specified by the Na Effect; neither too quickly (like a metal) nor too slowly (like an ideal dielectric). The ’836 Patent claims methods and apparatuses that apply energy that is localized around the needle electrodes, without an excess of Joule heating (as would be exhibited by a resistive material as opposed to the lossy dielectric of skin tissue). Thus, any analysis of the effects on tissue by substituting merely resistive material for the more complex properties of skin and then assuming galvanic conduction giving rise to (only) Joule heating is misapprehending the physics underlying the application of energy to tissue, and further misapprehending the Na Effect.

**D. The '836 Patent's Prosecution History**

65. 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* at 19-21, 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.

66. 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).

## VI. PETITIONER’S GROUNDS FOR REQUESTING *INTER PARTES* REVIEW ARE DEFICIENT

67. In my opinion, Petitioner fails to show any of the ’836 Patent claims are rendered obvious by the cited prior art, at least because, as explained in detail below, the prior art fails to teach several limitations of the claims, and a POSITA would not have been motivated to combine the cited prior art in the manner

Petitioner proposes. While Petitioner asserts that some of these claim limitations are inherently present, in my opinion Petitioner has not shown that those claim limitations are necessarily present in the cited disclosure.

68. Petitioner also fails to explain, beyond offering conclusory assertions, why a POSITA would have been motivated to combine the cited prior art references, or exactly how a POSITA would have allegedly modified them to arrive at the claimed invention. Additionally, Petitioner's suggested combinations often render the prior art references impractical or unusable for their intended purpose. In other words, absent hindsight, a POSITA would not have been motivated to combine the cited prior art references in the manner suggested by Petitioner.

**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**

69. 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 Ex. 1001 ('836 Patent), and Ganz alone or in view of Livneh fails to disclose or suggest multiple claim limitations.

70. The '836 Patent includes two independent claims, Claim 1 and Claim 14, both of which are reproduced below:

| '836 Patent, Claim 1                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | '836 Patent, Claim 14                                                                                                                                                                                                                                                                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1. A skin treatment apparatus, comprising:<br>a plurality of electrodes, the electrodes being bipolar and configured to be insertable into skin to be treated; and<br>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. | 14. A method of treating skin, comprising:<br>inserting a plurality of electrodes, the electrodes being bipolar into a section of skin to be treated; and<br>applying a Alternating Current (AC) Radio Frequency (RF) signal to the plurality of electrodes configured to cause coagulation around each electrode rather than coagulating between the electrodes. |

71. As discussed in detail below, Ganz does not disclose, inherently or otherwise, or suggest several limitations of the independent claims, for example:

- Ganz does not disclose or render obvious “a plurality of electrodes, the electrodes being bipolar,” that are “configured to cause coagulation around each electrode, rather than coagulating between the electrodes” as recited in Claims 1 and 14.
- Ganz does not disclose or render obvious “the plurality of electrodes configured to cause coagulation around each electrode, rather than coagulating between the electrodes,” as recited in Claims 1 and 14.
- Ganz does not disclose or render obvious “a radio frequency (RF) generation module, ... configured to provide an Alternating Current (AC) RF signal to the plurality of electrodes” in Claim 1 or “applying a Alternating Current (AC) Radio Frequency (RF) signal to the plurality of electrodes” in Claim 14.

72. Petitioner attempts to gap-fill these deficiencies in Ganz through inherency arguments and heavy reliance on the general knowledge of a POSITA. First, I understand that it is improper to rely on a person of skill’s knowledge as a

substitute for reasoned analysis and evidentiary support, especially when dealing with a limitation missing from the prior art references specified. Second, as explained below, the other references Petitioner tries to combine with Ganz each, themselves, lack various limitations of the claims. Finally, Petitioner fails to provide any reasoned explanation, beyond conclusory assertions, for why a POSITA would be motivated to either modify Ganz or combine it with references that teach different types of treatment than Ganz. Therefore, in my opinion, Ganz does not render obvious any of the '836 Patent claims, alone, or in combination with other references cited by Petitioner.

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

73. 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].<sup>4</sup> 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]

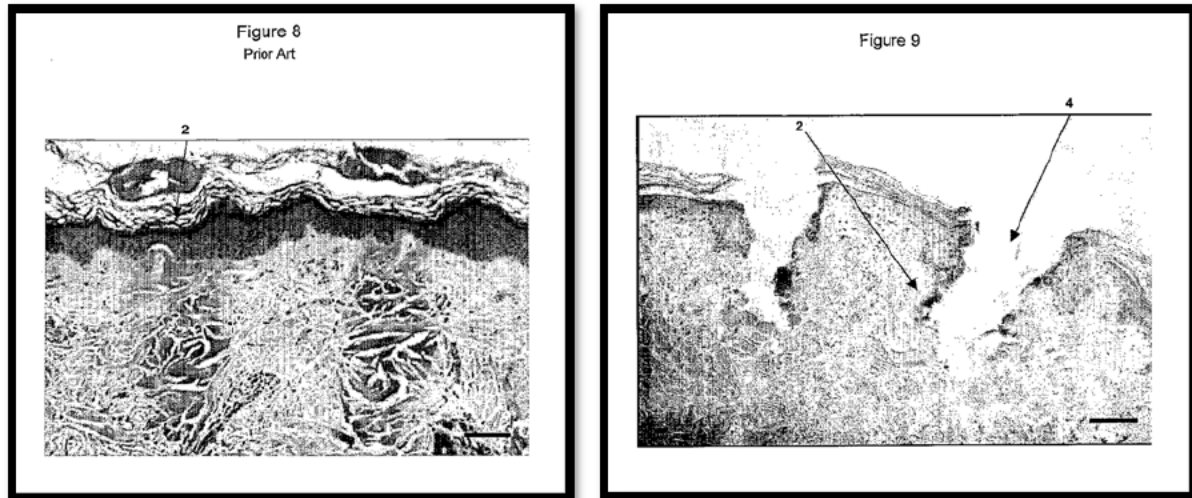
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<sup>4</sup> Ganz is a published patent application, U.S. Patent Application Publication No. 2007/0208340, that was published in 2007 and never issued as a patent. Ex. 1005.

leads to more aggressive healing responses.” *Id.*, [0032]. Ganz also defines “the term ‘perforation’” to mean “vertical areas of thermal damage or **ablation** to the tissue causing tissue necrosis.” *Id.*, [0027].

74. Thus, 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, rather than teaching coagulation of tissue around treatment electrodes (as in the ’836 Patent’s claimed approach). *Id.*, [0006]. Ganz also 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]. Put simply, Ganz discloses using energy to cauterize the holes created via Ganz’s treatment approach.

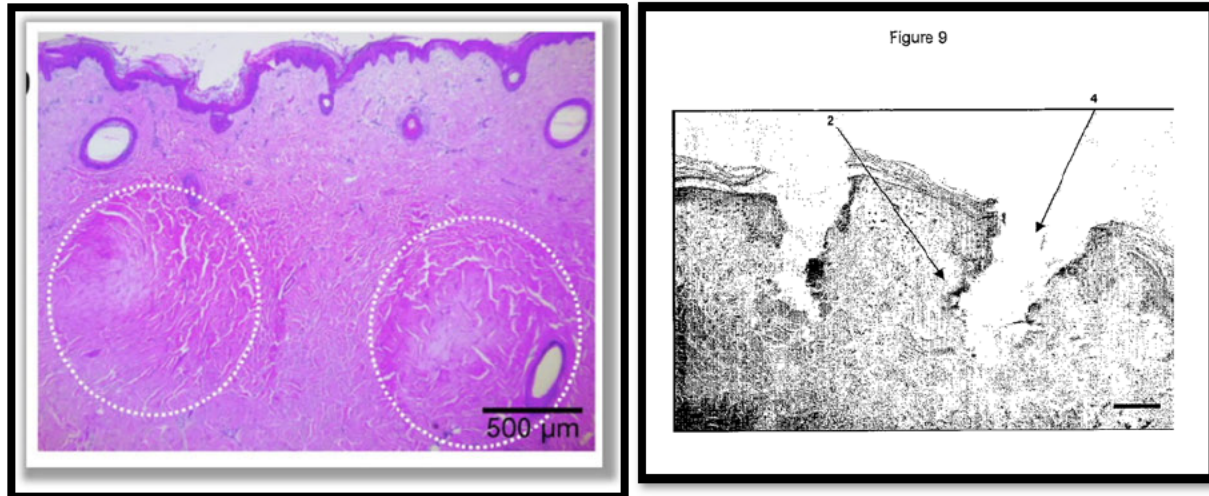
75. This distinction between treatment approaches that “merely impart[] coagulations into the skin[]” and the Ganz approach, which burns holes in the skin, is shown in Figures 8 and 9 below:



Ex. 1005, [0032]; *id.*, Figs. 8-9; Ex. 2142 (Goldberg Decl.), ¶¶38-30.

76. 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.), ¶30. Conversely, 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].

