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Via Electronic Mail (mcnamara337@usitc.gov) and EDIS

The Honorable MaryJoan McNamara
Administrative Law Judge
U.S. International Trade Commission
500 E Street, S.W.
Washington, D.C. 20436

RE: Certain Dermatological Treatment Devices and Components Thereof, Inv. No. 337-TA-1356

Dear Judge McNamara:

On behalf of Respondents Sung Hwan E&B Co., LTD. d/b/a SHEnB Co. LTD; Aesthetics Biomedical, Inc. Cartessa Aesthetics, LLC, Lutronic Corporation, Lutronic Aesthetics, Inc., also known as Lutronic, Inc. and Lutronic, LLC, Ilooda, Co., Ltd., Cutera, Inc., Jeisys Medical Inc., Cynosure, LLC, Rohrer Aesthetics, LLC, Rohrer Aesthetics, Inc., EndyMed Medical, Ltd., and EndyMed Medical, Inc., please see the enclosed Expert Report of Jean Woloszko, MD, Ph.D, which contains confidential business information, and the Appendix thereto.

Please do not hesitate to contact me should you have any questions.

Respectfully submitted,

/s/ Lesley M. Grossberg

Lesley M. Grossberg

Serendia, LLC
Exhibit 2004
EndyMed v. Serendia
IPR2024-00842
Ex. 2004-001

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

Before the Honorable MaryJoan McNamara
Administrative Law Judge

In the Matter of **CERTAIN DERMATOLOGICAL TREATMENT DEVICES AND COMPONENTS THEREOF**	**Investigation No. 337-TA-1356**

EXPERT REPORT OF JEAN WOLOSZKO, MD, PH.D.

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I. INTRODUCTION

1. I have been retained by counsel for Respondent Sung Hwan E&B Co., LTD. d/b/a SHEnB Co. LTD ("SHEnB"); Respondent Aesthetics Biomedical, Inc. ("AB"); Respondent Cartessa Aesthetics, LLC ("Cartessa"); Respondents Lutronic Corporation; Lutronic Aesthetics, Inc., also known as Lutronic, Inc. and Lutronic, LLC (collectively, "Lutronic"); Respondent Ilooda, Co., Ltd. ("Ilooda"); Respondent Cutera, Inc. ("Cutera"); Respondent Jeisys Medical Inc. ("Jeisys"); Respondent Cynosure, LLC ("Cynosure"); Respondents Rohrer Aesthetics, LLC and Rohrer Aesthetics, Inc. (collectively, "Rohrer"); Respondents EndyMed Medical, Ltd. and EndyMed Medical, Inc. (collectively, "EndyMed") (collectively "Respondents") as an independent expert in this ITC investigation, Inv. No. 337-TA-1356 ("Investigation"). I expect to testify concerning the subjects outlined in this report.

2. As part of my engagement I have been asked to provide analysis and expert opinions on the following topics: (a) the disclosure of U.S. Patent No. 9,480,836 (the "'836 Patent"); U.S. Patent No. 10,058,379 (the "'379 Patent"); U.S. Patent No. 11,406,444 (the "'444 Patent"); U.S. Patent No. 9,320,536 (the "'536 Patent"); U.S. Patent No. 9,775,774 (the "'774 Patent"); and U.S. Patent No. 10,869,812 (the "'812 Patent") (collectively, the "Asserted Patents") and (b) the validity of the claims of the Asserted Patents asserted by Complainant Serendia, LLC ("Complainant" or "Serendia").

3. Based on my review, the '836, '379, '444, '536, '774, and '812 Patents are directed to respective features of dermatological devices and methods of treating dermatological tissue, share the same named inventor (Dr. Na) and same prosecuting attorney (Mr. Richman), have been licensed together (*see, e.g.*, Complaint, Ex. 69), and I understand they are asserted together in the present ITC Investigation and related district court litigations.

4. I expect to be called to provide expert testimony regarding opinions formed resulting from my analysis of the issues considered in this report. Additionally, I may discuss my own work, teachings, and knowledge of the state of the art in the relevant time-period. I may rely on handbooks, textbooks, technical literature, and the like to demonstrate the state of the art in the relevant period and the evolution of relevant technologies. I may also rely on demonstratives, and visual representations of the testimony included herein.

5. This report is a description of the testimony I expect to offer in the Investigation. However, I respectfully reserve the right to supplement my analysis in response to any alternative opinions offered by Serendia. For example, it is my understanding that Serendia may submit an expert report relating to the subject matter addressed in this report. I reserve the right to rebut any positions taken in that rebuttal report. Further, to the extent that Serendia offers new theories of infringement I reserve the right to identify new prior art that invalidates the claims under Serendia's new infringement theories, as well as providing additional opinions regarding invalidity in view of additional prior art and regarding the disclosure of the Asserted Patents and file histories as they relate to such additional infringement opinions.

6. It is my understanding that discovery is ongoing. I reserve the right to modify or supplement my opinions, as well as the basis for my opinions, should any new documents, testimony, or other evidence emerge during this Investigation, including depositions that have yet to be taken or deposition transcripts that have not yet been completed.

7. Throughout this report, I refer to specific pages of patents and other technical documents, articles, and standards. These citations are illustrative and are not intended to convey that they are the only sources to support the propositions for which they are cited. For example, I

may refer to text describing a figure and in so doing incorporate the picture. Similarly, in citing to a picture I incorporate the corresponding text describing the picture.

II. RETENTION

8. I have been retained by counsel on behalf of Respondents as an expert in this Investigation. No part of my compensation is dependent upon the outcome of this Investigation or any issue in it. I am compensated at my standard rate of $550 per hour, plus reimbursement for expenses. I have no other interest in this litigation or with any of the parties.

III. BASIS FOR OPINIONS

A. Qualifications

9. I am an independent consultant. All my opinions stated in this report are based on my own personal knowledge and professional judgment.

10. The following is a brief summary of my background and qualifications, which are more fully set forth in my Biographical Summary, attached as Appendix A.

11. I currently work as an independent consultant for several medical device companies, most of them are involved in some type of RF electrosurgery products.

12. I received a Physics and Mathematics Certificate for Medical Research in 1977 and a Medical Degree from the Université Louis Pasteur in 1981. I received a Biomechanics and Kinesiology Certificate from the University of Montpellier in 1988. I specialized in Rehabilitation Medicine and completed a 3-year residency at the University of Montpellier in 1988. I completed my Medical Thesis at the University of Montpellier in 1988. I received a Ph.D. in Bioengineering from the University of Illinois at Chicago in 1992.

13. From 1981 until 1988, I worked at the INSERM (the French National Scientific Institute for Medical Research and Studies) as a Research Associate.

14. From 1983 until 1988 I worked part time as an Associate Physician at Center PROPARA, a Rehabilitation Center for Spinal Cord Injury patients.

15. I was the worldwide research manager for the Interstim Venture group of Medtronic, leading the research and development efforts in the field of urology, gastroenterology, and colorectal surgery from 1992 to 1998. In 1997, I became the Senior Manager of Medical Affairs at Medtronic Interventional Cardiology, driving the development of new technology in the interventional cardiology group.

16. I held multiple roles at ArthroCare Corporation from 1998 to 2014, including: Medical Director from 1998 to 2002; Vice President of Research and Development from 1999 to 2003; Vice President – Chief Technology Officer from 2003 to 2010; and Senior Vice President of Research and Development and Chief Technology Officer from 2010 to 2014. In my role in these positions, I was responsible for the growth of the research, product development, and innovation for ArthroCare which grew from a $12.5 million company to around $400 million. I led the development of the internationally patented RF based technology Coblation®. In my role of providing technical leadership, training, and education both internally as well as externally, I was able to develop and maintain over 65% market share for this plasma mediated radio-frequency surgical system for over 16 years which created a $250 million revenue stream. Additionally, throughout these positions, I drove innovation strategy, product development, process development, sustaining engineering, and manufacturing transfer throughout various areas of the organization including sports medicine, ENT, spine, cosmetic and plastic surgery, urology, gynecology, OEM partnerships, and wound management. This included driving the product development for the Visage division of ArthroCare Corp., that was

manufacturing and distributing radiofrequency systems for cosmetic surgery, including systems to improve skin condition and reduce wrinkles.

17. From 2014 to 2017, I was the Vice President of Research and Development Sports Medicine and ENT at Smith & Nephew, following the merger with ArthroCare in June 2014. In this position, I led innovation, research, technology, and product development for the Sports Medicine and ENT Franchises (over $1B business). I oversaw more than 150 people and a $35M+ budget.

18. From 2018 to 2020, I was the President and Chief Executive Officer of PeriphEX Corp. My primary role was launching new products and leading fund-raising activity for an innovative consumer product to address symptoms of Peripheral Neuropathy. The product was developed and launched in 4 months. I participated in setting up production, operations, clinical trials, marketing strategy and drove sales to both health care providers and direct consumers via eCommerce.

19. I have been consulting since 2017, providing technical and strategic support for several medical device companies engaged in various radiofrequency electro-surgical technologies.

20. I served as a member of the MT 17 International Electrotechnical Commission ("IEC") from 2008 until 2018. This organization prepares and publishes international standards for all electrical, electronic, and related technologies – collectively known as "electrotechnology." IEC standards cover a vast range of technologies. The IEC also manages four global conformity assessment systems that certify whether equipment, systems, or components conform to its international standards. The M17 committee is composed of about a dozen world experts in the field of electro-surgery and defines the 60601-2-2 standard for High

Frequency surgical equipment and high frequency surgical accessories. This standard is recognized by almost all countries in the world and defines the safety and other design requirements to which any electrosurgical equipment or accessory needs to comply to be registered and allowed for use in these countries.

21. I am a recognized expert in the medical device industry and most particularly in the field of high frequency surgical systems including those used to remodel the dermal layer.

22. I am one of and/or the first listed inventor on 114 U.S. Patents and over 55 European Patents for medical device technology; most of these patents are related to electrosurgical systems and methods. One of these patents, U.S. Patent No. 6,766,202, which has an earliest filing date of August 30, 1999, relates to systems and methods for intradermal collagen stimulation including using needle electrodes to apply radiofrequency to the dermis. As such, I am familiar with using radiofrequency and needle electrodes on tissue.

B. Preparation of this Report

23. The opinions stated in this report are based on my own personal knowledge, experience, and professional judgment. If called as a witness during the hearing in this matter, I am prepared to testify competently about these opinions.

24. In forming my opinions, I have considered, in addition to my own knowledge and experience: a) The documents and things listed in Appendix B to this report; and b) any other references referred to or cited in this report. Particularly, this report is based on my review of the ‘836, ‘379, ‘444, ‘536, ‘774, and ‘812 Patents, their respective file histories, and parts of the records and documents produced and made available for inspection in this Investigation to date (including the prior art documents discussed herein).

25. A copy of my Biographical Summary, including a listing of all publications I have authored during the past ten years, and all times I have testified as an expert at trial or by deposition within the preceding four years, is attached as Appendix A.

26. I reserve the right to update, supplement, or amend this report in view of additional information obtained through discovery, including expert discovery, or other information that may become available that affects the opinions set forth in this report.

IV. LEGAL UNDERSTANDINGS

27. I am not an attorney; however, I have been informed of several principles of patent law, which principles I used in arriving at my conclusions. In this section I describe my understanding of certain legal standards. I have been informed of these legal standards by Respondents' counsel and have applied my understanding of these legal standards in my analysis as detailed below.

A. Claim Construction

28. I understand that there are certain claim terms in contention and that the Administrative Law Judge ("ALJ") assigned to this Investigation has not yet issued a claim construction regarding these terms. The ITC Staff, Complainant, and Respondents proposed claim constructions, are set forth *infra*, in Section V. I understand that when the ALJ issues claim constructions for these terms, those constructions apply as a matter of law in this Investigation. In the interim, I have applied the different claim constructions proposed by the Staff of the International Trade Commission, Complainant, and Respondents. As to terms that were not construed, I understand that those terms are to be given their plain and ordinary meaning as understood by one of ordinary skill in the art at the time of the claimed invention and in light of the intrinsic evidence, which I understand includes the patent specification and

the prosecution history, including any references cited during prosecution, and including any post-grant proceedings at the Patent Office.

B. Invalidity

29. I understand that invalidity must be proven by clear and convincing evidence, and that is the standard I have used throughout my report. Furthermore, I understand that each patent claim is considered separately for purposes of invalidity.

30. It is my understanding that for purposes of determining invalidity of a patent claim it is necessary to determine the earliest effective filing date of each claim in order to determine what is prior art to each claim and ascertain which statutory text is applicable. I understand that the Leahy Smith America Invents Act ("AIA"), which was signed into law on September 16, 2011, amended the text of the Patent Act. I further understand that the changes to the Patent Act implemented by the AIA took effect on March 16, 2013, and are applicable to applications filed on or after March 16, 2013. I also understand that the changes implemented by the AIA do not apply to applications having an earliest effective filing date before March 16, 2013.

C. Patent Subject Matter Eligibility

31. I understand that patent claims that cover an "abstract idea" are not eligible for patent protection under 35 U.S.C. § 101. I understand that to determine if an alleged invention of a claim is an ineligible abstract idea, two inquiries must be performed. First, it must be determined if the claim is directed to an abstract idea. Second, if it is determined that the claim is directed to an abstract idea, it must be determined if the elements of the claim as a whole contain an inventive concept or meaningful limitation sufficient to transform the claimed abstract idea into a patent-eligible invention. I further understand that merely stating an abstract

idea and adding words that apply that abstract idea is not enough for patent eligibility; nor is limiting the use of an abstract idea to a particular technological environment. *Alice Corp. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2358 (2014). I also understand that claims lacking specificity as to how to achieve claimed results, and merely invoke generic processes and machinery are directed to abstract ideas or natural phenomena. *See Two-Way Media Ltd v. Comcast Cable Communs., LLC*, 874 F.3d 1329, 1337 (Fed. Cir. 2017) ("We look to whether the claims in the patent focus on a specific means or method, or are instead directed to a result or effect that itself is the abstract idea and merely invokes generic processes and machinery."); *Ericsson Inc. v. TCL Commun. Tech. Holdings Ltd.*, 955 F.3d 1317, *20-21 (Fed. Cir. 2020) ("the claims here do not 'ha[ve] the specificity required to transform a claim from one claiming only a result to one claiming a way of achieving it[,]' [and] "[m]erely claiming '… functions in general terms, without limiting them to technical means for performing the functions that are arguably an advance,' does not make a claim eligible at step one."); *Am. Axle & Mfg. v. Neapco Holdings LLC*, 939 F.3d 1355, 1364 (Fed. Cir. 2019) ("[a] patent is not good for an effect, or the result of a certain process, as that would prohibit all other persons from making the same thing by any means whatsoever."); *Am. Axle*, 939 F.3d at 1364-65 ("This distinction between results and means is fundamental to the step 1 eligibility analysis, including in law-of-nature cases, not just abstract-idea cases."). Additionally, it is my understanding that the Federal Circuit has instructed that in a § 101 analysis, the court should identify the "focus of the claimed advance over the prior art." *Affinity Labs of Tex., LLC v. DIRECTV, LLC*, 838 F.3d 1253, 1257 (Fed. Cir. 2016). The court can account for "the key distinguishing feature of the claims" reflected in the "prosecution history and the specification." *OIP Techs., Inc. v. Amazon.com, Inc.*, 788 F.3d 1359, 1363 (Fed. Cir. 2015). It is also my understanding that "[a]s the Supreme Court made

clear in Flook, neither … conventional additions, nor the limiting of the use of a natural law or mathematical formula to a particular process suffices to create patent eligibility." *Am. Axle*, 939 F.3d at 1368. It is also my understanding that "[i]t has been clear since *Alice* that a claimed invention's use of the ineligible concept to which it is directed cannot supply the inventive concept that renders the invention 'significantly more' than that ineligible concept." *See BSG Tech LLC v Buyseasons, Inc.*, 899 F.3d 1281, 1290 (Fed. Cir. 2018); *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743, 754 (Fed. Cir. 2019) ("to supply an inventive concept the sequence of claimed steps must do more than adapt a conventional [technique] to a newly discovered natural law; it must represent an inventive application beyond the discovery of the natural law itself.")

D. Anticipation

32. I understand that a patent claim is invalid as "anticipated" if all the limitations of that claim were present in a single device or method that was previously known of, used, or described in a single printed publication or patent such that a person having ordinary skill in the art, looking at the single reference, could make and use the claimed invention without undue experimentation.

33. I understand that a claim can be anticipated even if all the limitations of that claim are not expressly found in a prior art reference if the missing limitations are inherently present, *i.e.*, if the prior art necessarily functions in accordance with, or includes, the claim limitations. It is acceptable to examine evidence outside the prior art reference (extrinsic evidence) in determining whether a feature, while not expressly discussed in the reference, is necessarily present in it, *i.e.,* inherent.

34. I understand 35 U.S.C. § 102 sets forth bases under which a reference or system may be prior art. I also understand that depending on whether an application is pre-AIA or AIA, the wording of 35 U.S.C. § 102 differs. The wording of pre-AIA and AIA 35 U.S.C. § 102 are recited below.

Pre-AIA 35 U.S.C. § 102

A person shall be entitled to a patent unless —

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or

(c) he has abandoned the invention, or

(d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States, or

(e) the invention was described in — (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language; or

(f) he did not himself invent the subject matter sought to be patented, or

(g) (1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed,

or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

AIA 35 U.S.C. § 102

(a) Novelty; Prior Art.—A person shall be entitled to a patent unless—

(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or
(2) the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

(b) Exceptions.

(1) Disclosures made 1 year or less before the effective filing date of the claimed invention. —A disclosure made 1 year or less before the effective filing date of a claimed invention shall not be prior art to the claimed invention under subsection (a)(1) if—
(A) the disclosure was made by the inventor or joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or
(B) the subject matter disclosed had, before such disclosure, been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor.

E. Obviousness

35. I understand that the types of 35 U.S.C. § 102 prior art described above can individually be a basis for invalidating a patent, or these references can be combined to show a patent is invalid as obvious under 35 U.S.C. § 103.

36. I understand that the fact that a prior art reference may anticipate a patent claim presents no obstacle to relying on that reference as a basis for invalidity based on obviousness.

I have been informed that it is established law that a rejection for obviousness under § 103 can be based on a reference which happens to anticipate the claimed subject matter.

37. I understand that even if a single reference does not contain every limitation of a patent claim, it can still invalidate that claim if it renders the claimed invention obvious when considered by a person having ordinary skill in the art considering other prior art references or devices including the knowledge of those skilled in the art at the time of the alleged invention. If the differences between the claimed invention and the prior art are such that the claimed invention, as a whole, would have been obvious to a person having ordinary skill in the art at the time the invention was made, without the benefit of hindsight, then the claim is invalid.

38. I understand that a patent claim is obvious if, at the time the invention was made, it would have been obvious to one of ordinary skill in the art considering the teachings of the relevant prior art. I understand that the analysis of obviousness involves several factual inquiries including the scope and content of the prior art, the differences between the prior art and the claim, and the level of ordinary skill in the art at the time of the invention.

39. I understand that a reference qualifies as prior art for obviousness purposes when it is analogous to the claimed invention. The test for determining what art is analogous is: (1) whether the art is from the same field of endeavor, regardless of the problem addressed, and (2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved.

40. I understand that the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. In other words, when a claim simply arranges prior art elements with each performing the same function it had been known to perform and yields no more than one would expect from such an

arrangement, then such a combination is obvious. Moreover, when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another that is known in the field, the combination is likely to be obvious unless the combination yields an unpredictable result.

41. I understand that when a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If one of ordinary skill in the art can implement a predictable variation, such a variation is likely unpatentable. For the same reason, if a technique has been used to improve one device, and one of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. One question to consider is whether the improvement is more than the predictable use of prior art elements according to their established functions.

42. I understand that it may often be necessary, in a validity analysis, to look to interrelated teachings of multiple patents; the effects of demands known to the design community (*i.e.*, the goals considered by a typical practitioner in improving a product) or present in the marketplace; and the background knowledge possessed by one of ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.

43. I understand that a finding of obviousness can also be supported by some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

44. I understand that a validity analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim; it is appropriate to take account of the inferences and creative steps that one of ordinary skill in the art would employ. I understand that a person of ordinary skill is also a person of ordinary creativity.

45. I understand that a claim composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the prior art. I understand that it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed invention does. Therefore, I understand that in determining whether a claimed combination is obvious, the correct question is whether the combination was obvious to one of ordinary skill in the art at the time the patent application was filed. I understand that one of the ways in which subject matter can be proved obvious is by noting that there existed at the time of invention a known problem for which there was an obvious solution encompassed by the patent's claims. I understand that any need or problem known in the field of endeavor at the time of alleged invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.

46. I understand that one should not assume that a person of ordinary skill in the art attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem. Instead, I understand that since familiar items may have obvious uses beyond their primary purposes, in many cases one of ordinary skill in the art will be able to fit the teachings of multiple prior art references together like pieces of a puzzle.

47. I understand that, when there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, one of ordinary skill

in the art has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, then it is likely not a product of innovation but of ordinary skill and common sense. I understand that, in such an instance, the fact that the combination was obvious to try may show that the combination is obvious.

48. I understand that, when determining whether a claimed combination is obvious, the correct analysis is not whether one of ordinary skill in the art, writing on a blank slate, would have chosen the particular combination of elements described in the claim. Instead, I understand the correct analysis considers whether one of ordinary skill, facing the wide range of needs created by developments in the field of endeavor, would have seen a benefit to selecting the combination claimed.

F. Secondary Considerations

49. It is my understanding that, in order to rebut a showing of obviousness over the prior art, Serendia may attempt to show "secondary considerations" of non-obviousness, such as, for example, evidence of commercial success of the invention, long-felt but unsolved needs, failure of others, unexpected results, and evidence of industry acquiescence. I am further informed that, to support a finding of non-obviousness, the inventor must generally show a "nexus" between the secondary considerations and the features of the invention as claimed. For example, a secondary consideration such as commercial success is not relevant to non-obviousness unless the evidence shows that the commercial success was attributable to the

merits and features of the claimed invention as opposed to being attributable to features that already existed in the prior art.

G. Priority and Invention

50. As noted, I understand that the priority date is the earliest date to which a patent claim can claim priority and defines what materials are prior art to the patent application. I understand that generally, the date the patent is filed is the priority date; however, a provisional patent application filing date, if any, may be the priority date of a patent based on the provisional filing.

51. Under pre-AIA, the priority date may be the date the invention was conceived and reduced to practice. An invention is conceived when a definite and permanent idea of an operative invention is known. Conception is complete when one of ordinary skill in the art could make the invention without undue research or experimentation.

H. Persons of Ordinary Skill in the Art

52. I understand that the person of ordinary skill in the art ("POSA" or "POSITA") is a hypothetical person who is presumed to have known the relevant art at the time of the invention. Factors that may be considered in determining the level of ordinary skill in the art may include: (a) type of problems encountered in the art; (b) prior art solutions to those problems; (c) rapidity with which innovations are made; (d) sophistication of the technology; and (e) educational level of active workers in the field. In a given case, every factor may not be present, and one or more factors may predominate. I understand that the hypothetical person having ordinary skill in the art to which the claimed subject matter pertains would, of necessity have the capability of understanding the scientific and engineering principles applicable to the pertinent art.

53. I understand that references which do not qualify as prior art because they postdate the claimed invention may be relied upon to show the level of ordinary skill in the art at or around the time the invention was made. I understand that documents not available as prior art, because the documents were not widely disseminated, may be used to demonstrate the level of ordinary skill in the art. For example, a document may be relevant to establishing a motivation to combine which is implicit in the knowledge of one of ordinary skill in the art.

I. Written Description

54. I understand that the claims of a patent are unpatentable under 35 U.S.C. § 112 if the patent specification does not contain adequate written description of the claimed invention. Based on my involvement in the patent applications on which I am a named inventor, I am aware that in the patent application process, the Applicant may keep the originally filed claims, or change the claims between the time the patent application is first filed and the issuance of a patent. An Applicant may amend the claims or add new claims during prosecution but the written description requirement ensures that the issued claims correspond to the scope of the written description as provided in the original application.

55. I also understand that the written description requirement is satisfied if a POSITA reading the original patent application would have recognized that it describes the full scope of the claimed invention as it is finally claimed in the issued patent and that the inventor actually possessed that full scope by the filing date of the original application. The written description requirement may be satisfied by a combination of the words, figures and formulae contained in the patent application. The full scope of a claim or any particular requirement in a claim, need not

be expressly disclosed in the original patent application if a POSITA would have understood that the full scope is in the written description in the as-filed patent application.

J. Enablement

56. It is my further understanding that a patent claim is invalid under 35 U.S.C. § 112 for lack of enablement if the specification does not contain a sufficiently full and clear description of how to make and use the full scope of the claimed invention. To be enabling, the patent must permit a POSITA to make and use the full scope of the claimed invention at the time of original filing without having to conduct undue experimentation. In deciding whether a POSITA would have to experiment unduly in order to make and use the invention, I understand several factors, so-called *Wands* factors, may be considered including: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *In re Wands*, 858 F.2d 731, 736–37 (Fed. Cir. 1988). I understand that no one or more of these factors alone is dispositive. Rather, whether the degree of experimentation required is undue requires weighing these factors in the context of the claimed invention and the state of the art at the time of the original application. I also understand that analysis of the *Wands* factors is not mandatory.

57. Furthermore, it is my understanding that the Supreme Court has explained that "if a patent claims an entire class of processes, machines, manufactures, or compositions of matter, the patent's specification must enable a person skilled in the art to make and use the entire class. In other words, the specification must enable the full scope of the invention as

defined by its claims. The more one claims, the more one must enable." *Amgen, Inc. v. Sanofi*, 598 U.S. 594 (2023).

K. Indefiniteness

58. It is my understanding that patent claims are indefinite under pre-AIA 35 U.S.C. § 112, ¶ 2 or AIA 35 U.S.C. § 112(b), when they "fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 989, 901 (2014).

59. I further understand that patent claims are invalid under pre-AIA 35 U.S.C. § 112, ¶ 6 or AIA 35 U.S.C. § 112(f) for failing to adequately describe claimed structure that corresponds to the claimed function(s). Under pre-AIA § 112 ¶ 6 or AIA § 112(f), a patentee may draft claims "as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof." *Rain Computing, Inc. v. Samsung Elecs. Am., Inc.*, 989 F.3d 1002, 1005 (Fed. Cir. 2021). But such claims are construed to cover only "the structure, materials, or acts described in the specification as corresponding to the claimed function and equivalents thereof." *Id.* To "determine whether §112 ¶ 6 applies to a claim limitation, [courts] inquire [into] whether the words of the claim are understood by persons of ordinary skill in the art to have a sufficiently definite meaning as the name for structure." *Id.* If those words lack a sufficiently definite meaning, pre-AIA § 112 ¶ 6 or AIA § 112(f) applies.

L. Unenforceability of a Patent

60. I understand that inequitable conduct is an equitable defense to patent infringement that, if proven, bars enforcement of a patent. I also understand that a finding of inequitable conduct as to any single claim of a patent renders that entire patent unenforceable and may render unenforceable other related patents and applications in the same technology family.

61. I understand that inequitable conduct occurs when a patentee breaches his or her duty to the U.S. Patent and Trademark Office ("USPTO") of candor, good faith, and honesty. I understand that a party, including, for example, an applicant, an inventor, or the prosecuting attorney appearing before the USPTO, has a duty to disclose all information known to that individual to be material to patentability.

62. I understand that a party seeking to prove inequitable conduct must show that the patent applicant made misrepresentations or omissions material to patentability, and that he/she did so with the specific intent to mislead or deceive the USPTO, and that deceptive intent was the single most reasonable inference to be drawn from the evidence. I understand that a party can prove the element of materiality by showing that the patentee withheld or misrepresented information that, in the absence of the withholding or misrepresentation, would have prevented a patent claim from issuing. I understand that the specific intent to commit acts constituting inequitable conduct may be inferred from indirect and circumstantial evidence, but deceptive intent must be the single most reasonable inference drawn from the evidence.

63. I understand that prior art is material if there is a substantial likelihood that a reasonable Patent examiner would consider it important in deciding whether to allow the application to issue as a patent. In evaluating materiality, I understand this Court may refer to the definition provided in 37 C.F.R. § 1.56, by which the USPTO promulgated the duty of disclosure.

64. I understand that 37 C.F.R. § 1.56 states, in part:

> (a) … Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned.

> Information material to the patentability of a claim that is cancelled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:
>
> (1) Prior art cited in search reports of a foreign patent office in a counterpart application, and
>
> (2) The closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.
>
> (b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and
>
> (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
>
> (2) It refutes, or is inconsistent with, a position the applicant takes in:
>
> (i) Opposing an argument of unpatentability relied on by the Office, or
>
> (ii) Asserting an argument of patentability.
>
> A *prima facie* case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

65. I further understand that the duty of disclosure includes bringing to the USPTO's attention "any material prior art or other information cited or brought to [the attention of any individual associated with the filing or prosecution of a patent] in any related foreign application."

M.P.E.P. § 2001.06(a). I have been informed that "[t]he inference that such prior art or other information is material is especially strong where it has been used in rejecting the same or similar claims in the foreign application or where it has been identified in some manner as particularly relevant." *Id.*

V. CLAIM CONSTRUCTION

66. It is my understanding that the ALJ has yet to issue her claim construction. I understand that the Staff of the International Trade Commission, Complainant, and Respondents have agreed on the claim construction of the following terms and that I should apply these constructions in forming my opinion.

Agreed Terms for the '836, '379, and '444 Patents			
Term	**Claim(s)**	**Proposed by**	**Agreed Construction**
836 / 379 / 444 Preambles	836 Patent, claims 1, 14; 379 Patent, claims 1; 444 Patent, claims 1	Complainant	Preambles are limiting.
"configured to"	836 Patent, claims 1, 2, 14; 379 Patent, claims 1, 2; 444 Patent, claims 1, 2	Staff	Plain and ordinary meaning: adapted to
"radio frequency (RF) generation module"	836 Patent, claims 1, 2; 379 Patent, claims 1, 2; 444 Patent, claims 1, 2	Staff	Plain and ordinary meaning: a device that generates electrical signal(s) having a radio frequency

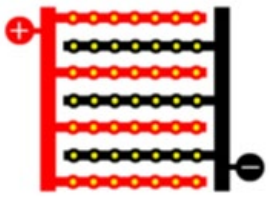
Agreed Terms for the '836, '379, and '444 Patents			
Term	**Claim(s)**	**Proposed by**	**Agreed Construction**
"nearest electrodes"	444 Patent, claim 1	Respondents	Plain and ordinary meaning: the closest neighboring electrodes
"electrodes configured to cause coagulation around each electrode rather than coagulating between the electrodes"	836 Patent, claims 1, 14	Staff	Plain and ordinary meaning: two or more electrodes adapted to cause coagulation around each electrode without such coagulation fully extending from one electrode to another electrode
"apply energy to body segments around each electrode rather than to body segments between the electrodes"	379 Patent, claim 1	Staff Respondents	Plain and ordinary meaning: energy application occurs around each electrode without such energy application fully extending from one electrode to another electrode (*i.e.*, the energy application must be configured such that energy application between electrodes does not extend continuously between the electrodes)
"electrodes being bipolar"; "electrodes are bipolar"	836 Patent, claims 1, 14; 379 Patent, claim 1; 444 Patent, claim 4	Respondents	Plain and ordinary meaning, 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)
"an RF signal"	444 Patent, claim 2	Staff	"an RF signal" in claim 2 of the 444 Patent refers to the same "RF signal with oscillating current" in claim 1 of the '444 Patent

Agreed Terms for the '536, '774, and '812 Patents			
Term	**Claim(s)**	**Proposed by**	**Agreed Construction**
536 / 774 / 812 preambles.	536 Patent, claims 1, 11; 774 Patent, claim 11; 812 Patent, claims 1, 12	Complainant Staff Respondents	Preambles are limiting
"extendable needles" vs. "extended needles" / "needles one of extending or extendable"	536 Patent, claim 1, 9, 11; 774 Patent, claim 11	Staff	Plain and ordinary meanings: extendable needles: needles that can be extended [from the deployable needle assembly end surface] extended needles: needles that are extended [from the deployable needle assembly end surface] needles one of extending or extendable: needles that are either extended or can be extended [from the device surface] (needles "extending" a desired distance from the surface covers non-extendable needles having a fixed length; "extendable" needles covers needles which are not fixed)
"a plurality of needles one of extending or extendable . . . the plurality of extended needles"	774 Patent, claim 11	Staff	Plain and ordinary meaning: two or more extendable needles or extending needles . . . the two or more extended needles
"a user holdable device releasably couplable deployable needle module end surface"	812 Patent, claim 1	Respondents	Plain and ordinary meaning: the end surface of the deployable needle module past which needles can be extended, the module is releasably couplable to a user holdable device proximal end

Agreed Terms for the '536, '774, and '812 Patents			
Term	**Claim(s)**	**Proposed by**	**Agreed Construction**
"a particular signal"	536 Patent, claim 11; 812 Patent, claim 13	Staff	Plain and ordinary meaning: an electrical motor control signal
"predetermined intensity"	536 Patent, claim 9; 812 Patent, claim 6	Staff	Plain and ordinary meaning: the electrical signal intensity selected for treatment

67. I understand that the terms that follow are at dispute, that the Staff of the International Trade Commission, Complainant, and Respondents propose the following constructions, and that I should consider each construction in formulating my opinions.

Disputed Terms for the '836, '379, and '444 Patents					
Term	**Claim(s)**	**Proposed by**	**Serendia's Construction**	**Respondents' Construction**	**Staff's Construction**
"plurality of electrodes"	836 Patent, claims 1, 2, 5, 9, 11, 12, 13, 14, 17, and 22; 379 Patent, 1, 2, 5, 7, 8, and 9; 444 Patent, 1, 2, 4, 5, 6, 7, 8, and 9	Respondents	Plain and ordinary meaning, which is two or more electrodes (which can be needles or pins).	Plurality of non-insulated electrodes.	two or more electrodes/needles/pins
"a plurality of electrodes, the electrodes being	836 Patent, claims 1, 14;	Respondents	*See* Serendia's proposed construction for "plurality of	*See* Respondents' construction for "plurality	*See* Staff's proposed construction for "plurality of electrodes" term and

Disputed Terms for the '836, '379, and '444 Patents					
Term	**Claim(s)**	**Proposed by**	**Serendia's Construction**	**Respondents' Construction**	**Staff's Construction**
bipolar"/ "a plurality of electrodes . . . the electrodes are bipolar"	379 Patent, claim 1; 444 Patent, claim 4		electrodes" and agreed-upon construction for bipolar electrodes terms	of electrodes" and agreed-upon construction for bipolar electrodes terms and excludes devices having rows of electrodes that are all positive or all negative polarity	agreed-upon construction for the bipolar electrodes terms; disclaimer as to INTRAcel configuration (alternating rows of commonly-polarized electrodes): 
"[a/an] Alternating Current (AC) [RF/Radio Frequency (RF)] signal" "an RF signal with oscillating current";	836 Patent, claims 1, 2, 14; 379 Patent, claims 1, 2; 444 Patent, claim 1	Staff Respondents	Plain and ordinary meaning: an electrical signal with oscillating current (current alternating polarities), and having a radio frequency (measured in MHz) *(same as Staff's construction)*	A signal combining an AC frequency rate and an RF frequency rate.	Plain and ordinary meaning: an electrical signal with oscillating current (current alternating polarities), and having a radio frequency (measured in MHz)
"…[causes/to cause] energy to be substantially applied to body segments around each electrode"	444 Patent, claims 1	Staff Respondents	Plain and ordinary meaning, [causes/to cause] energy to be substantially applied to body segments around each electrode (as	"substantially applied" renders the claims indefinite.	Indefinite (re "energy to be **substantially** applied")

Disputed Terms for the '836, '379, and '444 Patents					
Term	**Claim(s)**	**Proposed by**	**Serendia's Construction**	**Respondents' Construction**	**Staff's Construction**
			opposed to, *e.g.*, between the electrodes).		

Disputed Terms for the '536, '774, and '812 Patents					
Term	**Claim(s)**	**Proposed by**	**Serendia's Construction**	**Respondents' Construction**	**Staff's Construction**
"a user holdable device releasably couplable deployable needle assembly end surface" / "the releasably couplable deployable needle assembly end surface"	536 Patent, claims 1, 11; 812 Patent, claims 1, 12	Respondents	the deployable needle assembly end surface is the plane defined by the tips of the needles of the deployable needle assembly when the needles are not extended, the needle assembly can be movable within a needle module that is releasably couplable to the proximal end of a user holdable device *(same as Staff's construction)*	the end surface of a [user holdable device] deployable needle assembly from which the plurality of needles protrude, wherein the deployable needle assembly is releasably couplable to a [user holdable device] proximal end	The deployable needle assembly end surface is the plane defined by the tips of the needles of the deployable needle assembly when the needles are not extended, the needle assembly can be movable within a needle module that is releasably couplable to the proximal end of a user holdable device
"separatably"	536 Patent, claims 1, 11; 812 Patent, claims 1, 12	Complainant Staff	separable *(same as Staff's construction)*	Indefinite.	should be interpreted as "separable"

Disputed Terms for the '536, '774, and '812 Patents					
Term	**Claim(s)**	**Proposed by**	**Serendia's Construction**	**Respondents' Construction**	**Staff's Construction**
"draft shaft"	536 Patent, claim 13	Complainant Staff	drive shaft *(same as Staff's construction)*	Indefinite.	should be interpretated as "drive shaft"
"the deployable needle assembly mechanically separatably from the proximal end"	536 Patent, claims 1, 11	Respondents	the deployable needle assembly is mechanically separable from the proximal end of the user holdable device (the deployable needle assembly can be within a needle module that mechanically separates from the proximal end of the user holdable device) *(same as Staff's construction)*	Indefinite due to "separatably." To the extent the term is not held to be indefinite, the term should be construed as follows: the needle assembly has mechanical elements for coupling the needle assembly to and decoupling the needle assembly from the proximal end.	the deployable needle assembly is mechanically separable from the proximal end of the user holdable device (the deployable needle assembly can be within a needle module that mechanically separates from the proximal end of the user holdable device)
"energiz[e/ing] the plurality of extended needles"	536 Patent, claims 1, 9	Staff	This step [d], "energizing the plurality of extended needles," must be performed last. The claimed step [b], "communicating electrical signals from the proximal end to the plurality of the extendable needles," cannot occur after step [d] but otherwise may occur at any point	This step in the method must be performed last, and step [b] must be performed before steps [c]-[d]. *(same as Staff's construction)*	This step in the method must be performed last, and step [b] must be performed before steps [c]-[d].

Disputed Terms for the '536, '774, and '812 Patents					
Term	**Claim(s)**	**Proposed by**	**Serendia's Construction**	**Respondents' Construction**	**Staff's Construction**
			in the claimed process.		
"pulsed radio frequency signals"	774 Patent, claim 11	Staff Respondents	Plain meaning and ordinary meaning: radio frequency signals that are normally off and suddenly on for a period of time (*i.e.*, a rapid, transient change from a baseline to a different amplitude, followed by rapid return to baseline) *(same as Staff's construction)*	"a radio frequency signal that is normally off with an amplitude of zero and is suddenly on with a constant amplitude for a brief portion of time"	Plain meaning and ordinary meaning: radio frequency signals that are normally off and suddenly on for a period of time (*i.e.*, a rapid, transient change from a baseline to a different amplitude, followed by rapid return to baseline)
"mechanism for causing the plurality of the extendable needles to extend a desired distance from the end surface"	774 Patent, claim 13	Rohrer Respondents	This term is subject to 35 U.S.C. § 112(6) **Recited Function**: causing the plurality of the extendable needles to extend a desired distance from the end surface. **Corresponding Structures:**[1] A motor and LED module 922, depicted in Figs. 9A, 9C-D, 10A-E; and described at col. 13 lines 15-20,	This term is subject to 35 U.S.C. § 112(6) **Recited Function**: causing the plurality of the extendable needles to extend a desired distance from the end surface. **Corresponding Structure:** A motor as described at col. 14, lines 3-11; col. 10,	This term is subject to 35 U.S.C. § 112(6) **Recited Function**: causing the plurality of the extendable needles to extend a desired distance from the end surface. **Corresponding Structures**: A motor and LED module 922, depicted in Figs. 9A, 9C-D,

[1] Citations are to the '774 Patent.

Disputed Terms for the '536, '774, and '812 Patents					
Term	**Claim(s)**	**Proposed by**	**Serendia's Construction**	**Respondents' Construction**	**Staff's Construction**
			22-26; col. 14 lines 14-20, 29-34; or A needle deployment motor controller (NDMC) module 911B, depicted in Fig. 9B; and described at col. 10 lines 31-36, 51-55; or One or more motors 922A, depicted in Figs. 9C-D; and described at col. 10 lines 36-39, 55-59; col. 11 lines 57-60; col. 14 lines 3-11, 24-26; or One or more drive shafts 922C, depicted in Figs. 9C-D and 10A-E; and described at col. 11 lines 23-27, 53-57. And equivalents thereof. *(same as Staff's construction)*	lines 36-39; col. 14, lines 24-26. Or, in the alternative One or more motors, one or more drive shafts, and a motor controller (NDMC) module operating in concert as described at col. 10, lines 31-39, 51-59; col. 11, lines 23-27, 53-60; col. 13, lines 15-26; col. 14, lines 3-11, 14-34. And equivalents thereof under 35 U.S.C. § 112(6).	10A-E; and described at col. 13 lines 15-20, 22-26; col. 14 lines 14-20, 29-34; or A needle deployment motor controller (NDMC) module 911B, depicted in Fig. 9B; and described at col. 10 lines 31-36, 51-55; or One or more motors 922A, depicted in Figs. 9C-D; and described at col. 10 lines 36-39, 55-59; col. 11 lines 57-60; col. 14 lines 3-11, 24-26; or One or more drive shafts 922C, depicted in Figs. 9C-D and 10A-E; and described at col. 11 lines 23-27, 53-57. And equivalents thereof.

68. In interpreting the Asserted Patents, I have applied the constructions set forth in the tables above. For terms where alternate claim constructions are provided, I have applied these alternate claim constructions. For terms not construed, I have applied the plain and ordinary meaning as understood by one of ordinary skill in the art at the time of the claimed invention, in light of the intrinsic evidence, which I understand includes the patent specification and the prosecution history, including any prior art cited during the prosecution.

VI. LEVEL OF ORDINARY SKILL IN THE ART

69. In its Validity Contentions, Serendia asserts that the level of ordinary skill in the art for the Asserted Patents is someone who, as of the earliest effective filing date, typically has "(1) 7-10 years of experience with developing and/or using treatment systems for delivery of electromagnetic radiation energy to skin or other tissues, and (2) a related graduate engineering degree or M.D. and may have worked as part of a multidisciplinary team and drawn upon not only his or her own skills, but also taken advantage of certain specialized skills of others on the team when solving a technical problem." *See* Serendia's Validity Positions at 7-9. It is my understanding that Serendia bases this level of ordinary skill in the art on Patent Trial and Appeal Board decisions in the *inter partes* reviews of the '536, '774, '812, '836, and '379 Patents. *Id.*

70. It is my opinion that a POSITA in the field of the '836, '379, and '444 Patents at the time of the earliest effective priority date would have had (a) 7-10 years of experience with design and/or development electrosurgical systems for cosmetic or plastic surgical applications or any other medical applications, and (b) an engineering graduate degree and possibly also a M.D. As noted above, Serendia asserts that the '836, '379, and '444 Patents are entitled to a priority date of June 14, 2011. *Id.* As noted below, it is my belief that the '836, '379, and '444

Patents are not entitled to claim a priority date earlier than September 23, 2013, which is the date on which the application that issued as the '836 Patent was filed under 35 U.S.C. § 371. I believe the same level of ordinary skill would be applicable to either priority date.

71. It is also my opinion that a POSITA in the field of the '536, '774, and '812 Patents at the time of the earliest effective priority date would have had (a) 7-10 years of experience with design and/or development electrosurgical systems for cosmetic or plastic surgical applications or any other medical applications, and (b) an engineering graduate degree and possibly also a M.D. As noted above, Serendia asserts that the '536, '774, and '812 Patents are entitled to a priority date of March 15, 2010. It is my understanding that the Respondents assert that the '536, '774, and '812 Patents are not entitled to a priority date earlier than March 3, 2011. I believe the same level of ordinary skill would be applicable at either of these priority dates.

VII. TECHNOLOGY BACKGROUND

A. Overview of RF technology in medicine and its applications in dermatology

72. The Asserted Patents are generally directed to applying a radiofrequency signal to microneedle electrodes in the dermis to reduce wrinkles. As noted above, I was working on similar technology in 1999, more than a decade before Dr. Na. Generally, this technology involves inserting microneedle electrodes into the dermis layer and then applying radiofrequency current causing constriction and tightening of the skin and stimulating production of collagen as well as elastin. The technology relies partially on the heat generated by a radiofrequency current to coagulate tissue around the microneedle electrodes. Coagulation first occurs around the microneedle electrodes, where the current density is higher and

accordingly the heat is generated faster, and then spreads out, where the current density is lower and accordingly less heat is generated.

73. The use of electrical impulses and electrical discharges in surgical procedures has a long history dating back to the late 19th century. D'Arsonval applied high frequency electrical impulses to animals and noted that above about 10,000 Hz the neuromuscular response observed at lower frequencies was diminished significantly. Doyen treated skin blemishes with a spark-gap generator in 1909. Direct heating of tissue (endothermy) using high frequency radiofrequency (RF) energy was described by Wyeth in 1923. In the late 1920's, physician Harvey Cushing and physicist William Bovie developed an electrosurgical device and power source that eventually became a standard of care for cauterizing, cutting or desiccating tissue. In 1932, Ward described the history as well as some surgical applications following Cushing and Bovie's original work. RF ablation is the modern term for treating tissue by heating it with RF energy but does not usually involve physically cutting (resecting) or removing any volume of tissue; it usually generates sufficient heat to alter the tissue normal physiological function, and the "ablation" is a functional ablation. More recent histories and principles of electrosurgery have been compiled by Pollack *et al.* (2000), Smith and Smith (2001), and Malis (2006). Bovies, as devices using Cushing and Bovie's original ideas have become to be known, usually operate in a so-called monopolar mode, where the active electrode in the hand-held device is positioned above the target site on the tissue, and a spark discharge is drawn to the tissue. The electrical current flowing through the active electrode and the spark connects to the tissue and flows through the patient to a return electrode pad, usually placed on the back or thighs of the patient through a conducting adhesive gel, and then flows back to the power supply that generates the RF waveform. Bovies operating in an air environment can

produce very high temperature arcs, in local thermodynamic equilibrium (LTE) with the plume of ablating tissue char. Peak temperatures of about 2000°K (1,727°C) have been reported by Woloszko *et al.* in 2003. Due to the open-air environment with other potentially flammable gases present in ENT (Otorhinolaryngology, also called Ear, Nose, Throat) procedures in particular, precautions against airway fires need to be implemented[2] .

74. The principles of electro-surgery as described by Bovie in the 1920s were rapidly adopted in medicine, and since the second half of the twentieth century, such a system is used for almost any open surgical procedure. Most of these systems operate at frequencies around 460-485 kHz.

75. In 1995, Thapliyal and Eggers described a novel technology called Coblation, using RF current within a conductive liquid media (saline solution), that creates a glow discharge plasma. The plasma contains high energy very reactive particles that interact with tissue by breaking down the molecule, generating a volumetric removal (ablation) of tissue. This technology is widely used in arthroscopic surgery, ENT surgery, spine surgery, and cosmetic surgery. In 2001, Tasto and Amiel demonstrated that application of such RF energy, even at very low power, generates tissue healing, with creation of new blood vessels and new collagen. Tasto has shown in an animal study[3] that RF mediated plasma surgical treatment of healthy tendons could stimulate an angiogenic healing response. This was demonstrated by direct histology evidence of neovascular formation and through the expression of various histochemical analyses and the significant elevation of several growth factors like vascular

[2] Smith TL, Smith JM. Electrosurgery in otolaryngology-head and neck surgery: principles, advances, and complications. *Laryngoscope*. 2001 May;111(5):769-80.
[3] Tasto J. P., Cummings J., Medlock V., Harwood F., Hardesty R., and Amiel D. "The tendon treatment center: New horizons in the treatment of Tendinosis" *Arthroscopy* 19 (S1), 213-223 (2003).

endothelial growth factor (VEGF) and αv integrin 9, 28 days after treatment. This was accompanied by an increase in the size of the tendon. Various other studies have shown that plasma surgical systems can improve tissue healing by acting at various phases (hemostasis, inflammation, proliferation and remodeling) of the healing cascade: RF mediated plasma induces a controlled injury [4]; this is followed by the release of specific substances like cytokines or Heat Shock Protein35 (HSP70) demonstrating this controlled inflammation.

76. In the 1980s, other applications of RF energy in medicine, including the notion of RF ablation, was developed. The term ablation comes from the Latin "ablationem," which means "taking away;" its original meaning in medicine was to surgically remove a body part, but this has been extended to also include destruction of the function of a body part. Instead of using an electrode generating a high temperature arc to burn and remove tissue (similar to the pyrolytic effect used in self-cleaning ovens), RF was used to increase tissue temperature in a more controlled fashion by passing current between electrodes that made good contact with tissue. The term "RF ablation" is actually misleading and has been a very unfortunate choice. Most of the time tissue is not physically "ablated", resected or "removed", but simply heated or denatured. In some cases, the treated tissue is removed secondarily by the body's own immune system and replaced by new tissue. RF ablation is common and was first described in the 1990s. RF ablation is commonly used to treat cardiac arrhythmia, cancers of the kidney, liver, vertebral body, and other tissue. In some cases, the amount of tissue ablated, denatured or

[4] Vangsness Jr. C. T. *et al.*, "Radiofrequency thermal effects on the human meniscus: an in vitro analysis," *Arthroscopy* 18(5), 492-495 (2002); O'Neill C. W. *et al.*, "Percutaneous plasma decompression alters cytokine expression in injured porcine intervertebral discs," Spine J. 4(1), 88-98 (2004); Rhyu K. W. *et al.* "The short-term effects of electrosurgical ablation on proinflammatory mediator production by intervertebral disc cells in tissue culture," *Spine J.* 7(4), 451-458 (2007); Shimamoto N. *et al.*, "The healing process of back muscle injury: a comparative study of coblation electrosurgery and conventional electrosurgery," *The Spine Journal 2* (S1), 43 (2002).

coagulated is minimal or almost null, but the RF field has some healing effects on tissue. This was described in 1998 to generate new blood vessels in the myocardium (heart) in patients with heart failure, and then in tendons by Tasto *et al.* in 2002 (U. S. Patent No. 6,763,836 B2). Healing responses simply due to the RF field with no visible ablation has also been described (and also observed but unpublished by the author of this report). In the late 1990s, wrinkle reduction was done with an aggressive resurfacing laser employing RF technologies that required removing (ablating) a significant amount of the epidermis and therefore required a significant amount of "downtime" to allow for the epidermis and dermis to heal. More recently, wrinkle removal techniques using RF current have been described, that do not require any resection of the dermis or epidermis tissue and have minimum thermal effects. The electrosurgical technologies that cut or resect operate by creating a very hot arc discharge plasma that removes tissue through a pyrolytic effect, or through a low temperature glow discharge plasma that breaks down tissue molecules through a chemical effect (Stalder , 2001)[5], (Woloszko *et al.* 2002)[6], (Stalder *et al.* 2004)[7]; these technologies use a relatively high voltage, usually over 100V and up to several thousands of Volts. In contrast, the RF applications that generate heat only through Joule heating, whether they coagulate, ablate or only heat up tissue, use a lower voltage, usually below 120 Volts. In this report, to prevent any confusion regarding the notion of ablation, the term of "low voltage RF applications" is used to describe any RF

[5] Stalder KR, Woloszko J, Brown IG, Smith CD "Repetitive plasma discharges in saline solutions" *Applied Physics Letters* 2001, 79(27): 4503-4505.
6 Woloszko J, Stalder K,. R and Brown I. G. "Plasma Characteristics of Repetitively-Pulsed Electrical Discharges in Saline Solutions Used for Surgical Procedures" *IEEE Trans. On Plasma Sciences*, 30(3), June 2002, 1376-1383.
7 Stalder Kenneth R, McMillen Donald F and Woloszko Jean. "Electrosurgical plasmas" J. *Phys. D: Appl. Phys. 3*8 (2005) 1728–1738.

technology that generates tissue local temperature elevation without any (significant) tissue resection ("volumetric ablation"), whether or not any functional ablation is performed.

77. Moritz and Henrique described the effects of temperature elevation in skin tissue in 1947 and showed that the effect of heat in tissue depends on both the temperature and duration of exposure. Cell death can occur at temperatures as low as 50°C (42°C for brain cells) when exposed for a relatively long time. This process will accelerate as the temperature increases. At temperatures over 60°C, proteins in tissue change their structure and become more dense and less viscous. This is called "coagulation" and is similar to what is observed when boiling an egg. This is different than blood coagulation that also includes a more complex clot formation as a result of the hemostasis phenomenon. The exact temperature of coagulation varies slightly depending on the type of protein. For example, eggs can be cooked at precisely 63°C for 40-45 minutes, to the point at which the egg white is just cooked, but the yolk is still deliciously creamy and runny. The white is coagulated, while the yolk is not as they have a different molecular structure. Clinical applications of low voltage RF have grown since the 1990s and this technique is now widely used in cardiology to destroy dysfunctional myocardial cells that induce arrhythmia (such as atrial fibrillation), oncology to destroy tumors in the spine, kidney, and liver. RF ablation is also used in minimally invasive fashion, to destroy neural pathways near the spinal cord (rhizotomy) to stop some abnormal movements or reduce pain, or stop chronic runny nose symptoms, or to alter tissue or tissue function in other areas of the body. Most of the medical RF systems operate at frequencies around 460-480 kHz, but several companies have developed higher frequency systems (since the 1990s) to reduce effects on nerve stimulation or pain for surgeries such as neurosurgery or treatment of the skin.

78. It has to be noted that the way current propagates through tissue (impedance) varies greatly with the frequency of the RF signal. Impedance (resistance to the passage of current and resulting heat dissipation) decreases significantly when the frequency increases. All tissue types also have a different impedance. In 1996, Gabriel published an extensive list of various human tissue impedance (including skin) over a very broad frequency range.[8] The choice of frequency for a given electrosurgical application depends on several parameters. Lower frequencies have more risks of neuromuscular stimulation; however, because tissue has a higher impedance at lower frequencies, one can apply higher voltage while reducing the amount of current passing through tissue. This is a particularly good idea for applications in which an arc has to be formed such as monopolar electro cautery. The arc allows generation of very high temperatures while minimizing the amount of current passing through tissue, and therefore the "thermal margin" or zone of thermal damage around the treated area. Such electrosurgical systems usually operate between 250 and 590 kHz. For applications in which it is desired to heat up or coagulate a certain volume of tissue, one of the critical factors is the amount of energy dissipated into the tissue. The energy "E" is equal to the instantaneous power "P" multiplied by the time "t" of application ($E = P.t$). The power itself increases with the impedance "Z" and the square of the current intensity "I" . $P = Z.I^2$ and the current is also given by the Ohm's law: $I = U/R$. This means that when using a lower impedance, the current is higher with a similar voltage, and therefore a lower voltage can be used to dissipate the same amount of energy. Higher voltage increases the risk of generating an arc if contact quality is not very good or when using small electrodes with sharp edges. This usually does not play a significant role unless electrodes are so small and/or edges so sharp that the risk of generating

[8] S Gabriely, R W Lau and C Gabriel, The dielectric properties of biological tissues: II. Measurements in the frequency range 10 Hz to 20 GHz *Phys. Med. Biol.* 41 (1996) 2251–2269.

microarcs is significant. As an example, if the goal is to dissipate 1 Joule in 1 second, you need to dissipate a power of 1 Watt. If the circuit impedance is 100 Ohms, a voltage of 10 Volts will provide 1 watt; however, if the impedance is 200 Ohms, the voltage needs to be 14 Volts, and 22.5 Volts for 500 Ohms. Skin impedance decreases the most between 10 kHz and 200 kHz, by almost a factor of 1,000 (Gabriel, 1996), but over that frequency and up to 10 MHz, it only increases by a factor of about 2. Therefore, the risk of arcing is usually not a significant factor for frequencies over 200-500 kHz, and several other design considerations are taken into account when selecting the operating frequency.

79. When higher temperatures (usually over 60°C) are applied for longer periods of time, a more radical change in the proteins or collagen structure will take place, leading to contraction or shrinkage of tissue. This phenomenon is similar to what is observed when washing a wool sweater at too high of a temperature. This RF "shrinkage" technique has been used by companies such as Oratec, to shorten ligaments, tendons, articular capsules, or intervertebral discs in the spinal cord, as well as by companies such as Thermage Corp. in the 1990's to tighten the skin. It has to be noted that this shrinking phenomenon also weakens tissue, but the application of RF, as noted above, will lead to a secondary remodeling and healing of tissue. This is the mechanism that is used to reduce wrinkles and improve skin condition.

80. Standard electrosurgery for cutting and hemostasis of tissue only operates in a monopolar fashion. The handheld device is connected to one pole of a generator, while the other pole is connected to a neutral large electrode applied to the skin of the patient. In this configuration, the whole patient body is considered to have a potential equal to the neutral electrode, and a spark is formed when the active electrode is placed in close proximity or in

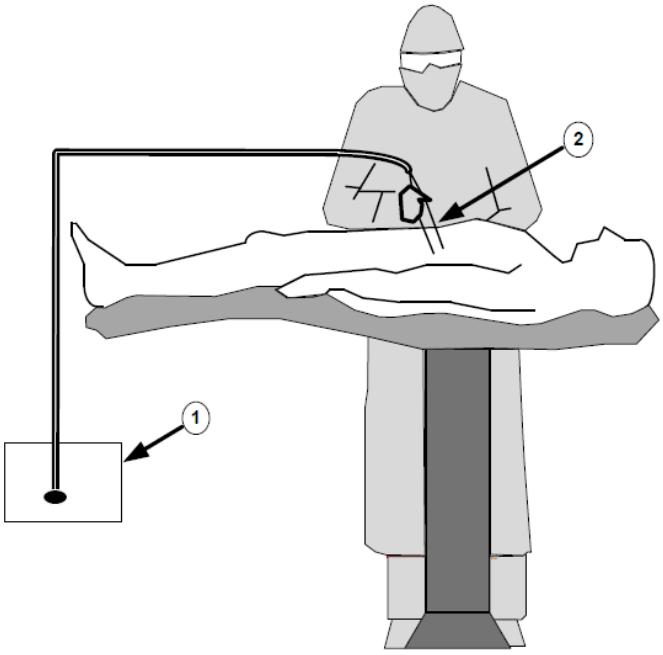
contact with any part of the body. There is one exception to this: the Hyfrecator system commercialized by Conmed for many years. It is a low power electrosurgical unit that uses patient's body capacitance to earth instead of a neutral electrode.

81. There is no polarity in an RF generator. Radio Frequency generators produce a voltage that oscillates around "0", such that each "pole" is alternatively of negative and positive polarity. The "positive" and "negative" phases don't have to be similar or even have the same shape as long as the amount of charges (measured by the surface area of the current waveform) is identical for both phase. For example, if the system delivers a single short pulse of one polarity, the opposite phase can be a long pulse with a very low current. Having an actual imbalance between the two poles, or "offset", in which the amount of charge emitted by each electrode is not balanced with a zero mean value can be harmful and is not allowed to be used in the US, Europe, China, Japan, most of Asia, and all other countries governed by the International Electrotechnical Commission (IEC) standards. Also, the output of these generators needs to be "floating", meaning isolated from earth for safety reasons; this means that the neutral electrode in a monopolar system should never be the "earth ground", but a floating pole isolated from ground. A POSITA has to be familiar with IEC 60601-2-2 as this international standard dictates how an RF or High Frequency generator has to be designed in order to be registered for use in most countries.

82. As a consequence of the above, all RF generators are designed as bipolar, meaning that there are at least two poles for the output. However, these RF generators can be used in monopolar or bipolar systems. Traditionally, the distinction between "bipolar" and "monopolar" electrosurgery had to do with how far apart the electrodes are on the human body. The earliest forms, like John Marshall in 1926, used needles held close together that had

opposite voltage potentials, *i.e*., bipolar pairs of needles. Both needles switched from positive to negative voltages, and therefore positive (+) to negative (-) currents, but did so at different times, with one rising while the other fell. Here positive and negative are arbitrary designators. One could equally refer to these as currents A and B, red and black, etc. Over the past 50 years, the terms "Mono" and "Bi-polar" for electrosurgery have been very well defined in the industry and the definition has no ambiguity for a POSITA. These terms are also defined by the IEC standard (and FDA).

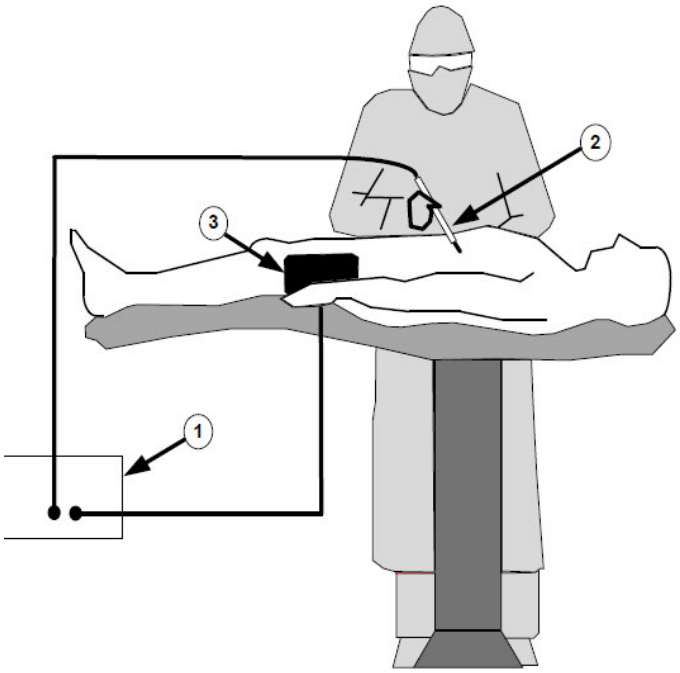
83. Bipolar is defined as a method of applying high frequency output current to a patient via multiple poles between two or more active electrodes without the need for a separately connected neutral electrode (or the need to use the patient's body capacitance to earth) in which an effect is intended in tissue near one or more active electrodes. A visual representation is shown in the figure below.



The bipolar method includes devices energizing pairs of active electrodes as well as devices

energizing groups of active electrodes where the high current source and return may have different numbers of electrodes.

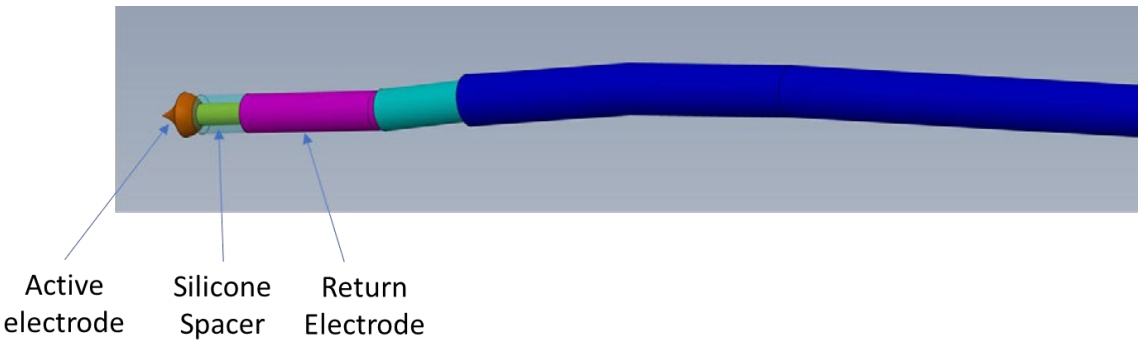
84. Monopolar is defined as a method of applying high frequency output current to a patient via an active electrode (single or multiple) and returning via a separately patient-connected Neutral electrode (or via the patient's body capacitance to earth) in which an effect is intended only in tissue at or near the active electrode(s). A visual representation of this is shown in the figure below.



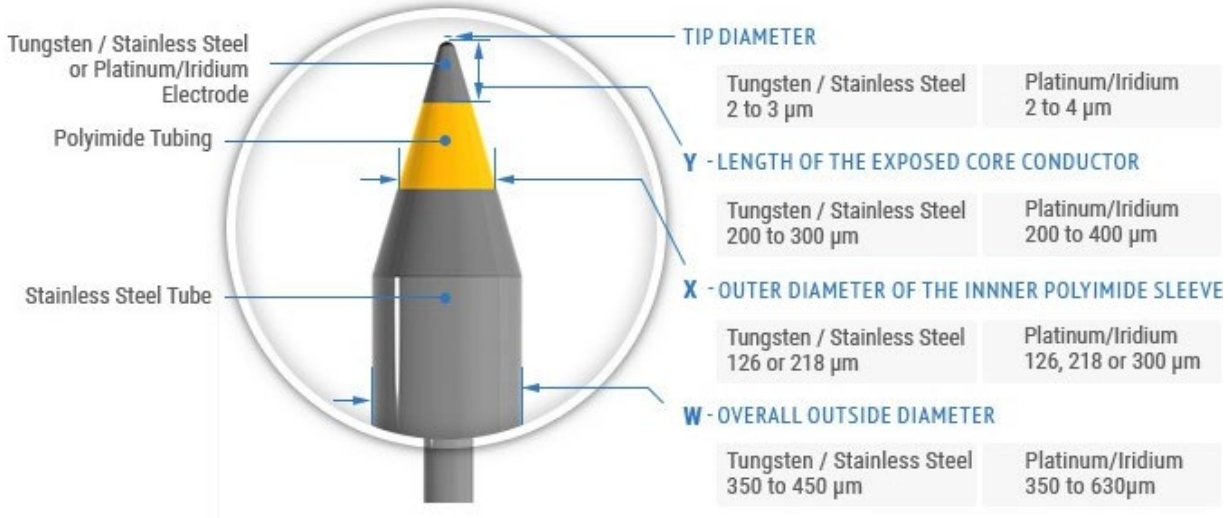
85. Therefore, in a monopolar system the handpiece includes electrode(s) connected to only 1 pole of the generator, and the current has to pass through a relatively large part of the body to the neutral electrode. An effect is expected only in the vicinity of the handpiece electrode(s). Monopolar RF electrosurgical generators need to have complex circuitry to ensure good contact quality under the neutral electrode so that no burn occurs. In bipolar systems, the accessory or handpiece includes two or more electrodes between which current passes. Usually, the current path is much shorter than in a monopolar configuration. In a bipolar system, the

electrodes can be configured such that both poles have a relatively similar configuration, and tissue effect happens around both poles. The IEC 60601-2-2:2017, standard, section 201.3.208: defines Bipolar as a method of applying HF current to a patient between two or more active electrodes without the need for a separately connected neutral electrode (or the need to use the patient's body capacitance to earth) in which an effect is intended in tissue near one or more active electrodes. It also adds as a note that the bipolar method includes devices energizing pairs of active electrodes as well as devices energizing groups of active electrodes where the HF current source and return may have different numbers of electrodes. This is seen with electrosurgical forceps or some of the microneedle arrangements described in the '836, '379 and '444 Patents as well as the "bipolar pairs" in the '536, '774, and '812 Patents. However, in some cases, bipolar systems include one or more active electrodes, and one or more "return" electrode with a surface area significantly larger than that of the active electrodes. In this configuration, tissue effect is only observed under the active electrode(s), and not under the return electrode(s).

86. The figure below shows such a bipolar RF device used for minimally invasive spine procedure designed and distributed by ArthroCare Corp since 2001, and now manufactured and distributed by Morgan Steer Orthopeadics Ltd. Because the "active" electrode is much smaller than the "return" electrode, and also has sharp edges that concentrate current, the density of current is much higher on the active electrode. Tissue effects are only observed in the proximity of the "active" electrode.



87. The ‘836, ‘379 and ‘444 Patents describe the notion of bipolar needles. What is described in the specification of the patents, are monopolar needles arranged in a bipolar configuration. They are arrays of monopolar needles (only one pole on each needle), but not all of the needles are of the same polarity. The array itself constitutes a bipolar device, but each needle is monopolar. More accurately, a bipolar needle is a needle that includes at least 2 electrodes electrically insulated from each other, and each of them connected to another pole of the RF generator as illustrated in the figure below.



Nonetheless, I understand that there is agreement in this Investigation regarding the meaning of bipolar electrodes, *i.e.*, electrodes change or alternate between being positive or negative as the

current alternates between them, and I have applied that meaning in forming my opinions in this Investigation.

88. Electrical engineers have defined Radio Frequency as any oscillatory signals between 10 kHz and 100,000 MHz. However, the electrosurgery expert community has restricted the definition of High Frequency or RF when used in medicine as any electrical signal with a frequency usually over 200 kHz. This is because lower frequency signals may induce significant nerve stimulation. The current IEC standard 60601-2-2:2018 section 201.8.4.102 defines High Frequency (when used for surgical equipment) as frequencies less than 5 MHz and generally greater than 200 kHz. The version of the Standard that was in place in 2013 was the 60601-2-2:2006 that defined High Frequency as frequencies over 200 MHz (the term "generally" was added after my intervention at the committee in 2006). The upper limit of 5 MHz has been added to the standard in its 2017 revision. This was done because the FDA considered that the physics of propagation of these higher frequency currents in tissue and their emission of interference signals were different. Most electrosurgical systems operate at frequencies between 450 and 490 kHz, because they are very effective at cutting or coagulating with no nerve stimulation. However, higher frequencies of 1, 2, or 4 MHz are also commonly used when operating close to nerves to further reduce the pain or neurostimulation that may be perceived by the patients. In 1926, John Marshall performed the first human RF electrosurgery using a bipolar pair of subdermal electrode needles operating at 2 MHz. Since 1949, Alan Ellan, the CEO of Ellman International, now Soniquence has manufactured RF electrosurgical systems operating at 4 MHz (monopolar) and 1.7 MHz (bipolar) that are used in many areas of medicine, including cosmetic surgery.

89. Continuous currents are usually not utilized for therapeutic uses as they can easily generate cellular damage or cellular death; very low power DC systems are sometimes used for very specific usage such as electroporation. Alternating currents that by definition have a zero-mean value, *i.e.*, the same amounts of charges are sent back and forth, are much more friendly for living cells. Most neurons, muscles and cardiac cells can respond to an electrical signal: each time the potential across their membrane changes at a certain rate and over a certain level, the membrane will trigger an action potential that will trigger either pain, muscle twitch, cardiac contraction, and so on. If a low frequency signal, such as a 50 or 60 Hz signal such as what is used in the AC outlets of most countries, passes close to the heart (for example between a hand and the foot, or between both hands), it will trigger a disorganized repeated contraction (also called fibrillation) of the myocardium at 50-60 Hz, preventing the heart from effectively pumping blood that may lead to death. Such a current applied to muscles or to nerves controlling muscles will lead to strong muscle contraction (tetanization). The latter effect is used for functional neuromuscular stimulation, and applied in very selected areas of the anatomy, avoiding any current path close to the heart. Overall, low frequency signals from a few Hz up to several kHz (several thousand cycles per second) can be dangerous and painful and are not used for any type of electro-surgery. Frequencies below 100-200 kHz are known to potentially induce neuromuscular stimulation and are not recommended for electro surgery. To prevent low frequency or DC components that can induce such undesirable effects, the IEC International safety committee (IEC 60601-2-2 section 201.8.4.102) requires the use of capacitance in series with the patient circuit (output stage of an RF generator). This by definition forces all Surgical HF generators to be AC generators and would prevent any high frequency or RF generator from entering the market (in most countries, including the U.S.,

Europe, most of Asia, including Korea) if they were RF DC generators, or had any DC component in their output signal.

90. It should be noted that although the standard requires that electrosurgical generators produce an AC signal (alternating across a zero-voltage value) certain conditions encountered in high voltage electrosurgery generate some arc discharge that may introduce some DC or low frequencies component. This is also discussed in the IEC 60601020 standard, Subclause 201. 2074 8.4.102 – "Neuromuscular stimulation: Due to the rectifying effect of arcs between the active electrode and the tissue, DC current, 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."

91. What happens to living tissue when bipolar RF is applied depends on how energy is applied. For Low voltage RF applications, tissues are heated up by the current passing through the tissue (Joule effect) similar to the current heating up the heating element of a kitchen stove. There is some analogy with cooking food: the effects depend on the amount of energy applied (how strong the flame is), how long it is applied for, and how much food you cook. One factor is how diffuse the heat is: if a lot of heat is applied to a small area of the food, it will create a small area that is very cooked, while the rest of the food remains relatively uncooked (*e.g.*, seared meat). The overall temperature elevation of the food is directly proportional to the amount of energy delivered or dissipated through the food. The energy is calculated by multiplying the power by the amount of time it is delivered. One could think that if you heat up food in 1 minute with a power of X watts, it will take 10 minutes with a power of X/10 Watts. In actuality, this is not the case; while the energy source is heating up the food, the ambient air that makes contact with the food will cool it down by convection. In low voltage

RF applications, the local blood flow will also cool down tissue. Therefore, it is not only energy that matters, but also how it is applied that matters. In many cases, whether it is for an electrical heater, microwave oven, skin laser treatment or electrosurgery, sending the energy in a discontinuous fashion is the best way to achieve a specific temperature and prevents overheating. This is called pulsing: the energy is applied for a certain time (e), then it is paused for a time (p). The ratio of $\frac{e}{e+p}$ is called the duty cycle. For example, if energy is applied for 1 second and then paused for 1 second, the duty cycle is 50%. If a power of 10 Watts (instantaneous power) is applied during the time it is on, the average power will be half of that, or 5 Watts.

92. In low voltage RF applications, most of the heat is dissipated through what is called Joule heating. When an electric current flows through a conducting medium (such as tissue which is composed of conductive ionic water-based solution [intra and extra-cellular fluid]) most of thermal energy is generated in a process called Joule heating. This is analogous to a bread toaster, which uses an oscillating current through resistor coils to generate heat which, indirectly, then heats the bread. In most RF applications, current flows through the tissue that forms a resistor (there also is a capacitive component, and the combination of resistive and capacitive and resistive components are included in the complex impedance "Z" value). The amount of energy, or heat, dissipated is given by the equation:

$$E = Z.I^2.\mathrm{t}$$

Where "E" is the amount of energy (in Joules), "Z" the impedance of the tissue (complex resistance given in 2 dimensions [real and imaginary part] of tissue to the passage of current), "I" the intensity of the current and "t" the time during which the current is applied. This is relatively simple for the resistance inside a toaster, where the resistive wire forming the heating

element is homogeneous. However, in the case of low voltage RF applications, current flows through various layers of tissue of various impedance. The current is also not homogeneous; what matters the most is what is called the current density. If we made imaginary lines in the tissue that would form very small little cubes, the current density would be the amount of current passing through each of these cubes. When the current is emitted by a small needle, all the current at close proximity to the needle is passing through a very small volume of tissue, and therefore has a high density. When the current travels further away from the electrode, the current density decreases. In a bipolar system where there are several electrodes of opposite polarity around an electrode, or if the electrodes are relatively far apart, the current density decreases with the square of the distance. This is a very fast decrease. Furthermore, the amount of energy is proportional to the square of the current (*see* equation below), and therefore the amount of energy dissipated (or heat) decreases with the fourth power of the distance. This means that the energy is always more concentrated around the electrodes, but some level of energy is always dissipated all the way between the poles to close the electrical circuit, and therefore in any tissue between the two electrodes of a bipolar circuit.

93. Current always flows between the 2 poles of a circuit; electrical charges travel at extremely high speed, almost of the same order of magnitude as light speed depending on the tissue permittivity. This means that as long as tissue does not have an infinite impedance, which is never the case, electrical current passes all the way between the 2 or more electrodes in a bipolar circuit, and some level of thermal energy is dissipated between them. However, given the sharp decrease in current density, the thermal energy dissipated close to the electrodes is significantly larger than in the middle of the gap between the electrodes, and the temperature increase further from each electrode, or in between 2 electrodes, is significantly less than at

close proximity to the electrode tips. Only when the temperature elevation is over 60-65°C a zone of coagulation around the electrodes is easy to observe. This will usually occur first at very close proximity to the electrode tips before occurring further away from the electrodes. The further apart the electrodes are, the lower the energy concentration between them, and the lower the chances are to have any coagulation in the gap all the way between them. However, while in most cases no coagulation or other changes in tissue are observed with the naked eye, sensitive measuring equipment would be able to measure such a temperature elevation anywhere between the 2 electrodes in a bipolar system. Although it can be extremely small, there is always some level of energy dissipated in the tissue located at all points between the 2 electrodes of a bipolar arrangement.

94. Modeling of current flow around electrodes has been performed for decades using a technique called Finite Element Analysis. The principle of this mathematical modeling is to reduce the continuous medium into very small volumes, compute the physical characteristics at the boundaries of each of these small volumes by solving multiple differential equations, and calculate the electrical field within this volume. In 2005, W. Mitchell and R. Sundararajan published such a model of the electric field distribution in biological tissues for various electrode configurations that show very well how the electrical field is concentrated around the tip of the electrodes (*see* figure below). An electrical field is the physical field that surrounds electrically charged particles and exerts force on all other charged particles in the field, either attracting or repelling them. It also refers to the physical field for a system of charged particles. This field generates the forces that make the charged particles (electrons or ions) move and generate a current. When the current passes through a medium with a given impedance (or resistance) it generates heat. When the medium is a biological tissue, this heat

will, when reaching a certain threshold, induce modification of the tissue structure. It will induce tissue coagulation when reaching a temperature of 60-65°C.

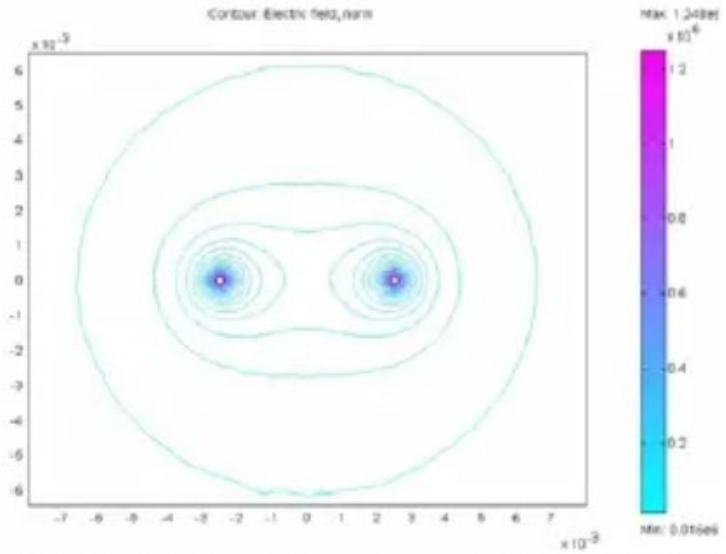


Fig. 5: Electric Field Distribution due to Needle Electrode Configuration

from W. Mitchell and R. Sundararajan. Electric Field Distribution in Biological Tissues for Various Electrode Configurations-A FEMLAB Stud; Proceedings of the COMSOL Multiphysics User's Conference 2005 Boston.

95. There are two other factors that will also concentrate the energy around the tip of the electrode: (1) the edge effect phenomenon, *i.e.*, that the current density is by far higher at the tip of a sharp edge, *e.g.*, the tip of a needle; and (2) current travels through metal (the electrode) by a flow of electrons, whereas current flows through tissue (or salt water) by a flow of ions. At the interface between the electrode and tissue, the metal from the electrode needs to give away and reabsorb electrons at its surface. At the surface of a steel electrode, a molecule of iron would alternatively change from Fe to Fe^{++}. This chemical reaction dissipates a certain amount of energy as well, which depends on the work function of the metal. Stainless steel, which is used the most frequently for RF needle electrodes, has a high work function, which means that there is a significant amount of energy, or heat dissipated at the surface of the

electrode. These physical phenomena have been well known for many years and explain why tissue would always heat up faster closely around the tip of a needle electrode. The largest energy density being around the tip of the electrodes explains why coagulation effects are observed first around the tip. The rate of heating being faster around the tip of the electrode, the coagulated lesion grows concentrically around the electrodes. When the opposite polarity electrode is of small size, and located at close proximity to the other electrode, the lesion loses its symmetrical shape and is more concentrated in the gap between the two electrodes. In bipolar needle configuration, a "close proximity" would be more or less equal to 2 or 3 times the diameter of the electrode.

96. There is another effect that will also affect the geometry for the heat dissipation. The impedance or resistance of the tissue to the passage of current will change as current passes through it. During the first phase of heating, the ionized water within the tissue increases its temperature, and saline solution resistance decreases with temperature. So, the tissue resistance initially goes down. However, as soon as the coagulation process starts, the content of water within tissue decreases, significantly increasing the resistance of tissue to passing electrical current. The current will follow the path of least resistance, which means that in time current will try to avoid the areas of tissue that are already coagulated, until all the tissue around the electrode is coagulated, greatly limiting the ability of tissue to pass any current, and significantly impeding the coagulation process. So, if the lesion initially grows around the tip of a needle, in time it will also grow up along the shaft of the needle where the tissue has a lower impedance. The growth of a lesion or coagulated tissue around RF electrodes has been studied for many decades, and many inventive solutions have been described and patented to better control them.

97. In summary, when applying RF current between two or more needle electrodes, unless they are extremely close from each other (less than 1 or 2 needle diameter distance), energy concentration, and therefore tissue effects, including coagulation, will always start around the tip of the electrodes. Then, when current is applied for longer, depending on many parameters, including electrode material and geometry, tissue characteristics, RF parameters (voltage, frequency, mode of regulation [current, power, voltage], and timing of the application (time of application, duty cycle, …), the zones of coagulation may intercept and provide some continuity between the various zones. This means that the natural effect of applying RF energy to a needle electrode in monopolar or bipolar mode would be to have the maximum amount of thermal energy dissipated just around the electrode tip. A great deal of effort is required in adjusting the various parameters to obtain a homogenous tissue effect between two electrodes for ablation of large tumors or for what is called vessel sealing. *See e.g.,* U.S. Patent No. 5,827,271 and U.S. Patent No. 10,806,506.

98. Similar to cooking, various effects can be observed when applying RF to tissue. Standard electrosurgery uses high voltage, usually over 1,000 Volts, that creates very high temperature sparks that in turn will "burn" tissue and create a thin layer of carbonization. This could be compared to the "black" stripes on a seared steak. In RF applications for the purpose of collagen remodeling, lower voltages are used, usually less than 100 Volts, and no carbonization should be observed. When energy is applied, the first effect is a simple warming of tissue, without any significant change in its structure or color; this is similar to the inside of a rare, cooked piece of meat, that is warm but still red. When heat is applied for a longer period or with more intensity, the temperature increases, and the tissue will change color and structure:

this is the coagulation effect. The red of the meat is replaced by a lighter brown color as observed in a well-done piece of meat.

99. Tissue effect also depends on how long the RF signal is applied to tissue. When RF passes through tissue, the thermal energy dissipated will increase the temperature almost linearly with time, and tissue can reach very high temperatures. Woloszko *et al.* (IEEE, 2002) reported a temperature of over 1,600 °C during monopolar electrosurgery in cut mode. These high temperatures have pyrolytic effects (just like a self-cleaning oven) that will vaporize tissue. To prevent removing tissue when in coagulation mode, electrosurgical generator manufacturers have been pulsing the RF signal using a very short time ON and a longer time OFF. The ratio between the time on and the time off, is called Duty Cycle; this cycle is repeated over time. The timing and pattern of the RF signal can determine various modes of operation of a given generator. As an example, the ValleyLab Force FX generator, which received FDA clearance in 1994 through 510k K944602, is using an RF signal of 240 kHz in coagulation/desiccate mode, with duty cycle of 8%; this cycle is repeated 39,000 times per second (39 kHz). In another mode, called "Spray" mode, the RF signal is an oscillating sinusoidal signal which is damped (meaning the amplitude decreases over time); the bursts are repeated at around 28 kHz. On top of that, a low frequency signal of around 250 Hz is used to modulate the envelope of the signal. It is my opinion that this type of low frequency modulation, used for at least 30 years, is similar to what is described in some of the Complainant patents in which an AC low frequency signal is combined with an RF signal (AC RF signal described with 2 frequencies: the RF and AC frequency).

100. In standard open surgery, most monopolar electro-surgery electrodes consist of a non-insulated piece of metal, mounted on an insulated handle. Most companies making electro-

surgical accessories (including electrodes) make needle electrodes such as those shown in the Figure below.



ConMed Disposable Needle Electrode (non insulated)_

101. However, for minimally invasive procedures, such as percutaneous procedures, most electrosurgical devices use insulation around the electrodes to only expose the part of the electrode(s) that is in contact with the target tissue. Inserting a needle through the skin to treat some superficial tissue under the epidermis would fall in the second category. U.S. Patent No. 5,546,954 to Yamado, filed in 1994, discloses a method and an apparatus using non insulated acupuncture needles connected to an RF generator (range of several hundred kHz to 40 MHz, preferred 2-10 MHz) to apply thermal stimulation to reactive electro-permeable points. In the '536, '774, and '812 Patents, Na describes the electrodes as acupuncture needles. *See e.g.,* '536 Patent at 2:66-67. U.S. Patent No. 5,957,862 to Lu *et al.* (filed January 1, 1997) describes an improved acupuncture device system using acupuncture needles connected to an RF generator; only the tips of the needles are conductive and the body of the needles are insulated or non-conductive. Since then, several electro-acupuncture systems using (partially) insulated or non-insulated needles have been used.

102. Many technologies have been developed over the years to improve the aspect of aging skin and to reduce or remove wrinkles or scars. In order to achieve this goal, researchers have approached the problem in multiple ways that include: (1) Increasing tension in the skin, and (2) regenerating the tissue matrix that is mostly composed of collagen and elastin. Various types of energy-based instruments that produce a controlled amount of heat, such as low voltage RF or some type of lasers, have demonstrated their ability to "shrink" the collagen matrix, and would presumably be good candidates for tightening the skin. Meanwhile, a controlled inflammatory process could, through a controlled healing process, regenerate the tissue matrix. In the 1990s, ablative techniques using various energy sources such as laser, plasma or RF were developed. The aggressive treatments were effective but had some risk of scarring (higher in darker or Asian skins) and they also required several weeks of "downtime" for the skin to heal. In 1997, ArthroCare Corp. developed a bipolar RF device to "resurface" the skin and reduce wrinkles. The RF in the device was generating plasma to remove the superficial layer of the skin, and also RF applied to tissue was shrinking the collagen in the dermis. The results of a multi-center clinical trial were published by Grekin in 2000[9], and also used for the FDA clearance of 510k K992180 for the Visage Cosmetic Surgery System, a bipolar high frequency electrosurgical device intended for general dermatological surgery that may include skin resurfacing for the treatment of wrinkles, rhytids, and furrows, as well as soft tissue resection/removal and hemostasis/coagulation. This technique, however effective, required a healing period of several months during which patients did not want to show their "red face" in public. In the same period, Thermage, also based in northern California, was using an RF system placed on the surface of the skin, together with a

[9] Grekin RC, Tope WD, Yarborough JM Jr, Olhoffer IH, Lee PK, Leffell DJ, Zachary CB. Electrosurgical facial resurfacing: a prospective multicenter study of efficacy and safety. *Arch Dermatol*. 2000 Nov;136(11):1309-16. doi: 10.1001/archderm.136.11.1309. PMID: 11074690.

cooling system protecting the epidermis, to remodel the skin. Both companies understood that the main target was to treat the dermis layer of the skin (located under the epidermis), and that a technology that would spare the epidermis and not require any down time would represent a better option.

103. Controlled traumatism of the skin can trigger a healing response that can improve the skin aspect. In 1995, Orentreich and Orentreich described subscision or dermal needling for scars.[10] In 1997, Camirand and Doucet described needle dermabrasion using a "tattoo pistol" without pigment to treat scars.[11] This was the beginning of the microneedle technique. From there, various systems such as the Dermaroller or the Derma Stamp using multiple microneedles (1-1.5 mm in length and around 0.1mm in diameter) were developed and used to improve skin aspect and reduce scars. The theory was that microneedling leads to the release of growth factors which stimulate the formation of new collagen (natural collagen) and elastin in the papillary dermis. In addition, new capillaries are formed; this neovascularization and neocollagenesis following treatment leads to reduction of scars.

104. Several studies in the early 2000s demonstrated that short pulses of radiofrequency signal applied to various types of tissue could induce a powerful healing response with creation of new collagen and new blood vessels.[12] Other sources of energy, such as mechanical vibrations of various wavelengths of LED lasers have also shown potential to induce some healing response as well. Micro needle systems inserted into the dermis and energized with mono or bipolar RF with bipolar RF were described in several U.S. patents such as *e.g.*, U.S. Patent No. 6,766,202 by

[10] Orentreich DS, Orentreich N. Subcutaneous incisionless (subcision) surgery for the correction of depressed scars and wrinkles. *Dermatol Surg*. 1995;21:6543–9.
[11] Camirand A, Doucet J. Needle dermabrasion. *Aesthet Plast Surg.* 1997;21:48–51.
[12] Tasto JP, Cummings J, Medlock V, Harwood F, Hardesty R, Amiel D. The tendon treatment center: new horizons in the treatment of tendinosis. *Arthroscopy.* 2003.

Underwood *et al.* or U.S. Patent No. 6,277,116 by Utley *et al.* in the early 2000s, as the precursor of the current micro-needling technology discussed in this report.

105. From the late 2000s to early 2010s, a number of companies started manufacturing RF microneedling devices that combined the effects of mechanical damage caused by microneedles and thermal damage caused by RF energy. Such examples include "Miratone" manufactured by Primaeva Medical (later renamed as "e-Prime" and then "Profound" after being acquired by Syneron-Candela), "INTRAcel" manufactured by Jeisys Medical, "DeÁge" manufactured by Dashin Enterprise, and "ScarLet" manufactured by ViOL, to name a few.

106. All of these products aimed at providing "fractional damage" to the dermis. "Fractional damage" means that there are areas of healthy tissues preserved among the areas damaged by needle insertion and RF energy application. Unlike complete ablation of the treatment area, fractional damage can induce faster wound healing processes promoted by healthy tissues surrounding the damaged tissues and almost no downtime. These devices had multiple microneedles used in monopolar and/or bipolar modes designed to provide thermal damage by coagulating the tissue in a fractional manner.

107. For example, the Miratone system includes an array of 5-pair of 30-gauge (0.30 mm) microneedle in combination with thermoelectric cooling to protect the epidermis during RF application. The proximal end of each microneedle is insulated with a biocompatible Teflon layer, leaving the distal 3mm exposed to form the electrode in tissue. A thermocouple embedded in the tip of each electrode pair is used to regulate the tissue temperature during treatment. The treating physician can select the desired target temperature and pulse duration as clinical endpoints. The DeÁge system (manufactured by Daeshin) is an RF microneedling

device [redacted]

108. Similarly, ScarLet (manufactured by ViOL) is an RF microneedling device, first registered in Korea on June 1, 2010, and offered for sale in Korea as early as September 2010. ScarLet employed 25 microneedles arranged in a 5x5 square shape. *See, e.g.*, Ilooda-0006770 (#18_D&PS Monthly Sept 2010_Translated_Certified). The system was registered under KFDA for cutting, hemostasis and coagulation of skin tissues using high frequency (RF) currents at 2 MHz. With the ScarLet system, healthcare providers were able to select either a bipolar mode or a monopolar mode. The system was designed to increase the temperature

causing coagulation around each electrode. SERENDIA-00017306 at -317. RF "on" time (*i.e.*, conduction time) was adjustable between 100 and 800 ms with 100 ms increment. *See, e.g.*, Ilooda-0006075 (Scarlet intro at 2). Depth of needle insertion was also adjustable between 0.5 mm and 3.5 mm with 0.1 mm increments. *See, e.g.*, Ilooda-0006075 (Scarlet intro at 2). The system has 3 modes of operations, cut, blend and coagulation and is rated at 2.0 Watts ±20% under a load of 500Ω in bipolar mode. The cut mode delivers a continuous RF signal (called Continuous Wave, "CW" by Viol) while both the coagulation and blend mode were pulsing the RF signal over the treatment duration with different duty cycles.

109. ViOL subsequently launched a RF microneedling product called "ScarLet S," which was first approved in Korea on January 7, 2015 . SERENDIA-00075908; Ilooda-0010211. I have been informed that Serendia contends that ScarLet S practiced the so-called "Na effect." It is only indicated for coagulation of tissue and does not have the 3 cut, coag (coagulation) and blend modes. The ScarLet S has 3 modes of operation (1, 2 and 3, respectively, rated at maximum powers of 2.5, 3.3 and 3.7 Watts under 500 Ω (Ilooda-0010215 at0010231-0010232). Mode 1 is recommended for treatment of the Face, Mode 2 for "Body" and mode 3 for "long" lesions (VIOL-00001455). Although the Graphical User Interface was greatly modified to make it more user friendly for the intended use, the main characteristics remained very similar to the ScarLet system.

110. The table below shows comparative specifications for the ScarLet and ScarLet S systems.

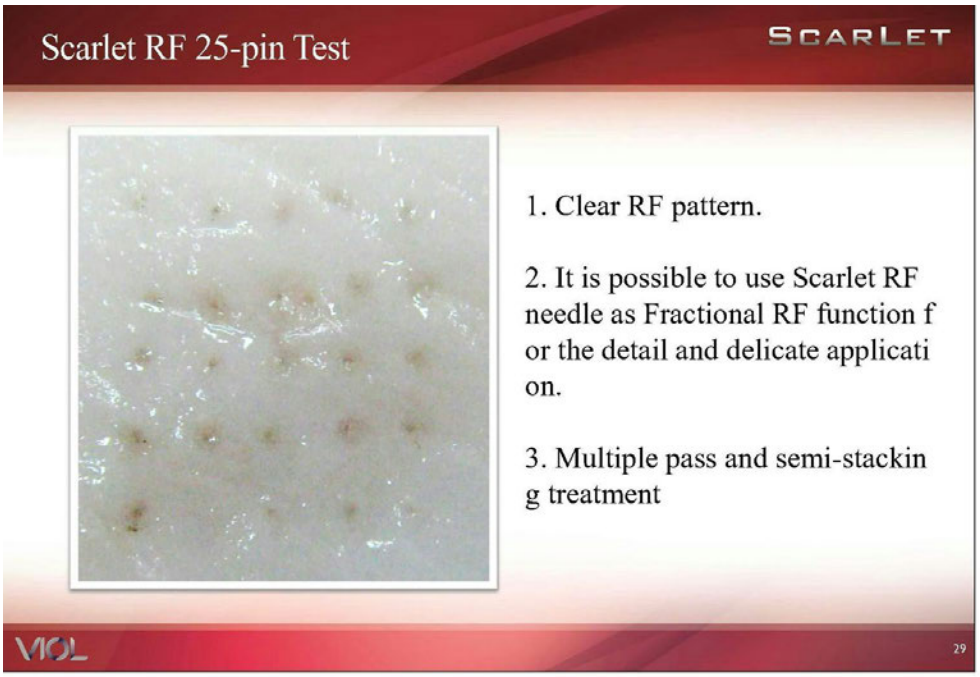
	ScarLet	**ScarLet S**
Indications for use	Cutting, hemostasis and coagulation of skin tissues	Tissue coagulation
Frequency	2 MHz ± 10%	2 MHz ± 10%
Rated Power (under 500 W)	2.0 W ± 20% (for all 3 modes)	2.5 W (mode 1) 3.3 W (mode 2)

	ScarLet	ScarLet S
		3.7 W (mode 3)
Modes of operations	Cut, blend, coag	1, 2, 3
Output adjustment	10 level (1 -10) [(1)] Cut: 0.01 – 1.91 W (0.07 – 0.33 W steps) Blend: 0.01 -2.02 W (0.16 – 0.35 W steps) Coag: 0.013 – 2.09 W (0.15 – 0.46 W steps)	10 level (1 -10) Mode 1: 1.70 – 2.50 W, (0.1 W steps) Mode 2: 2.00-3.30 W (0.2 or 0.2 W steps) Mode 3: 2.10 – 3.70 W (0.20 W steps)
Pulsing	Coag: continuous Blend and Cut: Pulsed	Continuous
Activation time (Duty)	100 – 800 ms (100 ms steps)	120, 200 and 300 ms
Off Time	100 ms (fix)	
Number of activations	Selectable to reach selected energy level (Total fluence)	Selectable to reach selected energy level (Total fluence)
Needles array	25 (5 x 5)	25 (5 x 5)
Exposed Needles length	0.5 – 3.5 mm	0.5 – 3.5 mm
Adjustment units of exposed needle length	0.1 mm	0.1 / 0.3 mm
Needles diameter	300 mm	300 mm
Needles spacing	2 mm	2 mm
Needle Insulation	None	None
The values in this table are taken from the following documents: • ScarLet: Ilooda-00010251, llooda-0006075, Ilooda-0003031, VIOL-00001455, Ilooda-0010197, SERNEDIA-00081274, SERENDIA-00073257_EN • ScarLet S: Ilooda-0010211, VIOL-00001455		

[(1)] power values for ScarLet are derived from the Voltage output in Ilooda-0000010251, and the 500 Ohms load. ($P=U^2/R$)

111. Based upon the specifications, the ScarLet S operates at slightly higher power in Mode 2 and 3 as compared with the ScarLet. However, Mode 1 of the ScarLet S, recommended for facial applications, has characteristics that overlap very much with those of the ScarLet in "Coag" (coagulation) mode. The ScarLet S has about 12.5% more power than ScarLet, but the power output is rated with a 20% tolerance, and ViOL did not recommend settings over level 8 for human skin. For the ScarLet, "Duty over 300 ms were not used even in hospital unless deep wound or burn. Level of 8 are too high for human skin" (Ilooda 0006078 page 14). Based on my review of these specifications, it would appear that the ScarLet system would be able to

replicate all of the parameters used with the ScarLet S in mode 1, that is used to treat facial skin in most patients. ViOL advertises that ScarLet S practices the "Na Effect" therefore the ScarLet system would also have been able to practice the "Na Effect." In the document SERENDIA-00081779, related to the ScarLet system, the material discussed on pages ending on SERENDIA-00081792–794 show that the ScarLet can control the size of the coagulative lesion around each electrode, which is required to perform the "Na Effect." Furthermore, in the same document, page 29 displays (*see* below) some experimental results that explicitly show that the ScarLet is able to operate in a Fractional RF mode that produces coagulative lesions around each electrode and leaving areas of healthy tissue between them, which replicates the "Na Effect". The same picture is used in a training document (VIOL-00001255 at -276) for the ScarLet SRF system that advertises creating coagulation zones in a water drop shape around each electrode, which is the characteristic feature of the Na Effect.



SERENDIA-00081779 at -1807.

B. Overview of the ‘836, ‘379, ‘444 Patents

112. The ‘836, ‘379, and ‘444 Patents are entitled “Skin treatment apparatus” and have identical specifications. The sole named inventor on these patents is Jongju Na.

113. The ‘836, ‘379, and ‘444 Patents claim priority to International Patent Application No. PCT/KR2012/004695, filed June 14, 2012, and to Korean Patent Application Nos. 10-2011-0057691 and 10-2011-0057692, both filed on June 14, 2011. Specifically, the ‘836 Patent is a U.S. National Stage Application of International Patent Application No. PCT/KR2012/004695, filed June 14, 2012, which lists Jongju Na and Jeong Gu Gwak as co-inventors. Korean Patent Application Nos. 10-2011-0057691 and 10-2011-0057692 list Jeong Gu Gwak and Jongju Na as co-inventors.

114. The ‘379 Patent is a continuation of the application that issued as the ‘836 Patent. The ‘444 Patent is a continuation of U.S. Patent Application No. 16/111,616 (now U.S. Patent No. 10,799,286), which is a continuation of the application that was issued as the ‘379 Patent.

115. The ‘836, ‘379, and ‘444 Patents are directed to devices and treatment methods that “employ bipolar needles, alternating current (AC) signals, and high frequency signals” (JXM-0007, ‘836 Patent, SERENDIA-00005759-00005774, at 3:46-48) where the bipolar needle (electrodes) are inserted into the skin and heated “to cause coagulation … around each needle.” (*Id.*, at 3:21-29).

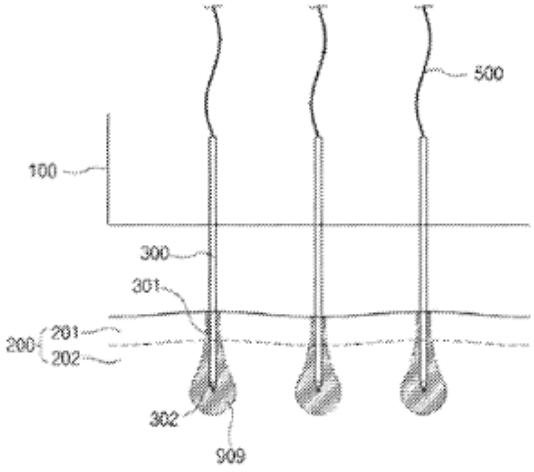


FIGURE 5

JXM-0008, '836 Patent, SERENDIA-00005759-00005774, JXM-0009,'379 Patent, SERENDIA-00005775-0000579, and JXM-0011, '444 Patent, SERENDIA-00005792-0000580, at Fig. 5.

116. The devices and methods of '836, '379, and '444 Patents are purportedly directed to changing the energy field around the needle electrodes. The specification describes how to obtain an "energy field" around the electrode; "energy field" is an undefined term that, except in some science fiction literature, is not a term used in physics, and furthermore, not to describe localized generation of heat. In physics, a "field" is a physical quantity, represented by a scalar, vector, or tensor, that has a value for each point in space and time. If we assign a broader meaning to the term "field" such as "a region or space in which an effect or force (such as gravity, electricity, or magnetism) exists," this assumes that there is "no energy" outside of this field. The specification of the '836, '379, and '444 Patents describes that each "needle may independently form an energy field about its tip, where the **energy field** may raise the temperature of adjacent tissue as a function of the tissue anatomy". *See e.g.*, '836 Patent at 3:57-60 (emphasis added). The specification further described that "[i]n another embodiment

the energy fields (generating heated areas in dermis) may be expanded and connected in dermis, but not in epidermis as shown in FIGS. 7 and 8." *See e.g.*, '836 Patent at 5:65-66. The description of the so called "energy field" in figures 7, 8, 9A, 9B and 9C seems to indicate the areas of tissue that have reached a temperature sufficient to get denatured and coagulate. This does not represent an "energy field." The energy dissipated in tissue is a function of the "current density", as discussed above, which decreases with the square of the distance from the needle. This "field" does not stop abruptly but decreases (rapidly) with distance. A POSITA knows that the local temperature is the result of the rate of energy dissipated, the time and timing of application and the rate of convection cooling. The POSITA also knows that the zone of coagulated tissue around the tip of the electrode will grow in time up to a limit and does not represent a "fixed energy field."

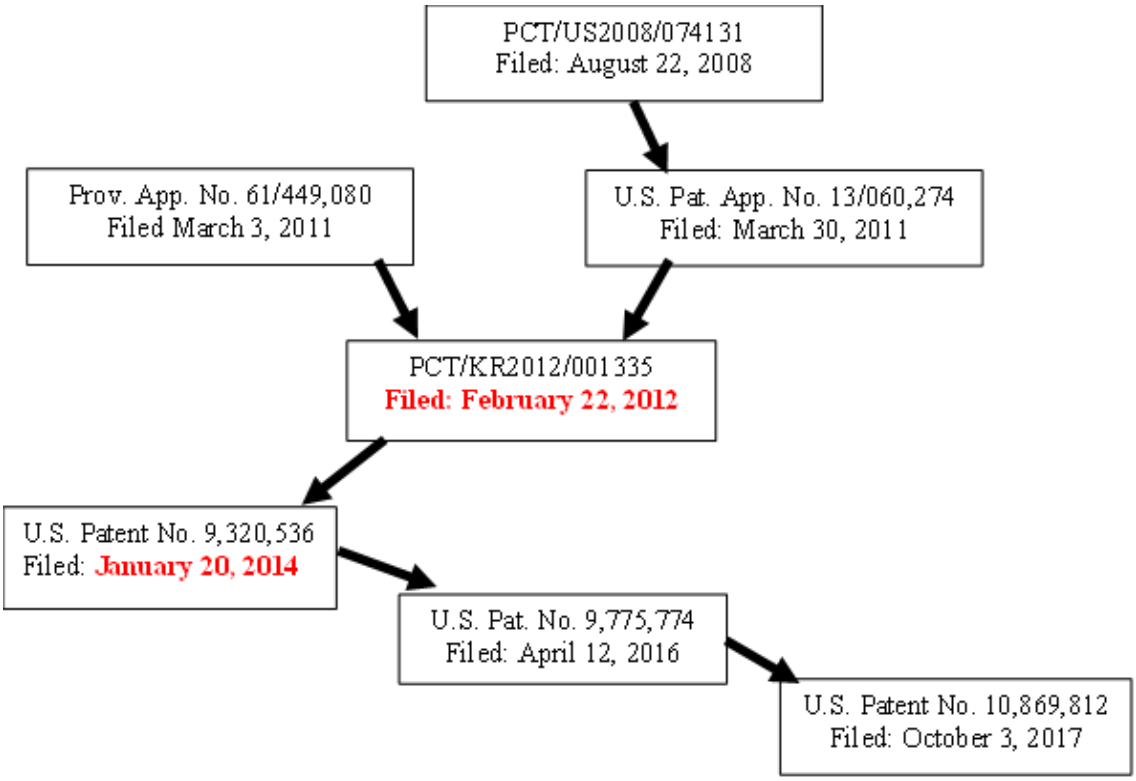
C. Overview of the '536, '774, and '812 Patents

117. The '536, '774, and '812 Patents are entitled "Method, system, and apparatus for dermatological treatment" and have identical specifications, and nearly identical claims. The sole named inventor on these patents is Jongju Na.

118. On its face, the '536 Patent is a U.S. National Stage of PCT/KR2012/001335, filed February 22, 2012. PCT/KR2012/001335, which published as WO20121/18293 and claims priority to U.S. Provisional Patent Application No. 61/449,080, filed March 3, 2011, and U.S. Patent Application No. 13/060,274 having a purported filing date of March 30, 2011. U.S. Patent Application No. 13/060,274, which lists Jongju Na and Merle Richman as inventors, in

turn is a U.S. National Stage of PCT/US2008/074131, filed August 22, 2008, which claims priority to Korean Patent Application No. 10-2008-0076993, filed August 6, 2008.[13]

119. The '774 Patent is a continuation of the application that issued as the '536 Patent. The '812 Patent is a continuation of the application that issued as the '774 Patent. A chart showing the priority chain for the '536, '774, and '812 Patents is provided below:



120. The '536, '774, and '812 Patents are directed to a handheld dermatological treatment apparatus having an electrical signal generator coupled to electrode needles which extend into the skin and have a disposable needle electrode cartridge module that can be removed

[13] It is my understanding that a PCT application cannot claim priority to an application having an effective filing date more than a year prior to the filing date of the PCT application.

and disposed after treatment. JXM-0001, '536 Patent, SERENDIA-00005809-00005842, at 2:51-55, 3:27-30, 9:17-30, 11:22-31, 13:49-57.

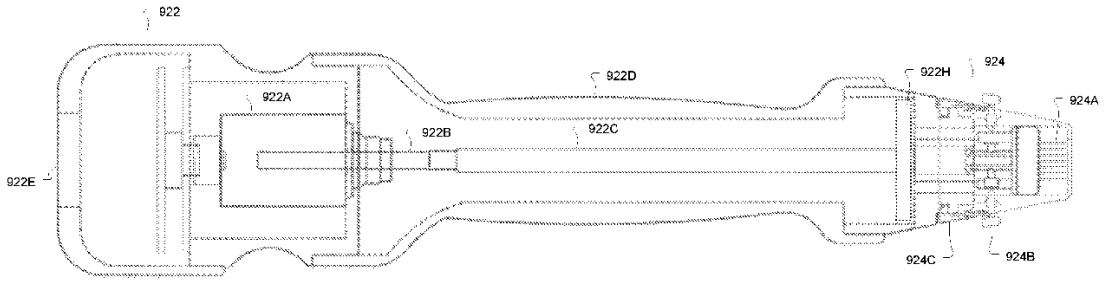


FIGURE 9C

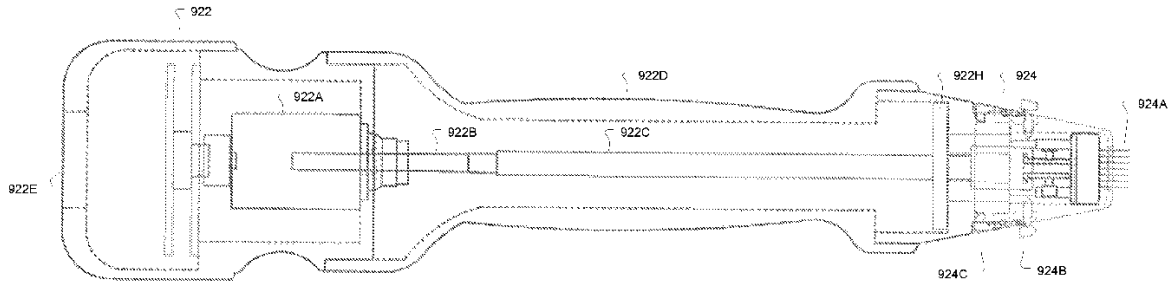


FIGURE 9D

JXM-0001, '536 Patent, SERENDIA-00005809-00005842, '812 Patent, JXM-0005, SERENDIA-00005876-0000590, and '774 Patent, JXM-0004, SERENDIA-00005843-00005875, Figs. 9C, 9D.

VIII. PROSECUTION HISTORY OF THE PATENTS-IN-SUIT

A. Prosecution History of the '836 Patent

121. As part of my analysis, I reviewed the prosecution history of the '836 Patent. U.S. Patent Application No. 14/006,930, the application that would ultimately issue as the '836 Patent, was filed on September 23, 2013. *See* Appx. 7 (Proposed JXM-0008) at JXM-0008.4 (dated "9/23/2013"). Among the initial application materials, Applicant submitted a transmittal cover sheet identifying "An English Language Translation of the International Application"

PCT/KR2012/004695 pursuant to 35 U.S.C. § 371(c)(2) (*id*. at JXM-0008.2 (cover sheet)) together with a translation of PCT/KR2012/004695 (*id*. at JXM-0008.18-34 (hereinafter, "translated Korean specification")). Applicant submitted a "substitute specification" shortly thereafter, purportedly to "correct[] grammatical and language issues" (*see id*. at JXM-0008.202), which in substance is reflected in the issued '836, '379, and '444 patents. *See id*. at JXM-0008.51-68.

122. The '930 application that issued as the '836 Patent was rejected during prosecution under pre-AIA 35 U.S.C. § 102(b) as being anticipated by U.S. Patent Application Publication No. 2005/0222565 ("Manstein"). Appx. 7 (Proposed JXM-0008), at JXM-0008.295. On October 9, 2015, Applicants conducted an interview with the Examiner where "Proposed claim amendments were discussed," which "included claiming ranges, AC signal, and subject matter from claim 6 involving electrodes switching polarity." *Id.*, at 308. As a result, Applicant amended the independent claims from "a high frequency Alternating Current (AC)" to "an Alternating Current (AC) RF signal." *Id*. at JXM-0008.371, 374. Applicant argued that this required an RF signal that is combined with an AC signal. *Id*. at JXM-0008.377-78. Applicant further argued that the prior art does not disclose "providing a high frequency AC signal," and that "critically," Manstein "teaches providing a RF signal in one embodiment ***OR*** an AC or DC signal in another embodiment." (emphasis in original). *Id*. On May 5, 2016, Applicant also argued, in response to a Final Office Action dated January 22, 2016, in order to overcome Manstein, and to "place the application in better condition for allowance," that "the electrodes have poles that change or alternate between being positive or negative as the current alternates," and Applicant amended their pending independent claims to

include the limitation of "the electrodes being bipolar." Appx. 7 (Proposed JXM-0008), at JXM-0008.344-45; *id.* at JXM-0008.336, 339 (amending then-claims 17 and 43).

123. The Examiner stated that the reason for allowance was that "[t]he examiner agrees … with the applicant's argument that the AC signal and RF signal are applied in different embodiments in the prior art (*see e.g.* [0032] of Manstein) and that there would be no motivation to combine the embodiments," and further noted that paragraph "[0052] of the applicant's specification is where the applicant discloses the RF AC signal being implemented in one embodiment." *Id*. at JXM-0008.391.

B. Prosecution History of the '379 Patent

124. As part of my analysis, I also reviewed the prosecution history of the '379 Patent. The application that issued as the '379 Patent was rejected during prosecution under AIA 35 U.S.C. § 103 as being obvious over Manstein in view of U.S. Patent Application Publication No. 2003/0195593 ("Ingle") or U.S. Patent Application Publication No. 2009/0093749 ("Shalev"). Appx. 9 (Proposed JXM-0010), at JXM-0010.231. In an attempt to overcome the prior art rejection, Applicant amended the independent claims to require the negative limitation that the energy is applied to body segments (*e.g.*, the dermis) around each electrode "rather than to body segments between electrodes." *Id.* at JXM-0010.244, 245, 247.

> 1. (Currently Amended) A mammalian body treatment apparatus, comprising:
>
> a plurality of electrodes, the electrodes being bipolar and configured to be insertable into a body segment to be treated; and
>
> a radio frequency (RF) generation module, the RF generation module electrically coupled to the plurality of electrodes and configured to provide an Alternating Current (AC) RF signal to the plurality of electrodes to ~~treat a section of a~~ apply energy to body segments around each electrode rather than to body segments between the electrodes.

Id., at JXM-0010.244.

11. (Currently Amended) A method of treating a mammalian body, comprising:

inserting a plurality of electrodes, the electrodes being bipolar into a body segment to be treated; and

applying an Alternating Current (AC) Radio Frequency (RF) signal to the plurality of electrodes to ~~treat a section of a~~ apply energy to body segments around each electrode rather than to body segments between the electrodes.

Id., at JXM-0010.245.

125. Thereafter, to obtain allowance, Applicant agreed to an Examiner's amendment of the independent claims. The Examiner then allowed the patent giving as the reasons for allowance that "[s]imilar to the parent application, the applicant is claiming coverage for the embodiment in figure 6." *Id.* at JXM-0010.268. In addition, the Examiner stated that the independent claims required "the current or energy forming around each needle [electrode] rather than between needle [electrodes]" and that "[t]he Examiner could not [sic] prior art that read on this embodiment. *Id*. at JXM-0010.268.

126. It is my belief that a POSITA, as well as any freshman electrical engineering undergraduate student, would understand that the Examiner's reasons for allowance do not have any scientific merit. Current and energy are not the same. Energy increases with the square of current as well as local resistance that is more concentrated around the electrode once the coagulation process has started. Current flows all the way between two poles having different voltage potentials and cannot form around a needle that only has a single pole with one voltage potential.

127. If high frequency current would only travel a short distance through a conductor, one would not be able to watch TV, as the 40-100 MHz frequencies energy signal carrying the TV signal would not even be able to carry the signal from the wall connector to the TV receptor, let alone from the broadcaster to your home located many miles away! Charges oscillate in an electrical conductor or even in a more complex medium such as the skin that has

lower permittivity and lower conductivity than a metal wire, by having the charges oscillating at the overall same rate and amplitude all along the circuit. The only attenuation in the case of bipolar system is due to the fact that the charges are distributed over a larger cross section when away from the electrodes, but when getting close to the other electrode the density is similar to that of the other electrode. This would be similar to having several circuits in parallel such as if you had water in a single pipe and in the middle of the way, divide this pipe in multiple pipes: the flow in each of the pipes is less than in the first one, but the sum of the flow of these multiple pipes is equal to the flow of the single pipe. Similar to that, in an electrical circuit, the current (number of charges moving per unit of time) is the same along the circuit, even if in some areas it is distributed to several smaller circuits.

128. After the '379 Patent issued, on February 10, 2022, a petition for Inter Partes Review ("IPR") was filed against the '379 Patent with the USPTO. *Id*. at JXM-0010.303.

129. In the Inter Partes Review ("IPR") for the '379 Patent, Complainant rejected a claim scope argued by the Petitioner where the claim language "apply energy to body segments around each electrode rather than to body segments between electrodes" would be interpreted to include merely "concentrat[ing] energy in a first area of the body around each electrode, while minimally affecting a second area of the body between adjacent electrodes." Appx. 20 (Proposed JXM-0031), at JXM-0031.10-11.

130. Instead, Complainant asserted a position that "the relevant intrinsic record supports a plain reading of the claim language at issue: 'apply energy to body segments around each electrode rather than to body segments between the electrodes' does not cover the application of energy concentrated in body segments and connected or intersecting between

electrodes, such as illustrated in FIG. 4, FIG. 7, and FIG. 8 of the '379 Patent." *Id*. at JXM-0031.19; *see also id*. at JXM-0031.14-15.

Describing FIG. 2 (reproduced below), the '379 patent explains that needles 301 "may not be located [in] close proximity because if the distance between electrodes or needles is too close, the energy field and the heated area generated by the applied energy field about each needle may be connected or intersect." '379 pat., 5:62-67. As shown in FIG. 2, the needles are spaced apart so that the energy field and heated area generated by the applied energy ***does not connect or intersect***.

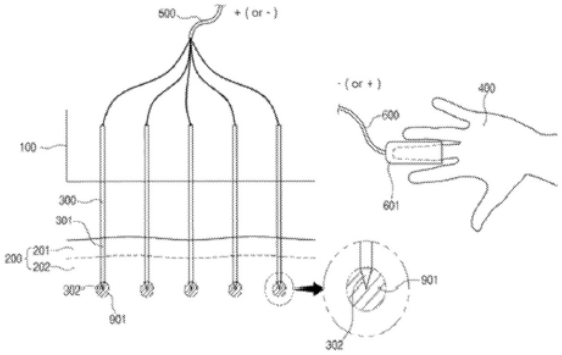


FIGURE 2

Id. at JXM-0031.14 (emphasis in original).

The '379 patent specification specifically contrasts an energy field that does not connect or intersect between electrodes, such as in FIG. 2, with the energy fields shown in FIGS. 7 and 8. In FIGS. 7 and 8, "the energy fields (generating heated areas in dermis) may be expanded and connected in dermis." '379 pat., 6:67-7:2. Therefore, the '379 patent clearly discloses that needles generate heated

* * *

Like the illustration shown in FIG. 2, the embodiments of FIG. 5 and FIG. 9B (reproduced below) illustrate energy fields that are focused around each electrode, and do not include heated areas that connect or intersect between electrodes. *See* '379 pat., 3:27-29 ("the heated area around the needle end tips may be oval or tear shaped as shown in FIG. 5."); 3:29-31 (describing embodiments in which "heat may not be concentrated between needles" and where "the heated area may be around each needle.").

Id. at JXM-0031.15.

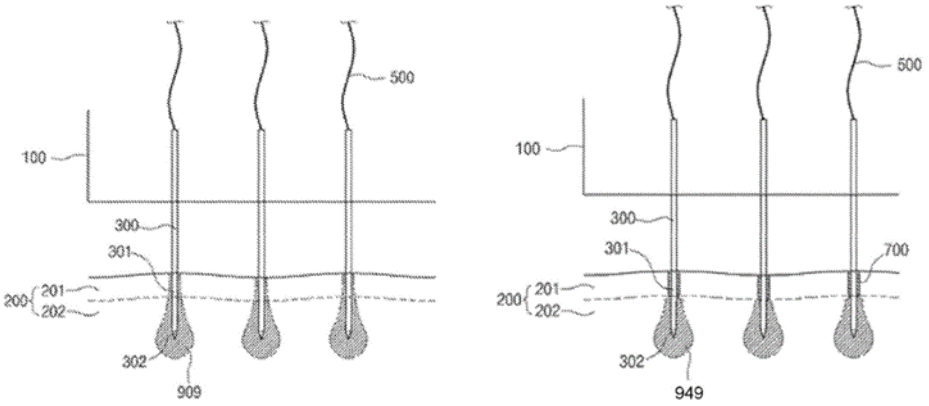


FIGURE 5 FIGURE 9B

Id., at 374.

131. The Board was persuaded by Complainant's arguments and found that "[t]he plain and ordinary meaning of this limitation as indicated by the phrase 'rather than,' ***precludes applying energy*** to body segments that extend continuously from one electrode to another," which "is consistent with the Specification, for example, Figure 5, a copy of which we reproduce below." Appx. 21 (Proposed JXM-0032), at JXM-0032.12-16 (emphasis added).

> Accordingly, we construe "apply energy to body segments around each electrode rather than to body segments between the electrodes" to mean that energy application occurs around each electrode without such energy application fully extending from one electrode to another electrode. In other words, the energy application must be configured such that energy application between electrodes does not extend continuously between the electrodes.

Id. at JXM-0032.16.

C. Prosecution History of the '444 Patent

132. As part of my analysis, I reviewed the prosecution history of the '444 Patent. The application that issued as the '444 Patent was rejected during prosecution under AIA 35 U.S.C. § 102(a)(1) as being anticipated by Manstein. Appx. 11 (Proposed JXM-0012), at JXM-0012.385. After Complainant agreed to the Examiner's suggestion to amend the independent claims (*Id*. at JXM-0012.387, 411, 414), the Examiner allowed the claims (*Id*. at JXM-0012.429).

133. In the reasons for allowance, the Examiner noted that the applicant included the allowable subject matter requiring the RF signal to be oscillating current" which is illustrated in figure 6. *Id.* The Examiner also stated that the claimed effect was that "RF energy flows around individual needles rather than between needles." *Id.* The Examiner explained that to achieve the claimed effect, such as the "effect illustrated in figures 5 and 9B,"[14] each individual needle electrode is "completing the positive/negative flow path itself." *Id.*

[14] In IPR2022-00593, Serendia also argued that the non-overlapping/non-intersecting energy field embodiments (*e.g.*, Figs. 2, 5, and 9B) require that the energy field for each electrode is only applied around the electrode (absolutely no energy is transferred between electrodes) (*See* Appx. 20 (Proposed JXM-0031), at JXM-0031.14-17).

Reasons for Allowance

The following is an examiner's statement of reasons for allowance: The applicant included the allowable subject matter requiring the RF signal to be oscillating current. This is illustrated in figure 6 of the applicant's drawings in which each individual needle changes polarity rapidly from negative to positive and vice versa. This produces the effect illustrated in figures 5 and 9B where the RF energy flows around individual needles rather than between needles as each individual needle is completing the positive/negative flow path itself. This subtle distinction does not appear to be disclosed in the Manstein reference.

Id.

134. Reviewing the Reasons for Allowance, it is my opinion that the POSITA would conclude that the Examiner allowed the application because he believed that the claims precluded any overlap of energy fields between adjacent bipolar electrodes; that is, the claim did not allow any electric current/RF energy to travel from a first electrode to a second, and vice versa. Rather, the Examiner believed the independent claims required that all electric current/RF energy leaving an electrode ***must return back to that electrode*** without traveling to another electrode, such that no energy is applied to body segments between electrodes. Stated otherwise, the Examiner allowed the claims because they preclude any overlap of energy between adjacent bipolar electrodes; any such overlap would mean that energy was traveling in a path between electrodes, which was disclosed by the cited art.