77. Additionally, histological images of tissue treated using the '836 Patent's claimed approach (on the left below) show different treatment results than histological images of tissue treated with Ganz approach (on the right below):



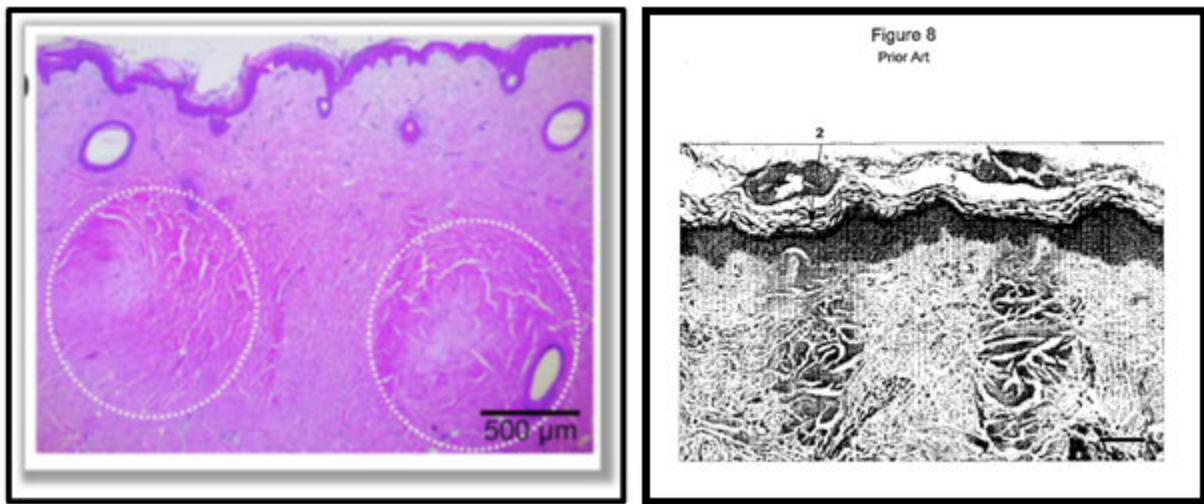
Compare Ex. 2032 (Na Nature Paper), Fig. 1b with Ex. 1005 (Ganz), Fig. 9.<sup>5</sup>

78. As shown above, the distinction between the '836 Patent's claimed treatment approach and Ganz's approach is readily apparent from evaluating treatment results from each. Specifically, as shown above, 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.*

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<sup>5</sup> In my opinion, based on the treatment technique described in Dr. Na's Nature Paper, along with evaluation of the histological images therein, the histological images shown in Dr. Na's Nature Paper correspond to treatment results using the '836 Patent's claimed treatment approach.

79. Similarly, by comparing the histological images of tissue 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), the distinction between the '836 Patent's claimed treatment approach and Ganz's approach is further illustrated:



*Compare* Ex. 2032 (Na Nature Paper), Fig. 1b *with* Ex. 1005 (Ganz), Fig. 8.

80. 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.

81. Notably, while Ganz intentionally creates “ablation holes” (Ex. 1005, [0006]), 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, Dr. Woloszko, testified 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.<sup>6</sup> Dr. Koch, Petitioner’s dermatologist 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; 41:3-10.

**2. Ganz Fails To Disclose Or Render Obvious “a plurality of electrodes, the electrodes being bipolar” that are “configured to cause coagulation around each electrode rather than coagulating between the electrodes”**

82. Ganz does not disclose or render obvious “a plurality of electrodes, the electrodes being bipolar,” that are “configured to cause coagulation around each electrode rather than coagulating between the electrodes.”

83. Ganz fails to disclose a plurality of “bipolar” electrodes “configured to cause coagulation around each electrode rather than coagulating between the

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<sup>6</sup> 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.

electrodes,” as claimed.<sup>7</sup> For this limitation, Petitioner simply points to disclosure of “bipolar electrodes” in Ganz, but claim 1 requires more than the mere presence of bipolar electrodes—it requires them to be configured to cause the claimed coagulation. *Id.* While Petitioner points to disclosure of coagulation in Ganz (*see, e.g.,* Pet. at 26-27 (citing Ex-1005 (Ganz), [0048])), Petitioner fails to show that *any* embodiment discussing coagulation utilizes *bipolar* electrodes, rather than monopolar electrodes that Ganz also discloses. Ex. 1005 (Ganz), [0011], [0013], [0055].

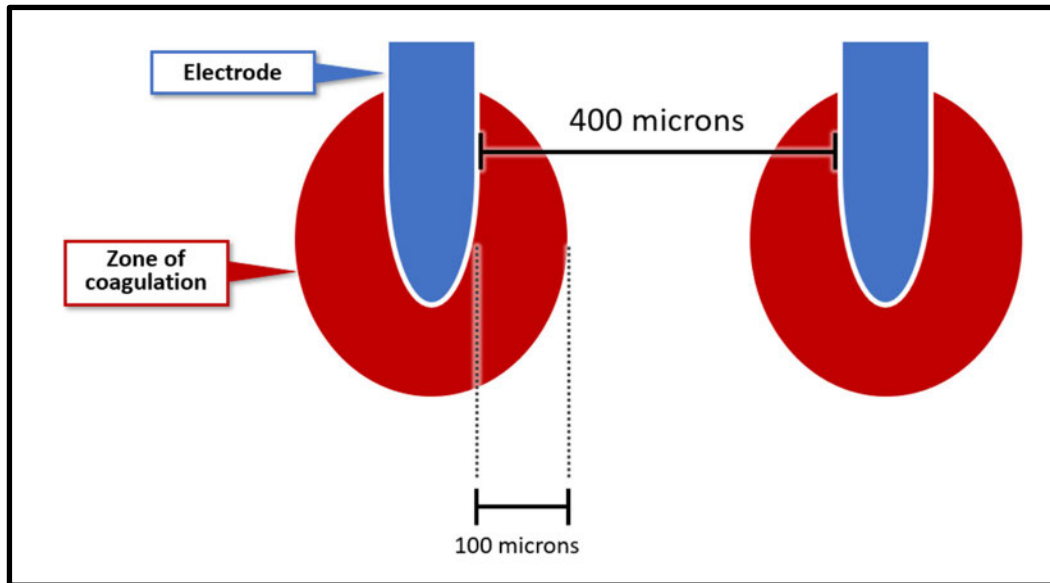
84. The only example in Ganz used a “monopolar electrode array.” Ex. 1005 (Ganz), [0065]. And Dr. Woloszko *admitted* that he cannot tell whether *any* of the “outcome[s] or results” in Ganz were obtained using bipolar electrodes because it is impossible to do so. Ex. 2012 (Woloszko Hr’g. Tr.) at 1038:13-15 (“**Q. So you don’t know whether Ganz shows any outcome or results using bipolar electrodes, right? A. That’s correct.**”). I understand that Dr. Woloszko also testified that the only example result discussed in Ganz involves a *monopolar* configuration. Ex. 2145 (Woloszko Oct. 10, 2024 Dep. Tr.), 65:17-19 (“**Q. Focusing on that**

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<sup>7</sup> Petitioner only argues that “Ganz discloses” this limitation. Pet. at 16. Petitioner does not contend that this limitation would have been obvious in view of Ganz and Livneh.

example in paragraph 65, that example involves monopolar, not bipolar, right? A. *That is correct.*”). Dr. Woloszko also testified 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.*”). Dr. Koch, Petitioner’s dermatological expert, also testified 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. In short, given the limited disclosure in Ganz, no one can identify how Ganz got the results that it produces.

85. 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 also relies on the following illustration of this text that Petitioner generated:



Pet. 27-28.

86. But Petitioner has not established that the treatment result ranges Petitioner relies on to create the above image were, or could be, produced using *bipolar* electrodes. Specifically, the portions of Ganz Petitioner cites, paragraphs [0028] and [0047]-[0048], do not disclose that perforations or coagulation within these ranges were generated.

87. For example, Paragraph [0028], describing Ganz's Figures 9 and 10, does not specify what electrode configuration was used. Ex. 1005, [0028]. And once again, 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.<sup>8</sup>

88. Similarly, paragraphs [0047] to [0048] do not specify what electrode configuration was used either. *Id.*, [0047], [0048]. And, while 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])), there is no disclosure in Ganz that this was, or even could be, achieved with bipolar electrodes. Once again, Dr. Woloszko testified that he cannot tell whether Ganz discloses any results using bipolar electrodes. Ex. 2012 (Woloszko Hr’g. Tr.), 1038:13-15.

89. Indeed, only discussion of “bipolar electrodes” in Ganz is in paragraphs [0011] and [0055]-[0056], where Ganz states that “either monopolar or bipolar electrodes” can be used. *Id.*, [0011], [0055], [0056]. However, nothing in these

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<sup>8</sup> I further understand that Dr. Woloszko 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.), 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.***”).

paragraphs explains how each configuration would affect the treated tissue, where coagulation could occur (if at all), and to what extent coagulation would occur in each configuration. *Id.* And, once again, 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.), 65:17-20 ("Q. Focusing on that example in paragraph 65, that example involves **monopolar**, **not bipolar**, right? A. **That is correct.**").<sup>9</sup>

90. I note that Dr. Koch asserts in his declaration that a POSITA would expect to see the same output results "using either modality." Ex. 1035, ¶34. But, as discussed above, this is plainly wrong, as prior art and scientific literature discussing bipolar and monopolar configurations demonstrate that they result in

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<sup>9</sup> Dr. Woloszko testified that he believes that "bipolar" electrodes actually refer to electrodes that have "both polarities on the same electrode" and that the "bipolar" electrodes discussed in the '836 Patent are actually "monopolar" needles arranged in a bipolar configuration. Ex. 2004 (Woloszko ITC Report), FN 19; Ex. 2145 (Woloszko Oct. 10, 2024 Dep. Tr.), 44:19-45:7; *see also* 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").

different treatment results. *Supra* at 19-21; *see also* Ex. 2142 (Goldberg Decl.), ¶¶16-18; Ex. 2004 (Woloszko ITC Invalidity Rpt.), ¶¶73-88 (explaining the background of monopolar and bipolar RF microneedling systems). Thus, a POSITA 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.

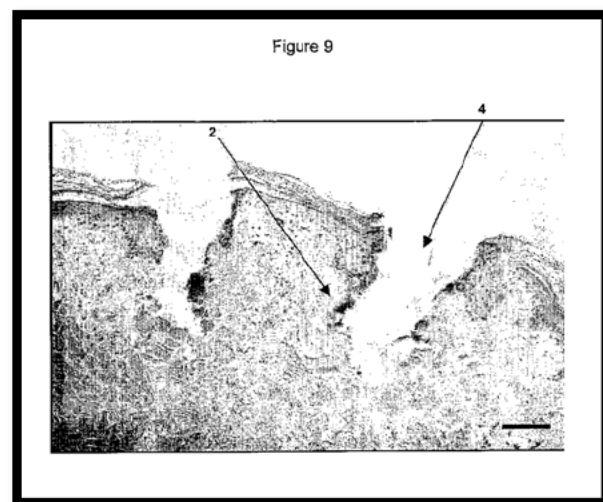
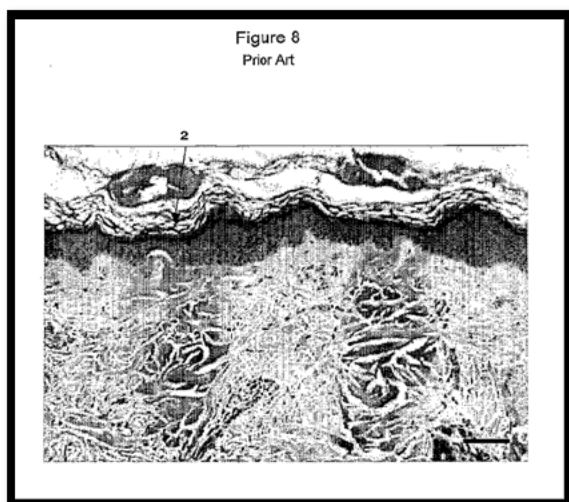
91. Petitioner's arguments here are thus akin to those that the Board already rejected. Specifically, I understand that the prior Petitioner relied on a video of a prior art device (the "INTRAcel" device), pointing to histological results showing coagulation around needle insertion points rather than extending between the needles. *Cartessa v. Serendia, LLC*, IPR2022-00594, Paper 9 at 35 (P.T.A.B. Feb. 10, 2022). 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.* Likewise here, Petitioner cannot show that Ganz teaches any results obtained using a bipolar modality (rather than a monopolar modality), because no one can tell whether Ganz discloses any results from 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.***").

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

92. Ganz does not disclose or render obvious “the plurality of electrodes configured to cause coagulation around each electrode rather than coagulating between the electrodes.”

93. In my opinion, which is informed by both my own evaluation of Ganz, as well as Dr. Goldberg’s assessment, Ganz fails to teach or suggest “the plurality of electrodes configured to cause coagulation around each electrode rather than coagulating between the electrodes.” As explained by Dr. Goldberg in his declaration, “Ganz is directed to creating holes in tissue when needles are inserted by causing death of the tissue, in contrast to techniques, such as the approach in the Na Effect Patents, that cause localized coagulation where energy is applied by a laser or needles.” *See* Ex. 2142 (Goldberg Decl.), ¶21. I agree that Ganz’s approach “creates perforations... which extend vertically into the tissue.” Ex. 1005 (Ganz), [0027]. I also agree that in Ganz, “the term ‘perforation’ means vertical areas of thermal damage or ablation to the tissue causing tissue necrosis.” *Id.*, [0027]. Necrosis refers to cell death in body tissue. *See* Ex. 2142 (Goldberg Decl.), ¶27. Therefore, Ganz is not causing coagulation around each electrode, but rather removes the tissue around each electrode. Put simply, Ganz is actually overheating and burning the epidermis in order to create its perforations.

94. For example, Ganz illustrates how his approach is different to producing localized coagulation around each electrode. Ganz shows the localized “coagulation,” “indicated at reference number 2,” in skin “treated using a FRAXEL infrared scanning laser” in Figure 8, copied below on the left. Ex. 1005 (Ganz), [0028]. Ganz contrasts this treated area 2, which has no perforation, with the “treated area 4” in Figure 9, which shows “a skin area treated in accordance with [his] invention.” *Id.* As Ganz explains, the “treated area 4 is clearly a perforation, which extends vertically into the skin.” *Id.* As can be seen in Figure 9, the skin that was in treated area 4 prior to treatment has been removed. *See* Ex. 2142 (Goldberg Decl.), ¶28. Ganz also claims that “[o]ne drawback with the FRAXEL laser is that the laser does not create perforations or vertical holes in the tissue, **but only causes zones of coagulation.**” Ex. 1005 (Ganz), [0006] (emphasis added). Ganz thus draws a distinction between tissue removal and zones of coagulation:



95. Ganz refers to “[a]reas or zones of coagulation 2 [that] can also be seen in the areas surrounding the perforation 4” in Figure 9. Ex. 1005 (Ganz), [0028]. As shown in figures 9 and 10 (showing a top view), the areas “2” representing the zones of coagulation are the periphery of the holes in the skin that have been burned or cauterized. Neither Figure 9 nor Figure 10 show zones of the coagulation of collagen within the dermis as shown in Figure 8. *See* Ex. 2142 (Goldberg Decl.), ¶29.

96. Therefore, I agree with Dr. Goldberg that, “[a]s illustrated in Figures 9 and 10, energy delivered to Ganz’s electrodes is used to cause the death of the cells in the tissue around each electrode and remove that tissue, leaving a hole in the skin. There is not coagulation around each electrode using Ganz’s approach because Ganz supplies sufficient energy to burn the skin around each electrode sufficiently to remove that tissue. A patient subjected to Ganz’s approach accordingly loses the tissue around each electrode.” *See* Ex. 2142 (Goldberg Decl.), ¶30.

97. I also agree with Dr. Goldberg’s opinion that “the localized coagulation around each needle electrode taught in the ’836 Patent is very different from Ganz’s approach of removing tissue around each electrode to create holes in the skin.” Ex. 2142 (Goldberg Decl.), ¶¶31-32.

98. In my opinion, Ganz uses RF energy to achieve perforations in the skin, *i.e.*, removal of the skin around each electrode, and is not configured to cause

coagulation around each electrode. Indeed, Ganz makes this same distinction, disclosing that the regions around the needles are removed to create perforations, i.e., “ablation holes,” “*rather than merely imparting coagulations into the skin.*” Ex. 1005 (Ganz), [0032] (emphasis added); *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.*”).

99. Indeed, Petitioner’s 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. 2146 (Koch Oct. 19, 2024 Dep. Tr.), 44:1-3; 44:11-13; 45:4-8. I also understand that Dr. Woloszko testified 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 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.*”).

100. I further understand that Dr. Woloszko provided different testimony during his deposition for this IPR proceeding, now testifying that he simply does not know whether Ganz’s results show ablation and removal of tissue surrounding the

electrodes. Ex. 2145 (Woloszko Oct. 10, 2024 Dep.), 50:10-19 (“*I don’t know what ablation holes mean really*” but “*it’s possible that the – that some tissue is removed.*”). And, faced with Ganz’s disclosure, Dr. Woloszko now admits 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.*”).

101. Petitioner’s other expert, Dr. Koch, likewise admits that Ganz discloses ablation. Ex. 2146 (Koch Oct. 19, 2024 Dep. Tr.), 44:1-13. However, Dr. Koch opines that *all* RF microneedling devices result in the same type of ablative thermal damage. Ex. 1035, ¶36. But Dr. Koch’s assertion is plainly wrong, as evident by the starkly different results shown in histological images from the Ganz treatment technique compared to histological differences from the ’836 Patent treatment technique. 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. 2142 (Goldberg Decl.), ¶¶31-33.

102. It is also important to note that 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 testified that they did **not** show ablation holes. Ex. 2146 (Koch Oct. 19, 2024 Dep. Tr.), 65:1-66:20. Moreover, 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.

103. 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].

104. 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. at 26-27 (emphasis in original). 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. As Dr. Goldberg explains, "there's no coagulation around the microneedles because the tissue is gone." Ex. 2142 (Goldberg Decl.) ¶39. Indeed, 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. 1005, ¶[1008]; 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.”).

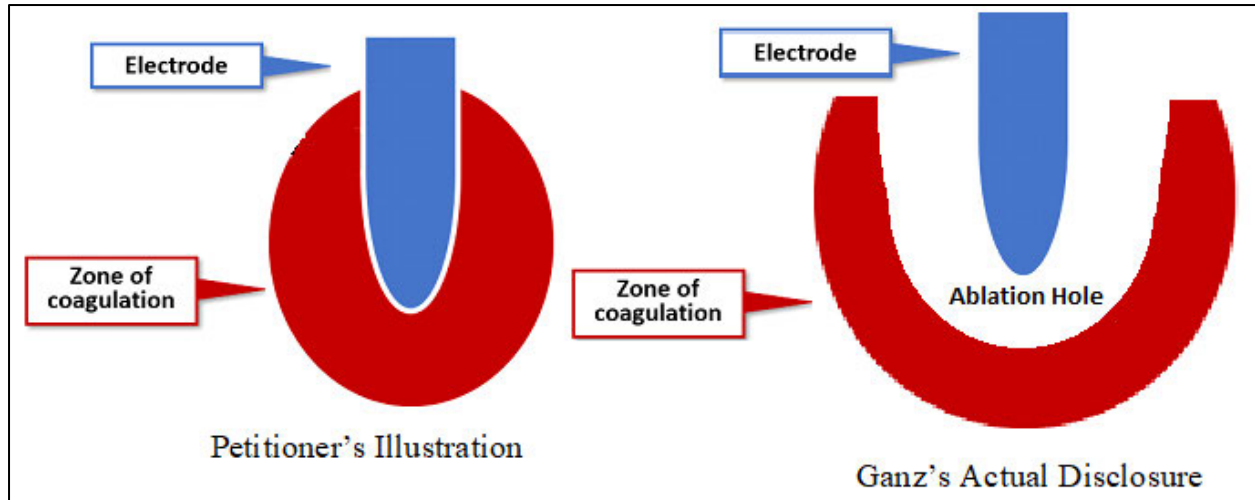
105. Petitioner asserts that “the claim limitation merely requires that coagulation be formed ‘around each electrode,’ not ‘immediately around each electrode.’” Pet. at 29. But by its plain language the claim requires “coagulation *around each electrode*”—not coagulation at the edges of holes created around each electrode. As discussed 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.) ¶39.

106. I understand that Petitioner also argues 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]. As Petitioner’s expert Dr. Koch explains, Ganz 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? **Yes.**”). As Dr. Goldberg explains, 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....”).