D. Prosecution History of the '536 Patent

135. As part of my analysis, I reviewed the prosecution history of the '536 Patent. U.S. Patent Application No. 13/825,083, the application that would ultimately issue as the '536 Patent, was filed on March 19, 2013, with 20 original claims, as a U.S. National Stage of

PCT/KR2012/001335. On August 27, 2015, the first Office Action on the merits issued indicating that claims 6, 7, 9, 16, 17, and 19 are objected to but otherwise allowable. In the reply dated March 20, 2015, the independent claims were amended to recite allowable subject matter. Subsequently the application was allowed.

E. Prosecution History of the '774 Patent

136. As part of my analysis, I reviewed the prosecution history of the '774 Patent. U.S. Patent Application No. 15/096,686, the application that would ultimately issue as the '774 Patent, was filed on April 12, 2016, with 20 original claims including exemplary independent claim 11.

> 11. An apparatus for treating dermatological tissue, comprising:
>
> a device including a distal end and a plurality of extendable needles, at least one needle extendable from the device distal end surface;
>
> a motor coupled to at least one needle that causes the at least one needle to extend a desired distance from the distal end surface when energized with a particular signal; and
>
> a signal generator electrically coupled to the at least one needle to cause vibration of the at least one needle when the at least one needle energized with a particular signal.

See Appx. 4 (Proposed JXM-0004) at JXM-0004.60. The claim also mentions that the signal generator coupled to the needle would cause the needle to vibrate. A high frequency signal does not cause an electrically conductive needle to vibrate unless it is connected to some kind of actuator, such as a piezo-electric crystal or other electro-magnetic actuator. Applicant submitted the Preliminary Amendment, in which Applicant canceled all 20 original claims and added 20 new claims, including independent claim 31 which became asserted independent claim 11 (reproduced below).

31. (Newly Added) An apparatus for treating dermatological tissue, comprising:

a device including a plurality of needles one of extending or extendable a desired distance from a surface, the desired distance selected to enable the plurality of needles to penetrate dermatological tissue; and

a signal generator electrically coupled to the plurality of extended needles to produce pulsed radio frequency signals across the plurality of needles to affect dermatological tissue near the plurality of needles.

Appx. 4 (Proposed JXM-0004) at JXM-0004.72–75. Here, Applicant introduced the term "pulsed radio frequency signal" for the first time without any explanation of the term. Neither the original claims nor the specification includes the phrase "pulsed radio frequency signal."

REMARKS

Claims 1-20 were pending. Claims 1-20 have been cancelled and claims 21-40 added. Upon entry of this preliminary amendment, claims 21-40 will be pending. Entry of this preliminary amendment is respectfully requested. Applicant has also amended the specification to correct minor grammatical or reference errors and replaced two drawings to correct errors. No new matter has been added. Entry of the preliminary amendments is respectfully requested.

Appx. 4 (Proposed JXM-0004) at JXM-0004.77. Applicant never commented on the term "pulsed radio frequency signal" during the prosecution of the '774 Patent.

137. After the '774 Patent issued, on December 28, 2021, a petition for inter partes review (IPR) was filed against the '774 Patent. Appx. 14 (Proposed JXM-0017). In the IPR for the '774 Patent, Serendia's expert, Paul Stauffer explained that the "pulsed" signals, as described in the specification, require the signal to be "normally off with an amplitude of zero" and then when "suddenly on," the signal goes to a predetermined amplitude (A1 or B1) for "a brief portion of time." Appx. 29 (Proposed RXM-0013 (Expert Declaration of Paul Stauffer, Ex. 2002 IPR2022-00376)) at RXM-0013.0013-16. It is my understanding that Serendia then adopted Mr. Stauffer's construction as its own in the instant proceeding. Appx. 15 (Proposed

JXM-0019) at JXM-0019.22 ("The plain and ordinary meaning of the claim limitation quoted above requires the 'application of a radio frequency signal that is normally off and suddenly on for a portion of time to two or more needles to subtly change but not irreversibly damage the skin near the needles.'") (citing Appx. 29 (Proposed RXM-0013, Stauffer Decl.,) ¶ 32).

F. Prosecution History of the '812 Patent

138. As part of my analysis, I reviewed the prosecution history of the '812 Patent. U.S. Patent Application No. 15/724,261, which issued as the '812 Patent, was filed on October 3, 2017, with 20 original claims. The initial filing included a substitute specification with mark-ups shown. On November 15, 2017, a Preliminary Amendment was filed which cancelled claims 1-20 and added claims 21-40. After two Office Actions on the merits and the filing of a terminal disclaimer over U.S. Patent No. 9,320,536. On August 7, 2018, the USPTO issued a Non-Final Office Action in which the claims were rejected for being obvious over WO 2005/09679 (Manstein) and KR 10-2011-0002210 to Dong and for obviousness type double patenting over the'536 Patent. On October 4, 2018, Merle Richman conducted an Applicant-Initiated Interview with Examiner David Comstock. During the Interview, Mr. Richman proposed adding the limitation "extendable" to the contacts. On October 30, 2018, a second interview was conducted with the Examiner to discuss a translation of the Yang reference obtained by the Examiner. During the interview, the Examiner indicated the claims might be allowable if the claims were amended to note that the needles move independently of the entire disposable section. The same day as the interview a Response under 37 C.F.R. 1.111 was filed, which amended the claims and argued that the claims were allowable based on the wording suggested by the Examiner. A Terminal Disclaimer over the '536 Patent was also filed. A Final Office Action was mailed on Mach 4, 2019. In the Final Office Action, the prior art

rejection was withdrawn but the obviousness type double patenting rejection was maintained due to certain deficiencies in the terminal disclaimer. The application was abandoned on September 17, 2019, for failure to respond to the Final Office Action. On April 10, 2020, a petition to revive was filed along with a response to the Final Office Action. The application was allowed on August 20, 2020. The issue fee was paid on November 19, 2020, and the '812 Patent issued on December 22, 2020.

IX. ASSERTED CLAIMS

139. It is my understanding that Serendia is currently asserting the claims listed in the Table below. The claimed subject matter of the asserted claims is briefly explained below.[15]

Asserted Patent	Asserted Claims
'836 Patent	1, 2, 5, 9, 11, 12, 13, 14, 17, and 22
'379 Patent	1, 2, 5, 7, 8, and 9
'444 Patent	1, 2, 4, 5, 6, 7, 8, and 9
'536 Patent	1, 4, 5, 9, 11, 13, 16, and 17
'774 Patent	13 and 14
'812 Patent	1, 5, 6, 10, 12, 13, 14, 16, 17, 18, and 19

A. Asserted claims of the '836 Patent

140. It is my understanding that Serendia asserts ten claims from the '836 Patent, including two independent claims, *i.e.*, claim 1 (apparatus) and claim 14 (method). The asserted independent claims require "a plurality of electrodes, the electrodes being bipolar and configured to be insertable into skin to be treated," (claim 1) or "inserting a plurality of

[15] The explanation of the claimed subject matter was taken from the Joint Technology Stipulation dated June 23, 2023.

electrodes, the electrodes being bipolar into a section of skin to be treated" (claim 14). *See, e.g., id.* at cls. 1 and 14. Claim 1 also recites "a radio frequency (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." *Id.* at cl. 1. Claim 14 also recites "applying a [*sic*] 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." *Id.* at cl. 14.

141. The RF generation module of claim 1 of the '836 Patent can be "configured to provide an AC RF signal to the plurality of electrodes for a predetermined time interval" (claim 2), and further, can have "each electrode of the plurality of electrodes has a length sufficient to reach skin dermis when inserted into skin," "the predetermined time interval is from 0.05 to 0.8 seconds" (claim 4), and can have "the closest neighboring electrodes have opposite polarities" (claim 5). *Id.* at cls. 2, 4, and 5. The method can include "providing an AC RF signal to the plurality of electrodes for a predetermined time interval," where "the skin segment to be treated is skin dermis," "each electrode of the plurality of electrodes has a length sufficient to reach skin dermis when inserted into skin," and "the predetermined time interval is from 0.05 to 0.8 seconds." *Id.* at cls. 15 and 17. Claim 22 adds to the method of claim 14 that a "predetermined time interval is from 0.05 to 0.8 seconds." *Id.* at cl. 22. The claimed apparatus can include needles that have a diameter between 0.25 mm and 0.30 mm (claim 9), the distance between electrodes can be between 1.3 mm and 3.0 mm (claim 11), the plurality of electrodes can be non-insulated (claim 12), or insulated except at their tips (claim 13). *See id.* at cls. 9, 11–13.

The claimed method can include that the RF is between 0.5 and 10 MHz (claim 22). *See id.* at cl. 22.

B. Asserted claims of the '379 Patent

142. It is my understanding that Serendia asserts six claims, including one independent claim from the '379 Patent. The asserted independent claim recites, a "mammalian body treatment apparatus" having "a plurality of electrodes, the electrodes being bipolar and configured to be insertable into a body segment to be treated; and a radio frequency (RF) generation module." '379 Patent at cl. 1. The RF generation module is "electrically coupled to the plurality of electrodes and configured to provide an RF signal with oscillating current to the plurality of electrodes to apply energy to body segments around each electrode rather than to body segments between the electrodes." *Id.*

143. The claimed apparatus can include an RF generation module configured to apply an RF signal to the electrodes for a "predetermined time interval" (claim 2). *Id.* at cl. 2. The electrodes can be configured so that "the closest neighboring electrodes hav[ing] opposite polarities" (claim 5) and so that they are spaced apart by "a distance of 1.3 mm to 3.0 mm" (claim 7), and the plurality electrodes can be non-insulated (claim 8), or insulated except at their tips (claim 9). *Id.* at cls. 5, 7–9.

C. Asserted claims of the '444 Patent

144. It is my understanding that Serendia asserts eight claims, including one independent claim, from the '444 Patent. The asserted independent claim recites a "mammalian body treatment apparatus" including "a plurality of electrodes, the nearest electrodes having opposite polarities and the electrodes configured to be deployable into a body segment to be treated." '444 Patent at cl. 1. The apparatus also includes "a radio frequency (RF) generation

module, the RF generation module electrically coupled to the plurality of electrodes and configured to provide an RF signal with oscillating current to the plurality of electrodes that causes energy to be substantially applied to body segments around each electrode." *Id.*

145. The claimed apparatus can include an RF generation module configured to apply an RF signal to the electrodes "for a predetermined time interval" (claim 2), bipolar electrodes (claim 4), electrodes "arranged into a plurality of rows and columns and neighboring electrodes in each of the plurality of rows [and] columns have opposite polarities" (claim 5), electrodes that form "a square configuration" (claim 6), electrodes that form "a rectangular configuration and their respective polarities form a "checkboard pattern" (claim 7), and wherein the plurality of electrodes are non-insulated (claim 8) or insulated except at their tips (claim 9). *See id.* at cls. 2, 4–9.

146. Thus, each of the asserted claims of the '836, '379, and '444 Patents recite: (1) a plurality of electrodes (*i.e.*, more than one electrode) and (2) an application of RF signal to the plurality of electrodes to cause coagulation or to apply energy to an area around each electrode, rather than between the electrodes. Most of the asserted claims of the '836, '379, and '444 Patents do not specify if the electrodes are insulated or non-insulated. Accordingly, I believe that these claims are broad enough to include both types of electrodes. *See* '836 Patent, claims 1, 2, 5, 9, 11, 12, 14, 17, 22; '379 Patent, claims 1, 5, 7; '444 Patent, claims 1, 2, 4, 5, 6, 7, 10. Only a limited number of the asserted claims of the'836, '379, and '444 Patents require a specific type of electrode. *See* '836 Patent, claims 12 (reciting non-insulated electrodes) & 13 (reciting insulated electrodes); '379 Patent, claim 8 (reciting non-insulated electrodes) & 9 (reciting insulated electrodes); '444 Patent, claims 8 (reciting non-insulated needles) & 9 (reciting insulated electrodes).

D. Asserted claims of the ‘536 Patent

147. It is my understanding that Serendia asserts eight claims, including two independent claims, from the ‘536 Patent. The asserted independent claims 1 and 11 recite a “method of treating dermatological tissue” and an “apparatus for treating dermatological tissue,” respectively. *Id.* at cl. 1 and cl. 11. The method of treating dermatological tissue comprises, “placing a user holdable device releasably couplable deployable needle assembly end surface on or near dermatological tissue to be treated, the holdable device including a proximal end and the releasably couplable deployable needle assembly” where “the deployable needle assembly mechanically separatably from the proximal end and including a plurality of needles extendable from the deployable needle assembly end surface” *Id.* at cl. 1. The method also comprises “one of the proximal end and the deployable needle assembly including at least one electrical conductor and the other including at least one restorably deflectable electrical contact couplable to the one of the proximal end and the deployable needle assembly at least one electrical conductor.” *Id.* The method further comprises “communicating electrical signals from the proximal end to the plurality of extendable needles; energizing a motor coupled to a plurality of extendable needles to cause a plurality of the extendable needles to extend a desired distance from the needle assembly end surface; and energizing the plurality of extended needles via a signal generator electrically coupled to the plurality of extended needles.” *Id.*

148. The apparatus for treating dermatological tissue similarly includes, “a user holdable device including a proximal end and a releasably couplable deployable needle assembly, the deployable needle assembly mechanically separatably from the proximal end and including a plurality of extendable needles, a plurality of the extendable needles extendable from a deployable needle assembly end surface, one of the proximal end and the deployable needle assembly including at least one electrical conductor and the other including at least one

restorably deflectable electrical contact couplable to the one of the proximal end and the deployable needle assembly at least one electrical conductor; a motor coupled to a plurality of extendable needles that causes the plurality of extendable needles to extend a desired distance from the needle assembly end surface when the motor is energized with a particular signal; and a signal generator electrically coupled to the plurality of extended needles to energize the plurality of extended needles." *Id.* at cl. 11.

149. The claimed proximal end of claim 1 can include "at least one embedded LED therein and further including energizing the LED when the signal generator is energized, the at least one embedded LED illuminating the deployable needle assembly when energized" (claim 4). *Id.* at cl. 4. The claimed proximal end of claim 11 can include "the needle deploying motor, the motor including a draft [*sic*] shaft releasably couplable to the deployable needle assembly" (claim 13). *Id.* at cl. 13. The claimed releasably couplable deployable needle assembly of claim 1 can include "a translucent section to communicate illumination from the least one embedded LED to the plurality of extendable needles" (claim 5). *See id.* at cl. 5. The claimed plurality of extendable needles of claim 1 can be deployed to a "predetermined depth" and energized to a "predetermined intensity for a predetermined duty cycle" (claim 9). *Id.* at cl. 9. The claimed restorably deflectable electrical contact of claim 11 can include "a depressible pin" (claim 16). *Id.* at cl. 16. The claimed deflectable electrical contact of claim 11 can be "coupled to a first plurality of the plurality of extendable needles and a second deflectable electrical contact is coupled to a second, different plurality of the plurality of extendable needles" (claim 17). *Id.* at cl. 17.

E. Asserted claims of the ‘774 Patent

150. It is my understanding that Serendia asserts two claims from the ‘774 Patent, dependent claims 13 and 14 which depend from independent claim 11 and dependent claim 12. Independent claim 11 recites “[a]n apparatus treating dermatological tissue,” which comprises, “a device including a plurality of needles one of extending or extendable a desired distance from a surface, the desired distance selected to enable the plurality of needles to penetrate dermatological tissue;” and “a signal generator electrically coupled to the plurality of extended needles to produce pulsed radio frequency signals across the plurality of needles to affect dermatological tissue near the plurality of needles.” ‘774 Patent at cl. 11. Claim 12 further requires the device to include “an end surface configured to be placed on or near dermatological tissue to be treated, the end surface including a plurality of needles extendable a desired distance from the end surface.” ‘774 Patent at cl. 12. The claimed apparatus can further include “a mechanism for causing the plurality of the extendable needles to extend a desired distance from the end surface” (claim 13), and “a motor coupled to the plurality of extendable needles that may be directed to cause the plurality of the extendable needles to extend a desired distance from the end surface” (claim 14). *Id.* at cls. 13 and 14.

F. Asserted claims of the ‘812 Patent

151. It is my understanding that Serendia asserts eleven claims, including two independent claims, from the ‘812 Patent. The asserted independent claims 1 and 12 recite a “method of treating dermatological tissue” and “apparatus for treating dermatological tissue,” respectively. ‘812 Pat. at cl. 1 and cl. 12. The method of treating dermatological tissue comprises, “placing a user holdable device releasably couplable deployable needle module end surface on or near dermatological tissue to be treated, the user holdable device including a

proximal end and the releasably couplable deployable needle module, the releasably couplable deployable needle module mechanically separatably from the user holdable device proximal end" which includes "a needle assembly including a plurality of needles." *Id.* at cl. 1. The needle assembly is "movable within the releasably couplable deployable needle module to extend the plurality of needles from the releasably couplable deployable needle assembly end surface while at least one electrical contact of the needle assembly remains electrically coupled to at least one electrical contact of the user holdable device proximal end." *Id.* The method further comprises communicating electrical signals from the user holdable device proximal end to the needle assembly via the electrical contacts. *Id.* Similarly, the apparatus for treating dermatological tissue includes, "a user holdable device including a proximal end and a releasably couplable deployable needle module, the releasably couplable deployable needle module mechanically separatably from the user holdable device proximal end," with "a needle assembly including a plurality of needles, the needle assembly movable within the releasably couplable deployable needle module to extend the plurality of needles from the releasably couplable deployable needle assembly end surface while at least one electrical contact of the needle assembly remains electrically coupled to at least one electrical contact of the user holdable device proximal end." *Id.* at cl. 12.

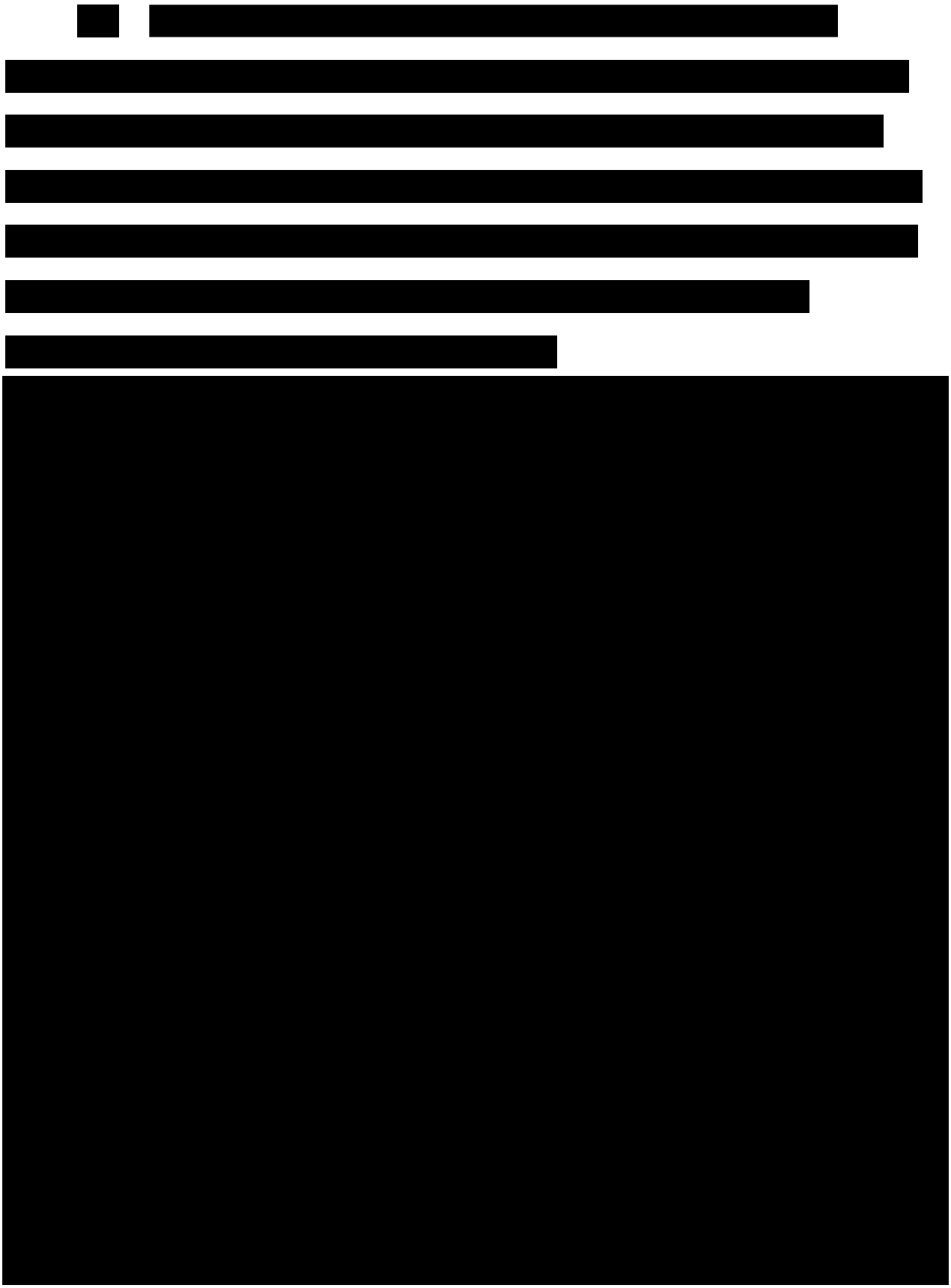
152. The claimed proximal end of claim 12 can include one or more embedded LEDs where the device further includes "a photonic signal generator electrically coupled to the least one embedded LED, the at least one embedded LED capable of illuminating the needle assembly when energized" (claim 17) or "a motor coupled to the needle assembly to extend the plurality of needles a desired distance from the releasably couplable deployable needle assembly end surface when the motor is energized with a particular signal" where "the user

holdable device proximal end includes the motor, the motor including a drive shaft releasably couplable to the needle assembly" (claim 16), or whereas the claimed needle assembly of claim 1 can have "a translucent section" where the user holdable device proximal end includes "at least one embedded LED therein and further including energizing the at least one embedded LED so the at least one embedded LED illuminates the releasably couplable deployable needle module" and the method further includes "energizing the least one embedded LED to illuminate the plurality of needles via the needle assembly translucent section," "energizing a motor coupled to the needle assembly to cause the plurality of the needles to extend a desired distance from the releasably couplable deployable needle module end surface," and "energizing the plurality of needles via a signal generator electrically coupled to the user holdable device proximal end." (claim 5). *See id.* at cls. 2, 3, 4, 5, 13, 16 and 17. The claimed method or apparatus can include "a motor coupled to the needle assembly to extend the plurality of needles a desired distance from the releasably couplable deployable needle assembly end surface when the motor is energized with a particular signal" (claim 13) and further, "a signal generator electrically coupled to the user holdable device proximal end to energize the plurality of needles" (claim 14), and the method of claim 1 may further include "energizing the motor to deploy the plurality of needles to a predetermined depth and directing the signal generator to energize the plurality of needles at a predetermined intensity for a predetermined duty cycle" and "energizing a motor coupled to the needle assembly to cause the plurality of the needles to extend a desired distance from the releasably couplable deployable needle module end surface" and "energizing the plurality of needles via a signal generator electrically coupled to the user holdable device proximal end" (claim 6). *Id.* at cls. 2, 3, 6, 13, and 14.

153. The claimed method can comprise "a first electrical contact . . . coupled to a first plurality of the plurality of needles and a second electrical contact of the at least one electrical contact is electrically coupled to a second, different plurality of the plurality of needles" (claim 10). *Id.* at cl. 10. The claimed electrical contacts of the apparatus can include "a pin that is extendable in the same direction as the plurality of needles" (claim 18). *Id.* at cl. 18. Additionally, claim 19 recites the "apparatus of claim 12, wherein one of the user holdable device proximal end and the needle assembly includes at least two extendable electrical contacts and the other includes at least two electrical contacts couplable to the at least two extendable electrical contacts" (claim 19). *Id.* at cl. 19.



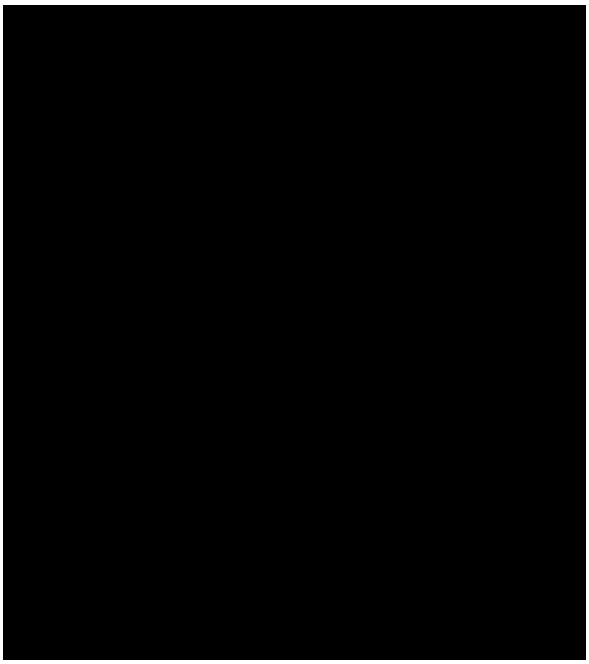




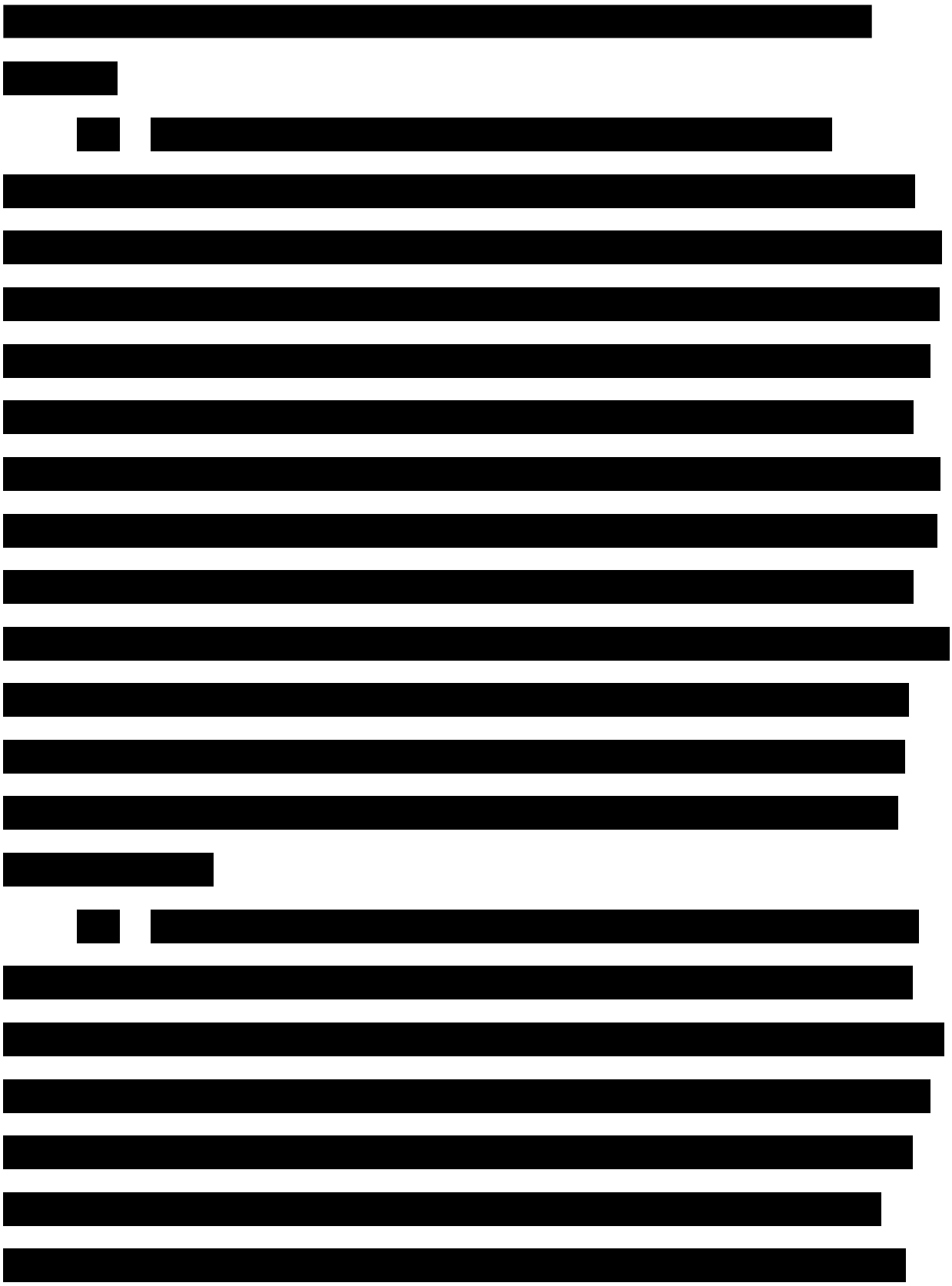




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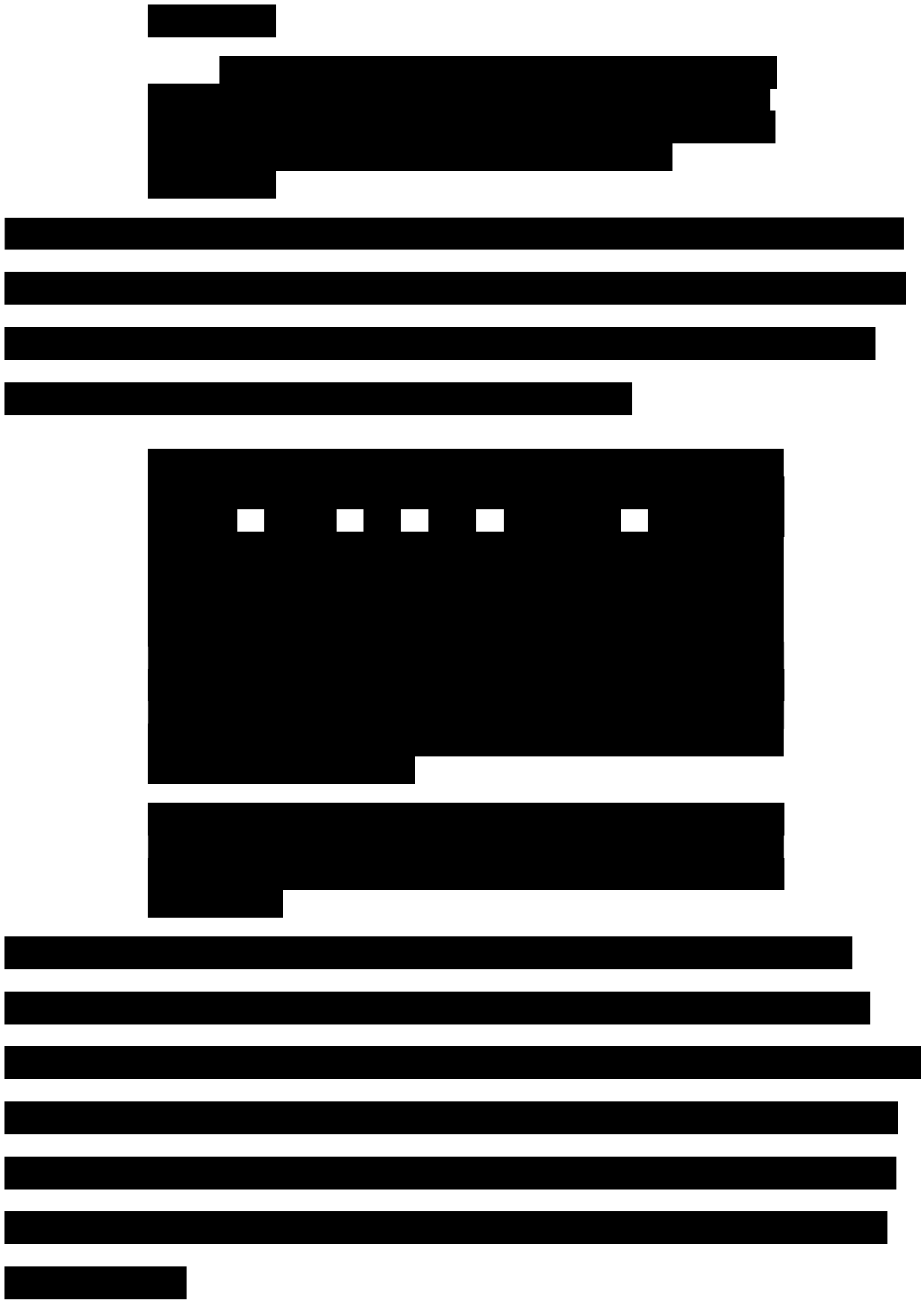








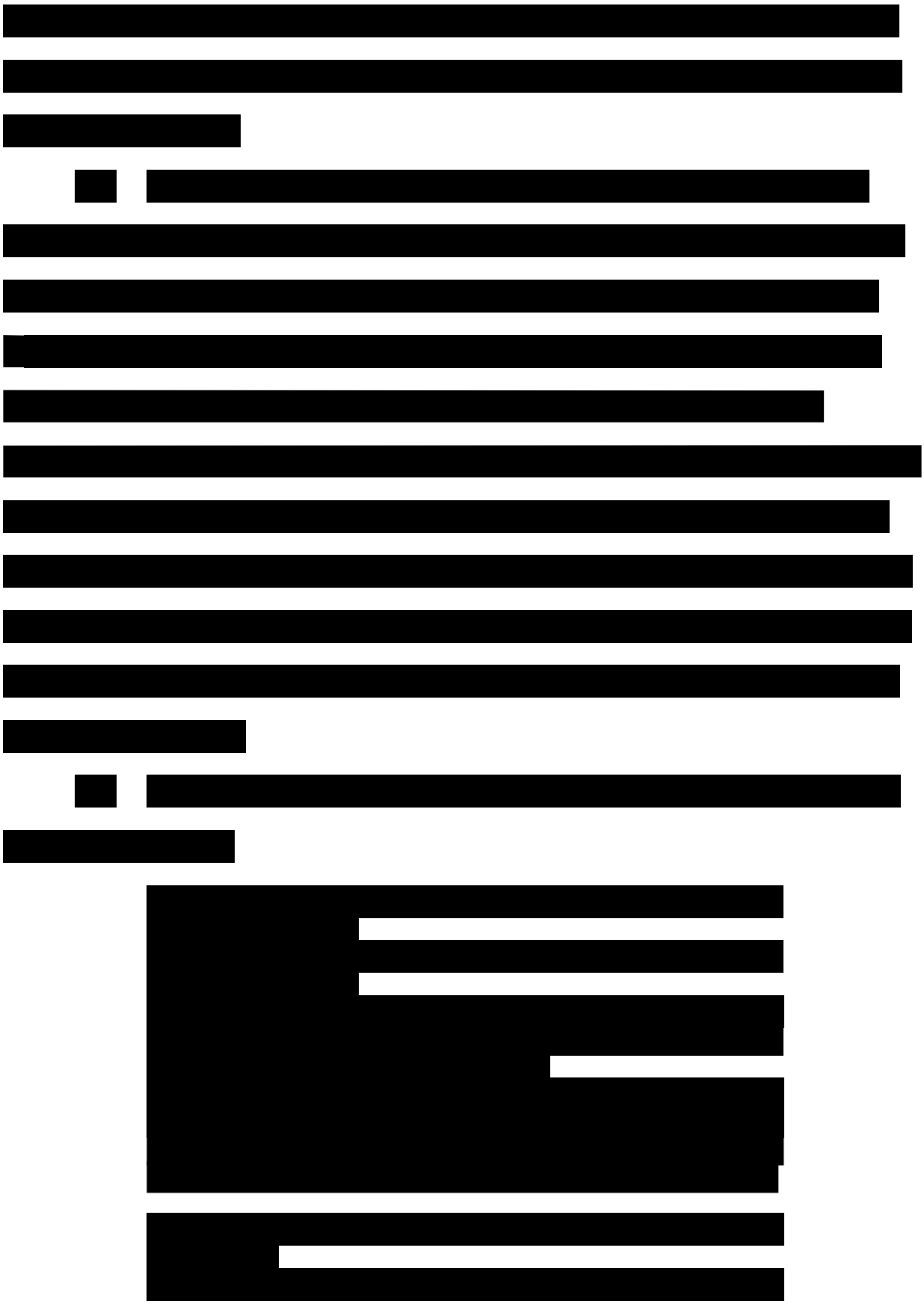


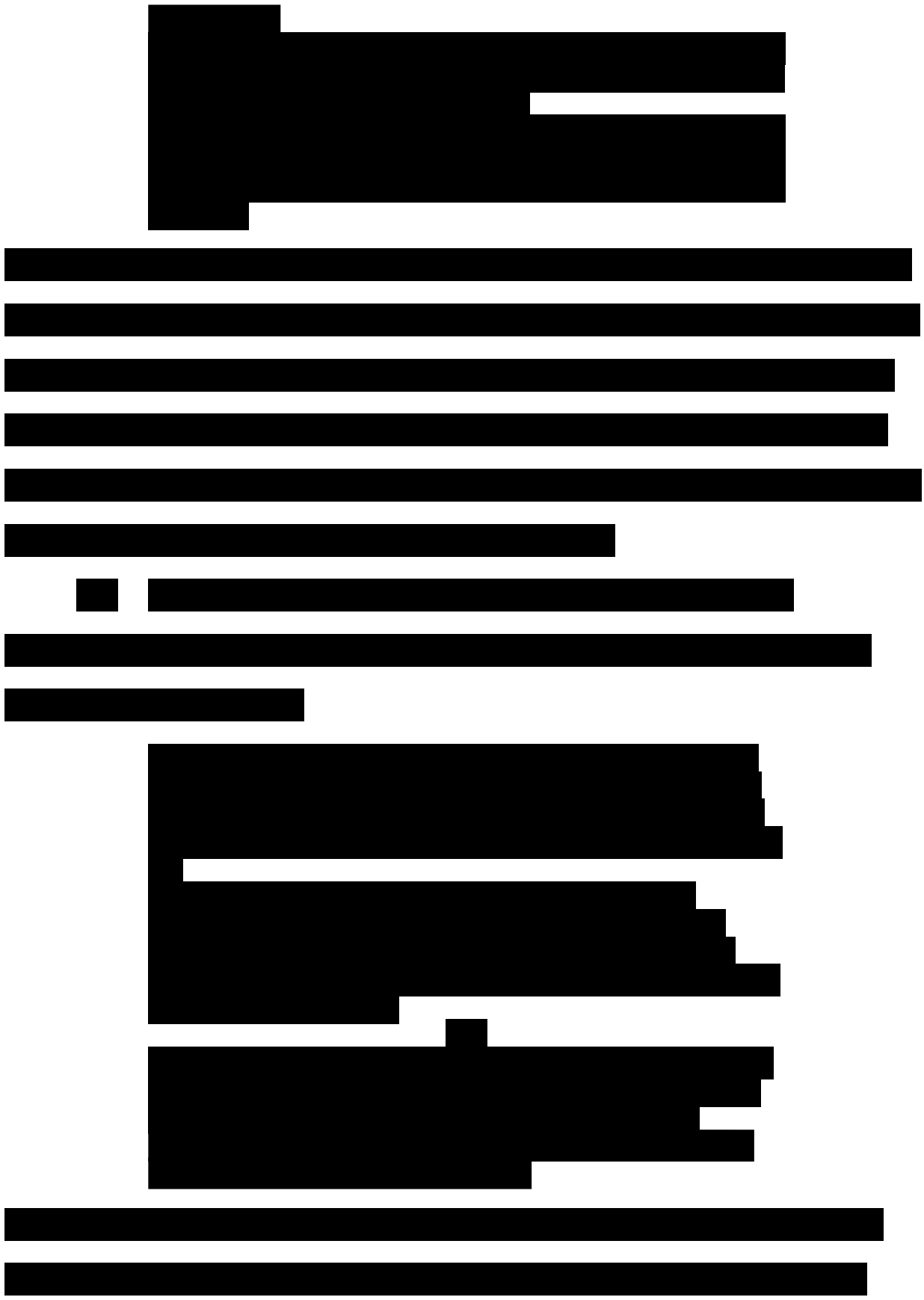


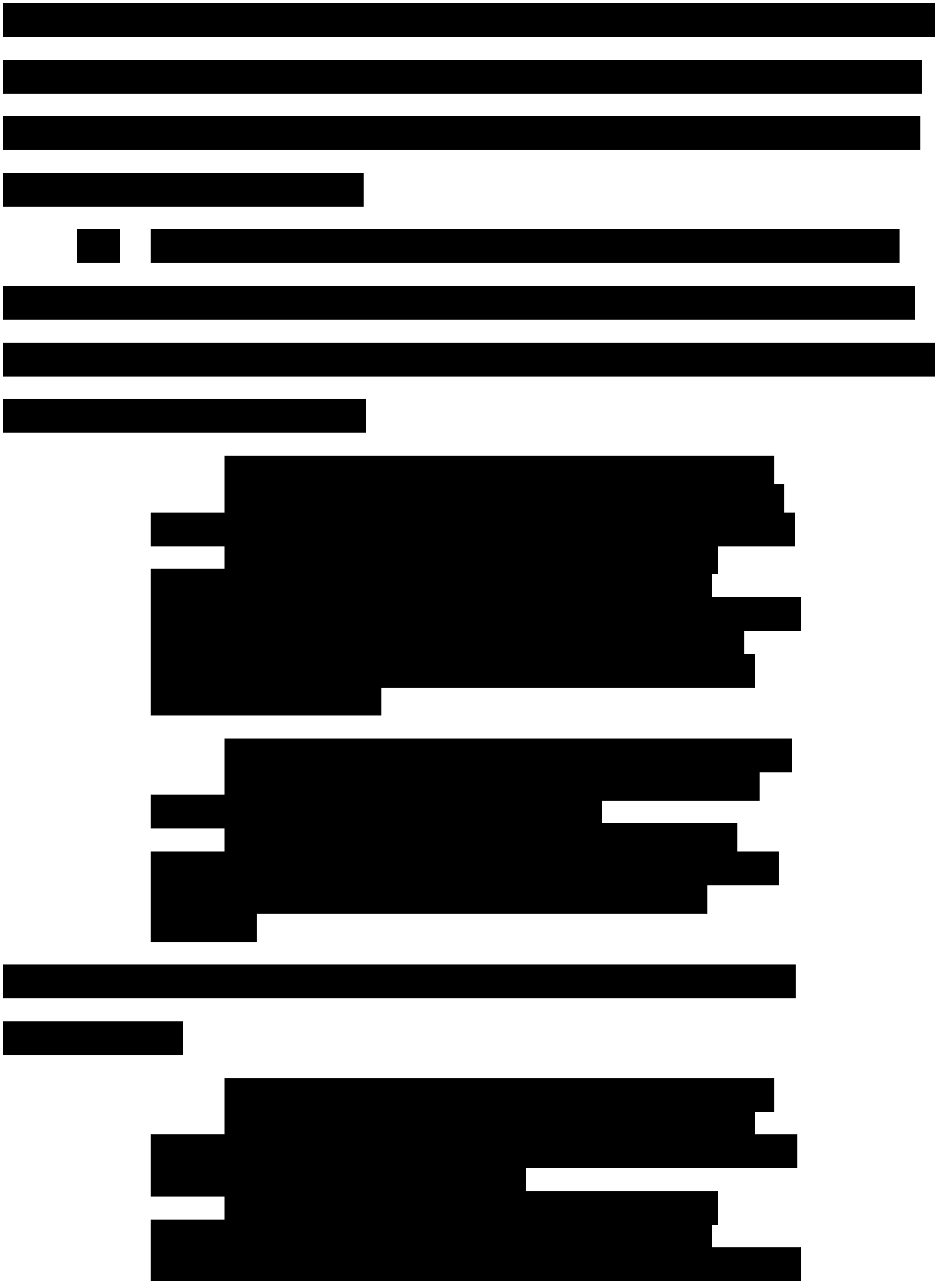




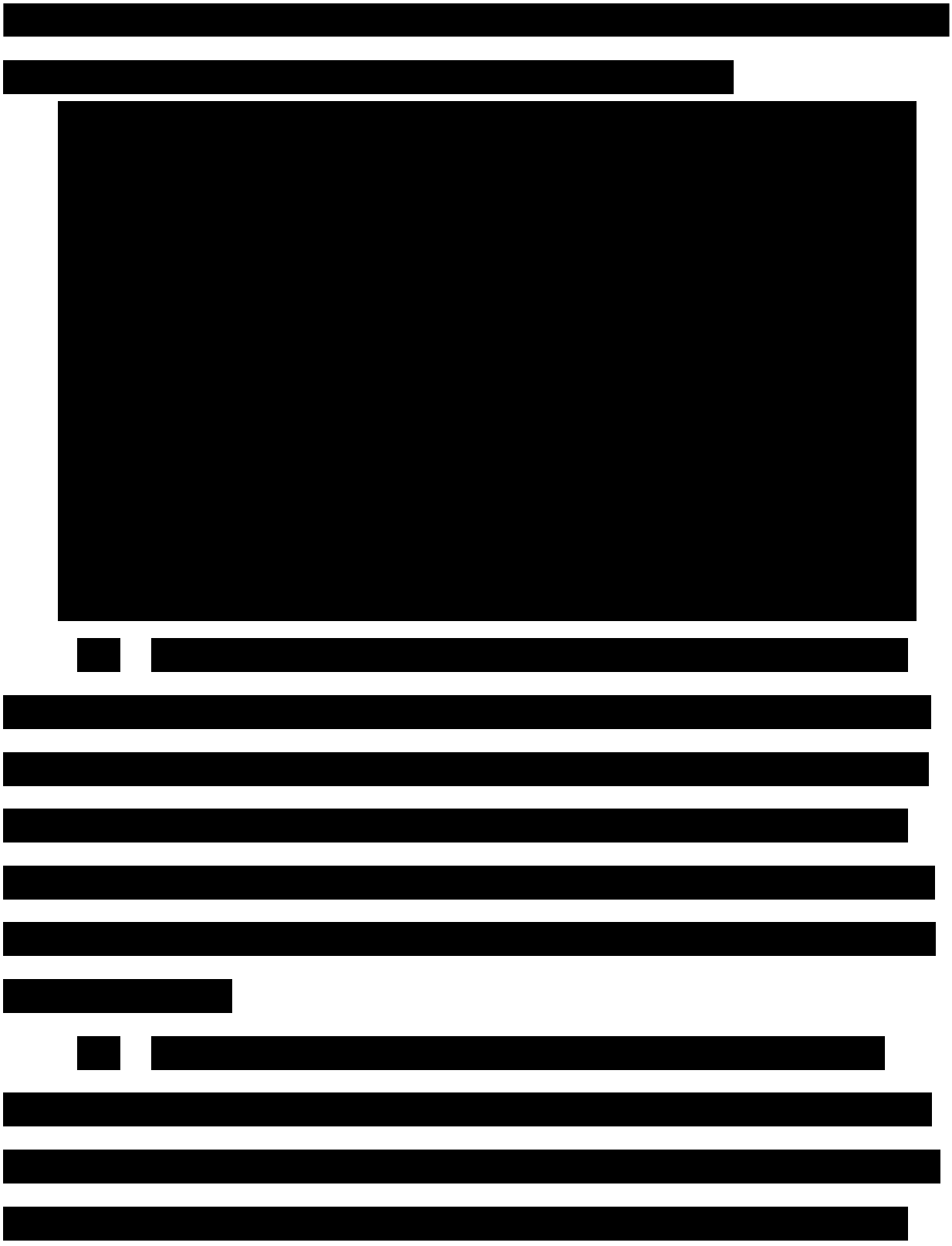




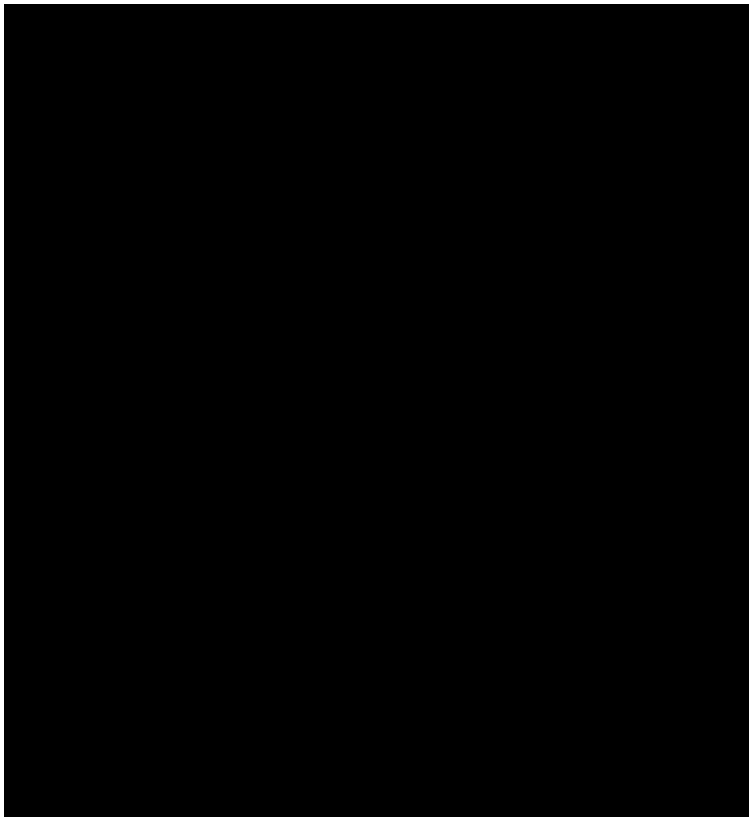








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XI. PATENT INELIGIBLE SUBJECT MATTER (Asserted Claims of the '836, '379, and '444 Patents)

194. It is my opinion that the asserted claims of the '836, '379, and '444 Patents are invalid as being directed to ineligible subject matter.

195. First, the Asserted Claims in the '836, '379, and '444 Patents are directed to the natural phenomena (and observation of the natural phenomena) of RF current flow and resulting tissue heating when applied to dermal tissue. These claims are also directed to the abstract idea of providing enough energy to achieve a desired effect around the needles, but not enough energy to cause coagulation between the needles. This is the case, regardless of whether the claimed effect is to avoid unduly damaging tissue ('836 Patent), to avoid overlapping energy fields ('379 Patent) or to cause energy to be substantially applied to body segments around each electrode ('444 Patent). These claims impermissibly attempt to monopolize an abstract result without reciting limitations that would be needed to produce the desired result.

196. Second, the additional limitations of the Asserted Claims fail to transform the abstract idea into patentable subject matter by adding something more. Nor is there an "ordered combination" of claim elements that "transform[s]" the nature of the claims into a patent-

eligible invention. *Alice*, 134 S. Ct. at 2355.

197. All asserted claims of the '836, '379, and '444 Patents strive to broadly claim a desired effect:

- "... to cause coagulation around each electrode rather than coagulating between the electrodes." '836 Patent at claims 1 and 14.
- "… to apply energy to body segments around each electrode rather than to body segments between the electrodes." '379 Patent at claims 1 and 10
- "… that causes energy to be substantially applied to body segments around each electrode." - '444 Patent at claim 1 and 10.

198. The specifications of the '836, '379, and '444 Patents describe the zone between the electrodes as "energy field" 909 as shown in Figure 5 of each patent. In the as-filed specification of the '836 Patent, item 909 of Figure 5 is described as using the alleged "Na-effect." In a 2015 article, the inventor of the '836, '379, and '444 Patents, Jongju Na, admitted that the so-called "Na-effect" is nothing more than an observation. See, Na *et al*., Sc*i Rep.* 5: 16735 at 2 (Nov. 13, 2015) ("oval and cocoon-shaped coagulation columns, which were generated around each microneedle electrode, were observed immediately after the emission of RF energy for 120 msec, 200 msec, and 300 msec."). In his deposition, Dr. Na testified that the "Na effect" was something that is observed. Transcript of Dr. Jongju Na, Volume 4, at 493:19-494:5.

> Q. So you were able to verify the conditions in which the Na effect was not observed?
> A. Well, in my invention and the Na effect – actually, just avoid any confusion, please understand that when I mix these words, I mean to refer to my invention.
> So I did observe, during the experiments under certain conditions, my invention that's described here was not observed.

Transcript of Dr. Jongju Na, Volume 4, at 493:19-494:5.

199. Dr. Na testified that the "Na effect" is a "phenomenon," and that the relationship between the "various parameter settings" is "almost like mathematical equation." Transcript of Dr. Jongju Na, Volume 1, at 101:3-19.

> Q So when you observed the so-called Na effect, what level of power and what level of conduction time did you use?
> A So if you look at the specification of my patent, you will see the definition which describes Na effect, of course, in so and so situations. And to see this phenomenon, for example, it's not like that you just use a certain conduction time, but rather depending on the various parameter settings that you have phenomenon or phenomenons and the – it's not like you use a set value for one component – one component of single value, but rather you actually use many different parameters.
> So it's like – it's kind of relative to the values. It's almost like mathematical equation.

Transcript of Dr. Jongju Na, Volume 1, at 101:3-19.

200. Dr. Na also testified that when he referred to "the Na effect," he "mean[s] to refer to his invention." Transcript of Dr. Jongju Na, Volume 4, at 493:19-494:5.

201. Moreover, the specifications state that the alleged "invention is a byproduct of newly discovered effects." '836 Patent, at 3:13-15; '379 Patent, at 3:13-15; '444 Patent, at 3:23:25.

202. Also, as I noted above, while the '836 Patent removed any references to the Na-effect in the substitute specification, the as-filed English translation of the Korean PCT application originally described "heating around the electrodes" as the "Na-effect." As discussed above, Serendia's alleged support in the claimed priority application for the following limitations is the disclosure of the Na-effect: (1) "coagulation around each electrode rather than coagulating between the electrodes" as claimed in the '536 Patent; (2) "apply[ing] energy to body segments around each electrode rather than to body segments between the electrode" as

claimed in the ‘379 Patent; and (3) “caus[ing] energy to be substantially applied to body segments around each electrode” as claimed in the ‘444 Patent. Applicant’s translated Korean priority application explains that the purported invention is the “Na-Effect,” whereby “the temperature is raised around the tip of each needle, not between needles.” Complaint Appendix A at p. 23, ¶¶ [30]-[31].

203. It is my understanding that even Complainant views the claims of these patents as merely being directed to a discovered effect, as evidenced by the fact that Complainant describes the ‘836, ‘379, and ‘444 Patents as “the ‘Na Effect Patents.’” Complainant’s Claim Construction Brief, at pg. 1 (citing JXM-0034, at JXM-0034.7).

204. Dr. Na also testified that his invention is “to cause coagulation around each electrode rather than coagulation between electrodes.” Transcript of Dr. Jongju Na, Volume 4, at 513:2-514:2; *see also* Transcript of Dr. Jongju Na, Volume 1, at 46:8-11 (“So my invention is – is about an independent coagulation around each electrode in a bipolar system with AC RF.”).

> Q. Will every microneedling device that is bipolar and applies an AC RF signal to electrodes achieve your invention?
> A. Sir, what I invented was that, as written there, when AC RF signals are delivered to bipolar electrodes, that causes coagulation around each electrode. So that is different from coagulation between electrodes. That is what my invention is about.
> Q. … My question is, will every microneedling device that employs bipolar needles and an RF generator applying RF AC current result in the invention that you just articulated?
> A. Sir, it would be unclear to say every RF generator would result in my invention. As written here, my invention is configured to cause coagulation around each electrode rather than coagulation between electrodes.
> So my invention is describing that kind of case.
>
> Transcript of Dr. Jongju Na, Volume 4, at 513:2-514:2.

205. When discussing the experiments Dr. Na performed when looking to observe what he refers to as the Na effect, Dr. Na characterized “cook[ing] only around the needle” as a “goal.” Transcript of Dr. Jongju Na, Volume 2, at 184:21-185:3 (“So those were the

frequencies that were considered and the – I also talked about that the conducted experiment, our goal was to cook only around the needle ...").

206. Based on my review, the claims of the '836, '379, and '444 Patents are also directed to the mental process of providing enough energy to achieve a desired effect around the needles, but not enough energy to cause coagulation between the needles or unduly damage tissue ('836 Patent) or to avoid overlapping energy fields ('379 and '444 Patents). The POSITA would understand that the claims require nothing more than for a specific electrode array geometry, selecting an output level, duty cycle, frequency (if adjustable) and total time of activation by the user of the equipment selecting which parameters to use. It is my understanding that merely selecting such RF output parameters by the user of the requirement is not patent-eligible subject matter. It is my understanding that the specifications even admit that the user must set several parameters (*e.g.*, manually) to achieve the desired result. '836 Patent, at 5:33-57; '444 Patent, at 5:46-6:3; '379 Patent, at 5:33:59.

207. Based on my review, the '836, '379, and '444 Patents' specification only recite a nonexclusive list of variables that the user must alter to achieve the desired coagulation pattern and energy field shapes. However, the claims do not instruct how the variables would need to be set to produce the desired Alternating Current (AC) Radio Frequency (RF) signal/RF signal with oscillating current.

208. For example, the specifications explain that "to achieve a desired energy field about the needle(s)," one must tune multiple variables, such as "distance between needles," "energy level (current, voltage)," "needle's thickness," "system resistance, AC frequency rate, high frequency rate," "needle length or needle depth," and a "proportional constant" somehow related to "Device resistance, needle resistance," and "skin resistance." '836 Patent, at 10:1-41;

‘379 Patent, at 10:1-43; ‘444 Patent, at 10:13-54.

209. The specification mentions that whether a user “generate[s] a desired energy field” also depends on the shape of the needles (‘836 Patent, at 9:58-63; ‘444 Patent, at 10:2-12; ‘379 Patent, at 9:58-67). However, in my opinion, although preferred ranges for some of the variables are provided, the specification does not explain (nor do the claims specify) *how* one must adjust all the other variables to achieve the desired effect for a given needle shape.

210. For example, the specifications explain that the energy field is smaller when the frequency is increased (‘836 Patent at 6:25-55). It is well known, as mentioned above, the energy dissipated in tissue is a function of the voltage applied and the tissue impedance. Tissue impedance is a function of the frequency applied. So, when the frequency increases, the voltage must be reduced to dissipate a similar power. However, changing frequency affects a few other parameters such as the energy dissipation at the tissue/needle interface, the loss of tissue applied voltage due to electrode polarization, the capacitive loss through the connection cable, meaning that other adjustments have to be made to obtain a similar outcome. Most RF generators used for low voltage RF applications are power regulated, *i.e*., the applied voltage changes automatically as a function of the tissue impedance to dissipate a constant amount of energy, but they are typically tuned for a specific frequency and therefore changing frequencies on these generators requires some adjustment of other parameters.

211. Nor does the specification limit the tunable parameters to just those enumerated. *See* ‘836 Patent, at 10:10-18 (“including”); 10:40-41 (“Other distance calculations are possible”); ‘444 Patent, at 10:22-30, 10:55-56; ‘379 Patent, at 10:10-18, 10:43-44.

212. In my opinion, the claims and specification of the ‘836, ‘379, and ‘444 Patents provides no guidance as to what the applied level of energy or power should be and, instead,

only provides a relatively wide range of voltages.

213. The specification of the '836, '379, and '444 Patents include a laundry list of no less than eight variables, such as "distance between needles," "energy level (current, voltage)," "needle's thickness," "system resistance, AC frequency rate, high frequency rate," "needle length or needle depth," and an a "proportional constant" somehow related to "Device resistance, needle resistance," and "skin resistance" that must all be tuned in relation to each other to achieve the desired result. Dr. Na also testified that the parameters must be tuned in relation to each other. *See* Transcript of Dr. Jongju Na, Volume 1, at 101:3-19; Transcript of Dr. Jongju Na, Volume 4, at 493:19-495:3.

> Q So when you observed the so-called Na effect, what level of power and what level of conduction time did you use?
> A So if you look at the specification of my patent, you will see the definition which describes Na effect, of course, in so and so situations. And to see this phenomenon, for example, it's not like that you just use a certain conduction time, but rather depending on the various parameter settings that you have phenomenon or phenomenons and the – it's not like you use a set value for one component – one component of single value, but rather you actually use many different parameters.
> So it's like – it's kind of relative to the values. It's almost like mathematical equation.
>
> Transcript of Dr. Jongju Na, Volume 1, at 101:3-19.

> Q. So you were able to verify the conditions in which the Na effect was not observed?
> A. … So I did observe, during the experiments, under certain conditions, my invention that's described here was not observed.
> Q What are some of the conditions that you referred to where your invention was not observed?
> A Sir, if you read the descriptions in my invention, there are parameters, conditions that affect. And so among the parameters – between the parameters, there are correlations. So if one condition changes, then that can affect other conditions, and it means another condition can change as well. … So if you ask me under what condition it is not observed, it is impossible for me to answer...
> Q. So you testified that if one condition changes, that can affect other conditions, right?
> A. Yes. I believe they are – there is a correlation.

Transcript of Dr. Jongju Na, Volume 4, at 493:19-495:3.

214. However, the specification of the '836, '379 and '444 Patents do not provide any example of full set of parameters that would achieve the desired effect. *See e.g.*, '836 Patent, at 10:1-41.

215. Based on my review, the claims fail to instruct how to adjust the foregoing parameters to achieve the desired result. Instead, and with respect to the '836 Patent for example, the independent claims require nothing more than applying "Alternating Current (AC) RF signal to the plurality of electrodes configured to cause coagulation around each electrode rather than coagulating between the electrodes" ('836 Patent, at claims 1 and 14) without referencing all of the parameters that the specification says must be tuned in relation to each other to achieve that desired result. Similarly, the '379 and '444 Patent's independent claims also simply require a desired effect (to apply energy to body segments around each electrode rather than to body segments between the electrodes," '379 Patent at claims 1 and 10, and "… that causes energy to be substantially applied to body segments around each electrode," '444 Patent at claim 1 and 10) without referencing all of the parameters that the specification says must be tuned in relation to each other to achieve that desired result. Therefore, in my opinion the asserted claims are abstract.

216. A specific coagulation pattern or energy field (and the relation between the variables needed to achieve that pattern) is merely an observed natural phenomenon similar to Hooke's law, which relates two/three physical observable qualities (mass and/or stiffness of an object to the frequency with which that object oscillates). I believe that claims 1 and 14 of the '836 Patent merely provide the general instructions to cause coagulation around each electrode rather than coagulating between the electrodes, which requires the POSITA to use their

knowledge of natural laws involving the correlation between coagulation/energy dissipation patterns and multiple different parameters, such as frequency, spacing, voltage, power, duty cycle or time of application and then engage in a trial-and-error process of changing the various possible parameters until the claimed result is achieved. As such, I believe that claims 1 and 14 merely recite a scientific principle.

217. The independent claims of the '379 and '444 Patents similarly merely provide general instructions "to apply energy to body segments around each electrode rather than between electrodes" (*see e.g.,* claim 1 of '379 Patent) or to "cause[] energy to be substantially applied to body segments around each electrode" (*see e.g.,* claim 1 of the '444 patent). Like the independent claims of the '836 Patent, practicing the independent claims of the '379 and '444 Patents also requires the POSITA to use their knowledge of natural laws involving the correlation between coagulation/energy dissipation patterns and multiple different parameters, such as frequency, spacing, voltage, power, duty cycle or time of application and then engage in a trial-and-error process of changing the various possible parameters until the claimed result is achieved. Measuring actual energy dissipation requires either to set up a precise Finite Element Analysis model or some very precise and complex equipment; none of these methods has been described in the '836, '379, and '444 Patents. As such, it is my opinion that the independent claims of the '379 and '444 patent also merely recite a scientific principle.

218. The rest of the asserted claims fare no better. While the '836 Patent's dependent claims 4 and 9, and the '379 Patent's dependent claim 7, each recite a single parameter value, in each case there are still at least 7 other parameters that must be tuned in relation to each other to achieve the desired result. While the '836 Patent's dependent claim 22 requires specific values for two parameters, this still leaves at least 6 other parameters that must be tuned in relation to

each other to achieve the desired result. No other asserted dependent claims reference any specific values for any of the tunable parameters.

219. Based on my review, the asserted claims lack specificity as to how to achieve the claimed result; instead, they are directed to the result or effect of preventing overlapping coagulation patterns, or overlapping energy fields, and merely invoke generic processes and machinery. It is my understanding that as such the claims are directed to abstract ideas or natural phenomena.

220. I have been informed that Complainant asserts that the claims "provide sufficient limitations to produce the intended results," because "[t]hey are limited to certain means," "[f]or example, claim 1 of the '836 Patent includes a plurality of electrodes being bipolar and configured to be insertable into a body segment to be treated and a radio frequency generation module electrically coupled to the plurality of electrodes to apply energy to body segments around each electrode rather to body segments between electrodes." Complainants' Initial Validity Contentions, at 410-411 ("The other Asserted Claims of the '836, '379, and '444 Patents include similar features").

221. However, in my assessment, this merely states the goal, not the means for achieving the desired result. What is left when the goal is omitted is nothing more than insertable bipolar electrodes coupled to a radio frequency generation module. As I discussed above, the specifications of these patents explain that these hardware elements standing alone are insufficient to achieve the desired results without the particular set of parameters being appropriately tuned.

222. Dr. Na also appears to agree that not every microneedling device that employs bipolar needles and an RF generator applying RF AC current would result in the claimed effect.

See Transcript of Dr. Jongju Na, Volume 4, at 513:14-514:2, 516:4-15, 510:4-15.

> Q. … My question is, will every microneedling device that employs bipolar needles and an RF generator applying RF AC current result in the invention that you just articulated?
> A. Sir, it would be unclear to say every RF generator would result in my invention. As written here, my invention is configured to cause coagulation around each electrode rather than coagulation between electrodes.
> So my invention is describing that kind of case.
>
> Transcript of Dr. Jongju Na, Volume 4, at 513:14-514:2.
>
> Q. Okay. So I just went over some of the different parameters that might – that are options disclosed in your patent.
> And my question is, not every bipolar microneedling device that can be made using the various options for each of those parameters will achieve your invention, correct?
> …
> A (In English.) I don't know.
> (Through interpreter.) Right, I do not know because what you described is incomplete hypothetical. So I do not know.
>
> *Id*., at 516:3-15.
>
> Q. What would you need to know about an RF microneedling device that has bipolar electrodes to be able to conclude with a high degree of confidence that your invention will be observed?
> CHECK INTERPRETER: (rendering interpretation.)
> (The interpreters conferred.)
> LEAD INTERPRETER: Why don't you go ahead.
> CHECK INTERPRETER: (Rendering interpretation.)
> A. That's too difficult a question.
>
> *Id*., at 510:4-15.

223. Also, Dr. Na testified that the needle electrodes in the Sylfirm X are bipolar. *Id*., at 218:3-20, 221:14-16, 223:7-16. When asked about whether applying AC/RF to tissue via the electrodes in the Sylfirm X causes coagulation around the electrodes, Dr. Na testified that it depends on which of the many correlated parameters are selected. Transcript of Dr. Jongju Na, Volume 2 at 230:21-231:15.

> Q Does applying ACRF to tissue via the electrodes in the Sylfirm X cause coagulation around the electrodes?

A Well, rather than saying the Sylfirm X do that, well, I'll just say it depends on which setting you select in Sylfirm X. It could or it could not.
Q In what setting would it – would applying ACRF to tissue via the electrodes cause coagulation around the electrodes?
A So it's not like there's one parameter for one -- each setting. There are many parameters that correlated. So you will have to understand the correlation. For example, in Sylfirm X in CW mode, coagulation can form around each electrode, but in the case of pulsed wave, coagulation around each electrode can occur or not – cannot occur.

Transcript of Dr. Jongju Na, Volume 2 at 230:21-231:15.

224. Based on my review, the claims at issue do not require specific steps, which include administering specific dose ranges. As I discussed above, the specifications include a laundry list of variables, that must all be tuned in relation to each other to achieve the desired result ('836 Patent, at 10:1-41), but the claims do not recite any such combination of parameters to achieve the desired outcome.

225. Rather, as I have shown above, the claims at issue simply recite the following abstract law/natural phenomena, but do not instruct how to specifically adjust/set the parameters, that the specification asserts are necessary to achieve the desired result:

- "... to cause coagulation around each electrode rather than coagulating between the electrodes" – '836 Patent at claims 1 and 14;
- "… to apply energy to body segments around each electrode rather than to body segments between the electrodes." – '379 Patent at claims 1 and 10; and
- "… that causes energy to be substantially applied to body segments around each electrode." – '444 Patent at claim 1 and 10.

It is my understanding that Complainants assert that the claims are specific enough to achieve the desired results because claim 14 of the '836 Patent, claim 10 of the '379 Patent, and claim 10 of the '444 Patent require inserting bipolar electrodes into skin and applying an "Alternating Current (AC) Radio Frequency (FR) signal"/ "RF signal with oscillating current" to the plurality of

electrodes to achieve the desired coagulation pattern or energy field pattern. Complainants' Initial Validity Contentions, at 407-408.

226. As discussed above, the specifications include a laundry list of variables (at least 8), such as "distance between needles," "energy level (current, voltage)," "needle's thickness," "system resistance, AC frequency rate, high frequency rate," "needle length or needle depth," and an a "proportional constant" somehow related to "Device resistance, needle resistance," and "skin resistance" that must all be tuned in relation to each other to achieve the desired coagulation pattern or energy field pattern. '836 Patent, at 10:1-41. The independent claims of the '836, '379, and '444 Patents do not include any specifics about any of these variables, let alone the interrelation between the variables.

227. The desired coagulation pattern (coagulation around each electrode rather than coagulation between the electrodes) or energy field patterns (apply energy to body segments around each electrode rather than to body segments between the electrodes/ cause energy to be substantially applied to the body segments around each electrode) are a law of nature (or natural phenomenon or abstract idea). As discussed above, the alleged inventor admitted that this is nothing more than an observation of a natural phenomenon. See, Na *et al.*, Sci Rep. 5: 16735 at 2 (Nov. 13, 2015). Furthermore, as I will explain below in the prior art section, this is not even new as it was described before the priority date of the '836, '379, and '444 Patents.

228. I do not believe that the structures, such as bipolar electrodes that are insertable into skin and coupled to a radio frequency (RF) generation module, are utilized in an unconventional way.

229. Accordingly, based on my review, the Asserted Claims in the '836, '379, and '444 Patents are directed to the observation of the natural phenomena of RF current flow when

applied to dermal tissue, are also directed to the abstract idea of providing enough energy to achieve a desired effect around the needles, but not enough energy to cause coagulation between the needles or unduly damage tissue (‘836 Patent) or to avoid overlapping coagulation pattern (‘379 and ‘444 Patents), without reciting any limitations that would be needed to produce the desired result.

230. Based on my review, the claims lack inventive concept because the claims and specification of the ‘836, ‘379, and ‘444 Patents are silent as to the operational parameters necessary to achieve the alleged Na-effect. As such, the claims seek to preempt the use of this natural phenomena. The formulas and limits given in the specification and claims do not provide a program, a set of settings, or a way of determining a program or set of settings.

231. Neither the claims nor the specification provides guidance regarding how much energy is to be applied, nor how to contain the energy “substantially around each electrode” but not “between the electrodes.” There is no guidance regarding to what temperature tissue should be raised, how quickly that temperature should be raised, to achieve effective treatment in the claimed restricted energy zones. The claims and specification of the ‘836, ‘379, and ‘444 Patents also provide no guidance as to what amount of energy (Joule) or power (Watts) should be applied, or how to combine the myriad choices for electrosurgical equipment adjustments, including: voltage (up to one hundred volts); AC frequency; RF frequency (anywhere in the HF range); and duty cycle that defines instantaneous power vs. average power.

232. Based on my review, the claims require controlling various known variables in order to achieve the desired effect around the needles (avoiding overlapping coagulation or overlapping energy fields), without any direction as to what the inputs for all the necessary variables should be. It is my understanding that this direction to engage in a conventional,

unbounded trial-and-error process does not make a patent eligible invention, even if the desired result to which that process is directed would be new and unconventional. But the claimed result is neither new nor unconventional. Many other low voltage RF systems on the market for many years have been controlling the size of the lesion or coagulation zones around the active electrodes in other parts of the body, using a very similar set up. Computer models have also been developed and validated prior to the earliest effective filing date of the '836, '379, and '444 Patents (*see e.g.*, Berube *et al.*, 2009) that were able to predict the size of the lesion (coagulation zone) around each needle in a micro-needle dermis bipolar ablation system, as a function of the various electrical parameters and time of exposure.

233. Based on my review and as shown by the attached prior art claim charts, the remaining features of the claims rely on conventional skill in the art at the time of the invention. In particular, RF microneedling using bipolar electrodes and RF energy was well known.

234. For example, as explained in the prior art sections of this report that follow, Ganz disclosed a microneedling device which caused coagulation by delivering RF energy to bipolar electrodes inserted into the skin and provides a concrete example with a specific set of parameters. Ganz at [0065]. As also explained in the prior art sections of this report that follow, Manstein also disclosed such a microneedling device.

235. U.S. Patent No. 8,608,737 to Mehta *et al.* ("Mehta"), which has an earliest effective filing date of February 6, 2009, also disclosed a microneedling device which caused coagulation by delivering RF energy to bipolar electrodes inserted into the skin. *See e.g.*, Mehta, at 2:63-3:17 (the probes (also called "energy transfer elements") "are inserted into the target tissue for a treatment cycle," as shown in FIG. 2A), 9:34-55 ("[T]he term probe" includes "bipolar RF" electrodes), 11:14-15 ("[T]he energy supply unit 90 may be a RF energy unit."),

17:59-18:3 (“adjacent electrode pairs can serve as opposite poles of a circuit”), *see also id*., at 11:21-24 (“RF energy”), 18:4-20 (“RF energy modality” for “electrode pairs”), 20:13-29 (“RF energy is often delivered in a pulsed fashion or for a specific duty cycle”), 24:46-60 (“the probe 108 can employ an RF energy mode to denature or coagulate collage in a dermal layer”), 25:30-55 (“RF delivery device having ten probe electrodes was configured to deliver energy via 5 independent and electrically isolated probe-electrode pairs”), 36:21-40 (“bipolar RF electrode device”), 37:25-34 (“five electrode pairs 5,” where “electrodes 104 of opposite polarity [are] in the electrode pair”), 40:45-57 (“bi-polar RF energy modality”); Figs. 2A, 2B, 13A, 13B, 13C.PCT Patent Application Publication No. WO 2007/064718 (“Hantash ‘718 PCT”), which was published on June 7, 2007 also disclosed a microneedling device which caused coagulation by delivering RF energy to bipolar electrodes inserted into the skin. *See e.g.*, Hantash ‘718 PCT, at [0013] (“shrinking collagen using radio frequency energy that is delivered to the target sites using a microneedle electrode array”), [0017] (“the microneedles are driven into the tissue”), [0034] (Fig. 1, shows “a radio frequency (RF) source 110 is [electrically] connected to an array of needles 115” to deliver energy to the skin 150 via the array of needle electrodes 115), [0035] (Fig. 1 shows a plurality of “the needles 115,” which “penetrate the surface of the skin 150,” and, “[w]hile the needles 115 are located within the skin 150, they can be powered by the RF source 110”), [0040] (“The RF source 110 may be bipolar”), [0047] (“One array includes all of the negative polarity needles 116 (return electrodes) and the other includes all of the positive polarity needles 117 (active electrodes)”), [0057] (“electrically connecting the needles 116 and 117 at the opposite ends of each local region of skin 150 to be treated to different poles of the RF source 110”), [0079] (“used to coagulate collagen within the skin”), Fig. 1, claims 1, 37, 42.

236. Hantash, B., *et al.*, “Pilot Clinical Study of a Novel Minimally Invasive Bipolar

Microneedle Radiofrequency Device*," Lasers in Surgery and Medicine*, 41:87-95 (2009) ("Hantash 2009") also disclosed a microneedling device which caused coagulation by delivering RF energy to bipolar electrodes inserted into the skin, and describes the influence of some parameters on the lesion size or overlap. *See e.g.*, Hantash 2009, Title ("Pilot Clinical Study of a Novel Minimally Invasive Bipolar Microneedle Radiofrequency Device"), 87 ("...A novel minimally invasive RF device employing a bipolar microneedle electrode system is introduced and its resultant thermal effects on human skin in vivo...An investigational 35 W RF device was configured to operate in bipolar mode delivering energy directly within the dermis using 5 microneedle electrode pairs … Treatment of the 15 human subjects illustrated the controlled creation of dermally located thermal coagulation zones, herein known as radiofrequency thermal zones"), 88 ("delivers bipolar RF current through a microneedle electrode assembly … This fractional radiofrequency (RFR^{TM}) system is capable of achieving fractional and contiguous treatment patterns while sparing the epidermis and key adnexal structures that contribute to rapid healing"), 89 ("The number of treatment applications is defined as the number of microelectrode assembly insertions, each constituted of five bipolar RF needle pairs), 89 ("release the electrodes into the skin"), 90 ("Fig. 1. Novel investigational radiofrequency device. A: Bipolar RF handpiece powered by a 35 W RF generator. B: Microelectrode assembly containing five bipolar RF 30 gauge needle pairs … D. Handpiece with RF needles in the deployed position..."), 91 ("Fig. 2. Deployment of investigational device. Treatment of human facial skin requires countertraction during microelectrode insertion. … depth of penetration upon needle insertion), 93 ("The use of minimally invasive microneedle electrode pairs and bipolar energy has several clear advantages."), 94 ("fractional RF device utilizing a minimally invasive bipolar microneedle delivery system for the treatment of human

skin" to generate "coagulated collagen … using an RF system"), Figs. 1, 2.

237. The Primaeva Medical Miratone System (also known as the Renesis System) (hereinafter "Miratone") was offered for sale, sold, and/or used in the United States by at least September 1, 2009. *See, e.g.*, [redacted]; Hantash, *et al.*, *Pilot Clinical Study of a Novel Minimally Invasive Bipolar Microneedle Radio Frequency Device,* LASERS IN SURGERY AND MEDICINE 41:87–95 (2009) ("Hantash 2009") (listing the "investigational 35 W bipolar RF device" as "Renesis, Primaeva Medical, Inc.") (*see* Ex. B-04, Claim Chart Comparing Hantash - Lasers in Surgery and '379 Patent, incorporated by reference herein)); Berube, *et al.*, *A Predictive Model of Minimally Invasive Fractional Radiofrequency Skin Treatment*, LASERS IN SURGERY AND MEDICINE 41:473–478 (2009) ("Berube") (listing the "bipolar FRF device" as "Miratone, Primaeva Medical, Inc."); Alexiades-Armenakas, *et al.*, *Blinded, Randomized, Quantitative Grading Comparison of Minimally Invasive, Fractional Radiofrequency and Surgical Face-lift to Treat Skin Laxity*, ARCH DERMATOL. 2010; 146(4):396–405 ("Alexiades") (study involved "[t]he Miratone minimally invasive bipolar fractional RF (FRF system (Primaeva Medical, Inc, Pleasanton, California)"); *see also* [redacted]

238. As shown above in regard to Hantash 2009, the Miratone system also disclosed a microneedling device which caused coagulation by delivering RF energy to bipolar electrodes inserted into the skin. *See also* Berube at 473 ("bipolar fractional radiofrequency (FRF) system … controlled creation of dermally located thermal coagulation zones, known as radiofrequency thermal zones"), Berube at 474 ("The bipolar FRF device (Miratone™, Primaeva Medical, Inc., Pleasanton, CA) modeled in this study consists of a 5-pair 30 gauge microneedle array in combination with thermoelectric cooling maintained at 10 [degrees] C to protect the epidermis during RF application [11]"), Berube at 477 ("These data confirm that bipolar RF current, when delivered from within tissue, preferentially follows the path of highest conductivity—which in this case leads to energy deposition almost entirely in the dermis."), Alexiades at 397 ("The Miratone minimally invasive bipolar fractional RF (FRF) system (Primaeva Medical, Inc, Pleasanton, California) heats the dermis from within using a microneedle electrode array. The microneedle electrodes are arranged in pairs between which bipolar RF energy is delivered. Thermal lesions are fractionally generated directly within the reticular dermis."), [redacted])

239. The ScarLet product manufactured by ViOL, Korea ("ScarLet") is a product that was in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention to which the '836 Patent could claim priority. *See, e.g.*, Ilooda-0005923 (Shim 2010_DKU Thesis 2010.12.01), Ilooda-0006075 (ScarLet intro), Ilooda-0006078

(#13_(Eng)_Shim 2010_DKU Thesis Dec 1 2010_Translated_Certified), Ilooda-0006210 (5-1. 스칼렛 최초허가), Ilooda-0006533 (Naver Blog The H Jan 10 2011), Ilooda-0006719 (#19-1_Naver Blog The H Jan 10 2011_Translated_Certified), Ilooda-0006770 (#18_D&PS Monthly Sept 2010_Translated_Certified), Ilooda-0006827 (D&PS Monthly September 2010), Ilooda-0008178 and translation thereof (Ilooda-0011601), Ilooda-0009318, Ilooda-0009319, Ilooda-0009322, Ilooda-0009339, Ilooda-0009669, Ilooda-0009673, Ilooda-0009678, Ilooda-0009791, Ilooda-0009795, Ilooda-0010031, Ilooda-0010042, SERENDIA-00017276, SERENDIA-00017306, SERENDIA-00031579, SERENDIA-00033637, SERENDIA-00033705, SERENDIA-00036286, SERENDIA-00052450, SERENDIA-00061017, SERENDIA-00066746, SERENDIA-00075908, and SERENDIA-00081664.

240. ScarLet also disclosed a microneedling device which caused coagulation by delivering RF energy to bipolar electrodes inserted into the skin. *See e.g.*, SERENDIA-0010042 at -046 ("ScarLet is a fractional RF device that combines the advantages of fractional laser with the advantages of RF nonablative devices … and each needle forms an accurate fractional thermal zone"), SERENDIA-00017306 at -320 ("RF energy")), SERENDIA-00017306 at –329 ("RF energy field"), SERENDIA-00017306 at -334 ("Clear RF pattern … It is possible to use ScarLet RF needle as Fractional RF function"), SERENDIA-00017306 at –337 ("coagulation is seen around needle"), Ilooda-0006078 (#13_(Eng)_Shim 2010_DKU Thesis Dec 1 2010_Translated_Certified at 6) ("The oscillation part generates a signal of 2 MHz by the signal transmitted from the control part and transmits it to the output part."), Ilooda-0006078 (#13_(Eng)_Shim 2010_DKU Thesis Dec 1 2010_Translated_Certified at 7) ("In RF devices (electrosurgical devices), if the two poles are located at the same end of the device, it is called a bipolar unit, and if there is only one pole at the end of the device, it is called a

monopolar or unipolar unit, but in this experiment, a bipolar unit was used. . . ."), Ilooda-0006078 (#13_(Eng)_Shim 2010_DKU Thesis Dec 1 2010_Translated_Certified at 10) ("BIPOLAR" … "DEPTH 1.0 mm"), *See also* 2.4. Bipolar Cut Mode Output Voltage of the Experiment Apparatus. Ilooda-0006078 (#13_(Eng)_Shim 2010_DKU Thesis Dec 1 2010_Translated_Certified at 11), Ilooda-0006075 (ScarLet intro at 2) ("NEEDLE DEPTH 0.5 mm ~ 3.4 mm (0.1 mm unit)" "RF CONDUCT TIME" "RF OUTPUT" "RF FREQENCY 2MHz" "ELECTRODE NO. 25 Pin").

241. [redacted]

242. [redacted]

[redacted]

243. Moreover, it is my understanding that Dr. Na testified that the RF signal generator he used to first observe what he refers to as the Na effect was sourced by Mr. Park, another individual, not named as an inventor on the Asserted Patents, from RF generators already being manufactured in the industry. Transcript of Dr. Jongju Na, Volume 2 at 182:21-183:8. I understand that Dr. Na testified that Mr. Park simply asked these manufactures "which would perform better, and the – by that I mean components that we would need for our purposes." Transcript of Dr. Jongju Na, Volume 2 at 183:22-184:4.

> A So those were the frequencies that were considered and the – I also talked about that the **RF generators that are actually manufactured in the industry** and what is the status of those RF generators and whether there were any good ones domestically available. And we need to study and look into these things. That's what I said.
>
> And after that **Mr. Pa[r]k was trying to source these items** and communicated what he found with me.
>
> And back to your question – to answer your question. So if 1 megahertz is used, then the heating time is slower rising, and then when you compare that with when using 2 megahertz in terms of the electricity that is applied to dermis and epidermis, I said that 2 megahertz would be better because
>
> …
>
> A Would be better because it's – it's less of it there compared to 1 megahertz. And then **Mr. Pa[r]k asked around many different companies and asking which would perform better, and the – by that I mean components that we would need for our purposes."**

Transcript of Dr. Jongju Na, Volume 2 at 182:21-184:4. (emphasis added.)

244. Accordingly, it is my understanding that the claims of the '836, '379, and '444 Patents are directed to an abstract concept.

245. I understand that a claim, even if directed to an abstract concept, may still be patentable if it adds meaningful limitations that confine the abstract idea, *i.e.,* an inventive concept. For the reasons set forth above and below, I do not believe that the limitations included in the independent or dependent claims confine the abstract idea such that the claims recite an inventive concept. Specifically, as discussed above, inserting bipolar electrodes into the skin and applying RF energy to the bipolar electrodes in the field of dermatology was well known. As noted above, Dr. Na testified the RF generator and components he used when he first observed what he called the Na effect were commercially available and selected based on the manufacturing companies' advice. *See* Transcript of Dr. Jongju Na, Volume 2 at 182:21-184:4. Moreover, the claims lack inventive concept because the claims and specifications of the '836, '379, and '444 Patents, including the claims that recite certain operational parameters, do not provide all of the operational parameters necessary to achieve the alleged Na-effect, and thus would preempt the use of this natural phenomena. The formulas and limits given in the specification and claims do not provide a program, a set of settings or a way of determining a program or set of settings.

246. I understand that Complainant has asserted that "Prior skin or mammalian body treatment" had the drawback of "burning both epidermis and dermis between the needles." Complainant has agreed as shown in document VIOL-00001255 at -1273 that competitive devices with insulated electrodes do not "burn" the epidermis. Complainant's Final Validity Contentions, at 407-408. However, not burning both the epidermis and dermis between needles is an abstract idea and/or natural phenomena under patent law. I understand that an abstract

idea or natural phenomena itself cannot be an inventive concept sufficient to transform that abstract idea or natural phenomena into a patentable invention.

247. Complainant's discussion of the "associated drawbacks" of other techniques, such as "massaging with a nutritious substance," "using a syringe to inject serum into the skin," "delivering high frequency energy indirectly to the dermis via the skin surface," and "using a single needle" (Complainant's Final Validity Contentions, at 408-408) are not related to RF bipolar microneedling[17]. Rather, they are discussions of other types of treatments, and, thus, the section of the specifications that Complainant quotes, is not discussing an improvement to RF microneedling devices.

248. Additionally, as outlined in sections XII. and XIII. below, the asserted claims are anticipated or obvious (*i.e.*, they do not have an inventive step).

249. Nothing about the ordered combination of claim elements transforms the nature of the claims into a patent-eligible invention.

XII. SUMMARY OF ANTICIPATION AND OBVIOUSNESS OPINIONS

250. It is my understanding that Respondents are asserting that that '379, '444, '774, and '812 patent are AIA patents and that therefore AIA § 102 and § 103 apply. For completeness, my assessment considers both AIA and pre-AIA § 102 and § 103.

251. In my assessment, and as will be explained below, the asserted claims of the Asserted Patents are anticipated and/or obvious in view of one or more of the following references:[18]

[17] As explained above, RF microneedling using bipolar electrodes and RF energy was well known.

[18] To reach these conclusions, I have reviewed the references and Respondent's Initial and Final Invalidity Contentions (including the Tables attached thereto). In addition to the reasons to

- U.S. Patent Publication No. 2007/0208340 A1 to Ganz
- WO 2007/064718 to Hantash ("Hantash '718 PCT")
- KR 10-0719395 to Kang ("Kang '395")
- KR 10-0852500 to Lee ("Lee '500")
- U.S. Patent No. 7,824,394 to Manstein ("Manstein")
- U.S. Patent No. 8,608,737 to Mehta *et al.* ("Mehta")
- U.S. Patent No. 10,799,285 to Mulholland ("Mulholland")
- WO 2010/016848 A2 to Na ("Na '848")
- U.S. Patent No. 6,766,202 to Underwood *et al.* ("Underwood")
- WO 2008/005477 A2 to Livneh ("Livneh")

252. These references are applied to the asserted patents as follows:

Prior Art for the '836 Patent, '379 Patent, and '444 Patent				
Country of Origin	**Patent or Publication Number**	**Filing Date**	**Issuance or Publication Date**	**Named Inventor**
US	8,608,737	04/20/2009	12/17/2013	Mehta
US	7,824,394	04/01/2005	11/02/2010	Manstein
US	2007/0208340A1	04/05/2005	09/06/2007	Ganz
US	6,766,202	04/30/2002	07/20/2004	Underwood
US	10,799,285	10/06/2009	10/13/2020	Mulholland
KR	10-0852500	03/31/2008	08/18/2008	Lee
WO	2007/064718	11/29/2006	06/07/2007	Hantash

combine certain references relied upon in this report, I agree with the reasons to combine the references as set forth in the Invalidity Contentions.

Prior Art for the '536 Patent, '774 Patent, and '812 Patent.				
Country of Origin	**Patent or Publication Number**	**Filing Date**	**Issuance or Publication Date**	**Named Inventor**
US	8,608,737	04/20/2009	12/17/2013	Mehta
KR	10-0852500	03/31/2008	08/18/2008	Lee
KR	10-0719395	11/23/2005	05/17/2007	Kang
US	10,799,285	10/06/2009	10/13/2020	Mulholland
WO	2010/016848	08/22/2008	02/11/2010	Na
WO	2007/064718	11/29/2006	06/07/2007	Hantash
WO	2008/005477 A2	07/05/2007	01/10/2008	Livneh

253. The Asserted Claims of the Asserted Patents are anticipated or obvious in view of each of the following prior art systems:

System	Date	Exemplary Evidence	Person or Entity with Knowledge
Daeshin Enterprise, Korea DeÁge system ("DeÁge")	[redacted]	• [redacted]	Daeshin Enterprise, 28 Digital-ro 330gi, Guro-gu, Seoul, Korea
ScarLet product manufactured by ViOL, Korea ("ScarLet")	06/11/2010	• SERENDIA-00017306; ScarLet intro • D&PS Monthly September 2010 • Shim 2010_DKU Thesis 2010.12.01 • Naver Blog The H Jan 10, 2011	ViOL, Korea (known to Complainant's counsel)
Primaeva Medical Miratone System (also known as the Renesis System) ("Miratone")	[redacted]	• [redacted]	Primaeva Medical, 1520 Centre Point Dr., Milpitas CA 95035

System	Date	Exemplary Evidence	Person or Entity with Knowledge
		[redacted] • Hantash, *et al.*, *Pilot Clinical Study of a Novel Minimally Invasive Bipolar Microneedle Radio Frequency Device,* Lasers in Surgery and Medicine 41:87–95 (2009) ("Hantash 2009") (listing the "investigational 35 W bipolar RF device" as "Renesis, Primaeva Medical, Inc.") • Berube, *et al.*, *A Predictive Model of Minimally Invasive Fractional Radiofrequency Skin Treatment*, Lasers in Surgery and Medicine 41:473–478 (2009) ("Berube") (listing the "bipolar FRF device" as "Miratone, Primaeva Medical, Inc.") • Alexiades-Armenakas, *et al.*, *Blinded, Randomized, Quantitative Grading Comparison of Minimally Invasive, Fractional Radiofrequency and Surgical Face-lift to Treat Skin Laxity*, Arch Dermatol. 2010; 146(4):396–405 ("Alexiades") (study involved "[t]he Miratone minimally invasive bipolar fractional RF (FRF system (Primaeva Medical, Inc, Pleasanton, California)") • [redacted]	

254. I understand that due to procedural requirements, the total number of references has been reduced to no more than four references per patent. Accordingly, this report focuses on these references. In my assessment, and as will be explained below, the asserted claims of the Asserted Patents are anticipated and/or obvious in view of one or more of the following references or prior art listed below:

- '836 Patent: Manstein, Ganz, Hantash, and/or ScarLet
- '379 Patent: Manstein, Ganz, Hantash, and/or Miratone

- ‘444 Patent: Ganz, Hantash, DeÁge, and/or ScarLet
- ‘536 Patent: Mehta, Kang ‘395, Na ‘848, and/or Miratone
- ‘774 Patent: Mehta, Mulholland, Na ‘848, and/or ScarLet
- ‘812 Patent: Mehta, Kang ‘395, Na ‘848, and/or ScarLet

255. Additionally, the prior art references cited include references that are related patent applications and issued patents that contain substantially the same subject matter (*e.g.*, published U.S. patent applications, issued U.S. Patents, foreign applications, or issued foreign patents). Any citation to or quotation from any of these patent applications or patents, therefore, should be understood as encompassing any parallel citation to the same subject matter in other related or corresponding applications or patents.

256. I reserve the right to later rely upon all references or portions of references discussed herein to supplement or amend the disclosures contained herein.

XIII. ANTICIPATION AND OBVIOUSNESS ANALYSIS

A. The Asserted Claims of the ‘836 are Anticipated or Rendered Obvious by the Prior Art

257. The Asserted Claims of the ‘836 Patent are invalid under 35 U.S.C. § 102 (pre-AIA or AIA) as anticipated by Ganz and/or are invalid under 35 U.S.C. § 103 (pre-AIA or AIA) as obvious in view of Ganz alone (in view of the knowledge of a POSITA) or in combination with one or more other references identified herein and/or in Respondents’ Invalidity Contentions, at least based on my understanding of Complainant’s application of the asserted claims in an effort to show infringement.

258. U.S. Patent Publication No. 2007/0208340A1 ("Ganz") qualifies as prior art to the '836 Patent under at least 35 U.S.C. § 102(a)(1) (AIA) because it was published prior to the earliest possible priority date of the '836 Patent.

259. To the extent that the '836 Patent is subject to pre-AIA law, Ganz qualifies as prior art under at least 35 U.S.C. § 102(b) (pre-AIA) because it is a patent that published more than one year before the filing of the earliest application to which the '836 Patent could claim priority. Ganz also qualifies as prior art under at least 35 U.S.C. § 102(a) (pre-AIA) because it is a patent that was published prior to the alleged invention of the '836 Patent.

260. Ganz in view of the knowledge of a POSITA renders certain limitations of the '836 Patent's Asserted Claims obvious. A POSITA would have understood that any limitations in the Asserted Claims arguably not explicitly disclosed by Ganz were obvious in view of the state of the relevant art. A POSITA would have been motivated to draw upon his or her knowledge of the relevant art to modify Ganz as necessary to achieve any of the claimed features and would have enjoyed a reasonable expectation of success in doing so. A POSITA would have enjoyed a reasonable expectation of success in combining and/or modifying the teachings of the foregoing prior art references and products, together with general knowledge of the art, to achieve the claimed subject matter, at least because the prior art itself discloses and/or practices the claimed methods and apparatuses to achieve the claimed results. A POSITA would have recognized that some of the relevant art, such as controlling a coagulated lesion size with RF is predictable, and that achieving the claimed subject matter would have been obvious to try or requires merely routine optimization and experimental validation. Optimization of parameters, such as the RF frequency, power, energy, voltage, timing duty cycle applied to microneedles, requires a significant amount of experimentation. However, the experimental

methodology to achieve unconnected coagulation zones is obvious to a POSITA, and the selection of the RF frequency would then become obvious to a POSITA.

261. To the extent Complainant alleges that Ganz does not disclose any particular limitation of the '836 Patent's Asserted Claims, either expressly or inherently, it would have been obvious to a POSITA as of the priority date of the '836 Patent to modify Ganz and/or combine the teachings of Ganz with the knowledge of a POSITA and/or with one or more of PCT Patent Application Publication No. WO 2007/064718 ("Hantash '718 PCT"), U.S. Patent No. 7,824,394 to Manstein ("Manstein"), and the ScarLet product manufactured by ViOL, Korea ("ScarLet").

262. Hantash '718 PCT and Manstein each qualify as prior art under at least AIA 35 U.S.C. § 102(a)(1) because they are patents that published before the filing of the earliest application to which the '836 Patent could claim priority.

263. To the extent the '836 Patent is treated under pre-AIA law, Hantash '718 PCT and Manstein each qualify as prior art under at least 35 U.S.C. § 102(b) (pre-AIA) because they were published more than one year before the filing of the earliest application to which the '836 Patent could claim priority.

264. ScarLet qualifies as prior art under at least 35 U.S.C. § 102(a) (pre-AIA) because it is a product that was in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention to which the '836 Patent could claim priority. *See, e.g.*, Ilooda-0005923 (Shim 2010_DKU Thesis 2010.12.01), Ilooda-0006075 (ScarLet intro), Ilooda-0006078 (#13_(Eng)_Shim 2010_DKU Thesis Dec 1 2010_Translated_Certified), Ilooda-0006210 (5-1. 스칼렛최초허가), Ilooda-0006533 (Naver Blog The H Jan 10 2011), Ilooda 0006719 (#19-1_Naver Blog The H Jan 10 2011_Translated_Certified), Ilooda-0006770

(#18_D&PS Monthly Sept 2010_Translated_Certified), Ilooda-0006827 (D&PS Monthly September 2010), Ilooda-0008178 and translation thereof (Ilooda-0011601), Ilooda-0009318, Ilooda-0009319, Ilooda-0009322, Ilooda-0009339, Ilooda-0009669, Ilooda-0009673, Ilooda-0009678, Ilooda-0009791, Ilooda-0009795, Ilooda-0010031, Ilooda-0010042, SERENDIA-00017276, SERENDIA-00017306, SERENDIA-00031579, SERENDIA-00033637, SERENDIA-00033705, SERENDIA-00036286, SERENDIA-00052450, SERENDIA-00061017, SERENDIA-00066746, SERENDIA-00075908, and SERENDIA-00081664.

265. To the extent that the '836 Patent is subject to AIA law, ScarLet qualifies as prior art under at least AIA 35 U.S.C. § 102(a)(1) because it is a product that was in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention to which the '836 Patent could claim priority. *See e.g.,* Ilooda-0005923 (Shim 2010_DKU Thesis 2010.12.01), Ilooda-0006075 (ScarLet intro), Ilooda-0006078 (#13_(Eng)_Shim 2010_DKU Thesis Dec 1 2010_Translated_Certified), Ilooda-0006210 (5-1. 스칼렛 최초허가), Ilooda-0006533 (Naver Blog The H Jan 10 2011), Ilooda-0006719 (#19-1_Naver Blog The H Jan 10 2011_Translated_Certified), Ilooda-0006770 (#18_D&PS Monthly Sept 2010_Translated_Certified), Ilooda-0006827 (D&PS Monthly September 2010), Ilooda-0008178 and translation thereof (Ilooda-0011601), Ilooda-0009318, Ilooda-0009319, Ilooda-0009322, Ilooda-0009339, Ilooda-0009669, Ilooda-0009673, Ilooda-0009678, Ilooda-0009791, Ilooda-0009795, Ilooda-0010031, Ilooda-0010042, SERENDIA-00017276, SERENDIA-00017306, SERENDIA-00031579, SERENDIA-00033637, SERENDIA-00033705, SERENDIA-00036286, SERENDIA-00052450, SERENDIA-00061017, SERENDIA-00066746, SERENDIA-00075908, and SERENDIA-00081664.

266. Ganz, Hantash ‘718 PCT, Manstein, and ScarLet discuss or address the same or substantially similar underlying apparatus and/or technology in the field of dermatological treatment and devices such that a POSITA would have understood that one or more of these references can be combined, according to known methods and/or by the simple substitution of one known equivalent element for another, to yield predictable results and with a reasonable expectation of success. A POSITA would also have been motivated to combine one or more of these reference in light of market forces in the industry, and the desire to improve features and performance, and/or in light of one or more teachings, suggestions, or motivations in the art. A POSITA would have enjoyed a reasonable expectation of success in combining and/or modifying the teachings of the foregoing prior art references and products, together with general knowledge of the art, to achieve the claimed subject matter, at least because the prior art itself discloses and/or practices the claimed methods and apparatuses to achieve the claimed results. A POSITA would have recognized that the relevant art is predictable, and that achieving the claimed subject matter requires merely routine optimization.

267. As shown below, under Complainant’s interpretation of “plurality of electrodes” (Complainant’s interpretation does not require non-insulated electrodes); and “[a/an] Alternating Current (AC) [RF/Radio Frequency (RF) signal” (Complainant’s interpretation requires an AC signal having a radio frequency), the Asserted Claims of the ‘836 Patent are invalid for at least the following reasons:

- Ganz anticipates claims 1, 12, 13, and 14;
- Ganz renders obvious claims 1, 12, 13, and 14;
- Ganz in view of Hantash ‘718 PCT renders obvious claims 2, 5, 12, 17, and 22.

- Ganz in view of Hantash '718 PCT and in further view of Manstein renders obvious claim 9, 11, and 13.

1. Claim 1 of the '836 Patent is anticipated by Ganz and/or obvious in view of Ganz.

268. It is my opinion that Ganz anticipates and/or renders obvious claim 1 of the '836 Patent as detailed below.

'836 Patent Claim 1		**Ganz**
1.0	A skin treatment apparatus, comprising:	Ganz discloses and/or renders obvious a skin treatment apparatus. *See, e.g.*, Ganz at [0001], [0016], [0027], [0029], [0030], [0033], and [0063], claim 1, 24. Specifically, Ganz discloses "a device and method for treating one or more layers of [skin] tissue," of a human. *Id*., at [0001]; *see also id*., at [0016] ("method for treating human skin"), [0029] ("treatment device"), [0030], claim 24 ("treating human skin"). Claims 1, 21, and 22 in Ganz recite tissue in general without limiting the tissue to a specific type of tissue, and therefore this could apply to any part of the body.
1.1	a plurality of electrodes, the electrodes being bipolar and configured to be insertable into skin to be treated; and	Ganz discloses and/or renders obvious a plurality of electrodes, the electrodes being bipolar and configured to be insertable into the skin to be treated. *See, e.g.*, Ganz, [0001], [0010], [0011], [0016], [0043], [0056], [0063], claims 1-13. Specifically, Ganz discloses a plurality of electrodes. *Id*. at [0011] ("The electrodes can be provided as a **plurality of electrode pairs** or even as an array of electrodes"); *see also id*. at [0010] ("the electrodes are provided in a pattern"), [0043] ("a **plurality of electrodes**"); *id.* at [0056] ("electrode pairs"); claim 1 ("**plurality of electrodes**"); *id.* at claim 13 ("wherein the **plurality of electrodes** are provided as an array of electrodes") (emphasis added.). *See* Ganz at [0001] "The invention relates to a device and method for treating one or more layers of tissue, for example by simultaneously imparting perforations into the one or more layers. In particular, the invention relates to a device and method for treating one or more layers of the skin to elicit a healing response which produces a more desirable skin appearance."

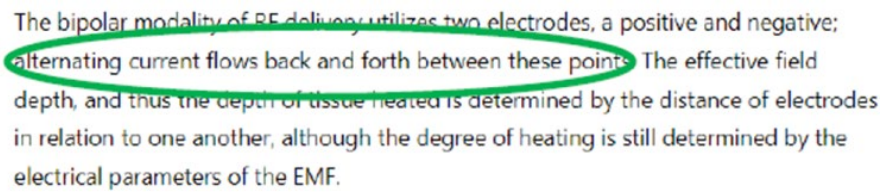
'836 Patent Claim 1		Ganz
		[0010] "In some embodiments, the invention provides a device for creating a pattern of perforations in a tissue. The device comprises a treating surface configured to be positioned in contact with tissue adjacent one or more tissue planes and a plurality of electrodes extending outwardly from the treating surface and adapted for imparting simultaneous perforations into one or more tissue layers, wherein the electrodes are provided in a pattern to impart a corresponding pattern of perforations in the one or more tissue layers. The electrode pattern can be selected to create perforations which are between about 30 to about 100 microns in diameter, up to about 1000 microns deep and spaced apart by between about 50 to about 400 microns. The electrode pattern can also be selected to create a zone of coagulative tissue surrounding each perforation. In some cases, the zone of coagulative tissue has a length of between about about [*sic*] 5 microns to about 100 microns. The electrodes can also have a depth and width for providing perforations being no more than about 2 mm in depth and about 0.5 mm in width. Likewise, the electrodes can have a spacing for providing perforations spaced apart by no more than about 5 mm or less." [0011] "The 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. A control device may also be coupled to the energy source. In preferred cases, the electrodes are RF electrodes and are configured for receiving RF energy. The electrodes can be provided as a plurality of electrode pairs or even as an array of electrodes. In some cases, the electrodes are monopolar electrodes whereas in other cases the electrodes are bipolar electrodes." [0016] "A method for treating human skin is also provided. The method includes identifying a target area of skin, providing a device adapted to simultaneously create a desired pattern of perforations into one or more layers of the target area of skin, and simultaneously perforating the target area to provide the desired pattern of perforations which elicit a healing response that produces a revitalized skin surface." [0043] "The treating surface generally includes a plurality of electrodes positioned about at least a portion of its circumference so that the electrodes come into contact with

'836 Patent Claim 1		Ganz
		the tissue. The electrodes can be provided about the entire surface of the treating surface or about a portion of the surface. The areas of tissue in contact with the electrodes are those areas which are perforated." [0056] "In other embodiments, the electrodes are provided as a bipolar electrode arrangement. In bipolar electrode arrangements, both the positive and negative electrodes serve as treating electrodes. In some cases, the bipolar electrodes are biopolar[*sic*] axial interlaced finger electrodes. In embodiments wherein the electrodes are provided as electrode pairs, biopolar[*sic*] electrodes are desirable, with one electrode in the pair being a positive electrode and the other electrode being a negative electrode. The electrodes can be shaped in such a way that the middle portion of distal portion is enlarged in order to create a zone of injury that is greater at the distal end compared to the proximal end. The base of the treatment pad or treating surface and various portions of the proximal electrodes can also be insulated in order to limit the coagulation injury to the distal end of the electrode as well." [0063] "Methods for vertically treating one or more layers of tissue in a tissue plane are also provided. The method generally includes simultaneously imparting perforations into one or more tissue layers in a tissue plane. In a preferred embodiment, a method is provided for simultaneously imparting perforations into one or more layers of skin. In many cases, skin areas along the face, neck, chest, and hands will be treated. The treatment area of the skin is first cleansed using a cleanser, for example a mild, gently abrasive skin cleanser. A topical may then be applied to the treatment area to numb the skin so that a patient will not feel and prickling or heat sensation during treatment. In some cases, the topical will be a lipid based topical anesthetic ointment. A treatment device according to any of the embodiments already described is provided and the treating surface is placed in contact with a desired area of the skin. The device is activated to create a plurality of perforations in the skin. In many cases, the same area of skin will be treated several times and usually at different time intervals." *See also* Ganz claims 1-13. Ganz discloses that the plurality of electrodes is configured to be inserted into the body segment to be treated (the skin), as evidenced

'836 Patent Claim 1		Ganz
		by the fact that the needles "simultaneously impart[] perforations into the one or more layers" of skin tissue. *Id*. at [0001]; *see also id*., at claim 1 (" a plurality of electrodes extending outwardly from the treating surface and adapted for imparting simultaneous perforations into one or more tissue layers, wherein the electrodes are provided in a pattern to impart a corresponding pattern of perforations in the one or more tissue layers"); *id.* at claim 4 (" wherein the electrode pattern is selected to create perforations which are between about 30 to about 100 microns in diameter, up to about 1000 microns deep and spaced apart by between about 50 to about 400 microns"); *id.* at claim 5 ("wherein the plurality of electrodes have a depth … for providing perforations being no more than about 2 mm in depth …"); *id.* at [0016] ("simultaneously perforating the target area to provide the desired pattern of perforations which elicit a healing response that produces a revitalized skin surface"); *id.* at [0063] ("The device is activated to create a plurality of perforations in the skin"). *See* Ganz at [0001] "The invention relates to a device and method for treating one or more layers of tissue, for example by simultaneously imparting perforations into the one or more layers. In particular, the invention relates to a device and method for treating one or more layers of the skin to elicit a healing response which produces a more desirable skin appearance." [0016] "A method for treating human skin is also provided. The method includes identifying a target area of skin, providing a device adapted to simultaneously create a desired pattern of perforations into one or more layers of the target area of skin, and simultaneously perforating the target area to provide the desired pattern of perforations which elicit a healing response that produces a revitalized skin surface." [0063] "Methods for vertically treating one or more layers of tissue in a tissue plane are also provided. The method generally includes simultaneously imparting perforations into one or more tissue layers in a tissue plane. In a preferred embodiment, a method is provided for simultaneously imparting perforations into one or more layers of skin. In many cases, skin areas along the face, neck, chest and hands will be treated. The treatment area of the skin is first cleansed using a cleanser, for example a mild, gently abrasive skin cleanser. A topical may then be applied to the treatment area

'836 Patent Claim 1		Ganz
		to numb the skin so that a patient will not feel and prickling or heat sensation during treatment. In some cases, the topical will be a lipid based topical anesthetic ointment. A treatment device according to any of the embodiments already described is provided and the treating surface is placed in contact with a desired area of the skin. The device is activated to create a plurality of perforations in the skin. In many cases, the same area of skin will be treated several times and usually at different time intervals." Ganz also discloses that the plurality of electrodes can be bipolar electrodes. *Id*. at [0011] ("the electrodes are **bipolar electrodes**"); *id.* at [0056] ("the electrodes are provided as a **bipolar electrode** arrangement … with one electrode in the pair being a positive electrode and the other electrode being a negative electrode"); *id.* at claim 11 ("wherein the plurality of electrodes are provided as a plurality of electrode pairs"); *id.* at claim 13 ("wherein the **plurality of electrodes are bipolar electrodes**") (emphasis added). The parties have agreed that "the electrodes being bipolar" should be construed as having a plain and ordinary meaning "the 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)[19]. *See* Post-Markman Hearing Joint Claim Construction Chart at 3. Ganz discloses that the "electrodes are RF electrodes and are configured for receiving RF energy." *Id*., at [0011]. In other words, a radio frequency signal is applied to the electrodes. Ganz discloses that the needle electrodes are coupled to an RF source. *Id*. at [0011] ("[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, …"). In other words, an RF generator (generating

[19] As mentioned above, it is my opinion that a "bipolar needle" means having both poles on the same needle (described in "Ganz as "Biopolar"), but the configuration described in the Na patent would be Monopolar needles arranged in a Bipolar configuration. However, for simplicity, Bipolar needle will be used as defined by the legal team. In this definition, Monopolar is referred as a configuration where current flows from one or more electrodes that deliver current to one or more ground electrodes. Using the "ground" as a refence for an electrosurgical instrument has been made illegal for many years. The term "Ground Electrode" should be replaced by "Neutral Electrode" as it is a floating reference, isolated for earth ground.

'836 Patent Claim 1		Ganz
		module) is configured to provide an RF signal to the plurality of electrodes. It was well-known in the art that a radio frequency signal is a type of alternating current (AC). *Radiofrequency Catheter Ablation for Cardiac Tachyarrhythmias*, Manolis, A.S., *et al*., *Ann Intern Med.* (1994) 121:452-461 at 452. Complainant also appears to agree that an RF signal is a type of "alternating current." *See* Complainant's Final Infringement Contentions, Ex. 64, at 25; Ex. 76, at 14; Ex. 22, at 11.  The bipolar modality of RF delivery utilizes two electrodes, a positive and negative; alternating current flows back and forth between these points. The effective field depth, and thus the depth of tissue heated is determined by the distance of electrodes in relation to one another, although the degree of heating is still determined by the electrical parameters of the EMF. Complainant's Final Infringement Contentions, Ex. 64, at 25; Ex. 76, at 14 (emphasis in original) (citing SERENDIA-00006562 (Dermatology Time RF Webpage) at SERENDIA-00006565). It was well-known in the art that an alternating current (AC) is a current that alternates polarities. Thus, a POSITA would have understood that Ganz's bipolar electrodes change or alternate between being positive or negative as the alternating current alternates between them. Complainant appears to agree since alternating current flowing back and forth (to different directions) means that the current alternates polarities relative to the 2 poles of the generator (*i.e.*, the polarities dictate the direction, and, thus, if the direction changes, then the polarities change.) *See* Complainant's Initial Infringement Contentions, Ex. 71, at 21; ("the Accused Product is configured to provide a RF signal with oscillating current (as evidenced in green) to the plurality of electrodes"), Ex. 77, at 14 (alternating current flows back and forth between" electrodes) (citing SERENDIA-00006562 (Dermatology Time RF Webpage) at SERENDIA-00006565). Also, in its *Markman* brief, I understand that Complainant took the position that an alternating current is synonymous with an oscillating current[20] which Complainant equates as a current that "alternates

[20]It is my scientific opinion that an AC current is a type of oscillating current, that oscillates around a "0" value; whereas an oscillating current could oscillate around another neutral value

'836 Patent Claim 1		Ganz
		polarities." Complainant's Claim Construction Brief, at 67-68 ("Breaking down the claim language, it specifies that the 'current' alternates or oscillates, i.e., it alternates polarities."). Complainant then states that "alternating current" is "electric current that reverses direction periodically, usually many times per second, and also states that "'alternating current' 'usually means that the current changes polarity with time.'" Complainant's Claim Construction Brief, at 68. Thus, there can be no dispute that when the RF signal (which is a type of AC signal) is applied to Ganz's electrodes, the electrodes change or alternate between being positive or negative as the current alternates between them. Accordingly, Ganz discloses a plurality of electrodes, the electrodes being bipolar and configured to be insertable into a body segment to be treated.
1.2	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	Ganz discloses and/or renders obvious a radio frequency (RF) generation module, the RF generation module electrically coupled to the plurality of electrodes. *See, e.g.,* Ganz at [0011], [0057], [0058], [0059], claims 7-8. Specifically, Ganz discloses that "[t]he device also includes an **energy source** coupled to the plurality of electrodes, the energy source configured to deliver energy," and that energy can be "**radio frequency**" energy. *Id*., at [0011] ("RF electrodes and are configured for receiving RF energy"); *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") (emphasis added). [0011] "The device also includes an energy source coupled to the plurality of electrodes, the energy source configured to deliver energy

not equal to "0". This would not be allowed in an electrosurgical generator that needs to have a "0" mean current due to the output blocking capacitor required by the IEC standard.

'836 Patent Claim 1		Ganz
		selected from the group consisting of radio frequency, non-ionizing ultraviolet radiation, or microwave radiation. A control device may also be coupled to the energy source. In preferred cases, the electrodes are RF electrodes and are configured for receiving RF energy. The electrodes can be provided as a plurality of electrode pairs or even as an array of electrodes. In some cases, the electrodes are monopolar electrodes whereas in other cases the electrodes are bipolar electrodes." [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, non-ionizing ultraviolet radiation and microwave radiation. In some cases, the electrodes are configured to provide power in the range of about 50 to about 200 watts per square centimeter. In other cases, the electrodes are configured to provide an energy of at least about 1 joule[] per square centimeter." [0058] "In preferred embodiments, the electrodes are configured as RF electrodes and RF energy is delivered to the electrodes. RF energy is particularly desirable for creating perforations of tissue since it does not cause the entire area of tissue being treated to heat up extensively. Rather, RF energy can penetrate the body and be absorbed by deeper tissues without heating up the surrounding tissues. Thus, a boundary is created between the treated tissue and those tissues surrounding the treated tissue. RF energy is also desirable since it is safe to use on tissues in areas near sensitive body parts, e.g., areas of skin near the eyes." [0059] "The energy source is configured for powering the electrodes at levels appropriate to provide a desired diameter and depth of perforation of tissue. The energy source may be manually controlled by the user and be adapted to allow the user to select the appropriate treatment time and power setting to obtain a controlled depth and/or width of perforation. The energy source can also be coupled to a controller, which may be a digital or analog controller for use with the energy source, including but not limited to an RF source, or a computer with software. When the computer controller is used it can include a CPU coupled through a system bus. The system may include a keyboard, a disk drive, or other non-volatile memory system, a display and other peripherals known in the art. A program memory and a data memory can also be coupled to the bus. The

'836 Patent Claim 1		Ganz
		energy source can be positioned at different positions in proximity to the treatment device." Thus, Ganz' RF energy source is a device that generates electrical signal(s) having a radio frequency. It was well-known in the art that a radio frequency signal is a high-frequency alternating current, which is usually over 200 KHz as defined by IEC 60601-2-:2009 section 201.8.4.102. (*see* above) alternating current (AC). 200 KHz is the equivalent of 0.2 MHz; *see* section 90. Thus, radio frequency signals are measured in MHz.[21] As discussed above in section V., Complainant also appears to agree that an RF signal is a type of "alternating current." *See* Complainant's Final Infringement Contentions, Ex. 64, at 25; Ex. 76, at 14; Ex. 22, at 11. Complainant appears to agree since alternating current flowing back and forth (to different directions) means that the current alternates polarities (*i.e.*, the polarities dictate the direction, and, thus, if the direction changes, then the polarities change.) Moreover, it was well-known in the art that an alternating current (AC) is an oscillating current that alternates polarities and is symmetric around a "Zero" value. Complainant appears to agree since alternating current flowing back and forth (to different directions) means that the current alternates polarities (*i.e.*, the polarities dictate the direction, and, thus, if the direction changes, then the polarities change.) *See* Complainant's Initial Infringement Contentions, Ex. 71, at 21; ("the Accused Product is configured to provide a RF signal with oscillating current (as evidenced in green) to the plurality of electrodes"), Ex. 77, at 14 (alternating current flows back and forth between" electrodes) (citing SERENDIA-00006562 (Dermatology Time RF Webpage) at SERENDIA-00006565). Also, in its *Markman* brief, I understand that Complainant took the position that an alternating current is synonymous with an oscillating current, which Complainant equates as a current that "alternates polarities." Complainant's Claim Construction Brief, at 67-68 ("Breaking down the claim language, it specifies that the 'current' alternates or oscillates, i.e., it alternates polarities."). Complainant then states that "alternating current" is "electric current that reverses

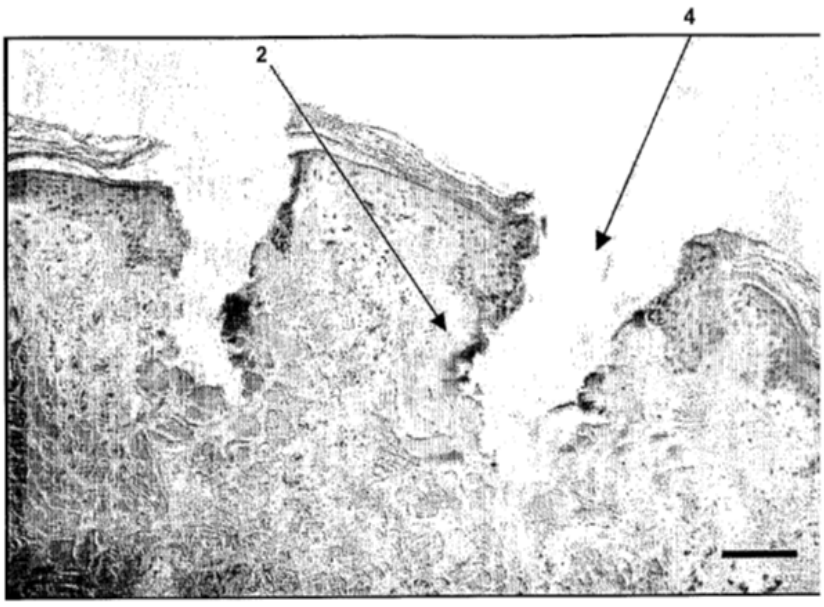
[21] '836 Patent, claim 22 depends from claim 14 (requiring "an Alternating Current (AC) Radio Frequency (RF) signal). Claim 22 requires that "the RF is from 0.5 to 10 MHz." Thus, if 0.5 MHz is considered to be measured in MHz, then 0.03 MHz is also measured in Mhz.

'836 Patent Claim 1		Ganz
		direction periodically, usually many times per second, and also states that "'alternating current' 'usually means that the current changes polarity with time.'" Complainant's Claim Construction Brief, at 68. In my opinion, an alternating current is a kind of oscillating but both terms are not synonymous, that demonstrates that Complainant lacks expertise in the art. Therefore, because Ganz provides a radio frequency (RF) signal to the electrodes, Ganz discloses providing an electrical signal with oscillating current (current alternating polarities) and having a radio frequency (measured in MHz). Accordingly, Ganz discloses that the RF generation module is coupled electrically to the plurality of electrodes and configured to provide an RF current to the plurality of electrodes. To the extent it is argued that RF signals do not inherently have frequencies measured in MHz[22] and/or that Ganz does not disclose an RF signal having a frequency measured in MHz, it would have further been obvious given the knowledge of a POSITA. For example, a POSITA would have known that (among other parameters) the frequency range of the RF source can be chosen based on the desired effects on various types of tissue and its influence on lesion size and geometry based on the intended application. *See* Hantash '718 PCT, [0040]; *see also id.* at [0052] ("With the proper choice of parameters, the treatment can be self-limiting to create treatment zones 160 of approximately uniform size across the treatment pattern 161. The self limiting nature of the treatment can be achieved by choosing the frequency of the RF source 110 to be a frequency for which the tissue resistivity (impedance) increases as the tissue is treated."); *id.* at [0079]. Ganz also teaches that the parameters and the configuration of the RF generator influences the depth and diameter of the lesion around each electrode. Ganz at [0059] ("The energy source is configured for powering the electrodes at levels appropriate to provide a desired diameter and depth of perforation of tissue."). One of Ganz's goals is to create zones of coagulation that are not connected so that "tissue layers surrounding the perforations are left untreated and contribute to tissue regeneration," thereby "promoting more aggressive healing." Ganz, at [0006]; *see also id*., at [0010]

[22] As discussed above, a POSITA would be familiar with the IEC 60601-2-2 that in 2012 defined high frequency for surgical equipment as a frequency over 200 KHz (0.2 MHz).