107. This is once again evident by comparing histological images of the '836 Patent treatment method (which shows no perforations) with those of Ganz's treatment method (which shows perforations / “ablation holes”). *Compare* Ex. 2032 (Na Nature Paper), Fig. 1b *with* Ex. 1005 (Ganz), Fig. 9. While both treatment methods used needles to puncture the skin, the Ganz treatment method left gaping holes where the electrode needles were inserted, resulting from the ablation and removal of tissue, while the '836 Patent treatment method kept this tissue intact. In short, 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. 2142 (Goldberg Decl.) ¶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.” *Id.* ¶39.

108. In view of Ganz's *actual* disclosure, a corrected version of Petitioner's “illustration” is shown below:



109. Petitioner also posits a hypothetical example “where the width of the perforation is the same as the width of the electrode.” Pet. at 28. Specifically, Petitioner relies on Ganz’s disclosure that “[t]he width of the perforation created will be at least the width of the electrode, and in many cases larger,” to argue that Ganz at least contemplates an embodiment where the width of the perforation is the same width as the electrodes. *Id.* (citing Ex-1005, [0053]). But Ganz’s technique would still apply energy to remove the tissue that existed where the electrode was inserted, and Petitioner identifies *no* example in Ganz of generating perforations the same size as electrodes. *See, e.g.*, Ex. 2142 (Goldberg Decl.) ¶40. Nor has Petitioner identified any disclosure in Ganz regarding whether (or how) such an example would have been achieved with bipolar electrodes (or when utilizing Alternating Current RF energy), or any disclosure in of where coagulation (if any) would be located. 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. As

discussed above, Ganz only discloses coagulation around the edges of holes, *i.e.*, “***surrounding each perforation.***” Ex-1005 (Ganz), [0010].

110. Indeed, Ganz discloses output powers that would almost certainly result in ablation and recitation of tissue surrounding where electrodes were inserted. 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* at 80-91), operates at a “Max” output power of just ***16 watts***. Ex. 2083 (Sylfirm Manual), 28.

111. In short, in my opinion it would not have been obvious to modify Ganz to cause coagulation around each electrode rather than coagulating between the electrodes. Once again, Ganz criticizes as inferior the localized “coagulation” caused by treatments “using a FRAXEL infrared scanning laser,” as shown in Figure 8 of Ganz (shown above). Ex. 1005 (Ganz), [0028]. Ganz complains that “[o]ne drawback with the FRAXEL laser is that the laser does not create perforations or vertical holes in the tissue, but only causes zones of coagulation.” Ex. 1005 (Ganz), [0006]. Ganz explains that his system is superior because it causes perforations rather than “only” producing coagulation. *Id.* Therefore, a POSITA would not have been motivated to cause coagulation around the electrodes, because doing so would

undermine Ganz's objective. Indeed, Petitioner does not explain why a POSITA would modify Ganz to include bipolar electrodes configured to cause coagulation around each electrode, rather than between them. And once again, Petitioner does not assess the advantages and disadvantages of any modification of Ganz.

112. Therefore, in my opinion, Ganz does not disclose, inherently or otherwise, or render obvious "the plurality of electrodes configured to cause coagulation around each electrode."

**4. Ganz does not disclose or render obvious "provid[ing] an Alternating Current (AC) RF signal to the plurality of electrodes."**

113. Ganz further does not disclose or render obvious "provid[ing] an Alternating Current (AC) RF signal to the plurality of electrodes." Ganz does not expressly disclose or mention alternating current or AC at all, nor is Alternating Current (AC) inherently disclosed by Ganz.

114. Rather, Petitioner asserts that "a POSITA would understand that Ganz's energy source provides alternating current (AC) having a radio frequency" because "[a] POSITA would know that in the field of skin treatment using RF energy to heat the tissue, the energy is delivered by an alternating current (AC) that oscillates at the RF frequency." Pet. at 22. I disagree because, as I explain below, a reference to RF does not necessarily refer to use of AC RF in this art, as illustrated, *e.g.*, by other patents in the field, including Dr. Woloszko's *own* patents.

115. Ganz states that “[t]he device also includes an energy source coupled to the plurality of electrodes, the energy source configured to deliver energy selected from the group consisting of radio frequency, non-ionizing ultraviolet radiation, or microwave radiation.” Ex. 1005 (Ganz) at [0011]; *see also id.* at [0057] (“The treatment device also includes an energy source coupled to the electrodes for delivering energy to the electrodes. The energy delivery device can deliver a variety of different types of energy including but not limited to, radio frequency energy...”); *id.* at [0058] (“In preferred embodiments, the electrodes are configured as RF electrodes and RF energy is delivered to the electrodes”); *id.* at [0059] (“the energy source, including but not limited to an RF source”); *id.* at claim 7 (“an energy source coupled to the plurality of electrodes, the energy source configured to deliver energy selected from the group consisting of radio frequency, non-ionizing ultraviolet radiation, or microwave radiation”); *id.* at claim 9 (“wherein the plurality of electrodes are RF electrodes and are configured for receiving RF energy”). Therefore, Ganz discloses a “radio frequency” energy as one of a number of types of energy that can be used, but Ganz does not provide any description of the nature of this RF energy. In my opinion, nothing in Ganz teaches that it is an “alternating current” “radio frequency” signal.

116. As discussed above, as reflected in other patents in the field, including Dr. Woloszko’s *own* patents, RF does not necessarily refer to use of alternating

current because it is used to refer to non-AC “voltage pulses” applied at a frequency in the RF range, as well as to AC RF. For example, Dr. Woloszko’s prior art patent U.S. Patent No. 6,766,202, which I understand Respondents relied upon earlier in this investigation, is about application of RF energy and teaches that this RF energy may be applied as “voltage pulses” at a rate within the radio frequency range or alternatively as alternating current. Ex. 2026 (U.S. Patent No. 6,766,202 to Underwood & Woloszko) at 5:31-34 (“The present invention applies high frequency (RF) electrical energy to one or more active electrodes adjacent [to] an external body surface, such as the outer surface of the skin, to modify the structure of tissue structures within the skin.”); 6:42-52 (“the voltage is usually delivered in a series of voltage pulses or alternating current of time varying voltage amplitude with a sufficiently high frequency (*e.g.*, on the order of 5 kHz to 20 MHz)”).

117. In addition to Underwood, the Chang reference explains that its “radio frequency generator” can provide RF of a “direct current pulse nature”: “[e]lectric fields may be generated in continuous wave form, such as sine, triangular, or square wave or similar, and at various frequencies, intensities, and polarizations in order to yield the exact desired heating to cause the desired precise cell injury” and that “[e]lectric fields maybe of a direct current pulse nature, as well.” Ex. 2034 (US 2011/0288543 to Chang) at [0017], [0035], [0036] (“This is the first hand-held radio frequency generator for use in an electro surgery device.”). Therefore, the technique

disclosed in Underwood and Chang, of using pulses of DC current, was well understood in the art as an alternative to alternating current.

118. Other patents from Dr. Woloszko demonstrate that references to RF in this field do not necessarily refer to alternating current. For example, U.S. Pat. No. 9,095,358 (“Woloszko ’358”), which traces priority to a U.S. patent application filed in 2009, in discussing “applications of Coblation (R) technology” where “high frequency (RF) electrical energy is applied,” refers to non-AC delivered in the RF range:

As discussed above, the voltage is usually delivered in a series of voltage pulses or alternating current of time varying voltage amplitude with a sufficiently high frequency (*e.g.*, on the order of 5 kHz to 20 MHz) such that the voltage is effectively applied continuously (as compared with, *e.g.*, lasers claiming small depths of necrosis, which are generally pulsed about 10 Hz to 20 Hz).

Ex. 2027 (Woloszko ’358) at 4:7-11, 6:28-34 (emphasis added); *see also id.* at 5:58-63 (“The voltage difference applied between the return electrode(s) and the active electrode(s) will be at high or radio frequency, typically between about 5 kHz and 20 MHz, usually being between about 30 kHz and 2.5 MHz, preferably being between about 50 kHz and 500 kHz, often less than 350 kHz, and often between about 100 kHz and 200 kHz.”).

119. Indeed, while Petitioner now asserts that AC RF is redundant, elsewhere Dr. Woloszko claimed use of AC RF in his own prior art patent, just like in the ’836 Patent: “The method of claim 32, wherein said step d) comprises applying

a radio frequency alternating-current voltage in the range of from about 200 volts RMS to 1500 volts RMS.” Ex. 2028 (U.S. Pat. No. 8,012,153) (“Woloszko ’153”) at Claim 32. If “radio frequency” always referred to use of alternating current, it would not have made sense for Dr. Woloszko to specify in the claims of his patent that the claimed RF was “alternating-current” in his own patent claim—that would have been redundant.

120. As these patents demonstrate, inventors specify when they mean AC RF in this field because, in this field, RF is also used to refer to the use of signals in the RF frequency range that are not “alternating current” signals. These patents, which include Dr. Woloszko’s own patents, are consistent with Dr. Na’s testimony that there are signals referred to as AC and DC RF signals in this field, which explains his specifying the use of AC RF (distinguishing non-AC RF signals). *See, e.g.*, Ex. 2035 (July 24, 2023 Na. Dep. Tr.) at 44:5-8 (“Q. What is the difference between AC RF and just RF? A. Well, for RF there are DC RF and also AC RF method as well.”). Thus, disclosure of RF energy in Ganz does not inherently disclose oscillating or alternating current.

121. Moreover, while Petitioner asserts that DC RF would not be used with electrosurgical devices due to IEC safety standards, it is not clear that the IEC standard cited by Petitioner applies for micro-coagulation. For example, it appears that micro-coagulation surgical devices are exempt from the standard. *See, e.g.*, Ex.

2076 (IEC 60601-2-2:2017) at section 201.1.1 (“HF surgical equipment having a rated output power not exceeding 50 W (for example for micro-coagulation, or for use in dentistry or ophthalmology) is exempt from certain of the requirements of this particular standard.”) This language similarly appears in the 2009 version which would have been in effect at the time of the invention. *See, e.g.*, Ex. 2077 (IEC 60601-2-2 (2009)) at section 201.1.1.

122. Furthermore, even if the standard did not exempt micro-coagulation surgical devices, the plain language from the section Petitioner cites does not preclude the use of DC RF systems, it merely states that one should use an appropriate value of series capacitance and shunt resistance to the extent DC or low frequency components are utilized:

Due to the rectifying effect of arcs between the ACTIVE ELECTRODE and tissue, DC and low frequency components may cause neuromuscular stimulation. This undesirable stimulation is effectively reduced by the use of an appropriate value of series capacitance and shunt resistance.

Ex. 2076 (IEC 60601-2-2 (2017)) at section 201.8.4.102.

123. The 2009 standard was “withdrawn” by the IEC and was amended in at least 2017 and 2018. *See* Ex. 2078 (<https://webstore.iec.ch/publication/2624>); *see also* Ex. 2077 (IEC 60601-2-2 (2009)). As shown below, the 2009 version uses less restrictive language than the 2017 version:

In order to minimize the possibility of neuromuscular stimulation, a capacitance shall be incorporated into the PATIENT circuit so that it is

effectively in series with the ACTIVE ELECTRODE or one conductor of a BIPOLAR ELECTRODE. This capacitance shall not exceed 5 nF for MONOPOLAR PATIENT circuits and 50 nF for BIPOLAR PATIENT circuits. The d.c. resistance between ACTIVE and NEUTRAL ELECTRODE terminals, or between the terminals of a BIPOLAR output circuit, shall not be less than 2 M  $\Omega$ .

Ex. 2077 (IEC 60601-2-2 (2009)) at section 201.8.4.102.

124. Additionally, as shown in Underwood, Chang, and Dr. Woloszko's own patents, regardless of the statements of the IEC, other patents in the relevant time period refer to non-AC RF. And while Petitioner asserts that the IEC standard forces all Surgical HF generators to be AC generators, there were DC electrosurgical devices on the market, which were evaluated against IEC 60601-2-2:2017 and approved for use by the FDA. *See, e.g.*, Ex. 2036 (K212871 FDA Letter).

125. Petitioner also relies on a statement made in one of Dr. Na's unrelated Korean patent application that "radio waves are basically alternating current." Pet. at 23-24 (quoting Ex. 1025, [0016]). But Na's characterization of RF energy in the context of *that specific patent application* says nothing about whether Ganz means to refer to AC or non-AC RF.

126. In short, Petitioner simply assumes that Ganz discloses AC RF and does not explain how or why a POSITA would have been motivated to use AC RF in the context of Ganz.

a) A POSITA Would Not Be Motivated To Combine Ganz And Livneh

127. Petitioner contends that, “[t]o the extent Ganz does not disclose” AC RF, “Ganz in combination with Livneh renders this limitation obvious,” arguing “POSITA implementing Ganz’s device would have been motivated to use Livneh’s power supply that provides an alternating current having a radio frequency.” Pet. at 24-25, 30-31. I disagree. Petitioner offers no evidence that Livneh’s power supply would be suitable for Ganz’s purpose. As discussed further below, Ganz is directed to applying sufficient energy to create “ablation holes” to prompt “an even more aggressive wound healing response.” Ex. 1005 (Ganz), [0006]. To achieve these ablation holes, Ganz discloses RF electrodes with substantial “power in the range of about 50 to about 200 watts per square centimeter and also configured to provide an energy of at least about 1 joule per square centimeter.” *Id.*, [0011]; *see also id.* [0065] (“A power of 50 watts and an energy of 1 joule were delivered to the electrode array.”). Livneh, however, discloses nothing about the wattage or energy level its power supply provides to electrodes. Petitioner does not address this issue either.

128. In my opinion, a POSITA would not have been motivated to use Livneh’s power supply in Ganz’s device, as Petitioner proposes. There is no evidence that Livneh’s power supply would work in Ganz’s device, let alone any suggestion that it would work as well or better than Ganz’s power supply. Livneh merely states that its power supply “preferably converts commercial AC electrical

power” to “an AC signal operating at a radio frequency,” but discloses no details about this power supply or any advantages compared to other power supplies, such as those that provide non-AC RF. Ex. 1006 (Livneh), [0037]. Therefore, in my opinion, Ganz alone, or in view of Livneh, does not disclose or render obvious “[a/an] Alternating Current (AC) [RF/Radio Frequency (RF)] signal.”

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

129. Petitioner has further failed to show that Ganz in view of a POSITA’s knowledge, and/or in further view of Livneh, discloses or renders obvious the limitations of 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.

130. 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 they do for claim 1 (Pet. at 36), Petitioner similarly has failed to demonstrate that independent claim 14 is invalid under these grounds. Likewise, because claims 15 and 23-24 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.

**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**

131. Petitioner has failed to show that Ganz in view of a POSITA's knowledge, and/or in further view of Livneh and Hantash, discloses or renders obvious the limitations of claims 2-10, 15-22, and 25. As discussed above, independent claim 14 of the '836 Patent is the method version of claim 1's system claim, and each of the other claims depend 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 Livneh and Hantash, discloses or renders obvious these claims for the same reasons discussed with respect to claim 1 of the '836 Patent.

132. 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**

133. 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. However, Ganz does not teach needles with a diameter from 0.25 mm to 0.30 mm, as Ganz is silent as to the diameter of the needles used to create the perforations. 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. Ganz further explains that the “width of the perforation created will be at least the width of the electrode, *and in many cases larger.*” *Id.*, [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.

134. 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. As discussed above, the needles used in Ganz are the same size or smaller than the perforations, which are 0.050-0.100 mm. Ganz expressly states that its perforations should be “so small that they cannot be seen with the naked eye.” 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. 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.

135. Additionally, a POSITA would be discouraged from combining Ganz with Hantash because they have different objectives. Ganz teaches creating “**ablation holes**” around each electrode to generate a more aggressive healing response. *Supra* at 45-46. In contrast, Hantash teaches the use of a controller with specialized “algorithms” to limit the energy delivered, thereby “**avoiding overheating** of the treated zones . . . .” Ex. 1007, [0018]. Thus, Ganz is about “overheating” to remove tissue, while Hantash is about avoiding this.

136. Ganz also teaches causing ablation and necrosis **around** each electrode to remove the tissue around each electrode. *Supra* at 44-47. 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 that extend **between** the treatment electrodes:

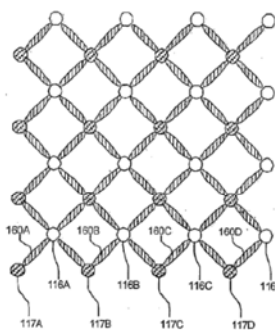


Figure 4A

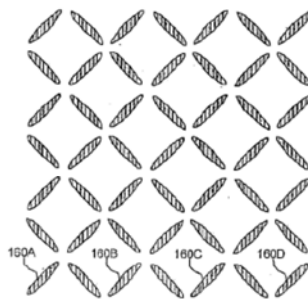


Figure 4B

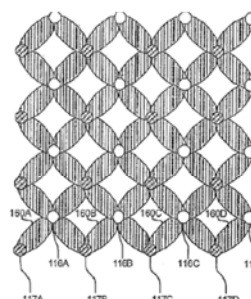


Figure 5A

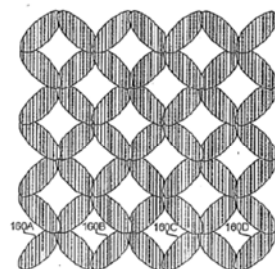
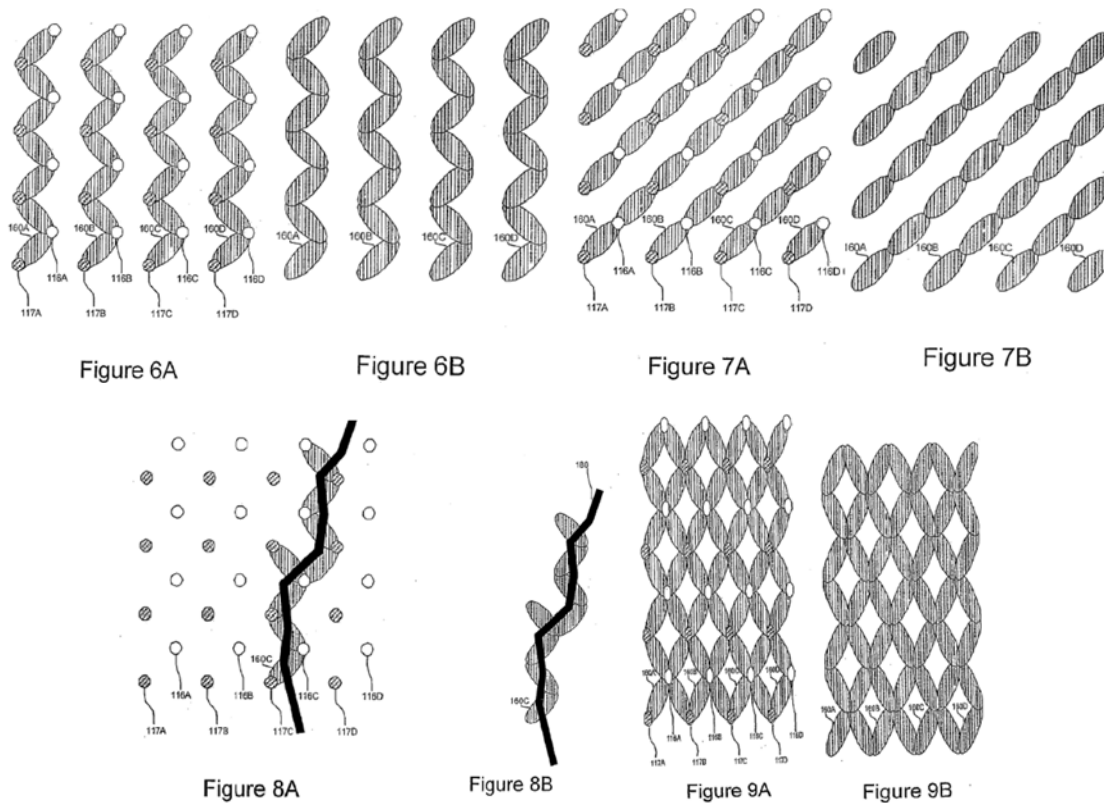


Figure 5B



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

137. 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. 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.