'836 Patent Claim 1		Ganz
		("zone of coagulative tissue surrounding each perforation"); *id.* at [0048] ("Zones of coagulation are also created in areas of tissue surrounding each perforation"); *id.* at [0058] ("RF energy is particularly desirable for creating perforations of tissue since it does not cause the entire area of tissue being treated to heat up extensively … Thus, a boundary is created between the treated tissue and those tissues surrounding the treated tissue"); *id.* at [0028] ("Areas or zones of coagulation 2 can also be seen in the areas surrounding the perforation"), *id.* at Fig. 9. Optimization of parameters, such as the RF frequency, power, energy, voltage, timing duty cycle applied to microneedles, requires a significant amount of experimentation; However, the experimental methodology to achieve unconnected coagulation zones is obvious to a POSITA, and the selection of the RF frequency would then become obvious to a POSITA. Therefore, in 2013, a POSITA would have been motivated to use an RF frequency measured in MHz, in the range of 0.2 to 5-10 MHz. In the original application, Na mentions that "[t]he required components for both Na-Effect and Na-Plus effect are bipolarity of needles, alternating current (AC), and high frequency." In the original filed claims, he mentions that the device and method have the high frequency range of 0.5 - 10MHz and also that the frequency of the alternating current is higher than 20Hz, including 20Hz. In fact, combining these two signals together could be either an "addition" or a "multiplication" of one by the other; although this is not defined at all in the patent specification, the most likely scenario, a multiplication of the two signals, would result in engineering terms, to modulating the amplitude of the high frequency signal following a sinewave (or similar) such that the envelope of the high frequency signal amplitude follows a sine wave that varies from 0 to its maximal amplitude in a cyclic fashion 20 or more times per second (Complainant's interpretation requires a signal combining an AC frequency rate and an RF frequency rate). Such a mode of operation has been used in standard electrosurgery for over 30 years in most Electrosurgical Units on the market and is described in section VII. of this report. Therefore, using a low frequency modulation for a high frequency signal has been described and used many times prior to the filing of this patent and would be obvious for a POSITA
1.3	configured to cause coagulation	Ganz discloses and/or renders obvious electrodes configured to cause coagulation around each electrode rather than coagulating between

'836 Patent Claim 1		Ganz
	around each electrode rather than coagulating between the electrodes.	the electrodes according to the claim. *See, e.g.*, Ganz, [0006], [0010], [0028], [0048], [0056], [0058], Fig. 9, claims 1-3. Specifically, Ganz discloses zones of coagulation, which are small vertical zones of damaged tissue with "tissues layers surrounding the perforations are left untreated." *Id.* at [0006]. The benefit of these areas of treated and untreated tissue is "that by leaving zones of untreated tissue in between the perforations, less scarring and/or pigmentations are visible." *Id.* The zone of coagulation is created surrounding each electrode. *Id.* at [0010] ("The electrode pattern can also be selected to create a **zone of coagulative tissue surrounding each perforation**.") (emphasis added); [0056] ("The base of the treatment pad or treating surface and various portions of the proximal electrodes can also be insulated in order to limit the coagulation injury to the distal end of the electrode as well."). Further, the zone of coagulation around the electrode is created by applying energy to each electrode. *Id.* at [0048] ("Zones of coagulation are also created in areas of tissue surrounding each perforation. The zones can extend from the perforation site into the tissue for a length ranging from about 5 microns to about 100 microns. The zone of coagulation can be varied by **changes in energy** and power levels.") (emphasis added); *id.* at [0058] ("In preferred embodiments, the electrodes are configured as RF electrodes and **RF energy is delivered to the electrodes**. RF energy is particularly desirable for creating perforations of tissue since it does not cause the entire area of tissue being treated to heat up extensively. Rather, RF energy can penetrate the body and be absorbed by deeper tissues without heating up the surrounding tissues. Thus, a boundary is created between the treated tissue and those tissues surrounding the treated tissue. RF energy is also desirable since it is safe to use on tissues in areas near sensitive body parts, e.g., areas of skin near the eyes.") (emphasis added). As shown in Figure 9 below, the apparatus causes energy to be applied to the electrodes which in turns causes coagulation around each electrode rather than between the electrodes. *Id.* at Fig. 9; *id.* at [0028] ("FIG. 9 illustrates a skin area treated in accordance with the invention. The treated area 4 is clearly a perforation, which extends vertically into the skin. Areas or zones of coagulation 2 can also be seen in the areas surrounding the perforation.").

'836 Patent Claim 1		Ganz
		 [0047]"In certain cases, the electrodes are patterned in order to create perforations being between about 30 to about 100 microns in diameter, up to about 1000 microns deep and spaced apart by between about 50 to about 400microns." [0048] "Zones of coagulation are also created in areas of tissue surrounding each perforation. The zones can extend from the perforation site into the tissue for a length ranging from about 5 microns to about 100 microns. The zone of coagulation can be varied by changes in energy and power levels." Ganz at [0047], [0048]. From [0047] and [0048] of Ganz, it appears that in most cases, the zones of coagulation extend to a distance (5-100 microns) less than the distance between the electrodes (100-1,000 microns, demonstrating the ability of creating coagulation zones that do not overlap. Ganz also explains how to control the size of the lesions by varying energy and power levels, showing once more that he is able to fully control lesions such that they do not overlap.

269. In view of at least the arguments set forth in the foregoing chart, claim 1 of the '836 Patent is anticipated and/or rendered obvious by the teachings of Ganz alone.

2. *Claim 2 of the '836 Patent is anticipated and/or rendered obvious over Ganz in view of Hantash '718 PCT.*

270. It is my opinion that claim 2 of the '836 Patent, which depends from claim 1, is anticipated and/or obvious in view of the teachings of Ganz in combination with the teachings of Hantash '718 PCT as detailed below.

'836 Patent Claim 2		**Ganz in view of Hantash '718 PCT**
2.0	The skin treatment apparatus of claim 1,	As discussed above with regard to claim 1, Ganz discloses a skin treatment apparatus device according to the claim. *See, e.g.*, Ganz at [0001], [0027], [0063], claim 1, 24. Specifically, Ganz discloses "a device and method for treating one or more layers of [skin] tissue," of a human. *Id*., at [0001]; *see also id*., at [0016] ("method for treating human skin"), [0029] ("treatment device"), [0030], claim 24 ("treating human skin"). Claims 1, 21, and 22 in Ganz recite tissue in general without limiting the tissue to a specific type of tissue, and therefore this could apply to any part of the body.
2.1	wherein the RF generation module is configured to provide an AC RF signal to the plurality of electrodes	As discussed above for limitation 1.2, Ganz discloses an RF generation module is configured to provide an AC RF signal to the plurality of electrodes. *See, e.g.*, Ganz, at [0011], [0048], [0057], [0058], [0059], claim 7-9. Specifically, Ganz discloses that "[t]he device also includes an **energy source coupled to the plurality of electrodes**, the energy source configured to deliver energy," and that energy can be "radio frequency" energy. *Id.*, at [0011] ("**RF electrodes and are configured for receiving RF energy**") (emphasis added); *see also id.*, at [0057] ("The energy delivery device can deliver a variety of different types of energy including but not limited to, radio frequency energy…"), [0058] ("In preferred embodiments, **the electrodes are configured as RF electrodes and RF energy is delivered to the electrodes**") (emphasis added), [0059] ("the energy source, including but not limited to **an RF source**") (emphasis added), 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"), claim 9 ("wherein the plurality of electrodes are RF electrodes and are configured for receiving RF energy"). Ganz discloses an AC RF signal for the reasons stated above for limitation 1.2.

'836 Patent Claim 2		Ganz in view of Hantash '718 PCT
2.2	for a predetermined time interval.	Ganz discloses a RF generation module is configured to provide an AC RF signal to the plurality of electrodes for a predetermined time interval according to the claim. *See e.g.*, *id.* at [0059] ("The energy source may be . . . adapted to allow the user to select the **appropriate treatment time**[.]") (emphasis added);*id.* at [0059] ("The energy source may be manually controlled by the user and be adapted to allow the user to select the **appropriate treatment time** and power setting to obtain a controlled depth and/or width of perforation") (emphasis added), . *id.* at [0063] ("In many cases, the same area of skin will be treated several times and usually at different time intervals."); *see also id.* at [0011] ("an energy source coupled to the plurality of electrodes…configured for receiving RF energy"); *id.* at [0057] ("energy source coupled to the electrodes for delivering energy to the electrodes," which can be " radio frequency energy"); *id.* at [0058] ("the electrodes are configured as RF electrodes and RF energy is delivered to the electrodes"); *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 8 ("a control device coupled to the energy source"). Specifically, Ganz discloses that "[t]he energy source may be manually controlled by the user and be adapted to allow the **user to select the appropriate treatment time**[,]" *i.e.*, a predetermined time interval. Ganz, at [0059]. And that usual treatment required several applications "at different time intervals." *Id.* at [0063]. To the extent Ganz does not explicitly or inherently disclose this limitation, it would have further been obvious in view of Hantash '718 PCT. For example, Hantash '718 PCT discloses a mammalian body treatment apparatus. Hantash '718 PCT at Title ("Method and apparatus for micro-needle array electrode treatment of tissue"); *id.* at Abstract ("system and method for revitalizing aging skin"); *id.* at [0002]; [0013]; [0014]; [0021]; *id.* at Fig. 1; claim 1 (for "human skin"). Hantash '718 PCT's device also has a plurality of bipolar electrodes configured to be deployable into a body segment to be treated, and a radio frequency (RF) generation module, the RF generation module electrically coupled to the plurality of electrodes and configured to provide an RF signal with oscillating current to the plurality of electrodes. Hantash '718 PCT, at [0035], *see also id*. at Abstract; *id.* at [0002] ("biological tissue treatment using electromagnetic energy delivered through an array of needle electrode [electrodes]"); *id.* at [0012], [0013], [0014], [0017] ("the microneedles are driven into the tissue"); *id.* at [0021], [0034] ("a radio frequency (RF) source 110 is [electrically] connected to an array of

'836 Patent Claim 2		Ganz in view of Hantash '718 PCT
		needles 115" to deliver energy to the skin 150 via the array of needle electrodes 115"); *id.* at [0035] ("While the needles 115 are located within the skin 150, they can be powered by the RF source 110"); *id.* at [0039] ("each of the needles 115 can comprise an electrically conductive shaft"); *id.* at [0040] ("bipolar" electrodes); *id.* at [0047] ("One array includes all of the negative polarity needles 116 (return electrodes) and the other includes all of the positive polarity needles 117 (active electrodes)"); *id.* at [0055], [0057] ("electrically connecting the needles 116 and 117 at the opposite ends of each local region of skin 150 to be treated to different poles of the RF source 110"); *id.* at [0061], [0068]-[0070], [0079] ("bipolar"); *id.* at Figs. 1, 3A; *id.* at claims 1, 37, 42. Hantash '718 PCT also discloses an example of providing an RF signal to a plurality of electrodes for "pulse duration of 400 ms" (Hantash '718 PCT, at [0077]) or "200 ms" (*id*., at [0078]). *See also id*. at [0018] (ensuring "enough thermal relaxation time at the treated zones and thereby avoiding overheating of the treated zones"). Thus, Hantash '718 PCT discloses that the RF generation module is configured to provide an AC RF signal to the plurality of electrodes for a predetermined time interval. Hantash '718 PCT also explains to adjust the treatment parameters to achieve the desired time at temperature (*See id.* at [0018], [0040], [0052], [0079]), in order to "create more localized electrical field profiles within the tissue or to create a discontinuous treatment pattern" in order to "reduce charring and over-treatment." *Id*. at [0056]. Hantash '718 PCT explains that it is safer and more desirable to create discrete small coagulation zones rather than larger connected coagulation zones so that the surrounding area is spared from damage and can assist with the healing process, which makes the healing process more through and faster as compared to continuous coagulation zones. *See id*. at [0058]. As discussed above, Ganz already discloses that "[t]he energy source may be manually controlled by the user and be adapted to allow the user to select the appropriate treatment time and power setting to obtain a controlled depth and/or width of perforation." Ganz, at [0059]. Thus, a POSITA would combine the teachings of Ganz with Hantash '718 PCT to select appropriate treatment times that are in predetermined time intervals (*e.g.*, 400 ms). A POSITA would have been motivated to allow the user to select different predetermined time intervals for applying the RF energy to the electrodes in order to achieve different coagulation patterns. For example, to create small discrete coagulation zones that do not connect

'836 Patent Claim 2		Ganz in view of Hantash '718 PCT
		between electrodes. This would allow for a quicker healing time, and thus would have been desirable.

271. In view of at least the arguments set forth in the foregoing chart, claim 2 of the '836 Patent is anticipated by/or rendered obvious by the teachings of Ganz alone or Ganz in view of Hantash '718 PCT.

3. Claim 5 of the '836 Patent is anticipated and/or rendered obvious over Ganz in view of Hantash '718 PCT.

272. It is my opinion that Claim 5, which depends from unasserted claim 4, is anticipated and/or obvious in view of the teachings of Ganz in combination with the teachings of Hantash '718 PCT as detailed below.

273. In view of the foregoing charts, claim 5 of the '836 Patent is anticipated by Ganz or rendered obvious over Ganz in view of Hantash '718 PCT.

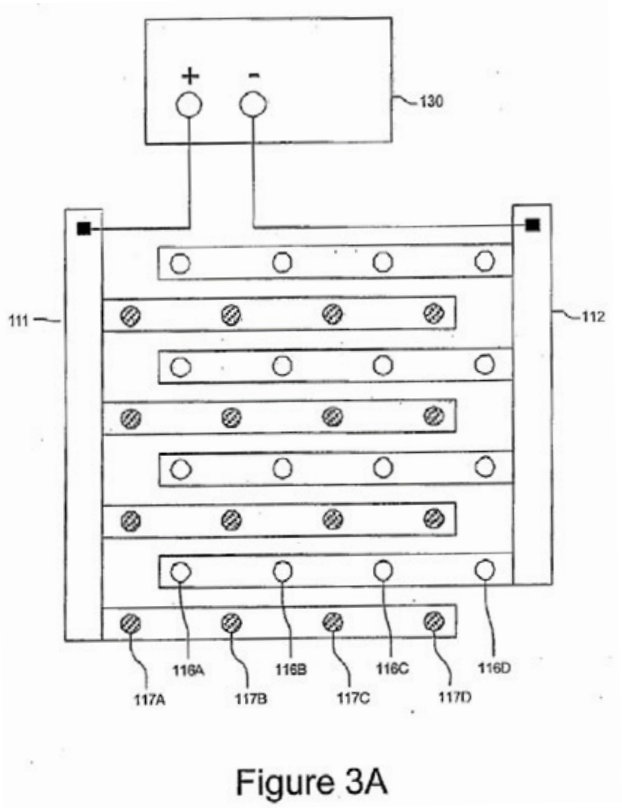
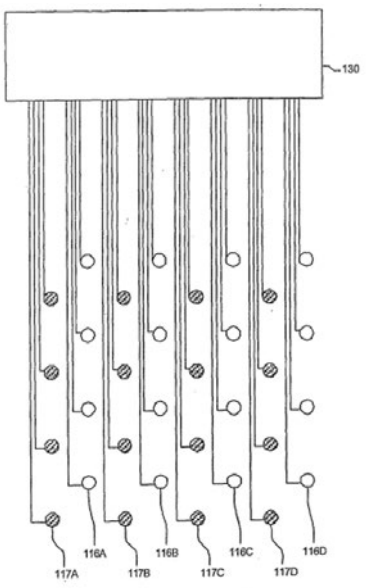
'836 Patent Claim 4		Ganz in view of Hantash '718 PCT and/or ScarLet
4.0	The skin treatment apparatus of claim 2, wherein each electrode of the plurality of electrodes has a length sufficient to reach skin dermis when inserted into skin	Ganz discloses and/or renders obvious wherein each electrode of the plurality of electrodes has a length sufficient to reach skin dermis when inserted into skin. *See, e.g.*, Ganz at [0036], [0050], [0051], [0059], [0063]. Specifically, Ganz discloses electrodes configured to be inserted into the skin as evidenced by the fact that the needles "simultaneously impart[] perforations into the one or more layers" of skin tissue. *Id.* at [0001]; *Id.* at [0036] ("The treatment device can be used to create perforations and Zones of coagulation across both the epidermis and dermis to activate fibroblasts…"), *see also id.* at claim 1 ("a plurality of electrodes extending outwardly from the treating surface and adapted for imparting simultaneous perforations into one or more tissue layers, wherein the electrodes are provided in a pattern to impart a corresponding pattern of perforations in the one or more tissue layers"); *id.* at claim 4 (" wherein the electrode pattern is selected to create perforations which are between about 30 to about 100 microns in diameter, up to about 1000 microns deep and spaced apart by between about 50 to about 400 microns"); *id.* at claim 5 ("wherein the plurality of electrodes have a depth … for providing perforations being no more than about 2 mm in depth …"); *id.*

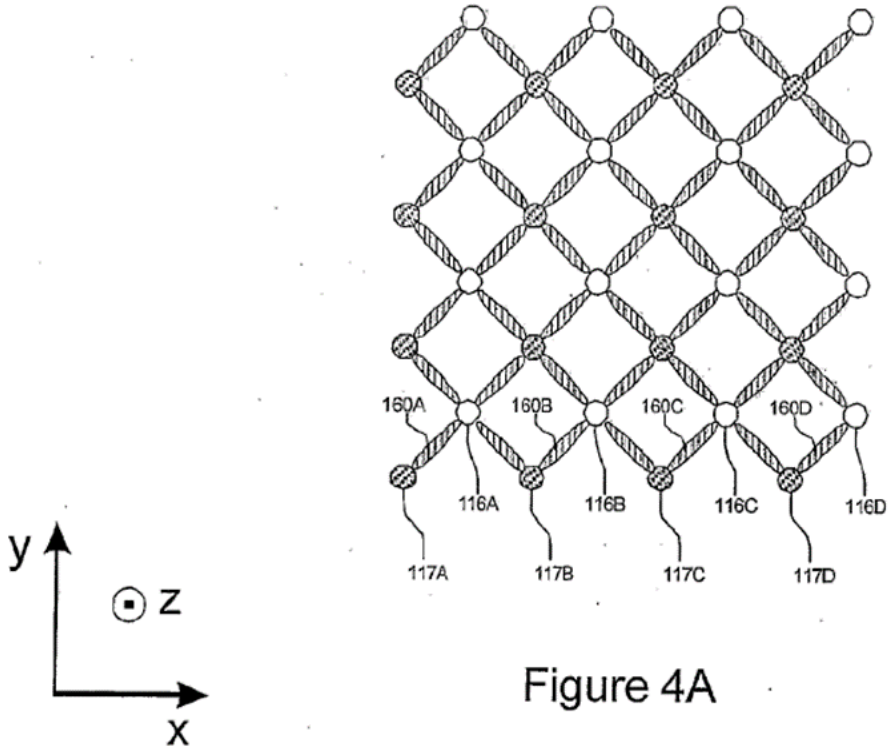
'836 Patent Claim 4		Ganz in view of Hantash '718 PCT and/or ScarLet
		at [0016] ("simultaneously perforating the target area to provide the desired pattern of perforations which elicit a healing response that produces a revitalized skin surface"); *id.* at [0047] ("Generally, the electrodes come into direct contact with the one or more tissue planes. So, the pattern of electrodes directly corresponds to the pattern of perforations desired in the tissue."); *id.* at [0063] ("The method generally includes simultaneously imparting perforations into one or more tissue layers in a tissue plane. . . . The device is activated to create a plurality of perforations in the skin"). [0048] "Zones of coagulation are also created in areas of tissue surrounding each perforation. The zones can extend from the perforation site into the tissue for a length ranging from about 5 microns to about 100 microns. The zone of coagulation can be varied by changes in energy and power levels." Hantash '718 PCT also teaches that the needles are configured to reach the dermis " *Id.* at [0035] (: In some embodiments of the invention, it is preferable that all the needles are arranged to primarily deliver treatment in the papillary dermis and/or the upper reticular dermis…"); claim 5.
4.1	and the predetermined time interval is from 0.05 to 0.8 seconds.	Ganz discloses and/or renders obvious wherein and the predetermined time interval is from 0.05 to 0.8 seconds according to the claim. *See, e.g.*, Ganz at [0059] "The energy source is configured for powering the electrodes at levels appropriate to provide a desired diameter and depth of perforation of tissue. The energy source may be manually controlled by the user and be adapted ***to allow the user to select the appropriate treatment time*** and power setting to obtain a controlled depth and/or width of perforation. The energy source can also be coupled to a controller, which may be a digital or analog controller for use with the energy source, including but not limited to an RF source, or a computer with software. When the computer controller is used it can include a CPU coupled through a system bus. The system may include a keyboard, a disk drive, or other non-volatile memory system, a display and other peripherals known in the art. A program memory and a data memory can also be coupled to the bus. The energy source can be positioned at different positions in proximity to the treatment device."

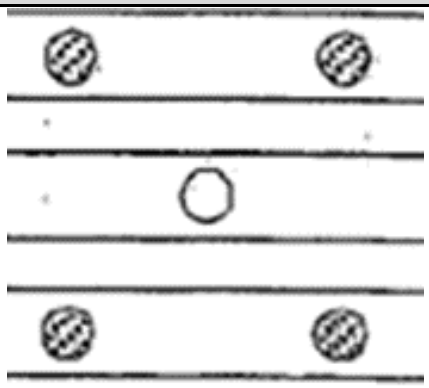
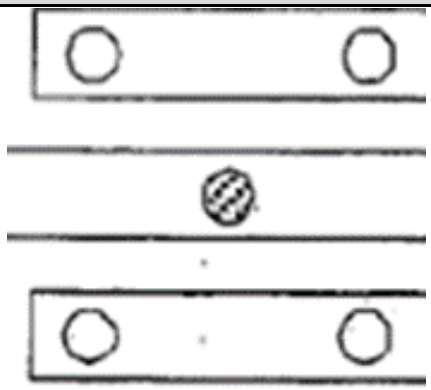
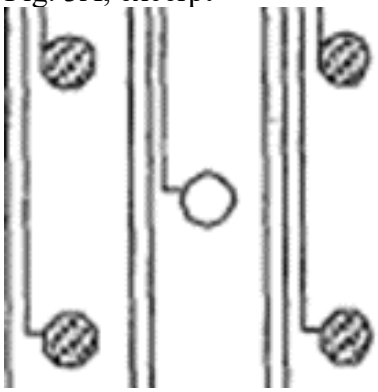
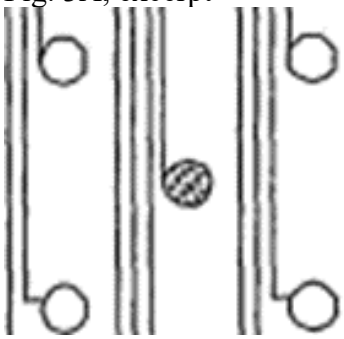
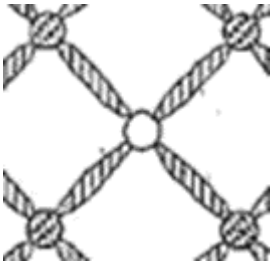
'836 Patent Claim 4		Ganz in view of Hantash '718 PCT and/or ScarLet
		To the extent Ganz does not explicitly or inherently disclose this limitation, it would have further been obvious in view of Hantash '718 PCT. Hantash '718 PCT discloses and/or renders obvious that the predetermined time interval is from 0.05 to 0.8 seconds. *See e.g.*, Hantash '718 PCT, At [0014]; [0018]; [0077]; [0078]. For example, Hantash '718 PCT discloses an example of providing an AC RF signal to the plurality of electrodes for "pulse duration of 400 ms" (Hantash '718 PCT, at [0077]) or "200 ms" (*id*., at [0078]). 200 ms and 400 ms are the equivalents of 0.2 seconds and 0.4 seconds, respectively. ScarLet also shows an adjustable Time ON of 0.100sec. to 0.800 seconds (Ilooda-0006239 19/32), which overlaps the time windows preconized by Na. 1. Specification of ScarLet Specification NEEDLE DEPTH: 0.5 mm ~ 3.5 mm (0.1 mm unit) RF CONDUCT. TIME: 100msec ~ 800msec (100msec unit) RF OUTPUT: 1) 1.5V ~ 40V 2) 40 ~ 200V RF E. FIELD WIDTH(at 1mm Depth): 82mm² RF FREQUENCY: 2MHz WEIGHT: 29Kg DIMENSION: 55cm(W) * 35cm(D) * 122cm(H) ELECTRODE NO.: 25 Pin SPOT SIZE: 1cm² Ilooda-0006061 (0006062)

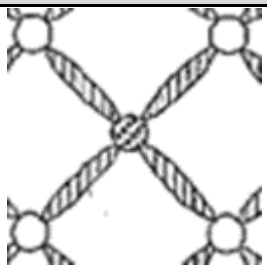
'836 Patent Claim 5		Ganz in view of Hantash '718 PCT and further in view of ScarLet
5.0	The skin treatment apparatus of claim 4, wherein the closest neighboring electrodes have opposite polarities.	As described above, claim 4 is anticipated by Ganz alone or Ganz in combination with Hantash '718 PCT and/or ScarLet. Ganz further discloses a skin treatment apparatus wherein the closest neighboring electrodes have opposite polarities. *See, e.g.,* Ganz at [0014], [0047], [0050], [0054], [0056]. Ganz discloses a plurality of electrodes arranged in rows columns. *Id.* at [0011], [0047], [0050]; *id.* at Figs. 5 & 7. Ganz further discloses the neighboring electrodes in the rows and columns have opposite polarities. *Id.* at [0056]. For example, Ganz discloses that "[a]ny desired pattern or electrode arrangement is within the scope of the invention," and that

'836 Patent Claim 5		Ganz in view of Hantash '718 PCT and further in view of ScarLet
		"the electrodes are bipolar" (*i.e.*, having opposite polarities). *Id.* at [0047] ("The electrodes are positioned on the treating surface in any manner to provide a desired pattern of perforations into the one or more tissue planes"); [0056] ("the electrodes are provided as a bipolar electrode arrangement"); *see also id.* at [0014] ("wherein the plurality of electrodes are arranged in a desired pattern"). In Ganz's bipolar embodiment, the electrodes come in pairs where "one electrode in the pair being a positive electrode and the other electrode being a negative electrode." *Id.* at [0056]. Thus, Ganz discloses neighboring electrodes wherein the closest neighboring electrodes have opposite polarities (interlaced finger electrodes). "In bipolar electrode arrangements, both the positive and negative electrodes serve as treating electrodes. In some cases, the bipolar electrodes are biopolar axial interlaced finger electrodes." To the extent that Ganz does not explicitly or inherently disclose the closest neighboring electrodes have opposite polarities, it would have further been obvious over Hantash '718 PCT. Hantash '718 PCT discloses and/or renders obvious that the closest neighboring electrodes have opposite polarities. *See e.g.*, Hantash '718 PCT, at [0021]; Fig. 1; [0047]; Fig. 3A; [0051]; Fig. 4A; Fig. 5A; claim 15; claim 16; claim 17. For example, as shown in Fig. 3A and 4A, reproduced below, the closest neighboring electrodes have opposite polarities. Hantash '718 PCT, at [0047] ("One array includes all of the negative polarity needles 116 (return electrodes) and the other includes all of the positive polarity needles 117 (active electrodes). In FIG 3, the negative needles 116 are open and the positive needles 117 are shaded."), [0051] ("FIG 4 A shows the treatment zones 160 that are created between nearest neighbor needles 115 that are connected to opposite poles of the RF source 110"), *see also id*., claims 15, 17 ("wherein the needles are spaced further apart in one direction compared to the other direction on the grid"), Fig. 5A.

'836 Patent Claim 5	Ganz in view of Hantash '718 PCT and further in view of ScarLet
	 Figure 3A *Id*. Fig. 3A.  Figure 3B *Id*. at Fig. 3B.

'836 Patent Claim 5	Ganz in view of Hantash '718 PCT and further in view of ScarLet
	 Figure 4A *Id*., Fig. 4A. For example, as can be seen in Fig. 3A and 3B, the closest electrodes to any given negative electrode (open circle) are positive electrodes (shaded circle). *Id*., at [0047]. In this example, the four shaded electrodes (positive) form a square, and the non-shaded (negative) electrode is in the center of the square. If the distance between the each of the 4 shaded electrodes is "a", the distance "D" between the non-shaded electrode and any of the neighboring shaded electrode is given by the formula (1/2 the diagonal of a square): $D = \frac{a*\sqrt{2}}{2} = \frac{a*1.414}{2} = 0.707a$. Therefore, the distance between the electrode of opposite polarities is 30% shorter than the distance between the electrodes of same polarities.

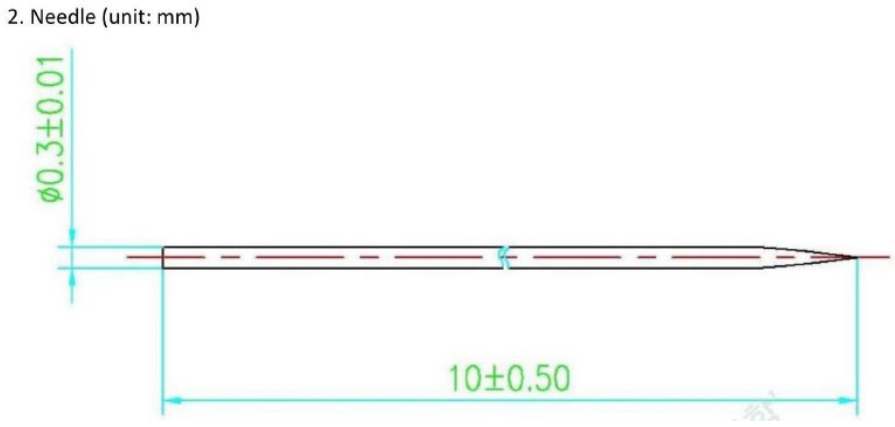
'836 Patent Claim 5	Ganz in view of Hantash '718 PCT and further in view of ScarLet
	  Fig. 3A, excerpt Fig. 3A, excerpt   Fig. 3B, excerpt Fig. 3B, excerpt As can be seen in Fig. 4A, the closest electrodes to any given negative electrode (open circle) are positive electrodes (shaded circle). *Id*., at [0047].  *Id*., Fig. 4A (excerpts). The closest electrodes to any given positive electrode (shaded circle) are negative electrodes (open circle)

'836 Patent Claim 5		Ganz in view of Hantash '718 PCT and further in view of ScarLet
		 *Id*., Fig. 4A (excerpts).

4. Claim 9 of the '836 Patent is rendered obvious over Ganz in view of Manstein or ScarLet.

274. It is my opinion that claim 9 is rendered obvious over Ganz in view of Manstein and/or in further view of ScarLet.

'836 Patent Claim 9		Ganz in view of Manstein or ScarLet
9.0	The skin treatment apparatus of claim 1,	As described above with regard to claim 1, Ganz discloses a skin treatment apparatus according to the claim. *See, e.g.*, Ganz, at [0001], [0016], [0027], [0029], [0030], [0033], [0063], claim 1, 24.
9.1	wherein the electrodes are needles and have a diameter from 0.25 mm to 0.30 mm.	Ganz discloses and/or renders obvious wherein the electrodes are needles and have a diameter from 0.25 mm to 0.30 mm according to the claim. *See, e.g.*, Ganz at [0053] "The width or diameter of each electrode pin can also be varied to provide a perforation having a desired width. For example, the electrodes of FIG. 5 and 6 have a larger width than the electrodes of FIGS. 3 and 4. In most cases, the width of each electrode pin on a particular treating surface will be the same, although this is not necessary. Electrode pins having different widths can be provided. The width of the perforation created will be at least the width of the electrode, and in many cases larger. The width of the perforation created depends not only on the width of the electrode, but also the level of energy discharged from the electrode. When more energy is discharged from the electrode, a larger perforation width and depth is created. Additionally, the width of perforation may be tapered with depth." [0065] "A freshly exercised pig skin was obtained. A monopolar electrode array was placed upon the skin. The array consisted of

		two 0.3 mm length needles placed in a row 500 microns apart. The array was hooked up to an electrical generator. A power of 50 watts and an energy of 1 joule were delivered to the electrode array. A 4 mm punch biopsy was taken and process for routine light microscopy. Upon examination of the tissue, both the epidermis and dermis were perforated by two equivalent vertical perforations. The perforations were widest at the top (50 to 100 microns in diameter) and tapered to a point at a depth of 250-300 microns. Throughout the edge of the injury, a 10-50 micron zone of coagulation was also seen.". It should be noted that a sharp needle always creates a perforation with a diameter significantly smaller than its diameter as the tissue is elastic and the needle is sharp; the perforation also shrinks during the coagulation process, and therefore perforations of 0.050-0.100 mm (50-100 microns) are most likely obtained with needles 2-4 times larger (0.100 – 0.400 mm) which would overlap the dimensions set by the '836 Patent. To the extent this limitation is not explicitly or inherently disclosed by Ganz , it would have been obvious given the disclosure in Manstein. Manstein discloses electrodes are needles and have a diameter from 0.25 mm to 0.30 mm. *See* Manstein at 7:41-45 ("In practicing the methods and apparatus of the present invention, the needles can have a width of about 500-1000 μm or preferably about 700-800 μm. Needles less than 500 um in diameter may also be used if they are mechanically strong enough."). To the extent this limitation is not explicitly or inherently disclosed by Ganz or Manstein, it would have been obvious given the disclosure in ScarLet. ScarLet discloses electrodes are needles and have a diameter from 0.25 mm to 0.30 mm. 

		Ilooda-0010141 at -152 (certified English translation of SERENDIA-00033705 at -715); Ilooda-0010117 at -126 (certified English translation of SERENDIA-00033637 at -645).

5. Claim 11 of the '836 Patent is rendered obvious over Ganz in view of Manstein and/or ScarLet.

275. It is my opinion that Claim 11 is rendered obvious over Ganz in view of Manstein and/or ScarLet.

'836 Patent Claim 11		Ganz in view of Manstein and/or ScarLet
11.0	The skin treatment apparatus of claim 1,	As described above with regard to claim 1, Ganz discloses a skin treatment apparatus according to the claim. *See, e.g.*, Ganz, at [0001], [0016], [0027], [0029], [0030], [0033], [0063], claim 1, 24.
11.1	wherein the closest neighboring electrodes are separated by a distance of 1.3 mm to 3.0 mm.	Ganz discloses the closest neighboring electrodes are separated by a distance of 1.3 mm to 3.0 mm according to the claim. *See, e.g.*, Ganz at [0052] "The electrodes can also be spaced apart at a desired length so that the perforations in tissue will also be spaced apart at that length. Any length between electrodes is within the scope of the invention. In some cases, each of the electrodes on a treating surface are spaced apart evenly whereas in other cases, some electrodes on a treating surface are space apart at a smaller length than other electrodes. The spacing of the electrodes can be adjusted in order to provide any desired spacing of perforations. With reference to the Figures, the electrodes of FIG. 3 have a larger spacing than the electrodes of FIG. 4. In certain embodiments, electrodes are provided on a treating surface have a spacing of less than about 5 mm, and preferably less than about 2 mm." *See also* Ganz at claim 6. To the extent this limitation is not explicitly or inherently disclosed by Ganz, it would have been obvious over Manstein. Manstein discloses and/or renders obvious the closest neighboring electrodes are separated by a distance of 1.3 mm to 3.0 mm. *See, e.g.*, Manstein at 7:61-64 ("The needle arrays may have any geometry appropriate for the desired treatment being performed. The spacing between adjacent needles is preferably greater than about 1 mm apart, and may be as large as about 2 cm.").

<table>
<tr><th colspan="2">‘836 Patent Claim 11</th><th>Ganz in view of Manstein and/or ScarLet</th></tr>
<tr><td></td><td></td><td>To the extent this limitation is not explicitly or inherently disclosed by Ganz or Manstein, it would have been obvious over ScarLet. ScarLet discloses and/or renders obvious the closest neighboring electrodes are separated by a distance of 1.3 mm to 3.0 mm. See, e.g.,

<table>
<tr><td>Image</td><td> 
</td></tr>
<tr><td>Product</td><td>Scarlet</td></tr>
<tr><td>Launch (KFDA 기준)</td><td>2010</td></tr>
<tr><td>Domestic Sales</td><td>X</td></tr>
<tr><td>International Sales</td><td>X</td></tr>
<tr><td>Certificates</td><td>CFDA</td></tr>
<tr><td></td><td></td></tr>
<tr><td>Needle Depth</td><td>0.5-3.5mm *0.1mm step</td></tr>
<tr><td>Needle Space</td><td>2mm</td></tr>
</table>
ViOL-00001455</td></tr>
</table>

6. *Claim 12 of the ‘836 Patent is anticipated by Ganz and/or rendered obvious over Ganz in view of Hantash ‘718 PCT*

276. It is my opinion that Claim 12 is anticipated and/or rendered obvious over Ganz in view of Hantash ‘718 PCT.

‘836 Patent Claim 12		Ganz in view of Hantash ‘718 PCT
12.0	The skin treatment apparatus of claim 1,	As described above with regard to claim 1, Ganz discloses a skin treatment apparatus according to the claim. *See, e.g.*, Ganz, at [0001], [0016], [0027], [0029], [0030], [0033], [0063], claim 1, 24.

'836 Patent Claim 12		Ganz in view of Hantash '718 PCT
12.1	wherein the plurality of electrodes are non-insulated.	Ganz discloses and/or renders obvious that the plurality of electrodes are non-insulated according to the claim. *See, e.g.*, Ganz at [0056] "In other embodiments, the electrodes are provided as a bipolar electrode arrangement. In bipolar electrode arrangements, both the positive and negative electrodes serve as treating electrodes. In some cases, the bipolar electrodes are biopolar axial interlaced finger electrodes. In embodiments wherein the electrodes are provided as electrode pairs, bipolar electrodes are desirable, with one electrode in the pair being a positive electrode and the other electrode being a negative electrode. The electrodes can be shaped in such a way that the middle portion of distal portion is enlarged in order to create a zone of injury that is greater at the distal end compared to the proximal end. The base of the treatment pad or treating surface and various portions of the proximal electrodes can also be insulated in order to limit the coagulation injury to the distal end of the electrode as well." *Id. at* [0056]. Thus, the default for Ganz is that the electrodes are not insulated. In view of what is discussed in section VII. regarding the well-known use of non-insulated RF acupuncture needles, a POSITA would also know that the default for this type of needle electrodes is that the needles are not insulated To the extent this limitation is not explicitly or inherently disclosed by Ganz, it would have been obvious to try non-insulated needles because there are only two options to try that would allow the needles to deliver RF energy to the skin: (1) non-insulated needles, and (2) partially insulated needles. It would have been routine experimentation to have tried these two options. Alternatively, .given the disclosure in Hantash '718 PCT. Hantash '718 PCT discloses and/or renders obvious that the plurality of electrodes are non-insulated. *See e.g.*, Hantash '718 PCT at [0014]; *id.* at [0038]; *id.* at [0039]; *id.* at claims 5-6. For example, Hantash '718 PCT discloses that "the needles 115 are 36-gauge electrically conductive needles," which "could be prepared by cutting commercially available long hypodermic needles." Hantash '718 PCT at [0038]; *see also id*. at [0039] ("the needles 115 are pointed and made of a solid conductive material such as, for example, metal"); *id.* at claim 5.

7. Claim 13 of the '836 Patent is anticipated by Ganz and/or rendered obvious over Ganz in view of Hantash '718 PCT and/or in further view of Manstein.

277. It is my opinion that Claim 13 is anticipated by Ganz and/or rendered obvious over Ganz in view of Hantash '718 PCT and/or in further view of Manstein.

'836 Patent Claim 13		Ganz in view of Hantash '718 PCT and/or in further view of Manstein
13.0	The skin treatment apparatus of claim 1,	As described above with regard to claim 1, Ganz discloses a skin treatment apparatus according to the claim. *See, e.g.*, Ganz, at [0001], [0016], [0027], [0029], [0030], [0033], [0063], claim 1, 24.
13.1	wherein each electrode of the plurality of electrodes is insulated except at its tip.	Ganz discloses and/or renders obvious wherein each electrode of the plurality of electrodes is insulated except at its tip according to the claim. *See, e.g.*, Ganz at [0056] "In other embodiments, the electrodes are provided as a bipolar electrode arrangement. In bipolar electrode arrangements, both the positive and negative electrodes serve as treating electrodes. In some cases, the bipolar electrodes are biopolar axial interlaced finger electrodes. In embodiments wherein the electrodes are provided as electrode pairs, biopolar electrodes are desirable, with one electrode in the pair being a positive electrode and the other electrode being a negative electrode. The electrodes can be shaped in such a way that the middle portion of distal portion is enlarged in order to create a zone of injury that is greater at the distal end compared to the proximal end. The base of the treatment pad or treating surface and various portions of the proximal electrodes can also be insulated in order to limit the coagulation injury to the distal end of the electrode as well." To the extent that Ganz does not explicitly or inherently disclose this limitation, it would have been obvious over Hantash '718 PCT. Hantash '718 PCT discloses that each electrode of the plurality of electrodes is insulated except at its tip. *See e.g.*, Hantash '718 PCT at [0039]; *id.* at claims 5-11. For example, Hantash '718 PCT disclose that "each of the needles 115 can comprise an electrically conductive shaft or coating that is coated on the surface with an electrically non-conductive material such as, for example, Teflon," and "[a]n electrically non-conductive coating material can be patterned in order to channel the RF treatment energy to a particular location where the electrically conductive shaft or coating contacts the skin through a gap in the patterned electrically non-conductive coating." *Id*. at [0039]; *see also id*. at claim 9 (the insulating layer

'836 Patent Claim 13		Ganz in view of Hantash '718 PCT and/or in further view of Manstein
		covers 10-95% of the length of the needle that is in the tissue); *id.* at claims 10-11. To the extent this limitation is not explicitly or inherently disclosed by Ganz or Ganz in view of Hantash '718 PCT, it would have also been obvious given the knowledge of a POSITA. A POSITA would have understood that insulating the needle except for the tip is one way of preventing unwanted heating or lesions of the epidermis (when targeting the dermis with the tip). *See e.g.*, Ganz, at [0056]. Thus, it would have been desirable to use needle electrodes that are insulated except at the tip. It would have also been obvious to try only insulating the needle except at its tip because in view of what is discussed above regarding the use of insulated and non-insulated RF acupuncture needles, a POSITA would also know very well the two options to try that would allow the needles to deliver RF energy to the skin via the tip of the needle: non-insulated needles, and partially insulated needles without any insulation on the tip. To the extent that Ganz, Hantash '718, or knowledge of a POSITA do not disclose this limitation, it would have been obvious in further view of Manstein. Manstein discloses each electrode of the plurality of electrodes is insulated except at its tip. *See, e.g.*, Manstein at 6:21-23 ("In a preferred embodiment of the present invention, the shafts of conductive needles 350 are electrically insulated except for the portion of the needle near the tip."). "Insulation 420 covers the shaft of needles 410 and 415 protruding from base 310 except for the region near the lower tip, and electrically insulates each conductive needle shaft from surround tissue 305." Manstein at 7:1-3

8. Claim 14 of the '836 Patent is anticipated and/or rendered obvious over Ganz.

278. It is my opinion that Claim 14 is anticipated and/or rendered obvious by Ganz.

'836 Patent Claim 14		Ganz
14.0	A method of treating skin, comprising:	Ganz discloses and/or renders obvious a method of treating skin as described in claim element 1.0 above.

'836 Patent Claim 14		Ganz
14.1	inserting a plurality of electrodes,	Ganz discloses and/or renders obvious inserting a plurality of electrodes. *See, e.g.*, Ganz at [0010] "In some embodiments, the invention provides a device for creating a pattern of perforations in a tissue. The device comprises a treating surface configured to be positioned in contact with tissue adjacent one or more tissue planes and a plurality of electrodes extending outwardly from the treating surface and adapted for imparting simultaneous perforations into one or more tissue layers, wherein the electrodes are provided in a pattern to impart a corresponding pattern of perforations in the one or more tissue layers." [0043] "The treating surface generally includes a plurality of electrodes positioned about at least a portion of its circumference so that the electrodes come into contact with the tissue. The electrodes can be provided about the entire surface of the treating surface or about a portion of the surface. The areas of tissue in contact with the electrodes are those areas which are perforated." [0001] "The invention relates to a device and method for treating one or more layers of tissue, for example by simultaneously imparting perforations into the one or more layers. In particular, the invention relates to a device and method for treating one or more layers of the skin to elicit a healing response which produces a more desirable skin appearance." [0010] In some embodiments, the invention provides a device for creating a pattern of perforations in a tissue. The device comprises a treating surface configured to be positioned in contact with tissue adjacent one or more tissue planes and a plurality of electrodes extending outwardly from the treating surface and adapted for imparting simultaneous perforations into one or more tissue layers, wherein the electrodes are provided in a pattern to impart a corresponding pattern of perforations in the one or more tissue layers. The electrode pattern can be selected to create perforations which are between about 30 to about 100 microns in diameter, up to about 1000 microns deep and spaced apart by between about 50 to about 400 microns. The electrode pattern can also be selected to create a zone of coagulative tissue surrounding each perforation. In some cases, the zone of coagulative tissue has a length of between about about [*sic*] 5 microns to

'836 Patent Claim 14		Ganz
		about 100 microns. The electrodes can also have a depth and width for providing perforations being no more than about 2 mm in depth and about 0.5 mm in width. Likewise, the electrodes can have a spacing for providing perforations spaced apart by no more than about 5 mm or less. [0011] "The 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. A control device may also be coupled to the energy source. In preferred cases, the electrodes are RF electrodes and are configured for receiving RF energy. The electrodes can be provided as a plurality of electrode pairs or even as an array of electrodes. In some cases, the electrodes are monopolar electrodes whereas in other cases the electrodes are bipolar electrodes." [0016] "A method for treating human skin is also provided. The method includes identifying a target area of skin, providing a device adapted to simultaneously create a desired pattern of perforations into one or more layers of the target area of skin, and simultaneously perforating the target area to provide the desired pattern of perforations which elicit a healing response that produces a revitalized skin surface." [0063] Methods for vertically treating one or more layers of tissue in a tissue plane are also provided. The method generally includes simultaneously imparting perforations into one or more tissue layers in a tissue plane. In a preferred embodiment, a method is provided for simultaneously imparting perforations into one or more layers of skin. In many cases, skin areas along the face, neck, chest and hands will be treated. The treatment area of the skin is first cleansed using a cleanser, for example a mild, gently abrasive skin cleanser. A topical may then be applied to the treatment area to numb the skin so that a patient will not feel and prickling or heat sensation during treatment. In some cases, the topical will be a lipid based topical anesthetic ointment. A treatment device according to any of the embodiments already described is provided and the treating surface is placed in contact with a desired area of the skin. The device is activated to create a plurality of perforations in the skin. In many cases, the same

'836 Patent Claim 14		Ganz
		area of skin will be treated several times and usually at different time intervals. *See also* Ganz claims 11, 13.
14.2	the electrodes being bipolar into a section of skin to be treated; and	Ganz discloses and/or renders obvious a method of treating skin wherein the electrodes being bipolar into a section of skin to be treated. *See* claim 1.1-1.2 above; *see also* Ganz at [0010] "In some embodiments, the invention provides a device for creating a pattern of perforations in a tissue. The device comprises a treating surface configured to be positioned in contact with tissue adjacent one or more tissue planes and a plurality of electrodes extending outwardly from the treating surface and adapted for imparting simultaneous perforations into one or more tissue layers, wherein the electrodes are provided in a pattern to impart a corresponding pattern of perforations in the one or more tissue layers." [0043] "The treating surface generally includes a plurality of electrodes positioned about at least a portion of its circumference so that the electrodes come into contact with the tissue. The electrodes can be provided about the entire surface of the treating surface or about a portion of the surface. The areas of tissue in contact with the electrodes are those areas which are perforated." [0001] "The invention relates to a device and method for treating one or more layers of tissue, for example by simultaneously imparting perforations into the one or more layers. In particular, the invention relates to a device and method for treating one or more layers of the skin to elicit a healing response which produces a more desirable skin appearance." [0010] In some embodiments, the invention provides a device for creating a pattern of perforations in a tissue. The device comprises a treating surface configured to be positioned in contact with tissue adjacent one or more tissue planes and a plurality of electrodes extending outwardly from the treating surface and adapted for imparting simultaneous perforations into one or more tissue layers, wherein the electrodes are provided in a pattern to impart a corresponding pattern of perforations in the one or more tissue layers. The electrode pattern can be selected to create perforations which are between about 30 to about 100 microns in diameter, up to

'836 Patent Claim 14		Ganz
		about 1000 microns deep and spaced apart by between about 50 to about 400 microns. The electrode pattern can also be selected to create a zone of coagulative tissue surrounding each perforation. In some cases, the zone of coagulative tissue has a length of between about about [*sic*] 5 microns to about 100 microns. The electrodes can also have a depth and width for providing perforations being no more than about 2 mm in depth and about 0.5 mm in width. Likewise, the electrodes can have a spacing for providing perforations spaced apart by no more than about 5 mm or less. [0011] "The 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. A control device may also be coupled to the energy source. In preferred cases, the electrodes are RF electrodes and are configured for receiving RF energy. The electrodes can be provided as a plurality of electrode pairs or even as an array of electrodes. In some cases, the electrodes are monopolar electrodes whereas in other cases the electrodes are bipolar electrodes." [0016] "A method for treating human skin is also provided. The method includes identifying a target area of skin, providing a device adapted to simultaneously create a desired pattern of perforations into one or more layers of the target area of skin, and simultaneously perforating the target area to provide the desired pattern of perforations which elicit a healing response that produces a revitalized skin surface." [0056] "In other embodiments, the electrodes are provided as a bipolar electrode arrangement. In bipolar electrode arrangements, both the positive and negative electrodes serve as treating electrodes. In some cases, the bipolar electrodes are biopolar[*sic*] axial interlaced finger electrodes. In embodiments wherein the electrodes are provided as electrode pairs, biopolar[*sic*] electrodes are desirable, with one electrode in the pair being a positive electrode and the other electrode being a negative electrode. The electrodes can be shaped in such a way that the middle portion of distal portion is enlarged in order to create a zone of injury that is greater at the distal end compared to the proximal end. The base of the treatment pad or treating surface and various portions of the proximal

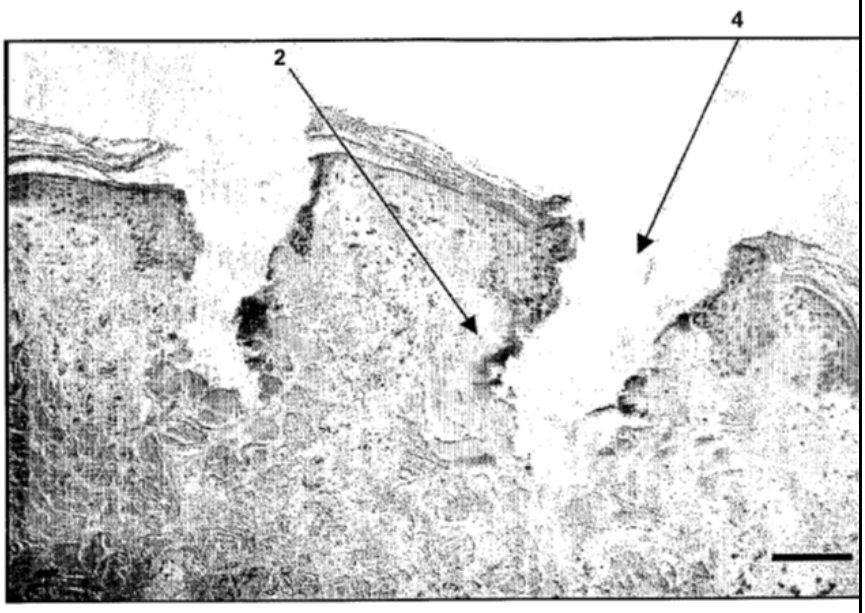
'836 Patent Claim 14		Ganz
		electrodes can also be insulated in order to limit the coagulation injury to the distal end of the electrode as well." [0063] "Methods for vertically treating one or more layers of tissue in a tissue plane are also provided. The method generally includes simultaneously imparting perforations into one or more tissue layers in a tissue plane. In a preferred embodiment, a method is provided for simultaneously imparting perforations into one or more layers of skin. In many cases, skin areas along the face, neck, chest and hands will be treated. The treatment area of the skin is first cleansed using a cleanser, for example a mild, gently abrasive skin cleanser. A topical may then be applied to the treatment area to numb the skin so that a patient will not feel and prickling or heat sensation during treatment. In some cases, the topical will be a lipid based topical anesthetic ointment. A treatment device according to any of the embodiments already described is provided and the treating surface is placed in contact with a desired area of the skin. The device is activated to create a plurality of perforations in the skin. In many cases, the same area of skin will be treated several times and usually at different time intervals." Ganz also discloses that the plurality of electrodes can be bipolar electrodes. *Id*. at [0011] ("the electrodes are **bipolar electrodes**"); *id.* at [0056] ("the electrodes are provided as a **bipolar electrode** arrangement … with one electrode in the pair being a positive electrode and the other electrode being a negative electrode"); *id.* at claim 11 ("wherein the plurality of electrodes are provided as a plurality of electrode pairs"); *id.* at claim 13 ("wherein the **plurality of electrodes are bipolar electrodes**") (emphasis added). The parties have agreed that "the electrodes being bipolar" should be construed as having a plain and ordinary meaning "the 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). *See* Post-Markman Hearing Joint Claim Construction Chart at 3.
14.3	applying a [*sic*] Alternating Current (AC) Radio Frequency (RF) signal to the	Ganz discloses and/or renders obvious applying an Alternating Current (AC) Radio Frequency (RF) signal to the plurality of electrodes according to the claim. *See* claim 1.2; *see also* Ganz at

'836 Patent Claim 14		Ganz
	plurality of electrodes	[0011] "The 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. A control device may also be coupled to the energy source. In preferred cases, the electrodes are RF electrodes and are configured for receiving RF energy. The electrodes can be provided as a plurality of electrode pairs or even as an array of electrodes. In some cases, the electrodes are monopolar electrodes whereas in other cases the electrodes are bipolar electrodes." [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, non-ionizing ultraviolet radiation and microwave radiation. In some cases, the electrodes are configured to provide power in the range of about 50 to about 200 watts per square centimeter. In other cases, the electrodes are configured to provide an energy of at least about 1 joules per square centimeter." [0058] "In preferred embodiments, the electrodes are configured as RF electrodes and RF energy is delivered to the electrodes. RF energy is particularly desirable for creating perforations of tissue since it does not cause the entire area of tissue being treated to heat up extensively. Rather, RF energy can penetrate the body and be absorbed by deeper tissues without heating up the surrounding tissues. Thus, a boundary is created between the treated tissue and those tissues surrounding the treated tissue. RF energy is also desirable since it is safe to use on tissues in areas near sensitive body parts, e.g., areas of skin near the eyes." [0059] The energy source is configured for powering the electrodes at levels appropriate to provide a desired diameter and depth of perforation of tissue. The energy source may be manually controlled by the user and be adapted to allow the user to select the appropriate treatment time and power setting to obtain a controlled depth and/or width of perforation. The energy source can also be coupled to a controller, which may be a digital or analog controller for use with the energy source, including but not limited to an RF source, or a computer with software. When the computer controller is

'836 Patent Claim 14		Ganz
		used it can include a CPU coupled through a system bus. The system may include a keyboard, a disk drive, or other non-volatile memory system, a display and other peripherals known in the art. A program memory and a data memory can also be coupled to the bus. The energy source can be positioned at different positions in proximity to the treatment device. *See also* Ganz claims 7-8. Further, it was well-known in the art that a radio frequency signal is generated from alternating current (AC). *Radiofrequency Catheter Ablation for Cardiac Tachyarrhythmias*, Manolis, A.S., *et al.*, Ann Intern Med. (1994) 121:452-461 at 452 ("Radiofrequency energy is a form of electrical energy, generated from low-power (15 to 60 V), high-frequency (30 KHz to 300 MHz) alternating current."). In the original application, Na mentions that "[t]he required components for both Na-Effect and Na-Plus effect are bipolarity of needles, alternating current (AC), and high frequency." In the original filing claims, he mentions that the device and method have the high frequency range of 0.5 - 10MHz and also that the frequency of the alternating current is higher than 20Hz, including 20Hz. In effect, combining these two signals together would result in engineering terms, to modulating the amplitude of the high frequency signal following a sinewave (or similar) such that the envelope of the high frequency signal amplitude follows a sine wave and that varies from 0 to its maximal amplitude in a cyclic fashion 20 or more times per second (Complainant's interpretation requires a signal combining an AC frequency rate and an RF frequency rate). Such a mode of operation has been used in standard electrosurgery for many years. As an example, the generator ValleyLab Force FX, which received FDA clearance in 1994 through 510k K944602 is using a 250 Hz envelope in 'spray mode': "Spray: 390 kHz damped sinusoidal bursts with a randomized repetition centered at 28 kHz. Frequencies include 21kHz < f < 35 kHz. Output is further **modulated by a random 250 Hz envelope** with a variable duty cycle." Therefore, using a low frequency modulation for a high frequency signal would be obvious for a POSITA.
14.4	configured to cause coagulation around each electrode rather than coagulating	Ganz discloses and/or renders obvious a method of treating skin that is configured to cause coagulation around each electrode rather than coagulating between the electrodes. *See* claim element 1.4 above; *see also* Ganz at

'836 Patent Claim 14		Ganz
	between the electrodes.	[0006] "Certain methods have been developed to treat one or more layers of skin without removing entire layers of tissue. One example of device which treats tissue in this manner is the FRAXEL infrared scanning laser. This device uses a scanner to direct a small 10-70 micron diameter laser beam across the tissue surface in order to create small vertical zones of coagulated tissue. One 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. Applicant has discovered that it is desirable to create vertical perforations or ablation holes in tissue, as this prompts an even more aggressive wound healing response than is currently seen. When perforations are created, tissue layers surrounding the perforations are left untreated and contribute to tissue regeneration. Thus, the treated tissue can heal and regenerate from all edges of the perforation wound, not just from the tissue areas underneath the wound. Perforations allow for a faster regeneration and healing time. The use of perforations are also advantageous in that by leaving zones of untreated tissue in between the perforations, less scarring and/or pigmentations are visible. Thus, there is a need for a device and method which imparts actual perforations into the skin, thereby promoting more aggressive healing." [0010] "In some embodiments, the invention provides a device for creating a pattern of perforations in a tissue. The device comprises a treating surface configured to be positioned in contact with tissue adjacent one or more tissue planes and a plurality of electrodes extending outwardly from the treating surface and adapted for imparting simultaneous perforations into one or more tissue layers, wherein the electrodes are provided in a pattern to impart a corresponding pattern of perforations in the one or more tissue layers. The electrode pattern can be selected to create perforations which are between about 30 to about 100 microns in diameter, up to about 1000 microns deep and spaced apart by between about 50 to about 400 microns. The electrode pattern can also be selected to create a zone of coagulative tissue surrounding each perforation. In some cases, the zone of coagulative tissue has a length of between about about[*sic*] 5 microns to about 100 microns. The electrodes can also have a depth and width for providing perforations being no more than about 2 mm in depth and about 0.5 mm in width. Likewise, the

'836 Patent Claim 14		Ganz
		electrodes can have a spacing for providing perforations spaced apart by no more than about 5 mm or less." [0048] Zones of coagulation are also created in areas of tissue surrounding each perforation. The zones can extend from the perforation site into the tissue for a length ranging from about 5 microns to about 100 microns. The zone of coagulation can be varied by changes in energy and power levels. [0056] In other embodiments, the electrodes are provided as a bipolar electrode arrangement. In bipolar electrode arrangements, both the positive and negative electrodes serve as treating electrodes. In some cases, the bipolar electrodes are biopolar axial interlaced finger electrodes. In embodiments wherein the electrodes are provided as electrode pairs, biopolar electrodes are desirable, with one electrode in the pair being a positive electrode and the other electrode being a negative electrode. The electrodes can be shaped in such a way that the middle portion of distal portion is enlarged in order to create a zone of injury that is greater at the distal end compared to the proximal end. The base of the treatment pad or treating surface and various portions of the proximal electrodes can also be insulated in order to limit the coagulation injury to the distal end of the electrode as well. [0058] "In preferred embodiments, the electrodes are configured as RF electrodes and RF energy is delivered to the electrodes. RF energy is particularly desirable for creating perforations of tissue since it does not cause the entire area of tissue being treated to heat up extensively. Rather, RF energy can penetrate the body and be absorbed by deeper tissues without heating up the surrounding tissues. Thus, a boundary is created between the treated tissue and those tissues surrounding the treated tissue. RF energy is also desirable since it is safe to use on tissues in areas near sensitive body parts, e.g., areas of skin near the eyes."

'836 Patent Claim 14		Ganz
		 [0028] "… FIG. 9 illustrates a skin area treated in accordance with the invention. The treated area 4 is clearly a perforation, which extends vertically into the skin. Areas or zones of coagulation 2 can also be seen in the areas surrounding the perforation." *See also* Ganz claims 1-3. > [0047], In certain cases, the electrodes are patterned in order to create perforations being between about 30 to about 100 microns in diameter, up to about 1000 microns deep and spaced apart by between about 50 to about 400microns." > [0048] Zones of coagulation are also created in areas of tissue surrounding each perforation. The zones can extend from the perforation site into the tissue for a length ranging from about 5 microns to about 100 microns. The zone of coagulation can be varied by changes in energy and power levels. From [0047] and [0048] of Ganz, it appears that in most cases, the zones of coagulation extend to a distance (5-100 microns) lesser than the distance between the electrodes (100-1,000 microns, demonstrating the ability of creating coagulation zones that do not overlap. Ganz also explains how to control the size of the lesions by varying energy and power levels, showing once more that he is able to fully control lesion such that they do not overlap.

9. Claim 17 of the '836 Patent is anticipated and/or rendered obvious over Ganz in view of Hantash '718 PCT.

279. It is my opinion that Claim 17, which depends from unasserted claim 15, is anticipated and/or obvious over Ganz in view of Hantash '718 PCT.

'836 Patent Claim 15		Ganz in view of Hantash '718 PCT
15.0	The method of treating skin of claim 14,	Ganz discloses a method of treating skin as described in claim elements 1.0 and 14.0. *See* Ganz at [0001] "The invention relates to a device and method for treating one or more layers of tissue, for example by simultaneously imparting perforations into the one or more layers. In particular, the invention relates to a device and method for treating one or more layers of the skin to elicit a healing response which produces a more desirable skin appearance." [0029] "The device and method also allow for controlled placement of perforations having a predetermined depth, width and degree of separation. Such perforations are so small that they cannot be seen with the naked eye. The treatment device is advantageous because it creates several perforations simultaneously with one or a few discharges of energy." [0030] "Many conditions can be treated by imparting a plurality of vertical perforations into tissue. In most cases, skin conditions are treated by creating perforations into the skin. For example, the device can be used on skin areas suffering from photo-aging or sun-damage. The device can also be used on skin areas exhibiting acne scars, burn scars, erythema, fine lines, wrinkles, irregular pigmentations, precancerous or cancerous lesions or other irregular conditions. The creation of perforations in the skin helps to revitalize or rejuvenate these irregular areas to make them more desirable in appearance. The zones of coagulation created in the tissue area surrounding each perforation also help to revitalize and rejuvenate skin." [0033] "The treatment device includes a treating surface, which is adapted to be placed in direct contact with a tissue adjacent a tissue plane to be treated. The treating surface is generally positioned adjacent to a tissue plane of the tissue to be treated. One or more layers of the tissue in the tissue plane

'836 Patent Claim 15		Ganz in view of Hantash '718 PCT
		can be treated. In some cases, it is desirable to only treat the outermost layer of tissue, while leaving the deeper layers untreated. In other cases, it is desirable to treat the deeper layers of tissue as well. The tissue to be treated can include almost any tissue. In some cases, the tissue includes one or more layers of organ tissue. In other cases, the tissue includes one or more layers of skin." [0063] Methods for vertically treating one or more layers of tissue in a tissue plane are also provided. The method generally includes simultaneously imparting perforations into one or more tissue layers in a tissue plane. In a preferred embodiment, a method is provided for simultaneously imparting perforations into one or more layers of skin. In many cases, skin areas along the face, neck, chest and hands will be treated. The treatment area of the skin is first cleansed using a cleanser, for example a mild, gently abrasive skin cleanser. A topical may then be applied to the treatment area to numb the skin so that a patient will not feel and prickling or heat sensation during treatment. In some cases, the topical will be a lipid based topical anesthetic ointment. A treatment device according to any of the embodiments already described is provided and the treating surface is placed in contact with a desired area of the skin. The device is activated to create a plurality of perforations in the skin. In many cases, the same area of skin will be treated several times and usually at different time intervals. *See also* Ganz claim 24.
15.1	including providing an AC RF signal to the plurality of electrodes for a predetermined time interval.	Ganz discloses and/or renders obvious providing an AC RF signal to the plurality of electrodes for a predetermined time interval, as claimed. *See, e.g.*, Ganz at [0011] "The 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. A control device may also be coupled to the energy source. In preferred cases, the electrodes are RF electrodes and are configured for receiving RF energy. The electrodes can be provided as a plurality of electrode pairs or even as an array of electrodes. In some cases, the electrodes are

'836 Patent Claim 15		Ganz in view of Hantash '718 PCT
		monopolar electrodes whereas in other cases the electrodes are bipolar electrodes." [0048] Zones of coagulation are also created in areas of tissue surrounding each perforation. The zones can extend from the perforation site into the tissue for a length ranging from about 5 microns to about 100 microns. The zone of coagulation can be varied by changes in energy and power levels. [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, non-ionizing ultraviolet radiation and microwave radiation. In some cases, the electrodes are configured to provide power in the range of about 50 to about 200 watts per square centimeter. In other cases, the electrodes are configured to provide an energy of at least about 1 joules per square centimeter." [0058] "In preferred embodiments, the electrodes are configured as RF electrodes and RF energy is delivered to the electrodes. RF energy is particularly desirable for creating perforations of tissue since it does not cause the entire area of tissue being treated to heat up extensively. Rather, RF energy can penetrate the body and be absorbed by deeper tissues without heating up the surrounding tissues. Thus, a boundary is created between the treated tissue and those tissues surrounding the treated tissue. RF energy is also desirable since it is safe to use on tissues in areas near sensitive body parts, e.g., areas of skin near the eyes." [0059] The energy source is configured for powering the electrodes at levels appropriate to provide a desired diameter and depth of perforation of tissue. The energy source may be manually controlled by the user and be adapted to allow the user to select the appropriate treatment time and power setting to obtain a controlled depth and/or width of perforation. The energy source can also be coupled to a controller, which may be a digital or analog controller for use with the energy source, including but not limited to an RF source, or a computer with software. When the computer controller is used it can include a CPU coupled through a system bus. The system may include a keyboard, a disk drive, or other non-volatile memory system, a display and other peripherals

'836 Patent Claim 15		Ganz in view of Hantash '718 PCT
		known in the art. A program memory and a data memory can also be coupled to the bus. The energy source can be positioned at different positions in proximity to the treatment device." Ganz discloses that "[t]he energy source may be manually controlled by the user and be adapted to allow the **user to select the appropriate treatment time**[,]" *i.e.*, a predetermined time interval. Ganz, at [0059]. And that usual treatment required several applications "at different time intervals." *Id.* at [0063]. *See also* Ganz claims 7-8. To the extent Ganz does not explicitly or inherently disclose this limitation, it would have further been obvious in view of Hantash '718 PCT. Hantash '718 PCT discloses providing an AC RF signal to the plurality of electrodes for a predetermined time interval. *See e.g.*, Hantash '718 PCT at [0018], [0077], [0078]. For example, Hantash '718 PCT discloses an example of providing an AC RF signal to the plurality of electrodes for "pulse duration of 400 ms" (Hantash '718 PCT, at [0077]) or "200 ms" (*id*., at [0078]). *See also id*. at [0018] (ensuring "enough thermal relaxation time at the treated zones and thereby avoiding overheating of the treated zones").

10. Claim 22 of the '836 Patent is anticipated and/or rendered obvious over Ganz in view of Hantash '718 PCT and/or ScarLet.

280. It is my opinion that Claim 22 is anticipated and/or obvious over Ganz in view of Hantash '718 PCT and/or ScarLet

Claim 22 of the '836 Patent		Ganz in view of Hantash '718 PCT and/or ScarLet
22.0	The method of treating skin of claim 14,	As described above with regard to claim 1 and 14, Ganz discloses a skin treatment apparatus according to the claim. *See, e.g.*, Ganz, at [0001], [0016], [0027], [0029], [0030], [0033], [0063], claim 1, 24.
22.1	wherein the RF is from 0.5 to 10 Mhz	Ganz discloses wherein the RF is from 0.5 to 10 Mhz according to the claim. *See, e.g.*, Ganz at [0058] "In preferred embodiments, the electrodes are configured as RF electrodes and RF energy is delivered to the electrodes. RF energy is particularly desirable for creating perforations of tissue since it does not cause the

Claim 22 of the '836 Patent		Ganz in view of Hantash '718 PCT and/or ScarLet
		entire area of tissue being treated to heat up extensively. Rather, RF energy can penetrate the body and be absorbed by deeper tissues without heating up the surrounding tissues. Thus, a boundary is created between the treated tissue and those tissues surrounding the treated tissue. RF energy is also desirable since it is safe to use on tissues in areas near sensitive body parts, e.g., areas of skin near the eyes." [0059] "The energy source is configured for powering the electrodes at levels appropriate to provide a desired diameter and depth of perforation of tissue. The energy source may be manually controlled by the user and be adapted to allow the user to select the appropriate treatment time and power setting to obtain a controlled depth and/or width of perforation. The energy source can also be coupled to a controller, which may be a digital or analog controller for use with the energy source, including but not limited to an RF source, or a computer with software. When the computer controller is used it can include a CPU coupled through a system bus. The system may include a keyboard, a disk drive, or other non-volatile memory system, a display and other peripherals known in the art. A program memory and a data memory can also be coupled to the bus. The energy source can be positioned at different positions in proximity to the treatment device." Furthermore, it was well-known in the art that a radio frequency signal for electrosurgical use is a high-frequency (usually 200 KHz to 5 MHz as defined by IEC 60601-2-2 section 201.8.4.102. (*see* section 90) alternating current (AC) alternating current (AC). 200 KHz is the equivalent of 0.2 MHz; *see* above. Thus, radio frequency signals are measured in MHz. To the extent Ganz does not explicitly or inherently disclose this limitation, it would have further been obvious in view of Hantash '718 PCT. Hantash '718 PCT discloses RF that is from 0.5 to 10 Mhz. *See e.g.*, Hantash '718 PCT at [0040], [0052], [0079]. For example, Hantash '718 PCT discloses "the frequency of the RF source can be chosen to be about 6.78 MHz", or "from 0.1 to 10 MHz or from 0.4 to 3 MHz". *Id*., at [0040]; *see also id*. [0079] ("0.47 MHz" rounds up to 0.5 MHz)."

Claim 22 of the '836 Patent		Ganz in view of Hantash '718 PCT and/or ScarLet
22.2	and the predetermined time interval is from 0.05 to 0.8 seconds.	Ganz discloses and/or renders obvious wherein the predetermined time interval is from 0.05 to 0.8 seconds according to the claim. *See, e.g.*, [0058] "In preferred embodiments, the electrodes are configured as RF electrodes and RF energy is delivered to the electrodes. RF energy is particularly desirable for creating perforations of tissue since it does not cause the entire area of tissue being treated to heat up extensively. Rather, RF energy can penetrate the body and be absorbed by deeper tissues without heating up the surrounding tissues. Thus, a boundary is created between the treated tissue and those tissues surrounding the treated tissue. RF energy is also desirable since it is safe to use on tissues in areas near sensitive body parts, e.g., areas of skin near the eyes." [0059] "The energy source is configured for powering the electrodes at levels appropriate to provide a desired diameter and depth of perforation of tissue. The energy source may be manually controlled by the user and be adapted to allow the user to select the appropriate treatment time and power setting to obtain a controlled depth and/or width of perforation. The energy source can also be coupled to a controller, which may be a digital or analog controller for use with the energy source, including but not limited to an RF source, or a computer with software. When the computer controller is used it can include a CPU coupled through a system bus. The system may include a keyboard, a disk drive, or other non-volatile memory system, a display and other peripherals known in the art. A program memory and a data memory can also be coupled to the bus. The energy source can be positioned at different positions in proximity to the treatment device." To the extent Ganz does not explicitly or inherently disclose this limitation, it would have further been obvious in view of Hantash '718 PCT. Hantash '718 PCT discloses the predetermined time interval is from 0.05 to 0.8 seconds. *See e.g.*, Hantash '718 PCT, At [0014]; [0018]; [0077]; [0078]. For example, Hantash '718 PCT discloses an example of providing an AC RF signal to the plurality of electrodes for "pulse duration of 400 ms" (Hantash '718 PCT, at [0077]) or "200 ms" (*id*., at [0078]). 200 ms and

Claim 22 of the '836 Patent		Ganz in view of Hantash '718 PCT and/or ScarLet
		400 ms are the equivalents of 0.2 seconds and 0.4 seconds, respectively. To the extent Ganz or Hantash '718 do not explicitly or inherently disclose this limitation, it would have been obvious in view of ScarLet. ScarLet shows an adjustable Time ON for 0.100sec. to 0.800 seconds, which overlaps the time windows preconized by Na. Ilooda-0006239 19/32. 1. Specification of ScarLet Specification NEEDLE DEPTH: 0.5 mm ~ 3.5 mm (0.1 mm unit) RF CONDUCT. TIME: 100msec ~ 800msec (100msec unit) RF OUTPUT: 1) 1.5V ~ 40V 2) 40 ~ 200V RF E. FIELD WIDTH(at 1mm Depth): 82mm² RF FREQUENCY: 2MHz WEIGHT: 29Kg DIMENSION: 55cm(W) * 35cm(D) * 122cm(H) ELECTRODE NO.: 25 Pin SPOT SIZE: 1cm² Ilooda-0006061 (0006062)

B. The Asserted Claims of the '379 are Anticipated or Rendered Obvious by the Prior Art

1. Ganz Anticipates and/or Renders Obvious the Asserted Claims of the '379 Patent

281. The Asserted Claims of the '379 Patent are invalid under 35 U.S.C. § 102 (pre-AIA or AIA) as anticipated by Ganz and/or are invalid under 35 U.S.C. § 103 (pre-AIA or AIA) as obvious in view of Ganz alone (in view of the knowledge of a POSITA) or in combination with one or more other references identified herein and/or in Respondents' Invalidity Contentions, at least based on my understanding of Complainant's application of the asserted claims in an effort to show infringement.

282. U.S. Patent Publication No. 2007/0208340A1 ("Ganz") qualifies as prior art under at least AIA 35 U.S.C. § 102(a)(1) because it is a patent that published before the filing of the earliest application to which the '379 Patent could claim priority.

283. To the extent that the '379 Patent is subject to pre-AIA law, Ganz qualifies as prior art under at least 35 U.S.C. § 102(b) (pre-AIA) because it is a patent that published more than one year before the filing of the earliest application to which the '379 Patent could claim priority. Ganz also qualifies as prior art under at least 35 U.S.C. § 102(a) (pre-AIA) because it is a patent that was published prior to the alleged invention of the '379 Patent.

284. The asserted claims of the '379 Patent are invalid under 35 U.S.C. § 102 (AIA or pre-AIA) as anticipated by Ganz, and/or are invalid under 35 U.S.C. § 103 (AIA or pre-AIA) as obvious in view of Ganz alone, or in combination with one or more PCT Patent Application Publication No. WO 2007/064718 ("Hantash '718 PCT"), U.S. Patent No. 7,824,394 to Manstein ("Manstein"), and ScarLet product manufactured by ViOL, Korea ("ScarLet") at least based on Respondents' understanding of Complainant's application of the asserted claims in an effort to show infringement.

285. Hantash '718 PCT and Manstein each qualify as prior art under at least AIA 35 U.S.C. § 102(a)(1) because it is a patent that published before the filing of the earliest application to which U.S. Patent No. 10,058,379 ("the '379 Patent") could claim priority.

286. To the extent the '379 Patent is treated under pre-AIA law, each of Hantash '718 PCT and Manstein qualify as prior art under at least 35 U.S.C. § 102(b) (pre-AIA) because each was published more than one year before the filing of the earliest application to which the '379 Patent could claim priority.

287. ScarLet qualifies as prior art under at least 35 U.S.C. § 102(a) (pre-AIA) because it is a product that was in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention to which the '379 Patent could claim priority. *See, e.g.*, Ilooda-0005923 (Shim 2010_DKU Thesis 2010.12.01), Ilooda-0006075 (ScarLet intro), Ilooda-0006078 (#13_(Eng)_Shim 2010_DKU Thesis Dec 1 2010_Translated_Certified), Ilooda-0006210 (5-1. 스칼렛최초허가), Ilooda-0006533 (Naver Blog The H Jan 10 2011), Ilooda 0006719 (#19-1_Naver Blog The H Jan 10 2011_Translated_Certified), Ilooda-0006770 (#18_D&PS Monthly Sept 2010_Translated_Certified), Ilooda-0006827 (D&PS Monthly September 2010), Ilooda-0008178 and translation thereof (Ilooda-0011601), Ilooda-0009318, Ilooda-0009319, Ilooda-0009322, Ilooda-0009339, Ilooda-0009669, Ilooda-0009673, Ilooda-0009678, Ilooda-0009791, Ilooda-0009795, Ilooda-0010031, Ilooda-0010042, SERENDIA-00017276, SERENDIA-00017306, SERENDIA-00031579, SERENDIA-00033637, SERENDIA-00033705, SERENDIA-00036286, SERENDIA-00052450, SERENDIA-00061017, SERENDIA-00066746, SERENDIA-00075908, and SERENDIA-00081664.

288. To the extent that the '379 Patent is subject to AIA law, ScarLet qualifies as prior art under at least AIA 35 U.S.C. § 102(a)(1) because it is a product that was in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention to which the '836 Patent could claim priority. *See e.g.,* Ilooda-0005923 (Shim 2010_DKU Thesis 2010.12.01), Ilooda-0006075 (ScarLet intro), Ilooda-0006078 (#13_(Eng)_Shim 2010_DKU Thesis Dec 1 2010_Translated_Certified), Ilooda-0006210 (5-1. 스칼렛 최초허가), Ilooda-0006533 (Naver Blog The H Jan 10 2011), Ilooda-0006719 (#19-1_Naver Blog The H Jan 10 2011_Translated_Certified), Ilooda-0006770 (#18_D&PS Monthly Sept 2010_Translated_Certified), Ilooda-0006827 (D&PS Monthly September 2010), Ilooda-

0008178 and translation thereof (Ilooda-0011601), Ilooda-0009318, Ilooda-0009319, Ilooda-0009322, Ilooda-0009339, Ilooda-0009669, Ilooda-0009673, Ilooda-0009678, Ilooda-0009791, Ilooda-0009795, Ilooda-0010031, Ilooda-0010042, SERENDIA-00017276, SERENDIA-00017306, SERENDIA-00031579, SERENDIA-00033637, SERENDIA-00033705, SERENDIA-00036286, SERENDIA-00052450, SERENDIA-00061017, SERENDIA-00066746, SERENDIA-00075908, and SERENDIA-00081664.

289. Ganz, Hantash '718 PCT, Manstein, and ScarLet discuss or address the same or substantially similar underlying apparatus and/or technology in the field of dermatological treatment and devices such that a POSITA would have understood that one or more of these references can be combined, according to known methods and/or by the simple substitution of one known equivalent element for another, to yield predictable results and with a reasonable expectation of success. A POSITA would also have been motivated to combine one or more of these reference in light of market forces in the industry, and the desire to improve features and performance, and/or in light of one or more teachings, suggestions, or motivations in the art. A POSITA would have enjoyed a reasonable expectation of success in combining and/or modifying the teachings of the foregoing prior art references and products, together with general knowledge of the art, to achieve the claimed subject matter, at least because the prior art itself discloses and/or practices the claimed methods and apparatuses to achieve the claimed results. A POSITA would have recognized that the relevant art is predictable, and that achieving the claimed subject matter requires merely routine optimization.

290. As shown below, under Complainant's interpretation of "apply energy to body segments around each electrode rather than to body segments between the electrodes," and, to the extent that Complainant asserts that "to apply energy to body segments around each

electrode rather than to body segments between the electrodes" has the same scope as "cause coagulation around each electrode rather than coagulating between the electrodes," recited in independent claim 1 of the '836 Patent:

- Ganz anticipates claims 1, 2, and 7-9 of the '379 Patent;
- Ganz renders obvious claims 1, 2, 5, and 7-9 of the '379 Patent;
- Ganz in view of ScarLet renders obvious claims 1, 2, 5, and 7-9 of the '379 Patent;
- Ganz in view of Hantash '718 PCT renders obvious claims 1, 2, 5, 7-9; and/or
- Ganz in view of Manstein renders obvious claim 7.

2. Claim 1 of the '379 Patent is Anticipated by Ganz and/or obvious over Ganz alone and/or in combination with Hantash '718 PCT or ScarLet

291. It is my opinion that Ganz anticipates and/or Ganz alone and/or in combination with Hantash '718 PCT or ScarLet renders obvious claim 1 of the '379 Patent as detailed below.

'379 Patent Claim 1		**Ganz alone and/or in combination with Hantash '718 PCT or ScarLet**
1.0	A skin treatment apparatus, comprising:	Ganz discloses a mammalian body treatment apparatus according to the claim. *See, e.g.*, Ganz, at [0001], [0016], [0027], [0029], [0030], [0033], [0063], claim 24. Specifically, Ganz discloses "a device and method for treating one or more layers of [skin] tissue," of a human. *Id*., at [0001]; *see also id*., at [0016] ("method for treating human skin"), [0029] ("treatment device"), [0030], claim 24 ("treating human skin"). Claims 1, 21, and 22 in Ganz recite tissue in general without limiting the tissue to a specific type of tissue, and therefore this could apply to any part of the body. Humans are mammals, and the invention is not limited to the skin.
1.1	a plurality of electrodes, the electrodes being bipolar and configured to be insertable into a	Ganz discloses a plurality of electrodes, the electrodes being bipolar and configured to be insertable into a body segment to be treated according to **the claim**. *See, e.g.*, Ganz, [0001], [0010], [0011], [0016], [0043], [0056], [0063], claims 1-13.

'379 Patent Claim 1		Ganz alone and/or in combination with Hantash '718 PCT or ScarLet
	body segment to be treated; and	Specifically, Ganz discloses a plurality of electrodes. *Id*., at [0011] ("The electrodes can be provided as a **plurality of electrode pairs** or even as an array of electrodes"); *see also id*., at [0010] ("the electrodes are provided in a pattern"), [0043] ("a **plurality of electrodes**"), [0056] ("electrode pairs"), claim 1 ("**plurality of electrodes**"), claim 13 ("wherein the **plurality of electrodes** are provided as an array of electrodes"). (emphasis added.) [0010] "In some embodiments, the invention provides a device for creating a pattern of perforations in a tissue. The device comprises a treating surface configured to be positioned in contact with tissue adjacent one or more tissue planes and a plurality of electrodes extending outwardly from the treating surface and adapted for imparting simultaneous perforations into one or more tissue layers, wherein the electrodes are provided in a pattern to impart a corresponding pattern of perforations in the one or more tissue layers. The electrode pattern can be selected to create perforations which are between about 30 to about 100 microns in diameter, up to about 1000 microns deep and spaced apart by between about 50 to about 400 microns. The electrode pattern can also be selected to create a zone of coagulative tissue surrounding each perforation. In some cases, the zone of coagulative tissue has a length of between about about [*sic*] 5 microns to about 100 microns. The electrodes can also have a depth and width for providing perforations being no more than about 2 mm in depth and about 0.5 mm in width. Likewise, the electrodes can have a spacing for providing perforations spaced apart by no more than about 5 mm or less." [0011] "The 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. A control device may also be coupled to the energy source. In preferred cases, the electrodes are RF electrodes and are configured for receiving RF energy. The electrodes can be provided as a plurality of electrode pairs or even as an array of electrodes. In some cases, the electrodes are monopolar

'379 Patent Claim 1		Ganz alone and/or in combination with Hantash '718 PCT or ScarLet
		electrodes whereas in other cases the electrodes are bipolar electrodes." [0043] "The treating surface generally includes a plurality of electrodes positioned about at least a portion of its circumference so that the electrodes come into contact with the tissue. The electrodes can be provided about the entire surface of the treating surface or about a portion of the surface. The areas of tissue in contact with the electrodes are those areas which are perforated." [0056] "In other embodiments, the electrodes are provided as a bipolar electrode arrangement. In bipolar electrode arrangements, both the positive and negative electrodes serve as treating electrodes. In some cases, the bipolar electrodes are biopolar[*sic*] axial interlaced finger electrodes. In embodiments wherein the electrodes are provided as electrode pairs, biopolar[*sic*] electrodes are desirable, with one electrode in the pair being a positive electrode and the other electrode being a negative electrode. The electrodes can be shaped in such a way that the middle portion of distal portion is enlarged in order to create a zone of injury that is greater at the distal end compared to the proximal end. The base of the treatment pad or treating surface and various portions of the proximal electrodes can also be insulated in order to limit the coagulation injury to the distal end of the electrode as well." Ganz discloses that the plurality of electrodes is configured to be inserted into the body segment to be treated (the skin), as evidenced by the fact that the needles "simultaneously impart[] perforations into the one or more layers" of skin tissue. *Id*., at [0001]; *see also id*., at claim 1 (" a plurality of electrodes extending outwardly from the treating surface and adapted for imparting simultaneous perforations into one or more tissue layers, wherein the electrodes are provided in a pattern to impart a corresponding pattern of perforations in the one or more tissue layers"), claim 4 (" wherein the electrode pattern is selected to create perforations which are between about 30 to about 100 microns in diameter, up to about 1000 microns deep and spaced apart by between about 50 to about 400 microns"), claim 5 (" wherein the plurality of electrodes have a depth … for providing perforations being no more than about 2 mm in depth …"), [0016] ("simultaneously perforating the target area to provide the desired

'379 Patent Claim 1		Ganz alone and/or in combination with Hantash '718 PCT or ScarLet
		pattern of perforations which elicit a healing response that produces a revitalized skin surface"), [0063] ("The device is activated to create a plurality of perforations in the skin"). [0001] "The invention relates to a device and method for treating one or more layers of tissue, for example by simultaneously imparting perforations into the one or more layers. In particular, the invention relates to a device and method for treating one or more layers of the skin to elicit a healing response which produces a more desirable skin appearance." [0016] "A method for treating human skin is also provided. The method includes identifying a target area of skin, providing a device adapted to simultaneously create a desired pattern of perforations into one or more layers of the target area of skin, and simultaneously perforating the target area to provide the desired pattern of perforations which elicit a healing response that produces a revitalized skin surface." [0063] Methods for vertically treating one or more layers of tissue in a tissue plane are also provided. The method generally includes simultaneously imparting perforations into one or more tissue layers in a tissue plane. In a preferred embodiment, a method is provided for simultaneously imparting perforations into one or more layers of skin. In many cases, skin areas along the face, neck, chest and hands will be treated. The treatment area of the skin is first cleansed using a cleanser, for example a mild, gently abrasive skin cleanser. A topical may then be applied to the treatment area to numb the skin so that a patient will not feel and prickling or heat sensation during treatment. In some cases, the topical will be a lipid based topical anesthetic ointment. A treatment device according to any of the embodiments already described is provided and the treating surface is placed in contact with a desired area of the skin. The device is activated to create a plurality of perforations in the skin. In many cases, the same area of skin will be treated several times and usually at different time intervals.

'379 Patent Claim 1		Ganz alone and/or in combination with Hantash '718 PCT or ScarLet
		Ganz also discloses that the plurality of electrodes can be bipolar electrodes. *Id*., at [0011] ("the electrodes are **bipolar electrodes**"), [0056] ("the electrodes are provided as a **bipolar electrode** arrangement … with one electrode in the pair being a positive electrode and the other electrode being a negative electrode"), claim 11 ("wherein the plurality of electrodes are provided as a plurality of electrode pairs"), claim 13 ("wherein the **plurality of electrodes are bipolar electrodes**") (emphasis added.) The parties have agreed that "the electrodes being bipolar" should be construed as having a plain and ordinary meaning "[23] the 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) Post-Markman Hearing Joint Claim Construction Chart, at 3. Ganz disclosed that the "electrodes are RF electrodes and are configured for receiving RF energy." *Id*., at [0011]. In other words, a radio frequency signal is applied to the electrodes. Ganz discloses that the needle electrodes are coupled to an RF source. *Id*. at [0011] ("[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, …"). In other words, an RF generator (generating module) is configured to provide an RF signal to the plurality of electrodes. It was well-known in the art that a radio frequency signal is a type of alternating current (AC). *Radiofrequency Catheter Ablation for Cardiac Tachyarrhythmias*, Manolis, A.S., *et al*., *Ann Intern Med.* (1994) 121:452-461 at 452. Complainant also appears to agree that an RF signal is a type of "alternating current." *See* Complainant's Final Infringement Contentions, Ex. 64, at 25; Ex. 76, at 14; Ex. 22, at 11.

[23] As mentioned in section VII above, it is my opinion that a "bipolar needle" means having both poles on the same needle, but the configuration described in the Na patent would be Monopolar needles arranged in a Bipolar configuration. However, for simplicity, Bipolar needle will be used as defined by the legal team. In this definition, Monopolar is referred as a configuration where current flows from one or more electrodes that deliver current to one or more ground electrodes. Using the "ground" as a refence for an electrosurgical instrument has been made illegal for many years. The term "Ground Electrode" should be replaced by "Neutral Electrode" as it is a floating reference, isolated for earth ground.

'379 Patent Claim 1		Ganz alone and/or in combination with Hantash '718 PCT or ScarLet
		The bipolar modality of RF delivery utilizes two electrodes, a positive and negative; alternating current flows back and forth between these points. The effective field depth, and thus the depth of tissue heated is determined by the distance of electrodes in relation to one another, although the degree of heating is still determined by the electrical parameters of the EMF. Complainant's Final Infringement Contentions, Ex. 64, at 25; Ex. 76, at 14 (emphasis in original) (citing SERENDIA-00006562 (Dermatology Time RF Webpage) at SERENDIA-00006565). It was well-known in the art that an alternating current (AC) is a current that alternates polarities. Thus, a POSITA would have understood that Ganz's bipolar electrodes change or alternate between being positive or negative as the alternating radiofrequency current alternates between them. Complainant appears to agree since alternating current flowing back and forth (to different directions) means that the current alternates polarities relative to the 2 poles of the generator (*i.e.*, the polarities dictate the current direction, and, thus, if the current direction changes, then the polarities change.) *See* Complainant's Initial Infringement Contentions, Ex. 71, at 21; ("the Accused Product is configured to provide a RF signal with oscillating current (as evidenced in green) to the plurality of electrodes"), Ex. 77, at 14 (alternating current flows back and forth between" electrodes) (citing SERENDIA-00006562 (Dermatology Time RF Webpage) at SERENDIA-00006565). Also, in its Markman brief, I understand that Complainant took the position that an alternating current is synonymous with an oscillating current[24], which Complainant equates as a current that "alternates polarities." Complainant's Claim Construction Brief, at 67-68 ("Breaking down the claim language, it specifies that the 'current' alternates or oscillates, i.e., it alternates polarities."). Complainant then states that "alternating current" is "electric current that reverses direction periodically, usually many times per second, and also states that "'alternating current' 'usually means that the current changes polarity with time.'" Complainant's Claim Construction Brief, at 68. In my opinion, alternating current is a type of oscillating current, but

[24] It is my scientific opinion that an AC current is a type of oscillating current, that oscillates around a "0" value; whereas an oscillating current could oscillate around another neutral value not equal to "0". This would not be allowed in an electrosurgical generator that needs to have a "0" mean current due to the output blocking capacitor required by the IEC standard.

'379 Patent Claim 1		Ganz alone and/or in combination with Hantash '718 PCT or ScarLet
		the two terms are not synonymous; that demonstrates that Complainant lacks expertise in the Art. Thus, there can be no dispute that when the RF signal (which is a type of AC signal) is applied to Ganz's electrodes, the electrodes change or alternate between being positive or negative as the current alternates between them. Accordingly, Ganz discloses a plurality of electrodes, the electrodes being bipolar and configured to be insertable into a body segment to be treated.
1.2	a radio frequency (RF) generation module, the RF generation module electrically coupled to the plurality of electrodes and configured to provide an RF signal with oscillating current to the plurality of electrodes	Ganz discloses and/or renders obvious a radio frequency (RF) generation module, the RF generation module electrically coupled to the plurality of electrodes and configured to provide an RF signal with oscillating current to the plurality of electrodes according to the claim. *See, e.g.,* Ganz, at [0011], [0057], [0058], [0059], claims 7-8. Specifically, Ganz discloses that "[t]he device also includes an **energy source** coupled to the plurality of electrodes, the energy source configured to deliver energy," and that energy can be "**radio frequency**" energy. *Id*., at [0011] ("RF electrodes and are configured for receiving RF energy"); *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**…"), [0058] ("In preferred embodiments, the electrodes are configured as RF electrodes and **RF energy is delivered to the electrodes**"), [0059] ("the energy source, including but not limited to an **RF source**"), 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"), claim 9 ("wherein the plurality of electrodes are RF electrodes and are configured for receiving RF energy"). (emphasis added). > [0011] "The 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. A control device may also be coupled to the energy source. In preferred cases, the electrodes are RF electrodes and are configured for receiving RF energy. The electrodes can be provided as

'379 Patent Claim 1		Ganz alone and/or in combination with Hantash '718 PCT or ScarLet
		a plurality of electrode pairs or even as an array of electrodes. In some cases, the electrodes are monopolar electrodes whereas in other cases the electrodes are bipolar electrodes." [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, non-ionizing ultraviolet radiation and microwave radiation. In some cases, the electrodes are configured to provide power in the range of about 50 to about 200 watts per square centimeter. In other cases, the electrodes are configured to provide an energy of at least about 1 joule[] per square centimeter." [0058] "In preferred embodiments, the electrodes are configured as RF electrodes and RF energy is delivered to the electrodes. RF energy is particularly desirable for creating perforations of tissue since it does not cause the entire area of tissue being treated to heat up extensively. Rather, RF energy can penetrate the body and be absorbed by deeper tissues without heating up the surrounding tissues. Thus, a boundary is created between the treated tissue and those tissues surrounding the treated tissue. RF energy is also desirable since it is safe to use on tissues in areas near sensitive body parts, e.g., areas of skin near the eyes." [0059] The energy source is configured for powering the electrodes at levels appropriate to provide a desired diameter and depth of perforation of tissue. The energy source may be manually controlled by the user and be adapted to allow the user to select the appropriate treatment time and power setting to obtain a controlled depth and/or width of perforation. The energy source can also be coupled to a controller, which may be a digital or analog controller for use with the energy source, including but not limited to an RF source, or a computer with software. When the computer controller is used it can include a CPU coupled through a system bus. The system may include a keyboard, a disk drive, or other non-volatile memory system, a display and other

'379 Patent Claim 1		Ganz alone and/or in combination with Hantash '718 PCT or ScarLet
		peripherals known in the art. A program memory and a data memory can also be coupled to the bus. The energy source can be positioned at different positions in proximity to the treatment device. Thus, Ganz' RF energy source is a device that generates electrical signal(s) having a radio frequency. It was well-known in the art that a radio frequency signal is a high-frequency alternating current, which is usually over 200 KHz and under to 5 MHz as defined by IEC 60601-2-2 section 201.8.4.102. (*see* section VII.) alternating current (AC). 200 KHz is the equivalent of 0.2 Mhz; see section VII. above. Thus, radio frequency signals are measured in MHz.[25] As discussed above, Complainant also appears to agree that an RF signal is a type of "alternating current." *See* Complainant's Final Infringement Contentions, Ex. 64, at 25; Ex. 76, at 14; Ex. 22, at 11. Complainant appears to agree since alternating current flowing back and forth (to different directions) means that the current alternates polarities (*i.e.*, the polarities dictate the direction, and, thus, if the direction changes, then the polarities change.) Moreover, it was well-known in the art that an alternating current (AC) is an oscillating current that alternates polarities and is symmetric around a "Zero" value. Complainant appears to agree since alternating current flowing back and forth (to different directions) means that the current alternates polarities (*i.e.*, the polarities dictate the direction, and, thus, if the direction changes, then the polarities change.) *See* Complainant's Initial Infringement Contentions, Ex. 71, at 21; ("the Accused Product is configured to provide a RF signal with oscillating current (as evidenced in green) to the plurality of electrodes"), Ex. 77, at 14 (alternating current flows back and forth between" electrodes) (citing SERENDIA-00006562 (Dermatology Time RF Webpage) at SERENDIA-00006565). Also, in its Markman brief, I understand that Complainant took the position that an alternating current is synonymous with an oscillating current, which Complainant equates as a current that "alternates polarities." Complainant's Claim Construction Brief, at 67-68

[25] '836 Patent, claim 22 depends from claim 14 (requiring "a[n] Alternating Current (AC) Radio Frequency (RF) signal). Claim 22 requires that "the RF is from 0.5 to 10 MHz." Thus, if 0.5 MHz is considered to be measured in MHz, then 0.03 MHz is also measured in Mhz.

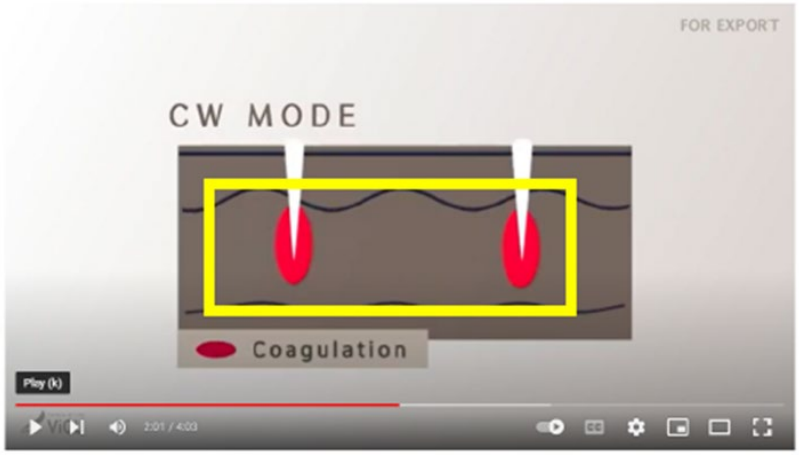
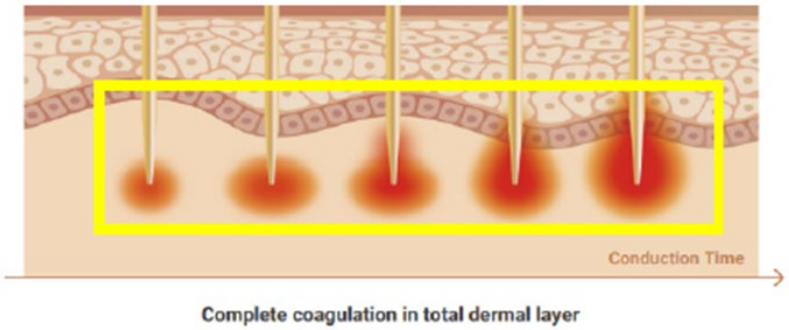
'379 Patent Claim 1		Ganz alone and/or in combination with Hantash '718 PCT or ScarLet
		("Breaking down the claim language, it specifies that the 'current' alternates or oscillates, i.e., it alternates polarities."). Complainant then states that "alternating current" is "electric current that reverses direction periodically, usually many times per second, and also states that "'alternating current' 'usually means that the current changes polarity with time.'" Complainant's Claim Construction Brief, at 68. In my opinion, an alternating current is a kind of oscillating current but both terms are not synonymous, that demonstrates that Complainant lacks expertise in the Art. Therefore, because Ganz provides a radio frequency (RF) signal to the electrodes, Ganz discloses providing an electrical signal with oscillating current (current alternating polarities) and having a radio frequency (measured in MHz). Accordingly, Ganz discloses that the RF generation module is electrically coupled to the plurality of electrodes and configured to provide an RF signal with oscillating current to the plurality of electrodes. To the extent that Complainant asserts that RF signals do not inherently have frequencies measured in MHz[26] and/or that Ganz does not disclose an RF signal having a frequency measured in MHz, it would have further been obvious given the knowledge of a POSITA and/or in further view of Hantash '718 PCT[27] For example, Hantash '718 PCT also discloses a mammalian body treatment apparatus. Hantash '718 PCT, Title ("Method and apparatus for micro-needle array electrode treatment of tissue"); Abstract ("system and method for revitalizing aging skin"); [0002]; [0013]; [0014]; [0021]; Fig. 1; claim 1 (for "human skin"). Hantash '718 PCT's device also has a plurality of bipolar electrodes configured to be insertable into a body segment to be treated, and a radio frequency (RF) generation module, the RF generation module electrically coupled to the plurality of electrodes and configured to provide an RF signal with oscillating current to the plurality of electrodes. Hantash '718 PCT, at [0035], *see also id*., at Abstract, [0002] ("biological tissue treatment using electromagnetic energy delivered through an array of needle electrode [electrodes]"), [0012], [0013], [0014], [0017]

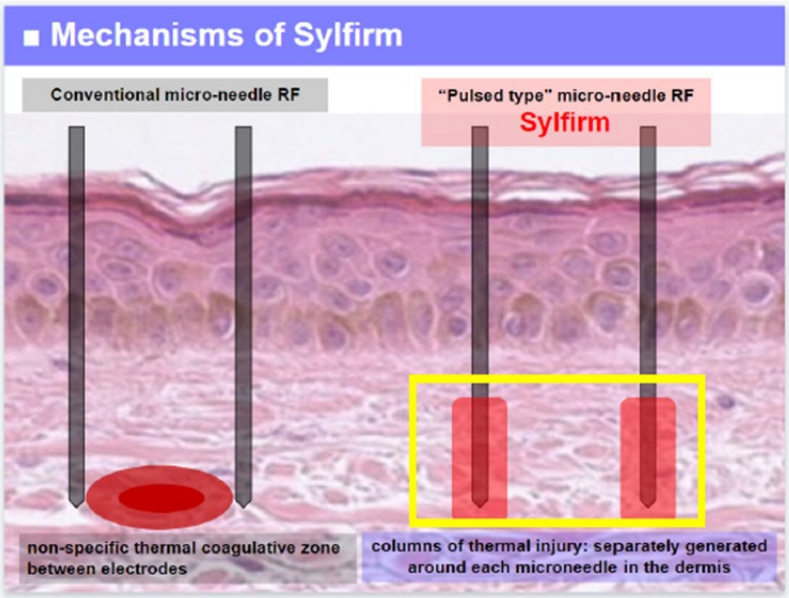
[26] As discussed above, a POSITA would be familiar with the IEC 60601-2-2 that in 2012 defined high frequency for surgical equipment as a frequency over 200 KHz (0.2 MHz).
[27]and also given the position of world experts forming the IEC MT17 committee that defined the IEC 60601-2-2 standard as described in section VII. above.

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		("the microneedles are driven into the tissue"), [0021], [0034] ("a radio frequency (RF) source 110 is [electrically] connected to an array of needles 115" to deliver energy to the skin 150 via the array of needle electrodes 115"), [0035] ("While the needles 115 are located within the skin 150, they can be powered by the RF source 110"), [0039] ("each of the needles 115 can comprise an electrically conductive shaft"), [0040] ("bipolar" electrodes), [0047] ("One array includes all of the negative polarity needles 116 (return electrodes) and the other includes all of the positive polarity needles 117 (active electrodes)"), [0055], [0057] ("electrically connecting the needles 116 and 117 at the opposite ends of each local region of skin 150 to be treated to different poles of the RF source 110"), [0061], [0068]-[0070], [0079] ("bipolar") Figs. 1, 3A, claims 1, 37, 42. Hantash '718 PCT gives examples of using RF signals having a frequency measured in MHz. Hantash '718 PCT, at [0040] ("frequency of the RF source can be chosen to be about 6.78 MHz or about 13.56 MHz," "from 0.1 to 10 MHz or from 0.4 to 3 MHz"), [0077], [0079]. A POSITA would have known that (among other parameters) the frequency range of the RF source can be chosen based on the desired effects on various types of tissue and its influence on lesion size and geometry based on the intended application. S*ee* Hantash '718 PCT, [0040]; *see* also [0052] ("With the proper choice of parameters, the treatment can be self limiting to create treatment zones 160 of approximately uniform size across the treatment pattern 161. The self limiting nature of the treatment can be achieved by choosing the frequency of the RF source 110 to be a frequency for which the tissue resistivity (impedance) increases as the tissue is treated."); [0079]. Ganz also teaches that the parameters and the configuration of the RF generator influence the depth and diameter of the lesion around each electrode. Ganz at [0059] ("The energy source is configured for powering the electrodes at levels appropriate to provide a desired diameter and depth of perforation of tissue.").
1.3	to apply energy to body segments around each electrode rather than to body segments between the electrodes.	One of Ganz's goals is to create zones of coagulation that are not connected so that "tissue layers surrounding the perforations are left untreated and contribute to tissue regeneration," thereby "promoting more aggressive healing." Ganz, at [0006]; *see also id*., at [0010] ("zone of coagulative tissue surrounding each perforation"); [0048] ("Zones of coagulation are also created in areas of tissue surrounding each perforation"), [0058] ("RF energy is particularly desirable for creating perforations of tissue since it does not cause the entire area of

'379 Patent Claim 1		Ganz alone and/or in combination with Hantash '718 PCT or ScarLet
		tissue being treated to heat up extensively … Thus, a boundary is created between the treated tissue and those tissues surrounding the treated tissue"), [0028] ("Areas or zones of coagulation 2 can also be seen in the areas surrounding the perforation"), Fig. 9. Optimization of parameters, such as the RF frequency, power, energy, voltage, timing duty cycle applied to microneedles, requires a significant amount of experimentation. However, the experimental methodology to achieve unconnected coagulation zones is obvious to a POSITA, and the selection of the RF frequency would then become obvious to a POSITA. Therefore, a POSITA would have been motivated to use an RF frequency measured in MHz, in the range of 0.2 to 5 MHz, like in Hantash '718 PCT. Accordingly, under Complainant's interpretation of "apply energy to body segments around each electrode rather than to body segments between the electrodes," Ganz in view of Hantash '718 PCT also renders obvious a radio frequency (RF) generation module, the RF generation module electrically coupled to the plurality of electrodes and configured to provide an RF signal with oscillating current to the plurality of electrodes. As explained below, under Complainant's interpretation, Ganz discloses and/or renders obvious to apply energy to body segments around each electrode rather than to body segments between the electrodes according to the claim. *See, e.g.,* [0010], [0028], [0048], [0056], [0058], Fig. 9, claims 1-3. I understand that, in its attempt to argue claims are patent eligible, Complainant has argued that the independent claims recite "limitations that would be needed to produce the desired result" (apply energy to body segments around each electrode rather than to body segments between the electrodes" because "claim 10 of the '379 Patent requires inserting a plurality of electrodes into a body segment to be treated where the electrodes are bipolar and applying an RF signal with oscillating current to the plurality of electrodes." Complainants' Initial Validity Contentions, at 407-408. As shown above, in regard to the limitation, "a plurality of electrodes, the electrodes being bipolar and configured to be insertable into a body segment to be treated", Ganz discloses inserting a plurality of electrodes into a body segment to be treated where the electrodes are bipolar. As shown above, in regard to the limitation, "a radio frequency (RF) generation module, the RF generation module

'379 Patent Claim 1		Ganz alone and/or in combination with Hantash '718 PCT or ScarLet
		electrically coupled to the plurality of electrodes and configured to provide an RF signal with oscillating current to the plurality of electrodes," Ganz discloses applying an RF signal with oscillating current to the plurality of electrodes under Complainant's and Staff's proposed construction for RF signal with oscillating current. Therefore, Complainant asserted that Ganz discloses the limitations that would be needed to apply energy to body segments around each electrode rather than to body segments between the electrodes. Thus, Complainant has essentially taken the position that Ganz discloses to apply energy to body segments around each electrode rather than to body segments between the electrodes under Complainant's and Staff's proposed construction for RF signal with oscillating current. Accordingly, based on Complainant's arguments discussed above, Ganz anticipates claim 1, or Ganz in view of Hantash '718 PCT renders obvious claim 1. In the '379 Patent, at 3:7-21, Dr. Na Asserts that: "In the present invention the term "to raise temperature" is used synonymously with " applying energy to achieve coagulation " where applying electrically energy to the body region may effectively raise the body region temperature." In other terms, he states that the zone of coagulation occurs when sufficient energy has been applied using application of RF energy. He therefore admits that there is a very close correlation between applying energy to body segment around each electrode around each electrode rather than to body segments between the electrodes and causing e coagulation around each electrode rather than coagulating between the electrodes Additionally, I understand that Complainant appears to assert that "to apply energy to body segments around each electrode rather than to body segments between the electrodes" has the same scope as "cause coagulation around each electrode rather than coagulating between the electrodes," recited in independent claim 1 of the '836 Patent, then Ganz discloses or renders this obvious. For example, in its domestic industry claim charts for the '379 Patent, Complainant ignores the language of "energy" and instead asserts this limitation is met by coagulation appearing only around electrodes but not being connected between electrodes: In the Domestic Industry Product, the RF generation module along with the plurality of electrodes is configured to apply energy to body segments around each electrode rather than to body segments between the electrodes (as shown below in yellow).

'379 Patent Claim 1		Ganz alone and/or in combination with Hantash '718 PCT or ScarLet
		Complainant's Final Infringement Contentions, Ex. 107, at pg. 23.  SERENDIA-00007811. *Id.*, at 24.  SERENDIA-00022192 at SERENDIA-00022193, 5. *Id.*, at 25.

'379 Patent Claim 1	Ganz alone and/or in combination with Hantash '718 PCT or ScarLet
	 VIOL-00000321 at VIOL-00000345. *Id.*, at 25. Therefore, to the extent that Complainant is asserting that "to apply energy to body segments around each electrode rather than to body segments between the electrodes" has the same scope as "cause coagulation around each electrode rather than coagulating between the electrodes," recited in independent claim 1 of the '836 Patent, then Ganz discloses or renders this obvious for the reasons set forth above in sections XII.A.1.1.3. Hantash '718 PCT teaches how the various parameters influence the size of the lesion (zone of coagulation), and Hantash '718 PCT provides concrete examples of the lesion's dimensions in diameter and height in [0077] in [0078]. In contrast, there is no such concrete example in the '836 Patent. This demonstrates that Hantash had a very good grasp on setting the various parameters to precisely control the lesion size around each electrode, and to determine whether or not the lesion would intercept or not. [0077] "FIG. 15 A shows the results of using of a needle pair that penetrated approximately 1-2 mm into the skin with a needle separation of 0.5 mm. A bipolar RF source operating at a frequency of 0.47 MHz, a power of 5 W, and a pulse duration of 400 ms was used. The treatment zone 260 that was created has dimensions of approximately 500 μm width and 600

'379 Patent Claim 1		Ganz alone and/or in combination with Hantash '718 PCT or ScarLet
		μm height. The aspect ratio of width to height of the treatment zone 260 is therefore approximately 5:6." [0078] "For FIG. 15B, the conditions were similar to those for FIG. 15 A except the pulse duration was 200 ms, the separation between the needles 115 was 1 mm, and the depth of needle penetration was approximately 0.5-1 mm. The treatment zone 261 that was created has dimensions of approximately 900 μm width and 250 μm height. The aspect ratio of width to height for the treatment zone 261 is therefore approximately 3.6:1." From [0047] and [0048] of Ganz, it appears that in most cases, the zones of coagulation extend to a distance (5-100 microns) less than the distance between the electrodes (100-1,000 microns, demonstrating the ability of creating coagulation zones that do not overlap. [0047] In certain cases, the electrodes are patterned in order to create perforations being between about 30 to about 100 microns in diameter, up to about 1000 microns deep and spaced apart by between about 50 to about 400microns." [0048] Zones of coagulation are also created in areas of tissue surrounding each perforation. The zones can extend from the perforation site into the tissue for a length ranging from about 5 microns to about 100 microns. The zone of coagulation can be varied by changes in energy and power levels. Ganz at [0047], [0048]. Ganz also explains how to control the size of the lesions by varying energy and power levels, showing once more that he is able to fully control lesions such that they do not overlap. Accordingly, under Complainants' interpretation of "apply energy to body segments around each electrode rather than to body segments between the electrodes," and, to the extent that Complainant asserts that "to apply energy to body segments around each electrode rather than to body segments between the electrodes" has the same scope as "cause coagulation around each electrode rather than coagulating between the electrodes," recited in independent claim 1 of the '836 Patent, then Ganz anticipated and/or Ganz in view of Hantash '718 PCT rendered obvious claim 1 of the '379 Patent.

'379 Patent Claim 1		Ganz alone and/or in combination with Hantash '718 PCT or ScarLet
		As discussed in section XII.A.1.1.3, ScarLet discloses and/or renders obvious electrodes configured to cause coagulation around each electrode rather than coagulating between the electrodes according to the claim. *See e.g.*, Ilooda-0010042 at -046; SERENDIA-00017306 at -334; SERENDIA-00017306 at -337; SERENDIA-00017306 at -321; SERENDIA-00017306 at -320. Under Complainants' interpretation of "apply energy to body segments around each electrode rather than to body segments between the electrodes," and, to the extent that Complainant asserts that "to apply energy to body segments around each electrode rather than to body segments between the electrodes" has the same scope as "cause coagulation around each electrode rather than coagulating between the electrodes," recited in independent claim 1 of the '836 Patent, then Ganz in view of ScarLet also rendered obvious claim 1 of the '379 Patent. *See* section XII.A.1.1.3.

3. Claim 2 of the '379 Patent is Anticipated by Ganz and/or obvious over Ganz alone and/or in combination with ScarLet or Hantash '718 PCT

292. Ganz discloses and/or Ganz alone or in combination with ScarLet renders obvious the mammalian body treatment apparatus of claim 1, wherein the RF generation module is configured to provide an RF signal to the plurality of electrodes according to the claim.

293. As shown above in regard to the limitation, a radio frequency (RF) generation module, the RF generation module electrically coupled to the plurality of electrodes and configured to provide an RF signal with oscillating current to the plurality of electrodes. *See, e.g.,* Ganz, at [0011], [0047], [0048], [0057], [0058], [0059], claim 8.

294. Ganz discloses and/or renders obvious that the RF generation module is configured to provide an RF signal to the plurality of electrodes for a predetermined time interval according to the claim. *See e.g.*, [0011], [0048], [0057] ("energy source coupled to the electrodes for delivering energy to the electrodes," which can be "radio frequency energy"),

[0058] ("the electrodes are configured as RF electrodes and RF energy is delivered to the electrodes"), *id.* at [0059] ("The energy source may be . . . adapted to allow the user to select the **appropriate treatment time**[.]") (emphasis added), 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"), claim 8 ("a control device coupled to the energy source").

295. For example, Ganz discloses that "[t]he energy source may be manually controlled by the user and be adapted to allow the user to select the appropriate treatment time [(a predetermined time interval)]." Ganz, at [0059] ("the energy source" can be "an RF source"); *see also id*. ("RF electrodes and are configured for receiving RF energy"):

> [0059] "The energy source is configured for powering the electrodes at levels appropriate to provide a desired diameter and depth of perforation of tissue. The energy source may be manually controlled by the user and be adapted to allow the user to select the appropriate treatment time and power setting to obtain a controlled depth and/or width of perforation. The energy source can also be coupled to a controller, which may be a digital or analog controller for use with the energy source, including but not limited to an RF source, or a computer with software. When the computer controller is used it can include a CPU coupled through a system bus. The system may include a keyboard, a disk drive, or other non-volatile memory system, a display and other peripherals known in the art. A program memory and a data memory can also be coupled to the bus. The energy source can be positioned at different positions in proximity to the treatment device."
>
> [0011] "The 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. A control device may also be coupled to the energy source. In preferred cases, the electrodes are RF electrodes and are configured for receiving RF energy. The electrodes can be provided as a plurality of electrode pairs or even as an array of electrodes. In some cases, the electrodes are monopolar electrodes whereas in other cases the electrodes are bipolar electrodes."
>
> [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, non-ionizing ultraviolet radiation and microwave radiation. In

> some cases, the electrodes are configured to provide power in the range of about 50 to about 200 watts per square centimeter. In other cases, the electrodes are configured to provide an energy of at least about 1 joules per square centimeter."
>
> [0058] "In preferred embodiments, the electrodes are configured as RF electrodes and RF energy is delivered to the electrodes. RF energy is particularly desirable for creating perforations of tissue since it does not cause the entire area of tissue being treated to heat up extensively. Rather, RF energy can penetrate the body and be absorbed by deeper tissues without heating up the surrounding tissues. Thus, a boundary is created between the treated tissue and those tissues surrounding the treated tissue. RF energy is also desirable since it is safe to use on tissues in areas near sensitive body parts, e.g., areas of skin near the eyes."

296. To the extent Complainant asserts that Ganz does not explicitly or inherently disclose this limitation, it would have further been obvious given the knowledge of a POSITA and/or in further view of Hantash '718 PCT.

297. For example, as discussed above in regard to the limitation, "a radio frequency (RF) generation module, the RF generation module electrically coupled to the plurality of electrodes and configured to provide an RF signal with oscillating current to the plurality of electrodes," Hantash '718 PCT discloses a mammalian body treatment apparatus that has a plurality of bipolar electrodes configured to be insertable into a body segment to be treated, and a radio frequency (RF) generation module, the RF generation module electrically coupled to the plurality of electrodes and configured to provide an RF signal with oscillating current to the plurality of electrodes.

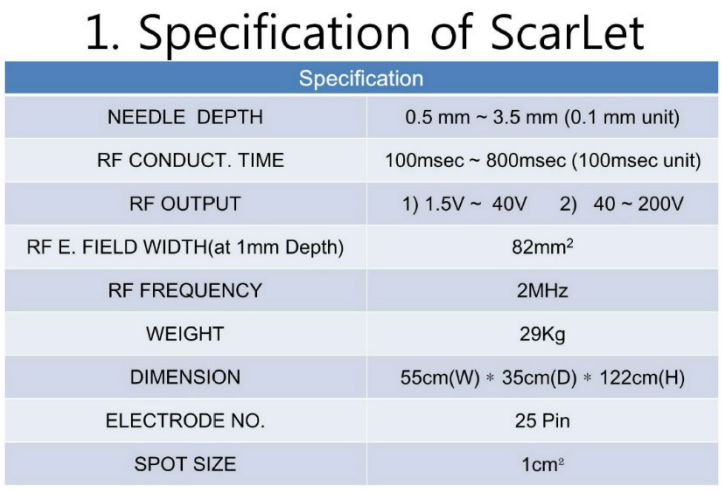
298. Hantash '718 PCT discloses an example of providing an RF signal to a plurality of electrodes for "pulse duration of 400 ms" (Hantash '718 PCT, at [0077]) or "200 ms" (*id*., at [0078]). *See also id*., at [0018] (ensuring "enough thermal relaxation time at the treated zones and thereby avoiding overheating of the treated zones"). Thus, Hantash '718 PCT discloses that the RF generation module is configured to provide an RF signal to the plurality of electrodes for a predetermined time interval.

299. Hantash ‘718 PCT also explains to adjust the treatment parameters to achieve the desired time at temperature (*See* Hantash, at [0018], [0040], [0052], [0077], [0079]), in order to “create more localized electrical field profiles within the tissue or to create a discontinuous treatment pattern” in order to “reduce charring and over-treatment.” *Id*., at [0056]. Hantash ‘718 PCT explains that it is safer and more desirable to create discrete small coagulation zones rather than larger connected coagulation zones so that the surrounding area is spared from damage and can assist with the healing process, which makes the healing process more through and faster as compared to continuous coagulation zones. *See id*., at [0058].

> “Each of the treatment patterns 161 - 166 desirably spares healthy tissue between the treatment zones 160. Sparing of healthy tissue between treatment zones 160 reduces the incidence of scarring and promotes rapid healing by allowing nutrients, cells, and cytokines to flow more quickly to the wounded areas to stimulate the wound healing response. The spared tissue also allows transport to the dermal-epidermal junction and the epidermis so that the epidermis can remain healthy or heal quickly following treatment.”
>
> Hantash ‘718 PCT, at [0058].

300. As discussed above, Ganz already discloses that “[t]he energy source may be manually controlled by the user and be adapted to allow the user to select the appropriate treatment time and power setting to obtain a controlled depth and/or width of perforation.” Ganz, at [0059].

301. To the extent Ganz or Hantash ‘718 do not explicitly or inherently disclose this limitation, it would have been obvious in view of ScarLet. ScarLet shows an adjustable Time ON for 0.100sec. to 0.800 seconds, which overlaps the time windows preconized by Na. Ilooda-0006239 19/32.



Ilooda-0006061 (0006062)

302. Thus, a POSITA would have been motivated to allow the user to select different predetermined time intervals for applying the RF energy to the electrodes in order to achieve different coagulation patterns. For example, to create small discrete coagulation zones that do not connect between electrodes. This would allow for a quicker healing time, which would have been desirable.

303. Accordingly, under Complainant's interpretation of "apply energy to body segments around each electrode rather than to body segments between the electrodes," and, to the extent that Complainant asserts that "to apply energy to body segments around each electrode rather than to body segments between the electrodes" has the same scope as "cause coagulation around each electrode rather than coagulating between the electrodes," recited in independent claim 1 of the '836 Patent, then Ganz in view of Hantash '718 PCT also rendered obvious claim 2.

4. Claim 5 of the '379 Patent is Anticipated by Ganz and/or obvious over Ganz alone and/or in combination with Hantash '718 PCT

304. Ganz alone or in combination with ScarLet or Hantash 718 PCT renders obvious the skin treatment apparatus of claim 1, wherein the closest neighboring electrodes have opposite polarities. *See, e.g.,* Ganz, at [0014], [0047], [0056].

305. For example, Ganz discloses that "[a]ny desired pattern or electrode arrangement is within the scope of the invention." *Id.*, at [0047] ("The electrodes are positioned on the treating surface in any manner to provide a desired pattern of perforations into the one or more tissue planes"); *see also id*., at [0014] ("wherein the plurality of electrodes are arranged in a desired pattern").

> [0014] "A method for creating a pattern of perforations in tissue is also provided. The method includes the steps of providing a device having a treating surface which includes a plurality of electrodes extending outwardly from the treating surface, wherein the plurality of electrodes are arranged in a desired pattern, placing the treating surface in contact with tissue adjacent to one or more tissue planes, and delivering energy to the electrodes to simultaneously impart perforations into one or more layers of the tissue, wherein the perforations correspond to the electrode pattern."

> [0047] "The electrodes are positioned on the treating surface in any manner to provide a desired pattern of perforations into the one or more tissue planes. Generally, the electrodes come into direct contact with the one or more tissue planes. So, the pattern of electrodes directly correspond to the pattern of perforations desired in the tissue. Any desired pattern or electrode arrangement is within the scope of the invention. In certain cases, the electrodes are patterned in order to create perforations being between about 30 to about 100 microns in diameter, up to about 1000 microns deep and spaced apart by between about 50 to about 400 microns. In other preferred cases, the electrodes have a depth and width for providing perforations being no more than about 2 mm in depth and about 0.5 mm in width. In yet other cases, the electrodes have a spacing for providing perforations spaced apart by no more than about 5 mm or less and more preferably no more than about 2 mm or less."

306. In Ganz's bipolar embodiment, the electrodes come in pairs where "one electrode in the pair being a positive electrode and the other electrode being a negative electrode." *Id*., at [0056].

> [0056] "In other embodiments, the electrodes are provided as a bipolar electrode arrangement. In bipolar electrode arrangements, both the positive and negative electrodes serve as treating electrodes. In some cases, the bipolar electrodes are biopolar[*sic*] axial interlaced finger electrodes. In embodiments wherein the electrodes are provided as electrode pairs, biopolar[*sic*] electrodes are desirable, with one electrode in the pair being a positive electrode and the other electrode being a negative electrode. The electrodes can be shaped in such a way that the middle portion of distal portion is enlarged in order to create a zone of injury that is greater at the distal end compared to the proximal end. The base of the treatment pad or treating surface and various portions of the proximal electrodes can also be insulated in order to limit the coagulation injury to the distal end of the electrode as well."

307. It would have been an obvious design choice for a POSITA as of the priority date of the '379 Patent to modify Ganz to use an electrode configuration where the closest neighboring electrodes have opposite polarities. The '379 Patent does not explain that there is any benefit to such a configuration as opposed to a configuration where, for example, a positive electrode is equally close to one or more negative electrodes and one or more positive electrodes.

308. Nor does the '379 Patent disclose that the claimed configuration of electrodes is part of how one achieves applying energy to body segments around each electrode rather than to body segments between the electrodes. To the extent Complainant argues there is a benefit for arranging the neighboring electrodes to have opposite polarities, optimization, through routine experimentation, of the arrangement of opposite polarity electrodes in an electrode array was obvious to a POSITA.

309. Accordingly, under Complainant's interpretation of "apply energy to body segments around each electrode rather than to body segments between the electrodes," and, to the extent that Complainant asserts that "to apply energy to body segments around each electrode rather than to body segments between the electrodes" has the same scope as "cause

coagulation around each electrode rather than coagulating between the electrodes," recited in independent claim 1 of the '836 Patent, then Ganz rendered obvious claim 5.