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

138. 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.

139. 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. 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.

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

140. 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. As discussed above, independent claim 14 of the '836 Patent is the method version of claim 1's system claim, and each of the other claims depend 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.

**D. Objective Indicia Support Non-Obviousness**

141. I further understand that Dr. Goldberg opines that certain objective indicia of non-obviousness further demonstrate that the '836 Patent claims are non-obvious. *See, e.g.,* Ex. 2142 (Goldberg Decl.) ¶¶42-71. With respect to commercialization of the '836 Patent's technology, based on my personal inspection of the Sylfirm X RF Microneedling Device and associated technical documentation, the Sylfirm X RF Microneedling Device practices the claimed invention. For example, as discussed below, the Sylfirm X practices claim 1 of the '836 Patent:

**1. “1[pre] A skin treatment apparatus, comprising:”**

142. It is my opinion that the Sylfirm X practices this limitation.

143. Patent Owner's internal documents confirm that the Sylfirm X practices this limitation. For example, a Sylfirm X User Manual shows that the Sylfirm X is an RF microneedling system used to treat the skin. *See* Ex. 2083 (Sylfirm X User Manual) at 4; Ex. 2084 (Sylfirm X Device Description) at 1-20; Ex. 2079 (Sylfirm X webpage) at 3; Ex. 2037 (Sylfirm X brochure) at 2.

**2. “1[a] a plurality of electrodes, the electrodes being bipolar and configured to be insertable into skin to be treated;”**

144. It is my opinion that the Sylfirm X practices this limitation.

145. With respect to the “configured to” portion of this limitation, I understand that in the ITC Investigation the parties agreed that the term carries its plain and ordinary meaning, which is “adapted to.” Ex-1028 (Markman Order), 39-40.

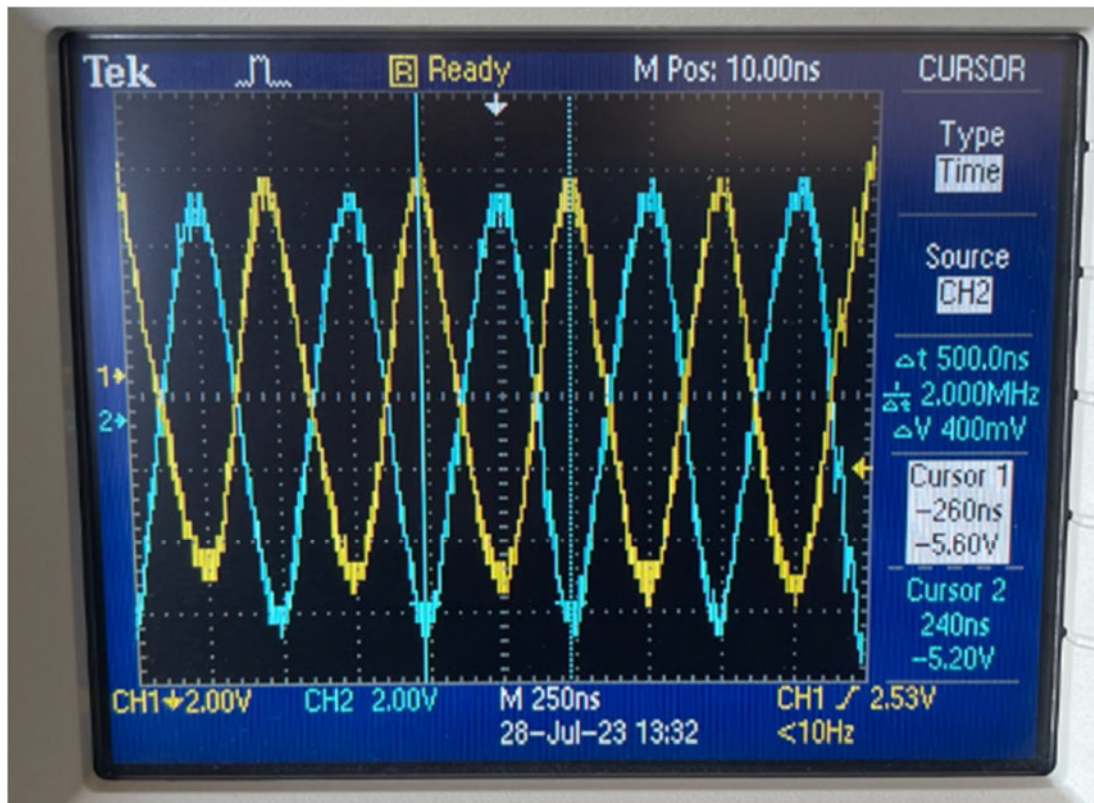
146. With respect to the “plurality of electrodes” portion of this term, I understand that the ALJ in the ITC Investigation construed this term to have its plain and ordinary meaning, *i.e.*, “two or more electrodes (which can be needles or pins).” The Sylfirm X practices this limitation literally because the product utilizes an array of electrode needles. For example, Patent Owner's documents confirm that the Sylfirm X utilizes an array of electrode needles. *See* Ex. 2037 (Sylfirm X brochure) at 9; *see also* Ex. 2086 (Domestic Industry Photos) at 9. Additionally, I personally inspected the Sylfirm X and confirmed the Sylfirm X includes a plurality of needle

electrodes. *See* Ex. 2087 (Thermal Testing Results) at 2-3; Ex. 2088 (Product Inspection Photographs) at slides 37-39.

147. With respect to the “electrodes being bipolar” portion of this limitation, I understand that the parties in the ITC agreed that the term “electrodes being bipolar” carries its plain and ordinary meaning, which is “electrodes change or alternate between being positive or negative as the current alternates between them (as opposed to a monopolar configuration where current flows from one or more electrodes that deliver current to one or more ground electrodes).” Ex-1028 (Markman Order), 39-40.

148. Patent Owner’s documents confirm that the electrodes in the Sylfirm X are bipolar. For example, a Sylfirm X Device Description document shows those microneedles of the Sylfirm X are bipolar electrodes. *See* Ex. 2084 (Sylfirm X Device Description) at 6-7; *see also* Ex. 2037 (Sylfirm X brochure) at 2; Ex. 2089 (RF Board Electrical Schematic) at 6; Ex. 2090 (Sylfirm X Waveform) at 3-4.

149. Additionally, I personally inspected the Sylfirm X and measured the signal on two complementary needles, indicating the bipolar nature of the system:

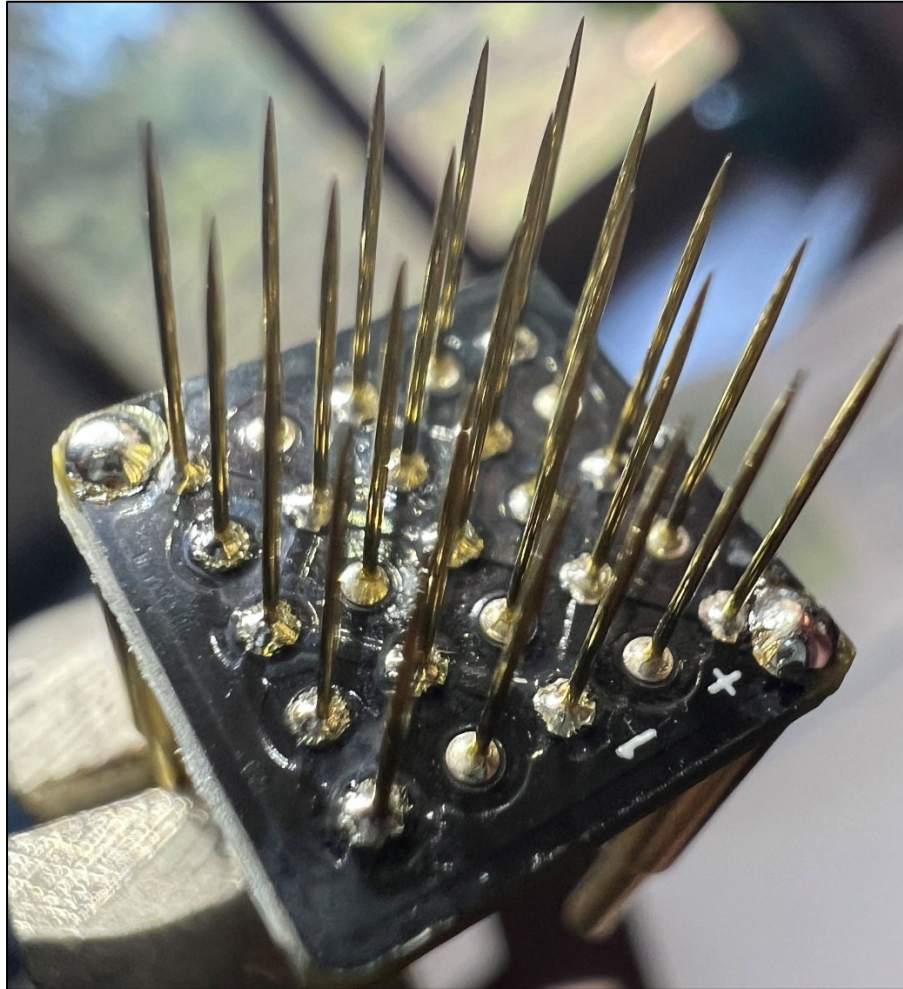


Ex. 2088 (Product Inspection Photographs) at slide 39; *see also* Ex. 2090 (Sylfirm X Waveform) at 3-4.

150. Additionally, as shown in Ex. 2088 (Product Inspection Photographs), I observed that the lines of the needle electrodes in the needle assemblies are all wired together, and that they alternate conductivity. I further confirmed that there was no ground pad, meaning RF current only flows between the needle electrodes.

151. I also understand that the ALJ in the ITC Investigation construed “electrodes being bipolar” to exclude the “Intracel” configuration, *i.e.*, alternating rows of commonly polarized electrodes. Ex-1028 (Markman Order), 53-54. I personally inspected the electrode needle arrays used with the Sylfirm X, and

confirmed that they are connected in a zigzag/chevron pattern, and not as “alternating rows of commonly-polarized electrodes.”





Exs. 2091-2094.

152. Finally, with respect to the “configured to be insertable into skin to be treated,” as discussed above, the plurality of electrodes of the Sylfirm X are configured to be insertable into skin to be treated. *See, e.g.*, Ex. 2083 (Sylfirm X User Manual) at 28.

3. **“1[b] 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.”**

153. It is my opinion that the Sylfirm X practices this limitation.

154. With respect to the “RF generation module” portion of this limitation, I understand that in the ITC Investigation the parties agreed that the term carries its plain and ordinary meaning, which is “a device that generates electrical signal(s) having a radio frequency.” Ex-1028 (Markman Order), 39-40.

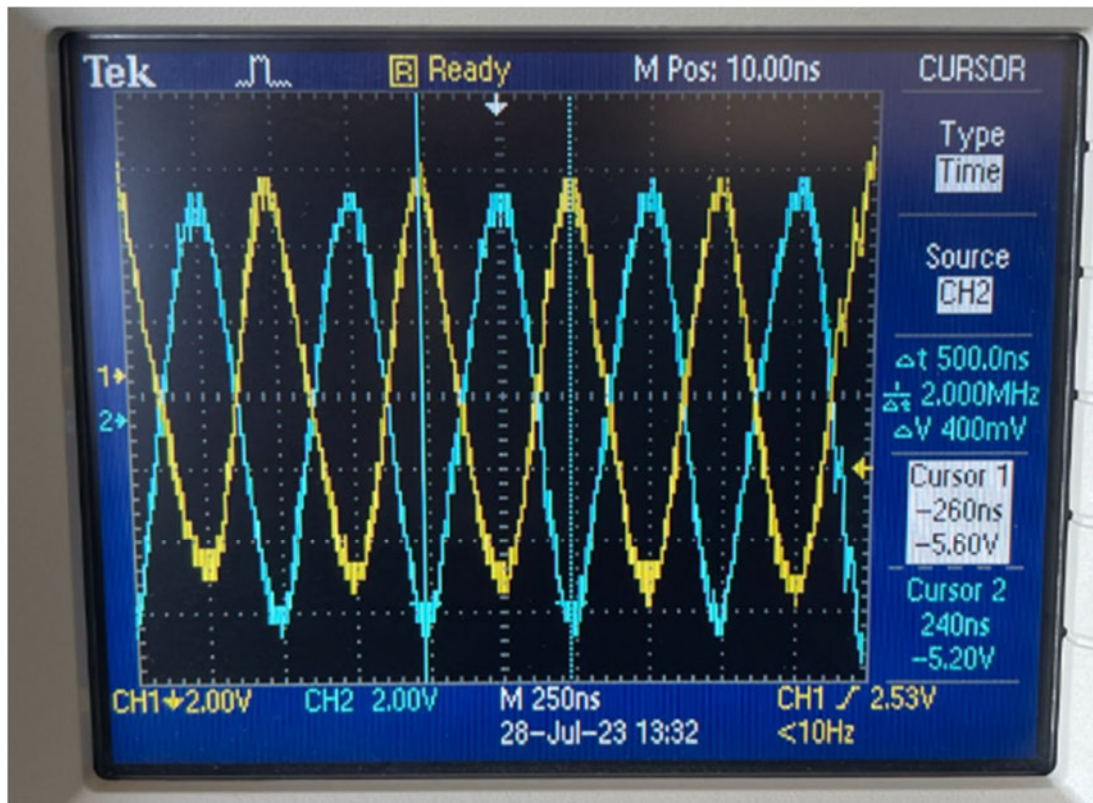
155. Patent Owner’s documents confirm that the Sylfirm X includes a radio frequency (RF) generation module electrically coupled to the plurality of electrodes. *See, e.g.*, Ex. 2037 (Sylfirm X brochure) at 2 (showing the Sylfirm X comprises an RF generation module); Ex. 2084 (Sylfirm X Device Description) at 15-16 (containing a block diagram that shows the RF signal generation process); Ex. 2086 (Domestic Industry Photos) at 4-5 (showing how the RF generation module of the Sylfirm X is electrically coupled to the plurality of electrodes via electrical cables); Ex. 2083 (Sylfirm X User Manual) at 28.

156. With respect to the “plurality of electrodes” term, as discussed above, it is my opinion that the Sylfirm X practices this limitation.

157. With respect to the “configured to provide an Alternating Current (AC) RF signal to the plurality of electrodes” portion of this limitation, I understand that

the ALJ in the ITC Investigation construed this term to have its plain and ordinary meaning, which is “an electrical signal with oscillating current (current alternating polarities), and having a radio frequency (measured in MHz).” The Sylfirm X practices this limitation literally because it utilizes an oscillating current applied at a radio frequency during treatment. For example, Patent Owner’s documents confirm that the RF generation module of the Sylfirm X is configured to provide an Alternating Current (AC) RF signal to the plurality of electrodes. *See* Ex. 2096 (Invasive Pulse-Type) at 2-4; *see also* Ex. 2095 (Medical Lasers journal article) at 2-3; Ex. 2037 (Sylfirm X brochure) at 2; Ex. 2086 (Domestic Industry Photos) at 2-3.

158. Additionally, as discussed above, I personally inspected the Sylfirm X and confirmed that it provides an Alternating Current (AC) RF signal:



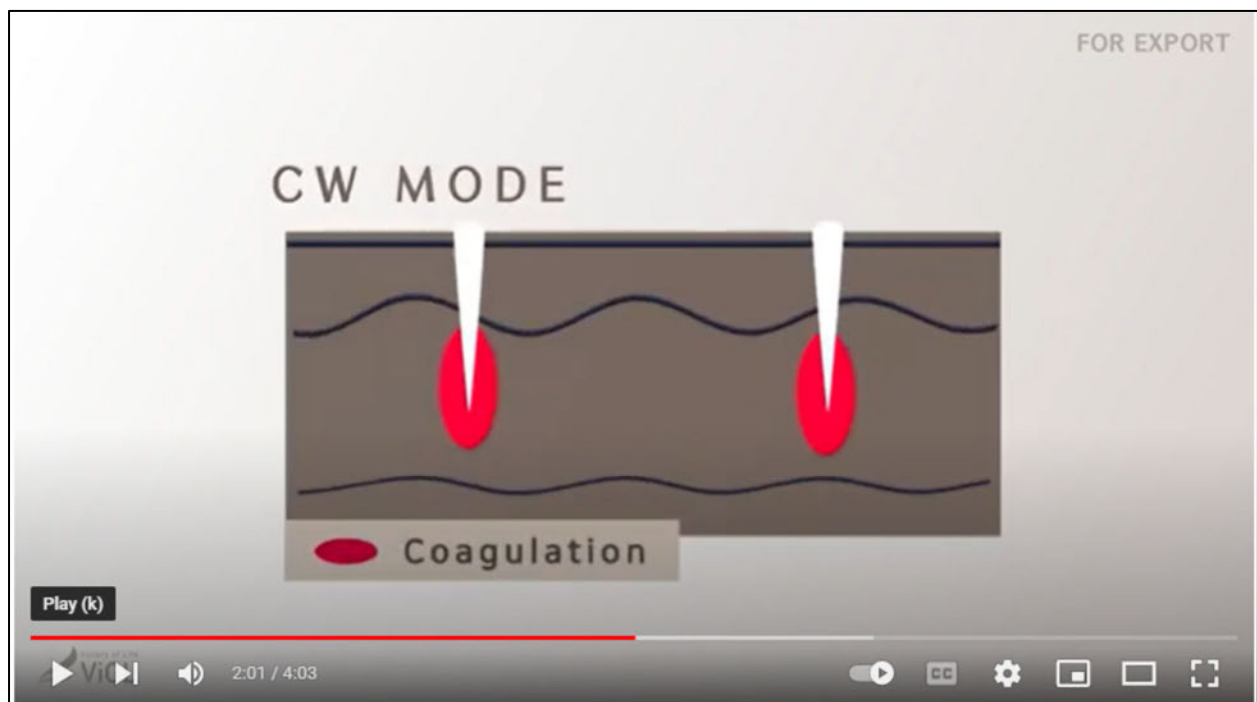
Ex. 2088 (Product Inspection Photographs) at slide 39; *see also* Ex. 2090 (Sylfirm X Waveform) at 3-4.

159. With respect to the “electrodes configured to cause coagulation around each electrode rather than coagulating between the electrodes” portion of this limitation, I understand that in the ITC Investigation the parties agreed that the term carries its plain and ordinary meaning, which is “two or more electrodes adapted to cause coagulation around each electrode without such coagulation fully extending from one electrode to another electrode.” Ex-1028 (Markman Order), 39-40.