310. Additionally, as discussed above in regard to the limitation, "a radio frequency (RF) generation module, the RF generation module electrically coupled to the plurality of electrodes and configured to provide an RF signal with oscillating current to the plurality of electrodes," Hantash '718 PCT discloses a mammalian body treatment apparatus that has a plurality of bipolar electrodes configured to be insertable into a body segment to be treated, and a radio frequency (RF) generation module, the RF generation module electrically coupled to the plurality of electrodes and configured to provide an RF signal with oscillating current to the plurality of electrodes.

311. Hantash '718 PCT also discloses that the closest neighboring electrodes have opposite polarities. For example, as shown in Fig. 3A, reproduced below, as well as Fig. 3B, the closest neighboring electrodes have opposite polarities. Hantash '718 PCT, at [0047] ("One array includes all of the negative polarity needles 116 (return electrodes) and the other includes all of the positive polarity needles 117 (active electrodes). In FIG 3, the negative needles 116 are open and the positive needles 117 are shaded"), *see also id*., claims 15, 17 ("wherein the needles are spaced further apart in one direction compared to the other direction on the grid"), Fig. 5A.

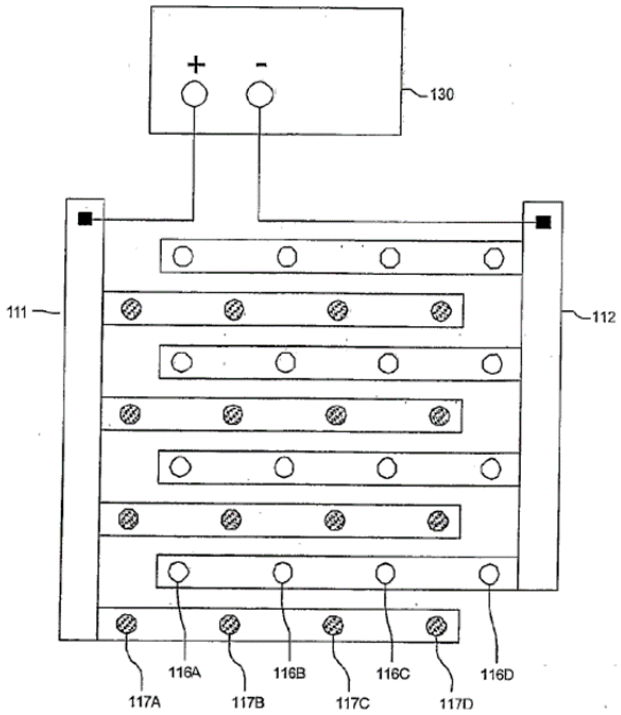


Figure 3A

Id., Fig. 3A

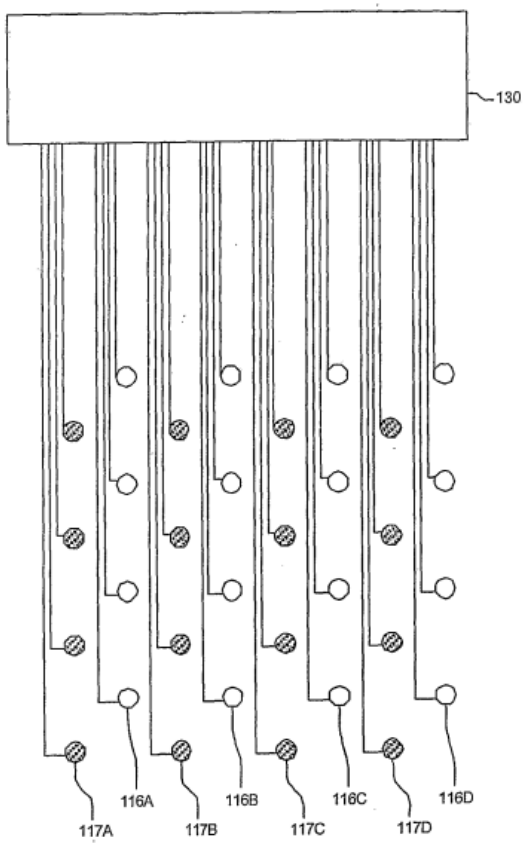
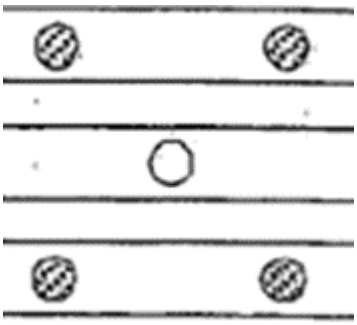


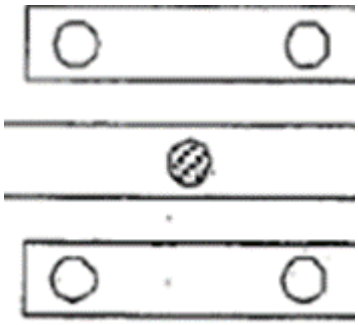
Figure 3B

Id., Fig. 3B

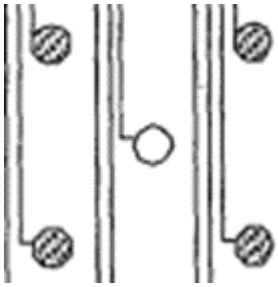
312. For example, as can be seen in Fig. 3A and 3B, the closest electrodes to any given negative electrode (open circle) are positive electrodes (shaded circle). *Id*., at [0047]. In this example, the four () shaded electrodes (positive) form a square, and the non-shaded (negative) electrode is in the center of the square. If the distance between the each of the four shaded electrodes is "a", then the distance "D" between the non-shaded electrode and any of the neighboring shaded electrode is given by the formula (1/2 the diagonal of a square): $D = \frac{a*\sqrt{2}}{2} = \frac{a*1.414}{2} = 0.707a$. Therefore, the distance between the electrode of opposite polarities is 30% shorter than the distance between the electrodes of same polarities.



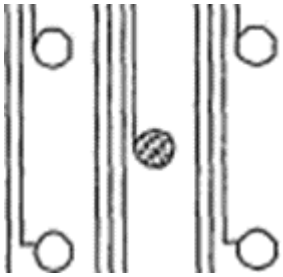
Id., at Fig. 3A, excerpt



Id., at Fig. 3A, excerpt



Id., at Fig. 3B, excerpt



Id., at Fig. 3B, excerpt

313. It would have been obvious design choice for a POSITA as of the priority date of the '379 Patent to modify Ganz in view of Hantash '718 PCT to use an electrode configuration where the closest neighboring electrodes have opposite polarities. As explained above, the '379 Patent does not explain that there is any benefit to such a configuration as opposed to a configuration where, for example, a positive electrode is equally close to one or more negative electrodes and one or more positive electrodes. Nor does the '379 Patent disclose that the claimed configuration of electrodes is part of how one achieves applying energy to body segments around each electrode rather than to body segments between the electrodes. To the extent Complainant argues there is a benefit for arranging the neighboring electrodes to have opposite polarities, optimization, through routine experimentation, of the arrangement of opposite polarity electrodes in an electrode array was obvious to a POSITA.

314. Accordingly, under Complainant's interpretation of "apply energy to body segments around each electrode rather than to body segments between the electrodes," and, to

the extent that Complainant asserts that "to apply energy to body segments around each electrode rather than to body segments between the electrodes" has the same scope as "cause coagulation around each electrode rather than coagulating between the electrodes," recited in independent claim 1 of the '836 Patent, then Ganz in view of Hantash '718 PCT also rendered obvious claim 5.

5. Claim 7 of the '379 Patent is Anticipated by Ganz and/or obvious over Ganz alone and/or in combination with Hantash '718 PCT and/or Manstein

315. Ganz discloses and/or Ganz alone or in combination with Hantash 718PCT and/or Manstein renders obvious "[t]he mammalian body treatment apparatus of claim 1, wherein the closest neighboring electrodes are separated by a distance of 1.3 mm to 3.0 mm." *See, e.g.,* Ganz, at [0010], [0049], [0052], claim 6.

316. Specifically, Ganz explains that the electrodes should have "a spacing of less than about 5 mm, and preferably less than about 2 mm." *Id*., at [0052]; *see also id*., at [0010] ("the electrodes can have a spacing for providing perforations spaced apart by no more than about 5 mm or less."), claim 6 ("wherein the plurality of electrodes have a spacing for providing perforations spaced apart by no more than about 5 mm or less").

> [0010] "In some embodiments, the invention provides a device for creating a pattern of perforations in a tissue. The device comprises a treating surface configured to be positioned in contact with tissue adjacent one or more tissue planes and a plurality of electrodes extending outwardly from the treating surface and adapted for imparting simultaneous perforations into one or more tissue layers, wherein the electrodes are provided in a pattern to impart a corresponding pattern of perforations in the one or more tissue layers. The electrode pattern can be selected to create perforations which are between about 30 to about 100 microns in diameter, up to about 1000 microns deep and spaced apart by between about 50 to about 400 microns. The electrode pattern can also be selected to create a zone of coagulative tissue surrounding each perforation. In some cases, the zone of coagulative tissue has a length of between about 5 microns to about 100 microns. The electrodes can also have a depth and width for providing perforations being no more than about 2 mm in depth and about 0.5 mm in width. Likewise, the

> electrodes can have a spacing for providing perforations spaced apart by no more than about 5 mm or less."
>
> [0052] "The electrodes can also be spaced apart at a desired length so that the perforations in tissue will also be spaced apart at that length. Any length between electrodes is within the scope of the invention. In some cases, each of the electrodes on a treating surface are spaced apart evenly whereas in other cases, some electrodes on a treating surface are space apart at a smaller length than other electrodes. The spacing of the electrodes can be adjusted in order to provide any desired spacing of perforations. With reference to the Figures, the electrodes of FIG. 3 have a larger spacing than the electrodes of FIG. 4. In certain embodiments, electrodes are provided on a treating surface have a spacing of less than about 5 mm, and preferably less than about 2 mm."

317. Ganz also disclosed an "electrode pattern can be selected to create perforations which are between about 30 to about 100 microns in diameter … and spaced apart by between about 50 to about 400 microns." *Id*., at [0010]; *see also id*., at [0049] ("[t]he electrodes can also be spaced apart at a desired length so that the perforations in tissue will also be spaced apart at that length.")

318. Thus, Ganz disclosed that the lower end of the range that the electrodes can be separated is 50 microns (0.05 mm) and the upper end of the range that the electrodes can be separated is less than 5 mm (or more preferably less than 2 mm).

319. Accordingly, Ganz discloses a range which overlaps with or encompasses the claimed range of 1.3 mm to 3.0 mm. However, the '379 Patent fails to support the criticality of the claimed separation distance. Among other things, the specification purports to include a formula for calculating electrode separation distance, but the formula is nonsensical. The claimed separation distances add nothing of patentable significance.

320. To the extent this limitation is not explicitly or inherently disclosed by Ganz, or rendered obvious by Ganz, it would have further been obvious in further view of the knowledge of a POSITA and/or in further view of Hantash '718 PCT or Manstein.

321. As discussed above, Ganz discloses spacing the needle electrodes within a range which overlaps with or encompasses the claimed range of 1.3 mm to 3.0 mm.

322. Ganz explained that "the spacing between electrodes can be varied along the treating surface, to create certain desired affects." *Id*., at [0049]; *see also id*., at [0052] ("Any length between electrodes is within the scope of the invention," and "[t]he spacing of the electrodes can be adjusted in order to provide any desired spacing of perforations").

> [0049] "It should be understood that not all of the electrodes present on a treating surface need to be of the same size. Also, the spacing between electrodes can be varied along the treating surface, to create certain desired affects. In some cases, the electrodes in the center of the treating surface are spaced more closely than the electrodes on the edges of the treating surface. This provides for a feathered effect, so that no sharp lines are seen at the areas where the treated skin meet the untreated skin."

323. Optimization, through routine experimentation, of the spacing of the needle electrodes to create a desired effect was within the capabilities of a POSITA.

324. Moreover, the spacing of the needles within a range of 1.3 mm to 3.0 mm is a design choice that would have been obvious to a POSITA.

325. For example, one of Ganz's goals is to create zones of coagulation that are not connected so that "tissue layers surrounding the perforations are left untreated and contribute to tissue regeneration," thereby "promoting more aggressive healing." Ganz, at [0006]; *see also id*., at [0010] ("zone of coagulative tissue surrounding each perforation"); [0048] ("Zones of coagulation are also created in areas of tissue surrounding each perforation"), [0058] ("RF energy is particularly desirable for creating perforations of tissue since it does not cause the entire area of tissue being treated to heat up extensively … Thus, a boundary is created between the treated tissue and those tissues surrounding the treated tissue"), [0028] ("Areas or zones of coagulation 2 can also be seen in the areas surrounding the perforation"), Fig. 9.

326. Therefore, a POSITA would have been motivated to attempt to optimize the spacing between the needles in Ganz to achieve a better healing process.

327. Alternatively, Manstein also disclosed a skin treatment apparatus (Manstein, at Title, Abstract) that has a plurality of bipolar electrodes configured to be inserted into skin. Manstein at 4:22-24 ("inserting an array of needles into a region of skin to a predetermined depth"), 7:13-22 ("electrodes in … bipolar modes"). Manstein's device also included a radio frequency (RF) generation module, the RF generation module electrically coupled to the plurality of electrodes. Manstein at 4:24-28 ("Radio frequency pulses of electrical current are then applied to one or more of the needles, which can function as electrodes in monopolar or bipolar modes to create regions of thermal damage and/or necrosis in the tissue surrounding the tips of the needles."); Manstein at 5:42-44 ("In one exemplary embodiment, the energy source 320 is a radio frequency (RF) device capable of outputting signals having frequencies in a desired range.")

328. Manstein explained that "[t]he needle arrays may have any geometry appropriate for the desired treatment being performed," and that "[t]he spacing between adjacent needles is preferably greater than about 1 mm apart, and may be as large as about 2 cm." Manstein at 7:61-64.

329. Thus, Manstein also discloses a needle separation distance that overlaps with the claimed range of 1.3 mm to 3.0 mm.

330. Manstein's preference is that the needles are separated by a distance greater than 1 mm, while Ganz preference is that the needles are separated by a distance less than 2mm (Ganz, at [0052]).

331. A POSITA would have known that the closer the electrodes are located to each other, the more likely that, when applying energy to the electrodes, the coagulation zones will be connected, as opposed to electrodes that are located further away from each other. This is a simple matter of thermodynamics that can be modelled using Finite Element Analysis Technique. The closer the electrodes are to each other, the smaller the distance the current travels. Thus, the energy is more concentrated (current density *see* above) in the path between electrodes since the current does not travel far from the electrodes and has less space to "spread" from the electrodes. As electrodes are placed further apart, the current has more volume of tissue to spread apart between the electrodes. Therefore, as the distance between positive and negative electrodes increases, the energy density (square of current density) becomes less concentrated in the space between neighboring electrodes.

332. One of Manstein's goals is to achieve "fractional wounding" (Manstein at 4:7-11), which includes techniques for creating controlled thermal damage to avoid damaging certain tissue. Specifically, Manstein discloses thermal damage "surrounding the tips of the needles." Manstein, at 4:24-28; *see also id*., at 6:23-26 ("In the apparatus of FIG. 3, application of RF current to the needles 350 causes heating in the exposed tip region, inducing thermal damage regions 370 around the tip of each needle"), Manstein at 8:6-9 ("In any array geometry, the pattern of damage and resultant tissue reshaping may be controlled with some precision by adjusting the intensity and duration of power transmitted to single needles or pairs of needles.")

333. As discussed above, one of Ganz's goals is to create zones of coagulation that are not connected so that "tissue layers surrounding the perforations are left untreated and contribute to tissue regeneration," thereby "promoting more aggressive healing." Ganz, at [0006]; *see also id*., at [0010]; [0048], [0058], [0028], Fig. 9.

334. Therefore, a POSITA would have been motivated to keep the separation between needles greater than 1 mm, as taught by Manstein, in order to generate unconnected zones of coagulation around the electrodes to enable a better healing process.

335. Thus, the combination of Ganz and Manstein renders obvious a needle separation range of greater than 1 mm to a separation less than 2 mm, which is a range that overlaps with the claimed 1.3 mm to 3.0 mm.

336. Alternatively, as discussed above in regard to limitation 1.2 above, Hantash '718 PCT discloses a mammalian body treatment apparatus that has a plurality of bipolar electrodes configured to be insertable into a body segment to be treated, and a radio frequency (RF) generation module, the RF generation module electrically coupled to the plurality of electrodes and configured to provide an RF signal with oscillating current to the plurality of electrodes.

337. Hantash '718 PCT discloses an example "needle separation of 0.5 mm" (*Id*., at [0077]); and an example where "the separation between the needles was 1 mm." (*id*., at [0078]). Hantash '718 PCT discloses "smaller treatment zones are within the scope of the invention and the size and location of the treatment zones will be application specific." Hantash '718 PCT, at [0079].

338. Hantash '718 PCT discloses choosing "spacing between the negative needles 116 and the positive needles 117" based on the shape of the treatment zone to be created. *Id*., at [0048]. Hantash '718 PCT explains that "[a]t high RF pulse energies and/or close spacing of the array of needles 115, the treatment zones 160 can be created such that the treatment zones 160 merge together to form a continuous treatment pattern 162 as shown in FIGS. 5 A and 5B." Hantash '718 PCT, at [0053]; *see also id*., at [0059] ("Other patterns can be used to create different effects based on particular applications."). Conversely, this means it was known that

coagulation is found closer to a given electrode as the RF energy increases and/or that chances of lesions generated by different electrodes overlapping increase as the spacing between needles decreases.

339. Thus, when Hantash '718 PCT explains to use a smaller treatment zone, a POSITA would have understood that can be accomplished by increasing the 0.5 mm to 1 mm needle separation range initially disclosed by Hantash '718 PCT.

340. As discussed above, one of Ganz's goals is to create zones of coagulation that are not connected. In view of Ganz's disclosure of using a needle separation of less than 5 mm, and preferably less than 2 mm, it would have been obvious to increase the upper limit of Hantash '718 PCT's 0.5 mm to 1 mm needle separation range to be less than 5 mm, and preferably less than 2 mm. That would lead to a needle separation of 0.5 mm to less than 5 mm, or more preferably a needle separation of 0.5 mm to less than 2 mm, which is a range falling within the claimed 1.3 mm to 3.0 mm needle separation range.

6. Claim 8 of the '379 Patent is Anticipated by Ganz and/or obvious over Ganz alone and/or in combination with Hantash '718 PCT

341. As shown below, Ganz discloses or Ganz alone or in combination with ScarLet renders obvious "[t]he mammalian body treatment apparatus of claim 1, wherein the plurality of electrodes are non-insulated."

342. Specifically, Ganz discloses the option that "various portions of the proximal electrodes can also be insulated in order to limit the coagulation injury to the distal end of the electrode as well." *Id*., at [0056]. Thus, the default for Ganz is that the electrodes are not insulated. In view of the discussion above regarding the well-known use of non-insulated RF acupuncture needles, a POSITA would also know that the default for this type of needle electrodes is that the needles are not insulated.

> [0056] "In other embodiments, the electrodes are provided as a bipolar electrode arrangement. In bipolar electrode arrangements, both the positive and negative electrodes serve as treating electrodes. In some cases, the bipolar electrodes are bipolar axial interlaced finger electrodes. In embodiments wherein the electrodes are provided as electrode pairs, bipolar electrodes are desirable, with one electrode in the pair being a positive electrode and the other electrode being a negative electrode. The electrodes can be shaped in such a way that the middle portion of distal portion is enlarged in order to create a zone of injury that is greater at the distal end compared to the proximal end. The base of the treatment pad or treating surface and various portions of the proximal electrodes can also be insulated in order to limit the coagulation injury to the distal end of the electrode as well."

Accordingly, under Complainants' interpretation of "apply energy to body segments around each electrode rather than to body segments between the electrodes," and, to the extent that Complainant asserts that "to apply energy to body segments around each electrode rather than to body segments between the electrodes" has the same scope as "cause coagulation around each electrode rather than coagulating between the electrodes," recited in independent claim 1 of the '836 Patent, then Ganz anticipated claim 8, or Ganz in view of Hantash '718 PCT rendered obvious claim 8.

343. To the extent that Complainant asserts that Ganz does not disclose to use non-insulated electrodes, it would have been obvious to try non-insulated needles because there are only two options to try that would allow the needles to deliver RF energy to the skin: (1) non-insulated needles, and (2) partially insulated needles. It would have been routine experimentation to have tried these two options.

344. Alternatively, as discussed above in regard to limitation 1.2 above, Hantash '718 PCT discloses a mammalian body treatment apparatus that has a plurality of bipolar electrodes configured to be insertable into a body segment to be treated, and a radio frequency (RF) generation module, the RF generation module electrically coupled to the plurality of electrodes and configured to provide an RF signal with oscillating current to the plurality of electrodes.

345. Hantash '718 PCT discloses that "the needles 115 are 36-gauge electrically conductive needles," which "could be prepared by cutting commercially available long hypodermic needles." Hantash '718 PCT, at [0038]; *see also id*., at [0039] ("the needles 115 are pointed and made of a solid conductive material such as, for example, metal"), claim 5.

346. Accordingly, under Complainants' interpretation of "apply energy to body segments around each electrode rather than to body segments between the electrodes," and, to the extent that Complainant asserts that "to apply energy to body segments around each electrode rather than to body segments between the electrodes" has the same scope as "cause coagulation around each electrode rather than coagulating between the electrodes," recited in independent claim 1 of the '836 Patent, then Ganz in combination with the knowledge of a POSITA and/or Hantash '718 PCT rendered obvious claim 8.

7. Claim 9 of the '379 Patent is Anticipated by Ganz and/or obvious over Ganz alone and/or in combination with Hantash '718 PCT

347. As shown below, Ganz discloses or Ganz alone or in combination with ScarLet renders obvious "[t]he mammalian body treatment apparatus of claim 1, wherein each electrode of the plurality of electrodes is insulated except at its tip."

348. Specifically, Ganz disclosed an embodiment where the "various portions of the proximal electrodes can be insulated in order to limit the coagulation injury to the distal end of the electrode" *Id*., at [0056].

> [0056] "In other embodiments, the electrodes are provided as a bipolar electrode arrangement. In bipolar electrode arrangements, both the positive and negative electrodes serve as treating electrodes. In some cases, the bipolar electrodes are biopolar axial interlaced finger electrodes. In embodiments wherein the electrodes are provided as electrode pairs, biopolar electrodes are desirable, with one electrode in the pair being a positive electrode and the other electrode being a negative electrode. The electrodes can be shaped in such a way that the middle portion of distal portion is enlarged in order to create a zone of injury that is

> greater at the distal end compared to the proximal end. The base of the treatment pad or treating surface and various portions of the proximal electrodes can also be insulated in order to limit the coagulation injury to the distal end of the electrode as well."

349. A POSITA would have understood the distal end of the electrode to be the tip and the proximal end of the electrode to be the section of the electrode furthest from the tip. Therefore, a POSITA would have understood that Ganz disclosed an embodiment where the electrodes are insulated except at its tip (except at its distal end).

350. Accordingly, under Complainant's interpretation of "apply energy to body segments around each electrode rather than to body segments between the electrodes," and, to the extent that Complainant asserts that "to apply energy to body segments around each electrode rather than to body segments between the electrodes" has the same scope as "cause coagulation around each electrode rather than coagulating between the electrodes," recited in independent claim 1 of the '836 Patent, then Ganz anticipated claim 9 or Ganz in view of Hantash '718 PCT rendered obvious claim 9.

351. To the extent Complainant asserts that this limitation is not explicitly or inherently disclosed by Ganz or Ganz in view of Hantash '718 PCT, it would have also been obvious given the knowledge of a POSITA .

352. A POSITA would have understood that insulating the needle except for the tip is one way of preventing unwanted heating or lesions of the epidermis (when targeting the dermis with the tip). *See e.g.*, Ganz, at [0056]. Thus, it would have been desirable to use needle electrodes that are insulated except at the tip.

353. It would have also been obvious to try only insulating the needle except at its tip because in view of the discussion above regarding the use of insulated and non-insulated RF acupuncture needles, a POSITA would also know very well the two options to try that would

allow the needles to deliver RF energy to the skin via the tip of the needle: non-insulated needles, and partially insulated needles without any insulation on the tip.

354. Accordingly, under Complainants' interpretation of "apply energy to body segments around each electrode rather than to body segments between the electrodes," and, to the extent that Complainant asserts that "to apply energy to body segments around each electrode rather than to body segments between the electrodes" has the same scope as "cause coagulation around each electrode rather than coagulating between the electrodes," recited in independent claim 1 of the '836 Patent, then Ganz in view of Hantash '718 PCT rendered obvious claim 9.

8. Manstein Anticipates and/or Renders Obvious the Asserted Claims of the '379 Patent alone or in combination with Hantash '718 PCT and/or Ganz

355. The Asserted Claims of the '836 Patent are invalid under 35 U.S.C. § 102 (pre-AIA or AIA) as anticipated by Manstein and/or are invalid under 35 U.S.C. § 103 (pre-AIA or AIA) as obvious in view of Manstein alone (in view of the knowledge of a POSITA) or in combination with one or more other references identified herein and/or in Respondents' Invalidity Contentions, at least based on my understanding of Complainant's application of the asserted claims in an effort to show infringement.

356. U.S. Patent No. 7,824,394 to Manstein ("Manstein"), qualifies as prior art under at least AIA 35 U.S.C. § 102(a)(1) because it is a patent that published more than one year before the filing of the earliest application to which U.S. Patent No. 10,058,379 ("the '379 Patent") could claim priority.

357. To the extent that the '379 Patent is subject to pre-AIA law, Manstein qualifies as prior art under at least 35 U.S.C. § 102(b) because it is a patent that was filed prior to the alleged invention of the '379 Patent. Manstein also qualifies as prior art under at least 35

U.S.C. § 102(a) (pre-AIA) because it is a patent that was published prior to the alleged invention of the '379 Patent.

358. To the extent Complainant alleges that Manstein does not disclose any particular limitation of the asserted claims of the '379 Patent, either expressly or inherently, it would have been obvious to a POSITA as of the priority date of the '379 Patent to modify Manstein and/or to combine the teachings of Manstein with the knowledge of a POSITA and/or with PCT Patent Application Publication No. WO 2007/064718 ("Hantash '718 PCT").

359. Hantash '718 PCT qualifies as prior art under at least AIA 35 U.S.C. § 102(a)(1) because it is a patent that published before the filing of the earliest application to which U.S. Patent No. 10,058,379 ("the '379 Patent") could claim priority.

360. To the extent the '379 Patent is treated under pre-AIA law, Hantash '718 PCT qualifies as prior art under at least 35 U.S.C. § 102(b) (pre-AIA) because it was published more than one year before the filing of the earliest application to which the '379 Patent could claim priority.

361. Ganz, Hantash '718 PCT, and Manstein discuss or address the same or substantially similar underlying apparatus and/or technology in the field of dermatological treatment and devices such that a POSITA would have understood that these one or more of these references can be combined, according to known methods and/or by the simple substitution of one known, equivalent element for another, to yield predictable results and with a reasonable expectation of success. A POSITA would also have been motivated to combine one or more of these reference in light of market forces in the industry, and the desire to improve features and performance, and/or in light of one or more teachings, suggestions, or motivations in the art. A POSITA would have enjoyed a reasonable expectation of success in

combining and/or modifying the teachings of the foregoing prior art references and products, together with general knowledge of the art, to achieve the claimed subject matter, at least because the prior art itself discloses and/or practices the claimed methods and apparatuses to achieve the claimed results. A POSITA would have recognized that the relevant art is predictable, and that achieving the claimed subject matter requires merely routine optimization.

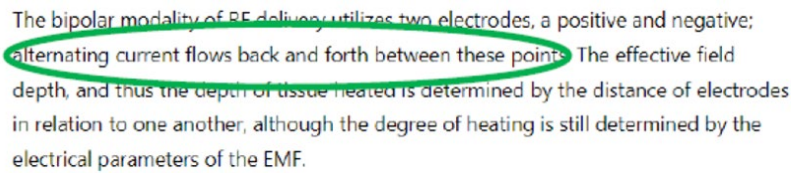
362. The asserted claims of the '379 Patent are invalid under 35 U.S.C. § 102 (AIA or pre-AIA) as anticipated by Manstein, and/or are invalid under 35 U.S.C. § 103 (AIA or pre-AIA) as obvious in view of Manstein alone, or in combination with one or more other references identified herein, at least based on Respondents' understanding of Complainant's application of the asserted claims in an effort to show infringement.

363. As shown below, under Complainant's interpretation of "apply energy to body segments around each electrode rather than to body segments between the electrodes," and, to the extent that Complainant asserts that "to apply energy to body segments around each electrode rather than to body segments between the electrodes" has the same scope as "cause coagulation around each electrode rather than coagulating between the electrodes," recited in independent claim 1 of the '836 Patent. Manstein anticipates claims 1, 2, 7, and 9, or renders obvious claims 1, 2, and 7-9. Further, Manstein, in view of Hantash '718 PCT, renders obvious claims 1, 2, 5, and 7-9.

9. Claim 1 of the '379 Patent is Anticipated by Manstein and/or obvious over Manstein alone and/or in combination with Hantash '718 PCT

364. It is my opinion that Manstein anticipates and/or Manstein alone and/or in combination with Hantash '718 PCT renders obvious claim 1 of the '379 Patent as detailed below.

'379 Patent Claim 1		Manstein alone and/or in combination with Hantash '718 PCT
1.0	A skin treatment apparatus, comprising:	Manstein discloses and/or renders obvious "a mammalian body treatment apparatus." *See, e.g.,* Manstein at Title, Abstract. Specifically, Manstein discloses a "[m]ethod and apparatus for dermatological treatment and tissue reshaping." Manstein, Title; *see also id*., at Abstract ("The present invention provides improved methods and apparatus for skin treatment and tissue remodeling.") A POSITA would have understood that the skin (body part) to be treated is the skin of a human (a type of mammal).
1.1	a plurality of electrodes, the electrodes being bipolar and configured to be insertable into a body segment to be treated; and	Manstein discloses and/or renders obvious a plurality of electrodes, the electrodes being bipolar and configured to be insertable into a body segment to be treated. *See, e.g.,* Manstein, at 4:24-28, 7:13-22, Fig. 4. Specifically, Manstein discloses inserting a plurality of needle electrodes 415 ("array of needles") "into a region of skin to a predetermined depth." Manstein at 4:22-24; *see also id*., at 7:13-22, Fig. 4. The electrodes can be bipolar. Manstein at 4:24-28 ("Radio frequency pulses of electrical current are then applied to one or more of the needles, which can function as electrodes in monopolar or bipolar modes to create regions of thermal damage and/or necrosis in the tissue surrounding the tips of the needles."); Manstein at 7:13-22. "Needles 410 and 415 are shown operating in bipolar mode in another embodiment of the present invention. Needle 410 is a positive electrode delivering RF or other current to the tip region of the needle from the energy source via conductor 430. Needle 415 functions as a grounding electrode that is connected to the ground of the energy source via conductor 431. In this configuration the applied current will travel through the tissue between the tips of the needles 410 and 415 generating an elongated region of thermal damage 425 around and between the tips of the two needles." Manstein at 7:13-22. Manstein also discloses providing a radio frequency (RF) signal to the electrode needles. Manstein at 7:13-22 ("Radio frequency pulses of electrical current are then applied to one or more of the needles, which can function as electrodes in monopolar or bipolar modes to create regions of thermal damage and/or necrosis in the tissue surrounding the tips of the needles."); *see also id*., at 5:42-44.

'379 Patent Claim 1		Manstein alone and/or in combination with Hantash '718 PCT
		It was well-known in the art that a radio frequency signal is a type of alternating current (AC). *Radiofrequency Catheter Ablation for Cardiac Tachyarrhythmias*, Manolis, A.S., *et al*., *Ann Intern Med.* (1994) 121:452-461 at 452. Complainant also appears to agree that an RF signal is a type of "alternating current." *See* Complainant's Final Infringement Contentions, Ex. 64, at 25; Ex. 76, at 14; Ex. 22, at 11.  The bipolar modality of RF delivery utilizes two electrodes, a positive and negative; alternating current flows back and forth between these points. The effective field depth, and thus the depth of tissue heated is determined by the distance of electrodes in relation to one another, although the degree of heating is still determined by the electrical parameters of the EMF. Complainant's Final Infringement Contentions, Ex. 64, at 25; Ex. 76, at 14 (emphasis in original) (citing SERENDIA-00006562 (Dermatology Time RF Webpage) at SERENDIA-00006565). It was well-known in the art that an alternating current (AC) is a current that alternates polarities. Thus, a POSITA would have understood that Manstein's bipolar electrodes change or alternate between being positive or negative (relatively to each other) as the alternating current alternates between them. Complainant appears to agree since alternating current flowing back and forth (to different directions) means that the current alternates polarities relative to the 2 poles of the generator (*i.e.*, the polarities dictate the direction, and, thus, if the direction changes, then the polarities change.) *See* Complainant's Initial Infringement Contentions, Ex. 71, at 21; ("the Accused Product is configured to provide a RF signal with oscillating current (as evidenced in green) to the plurality of electrodes"), Ex. 77, at 14 (alternating current flows back and forth between" electrodes) (citing SERENDIA-00006562 (Dermatology Time RF Webpage) at SERENDIA-00006565). Also, in its Markman brief, I understand Complainant took the position that an alternating current is synonymous with an oscillating current, which Complainant equates as a current that "alternates polarities." Complainant's Claim Construction Brief, at 67-68 ("Breaking down the claim language, it specifies that the 'current' alternates or oscillates, i.e., it alternates polarities."). Complainant then states that "alternating current" is "electric current that reverses direction periodically, usually many times per second, and also states that "'alternating current' 'usually means that the current changes polarity with time.'" Complainant's Claim Construction Brief, at 68[28]. In my opinion, an

[28] *See* my opinion refences in footnote 24 on page 131.

'379 Patent Claim 1		Manstein alone and/or in combination with Hantash '718 PCT
		alternating current is a kind of oscillating but both terms are not synonymous, that demonstrates that Complainant lacks expertise in the Art. Accordingly, there can be no dispute that when the RF signal (which is a type of AC signal) is applied to Manstein's electrodes, the electrodes change or alternate between being positive or negative as the current alternates between them.
1.2	a radio frequency (RF) generation module, the RF generation module electrically coupled to the plurality of electrodes and configured to provide an RF signal with oscillating current to the plurality of electrodes	Manstein discloses and/or renders obvious a radio frequency (RF) generation module, the RF generation module electrically coupled to the plurality of electrodes and configured to provide an RF signal with oscillating current to the plurality of electrodes. *See, e.g.*, Manstein, at 4:24-8, 5:42-44, 5:47-51. Specifically, Manstein discloses that "[r]adio frequency pulses of electrical current are then applied to one or more of the needles, which can function as electrodes in monopolar or bipolar modes to create regions of thermal damage and/or necrosis in the tissue surrounding the tips of the needles." Manstein at 4:24-8. "In one exemplary embodiment, the energy source 320 is a radio frequency (RF) device capable of outputting signals having frequencies in a desired range." Manstein at 5:42-44; *see also id*., at 5:47-51 ("The energy source 320 receives these setting, and generates a current directed to and from specified needles for selectable or predetermined durations, intensities, and sequences based on these settings"). It was well-known in the art that a radio frequency signal is a high-frequency (30 KHz to 300 MHz) alternating current (AC). *Radiofrequency Catheter Ablation for Cardiac Tachyarrhythmias*, Manolis, A.S., *et al.*, Ann Intern Med. (1994) 121:452-461 at 452. More precisely for surgical use 0.2 to 5 MHz *IEC 60601-2-2 section 201.8.4.102*. 200 KHz is the equivalent of 0.2 Mhz. Thus, radio frequency signals are measured in MHz.[29] As discussed above in regard to limitation 1.1, Complainant also appears to agree that an RF signal is a type of "alternating current." *See* Complainant's Final Infringement Contentions, Ex. 64, at 25; Ex. 76, at 14; Ex. 22, at 11. Complainant appears to agree since alternating current flowing back and forth (to different directions)

[29] '836 Patent, claim 22 depends from claim 14 (requiring "a[n] Alternating Current (AC) Radio Frequency (RF) signal). Claim 22 requires that "the RF is from 0.5 to 10 MHz." Thus, if 0.5 MHz is considered to be measured in MHz, then 0.03 MHz
is also measured in Mhz.

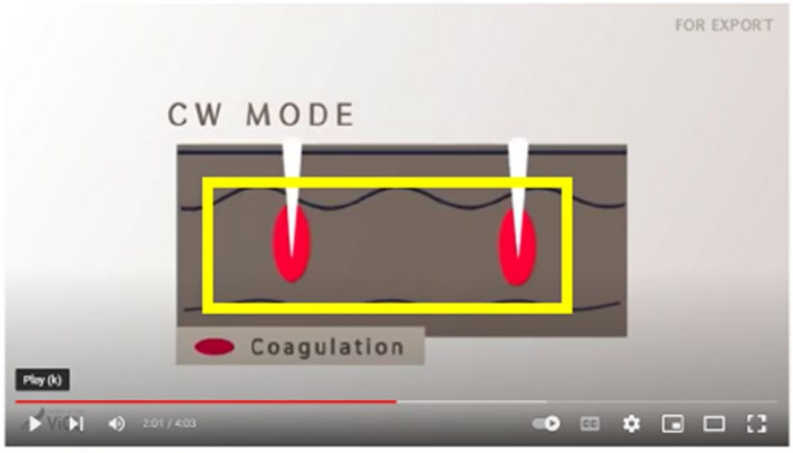
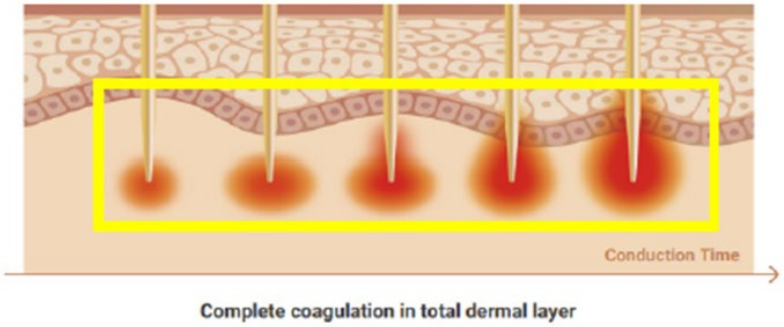
'379 Patent Claim 1		Manstein alone and/or in combination with Hantash '718 PCT
		means that the current alternates polarities (*i.e.*, the polarities dictate the current direction, and, thus, if the direction changes, then the polarities change.) Moreover, it was well-known in the art that an alternating current (AC) is an oscillating current with a neutral value of "zero Volts" that alternates polarities. Complainant appears to agree since alternating current flowing back and forth (to different directions) means that the current alternates polarities (*i.e.*, the polarities dictate the direction of the current, and, thus, if the direction changes, then the polarities change.) *See* Complainant's Initial Infringement Contentions, Ex. 71, at 21; ("the Accused Product is configured to provide a RF signal with oscillating current (as evidenced in green) to the plurality of electrodes"), Ex. 77, at 14 (alternating current flows back and forth between" electrodes) (citing SERENDIA-00006562 (Dermatology Time RF Webpage) at SERENDIA-00006565). Also, in its Markman brief, I understand that Complainant took the position that an alternating current is synonymous with an oscillating current, which Complainant equates as a current that "alternates polarities." Complainant's Claim Construction Brief, at 67-68 ("Breaking down the claim language, it specifies that the 'current' alternates or oscillates, i.e., it alternates polarities."). Complainant then states that "alternating current" is "electric current that reverses direction periodically, usually many times per second, and also states that "'alternating current' 'usually means that the current changes polarity with time.'" Complainant's Claim Construction Brief, at 68. In my opinion, alternating current is a type of oscillating current, but the two terms are not synonymous; that demonstrates that Complainant lacks expertise in the Art. Therefore, because Manstein provides a radio frequency (RF) signal to the electrodes, Manstein discloses providing an electrical signal with oscillating current (current alternating polarities) and having a radio frequency (measured in MHz). Accordingly, Manstein discloses that the RF generation module electrically is coupled to the plurality of electrodes and configured to provide an RF signal with oscillating current to the plurality of electrodes. To the extent that Complainant asserts that RF signals do not inherently have frequencies measured in MHz and/or that Manstein does not disclose an RF signal having a frequency measured in

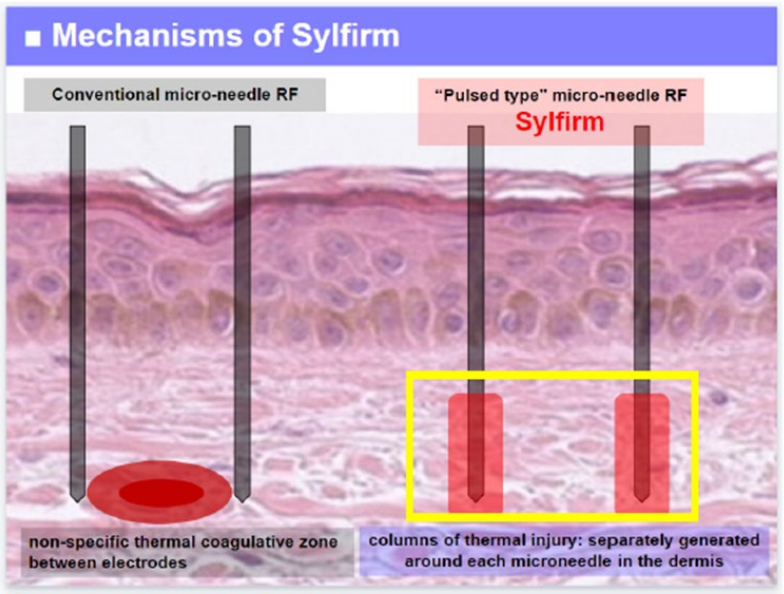
'379 Patent Claim 1		Manstein alone and/or in combination with Hantash '718 PCT
		MHz[30], it would have further been obvious given the knowledge of a POSITA and/or in further view of Hantash '718 PCT. For example, Hantash '718 PCT also discloses a mammalian body treatment apparatus. Hantash '718 PCT, Title ("Method and apparatus for micro-needle array electrode treatment of tissue"); Abstract ("system and method for revitalizing aging skin"); [0002]; [0013]; [0014]; [0021]; Fig. 1; claim 1 (for "human skin"). Hantash '718 PCT's device also has a plurality of bipolar electrodes configured to be insertable into a body segment to be treated, and a radio frequency (RF) generation module, the RF generation module electrically coupled to the plurality of electrodes and configured to provide an RF signal with oscillating current to the plurality of electrodes. Hantash '718 PCT, at [0035], *see also id*., at Abstract, [0002] ("biological tissue treatment using electromagnetic energy delivered through an array of needle electrode [electrodes]"), [0012], [0013], [0014], [0017] ("the microneedles are driven into the tissue"), [0021], [0034] ("a radio frequency (RF) source 110 is [electrically] connected to an array of needles 115" to deliver energy to the skin 150 via the array of needle electrodes 115"), [0035] ("While the needles 115 are located within the skin 150, they can be powered by the RF source 110"), [0039] ("each of the needles 115 can comprise an electrically conductive shaft"), [0040] ("bipolar" electrodes), [0047] ("One array includes all of the negative polarity needles 116 (return electrodes) and the other includes all of the positive polarity needles 117 (active electrodes)"), [0055], [0057] ("electrically connecting the needles 116 and 117 at the opposite ends of each local region of skin 150 to be treated to different poles of the RF source 110"), [0061], [0068]-[0070], [0079] ("bipolar") Figs. 1, 3A, claims 1, 37, 42. Hantash '718 PCT gives examples of using RF signals having a frequency measured in MHz. Hantash '718 PCT, at [0040] ("frequency of the RF source can be chosen to be about 6.78 MHz or about 13.56 MHz," "from 0.1 to 10 MHz or from 0.4 to 3 MHz"), [0077], [0079]. A POSITA would have known that "[t]he frequency range of the RF source can be chosen in combination with other parameters based on the desired treatment zone profile including for example treatment

[30] The unit used to measure the frequency is not an indictor with whether it is within the RF range. As am example, a signal of 5.10^{-5}MHz is actually 50 Hz, the frequency of the AC signal in the US main outlets. The "M" before Hz, (Mega) means 1 million or 10^6, so 1 MHz = 10^6Hz or 10^3 KHz. So, a 10 MHz signal can also be measured in KHz. Most High Frequency electrosurgical systems measure the RF frequency KHz.

'379 Patent Claim 1		Manstein alone and/or in combination with Hantash '718 PCT
		zone size, treatment zone shape, treatment zone aspect ratio, and treatment zone spacing" based on the intended application. Hantash '718 PCT, at [0040]; *see also* [0052] ("With the proper choice of parameters, the treatment can be self limiting to create treatment zones 160 of approximately uniform size across the treatment pattern 161. The self limiting nature of the treatment can be achieved by choosing the frequency of the RF source 110 to be a frequency for which the tissue resistivity (impedance) increases as the tissue is treated."); [0079]. Moreover, it was well known that it is safer and more desirable to create discrete small coagulation zones rather than larger connected coagulation zones so that the surrounding area is spared from damage and can assist with the healing process, which makes the healing process more through and faster as compared to continuous coagulation zones. Hantash '718 PCT, at [0058]. The undamaged tissue can assist in the healing process for the treated zones. *Id*. Optimization of parameters, such as the RF frequency, power, energy, voltage, timing duty cycle applied to microneedles, requires a significant amount of experimentation; however, the experimental methodology to achieve unconnected coagulation zones is obvious to a POSITA, and the selection of the RF frequency is a design choice that would have then become obvious to a POSITA. Therefore, a POSITA would have been motivated to use an RF frequency measured in MHz, in the order of 0.1 to 5-10 MHz like in Hantash '718 PCT. Accordingly, Manstein in view of Hantash '718 PCT also discloses a radio frequency (RF) generation module, the RF generation module electrically coupled to the plurality of electrodes and configured to provide an RF signal with oscillating current to the plurality of electrodes.
1.3	to apply energy to body segments around each electrode rather than to body segments between the electrodes.	As shown below, under Complainant's interpretation, Manstein discloses and/or renders obvious to apply energy to body segments around each electrode rather than to body segments between the electrodes. *See, e.g.*, Manstein, at 4:7-11, 4:24-28, 6:23-26, 6:36-38, 7:13-26, 8:6-9, Fig. 3. "One method in accordance with the present invention comprises inserting an array of needles into a region of skin to a predetermined depth. Radio frequency pulses of electrical current are then applied to one or more of the needles, which

'379 Patent Claim 1		Manstein alone and/or in combination with Hantash '718 PCT
		can function as electrodes in monopolar or bipolar modes to create regions of thermal damage and/or necrosis in the tissue Surrounding the tips of the needles." *id. at:* 4:23-29 I understand that, in its attempt to argue claims are patent eligible, Complainant has argued that the independent claims recite "limitations that would be needed to produce the desired result" (apply energy to body segments around each electrode rather than to body segments between the electrodes" because "claim 10 of the '379 Patent requires inserting a plurality of electrodes into a body segment to be treated where the electrodes are bipolar and applying an RF signal with oscillating current to the plurality of electrodes." Complainants' Initial Validity Contentions, at 407-408. As show above, in regard to limitation "a plurality of electrodes, the electrodes being bipolar and configured to be insertable into a body segment to be treated," Manstein discloses inserting a plurality of electrodes into a body segment to be treated where the electrodes are bipolar. As shown above, in regard to limitation, "a radio frequency (RF) generation module, the RF generation module electrically coupled to the plurality of electrodes and configured to provide an RF signal with oscillating current to the plurality of electrodes," under Complainant's and Staff's proposed construction for RF signal with oscillating current, Manstein discloses applying an RF signal with oscillating current to the plurality of electrodes. Therefore, Complainant asserted that Manstein discloses the limitations that would be needed to apply energy to body segments around each electrode rather than to body segments between the electrodes. Thus, Complainant has essentially taken the position that Manstein discloses to apply energy to body segments around each electrode rather than to body segments between the electrodes under Complainant's and Staff's proposed construction for RF signal with oscillating current. Accordingly, based on Complainant's arguments discussed above, Manstein anticipates claim 1, or Manstein in view of Hantash '718 PCT renders obvious claim 1. Additionally, Complainant appears to assert that "to apply energy to body segments around each electrode rather than to body segments between the electrodes" has the same scope as "cause coagulation

'379 Patent Claim 1	Manstein alone and/or in combination with Hantash '718 PCT
	around each electrode rather than coagulating between the electrodes," recited in independent claim 1 of the '836 Patent, then Manstein discloses or renders this obvious. For example, in its domestic industry claim charts for the '379 Patent, Complainant ignores the language of "energy" and instead asserts this limitation is met by coagulation appearing only around electrodes but not being connected between electrodes: > In the Domestic Industry Product, the RF generation module along with the plurality of electrodes is configured to apply energy to body segments around each electrode rather than to body segments between the electrodes (as shown below in yellow). Complainant's Final Infringement Contentions, Ex. 107, at pg. 23.  SERENDIA-00007811. *Id.*, at 24.  SERENDIA-00022192 at SERENDIA-00022193, 5.

'379 Patent Claim 1	Manstein alone and/or in combination with Hantash '718 PCT
	Id., at 25.  VIOL-00000321 at VIOL-00000345. *Id.*, at 25. Therefore, to the extent that Complainant is asserting that "to apply energy to body segments around each electrode rather than to body segments between the electrodes" has the same scope as "cause coagulation around each electrode rather than coagulating between the electrodes," recited in independent claim 1 of the '836 Patent, then Manstein discloses or renders this obvious for the reasons. *See, e.g.,* *See* Figure 3 of Manstein. "Electromagnetic radiation is directed to portions of a target area within the skin or deeper tissue using minimally invasive methods, causing fractional wounding of the portions of the target area." Manstein at 4:7-11. "Radio frequency pulses of electrical current are then applied to one or more of the needles, which can function as electrodes in monopolar or bipolar modes to create regions of thermal damage and/or necrosis in the tissue surrounding the tips of the needles." Manstein at 4:24-28. "In the apparatus of FIG. 3, application of RF current to the needles 350 causes heating in the exposed tip region, inducing thermal damage regions 370 around the tip of each needle." Manstein at 6:23-26. "Needles 410 and 415 are shown operating in bipolar mode in another embodiment of the present invention. Needle 410 is a positive electrode delivering RF or other current to the tip region of the needle from the energy source via conductor 430." Manstein at 7:13-26. "In

'379 Patent Claim 1		Manstein alone and/or in combination with Hantash '718 PCT
		any array geometry, the pattern of damage and resultant tissue reshaping may be controlled with some precision by adjusting the intensity and duration of power transmitted to single needles or pairs of needles." Manstein at 8:6-9.

10. Claim 2 of the '379 Patent is Anticipated by Manstein and/or obvious over Manstein alone and/or in combination with Hantash '718 PCT

365. Manstein discloses and/or renders obvious "[t]he mammalian body treatment apparatus of claim 1, wherein the RF generation module is configured to provide an RF signal to the plurality of electrodes." *See, e.g.,* Manstein at 5:42-44, 5:47-51.

366. Specifically, Manstein disclosed that "the energy source 320 is a radio frequency (RF) device capable of outputting signals having frequencies in a desired range." Manstein at 5:42-44. *See also id*., at 5:47-51 ("The energy source 320 receives these setting, and generates a current directed to and from specified needles for selectable or predetermined durations, intensities, and sequences based on these settings").

367. Manstein discloses and/or renders obvious applying the RF signal for a predetermined time interval. *See, e.g.*, Manstein, at 5:47-51; 8:6-9. Specifically, Manstein discloses applying the energy to the needles for "predetermined durations" (predetermined time intervals). Manstein at 5:47-51 ("The energy source 320 receives these setting, and generates a current directed to and from specified needles for selectable or **predetermined durations**, intensities, and sequences based on these settings") (emphasis added); *see also id*., at 8:6-9 ("In any array geometry, the pattern of damage and resultant tissue reshaping may be controlled with some precision by adjusting the intensity and **duration of power transmitted** to single needles or pairs of needles") (emphasis added.)

11. Claim 5 of the '379 Patent is Anticipated by Manstein and/or obvious over Manstein alone and/or in combination with Hantash '718 PCT

368. Manstein in view of the knowledge of a POSITA and/or Hantash '718 PCT renders obvious "[t]he skin treatment apparatus of claim 1, wherein the closest neighboring electrodes have opposite polarities." *See, e.g.*, Manstein, at 7:13-22, Fig. 4.

> "Needles 410 and 415 are shown operating in bipolar mode in another embodiment of the present invention. Needle 410 is a positive electrode delivering RF or other current to the tip region of the needle from the energy source via conductor 430. Needle 415 functions as a grounding electrode that is connected to the ground of the energy source via conductor 431. In this configuration of 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." Manstein at 7:13-22.

369. It would have been an obvious design choice for a POSITA as of the priority date of the '379 Patent to modify Manstein in view of Hantash to use an electrode configuration where the closest neighboring electrodes have opposite polarities. The '379 Patent does not explain that there is any benefit to such a configuration as opposed to a configuration where, for example, a positive electrode is equally close to one or more negative electrodes and one or more positive electrodes. A POSITA understands that having an electrode surrounded by electrodes of opposite polarities as their closet neighbors would make the electrical field more symmetrical and create a lesion (zone of coagulation) with a more symmetrical or "circular" cross section.

370. Nor does the '379 Patent disclose that the claimed configuration of electrodes is part of how one achieves applying energy to body segments around each electrode rather than to body segments between the electrodes. To the extent Complainant argues there is a benefit for arranging the neighboring electrodes to have opposite polarities, optimization, through routine experimentation, of the arrangement of opposite polarity electrodes in an electrode array was obvious to a POSITA.

371. For example, as discussed above, Hantash '718 PCT discloses a mammalian body treatment apparatus that has a plurality of bipolar electrodes configured to be insertable into a body segment to be treated, and a radio frequency (RF) generation module, the RF generation module electrically coupled to the plurality of electrodes and configured to provide an RF signal with oscillating current to the plurality of electrodes.

372. Hantash '718 PCT discloses that the closest neighboring electrodes have opposite polarities. For example, as shown in Fig. 3A reproduced below, and Fig. 3B, the closest neighboring electrodes have opposite polarities. Hantash '718 PCT, at [0047] ("One array includes all of the negative polarity needles 116 (return electrodes) and the other includes all of the positive polarity needles 117 (active electrodes). In FIG 3, the negative[31] needles 116 are open and the positive needles 117 are shaded."), [0051] ("FIG 4 A shows the treatment zones 160 that are created between nearest neighbor needles 115 that are connected to opposite poles of the RF source 110"), *see also id*., claims 15, 17 ("wherein the needles are spaced further apart in one direction compared to the other direction on the grid"), Fig. 5A.

[31] Negative or Positive electrode naming is a convention, as in an RF generator, the output current is alternating, and there is no actual positive or negative electrode, as they alternate hundreds of thousands or millions of time per second. We can call an electrode " positive" as a specific time, knowing that less than a few microsecond later, it will change again.

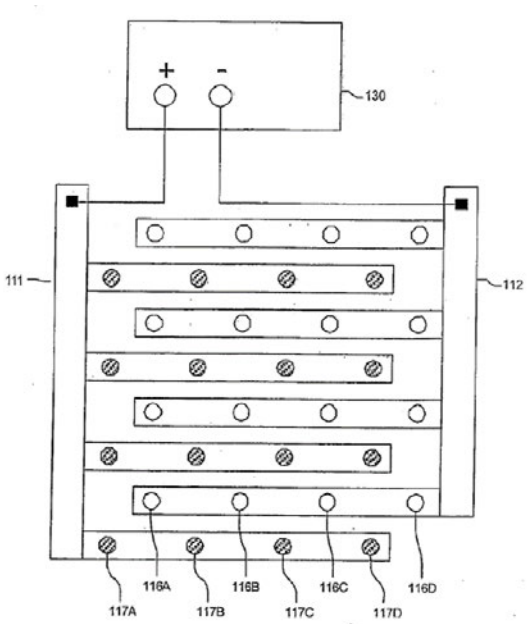


Figure 3A

Id., Fig. 3A.

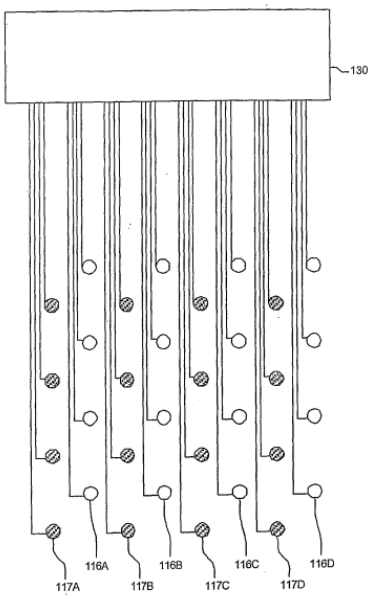


Figure 3B

Id., Fig. 3B

373. For example, as can be seen in Fig. 3A and 3B, the closest electrodes to any given negative electrode (open circle) are positive electrodes (shaded circle). *Id.*, at [0047]. In this example, the four shaded electrodes (positive) from a square, and the non-shaded (negative) electrode is in the center of the square. If the distance between the each of the 4 shaded electrodes is "a", then the distance "D" between the non-shaded electrode and any of the neighboring shaded electrode is given by the formula (1/2 the diagonal of a square): $D = \frac{a*\sqrt{2}}{2} = \frac{a*1.414}{2} = 0.707a$. Therefore, the distance between the electrode of opposite polarities is 30% shorter than the distance between the electrodes of same polarities.

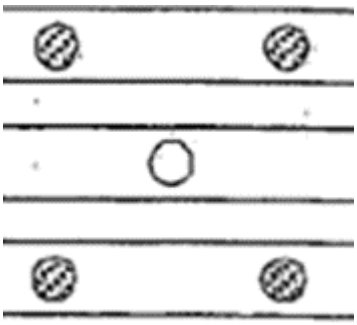


Fig. 3A, excerpt

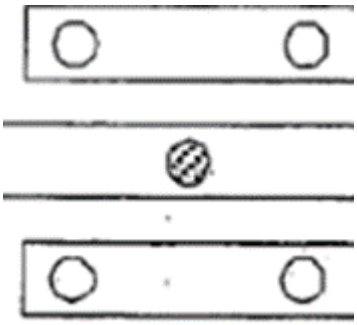


Fig. 3A, excerpt

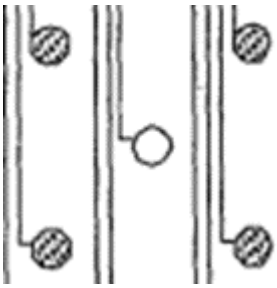


Fig. 3B, excerpt

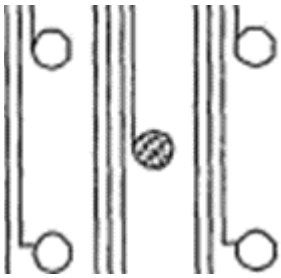


Fig. 3B, excerpt

374. It would have been obvious design choice for a POSITA as of the priority date of the '379 Patent to modify Manstein in view of Hantash '718 PCT to use an electrode configuration where the closest neighboring electrodes have opposite polarities. As explained above, the '379 Patent does not explain that there is any benefit to such a configuration as opposed to a configuration where, for example, a positive electrode is equally close to one or more negative electrodes and one or more positive electrodes. Nor does the '379 Patent disclose that the claimed configuration of electrodes is part of how one achieves applying energy to body segments around each electrode rather than to body segments between the electrodes. To the extent Complainant argues there is a benefit for arranging the neighboring electrodes to have opposite polarities, optimization, through routine experimentation, of the arrangement of opposite polarity electrodes in an electrode array was obvious to a POSITA.

375. Accordingly, under Complainant's interpretation of "apply energy to body segments around each electrode rather than to body segments between the electrodes," and, to the extent that Complainant asserts that "to apply energy to body segments around each electrode rather than to body segments between the electrodes" has the same scope as "cause coagulation around each electrode rather than coagulating between the electrodes," recited in independent claim 1 of the '836 Patent, then Manstein in view of Hantash '718 PCT also rendered obvious claim 5.

12. Claim 7 of the '379 Patent is Anticipated by Manstein and/or obvious over Manstein alone and/or in combination with Hantash '718 PCT

376. Manstein discloses and/or renders obvious "[t]he mammalian body treatment apparatus of claim 1, wherein the closest neighboring electrodes are separated by a distance of 1.3 mm to 3.0 mm." *See, e.g.*, Manstein at 7:61-64.

377. Specifically, Manstein discloses that "[t]he spacing between adjacent needles is preferably greater than about 1 mm apart, and may be as large as about 2 cm," and that "[t]he needle arrays may have any geometry appropriate for the desired treatment being performed. Manstein at 7:61-64.

378. Thus, Manstein's disclosed range for the spacing between adjacent needle electrodes overlaps or encompasses the claimed range of 1.3 mm to 3.0 mm. However, the '379 Patent fails to support the criticality of the claimed separation distance. Among other things, the specification purports to include a formula for calculating electrode separation distance, but the formula is nonsensical. The claimed separation distances add nothing of patentable significance.

379. Therefore, under Complainant's interpretation of "apply energy to body segments around each electrode rather than to body segments between the electrodes," and, to

the extent that Complainant asserts that "to apply energy to body segments around each electrode rather than to body segments between the electrodes" has the same scope as "cause coagulation around each electrode rather than coagulating between the electrodes," recited in independent claim 1 of the '836 Patent, then Manstein anticipated or rendered obvious claim 7 or Manstein in view of Hantash '718 PCT rendered obvious claim 7.

380. Optimization, through routine experimentation, of the spacing of the needle electrodes as a function of electrodes dimension and other electrical parameters to create a desired effect was also within the capabilities of a POSITA. Moreover, the spacing of the needles within a range of 1.3 mm to 3.0 mm is a design choice that would have been obvious to a POSITA.

13. Claim 8 of the '379 Patent is Anticipated by Manstein and/or obvious over Manstein alone and/or in combination with Hantash '718 PCT

381. Manstein alone, or in further view of Hantash '718 PCT renders obvious "[t]he mammalian body treatment apparatus of claim 1, wherein the plurality of electrodes are non-insulated."

382. Manstein discloses that the electrodes are made of a conductive material in claim 2 and in 10:1-4 "The apparatus of paragraph 1 wherein one or more of the needles are electrically conductive and the energy source is configured to supply RF current individually to one or more of the needles."

383. As discussed above, Manstein's needle electrodes are designed to deliver RF energy to the skin. It would have been obvious to try non-insulated needle electrodes because in view of what is discussed in Section VII. regarding the use of non-insulated RF acupuncture needles it is the simplest option among the two options to try that would allow the needle electrodes to deliver RF energy to the skin: (1) non-insulated needles, and (2) partially insulated

needles. It would have been routine experimentation to have tried these two options and various coverages of insulation. A good engineer always tries to remove excess parts or processes, and removing the insulation process on the needles would be obvious to a POSITA.

384. Alternatively, as discussed above in regard to limitation 1.2 above, Hantash '718 PCT discloses a mammalian body treatment apparatus that has a plurality of bipolar electrodes configured to be insertable into a body segment to be treated, and a radio frequency (RF) generation module, the RF generation module electrically coupled to the plurality of electrodes and configured to provide an RF signal with oscillating current to the plurality of electrodes.

385. Hantash '718 PCT discloses that "the needles 115 are 36-gauge electrically conductive needles," which "could be prepared by cutting commercially available long hypodermic needles." Hantash '718 PCT, at [0038]; *see also id*., at [0039] ("the needles 115 are pointed and made of a solid conductive material such as, for example, metal"), claim 5.

386. Accordingly, under Complainants' interpretation of "apply energy to body segments around each electrode rather than to body segments between the electrodes," and, to the extent that Complainant asserts that "to apply energy to body segments around each electrode rather than to body segments between the electrodes" has the same scope as "cause coagulation around each electrode rather than coagulating between the electrodes," recited in independent claim 1 of the '836 Patent, then Manstein in combination with the knowledge of a POSITA and/or Hantash '718 PCT rendered obvious claim 8.

14. Claim 9 of the '379 Patent is Anticipated by Manstein and/or obvious over Manstein alone and/or in combination with Hantash '718 PCT

387. Manstein discloses "[t]he mammalian body treatment apparatus of claim 1 each electrode of the plurality of electrodes is insulated except at its tip." *See, e.g.*, Manstein at col. 6 lines 21-23 ("In a preferred embodiment of the present invention, the shafts of conductive

needles 350 are electrically **insulated except for the portion of the needle near the tip**") (emphasis added); Manstein at 7:1-3 ("Insulation 420 covers the shaft of needles 410 and 415 protruding from base 310 **except for the region near the lower tip**, and electrically insulates each conductive needle shaft from surround tissue 305"), (emphasis added).

388. Accordingly, under Complainants' interpretation of "apply energy to body segments around each electrode rather than to body segments between the electrodes," and, to the extent that Complainant asserts that "to apply energy to body segments around each electrode rather than to body segments between the electrodes" has the same scope as "cause coagulation around each electrode rather than coagulating between the electrodes," recited in independent claim 1 of the '836 Patent, then Manstein anticipated claim 9 or Manstein in view of Hantash '718 PCT rendered obvious claim 9.

C. The Asserted Claims of the '444 Patent are Anticipated or Rendered Obvious by the Prior Art

389. The Asserted Claims of the '444 Patent are invalid under 35 U.S.C. § 102 (pre-AIA or AIA) as anticipated by Ganz, and/or are invalid under 35 U.S.C. § 103 (pre-AIA or AIA) as obvious in view of Ganz alone (in view of the knowledge of a POSITA), or in combination with one or more other references identified herein and/or in Respondents' Invalidity Contentions, at least based on Respondents' understanding of Complainant's application of the asserted claims in an effort to show infringement.

390. U.S. Patent Publication No. 2007/0208340A1 ("Ganz") anticipates and/or renders each and every limitation of the '444 Patent's Asserted Claims obvious.

391. Ganz qualifies as prior art qualifies under at least 35 U.S.C. § 102(a)(1) (AIA) because it was published prior to the earliest possible priority date of the '444 Patent. To the extent that the '444 Patent is subject to pre-AIA law, Ganz qualifies as prior art under at least 35

U.S.C. § 102(b) (pre-AIA) because it is a patent that published more than one year before the filing of the earliest application to which the '444 Patent could claim priority. Ganz also qualifies as prior art under at least 35 U.S.C. § 102(a) (pre-AIA) because it is a patent that was published prior to the alleged invention of the '444 Patent.

392. Ganz in view of the knowledge of a POSITA renders each and every limitation of the '444 Patent's Asserted Claims obvious. A POSITA would have understood that any limitations in the Asserted Claims arguably not explicitly disclosed by Ganz were obvious in view of the state of the relevant art. A POSITA would have been motivated to draw upon his or her knowledge of the relevant art to modify Ganz as necessary to achieve any of the claimed features and would have enjoyed a reasonable expectation of success in doing so. A POSITA would have enjoyed a reasonable expectation of success in combining and/or modifying the teachings of the foregoing prior art references and products, together with general knowledge of the art, to achieve the claimed subject matter, at least because the prior art itself discloses and/or practices the claimed methods and apparatuses to achieve the claimed results. A POSITA would have recognized that the relevant art is predictable, and that achieving the claimed subject matter would have been obvious to try or requires merely routine optimization.

393. To the extent Complainant alleges that Ganz does not disclose any particular limitation of the '444 Patent's Asserted Claims, either expressly or inherently, it would have been obvious to a POSITA as of the priority date of the '444 Patent to modify Ganz and/or combine the teachings of Ganz with the knowledge of a POSITA and/or with one or more of PCT Patent Application Publication No. WO 2007/064718 ("Hantash '718 PCT"), ScarLet product manufactured by ViOL, Korea ("ScarLet"), and The DeÁge product manufactured by

Dashin Enterprise, Korea ("DeÁge") in a manner that would have rendered the Asserted Claims invalid as obvious.

394. Hantash '718 PCT qualifies as prior art qualifies under at least 35 U.S.C. § 102(a)(1) (AIA) because it was patent published prior to the earliest possible priority date of the '444 Patent.

395. To the extent that the '444 Patent is subject to pre-AIA law, Hantash '718 PCT qualifies as prior art under at least 35 U.S.C. § 102(b) (pre-AIA) because it is a patent that published more than one year before the filing of the earliest application to which the '444 Patent could claim priority.

396. ScarLet qualifies as prior art under at least 35 U.S.C. § 102(a)(1) (AIA) because it is a product that was in public used, on sale, or otherwise available to the public before the effective filing date of the claimed invention to which the '444 Patent could claim priority. *See, e.g.*, Ilooda-0005923 (Shim 2010_DKU Thesis 2010.12.01), Ilooda-0006075 (ScarLet intro), Ilooda-0006078 (#13_(Eng)_Shim 2010_DKU Thesis Dec 1 2010_Translated_Certified), Ilooda-0006210 (5-1. 스칼렛최초허가), Ilooda-0006533 (Naver Blog The H Jan 10 2011), Ilooda-0006719 (#19-1_Naver Blog The H Jan 10 2011_Translated_Certified), Ilooda-0006770 (#18_D&PS Monthly Sept 2010_Translated_Certified), Ilooda-0006827 (D&PS Monthly September 2010), Ilooda-0008178 and translation thereof (Ilooda-0011601), Ilooda-0009318, Ilooda-0009319, Ilooda-0009322, Ilooda-0009339, Ilooda-0009669, Ilooda-0009673, Ilooda-0009678, Ilooda-0009791, Ilooda-0009795, Ilooda-0010031, Ilooda-0010042, SERENDIA-00017276, SERENDIA-00017306, SERENDIA-00031579, SERENDIA-00033637, SERENDIA-00033705, SERENDIA-00036286, SERENDIA-00052450, SERENDIA-00061017, SERENDIA-00066746, SERENDIA-00075908, and SERENDIA-00081664.

397. To the extent that the '444 Patent is subject to pre-AIA law, ScarLet qualifies as prior art under at least pre-AIA 35 U.S.C. § 102(a) because it is a product that was in public used, on sale, or otherwise available to the public in the United States before the effective filing date of the claimed invention to which the '444 Patent could claim priority. *See, e.g.*, Ilooda-0005923 (Shim 2010_DKU Thesis 2010.12.01), Ilooda-0006075 (ScarLet intro), Ilooda-0006078 (#13_(Eng)_Shim 2010_DKU Thesis Dec 1 2010_Translated_Certified), Ilooda-0006210 (5-1. 스칼렛 최초허가), Ilooda-0006533 (Naver Blog The H Jan 10 2011), Ilooda-0006719 (#19-1_Naver Blog The H Jan 10 2011_Translated_Certified), Ilooda-0006770 (#18_D&PS Monthly Sept 2010_Translated_Certified), Ilooda-0006827 (D&PS Monthly September 2010), Ilooda-0008178 and translation thereof (Ilooda-0011601), Ilooda-0009318, Ilooda-0009319, Ilooda-0009322, Ilooda-0009339, Ilooda-0009669, Ilooda-0009673, Ilooda-0009678, Ilooda-0009791, Ilooda-0009795, Ilooda-0010031, Ilooda-0010042, SERENDIA-00017276, SERENDIA-00017306, SERENDIA-00031579, SERENDIA-00033637, SERENDIA-00033705, SERENDIA-00036286, SERENDIA-00052450, SERENDIA-00061017, SERENDIA-00066746, SERENDIA-00075908, and SERENDIA-00081664.

398. [redacted]

[redacted]

399. To the extent that the ‘444 Patent is subject to pre-AIA law, [redacted]

400. Ganz, Hantash ‘718 PCT, ScarLet, and DeÁge discuss or address the same or substantially similar underlying apparatus and/or technology in the field of dermatological treatment and devices such that a POSITA would have understood that these one or more references can be combined, according to known methods and/or by the simple substitution of

one known, equivalent element for another, to yield predictable results and with a reasonable expectation of success. A POSITA would also have been motivated to combine one or more of these reference in light of market forces in the industry, and the desire to improve features and performance, and/or in light of one or more teachings, suggestions, or motivations in the art. A POSITA would have enjoyed a reasonable expectation of success in combining and/or modifying the teachings of the foregoing prior art references and products, together with general knowledge of the art, to achieve the claimed subject matter, at least because the prior art itself discloses and/or practices the claimed methods and apparatuses to achieve the claimed results. A POSITA would have recognized that the relevant art is predictable, and that achieving the claimed subject matter requires merely routine optimization.

401. As shown below, under Complainant's interpretation of "plurality of electrodes" (Complainant's interpretation does not require non-insulated electrodes), "RF signal with oscillating current" (Complainant's interpretation requires a current oscillating polarities and having a radio frequency), "energy to be substantially applied to body segments" (Complainant's interpretation requires energy around each electrodes as opposed to between electrodes), the Asserted Claims of the '444 Patent are invalid for at least the following reasons:

- Ganz anticipates claims 1, 4, 8, and 9;
- Ganz renders obvious claims 1, 8, and 9;
- Ganz in view of ScarLet renders obvious claim 1, 4, 8, and 9.
- Ganz in view of ScarLet anticipates claim 1.
- Ganz in view of Hantash '718 PCT renders obvious claims 2 and 7;
- Ganz in view of ScarLet and in further view of Hantash '718 PCT renders obvious claims 2 and 7;

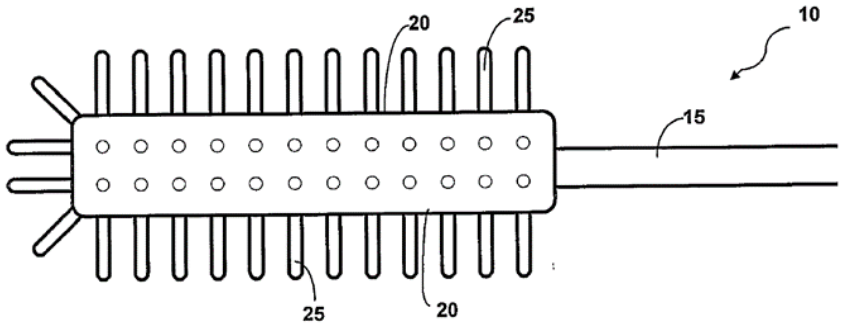
- Ganz in view of Hantash '718 PCT and in further view of ScarLet and/or DeÁge renders obvious claim 5; and/or
- Ganz in view of Hantash '718 PCT and in further view of ScarLet renders obvious claim 6.

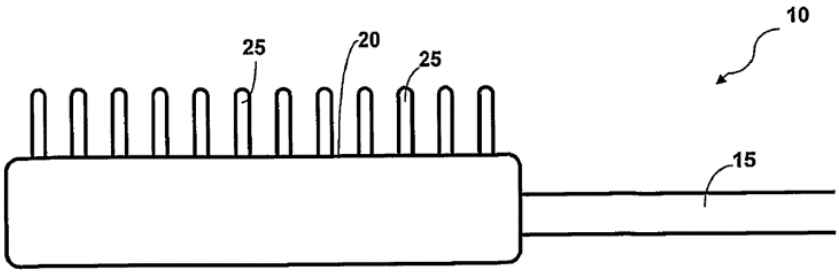
402. I reserve the right to amend or supplement the claim charts set forth below at a later date for the reasons discussed below.

1. Claim 1 of the '444 Patent *is Anticipated by Ganz and/or Obvious in view of Ganz alone and/or in combination with ScarLet*

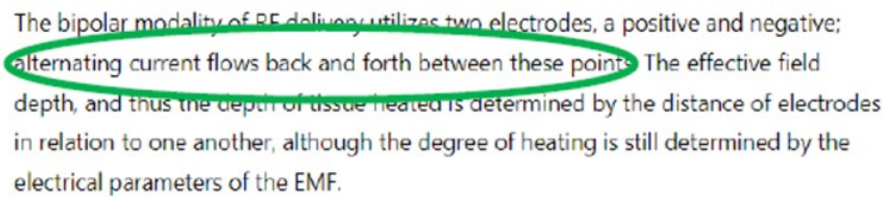
403. Claim 1 of the '444 Patent is anticipated by Ganz and/or obvious in view of the teachings of Ganz alone and/or in view of ScarLet:

'444 Patent Claim 1		Ganz alone and/or in combination with ScarLet
1.0	A mammalian body treatment apparatus, comprising:	Ganz discloses a mammalian body treatment apparatus according to the claim. *See, e.g.*, Specifically, Ganz discloses "a **device** and method for treating one or more layers of [skin] tissue," of a human. Ganz at [0001] (emphasis added); *see also id.*, [00016] ("[A] method for **treating human skin**[.]") (emphasis added); [0027], [0029], [0030]; Ganz claim 24 (claiming a method to treat human skin). Claims 1, 21, and 22 in Ganz recite tissue in general without limiting the tissue to a specific type of tissue, and therefore this could apply to any part of the body. *See* Ganz, Claims 1, 21, and 22. As disclosed in Ganz, the apparatus is intended to be used on human skin. The skilled artisan would recognize that: a human is a type of mammal, and the skin is a part of the body. One embodiment of Ganz's treatment apparatus, reproduced below, included a "treatment device having a plurality of electrode pins," which included "RF energy [] delivered to the electrodes" to create perforations in the skin. *Id.* at [0045], [0058]; *see also id.* at [0033] ("The treatment device includes a treating surface, which is adapted to be placed in direct contact with a tissue adjacent a tissue plane to be

'444 Patent Claim 1		Ganz alone and/or in combination with ScarLet
		treated. The treating surface is generally positioned adjacent to a tissue plane of the tissue to be treated."), [0063].
1.1	a plurality of electrodes having opposite polarities and the electrodes configured to be deployable into a body segment to be treated; and	Ganz discloses a plurality of electrodes having opposite polarities and the electrodes configured to be deployable into a body segment to be treated according to the claim. *See, e.g.*, Ganz, [0001], [0010], [0011], [0014], [0016], [0043], [0044], [0047], [0055], [0056], [0063], Ganz claim 1-13. **Figure 2**  *Id.* at Fig. 2. Specifically, Ganz discloses a "plurality of electrodes." *Id.* at [0011] ("The electrodes can be provided as a **plurality of electrode** pairs or even as an array of electrodes") (emphasis added); *see also id.*, at [0010] ("a plurality of electrodes extending outwardly from the treating surface"), [0014] ("a device having a treating surface which **includes a plurality of electrodes**") (emphasis added), [0043] ("includes a plurality of electrodes"), [0056] ("electrode pairs"), claim 1 ("plurality of electrodes"), claim 13 ("wherein the plurality of electrodes are provided as an array of electrodes"). Indeed, as shown in Figure 1, the "treatment device 10 ha[s] . . . [a] **plurality of electrode pins** 25 . . .." *Id.* at [00045] (emphasis added), Figure 1.

'444 Patent Claim 1	Ganz alone and/or in combination with ScarLet
	Figure 1  Ganz also discloses that the plurality of electrodes have opposite polarities. *See, e.g.*, Ganz, [0011], [0055], [0056], claim 11, claim 13. Specifically, Ganz discloses that the electrodes can be "bipolar," which have opposite polarities. *Id.* at [0011] ("the electrodes are bipolar electrodes"). In this bipolar configuration, Ganz discloses that electrodes have opposite polarities, *i.e.*, one electrode is positive and the other electrode is negative. *Id.* at [0056] ("In bipolar electrode arrangements, **both the positive and negative electrodes serve as treating electrodes**.") (emphasis added); *see also id.* ("In embodiments where the electrodes are provided in electrode pairs, . . . one electrode in the pair being a positive electrode and the other electrode being a negative electrode."). The parties have agreed that "the electrodes being bipolar"[32] should be construed as having a plain and ordinary meaning "organized in a bipolar setup," which is the electrodes change or alternate between being positive or negative as the current flows between them in alternate directions Post-Markman Hearing Joint Claim Construction Chart, at 3. Ganz disclosed that the "electrodes are RF electrodes and are configured for receiving RF energy." *Id.*, at [0011]. In other words, a radio frequency signal is applied to the electrodes. Ganz discloses that the needle electrodes are coupled to an RF source. *Id*. at [0011] ("[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, …"). In

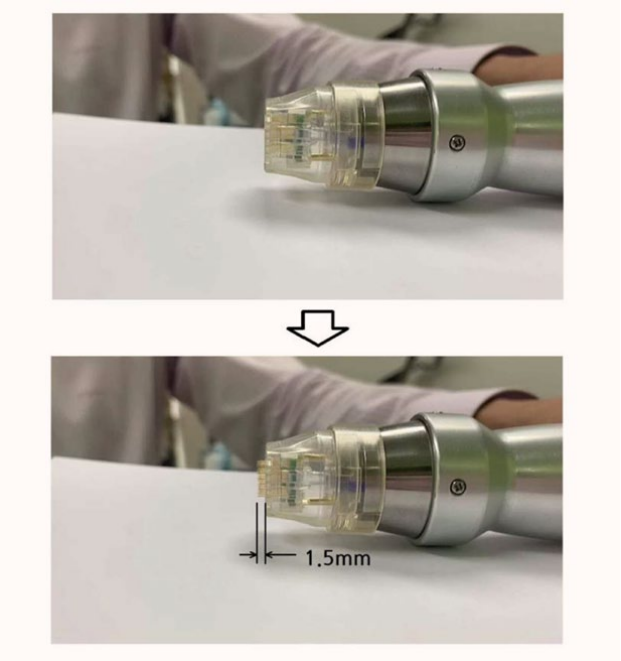
[32] As mentioned above, it is my opinion that a "bipolar needle" means having both poles on the same needle, but the configuration described in the Na patent would be Monopolar needles arranged in a Bipolar configuration. What is described in the Na patents are monopolar electrodes in a bipolar configuration or arrangement as mentioned by Ganz in [0056].

'444 Patent Claim 1		Ganz alone and/or in combination with ScarLet
		other words, an RF generator (generating module) is configured to provide an RF signal to the plurality of electrodes. It was well-known in the art that a radio frequency signal is a type of alternating current (AC). *Radiofrequency Catheter Ablation for Cardiac Tachyarrhythmias*, Manolis, A.S., *et al*., *Ann Intern Med.* (1994) 121:452-461 at 452. Complainant also appears to agree that an RF signal is a type of "alternating current." *See* Complainant's Final Infringement Contentions, Ex. 64, at 25; Ex. 76, at 14; Ex. 22, at 11.  The bipolar modality of RF delivery utilizes two electrodes, a positive and negative; alternating current flows back and forth between these points. The effective field depth, and thus the depth of tissue heated is determined by the distance of electrodes in relation to one another, although the degree of heating is still determined by the electrical parameters of the EMF. Complainant's Final Infringement Contentions, Ex. 64, at 25; Ex. 76, at 14 (emphasis in original) (citing SERENDIA-00006562 (Dermatology Time RF Webpage) at SERENDIA-00006565). It was well-known in the art that an alternating current (AC) is a current that alternates polarities. Thus, a POSITA would have understood that Ganz's bipolar electrodes change or alternate between being positive or negative as the alternating radiofrequency current alternates between them. Complainant appears to agree since alternating current flowing back and forth (to different directions) means that the current alternates polarities relative to the 2 poles of the generator (*i.e.*, the polarities dictate the direction of the current, and, thus, if the current direction changes, then the polarities change.) *See* Complainant's Initial Infringement Contentions, Ex. 71, at 21; ("the Accused Product is configured to provide a RF signal with oscillating current (as evidenced in green) to the plurality of electrodes"), Ex. 77, at 14 (alternating current flows back and forth between" electrodes) (citing SERENDIA-00006562 (Dermatology Time RF Webpage) at SERENDIA-00006565). Also, in its Markman brief, I understand that Complainant took the position that an alternating current is synonymous with an oscillating current[33], which Complainant equates as a current that "alternates

[33] It is my scientific opinion that an AC current is a type of oscillating current, that oscillates around a "0" value; whereas an oscillating current could oscillate around another neutral value

'444 Patent Claim 1		Ganz alone and/or in combination with ScarLet
		polarities." Complainant's Claim Construction Brief, at 67-68 ("Breaking down the claim language, it specifies that the 'current' alternates or oscillates, i.e., it alternates polarities."). Complainant then states that "alternating current" is "electric current that reverses direction periodically, usually many times per second, and also states that "'alternating current' 'usually means that the current changes polarity with time.'" Complainant's Claim Construction Brief, at 68. Thus, there can be no dispute that when the RF signal (which is a type of AC signal) is applied to Ganz's electrodes, the electrodes change or alternate between being positive or negative as the current alternates between them. Ganz further discloses the electrodes configured to be deployable into a body segment to be treated (*i.e.*, the skin), as evidenced by the fact that the needles "simultaneously impart[] perforations into the one or more layers" of skin tissue. *Id.*, at [0001]; *see also id.*, at claim 1 (" a plurality of electrodes extending outwardly from the treating surface and adapted for imparting simultaneous perforations into one or more tissue layers, wherein the electrodes are provided in a pattern to impart a corresponding pattern of perforations in the one or more tissue layers"), claim 4 (" wherein the electrode pattern is selected to create perforations which are between about 30 to about 100 microns in diameter, up to about 1000 microns deep and spaced apart by between about 50 to about 400 microns"), claim 5 (" wherein the plurality of electrodes have a depth … for providing perforations being no more than about 2 mm in depth …") [0016] ("simultaneously perforating the target area to provide the desired pattern of perforations which elicit a healing response that produces a revitalized skin surface"), [0047] ("Generally, the electrodes come into direct contact with the one or more tissue planes. So, the pattern of electrodes directly correspond to the pattern of perforations desired in the tissue."), [0063] ("The method generally includes simultaneously imparting perforations into one or more tissue layers in a tissue plane. . . .The device is activated to create a plurality of perforations in the skin"). Ganz also specifically describes "deploying the electrodes" to "expose the treating surface." *Id.*, [0042]. [0042]: "When the treating surface is expandable and desired to be expanded inside of the body, it may be desirable to provide the member in a folded positioned and placed within a

not equal to "0". This would not be allowed in an electrosurgical generator that needs to have a "0" mean current due to the output blocking capacitor required by the IEC60601-2-2 standard.

‘444 Patent Claim 1	Ganz alone and/or in combination with ScarLet
	sheath during positioning of the distal end within the body. This prevents the treating surface from taking up too much space, so the distal end can be guided through narrower channels in the body. Once the distal end is positioned at a desired site in the body, the sheath can be removed, for example by retracting it along the shaft to expose the treating surface. Accordingly, Ganz discloses that an apparatus that has a plurality of electrodes with opposite polarities (*i.e.*, positive and negative) that are configured to be deployable into the skin to be treated. To the extent Complainant asserts that Ganz does not explicitly or inherently disclose this limitation, it would have further been obvious in view of ScarLet. ScarLet discloses a mammalian body treatment apparatus, according to the claim, wherein the electrodes are configured to be deployable into a body segment to be treated according to the claim. *See, e.g.*, Ilooda-0008178 at -234.  [Plaintiff's Exhibits 22-10 and 22-11: 1.5 mm protrusion of the needles due to protrusion of the driv Ilooda-0008178 at -234.

'444 Patent Claim 1		Ganz alone and/or in combination with ScarLet
		The figures above show how the needle electrodes in the ScarLet device can be **deployed** from a retracted position (above) to an extended, deployed position (below). Ilooda-0008178 at –234. As taught in Ganz, a POSITA would be motivated to combine Ganz and ScarLet to create "deployable" electrodes because keeping the electrodes in a folded and protected position prior to use protects the electrodes and prevents the electrodes from taking up too much space. *See* Ganz, [0042]. Accordingly, Ganz, in view of ScarLet discloses that an apparatus that has a plurality of electrodes with opposite polarities (*i.e.*, positive and negative) that are configured to be deployable into the skin to be treated.
1.2	a radio frequency (RF) generation module, the RF generation module electrically coupled to the plurality of electrodes and configured to provide an RF signal with oscillating current to the plurality of electrodes	Ganz discloses and/or renders obvious a radio frequency (RF) generation module, the RF generation module electrically coupled to the plurality of electrodes and configured to provide an RF signal with oscillating current to the plurality of electrodes according to the claim. *See, e.g.*, Ganz, at [0011], [0057], [0058], [0059], claims 7-9. Specifically, Ganz discloses that "[t]he device also includes an **energy source coupled to the plurality of electrodes**, the energy source configured to deliver energy," and that energy can be "radio frequency" energy. *Id.*, at [0011] ("**RF electrodes and are configured for receiving RF energy**") (emphasis added); *see also id.*, at [0057] ("The energy delivery device can deliver a variety of different types of energy including but not limited to, radio frequency energy…"), [0058] ("In preferred embodiments, **the electrodes are configured as RF electrodes and RF energy is delivered to the electrodes**") (emphasis added), [0059] ("the energy source, including but not limited to **an RF source**") (emphasis added), 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"), claim 9 ("wherein the plurality of electrodes are RF electrodes and are configured for receiving RF energy"). Ganz also discloses an RF signal with oscillating current to the plurality of electrodes. It was well-known in the art that a radio frequency (RF) signal is (AC), and AC is inherently oscillating current, and therefore, a radio frequency signal is inherently generated from oscillating current. *Radiofrequency Catheter Ablation for Cardiac Tachyarrhythmias*, Manolis, A.S., *et al.*, Ann Intern Med. (1994) 121:452-461 at 452 ("Radiofrequency energy is a form of

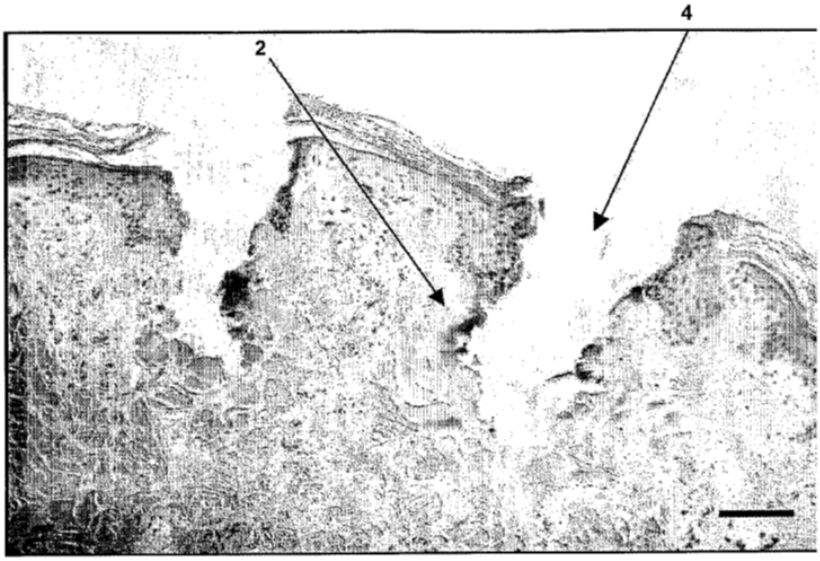
'444 Patent Claim 1		Ganz alone and/or in combination with ScarLet
		electrical energy, generated from low-power (15 to 60 V), high-frequency (30 KHz to 300 MHz) alternating current."); *Catheter Ablation Using Radiofrequency Energy*, Borggrefe, M., *et al.*, *Clin. Cardiol.* (1990) 13: 127-131 at 128, Fig. 1 (showing oscilloscopic recordings of current wave forms of radiofrequency current). Thus, Ganz' RF energy source is a device that generates electrical signal(s) having a radio frequency. It was well-known in the art that a radio frequency signal for electrosurgical use is a high frequency (usually 200 KHz to 5 MHz as defined by IEC 60601-2-2 section 201.8.4.102. (*see* section 90) alternating current (AC) alternating current (AC). 200 KHz is the equivalent of 0.2 MHz. *See* Section 90. Thus, radio frequency signals are measured in MHz. As discussed above, Complainant also appears to agree that an RF signal is a type of "alternating current." *See* Complainant's Final Infringement Contentions, Ex. 64, at 25; Ex. 76, at 14; Ex. 22, at 11. Complainant appears to agree since alternating current flowing back and forth (to different directions) means that the current alternates polarities (*i.e.*, the polarities dictate the direction, and, thus, if the direction changes, then the polarities change.). Moreover, it was well-known in the art that an alternating current (AC) is an oscillating current that alternates polarities and is symmetric around a "Zero" value. Complainant appears to agree since alternating current flowing back and forth (to different directions) means that the current alternates polarities (*i.e.*, the polarities dictate the direction, and, thus, if the direction changes, then the polarities change.) *See* Complainant's Initial Infringement Contentions, Ex. 71, at 21; ("the Accused Product is configured to provide a RF signal with oscillating current (as evidenced in green) to the plurality of electrodes"), Ex. 77, at 14 (alternating current flows back and forth between" electrodes) (citing SERENDIA-00006562 (Dermatology Time RF Webpage) at SERENDIA-00006565). Also, in its Markman brief, I understand that Complainant took the position that an alternating current is synonymous with an oscillating current, which Complainant equates as a current that "alternates polarities." Complainant's Claim Construction Brief, at 67-68 ("Breaking down the claim language, it specifies that the 'current' alternates or oscillates, i.e., it alternates polarities."). Complainant then states that "alternating current" is "electric current that reverses direction periodically, usually many times per second, and also states

'444 Patent Claim 1		Ganz alone and/or in combination with ScarLet
		that "'alternating current' 'usually means that the current changes polarity with time.'" Complainant's Claim Construction Brief, at 68. In my opinion, this is an incomplete definition, that demonstrates that Complainant lacks expertise in the Art. Therefore, because Ganz provides a radio frequency (RF) signal to the electrodes, Ganz discloses providing an electrical signal with oscillating current (current alternating polarities), and having a radio frequency (measured in MHz). To the extent it is argued that RF signals do not inherently have frequencies measured in MHz[34] and/or that Ganz does not disclose an RF signal having a frequency measured in MHz, it would have further been obvious given the knowledge of a POSITA. For example, a POSITA would have known that (among other parameters) the frequency range of the RF source can be chosen based on the desired effects on various types of tissue and its influence on lesion size and geometry based on the intended application. *See* Hantash '718 PCT, [0040]; *see also id.* at [0052] ("With the proper choice of parameters, the treatment can be self limiting to create treatment zones 160 of approximately uniform size across the treatment pattern 161. The self limiting nature of the treatment can be achieved by choosing the frequency of the RF source 110 to be a frequency for which the tissue resistivity (impedance) increases as the tissue is treated."); *id.* at [0079]. Ganz also teaches that the parameters and the configuration of the RF generator influences the depth and diameter of the lesion around each electrode. Ganz at [0059] ("The energy source is configured for powering the electrodes at levels appropriate to provide a desired diameter and depth of perforation of tissue."). Optimization of parameters, such as the RF frequency, power, energy, voltage, timing duty cycle applied to microneedles, requires a significant amount of experimentation. However, the experimental methodology to achieve unconnected coagulation zones is obvious to a POSITA, and the selection of the RF frequency would then become obvious to a POSITA.

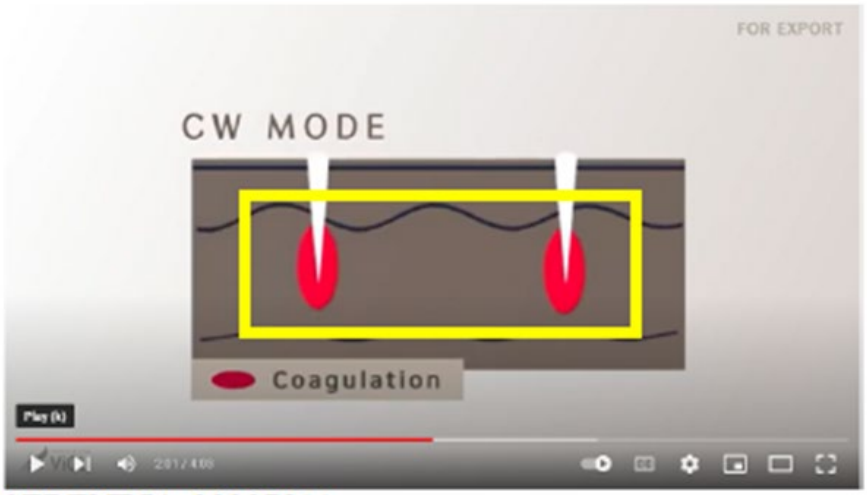
[34] As discussed above, a POSITA would be familiar with the IEC 60601-2-2 that in 2012 defined high frequency for surgical equipment (commonly known as RF) as a frequency over 200 KHz (0.2 MHz).

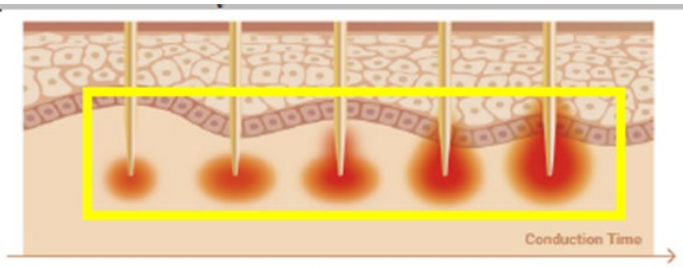
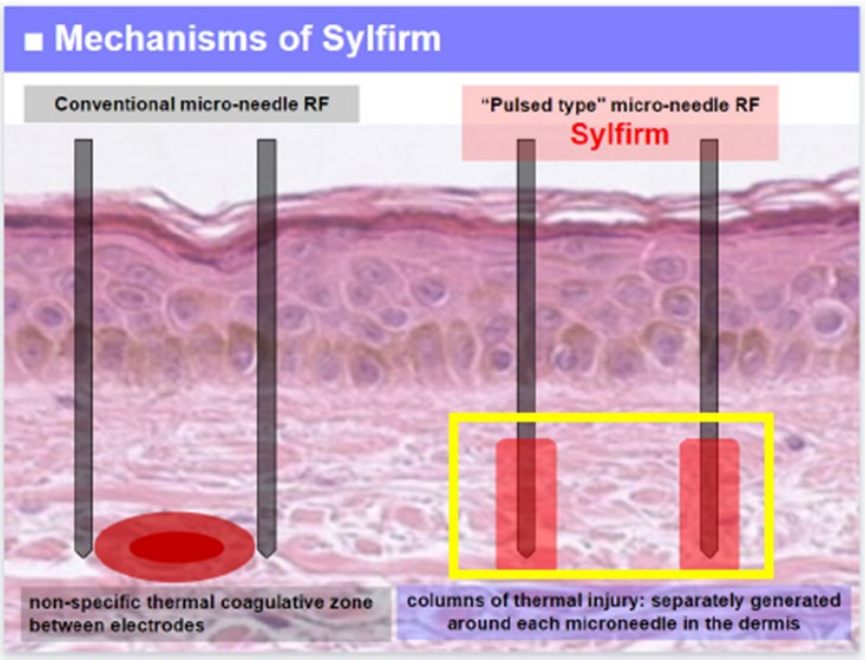
'444 Patent Claim 1		Ganz alone and/or in combination with ScarLet
		Therefore, a POSITA would have been motivated to use an RF frequency measured in MHz, in the range of 0.2 to 5 MHz. In the original application, Na mentions that "[t]he required components for both Na-Effect and Na-Plus effect are bipolarity of needles, alternating current (AC), and high frequency." In the original filing claims, he mentions that the device and method have the high frequency range of 0.5 - 10MHz and also that the frequency of the alternating current is higher than 20Hz, including 20Hz. In fact, combining these two signals together could be either an "addition" or a "multiplication" of one by the other; although this is not defined at all in the patent specification, the most likely scenario, a multiplication of the two signals, would result in engineering terms, to modulating the amplitude of the high frequency signal following a sinewave (or similar) such that the envelope of the high frequency signal amplitude follows a sine wave that varies from 0 to its maximal amplitude in a cyclic fashion 20 or more times per second (Complainant's interpretation requires a signal combining an AC frequency rate and an RF frequency rate). Such a mode of operation has been used in standard electrosurgery for over 30 years in most Electrosurgical Units on the market and is described in section VII. of this report. Therefore, using a low frequency modulation for a high frequency signal has been described and used many times prior to the filing of this patent and would be obvious for a POSITA. Accordingly, Ganz discloses and/or renders obvious that the RF generation module electrically is coupled to the plurality of electrodes and configured to provide an RF signal with oscillating current to the plurality of electrodes.
1.3	that causes energy to be substantially applied to body segments around each electrode.	Under Complainant's interpretation of this limitation, Ganz discloses "causing energy to be substantially applied to body segments around each electrode" according to the claim. *See, e.g.*, Ganz, [0006], [0010], [0028], [0048], [0056], [0058], Fig. 9, claims 1-3. Specifically, Ganz discloses zones of coagulation, which are small vertical zones of damaged tissue with "tissues layers surrounding the perforations are left untreated." *Id.* at [0006] [The benefit of these areas of treated and untreated tissue is "that by leaving zones of untreated tissue in between the perforations, less scarring and/or pigmentations are visible." *Id.* The zone of coagulation is created surrounding each electrode. *Id.* at [0010] ("The electrode pattern can also be selected to create a **zone of coagulative tissue surrounding each perforation**.") (emphasis added); [0056] ("The base of the treatment pad or treating surface and various portions of the proximal

‘444 Patent Claim 1		Ganz alone and/or in combination with ScarLet
		electrodes can also be insulated in order to limit the coagulation injury to the distal end of the electrode as well.”). A POSITA would have understood that each perforation is created by each electrode. Further, the zone of coagulation around the electrode is created by applying energy to each electrode. *Id.* at [0048] (“Zones of coagulation are also created in areas of tissue surrounding each perforation. The zones can extend from the perforation site into the tissue for a length ranging from about 5 microns to about 100 microns. The zone of coagulation can be varied by **changes in energy** and power levels.”) (emphasis added); [0058] (“In preferred embodiments, the electrodes are configured as RF electrodes and **RF energy is delivered to the electrodes**. RF energy is particularly desirable for creating perforations of tissue since it does not cause the entire area of tissue being treated to heat up extensively. Rather, RF energy can penetrate the body and be absorbed by deeper tissues without heating up the surrounding tissues. Thus, a boundary is created between the treated tissue and those tissues surrounding the treated tissue. RF energy is also desirable since it is safe to use on tissues in areas near sensitive body parts, *e.g.*, areas of skin near the eyes.”) (emphasis added). In The ‘444 Patent, at 3:15-18, Dr. Na Asserts that: “In the present invention the term “to raise temperature” is used synonymously with " applying energy to achieve coagulation ” where applying electrically energy to the body region may effectively raise the body region temperature.” In other terms, he states that the zone of coagulation occurs when sufficient energy has been applied using application of RF energy. He therefore admits that there is a very close correlation between applying energy to body segment around each electrode around each electrode rather than to body segments between the electrodes and causing e coagulation around each electrode rather than coagulating between the electrodes. We can therefore admit that the zones if tissue where energy is substantially applied are identified by the presence of coagulation. As shown in Figure 9, the apparatus causes energy to be applied to the electrodes which in turns causes the energy to be applied to the body segments surrounding the electrodes. *Id.* at [0028] (“… FIG. 9 illustrates a skin area treated in accordance with the invention. The treated area 4 is clearly a perforation, which extends vertically into the skin. Areas or zones of coagulation 2 can also be seen in the areas surrounding the perforation.”).

‘444 Patent Claim 1	Ganz alone and/or in combination with ScarLet
	 Furthermore, Ganz discloses that the electrodes are spaced apart by between 50 to about 400 microns. *Id* at [0047] (“In certain cases, the electrodes are patterned in order to create perforations being between about 30 to about 100 microns in diameter, up to about 1000 microns deep and spaced apart by between about 50 to about 400microns.”) .Ganz further discloses that the zones of coagulation extend from 5 microns to 100 microns. *Id. at* [0048] (“Zones of coagulation are also created in areas of tissue Surrounding each perforation. The Zones can extend from the perforation site into the tissue for a length ranging from about 5 microns to about 100 microns. The Zone of coagulation can be varied by changes in energy and power levels.”). In most cases, the zones of coagulation extend to a distance lesser than the distance between the electrodes, demonstrating the ability of creating coagulation zones that do not overlap (*i.e.*, around each electrode). Ganz also explains how to control the size of the lesions by varying energy and power levels, showing once more that the Ganz device is able to fully control coagulation such that they do not overlap. I understand that, in its attempt to argue claims are patent eligible, Complainant has argued that the independent claims recite “limitations that would be needed to produce the desired result” (apply energy to body segments around each electrode rather than to body segments between the electrodes” because “claim 10 of the ‘444 Patent requires deploying a plurality of electrodes into a body segment to be treated where the nearest electrodes having opposite polarities and applying an RF signal with oscillating current to the plurality of electrodes to

'444 Patent Claim 1		Ganz alone and/or in combination with ScarLet
		cause energy to be substantially applied to body segments around each electrode." Complainants' Initial Validity Contentions, at 407-408. As shown in regard to limitation 1.1 above, Ganz discloses inserting a plurality of electrodes into a body segment to be treated where the electrodes are bipolar, and, as shown in regard to limitation 1.2 above, under Complainant's and Staff's proposed construction for RF signal with oscillating current, Ganz discloses applying an RF signal with oscillating current to the plurality of electrodes. Therefore, Complainant asserted that Ganz discloses the limitations that would be needed to cause energy to be substantially applied to body segments around each electrode rather than to body segments between the electrodes. Thus, Complainant has essentially taken the position that Ganz discloses to cause energy to be substantially applied to body segments around each electrode rather than to body segments between the electrodes under Complainant's and Staff's proposed construction for RF signal with oscillating current. Additionally, I understand that Complainant appears to assert that "causes energy to be substantially applied to body segments around each electrode" has the same scope as "cause coagulation around each electrode rather than coagulating between the electrodes," recited in independent claim 1 of the '836 Patent, then Ganz discloses or renders this obvious. For example, in its domestic industry claim charts for the '444 Patent, Complainant ignores the language of "energy" and instead asserts this limitation is met by coagulation appearing only around electrodes but not being connected between electrodes: In the Domestic Industry Product, the RF generation module along with the plurality of electrodes is configured to apply energy to body segments around each electrode rather than to body segments between the electrodes (as shown below in yellow). Complainant's Final Infringement Contentions, Ex. 108, at pg. 23.

‘444 Patent Claim 1		Ganz alone and/or in combination with ScarLet
		 SERENDIA-00007811. *Id.* at 24.

‘444 Patent Claim 1	Ganz alone and/or in combination with ScarLet
	 Complete coagulation in total dermal layer SERENDIA-00022192 at SERENDIA-00022193, 5.  VIOL-00000321 at VIOL-00000345. *Id.* at 25. Therefore, to the extent that Complainant is asserting that “that causes energy to be substantially applied to body segments around each electrode” has the same scope as “cause coagulation around each electrode rather than coagulating between the electrodes,” recited in independent claim 1 of the ‘836 Patent, then Ganz discloses or renders this obvious for the reasons set forth in Exhibit R, the claim chart for invalidity of the ‘836 Patent in view of Ganz. To the extent Complainant argues Ganz does not disclose or render obvious this limitation, it would have further been obvious in view of ScarLet. ScarLet discloses a mammalian body treatment apparatus, according to the claim, wherein energy is substantially applied to body

'444 Patent Claim 1		Ganz alone and/or in combination with ScarLet
		segments around each electrode. *See, e.g.*, Ilooda-0010042 at -046; SERENDIA-00017306 at -334; SERENDIA-00017306 at -337; SERENDIA-00017306 at -321; SERENDIA-00017306 at -320. As I explain in more detail in the Technology Background section and with respect to claim 1 of the '836 Patent, the ScarLet system was designed to cause coagulation around each electrode. *See* Sections VII.A, XIII.A.1 *supra*. A POSITA would have been motivated to combine Ganz and ScarLet for the reasons discussed above. Accordingly, Ganz alone and/or in view of ScarLet discloses this limitation.

404. In view of the foregoing chart, claim 1 of the '444 Patent is anticipated by Ganz and/or rendered obvious by the teachings of Ganz alone or Ganz in view of ScarLet.

2. Claim 2 of the '444 Patent *is Anticipated by Ganz and/or rendered Obvious over Ganz in view of Hantash '718 PCT*

405. Claim 2 of the '444 Patent, which depends from claim 1, is anticipated by Ganz and/or obvious in view of the teachings of Ganz in combination with the teachings of Hantash '718 PCT and/or is rendered obvious by the teachings in Ganz in view of ScarLet and in further view of Hantash '718 PCT:

'444 Patent Claim 2		Ganz in view of Hantash '718 PCT
2.0	The mammalian body treatment apparatus of claim 1,	As shown above in regard to claim 1, Ganz discloses a mammalian body treatment apparatus according to the claim. *See, e.g.*, Ganz, at [0001], [0016], [0027], [0029], [0030], [0033], [0063], claim 24. To the extent Complainant asserts that Ganz does not explicitly or inherently disclose this limitation, it would have further been obvious in view of ScarLet. As shown above in regard to claim 1, Ganz in view of ScarLet discloses a mammalian body treatment apparatus according to the claim. *See* '444 Patent Claim 1.
2.1	wherein the RF generation module is configured to provide an	As shown above in regard to limitation 1.2, Ganz discloses wherein the RF generation module is configured to provide an RF signal to the plurality of electrodes according to the

'444 Patent Claim 2		Ganz in view of Hantash '718 PCT
	RF signal to the plurality of electrodes	claim. *See, e.g.*, Ganz, at [0011], [0057], [0058], [0059], claim 7-9. Specifically, Ganz discloses that "[t]he device also includes an **energy source coupled to the plurality of electrodes**, the energy source configured to deliver energy," and that energy can be "radio frequency" energy. *Id.*, at [0011] ("**RF electrodes and are configured for receiving RF energy**") (emphasis added); *see also id.*, at [0057] ("The energy delivery device can deliver a variety of different types of energy including but not limited to, radio frequency energy…"), [0058] ("In preferred embodiments, **the electrodes are configured as RF electrodes and RF energy is delivered to the electrodes**") (emphasis added), [0059] ("the energy source, including but not limited to **an RF source**") (emphasis added), 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"), claim 9 ("wherein the plurality of electrodes are RF electrodes and are configured for receiving RF energy"). Accordingly, Ganz discloses that the RF generation module electrically is coupled to the plurality of electrodes and configured to provide an RF signal to the plurality of electrodes.
2.2	for a predetermined time interval.	Ganz discloses wherein the RF generation module is configured to provide an RF signal to the plurality of electrodes for a predetermined time interval according to the claim. *See e.g.*, [0059] ("The energy source may be . . . adapted to allow the user to select the **appropriate treatment time**[.]") (emphasis added); [0063] ("In many cases, the same area of skin will be treated several times and usually at different time intervals."); *see also id.*, at [0011] ("an energy source coupled to the plurality of electrodes… configured for receiving RF energy"), [0057] ("energy source coupled to the electrodes for delivering energy to the electrodes," which can be " radio frequency energy"), [0058] ("the electrodes are configured as RF electrodes and RF energy is delivered to the electrodes"), 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

'444 Patent Claim 2		Ganz in view of Hantash '718 PCT
		radiation, or microwave radiation"), claim 8 ("a control device coupled to the energy source"). Specifically, Ganz discloses that "[t]he energy source may be manually controlled by the user and be adapted to allow the **user to select the appropriate treatment time**[,]" *i.e.*, a predetermined time interval. Ganz, at [0059]. And that usual treatment required several applications "at different time intervals." *Id.* at [0063]. Accordingly, under Complainants' interpretation of "causes energy to be substantially applied to body segments around each electrode rather than to body segments between the electrodes," and, to the extent that Complainant asserts that "causes energy to be substantially applied to body segments around each electrode rather than to body segments between the electrodes" has the same scope as "cause coagulation around each electrode rather than coagulating between the electrodes," recited in independent claim 1 of the '836 Patent, then Ganz anticipated claim 2. Accordingly, Ganz discloses that the RF generation module electrically is coupled to the plurality of electrodes and configured to provide an RF signal to the plurality of electrodes according to the claim. To the extent Complainant asserts that Ganz does not explicitly or inherently disclose this limitation, it would have further been obvious in view of Hantash '718 PCT. For example, Hantash '718 PCT discloses a mammalian body treatment apparatus. Hantash '718 PCT, Title ("Method and apparatus for micro-needle array electrode treatment of tissue"); Abstract ("system and method for revitalizing aging skin"); [0002]; [0013]; [0014]; [0021]; Fig. 1; claim 1 (for "human skin"). Hantash '718 PCT's device also has a plurality of bipolar electrodes configured to be deployable into a body segment to be treated, and a radio frequency (RF) generation module, the RF generation module electrically coupled to the plurality of electrodes and configured to provide an RF signal with oscillating current to the plurality of electrodes. Hantash '718 PCT, at [0035], *see also id*., at Abstract, [0002] ("biological tissue treatment using electromagnetic energy delivered through an array of needle electrode [electrodes]"), [0012], [0013], [0014],

‘444 Patent Claim 2		Ganz in view of Hantash ‘718 PCT
		[0017] (“the microneedles are driven into the tissue”), [0021], [0034] (“a radio frequency (RF) source 110 is [electrically] connected to an array of needles 115” to deliver energy to the skin 150 via the array of needle electrodes 115”), [0035] (“While the needles 115 are located within the skin 150, they can be powered by the RF source 110”), [0039] (“each of the needles 115 can comprise an electrically conductive shaft”), [0040] (“bipolar” electrodes), [0047] (“One array includes all of the negative polarity needles 116 (return electrodes) and the other includes all of the positive polarity needles 117 (active electrodes)”), [0055], [0057] (“electrically connecting the needles 116 and 117 at the opposite ends of each local region of skin 150 to be treated to different poles of the RF source 110”), [0061], [0068]-[0070], [0079] (“bipolar”) Figs. 1, 3A, claims 1, 37, 42. Hantash ‘718 PCT also discloses an example of providing an RF signal to a plurality of electrodes for “pulse duration of 400 ms” (Hantash ‘718 PCT, at [0077]) or “200 ms” (*id*., at [0078]). *See also id*., at [0018] (ensuring “enough thermal relaxation time at the treated zones and thereby avoiding overheating of the treated zones”). Thus, Hantash ‘718 PCT discloses that the RF generation module is configured to provide an RF signal to the plurality of electrodes for a predetermined time interval. Hantash ‘718 PCT also explains to adjust the treatment parameters to achieve the desired time at temperature (*See* Hantash, at [0018], [0040], [0052], [0079]), in order to “create more localized electrical field profiles within the tissue or to create a discontinuous treatment pattern” in order to “reduce charring and over-treatment.” *Id*., at [0056]. Hantash ‘718 PCT explains that it is safer and more desirable to create discrete small coagulation zones rather than larger connected coagulation zones so that the surrounding area is spared from damage and can assist with the healing process, which makes the healing process more through and faster as compared to continuous coagulation zones. *See id*., at [0058]. As discussed above, Ganz already discloses that “[t]he energy source may be manually controlled by the user and be adapted to allow the user to select the appropriate treatment time and power setting to obtain a controlled depth

'444 Patent Claim 2		Ganz in view of Hantash '718 PCT
		and/or width of perforation." Ganz, at [0059]. Thus, a POSITA would combine the teachings of Ganz with Hantash '718 PCT to select appropriate treatment times that are in predetermined time intervals (*e.g.*, 400 ms). Accordingly, under Complainants' interpretation of "causes energy to be substantially applied to body segments around each electrode rather than to body segments between the electrodes," and, to the extent that Complainant asserts that "causes energy to be substantially applied to body segments around each electrode rather than to body segments between the electrodes" has the same scope as "cause coagulation around each electrode rather than coagulating between the electrodes," recited in independent claim 1 of the '836 Patent, then Ganz in view of Hantash '718 PCT also rendered obvious claim 2. A POSITA would have been motivated to allow the user to select different predetermined time durations for applying the RF energy to the electrodes in order to achieve different coagulation patterns. For example, to create small discrete coagulation zones that do not connect between electrodes. This would allow for a quicker healing time, and thus would have been desirable.

406. In view of the foregoing chart, claim 2 of the '444 Patent is anticipated by the teachings of Ganz. Further, to the extent Complainant is arguing that any of the foregoing limitations are not explicitly are inherently disclosed in Ganz, such limitations would have been obvious in view of Hantash '718 PCT and/or obvious in view of Ganz and ScarLet in combination with Hantash '718 PCT.

3. Claim 4 of the ‘444 Patent *is anticipated by Ganz and/or obvious by Ganz in view of ScarLet*

407. Claim 4 of the ‘444 Patent, which depends from claim 1, is anticipated by the teachings in Ganz and/or rendered obvious by Ganz in view of ScarLet:

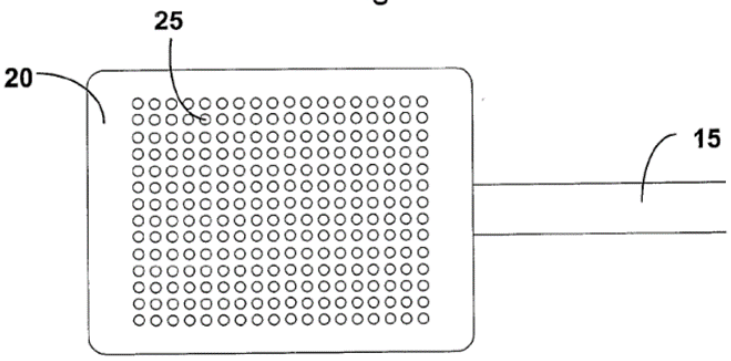
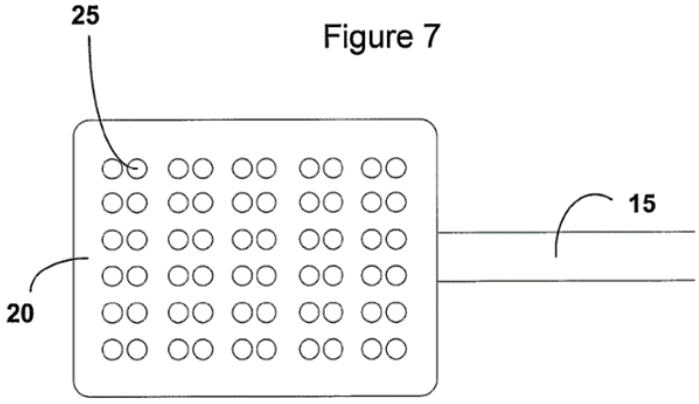
‘444 Patent Claim 4		Ganz alone and/or in combination with ScarLet
4.0	The mammalian body treatment apparatus of claim 1,	As shown above in regard to claim 1, Ganz discloses a mammalian body treatment apparatus according to the claim. *See, e.g.*, Ganz, at [0001], [0016], [0027], [0029], [0030], [0033], [0063], claim 24. To the extent Complainant asserts that Ganz does not explicitly or inherently disclose this limitation, it would have further been obvious in view of ScarLet. As shown above in regard to claim 1, Ganz in view of ScarLet discloses a mammalian body treatment apparatus according to the claim. *See* ‘444 Patent Claim 1.
4.1	wherein the electrodes are bipolar.	Ganz discloses wherein the electrodes are bipolar according to the claim. *See, e.g.*, Ganz at [0011], [0055], [0056], claim 13. Specifically, Ganz discloses that “the electrodes are **bipolar electrodes**.” *Id.* at [0011] (emphasis added). And that bipolar electrodes are desirable. *Id.* at [0056]. Further, Ganz discloses that in the “bipolar electrode arrangement” that “both the positive and negative electrodes serve as treating electrodes.” *Id.* at [0056]. Accordingly, under Complainants’ interpretation of “causes energy to be substantially applied to body segments around each electrode rather than to body segments between the electrodes,” and, to the extent that Complainant asserts that “causes energy to be substantially applied to body segments around each electrode rather than to body segments between the electrodes” has the same scope as “cause coagulation around each electrode rather than coagulating between the electrodes,” recited in independent claim 1 of the ‘836 Patent, then Ganz anticipated claim 4. Thus, Ganz discloses the mammalian treatment apparatus of claim 1 having bipolar electrodes.

408. In view of the foregoing chart, claim 4 of the '444 Patent is anticipated by the teachings of Ganz and/or rendered obvious by the teachings of Ganz alone and/or in view of ScarLet.