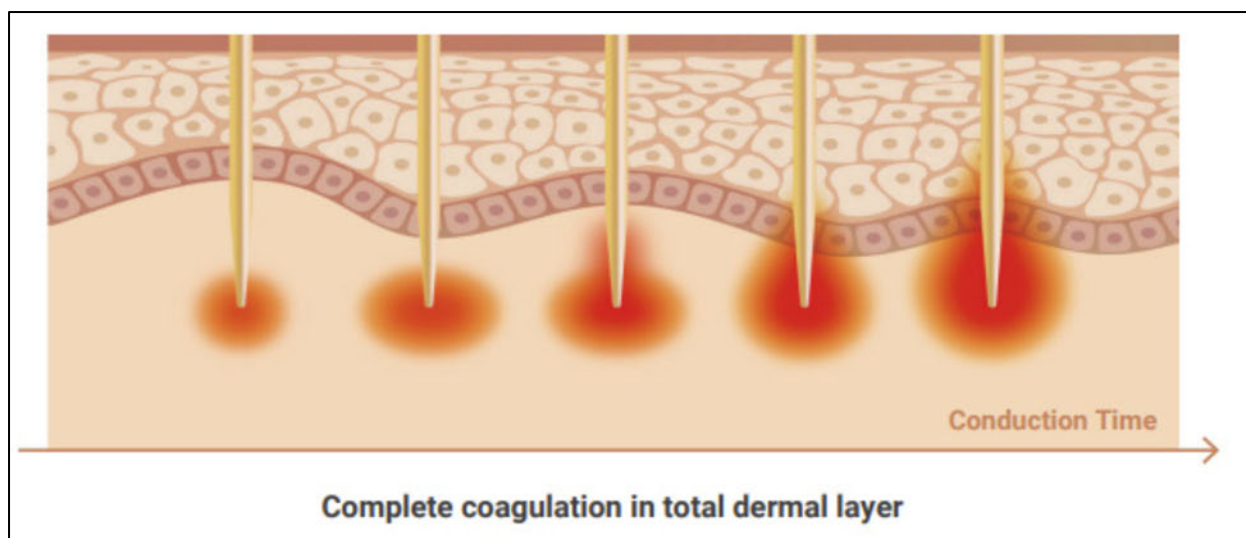
160. Patent Owner’s documents confirm that in the Sylfirm X, the RF generation module along with the plurality of electrodes are configured to cause

coagulation around each electrode rather than coagulating between the electrodes. *See* Ex. 2097 (Sylfirm X instructional video 1) (showing application of energy at the end of needle electrodes); *see also* Ex. 2099 (Sylfirm X instructional video 2) (showing targeted coagulation around needle electrodes); Ex. 2037 (Sylfirm X brochure) at 2, 4; Ex. 2102 (Sylfirm X presentation) at 25 (showing “columns of thermal injury” “separately generated around each microneedle in the dermis”).

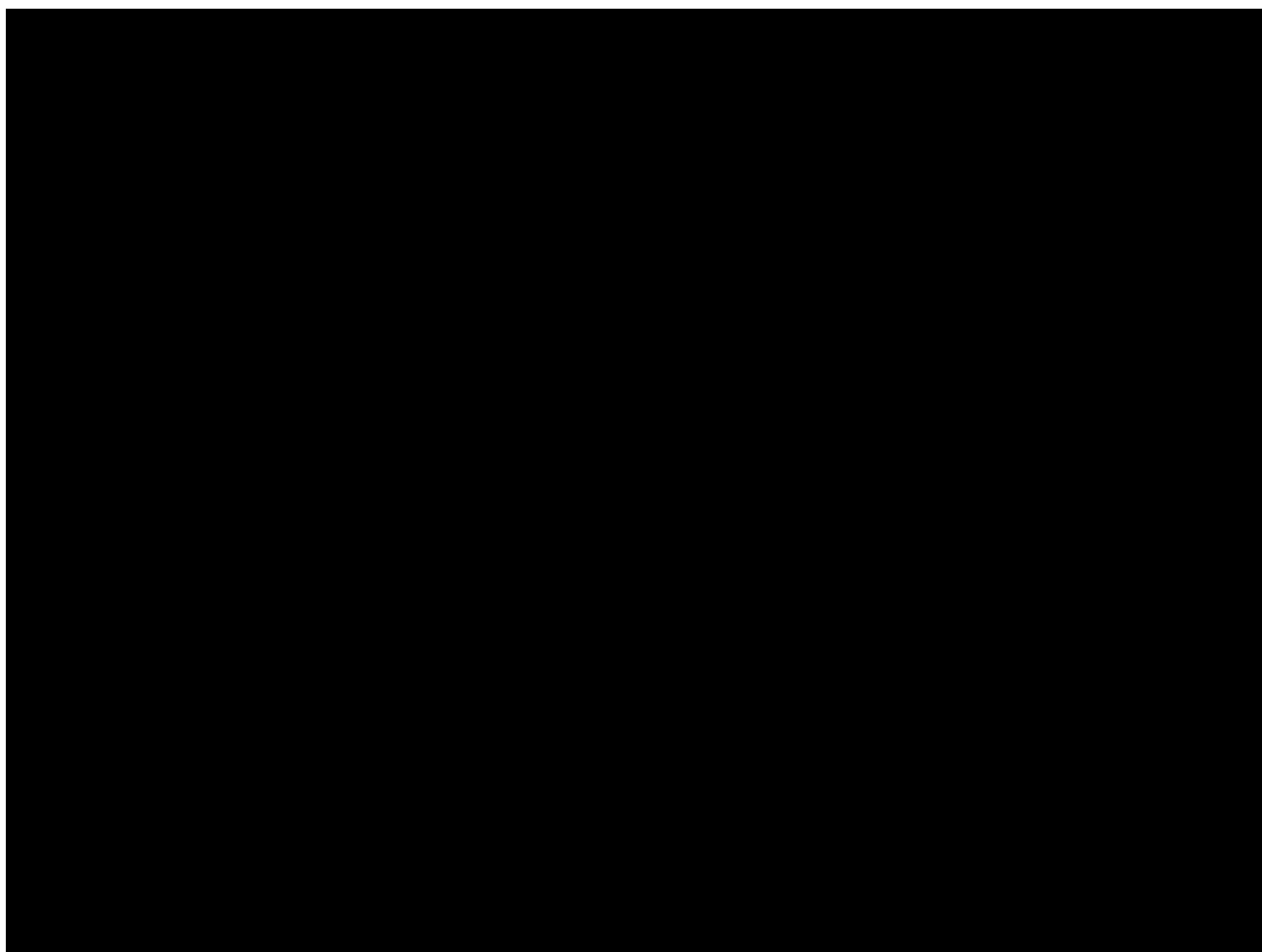
161. For example, the Sylfirm X is marketed as being configured to cause coagulation around each electrode rather than coagulating between them:



Ex. 2099 (Sylfirm X instructional video 2) at 2'01”.

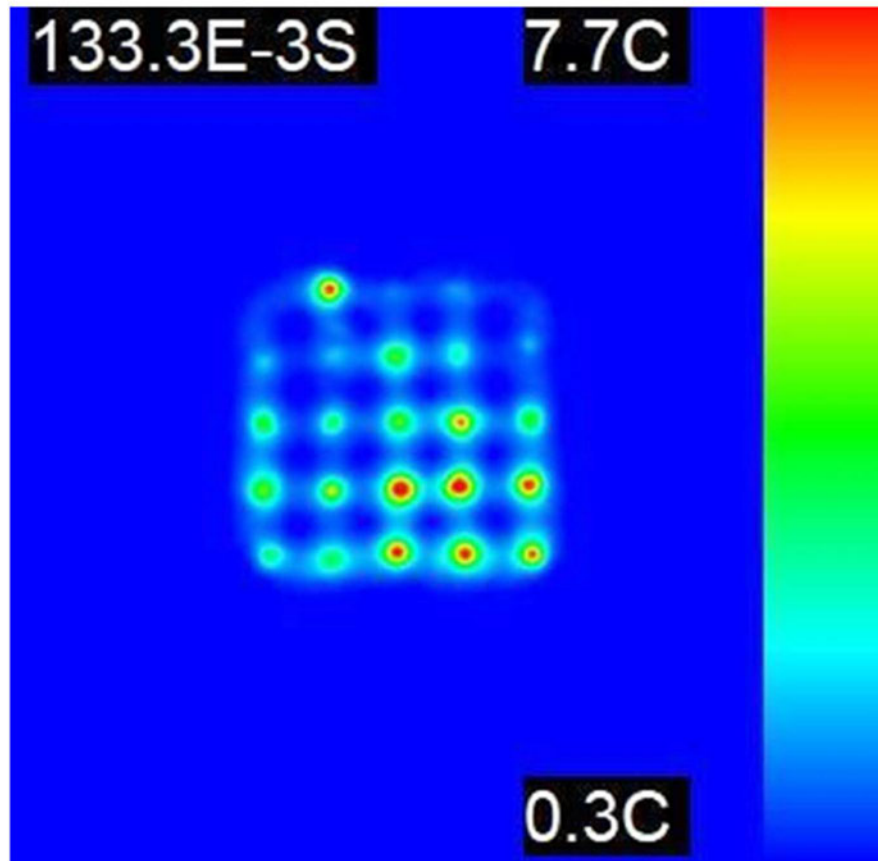


Ex. 2037 (Sylfirm X brochure) at 2, 4.



Ex. 2102 (Sylfirm X presentation) at 25.

162. Additionally, I performed heat mapping tests for the electrode arrays of the Sylfirm X, with these tests confirming that heat is substantially focused around each needle electrode during treatment:



Ex. 2087 (Sylfirm X, 2 MHz, -11 dBm, 120ms pulse) at 4.

163. Thus, because the Sylfirm X practices the '836 Patent, there is a nexus between any commercial success and the '836 Patent. Conversely, since the prior art does not practice the '836 Patent (as discussed above), there is no nexus between any of the prior art Petitioner has identified and any commercial success.

**E. Reservations of Rights**

164. This declaration is based upon my present experience, education, and analysis of the materials available to me. I also reserve the right to supplement my opinions in response to any additional material or information made available to me. In addition, I also reserve the right to present my opinions including through the preparation of demonstratives, graphics, charts, etc., to further illustrate my testimony. The citations provided in my declaration are exemplary, and I reserve the right to rely on any other portions of the cited documents, or any other available document or information, which help to better explain my opinions or rebut any opinions offered by Petitioner or its experts. I also reserve the right to rely on documents and information discussed in my other declaration and testimony in this action. I also reserve the right to testify on issues that help to better explain my opinion for the benefit of the Board. In addition, to the extent my opinions are challenged or rebutted during deposition or at a hearing, and there is additional evidence to clarify or rebut the opinions of Petitioner's experts or lawyers, I reserve the right to offer that testimony.

**VII. CONCLUSION**

165. I declare under penalty of perjury that the foregoing is true and correct.

Executed on Nov. 10, 2024 (date), in Los Angeles, CA (city, state).

A handwritten signature in black ink, appearing to read "Daniel W. van der Weide", enclosed within a rectangular box.

Daniel W. van der Weide