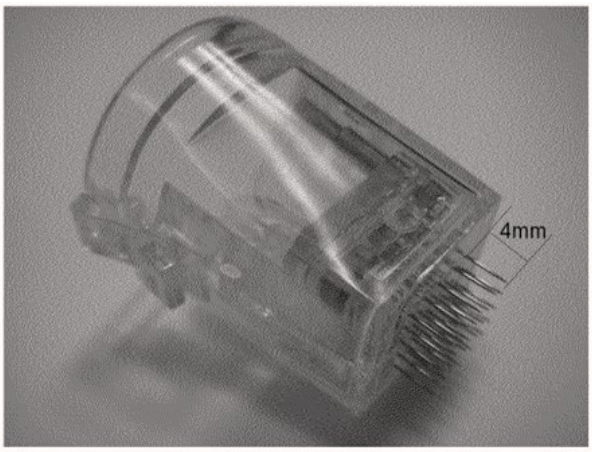
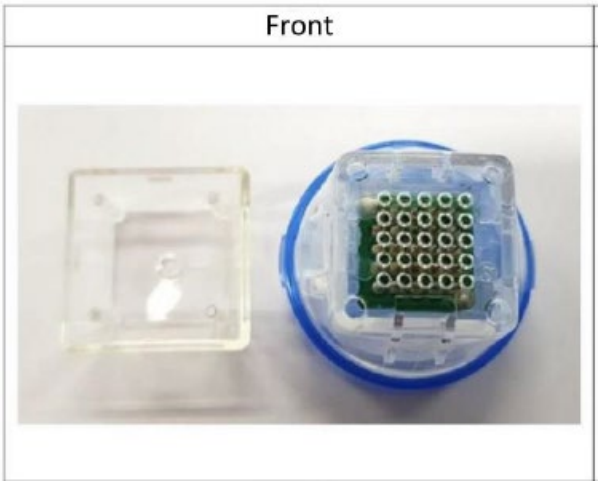
4. Claim 5 of the '444 Patent *is Obvious over Ganz in view of Hantash '718 PCT and in further view of ScarLet and/or DeÁge*

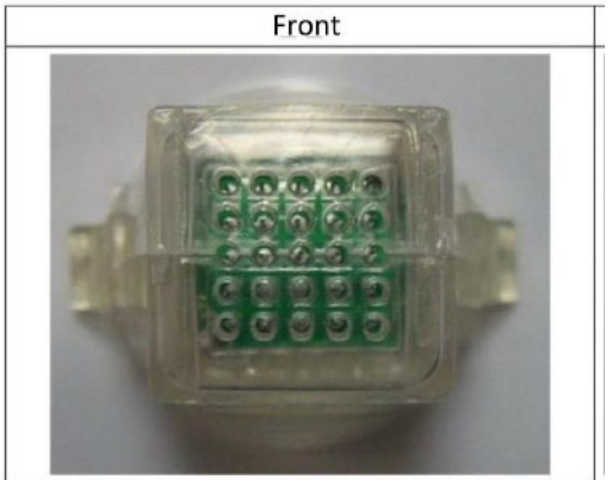
409. Claim 5 of the '444 Patent, which depends from claim 1, is rendered obvious by the teachings in Ganz in view of Hantash '718 PCT and in further view of ScarLet and/or DeÁge:

'444 Patent Claim 5		Ganz in view of Hantash '718 PCT and further view of ScarLet and/or DeÁge
5.0	The mammalian body treatment apparatus of claim 1,	As shown above in regard to claim 1, Ganz discloses a mammalian body treatment apparatus according to the claim. *See, e.g.*, Ganz, at [0001], [0016], [0027], [0029], [0030], [0033], [0063], claim 24. To the extent Complainant asserts that Ganz does not explicitly or inherently disclose this limitation, it would have further been obvious in view of ScarLet. As shown above in regard to claim 1, Ganz in view of ScarLet discloses a mammalian body treatment apparatus according to the claim. *See* '444 Patent Claim 1.
5.1	wherein the plurality of electrodes is arranged into a plurality of rows and columns and	Ganz discloses a mammalian body treatment apparatus wherein the plurality of electrodes is arranged into a plurality of rows and columns and neighboring electrodes in each of the plurality of rows columns according to the claim. *See, e.g.*, Ganz [0014], [0047], [0050], [0054]. Specifically, the electrodes on the device are "arranged in a desired pattern," including "orderly pattern[s]" such as rows and columns, as shown in Figure 5 and Figure 7. *Id.* at [0047], [0050], Figs. 5 & 7. In these figures, Ganz discloses two various embodiments of electrodes arranged in a plurality of rows and columns. *Id.* at Figs. 5 & 7

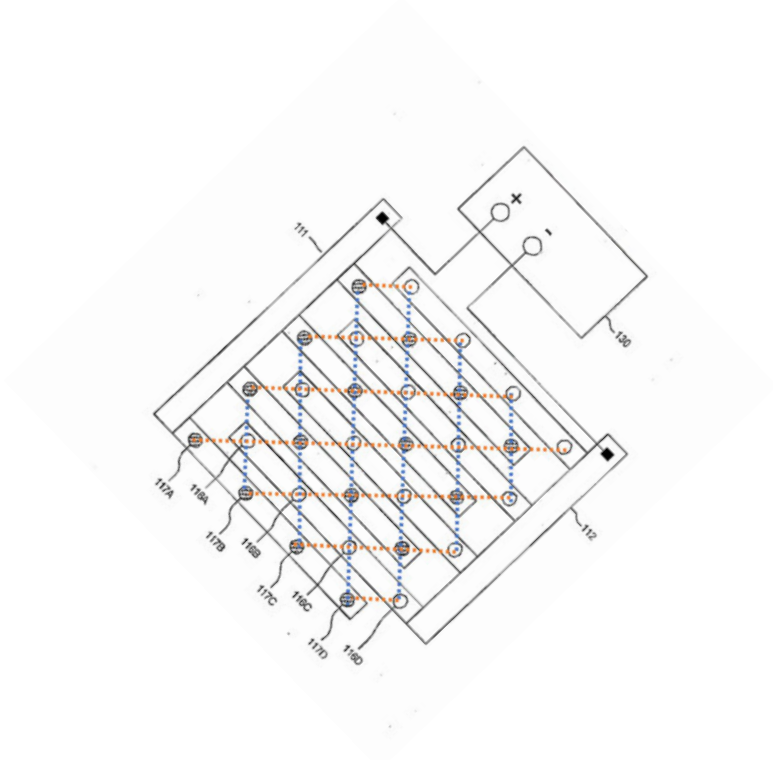
‘444 Patent Claim 5	Ganz in view of Hantash ‘718 PCT and further view of ScarLet and/or DeÁge
	Figure 5  Ganz, Fig. 5. Figure 7  Ganz, Fig. 7. To the extent that Complainant asserts that Ganz does not disclose the plurality of electrodes is arranged into a plurality of rows and columns, it would have further been obvious given the knowledge of a POSITA and/or in further view of ScarLet. ScarLet discloses a mammalian body treatment apparatus, according to the claim, wherein the plurality of electrodes is arranged into a plurality of rows and columns and neighboring electrodes in each of the plurality of rows columns according to the claim. For example, ScarLet includes numerous embodiments which disclose this limitation:

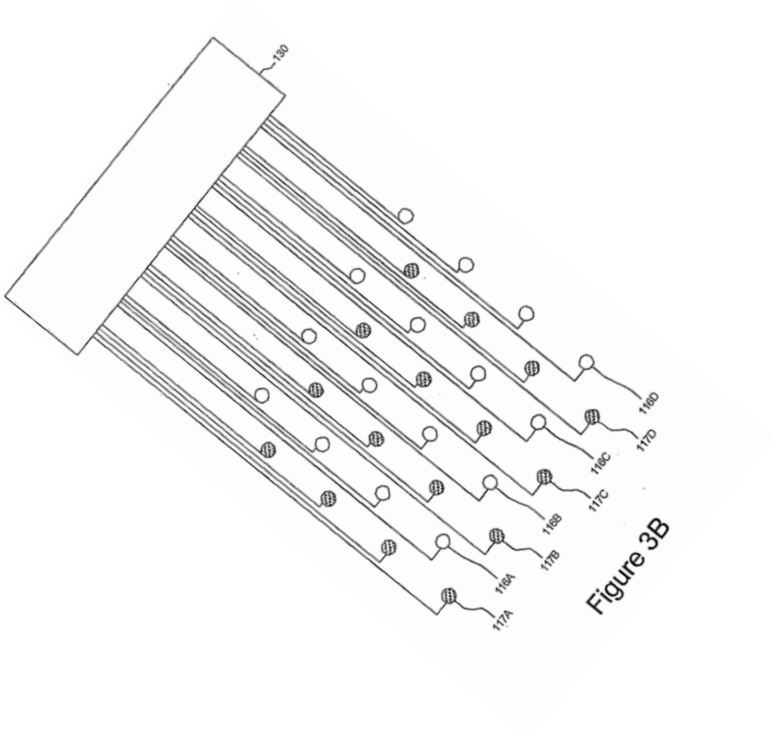
‘444 Patent Claim 5		Ganz in view of Hantash ‘718 PCT and further view of ScarLet and/or DeÁge
		1. Specification of ScarLet Specification NEEDLE DEPTH: 0.5 mm ~ 3.5 mm (0.1 mm unit) RF CONDUCT. TIME: 100msec ~ 800msec (100msec unit) RF OUTPUT: 1) 1.5V ~ 40V 2) 40 ~ 200V RF E. FIELD WIDTH(at 1mm Depth): 82mm² RF FREQUENCY: 2MHz WEIGHT: 29Kg DIMENSION: 55cm(W) * 35cm(D) * 122cm(H) ELECTRODE NO.: 25 Pin SPOT SIZE: 1cm² Ilooda-0006075 (ScarLet intro at 2).  SERENDIA-00017306 at -337.

‘444 Patent Claim 5		Ganz in view of Hantash ‘718 PCT and further view of ScarLet and/or DeÁge
		 SERENDIA-00034572 at -574. ② Scarlet Tip 2  Ilooda-0010141 at -147 (certified English translation of SERENDIA-00033705 at -710).

'444 Patent Claim 5		Ganz in view of Hantash '718 PCT and further view of ScarLet and/or DeÁge
		Shape and structure – Appearance 1. Photos of appearance 1) Overall appearance of the electrode ① Scarlet Tip  Ilooda-0010141 at -146 (certified translation of SERENDIA-00033705 at -709). As shown above, ScarLet discloses electrodes in arrangements that contain columns and rows. For example, one such embodiment is an arrangement of 5 columns and 5 rows. Ilooda-0010141 at -146 (certified translation of SERENDIA-00033705 at -709). A POSITA would be motivated to combine Ganz and ScarLet because a POSITA would be motivated to modify the arrangement of electrodes through routine experimentation and optimization. Thus, Ganz in view of ScarLet discloses the mammalian treatment apparatus of claim 1 having the plurality of electrodes arranged into a plurality of rows and columns.
5.2	neighboring electrodes in each of the plurality of rows columns have opposite polarities.	Ganz discloses a mammalian body treatment apparatus wherein the plurality of electrodes is arranged into a plurality of rows and columns and neighboring electrodes in each of the plurality of rows columns have opposite polarities according to the claim. *See, e.g.,* Ganz at [0014], [0047], [0050], [0054], [0056].

'444 Patent Claim 5		Ganz in view of Hantash '718 PCT and further view of ScarLet and/or DeÁge
		As shown above in regard to section 5.1 of claim 5, Ganz discloses a plurality of electrodes arranged in rows columns. *Id.* at [0011], [0047], [0050], Figs. 5 & 7. Ganz further discloses the neighboring electrodes in the rows and columns have opposite polarities. *Id.* at [0056]. For example, Ganz discloses that "[a]ny desired pattern or electrode arrangement is within the scope of the invention," and that "the electrodes are bipolar" (*i.e.*, having opposite polarities). *Id.*, at [0047] ("The electrodes are positioned on the treating surface in any manner to provide a desired pattern of perforations into the one or more tissue planes"); [0056] ("the electrodes are provided as a bipolar electrode arrangement"); *see also id.*, at [0014] ("wherein the plurality of electrodes are arranged in a desired pattern"). In Ganz's bipolar embodiment, the electrodes come in pairs where "one electrode in the pair being a positive electrode and the other electrode being a negative electrode." *Id.*, at [0056]. Thus, Ganz discloses neighboring electrodes in each of the plurality of rows columns having opposite polarities. To the extent that Complainant asserts that Ganz does not disclose the plurality of electrodes is arranged into a plurality of rows and columns and neighboring electrodes in each of the plurality of rows columns have opposite polarities, it would have further been obvious over Hantash '718 PCT and/or in further view of ScarLet. Hantash '718 PCT discloses a mammalian body treatment apparatus, according to the claim (*see* claim element 2.2 above). Hantash '718 PCT also discloses that the neighboring electrodes in each of the plurality of rows columns have opposite polarities. *See, e.g.*, Hantash '718 PCT, Fig. 2; Fig. 3A; Fig. 3B; Fig. 4A; [0044]; [0047]; Fig. 5A. Specifically, as shown in Fig. 3A and 4A, reproduced below, the closest neighboring electrodes have opposite polarities. Hantash '718 PCT, at [0047] ("One array includes all of the negative polarity needles 116 (return electrodes) and the other includes all of the positive polarity needles 117 (active electrodes). For example, as shown in Fig. 3A, reproduced below, as well as Fig. 3B, the closest neighboring electrodes have opposite polarities. Hantash '718 PCT, at [0047] ("One

'444 Patent Claim 5		Ganz in view of Hantash '718 PCT and further view of ScarLet and/or DeÁge
		array includes all of the negative polarity needles 116 (return electrodes) and the other includes all of the positive polarity needles 117 (active electrodes). *See also id*., claims 15, 17 ("wherein the needles are spaced further apart in one direction compared to the other direction on the grid"); Fig 4A; Fig. 5A.  Hantash '718 PCT, Fig. 3A (annotated)**.** The red and blue dotted lines in Figure 3A (above) show the row of columns in which adjacent electrodes are of opposite polarity.

‘444 Patent Claim 5	Ganz in view of Hantash ‘718 PCT and further view of ScarLet and/or DeÁge
	 *Id*., Fig. 3B It would have been obvious design choice for a POSITA as of the priority date of the ‘444 Patent to modify Ganz in view of Hantash ‘718 PCT to use an electrode configuration where the closest neighboring electrodes have opposite polarities. As explained above, the ‘444 Patent does not explain that there is any benefit to such a configuration as opposed to a configuration where, for example, a positive electrode is equally close to one or more negative electrodes and one or more positive electrodes. Nor does the ‘444 Patent disclose that the claimed configuration of electrodes is part of how one achieves applying energy to body segments around each electrode rather than to body segments between the electrodes. To the extent Complainant argues there is a benefit for arranging the neighboring electrodes to have opposite polarities, optimization, through routine experimentation, of the arrangement of opposite polarity electrodes in an electrode array was obvious to a POSITA. Accordingly, under Complainants’ interpretation of “causes energy to be substantially applied to body segments around each electrode rather than to body segments between the

'444 Patent Claim 5		Ganz in view of Hantash '718 PCT and further view of ScarLet and/or DeÁge
		electrodes," and, to the extent that Complainant asserts that "causes energy to be substantially applied to body segments around each electrode rather than to body segments between the electrodes" has the same scope as "cause coagulation around each electrode rather than coagulating between the electrodes," recited in independent claim 1 of the '836 Patent, then Ganz in view of Hantash '718 PCT also rendered obvious claim 5. ScarLet discloses a mammalian body treatment apparatus, according to the claim, wherein the plurality of electrodes is arranged into a plurality of rows and columns and neighboring electrodes in each of the plurality of rows columns have opposite polarities according to the claim. For example, the ScarLet display screen in the following figure notes the electrodes are "bipolar," and thus have opposite polarities:  Figure 2-3. An example of a lab display (touch screen) Ilooda-0006770 (#13_(Eng)_Shim 2010_DKU Thesis Dec 1 2010_Translated_Certified at 10). ScarLet explains: "In RF devices (electrosurgical devices), if the two poles are located at the same end of the device, it

'444 Patent Claim 5		Ganz in view of Hantash '718 PCT and further view of ScarLet and/or DeÁge
		is called a bipolar unit, and if there is only one pole at the end of the device, it is called a monopolar or unipolar unit, but in this experiment, a bipolar unit was used. . . ." Ilooda-0006770 (#13_(Eng)_Shim 2010_DKU Thesis Dec 1 2010_Translated_Certified at 7). *See also* 2.4. Bipolar Cut Mode Output Voltage of the Experiment Apparatus. Ilooda-0006770 (#13_(Eng)_Shim 2010_DKU Thesis Dec 1 2010_Translated_Certified at 11). Thus, ScarLet discloses that its electrodes are bipolar, having two opposite polarities (or "poles") at the same end of the device. Ilooda-0006770 (#13_(Eng)_Shim 2010_DKU Thesis Dec 1 2010_Translated_Certified at 7). Read together, ScarLet discloses a mammalian body treatment apparatus wherein the plurality of electrodes is arranged into a plurality of rows and columns and neighboring electrodes in each of the plurality of rows columns have opposite polarities. *Id.* ScarLet discloses the mammalian treatment apparatus of claim 1 where neighboring electrodes in each of the plurality of rows columns have opposite polarities. Na Tr. 226:8-228:3 (Q Does the original Scarlet from that 2010 KFDA document have the checkerboard pattern of needle arrangement? A It was in five-by-five rows. . . . Q In the bipolar mode, would they have opposite polarity to the central electrode, as opposed to the 3:00 and the 6:00? A Right. So if you look at the electrodes in the Scarlet in the 2010 KFDA approval sheet. And so if you use bipolar mode, then the electrodes next to that is done to have opposite polarity.). A POSITA would be motivated to combine Ganz and ScarLet because a POSITA would be motivated to modify the arrangement of electrodes through routine experimentation and optimization. DeÁge discloses a mammalian body treatment apparatus, according to the claim, wherein the plurality of electrodes is arranged into a plurality of rows and columns and neighboring electrodes in each of the plurality of rows columns have opposite polarities according to the claim. [redacted]

‘444 Patent Claim 5	Ganz in view of Hantash ‘718 PCT and further view of ScarLet and/or DeÁge
	[redacted] [redacted] [redacted] [redacted] A POSITA would be motivated to combine Ganz and DeÁge because a POSITA would be motivated to modify the

'444 Patent Claim 5		Ganz in view of Hantash '718 PCT and further view of ScarLet and/or DeÁge
		arrangement of electrodes through routine experimentation and optimization. Thus, Ganz in view of Hantash '718 PCT and in further view of ScarLet discloses the mammalian treatment apparatus of claim 1 having the plurality of electrodes is arranged into a plurality of rows and columns and neighboring electrodes in each of the plurality of rows columns have opposite polarities.

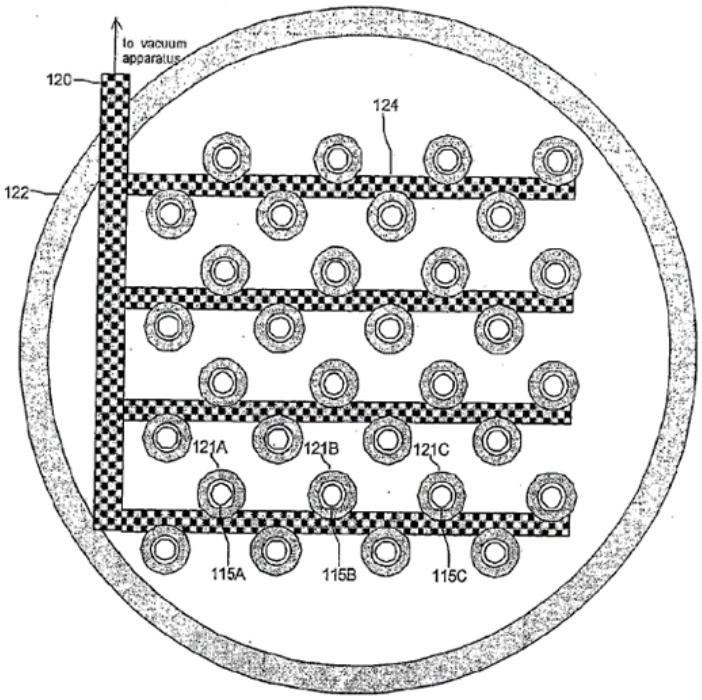
410. In view of the foregoing chart, claim 5 of the '444 Patent is anticipated by the teachings of Ganz. Further, to the extent Complainant is arguing that any of the foregoing limitations are not explicitly are inherently disclosed in Ganz, such limitations would have been obvious in view of ScarLet and/or DeÁge. A POSITA would be motivated to combine Ganz and ScarLet and/or DeÁge because a POSITA would modify the arrangement of electrodes through routine experimentation and optimization.

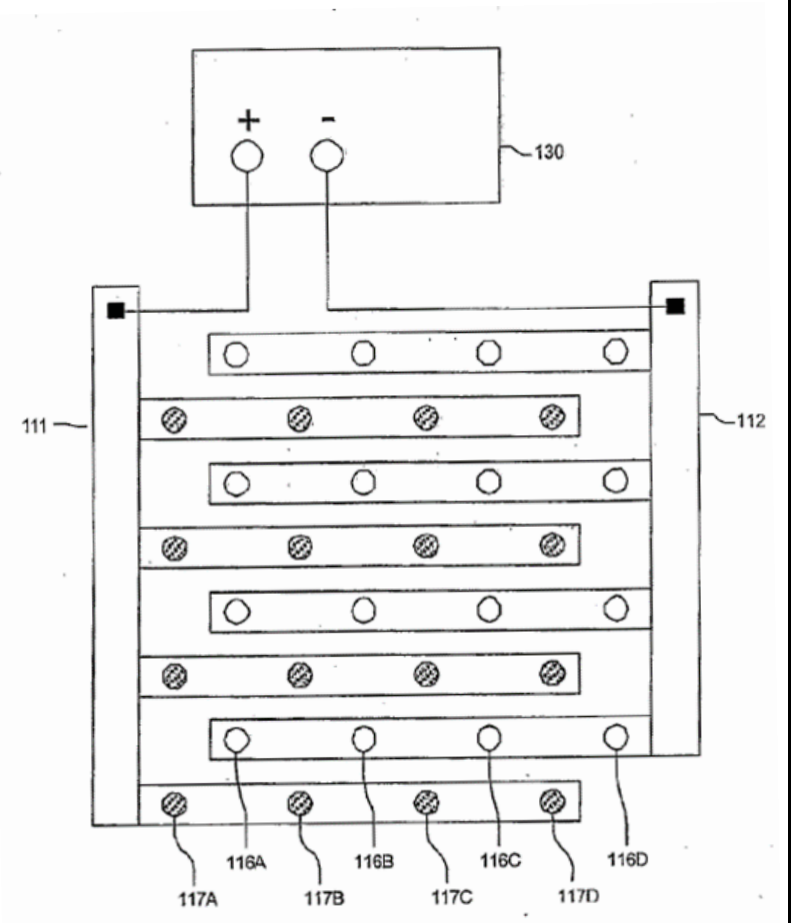
5. *Claim 6 of the* '444 Patent *is obvious over Ganz in view of Hantash '718 PCT and in further view of ScarLet*

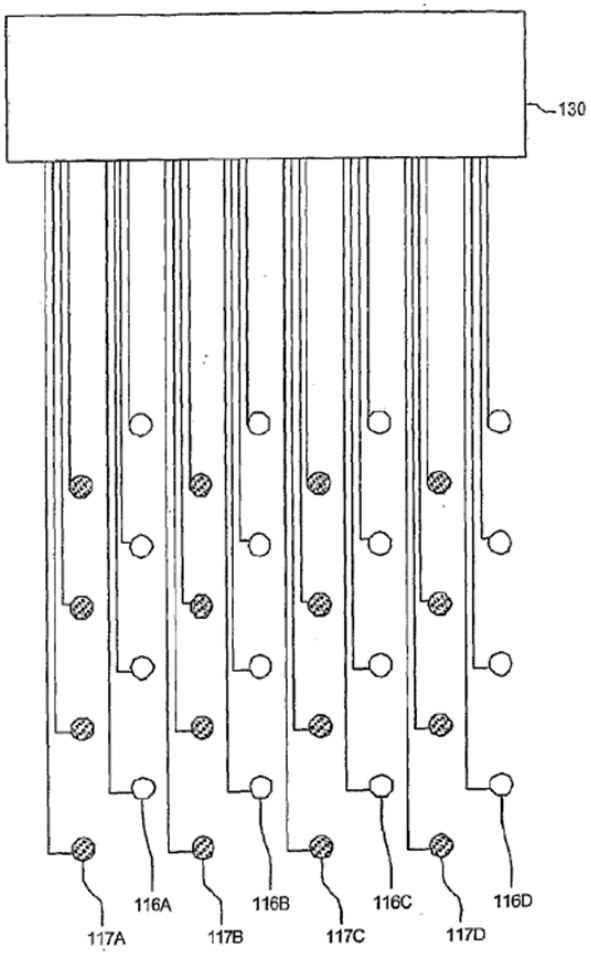
411. Claim 6 of the '444 Patent, which depends from claim 1, is obvious in view of the teachings of Ganz in combination with the teachings of Hantash and/or ScarLet:

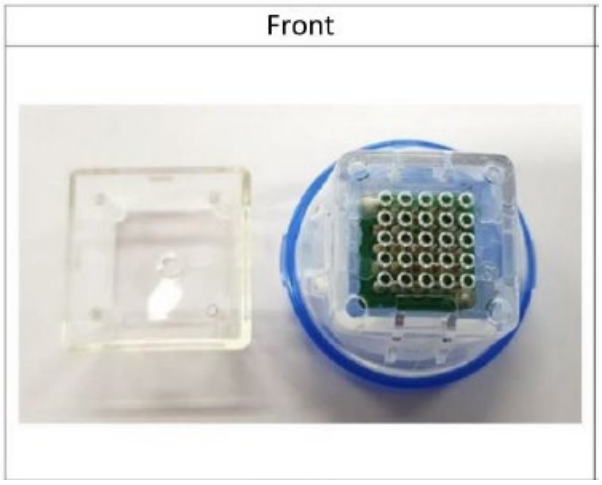
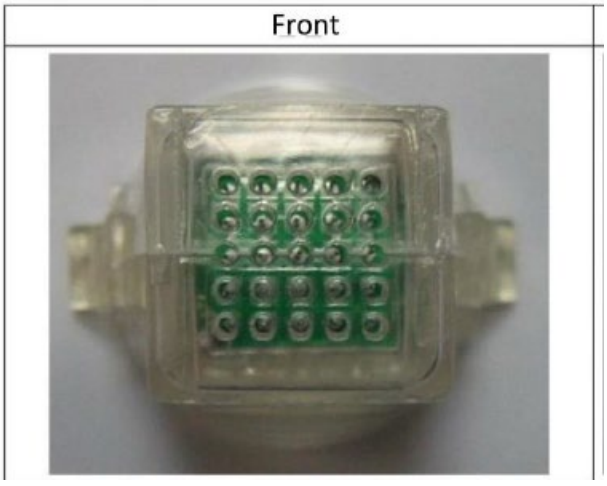
'444 Patent Claim 6		Ganz in view of Hantash '718 PCT in combination with ScarLet
6.0	The mammalian body treatment apparatus of claim 1,	As shown above in regard to claim 1, Ganz discloses a mammalian body treatment apparatus according to the claim. *See, e.g.*, Ganz, at [0001], [0016], [0027], [0029], [0030], [0033], [0063], claim 24. To the extent Complainant asserts that Ganz does not explicitly or inherently disclose this limitation, it would have further been obvious in view of ScarLet. As shown above in regard to claim 1, Ganz in view of ScarLet discloses a

‘444 Patent Claim 6		Ganz in view of Hantash ‘718 PCT in combination with ScarLet
		mammalian body treatment apparatus according to the claim. *See* ‘444 Patent Claim 1.
6.1	wherein the plurality of electrodes forms a square configuration.	Ganz discloses and/or renders obvious the plurality of electrodes forms a square configuration according to the claim. *See, e.g.*, Ganz at [0014], [0037], [0045], [0054], [0056]. Specifically, Ganz disclose that “[a]ny desired pattern or electrode arrangement is within the scope of the invention.” *Id.*, at [0047]; *see also id.*, at [0037] (“The treating surface of the treatment device can be provided in any desired shape or configuration.”). To the extent that Complainant asserts that Ganz does not disclose the plurality of electrodes is arranged into a plurality of rows and columns and neighboring electrodes in each of the plurality of rows columns have opposite polarities, it would have further been obvious over Hantash ‘718 PCT and/or in further view of ScarLet. Hantash ‘718 PCT discloses a mammalian body treatment apparatus, according to the claim, wherein the plurality of electrodes forms a square configuration according to the claim. For example, Hantash ‘718 PCT Figures 2, 3A,and 3B, discloses square configurations. *See also* Hantash ‘718 PCT, at [0044], [0047].

‘444 Patent Claim 6	Ganz in view of Hantash ‘718 PCT in combination with ScarLet
	 Figure 2 Hantash ‘718 PCT, Fig. 2

‘444 Patent Claim 6	Ganz in view of Hantash ‘718 PCT in combination with ScarLet
	 Figure 3A Hantash ‘718 PCT, Fig. 3A.

‘444 Patent Claim 6	Ganz in view of Hantash ‘718 PCT in combination with ScarLet
	 Figure 3B Hantash ‘718 PCT, Fig. 3B. As disclosed in Hantash ‘718 PCT, the electrode pattern can be a “regular” pattern, such as a square. *Id.* at [0044]. ScarLet discloses a mammalian body treatment apparatus, according to the claim, wherein the plurality of electrodes forms a square configuration according to the claim. Specifically, the ScarLet needle tips have options that are in a 5 by 5 square arrangement:

'444 Patent Claim 6	Ganz in view of Hantash '718 PCT in combination with ScarLet
	② Scarlet Tip 2  Ilooda-0010141 at -147 (certified English translation of SERENDIA-00033705 at -710). **Shape and structure – Appearance** 1. Photos of appearance 1) Overall appearance of the electrode ① Scarlet Tip  Ilooda-0010141 at -146 (certified translation of SERENDIA-00033705 at -709).

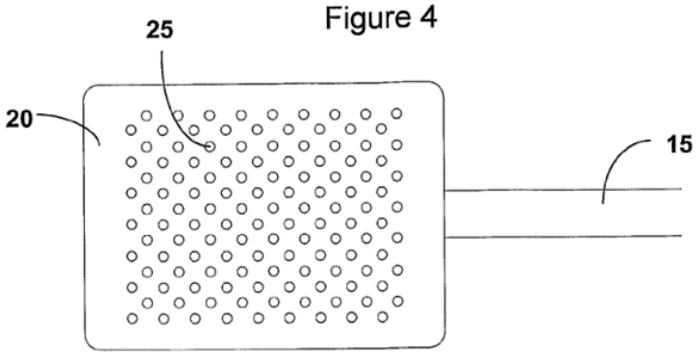
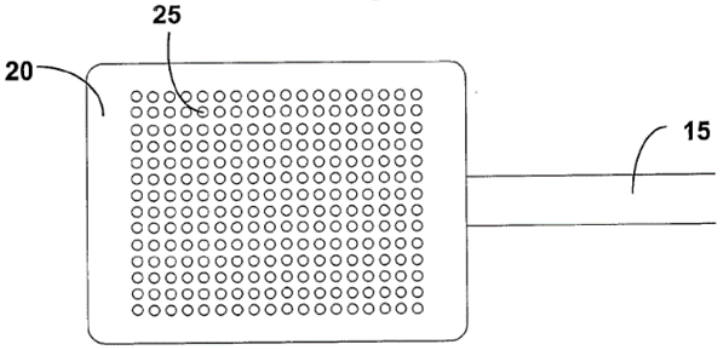
'444 Patent Claim 6		Ganz in view of Hantash '718 PCT in combination with ScarLet
		A POSITA would be motivated to combine Ganz and ScarLet because a POSITA would modify the arrangement of electrodes through routine experimentation and optimization. Thus, Ganz in view of Hantash '718 PCT and in further view of ScarLet or DeÁge discloses the mammalian treatment apparatus of claim 1 having the plurality of electrodes is arranged into a plurality of rows and columns and neighboring electrodes in each of the plurality of rows columns have opposite polarities.

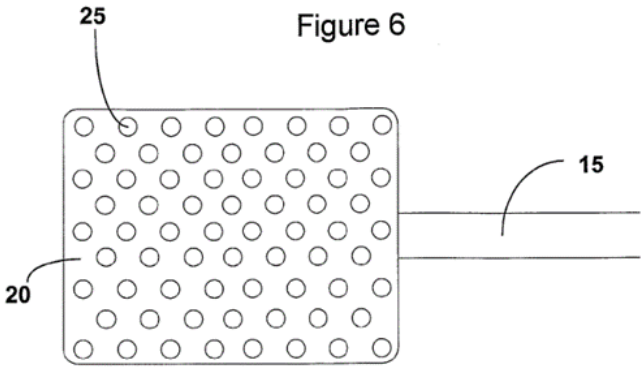
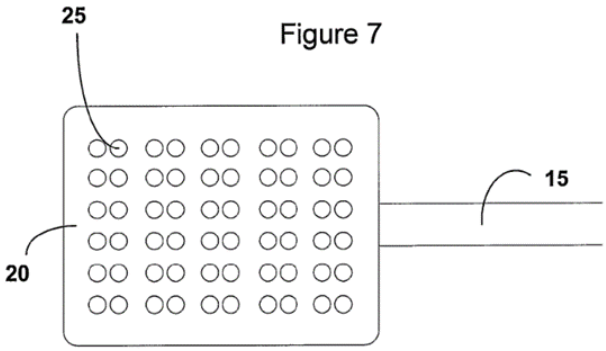
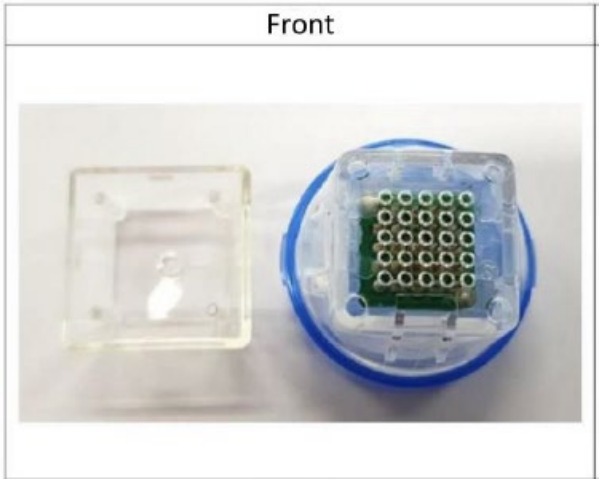
412. In view of the foregoing chart, claim 6 of the '444 Patent is anticipated by the teachings of Ganz. Further, to the extent Complainant is arguing that any of the foregoing limitations are not explicitly are inherently disclosed in Ganz, such limitations would have been obvious in view of Hantash '718 PCT and in further view of ScarLet. A POSITA would be motivated to combine Ganz and/or Hantash '718 PCT and ScarLet because a POSITA would modify the arrangement of electrodes through routine experimentation and optimization.

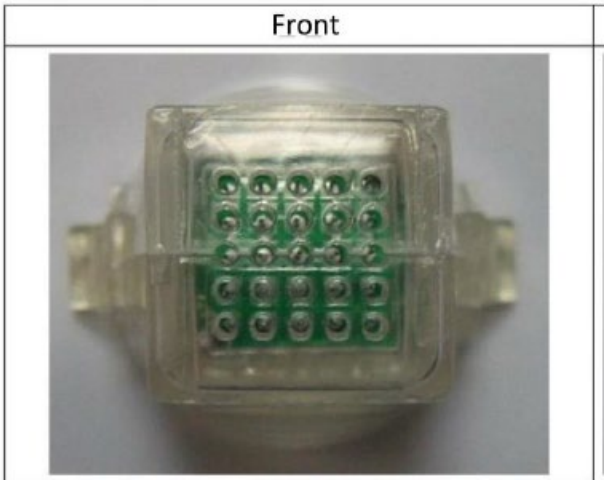
6. Claim 7 of the '444 Patent *is obvious over Ganz in view of Hantash '718 PCT and/or obvious by Ganz in view of ScarLet and in further view of Hantash '718 PCT*

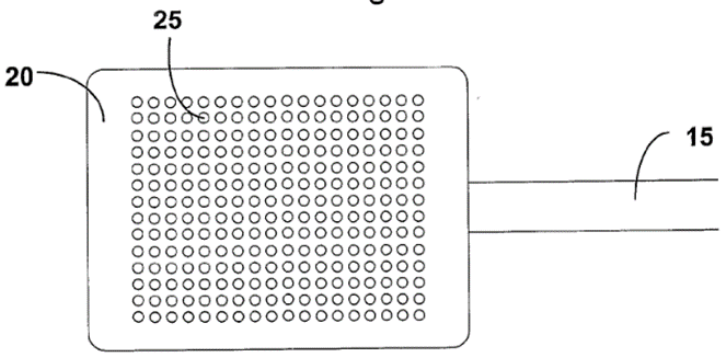
413. Claim 7 of the '444 Patent, which depends from claim 1, is obvious in view of the teachings of Ganz in combination with the teachings of Hantash '718 PCT and/or rendered obvious by the teachings of Ganz in combination with ScarLet and Hantash '718 PCT:

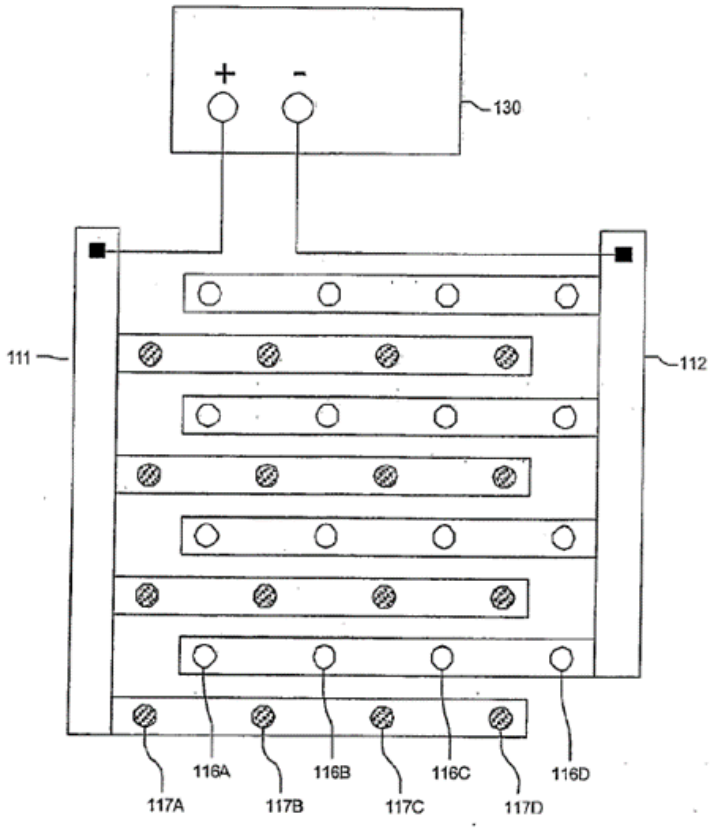
'444 Patent Claim 7		Ganz in view of Hantash '718 PCT and/or Ganz in combination with ScarLet and Hantash '718 PCT
7.0	The mammalian body treatment apparatus of claim 1,	As shown above in regard to claim 1, Ganz discloses a mammalian body treatment apparatus according to the claim. *See, e.g.*, Ganz, at [0001], [0016], [0027], [0029], [0030], [0033], [0063], claim 24. To the extent Complainant asserts that Ganz does not explicitly or inherently disclose this limitation, it would have further been obvious in view of ScarLet. As shown above in regard to claim 1, Ganz in view of

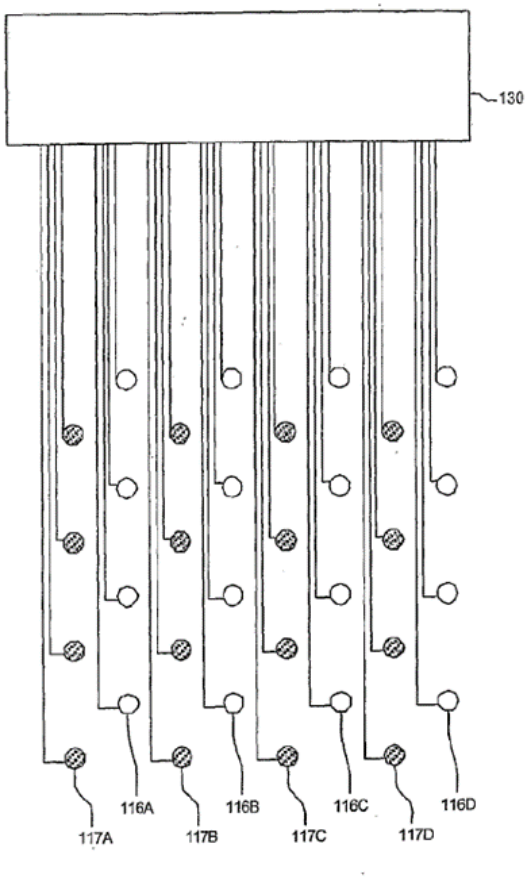
'444 Patent Claim 7		Ganz in view of Hantash '718 PCT and/or Ganz in combination with ScarLet and Hantash '718 PCT
		ScarLet discloses a mammalian body treatment apparatus according to the claim. *See* '444 Patent Claim 1.
7.1	wherein the plurality of electrodes forms a rectangular configuration	Ganz discloses and/or renders obvious the plurality of electrodes forms a rectangular configuration according to the claim. *See, e.g.*, Ganz at [0014], [0037], [0047], [0054], [0056]. Specifically, the electrodes on the device are "arranged in a desired pattern," including "orderly pattern[s]" such as a rectangular configuration, as shown in Figures 4, 5, 6 and 7. *Id.* at [0047], [0050], Figs. 4-7; *see also id.*, at [0037] ("The treating surface of the treatment device can be provided in any desired shape or configuration."). In these figures, Ganz discloses four various embodiments of electrodes arranged in a rectangular configuration. *Id.* at Figs. 4-7. Figure 4  Ganz, Fig. 4. Figure 5  Ganz, Fig. 5.

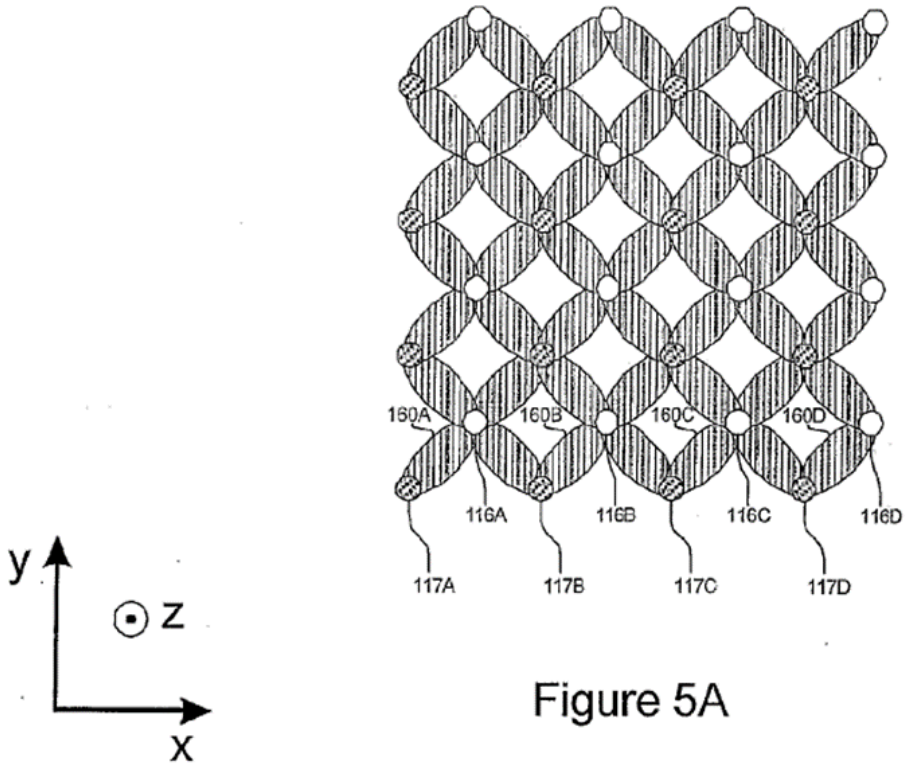
‘444 Patent Claim 7	Ganz in view of Hantash ‘718 PCT and/or Ganz in combination with ScarLet and Hantash ‘718 PCT
	 Ganz, Fig. 6.  Ganz, Fig. 7. ② Scarlet Tip 2 

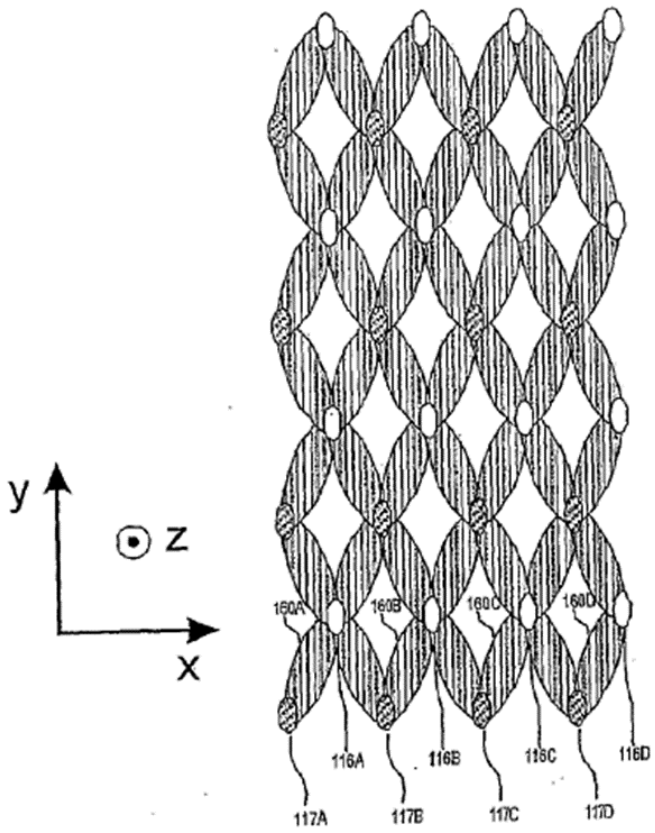
'444 Patent Claim 7		Ganz in view of Hantash '718 PCT and/or Ganz in combination with ScarLet and Hantash '718 PCT
		Ilooda-0010141 at -147 (certified English translation of SERENDIA-00033705 at -710). **Shape and structure – Appearance** 1. Photos of appearance 1) Overall appearance of the electrode ① Scarlet Tip  Ilooda-0010141 at -146 (certified translation of SERENDIA-00033705 at -709).
7.2	and their respective polarities form a checkboard pattern.	Ganz discloses the plurality of electrodes forms a rectangular configuration and their respective polarities form a checkboard pattern according to the claim. *See, e.g.*, Ganz at [0014], [0037], [0047], Fig, 4-7, [0054], [0056]. As shown above, Ganz teaches that the electrodes are in a square or rectangular configuration (claim element 6.1). *Id.*, at [0047] ("[a]ny desired pattern or electrode arrangement is within the scope of the invention."); *see also id.*, at Fig. 5.

'444 Patent Claim 7		Ganz in view of Hantash '718 PCT and/or Ganz in combination with ScarLet and Hantash '718 PCT
		Figure 5  Ganz, Fig. 5. As shown above, Ganz also teaches that the electrodes have opposite polarities (claim element 5.2). *Id.*, at [0014], [0047], [0050], [0054], [0056]. And in Ganz's bipolar embodiment, the electrodes come in pairs where "one electrode in the pair being a positive electrode and the other electrode being a negative electrode." *Id.*, at [0056]. As a result of the electrodes having opposite polarities, they form a checkboard pattern. To the extent that Complainant asserts that Ganz does not disclose wherein the plurality of electrodes forms a rectangular configuration and their respective polarities form a checkboard pattern, it would have further been obvious in view of Hantash '718 PCT. Hantash '718 PCT discloses a mammalian body treatment apparatus, according to the claim, wherein the electrodes forms a rectangular configuration and their respective polarities form a checkboard pattern according to the claim. For example, Figures 3A, 3B, 4A, 5A, and 9A disclose rectangular electrode arrangements that form a checkboard pattern. Hantash '718 PCT at Figures 3A, 3B, 4A, 5A, and 9A.

'444 Patent Claim 7	Ganz in view of Hantash '718 PCT and/or Ganz in combination with ScarLet and Hantash '718 PCT
	 Figure 3A Hantash '718 PCT, Fig. 3A.

‘444 Patent Claim 7	Ganz in view of Hantash ‘718 PCT and/or Ganz in combination with ScarLet and Hantash ‘718 PCT
	 Figure 3B Hantash ‘718 PCT, Fig. 3B.

'444 Patent Claim 7		Ganz in view of Hantash '718 PCT and/or Ganz in combination with ScarLet and Hantash '718 PCT
		 Figure 5A Hantash '718 PCT, Fig. 5A.

'444 Patent Claim 7	Ganz in view of Hantash '718 PCT and/or Ganz in combination with ScarLet and Hantash '718 PCT
	 Figure 9A Hantash '718 PCT, Fig. 9A. A POSITA would be motivated to combine Ganz and Hantash '718 PCT because a POSITA would modify the arrangement of electrodes through routine experimentation and optimization. Thus, Ganz in view of Hantash '718 PCT discloses the mammalian treatment apparatus of claim 1 where the plurality of electrodes forms a square configuration with a checkboard pattern. ScarLet discloses the mammalian treatment apparatus of claim 1 where the plurality of electrodes forms a square configuration with a checkboard pattern. Na Tr. 226:8-228:3. (Q Does the original Scarlet from that 2010 KFDA document have the checkerboard pattern of needle arrangement? A It was in five-by-five rows. . . . Q In the bipolar mode, would they have opposite polarity to the central electrode, as opposed to the 3:00 and the 6:00? A Right. So if you look at the electrodes in the Scarlet in the 2010

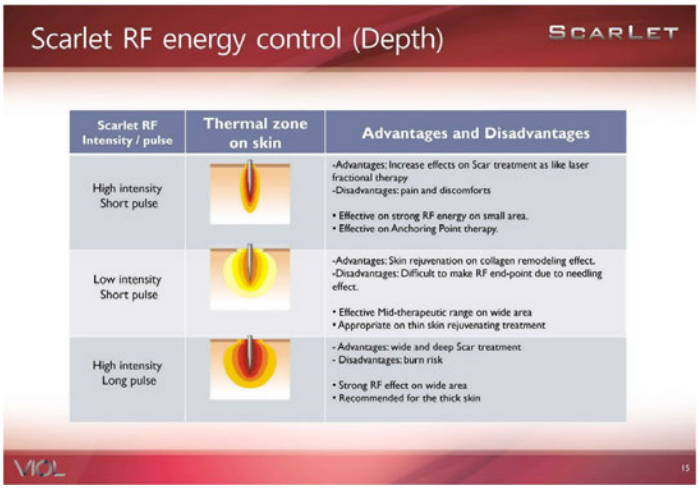
'444 Patent Claim 7		Ganz in view of Hantash '718 PCT and/or Ganz in combination with ScarLet and Hantash '718 PCT
		KFDA approval sheet. And so if you use bipolar mode, then the electrodes next to that is done to have opposite polarity.)

414. In view of the foregoing chart, claim 7 of the '444 Patent is anticipated by the teachings of Ganz. Further, to the extent Complainant is arguing that any of the foregoing limitations are not explicitly are inherently disclosed in Ganz, such limitations would have been obvious in view of Hantash '718 PCT and/or obvious by the teachings of Ganz in view of ScarLet and in further view of Hantash '718 PCT. A POSITA would be motivated to combine Ganz and Hantash '718 PCT because a POSITA would modify the arrangement of electrodes through routine experimentation and optimization.

7. Claim 8 of the '444 Patent *is Anticipated and/or rendered Obvious by Ganz alone and/or in combination with ScarLet*

415. Claim 8 of the '444 Patent, which depends from claim 1, is anticipated and/or rendered obvious by the teachings of Ganz and/or by the teachings of Ganz in view of ScarLet:

'444 Patent Claim 8		Ganz alone and/or in combination with ScarLet
8.0	The mammalian body treatment apparatus of claim 1,	As shown above in regard to claim 1, Ganz discloses a mammalian body treatment apparatus according to the claim. *See, e.g.*, Ganz, at [0001], [0016], [0027], [0029], [0030], [0033], [0063], claim 24. To the extent Complainant asserts that Ganz does not explicitly or inherently disclose this limitation, it would have further been obvious in view of ScarLet. As shown above in regard to claim 1, Ganz in view of ScarLet discloses a mammalian body treatment apparatus according to the claim. *See* '444 Patent Claim 1.
8.1	wherein the plurality of electrodes are non-insulated.	Ganz discloses and/or renders obvious the plurality of electrodes are non-insulated according to the claim. *See, e.g.*, Ganz, at [0056].

‘444 Patent Claim 8		Ganz alone and/or in combination with ScarLet
		Specifically, Ganz discloses the option that “various portions of the proximal electrodes can also be insulated in order to limit the coagulation injury to the distal end of the electrode as well.” *Id.*, at [0056]. Thus, Ganz discloses that the electrodes can be insulated or non-insulated, with the default being not insulated. A POSITA would also know that the default for medical needles is that the needles are not insulated. To the extent Complainant asserts that this limitation is not explicitly or inherently disclosed by Ganz, it would have been obvious given the knowledge of a POSITA. In view of what is discussed above in section VII. regarding the well-known use of non-insulated RF acupuncture needles, a POSITA would also know that the default for this type of needle electrodes is that the needles are not insulated, and that non insulated electrodes represents one of the two options available for electrodes at the time of application: non-insulated or partially insulated.  SERENDIA-00017306 at -320. Accordingly, under Complainants’ interpretation of “causes energy to be substantially applied to body segments around each electrode rather than to body segments between the electrodes,” and, to the extent that Complainant asserts that “causes energy to be substantially applied to body segments around each electrode rather than to body segments between the electrodes” has the same scope as “cause coagulation around each electrode rather than coagulating between the

'444 Patent Claim 8		Ganz alone and/or in combination with ScarLet
		electrodes," recited in independent claim 1 of the '836 Patent, then Ganz in view of the knowledge of a POSITA or in view of Scarlet also rendered obvious claim 8.

416. In view of the foregoing chart, claim 8 of the '444 Patent is anticipated and/or rendered obvious by the teachings of Ganz alone and/or by the teachings of Ganz in view of ScarLet.

8. Claim 9 of the '444 Patent *is anticipated by and/or rendered obvious by Ganz*

417. Claim 9 of the '444 Patent, which depends from claim 1, is anticipated by and/or rendered obvious by the teachings of Ganz and/or by the teachings of Ganz:

'444 Patent Claim 9		Ganz
9.0	The mammalian body treatment apparatus of claim 1,	As shown above in regard to claim 1, Ganz discloses a mammalian body treatment apparatus according to the claim. *See, e.g.*, Ganz, at [0001], [0016], [0027], [0029], [0030], [0033], [0063], claim 24. To the extent Complainant asserts that Ganz does not explicitly or inherently disclose this limitation it would have been obvious to a POSITA.
9.1	wherein each electrode of the plurality of electrodes is insulated except at its tip.	Ganz discloses and/or renders obvious wherein each electrode of the plurality of electrodes is insulated except at its tip according to the claim. *See, e.g.*, Ganz, at [0056]. Specifically, Ganz disclosed an embodiment where the "various portions of the proximal electrodes can be insulated in order to limit the coagulation injury to the distal end of the electrode" *Id.,* at [0056]. A POSITA would have understood the distal end of the electrode to be the tip and the proximal end of the electrode to be the section of the electrode furthest from the tip. Therefore, a POSITA would have understood that Ganz disclosed an embodiment where the electrodes are insulated except at its tip (except at its distal end).

‘444 Patent Claim 9		Ganz
		To the extent Complainant asserts that this limitation is not explicitly or inherently disclosed by Ganz, it would have been obvious given the knowledge of a POSITA. A POSITA would have understood that insulating the needle except for the tip is one way of preventing unwanted heating or lesions of the epidermis (when targeting the dermis with the tip). *See, e.g.*, Ganz, at [0056]. Thus, it would have been desirable to use needle electrodes that are insulated except at the tip. It would have also been obvious to try only insulating the needle except at its tip because there are only two options to try that would allow the needles to deliver RF energy to the skin via the tip of the needle: non-insulated needles, and partially insulated needles without any insulation on the tip. Accordingly, under Complainants’ interpretation of “causes energy to be substantially applied to body segments around each electrode rather than to body segments between the electrodes,” and, to the extent that Complainant asserts that “causes energy to be substantially applied to body segments around each electrode rather than to body segments between the electrodes” has the same scope as “cause coagulation around each electrode rather than coagulating between the electrodes,” recited in independent claim 1 of the ‘836 Patent, then Ganz in view of the knowledge of a POSITA also rendered obvious claim 9.

418. In view of the foregoing chart, claim 9 of the ‘444 Patent is anticipated and/or rendered obvious by the teachings of Ganz alone and/or by the teachings of Ganz in view of ScarLet.

D. The Asserted Claims of the ‘536 Patent are Anticipated or Rendered Obvious by the Prior art.

419. The Asserted Claims of the ‘536 Patent are invalid under 35 U.S.C. § 102 (pre-AIA or AIA) as anticipated by Mehta and/or are invalid under 35 U.S.C. § 103 (pre-AIA or AIA) as obvious in view of Mehta alone (in view of the knowledge of a POSITA) or in

combination with one or more other references identified herein and/or in Respondents' Invalidity Contentions, at least based on my understanding of Complainant's application of the asserted claims in an effort to show infringement.

420. U.S. Patent No. 8,608,737 ("Mehta") qualifies as prior art under at least AIA 35 U.S.C. § 102(a)(1) because it is a patent that published before the filing of the earliest application to which the '536 Patent could claim priority.

421. To the extent the '812 Patent is subject to pre-AIA law, Mehta qualifies as prior art under at least 35 U.S.C. § 102(e) (pre-AIA) because it is a patent that was filed prior to the alleged invention of the '536 Patent.

422. It is my opinion that U.S. Patent No. 8,608,737 ("Mehta") anticipates and/or renders each and every limitation of the '536 Patent's Asserted Claims obvious.

423. Mehta in view of the knowledge of a POSITA renders each and every limitation of the '536 Patent's Asserted Claims obvious. A POSITA would have understood that any limitations in the Asserted Claims arguably not explicitly disclosed by Mehta were obvious in view of the state of the relevant art. A POSITA would have been motivated to draw upon his or her knowledge of the relevant art to modify Mehta as necessary to achieve any of the claimed features and would have enjoyed a reasonable expectation of success in doing so. A POSITA would have enjoyed a reasonable expectation of success in combining and/or modifying the teachings of the foregoing prior art references and products, together with general knowledge of the art, to achieve the claimed subject matter, at least because the prior art itself discloses and/or practices the claimed methods and apparatuses to achieve the claimed results. A POSITA would have recognized that the relevant art is predictable, and that achieving the claimed subject matter would have been obvious to try or requires merely routine optimization.

424. To the extent Mehta does not render one or more claim limitations of the '536 Patent's Asserted Claims obvious, Mehta in view of one or more of Na '848 and/or Kang '395. Mehta, Na '848 and Kang '395 discuss or address the same or substantially similar underlying apparatus and/or technology in the field of dermatological treatment and devices such that a POSITA would have understood that these one or more of these references can be combined, according to known methods and/or by the simple substitution of one known, equivalent element for another, to yield predictable results and with a reasonable expectation of success.

425. A POSITA would also have been motivated to combine one or more of these reference in light of market forces in the industry, and the desire to improve features and performance, and/or in light of one or more teachings, suggestions, or motivations in the art. A POSITA would have enjoyed a reasonable expectation of success in combining and/or modifying the teachings of the foregoing prior art references and products, together with general knowledge of the art, to achieve the claimed subject matter, at least because the prior art itself discloses and/or practices the claimed methods and apparatuses to achieve the claimed results. A POSITA would have recognized that the relevant art is predictable, and that achieving the claimed subject matter would have been obvious to try or requires merely routine optimization.

426. Mehta qualifies as prior art under at least 35 U.S.C. § 102(e) (pre-AIA) because it is a patent issued from a patent application filed before the earliest possible priority date of the '536 Patent. The pre-grant publication of the Mehta patent application (U.S. Pub. No. 2010/0204695) also qualifies as prior art under at least 35 U.S.C. § 102(a) (pre-AIA) because it was published prior to the earliest possible priority date of the '536 Patent.

427. To the extent Complainant alleges that Mehta does not disclose any particular limitation of the asserted claims of the '536 Patent, either expressly or inherently, it would have

been obvious to a POSITA as of the priority date of the '536 Patent to modify Mehta and/or to combine the teachings of Mehta with the knowledge of a POSITA and/or with one or more of International Publication No. WO2010/016848 ("Na '848") and Korean Publication No. KR 10-0719395 ("Kang '395") in a manner that would have rendered the asserted claims invalid as obvious.

428. Na '848 qualifies as prior art under at least 35 U.S.C. § 102(b) (pre-AIA) because it is a patent publication that published more than one year before the filing of the earliest application to which the '536 Patent could claim priority. Na '848 also qualifies as prior art under at least 35 U.S.C. § 102(a) (pre-AIA) because it is a patent publication of a patent application by a different inventive entity that was published prior to the earliest possible priority date of the '536 Patent. Na '848 also qualifies as prior art under at least 35 U.S.C. § 102(e) (pre-AIA) because it is a patent publication of a patent application filed by a different inventive entity prior to the earliest possible priority date of the '536 Patent.

429. Kang '395 qualifies as prior art under at least 35 U.S.C. § 102(b) (pre-AIA) because it is a patent that published more than one year before the filing of the earliest application to which the '536 Patent could claim priority. Kang '395 also qualifies as prior art under at least 35 U.S.C. § 102(a) (pre-AIA) because it is a patent issued from a patent application by another that was published prior to the earliest possible priority date of the '536 Patent.

430. Mehta, Na '848 and Kang '395 discuss or address the same or substantially similar underlying apparatus and/or technology in the field of dermatological treatment and devices such that a POSITA would have understood that these one or more of these references can be combined, according to known methods and/or by the simple substitution of one known,

equivalent element for another, to yield predictable results and with a reasonable expectation of success. A POSITA would also have been motivated to combine one or more of these reference in light of market forces in the industry, and the desire to improve features and performance, and/or in light of one or more teachings, suggestions, or motivations in the art. A POSITA would have enjoyed a reasonable expectation of success in combining and/or modifying the teachings of the foregoing prior art references and products, together with general knowledge of the art, to achieve the claimed subject matter, at least because the prior art itself discloses and/or practices the claimed methods and apparatuses to achieve the claimed results. A POSITA would have recognized that the relevant art is predictable, and that achieving the claimed subject matter requires merely routine optimization.

431. The asserted claims of the '536 Patent are invalid under 35 U.S.C. § 102 (pre-AIA) as anticipated by Mehta, and/or are invalid under 35 U.S.C. § 103 (pre-AIA) as obvious in view of Mehta alone (in view of the knowledge of a POSITA), or in combination with one or more other references identified herein and/or in Respondents' Invalidity Contentions, at least based on Respondents' understanding of Complainant's application of the asserted claims in an effort to show infringement.

432. As shown below, under Complainant's interpretation of "a user holdable device releasably couplable deployable needle assembly end surface" (Complainant's interpretation does not appear to require this end surface to be an actual surface of the needle assembly), "the deployable needle assembly mechanically separatably from the proximal end" (Complainant's interpretation does not appear to require the assembly to be mechanically separable and apparently may be satisfied based on a module containing the assembly being mechanically separable), and "communicating electrical signals from the proximal end to the plurality of the

extendable needles… energizing the plurality of extended needles via a signal generator electrically coupled to the plurality of extended needles" (Complainant's interpretation apparently allows for these two separate steps to be actually be satisfied by only a single step and/or for these two steps to be performed in any order), the asserted claims of the '536 Patent are invalid for at least the following reasons:

Mehta anticipates claims 1, 11, 13, 16, and 17;

Mehta renders obvious claims 1, 4, 5, 9, 11, 13, 16, and 17;

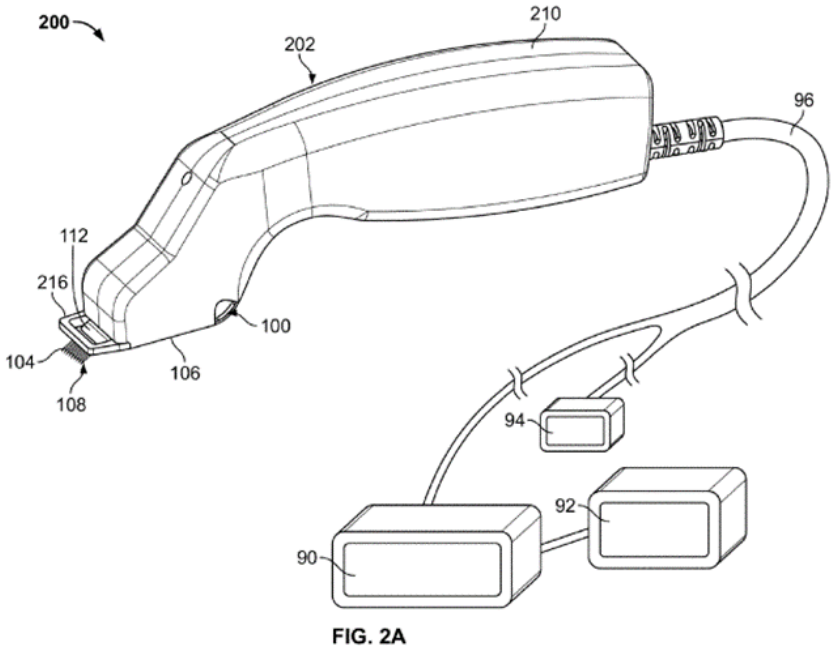
Mehta in view of Na '848 renders obvious claims 4, 5, and 9; and/or

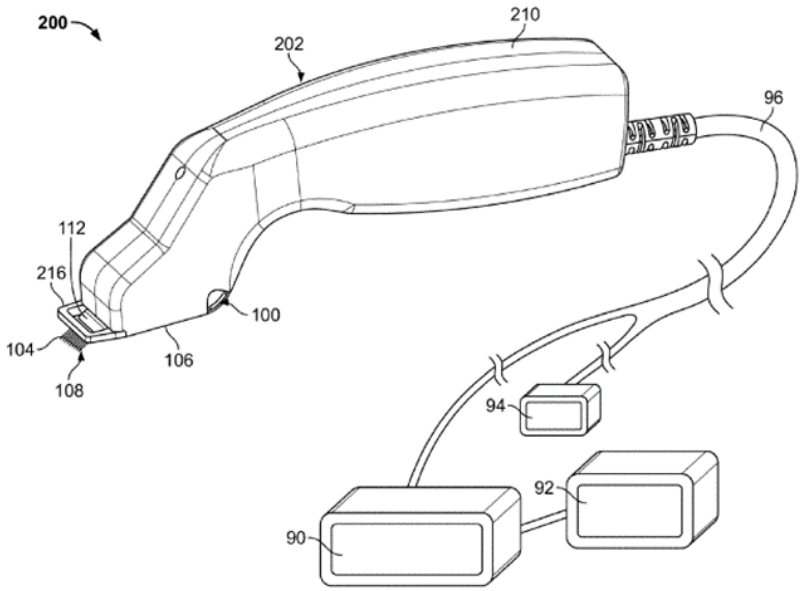
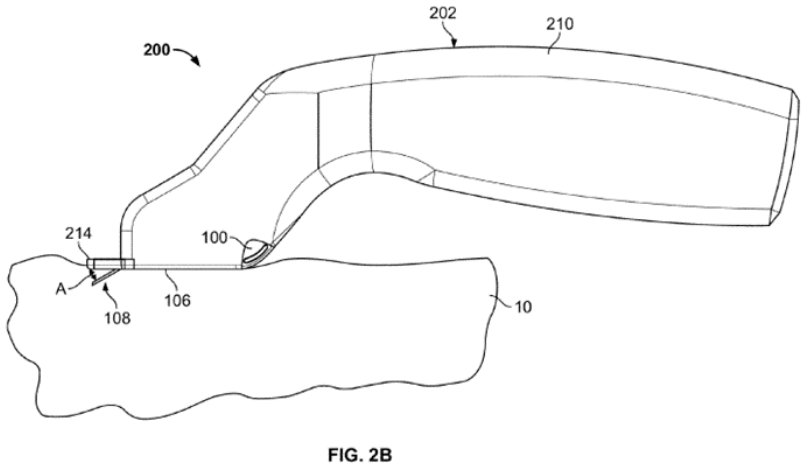
Mehta in view of Kang '395 renders obvious claims 4 and 5.

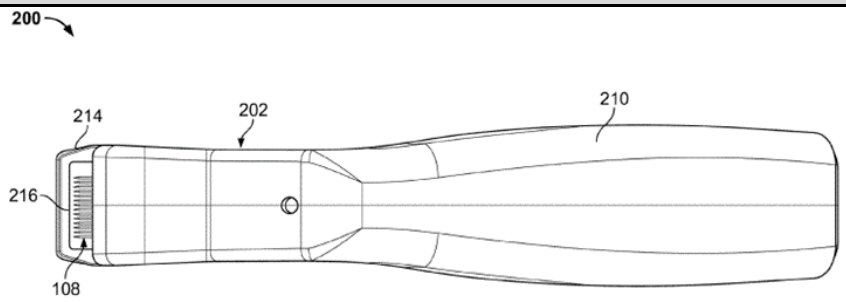
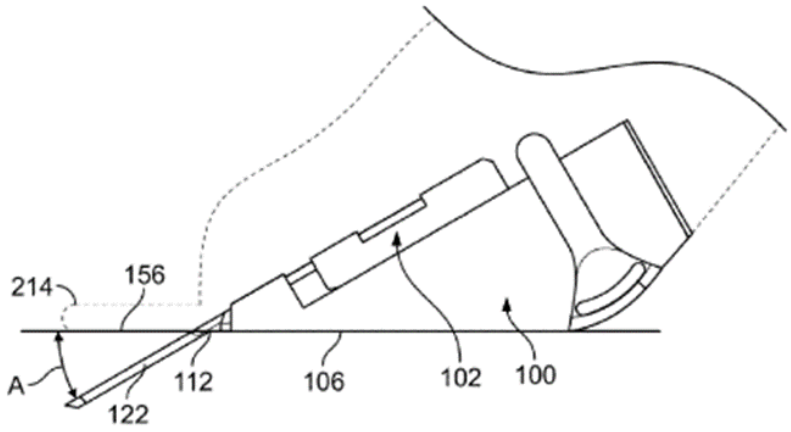
1. Claim 1 of the '536 Patent is Anticipated by the teachings of Mehta

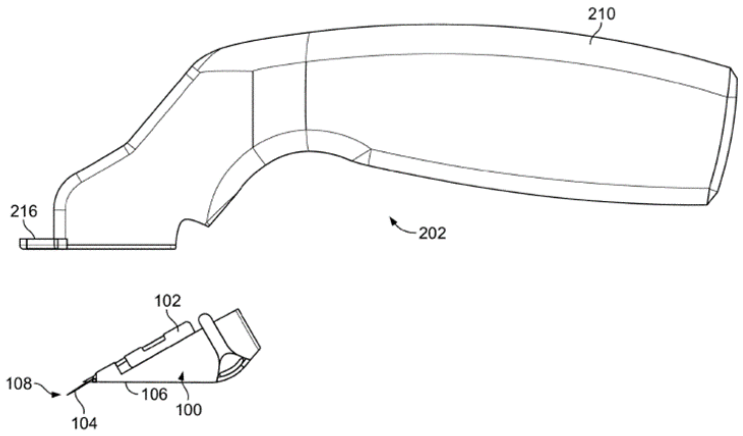
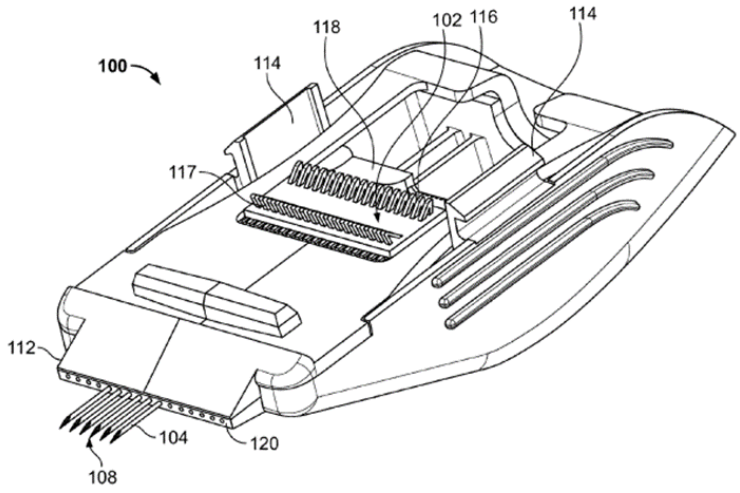
433. It is my opinion that claim 1 of the '536 Patent is anticipated by Mehta and/or rendered obvious by Mehta alone.

'536 Patent Claim 1		**Mehta**
1.0	1. A method of treating dermatological tissue, comprising:	Mehta discloses a method of treating dermatological tissue according to the claim. *See, e.g.,* Mehta, at 1:14-19; 2:3-12; 2:13-21; 2:22-29; 2:30-33; 2:37-57; 2:58-62; 2:37-57; 2:63-3:17; 6:30-37; 7:52-59; 7:60-8:5; 8:6-12; 8:54-65; 9:34-55; Fig. 2A; 10:66-11:13; 12:23-30; Fig. 2B; 7:19-22; Fig. 10A; 10:66-11:13; 19:17-25; 19:66-20:12; 22:53-62; 23:55-24:4; Fig. 7E; and 24:5-12. Specifically, Mehta discloses "systems and method" to "treat tissue in the human body," and "[i]n a particular variation," to "**treat** cosmetic conditions affecting **the skin** of various body parts, including face, neck, and other areas traditionally prone to wrinkling, lines, sagging and other distortions of the **skin**." Mehta, at 1:14-19 (emphasis added); *see also id*., at 2:3-21; 2:37-57 ("systems and methods" to "to shrink collagen tissue in the dermis"), 7:52-8:12, 8:54-65, 19:17-25, 19:66-20:12, 22:53-62. Mehta's skin treatment apparatus 200, reproduced below, included "a system [200] for monitoring energy delivery from an energy supply unit [90] to" the skin, which included "a treatment unit [202] having a device body," [210] "a first plurality of energy transfer elements,"

'536 Patent Claim 1		Mehta
		(104) and "a graphical user interface" (320). *Id*., at 2:63-3:17; *see also id*., at 9:34-55, 10:66-11:13.  FIG. 2A *Id*., Fig. 2A.
1.1	placing a user holdable device releasably couplable deployable needle assembly end surface on or near dermatological tissue to be treated,	Mehta discloses placing a user holdable device releasably couplable deployable needle assembly end surface on or near dermatological tissue to be treated. *See, e.g.*, Mehta, at 1:14-19; 2:3-12; 2:13-21; 2:63-3:17; 3:29-39; 4:1-18; 4:19-30; 4:35-43; 4:63-5:2; 4:35-43; 4:63-5:2; 5:3-15; 5:49-57; 6:30-37; 6:64-65; 7:52-59; 7:60-8:5; 9:34-55; Fig. 2A; 9:56-64; 9:65-10:7; 10:33-39; 10:40-47; 10:48-52; 12:23-30; Fig. 2B; 12:31-46; 12:47-58; 12:59-13:4; 13:5-15; 13:16-36; Fig. 2C; 13:45-53; 13:16-36; 13:54-57; Fig. 3A; 13:58-14:4; 14:5-19; Fig. 2D; 14:20-29; 15:27-33; Fig. 4A; 15:34-54; 15:55-16:11; 16:19-33; 16:42-58; 16:59-17:12.; 17:46-58; 17:59-18:3; 18:21-37; Fig. 5; 18:37-45; 21:1-13; Fig .7A; 21:14-21; 21:22-34; Fig. 7B; 21:34-42; 21:43-62; 23:11-27; 32:16-25; 35:8-22; Fig. 12A; Fig. 12B; 37:7-17. Mehta discloses that the tissue that is treated is skin (dermatological tissue). *Id*., at 1:14-19, 7:52-59. Mehta's system includes "a treatment unit [202] having a device body [210]," which "includes a tissue engaging surface that allows orientation of the device body on the surface of [skin] tissue [10]," and a stabilization plate [214] to the tissue engaging surface. Mehta,

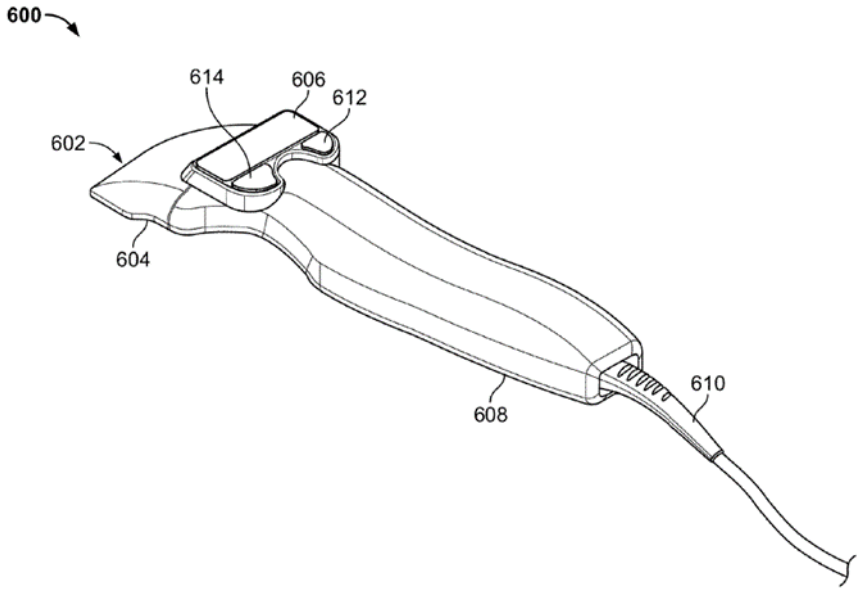
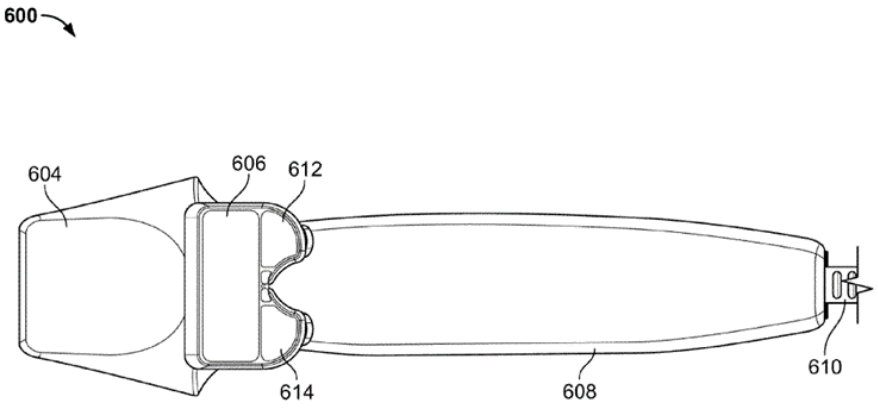
'536 Patent Claim 1		Mehta
		at 2:63-3:17, *see also id*., at 4:1-18, 4:63-5:2, 9:36-39, 10:40-52, 12:23-46, 12:47-58 (tissue engaging surface engages "skin tissue"), 12:59-13:15, 13:45-53, 32:16-25.  FIG. 2A *Id*., Fig. 2A.  FIG. 2B *Id*., Fig. 2B

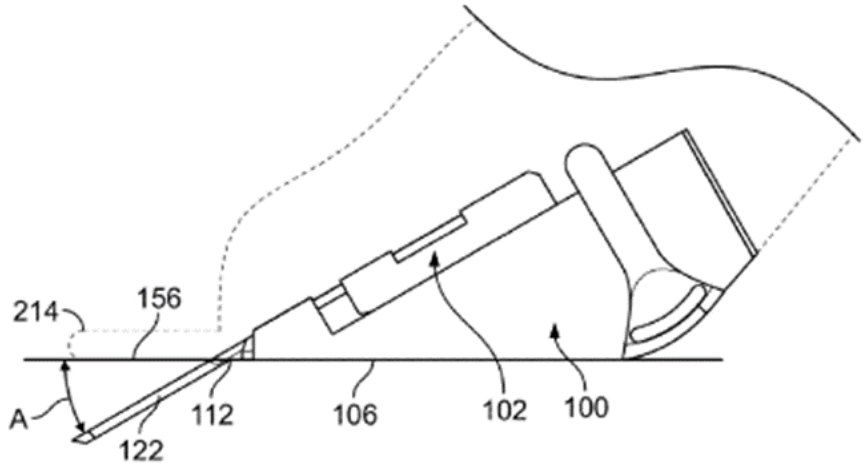
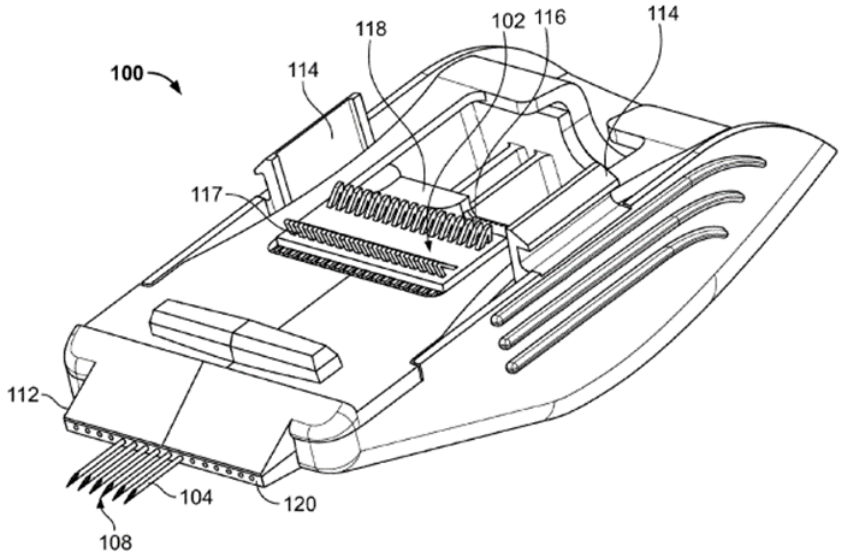
'536 Patent Claim 1	Mehta
	 FIG. 2C *Id*., Fig. 2C "FIG. 7A illustrates a partial side view of the … tissue engaging surface 106" and "stabilization plate 214" placed against the skin tissue. *Id*., at 21:1-13; *see also id*., at 21:22-34, Fig. 7B.  FIG. 7A *Id*., Fig. 7A. Mehta's user holdable device also includes "cartridges [100] that are removably coupled to the device body [210], where at least the plurality of first [needle] electrodes [104] and the tissue engaging surface [106] are located on or in the cartridge body." *Id*., at 4:63-66; *see also id*., at 9:34-55, 13:5-15, 15:55-16:1 ("FIG. 4A also shows the electrodes 104 in the electrode assembly 102 as having connection or contact portions 116 that couple to a connection board on a treatment unit to provide an electrical pathway from the power supply to the

'536 Patent Claim 1		Mehta
		electrodes 104") 35:8-10[35] "FIG. 2D shows the treatment system 202 of FIG. 2A where the cartridge assembly 100 and device body 210 are separated." *Id*., at 14:5-19.  FIG. 2D *Id*., Fig. 2D. As shown in Fig. 4, reproduced below, the "cartridge body 100" may include "retention fasteners 114 allowing for coupling with the device body as well as removal from the device body … to permit removable coupling." *Id*., at 15:27-33; *see also id*., at 16:42-58.  FIG. 4A *Id*., Fig. 4A.

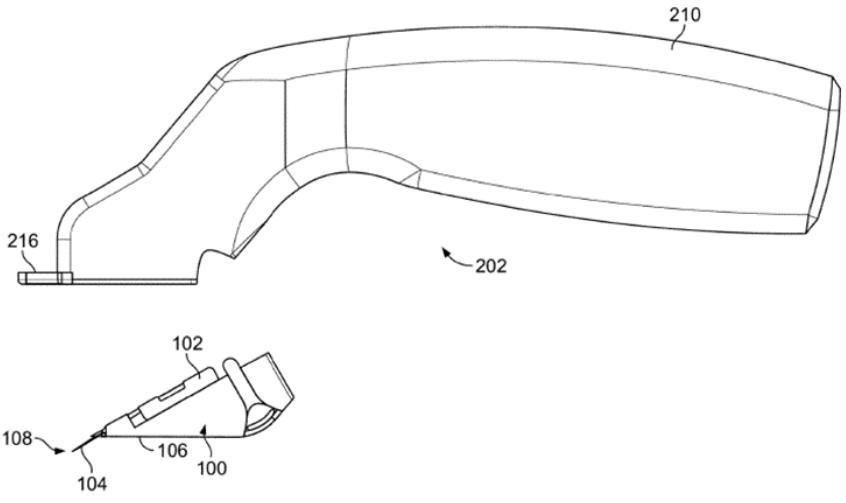
[35] Mehta refers to energy transfer elements and probes synonymously, and explains these are needle electrodes. *Id*., at 49:43-53, 40:45-57, 12:23-20, 12:47-58, 16:59-17:12, 31:37-41.

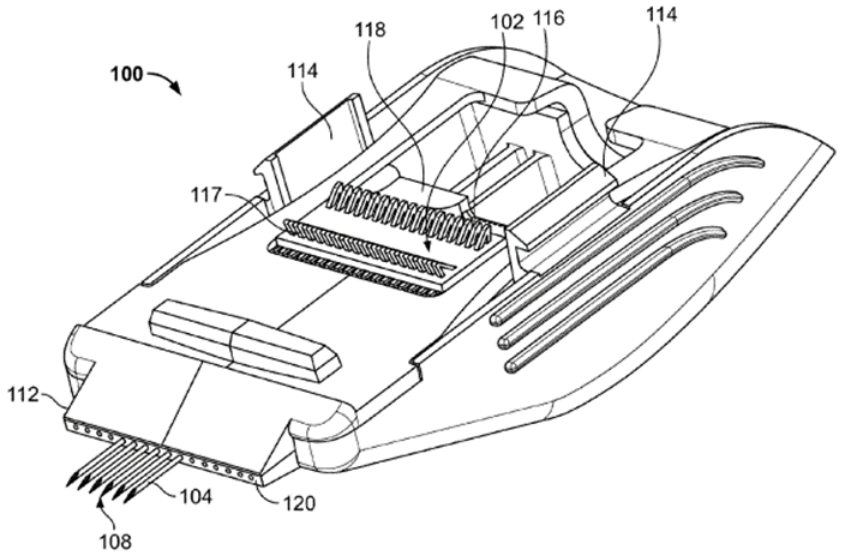
'536 Patent Claim 1		Mehta
		The needle electrodes are deployable from the cartridge. For example, Mehta discloses that the "tissue engaging surface and stabilization plate are positioned such that … the tissue engaging surface is placed on the surface of tissue" so a "first plurality of energy transfer elements is advanced into the surface of tissue." *Id*., at 4:10-18; *see also id*., at 5:3-15, 12:23-30, 13:16-36 ("the probes are deployed into tissue subsequent to placement of the device body 210 against the tissue"), 13:58-14:4, 15:34-54, 16:19-33, 18:21-37, 21:43-62, 37:7-8 ("layer of skin in which the needles were deployed"). Mehta's "device body" 210 has a "handle portion" (*id*., at 4:1-18; *see also id*., at 9:34-39, 35:8-10, Figs. 12A, 12B), and thus, Mehta discloses a user holdable device (*id*, at 9:56-64 ("can be grasped by the hand")). Thus, Mehta's cartridge includes a releasably couplable deployable needle assembly for a user holdable device, and Mehta's cartridge includes an end surface (*e.g.*, according to Complainant's interpretation, a plane corresponding to the tips of the needles when the needles are not extended) which is placed on near dermatological tissue (skin) to be treated.
1.2	the holdable device including a proximal end and the releasably couplable deployable needle assembly,	Mehta discloses the holdable device including a proximal end and the releasably couplable deployable needle assembly, *See, e.g.* discussion and citations above regarding Mehta for limitation 1.1;.*see also, e.g.*, Mehta, at 4:1-18; 4:19-30; 4:63-5:2; 5:3-15; 5:49-57; 6:30-37; 6:64-65; 9:34-55; Fig. 2A; 9:56-64; 9:65-10:7; 10:33-39; 10:48-52; 12:23-30; Fig. 2B; 12:31-46; 12:47-58; 12:59-13:4; 13:5-15; 13:16-36; 13:54-57; Fig. 3A; 13:58-14:4; 14:5-19; Fig. 2D; 14:20-29; 15:27-33; Fig. 4A; 15:34-54; 15:55-16:11; 16:12-18; 16:19-33; 16:42-58; 16:59-17:12; 17:46-58; Fig. 4F; 17:59-18:3; 18:21-37; Fig. 5; 18:37-45; 21:1-13; Fig .7A; 21:14-21; 21:22-34; Fig. 7B; 21:34-42; 21:43-62; 23:11-27; Fig. 7C; 31:37-41; 32:16-25; 35:8-22; Fig. 12A; Fig. 12B; 37:7-17. As shown in the discussion of limitation 1.1 above, Mehta's user holdable device includes the releasably couplable deployable needle assembly. Mehta's device body has "an electrical lead 610 on the proximal end," which connects to "the detachable cartridge 604 on [the] distal end 602." Mehta, at 35:8-10.

'536 Patent Claim 1		Mehta
		 FIG. 12A *Id.*, Fig. 12A.  FIG. 12B *Id.*, Fig. 12B.

‘536 Patent Claim 1		Mehta
		 FIG. 7A *Id.*, Fig. 7A.  FIG. 4A *Id.*, Fig. 4A.
1.3	the deployable needle assembly mechanically	Mehta discloses the deployable needle assembly mechanically separatably [36] from the proximal end and including a plurality of needles extendable from the deployable needle assembly end surface.

[36] Mehta refers to energy transfer elements and probes synonymously, and explains these are needle electrodes. *Id*., at 49:43-53, 40:45-57, 12:23-20, 12:47-58, 16:59-17:12, 31:37-41.

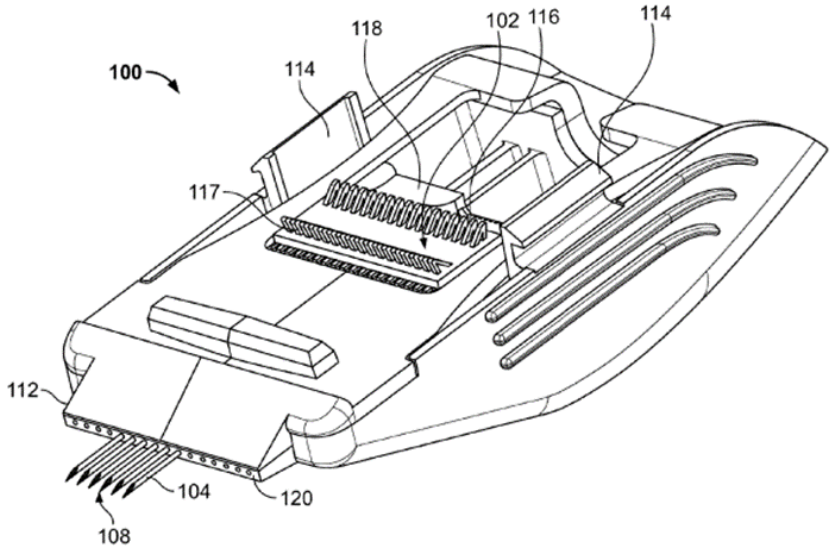
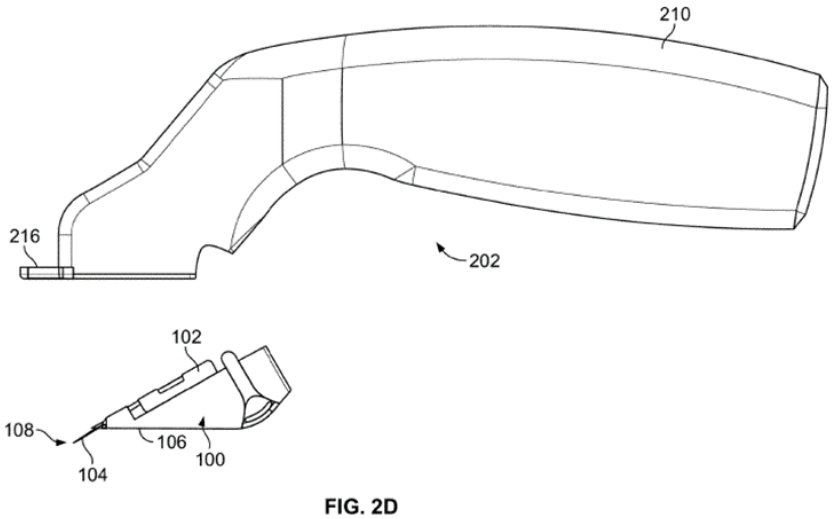
'536 Patent Claim 1		Mehta
	separatably from the proximal end and including a plurality of needles extendable from the deployable needle assembly end surface,	*See, e.g.*, Mehta, at 4:1-18; 4:19-30; 6:64-65; 4:63-5:2; 5:3-15; 5:49-57; 6:30-37; 6:64-65; 9:34-55; Fig. 2A; 9:56-64; 9:65-10:7; 10:33-39; 10:48-52; 12:23-30; Fig. 2B; 12:31-46; 12:47-58; 12:47-58; 12:59-13:4; 13:5-15; 13:16-36; 13:54-57; Fig. 3A; 14:5-19; Fig. 2D; 14:20-29; 15:27-33; Fig. 4A; 15:34-54; 15:55-16:11; 16:19-33; 16:42-58; 16:59-17:12; 17:46-58; Fig. 4F; 17:59-18:3; 18:21-37; Fig. 5; 18:37-45; 21:1-13; Fig .7A; 21:14-21; 21:22-34; Fig. 7B; 21:34-42; 21:43-62; 23:11-27; Fig. 7C; 31:37-41; 32:16-25; 35:8-22; Fig. 12A; Fig. 12B; 37:7-17; 6:64-65. To the extent that "separatably" does not render claim 1 indefinite, and is construed to be "separable" and in accordance with Complainant's proposed interpretation of "mechanically separable" which allows for this limitation to be met solely based on the module, rather than the assembly, being separable, Mehta's releasably couplable deployable needle assembly is mechanically separable from the user holdable device's proximal end, and includes a plurality of needles. Further, Mehta expressly discloses that the needle assembly itself include mechanical elements for coupling to and decoupling from the proximal end, and also anticipates under Respondents' construction (*see* discussion below). Mehta's cartridge body is removably attachable to the device body's "proximal end." Mehta, at 35:8-10, Figs. 12A, 12B; *see also id*., at 4:63-66, 6:64-65, 9:34-55, 13:5-15, 14:5-19, 35:8-10.  FIG. 2D *Id*., Fig. 2D.

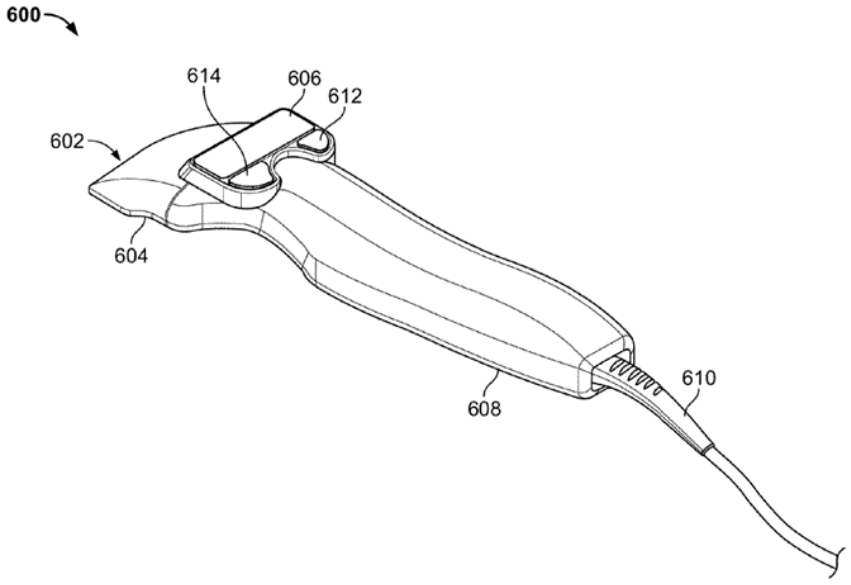
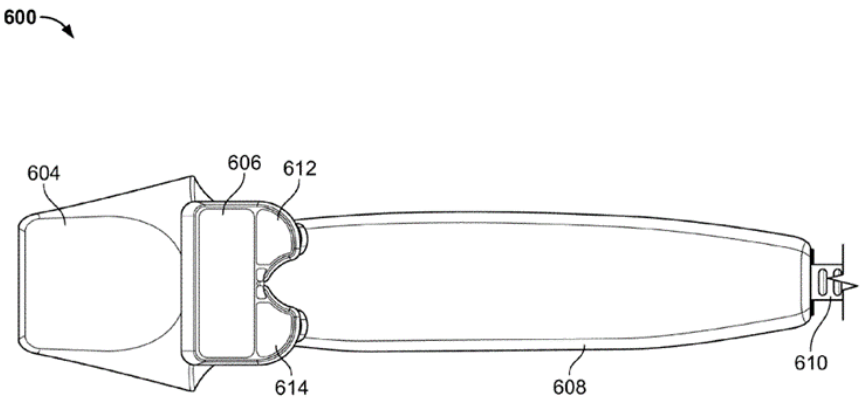
‘536 Patent Claim 1		Mehta
		As shown in Fig. 4, reproduced below, the “cartridge body 100” may include mechanical connectors, such as “retention fasteners 114 allowing for [mechanical] coupling with the device body as well as removal from the device body … to permit removable coupling.” *Id*., at 15:27-33; *see also id*., at 16:42-58.  FIG. 4A *Id*., Fig. 4A. I understand Serendia is interpreting the needle assembly end surface as follows: “the deployable needle assembly end surface is the plane defined by the tips of the needles of the deployable needle assembly when the needles are not extended, the needle assembly can be movable within a needle module that is releasably couplable to the proximal end of a user holdable device.” Under Serendia’s construction, Mehta’s releasably couplable deployable needle assembly includes a plurality of needles extendable from the deployable needle assembly end surface. *Id*., at 4:63-5:2 (“at least the plurality of first electrodes … are located on or in the cartridge body”), 9:34-55, 9:65-10:7, 10:33-39 (“driving the probe array 108 from the cartridge 100”), 12:23-30, 14:5-19 (“The cartridge 100 can also be configured to provide the probes 104 on a probe assembly 102 that is slidable relative to the cartridge body 100

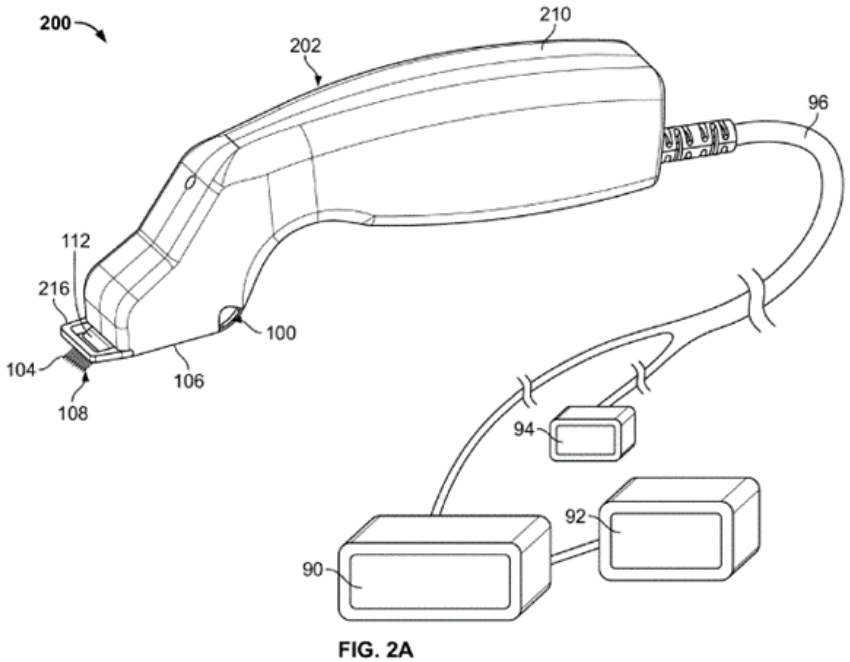
'536 Patent Claim 1		Mehta
		and device body 210"), Fig. 2D, 15:34-54, 15:55-16:11, 17:46-58, 18:21-37, 21:1-13, 7A, 23:11-27. [37] Mehta further discloses that the "the electrode assembly 102 can include a coupling portion or structure 118 that mates with an actuating member in the device body": > The cartridge body 100 further includes an ***electrode assembly 102*** that is moveable or slidable within the cartridge body 100. The mode of movement of the actuator can include those modes that are used in such similar applications. Examples of these modes include, sliding, rotation, incremental indexing (via a ratchet-type system), stepping (via a[] step-motor) Accordingly, ***the electrode assembly 102 can include a coupling portion or structure 118 that mates with an actuating member in the device body***. In the illustrated example, the electrode assembly 102 is in a treatment position (e.g., the array 108 extends from the cartridge 100 allowing for treatment). ***The electrode assembly 102 includes any number of electrodes 104 that form an array 108 and are extendable and retractable from a portion 104 of the cartridge 100*** (as noted above, the electrodes can alternatively extend from the device body, or other parts of the system). As noted above, although the illustrated example shows an array 108 of 1×6 electrodes 104, the array can comprise any dimension of M×N electrodes where the limits are driven by the nature of the treatment site as well as the type of energy delivery required. *Id.*, at 15:34-54.
1.4	one of the proximal end and the deployable needle assembly including at least one electrical conductor and the other including at least one restorably deflectable	Mehta discloses one of the proximal end and the deployable needle assembly including at least one electrical conductor and the other including at least one restorably deflectable electrical contact couplable to the one of the proximal end and the deployable needle assembly at least one electrical conductor. *See, e.g.*, Mehta, at 3:57-67; 4:1-18; 5:16-25; 5:49-57; 6:30-37; 15:27-33; Fig. 4A; 15:34-54; 15:55-16:11; 16:12-18; 16:42-58; 16:59-17:12; 17:59-18:3; 25:30-55; 26:60-27:22; 40:45-57. Mehta discloses that the needle assembly is movable within the releasably couplable deployable needle assembly to extend the

[37] Mehta refers to energy transfer elements and probes synonymously, and explains these are needle electrodes. *Id*., at 49:43-53, 40:45-57, 12:23-20, 12:47-58, 16:59-17:12, 31:37-41.

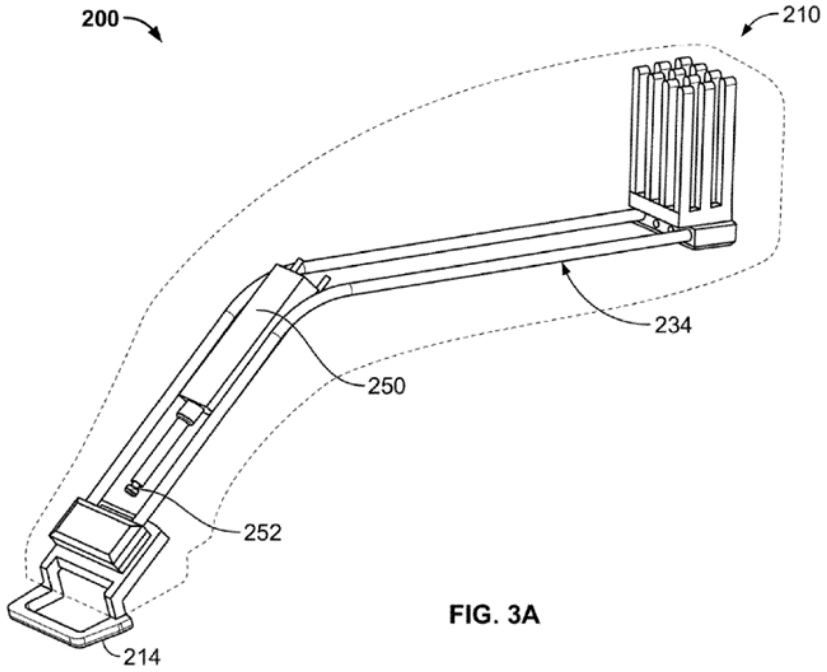
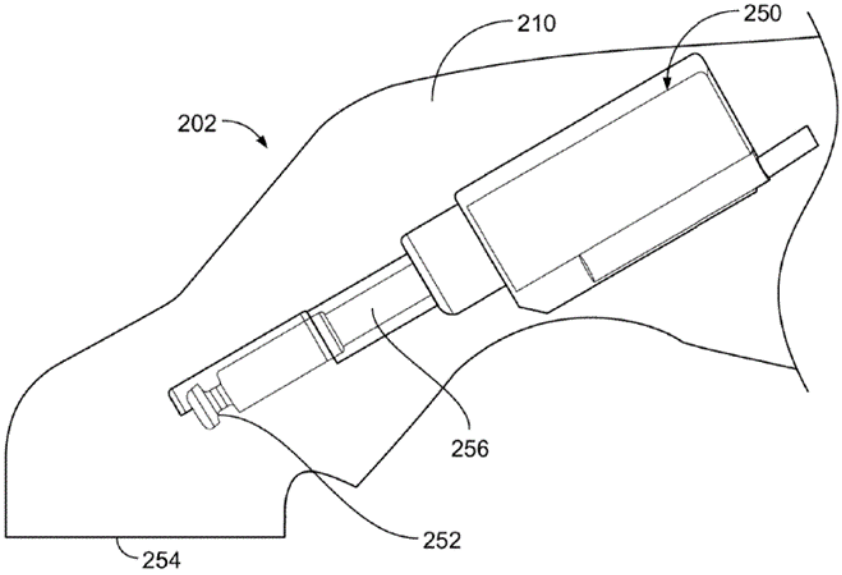
'536 Patent Claim 1		Mehta
	electrical contact couplable to the one of the proximal end and the deployable needle assembly at least one electrical conductor;	plurality of needles from the releasably couplable deployable needle assembly end surface. Mehta, at 14:5-19 ("The cartridge 100 can also be configured to provide the probes 104 on a probe assembly 102 that is slidable relative to the cartridge body 100 and device body 210"), *id*., at 4:63-5:2, 5:3-15, 9:34-55 ("one or more probes 104 extending from the body 210 … the probes 103 can optionally extend from a front portion 112 of the cartridge 100," or "from a front face of the device body or from any surface of the device body/cartridge"), 15:34-54 ("The cartridge body 100 further includes an electrode assembly 102 that is moveable or slidable within the cartridge body 100"), 15:55-16:11, 16:42-58, 21:1-13; *See also id*., at 4:1-18, 10:33-39, 12:23-30, 13:5-36. The needle assembly is movable, such that the needles can be extended while at least one electrical contact of the needle assembly remains electrically coupled to at least one electrical contact of the user holdable device proximal end. For example, as shown in Fig. 4A, reproduced below, "the electrodes 104 in the electrode assembly 102 as having connection or contact portions 116 that couple to a connection board on a treatment unit to provide an electrical pathway from the power supply to the electrodes 104," and "the electrode assembly 102 as well as the connection portions 116 moves" so that the electrodes remain electrically connected to the "power supply" when extended. *Id*., at 15:55-16:11; *see also id*., at 16:12-18 (for example, by using "**spring contacts or spring pins**" for the electrical "**connection portions 116**" so that "the connection portions 116 can maintain contact with a corresponding contact point trace on a connection board during movement of the electrode assembly 102"), 35:8-22 ("electrical lead 610 on the proximal end"); *see also id*., at 10:53-65, 12:5-14,25:30-55, Fig. 2A.

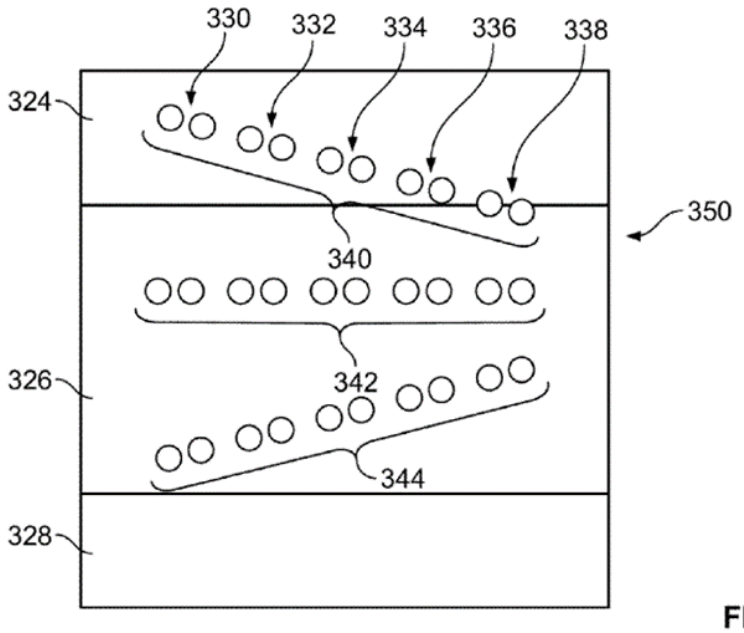
‘536 Patent Claim 1		Mehta
		 FIG. 4A *Id*., Fig. 4A.  FIG. 2D *Id*., Fig. 2D.

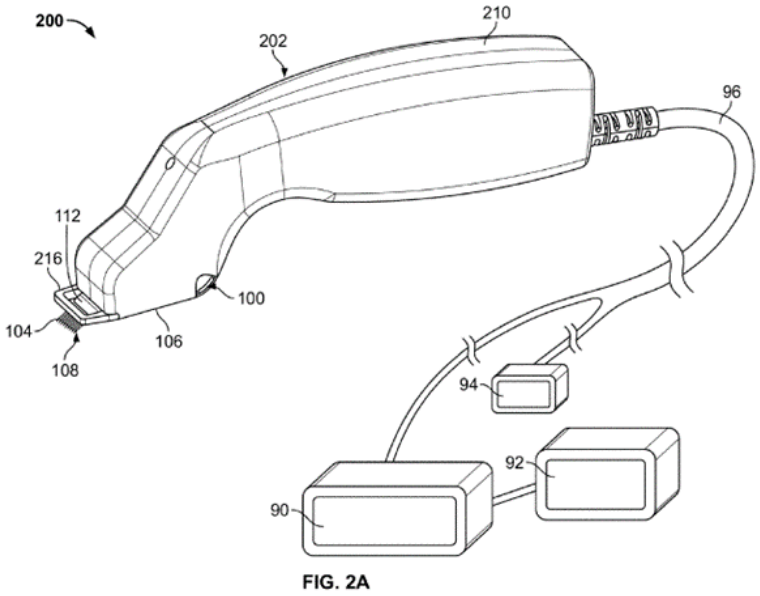
‘536 Patent Claim 1	Mehta
	 FIG. 12A *Id*., Fig. 12A.  FIG. 12B *Id*., Fig. 12B. Mehta describes spring contacts, that are inherently restorably deflectable, and spring pins, also called Pogo pins. It is my understanding that Serendia is interpreting “pogo” pins (*e.g.*, spring pins) as being restorably deflectable contacts.

'536 Patent Claim 1		Mehta
		Therefore, Mehta discloses that the deployable needle assembly includes at least one electrical deflectable contact couplable to an electrical conductor of the proximal end, so that the needles can stay connected to the RF energy source. The electrical contact of the needle assembly is restorably deflectable, for example, based on being configured as a spring contact or a spring pin (*see* Mehta, element 116 of Fig. 4A). Otherwise, the needles would not be able to be powered by the RF unit when extended into the skin, which is the whole purpose of the electrical connection between the needles and the RF source.
1.5	communicating electrical signals from the proximal end to the plurality of the extendable needles;	Mehta discloses communicating electrical signals from the proximal end to the plurality of the extendable needles. *See, e.g.*, Mehta, at 2:58-62; 2:63-3:17; 3:40-56; 3:57-67; 4:1-18; 5:3-15; 5:26-33; 5:49-57; 9:34-55; 10:53-65; Fig. 2A; 15:55-16:11; Fig. 4A; 18:4-20; 24:46-60; 25:30-55; 26:60-27:22; 41:40-43; 41:55-58. Mehta discloses that the energy supply unit 90 is coupled to the proximal end of the user holdable device (treatment unit 202). Mehta, at 10:53-65.  FIG. 2A *Id.*, Fig. 2A. The electrical signals from the energy supply unit are then communicated from the user holdable device's proximal end to the

'536 Patent Claim 1		Mehta
		needle assembly via the electrical contacts. *Id*., at 2:63-3:17 ("a connector adapted to couple the energy supply unit to the" needle electrodes), 15:55-16:11 (the connections "provide an electrical pathway from the power supply to the electrodes 104" for energy delivery), 18:4-20 ("RF … current" is supplied to the needle electrodes), 24:46-60, 25:30-55 ("RF treatment current" is delivered to the electrodes); *see also id*., at 2:58-62, 3:40-67, 5:3-15, 5:26-33, 5:49-57, 10:53-65, Figs. 2A, 4A Mehta also discuss communication to the plurality of extendable needles prior to initiating the treatment: > FIG. 9D shows a flow chart of pre-treatment checks. This flow chart outlines the system process for performing checks prior to delivering a treatment. Several conditions must be met prior to delivering treatment to the tissue. This pre-treatment check verifies that a start command was received, that the tissue resistance (Rcheck) is complete, and that the temperature measurements are valid. To initiate the pre-treatment and treatment process, the start command must be received by the generator (*i.e.*, user presses start button) 423. *Id.* 29:54-62
1.6	energizing a motor coupled to a plurality of extendable needles to cause a plurality of the extendable needles to extend a desired distance from the needle assembly end surface; and	Mehta discloses energizing a motor coupled to a plurality of extendable needles to cause the plurality of extendable needles to extend a desired distance from the needle assembly end surface. *See, e.g.*, Mehta, at 3:29-39; 3:40-41; 4:63-5:2; 5:3-15; 6:64-65; 9:34-55; 10:33-39; 12:5-14; 12:31-46; 13:54-57; Fig. 3A; 13:58-4; 15:27-33; 15:55-16:11; Fig. 4A; 16:42-58; 16:59-17:12; 18:21-37; Fig. 5; 23:55-24:4; Fig. 7E; 24:46-60; 32:46-62; Fig. 10B; 32:63-33:14; 33:15-29; 33:30-34; 33:57-13; Fig. 10E; 34:38-45; 35:8-22; Fig. 12A; Fig. 12B; and 36:21-40. For example, Mehta discloses that "the cartridge and/or energy delivery elements can be coupled to an actuator, where movement of the actuator causes advancement or retraction of the first plurality of electrodes" (Mehta, at 4:63-5:2), and the "[e]xamples of such actuators include, but are not limited to … motors" "driven by the control system/energy supply unit 90" (*id*., at 10:33-39). *See also id*., at 12:5-14, 13:58-4 ("the actuator 250 comprises a motor"), 16:59-17:12, 18:21-37.

‘536 Patent Claim 1	Mehta
	 FIG. 3A *Id.*, Fig. 3A.  FIG. 5 *Id.*, Fig. 5.

'536 Patent Claim 1		Mehta
		Mehta discloses energizing a motor coupled to the needle assembly to cause the plurality of the needles to extend a desired distance from the releasably couplable deployable needle assembly end surface. (In Mehta's description and terminology, it would be a certain distance from the needle cartridge tissue engaging surface.) For example, Mehta discloses that the physician can check if the needles extended to the desired distance using a "virtual depiction 350 of the depth or location of the probe array," as shown in Fig. 10B, reproduced below. *Id*., at 32:46-62; *see also id*., at 32:63-33:14 ("desired probe location … represent the desired depth of placement for providing a treatment"), 33:15-29, 33:30-34 ("the system described herein can be adjusted to guide probe placement within the first or third layers 324 or 328 depending on the type of treatment being applied"), 33:57-34:13, 34:38-45, 35:8-22 ("The physician can use the information [displayed on the screen] to make decisions and then adjustments by using the actuators 612 and 614"), 36:21-40 (desired distance relates to the depth of the 6 mm needle with it "enter[s] the epidermis at a 20° angle to the skin surface for a distance of 6 mm"), Fig. 10E.  FIG. 10B *Id*., Fig. 10B.
1.7	energizing the plurality of extended needles via a signal generator	I understand that Serendia has construed this "energizing" step as follows: "This step [d], 'energizing the plurality of extended needles,' must be performed last. The claimed step [b], 'communicating electrical signals from the proximal end to the plurality of the

'536 Patent Claim 1		Mehta
	electrically coupled to the plurality of extended needles.	extendable needles,' cannot occur after step [d] but otherwise may occur at any point in the claimed process." Under Serendia's construction, Mehta discloses energizing the plurality of extended needles via a signal generator electrically coupled to the plurality of extended needles. *See, e.g.*, Mehta, at 2:58-62; 2:63-17; 3:40-56; 3:57-67; 4:1-18; 5:3-15; 5:16-25; 5:26-33; 5:49-57; 7:16-18; 8:13-23; 9:34-55; 10:17-25; 12:5-14; 10:53-65; Fig. 2A; 11:14-20; 11:21-52; 15:55-16:11; Fig. 4A; 17:59-18:3; 18:4-20; 18:64-19:8; 19:66-20:12; 20:13-29; 20:29-47; Fig. 6; 24:46-60; 25:30-55; 26:41-59; 26:60-27:22; 37:25-34; Fig. 13A; 40:39-44; 40:45-57; 41:40-43; 41:55-58; 42:9-15. Mehta discloses energizing the plurality of needles via an electrical contact. Mehta also discloses that a signal generator (energy supply unit 90) is coupled to the proximal end of the user holdable device (treatment unit 202). Mehta, at 10:53-65; *see also* 36:21-40 (RF "generator").  FIG. 2A *Id*., Fig. 2A. Mehta discloses energizing the plurality of needles via the signal generator electrically coupled to the user holdable device proximal end. *Id*. at 15:55-16:11 ("electrodes can be energized"), 24:46-60, 36:21-40, 37:25-35 ("passing current 107 between adjacent

'536 Patent Claim 1		Mehta
		electrodes 104 of opposite polarity in the electrode pair"), 41:55-58, 42:9-15.

434. In view of the foregoing chart, claim 1 of the '536 Patent is anticipated by the teachings of Mehta. Further, to the extent Complainant argues that any of the foregoing limitations is not explicitly or inherently disclosed by Mehta, such limitations would have been obvious given the knowledge of a POSITA. The teachings of Mehta are so similar to what is claimed that any alleged difference between the teachings of Mehta and what is claimed would not have been of patentable significance given the knowledge of a POSITA.

2. Claim 4 of the '536 Patent, which depends from claim 1, is Obvious in view of the teachings of Mehta given the knowledge of a POSITA and/or in combination with the teachings of Na '848 and/or Kang '395:

435. It is my opinion that claim 4 of the '536 Patent is rendered obvious by Mehta (in view of the knowledge of a POSITA) and/or Mehta in view of Na '848 and/or Kang '395.

'536 Patent Claim 4		Mehta alone and/or in combination with Na '848 and/or Kang '395
4.0	4. The method of claim 1, wherein the proximal end further includes at least one embedded LED therein and further including energizing the LED when the signal generator is energized, the at least one embedded LED illuminating the deployable	Mehta renders obvious that the proximal end further includes at least one embedded LED therein and further including energizing the LED when the signal generator is energized, the at least one embedded LED illuminating the deployable needle assembly when energized. For example, Mehta discloses that "stabilization plate 214" includes a "window" comprising "transparent material" through which the "energy transfer elements" (*i.e.*, the needles) can be viewed, and Mehta also discloses that the system includes "LEDs." Mehta also discloses that additional variations of energy such as laser or pulsed light can be used in combination with RF (11:14:20). Used in combination means that they are activated concomitantly. Mehta then suggests that "[i]n one variation, the energy source/supply 94 and associated energy transfer element may comprise laser, light or other similar types of radiant energy (e.g., visible, ultra violet, or infrared light)." (11:30-33). Mehta also suggests that the light that can be delivered via a diode (11:29) is "delivered via the same energy transfer element [as the RF]

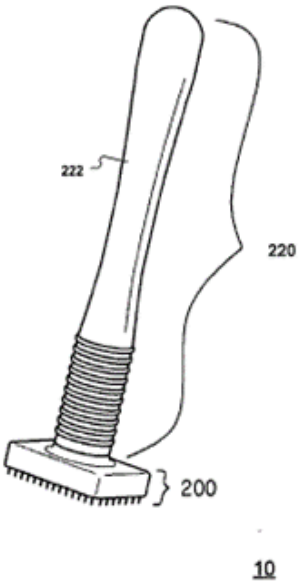
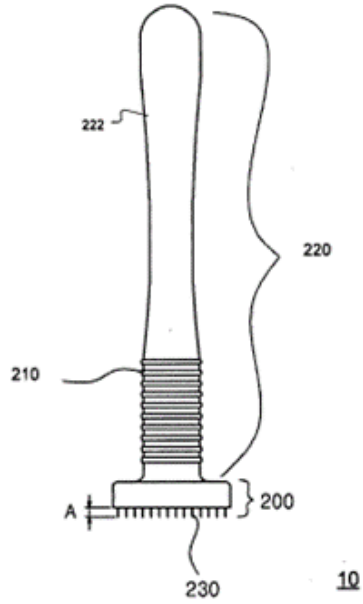
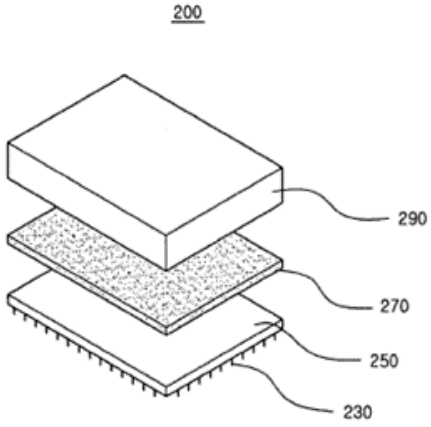
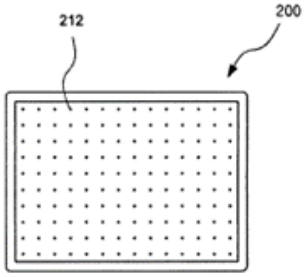
'536 Patent Claim 4		Mehta alone and/or in combination with Na '848 and/or Kang '395
	needle assembly when energized.	located at the working end of a treatment unit **202**." Mehta at 11:23-27. [38] With having the Light Emitting Diode delivering the light on the needle electrodes, it would have been obvious to a POSITA to utilize an LED to illuminate the needles of the deployable needle assembly in view of these teachings of Mehta, so that an operator of the treatment device can better *see* the placement of the needles onto the skin while the treatment is being performed. *See, e.g.*: > The device may also include a window located between the stabilization plate and the tissue engaging Surface, where the window is configured to permit direct visualization of advancement of the energy transfer elements into the entry point. In some variations, the window is sized to outline a perimeter of the energy delivery region created by the energy transfer elements. In additional variations, the window is sized to outline a distal length of the energy transfer elements when extended. Alternatively, the entire stabilization plate can be sized to outline a perimeter of the energy delivery region created by the energy transfer elements or to outline a distal length of the energy transfer elements when extended. Mehta, at 4:19-34. > The window can comprise an opening in the stabilization plate or the window can comprise a transparent material having an outline or mark to denote the perimeter of the window. Mehta, at 4:31-34. > In one variation, the energy supply unit **90** may be a RF energy unit. Additional variations of energy supply units may include power supplies to provide or remove thermal energy, to provide ultrasound energy, microwave energy, laser energy, pulsed light energy, and infrared energy. Furthermore, the systems may include combinations of such energy modalities. Mehta, at 11:14-20. > For example, in addition to the use of RF energy, other therapeutic methods and devices can be used in combination with RF energy to provide additional or more efficacious

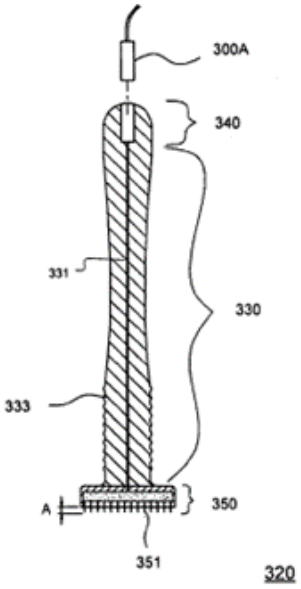
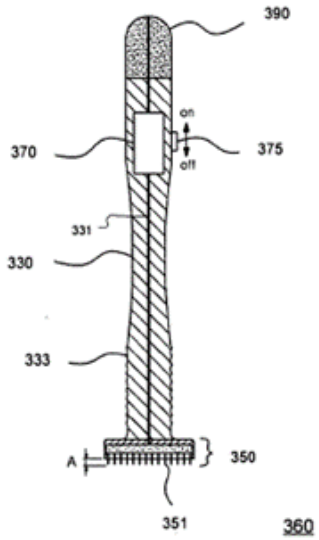
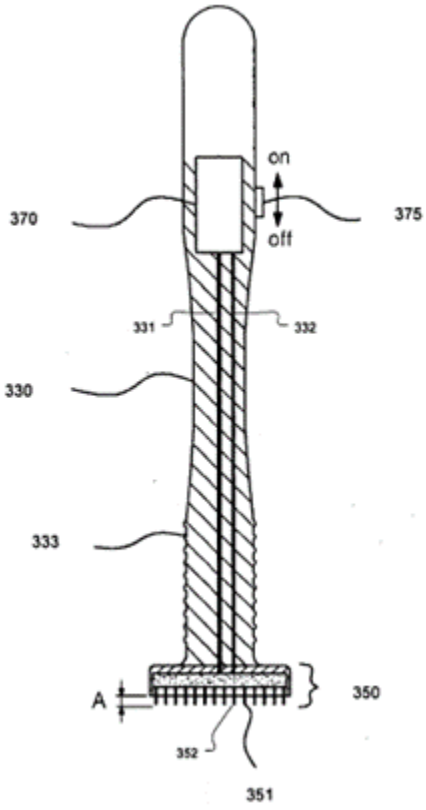
[38] Mehta refers to energy transfer elements and probes synonymously, and explains that these are needle electrodes.

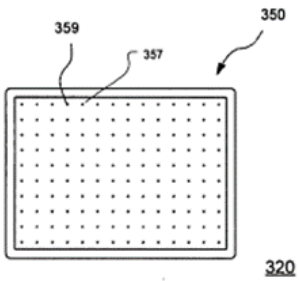
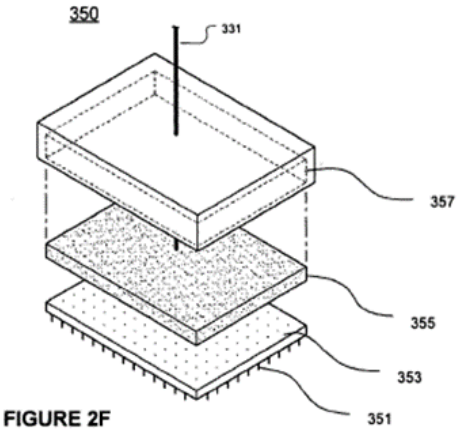
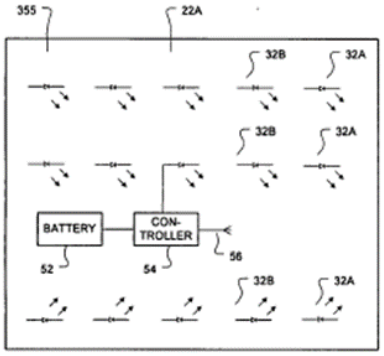
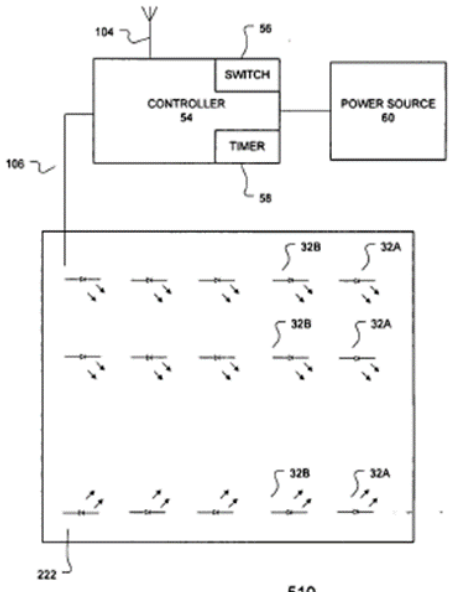
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		treatments. For example, as shown in FIG. **2A**, additional energy sources **90** can be delivered via the same or additional energy transfer elements located at the working end of a treatment unit 202. Alternatively, the radiant energy may be supplied by the energy source/supply **90** that is coupled to a diode, fiber, or other emitter at the distal end of the treatment unit **202**. In one variation, the energy source/supply 94 and associated energy transfer element may comprise laser, light or other similar types of radiant energy (e.g., visible, ultraviolet, or infrared light). For example, intense pulsed light having a wavelength between 300 and 12000 nm can also be used in conjunction with RF current to heat a targeted tissue. Such associated transfer elements may comprise sources of light at the distal end of the treatment unit **202**. These transfer elements may be present on the cartridge 100, on the device body **210** or even on the cooling unity **234**. More specifically a coherent light source or laser energy can be used in conjunction with RF to heat a targeted tissue. Examples of lasers that can be used include erbium fiber, CO_2, diode, flashlamp pumped, Nd:YAG, dye, argon, ytterbium, and Er:YAG among others. More than one laser or light source can be used in combination with RF to further enhance the effect. For example, a pulsed infra-red light source can be used to heat the skin surface, an Nd:YAG laser can be used to heat specific chromophores or dark matter below the surface of the skin, and RF current can be applied to a specific layer within or below the skin; the combination of which provides the optimal results for skin tightening, acne treatment, lipolysis, wart removal or any combination of these treatments. Mehta, at 11:21-53. FIG. **2C** shows a top view of the treatment unit **202** of FIG. **2B**. In this variation, the stabilization plate **214** includes a feature **216** such as (a window or an opening) that permits a physician to directly observe insertion of the probe array 108 through the stabilization plate **214**. In additional variations of the system **200**, the stabilization plate **214** can be fabricated to be transparent and the feature **216** can comprise a marking to outline the tissue region in which the probes will be inserted. Such features of the stabilization plate **214** are important when the probes are deployed into tissue subsequent to placement of the device body **210** against tissue. A physician can rely upon the stabilization plate **214** or the feature **216** as confirmation for the intended treatment area and avoid body structures where

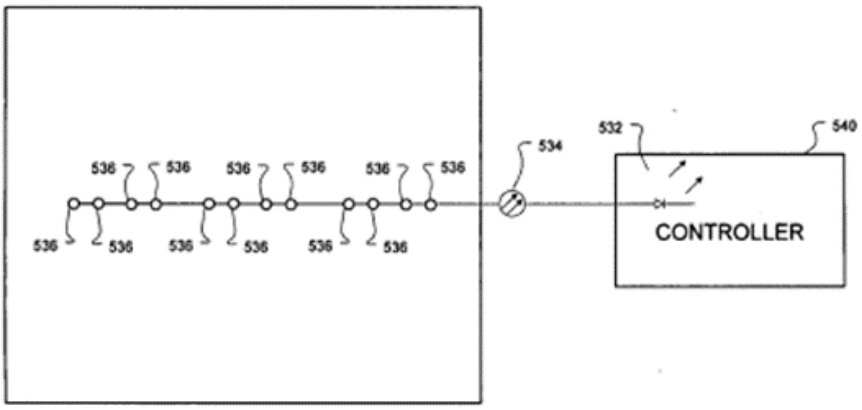
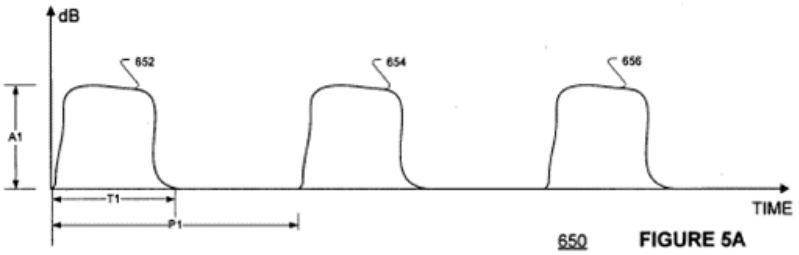
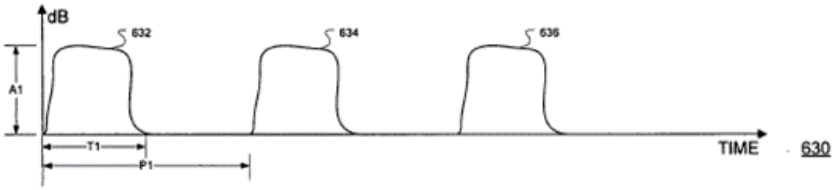
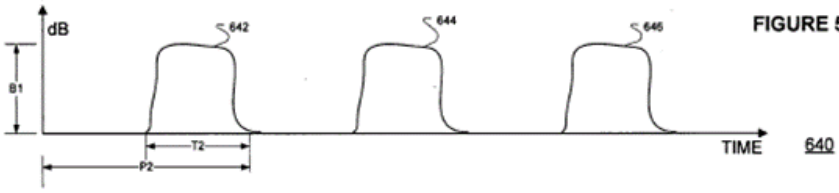
'536 Patent Claim 4		Mehta alone and/or in combination with Na '848 and/or Kang '395
		treatment would be undesirable. For example, if a physician intends to avoid insertion of the probe array **108** into a particular tissue structure, the stabilization plate **214** or feature **216** permits the physician to situate the treatment unit **202** while avoiding the region in question. In certain variations, the outline of the feature **216** or the stabilization plate **214** itself aligns (in a normal plane) with the distal end of the probe array **108**. Mehta, at 13:16-36. FIG. **7B** illustrates a magnified view of the probes **104** entering tissue **20** at an oblique angle A with the tissue engaging surface **106** resting on the surface of the tissue **20**. As is shown, the probe **104** can include an active area **122**. Generally, the term "active area" refers to the part of the probe through which energy is transferred to or from the tissue. For example, the active area could be a conductive portion of a probe, it can be a resistively heated portion of the probe, or even comprise a window through which energy transmits to the tissue. Although this variation shows the active area **122** as extending over a portion of the probe, variations of the device include probes **104** having larger or smaller active areas **122**. Mehta, at 21:22-33. FIG. **7D** shows an aspect for use with methods and devices of the invention that allows marking of the treatment site. As shown, the cartridge **100** may include one or more marking lumens **226**, **230** that are coupled to a marking ink **98**. During use, a medical practitioner may be unable to see areas once treated. The use of marking allows the practitioner to place a mark at the treatment location to avoid excessive treatments. As shown, a marking lumen **226** may be placed proximate to the probe **104**. Alternatively, or in combination, marking may occur at or near the cooling surface **216** since the cooling surface is directly above the treated region of tissue. The marking lumens may be combined with or replaced by marking pads. Furthermore, any type of medically approved dye may be used to mark. Alternatively, the dye may comprise a substance that is visible under certain wavelengths of light. Naturally, such a feature permits marking and visualization by the practitioner given illumination by the proper light source but

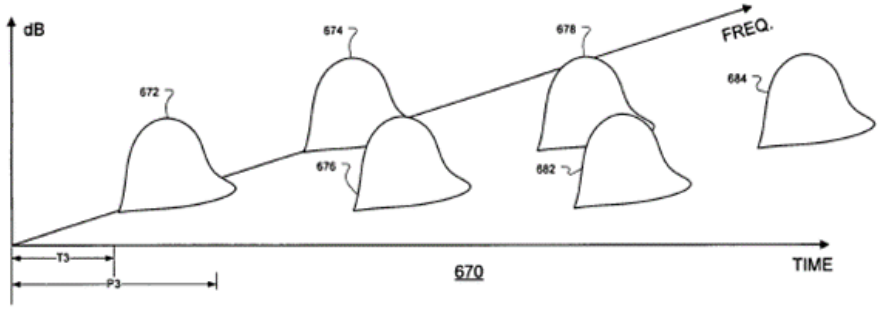
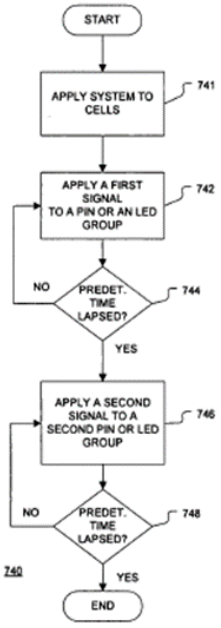
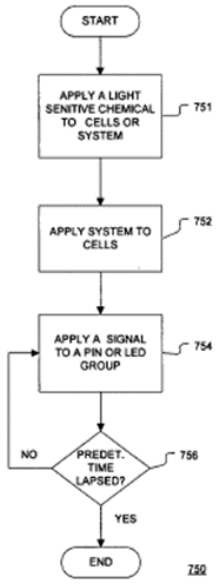
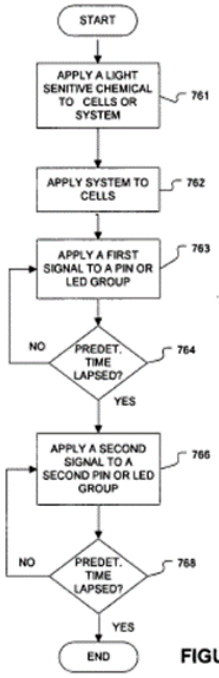
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		prevents the patient from seeing the dye subsequent to the treatment. Mehta, at 23:36-54. In an alternative variation, the probe can employ light at two wave lengths 650 nm and 805 nm from a light source into the adjacent tissue. The light is partially absorbed and partially reflected based on the amount of hemoglobin in red blood cells in the adjacent tissue. The reflected light is captured by a fiber optics placed in or near the probe and directed to a detector which provides a reading to the energy controller. This reading can be used to stop energy delivery when the red blood cells in the adjacent tissue have been coagulated (the desired treatment end point) and as a result the light reflection reading has changed. Mehta, at 25:4-15. This claim would have further been obvious in view of Mehta in combination with Na '848. Na '848, in combination with Mehta, renders obvious the proximal end further including at least one embedded LED therein and energizing the LED when the signal generator is energized, the at least one embedded LED illuminating the deployable needle assembly when energized. For example, with respect to a "dermalogical treatment apparatus" having a plurality of "pins or needles" through which an electrical signal may be applied to tissue under the skin, Na '848 discloses that the handheld apparatus includes "a plurality of embedded LEDs 32A, 32B" embedded in the proximal end of the apparatus, which are energized to illuminate needles of the apparatus. *See, e.g.*,

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	 FIGURE 1A  FIGURE 1B  FIGURE 1C  FIGURE 1D

'536 Patent Claim 4	Mehta alone and/or in combination with Na '848 and/or Kang '395
	 FIGURE 2B  FIGURE 2C  FIGURE 2D

‘536 Patent Claim 4	Mehta alone and/or in combination with Na ‘848 and/or Kang ‘395
	 FIGURE 2E  FIGURE 2F  FIGURE 4A 520  FIGURE 4B 510

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	 530 FIGURE 4C  650 FIGURE 5A  630  640 FIGURE 5B

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	 FIGURE 6  FIGURE 7A  FIGURE 7B  FIGURE 7C [0034] ***In any of the above apparatus 10, 320, 350, 360, 400, 460, the plate or roller 200, 350, 450 may include a plurality of embedded LEDs 32A, 32B***, a battery 52, a controller 54, and an antenna 56 as shown in FIG. 4A. ***In an embodiment the LED 32A may be configured to emit energy of a first particular frequency range and the LED 32B may be configured to emit energy of a second particular frequency range***. The surface 22 of a roller 450, plate 200, 350, 450 may also be embedded with a chemical 22A that may be used to treat dermalogical cells. The chemical 22A may be reactive to the first and the second frequency ranges. Further dermalogical cells may be reactive to the first and the second frequency ranges. In addition, the combination of the chemical 22 A and the application of the first and

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		the second frequency ranges to the chemical 22A and dermalogical cells may have a synergetic effect. [0036] In an embodiment the local controller 54 and battery 52 may also be embedded in the upper section 290, 357, pin section 230, 351, or the handle 220, 330, or separately between these sections. ***The controller 54 may be electrically coupled to the one or more LEDS 32A, 32B. The controller 54 may also be coupled to a battery 52. The controller 54 may generate one or more signals for LEDs 32A, 32B as a function of a user switch 75, 56. The signals may vary as a function of the first and second frequency ranges. The controller 54 may include one or more timers 58 that may limit the application of energy to the LEDs 32A, 32B to predetermined time intervals.*** In an embodiment the controller may also be coupled to an antenna 56 to receive or transmit one or more signals related to the transmission of energy to one or more LEDs 32A, 32B. In an embodiment the system 10 may be configured to treat a particular segment of dermalogical cells such as a face. The apparatus 10 may be configured to conform to a user's anatomy so that emitted light is focused on dermalogical cells. In another embodiment 200, the system 200 may be configured to treat another anatomical region including dermalogical cells on an arm, leg, chest, hands, feet, neck, or other region. [0037] In an embodiment 510 shown in FIG. 4B, a controller 54, an antenna 104, and a power source 60 may be located in external to the apparatus 10, 320, 360. The power source 60 may be coupled to the controller 54. ***The controller 54 may be coupled to one or more LEDs 32A, 32B via one or more electric wires 106. The controller 54 may generate one or more signals for LEDs 32A, 32B as a function of the user switch 56. The signals may vary as a function of the first and second frequency ranges. The controller 54 may include one or more timers 58 that may limit the application of energy to the LEDs 32A, 32B to predetermined time intervals. In an embodiment the controller may also be coupled to an antenna 104 to receive or transmit one or more signals related to the transmission of energy to one or more LEDs 32A, 32B.*** [0038] ***In any of the above apparatus 10, 320, 350, 360, 400, 460, the plate or roller 200, 350, 450 may include a plurality of embedded LED lens 536, a fiber optic pathway 534, and an LED 532. In this embodiment the LED 532 may be coupled to lens 536 via the fiber optic pathway 534. The controller 540 may generate an LED signal via the LED 532 that is transmitted to dermalogical cells via the lens 536 and the fiber optic pathway 534.***

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		[0039] ***FIGS.5A-5B are diagrams of electrical signal waveforms 650, 630, 640 that may be applied to one or more LEDs 32A, 32B, 532*** and to the pins 230, 351, 451 according to various embodiments. ***The signal waveform 650 includes several square -wave pulses 652, 654, 656 that may be applied to an LED 32A, 32B, 532.*** Each pulse 652, 654, 656 may a have a similar magnitude and envelope. ***The waveform 650 may be used to energize an LED 32A, 32B, 532 and to the pins 230, 351, 451 periodically Pl for a predetermined interval Tl where each pulse 652, 654, 656 has a[n] amplitude Al.*** In an embodiment, Al may be about 0.1 milliamperes (mA) to 10 mA, the pulse width Tl may be about 100 microsecond (μs) to 500 μs and the period Pl may from 100 ms to 500 ms as a function of the energy required to create capacitance in a liquid. In another embodiment, Al may be about 0.5 milliamperes (mA) to 5 mA, the pulse width Tl may be about 200 microsecond (μs) and the period Pl may about 250 ms as a function of the ***energy to drive an LED*** or cause one or more pins 230, 351, 451 to vibrate. [0040] ***In FIG. 5B a signal waveform 630 may be applied to a first LED 32A, 32B, 532 module or group*** and to the pins 230, 351 , 451 and ***a second waveform 640 may be applied or used to energize a second LED 32A, 32B, 532 module*** and the pins 230, 351, 451, 352. The signal waveform 630 includes several square-wave pulses 632, 634, and 636 and the signal waveform 640 includes several square-wave pulses 642, 644, and 646. Each pulse 632, 634, 636, 642, 644, 646 may a have a similar magnitude and envelope. ***The waveform 630 may be used to energize a first LED 32A, 32B, 332 module*** and the pins 230, 351, 451 periodically Pl for a predetermined interval Tl where each pulse 632, 634, 636 has an amplitude Al. ***The waveform 640 may be used to energize a second LED 32A, 32B, 332 module*** and the pins 230, 351, 451 periodically P2 for a predetermined interval T2 where each pulse 642, 644, 646 has an amplitude Bl. The pulse width Tl, T2 may be about 100 microsecond (μs) to 500 μs and the period Pl, P2 may from 100 ms to 500 ms as a function of the energy to affect dermalogical cells or chemicals 22A. In another embodiment, Al, A2 may be about 0.5 milliamperes (mA) to 5 mA, the pulse width Tl, T2 may be about 200 microsecond (μs) and the period Pl, P2 may about 250 ms as a function of the energy required to affect dermalogical cells or chemicals 22 A. In an embodiment the pulses 632, 634, 636 do not substantially overlap the pulses 642, 644, 646. In an embodiment Tl > T2 and P2 is an integer multiple of Pl . [0041] FIG. 6 depicts a waveform 670 that includes multiple pulses 672, 674, 676, 678, 682, and 684 that may not overlap in the time or the frequency domain. In an embodiment each pulse 672, 674, 676,

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		678, 682, and 684 may have a pulse width T3, and frequency spectrum width Fl and period P3. The pulse 672 is frequency offset from the pulse 674, the pulse 676 is frequency offset from the pulse 678, and the pulse 682 is frequency offset from the pulse 684. ***The pulses 672, 674, 676, 678, 682, and 684 may be applied to an LED module*** to affect dermalogical cells or chemicals 22A and the pins 230, 351, 451. ***Pulses 672, 674 having different frequency spectrums may enable different LED stimulation. In an embodiment the pulses 672, 676, 682 may be applied to a first LED module and the pulses 674, 678, 684 may be applied to a second LED module. The frequency separation between the respective pulses may enable simultaneous energization of a first and a second LED module*** and the pins 230, 351, 451 and subsequent and independent spectrum generation. [0042] In an embodiment the invention may employ the algorithm 740 shown in FIG. 7A to apply therapy to dermalogical cells. A user, clinician, or equipment may place an apparatus 10, 320, 360, 360, 400, 460 on dermalogical cells to be treated (activity 741) including pressing the apparatus against the cells firmly enough to embed one or more pins 251 , 351 , 451 in the cells. ***A first signal such as shown in FIGS. 5A, 5B, and 6 may be applied to a first LED module or group (32A)*** and the pins 230, 351, 451 of a dermalogical apparatus 10, 320, 360, 360, 400, 460 (activity 742) for a predetermined time period (activity 744). ***A second signal such as shown in FIGS. 5 A, 5B, and 6 may be applied to a second LED module or group (32B)*** and the pins 230, 351, 451 of a dermalogical apparatus 10, 320, 360, 360, 400, 460 (activity 746) for a predetermined time period (activity 748). The signals applied to the groups may be selected to stimulate dermalogical cells or chemicals 22A or cause vibration of one or more pins 251, 351, 451. [0043] In another embodiment the invention may employ the algorithm 750 shown in FIG. 7B to apply therapy to dermalogical cells. A user, clinician, or equipment may apply a light sensitive chemical on an apparatus 10, 320, 360, 360, 400, 460 or on dermalogical cells to be treated (activity 751). The user, clinician, or equipment may place apparatus 10, 320, 360, 360, 400, 460 on dermalogical cells to be treated (activity 752). ***A signal such as shown in FIGS. 5A, 5B, and 6 may be applied to a LED module or group (32A or 32B)*** and the pins 230, 351 , 451 (activity 354) for a predetermined time period (activity 356). [0044] In another embodiment the invention may employ the algorithm 760 shown in FIG. 7C to apply therapy to dermalogical cells. A user, clinician, or equipment may apply a light sensitive chemical on an

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		apparatus 10, 320, 360, 360, 400, 460 or on dermalogical cells to be treated (activity 761). The user, clinician, or equipment may place an apparatus 10, 320, 360, 360, 400, 460 on dermalogical cells to be treated (activity 762). ***A first signal such as shown in FIGS. 5A, 5B, and 6 may be applied to a first LED module or group (32A)*** and one or more pins 251, 351, 451 of a dermalogical apparatus 10, 320, 360, 360, 400, 460 (activity 763) for a predetermined time period (activity 764). ***A second signal such as shown in FIGS. 5 A, 5B, and 6 may be applied to a second LED module or group (32B)*** and one or more pins 251 , 351, 451 of a dermalogical apparatus 10, 320, 360, 360, 400, 460 (activity 766) for a predetermined time period (activity 768). [0045] The apparatus 10, 320, 360, 360, 400, 460 may be used to employ cosmetic or medications or other chemicals directly on dermalogical cells such as skin with the addition of light of specific frequencies for treatment and healing of epidermal cells of the skin or tissue below the skin with the object of assisting the agents used in delivery, uptake, action and function more effectively. ***The LEDs 32A, 32B may create the specific frequencies of light.*** The apparatus 10, 320, 360, 360, 400, 460, light application may enable cosmetic or medication or other active chemicals 22A on dermalogical cells for longer time periods while preventing dehydration of the applied substances. Such light application may improve the efficacy of cosmetic or medication or other active chemical as a function of the selected wavelengths or frequencies. [0046] Further the dermalogical system application may increase cellular activity and help heal tissue faster and facilitate the delivery, uptake and use in the cell of the cosmetics, medications, or chemicals 22A used. The LED light of specific frequencies may increase fibroblast production and collagen as well as other activities of the cell including stimulating the organelles and mitochondria to produce ATP for cell energy for functioning, decreasing treatment time and facilitate healing. The apparatus 10, 320, 360, 360, 400, 460 make the agents used on the body more efficacious and useful to the body on a cellular level. [0047] The apparatus 10, 320, 360, 360, 400, 460 may stimulate the basic energy processes in the mitochondria (energy compartments) of each cell, particularly when near-infrared light is used to activate the color sensitive chemicals (chromophores, cytochrome systems) inside but not limited to these spectrum alone as the UV, other visible and IR spectrums may also be usable. In an embodiment optimal LED wavelengths for skin repair may include 640, 680, 730 nanometers (nm) wavelengths to IR 880 nm. Further application of blue light 400

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		nm to 490 via the apparatus 10, 320, 360, 360, 400, 460 may inhibit the growth and kill bacteria, fungus in and on dermalogical cells. The apparatus 10, 320, 360, 360, 400, 460 may be employed to apply cosmetics, medications and/or other actives directly to the skin and maintain their presence long-term while using LED or other actinic light to increase their effect on the cells and tissue in the body. The apparatus 10, 320, 360, 360, 400, 460 are also highly portability and enable user mobility during treatment. [0051] The microphone 808 and speaker 802 may be incorporated into the device 780. The microphone 808 and speaker 802 may also be separated from the device 780. Received data may be transmitted to the CPU 782 via a bus 796 where the data may include signals for an LED 32A, 32B, 332 or optical module or wires 331, 458. The transceiver ASIC 816 may include an instruction set necessary to communicate data, screens, or signals. The ASIC 816 may be coupled to the antenna 804 to communicate wireless messages, pages, and signal information within the signal. When a message is received by the transceiver ASIC 816, its corresponding data may be transferred to the CPU 782 via the serial bus 796. The data can include wireless protocol, overhead information, and data to be processed by the device 780 in accordance with the methods described herein. [0052] The D/A and A/D convertor 815 may be coupled to one or more optical modules to generate a signal to be used to energize one of the optical modules. The D/A and A/D converter 815 may also be coupled to one devices such as LEDs 32A, 32B and the pins 251, 351, 451. Any of the components previously described can be implemented in a number of ways, including embodiments in software. Any of the components previously described can be implemented in a number of ways, including embodiments in software. Thus, the LEDs 32A, 32B, pins 251, 351, 451, controllers 54, switch 56, timers 58, controller 320 may all be characterized as "modules" herein. The modules may include hardware circuitry, single or multi-processor circuits, memory circuits, software program modules and objects, firmware, and combinations thereof, as desired by the architect of the system 10, 30, 50, 60 and as appropriate for particular implementations of various embodiments. This claim would have further been obvious in view of Mehta in combination with Kang '395. Kang '395, in combination with Mehta, renders obvious the proximal end further including at least one embedded LED therein and further including energizing the LED when the signal generator is energized,

'536 Patent Claim 4		Mehta alone and/or in combination with Na '848 and/or Kang '395
		the at least one embedded LED illuminating the deployable needle assembly when energized. For example, with respect to a "high-frequency handpiece" for treating skin, Kang discloses that the handpiece "is equipped with a light-emitting member," whereby the light-emitting member may be an LED and may be utilized to emit light to be able to see the position of where the "heating part 230" (*e.g.*, an insertable needle) is being inserted. *See, e.g.*: > "Furthermore, the handpiece of the present invention is equipped with a light-emitting member so that the position of the heating part of the handpiece inserted into the skin can be easily discerned from outside of the skin as well." Kang '395 at 4. > "Furthermore, by adopting and attaching various light-emitting members 250 of a fine size, such as a fiber or an LED, to the end of the heating part 200, the heating part 220 of the handpiece 200 inserted into the skin emits a predetermined color at the same time as the high frequency is applied, so that the position of the heating part 220 of the handpiece 200 can be easily discerned even from outside of the skin as well." Kang '395 at 4. "In addition, as for the heating part 230 of the handpiece 200, which is inserted into the skin and heats the skin while moving in a reciprocating manner, its position cannot be identified because of the skin of the skin [*sic*], but since the light-emitting member 250 provided on one side of the heating part 230 emits light, it is possible to perform a procedure while accurately identifying the position of the heating part 230 with the naked eye even from outside of the thin skin." Kang '395 at 5. It would have been obvious to a POSITA as of the priority date of the '536 Patent to modify Mehta and/or to combine the teachings of Mehta with the teachings of Na '848 and/or with the teachings of Kang '395 in a manner that would have rendered claim 4 obvious. For example, Kang '395 discloses an LED for illuminating a deployable needle assembly when energized. *See, e.g.*, Kang '395 at 4. Na '848 also discusses the use of an LED illuminated when needles are energized. *See, e.g.*, Na '848 at Figs. 4A-4C, Figs. 5A-5B, Fig. 6, Figs. 7A-7C, [0034], [0036]-[0047]. As of the priority date of the '536 Patent, it was well known to use LEDs as indicators for power being on and to illuminate small areas. The use of an LED on such a device was an

'536 Patent Claim 4		Mehta alone and/or in combination with Na '848 and/or Kang '395
		obvious design choice for the person of ordinary skill looking to provide a power on indicator or to illuminate the treatment area, as evidenced by the express teachings of Na '848 and Kang '395. Adding an LED to the proximal end of the treatment apparatus of Mehta and utilizing the LED to illuminate the needles of the treatment apparatus of Mehta would have been an obvious design choice in view of the teachings of Na '848 and Kang '395 with regard to the user of LEDs for illumination and further in view of the teachings of Mehta with regard to the use of a window in the stabilization plate of Mehta. The treatment apparatuses disclosed in Mehta, Na '848 and Kang '395, are all in the same field, all have similar structure, and are all used for similar purposes. This modification would not have required anything beyond routine engineering, and the addition of LED illumination would have furthered the purpose of Mehta's stabilization plate window with respect to allowing a user of the treatment apparatus to observe the area in which the treatment is being applied.

436. In view of the foregoing chart, claim 4 of the '536 Patent is rendered obvious by Mehta in view of the knowledge of a POSITA, and/or further in view of the teachings of Na '848 and/or the teachings of Kang '395. The teachings of Mehta are so similar to what is claimed that any alleged difference between the teachings of Mehta and what is claimed would not have been of patentable significance given the knowledge of a POSITA and/or further in view of the teachings of Na '848 and/or the teachings of Kang '395. in the art and/or further in view of the teachings of Na '848 and/or the teachings of Kang '395.

3. Claim 5 of the '536 Patent is Anticipated by Mehta and/or obvious over Mehta alone (in view of the knowledge of a POSITA) and/or in combination with Na 848 and Kang 395

437. Claim 5 of the '536 Patent, which depends from claim 4, is anticipated by or obvious in view of the teachings of Mehta given the knowledge of a POSITA and/or in combination with the teachings of Na '848 and/or Kang '395:

'536 Patent Claim 5		Mehta alone and/or in combination with Na '848 and/or Kang '395
5.0	5. The method of claim 4, wherein the releasably couplable deployable needle assembly includes a translucent section to communicate illumination from the least one embedded LED to the plurality of extendable needles.	Mehta in view of the general knowledge of a POSITA renders obvious that the releasably couplable deployable needle assembly includes a translucent section to communicate illumination from the least one embedded LED to the plurality of extendable needles. For example, Mehta discloses that "stabilization plate 214" includes a "window" comprising "transparent material" through which the "energy transfer elements" (*i.e.*, the needles) can be viewed, and Mehta also discloses that the system includes "LEDs." It would have been obvious to a POSITA to utilize an LED to illuminate the needles of the deployable needle assembly in view of these teachings of Mehta, so that an operator of the treatment device can better see the placement of the needles onto the skin while the treatment is being performed. *See, e.g.,* discussion and citations above regarding Mehta for limitation 4.0. This claim would have further been obvious in view of Mehta in combination with Na '848. Na '848, in combination with Mehta, renders obvious that the needle assembly includes a translucent section to communicate illumination from the least one embedded LED to the plurality of needles. For example, with respect to a "dermalogical treatment apparatus" having a plurality of "pins or needles" through which an electrical signal may be applied to tissue under the skin, Na '848 discloses that the handheld apparatus includes "a plurality of embedded LEDs 32A, 32B" embedded in the proximal end of the apparatus, which are energized to illuminate needles of the apparatus, and Na further discloses that "pin section 250, 353 ***may be translucent***" to allow the light from the LEDs to illuminate the plurality of needles. *See, e.g.*, discussion and citations above regarding Na '848 for limitation 4.0; *see also, e.g.*: > [0035] In an embodiment the chemical 22A may be applied directly to the dermalogical cells to be treated. In a further embodiment a chemical 22A may not be employed in addition to the apparatus 10, 320, 350, 360, 400, 460. ***In an embodiment the pin section 250, 353, may be translucent and comprised of a polyurethane, medical silicon, or other pliable, translucent, hypoallergenic material***. This claim would have further been obvious in view of Mehta in combination with Kang '395.

'536 Patent Claim 5		Mehta alone and/or in combination with Na '848 and/or Kang '395
		Kang '395, in combination with Mehta, that the needle assembly includes a translucent section to communicate illumination from the least one embedded LED to the plurality of needles. For example, with respect to a "high-frequency handpiece" for treating skin, Kang discloses that the handpiece "is equipped with a light-emitting member," whereby the light-emitting member may be an LED and may be utilized to emit light to be able to see the position of where the "heating part 230" (*e.g.*, an insertable needle) is being inserted, and thus, to the extent that any portion of the needle assembly is in the path between the LED and the heating part that is inserted into the skin, it would have been obvious to a POSITA to have used translucent material for that section. *See, e.g.,* discussion and citations above regarding Kang '395 for limitation 4.0. It would have been obvious to a POSITA as of the priority date of the '536 Patent to modify Mehta and/or to combine the teachings of Mehta with the teachings of Na '848 and/or with the teachings of Kang '395 in a manner that would have rendered claim 5 obvious. For example, Mehta discusses the use of transparent or translucent materials to view the needles during treatment. *See, e.g.*, Mehta at 4:19-34 & 13:16-36. Kang '395 discloses an LED for illuminating a deployable needle assembly when energized. *See, e.g.*, Kang '395 at 4. Na '848 discusses both the use of an LED to illuminate needles when energized (*see, e.g.*, Na '848 at Figs. 4A-4C, Figs. 5A-5B, Fig. 6, Figs. 7A-7C, [0034], [0036]-[0047]), as well as use of a pin section being made of a translucent material (*see, e.g.*, Na '848 at [0035]). Thus, as of the priority date of the '536 Patent, it was well known to use LEDs as indicators for power being on and to illuminate small areas and to use translucent material for viewing a treatment area where a treatment device is being inserted. The use of an LED with a translucent viewing area was an obvious design choice for the person of ordinary skill that wishes to see what is happening in a treatment area, as evidenced by the express teachings of Mehta, Na '848 and Kang '395. Utilizing a translucent viewing area in connection with an LED for illumination would have been an obvious design choice in view of the teachings of Na '848 and Kang '395 with regard to the user of LEDs for illumination and further in view of the teachings of Mehta with regard to the use of a window in the stabilization plate of Mehta. The treatment apparatuses disclosed in Mehta, Na '848 and Kang '395, are all in the same field, all have similar structure, and are all used for similar purposes. This modification would not have required anything beyond routine engineering, and the use of LED illumination

'536 Patent Claim 5		Mehta alone and/or in combination with Na '848 and/or Kang '395
		together with Mehta's stabilization plate window would have furthered the purpose of Mehta's stabilization plate window with respect to allowing a user of the treatment apparatus to observe the area in which the treatment is being applied.

438. In view of the foregoing chart, claim 5 of the '536 Patent is anticipated by and/or rendered obvious by Mehta in view of the knowledge of a POSITA, and/or further in view of the teachings of Na '848 and/or the teachings of Kang '395. The teachings of Mehta are so similar to what is claimed that any alleged difference between the teachings of Mehta and what is claimed would not have been of patentable significance given the knowledge of a POSITA and/or further in view of the teachings of Na '848 and/or the teachings of Kang '395.

4. Claim 9 of the '536 Patent is Anticipated by Mehta and/or Obvious over Mehta alone (in view of the knowledge of a POSITA) and/or in combination with Na '848

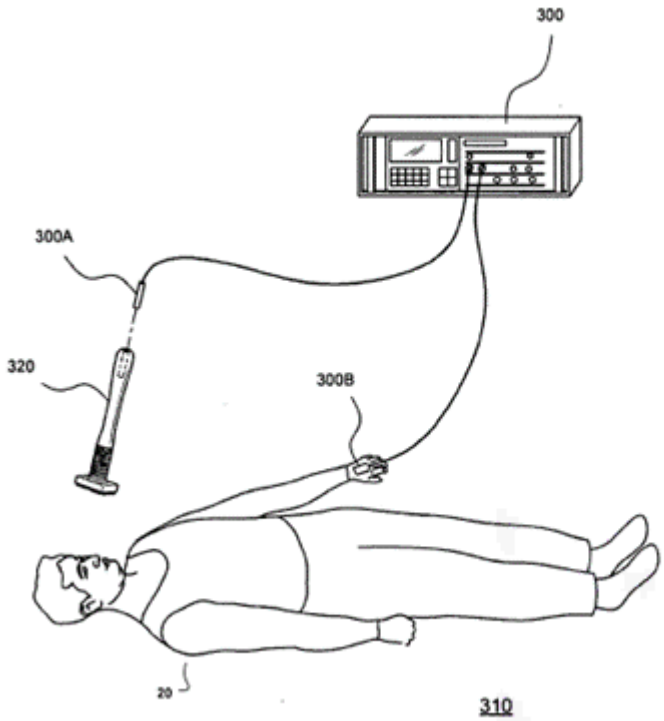
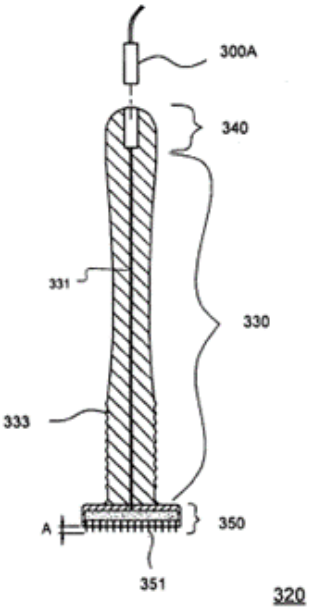
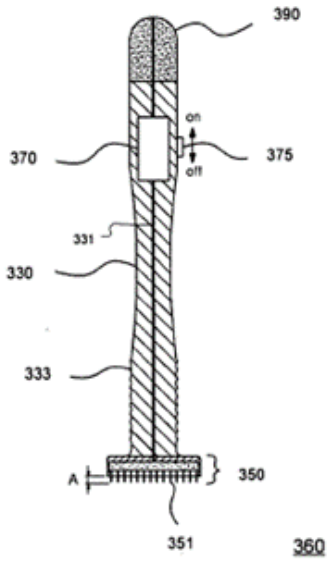
439. Claim 9 of the '536 Patent, which depends from claim 1, is anticipated by Mehta and/or obvious in view of the teachings of Mehta given the knowledge of a POSITA and/or in combination with the teachings of Na '848:

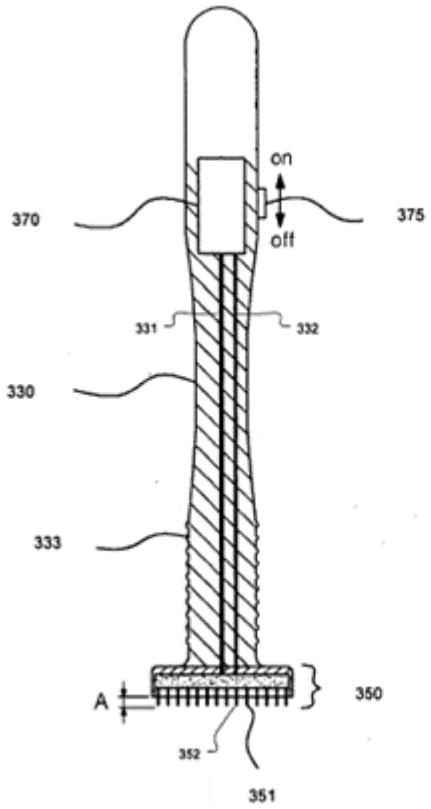
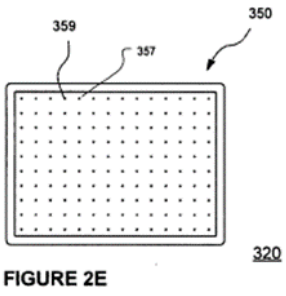
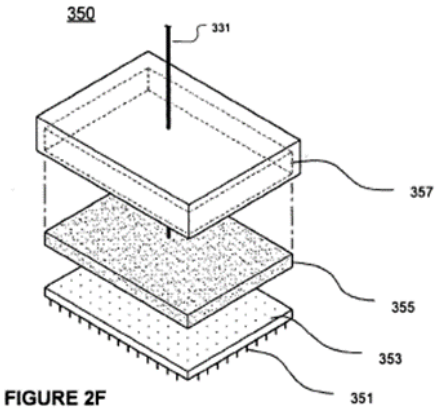
'536 Patent Claim 9		Mehta alone and/or in combination with Na '848
9.0	9. The method of claim 1, further comprising deploying the plurality of extendable needles to a predetermined depth and employing the signal generator to energize the plurality of	Mehta discloses deploying the plurality of extendable needles to a predetermined depth and employing the signal generator to energize the plurality of extended needles to a predetermined intensity for a predetermined duty cycle. Mehta discloses energizing a motor coupled to the needle assembly to cause the plurality of the needles to extend a desired distance from the releasably couplable deployable needle assembly end surface. *See, e.g.,* Mehta, at 10:33-39 ("motors" "driven by the control system/energy supply unit 90"), 12:5-14, 13:58-4, 16:59-17:12, 18:21-37, 32:46-33:34, 33:57-13, 33:57-13, 34:38-45, 35:8-22, 36:21-40, Figs. 10B, 10E.

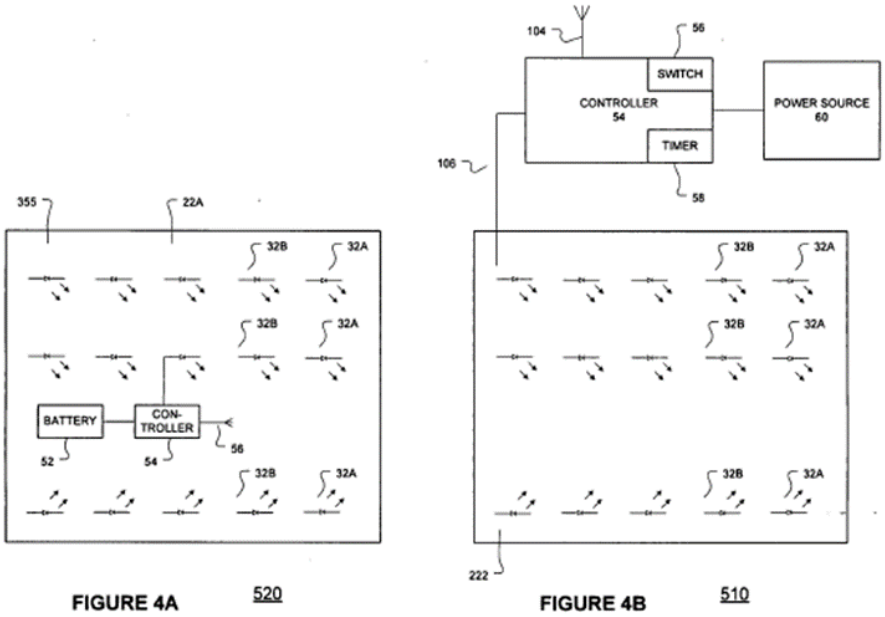
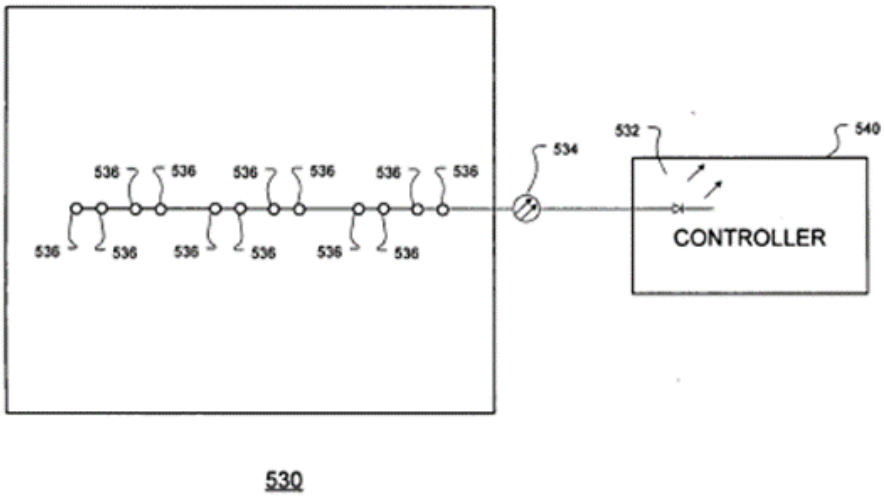
'536 Patent Claim 9		Mehta alone and/or in combination with Na '848
	extended needles to a predetermined intensity for a predetermined duty cycle.	Mehta's discloses that the needles may be inserted to a desired distance/depth which is a predetermined depth. *See id*., at 32:46-33:34, 33:57-34:13, 34:38-45, 35:8-22. Thus, Mehta discloses energizing the motor to deploy the plurality of needles to a predetermined depth. *See, e.g.* discussion and citations above regarding Mehta for limitation 1.6; *see also, e.g.*, Mehta, at 1:27-31, 1:32-42, 1:65-2:2, 2:3-12, 2:13-21, 2:22-29, 3:40-41, 3:57-67, 5:49-57, 5:58-6:2, 7:40-44, 8:45-53, 8:54-65, 10:8-16, 10:17-25, 12:5-14, 17:32-45, 17:59-18:3, 18:4-20, 18:64-19:8, 19:17-25, 19:26-44, 19:4-65, 22:53-62, 24:5-12, 24:46-60, 25:4-15, 25:24-29, 25:30-55, 25:64-67, 26:41-59, 26:60-27:22, 35:8-22, 36:54-37:6, 37:25-34, Fig. 13A, 37:35-41, 37:42-64, 37:65-38:21, 38:22-57, 38:58-67, 39:1-8, 39:9-27, 39:28-41, 39:58-40:4, 40:5-38, 40:39-44, 42:9-15. "Energize the plurality of extended needle to a predetermined intensity", may mean (1) literally a predetermined intensity of energy (in electrical terms the intensity of the energy would be the rate of energy also called "power" expressed in Watts), or (2) the intensity would mean the intensity "I" of the current as mentioned the '536 Patent at 13:33-35 "In a blend operational mode (activity 934A), a user may select the electrical signal intensity, start delay, and duty cycle (activity 934 B)…." 13:33-35. Mehta describes both: (1) Mehta discloses that energy can be maintained at a predetermined energy level in 19:28: "In one mode, the system can simply monitor the amount of energy being applied to the target site. This process involves applying energy and maintaining that energy at a certain pre-determined level." And (2) Mehta discloses that the generator can produce a predetermined intensity of current in 25:42-45 "When the impedance of a pair was within a predetermined level the controller directed delivery of RF treatment current to that pair." Mehta further discloses "applying energy to the electrode array from the energy source during a treatment cycle where the energy applied to each electrode pair is adjusted based upon the identified tissue layer." *See* Mehta, at 3:42-56. Mehta discloses that the needles are energized at a predetermined intensity. *Id*., at 3:57-67 ("by selecting a set of controller parameters based on the identified tissue layer … the method further comprising supplying an initial energy level from the energy source between the electrodes … and modifying the initial energy level using the controller parameters to obtain a target temperature in the injured tissue"), 5:49-57, 5:58-6:2 ("the system can stop application of energy if a parameter measured by the probes exceeds a pre-determined value or range of

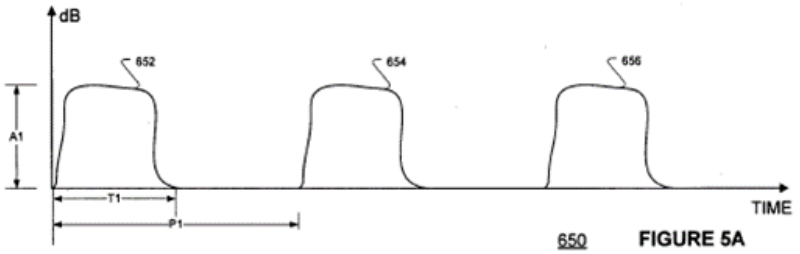
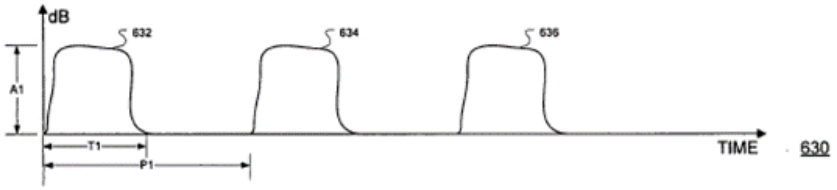
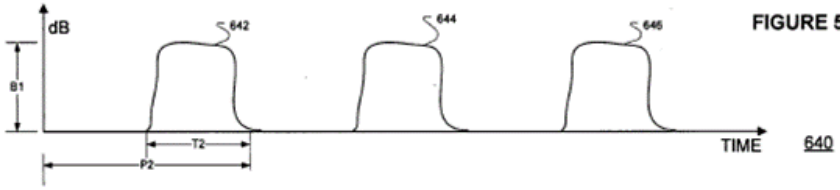
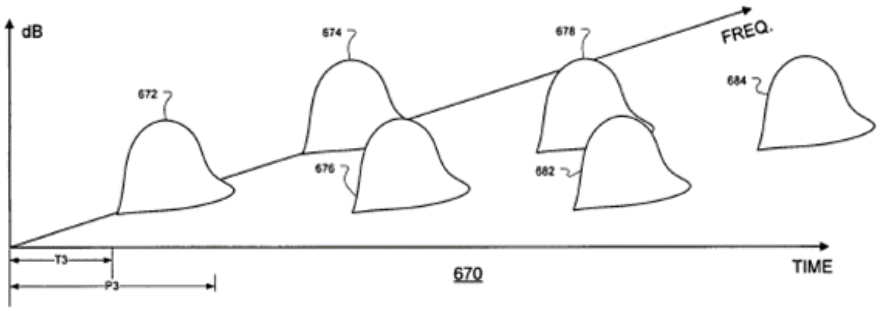
'536 Patent Claim 9		Mehta alone and/or in combination with Na '848
		values," and "[s]uch a measured parameter can include … applied energy"), 15:55-16:11 ("electrodes can be energized"). "Some examples of the pre-determined values include limiting energy delivery to [a predetermined intensity, such as] between 2 and 4 joules." *Id*., at 5:58-6:2; *see also id*., at 18:64-19:8 ("the controller can adjust the maximum parameters (maximum voltage, maximum current, maximum power, maximum impedance, maximum applied energy), and/or target parameters"), 19:26-44 ("maintaining that energy at a certain pre-determined level"), 20:48-49 ("**energy delivery control systems other than those described above can be employed**."), 25:24-29, 26:60-27:22, 27:66-28:6, 33:57-34:13, 3:40-41 ("**The graphical user interface can be configured to allow a user to adjust at least one parameter of the energy supply unit**."); *see also id*., at 12:5-14, 20:29-55 ("The controller compares the measured temperature to a desired temperature," and "[b]ased on the difference, the energy parameters are adjusted for the subsequent energy pulse"). "In addition, the graphical user interface can further comprise: a treatment counter indicator configured to show a number of treatment cycles applied by the energy supply unit." *Id*., at 3:29-39. Mehta also energizes the needles using RF energy "RF energy is often delivered in a pulsed fashion or ***for a specific duty cycle*** to prevent stressing the components of that system." *Id*., at 20:13-28; *see also id*., at 19:26-44 ("pre-determined amount[s] of time" for the energizing the needles), 19:45-65 ("***pre-determined cycle*** or dwell time … for precise control in maintaining the target site at the pre-determined temperature"), 27:66-28:6, 33:57-34:13, 34:14-24, Fig. 10E; *see also* Mehta, at col. 20:21-28: "In another variation, ***the duty cycle*** of variations of the present system ***can be pulsed so that temperature measurements can be taken between the pulsed deliveries of energy***. Pulsing the energy delivery allows for an improved temperature measurement in the period between energy deliveries and provides precise control of energy delivery when the goal of the energy delivery is to reach a pre-determined temperature for a pre-determined time." Thus, Mehta discloses employing the signal generator to energize the plurality of extended needles to a predetermined intensity for a predetermined duty cycle. *See, e.g.*, discussion and citations above regarding Mehta for limitation 1.6; Mehta, at 1:27-31, 1:32-42, 1:65-2:2, 2:3-12, 2:13-21, 2:22-29, 3:40-41, 3:57-67, 5:49-57, 5:58-6:2, 7:40-44, 8:45-53, 8:54-65, 10:8-16, 10:17-25, 12:5-14, 17:32-45, 17:59-18:3, 18:4-20, 18:64-19:8, 19:17-25, 19:26-44, 19:4-65, 22:53-

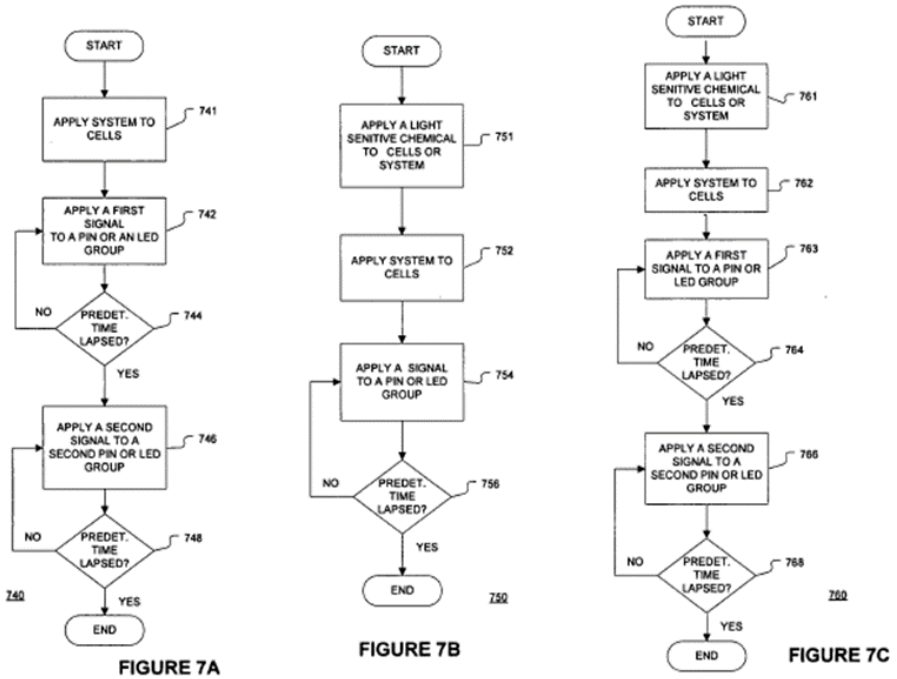
'536 Patent Claim 9		Mehta alone and/or in combination with Na '848
		62, 24:5-12, 24:46-60, 25:4-15, 25:24-29, 25:30-55, 25:64-67, 26:41-59, 26:60-27:22, 35:8-22, 36:54-37:6, 37:25-34, Fig. 13A, 37:35-41, 37:42-64, 37:65-38:21, 38:22-57, 38:58-67, 39:1-8, 39:9-27, 39:28-41, 39:58-40:4, 40:5-38, 40:39-44, 42:9-15; *see also, e.g.*, Mehta, at 3:40-41; 3:42-55; 3:57-67; 5:49-57; 5:58-6:2; 12:5-14; 18:64-19:8; 19:26-44; 19:45-65; 20:13-28; 20:29-55; Fig. 6; 24:5-12; 25:24-29; 26:60-27:22; 27:66-28:6; 28:49-50; 33:57-34:13; 34:14-24; 35:8-22; 36:21-40; and 40:5-38. To the extent that Complainant alleges that Mehta alone does not disclose or render obvious "employing the signal generator to energize the plurality of extended needles to a predetermined intensity for a predetermined duty cycle," this limitation would have further been obvious in view of Mehta in combination with Na '848. Na '848, in combination with Mehta, renders obvious employing the signal generator to energize the plurality of extended needles to a predetermined intensity for a predetermined duty cycle. For example, with respect to a "dermalogical treatment apparatus" having a plurality of "pins or needles" through which an electrical signal may be applied to tissue under the skin, Na '848 discloses that "a signal generator" energizes a plurality of needles extended into a patient's skin using periodic pulses having a predetermined intensity. *See, e.g.* [0039] ("***The waveform 650 may be used to energize an LED 32A, 32B, 532 and to the pins 230, 351, 451 periodically Pl for a predetermined interval Tl where each pulse 652, 654, 656 has a[n] amplitude Al. In an embodiment, Al may be about 0.1 milliamperes (mA) to 10 mA, the pulse width Tl may be about 100 microsecond (µs) to 500 µs and the period Pl may from 100 ms to 500 ms*** as a function of the energy required to create capacitance in a liquid. ***In another embodiment, Al may be about 0.5 milliamperes (mA) to 5 mA, the pulse width Tl may be about 200 microsecond (µs) and the period Pl may about 250 ms*** as a function of the energy to drive an LED or cause one or more pins 230, 351, 451 to vibrate."); *see also, e.g.*:

‘536 Patent Claim 9		Mehta alone and/or in combination with Na ‘848
		 FIGURE 2A  FIGURE 2B  FIGURE 2C

'536 Patent Claim 9		Mehta alone and/or in combination with Na '848
		 FIGURE 2D  FIGURE 2E  FIGURE 2F

‘536 Patent Claim 9	Mehta alone and/or in combination with Na ‘848
	 FIGURE 4A 520 FIGURE 4B 510  530 FIGURE 4C

'536 Patent Claim 9	Mehta alone and/or in combination with Na '848
	 650 FIGURE 5A  630  640 FIGURE 5B  670 FIGURE 6

'536 Patent Claim 9	Mehta alone and/or in combination with Na '848
	 FIGURE 7A FIGURE 7B FIGURE 7C [0026] FIG. 2 A is a simplified diagram of a dermalogical treatment architecture 310 according to various embodiments. Architecture 310 includes an acupuncture apparatus 320 and ***an electrical signal generation system 300. The the [sic] electrical signal generation system 300 may be electrically coupled to the acupuncture apparatus 320 via one or more wires 300A and to a mammal 20 to be treated via one or more wires 300B***. FIG. 2B is a simplified cross-sectional diagram of the acupuncture apparatus 320 according to various embodiments. The apparatus 320 may include a handle 330, elastic section 333, electrical interface 340, internal wire(s) 33 land plate 350. The pins 351 may have a length A (0.3 mm to 2.1 mm in an embodiment) where at least one pin 351 is electrically coupled to the electrical interface 340 via the internal wire 331. The electrical interface 340 may be removably connected to the system 300 wire 300A. [0027] ***The electrical signal generation system 300 may generate a vary of signals (such as shown in FIGS. 5 A to 6) to vibrate one or more pins 351 electrically coupled to the system 300 via the internal wire 331 and lead 300A. A pin vibration 351 may increase the micro-wound or cut formed in dermis by the pin 351.*** FIG. 2C is a simplified cross-sectional diagram of an acupuncture apparatus 360 according to various embodiments. The apparatus 360 may include a handle 330, an

'536 Patent Claim 9		Mehta alone and/or in combination with Na '848
		elastic section 333, an electrical conductive interface 390, internal wire(s) 331, signal generator 370, switch 375, and plate 350. ***The signal generator 370 may be coupled to at least one pin 351 via internal wire 331 and coupled to the conductive interface 390.*** [0028] ***The signal generator or module 370 may generate a vary of signals (such as shown in FIGS. 5 A to 6) to vibrate one or more pins 351 electrically coupled to the system 300 via the internal wire 331 and the conductive interface 390.*** In operation a user 20 may touch the conductive interface 390 and place one or more electrically coupled pins 351 in contact with their dermis to form an electrical pathway from the pin 351 to the electrical conductive interface 390. The signal generator 370 may include a battery to supply energy to generate one or more electrical signals. ***The switch 375 coupled to the generator 370 may cause the generator to produce one or more electrical signals for a predetermined time interval or until the switch 375 is triggered again.*** As noted a pin vibration 351 may increase the micro-wound or cut formed in dermis by the pin 351. [0029] FIG. 2D is a simplified cross-sectional diagram of an acupuncture apparatus 362 according to various embodiments. The apparatus 362 may include a handle 330, an elastic section 333, internal wire(s) 331, 332, ***signal generator 370***, switch 375, and plate 350. ***The signal generator 370 may be coupled to at least one pin 351 via internal wire 331 and coupled to at least one other pin 352 via internal wire 332.*** When active the pins 351, 352 may form at least one dipole pair. ***The signal generator or module 370 may generate a vary of signals (such as shown in FIGS. 5A to 6) to vibrate one or more dipole pair or bipolar pins 351, 352.*** [0033] ***FIGS. 3A and 3B are simplified isometric diagrams of acupuncture apparatus 400, 460 including at least one pin 451 that may be coupled to an electrical signal via an internal wire 458.*** Each apparatus 400, 460 includes curved roller 450 having a plurality of acupuncture pins 451 where the pins 451 may be similar to pins 351. In apparatus 400, the electrical lead wire 400A may be coupled to an electrical interface 410 in the apparatus handle 430 where the interface 410 is electrically coupled to the internal wire 458. In apparatus 460, the handle 430 may include ***a signal generator 470*** similar to generator 370, switch 475, and conduction surface 490. Apparatus 460 may operate similar to apparatus 360 in operation other than the

'536 Patent Claim 9		Mehta alone and/or in combination with Na '848
		rolling capability of the apparatus 460, 400. In an embodiment the rollers 450 may have various configurations to conform to a dermal area to be treated. [0039] ***FIGS.5A-5B are diagrams of electrical signal waveforms 650, 630, 640 that may be applied*** to one or more LEDs 32A, 32B, 532 and ***to the pins 230, 351, 451*** according to various embodiments. ***The signal waveform 650 includes several square -wave pulses 652, 654, 656 that may be applied to an LED 32A, 32B, 532. Each pulse 652, 654, 656 may a have a similar magnitude and envelope. The waveform 650 may be used to energize an LED 32A, 32B, 532 and to the pins 230, 351, 451 periodically Pl for a predetermined interval Tl where each pulse 652, 654, 656 has a[n] amplitude Al. In an embodiment, Al may be about 0.1 milliamperes (mA) to 10 mA, the pulse width Tl may be about 100 microsecond (µs) to 500 µs and the period Pl may from 100 ms to 500 ms*** as a function of the energy required to create capacitance in a liquid. ***In another embodiment, Al may be about 0.5 milliamperes (mA) to 5 mA, the pulse width Tl may be about 200 microsecond (µs) and the period Pl may about 250 ms*** as a function of the energy to drive an LED or cause one or more pins 230, 351, 451 to vibrate. [0040] ***In FIG. 5B a signal waveform 630 may be applied*** to a first LED 32A, 32B, 532 module or group and ***to the pins 230, 351 , 451*** and ***a second waveform 640 may be applied or used to energize*** a second LED 32A, 32B, 532 module and ***the pins 230, 351, 451, 352***. ***The signal waveform 630 includes several square-wave pulses 632, 634, and 636 and the signal waveform 640 includes several square-wave pulses 642, 644, and 646.*** Each pulse 632, 634, 636, 642, 644, 646 may a have a similar magnitude and envelope. ***The waveform 630 may be used to energize*** a first LED 32A, 32B, 332 module and ***the pins 230, 351, 451 periodically Pl for a predetermined interval Tl*** where each pulse 632, 634, 636 has an amplitude Al. ***The waveform 640 may be used to energize*** a second LED 32A, 32B, 332 module and ***the pins 230, 351, 451 periodically P2 for a predetermined interval T2*** where each pulse 642, 644, 646 has an amplitude Bl. ***The pulse width Tl, T2 may be about 100 microsecond (µs) to 500 µs and the period Pl, P2 may from 100 ms to 500 ms*** as a function of the energy to affect dermalogical cells or chemicals 22A. ***In another embodiment, Al, A2 may be about 0.5 milliamperes (mA) to 5 mA, the pulse width Tl, T2 may be about 200 microsecond (µs) and the***

'536 Patent Claim 9		Mehta alone and/or in combination with Na '848
		period Pl, P2 may about 250 ms as a function of the energy required to affect dermalogical cells or chemicals 22 A. ***In an embodiment the pulses 632, 634, 636 do not substantially overlap the pulses 642, 644, 646. In an embodiment Tl > T2 and P2 is an integer multiple of Pl .*** [0041] FIG. 6 depicts a waveform 670 that includes multiple pulses 672, 674, 676, 678, 682, and 684 that may not overlap in the time or the frequency domain. ***In an embodiment each pulse 672, 674, 676, 678, 682, and 684 may have a pulse width T3, and frequency spectrum width Fl and period P3***. The pulse 672 is frequency offset from the pulse 674, the pulse 676 is frequency offset from the pulse 678, and the pulse 682 is frequency offset from the pulse 684. ***The pulses 672, 674, 676, 678, 682, and 684 may be applied to*** an LED module to affect dermalogical cells or chemicals 22A and ***the pins 230, 351, 451.*** Pulses 672, 674 having different frequency spectrums may enable different LED stimulation. In an embodiment the pulses 672, 676, 682 may be applied to a first LED module and the pulses 674, 678, 684 may be applied to a second LED module. The frequency separation between the respective pulses may enable ***simultaneous energization of*** a first and a second LED module and ***the pins 230, 351, 451*** and subsequent and independent spectrum generation. [0042] In an embodiment the invention may employ the algorithm 740 shown in FIG. 7A to apply therapy to dermalogical cells. A user, clinician, or equipment may place an apparatus 10, 320, 360, 360, 400, 460 on dermalogical cells to be treated (activity 741) including pressing the apparatus against the cells firmly enough to embed one or more pins 251, 351 , 451 in the cells. ***A first signal such as shown in FIGS. 5A, 5B, and 6 may be applied to*** a first LED module or group (32A) and ***the pins 230, 351, 451 of a dermalogical apparatus 10, 320, 360, 360, 400, 460 (activity 742) for a predetermined time period (activity 744)***. ***A second signal such as shown in FIGS. 5 A, 5B, and 6 may be applied to*** a second LED module or group (32B) and ***the pins 230, 351, 451 of a dermalogical apparatus 10, 320, 360, 360, 400, 460 (activity 746) for a predetermined time period (activity 748)***. The signals applied to the groups may be selected to stimulate dermalogical cells or chemicals 22A or cause vibration of one or more pins 251, 351, 451. [0043] In another embodiment the invention may employ the algorithm 750 shown in FIG. 7B to apply therapy to

'536 Patent Claim 9		Mehta alone and/or in combination with Na '848
		dermalogical cells. A user, clinician, or equipment may apply a light sensitive chemical on an apparatus 10, 320, 360, 360, 400, 460 or on dermalogical cells to be treated (activity 751). The user, clinician, or equipment may place apparatus 10, 320, 360, 360, 400, 460 on dermalogical cells to be treated (activity 752). ***A signal such as shown in FIGS. 5A, 5B, and 6 may be applied to*** a LED module or group (32A or 32B) and ***the pins 230, 351, 451 (activity 354) for a predetermined time period (activity 356)***. [0044] In another embodiment the invention may employ the algorithm 760 shown in FIG. 7C to apply therapy to dermalogical cells. A user, clinician, or equipment may apply a light sensitive chemical on an apparatus 10, 320, 360, 360, 400, 460 or on dermalogical cells to be treated (activity 761). The user, clinician, or equipment may place an apparatus 10, 320, 360, 360, 400, 460 on dermalogical cells to be treated (activity 762). ***A first signal such as shown in FIGS. 5A, 5B, and 6 may be applied to*** a first LED module or group (32A) and ***one or more pins 251, 351, 451 of a dermalogical apparatus 10, 320, 360, 360, 400, 460 (activity 763) for a predetermined time period (activity 764)***. ***A second signal such as shown in FIGS. 5 A, 5B, and 6 may be applied to*** a second LED module or group (32B) and ***one or more pins 251 , 351 , 451 of a dermalogical apparatus 10, 320, 360, 360, 400, 460 (activity 766) for a predetermined time period (activity 768).*** It would have been obvious to a POSITA as of the priority date of the '536 Patent to modify Mehta and/or to combine the teachings of Mehta with the teachings of Na '848 in a manner that would have rendered claim 9 obvious. For example, Mehta discusses deploying needles to a predetermined depth, and energizing the extended needle to a predetermined intensity and for a predetermined duty cycle. *See, e.g.*, Mehta at 5:58-6:2, 18:64-19:8, 19:26-44, 19:45-65, 20:13-28, 20:29-55, Fig. 6, 26:60-27:22, 33:57-34:13, 40:5-38. Na '848, also discusses applying energy to needles extended into skin using a predetermined intensity and predetermined duty cycle to achieve a desired treatment effect. *See, e.g.*, Na '848 at Figs. 5A-5B, Fig. 6, [0039]-[0041]. Thus, as of the priority date of the '536 Patent, it was well known to adjust the depth at which energy is applied to dermis tissue, as well as the intensity and duty cycle of the energy, to achieve a desired result. It would therefore have been obvious to try the process parameters disclosed in these various prior art references in conjunction with achieving desired treatment results.

'536 Patent Claim 9		Mehta alone and/or in combination with Na '848
		The use of a predetermined intensity and a predetermined duty cycle for energizing a plurality of extended needles was an obvious design choice for a person of ordinary skill to achieve a desired treatment effect corresponding to the respective intensity and duty cycle. The treatment apparatuses disclosed in Mehta and Na '848 are in the same field, have similar structure, and are used for similar purposes. This modification would not have required anything beyond routine engineering to appropriately program the control software used in Mehta, and the use of a predetermined intensity and duty cycle would have furthered the purpose of Mehta's treatment apparatus with respect to achieving a reproducible and desirable treatment effect corresponding to the respective intensity and duty cycle.

440. In view of the foregoing chart, claim 9 of the '536 Patent is anticipated by the teachings of Mehta. Further, to the extent Complainant argues that any of the foregoing limitations is not explicitly or inherently disclosed by Mehta, such limitations would have been obvious given the knowledge of a POSITA, and/or further in view of the teachings of Na '848. The teachings of Mehta are so similar to what is claimed that any alleged difference between the teachings of Mehta and what is claimed would not have been of patentable significance given the knowledge of a POSITA.

5. Claim 11 of the '536 Patent is Anticipated by Mehta and/or Obvious over Mehta

441. Claim 11 of the '536 Patent is anticipated by the teachings of Mehta:

'536 Patent Claim 11		Mehta
11.0	11. An apparatus for treating dermatological tissue, comprising:	Mehta discloses an apparatus for treating dermatological tissue. *See, e.g.,* discussion and citations above regarding Mehta for limitation 1.0.
11.1	a user holdable device including a proximal end and a releasably couplable deployable needle assembly,	Mehta discloses a user holdable device including a proximal end and a releasably couplable deployable needle assembly. *See, e.g.*, discussion and citations above regarding Mehta for limitations 1.1 and 1.2.

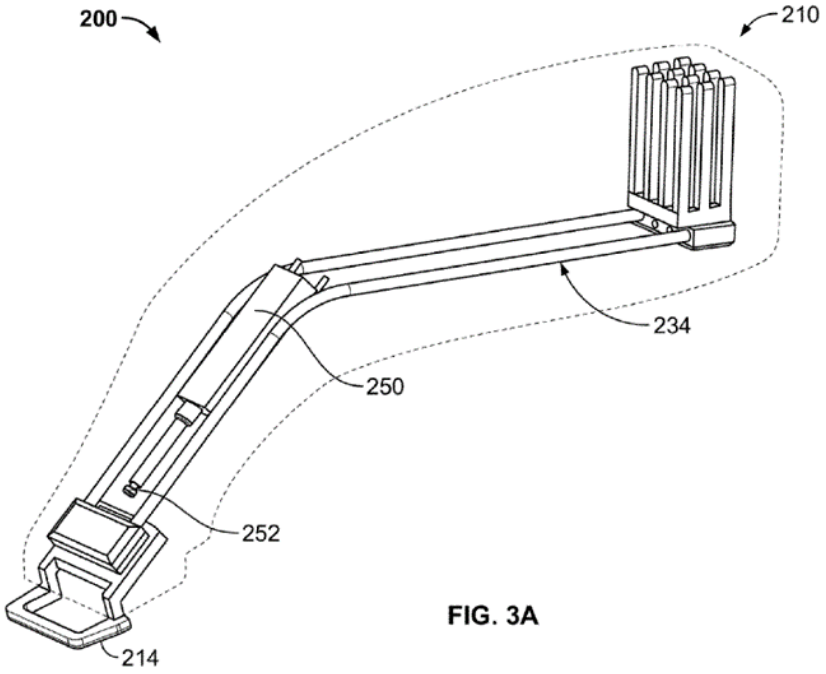
'536 Patent Claim 11		Mehta
11.2	the deployable needle assembly mechanically separatably from the proximal end and including a plurality of extendable needles,	Mehta discloses the deployable needle assembly mechanically separatably from the proximal end and including a plurality of extendable needles. *See, e.g.*, discussion and citations above regarding Mehta for limitation 1.3.
11.3	a plurality of the extendable needles extendable from a deployable needle assembly end surface,	Mehta discloses that the plurality of the extendable needles are extendable from a deployable needle assembly end surface. *See, e.g.*, discussion and citations above regarding Mehta for limitations 1.1, 1.3 and 1.6.
11.4	one of the proximal end and the deployable needle assembly including at least one electrical conductor and the other including at least one restorably deflectable electrical contact couplable to the one of the proximal end and the deployable needle assembly at least one electrical conductor;	Mehta discloses that one of the proximal end and the deployable needle assembly includes at least one electrical conductor and the other includes at least one restorably deflectable electrical contact couplable to the one of the proximal end and the deployable needle assembly at least one electrical conductor. *See, e.g.*, discussion and citations above regarding Mehta for limitation 1.4.
11.5	a motor coupled to a plurality of extendable needles that causes the plurality of extendable needles to extend a desired distance from the needle assembly end surface when the motor is energized with a particular signal; and	Mehta discloses a motor coupled to a plurality of extendable needles that causes the plurality of extendable needles to extend a desired distance from the needle assembly end surface when the motor is energized with a particular signal. *See, e.g.*, discussion and citations above regarding Mehta for limitation 1.6.
1.6	a signal generator electrically coupled to the plurality of extended needles to energize the plurality of extended needles.	Mehta discloses a signal generator electrically coupled to the plurality of extended needles to energize the plurality of extended needles. *See, e.g.*, discussion and citations above regarding Mehta for limitations 1.5 and 1.7.

442. In view of the foregoing chart, claim 11 of the '536 Patent is anticipated by the teachings of Mehta. Further, to the extent Complainant argues that any of the foregoing limitations is not explicitly or inherently disclosed by Mehta, such limitations would have been obvious given the knowledge of a POSITA. The teachings of Mehta are so similar to what is claimed that any alleged difference between the teachings of Mehta and what is claimed would not have been of patentable significance given the knowledge of a POSITA.

6. Claim 13 of the '536 Patent is Anticipated by Mehta and/or Obvious over Mehta

443. Claim 13 of the '536 Patent, which depends from claim 11, is anticipated by the teachings of Mehta:

'536 Patent Claim 13		**Mehta**
13.0	13. The apparatus of claim 11, wherein the proximal end includes the needle deploying motor, the motor including a draft shaft releasably couplable to the deployable needle assembly.	To the extent that "draft shaft" is not indefinite and is corrected to "drive shaft" by the ALJ, Mehta discloses that the proximal end includes the needle deploying motor, the motor including a draft/drive shaft releasably couplable to the deployable needle assembly. *See, e.g.,* discussion and citations above regarding Mehta for limitation 1.6; *see also, e.g.*, Mehta, at 4:63-5:2; 5:3-15; 6:64-65; 9:34-55; 10:33-39; 13:54-57; Fig. 3A; 13:58-4; 15:27-33; 15:55-16:11; Fig. 4A; 16:42-58; 16:59-17:12; 18:21-37; Fig. 5; 35:8-22; Fig. 12A; and Fig. 12B. As discussed and shown above with regard to limitation 1.6, Mehta discloses an actuator that can be a motor. The motor 250 is part of the proximal end of the user holdable device 210, and is "coupled to the [needle] array at a distal end of a **[drive] shaft** (emphasis added) 252. Mehta, at 13:58-14:4, *see also id*., at 13:54-57, 18:21-37, 35:8-22, Figs. 3A, 5, 12A, 12B.

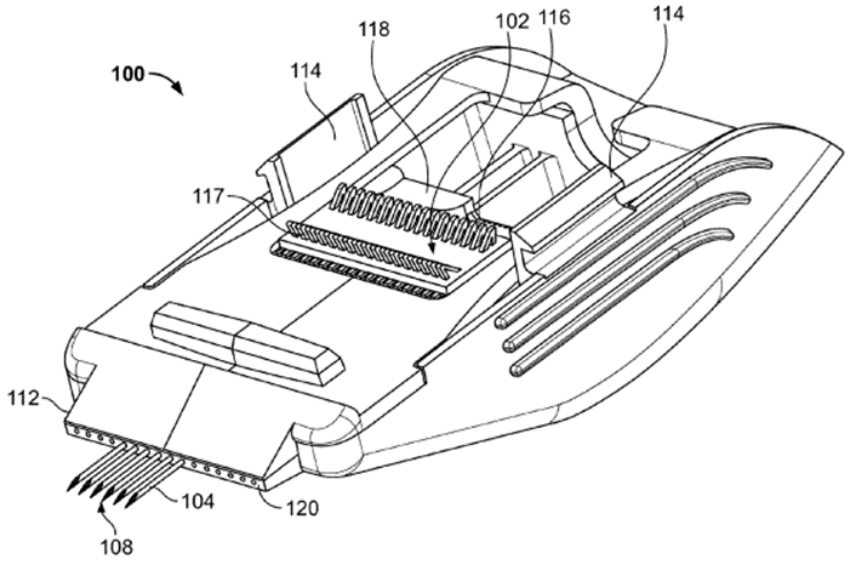
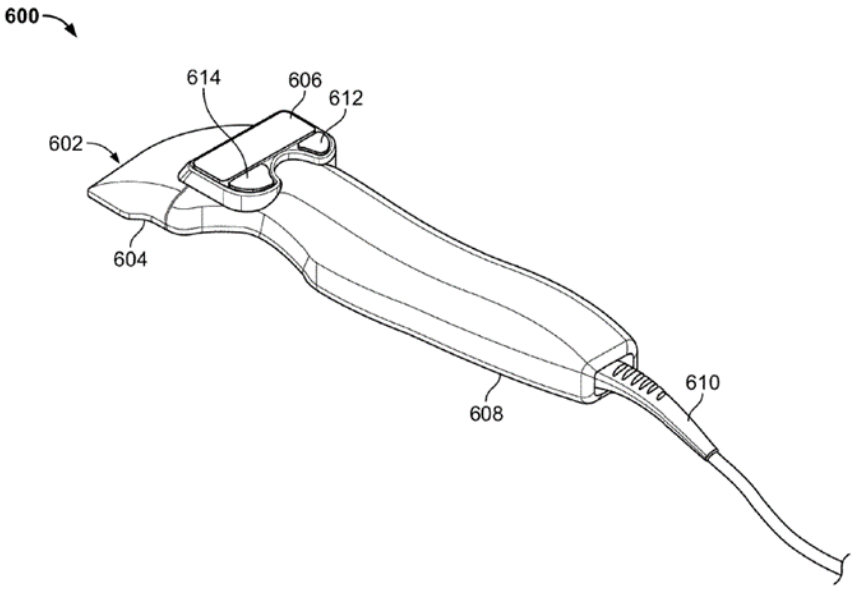
‘536 Patent Claim 13		Mehta
		 FIG. 3A As discussed and shown above with regard to limitation 1.1, Mehta’s needle assembly (within a needle cartridge) is releasably couplable to the user holdable device. *See, e.g.,* discussion and citations above regarding Mehta for limitation 1.1. Thus, Mehta’s drive shaft, which is located in the user holdable device, is releasably couplable to the needle assembly.

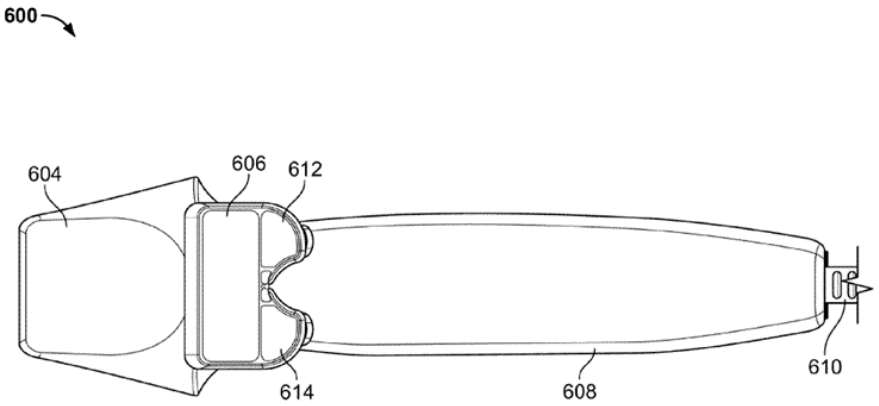
444. In view of the foregoing chart, claim 13 of the ‘536 Patent is anticipated by the teachings of Mehta. Further, to the extent Complainant argues that any of the foregoing limitations is not explicitly or inherently disclosed by Mehta, such limitations would have been obvious given the knowledge of a POSITA. The teachings of Mehta are so similar to what is claimed that any alleged difference between the teachings of Mehta and what is claimed would not have been of patentable significance given the knowledge of a POSITA.

7. Claim 16 of the ‘536 Patent *is Anticipated by Mehta and/or Obvious over Mehta*

445. Claim 16 of the ‘536 Patent, which depends from claim 11, is anticipated by the teachings of Mehta:

‘536 Patent Claim 16		Mehta
16.0	16. The apparatus of claim 11, the wherein at least one restorably deflectable electrical contact includes a depressible pin.	Mehta discloses that the at least one restorably deflectable electrical contact includes a depressible pin. *See, e.g.,* discussion and citations above regarding Mehta for limitation 1.4; *see also, e.g.*, Mehta, at 16:12-18 and Fig. 4A. As discussed above, the needle assembly is movable, such that the needles can be extended while at least one electrical contact of the needle assembly remains electrically coupled to at least one electrical contact of the user holdable device proximal end. For example, as shown in Fig. 4A, reproduced below, “the electrodes 104 in the electrode assembly 102 as having connection or contact portions 116 that couple to a connection board on a treatment unit to provide an electrical pathway from the power supply to the electrodes 104,” and “the electrode assembly 102 as well as the connection portions 116 moves” so that the electrodes remain electrically connected to the “power supply” when extended. *Id*., at 15:55-16:11; *see also id*., at 16:12-18 (for example, by using “**spring contacts or spring pins**” for the electrical “connection portions 116” so that “the connection portions 116 can maintain contact with a corresponding contact point trace on a connection board during movement of the electrode assembly 102”), 35:8-22 (“electrical lead 610 on the proximal end”); *see also id*., at 10:53-65, 12:5-14,25:30-55, Fig. 2A. Spring contacts and spring pins, used for the electrical “connection portions 116,” constitute depressible pins.

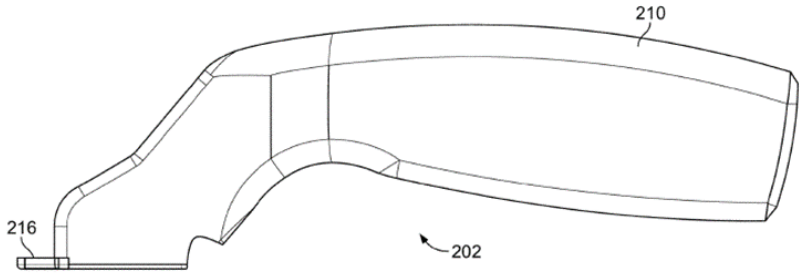
‘536 Patent Claim 16		Mehta
		 FIG. 4A *Id*., Fig. 4A.  FIG. 12A *Id*., Fig. 12A.

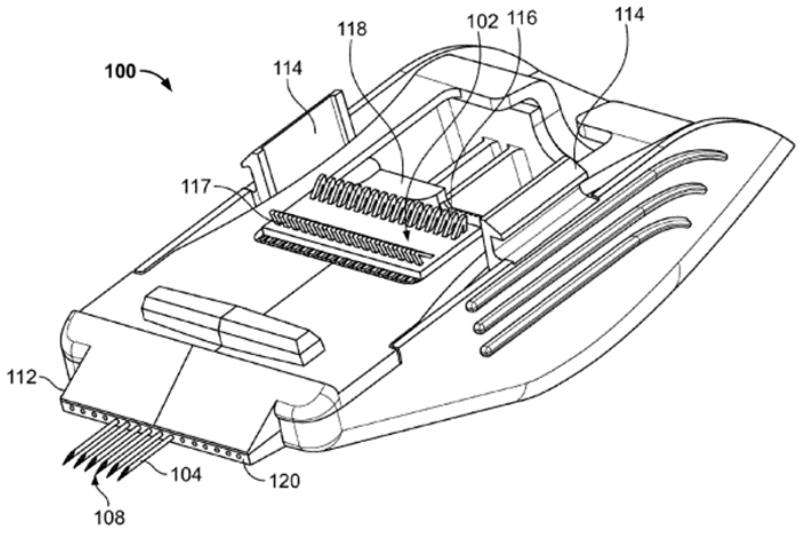
'536 Patent Claim 16		Mehta
		 FIG. 12B *Id*., Fig. 12B. To the extent that Complainant argues that the "depressible pin" is not explicitly disclosed by Mehta's teachings, it is inherent that the mating surface of a spring pin or other compression electrical contact deflects in a direction that is generally perpendicular to a corresponding electrical contact mating surface to ensure a solid connection of the two conducting surfaces, such that the spring pin is "depressible." Therefore, Mehta discloses at least one restorably deflectable electrical contact which includes a depressible pin. The depressible pins in Mehta connect the needles to the energy supply unit so that the energy can be transmitted to the needles when extended.

446. . In view of the foregoing chart, claim 16 of the '536 Patent is anticipated by the teachings of Mehta. Further, to the extent Complainant argues that any of the foregoing limitations is not explicitly or inherently disclosed by Mehta, such limitations would have been obvious given the knowledge of a POSITA. The teachings of Mehta are so similar to what is claimed that any alleged difference between the teachings of Mehta and what is claimed would not have been of patentable significance given the knowledge of a POSITA.

8. Claim 17 of the '536 Patent is Anticipated by Mehta and/or Obvious over Mehta alone (in view of the knowledge of a POSITA) and/or in combination with Na '848

447. Claim 17 of the '536 Patent, which depends from claim 11, is anticipated by Mehta and/or obvious in view of the teachings of Mehta given the knowledge of a POSITA and/or in combination with the teachings of Na '848:

'536 Patent Claim 17		Mehta alone and/or in combination with Na '848
17.0	17. The apparatus of claim 11, wherein a first deflectable electrical contact is coupled to a first plurality of the plurality of extendable needles and a second deflectable electrical contact is coupled to a second, different plurality of the plurality of extendable needles.	Mehta discloses that a first deflectable electrical contact is coupled to a first plurality of the plurality of extendable needles and a second deflectable electrical contact is coupled to a second, different plurality of the plurality of extendable needles. *See, e.g.,* discussion and citations above regarding Mehta for limitation 1.4; *see also, e.g.*, Mehta, at 16:12-18; Fig. 4A; 16:59-17:12; Fig. 4C; and 36:21-40. In view of the discussion above regarding limitation 1.4, Mehta discloses a plurality of deflectable electrical contacts (*e.g.*, spring contacts or spring pins forming connection or contact portions 116 for respective electrodes/needles 104) for connecting respective needles to the RF energy source, so that the needles are able to be powered by the RF unit when extended into the skin via the electrical connection.  FIG. 2D *Id.*, Fig. 2D.

‘536 Patent Claim 17		Mehta alone and/or in combination with Na ‘848
		 FIG. 4A *Id*., Fig. 4A. The cartridge body 100 further includes an ***electrode assembly 102*** that is moveable or slidable within the cartridge body 100. The mode of movement of the actuator can include those modes that are used in such similar applications. Examples of these modes include, sliding, rotation, incremental indexing (via a ratchet-type system), stepping (via an [*sic*] step-motor) Accordingly, the electrode assembly 102 can include a coupling portion or structure 118 that mates with an actuating member in the device body. In the illustrated example, the electrode assembly 102 is in a treatment position (e.g., the array 108 extends from the cartridge 100 allowing for treatment). The electrode assembly 102 includes any number of electrodes 104 that form an array 108 and are extendable and retractable from a portion 104 of the cartridge 100 (as noted above, the electrodes can alternatively extend from the device body, or other parts of the system). As noted above, although the illustrated example shows an array 108 of 1×6 electrodes 104, the array can comprise any dimension of M×N electrodes where the limits are driven by the nature of the treatment site as well as the type of energy delivery required. FIG. 4A **also shows the electrodes 104 in the electrode assembly 102 as having connection or contact portions**

'536 Patent Claim 17		Mehta alone and/or in combination with Na '848
		116 that couple to a connection board on a treatment unit to provide an electrical pathway from the power supply(emphasis added) to the electrodes 104. In the illustrated variation, the electrode assembly 102 as well as the connection portions 116 moves. Such a feature allows for selective connection of the electrodes with the power supply. For example, in certain variations of the system, the electrodes are only coupled to the power supply when in a treatment position and are incapable of delivering energy when in a retracted position. In another variation, the electrode assembly and connection board are configured to permit temperature detection at all times but only energy delivery in the treatment position. Such customization can prevent energy delivery in an unintended location, for example, when the electrodes have an insulation that only allows energy delivery at the distal tip and the intended location of energy delivery is at specific depth in the target tissue that corresponds to the length of the extended electrode the electrode cannot delivery energy to an unintended shallower location when it is not fully extended. However, any number of variations is possible. For example, the system can be configured so that the electrodes can be energized whether in the treatment or retracted positions. The connection portions 116 can be fabricated in any number of configurations as well. For example, as shown, the connection **portions** 116 comprise **spring contacts or spring pins** (emphasis added) of the type shown. Accordingly, the connection portions 116 can maintain contact with a corresponding contact point trace on a connection board during movement of the electrode assembly 102[.] Mehta at col. 15:34-col. 16:18. Mehta further discloses that, as shown in Fig. 4C, "the electrode assembly 102 can have multiple connection portions 116, 117 per individual electrode. Mehta, at 16:59-17:12. Also, Mehta discloses multiple bipolar pairs of electrodes. *Id*., at 36:21-40 ("Patents were treated with a PID controller ***bipolar*** RF electrode device (a frequency of 460 kHz) configured with 5 pairs of 30 gauge electrodes"). In one example, "[e]ach of the 5 electrode pairs were controlled independently by the generator," (*id*., at 36:21-40), which means that each of the pairs has its own electrical contact that couples that pair to the generator (otherwise, each electrode pair would receive the same

'536 Patent Claim 17		Mehta alone and/or in combination with Na '848
		amount of energy and thus would not be independently controlled by the generator). *See also, e.g.*, Mehta, col. 9:43-48 ("The term probes 104 (for purposes of this disclosure) is intended to include any electrode, energy transfer element (e.g., ….***bipolar RF***…), or source of therapeutic treatment."). A POSITA would understand that means that the RF source has two output terminals, a first electrical contact electrically couples a first plurality of needles to the positive terminal, and a second electrical contact electrically couples a second plurality of needles to the negative terminal. To the extent that Complainant argues that the "deflectable electrical contacts" are not explicitly disclosed by Mehta's teachings, it is inherent that the mating surface of a spring pin or other compression electrical contact deflects in a direction that is generally perpendicular (at least in one plane) to a corresponding electrical contact mating surface to ensure a solid connection of the two conducting surfaces. Further, to the extent that Complainant argues that Mehta does not explicitly disclose first and second pluralities of electrodes being respectively coupled to first and second contacts, it is inherent that one set of electrodes would be connected to a first electrical contact, that is in turn connected to a first output of an RF generator at a first voltage potential, and a second set of electrodes would be connected to a second output of the RF generator at a second voltage potential, as Mehta discloses bipolar pairs of electrode (*see* discussion above), and to use bipolar electrodes, at least one electrode needs to be at a different voltage potential from another electrode to complete a circuit for current flow. Thus, having electrode pairs that are independently controllable, as taught by Mehta, would inherently disclose to a person of ordinary art respective contacts being respectively coupled to respective pluralities of electrodes. To the extent that Complainant alleges that Mehta alone does not disclose or render obvious claim 17, this claim would have further been obvious in view of Mehta in combination with Na '848. Na '848, in combination with Mehta, renders obvious "wherein a first deflectable electrical contact is coupled to a first plurality of the plurality of extendable needles and a second deflectable

'536 Patent Claim 17		Mehta alone and/or in combination with Na '848
		electrical contact is coupled to a second, different plurality of the plurality of extendable needles." As discussed above, Mehta discloses a plurality of deflectable electrical contacts coupled to respective electrodes. Further, with respect to a "dermalogical treatment apparatus" having a plurality of "pins or needles" through which an electrical signal may be applied to tissue under the skin, Na '848 discloses, for example, that different sets of pins are coupled to different contacts, including "at least one pin 351" which is electrically coupled via "wire 331" and "at least one other pin 351" which is coupled to "a second wire 332." [0029] FIG. 2D is a simplified cross-sectional diagram of an acupuncture apparatus 362 according to various embodiments. The apparatus 362 may include a handle 330, an elastic section 333, internal wire(s) 331, 332, signal generator 370, switch 375, and plate 350. ***The signal generator 370 may be coupled to at least one pin 351 via internal wire 331 and coupled to at least one other pin 352 via internal wire 332***. When active the pins 351, 352 may form at least one dipole pair. The signal generator or module 370 may generate a vary of signals (such as shown in FIGS. 5A to 6) to vibrate one or more dipole pair or bipolar pins 351, 352. [0030] FIG. 2F includes a simplified exploded view of an embodiment of an acupuncture plate 350 including at least one electrically coupled pin 351 according to various embodiments. The plate 350 may include an upper, substantially rigid section or layer 357, deformable or elastic section 355 or layer, and acupuncture section or layer 353. ***The acupuncture section 353 may include a plurality of acupuncture pins or needles 351 where at least one pin 351 is electrically coupled to the wire 331. In a bipolar configuration a second wire 332 may be coupled to at least one other pin 351. FIG. 2E is a simplified bottom view of the plate 350 showing the pins or needles 359, 357 where the pins may be electrically coupled to a first wire 331 and a second wire 332 to form dipole pair (bipolar pins).*** It would have been obvious to a POSITA as of the priority date of the '536 Patent to modify Mehta and/or to combine the teachings of Mehta with the teachings of Na '848 in a manner that would have rendered claim 17 obvious. For example, Mehta discusses a plurality of deflectable electrical contacts (*e.g.*, spring contacts or spring pins forming connection or contact portions 116 for

'536 Patent Claim 17		Mehta alone and/or in combination with Na '848
		respective electrodes/needles 104) for connecting respective needles to the RF energy source, as well as bipolar operation of the needles based on signals applied through the contacts. *See, e.g.*, discussion and citations above regarding Mehta for limitation 1.4. Na '848 also discusses having respective contacts coupled to respective sets of needles for bipolar operation. *See, e.g.*, Na '848 at [0029]-[0030], Fig. 2D. Thus, as of the priority date of the '536 Patent, it was well known to use plural electrical contacts to provide electrical signal to different needle electrodes or groups of needle electrodes, particularly with respect to bipolar operation, and to use deflectable contacts for maintaining an electrical connection. It would also have been obvious to try the claimed electrode configuration (having two deflectable contacts coupled to respective sets of electrodes) along with bipolar operation according to these various prior art references in order to determine whether this configuration provides a desirable heating pattern for skin treatment purposes, as well as to determine whether this configuration provides for reliable electrical contact during the treatment. The use of two deflectable contacts for coupling to two respective sets of needles for bipolar treatment was an obvious design choice for a person of ordinary skill to achieve a desired treatment effect. The treatment apparatuses disclosed in Mehta and Na '848 are in the same field, have similar structure, and are used for similar purposes. This modification would not have required anything beyond routine engineering to appropriately connect respective needles to respective contacts, and the use of this configuration would have furthered the purpose of Mehta's treatment apparatus in connection with providing bipolar RF treatments.

448. In view of the foregoing chart, claim 17 of the '536 Patent is anticipated by the teachings of Mehta. Further, to the extent Complainant argues that any of the foregoing limitations is not explicitly or inherently disclosed by Mehta, such limitations would have been obvious given the knowledge of a POSITA, and/or further in view of the teachings of Na '848. The teachings of Mehta are so similar to what is claimed that any alleged difference between the teachings of Mehta and what is claimed would not have been of patentable significance given the knowledge of a POSITA.

E. The Asserted Claims of the '774 Patent were Anticipated or Rendered Obvious by the Prior Art

449. As detailed in the charts below, it is my opinion that the Asserted Claims of the '774 Patent are invalid under 35 U.S.C. § 102 (pre-AIA or AIA) as anticipated by Mehta. To the extent that Mehta does not anticipate claims 13 and 14 of the '774 Patent, Mehta (in view of the knowledge of a POSITA) renders obvious claims 13 and 14 of the '774 Patent. To the extent that Mehta does not anticipate and/or render obvious claims 13 and 14 of the '774 Patent, the claims would have been obvious over Mehta in view of Na '848.As detailed in the charts below, it is my opinion that ScarLet anticipates asserted claims 13 and 14 of the '774 Patent. To the extent that ScarLet does not anticipate claims 13 and 14 of the '774 Patent, ScarLet (in view of the knowledge of a POSITA) rendered obvious claims 13 and 14 of the '774 Patent. To the extent that ScarLet does not anticipate and/or render obvious claims 13 and 14 of the '774 Patent, the claims would have been obvious over ScarLet in view of Na '848.

450. As detailed in the charts below, it is my opinion that Mulholland anticipates asserted claims 13 and 14 of the '774 Patent. To the extent that Mulholland does not anticipate claims 13 and 14 of the '774 Patent, Mulholland (in view of the knowledge of a POSITA) rendered obvious claims 13 and 14 of the '774 Patent. To the extent that Mulholland does not anticipate and/or render obvious claims 13 and 14 of the '774 Patent, the claims would have been obvious over Mulholland in view of Na '848.

451. As detailed in the charts below, it is my opinion that Na '848 (in view of the knowledge of a POSITA) rendered obvious claims 13 and 14 of the '774 Patent. To the extent that Na '848 does not anticipate and/or render obvious claims 13 and 14 of the '774 Patent, the claims would have been obvious over Na '848 in view of Mehta, ScarLet, and/or Mulholland.

452. U.S. Patent No. 8,608,737 ("Mehta") qualifies as prior art under at least AIA 35 U.S.C. § 102(a)(1) because it is a patent that published before the filing of the earliest application to which U.S. Patent No. 9,775,774 ("the '774 Patent") could claim priority.

453. To the extent that the '774 Patent is subject to pre-AIA law, Mehta qualifies as prior art at least under 35 U.S.C. § 102(e) (pre-AIA) because it is a patent that was filed prior to the alleged invention of the '774 Patent.

454. International Publication No. WO2010/016848 ("Na '848"), published February 11, 2010, qualifies as prior art under at least AIA 35 U.S.C. § 102(a)(1) because it is a patent that published before the filing of the earliest application to which the '774 Patent could claim priority.

455. To the extent that the '812 Patent is subject to pre-AIA law, Na '774 qualifies as prior art under at least 35 U.S.C. § 102(b) (pre-AIA) because it is a patent that published more than one year before the filing of the earliest application to which the '812 Patent could claim priority. Na '848 also qualifies as prior art under at least 35 U.S.C. § 102(a) (pre-AIA) because it is a patent that was published prior to the alleged invention of the '812 Patent.

456. The ScarLet product manufactured by ViOL, Korea ("ScarLet") qualifies as prior art under at least AIA 35 U.S.C. § 102(a)(1) because it is a product that was in public used, on sale, or otherwise available to the public before the effective filing date of the claimed invention to which the '774 Patent could claim priority. *See, e.g.*, Ilooda-0005923 (Shim 2010_DKU Thesis 2010.12.01), Ilooda-0006075 (Scarlet intro), Ilooda-0006078 (#13_(Eng)_Shim 2010_DKU Thesis Dec 1 2010_Translated_Certified), Ilooda-0006210 (5-1. 스칼렛 최초허가),Ilooda-0006533 (Naver Blog The H Jan 10 2011), Ilooda-0006719 (#19-1_Naver Blog The H Jan 10 2011_Translated_Certified), Ilooda-0006770 (#18_D&PS Monthly Sept

2010_Translated_Certified), Ilooda-0006827 (D&PS Monthly September 2010), Ilooda-0008178 and translation thereof (Ilooda-0011601), Ilooda-0009318, Ilooda-0009319, Ilooda-0009322, Ilooda-0009339, Ilooda-0009669, Ilooda-0009673, Ilooda-0009678, Ilooda-0009791, Ilooda-0009795, Ilooda-0010031, Ilooda-0010042, SERENDIA-00017276, SERENDIA-00017306, SERENDIA-00031579, SERENDIA-00033637, SERENDIA-00033705, SERENDIA-00036286, SERENDIA-00052450, SERENDIA-00061017, SERENDIA-00066746, SERENDIA-00075908, and SERENDIA-00081664.

457. United States Patent No. 10,799,285 ("Mulholland") qualifies as prior art under at least AIA 35 U.S.C. § 102(a)(2) because its patent application was filed before the alleged effective filing date of the '774 Patent and named another inventor. Mulholland issued as the '285 patent on October 13, 2020.

458. To the extent that the '774 Patent is subject to pre-AIA law, Mulholland qualifies as prior art under at least 35 U.S.C. § 102(e) (pre-AIA) because its patent application was filed before the alleged effective filing date of the '774 Patent and named another inventor. Mulholland issued as the '285 patent on October 13, 2020.

1. Claims 13 and 14 of the '774 Patent are Anticipated by Mehta and/or rendered Obvious by Mehta alone or Mehta in view of Na '848.

459. It is my opinion that Mehta anticipates and/or renders obvious each asserted claim of the '774 Patent.

460. Mehta in view of the knowledge of a POSITA renders each of the '774 Patent's asserted claims obvious. A POSITA would have understood that any limitations in the Asserted Claims arguably not explicitly disclosed by Mehta were obvious in view of the state of the relevant art. A POSITA would have been motivated to draw upon his or her knowledge of the relevant art to modify Mehta as necessary to achieve any of the claimed features and would

have enjoyed a reasonable expectation of success in doing so. A POSITA would have enjoyed a reasonable expectation of success in combining and/or modifying the teachings of Mehta, together with general knowledge of the art, to achieve the claimed subject matter, at least because the prior art itself discloses and/or practices the claimed methods and apparatuses to achieve the claimed results. A POSITA would have recognized that the relevant art is predictable, and that achieving the claimed subject matter would have been obvious to try or requires merely routine optimization.

461. To the extent Mehta does not render one or more of the '774 Patent's asserted claims obvious, the claims would have been obvious over Mehta in view of Na '848. Mehta and Na '848 discuss or address the same or substantially similar underlying apparatus and/or technology in the field of dermatological treatment and devices such that a POSITA would have understood that these references can be combined, according to known methods and/or by the simple substitution of one known, equivalent element for another, to yield predictable results and with a reasonable expectation of success.

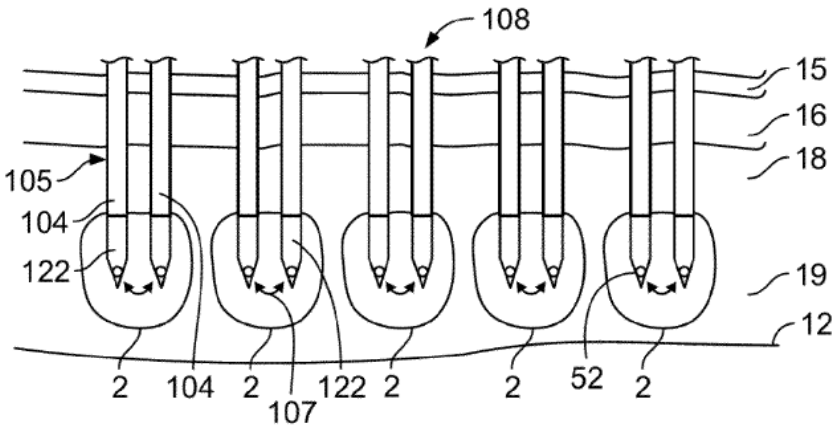
462. A POSITA would also have been motivated to combine Mehta and Na '848 in light of market forces in the industry, and the desire to improve features and performance, and/or in light of one or more teachings, suggestions, or motivations in the art. A POSITA would have enjoyed a reasonable expectation of success in combining and/or modifying the teachings of the foregoing prior art references and products, together with general knowledge of the art, to achieve the claimed subject matter, at least because the prior art itself discloses and/or practices the claimed methods and apparatuses to achieve the claimed results. A POSITA would have recognized that the relevant art is predictable, and that achieving the claimed subject matter would have been obvious to try or requires merely routine optimization.

463. Claims 13 and 14 of the'774 Patent depend from unasserted claim 12, which ultimately depends from unasserted claim 11. It is my opinion that claims 13 and 14 are anticipated by Mehta and/or rendered obvious by Mehta (in view of the knowledge of a POSITA) and/or Mehta in view of Na '848 as detailed below:

'774 Patent Claim 11		**Mehta alone and/or Mehta in view of Na '848**
11.0	11. An apparatus for treating dermatological tissue, comprising:	***Claim 11 of the '774 Patent is anticipated by Mehta and/or rendered obvious by Mehta alone or Mehta in view of Na '848*** Mehta discloses and/or renders obvious an apparatus for treating dermatological tissue. *See e.g.,* Mehta, at 1:14-19; 2:3-12; 2:13-21; 2:22-29; 2:30-33; 2:37-57; 2:58-62; 2:37-57; 2:63-3:17; 6:30-37; 7:52-59; 7:60-8:5; 8:6-12; 8:54-65; 9:34-55; Fig. 2A; 10:66-11:13; 12:23-30; Fig. 2B; 7:19-22; Fig. 10A; 10:66-11:13; 19:17-25; 19:66-20:12; 22:53-62; 23:55-24:4; Fig. 7E; and 24:5-12. Specifically, Mehta discloses "systems and method" to "treat tissue in the human body," and "[i]n a particular variation," to "**treat** cosmetic conditions affecting **the skin** of various body parts, including face, neck, and other areas traditionally prone to wrinkling, lines, sagging and other distortions of the **skin**." Mehta, at 1:14-19 (emphasis added); *see also id*., at 2:3-21; 2:37-57 ("systems and methods" to "to shrink collagen tissue in the dermis"), 7:52-8:12, 8:54-65, 19:17-25, 19:66-20:12, 22:53-62. Mehta's skin treatment apparatus 200 included "a system [200] for monitoring energy delivery from an energy supply unit [90] to" the skin, which included "a treatment unit [202] having a device body," [210] "a first plurality of energy transfer elements," (104) and "a graphical user interface" (320). *Id*., at 2:63-3:17; *see also id*., at 9:34-55, 10:66-11:13. *Id*., Fig. 2A.
11.1	a device including a plurality of needles one of extending or extendable a desired distance from a surface, the desired	Mehta discloses and/or renders obvious a device including a plurality of needles one of extending or extendable a desired distance from a surface, the desired distance selected to enable the plurality of needles to penetrate dermatological tissue. *See e.g.*, Mehta, at 1:14-19; 2:3-12; 2:13-21; 2:63-3:17; 3:29-39; 4:1-18; 4:19-30; 4:35-43; 4:63-5:2; 5:3-1; 5:16-25; 5:49-57; 6:30-37; 6:64-65; 7:52-59; 9:34-55; Fig. 2A; 9:56-64; 9:65-10:7; 10:33-39; 10:40-47; 10:48-52; 12:23-30; Fig. 2B; 12:31-46; 12:47-58; 12:59-13:4; 13:5-15; 13:16-36; Fig. 2C; 13:45-53; 13:54-57; Fig. 3A; 13:58-14:4; 14:5-19; Fig. 2D; 14:20-29; 15:34-54; 16:19-

'774 Patent Claim 11		Mehta alone and/or Mehta in view of Na '848
	distance selected to enable the plurality of needles to penetrate dermatological tissue; and	33; 16:59-17:12; 17:46-58; Fig. 4F; 18:21-37; Fig. 5; 21:1-13; Fig .7A; 21:14-21; 21:22-34; Fig. 7B; 21:34-42; 21:43-62; 23:11-27; Fig. 7C; 25:30-55; 32:16-25; and 37:7-17. For example, Mehta discloses that "the cartridge and/or energy delivery elements can be coupled to an actuator, where movement of the actuator causes advancement or retraction of the first plurality of electrodes" (Mehta, at 4:63-5:2), and the "[e]xamples of such actuators include, but are not limited to … motors" "driven by the control system/energy supply unit 90" (*id*., at 10:33-39). *See also id*., at 12:5-14, 13:58-4 ("the actuator 250 comprises a motor"), 16:59-17:12, 18:21-37. *Id.*, Fig. 3A. *Id*., Fig. 5. Mehta discloses energizing a motor coupled to the needle assembly to cause the plurality of the needles to extend a desired distance from the releasably couplable deployable needle module end surface. For example, Mehta discloses that the physician can check if the needles extended to the desired distance using a "virtual depiction 350 of the depth or location of the probe array," as shown in Fig. 10B. *Id*., at 32:46-62; *see also id*., at 32:63-33:14 ("desired probe location … represent the desired depth of placement for providing a treatment"), 33:15-29, 33:30-34 ("the system described herein can be adjusted to guide probe placement within the first or third layers 324 or 328 depending on the type of treatment being applied"), 33:57-34:13, 34:38-45, 35:8-22 ("The physician can use the information [displayed on the screen] to make decisions and then adjustments by using the actuators 612 and 614"), 36:21-40 (desired distance relates to the depth of the 6 mm needle with it "enter[s] the epidermis at a 20° angle to the skin surface for a distance of 6 mm"), Fig. 10E. *Id*., Fig. 10B. Mehta discloses the **tissue engaging surface** (12:47) to control the depth of penetration in the skin: **"**The stabilization Surface, in conjunction with the tissue engaging surface 106, can also be used to hold and therefore tension the skin at the insertion points to facilitate the needle insertion in the skin." *Id.*at 12:54:58
11.2	a signal generator electrically coupled to the	Mehta discloses and/or renders obvious a signal generator electrically coupled to the plurality of extended needles to produce pulsed radio frequency signals across the plurality of needles to affect dermatological tissue near the plurality of needles. *See e.g.*, Mehta, at

'774 Patent Claim 11		Mehta alone and/or Mehta in view of Na '848
	plurality of extended needles to produce pulsed radio frequency signals across the plurality of needles to affect dermatological tissue near the plurality of needles.	1:27-31; 1:32-42; 1:65-2:2; 2:3-12; 2:13-21; 2:22-29; 2:58-62; 2:63-17; 3:40-56; 3:57-67; 4:1-18; 5:3-15; 5:16-25; 5:26-33; 5:49-57; 5:58-6:2; 7:16-18; 7:40-44; 8:13-23; 8:45-53; 8:54-65; 9:34-55; 10:8-16; 10:17-25; 10:53-65; Fig. 2A; 11:14-20; 11:21-52; 12:5-14; 15:55-16:11; Fig. 4A; 17:59-18:3; 18:4-20; 18:64-19:8; 19:17-25; 19:26-44; 19:4-65; 19:66-20:12; 20:13-29; 20:29-47; Fig. 6; 22:53-62; 24:5-12; 24:46-60; 25:24-29; 25:30-55; 25:64-67; 26:41-59; 26:60-27:22; 35:8-22; 36:54-37:6; 37:25-34; Fig. 13A; 37:35-41; 37:42-64; 37:65-38:21; 38:22-57; 38:58-67; 39:1-8; 39:9-27; 39:28-41; 39:58-40:4; 40:5-38; 40:39-44; 40:45-57; 41:40-43; 41:55-58.; and 42:9-15. Specifically, Mehta discloses that the "system 200 also includes an energy supply unit 90 [electrically] coupled to the treatment unit 202 via a cable 96 or other means. Mehta, at 10:53-55, *see also id*., at 2:63-3:17 ("a connector adapted to couple the energy supply unit to the plurality of" electrodes); *see also id*., at 3:40-56, 4:9-10, 5:26-33 ("power supply coupled to the [electrode] probe), 18:4-20 ("electrode pairs that are coupled to a single channel of a power supply"), claim 1 ("applying energy to the electrode array from the energy source"), claim 5. *Id*., Fig. 2A. As shown in Fig. 4A, "the electrodes 104 in the electrode assembly 102 as having connection or contact portions 116 … to provide an electrical pathway from the power supply to the electrodes 104." *Id*., at 15:55-16:11. *Id*., Fig. 4A. "[T]he energy supply unit 90 may be a RF energy unit." *Id*., at 11:14-15; *see also id*., at 11:21-24 ("RF energy"), *id*., at 18:4-20 ("RF energy modality"), 20:13-29 ("RF energy is often delivered in a pulsed fashion or for a specific duty cycle"), 25:30-55 ("RF delivery device having ten probe electrodes was configured to deliver energy via 5 independent and electrically isolated probe-electrode pairs"), 40:45-57 ("bi-polar RF energy modality") Mehta discloses that the signal generator produces pulsed radio frequency signals across the plurality of needles to affect dermatological tissue near the plurality of needle. *Id*. at 15:55-16:11 ("electrodes can be energized"), 20:13-29 ("RF energy is often delivered in a **pulsed fashion or for a specific duty cycle**"), 24:46-60, 36:21-40, 37:25-35 ("passing current 107 between adjacent electrodes

'774 Patent Claim 11		Mehta alone and/or Mehta in view of Na '848
		104 of opposite polarity in the electrode pair"), 41:55-58, 42:9-15, 11:53-12:4. Mehta discloses that the RF signal produced across the plurality of needles affects dermatological tissue near the plurality of needles. "FIG. 13A shows an example illustration of an array of probes 108 comprising five electrode pairs 105 inserted into a reticular dermis layer 19 to create a series of discrete fractional lesions 2 leaving tissue in the adjacent epidermal layer 16 and Subcutaneous layer 12 undamaged. Essentially, the Zones of thermal coagulation are located in the reticular dermis 19 and are typically entirely surrounded by a spared Zone of normal dermis. This is accomplished by passing current 107 between adjacent electrodes 104 of opposite polarity in the electrode pair." *Id*. 37:25-34  *Id*., Fig. 13A. I understand that the parties disagree as to the meaning of the claim term "pulsed radio frequency signals." To the extent that this claim limitation is not explicitly or inherently disclosed by Mehta, it would have been obvious given the knowledge of a POSITA. For example, as noted above, Mehta discloses "the energy supply unit 90 may be a RF energy unit, *id*. at 11:14-15, and that "RF energy is often ***delivered in a pulsed fashion or for a specific duty cycle***," *id*. at 20:13-29. As of the priority date of the '774 Patent, it was well known how to create pulsed radio frequency signals with an RF energy unit. *See* above. The selection of pulsed radio frequency signals is a design choice that would have been obvious to a POSITA.

'774 Patent Claim 11		Mehta alone and/or Mehta in view of Na '848
		Moreover, in my opinion, it would have been obvious to incorporate "pulsed radio frequency signals" in the Mehta device in view of the teachings of Na '848 and the basic knowledge of waveforms used. I understand that Na '848 is part of the same patent family as the '774 Patent. The disclosures of the pulsed signals in Na '848 are identical to those in the '774 Patent. For example, Na '848 discloses: [0028] ***The signal generator or module 370 may generate a vary of signals (such as shown in FIGS. 5 A to 6) to vibrate one or more pins 351 electrically coupled to the system 300 via the internal wire 331 and the conductive interface 390. In operation a user 20 may touch the conductive interface 390 and place one or more electrically coupled pins 351 in contact with their dermis to form an electrical pathway from the pin 351 to the electrical conductive interface 390.*** The signal generator 370 may include a battery to supply energy to generate one or more electrical signals. ***The switch 375 coupled to the generator 370 may cause the generator to produce one or more electrical signals for a predetermined time interval or until the switch 375 is triggered again. As noted a pin vibration 351 may increase the micro-wound or cut formed in dermis by the pin 351.*** [0029] FIG. 2D is a simplified cross-sectional diagram of an acupuncture apparatus 362 according to various embodiments. The apparatus 362 may include a handle 330, an elastic section 333, internal wire(s) 331, 332, ***signal generator 370***, switch 375, and plate 350. ***The signal generator 370 may be coupled to at least one pin 351 via internal wire 331 and coupled to at least one other pin 352 via internal wire 332.*** When active the pins 351, 352 may form at least one dipole pair. ***The signal generator or module 370 may generate a vary of signals (such as shown in FIGS. 5A to 6) to vibrate one or more dipole pair or bipolar pins 351, 352.*** [0033] ***FIGS. 3A and 3B are simplified isometric diagrams of acupuncture apparatus 400, 460 including at least one pin 451 that may be coupled to an electrical signal via an internal wire 458.*** Each apparatus 400, 460 includes curved roller 450 having a plurality of acupuncture pins 451 where the pins 451 may be similar to pins 351. In apparatus 400, the electrical lead wire 400A may be coupled to an electrical interface 410 in the apparatus handle 430 where the interface 410 is electrically coupled to the internal wire 458. In apparatus 460, the handle 430 may include ***a signal generator 470*** similar to generator 370, switch 475, and conduction surface 490. Apparatus 460 may operate similar to apparatus 360 in operation other than the rolling capability of the apparatus 460, 400. In an embodiment the rollers 450

'774 Patent Claim 11		Mehta alone and/or Mehta in view of Na '848
		may have various configurations to conform to a dermal area to be treated. [0039] ***FIGS.5A-5B are diagrams of electrical signal waveforms 650, 630, 640 that may be applied*** to one or more LEDs 32A, 32B, 532 and ***to the pins 230, 351, 451 according to various embodiments***. ***The signal waveform 650 includes several square -wave pulses 652, 654, 656*** that may be applied to an LED 32A, 32B, 532. Each pulse 652, 654, 656 may a have a similar magnitude and envelope. ***The waveform 650 may be used to energize*** an LED 32A, 32B, 532 and to ***the pins 230, 351, 451 periodically Pl for a predetermined interval Tl where each pulse 652, 654, 656 has a[n] amplitude Al***. In an embodiment, Al may be about 0.1 milliamperes (mA) to 10 mA, the pulse width Tl may be about 100 microsecond (μs) to 500 μs and the period Pl may from 100 ms to 500 ms as a function of the energy required to create capacitance in a liquid. In another embodiment, Al may be about 0.5 milliamperes (mA) to 5 mA, the pulse width Tl may be about 200 microsecond (μs) and the period Pl may about 250 ms as a function of the energy to drive an LED or cause one or more pins 230, 351, 451 to vibrate. [0040] ***In FIG. 5B a signal waveform 630 may be applied*** to a first LED 32A, 32B, 532 module or group and ***to the pins 230, 351 , 451*** and ***a second waveform 640 may be applied or used to energize*** a second LED 32A, 32B, 532 module and ***the pins 230, 351, 451, 352***. ***The signal waveform 630 includes several square-wave pulses 632, 634, and 636 and the signal waveform 640 includes several square-wave pulses 642, 644, and 646. Each pulse 632, 634, 636, 642, 644, 646 may a have a similar magnitude and envelope. The waveform 630 may be used to energize*** a first LED 32A, 32B, 332 module and ***the pins 230, 351, 451 periodically Pl for a predetermined interval Tl where each pulse 632, 634, 636 has an amplitude Al***. ***The waveform 640 may be used to energize*** a second LED 32A, 32B, 332 module and ***the pins 230, 351, 451 periodically P2 for a predetermined interval T2 where each pulse 642, 644, 646 has an amplitude Bl***. The pulse width Tl, T2 may be about 100 microsecond (μs) to 500 μs and the period Pl, P2 may from 100 ms to 500 ms as a function of the energy to affect dermalogical cells or chemicals 22A. In another embodiment, Al, A2 may be about 0.5 milliamperes (mA) to 5 mA, the pulse width Tl, T2 may be about 200 microsecond (μs) and the period Pl, P2 may about 250 ms as a function of the energy required to affect dermalogical cells or chemicals 22 A. In an embodiment the pulses 632, 634, 636 do not substantially overlap the pulses 642, 644, 646. In an embodiment Tl > T2 and P2 is an integer multiple of Pl .

'774 Patent Claim 11		Mehta alone and/or Mehta in view of Na '848
		[0041] ***FIG. 6 depicts a waveform 670 that includes multiple pulses 672, 674, 676, 678, 682, and 684 that may not overlap in the time or the frequency domain. In an embodiment each pulse 672, 674, 676, 678, 682, and 684 may have a pulse width T3, and frequency spectrum width Fl and period P3. The pulse 672 is frequency offset from the pulse 674, the pulse 676 is frequency offset from the pulse 678, and the pulse 682 is frequency offset from the pulse 684. The pulses 672, 674, 676, 678, 682, and 684 may be applied to*** an LED module to affect dermalogical cells or chemicals 22A and ***the pins 230, 351, 451***. Pulses 672, 674 having different frequency spectrums may enable different LED stimulation. In an embodiment the pulses 672, 676, 682 may be applied to a first LED module and the pulses 674, 678, 684 may be applied to a second LED module. ***The frequency separation between the respective pulses may enable simultaneous energization of a first and a second LED module and the pins 230, 351, 451*** and subsequent and independent spectrum generation. [0042] In an embodiment the invention may employ the algorithm 740 shown in FIG. 7A to apply therapy to dermalogical cells. A user, clinician, or equipment may place an apparatus 10, 320, 360, 360, 400, 460 on dermalogical cells to be treated (activity 741) including pressing the apparatus against the cells firmly enough to embed one or more pins 251 , 351 , 451 in the cells. ***A first signal such as shown in FIGS. 5A, 5B, and 6 may be applied to*** a first LED module or group (32A) and ***the pins 230, 351, 451 of a dermalogical apparatus 10, 320, 360, 360, 400, 460 (activity 742) for a predetermined time period (activity 744)***. ***A second signal such as shown in FIGS. 5 A, 5B, and 6 may be applied to*** a second LED module or group (32B) and ***the pins 230, 351, 451 of a dermalogical apparatus 10, 320, 360, 360, 400, 460 (activity 746) for a predetermined time period (activity 748)***. The signals applied to the groups may be selected to stimulate dermalogical cells or chemicals 22A or cause vibration of one or more pins 251, 351, 451. [0043] In another embodiment the invention may employ the algorithm 750 shown in FIG. 7B to apply therapy to dermalogical cells. A user, clinician, or equipment may apply a light sensitive chemical on an apparatus 10, 320, 360, 360, 400, 460 or on dermalogical cells to be treated (activity 751). The user, clinician, or equipment may place apparatus 10, 320, 360, 360, 400, 460 on dermalogical cells to be treated (activity 752). ***A signal such as shown in FIGS. 5A, 5B, and 6 may be applied to*** a LED module or group (32A or 32B) and ***the pins 230, 351 , 451 (activity 354) for a predetermined time period (activity 356)***.

'774 Patent Claim 11		Mehta alone and/or Mehta in view of Na '848
		[0044] In another embodiment the invention may employ the algorithm 760 shown in FIG. 7C to apply therapy to dermalogical cells. A user, clinician, or equipment may apply a light sensitive chemical on an apparatus 10, 320, 360, 360, 400, 460 or on dermalogical cells to be treated (activity 761). The user, clinician, or equipment may place an apparatus 10, 320, 360, 360, 400, 460 on dermalogical cells to be treated (activity 762). ***A first signal such as shown in FIGS. 5A, 5B, and 6 may be applied to*** a first LED module or group (32A) and ***one or more pins 251, 351, 451 of a dermalogical apparatus 10, 320, 360, 360, 400, 460 (activity 763) for a predetermined time period (activity 764)***. ***A second signal such as shown in FIGS. 5 A, 5B, and 6 may be applied to*** a second LED module or group (32B) and ***one or more pins 251 , 351 , 451 of a dermalogical apparatus 10, 320, 360, 360, 400, 460 (activity 766) for a predetermined time period (activity 768).*** The POSITA would have understood from Na '848 the benefit of including a "variety of signals" including pulsed radio frequency signals in a dermatological device. It was well-known that providing a variety of signal types, including pulsed radio frequency signals, was advantageous with respect to providing dermatological treatments. Therefore, the POSITA would have been motivated to modify the Mehta device with the pulsed radio frequency signals of Na '848. Configuring Mehta's RF energy unit to supply pulsed radio frequency signals would have been a matter of routine engineering as of the priority date of the '774 Patent, as evidenced by the numerous dermatological treatment device which included pulsed radio frequency signals for this purpose.

464. In view of the foregoing chart, claim 11 of the '774 Patent is anticipated by the teachings of Mehta. Further, to the extent Complainant argues that any of the foregoing limitations are not explicitly or inherently disclosed by Mehta, such limitations would have been obvious given the knowledge of a POSITA, and/or further in view of the teachings of Na '848. The teachings of Mehta are so similar to what is claimed that any alleged difference between the teachings of Mehta and what is claimed would not have been of patentable significance given the knowledge of a POSITA.

465. It is my opinion that claim 12 of the '774 Patent is anticipated by Mehta and/or rendered obvious by Mehta alone or Mehta in view of Na '848 as detailed below:

'774 Patent Claim 12		Mehta alone and/or Mehta in view of Na '848
12	12. The apparatus for treating dermatological tissue of claim 11, wherein the device includes an end surface configured to be placed on or near dermatological tissue to be treated, the end surface including a plurality of needles extendable a desired distance from the end surface.	***Claim 12 of the '774 Patent is anticipated by Mehta and/or rendered obvious by Mehta alone or Mehta in view of Na '848*** Mehta discloses and/or renders obvious (either alone or in view of Na '848) the apparatus for treating dermatological tissue of claim 11. *See* claim 11. Mehta discloses and/or renders obvious that the device includes an end surface configured to be placed on or near dermatological tissue to be treated, the end surface including a plurality of needles extendable a desired distance from the end surface. *See e.g.*, Mehta discloses that the tissue that is treated is skin (dermatological tissue) *Id*., at 1:14-19, 7:52-59. Mehta's system includes "a treatment unit [202] having a device body [210]," which "includes a tissue engaging surface that allows orientation of the device body on the surface of [skin] tissue [10]," and a stabilization plate [214] to the tissue engaging surface. Mehta, at 2:63-3:17, *see also id*., at 4:1-18, 4:63-5:2, 9:36-39, 10:40-52, 12:23-46, 12:47-58 (tissue engaging surface engages "skin tissue"), 12:59-13:15, 13:45-53, 32:16-25. *Id*., Fig. 2A. *Id*., Fig. 2B *Id*., Fig. 2C "FIG. 7A illustrates a partial side view of the … tissue engaging surface 106" and "stabilization plate 214" placed against the skin tissue. *Id*., at 21:1-13; *see also id*., at 21:22-34, Fig. 7B. *Id*., Fig. 7A. Mehta's user holdable device also includes "cartridges [100] that are removably coupled to the device body [210], where at least the plurality of first [needle] electrodes [104] and the tissue engaging surface [106] are located on or in the cartridge body." *Id*., at 4:63-66; *see also id*., at 9:34-55, 13:5-15, 35:8-

'774 Patent Claim 12		Mehta alone and/or Mehta in view of Na '848
		10. "FIG. 2D shows the treatment system 202 of FIG. 2A where the cartridge assembly 100 and device body 210 are separated." *Id*., at 14:5-19. *Id*., Fig. 2D. As shown in Fig. 4, the "cartridge body 100" may include "retention fasteners 114 allowing for coupling with the device body as well as removal from the device body … to permit removable coupling." *Id*., at 15:27-33; *see also id*., at 16:42-58. *Id*., Fig. 4A. The needle electrodes are deployable from the cartridge. For example, Mehta discloses that the "tissue engaging surface and stabilization plate are positioned such that … the tissue engaging surface is placed on the surface of tissue" so a "first plurality of energy transfer elements is advanced into the surface of tissue." *Id*., at 4:10-18; *see also id*., at 5:3-15, 12:23-30, 13:16-36 ("the probes are deployed into tissue subsequent to placement of the device body 210 against the tissue"), 13:58-14:4, 15:34-54, 16:19-33, 18:21-37, 21:43-62, 37:7-8 ("layer of skin in which the needles were deployed"). Mehta's "device body" 210 has a "handle portion" (*id*., at 4:1-18; *see also id*., at 9:34-39, 35:8-10, Figs. 12A, 12B), and thus, Mehta discloses a user holdable device (*id*, at 9:56-64 ("can be grasped by the hand")). Mehta discloses that "the cartridge and/or energy delivery elements can be coupled to an actuator, where movement of the actuator causes advancement or retraction of the first plurality of electrodes" (Mehta, at 4:63-5:2), and the "***[e]xamples of such actuators include, but are not limited to … motors***" "driven by the control system/energy supply unit 90" (*id*., at 10:33-39) (emphasis added). *See also id*., at 12:5-14, 13:58-4 ("the actuator 250 comprises a motor"), 16:59-17:12, 18:21-37. *Id.*, Fig. 3A. *Id*., Fig. 5. Mehta discloses energizing a motor coupled to the needle assembly to cause the plurality of the needles to extend a desired distance from the releasably couplable deployable needle module end surface. For example, Mehta discloses that the physician can check if the needles extended to the desired distance using a "virtual depiction 350 of the

'774 Patent Claim 12		Mehta alone and/or Mehta in view of Na '848
		depth or location of the probe array," as shown in Fig. 10B. *Id*., at 32:46-62; *see also id*., at 32:63-33:14 ("desired probe location … represent the desired depth of placement for providing a treatment"), 33:15-29, 33:30-34 ("the system described herein can be adjusted to guide probe placement within the first or third layers 324 or 328 depending on the type of treatment being applied"), 33:57-34:13, 34:38-45, 35:8-22 ("The physician can use the information [displayed on the screen] to make decisions and then adjustments by using the actuators 612 and 614"), 36:21-40 (desired distance relates to the depth of the 6 mm needle with it "enter[s] the epidermis at a 20° angle to the skin surface for a distance of 6 mm"), Fig. 10E. To the extent that this claim limitation is not explicitly or inherently disclosed by Mehta, it would have been obvious given the knowledge of a POSITA. For example, at least Mehta, Mulholland, ScarLet and Lee '500 each disclose a plurality of needles extendable a desired distance from an end surface, disclose various mechanisms for causing the plurality of extendable needles to extend a desired distance from the end surface and a motor coupled to the plurality of extendable needles that may be directed to cause the plurality of the extendable needles to extend a desired distance from the end surface. *See, e.g.*, Mehta at 3:29-39; 3:40-41; 4:63-5:2; 5:3-15; 6:64-65; 9:34-55; 10:33-39; 12:5-14; 13:54-57; Fig. 3A; 13:58-4; 15:27-33; 15:55-16:11; Fig. 4A; 16:42-58; 16:59-17:12; 18:21-37; Fig. 5; 32:46-62; Fig. 10B; 32:63-33:14; 33:15-29; 33:30-34; 33:57-13; Fig. 10E; 34:38-45; 35:8-22; Fig. 12A; and Fig. 12B; Mulholland at 4:45-48, 5:11-26, 6:65-8:10, 7:19-31; ScarLet at SERENDIA-00017328, SERENDIA-00017331, Ilooda-0006078 (at 7); Lee '500 at Para. 42, 43, 44, 52, 53, 55, 56, 61; claims 1, 2, 7. As of the priority date of the '774 Patent, it was well known that controlling the depth of penetration for the needles and being able to retract the needles was advantageous with respect to providing dermatological treatments. *See, e.g.*, Hantash 2009 at pg. 88; pg. 90; pg. 92; Figs. 2, 1; Hantash 718 PCT at [0017]; [0035]; [0041]; [0042]; [0045]; [0046]; [0068]; [0069]; and [0070]; Mehta at 3:29-39; 3:40-41; 4:63-5:2; 5:3-15; 6:64-65; 9:34-55; 10:33-39; 12:5-14; 13:54-57; Fig. 3A; 13:58-4; 15:27-33; 15:55-16:11; Fig. 4A; 16:42-58; 16:59-17:12; 18:21-37; Fig. 5; 32:46-62; Fig. 10B; 32:63-33:14; 33:15-29; 33:30-34; 33:57-13; Fig. 10E; 34:38-45; 35:8-22; Fig. 12A; and Fig. 12B; Mulholland at 4:45-48, 5:11-26, 6:65-8:10, 7:19-31; ScarLet at SERENDIA-00017328, SERENDIA-00017331, Ilooda-0006078 (at 7); Lee '500 at Para. 42, 43, 44, 52, 53, 55, 56, 61; claims 1, 2, 7. To the extent Mehta does not explicitly disclose that the needles of a dermatological treatment device are extendable using a motor, it would

'774 Patent Claim 12		Mehta alone and/or Mehta in view of Na '848
		have been obvious to modify the dermatological treatment device to make the needles retractable and extendable to a desired depth using a motor connected to the needles to achieve enhanced safety (by having the needles retracted when not in use) and enhanced customizability of treatment (by specifying the needle penetration depth). *See id.* Configuring a plurality of needles to be attached to a motor would have been a matter of routine engineering as of the priority date of the '774 Patent, as evidenced by the numerous dermatological treatment devices which included a motor for this purpose. Additionally, as of the priority date of the '774 Patent, it was well known how to create linear force using various manual and automated mechanisms, including a motor. The selection of the mechanism to achieve this purpose is a design choice that would have been obvious to a POSITA.

466. In view of the foregoing chart, claim 12 of the '774 Patent is anticipated by the teachings of Mehta. Further, to the extent Complainant argues that any of the foregoing limitations are not explicitly or inherently disclosed by Mehta, such limitations would have been obvious given the knowledge of a POSITA, and/or further in view of the teachings of Na '848. The teachings of Mehta are so similar to what is claimed that any alleged difference between the teachings of Mehta and what is claimed would not have been of patentable significance given the knowledge of a POSITA.

467. It is my opinion that Claim 13 of the '774 Patent is anticipated by Mehta and/or rendered obvious by Mehta alone or Mehta in view of Na '848 as detailed below:

'774 Patent Claim 13		Mehta alone and/or Mehta in view of Na '848
13	13. The apparatus for treating dermatological tissue of claim 12, further including a mechanism for causing the	***Claim 13 of the '774 Patent is anticipated by Mehta and/or rendered obvious by Mehta alone or Mehta in view of Na '848*** Mehta discloses and/or renders obvious (either alone or in view of Na '848) the apparatus for treating dermatological tissue of claim 12. *See* claim 12.

'774 Patent Claim 13		Mehta alone and/or Mehta in view of Na '848
	plurality of the extendable needles to extend a desired distance from the end surface.	Mehta discloses and/or renders obvious a mechanism for causing the plurality of the extendable needles to extend a desired distance from the end surface. *See e.g.*, Mehta discloses that "the cartridge and/or energy delivery elements can be coupled to an actuator, where movement of the actuator causes advancement or retraction of the first plurality of electrodes" (Mehta, at 4:63-5:2), and the "[e]xamples of such actuators include, but are not limited to … motors" "driven by the control system/energy supply unit 90" (*id*., at 10:33-39). *See also id*., at 12:5-14, 13:58-4 ("the actuator 250 comprises a motor"), 16:59-17:12, 18:21-37. *Id.*, Fig. 3A. *Id*., Fig. 5. Mehta discloses energizing a motor coupled to the needle assembly to cause the plurality of the needles to extend a desired distance from the releasably couplable deployable needle module end surface. For example, Mehta discloses that the physician can check if the needles extended to the desired distance using a "virtual depiction 350 of the depth or location of the probe array," as shown in Fig. 10B. *Id*., at 32:46-62; *see also id*., at 32:63-33:14 ("desired probe location … represent the desired depth of placement for providing a treatment"), 33:15-29, 33:30-34 ("the system described herein can be adjusted to guide probe placement within the first or third layers 324 or 328 depending on the type of treatment being applied"), 33:57-34:13, 34:38-45, 35:8-22 ("The physician can use the information [displayed on the screen] to make decisions and then adjustments by using the actuators 612 and 614"), 36:21-40 (desired distance relates to the depth of the 6 mm needle with it "enter[s] the epidermis at a 20° angle to the skin surface for a distance of 6 mm"), Fig. 10E. To the extent that this claim limitation is not explicitly or inherently disclosed by Mehta, it would have been obvious given the knowledge of a POSITA. For example, at least Mehta, Mulholland, ScarLet and Lee '500 each disclose a plurality of needles extendable a desired distance from an end surface, disclose various mechanisms for causing the plurality of extendable needles to extend a desired distance from the end surface and a motor coupled to the plurality of extendable needles that may be directed to cause the plurality of the extendable needles to extend a desired distance from the end surface. *See, e.g.*, Mehta at 3:29-39; 3:40-41; 4:63-5:2; 5:3-15; 6:64-65; 9:34-55; 10:33-39; 12:5-14; 13:54-57; Fig. 3A; 13:58-4; 15:27-33; 15:55-16:11; Fig. 4A; 16:42-58; 16:59-17:12; 18:21-37; Fig. 5; 32:46-62; Fig. 10B;

'774 Patent Claim 13		Mehta alone and/or Mehta in view of Na '848
		32:63-33:14; 33:15-29; 33:30-34; 33:57-13; Fig. 10E; 34:38-45; 35:8-22; Fig. 12A; and Fig. 12B; Mulholland at 4:45-48, 5:11-26, 6:65-8:10, 7:19-31; ScarLet at SERENDIA-00017328, SERENDIA-00017331, Ilooda-0006078 (at 7); Lee '500 at Para. 42, 43, 44, 52, 53, 55, 56, 61; claims 1, 2, 7. As of the priority date of the '774 Patent, it was well known that controlling the depth of penetration for the needles and being able to retract the needles was advantageous with respect to providing dermatological treatments. *See, e.g.*, Hantash 2009 at pg. 88; pg. 90; pg. 92; Figs. 2, 1; Hantash 718 PCT at [0017]; [0035]; [0041]; [0042]; [0045]; [0046]; [0068]; [0069]; and [0070]; Mehta at 3:29-39; 3:40-41; 4:63-5:2; 5:3-15; 6:64-65; 9:34-55; 10:33-39; 12:5-14; 13:54-57; Fig. 3A; 13:58-4; 15:27-33; 15:55-16:11; Fig. 4A; 16:42-58; 16:59-17:12; 18:21-37; Fig. 5; 32:46-62; Fig. 10B; 32:63-33:14; 33:15-29; 33:30-34; 33:57-13; Fig. 10E; 34:38-45; 35:8-22; Fig. 12A; and Fig. 12B; Mulholland at 4:45-48, 5:11-26, 6:65-8:10, 7:19-31; ScarLet at SERENDIA-00017328, SERENDIA-00017331, Ilooda-0006078 (at 7); Lee '500 at Para. 42, 43, 44, 52, 53, 55, 56, 61; claims 1, 2, 7. To the extent Mehta does not explicitly disclose that the needles of a dermatological treatment device are extendable using a motor, it would have been obvious to modify the dermatological treatment device to make the needles retractable and extendable to a desired depth using a motor connected to the needles to achieve enhanced safety (by having the needles retracted when not in use) and enhanced customizability of treatment (by specifying the needle penetration depth). *See id.* Configuring a plurality of needles to be attached to a motor would have been a matter of routine engineering as of the priority date of the '774 Patent, as evidenced by the numerous dermatological treatment devices which included a motor for this purpose. Additionally, as of the priority date of the '774 Patent, it was well known how to create linear force using various manual and automated mechanisms, including a motor. The selection of the mechanism to achieve this purpose is a design choice that would have been obvious to a POSITA.

468. In view of the foregoing chart, claim 13 of the '774 Patent is anticipated by the teachings of Mehta. Further, to the extent Complainant argues that any of the foregoing limitations are not explicitly or inherently disclosed by Mehta, such limitations would have

been obvious given the knowledge of a POSITA, and/or further in view of the teachings of Na '848. The teachings of Mehta are so similar to what is claimed that any alleged difference between the teachings of Mehta and what is claimed would not have been of patentable significance given the knowledge of a POSITA.

469. It is my opinion that Claim 14 of the '774 Patent is anticipated by Mehta and/or rendered obvious by Mehta alone or Mehta in view of Na '848 as detailed below:

'774 Patent Claim 14		Mehta alone and/or Mehta in view of Na '848
14	14. The apparatus for treating dermatological tissue of claim 12, further including a motor coupled to the plurality of extendable needles that may be directed to cause the plurality of the extendable needles to extend a desired distance from the end surface.	***Claim 14 of the '774 Patent is anticipated by Mehta and/or rendered obvious by Mehta alone or Mehta in view of Na '848*** Mehta discloses and/or renders obvious (either alone or in view of Na '848) the apparatus for treating dermatological tissue of claim 12. *See* claim 12. Mehta discloses and/or renders obvious a motor coupled to the plurality of extendable needles that may be directed to cause the plurality of the extendable needles to extend a desired distance from the end surface. *See e.g.*, Mehta discloses that "the cartridge and/or energy delivery elements can be coupled to an actuator, where movement of the actuator causes advancement or retraction of the first plurality of electrodes" (Mehta, at 4:63-5:2), and the "[e]xamples of such actuators include, but are not limited to … motors" "driven by the control system/energy supply unit 90" (*id*., at 10:33-39). *See also id*., at 12:5-14, 13:58-4 ("the actuator 250 comprises a motor"), 16:59-17:12, 18:21-37. *Id.*, Fig. 3A. *Id*., Fig. 5. Mehta discloses energizing a motor coupled to the needle assembly to cause the plurality of the needles to extend a desired distance from the releasably couplable deployable needle module end surface. For example, Mehta discloses that the physician can check if the needles extended to the desired distance using a "virtual depiction 350 of the depth or location of the probe array," as shown in Fig. 10B. *Id*., at 32:46-62; *see also id*., at 32:63-33:14 ("desired probe location …

'774 Patent Claim 14		Mehta alone and/or Mehta in view of Na '848
		represent the desired depth of placement for providing a treatment"), 33:15-29, 33:30-34 ("the system described herein can be adjusted to guide probe placement within the first or third layers 324 or 328 depending on the type of treatment being applied"), 33:57-34:13, 34:38-45, 35:8-22 ("The physician can use the information [displayed on the screen] to make decisions and then adjustments by using the actuators 612 and 614"), 36:21-40 (desired distance relates to the depth of the 6 mm needle with it "enter[s] the epidermis at a 20° angle to the skin surface for a distance of 6 mm"), Fig. 10E. To the extent that this claim limitation is not explicitly or inherently disclosed by Mehta, it would have been obvious given the knowledge of a POSITA. For example, at least Mehta, Mulholland, ScarLet and Lee '500 each disclose a plurality of needles extendable a desired distance from an end surface, disclose various mechanisms for causing the plurality of extendable needles to extend a desired distance from the end surface and a motor coupled to the plurality of extendable needles that may be directed to cause the plurality of the extendable needles to extend a desired distance from the end surface. *See, e.g.*, Mehta at 3:29-39; 3:40-41; 4:63-5:2; 5:3-15; 6:64-65; 9:34-55; 10:33-39; 12:5-14; 13:54-57; Fig. 3A; 13:58-4; 15:27-33; 15:55-16:11; Fig. 4A; 16:42-58; 16:59-17:12; 18:21-37; Fig. 5; 32:46-62; Fig. 10B; 32:63-33:14; 33:15-29; 33:30-34; 33:57-13; Fig. 10E; 34:38-45; 35:8-22; Fig. 12A; and Fig. 12B; Mulholland at 4:45-48, 5:11-26, 6:65-8:10, 7:19-31; ScarLet at SERENDIA-00017328, SERENDIA-00017331, Ilooda-0006078 (at 7); Lee '500 at Para. 42, 43, 44, 52, 53, 55, 56, 61; claims 1, 2, 7. As of the priority date of the '774 Patent, it was well known that controlling the depth of penetration for the needles and being able to retract the needles was advantageous with respect to providing dermatological treatments. *See, e.g.*, Hantash 2009 at pg. 88; pg. 90; pg. 92; Figs. 2, 1; Hantash 718 PCT at [0017]; [0035]; [0041]; [0042]; [0045]; [0046]; [0068]; [0069]; and [0070]; Mehta at 3:29-39; 3:40-41; 4:63-5:2; 5:3-15; 6:64-65; 9:34-55; 10:33-39; 12:5-14; 13:54-57; Fig. 3A; 13:58-4; 15:27-33; 15:55-16:11; Fig. 4A; 16:42-58; 16:59-17:12; 18:21-37; Fig. 5; 32:46-62; Fig. 10B; 32:63-33:14; 33:15-29; 33:30-34; 33:57-13; Fig. 10E; 34:38-45; 35:8-22; Fig. 12A; and Fig. 12B; Mulholland at 4:45-48, 5:11-26, 6:65-8:10, 7:19-31; ScarLet at SERENDIA-00017328, SERENDIA-00017331, Ilooda-0006078 (at 7); Lee '500 at Para. 42, 43, 44, 52, 53, 55, 56, 61; claims 1, 2, 7. To the extent Mehta does not explicitly disclose that the needles of a dermatological treatment device are extendable using a motor, it would have been obvious to modify the dermatological treatment device to make the needles retractable and extendable to a desired depth using a

'774 Patent Claim 14		Mehta alone and/or Mehta in view of Na '848
		motor connected to the needles to achieve enhanced safety (by having the needles retracted when not in use) and enhanced customizability of treatment (by specifying the needle penetration depth). *See id.* Configuring a plurality of needles to be attached to a motor would have been a matter of routine engineering as of the priority date of the '774 Patent, as evidenced by the numerous dermatological treatment devices which included a motor for this purpose. Additionally, as of the priority date of the '774 Patent, it was well known how to create linear force using various manual and automated mechanisms, including a motor. The selection of the mechanism to achieve this purpose is a design choice that would have been obvious to a POSITA.

470. In view of the foregoing chart, claim 14 of the '774 Patent is anticipated by the teachings of Mehta. Further, to the extent Complainant argues that any of the foregoing limitations are not explicitly or inherently disclosed by Mehta, such limitations would have been obvious given the knowledge of a POSITA, and/or further in view of the teachings of Na '848. The teachings of Mehta are so similar to what is claimed that any alleged difference between the teachings of Mehta and what is claimed would not have been of patentable significance given the knowledge of a POSITA.

2. Claims 13 and 14 of the '774 Patent are Anticipated by ScarLet and/or rendered Obvious by ScarLet alone and/or ScarLet in view of Na '848

471. It is my opinion that ScarLet anticipates and/or renders obvious each asserted claim of the '774 Patent.

472. ScarLet in view of the knowledge of a POSITA renders each of the '774 Patent's asserted claims obvious. A POSITA would have understood that any limitations in the Asserted Claims arguably not explicitly disclosed by ScarLet were obvious in view of the state of the relevant art. A POSITA would have been motivated to draw upon his or her knowledge of the

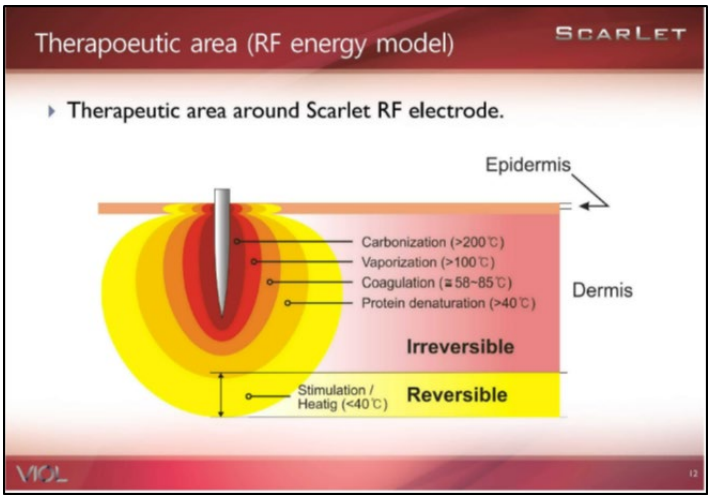
relevant art to modify ScarLet as necessary to achieve any of the claimed features and would have enjoyed a reasonable expectation of success in doing so. A POSITA would have enjoyed a reasonable expectation of success in combining and/or modifying the teachings of ScarLet, together with general knowledge of the art, to achieve the claimed subject matter, at least because the prior art itself discloses and/or practices the claimed methods and apparatuses to achieve the claimed results. A POSITA would have recognized that the relevant art is predictable, and that achieving the claimed subject matter would have been obvious to try or requires merely routine optimization.

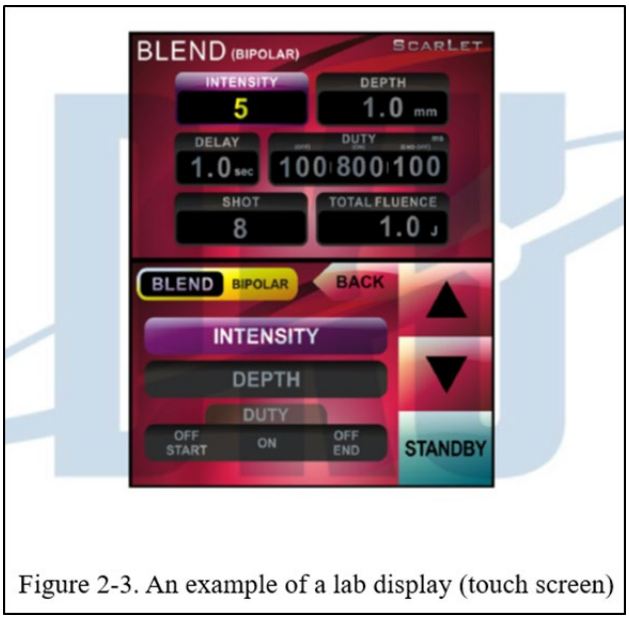
473. To the extent ScarLet does not render one or more of the '774 Patent's asserted claims obvious, the claims would have been obvious over ScarLet in view of Na '848. ScarLet and Na '848 discuss or address the same or substantially similar underlying apparatus and/or technology in the field of dermatological treatment and devices such that a POSITA would have understood that these references can be combined, according to known methods and/or by the simple substitution of one known, equivalent element for another, to yield predictable results and with a reasonable expectation of success.

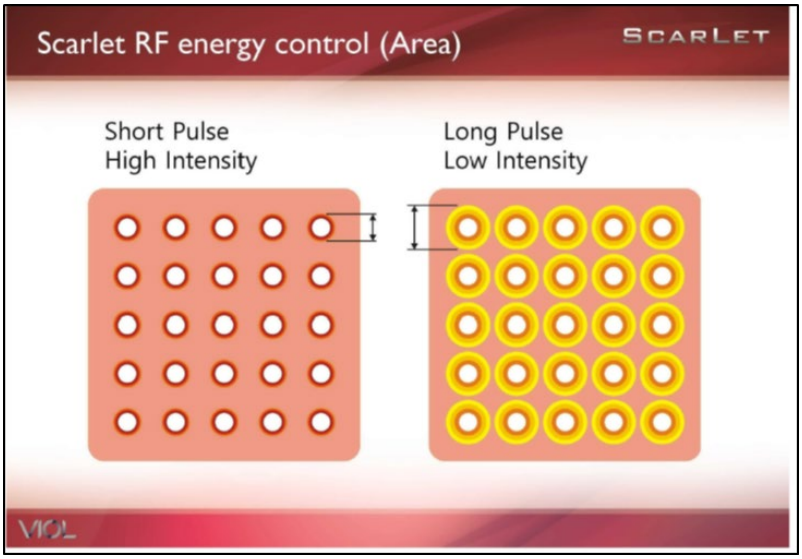
474. A POSITA would also have been motivated to combine ScarLet and Na '848 in light of market forces in the industry, and the desire to improve features and performance, and/or in light of one or more teachings, suggestions, or motivations in the art. A POSITA would have enjoyed a reasonable expectation of success in combining and/or modifying the teachings of the foregoing prior art references and products, together with general knowledge of the art, to achieve the claimed subject matter, at least because the prior art itself discloses and/or practices the claimed methods and apparatuses to achieve the claimed results. A POSITA

would have recognized that the relevant art is predictable, and that achieving the claimed subject matter would have been obvious to try or requires merely routine optimization.

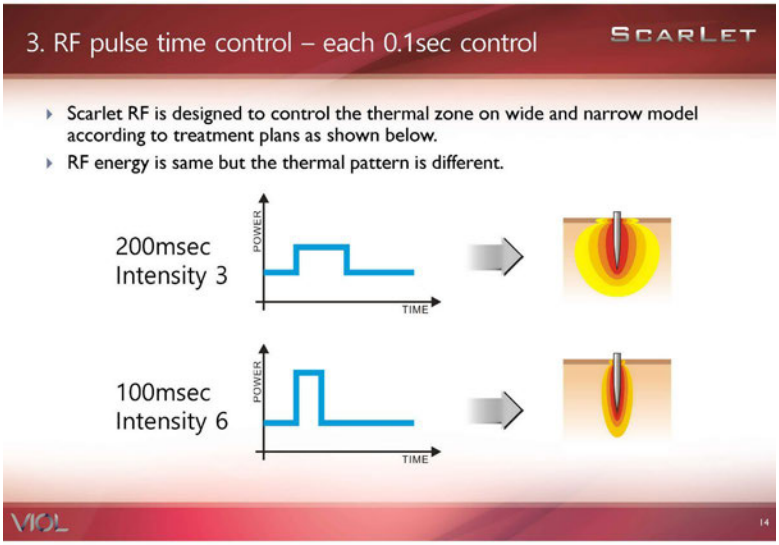
475. Claims 13 and 14 of the '774 Patent depend from unasserted claim 12, which ultimately depends from unasserted claim 11. It is my opinion that claims 13 and 14 are anticipated by ScarLet and/or rendered obvious by ScarLet (in view of the knowledge of a POSITA) and/or ScarLet in view of Na '848 as detailed below:

'774 Patent Claim 11		**ScarLet and/or ScarLet in view of Na '848**
11.0	11. An apparatus for treating dermatological tissue, comprising:	***Claim 11 of the '774 Patent is anticipated by ScarLet and/or rendered obvious by ScarLet alone or ScarLet in view of Na '848.*** To the extent the preamble is limiting, ScarLet discloses and/or renders obvious an apparatus for treating dermatological tissue. *See, e.g.*, "ScarLet has the meaning of (scar + Lifting). Since the RF of 2Mhz is applied with Long Pulse from 100ms-800ms through Micro Needle, it can give various thermal effects to the skin tissue, and VIOL's uniquely creative technology has dramatically reduced skin pain. It has increased the convenience of medical professionals and patients at the same time." (D&PS Monthly September 2010 at 3.)  SERENDIA-00017306 at -317.

'774 Patent Claim 11		ScarLet and/or ScarLet in view of Na '848
11.1	a device including a plurality of needles one of extending or extendable a desired distance from a surface, the desired distance selected to enable the plurality of needles to penetrate dermatological tissue; and	ScarLet discloses and/or renders obvious a device including a plurality of needles  Ilooda-0006772 page 4 ScarLet discloses and/or renders obvious a device including a plurality of needles one of extending or extendable a desired distance from a surface, the desired distance selected to enable the plurality of needles to penetrate dermatological tissue. *See, e.g.*,  Figure 2-3. An example of a lab display (touch screen) Ilooda-0006078 (#13_(Eng)_Shim 2010_DKU Thesis Dec 1 2010_Translated_Certified at 10)

'774 Patent Claim 11		ScarLet and/or ScarLet in view of Na '848
		"Intensity displays the intensity of the output and depth displays the distance the linear motor advances within the range 0.5-3.5mm. Delay displays the waiting time before the linear motor moves forward and then backward again. Duty displays the high frequency output time within the range of 0.3-1.0 seconds, where off start is the linear motor forward waiting time, on is the output time, and off end is the linear motor reverse waiting time. Shot counts the number of shots and total fluence displays the total amount of energy. Intensity, depth, and duty are adjustable on the device. The foot switch is used to interrupt the output, and the hand piece connects the electrosurgical electrodes to the mating cap at the end of the hand piece to coagulate and incise through high-frequency current." Ilooda-0006078 (#13_(Eng)_Shim 2010_DKU Thesis Dec 1 2010_Translated_Certified at 7)
11.2	a signal generator electrically coupled to the plurality of extended needles to produce pulsed radio frequency signals across the plurality of needles to affect dermatological tissue near the plurality of needles.	ScarLet discloses and/or renders obvious a signal generator electrically coupled to the plurality of extended needles to produce pulsed radio frequency signals across the plurality of needles to affect dermatological tissue near the plurality of needles. *See, e.g.*,  SERENDIA-00017306 at -321.

'774 Patent Claim 11		ScarLet and/or ScarLet in view of Na '848
		 SERENDIA-00017306 at -334.  SERENDIA-00017306 at -337.

'774 Patent Claim 11		ScarLet and/or ScarLet in view of Na '848
		 SERENDIA-00017306 at -319 The selection of "duty" defines the duration of the pulse of RF "Duty displays the high frequency output time within the range of 0.3-1.0 seconds" (Ilooda-0006078 (#13_(Eng)_Shim 2010_DKU Thesis Dec 1 2010_Translated_Certified at 7). I understand that the parties disagree as to the meaning of the claim term "pulsed radio frequency signals." To the extent that this claim limitation is not explicitly or inherently disclosed by ScarLet, it would have been obvious given the knowledge of a POSITA. For example, as noted above, ScarLet discloses "ScarLet RF energy control" in both "Short Pulse" and "Long Pulse." As of the priority date of the '774 Patent, it was common practice to create pulsed radio frequency signals with an RF energy unit, *see above.* The selection of pulsed radio frequency signals is a design choice that would have been obvious to a POSITA. Moreover, in my opinion, it would have been obvious to incorporate "pulsed radio frequency signals" in the ScarLet device in view of the teachings of Na '848. I understand that Na '848 is part of the same patent family as the '774 Patent. The disclosures of the pulsed signals in Na '848 are identical to those in the '774 Patent. For example, Na '848 discloses: [0028] ***The signal generator or module 370 may generate a vary of signals (such as shown in FIGS. 5 A to 6) to vibrate one or more pins 351 electrically coupled to the system 300 via the internal wire 331 and the conductive interface 390. In operation a user 20 may touch the conductive interface***

'774 Patent Claim 11		ScarLet and/or ScarLet in view of Na '848
		390 and place one or more electrically coupled pins 351 in contact with their dermis to form an electrical pathway from the pin 351 to the electrical conductive interface 390. The signal generator 370 may include a battery to supply energy to generate one or more electrical signals. ***The switch 375 coupled to the generator 370 may cause the generator to produce one or more electrical signals for a predetermined time interval or until the switch 375 is triggered again. As noted a pin vibration 351 may increase the micro-wound or cut formed in dermis by the pin 351.*** [0029] FIG. 2D is a simplified cross-sectional diagram of an acupuncture apparatus 362 according to various embodiments. The apparatus 362 may include a handle 330, an elastic section 333, internal wire(s) 331, 332, ***signal generator 370***, switch 375, and plate 350. ***The signal generator 370 may be coupled to at least one pin 351 via internal wire 331 and coupled to at least one other pin 352 via internal wire 332.*** When active the pins 351, 352 may form at least one dipole pair. ***The signal generator or module 370 may generate a vary of signals (such as shown in FIGS. 5A to 6) to vibrate one or more dipole pair or bipolar pins 351, 352.*** [0033] ***FIGS. 3A and 3B are simplified isometric diagrams of acupuncture apparatus 400, 460 including at least one pin 451 that may be coupled to an electrical signal via an internal wire 458.*** Each apparatus 400, 460 includes curved roller 450 having a plurality of acupuncture pins 451 where the pins 451 may be similar to pins 351. In apparatus 400, the electrical lead wire 400A may be coupled to an electrical interface 410 in the apparatus handle 430 where the interface 410 is electrically coupled to the internal wire 458. In apparatus 460, the handle 430 may include ***a signal generator 470*** similar to generator 370, switch 475, and conduction surface 490. Apparatus 460 may operate similar to apparatus 360 in operation other than the rolling capability of the apparatus 460, 400. In an embodiment the rollers 450 may have various configurations to conform to a dermal area to be treated. [0039] ***FIGS.5A-5B are diagrams of electrical signal waveforms 650, 630, 640 that may be applied*** to one or more LEDs 32A, 32B, 532 and ***to the pins 230, 351, 451 according to various embodiments***. ***The signal waveform***

'774 Patent Claim 11		ScarLet and/or ScarLet in view of Na '848
		650 includes several square -wave pulses 652, 654, 656 that may be applied to an LED 32A, 32B, 532. Each pulse 652, 654, 656 may a have a similar magnitude and envelope. ***The waveform 650 may be used to energize*** an LED 32A, 32B, 532 and to ***the pins 230, 351, 451 periodically Pl for a predetermined interval Tl where each pulse 652, 654, 656 has a[n] amplitude Al***. In an embodiment, Al may be about 0.1 milliamperes (mA) to 10 mA, the pulse width Tl may be about 100 microsecond (μs) to 500 μs and the period Pl may from 100 ms to 500 ms as a function of the energy required to create capacitance in a liquid. In another embodiment, Al may be about 0.5 milliamperes (mA) to 5 mA, the pulse width Tl may be about 200 microsecond (μs) and the period Pl may about 250 ms as a function of the energy to drive an LED or cause one or more pins 230, 351, 451 to vibrate. [0040] ***In FIG. 5B a signal waveform 630 may be applied*** to a first LED 32A, 32B, 532 module or group and ***to the pins 230, 351 , 451*** and ***a second waveform 640 may be applied or used to energize*** a second LED 32A, 32B, 532 module and ***the pins 230, 351, 451, 352***. ***The signal waveform 630 includes several square-wave pulses 632, 634, and 636 and the signal waveform 640 includes several square-wave pulses 642, 644, and 646. Each pulse 632, 634, 636, 642, 644, 646 may a have a similar magnitude and envelope. The waveform 630 may be used to energize*** a first LED 32A, 32B, 332 module and ***the pins 230, 351, 451 periodically Pl for a predetermined interval Tl where each pulse 632, 634, 636 has an amplitude Al***. ***The waveform 640 may be used to energize*** a second LED 32A, 32B, 332 module and ***the pins 230, 351, 451 periodically P2 for a predetermined interval T2 where each pulse 642, 644, 646 has an amplitude Bl***. The pulse width Tl, T2 may be about 100 microsecond (μs) to 500 μs and the period Pl, P2 may from 100 ms to 500 ms as a function of the energy to affect dermalogical cells or chemicals 22A. In another embodiment, Al, A2 may be about 0.5 milliamperes (mA) to 5 mA, the pulse width Tl, T2 may be about 200 microsecond (μs) and the period Pl, P2 may about 250 ms as a function of the energy required to affect dermalogical cells or chemicals 22 A. In an embodiment the pulses 632, 634, 636 do not substantially overlap the pulses 642, 644, 646. In an embodiment Tl > T2 and P2 is an integer multiple of Pl .

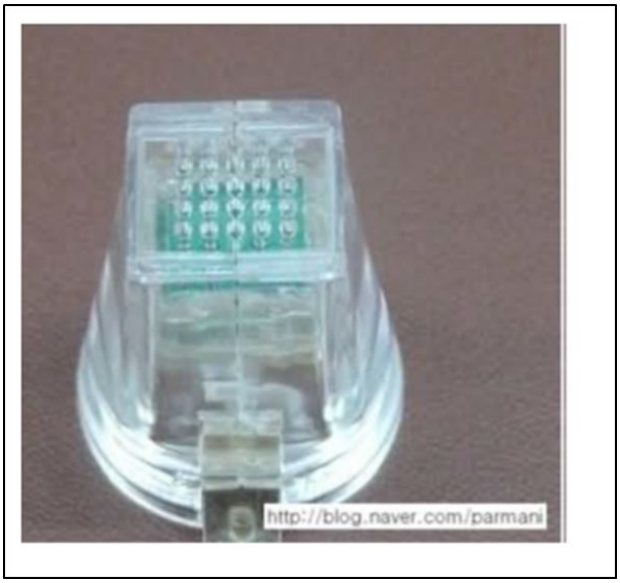
'774 Patent Claim 11		ScarLet and/or ScarLet in view of Na '848
		[0041] ***FIG. 6 depicts a waveform 670 that includes multiple pulses 672, 674, 676, 678, 682, and 684 that may not overlap in the time or the frequency domain. In an embodiment each pulse 672, 674, 676, 678, 682, and 684 may have a pulse width T3, and frequency spectrum width Fl and period P3. The pulse 672 is frequency offset from the pulse 674, the pulse 676 is frequency offset from the pulse 678, and the pulse 682 is frequency offset from the pulse 684. The pulses 672, 674, 676, 678, 682, and 684 may be applied to*** an LED module to affect dermalogical cells or chemicals 22A and ***the pins 230, 351, 451***. Pulses 672, 674 having different frequency spectrums may enable different LED stimulation. In an embodiment the pulses 672, 676, 682 may be applied to a first LED module and the pulses 674, 678, 684 may be applied to a second LED module. ***The frequency separation between the respective pulses may enable simultaneous energization of a first and a second LED module and the pins 230, 351, 451*** and subsequent and independent spectrum generation. [0042] In an embodiment the invention may employ the algorithm 740 shown in FIG. 7A to apply therapy to dermalogical cells. A user, clinician, or equipment may place an apparatus 10, 320, 360, 360, 400, 460 on dermalogical cells to be treated (activity 741) including pressing the apparatus against the cells firmly enough to embed one or more pins 251 , 351 , 451 in the cells. ***A first signal such as shown in FIGS. 5A, 5B, and 6 may be applied to*** a first LED module or group (32A) and ***the pins 230, 351, 451 of a dermalogical apparatus 10, 320, 360, 360, 400, 460 (activity 742) for a predetermined time period (activity 744)***. ***A second signal such as shown in FIGS. 5 A, 5B, and 6 may be applied to*** a second LED module or group (32B) and ***the pins 230, 351, 451 of a dermalogical apparatus 10, 320, 360, 360, 400, 460 (activity 746) for a predetermined time period (activity 748)***. The signals applied to the groups may be selected to stimulate dermalogical cells or chemicals 22A or cause vibration of one or more pins 251, 351, 451. [0043] In another embodiment the invention may employ the algorithm 750 shown in FIG. 7B to apply therapy to dermalogical cells. A user, clinician, or equipment may apply a light sensitive chemical on an apparatus 10, 320, 360, 360, 400, 460 or on dermalogical cells to be treated

'774 Patent Claim 11		ScarLet and/or ScarLet in view of Na '848
		(activity 751). The user, clinician, or equipment may place apparatus 10, 320, 360, 360, 400, 460 on dermalogical cells to be treated (activity 752). ***A signal such as shown in FIGS. 5A, 5B, and 6 may be applied to*** a LED module or group (32A or 32B) and ***the pins 230, 351 , 451 (activity 354) for a predetermined time period (activity 356)***. [0044] In another embodiment the invention may employ the algorithm 760 shown in FIG. 7C to apply therapy to dermalogical cells. A user, clinician, or equipment may apply a light sensitive chemical on an apparatus 10, 320, 360, 360, 400, 460 or on dermalogical cells to be treated (activity 761). The user, clinician, or equipment may place an apparatus 10, 320, 360, 360, 400, 460 on dermalogical cells to be treated (activity 762). ***A first signal such as shown in FIGS. 5A, 5B, and 6 may be applied to*** a first LED module or group (32A) and ***one or more pins 251, 351, 451 of a dermalogical apparatus 10, 320, 360, 360, 400, 460 (activity 763) for a predetermined time period (activity 764)***. ***A second signal such as shown in FIGS. 5 A, 5B, and 6 may be applied to*** a second LED module or group (32B) and ***one or more pins 251 , 351 , 451 of a dermalogical apparatus 10, 320, 360, 360, 400, 460 (activity 766) for a predetermined time period (activity 768).*** The POSITA would have understood from Na '848 the benefit of including a "variety of signals" including pulsed radio frequency signals in a dermatological device. It was well-known that providing a variety of signal types, including pulsed radio frequency signals, was advantageous with respect to providing dermatological treatments. Therefore, the POSITA would have been motivated to modify the ScarLet device with the pulsed radio frequency signals of Na '848. Configuring ScarLet's RF energy unit to supply pulsed radio frequency signals would have been a matter of routine engineering as of the priority date of the '774 Patent, as evidenced by the numerous dermatological treatment devices which included pulsed radio frequency signals for this purpose.

476. In view of the foregoing chart, claim 11 of the '774 Patent is anticipated by the teachings of ScarLet. Further, to the extent Complainant argues that any of the foregoing limitations are not explicitly or inherently disclosed by ScarLet, such limitations would have

been obvious given the knowledge of a POSITA, and/or further in view of the teachings of Na '848. The teachings of ScarLet are so similar to what is claimed that any alleged difference between the teachings of ScarLet and what is claimed would not have been of patentable significance given the knowledge of a POSITA.

477. It is my opinion that Claim 12 of the '774 Patent is anticipated by ScarLet and/or rendered obvious by ScarLet alone or ScarLet in view of Na '848 as detailed below:

'774 Patent Claim 12		**ScarLet and/or ScarLet in view of Na '848**
12.0	12. The apparatus for treating dermatological tissue of claim 11, wherein the device includes an end surface configured to be placed on or near dermatological tissue to be treated, the end surface including a plurality of needles extendable a desired distance from the end surface.	***Claim 12 of the '774 Patent is anticipated by ScarLet and/or rendered obvious by ScarLet alone or ScarLet in view of Na '848.*** ScarLet discloses and/or renders obvious (either alone or in view of Na '848) the apparatus for treating dermatological tissue of claim 11. *See* claim 11. ScarLet discloses and/or renders obvious the device includes an end surface configured to be placed on or near dermatological tissue to be treated, the end surface including a plurality of needles extendable a desired distance from the end surface. *See, e.g.*,  Ilooda-0006719 (#19-1_Naver Blog The H Jan 10 2011_Translated_Certified at 5)

‘774 Patent Claim 12		ScarLet and/or ScarLet in view of Na ‘848
		 Ilooda-0006770 (#18_D&PS Monthly Sept 2010_Translated_Certified at 4).  Ilooda-0006770 (#18_D&PS Monthly Sept 2010_Translated_Certified at 4).

‘774 Patent Claim 12		ScarLet and/or ScarLet in view of Na ‘848

1. Specification of ScarLet

Specification	
NEEDLE DEPTH	0.5 mm ~ 3.5 mm (0.1 mm unit)
RF CONDUCT. TIME	100msec ~ 800msec (100msec unit)
RF OUTPUT	1) 1.5V ~ 40V 2) 40 ~ 200V
RF E. FIELD WIDTH(at 1mm Depth)	82mm^2
RF FREQUENCY	2MHz
WEIGHT	29Kg
DIMENSION	55cm(W) * 35cm(D) * 122cm(H)
ELECTRODE NO.	25 Pin
SPOT SIZE	1cm^2

Ilooda-0006075 (ScarLet intro at 2).



Figure 2-3. An example of a lab display (touch screen)

Ilooda-0006078 (#13_(Eng)_Shim 2010_DKU Thesis Dec 1 2010_Translated_Certified at 10).

“Intensity displays the intensity of the output and depth displays the distance the linear motor advances within the range 0.5-3.5mm. Delay displays the waiting time before the linear motor moves forward and then backward again. Duty displays the high frequency output time within the range of 0.3-1.0 seconds, where off start is the linear motor forward waiting time, on is the output time, and off end is the linear motor reverse waiting time. Shot

'774 Patent Claim 12		ScarLet and/or ScarLet in view of Na '848

counts the number of shots and total fluence displays the total amount of energy. Intensity, depth, and duty are adjustable on the device. The foot switch is used to interrupt the output, and the hand piece connects the electrosurgical electrodes to the mating cap at the end of the hand piece to coagulate and incise through high-frequency current."

Ilooda-0006078 (#13_(Eng)_Shim 2010_DKU Thesis Dec 1 2010_Translated_Certified at 7).

SCARLET SYSTEM MODE

5.4.1 To Operate COAG Mode

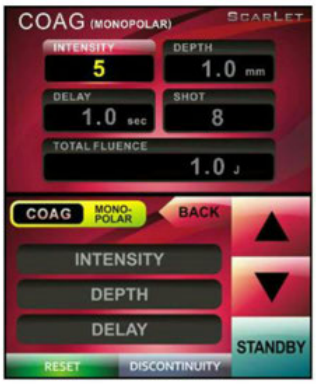


Figure 5-7. COAG Mode LCD Screen

Name	Description.
INTENSITY	Displays the output intensity.
DEPTH	Displays the distance the linear motor advances (range: 0.5 to 3.5 mm).
DELAY	Displays the wait time before the linear motor moves forward and then backward again.
SHOT	Counts the number of outputs.
TOTAL FLUENCE	Displays the total amount of energy.

Table 5-5. COAG Mode Top LCD Screen Descriptions Table

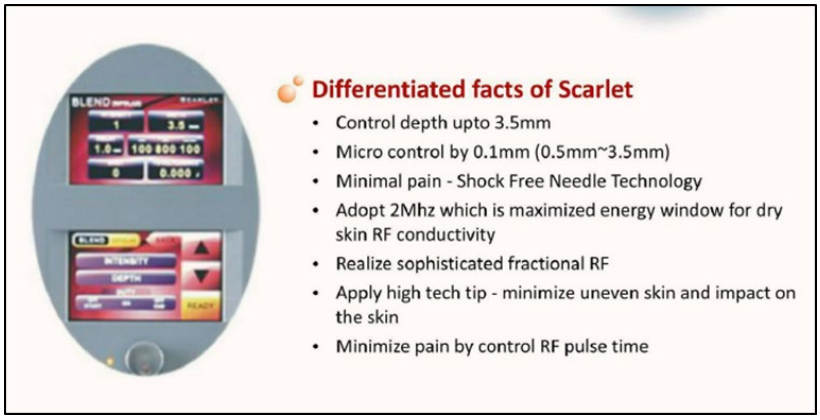
Ilooda-0011405 at -471 (certified English translation of SERENDIA-00073257 at -298).

To the extent that this claim limitation is not explicitly or inherently disclosed by ScarLet, it would have been obvious given the knowledge of a POSITA. For example, at least Mehta, Mulholland, ScarLet and Lee '500 each disclose a plurality of needles extendable a desired distance from an end surface, disclose various mechanisms for causing the plurality of extendable needles to extend a desired distance from the end surface and a motor coupled

'774 Patent Claim 12		ScarLet and/or ScarLet in view of Na '848
		to the plurality of extendable needles that may be directed to cause the plurality of the extendable needles to extend a desired distance from the end surface. *See, e.g.*, Mehta at 3:29-39; 3:40-41; 4:63-5:2; 5:3-15; 6:64-65; 9:34-55; 10:33-39; 12:5-14; 13:54-57; Fig. 3A; 13:58-4; 15:27-33; 15:55-16:11; Fig. 4A; 16:42-58; 16:59-17:12; 18:21-37; Fig. 5; 32:46-62; Fig. 10B; 32:63-33:14; 33:15-29; 33:30-34; 33:57-13; Fig. 10E; 34:38-45; 35:8-22; Fig. 12A; and Fig. 12B; Mulholland at 4:45-48, 5:11-26, 6:65-8:10, 7:19-31; ScarLet at SERENDIA-00017328, SERENDIA-00017331, Ilooda-0006078 (at 7); Lee '500 at Para. 42, 43, 44, 52, 53, 55, 56, 61; claims 1, 2, 7. As of the priority date of the '774 Patent, it was well known that controlling the depth of penetration for the needles and being able to retract the needles was advantageous with respect to providing dermatological treatments. *See, e.g.*, Hantash 2009 at pg. 88; pg. 90; pg. 92; Figs. 2, 1; Hantash 718 PCT at [0017]; [0035]; [0041]; [0042]; [0045]; [0046]; [0068]; [0069]; and [0070]; Mehta at 3:29-39; 3:40-41; 4:63-5:2; 5:3-15; 6:64-65; 9:34-55; 10:33-39; 12:5-14; 13:54-57; Fig. 3A; 13:58-4; 15:27-33; 15:55-16:11; Fig. 4A; 16:42-58; 16:59-17:12; 18:21-37; Fig. 5; 32:46-62; Fig. 10B; 32:63-33:14; 33:15-29; 33:30-34; 33:57-13; Fig. 10E; 34:38-45; 35:8-22; Fig. 12A; and Fig. 12B; Mulholland at 4:45-48, 5:11-26, 6:65-8:10, 7:19-31; ScarLet at SERENDIA-00017328, SERENDIA-00017331, Ilooda-0006078 (at 7); Lee '500 at Para. 42, 43, 44, 52, 53, 55, 56, 61; claims 1, 2, 7. To the extent ScarLet does not explicitly disclose that the needles of a dermatological treatment device are extendable using a motor, it would have been obvious to modify the dermatological treatment device to make the needles retractable and extendable to a desired depth using a motor connected to the needles to achieve enhanced safety (by having the needles retracted when not in use) and enhanced customizability of treatment (by specifying the needle penetration depth). *See id.* Configuring a plurality of needles to be attached to a motor would have been a matter of routine engineering as of the priority date of the '774 Patent, as evidenced by the numerous dermatological treatment devices which included a motor for this purpose. Additionally, as of the priority date of the '774 Patent, it was well known how to create linear force using various manual and automated mechanisms, including a motor. The selection of the mechanism to achieve this purpose is a design choice that would have been obvious to a POSITA.

478. In view of the foregoing chart, claim 12 of the '774 Patent is anticipated by the teachings of ScarLet. Further, to the extent Complainant argues that any of the foregoing limitations are not explicitly or inherently disclosed by ScarLet, such limitations would have been obvious given the knowledge of a POSITA, and/or further in view of the teachings of Na '848. The teachings of ScarLet are so similar to what is claimed that any alleged difference between the teachings of ScarLet and what is claimed would not have been of patentable significance given the knowledge of a POSITA.

479. It is my opinion that Claim 13 of the '774 Patent is anticipated by ScarLet and/or rendered obvious by ScarLet alone or ScarLet in view of Na '848 as detailed below:

'774 Patent Claim 13		**ScarLet and/or ScarLet in view of Na '848**
13.0	13. The apparatus for treating dermatological tissue of claim 12, further including a mechanism for causing the plurality of the extendable needles to extend a desired distance from the end surface.	***Claim 13 of the '774 Patent is anticipated by ScarLet and/or rendered obvious by ScarLet alone or ScarLet in view of Na '848.*** ScarLet discloses and/or renders obvious (either alone or in view of Na '848) the apparatus for treating dermatological tissue of claim 12. *See* claim 12. ScarLet discloses and/or renders obvious a mechanism for causing the plurality of the extendable needles to extend a desired distance from the end surface. *See, e.g.*,  Ilooda-0010031 at -033.

'774 Patent Claim 13	ScarLet and/or ScarLet in view of Na '848

5.4.1 To Operate COAG Mode

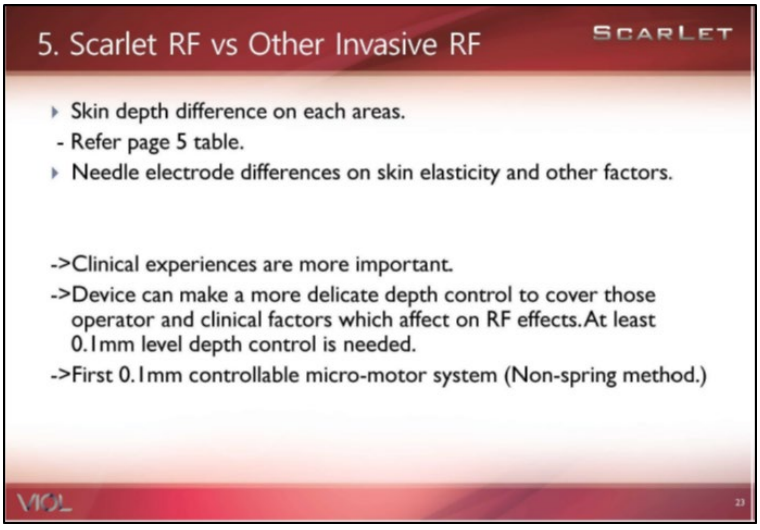


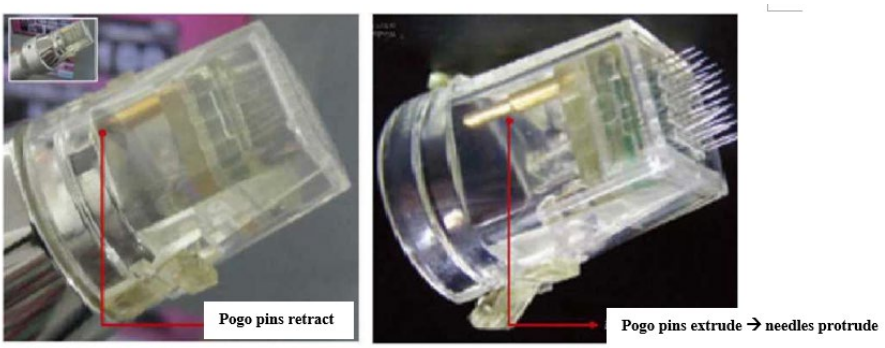
Figure 5-7. COAG Mode LCD Screen

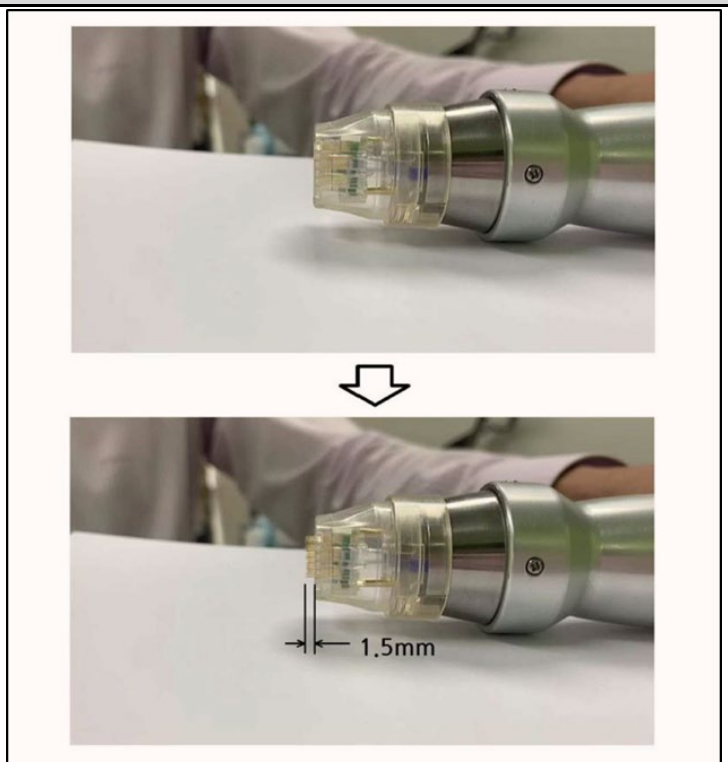
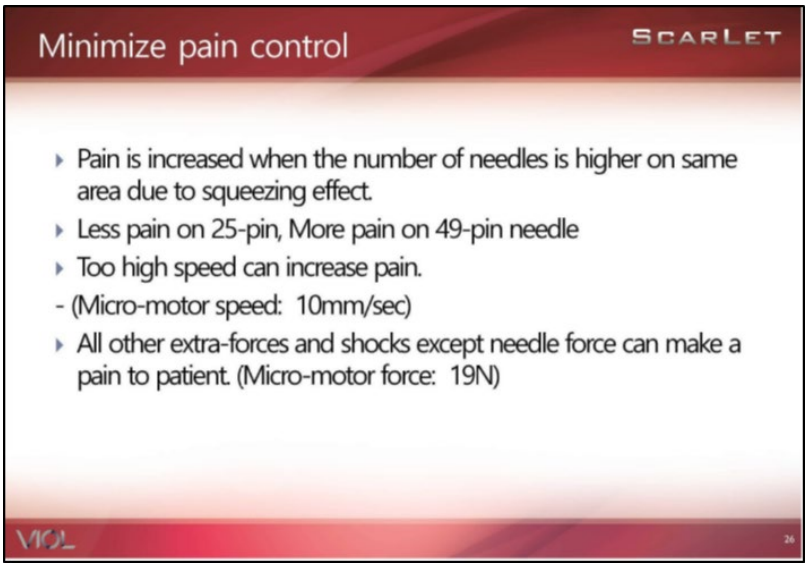
Name	Description.
INTENSITY	Displays the output intensity.
DEPTH	Displays the distance the linear motor advances (range: 0.5 to 3.5 mm).
DELAY	Displays the wait time before the linear motor moves forward and then backward again.
SHOT	Counts the number of outputs.
TOTAL FLUENCE	Displays the total amount of energy.

Table 5-5. COAG Mode Top LCD Screen Descriptions Table

Ilooda-0011405 at -471 (certified English translation of SERENDIA-00073257 at -298).



'774 Patent Claim 13		ScarLet and/or ScarLet in view of Na '848
		SERENDIA-00017306 at -328. **Performance** 1. Product configuration This product is a disposable electrode for a hand-operated electrosurgical device, and consists of an electrode that applies RF current to the human body and a cartridge cap. 2. Performance 1) Functional characteristics: Block RF electricity flow except in exposed areas. 2) RF leakage current: 1.16 mA 3) Length of the electrode exposed: 0.5 – 3.5mm (Adjustable in the Depth menu on the electrosurgical device) Ilooda-0010141 at -157 (certified English translation of SERENDIA-00033705 at -720).  Ilooda-0008178 at -232.

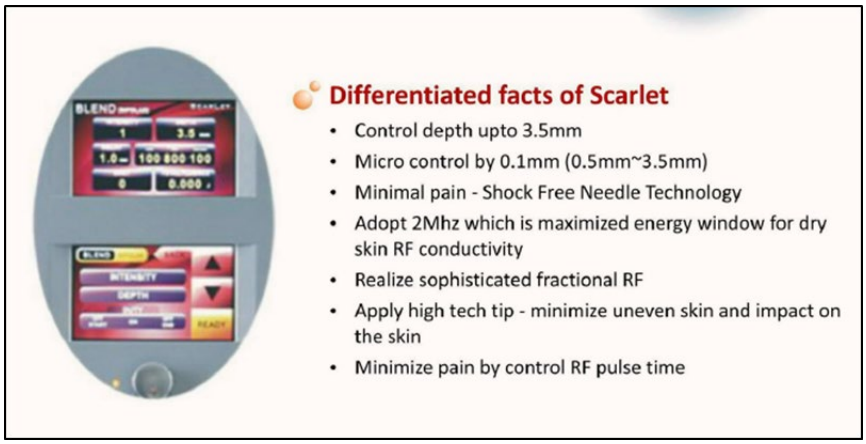
‘774 Patent Claim 13		ScarLet and/or ScarLet in view of Na ‘848
		 [Plaintiff's Exhibits 22-10 and 22-11: 1.5 mm protrusion of the needles due to protrusion of the drive shaft]. Ilooda-0008178 at -234.  SERENDIA-00017306 at -331. “Intensity displays the intensity of the output and depth displays the distance the linear motor advances within the range 0.5-3.5mm.

'774 Patent Claim 13		ScarLet and/or ScarLet in view of Na '848
		Delay displays the waiting time before the linear motor moves forward and then backward again. Duty displays the high frequency output time within the range of 0.3-1.0 seconds, where off start is the linear motor forward waiting time, on is the output time, and off end is the linear motor reverse waiting time. Shot counts the number of shots and total fluence displays the total amount of energy. Intensity, depth, and duty are adjustable on the device. The foot switch is used to interrupt the output, and the hand piece connects the electrosurgical electrodes to the mating cap at the end of the hand piece to coagulate and incise through high-frequency current." Ilooda-0006078 (#13_(Eng)_Shim 2010_DKU Thesis Dec 1 2010_Translated_Certified at 7). To the extent that this claim limitation is not explicitly or inherently disclosed by ScarLet, it would have been obvious given the knowledge of a POSITA. For example, at least Mehta, Mulholland, ScarLet and Lee '500 each disclose a plurality of needles extendable a desired distance from an end surface, disclose various mechanisms for causing the plurality of extendable needles to extend a desired distance from the end surface and a motor coupled to the plurality of extendable needles that may be directed to cause the plurality of the extendable needles to extend a desired distance from the end surface. *See, e.g.*, Mehta at 3:29-39; 3:40-41; 4:63-5:2; 5:3-15; 6:64-65; 9:34-55; 10:33-39; 12:5-14; 13:54-57; Fig. 3A; 13:58-4; 15:27-33; 15:55-16:11; Fig. 4A; 16:42-58; 16:59-17:12; 18:21-37; Fig. 5; 32:46-62; Fig. 10B; 32:63-33:14; 33:15-29; 33:30-34; 33:57-13; Fig. 10E; 34:38-45; 35:8-22; Fig. 12A; and Fig. 12B; Mulholland at 4:45-48, 5:11-26, 6:65-8:10, 7:19-31; ScarLet at SERENDIA-00017328, SERENDIA-00017331, Ilooda-0006078 (at 7); Lee '500 at Para. 42, 43, 44, 52, 53, 55, 56, 61; claims 1, 2, 7. As of the priority date of the '774 Patent, it was well known that controlling the depth of penetration for the needles and being able to retract the needles was advantageous with respect to providing dermatological treatments. *See, e.g.*, Hantash 2009 at pg. 88; pg. 90; pg. 92; Figs. 2, 1; Hantash 718 PCT at [0017]; [0035]; [0041]; [0042]; [0045]; [0046]; [0068]; [0069]; and [0070]; Mehta at 3:29-39; 3:40-41; 4:63-5:2; 5:3-15; 6:64-65; 9:34-55; 10:33-39; 12:5-14; 13:54-57; Fig. 3A; 13:58-4; 15:27-33; 15:55-16:11; Fig. 4A; 16:42-58; 16:59-17:12; 18:21-37; Fig. 5; 32:46-62; Fig. 10B; 32:63-33:14; 33:15-29; 33:30-34; 33:57-13; Fig. 10E; 34:38-45; 35:8-22; Fig. 12A; and Fig. 12B; Mulholland at 4:45-48, 5:11-26, 6:65-8:10, 7:19-31; ScarLet at SERENDIA-00017328, SERENDIA-00017331, Ilooda-0006078 (at 7); Lee '500 at Para. 42, 43, 44, 52, 53, 55, 56,

'774 Patent Claim 13		ScarLet and/or ScarLet in view of Na '848
		61; claims 1, 2, 7. To the extent ScarLet does not explicitly disclose that the needles of a dermatological treatment device are extendable using a motor, it would have been obvious to modify the dermatological treatment device to make the needles retractable and extendable to a desired depth using a motor connected to the needles to achieve enhanced safety (by having the needles retracted when not in use) and enhanced customizability of treatment (by specifying the needle penetration depth). *See id.* Configuring a plurality of needles to be attached to a motor would have been a matter of routine engineering as of the priority date of the '774 Patent, as evidenced by the numerous dermatological treatment devices which included a motor for this purpose. Additionally, as of the priority date of the '774 Patent, it was well known how to create linear force using various manual and automated mechanisms, including a motor. The selection of the mechanism to achieve this purpose is a design choice that would have been obvious to a POSITA.

480. In view of the foregoing chart, claim 13 of the '774 Patent is anticipated by the teachings of ScarLet. Further, to the extent Complainant argues that any of the foregoing limitations are not explicitly or inherently disclosed by ScarLet, such limitations would have been obvious given the knowledge of a POSITA, and/or further in view of the teachings of Na '848. The teachings of ScarLet are so similar to what is claimed that any alleged difference between the teachings of ScarLet and what is claimed would not have been of patentable significance given the knowledge of a POSITA.

481. It is my opinion that Claim 14 of the '774 Patent is anticipated by ScarLet and/or rendered obvious by ScarLet alone or ScarLet in view of Na '848 as detailed below:

'774 Patent Claim 14		ScarLet and/or ScarLet in view of Na '848
14.0	14. The apparatus for treating dermatological tissue of claim 12, further including a motor coupled to the plurality of extendable needles that may be directed to cause the plurality of the extendable needles to extend a desired distance from the end surface.	***Claim 14 of the '774 Patent is anticipated by ScarLet and/or rendered obvious by ScarLet alone or ScarLet in view of Na '848.*** ScarLet discloses and/or renders obvious (either alone or in view of Na '848) the apparatus for treating dermatological tissue of claim 12. *See* claim 12. ScarLet discloses and/or renders obvious a motor coupled to the plurality of extendable needles that may be directed to cause the plurality of the extendable needles to extend a desired distance from the end surface. *See, e.g.*, **Performance** 1. Product configuration This product is a disposable electrode for a hand-operated electrosurgical device, and consists of an electrode that applies RF current to the human body and a cartridge cap. 2. Performance 1) Functional characteristics: Block RF electricity flow except in exposed areas. 2) RF leakage current: 1.16 mA 3) Length of the electrode exposed: 0.5 – 3.5mm (Adjustable in the Depth menu on the electrosurgical device) Ilooda-0010141 at -157 (certified English translation of SERENDIA-00033705 at -720).  Ilooda-0010031 at -033.

‘774 Patent Claim 14	ScarLet and/or ScarLet in view of Na ‘848

5.4.1 To Operate COAG Mode

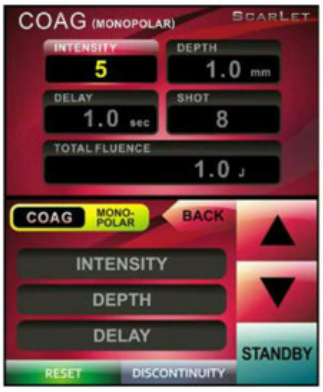
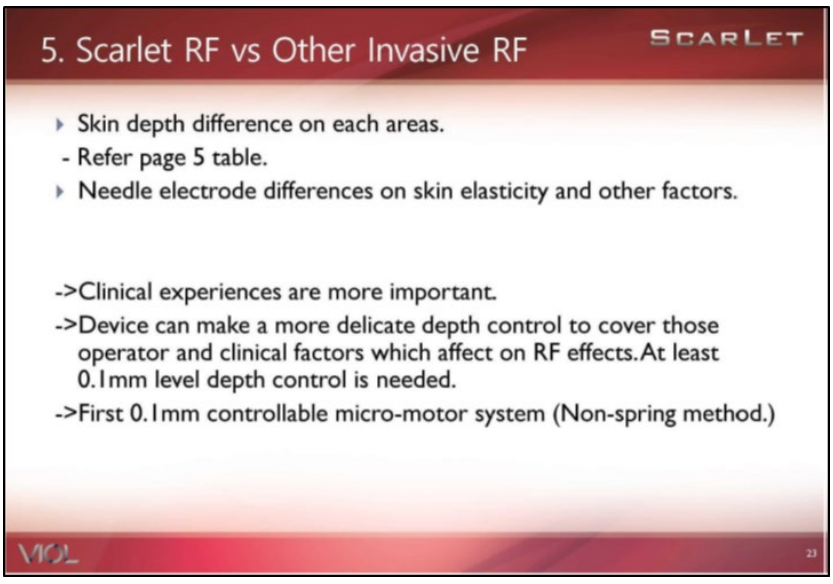


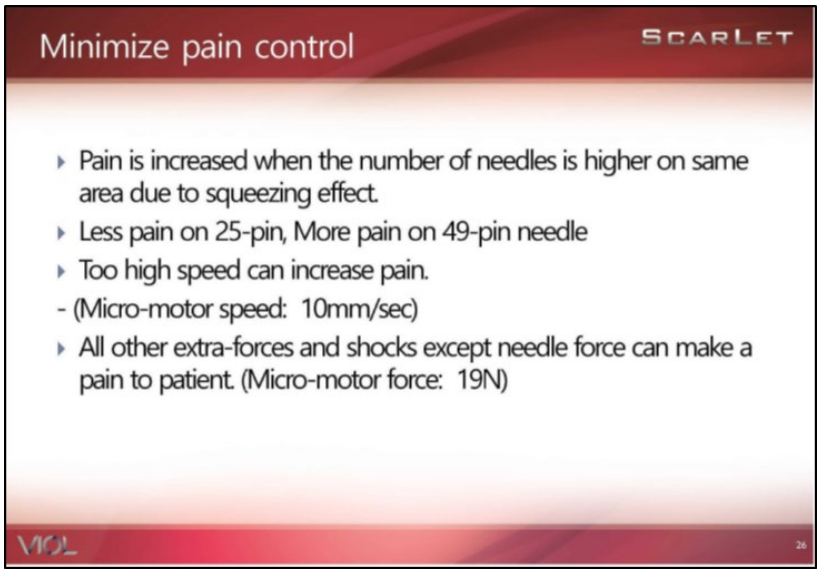
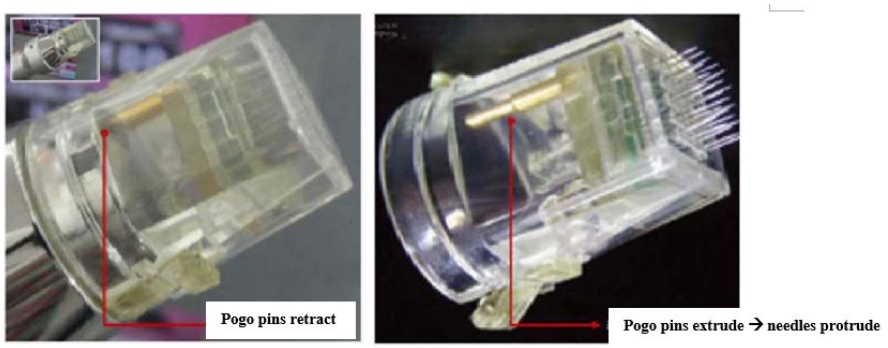
Figure 5-7. COAG Mode LCD Screen

Name	Description.
INTENSITY	Displays the output intensity.
DEPTH	Displays the distance the linear motor advances (range: 0.5 to 3.5 mm).
DELAY	Displays the wait time before the linear motor moves forward and then backward again.
SHOT	Counts the number of outputs.
TOTAL FLUENCE	Displays the total amount of energy.

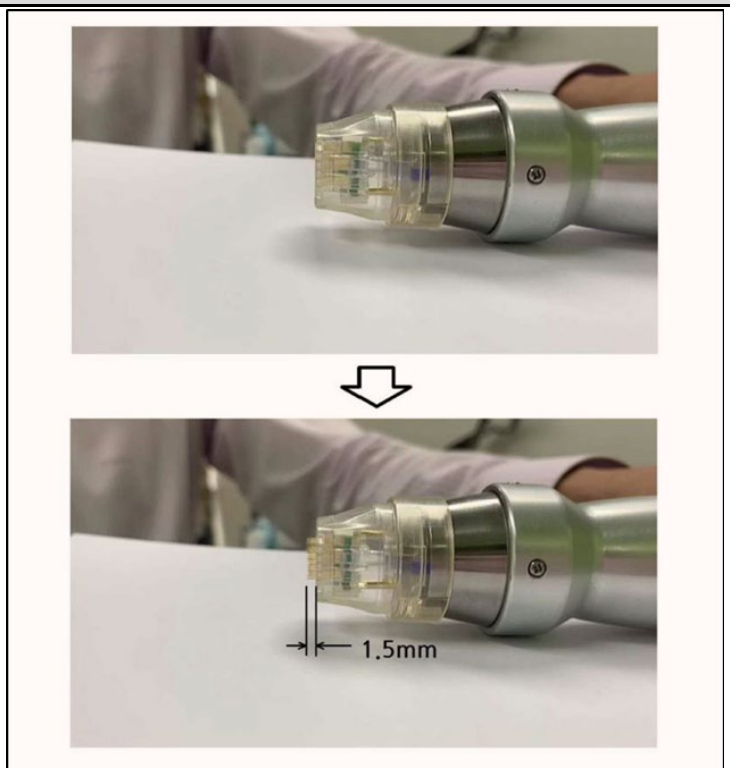
Table 5-5. COAG Mode Top LCD Screen Descriptions Table

Ilooda-0011405 at -471 (certified English translation of SERENDIA-00073257 at -298).



'774 Patent Claim 14		ScarLet and/or ScarLet in view of Na '848
		SERENDIA-00017306 at -328.  SERENDIA-00017306 at -331.  Ilooda-0008178 at -232.

'774 Patent Claim 14	ScarLet and/or ScarLet in view of Na '848



[Plaintiff's Exhibits 22-10 and 22-11: 1.5 mm protrusion of the needles due to protrusion of the drive shaft].

Ilooda-0008178 at -234.

Figure 5-5. BLEND mode LCD screen.

Name	Description.
INTENSITY	Displays the output intensity.
DEPTH	Displays the distance the linear motor advances (range: 0.5 to 3.5 mm).
DELAY	Displays the wait time before the linear motor moves forward and then backward again.
DUTY	Displays the high frequency output time (range: 0.3 to 1.0 seconds). OFF START: Linear motor advance wait time ON: Output time OFF END: Linear Motor Reverse Wait Time
SHOT	Counts the number of outputs.
TOTAL FLUENCE	Displays the total amount of energy.

Table 5-3. BLEND Mode Top LCD Screen Descriptions Table

SERENDIA-00073257 at –294

'774 Patent Claim 14		ScarLet and/or ScarLet in view of Na '848
		"Intensity displays the intensity of the output and depth displays the distance the linear motor advances within the range 0.5-3.5mm. Delay displays the waiting time before the linear motor moves forward and then backward again. Duty displays the high frequency output time within the range of 0.3-1.0 seconds, where off start is the linear motor forward waiting time, on is the output time, and off end is the linear motor reverse waiting time. Shot counts the number of shots and total fluence displays the total amount of energy. Intensity, depth, and duty are adjustable on the device. The foot switch is used to interrupt the output, and the hand piece connects the electrosurgical electrodes to the mating cap at the end of the hand piece to coagulate and incise through high-frequency current." Ilooda-0006078 (#13_(Eng)_Shim 2010_DKU Thesis Dec 1 2010_Translated_Certified at 7). To the extent that this claim limitation is not explicitly or inherently disclosed by ScarLet, it would have been obvious given the knowledge of a POSITA. For example, at least Mehta, Mulholland, ScarLet and Lee '500 each disclose a plurality of needles extendable a desired distance from an end surface, disclose various mechanisms for causing the plurality of extendable needles to extend a desired distance from the end surface and a motor coupled to the plurality of extendable needles that may be directed to cause the plurality of the extendable needles to extend a desired distance from the end surface. *See, e.g.*, Mehta at 3:29-39; 3:40-41; 4:63-5:2; 5:3-15; 6:64-65; 9:34-55; 10:33-39; 12:5-14; 13:54-57; Fig. 3A; 13:58-4; 15:27-33; 15:55-16:11; Fig. 4A; 16:42-58; 16:59-17:12; 18:21-37; Fig. 5; 32:46-62; Fig. 10B; 32:63-33:14; 33:15-29; 33:30-34; 33:57-13; Fig. 10E; 34:38-45; 35:8-22; Fig. 12A; and Fig. 12B; Mulholland at 4:45-48, 5:11-26, 6:65-8:10, 7:19-31; ScarLet at SERENDIA-00017328, SERENDIA-00017331, Ilooda-0006078 (at 7); Lee '500 at Para. 42, 43, 44, 52, 53, 55, 56, 61; claims 1, 2, 7. As of the priority date of the '774 Patent, it was well known that controlling the depth of penetration for the needles and being able to retract the needles was advantageous with respect to providing dermatological treatments. *See, e.g.*, Hantash 2009 at pg. 88; pg. 90; pg. 92; Figs. 2, 1; Hantash 718 PCT at [0017]; [0035]; [0041]; [0042]; [0045]; [0046]; [0068]; [0069]; and [0070]; Mehta at 3:29-39; 3:40-41; 4:63-5:2; 5:3-15; 6:64-65; 9:34-55; 10:33-39; 12:5-14; 13:54-57; Fig. 3A; 13:58-4; 15:27-33; 15:55-16:11; Fig. 4A; 16:42-58; 16:59-17:12; 18:21-37; Fig. 5; 32:46-62; Fig. 10B; 32:63-33:14; 33:15-29; 33:30-34; 33:57-13; Fig. 10E; 34:38-45; 35:8-22; Fig. 12A; and Fig. 12B; Mulholland at 4:45-48, 5:11-26, 6:65-8:10, 7:19-31; ScarLet at SERENDIA-00017328, SERENDIA-00017331,

'774 Patent Claim 14		ScarLet and/or ScarLet in view of Na '848
		Ilooda-0006078 (at 7); Lee '500 at Para. 42, 43, 44, 52, 53, 55, 56, 61; claims 1, 2, 7. To the extent ScarLet does not explicitly disclose that the needles of a dermatological treatment device are extendable using a motor, it would have been obvious to modify the dermatological treatment device to make the needles retractable and extendable to a desired depth using a motor connected to the needles to achieve enhanced safety (by having the needles retracted when not in use) and enhanced customizability of treatment (by specifying the needle penetration depth). *See id.* Configuring a plurality of needles to be attached to a motor would have been a matter of routine engineering as of the priority date of the '774 Patent, as evidenced by the numerous dermatological treatment devices which included a motor for this purpose. Additionally, as of the priority date of the '774 Patent, it was well known how to create linear force using various manual and automated mechanisms, including a motor. The selection of the mechanism to achieve this purpose is a design choice that would have been obvious to a POSITA.

482. In view of the foregoing chart, claim 14 of the '774 Patent is anticipated by the teachings of ScarLet. Further, to the extent Complainant argues that any of the foregoing limitations are not explicitly or inherently disclosed by ScarLet, such limitations would have been obvious given the knowledge of a POSITA, and/or further in view of the teachings of Na '848. The teachings of ScarLet are so similar to what is claimed that any alleged difference between the teachings of ScarLet and what is claimed would not have been of patentable significance given the knowledge of a POSITA.

3. Claims 13 and 14 of the '774 Patent are Anticipated by Mulholland and/or rendered Obvious by Mulholland alone and/or Mulholland in view of Na '848

483. It is my opinion that Mulholland anticipates and/or renders obvious each asserted claim of the '774 Patent.

484. Mulholland in view of the knowledge of a POSITA renders each of the '774 Patent's asserted claims obvious. A POSITA would have understood that any limitations in the Asserted Claims arguably not explicitly disclosed by Mulholland were obvious in view of the state of the relevant art. A POSITA would have been motivated to draw upon his or her knowledge of the relevant art to modify Mulholland as necessary to achieve any of the claimed features and would have enjoyed a reasonable expectation of success in doing so. A POSITA would have enjoyed a reasonable expectation of success in combining and/or modifying the teachings of Mulholland, together with general knowledge of the art, to achieve the claimed subject matter, at least because the prior art itself discloses and/or practices the claimed methods and apparatuses to achieve the claimed results. A POSITA would have recognized that the relevant art is predictable, and that achieving the claimed subject matter would have been obvious to try or requires merely routine optimization.

485. To the extent Mulholland does not render one or more of the '774 Patent's asserted claims obvious, the claims would have been obvious over Mulholland in view of Na '848. Mulholland and Na '848 discuss or address the same or substantially similar underlying apparatus and/or technology in the field of dermatological treatment and devices such that a POSITA would have understood that these references can be combined, according to known methods and/or by the simple substitution of one known, equivalent element for another, to yield predictable results and with a reasonable expectation of success.

486. A POSITA would also have been motivated to combine Mulholland and Na '848 in light of market forces in the industry, and the desire to improve features and performance, and/or in light of one or more teachings, suggestions, or motivations in the art. A POSITA would have enjoyed a reasonable expectation of success in combining and/or modifying the

teachings of the foregoing prior art references and products, together with general knowledge of the art, to achieve the claimed subject matter, at least because the prior art itself discloses and/or practices the claimed methods and apparatuses to achieve the claimed results. A POSITA would have recognized that the relevant art is predictable, and that achieving the claimed subject matter would have been obvious to try or requires merely routine optimization.

487. Claims 13 and 14 of the '774 Patent depend from unasserted claim 12, which ultimately depends from unasserted claim 11. It is my opinion that claims 13 and 14 are anticipated by Mulholland and/or rendered obvious by Mulholland (in view of the knowledge of a POSITA) and/or Mulholland in view of Na '848 as detailed below:

'774 Patent Claim 11		**Mulholland and/or Mulholland in view of Na '848**
11.0	11. An apparatus for treating dermatological tissue, comprising:	***Claim 11 of the '774 Patent is anticipated by Mulholland and/or rendered obvious by Mulholland in view of Mehta, ScarLet, and/or Na '848.*** To the extent the preamble is limiting, Mulholland discloses and/or renders obvious an apparatus for treating dermatological tissue according to the claim. *See, e.g.*, "The invention is a skin rejuvenation resurfacing procedure and its associated apparatus wherein a punctile resurfacing procedure is performed on a subject patient using an oscillating, reciprocating high speed, non-thermal or thermal, needle-based device 12 for inducing mechanical and/or electrocoagulative trauma to an area of the skin to be treated." Mulholland at 6:14–23. "The skin area to be treated is treated using the needle-based device **12** by passing in a first direction. Then an alternating pass is done in a generally criss-crossing, random or circular pattern to the first direction and the treatment is repeated in this alternating criss-crossing, random or circular pattern. The typical desired number of passes made over the area of the skin to be treated in the criss-crossing pattern is one to 20 or more passes in each direction of the criss-crossing, circular or random pattern." Mulholland at 6:29-37.

'774 Patent Claim 11		Mulholland and/or Mulholland in view of Na '848
11.1	a device including a plurality of needles one of extending or extendable a desired distance from a surface, the desired distance selected to enable the plurality of needles to penetrate dermatological tissue; and	Mulholland discloses and/or renders obvious a device including a plurality of needles one of extending or extendable a desired distance from a surface, the desired distance selected to enable the plurality of needles to penetrate dermatological tissue. *See, e.g.*, Mulholland at Fig.3. "The hand piece and tip is placed over the skin with direct contact of the needle tip with the skin. By activating the device, the reciprocating oscillations ("in and out" motions of the needle tip) begin and, with each reciprocation the needles penetrate into the dermis, according to the depth that was set on by the adjustment of the plastic tip protector. The hand piece is then passed over the treated area. A few passes can be applied to the same area to increase treatment effect. With each pass there is a small amount of pin-point bleeding, which stops very quickly, due to the fractional nature of the injury and the presence of bridging epidermal skin segments. Most of the trauma is dermal and ecchymosis (bruising) is induced under the skin. It is the post dermal inflammation that will determine the level of new dermal substrate formation. After each pass, the small amount of blood residual on the surface is wiped off, clotting occurs very quickly and the next pass initiated. In order to reduce bleeding, thermal energy can be applied to coagulate the blood vessels in the wound. To coagulate the blood, the needles can be preheated prior to each insertion or RF energy can be applied to the needles. Amount of thermal or RF energy delivered to the tissue is controlled by dwelling time of the reciprocating mechanism." Mulholland at 3:66–4:22. "The inventive procedure is a skin rejuvenation resurfacing procedure comprising performing a punctile resurfacing procedure using an oscillating, reciprocating high speed, non-thermal or thermal, needle-based device for inducing mechanical trauma to an area of the skin to be treated." Mulholland at 5:27–31. "Reciprocation of needles can be done using a solenoid, motor with eccentric mechanism or piezoelectric element. Reciprocation depth depends on application and can be in the range from 0.5 mm up to 500 mm." Mulholland at 4:45–48. "Features of the needle-based device that are used and/or beneficial in the novel procedure are the more closely spaced needle configuration for more precise fractional dermal injury, possible pre-heating of the needles, the reciprocating mechanical handpiece for more rapid and predictable treatment of areas, the adjustable tip

'774 Patent Claim 11		Mulholland and/or Mulholland in view of Na '848
		for more control over the depth of the dermal injury, the hand held motor, comfortable, light and AC out of the wall power source (although DC current is also contemplated), the disposable needle tip and plastic tip guide, the device headpiece and sheath can be reused, the low cost of operation, the fact that the procedure does not use a laser device to directly create the fractional injury (but a laser or RF feature may be used to heat the needle), making it safer for the operator and patient, and that there is little risk of scars or hypopigmentation as needle-based device causes a non-thermal mediated injury." Mulholland at 5:11–26. "The needle-based device **12** comprises a hand-held portion **12** *a* housing means for oscillating and reciprocating an elongate needle portion **12** *b*. This a commercially available hand piece, also referred to as head piece, which houses the motor and oscillating means (not shown) and to which the elongate needle portion **12** *b* is connected at one end and in mechanical communication with the means for oscillating and reciprocating said needle portion **12** *b*. Typically, the needles **12** *d* oscillate/reciprocate at about 1 cycle per second to about 500 cycles per second. As mentioned above, the elongate needle portion **12** *b* has at its opposite end, a plurality of needles **12** *d* configured in a desired array, such as 2×6." Mulholland at 6:65–7:10. "A needle tip protector **12** *e* is attached over the plurality of needles **12** *d* and is slidably operable over the plurality of needles **12** *d* for serving as the needle depth adjustment means for obtaining the desired depth of needle penetration of said needle tips to the skin area being treated. Typically, the slidable protector is engaged with the end of the sheath **12** *c* and is pushed into or pulled away from the end of the sheath **12** *c* so that when the needle tips are extended at the maximum reciprocation distance away from hand piece **12** *a*, the distance between the tips and the protector edge equates to the maximum penetration depth desired to accomplish the desired treatment." Mulholland at 7:19–31 Mulholland at Fig.2A. Mulholland at Figs.4A & 4B. 1. An apparatus for use in a skin resurfacing and collagen remodeling procedure through creating of a mechanical trauma transdermally, the apparatus comprising : a needle array comprising a plurality of needles ;

'774 Patent Claim 11		Mulholland and/or Mulholland in view of Na '848
		a needle tip protector attached over the plurality of needles ; a reciprocating mechanism connected to the needle array and providing cyclic in and out movement of the plurality of needles between a completely retracted position within the needle tip protector to a completely extended position corresponding to a maximum skin penetration depth , with oscillating frequency at a predetermined cycles per second ; and an RF source connected to the needle array such that RF energy from the RF source is deliverable transdermally through the plurality of needles during the cyclic skin penetration wherein a RF power and the oscillating frequency of the plurality of needles are set to create tissue and blood coagulation around each of the plurality of needles during skin penetration . 2. The apparatus according to claim 1 , wherein the maximum skin penetration depth of the plurality of needles is adjustable from about 0.5 mm to about 500 mm . Mulholland claims 1 and 2
11.2	a signal generator electrically coupled to the plurality of extended needles to produce pulsed radio frequency signals across the plurality of needles to affect dermatological tissue near the plurality of needles.	Mulholland discloses and/or renders obvious a signal generator electrically coupled to the plurality of extended needles to produce pulsed radio frequency signals across the plurality of needles to affect dermatological tissue near the plurality of needles. *See, e.g.*, Mulholland at Fig.1. "To coagulate the blood, the needles can be preheated prior to each insertion or RF energy can be applied to the needles. Amount of thermal or RF energy delivered to the tissue is controlled by dwelling time of the reciprocating mechanism." Mulholland at 4:18-22. "Electromagnetic energy can be applied in ***pulsed manner*** and synchronized with needle array reciprocation." Mulholland at 4:43-44 (emphasis added). "An alternative embodiment shown in FIG. 5 comprises platform and hand piece **51**. The platform comprises of an AC/DC convertor converting AC power from the wall plug in stabilized DC voltage,

'774 Patent Claim 11		Mulholland and/or Mulholland in view of Na '848
		RF generator converting DC voltage from AC/DC convertor in high frequency alternating current, controller controlling RF power delivery to hand piece **51** and reciprocating speed and amplitude. Signals from controller, DC voltage and RF power are delivered to the hand piece **51** through harness **53**. Hand piece comprising reciprocating mechanism **52** powered by DC voltage from AC/DC converter and controlled by controller. Needle array **54** is mechanically connected to the reciprocating mechanism **52** and electrically to the RF generator through the harness **53**. RF energy is delivered to the tissue when needles get in contact with tissue and RF circuit is closed. When needle array **54** is moved back by reciprocating mechanism **52** the RF circuit is opened and RF energy delivery is terminated. RF power and reciprocation speed are adjusted to create coagulation of tissue around the needle. The heated needles may penetrate the skin and subcutaneous tissues to about from 0.5 mm to about 500 mm." Mulholland at 7:32–54. Mulholland at Fig.5. "Heating temperature and reciprocation speed are adjusted to create coagulation of tissue around the needle. The needles in the needle array may be preheated using contact with a hot element and may be preheated into the skin to the depth of from about 0.5 mm to about 500 mm." Mulholland at 8:7–11. I understand that the parties disagree as to the meaning of the claim term "pulsed radio frequency signals." To the extent that this claim limitation is not explicitly or inherently disclosed by Mulholland, it would have been obvious given the knowledge of a POSITA. For example, as noted above, Mulholland discloses an "RF generator converting DC voltage from AC/DC convertor in high frequency alternating current, controller controlling RF power delivery to hand piece **51**." Mulholland at 7:32–54. Mulholland further discloses that RF power and reciprocation speed are adjusted to create coagulation of tissue around the needle." *Id*. Mulholland describes that the RF signal is turned on and off in a cyclic fashion, thus forming a pulsed RF signal: "RF energy is delivered to the tissue when needles get in contact with tissue and RF circuit is closed. When needle array 54 is moved back by reciprocating mechanism 52 the RF circuit is open and Rf energy is terminated. RF energy

'774 Patent Claim 11		Mulholland and/or Mulholland in view of Na '848
		and reciprocating speed are adjusted to create coagulation of tissue around the needle ." Mulholland at 7:46-51. Mulholland further discloses: "To coagulate the blood, the needles can be preheated prior to each insertion or RF energy can be applied to the needles. Amount of thermal or RF energy delivered to the tissue is controlled by dwelling time of the reciprocating mechanism. . . . Electromagnetic energy can be applied in ***pulsed manner*** and synchronized with needle array reciprocation." Mulholland at 4:18-44 (emphasis added). As of the priority date of the '774 Patent, it was well known how to create pulsed radio frequency signals with an RF generator and controller. The selection of pulsed radio frequency signals was well established (*see* above) at that time and is a design choice that would have been obvious to a POSITA. Moreover, in my opinion, it would have been obvious to incorporate "pulsed radio frequency signals" in the Mulholland device in view of the teachings of Na '848. I understand that Na '848 is part of the same patent family as the '774 Patent. The disclosures of the pulsed signals in Na '848 are identical to those in the '774 Patent. For example, Na '848 discloses: [0028] ***The signal generator or module 370 may generate a vary of signals (such as shown in FIGS. 5 A to 6) to vibrate one or more pins 351 electrically coupled to the system 300 via the internal wire 331 and the conductive interface 390. In operation a user 20 may touch the conductive interface 390 and place one or more electrically coupled pins 351 in contact with their dermis to form an electrical pathway from the pin 351 to the electrical conductive interface 390.*** The signal generator 370 may include a battery to supply energy to generate one or more electrical signals. ***The switch 375 coupled to the generator 370 may cause the generator to produce one or more electrical signals for a predetermined time interval or until the switch 375 is***

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		triggered again. As noted a pin vibration 351 may increase the micro-wound or cut formed in dermis by the pin 351. [0029] FIG. 2D is a simplified cross-sectional diagram of an acupuncture apparatus 362 according to various embodiments. The apparatus 362 may include a handle 330, an elastic section 333, internal wire(s) 331, 332, ***signal generator 370***, switch 375, and plate 350. ***The signal generator 370 may be coupled to at least one pin 351 via internal wire 331 and coupled to at least one other pin 352 via internal wire 332.*** When active the pins 351, 352 may form at least one dipole pair. ***The signal generator or module 370 may generate a vary of signals (such as shown in FIGS. 5A to 6) to vibrate one or more dipole pair or bipolar pins 351, 352.*** [0033] ***FIGS. 3A and 3B are simplified isometric diagrams of acupuncture apparatus 400, 460 including at least one pin 451 that may be coupled to an electrical signal via an internal wire 458.*** Each apparatus 400, 460 includes curved roller 450 having a plurality of acupuncture pins 451 where the pins 451 may be similar to pins 351. In apparatus 400, the electrical lead wire 400A may be coupled to an electrical interface 410 in the apparatus handle 430 where the interface 410 is electrically coupled to the internal wire 458. In apparatus 460, the handle 430 may include ***a signal generator 470*** similar to generator 370, switch 475, and conduction surface 490. Apparatus 460 may operate similar to apparatus 360 in operation other than the rolling capability of the apparatus 460, 400. In an embodiment the rollers 450 may have various configurations to conform to a dermal area to be treated. [0039] ***FIGS.5A-5B are diagrams of electrical signal waveforms 650, 630, 640 that may be applied*** to one or more LEDs 32A, 32B, 532 and ***to the pins 230, 351, 451 according to various embodiments***. ***The signal waveform 650 includes several square -wave pulses 652, 654, 656*** that may be applied to an LED 32A, 32B, 532. Each pulse 652, 654, 656 may a have a similar magnitude and envelope. ***The waveform 650 may be used to energize*** an LED 32A, 32B, 532 and to ***the pins 230, 351, 451 periodically Pl for a predetermined interval Tl where each pulse 652, 654, 656 has a[n] amplitude Al***. In an embodiment, Al may be about 0.1 milliamperes (mA) to 10 mA, the pulse width Tl may be

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		about 100 microsecond (μs) to 500 μs and the period Pl may from 100 ms to 500 ms as a function of the energy required to create capacitance in a liquid. In another embodiment, Al may be about 0.5 milliamperes (mA) to 5 mA, the pulse width Tl may be about 200 microsecond (μs) and the period Pl may about 250 ms as a function of the energy to drive an LED or cause one or more pins 230, 351, 451 to vibrate. [0040] ***In FIG. 5B a signal waveform 630 may be applied*** to a first LED 32A, 32B, 532 module or group and ***to the pins 230, 351 , 451*** and ***a second waveform 640 may be applied or used to energize*** a second LED 32A, 32B, 532 module and ***the pins 230, 351, 451, 352***. ***The signal waveform 630 includes several square-wave pulses 632, 634, and 636 and the signal waveform 640 includes several square-wave pulses 642, 644, and 646. Each pulse 632, 634, 636, 642, 644, 646 may a have a similar magnitude and envelope. The waveform 630 may be used to energize*** a first LED 32A, 32B, 332 module and ***the pins 230, 351, 451 periodically Pl for a predetermined interval Tl where each pulse 632, 634, 636 has an amplitude Al***. ***The waveform 640 may be used to energize*** a second LED 32A, 32B, 332 module and ***the pins 230, 351, 451 periodically P2 for a predetermined interval T2 where each pulse 642, 644, 646 has an amplitude Bl***. The pulse width Tl, T2 may be about 100 microsecond (μs) to 500 μs and the period Pl, P2 may from 100 ms to 500 ms as a function of the energy to affect dermalogical cells or chemicals 22A. In another embodiment, Al, A2 may be about 0.5 milliamperes (mA) to 5 mA, the pulse width Tl, T2 may be about 200 microsecond (μs) and the period Pl, P2 may about 250 ms as a function of the energy required to affect dermalogical cells or chemicals 22 A. In an embodiment the pulses 632, 634, 636 do not substantially overlap the pulses 642, 644, 646. In an embodiment Tl > T2 and P2 is an integer multiple of Pl . [0041] ***FIG. 6 depicts a waveform 670 that includes multiple pulses 672, 674, 676, 678, 682, and 684 that may not overlap in the time or the frequency domain. In an embodiment each pulse 672, 674, 676, 678, 682, and 684 may have a pulse width T3, and frequency spectrum width Fl and period P3. The pulse 672 is frequency offset from the pulse 674, the pulse 676 is frequency offset from the pulse 678, and the pulse 682 is frequency offset from the pulse 684. The pulses 672, 674, 676, 678, 682, and 684***

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		may be applied to an LED module to affect dermalogical cells or chemicals 22A and ***the pins 230, 351, 451***. Pulses 672, 674 having different frequency spectrums may enable different LED stimulation. In an embodiment the pulses 672, 676, 682 may be applied to a first LED module and the pulses 674, 678, 684 may be applied to a second LED module. ***The frequency separation between the respective pulses may enable simultaneous energization of a first and a second LED module and the pins 230, 351, 451*** and subsequent and independent spectrum generation. [0042] In an embodiment the invention may employ the algorithm 740 shown in FIG. 7A to apply therapy to dermalogical cells. A user, clinician, or equipment may place an apparatus 10, 320, 360, 360, 400, 460 on dermalogical cells to be treated (activity 741) including pressing the apparatus against the cells firmly enough to embed one or more pins 251 , 351 , 451 in the cells. ***A first signal such as shown in FIGS. 5A, 5B, and 6 may be applied to*** a first LED module or group (32A) and ***the pins 230, 351, 451 of a dermalogical apparatus 10, 320, 360, 360, 400, 460 (activity 742) for a predetermined time period (activity 744)***. ***A second signal such as shown in FIGS. 5 A, 5B, and 6 may be applied to*** a second LED module or group (32B) and ***the pins 230, 351, 451 of a dermalogical apparatus 10, 320, 360, 360, 400, 460 (activity 746) for a predetermined time period (activity 748)***. The signals applied to the groups may be selected to stimulate dermalogical cells or chemicals 22A or cause vibration of one or more pins 251, 351, 451. [0043] In another embodiment the invention may employ the algorithm 750 shown in FIG. 7B to apply therapy to dermalogical cells. A user, clinician, or equipment may apply a light sensitive chemical on an apparatus 10, 320, 360, 360, 400, 460 or on dermalogical cells to be treated (activity 751). The user, clinician, or equipment may place apparatus 10, 320, 360, 360, 400, 460 on dermalogical cells to be treated (activity 752). ***A signal such as shown in FIGS. 5A, 5B, and 6 may be applied to*** a LED module or group (32A or 32B) and ***the pins 230, 351 , 451 (activity 354) for a predetermined time period (activity 356)***. [0044] In another embodiment the invention may employ the algorithm 760 shown in FIG. 7C to apply therapy to

'774 Patent Claim 11		Mulholland and/or Mulholland in view of Na '848
		dermalogical cells. A user, clinician, or equipment may apply a light sensitive chemical on an apparatus 10, 320, 360, 360, 400, 460 or on dermalogical cells to be treated (activity 761). The user, clinician, or equipment may place an apparatus 10, 320, 360, 360, 400, 460 on dermalogical cells to be treated (activity 762). ***A first signal such as shown in FIGS. 5A, 5B, and 6 may be applied to*** a first LED module or group (32A) and ***one or more pins 251, 351, 451 of a dermalogical apparatus 10, 320, 360, 360, 400, 460 (activity 763) for a predetermined time period (activity 764)***. ***A second signal such as shown in FIGS. 5 A, 5B, and 6 may be applied to*** a second LED module or group (32B) and ***one or more pins 251 , 351 , 451 of a dermalogical apparatus 10, 320, 360, 360, 400, 460 (activity 766) for a predetermined time period (activity 768).*** The POSITA would have understood from Na '848 the benefit of including a "variety of signals" including pulsed radio frequency signals in a dermatological device. It was well-known that providing a variety of signal types, including pulsed radio frequency signals, was advantageous with respect to providing dermatological treatments. Therefore, the POSITA would have been motivated to modify the Mulholland device with the pulsed radio frequency signals of Na '848. Configuring Mulholland's RF generator and controller to supply pulsed radio frequency signals would have been a matter of routine engineering as of the priority date of the '774 Patent, as evidenced by the numerous dermatological treatment devices which included pulsed radio frequency signals for this purpose.

488. In view of the foregoing chart, claim 11 of the '774 Patent is anticipated by the teachings of Mulholland. Further, to the extent Complainant argues that any of the foregoing limitations are not explicitly or inherently disclosed by Mulholland, such limitations would have been obvious given the knowledge of a POSITA, and/or further in view of the teachings of Na '848. The teachings of Mulholland are so similar to what is claimed that any alleged difference between the teachings of Mulholland and what is claimed would not have been of patentable significance given the knowledge of a POSITA.

489. It is my opinion that Claim 12 of the '774 Patent is anticipated by Mulholland and/or rendered obvious by Mulholland alone or Mulholland in view of Na '848 as detailed below:

'774 Patent Claim 12		Mulholland and/or Mulholland in view of Na '848
12.0	12. The apparatus for treating dermatological tissue of claim 11, wherein the device includes an end surface configured to be placed on or near dermatological tissue to be treated, the end surface including a plurality of needles extendable a desired distance from the end surface.	***Claim 12 of the '774 Patent is anticipated by Mulholland and/or rendered obvious by Mulholland alone or Mulholland in view of Na '848.*** Mulholland discloses and/or renders obvious (either alone or in view of Na '848) the apparatus for treating dermatological tissue of claim 11. *See* claim 11. Mulholland discloses and/or renders obvious the device includes an end surface configured to be placed on or near dermatological tissue to be treated, the end surface including a plurality of needles extendable a desired distance from the end surface. *See, e.g.*, Mulholland at Fig.3. "The hand piece and tip is placed over the skin with direct contact of the needle tip with the skin. By activating the device, the reciprocating oscillations ("in and out" motions of the needle tip) begin and, with each reciprocation the needles penetrate into the dermis, according to the depth that was set on by the adjustment of the plastic tip protector. The hand piece is then passed over the treated area. A few passes can be applied to the same area to increase treatment effect. With each pass there is a small amount of pin-point bleeding, which stops very quickly, due to the fractional nature of the injury and the presence of bridging epidermal skin segments. Most of the trauma is dermal and ecchymosis (bruising) is induced under the skin. It is the post dermal inflammation that will determine the level of new dermal substrate formation. After each pass, the small amount of blood residual on the surface is wiped off, clotting occurs very quickly and the next pass initiated. In order to reduce bleeding, thermal energy can be applied to coagulate the blood vessels in the wound. To coagulate the blood, the needles can be preheated prior to each insertion or RF energy can be applied to the needles. Amount of thermal

'774 Patent Claim 12		Mulholland and/or Mulholland in view of Na '848
		or RF energy delivered to the tissue is controlled by dwelling time of the reciprocating mechanism." Mulholland at 3:66–4:22. "The inventive procedure is a skin rejuvenation resurfacing procedure comprising performing a punctile resurfacing procedure using an oscillating, reciprocating high speed, non-thermal or thermal, needle-based device for inducing mechanical trauma to an area of the skin to be treated." Mulholland at 5:27–31. "Reciprocation of needles can be done using a solenoid, motor with eccentric mechanism or piezoelectric element. Reciprocation depth depends on application and can be in the range from 0.5 mm up to 500 mm." Mulholland at 4:45–48. "Features of the needle-based device that are used and/or beneficial in the novel procedure are the more closely spaced needle configuration for more precise fractional dermal injury, possible pre-heating of the needles, the reciprocating mechanical handpiece for more rapid and predictable treatment of areas, the adjustable tip for more control over the depth of the dermal injury, the hand held motor, comfortable, light and AC out of the wall power source (although DC current is also contemplated), the disposable needle tip and plastic tip guide, the device headpiece and sheath can be reused, the low cost of operation, the fact that the procedure does not use a laser device to directly create the fractional injury (but a laser or RF feature may be used to heat the needle), making it safer for the operator and patient, and that there is little risk of scars or hypopigmentation as needle-based device causes a non-thermal mediated injury." Mulholland at 5:11–26. "The needle-based device **12** comprises a hand-held portion **12** *a* housing means for oscillating and reciprocating an elongate needle portion **12** *b*. This a commercially available hand piece, also referred to as head piece, which houses the motor and oscillating means (not shown) and to which the elongate needle portion **12** *b* is connected at one end and in

'774 Patent Claim 12		Mulholland and/or Mulholland in view of Na '848
		mechanical communication with the means for oscillating and reciprocating said needle portion **12** *b*. Typically, the needles **12** *d* oscillate/reciprocate at about 1 cycle per second to about 500 cycles per second. As mentioned above, the elongate needle portion **12** *b* has at its opposite end, a plurality of needles **12** *d* configured in a desired array, such as 2×6." Mulholland at 6:65–7:10. "A needle tip protector **12** *e* is attached over the plurality of needles **12** *d* and is slidably operable over the plurality of needles **12** *d* for serving as the needle depth adjustment means for obtaining the desired depth of needle penetration of said needle tips to the skin area being treated. Typically, the slidable protector is engaged with the end of the sheath **12** *c* and is pushed into or pulled away from the end of the sheath **12** *c* so that when the needle tips are extended at the maximum reciprocation distance away from hand piece **12** *a*, the distance between the tips and the protector edge equates to the maximum penetration depth desired to accomplish the desired treatment." Mulholland at 7:19–31. Mulholland at Fig.2A. Mulholland at Figs.4A & 4B. The end of the slidable protector is obviously in contact with the skin (tissue to be treated) and the needles are extendable a desirable distance form the end of this surface. To the extent that this claim limitation is not explicitly or inherently disclosed by Mulholland, it would have been obvious given the knowledge of a POSITA. For example, at least Mehta, Mulholland, ScarLet and Lee '500 each disclose a plurality of needles extendable a desired distance from an end surface, disclose various mechanisms for causing the plurality of extendable needles to extend a desired distance from the end surface and a motor coupled to the plurality of extendable needles that may be directed to cause the plurality of the extendable needles to extend a desired distance from the end surface. *See, e.g.*, Mehta at 3:29-39; 3:40-41; 4:63-5:2; 5:3-15; 6:64-65; 9:34-55; 10:33-39; 12:5-14; 13:54-57; Fig. 3A; 13:58-4; 15:27-33; 15:55-16:11; Fig. 4A; 16:42-58; 16:59-17:12; 18:21-37; Fig. 5; 32:46-62; Fig. 10B; 32:63-33:14; 33:15-29; 33:30-34; 33:57-13; Fig. 10E; 34:38-45; 35:8-22; Fig. 12A; and Fig.

'774 Patent Claim 12		Mulholland and/or Mulholland in view of Na '848
		12B; Mulholland at 4:45-48, 5:11-26, 6:65-8:10, 7:19-31; ScarLet at SERENDIA-00017328, SERENDIA-00017331, Ilooda-0006078 (at 7); Lee '500 at Para. 42, 43, 44, 52, 53, 55, 56, 61; claims 1, 2, 7. As of the priority date of the '774 Patent, it was well known that controlling the depth of penetration for the needles and being able to retract the needles was advantageous with respect to providing dermatological treatments. *See, e.g.*, Hantash 2009 at pg. 88; pg. 90; pg. 92; Figs. 2, 1; Hantash 718 PCT at [0017]; [0035]; [0041]; [0042]; [0045]; [0046]; [0068]; [0069]; and [0070]; Mehta at 3:29-39; 3:40-41; 4:63-5:2; 5:3-15; 6:64-65; 9:34-55; 10:33-39; 12:5-14; 13:54-57; Fig. 3A; 13:58-4; 15:27-33; 15:55-16:11; Fig. 4A; 16:42-58; 16:59-17:12; 18:21-37; Fig. 5; 32:46-62; Fig. 10B; 32:63-33:14; 33:15-29; 33:30-34; 33:57-13; Fig. 10E; 34:38-45; 35:8-22; Fig. 12A; and Fig. 12B; Mulholland at 4:45-48, 5:11-26, 6:65-8:10, 7:19-31; ScarLet at SERENDIA-00017328, SERENDIA-00017331, Ilooda-0006078 (at 7); Lee '500 at Para. 42, 43, 44, 52, 53, 55, 56, 61; claims 1, 2, 7. To the extent Mulholland does not explicitly disclose that the needles of a dermatological treatment device are extendable using a motor, it would have been obvious to modify the dermatological treatment device to make the needles retractable and extendable to a desired depth using a motor connected to the needles to achieve enhanced safety (by having the needles retracted when not in use) and enhanced customizability of treatment (by specifying the needle penetration depth). *See id.* Configuring a plurality of needles to be attached to a motor would have been a matter of routine engineering as of the priority date of the '774 Patent, as evidenced by the numerous dermatological treatment devices which included a motor for this purpose. Additionally, as of the priority date of the '774 Patent, it was well known how to create linear force using various manual and automated mechanisms, including a motor. The selection of the mechanism to achieve this purpose is a design choice that would have been obvious to a POSITA.

490. In view of the foregoing chart, claim 12 of the '774 Patent is anticipated by the teachings of Mulholland. Further, to the extent Complainant argues that any of the foregoing limitations are not explicitly or inherently disclosed by Mulholland, such limitations would have been obvious given the knowledge of a POSITA, and/or further in view of the teachings of Na

‘848. The teachings of Mulholland are so similar to what is claimed that any alleged difference between the teachings of Mulholland and what is claimed would not have been of patentable significance given the knowledge of a POSITA.

491. It is my opinion that Claim 13 of the ‘774 Patent is anticipated by Mulholland and/or rendered obvious by Mulholland alone or Mulholland in view of Na ‘848 as detailed below:

‘774 Patent Claim 13		Mulholland and/or Mulholland in view of Na ‘848
13.0	13. The apparatus for treating dermatological tissue of claim 12, further including a mechanism for causing the plurality of the extendable needles to extend a desired distance from the end surface.	***Claim 13 of the ‘774 Patent is anticipated by Mulholland and/or rendered obvious by Mulholland alone or Mulholland in view of Na ‘848.*** Mulholland discloses and/or renders obvious (either alone or in view of Na ‘848) the apparatus for treating dermatological tissue of claim 12. *See* claim 12. Mulholland discloses and/or renders obvious a mechanism for causing the plurality of the extendable needles to extend a desired distance from the end surface. *See, e.g.*, “Reciprocation of needles can be done using a solenoid, motor with eccentric mechanism or piezoelectric element. Reciprocation depth depends on application and can be in the range from 0.5 mm up to 500 mm.” Mulholland at 4:45–48. “Features of the needle-based device that are used and/or beneficial in the novel procedure are the more closely spaced needle configuration for more precise fractional dermal injury, possible pre-heating of the needles, the reciprocating mechanical handpiece for more rapid and predictable treatment of areas, the adjustable tip for more control over the depth of the dermal injury, the hand held motor, comfortable, light and AC out of the wall power source (although DC current is also contemplated), the disposable needle tip and plastic tip guide, the device headpiece and sheath can be reused, the low cost of operation, the fact that the procedure does not use a laser device to directly create the fractional injury (but a laser or RF feature may be used to

'774 Patent Claim 13		Mulholland and/or Mulholland in view of Na '848
		heat the needle), making it safer for the operator and patient, and that there is little risk of scars or hypopigmentation as needle-based device causes a non-thermal mediated injury." Mulholland at 5:11–26. "The needle-based device **12** comprises a hand-held portion **12** *a* housing means for oscillating and reciprocating an elongate needle portion **12** *b*. This a commercially available hand piece, also referred to as head piece, which houses the motor and oscillating means (not shown) and to which the elongate needle portion **12** *b* is connected at one end and in mechanical communication with the means for oscillating and reciprocating said needle portion **12** *b*. Typically, the needles **12** *d* oscillate/reciprocate at about 1 cycle per second to about 500 cycles per second. As mentioned above, the elongate needle portion **12** *b* has at its opposite end, a plurality of needles **12** *d* configured in a desired array, such as 2×6." Mulholland at 6:65–7:10. "A needle tip protector **12** *e* is attached over the plurality of needles **12** *d* and is slidably operable over the plurality of needles **12** *d* for serving as the needle depth adjustment means for obtaining the desired depth of needle penetration of said needle tips to the skin area being treated. Typically, the slidable protector is engaged with the end of the sheath **12** *c* and is pushed into or pulled away from the end of the sheath **12** *c* so that when the needle tips are extended at the maximum reciprocation distance away from hand piece **12** *a*, the distance between the tips and the protector edge equates to the maximum penetration depth desired to accomplish the desired treatment." Mulholland at 7:19–31 Mulholland clearly teaches that a motor is attached to and in mechanical communication to the plurality of extendable needles to extend them a desired distance from the end surface of the protector. To the extent that this claim limitation is not explicitly or inherently disclosed by Mulholland, it would have been obvious given the knowledge of a POSITA. For example, at least Mehta, Mulholland, ScarLet and Lee '500 each disclose a plurality of needles extendable a desired distance from an end surface, disclose various mechanisms

'774 Patent Claim 13		Mulholland and/or Mulholland in view of Na '848
		for causing the plurality of extendable needles to extend a desired distance from the end surface and a motor coupled to the plurality of extendable needles that may be directed to cause the plurality of the extendable needles to extend a desired distance from the end surface. *See, e.g.*, Mehta at 3:29-39; 3:40-41; 4:63-5:2; 5:3-15; 6:64-65; 9:34-55; 10:33-39; 12:5-14; 13:54-57; Fig. 3A; 13:58-4; 15:27-33; 15:55-16:11; Fig. 4A; 16:42-58; 16:59-17:12; 18:21-37; Fig. 5; 32:46-62; Fig. 10B; 32:63-33:14; 33:15-29; 33:30-34; 33:57-13; Fig. 10E; 34:38-45; 35:8-22; Fig. 12A; and Fig. 12B; Mulholland at 4:45-48, 5:11-26, 6:65-8:10, 7:19-31; ScarLet at SERENDIA-00017328, SERENDIA-00017331, Ilooda-0006078 (at 7); Lee '500 at Para. 42, 43, 44, 52, 53, 55, 56, 61; claims 1, 2, 7. As of the priority date of the '774 Patent, it was well known that controlling the depth of penetration for the needles and being able to retract the needles was advantageous with respect to providing dermatological treatments. *See, e.g.*, Hantash 2009 at pg. 88; pg. 90; pg. 92; Figs. 2, 1; Hantash 718 PCT at [0017]; [0035]; [0041]; [0042]; [0045]; [0046]; [0068]; [0069]; and [0070]; Mehta at 3:29-39; 3:40-41; 4:63-5:2; 5:3-15; 6:64-65; 9:34-55; 10:33-39; 12:5-14; 13:54-57; Fig. 3A; 13:58-4; 15:27-33; 15:55-16:11; Fig. 4A; 16:42-58; 16:59-17:12; 18:21-37; Fig. 5; 32:46-62; Fig. 10B; 32:63-33:14; 33:15-29; 33:30-34; 33:57-13; Fig. 10E; 34:38-45; 35:8-22; Fig. 12A; and Fig. 12B; Mulholland at 4:45-48, 5:11-26, 6:65-8:10, 7:19-31; ScarLet at SERENDIA-00017328, SERENDIA-00017331, Ilooda-0006078 (at 7); Lee '500 at Para. 42, 43, 44, 52, 53, 55, 56, 61; claims 1, 2, 7. To the extent Mulholland does not explicitly disclose that the needles of a dermatological treatment device are extendable using a motor, it would have been obvious to modify the dermatological treatment device to make the needles retractable and extendable to a desired depth using a motor connected to the needles to achieve enhanced safety (by having the needles retracted when not in use) and enhanced customizability of treatment (by specifying the needle penetration depth). *See id.* Configuring a plurality of needles to be attached to a motor would have been a matter of routine engineering as of the priority date of the '774 Patent, as evidenced by the numerous dermatological treatment devices which included a motor for this purpose. Additionally, as of the priority date of the '774 Patent, it was well known how to create linear force using various manual and automated mechanisms, including a motor. The selection of the

'774 Patent Claim 13		Mulholland and/or Mulholland in view of Na '848
		mechanism to achieve this purpose is a design choice that would have been obvious to a POSITA.

492. In view of the foregoing chart, claim 13 of the '774 Patent is anticipated by the teachings of Mulholland. Further, to the extent Complainant argues that any of the foregoing limitations are not explicitly or inherently disclosed by Mulholland, such limitations would have been obvious given the knowledge of a POSITA, and/or further in view of the teachings of Na '848. The teachings of Mulholland are so similar to what is claimed that any alleged difference between the teachings of Mulholland and what is claimed would not have been of patentable significance given the knowledge of a POSITA.

493. It is my opinion that Claim 14 of the '774 Patent is anticipated by Mulholland and/or rendered obvious by Mulholland alone or Mulholland in view of Na '848 as detailed below:

'774 Patent Claim 14		Mulholland and/or Mulholland in view of Na '848
14.0	14. The apparatus for treating dermatological tissue of claim 12, further including a motor coupled to the plurality of extendable needles that may be directed to cause the plurality of the extendable needles to	***Claim 14 of the '774 Patent is anticipated by Mulholland and/or rendered obvious by Mulholland alone or Mulholland in view of Na '848.*** Mulholland discloses and/or renders obvious (either alone or in view of Na '848) the apparatus for treating dermatological tissue of claim 12. *See* claim 12. Mulholland discloses and/or renders obvious a motor coupled to the plurality of extendable needles that may be directed to cause the plurality of the extendable needles to extend a desired distance from the end surface. *See, e.g.*, "Reciprocation of needles can be done using a solenoid, motor with eccentric mechanism or piezoelectric element. Reciprocation depth

'774 Patent Claim 14		Mulholland and/or Mulholland in view of Na '848
	extend a desired distance from the end surface.	depends on application and can be in the range from 0.5 mm up to 500 mm." Mulholland at 4:45–48. "Features of the needle-based device that are used and/or beneficial in the novel procedure are the more closely spaced needle configuration for more precise fractional dermal injury, possible pre-heating of the needles, the reciprocating mechanical handpiece for more rapid and predictable treatment of areas, the adjustable tip for more control over the depth of the dermal injury, the hand held motor, comfortable, light and AC out of the wall power source (although DC current is also contemplated), the disposable needle tip and plastic tip guide, the device headpiece and sheath can be reused, the low cost of operation, the fact that the procedure does not use a laser device to directly create the fractional injury (but a laser or RF feature may be used to heat the needle), making it safer for the operator and patient, and that there is little risk of scars or hypopigmentation as needle-based device causes a non-thermal mediated injury." Mulholland at 5:11–26. "The needle-based device **12** comprises a hand-held portion **12** *a* housing means for oscillating and reciprocating an elongate needle portion **12** *b*. This a commercially available hand piece, also referred to as head piece, which houses the motor and oscillating means (not shown) and to which the elongate needle portion **12** *b* is connected at one end and in mechanical communication with the means for oscillating and reciprocating said needle portion **12** *b*. Typically, the needles **12** *d* oscillate/reciprocate at about 1 cycle per second to about 500 cycles per second. As mentioned above, the elongate needle portion **12** *b* has at its opposite end, a plurality of needles **12** *d* configured in a desired array, such as 2×6." Mulholland at 6:65–7:10. "A needle tip protector **12** *e* is attached over the plurality of needles **12** *d* and is slidably operable over the plurality of needles **12** *d* for serving as the needle depth adjustment means for obtaining the desired depth of needle penetration of said needle tips to the skin area being treated. Typically, the slidable protector is engaged with the end of the sheath **12** *c* and is pushed into or pulled away from the end of the

'774 Patent Claim 14		Mulholland and/or Mulholland in view of Na '848
		sheath **12** *c* so that when the needle tips are extended at the maximum reciprocation distance away from hand piece **12** *a*, the distance between the tips and the protector edge equates to the maximum penetration depth desired to accomplish the desired treatment." Mulholland at 7:19–31 To the extent that this claim limitation is not explicitly or inherently disclosed by Mulholland, it would have been obvious given the knowledge of a POSITA. For example, at least Mehta, Mulholland, ScarLet and Lee '500 each disclose a plurality of needles extendable a desired distance from an end surface, disclose various mechanisms for causing the plurality of extendable needles to extend a desired distance from the end surface and a motor coupled to the plurality of extendable needles that may be directed to cause the plurality of the extendable needles to extend a desired distance from the end surface. *See, e.g.*, Mehta at 3:29-39; 3:40-41; 4:63-5:2; 5:3-15; 6:64-65; 9:34-55; 10:33-39; 12:5-14; 13:54-57; Fig. 3A; 13:58-4; 15:27-33; 15:55-16:11; Fig. 4A; 16:42-58; 16:59-17:12; 18:21-37; Fig. 5; 32:46-62; Fig. 10B; 32:63-33:14; 33:15-29; 33:30-34; 33:57-13; Fig. 10E; 34:38-45; 35:8-22; Fig. 12A; and Fig. 12B; Mulholland at 4:45-48, 5:11-26, 6:65-8:10, 7:19-31; ScarLet at SERENDIA-00017328, SERENDIA-00017331, Ilooda-0006078 (at 7); Lee '500 at Para. 42, 43, 44, 52, 53, 55, 56, 61; claims 1, 2, 7. As of the priority date of the '774 Patent, it was well known that controlling the depth of penetration for the needles and being able to retract the needles was advantageous with respect to providing dermatological treatments. *See, e.g.*, Hantash 2009 at pg. 88; pg. 90; pg. 92; Figs. 2, 1; Hantash 718 PCT at [0017]; [0035]; [0041]; [0042]; [0045]; [0046]; [0068]; [0069]; and [0070]; Mehta at 3:29-39; 3:40-41; 4:63-5:2; 5:3-15; 6:64-65; 9:34-55; 10:33-39; 12:5-14; 13:54-57; Fig. 3A; 13:58-4; 15:27-33; 15:55-16:11; Fig. 4A; 16:42-58; 16:59-17:12; 18:21-37; Fig. 5; 32:46-62; Fig. 10B; 32:63-33:14; 33:15-29; 33:30-34; 33:57-13; Fig. 10E; 34:38-45; 35:8-22; Fig. 12A; and Fig. 12B; Mulholland at 4:45-48, 5:11-26, 6:65-8:10, 7:19-31; ScarLet at SERENDIA-00017328, SERENDIA-00017331, Ilooda-0006078 (at 7); Lee '500 at Para. 42, 43, 44, 52, 53, 55, 56, 61; claims 1, 2, 7. To the extent Mulholland does not explicitly disclose that the needles of a dermatological treatment device are extendable using a motor, it would have been obvious to modify the dermatological treatment device to make the needles retractable and extendable to a desired depth using a motor connected to the needles to achieve enhanced safety (by having the needles retracted when not

'774 Patent Claim 14		Mulholland and/or Mulholland in view of Na '848
		in use) and enhanced customizability of treatment (by specifying the needle penetration depth). *See id.* Configuring a plurality of needles to be attached to a motor would have been a matter of routine engineering as of the priority date of the '774 Patent, as evidenced by the numerous dermatological treatment devices which included a motor for this purpose. Additionally, as of the priority date of the '774 Patent, it was well known how to create linear force using various manual and automated mechanisms, including a motor. The selection of the mechanism to achieve this purpose is a design choice that would have been obvious to a POSITA.

494. In view of the foregoing chart, claim 14 of the '774 Patent is anticipated by the teachings of Mulholland. Further, to the extent Complainant argues that any of the foregoing limitations are not explicitly or inherently disclosed by Mulholland, such limitations would have been obvious given the knowledge of a POSITA, and/or further in view of the teachings of Na '848. The teachings of Mulholland are so similar to what is claimed that any alleged difference between the teachings of Mulholland and what is claimed would not have been of patentable significance given the knowledge of a POSITA.

4. Claims 13 and 14 of the '774 Patent are rendered Obvious by Na '848 alone or Na '848 in view of Mehta, ScarLet, and/or Mulholland

495. It is my opinion that Na '848 renders obvious each asserted claim of the '774 Patent.

496. Na '848 in view of the knowledge of a POSITA renders each of the '774 Patent's asserted claims obvious. A POSITA would have understood that any limitations in the Asserted Claims arguably not explicitly disclosed by Na '848 were obvious in view of the state of the relevant art. A POSITA would have been motivated to draw upon his or her knowledge of the

relevant art to modify Na '848 as necessary to achieve any of the claimed features and would have enjoyed a reasonable expectation of success in doing so. A POSITA would have enjoyed a reasonable expectation of success in combining and/or modifying the teachings of Na '848, together with general knowledge of the art, to achieve the claimed subject matter, at least because the prior art itself discloses and/or practices the claimed methods and apparatuses to achieve the claimed results. A POSITA would have recognized that the relevant art is predictable, and that achieving the claimed subject matter would have been obvious to try or requires merely routine optimization.

497. To the extent Na '848 does not render one or more of the '774 Patent's asserted claims obvious, the claims would have been obvious over Na '848 in view of Mehta, ScarLet, and/or Mulholland. Na '848, Mehta, ScarLet, and/or Mulholland discuss or address the same or substantially similar underlying apparatus and/or technology in the field of dermatological treatment and devices such that a POSITA would have understood that these references can be combined, according to known methods and/or by the simple substitution of one known, equivalent element for another, to yield predictable results and with a reasonable expectation of success.

498. A POSITA would also have been motivated to combine Na '848 with Mehta, ScarLet, and/or Mulholland in light of market forces in the industry, and the desire to improve features and performance, and/or in light of one or more teachings, suggestions, or motivations in the art. A POSITA would have enjoyed a reasonable expectation of success in combining and/or modifying the teachings of the foregoing prior art references and products, together with general knowledge of the art, to achieve the claimed subject matter, at least because the prior art itself discloses and/or practices the claimed methods and apparatuses to achieve the claimed

results. A POSITA would have recognized that the relevant art is predictable, and that achieving the claimed subject matter would have been obvious to try or requires merely routine optimization.

499. Claims 13 and 14 of the'774 Patent depend from unasserted claim 12, which ultimately depends from unasserted claim 11. It is my opinion that claims 13 and 14 are rendered obvious by Na '848 (in view of the knowledge of a POSITA) or Na '848 in view of Mehta, ScarLet, and/or Mulholland as detailed below:

'774 Patent Claim 11		**Na '848 and/or Na '848 in view of Mehta, ScarLet, and/or Mulholland**
11.0	11. An apparatus for treating dermatological tissue, comprising:	***Claim 11 of the '774 Patent is rendered obvious by Na '848 alone or Na '848 in view of Mehta, ScarLet, and/or Mulholland.*** To the extent the preamble is limiting, Na '848 discloses and/or renders obvious an apparatus for treating dermatological tissue. *See, e.g.*: Na '848 at Fig. 2A Technical Field [0002] Various embodiments described herein relate generally to treating dermalogical tissue, including systems, and methods used in treating dermalogical tissue. Background Information [0003] It may be desirable to treat dermalogical tissue, the present invention provides such treatment. [0008] FIG. 2A is a simplified isometric diagram of a dermalogical treatment architecture according to various embodiments.
11.1	a device including a plurality of needles one of extending or extendable a desired distance from a surface, the desired distance selected	Na '848 discloses and/or renders obvious a device including a plurality of needles one of extending or extendable a desired distance from a surface, the desired distance selected to enable the plurality of needles to penetrate dermatological tissue. *See, e.g.*: Na '848 at Fig. 2A

'774 Patent Claim 11		Na '848 and/or Na '848 in view of Mehta, ScarLet, and/or Mulholland
	to enable the plurality of needles to penetrate dermatological tissue; and	Na '848 at Fig. 7A, 7B, 7C Technical Field [0002] Various embodiments described herein relate generally to treating dermalogical tissue, including systems, and methods used in treating dermalogical tissue. Background Information [0003] It may be desirable to treat dermalogical tissue, the present invention provides such treatment. [0026] FIG. 2 A is a simplified diagram of a dermalogical treatment architecture 310 according to various embodiments. Architecture 310 includes an acupuncture apparatus 320 and an electrical signal generation system 300. The [*sic*] electrical signal generation system 300 may be electrically coupled to the acupuncture apparatus 320 via one or more wires 300A and to a mammal 20 to be treated via one or more wires 300B. FIG. 2B is a simplified cross-sectional diagram of the acupuncture apparatus 320 according to various embodiments. The apparatus 320 may include a handle 330, elastic section 333, electrical interface 340, internal wire(s) 33 land plate 350. ***The pins 351 may have a length A (0.3 mm to 2.1 mm in an embodiment)*** where at least one pin 351 is electrically coupled to the electrical interface 340 via the internal wire 331. The electrical interface 340 may be removably connected to the system 300 wire 300A. [0027] The electrical signal generation system 300 may generate a vary of signals (such as shown in FIGS. 5 A to 6) to vibrate one or more pins 351 electrically coupled to the system 300 via the internal wire 331 and lead 300A. A pin vibration 351 may increase the micro-wound or cut formed in dermis by the pin 351. FIG. 2C is a simplified cross-sectional diagram of an acupuncture apparatus 360 according to various embodiments. The apparatus 360 may include a handle 330, an elastic section 333, an electrical conductive interface 390, internal wire(s) 331, signal generator 370, switch 375, and plate 350. The signal generator 370 may be coupled to at least one pin 351 via internal wire 331 and coupled to the conductive interface 390.

'774 Patent Claim 11		Na '848 and/or Na '848 in view of Mehta, ScarLet, and/or Mulholland
		[0028] The signal generator or module 370 may generate a vary of signals (such as shown in FIGS. 5 A to 6) to vibrate one or more pins 351 electrically coupled to the system 300 via the internal wire 331 and the conductive interface 390. ***In operation a user 20 may touch the conductive interface 390 and place one or more electrically coupled pins 351 in contact with their dermis to form an electrical pathway from the pin 351 to the electrical conductive interface 390.*** The signal generator 370 may include a battery to supply energy to generate one or more electrical signals. The switch 375 coupled to the generator 370 may cause the generator to produce one or more electrical signals for a predetermined time interval or until the switch 375 is triggered again. As noted a pin vibration 351 may increase the micro-wound or cut formed in dermis by the pin 351. [0042] In an embodiment the invention may employ the algorithm 740 shown in FIG. 7A to apply therapy to dermalogical cells. ***A user, clinician, or equipment may place an apparatus 10, 320, 360, 360, 400, 460 on dermalogical cells to be treated (activity 741) including pressing the apparatus against the cells firmly enough to embed one or more pins 251 , 351 , 451 in the cells.*** A first signal such as shown in FIGS. 5A, 5B, and 6 may be applied to a first LED module or group (32A) and the pins 230, 351, 451 of a dermalogical apparatus 10, 320, 360, 360, 400, 460 (activity 742) for a predetermined time period (activity 744). A second signal such as shown in FIGS. 5 A, 5B, and 6 may be applied to a second LED module or group (32B) and the pins 230, 351, 451 of a dermalogical apparatus 10, 320, 360, 360, 400, 460 (activity 746) for a predetermined time period (activity 748). The signals applied to the groups may be selected to stimulate dermalogical cells or chemicals 22A or cause vibration of one or more pins 251, 351, 451. [0043] In another embodiment the invention may employ the algorithm 750 shown in FIG. 7B to apply therapy to dermalogical cells. A user, clinician, or equipment may apply a light sensitive chemical on an apparatus 10, 320, 360, 360, 400, 460 or on dermalogical cells to be treated (activity 751). ***The user, clinician, or equipment may place apparatus 10, 320, 360, 360, 400, 460 on dermalogical cells to be treated (activity 752).*** A signal such as shown in FIGS. 5A, 5B, and 6 may be applied to a LED module or group (32A or 32B) and

'774 Patent Claim 11		Na '848 and/or Na '848 in view of Mehta, ScarLet, and/or Mulholland
		the pins 230, 351 , 451 (activity 354) for a predetermined time period (activity 356). [0044] In another embodiment the invention may employ the algorithm 760 shown in FIG. 7C to apply therapy to dermalogical cells. A user, clinician, or equipment may apply a light sensitive chemical on an apparatus 10, 320, 360, 360, 400, 460 or on dermalogical cells to be treated (activity 761). ***The user, clinician, or equipment may place an apparatus 10, 320, 360, 360, 400, 460 on dermalogical cells to be treated (activity 762)***. A first signal such as shown in FIGS. 5A, 5B, and 6 may be applied to a first LED module or group (32A) and one or more pins 251, 351, 451 of a dermalogical apparatus 10, 320, 360, 360, 400, 460 (activity 763) for a predetermined time period (activity 764). A second signal such as shown in FIGS. 5 A, 5B, and 6 may be applied to a second LED module or group (32B) and one or more pins 251 , 351 , 451 of a dermalogical apparatus 10, 320, 360, 360, 400, 460 (activity 766) for a predetermined time period (activity 768). **Na '848 further discloses and/or renders obvious that the surface includes a plurality of needles extending a desired distance from the surface.** *See, e.g.*: Na'848 at ¶¶ [0004] - [0014] [0023] FIG. 1C includes a simplified exploded view of an embodiment of an acupuncture plate 200 according to various embodiments. The plate 200 may include an upper, substantially rigid section or layer 290, deformable or elastic section 270 or layer, and acupuncture section or layer 250. ***The acupuncture section 250 may include a plurality of acupuncture pins or needles 230. FIG. ID is a simplified bottom view of the plate 200 showing the location or holes 212 for the pins or needles 230***. In an embodiment the plate 200 may have a rectangular cross section having a dimensional about 1 to 4 cm in width and about 1 to 6 cm in length. The plate 200 may any shape including circular, elliptical, polygon, or other shape where the shape may be particular to a dermalogical area to be treated.

'774 Patent Claim 11		Na '848 and/or Na '848 in view of Mehta, ScarLet, and/or Mulholland
		[0024] ***In an embodiment the plate may include about 140 pins or needles 230 uniformly separated. Each needle may be about 0.1 to 0.4 mm in diameter and 0.2 mm to 1.4 mm in length including 0.3 mm in diameter and 0.8 mm in length in an embodiment.*** The elastic section or layer 270 may be comprised of a combination of elastomeric materials and non-elastomeric materials. The elastomeric materials may include plastics, rubber (synthetic or natural), and spring(s). The pin section 230 may be coupled directly or indirectly to the upper section 290 via the elastic section 250, including via glues, screws, welds, or other connection. In an embodiment the pin section 250 may include elastomers to enable at least partial deformation of the pin section 250 about the pins 230. [0026] FIG. 2 A is a simplified diagram of a dermalogical treatment architecture 310 according to various embodiments. Architecture 310 includes an acupuncture apparatus 320 and an electrical signal generation system 300. The [*sic*] electrical signal generation system 300 may be electrically coupled to the acupuncture apparatus 320 via one or more wires 300A and to a mammal 20 to be treated via one or more wires 300B. FIG. 2B is a simplified cross-sectional diagram of the acupuncture apparatus 320 according to various embodiments. The apparatus 320 may include a handle 330, elastic section 333, electrical interface 340, internal wire(s) 33 land plate 350. ***The pins 351 may have a length A (0.3 mm to 2.1 mm in an embodiment) where at least one pin 351 is electrically coupled to the electrical interface 340 via the internal wire 331.*** The electrical interface 340 may be removably connected to the system 300 wire 300A. [0030] ***FIG. 2F includes a simplified exploded view of an embodiment of an acupuncture plate 350 including at least one electrically coupled pin 351 according to various embodiments.*** The plate 350 may include an upper, substantially rigid section or layer 357, deformable or elastic section 355 or layer, and acupuncture section or layer 353. ***The acupuncture section 353 may include a plurality of acupuncture pins or needles 351 where at least one pin 351 is electrically coupled to the wire 331.*** In a bipolar configuration a second wire 332 may be coupled to at least one other pin 351. ***FIG. 2E is a simplified bottom view of the plate 350 showing the pins or needles 359, 357 where the pins may be***

'774 Patent Claim 11		Na '848 and/or Na '848 in view of Mehta, ScarLet, and/or Mulholland
		electrically coupled to a first wire 331 and a second wire 332 to form dipole pair (bipolar pins). [0032] ***In an embodiment the plate may include about 140 pins or needles 351 uniformly separated. Each needle may be about*** 0.1 to 0.4 mm in diameter and ***0.2 mm to 1.4 mm in length*** including 0.3 mm in diameter and 0.8 mm in length in an embodiment. The elastic section or layer 355 may be comprised of a combination of elastomeric materials and non-elastomeric materials. The elastomeric materials may include plastics, rubber (synthetic or natural), and spring(s). The pin section 353 may be coupled directly or indirectly to the upper section 357 via the elastic section 353, including via glues, screws, welds, or other connection. In an embodiment the pin section 353 may include elastomers to enable at least partial deformation of the pin section 353 about the pins 351. [0033] ***FIGS. 3A and 3B are simplified isometric diagrams of acupuncture apparatus 400, 460 including at least one pin 451 that may be coupled to an electrical signal via an internal wire 458. Each apparatus 400, 460 includes curved roller 450 having a plurality of acupuncture pins 451 where the pins 451 may be similar to pins 351.*** In apparatus 400, the electrical lead wire 400A may be coupled to an electrical interface 410 in the apparatus handle 430 where the interface 410 is electrically coupled to the internal wire 458. In apparatus 460, the handle 430 may include a signal generator 470 similar to generator 370, switch 475, and conduction surface 490. Apparatus '848 at ¶¶ [0022] [0025] [0027] [0028] [0029] [0031] To the extent that this claim limitation is not explicitly or inherently disclosed by Na '848, it would have been obvious given the knowledge of a POSITA and/or further in view of Mehta, Mulholland, and ScarLet. For example, at least Mehta, Mulholland, ScarLet and Lee '500 each disclose a plurality of needles extendable a desired distance from an end surface, disclose various mechanisms for causing the plurality of extendable needles to extend a desired distance from the end surface and a motor coupled to the plurality of extendable needles that may be directed to cause the plurality of the extendable needles to extend a desired distance from the end surface. *See, e.g.*, Mehta at 3:29-39; 3:40-41; 4:63-5:2; 5:3-15; 6:64-65; 9:34-55; 10:33-39; 12:5-14; 13:54-57; Fig. 3A; 13:58-4; 15:27-33; 15:55-16:11; Fig. 4A; 16:42-58; 16:59-17:12; 18:21-37; Fig. 5; 32:46-62; Fig. 10B; 32:63-33:14; 33:15-29; 33:30-34; 33:57-13; Fig. 10E; 34:38-45; 35:8-22; Fig.

'774 Patent Claim 11		Na '848 and/or Na '848 in view of Mehta, ScarLet, and/or Mulholland
		12A; and Fig. 12B; Mulholland at 4:45-48, 5:11-26, 6:65-8:10, 7:19-31; ScarLet at SERENDIA-00017328, SERENDIA-00017331, Ilooda-0006078 (at 7); Lee '500 at Para. 42, 43, 44, 52, 53, 55, 56, 61; claims 1, 2, 7. As of the priority date of the '774 Patent, it was well known that controlling the depth of penetration for the needles and being able to retract the needles was advantageous with respect to providing dermatological treatments. *See, e.g.*, Hantash 2009 at pg. 88; pg. 90; pg. 92; Figs. 2, 1; Hantash 718 PCT at [0017]; [0035]; [0041]; [0042]; [0045]; [0046]; [0068]; [0069]; and [0070]; Mehta at 3:29-39; 3:40-41; 4:63-5:2; 5:3-15; 6:64-65; 9:34-55; 10:33-39; 12:5-14; 13:54-57; Fig. 3A; 13:58-4; 15:27-33; 15:55-16:11; Fig. 4A; 16:42-58; 16:59-17:12; 18:21-37; Fig. 5; 32:46-62; Fig. 10B; 32:63-33:14; 33:15-29; 33:30-34; 33:57-13; Fig. 10E; 34:38-45; 35:8-22; Fig. 12A; and Fig. 12B; Mulholland at 4:45-48, 5:11-26, 6:65-8:10, 7:19-31; ScarLet at SERENDIA-00017328, SERENDIA-00017331, Ilooda-0006078 (at 7); Lee '500 at Para. 42, 43, 44, 52, 53, 55, 56, 61; claims 1, 2, 7. To the extent Na '848 does not explicitly disclose that the needles of a dermatological treatment device are extendable using a motor, it would have been obvious to modify the dermatological treatment device to make the needles retractable and extendable to a desired depth using a motor connected to the needles to achieve enhanced safety (by having the needles retracted when not in use) and enhanced customizability of treatment (by specifying the needle penetration depth). *See id.* Configuring a plurality of needles to be attached to a motor would have been a matter of routine engineering as of the priority date of the '774 Patent, as evidenced by the numerous dermatological treatment devices which included a motor for this purpose. Additionally, as of the priority date of the '774 Patent, it was well known how to create linear force using various manual and automated mechanisms, including a motor. The selection of the mechanism to achieve this purpose is a design choice that would have been obvious to a POSITA.
11.2	a signal generator electrically coupled to the plurality of extended needles to produce pulsed radio frequency	Na '848 discloses and/or renders obvious a signal generator electrically coupled to the plurality of extended needles to produce pulsed radio frequency signals across the plurality of needles to affect dermatological tissue near the plurality of needles. *See, e.g.*, Na '841 at Figs. 2A–D, 3A, 5A, 5B, 6, 7A–C

'774 Patent Claim 11		Na '848 and/or Na '848 in view of Mehta, ScarLet, and/or Mulholland
	signals across the plurality of needles to affect dermatological tissue near the plurality of needles.	[0026] FIG. 2 A is a simplified diagram of a dermalogical treatment architecture 310 according to various embodiments. Architecture 310 includes an acupuncture apparatus 320 and ***an electrical signal generation system 300***. The the [*sic*] ***electrical signal generation system 300 may be electrically coupled to the acupuncture apparatus 320 via one or more wires 300A and to a mammal 20 to be treated via one or more wires 300B***. FIG. 2B is a simplified cross-sectional diagram of the acupuncture apparatus 320 according to various embodiments. The apparatus 320 may include a handle 330, elastic section 333, electrical interface 340, internal wire(s) 33 land plate 350. ***The pins 351 may have a length A (0.3 mm to 2.1 mm in an embodiment)*** where at least one pin 351 is electrically coupled to the electrical interface 340 via the internal wire 331. The electrical interface 340 may be removably connected to the system 300 wire 300A. [0027] ***The electrical signal generation system 300 may generate a vary of signals (such as shown in FIGS. 5 A to 6) to vibrate one or more pins 351 electrically coupled to the system 300 via the internal wire 331 and lead 300A. A pin vibration 351 may increase the micro-wound or cut formed in dermis by the pin 351***. FIG. 2C is a simplified cross-sectional diagram of an acupuncture apparatus 360 according to various embodiments. The apparatus 360 may include a handle 330, an elastic section 333, an electrical conductive interface 390, internal wire(s) 331, ***signal generator 370***, switch 375, and plate 350. ***The signal generator 370 may be coupled to at least one pin 351 via internal wire 331 and coupled to the conductive interface 390.*** [0028] ***The signal generator or module 370 may generate a vary of signals (such as shown in FIGS. 5 A to 6) to vibrate one or more pins 351 electrically coupled to the system 300 via the internal wire 331 and the conductive interface 390. In operation a user 20 may touch the conductive interface 390 and place one or more electrically coupled pins 351 in contact with their dermis to form an electrical pathway from the pin 351 to the electrical conductive interface 390.*** The signal generator 370 may include a battery to supply energy to generate one or more electrical signals. ***The switch 375 coupled to the generator 370 may cause the generator to produce one or more electrical signals for a predetermined time interval or until the switch 375 is triggered again. As***

'774 Patent Claim 11		Na '848 and/or Na '848 in view of Mehta, ScarLet, and/or Mulholland
		noted a pin vibration 351 may increase the micro-wound or cut formed in dermis by the pin 351. [0029] FIG. 2D is a simplified cross-sectional diagram of an acupuncture apparatus 362 according to various embodiments. The apparatus 362 may include a handle 330, an elastic section 333, internal wire(s) 331, 332, ***signal generator 370***, switch 375, and plate 350. ***The signal generator 370 may be coupled to at least one pin 351 via internal wire 331 and coupled to at least one other pin 352 via internal wire 332.*** When active the pins 351, 352 may form at least one dipole pair. ***The signal generator or module 370 may generate a vary of signals (such as shown in FIGS. 5A to 6) to vibrate one or more dipole pair or bipolar pins 351, 352.*** [0033] ***FIGS. 3A and 3B are simplified isometric diagrams of acupuncture apparatus 400, 460 including at least one pin 451 that may be coupled to an electrical signal via an internal wire 458.*** Each apparatus 400, 460 includes curved roller 450 having a plurality of acupuncture pins 451 where the pins 451 may be similar to pins 351. In apparatus 400, the electrical lead wire 400A may be coupled to an electrical interface 410 in the apparatus handle 430 where the interface 410 is electrically coupled to the internal wire 458. In apparatus 460, the handle 430 may include ***a signal generator 470*** similar to generator 370, switch 475, and conduction surface 490. Apparatus 460 may operate similar to apparatus 360 in operation other than the rolling capability of the apparatus 460, 400. In an embodiment the rollers 450 may have various configurations to conform to a dermal area to be treated. [0039] ***FIGS.5A-5B are diagrams of electrical signal waveforms 650, 630, 640 that may be applied*** to one or more LEDs 32A, 32B, 532 and ***to the pins 230, 351, 451 according to various embodiments***. ***The signal waveform 650 includes several square -wave pulses 652, 654, 656*** that may be applied to an LED 32A, 32B, 532. Each pulse 652, 654, 656 may a have a similar magnitude and envelope. ***The waveform 650 may be used to energize*** an LED 32A, 32B, 532 and to ***the pins 230, 351, 451 periodically Pl for a predetermined interval Tl where each pulse 652, 654, 656 has a[n] amplitude Al***. In an embodiment, Al may be about 0.1 milliamperes (mA) to 10 mA, the pulse width Tl may be about 100 microsecond (μs) to 500 μs and the period Pl may from 100 ms to 500 ms as a

'774 Patent Claim 11		Na '848 and/or Na '848 in view of Mehta, ScarLet, and/or Mulholland
		function of the energy required to create capacitance in a liquid. In another embodiment, Al may be about 0.5 milliamperes (mA) to 5 mA, the pulse width Tl may be about 200 microsecond (μs) and the period Pl may about 250 ms as a function of the energy to drive an LED or cause one or more pins 230, 351, 451 to vibrate. [0040] ***In FIG. 5B a signal waveform 630 may be applied*** to a first LED 32A, 32B, 532 module or group and ***to the pins 230, 351 , 451*** and ***a second waveform 640 may be applied or used to energize*** a second LED 32A, 32B, 532 module and ***the pins 230, 351, 451, 352***. ***The signal waveform 630 includes several square-wave pulses 632, 634, and 636 and the signal waveform 640 includes several square-wave pulses 642, 644, and 646. Each pulse 632, 634, 636, 642, 644, 646 may a have a similar magnitude and envelope. The waveform 630 may be used to energize*** a first LED 32A, 32B, 332 module and ***the pins 230, 351, 451 periodically Pl for a predetermined interval Tl where each pulse 632, 634, 636 has an amplitude Al***. ***The waveform 640 may be used to energize*** a second LED 32A, 32B, 332 module and ***the pins 230, 351, 451 periodically P2 for a predetermined interval T2 where each pulse 642, 644, 646 has an amplitude Bl***. The pulse width Tl, T2 may be about 100 microsecond (μs) to 500 μs and the period Pl, P2 may from 100 ms to 500 ms as a function of the energy to affect dermalogical cells or chemicals 22A. In another embodiment, Al, A2 may be about 0.5 milliamperes (mA) to 5 mA, the pulse width Tl, T2 may be about 200 microsecond (μs) and the period Pl, P2 may about 250 ms as a function of the energy required to affect dermalogical cells or chemicals 22 A. In an embodiment the pulses 632, 634, 636 do not substantially overlap the pulses 642, 644, 646. In an embodiment Tl > T2 and P2 is an integer multiple of Pl . [0041] ***FIG. 6 depicts a waveform 670 that includes multiple pulses 672, 674, 676, 678, 682, and 684 that may not overlap in the time or the frequency domain. In an embodiment each pulse 672, 674, 676, 678, 682, and 684 may have a pulse width T3, and frequency spectrum width Fl and period P3. The pulse 672 is frequency offset from the pulse 674, the pulse 676 is frequency offset from the pulse 678, and the pulse 682 is frequency offset from the pulse 684. The pulses 672, 674, 676, 678, 682, and 684 may be applied to*** an LED module to affect dermalogical cells or chemicals 22A and ***the***

'774 Patent Claim 11		Na '848 and/or Na '848 in view of Mehta, ScarLet, and/or Mulholland
		pins 230, 351, 451. Pulses 672, 674 having different frequency spectrums may enable different LED stimulation. In an embodiment the pulses 672, 676, 682 may be applied to a first LED module and the pulses 674, 678, 684 may be applied to a second LED module. ***The frequency separation between the respective pulses may enable simultaneous energization of a first and a second LED module and the pins 230, 351, 451*** and subsequent and independent spectrum generation. [0042] In an embodiment the invention may employ the algorithm 740 shown in FIG. 7A to apply therapy to dermalogical cells. A user, clinician, or equipment may place an apparatus 10, 320, 360, 360, 400, 460 on dermalogical cells to be treated (activity 741) including pressing the apparatus against the cells firmly enough to embed one or more pins 251 , 351 , 451 in the cells. ***A first signal such as shown in FIGS. 5A, 5B, and 6 may be applied to*** a first LED module or group (32A) and ***the pins 230, 351, 451 of a dermalogical apparatus 10, 320, 360, 360, 400, 460 (activity 742) for a predetermined time period (activity 744)***. ***A second signal such as shown in FIGS. 5 A, 5B, and 6 may be applied to*** a second LED module or group (32B) and ***the pins 230, 351, 451 of a dermalogical apparatus 10, 320, 360, 360, 400, 460 (activity 746) for a predetermined time period (activity 748)***. The signals applied to the groups may be selected to stimulate dermalogical cells or chemicals 22A or cause vibration of one or more pins 251, 351, 451. [0043] In another embodiment the invention may employ the algorithm 750 shown in FIG. 7B to apply therapy to dermalogical cells. A user, clinician, or equipment may apply a light sensitive chemical on an apparatus 10, 320, 360, 360, 400, 460 or on dermalogical cells to be treated (activity 751). The user, clinician, or equipment may place apparatus 10, 320, 360, 360, 400, 460 on dermalogical cells to be treated (activity 752). ***A signal such as shown in FIGS. 5A, 5B, and 6 may be applied to*** a LED module or group (32A or 32B) and ***the pins 230, 351 , 451 (activity 354) for a predetermined time period (activity 356)***. [0044] In another embodiment the invention may employ the algorithm 760 shown in FIG. 7C to apply therapy to dermalogical cells. A user, clinician, or equipment may apply a light sensitive chemical on an apparatus 10, 320, 360, 360,

'774 Patent Claim 11		Na '848 and/or Na '848 in view of Mehta, ScarLet, and/or Mulholland
		400, 460 or on dermalogical cells to be treated (activity 761). The user, clinician, or equipment may place an apparatus 10, 320, 360, 360, 400, 460 on dermalogical cells to be treated (activity 762). ***A first signal such as shown in FIGS. 5A, 5B, and 6 may be applied to*** a first LED module or group (32A) and ***one or more pins 251, 351, 451 of a dermalogical apparatus 10, 320, 360, 360, 400, 460 (activity 763) for a predetermined time period (activity 764)***. ***A second signal such as shown in FIGS. 5 A, 5B, and 6 may be applied to*** a second LED module or group (32B) and ***one or more pins 251 , 351 , 451 of a dermalogical apparatus 10, 320, 360, 360, 400, 460 (activity 766) for a predetermined time period (activity 768).***

500. In view of the foregoing chart, claim 11 of the '774 Patent would have been obvious over Na '848 given the knowledge of a POSITA, and/or further in view of the teachings of Mehta, ScarLet, and/or Mulholland. The teachings of Na '848 are so similar to what is claimed that any alleged difference between the teachings of Na '848 and what is claimed would not have been of patentable significance given the knowledge of a POSITA.

501. It is my opinion that Claim 12 of the '774 Patent is rendered obvious by Na '848 alone or Na '848 in view of Mehta, ScarLet, and/or Mulholland as detailed below:

'774 Patent Claim 12		Na '848 and/or Na '848 in view of Mehta, ScarLet, and/or Mulholland
12.0	12. The apparatus for treating dermatological tissue of claim 11, wherein the device includes an end surface configured to be placed on or near dermatological tissue to be	***Claim 12 of the '774 Patent is rendered obvious by Na '848 alone or in view of Mehta, ScarLet, and/or Mulholland.*** Na '848 renders obvious (either alone or in view of Mehta, ScarLet and/or Mulholland) the apparatus for treating dermatological tissue of claim 11. *See* claim 11. Na '848 discloses and/or renders obvious that the device includes an end surface configured to be placed on or near dermatological tissue to be treated, the end surface including a plurality of needles extendable a desired distance from the end surface.

'774 Patent Claim 12		Na '848 and/or Na '848 in view of Mehta, ScarLet, and/or Mulholland
	treated, the end surface including a plurality of needles extendable a desired distance from the end surface.	*See, e.g.*, citations for element 11.1 above. To the extent that this claim limitation is not explicitly or inherently disclosed by Na '848, it would have been obvious given the knowledge of a POSITA and/or further in view of Mehta, Mulholland, and ScarLet. For example, at least Mehta, Mulholland, ScarLet and Lee '500 each disclose a plurality of needles extendable a desired distance from an end surface, disclose various mechanisms for causing the plurality of extendable needles to extend a desired distance from the end surface and a motor coupled to the plurality of extendable needles that may be directed to cause the plurality of the extendable needles to extend a desired distance from the end surface. *See, e.g.*, Mehta at 3:29-39; 3:40-41; 4:63-5:2; 5:3-15; 6:64-65; 9:34-55; 10:33-39; 12:5-14; 13:54-57; Fig. 3A; 13:58-4; 15:27-33; 15:55-16:11; Fig. 4A; 16:42-58; 16:59-17:12; 18:21-37; Fig. 5; 32:46-62; Fig. 10B; 32:63-33:14; 33:15-29; 33:30-34; 33:57-13; Fig. 10E; 34:38-45; 35:8-22; Fig. 12A; and Fig. 12B; Mulholland at 4:45-48, 5:11-26, 6:65-8:10, 7:19-31; ScarLet at SERENDIA-00017328, SERENDIA-00017331, Ilooda-0006078 (at 7); Lee '500 at Para. 42, 43, 44, 52, 53, 55, 56, 61; claims 1, 2, 7. As of the priority date of the '774 Patent, it was well known that controlling the depth of penetration for the needles and being able to retract the needles was advantageous with respect to providing dermatological treatments. *See, e.g.*, Hantash 2009 at pg. 88; pg. 90; pg. 92; Figs. 2, 1; Hantash 718 PCT at [0017]; [0035]; [0041]; [0042]; [0045]; [0046]; [0068]; [0069]; and [0070]; Mehta at 3:29-39; 3:40-41; 4:63-5:2; 5:3-15; 6:64-65; 9:34-55; 10:33-39; 12:5-14; 13:54-57; Fig. 3A; 13:58-4; 15:27-33; 15:55-16:11; Fig. 4A; 16:42-58; 16:59-17:12; 18:21-37; Fig. 5; 32:46-62; Fig. 10B; 32:63-33:14; 33:15-29; 33:30-34; 33:57-13; Fig. 10E; 34:38-45; 35:8-22; Fig. 12A; and Fig. 12B; Mulholland at 4:45-48, 5:11-26, 6:65-8:10, 7:19-31; ScarLet at SERENDIA-00017328, SERENDIA-00017331, Ilooda-0006078 (at 7); Lee '500 at Para. 42, 43, 44, 52, 53, 55, 56, 61; claims 1, 2, 7. To the extent Na '848 does not explicitly disclose that the needles of a dermatological treatment device are extendable using a motor, it would have been obvious to modify the dermatological treatment device to make the needles retractable and extendable to a desired depth using a motor connected to the needles to achieve enhanced safety (by having the needles retracted when not in use) and enhanced customizability of treatment (by specifying the needle penetration depth). *See id.* Configuring a plurality of needles to be attached to a motor would have been a matter of routine engineering as of the priority date of the

'774 Patent Claim 12		Na '848 and/or Na '848 in view of Mehta, ScarLet, and/or Mulholland
		'774 Patent, as evidenced by the numerous dermatological treatment devices which included a motor for this purpose. Additionally, as of the priority date of the '774 Patent, it was well known how to create linear force using various manual and automated mechanisms, including a motor. The selection of the mechanism to achieve this purpose is a design choice that would have been obvious to a POSITA.

502. In view of the foregoing chart, claim 12 of the '774 Patent would have been obvious over Na '848 given the knowledge of a POSITA, and/or further in view of the teachings of Mehta, ScarLet, and/or Mulholland. The teachings of Na '848 are so similar to what is claimed that any alleged difference between the teachings of Na '848 and what is claimed would not have been of patentable significance given the knowledge of a POSITA.

503. It is my opinion that Claim 13 of the '774 Patent is rendered obvious by Na '848 alone or Na '848 in view of Mehta, ScarLet, and/or Mulholland as detailed below:

'774 Patent Claim 13		Na '848 and/or Na '848 in view of Mehta, ScarLet, and/or Mulholland
13.0	13. The apparatus for treating dermatological tissue of claim 12, further including a mechanism for causing the plurality of the extendable needles to extend a desired distance from the end surface.	***Claim 13 of the '774 Patent is rendered obvious by Na '848 alone or in view of Mehta, ScarLet, and/or Mulholland.*** Na '848 renders obvious (either alone or in view of Mehta, ScarLet and/or Mulholland) the apparatus for treating dermatological tissue of claim 12. *See* claim 12. Na '848 discloses and/or renders obvious that the device includes a mechanism for causing the plurality of the extendable needles to extend a desired distance from the end surface. To the extent that this claim limitation is not explicitly or inherently disclosed by Na '848, it would have been obvious given the knowledge of a POSITA and/or further in view of Mehta, Mulholland, and ScarLet. For example, at least Mehta, Mulholland, ScarLet and Lee '500 each disclose a plurality of needles extendable a desired distance from an end surface, disclose various mechanisms for causing the

'774 Patent Claim 13		Na '848 and/or Na '848 in view of Mehta, ScarLet, and/or Mulholland
		plurality of extendable needles to extend a desired distance from the end surface and a motor coupled to the plurality of extendable needles that may be directed to cause the plurality of the extendable needles to extend a desired distance from the end surface. *See, e.g.*, Mehta at 3:29-39; 3:40-41; 4:63-5:2; 5:3-15; 6:64-65; 9:34-55; 10:33-39; 12:5-14; 13:54-57; Fig. 3A; 13:58-4; 15:27-33; 15:55-16:11; Fig. 4A; 16:42-58; 16:59-17:12; 18:21-37; Fig. 5; 32:46-62; Fig. 10B; 32:63-33:14; 33:15-29; 33:30-34; 33:57-13; Fig. 10E; 34:38-45; 35:8-22; Fig. 12A; and Fig. 12B; Mulholland at 4:45-48, 5:11-26, 6:65-8:10, 7:19-31; ScarLet at Ilooda-0011405 at -471 (certified English translation of SERENDIA-00073257 at -298), SERENDIA-00017328, SERENDIA-00017331, Ilooda-0006078 (at 7); Lee '500 at Para. 42, 43, 44, 52, 53, 55, 56, 61; claims 1, 2, 7. As of the priority date of the '774 Patent, it was well known that controlling the depth of penetration for the needles and being able to retract the needles was advantageous with respect to providing dermatological treatments. *See, e.g.*, Hantash 2009 at pg. 88; pg. 90; pg. 92; Figs. 2, 1; Hantash 718 PCT at [0017]; [0035]; [0041]; [0042]; [0045]; [0046]; [0068]; [0069]; and [0070]; Mehta at 3:29-39; 3:40-41; 4:63-5:2; 5:3-15; 6:64-65; 9:34-55; 10:33-39; 12:5-14; 13:54-57; Fig. 3A; 13:58-4; 15:27-33; 15:55-16:11; Fig. 4A; 16:42-58; 16:59-17:12; 18:21-37; Fig. 5; 32:46-62; Fig. 10B; 32:63-33:14; 33:15-29; 33:30-34; 33:57-13; Fig. 10E; 34:38-45; 35:8-22; Fig. 12A; and Fig. 12B; Mulholland at 4:45-48, 5:11-26, 6:65-8:10, 7:19-31; ScarLet at Ilooda-0011405 at -471 (certified English translation of SERENDIA-00073257 at -298), SERENDIA-00017328, SERENDIA-00017331, Ilooda-0006078 (at 7); Lee '500 at Para. 42, 43, 44, 52, 53, 55, 56, 61; claims 1, 2, 7. To the extent Na '848 does not explicitly disclose that the needles of a dermatological treatment device are extendable using a motor, it would have been obvious to modify the dermatological treatment device to make the needles retractable and extendable to a desired depth using a motor connected to the needles to achieve enhanced safety (by having the needles retracted when not in use) and enhanced customizability of treatment (by specifying the needle penetration depth). *See id.* Configuring a plurality of needles to be attached to a motor would have been a matter of routine engineering as of the priority date of the '774 Patent, as evidenced by the numerous dermatological treatment devices which included a motor for this purpose. Additionally, as of the priority date of the '774 Patent, it was well known how to create linear force using various manual and automated mechanisms, including a motor. The selection of the mechanism to

'774 Patent Claim 13		Na '848 and/or Na '848 in view of Mehta, ScarLet, and/or Mulholland
		achieve this purpose is a design choice that would have been obvious to a POSITA.

504. In view of the foregoing chart, claim 13 of the '774 Patent would have been obvious over Na '848 given the knowledge of a POSITA, and/or further in view of the teachings of Mehta, ScarLet, and/or Mulholland. The teachings of Na '848 are so similar to what is claimed that any alleged difference between the teachings of Na '848 and what is claimed would not have been of patentable significance given the knowledge of a POSITA.

505. It is my opinion that Claim 14 of the '774 Patent is rendered obvious by Na '848 alone or Na '848 in view of Mehta, ScarLet, and/or Mulholland as detailed below:

'774 Patent Claim 14		Na '848 and/or Na '848 in view of Mehta, ScarLet, and/or Mulholland
14.0	14. The apparatus for treating dermatological tissue of claim 12, further including a motor coupled to the plurality of extendable needles that may be directed to cause the plurality of the extendable needles to extend a desired distance from the end surface.	***Claim 14 of the '774 Patent is rendered obvious by Na '848 alone or in view of Mehta, ScarLet, and/or Mulholland.*** Na '848 renders obvious (either alone or in view of Mehta, ScarLet and/or Mulholland) the apparatus for treating dermatological tissue of claim 12. *See* claim 12. Na '848 discloses and/or renders obvious that the device includes a motor coupled to the plurality of extendable needles that may be directed to cause the plurality of the extendable needles to extend a desired distance from the end surface. To the extent that this claim limitation is not explicitly or inherently disclosed by Na '848, it would have been obvious given the knowledge of a POSITA and/or further in view of Mehta, Mulholland, and ScarLet. For example, at least Mehta, Mulholland, ScarLet and Lee '500 each disclose a plurality of needles extendable a desired distance from an end surface, disclose various mechanisms for causing the plurality of extendable needles to extend a desired distance from the end surface and a motor coupled to the plurality of extendable needles that may be directed to cause the plurality of the extendable needles to extend a desired distance from the end surface. *See, e.g.*, Mehta at 3:29-39; 3:40-41; 4:63-5:2; 5:3-15; 6:64-65; 9:34-55; 10:33-39; 12:5-

'774 Patent Claim 14		Na '848 and/or Na '848 in view of Mehta, ScarLet, and/or Mulholland
		14; 13:54-57; Fig. 3A; 13:58-4; 15:27-33; 15:55-16:11; Fig. 4A; 16:42-58; 16:59-17:12; 18:21-37; Fig. 5; 32:46-62; Fig. 10B; 32:63-33:14; 33:15-29; 33:30-34; 33:57-13; Fig. 10E; 34:38-45; 35:8-22; Fig. 12A; and Fig. 12B; Mulholland at 4:45-48, 5:11-26, 6:65-8:10, 7:19-31; ScarLet at Ilooda-0011405 at -471 (certified English translation of SERENDIA-00073257 at -298), SERENDIA-00017328, SERENDIA-00017331, Ilooda-0006078 (at 7); Lee '500 at Para. 42, 43, 44, 52, 53, 55, 56, 61; claims 1, 2, 7. As of the priority date of the '774 Patent, it was well known that controlling the depth of penetration for the needles and being able to retract the needles was advantageous with respect to providing dermatological treatments. *See, e.g.*, Hantash 2009 at pg. 88; pg. 90; pg. 92; Figs. 2, 1; Hantash 718 PCT at [0017]; [0035]; [0041]; [0042]; [0045]; [0046]; [0068]; [0069]; and [0070]; Mehta at 3:29-39; 3:40-41; 4:63-5:2; 5:3-15; 6:64-65; 9:34-55; 10:33-39; 12:5-14; 13:54-57; Fig. 3A; 13:58-4; 15:27-33; 15:55-16:11; Fig. 4A; 16:42-58; 16:59-17:12; 18:21-37; Fig. 5; 32:46-62; Fig. 10B; 32:63-33:14; 33:15-29; 33:30-34; 33:57-13; Fig. 10E; 34:38-45; 35:8-22; Fig. 12A; and Fig. 12B; Mulholland at 4:45-48, 5:11-26, 6:65-8:10, 7:19-31; ScarLet at Ilooda-0011405 at -471 (certified English translation of SERENDIA-00073257 at -298), SERENDIA-00017328, SERENDIA-00017331, Ilooda-0006078 (at 7); Lee '500 at Para. 42, 43, 44, 52, 53, 55, 56, 61; claims 1, 2, 7. To the extent Na '848 does not explicitly disclose that the needles of a dermatological treatment device are extendable using a motor, it would have been obvious to modify the dermatological treatment device to make the needles retractable and extendable to a desired depth using a motor connected to the needles to achieve enhanced safety (by having the needles retracted when not in use) and enhanced customizability of treatment (by specifying the needle penetration depth). *See id.* Configuring a plurality of needles to be attached to a motor would have been a matter of routine engineering as of the priority date of the '774 Patent, as evidenced by the numerous dermatological treatment devices which included a motor for this purpose. Additionally, as of the priority date of the '774 Patent, it was well known how to create linear force using various manual and automated mechanisms, including a motor. The selection of the mechanism to achieve this purpose is a design choice that would have been obvious to a POSITA.

506. In view of the foregoing chart, claim 14 of the '774 Patent is obvious over Na '848 given the knowledge of a POSITA, and/or further in view of the teachings of Mehta, ScarLet, and/or Mulholland. The teachings of Na '848 are so similar to what is claimed that any alleged difference between the teachings of Na '848 and what is claimed would not have been of patentable significance given the knowledge of a POSITA.

F. The Asserted Claims of the '812 Patent are Anticipated or Rendered Obvious by the Prior Art

507. It is my opinion that U.S. Patent No. 8,608,737 ("Mehta") anticipates and/or, in view of the knowledge of a POSITA, renders each and every limitation of the '812 Patent's Asserted Claims obvious. Specifically, it is my opinion that Mehta anticipates and/or renders obvious claims 1-6, 10, 12-14, and 16-19 of the '812 Patent. To the extent that Mehta does not anticipate and/or render these claims obvious, these claims would have been obvious over Mehta in view of Na '844, ScarLet, and/or Kang '395. It is also opinion that Na '848 in view of Mehta renders obvious claims 1-6, 10, 12-14, and 16-19 of the '812 Patent. To reach these conclusions, I have relied on the claim construction outlined in Section V. above. I have based my analysis on the agreed upon claim constructions for the '812 Patent. For the disputed terms in claims 1 and 12, I have conducted my analysis in view of the claim construction proposed by Respondents and the Serendia, which is identical to the Staff's Construction.

508. U.S. Patent No. 8,608,737 ("Mehta") qualifies as prior art under at least AIA 35 U.S.C. § 102(a)(1) because it is a patent that published before the filing of the earliest application to which the '812 Patent could claim priority.

509. To the extent the '812 Patent is subject to pre-AIA law, Mehta qualifies as prior art under at least 35 U.S.C. § 102(e) (pre-AIA) because it is a patent that was filed prior to the alleged invention of the '812 Patent.

510. The ScarLet product manufactured by ViOL, Korea ("ScarLet") qualifies as prior art under at least AIA 35 U.S.C. § 102(a)(1) because it is a product that was in public used, on sale, or otherwise available to the public before the effective filing date of the claimed invention to which the '812 Patent could claim priority. *See, e.g.*, Ilooda-0005923 (Shim 2010_DKU Thesis 2010.12.01), Ilooda-0006075 (ScarLet intro), Ilooda-0006078 (#13_(Eng)_Shim 2010_DKU Thesis Dec 1 2010_Translated_Certified), Ilooda-0006210 (5-1. 스칼렛 최초허가), Ilooda-0006533 (Naver Blog The H Jan 10 2011), Ilooda-0006719 (#19-1_Naver Blog The H Jan 10 2011_Translated_Certified), Ilooda-0006770 (#18_D&PS Monthly Sept 2010_Translated_Certified), Ilooda-0006827 (D&PS Monthly September 2010), Ilooda-0008178 and translation thereof (Ilooda-0011601), Ilooda-0009318, Ilooda-0009319, Ilooda-0009322, Ilooda-0009339, Ilooda-0009669, Ilooda-0009673, Ilooda-0009678, Ilooda-0009791, Ilooda-0009795, Ilooda-0010031, Ilooda-0010042, SERENDIA-00017276, SERENDIA-00017306, SERENDIA-00031579, SERENDIA-00033637, SERENDIA-00033705, SERENDIA-00036286, SERENDIA-00052450, SERENDIA-00061017, SERENDIA-00066746, SERENDIA-00075908, and SERENDIA-00081664.

511. International Publication No. WO2010/016848 ("Na '848"), published February 11, 2010, qualifies as prior art under at least AIA 35 U.S.C. § 102(a)(1) because it is a patent that published before the filing of the earliest application to which the '812 Patent could claim priority.

512. To the extent that the '812 Patent is subject to pre-AIA law, Na '848 qualifies as prior art under at least 35 U.S.C. § 102(b) (pre-AIA) because it is a patent that published more than one year before the filing of the earliest application to which the '812 Patent could claim

priority. Na '848 also qualifies as prior art under at least 35 U.S.C. § 102(a) (pre-AIA) because it is a patent that was published prior to the alleged invention of the '812 Patent.

513. KR 10-0719395 ("Kang '395") qualifies as prior art under at least AIA 35 U.S.C. § 102(a)(1) because it is a patent that published before the filing of the earliest application to which the '812 Patent could claim priority.

514. To the extent that the '812 Patent is subject to pre-AIA law, Kang '395 qualifies as prior art under at least 35 U.S.C. § 102(b) (pre-AIA) because it is a patent that published more than one year before the filing of the earliest application to which the '812 Patent could claim priority.

515. Kang '395 also qualifies as prior art under at least 35 U.S.C. § 102(a) (pre-AIA) because it is a patent that was published prior to the alleged invention of the '812 Patent.

516. The ALJ has not yet construed the claims and therefore the meaning of the terms in the claims has yet to be resolved by the ALJ. The support identified here for this limitation is responsive to Complainant's infringement allegations, which Respondents disagree with. As such, nothing in Respondents' claim charts should be construed as an admission regarding infringement, either literally or under the doctrine of equivalents, or as an admission regarding Respondents' understanding of the proper scope of the asserted claims. Respondents reserve the right to rely on additional citations or sources of evidence that also may be applicable, or that may become applicable in light of claim construction, changes in Complainant's infringement contentions, and/or information obtained during discovery as the case progresses.

517. To the extent Complainant alleges that Mehta does not disclose any particular limitation of the asserted claims of the '812 Patent, either expressly or inherently, it would have been obvious to a POSITA as of the priority date of the '812 Patent to modify Mehta and/or to

combine the teachings of Mehta with other prior art references, including but not limited to the present prior art references cited in the Cover Pleading and the relevant section(s) of claim charts for other prior art references for the '812 Patent in a manner that would have rendered the asserted claims invalid as obvious.

518. To the extent Complainant alleges that Na '848 does not disclose any particular limitation of the asserted claims of the '812 Patent, either expressly or inherently, it would have been obvious to a POSITA as of the priority date of the '812 Patent to modify Na '848 and/or to combine the teachings of Na '848 with other prior art references, including but not limited to the present prior art references cited in the Cover Pleading and the relevant section(s) of claim charts for other prior art references for the '812 Patent in a manner that would have rendered the asserted claims invalid as obvious.

519. It is my opinion that the asserted claims of the '812 Patent are invalid under 35 U.S.C. § 102 as anticipated by Mehta, and/or are invalid under 35 U.S.C. § 103 as obvious in view of Mehta alone, or in combination with one or more of ScarLet, Na '848, and/or Kang '395 as follows:

Mehta anticipates claims 1, 5, 6, 10, 12, 13, 14, 16, 17, 18, and 19;

Mehta alone renders obvious claims 1, 5, 6, 10, 12, 13, 14, 16, 17, 18, and

Mehta in view of ScarLet, Na '848, and/or Kang '395 renders obvious claims 5, 6, and 18.

520. Furthermore, the asserted claims of the '812 Patent are invalid under 35 U.S.C. § 103 (AIA or pre-AIA) as obvious in view of Na '848 in light of Mehta.

521. It is my understanding that while Serendia has asserted claims 1, 5 and 6 of the '812 Patent, claims 2-4 were not included in the list of asserted claims. Asserted claim 5

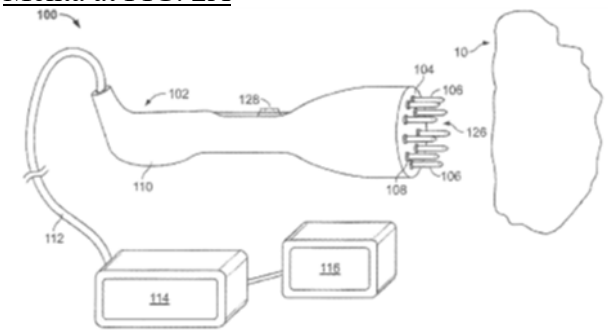
depends on claims 2-4. Asserted claim 6 depends on claims 2-3. For completeness of my analysis, I have also included these claims.

522. In my opinion, a POSITA would have been motivated to combine the disclosures of Mehta, ScarLet, Na '848, and/or Kang '395. Mehta, ScarLet, Na '848, and/or Kang '395 discuss or address the same or substantially similar underlying apparatus and/or technology in the field of dermatological treatment and devices such that a POSITA would have understood that these one or more of these references can be combined, according to known methods and/or by the simple substitution of one known, equivalent element for another, to yield predictable results and with a reasonable expectation of success. A POSITA would also have been motivated to combine one or more of these reference in light of market forces in the industry, and the desire to improve features and performance, and/or in light of one or more teachings, suggestions, or motivations in the art. A POSITA would have enjoyed a reasonable expectation of success in combining and/or modifying the teachings of the foregoing prior art references and products, together with general knowledge of the art, to achieve the claimed subject matter, at least because the prior art itself discloses and/or practices the claimed methods and apparatuses to achieve the claimed results. A POSITA would have recognized that the relevant art is predictable, and that achieving the claimed subject matter requires merely routine optimization.

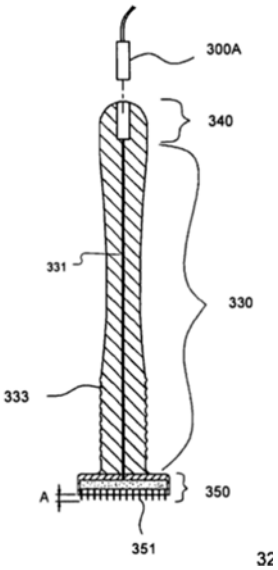
523. Furthermore, each of Mehta, Kang '395, ScarLet, and Na '848 references pertain to the treatment of skin with microneedles or with microneedles and RF. As such, they are in the same field of technical endeavor. The U.S. equivalent of Na '848 issued as U.S. Patent No. 8,979,912, which lists International Classification A61N 5/06 on face. Kang '395 is in related International Classification No. A61N 5/067. Na '848 is in International Classification A61B 18/20. Mehta is in related International Classification A61B 18/18. As shown in the table

below, a POSITA would recognize from the figures of Mehta, Na '848, and the ScarLet System that these references and/or prior systems disclose micro-needling devices used for wrinkle removal that related to each other and to the apparatus and methods claimed in the Asserted Patents. Kang '395 also describes a system for wrinkle removal. Accordingly, the POSITA would therefore be motivated to combine Na '848, Kang '395, and the ScarLet system.

Mehta at FIG. 2A



WO 2010/016848 to Na and Richman FIG 2B



ScarLet System



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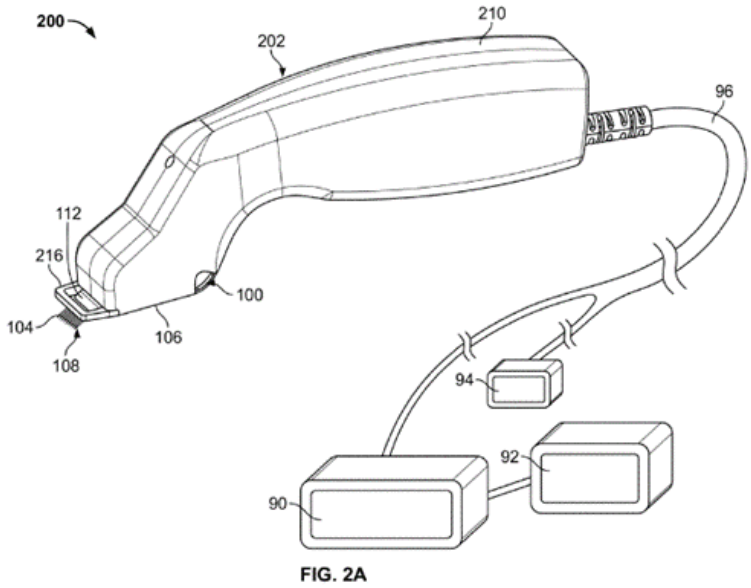


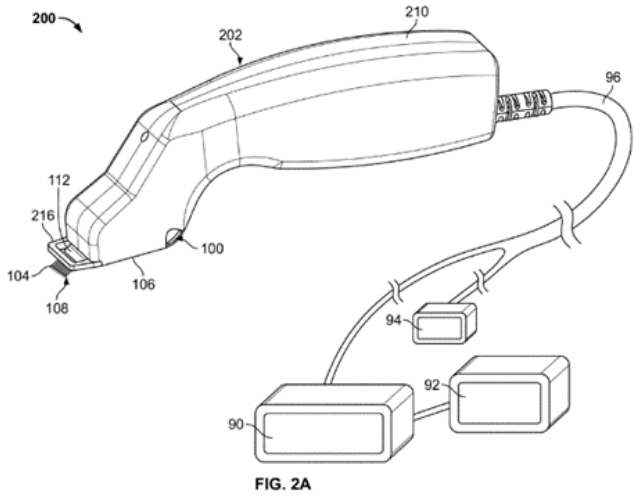
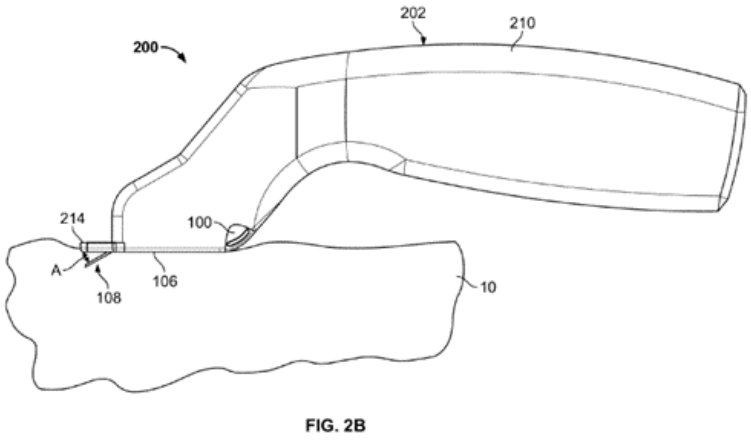
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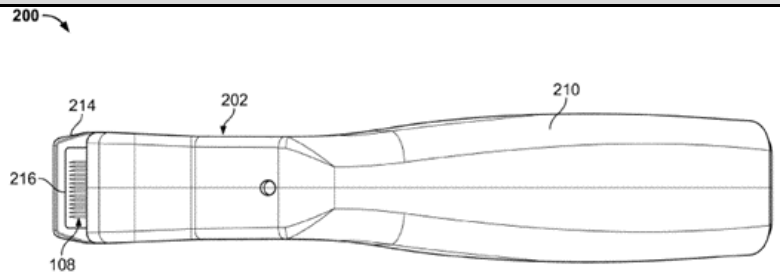
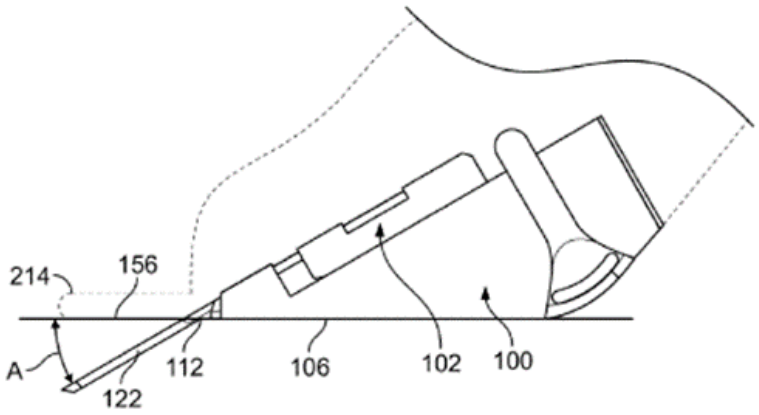
1. Claim 1 of the '812 Patent is Anticipated by Mehta and/or Obvious over Mehta alone

524. It is my opinion that Mehta anticipated and/or rendered obvious claim 1 of the '812 Patent as detailed below.

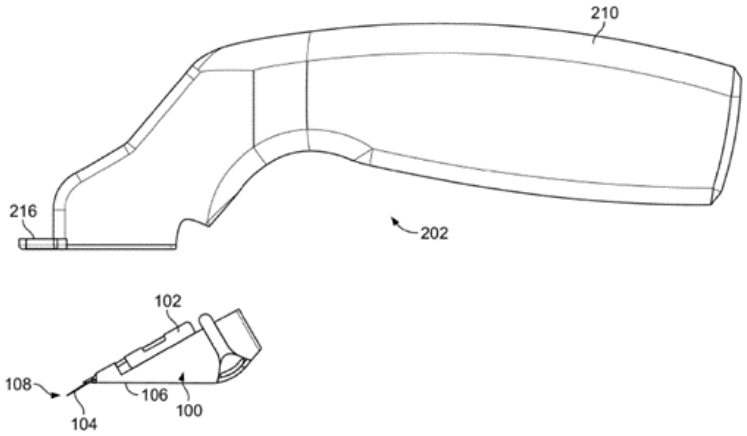
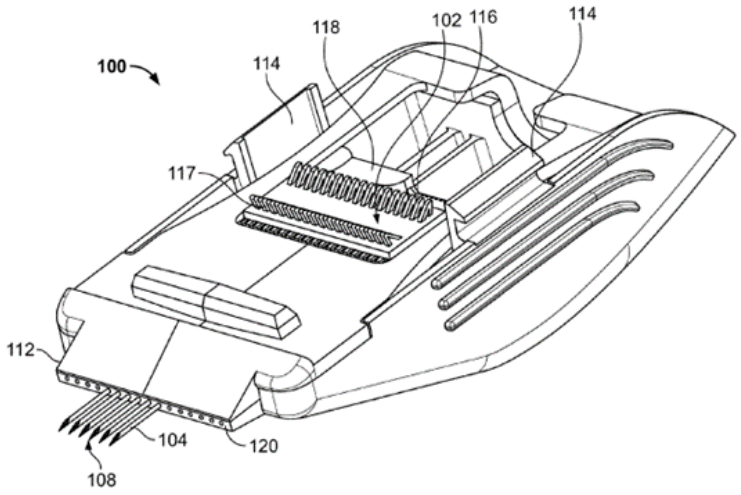
'812 Patent Claim 1		Mehta alone
1.0	1. A method of treating dermatological tissue, comprising:	***Claim 1 of the '812 Patent is anticipated by Mehta and/or rendered obvious by Mehta alone.*** Mehta discloses the method of treating dermatological tissue according to the claim. *See e.g.,* Mehta, at 1:14-19; 2:3-12; 2:13-21; 2:22-29; 2:30-33; 2:37-57; 2:58-62; 2:37-57; 2:63-3:17; 6:30-37; 7:52-59; 7:60-8:5; 8:6-12; 8:54-65; 9:34-55; Fig. 2A; 10:66-11:13; 12:23-30; Fig. 2B; 7:19-22; Fig. 10A; 10:66-11:13; 19:17-25; 19:66-20:12; 22:53-62; 23:55-24:4; Fig. 7E; and 24:5-12. Specifically, Mehta discloses "systems and method" to "treat tissue in the human body," and "[i]n a particular variation," to "**treat** cosmetic conditions affecting **the skin** of various body parts, including face, neck, and other areas traditionally prone to wrinkling, lines, sagging and other distortions of the **skin**." Mehta, at 1:14-19 (emphasis added); *see also id*., at 2:3-21; 2:37-57 ("systems and methods" to "to shrink collagen tissue in the dermis"), 7:52-8:12, 8:54-65, 19:17-25, 19:66-20:12, 22:53-62. Mehta's skin treatment apparatus **200**, reproduced below, included "a system [**200**] for monitoring energy delivery from an energy supply unit [90] to" the skin, which included

'812 Patent Claim 1		Mehta alone
		"a treatment unit [**202**] having a device body," [**210**] "a first plurality of energy transfer elements," (**104**) and "a graphical user interface" (**320**). *Id*., at 2:63-3:17; *see also id*., at 9:34-55, 10:66-11:13.  FIG. 2A *Id*., Fig. 2A.
1.1	placing a user holdable device releasably couplable deployable needle module end surface on or near dermatological tissue to be treated,	Mehta discloses placing a user holdable device releasably couplable deployable needle module end surface on or near dermatological tissue to be treated. *See e.g.*, Mehta, at 1:14-19; 2:3-12; 2:13-21; 2:63-3:17; 3:29-39; 4:1-18; 4:19-30; 4:35-43; 4:63-5:2; 4:35-43; 4:63-5:2; 5:3-15; 5:49-57; 6:30-37; 6:64-65; 7:52-59; 7:60-8:5; 9:34-55; Fig. 2A; 9:56-64; 9:65-10:7; 10:33-39; 10:40-47; 10:48-52; 12:23-30; Fig. 2B; 12:31-46; 12:47-58; 12:59-13:4; 13:5-15; 13:16-36; Fig. 2C; 13:45-53; 13:16-36; 13:54-57; Fig. 3A; 13:58-14:4; 14:5-19; Fig. 2D; 14:20-29; 15:27-33; Fig. 4A; 15:34-54; 15:55-16:11; 16:19-33; 16:42-58; 16:59-17:12.; 17:46-58; 17:59-18:3; 18:21-37; Fig. 5; 18:37-45; 21:1-13; Fig .7A; 21:14-21; 21:22-34; Fig. 7B; 21:34-42; 21:43-62; 23:11-27; 32:16-25; 35:8-22; Fig. 12A; Fig. 12B; 37:7-17. Mehta discloses that the tissue that is treated is skin (dermatological tissue) *Id*., at 1:14-19, 7:52-59. Mehta's system includes "a treatment unit [**202**] having a device body [**210**]," which "includes a tissue engaging surface that allows orientation of the device body on the

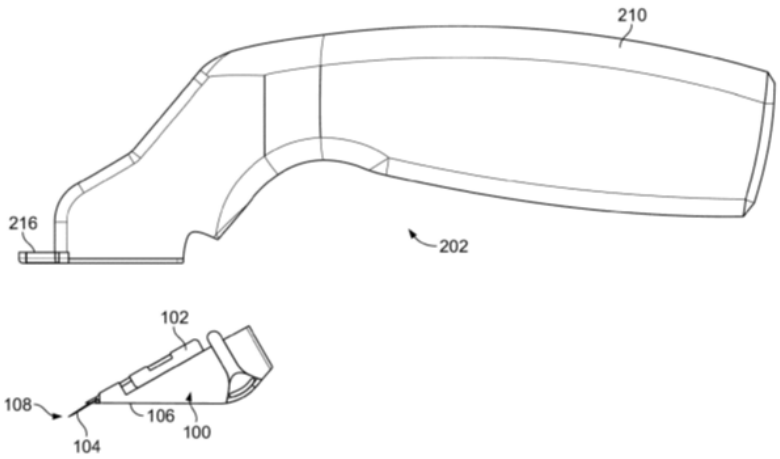
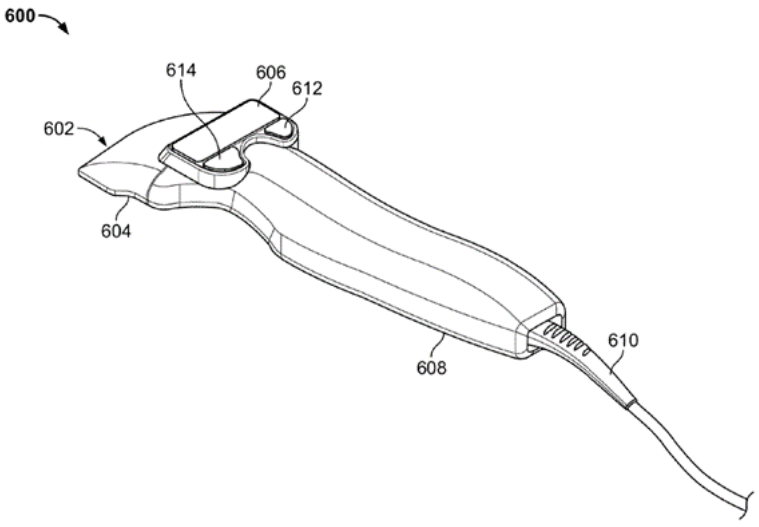
‘812 Patent Claim 1		Mehta alone
		surface of [skin] tissue [10],” and a stabilization plate [**214**] to the tissue engaging surface. Mehta, at 2:63-3:17, *see also id*., at 4:1-18, 4:63-5:2, 9:36-39, 10:40-52, 12:23-46, 12:47-58 (tissue engaging surface engages “skin tissue”), 12:59-13:15, 13:45-53, 32:16-25.  FIG. 2A *Id*., Fig. 2A.  FIG. 2B *Id*., Fig. 2B

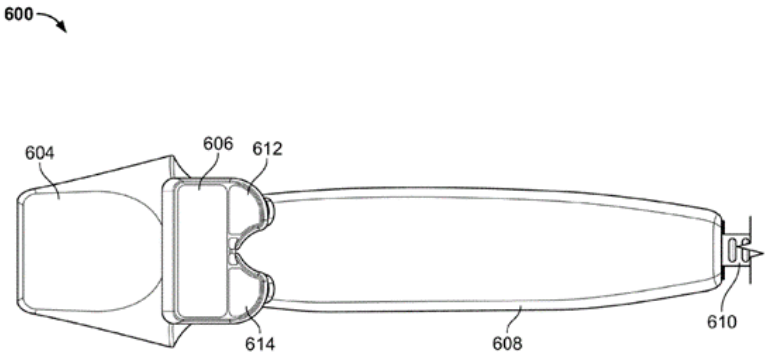
'812 Patent Claim 1		Mehta alone
		 FIG. 2C *Id*., Fig. 2C "FIG. 7A illustrates a partial side view of the … tissue engaging surface **106**" and "stabilization plate **214**" placed against the skin tissue. *Id*., at 21:1-13; *see also id*., at 21:22-34, Fig. 7B.  FIG. 7A *Id*., Fig. 7A. Mehta's user holdable device also includes "cartridges [**100**] that are removably coupled to the device body [**210**], where at least the plurality of first [needle] electrodes [**104**] and the tissue engaging surface [**106**] are located on or in the cartridge body." *Id*., at 4:63-66; *see also id*., at 9:34-55, 13:5-15, 35:8-10.[39] "FIG. 2D shows the treatment system

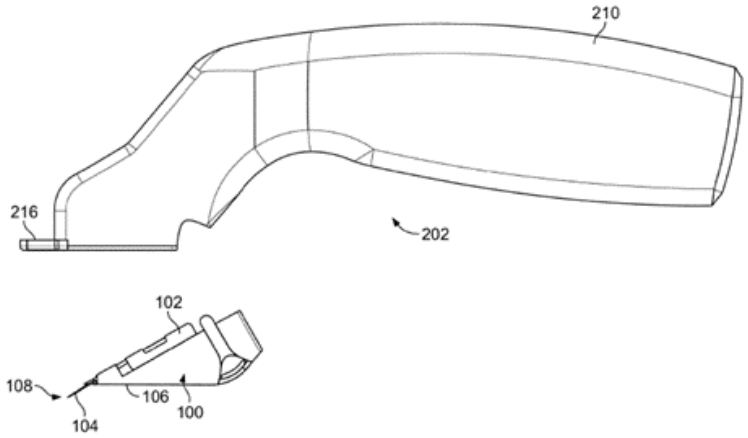
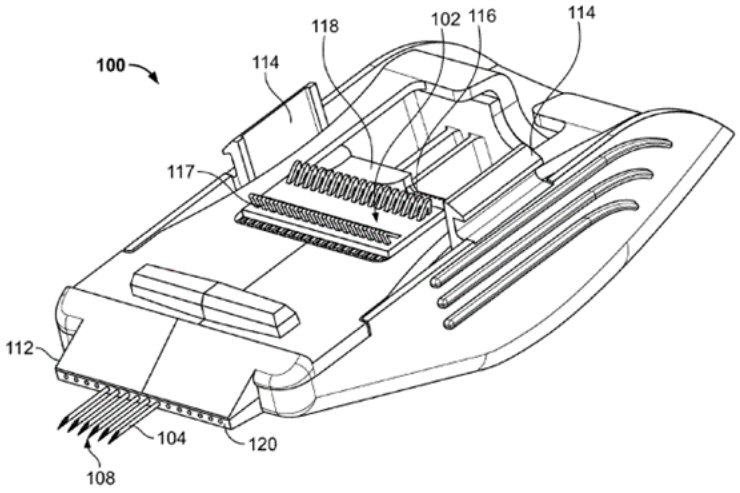
[39] Mehta refers to energy transfer elements and probes synonymously and explains these are needle electrodes. *Id*., at 49:43-53, 40:45-57, 12:23-20, 12:47-58, 16:59-17:12, 31:37-41.

‘812 Patent Claim 1		Mehta alone
		202 of FIG. 2A where the cartridge assembly **100** and device body **210** are separated.” *Id*., at 14:5-19.  FIG. 2D *Id*., Fig. 2D. As shown in Fig. 4, reproduced below, the “cartridge body **100**” may include “retention fasteners **114** allowing for coupling with the device body as well as removal from the device body … to permit removable coupling.” *Id*., at 15:27-33; *see also id*., at 16:42-58.  FIG. 4A *Id*., Fig. 4A. The needle electrodes are deployable from the cartridge. For example, Mehta discloses that the “tissue engaging surface and stabilization plate are positioned such that … the tissue

'812 Patent Claim 1		Mehta alone
		engaging surface is placed on the surface of tissue" so a "first plurality of energy transfer elements is advanced into the surface of tissue." *Id*., at 4:10-18; *see also id*., at 5:3-15, 12:23-30, 13:16-36 ("the probes are deployed into tissue subsequent to placement of the device body **210** against the tissue"), 13:58-14:4, 15:34-54, 16:19-33, 18:21-37, 21:43-62, 37:7-8 ("layer of skin in which the needles were deployed"). Mehta's "device body" **210** has a "handle portion" (*id*., at 4:1-18; *see also id*., at 9:34-39, 35:8-10, Figs. 12A, 12B), and thus, Mehta discloses a user holdable device (*id*, at 9:56-64 ("can be grasped by the hand")). Thus, Mehta's cartridge is a releasably couplable deployable needle module for a user holdable device, and Mehta's cartridge includes an end surface (tissue engaging surface and/or stabilization plate) which is placed on near dermatological tissue (skin) to be treated.
1.2	the user holdable device including a proximal end and the releasably couplable deployable needle module,	Mehta discloses the holdable device including a proximal end and the releasably couplable deployable needle module, *See e.g.*, Mehta, at 4:1-18; 4:19-30; 4:63-5:2; 5:3-15; 5:49-57; 6:30-37; 6:64-65; 9:34-55; Fig. 2A; 9:56-64; 9:65-10:7; 10:33-39; 10:48-52; 12:23-30; Fig. 2B; 12:31-46; 12:47-58; 12:59-13:4; 13:5-15; 13:16-36; 13:54-57; Fig. 3A; 13:58-14:4; 14:5-19; Fig. 2D; 14:20-29; 15:27-33; Fig. 4A; 15:34-54; 15:55-16:11; 16:12-18; 16:19-33; 16:42-58; 16:59-17:12; 17:46-58; Fig. 4F; 17:59-18:3; 18:21-37; Fig. 5; 18:37-45; 21:1-13; Fig .7A; 21:14-21; 21:22-34; Fig. 7B; 21:34-42; 21:43-62; 23:11-27; Fig. 7C; 31:37-41; 32:16-25; 35:8-22; Fig. 12A; Fig. 12B; 37:7-17. "FIG. 2D shows the treatment system of FIG. 2A where the cartridge assembly and device body are detachable." Mehta, at 6:41-42.

'812 Patent Claim 1		Mehta alone
		 FIG. 2D *Id*., Fig. 2D. "FIG. 2D shows the treatment system **202** of FIG. 2A where the cartridge assembly **100** and device body **210** are separated." Mehta, at 14:5-7. As shown in the discussion of limitation 1.1 above, Mehta's user holdable device includes the releasably couplable deployable needle module. Mehta's device body has "an electrical lead **610** on the proximal end," which connects to "the detachable cartridge **604** on [the] distal end **602**." Mehta, at 35:8-10.  FIG. 12A

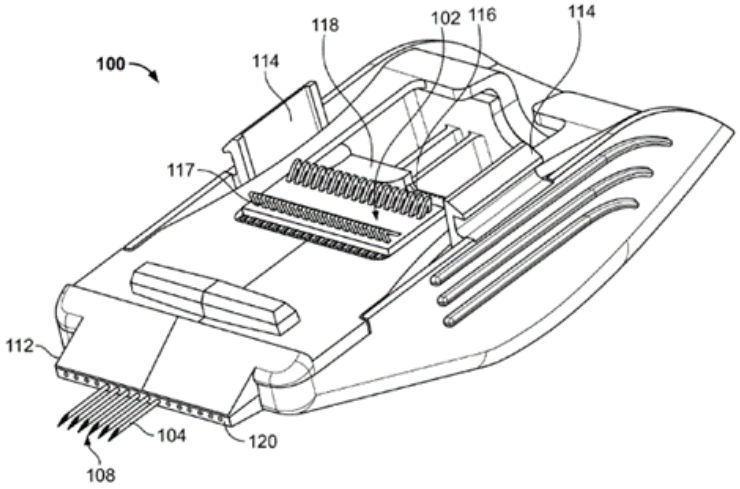
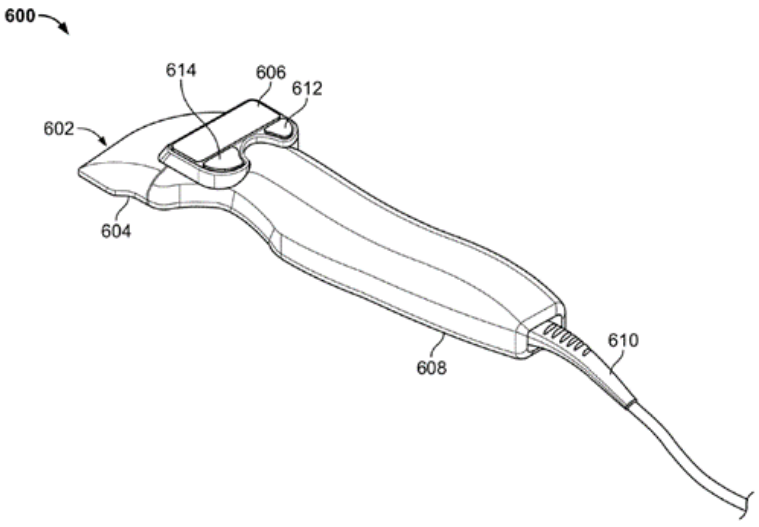
'812 Patent Claim 1		Mehta alone
		Id., Fig. 12A.  FIG. 12B *Id*., Fig. 12B.
1.3	the releasably couplable deployable needle module mechanically separatably from the user holdable device proximal end and including a needle assembly including a plurality of needles,	Mehta discloses the releasably couplable deployable needle module mechanically separatably from the user holdable device proximal end and including a needle assembly including a plurality of needles. *See e.g.*, Mehta, at 4:1-18; 4:19-30; 6:64-65; 4:63-5:2; 5:3-15; 5:49-57; 6:30-37; 6:64-65; 9:34-55; Fig. 2A; 9:56-64; 9:65-10:7; 10:33-39; 10:48-52; 12:23-30; Fig. 2B; 12:31-46; 12:47-58; 12:47-58; 12:59-13:4; 13:5-15; 13:16-36; 13:54-57; Fig. 3A; 14:5-19; Fig. 2D; 14:20-29; 15:27-33; Fig. 4A; 15:34-54; 15:55-16:11; 16:19-33; 16:42-58; 16:59-17:12; 17:46-58; Fig. 4F; 17:59-18:3; 18:21-37; Fig. 5; 18:37-45; 21:1-13; Fig .7A; 21:14-21; 21:22-34; Fig. 7B; 21:34-42; 21:43-62; 23:11-27; Fig. 7C; 31:37-41; 32:16-25; 35:8-22; Fig. 12A; Fig. 12B; 37:7-17; 6:64-65. To the extent that "separatably" does not render claim 1 indefinite, and is construed to be separatable, Mehta's releasably couplable deployable needle module is mechanically separatable from the user holdable device's proximal end, and includes a needle assembly including a plurality of needles. Mehta's cartridge body is removably attachable to the device body's "proximal end." Mehta, at 35:8-10, Figs. 12A, 12B;

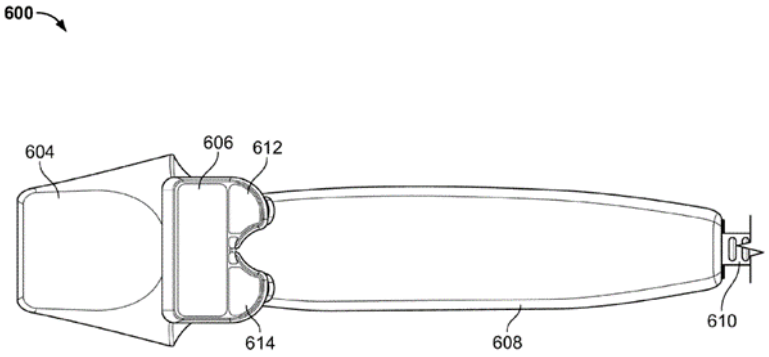
'812 Patent Claim 1		Mehta alone
		see also id., at 4:63-66, 6:64-65, 9:34-55, 13:5-15, 14:5-19, 35:8-10.  FIG. 2D *Id*., Fig. 2D. As shown in Fig. 4, reproduced below, the "cartridge body **100**" may include mechanical connectors, such as "retention fasteners **114** allowing for [mechanical] coupling with the device body as well as removal from the device body … to permit removable coupling." *Id*., at 15:27-33; *see also id*., at 16:42-58.  FIG. 4A *Id*., Fig. 4A. Mehta's releasably couplable deployable needle module includes a needle assembly including a plurality of needles.

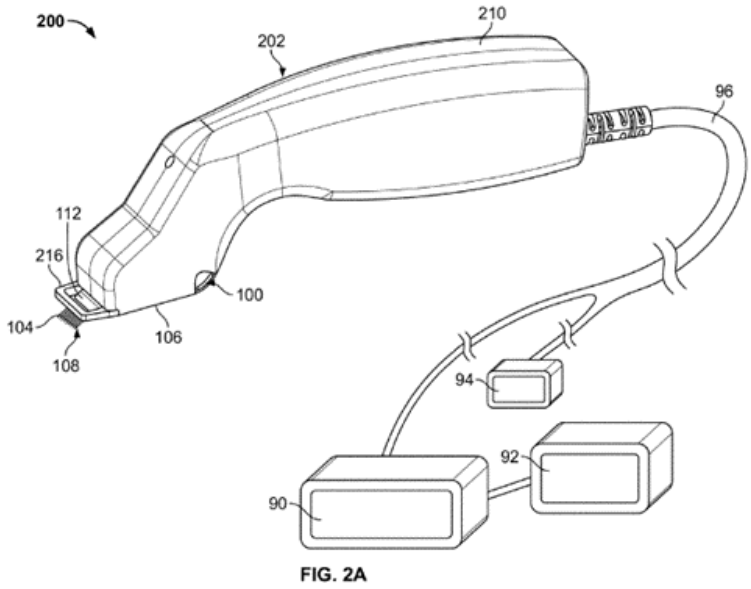
'812 Patent Claim 1		Mehta alone
		Id., at 15:55-16:1 ("FIG. 4A also shows the electrodes **104** in the electrode assembly **102** as having connection or contact portions **116** that couple to a connection board on a treatment unit to provide an electrical pathway from the power supply to the electrodes **104**"); 4:63-5:2 ("at least the plurality of first electrodes … are located on or in the cartridge body"), 9:34-55, 9:65-10:7, 10:33-39 ("driving the probe array **108** from the cartridge **100**"), 12:23-30, 14:5-19 ("The cartridge **100** can also be configured to provide the probes **104** on a probe assembly **102** that is slidable relative to the cartridge body **100** and device body **210**"), Fig. 2D, , 15:34-54, 15:55-16:11, 17:46-58, 18:21-37, 21:1-13, 7A, 23:11-27.[40]
1.4	the needle assembly movable within the releasably couplable deployable needle module to extend the plurality of needles from the releasably couplable deployable needle assembly end surface while at least one electrical contact of the needle assembly remains electrically coupled to at least one electrical contact of the user holdable device proximal end; and	Mehta discloses placing a user holdable device releasably couplable deployable needle module end surface on or near dermatological tissue to be treated, the user holdable device including a proximal end and the releasably couplable deployable needle module, the releasably couplable deployable needle module mechanically separatably from the user holdable device proximal end and including a needle assembly including a plurality of needles, the needle assembly movable within the releasably couplable deployable needle module to extend the plurality of needles from the releasably couplable deployable needle assembly end surface while at least one electrical contact of the needle assembly remains electrically coupled to at least one electrical contact of the user holdable device proximal end. *See e.g.*, Mehta, at 1:14-19; 2:3-12; 2:13-21; 2:58-62; 2:63-3:17; 3:29-39; 3:40-41; 3:57-67; 4:1-18; 4:19-30; 4:35-43; 4:63-5:2; 5:3-15; 5:16-25; 5:26-33; 5:49-57; 6:30-37; 6:64-65; 7:52-59; 7:60-8:5; 8:13-23; 9:34-55; Fig. 2A; 9:56-64; 9:65-10:7; 10:17-25; 10:33-39; 10:40-47; 10:48-52; 10:53-65; Fig. 2A; 11:14-20; 11:21-52; 12:5-14; 12:23-30; Fig. 2B; 12:31-46; 12:47-58; 12:59-13:4; 13:5-15; 13:16-36; Fig. 2C; 13:45-53; 13:54-57; Fig. 3A; 3:58-14:4; 14:5-19; Fig. 2D; 14:20-29; 15:27-33; Fig. 4A; 15:34-54; 15:55-16:11; 16:12-18; 16:19-33; 16:42-58; 16:59-17:12; 17:46-58; Fig. 4F; 17:59-18:3; 18:4-20; 18:21-37; Fig. 5; 18:37-45; 18:64-19:8; 19:66-20:12; 20:13-29; 20:29-47; Fig. 6; 21:1-13; Fig .7A; 21:14-21; 21:22-34; Fig. 7B; 21:34-42; 21:43-62; 23:11-27;

[40] Mehta refers to energy transfer elements and probes synonymously and explains these are needle electrodes. *Id*., at 49:43-53, 40:45-57, 12:23-20, 12:47-58, 16:59-17:12, 31:37-41.

'812 Patent Claim 1		Mehta alone
		Fig. 7C; 25:30-55; 26:60-27:22; 31:37-41; 32:16-25; 35:8-22; Fig. 12A; Fig. 12B; 37:7-17; 40:45-57. Mehta discloses that the needle assembly movable within the releasably couplable deployable needle module to extend the plurality of needles from the releasably couplable deployable needle assembly end surface. Mehta, at 14:5-19 ("The cartridge **100** can also be configured to provide the probes **104** on a probe assembly **102** that is slidable relative to the cartridge body **100** and device body **210**"), *id*., at 4:63-5:2, 5:3-15, 9:34-55 ("one or more probes **104** extending from the body **210** … the probes **103** can optionally extend from a front portion **112** of the cartridge **100**," or "from a front face of the device body or from any surface of the device body/cartridge"), 15:34-54 ("The cartridge body **100** further includes an electrode assembly **102** that is moveable or slidable within the cartridge body **100**"), 15:55-16:11, 16:42-58, 21:1-13; *See also id*., at 4:1-18, 10:33-39, 12:23-30, 13:5-36. The needle assembly is movable, such that the needles can be extended while at least one electrical contact of the needle assembly remains electrically coupled to at least one electrical contact of the user holdable device proximal end. For example, as shown in Fig. 4A, reproduced below, "the electrodes **104** in the electrode assembly **102** as having connection or contact portions **116** that couple to a connection board on a treatment unit to provide an electrical pathway from the power supply to the electrodes **104**," and "the electrode assembly **102** as well as the connection portions **116** moves" so that the electrodes remain electrically connected to the "power supply" when extended. *Id*., at 15:55-16:11; *see also id*., at 16:12-18 (for example, by using "spring contacts or spring pins" for the electrical "connection portions **116**" so that "the connection portions **116** can maintain contact with a corresponding contact point trace on a connection board during movement of the electrode assembly **102**"), 35:8-22 ("electrical lead **610** on the proximal end"); *see also id*., at 10:53-65, 12:5-14,25:30-55, Fig. 2A.

‘812 Patent Claim 1		Mehta alone
		 FIG. 4A *Id*., Fig. 4A.  FIG. 12A *Id*., Fig. 12A.

'812 Patent Claim 1		Mehta alone
		 FIG. 12B *Id.*, Fig. 12B. Accordingly, Mehta discloses that the needle assembly movable within the releasably couplable deployable needle module to extend the plurality of needles from the releasably couplable deployable needle assembly end surface while at least one electrical contact of the needle assembly remains electrically coupled to at least one electrical contact of the user holdable device proximal end.
1.5	communicating electrical signals from the user holdable device proximal end to the needle assembly via the electrical contacts.	Mehta discloses communicating electrical signals from the user holdable device proximal end to the needle assembly via the electrical contacts. *See e.g.*, Mehta, at 2:58-62; 2:63-3:17; 3:40-56; 3:57-67; 4:1-18; 5:3-15; 5:26-33; 5:26-33; 9:34-55; 10:53-65; Fig. 2A; 15:55-16:11; Fig. 4A; 18:4-20; 24:46-60; 25:30-55; 26:60-27:22; 41:40-43; 41:55-58. Mehta discloses that the energy supply unit 90 is coupled to the proximal end of the user holdable device (treatment unit **202**). Mehta, at 10:53-65.

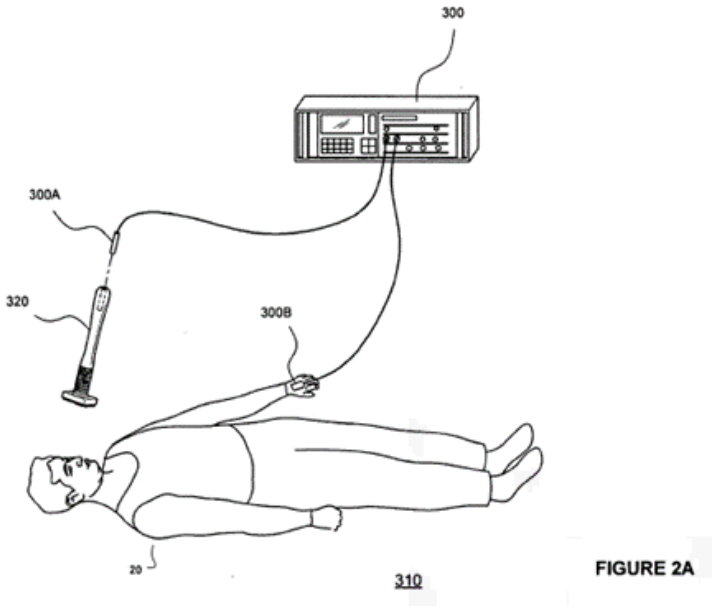
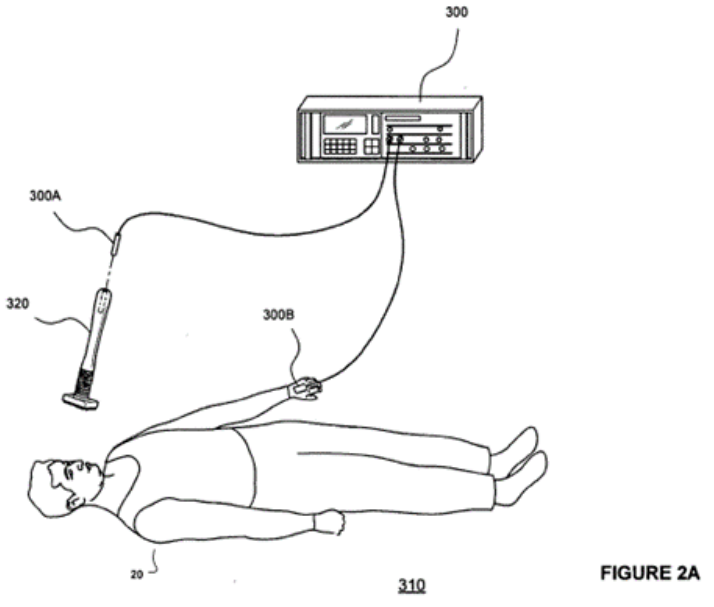
‘812 Patent Claim 1		Mehta alone
		 FIG. 2A *Id*., Fig. 2A. The electrical signals from the energy supply unit are then communicated from the user holdable device’s proximal end to the needle assembly via the electrical contacts. *Id*., at 2:63-3:17 (“a connector adapted to couple the energy supply unit to the” needle electrodes), 15:55-16:11 (the connections “provide an electrical pathway from the power supply to the electrodes **104**” for energy delivery), 18:4-20 (“RF … current” is supplied to the needle electrodes), 24:46-60, 25:30-55 (“RF treatment current” is delivered to the electrodes); *see also id*., at 2:58-62, 3:40-67, 5:3-15, 5:26-33, 5:49-57, 10:53-65, Figs. 2A, 4A.

525. In view of the foregoing chart, claim 1 of the ‘812 patent is anticipated by the teachings of Mehta. Further, to the extent Complainant argues that any of the foregoing limitations is not explicitly or inherently disclosed by Mehta, such limitations would have been obvious given the knowledge of a POSITA. The teachings of Mehta are so similar to what is claimed that any alleged difference between the teachings of Mehta and what is claimed would not have been of patentable significance given the knowledge of a POSITA.

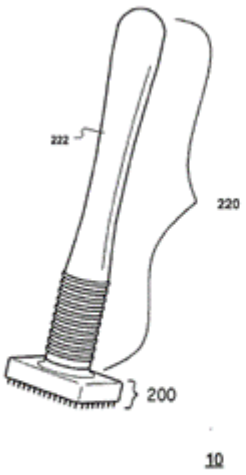
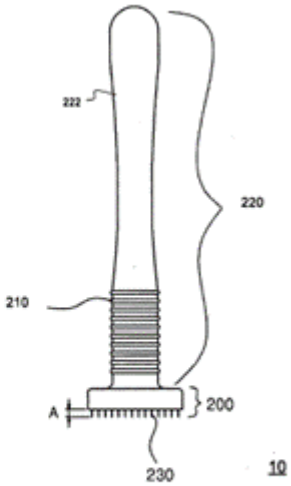
2. Claim 1 of the '812 Patent is rendered Obvious by Na '848 in view of Mehta

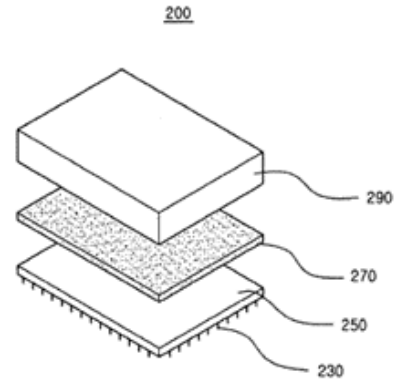
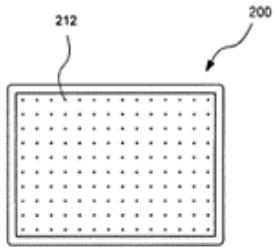
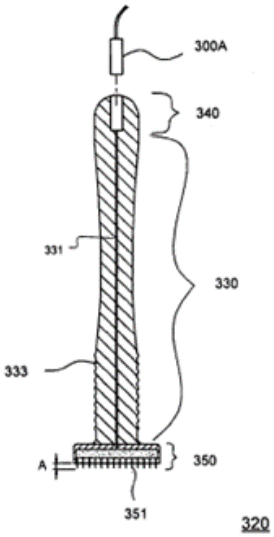
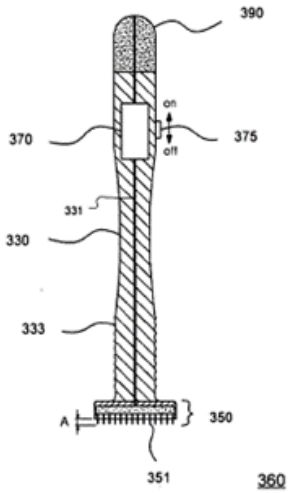
526. It is my opinion that Na '848 in combination with Mehta renders claim 1 of the '812 Patent as detailed below. In addition to the reasons described above, the POSITA would have been motivated to combine Na '848 and Mehta because they are in the same field of endeavor and solve similar technical problems. Mehta provides a solution for the need to provide an electrode array to "provide deep uniform heating by applying energy to tissue below the epidermis to cause deep structures of the skin to immediately tighten." Mehta at 2:6-9. Na '848 similarly provides an apparatus for treating dermatological tissue with an electrode array. Na at [0003] and *e.g.,* FIG. 1A.

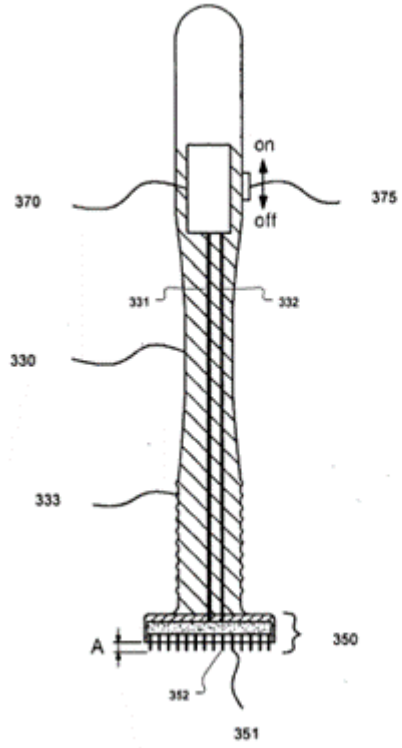
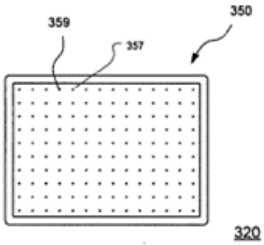
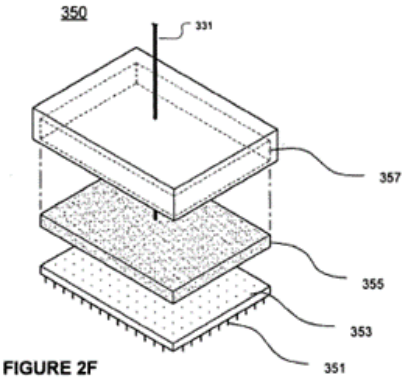
'812 Patent Claim 1		**Na '848 in view of Mehta**
1.0	1. A method of treating dermatological tissue, comprising:	***Claim 1 of the '812 Patent is Rendered obvious by Na '848 in view of Mehta.*** To the extent the preamble is limiting, Na '848 discloses and/or renders obvious a method of treating dermatological tissue according to the claim. *See, e.g.*, Na '848 at [0002–0003], [0008], FIG 2A. Na '848 discloses that **"**[v]arious embodiments described herein relate generally to treating dermalogical [*dermatological]* tissue, including systems, and methods used in treating dermalogical *[dermatological]* tissue.**"** (*id*. at [0002]), and that **"**[i]t may be desirable to treat dermalogical *[dermatological]* tissue, the present invention provides such treatment**"** (*id*. at [0003]). FIG. 2A is a simplified isometric diagram of a dermalogical *(dermatological)* treatment architecture according to various embodiments of Na '848:

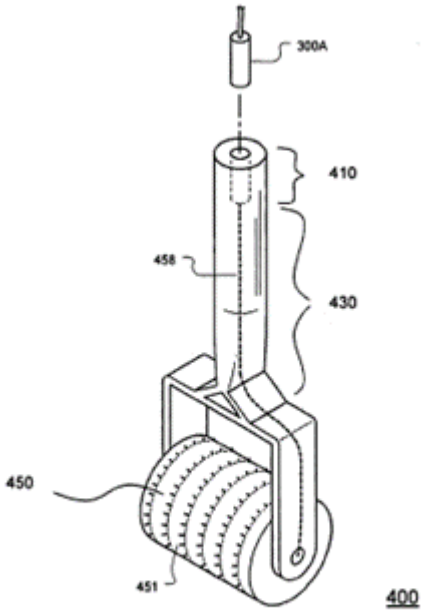
'812 Patent Claim 1		Na '848 in view of Mehta
		 FIGURE 2A
1.1 & 1.2 & 1.3	placing a user holdable device releasably couplable deployable needle module end surface on or near dermatological tissue to be treated, the user holdable device including a proximal end and the releasably couplable deployable needle module, the releasably couplable deployable needle module mechanically separatably from the user holdable device proximal end and including a needle assembly including a plurality of needles,	Na '848 discloses and/or renders obvious placing a user holdable device needle module end surface on or near dermatological tissue to be treated. FIG. 2A is a simplified isometric diagram of a dermalogical (*sic*) treatment architecture according to various embodiments of Na '848:  FIGURE 2A Na '848 describes FIG. 2A as

'812 Patent Claim 1		Na '848 in view of Mehta
		a simplified diagram of a dermalogical [*sic*] treatment architecture **310** according to various embodiments. Architecture **310** includes an acupuncture apparatus **320** and an electrical signal generation system **300**. The the [*sic*] electrical signal generation system **300** may be electrically coupled to the acupuncture apparatus **320** via one or more wires **300**A and to a mammal **20** to be treated via one or more wires **300B**. FIG. 2B is a simplified cross-sectional diagram of the acupuncture apparatus **320** according to various embodiments. The apparatus **320** may include a handle **330**, elastic section **333**, electrical interface **340**, internal wire(s) **33** land plate **350**. The pins **351** may have a length A (0.3 mm to 2.1 mm in an embodiment) where at least one pin **351** is electrically coupled to the electrical interface **340** via the internal wire **331**. The electrical interface **340** may be removably connected to the system **300** wire **300A**. *Id*. at [0026]. Na '848 discloses that the "apparatus **360** may include a handle **330**, an elastic section **333**, an electrical conductive interface **390**, internal wire(s) **331**, signal generator **370**, switch **375**, and plate **350**,**"** and that the **"**signal generator **370** may be coupled to at least one pin **351** via internal wire **331** and coupled to the conductive interface **390**." *Id*. at [0027]. Na '848 further discloses that a "user, clinician, or equipment may place an apparatus **10**, **320**, **360**, **360**, **400**, **460** on dermalogical cells to be treated (activity **741**) including pressing the apparatus against the cells firmly enough to embed one or more pins **251**, **351**, **451** in the cells," (*id*. at [0042]), and that the **"**user, clinician, or equipment may place apparatus **10**, **320**, **360**, **360**, **400**, **460** on dermalogical cells to be treated (activity **752**)," (*id*. at [0043]). It further discloses that the **"**user, clinician, or equipment may place an apparatus **10**, **320**, **360**, **360**, **400**, **460** on dermalogical cells to be treated (activity **762**).**"** *Id*. at [0044]. Na '848 further discloses that the holdable device includes a proximal end and the needle module, and the needle module including a needle assembly including a plurality of needles. FIG. 1A is a simplified isometric diagram of a dermalogical treatment apparatus according to various embodiments. *Id*. at [0004]. FIG. 1B is a simplified, side diagram of the

'812 Patent Claim 1		Na '848 in view of Mehta
		dermalogical treatment apparatus according to various embodiments. *Id*. at [0005]. FIG. 1C is a simplified, exploded view of layers of the dermalogical treatment apparatus according to various embodiments. *Id*. at [0006]. FIG. *ID* is a simplified view of a layer of a dermalogical treatment apparatus according to various embodiments. *Id*. at [0007]. FIG. 2A is a simplified isometric diagram of a dermalogical treatment architecture according to various embodiments. *Id*. at [0008]. FIG. 2B is a simplified cross-sectional diagram of a dermalogical treatment apparatus according to various embodiments. *Id*. at [0009]. FIG. 2C is a simplified cross-sectional diagram of another dermalogical treatment apparatus according to various embodiments. *Id*. at [0010]. FIG. 2D is a simplified cross-sectional diagram of another dermalogical treatment apparatus according to various embodiments. *Id*. at [0011]. FIG. 2E is a simplified view of a layer of a dermalogical treatment apparatus according to various embodiments. *Id*. at [0012]. FIG. 2F is a simplified, exploded view of layers of the dermalogical treatment apparatus according to various embodiments. *Id*. at [0013]. FIG. 3 A is a simplified isometric diagram of a dermalogical treatment apparatus according to various embodiments. *Id*. at [0014].  FIGURE 1A  FIGURE 1B

'812 Patent Claim 1		Na '848 in view of Mehta
		 FIGURE 1C  FIGURE 1D  FIGURE 2B  FIGURE 2C

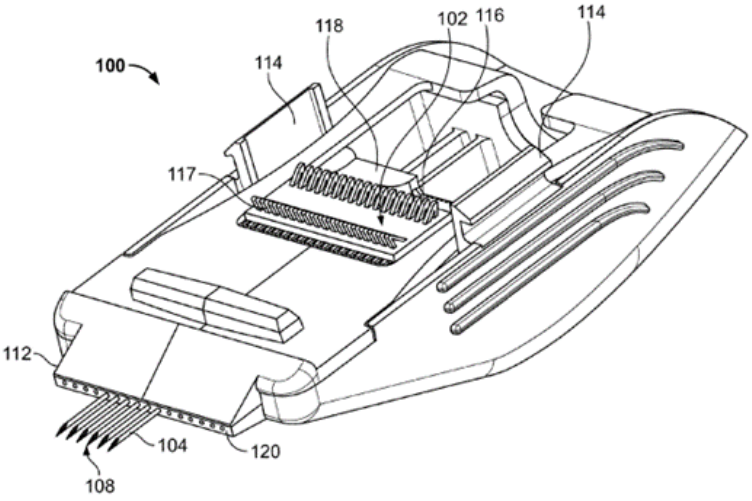
‘812 Patent Claim 1		Na ‘848 in view of Mehta
		 FIGURE 2D 362  FIGURE 2E  FIGURE 2F

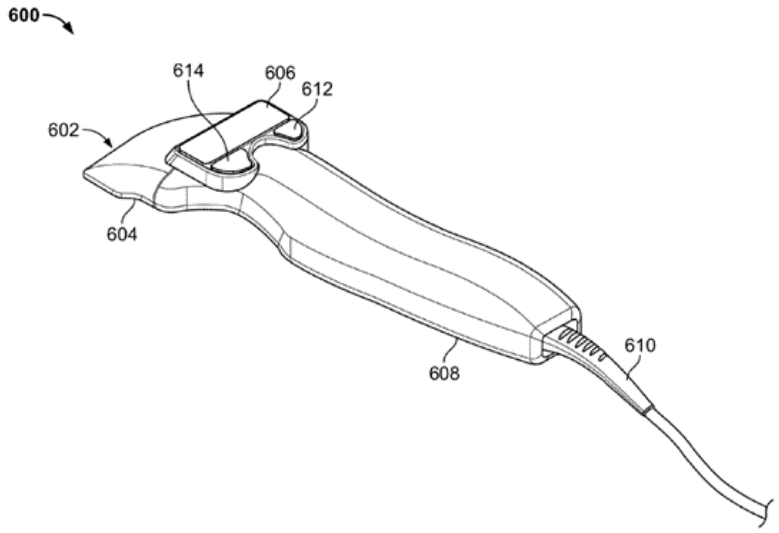
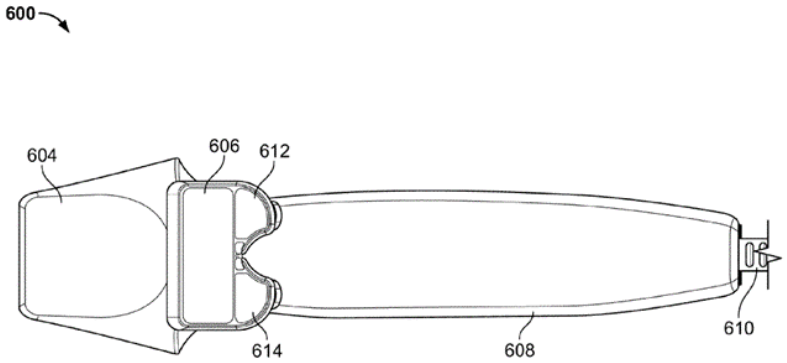
'812 Patent Claim 1		Na '848 in view of Mehta
		 FIGURE 3A Na '848 further discloses that the **"**apparatus **10** may include a user handle **220** coupled to an acupuncture plate **200**.**"** *Id*. at [0022]. **"**In an embodiment the plate **200** may be elastically coupled to the handle segment **222** via an elastomeric section **210**.**"** *Id*. "The acupuncture section **250** may include a plurality of acupuncture pins or needles **230**. FIG. *ID* is a simplified bottom view of the plate **200** showing the location or holes **212** for the pins or needles **230**.**"** *Id*. at [0023]. Na '848 further discloses a needle assembly including a plurality of needles: In an embodiment the plate may include about **140** pins or needles **230** uniformly separated. Each needle may be about 0.1 to 0.4 mm in diameter and 0.2 mm to 1.4 mm in length including 0.3 mm in diameter and 0.8 mm in length in an embodiment. The elastic section or layer **270** may be comprised of a combination of elastomeric materials and non-elastomeric materials. The elastomeric materials may include plastics, rubber (synthetic or natural), and spring(s). The pin section **230** may be coupled directly or indirectly to the upper section **290** via the elastic section **250**, including via glues, screws, welds, or other connection. In an

'812 Patent Claim 1		Na '848 in view of Mehta
		embodiment the pin section **250** may include elastomers to enable at least partial deformation of the pin section **250** about the pins **230**. *Id*. at [0024]. Na '848 further discloses that **"**[i]n operation a user may employ the apparatus **10** to create a plurality of micro-wounds or holes in dermalogical layers of a mammal's **20** skin or dermis.**"** *Id*. at [0025]. Further: Architecture **310** includes an acupuncture apparatus **320** and an electrical signal generation system **300**. The the [*sic*] electrical signal generation system **300** may be electrically coupled to the acupuncture apparatus **320** via one or more wires **300A** and to a mammal **20** to be treated via one or more wires **300B**. FIG. 2B is a simplified cross-sectional diagram of the acupuncture apparatus **320** according to various embodiments. The apparatus **320** may include a handle **330**, elastic section **333**, electrical interface **340**, internal wire(s) **33** land plate **350**. The pins **351** may have a length A (0.3 mm to 2.1 mm in an embodiment) where at least one pin **351** is electrically coupled to the electrical interface **340** via the internal wire **331**. The electrical interface **340** may be removably connected to the system **300** wire **300A**. *Id*. at [0026]. The apparatus **362** may include a handle **330**, an elastic section **333**, internal wire(s) **331**, **332**, signal generator **370**, switch **375**, and plate **350**. The signal generator **370** may be coupled to at least one pin **351** via internal wire **331** and coupled to at least one other pin **352** via internal wire **332**. When active the pins **351**, **352** may form at least one dipole pair. The signal generator or module **370** may generate a vary of signals (such as shown in FIGS. 5A to 6) to vibrate one or more dipole pair or bipolar pins **351**, **352**. *Id*. at [0029]. FIG. 2F includes a simplified exploded view of an embodiment of an acupuncture plate **350** including at least one electrically coupled pin **351** according to various embodiments. The plate **350** may include an upper, substantially rigid section or layer **357**, deformable or elastic section **355** or layer, and

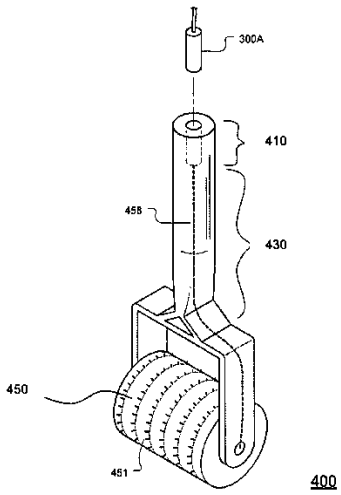
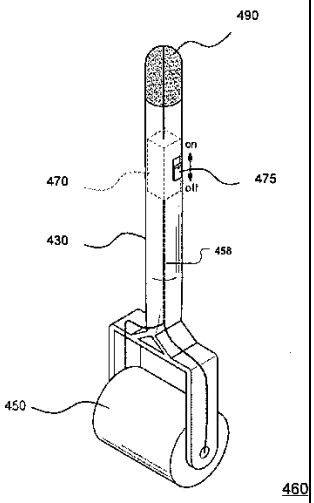
'812 Patent Claim 1		Na '848 in view of Mehta
		acupuncture section or layer **353**. The acupuncture section **353** may include a plurality of acupuncture pins or needles **351** where at least one pin **351** is electrically coupled to the wire **331**. In a bipolar configuration a second wire **332** may be coupled to at least one other pin **351**. FIG. 2E is a simplified bottom view of the plate **350** showing the pins or needles **359**, **357** where the pins may be electrically coupled to a first wire **331** and a second wire **332** to form dipole pair (bipolar pins). *Id*. at [0030]. In an embodiment the plate **350** may have a rectangular cross section having a dimensional about 1 to 4 cm in width and about 1 to 6 cm in length. The plate **350** may any shape including circular, elliptical, polygon, or other shape where the shape may be particular to a dermalogical area to be treated. *Id*. at [0031]. In an embodiment the plate may include about **140** pins or needles **351** uniformly separated. Each needle may be about 0.1 to 0.4 mm in diameter and 0.2 mm to 1.4 mm in length including 0.3 mm in diameter and 0.8 mm in length in an embodiment. The elastic section or layer **355** may be comprised of a combination of elastomeric materials and non-elastomeric materials. The elastomeric materials may include plastics, rubber (synthetic or natural), and spring(s). The pin section **353** may be coupled directly or indirectly to the upper section **357** via the elastic section **353**, including via glues, screws, welds, or other connection. In an embodiment the pin section **353** may include elastomers to enable at least partial deformation of the pin section **353** about the pins **351**. *Id*. at [0032]. FIGS. 3A and 3B are simplified isometric diagrams of acupuncture apparatus **400**, **460** including at least one pin **451** that may be coupled to an electrical signal via an internal wire **458**. Each apparatus **400**, **460** includes curved roller **450** having a plurality of acupuncture pins **451** where the pins **451** may be similar to pins **351**. In apparatus **400**, the electrical lead wire **400A** may be

'812 Patent Claim 1		Na '848 in view of Mehta
		coupled to an electrical interface **410** in the apparatus handle **430** where the interface **410** is electrically coupled to the internal wire **458**. In apparatus **460**, the handle **430** may include a signal generator **470** similar to generator **370**, switch **475**, and conduction surface **490**. Apparatus **460** may operate similar to apparatus **360** in operation other than the rolling capability of the apparatus **460**, **400**. In an embodiment the rollers **450** may have various configurations to conform to a dermal area to be treated. *Id*. at [0033]. In this description, the needle assembly includes an electrical connector that allows the assembly to be "releasably couplable" with at least one electrical contact. Figures 2B and 2C of Na' 848 do not clearly show how much of the handle is part of the cable connector and how much is part of the disposable (releasably couplable) needle assembly. However, many electrosurgical accessories include a reusable handle to which a disposable electrode set can be easily coupled mechanically and electrically. Thus, for a POSITA, it would be obvious that the "needle assembly" connects to a "reusable handle" and is releasably couplable. Mehta also teaches clearly that the needle assembly is releasable and couplable, which would make this choice even more obvious for a POSITA.
1.4	the needle assembly movable within the releasably couplable deployable needle module to extend the plurality of needles from the releasably couplable deployable needle assembly end surface while at least one electrical contact of the needle assembly remains electrically coupled to at least one electrical contact of the user holdable device proximal end; and	Mehta discloses that the needle assembly movable within the releasably couplable deployable needle module to extend the plurality of needles from the releasably couplable deployable needle assembly end surface. Mehta, at 14:5-19 (**"**The cartridge **100** can also be configured to provide the probes **104** on a probe assembly **102** that is slidable relative to the cartridge body **100** and device body **210"**), *id*., at 4:63-5:2, 5:3-15, 9:34-55 (**"**one or more probes **104** extending from the body **210** … the probes **103** can optionally extend from a front portion **112** of the cartridge **100**,**"** or **"**from a front face of the device body or from any surface of the device body/cartridge**"**), 15:34-54 (**"**The cartridge body **100** further includes an electrode assembly **102** that is moveable or slidable within the cartridge body **100"**), 15:55-16:11, 16:42-58, 21:1-13; *See also id*., at 4:1-18, 10:33-39, 12:23-30, 13:5-36.

'812 Patent Claim 1		Na '848 in view of Mehta
		The needle assembly is movable, such that the needles can be extended while at least one electrical contact of the needle assembly remains electrically coupled to at least one electrical contact of the user holdable device proximal end. For example, as shown in Fig. 4A, reproduced below, **"**the electrodes **104** in the electrode assembly **102** as having connection or contact portions **116** that couple to a connection board on a treatment unit to provide an electrical pathway from the power supply to the electrodes **104**,**"** and **"**the electrode assembly **102** as well as the connection portions **116** moves**"** so that the electrodes remain electrically connected to the **"**power supply**"** when extended. *Id*., at 15:55-16:11; *see also id*., at 16:12-18 (for example, by using **"**spring contacts or spring pins**"** for the electrical **"**connection portions **116"** so that **"**the connection portions **116** can maintain contact with a corresponding contact point trace on a connection board during movement of the electrode assembly **102"**), 35:8-22 (**"**electrical lead **610** on the proximal end**"**); *see also id*., at 10:53-65, 12:5-14,25:30-55, Fig. 2A.  FIG. 4A *Id*., Fig. 4A.

'812 Patent Claim 1		Na '848 in view of Mehta
		 FIG. 12A *Id*., Fig. 12A.  FIG. 12B *Id*., Fig. 12B. Accordingly, Mehta discloses that the needle assembly movable within the releasably couplable deployable needle module to extend the plurality of needles from the releasably couplable deployable needle assembly end surface while at least one electrical contact of the needle assembly remains electrically coupled to at least one electrical contact of the user holdable device proximal end.

'812 Patent Claim 1		Na '848 in view of Mehta
1.5	communicating electrical signals from the user holdable device proximal end to the needle assembly via the electrical contacts.	Na '848 discloses and/or renders obvious communicating electrical signals from the user holdable device proximal end to the needle assembly via the electrical contacts. Na '848 discloses that the **"**[a]rchitecture **310** includes an acupuncture apparatus **320** and an electrical signal generation system **300**,**"** and that the **"**electrical signal generation system **300** may be electrically coupled to the acupuncture apparatus **320** via one or more wires **300A** and to a mammal **20** to be treated via one or more wires **300B**. Na '848 at [0026]. **"**The apparatus **320** may include a handle **330**, elastic section **333**, electrical interface **340**, internal wire(s) **33** land plate **350**.**"** *Id*. **"**The pins **351** may have a length A (0.3 mm to 2.1 mm in an embodiment) where at least one pin **351** is electrically coupled to the electrical interface **340** via the internal wire **331**.**"** *Id.; see also id*. at [0027] (**"**The signal generator **370** may be coupled to at least one pin **351** via internal wire **331** and coupled to the conductive interface **390**.**"**); [0028] **"**The signal generator or module **370** may generate a vary of signals (such as shown in FIGS. 5 A to 6) to vibrate one or more pins **351** electrically coupled to the system **300** via the internal wire **331** and the conductive interface **390**….The switch **375** coupled to the generator **370** may cause the generator to produce one or more electrical signals for a predetermined time interval or until the switch **375** is triggered again.**"**). Na '848 further discloses that the **"**signal generator **370** may be coupled to at least one pin **351** via internal wire **331** and coupled to at least one other pin **352** via internal wire **332**. *Id*. at [0029]. **"**The signal generator or module **370** may generate a vary of signals (such as shown in FIGS. 5A to 6) to vibrate one or more dipole pair or bipolar pins **351**, **352**.**"** *Id*. FIGS. 3A and 3B are simplified isometric diagrams of acupuncture apparatus **400**, **460** including at least one pin **451** that may be coupled to an electrical signal via an internal wire **458**.**"** *Id* at [0033]. **"**In apparatus **400**, the electrical lead wire **400A** may be coupled to an electrical interface **410** in the apparatus handle **430** where the interface **410** is electrically coupled to the internal wire **458**.**"** *Id*.

'812 Patent Claim 1		Na '848 in view of Mehta
		 FIGURE 3A  FIGURE 3B *Id*. at FIGs 3A and 3B.

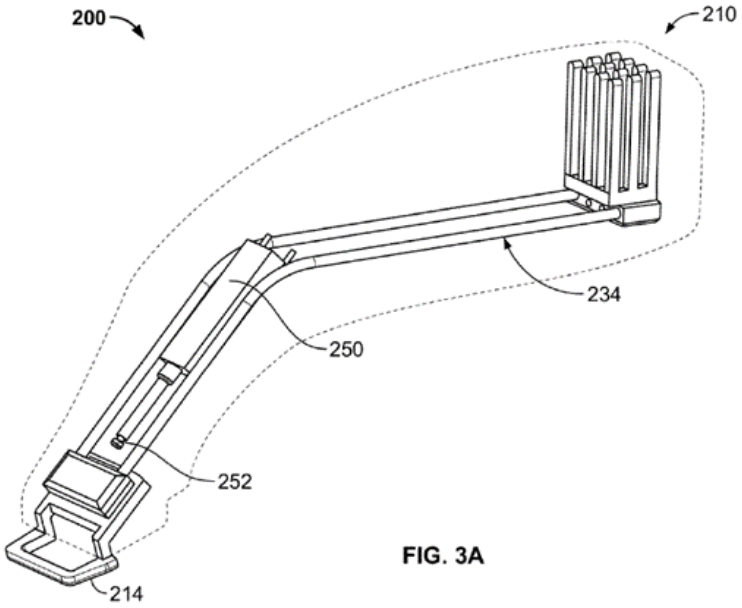
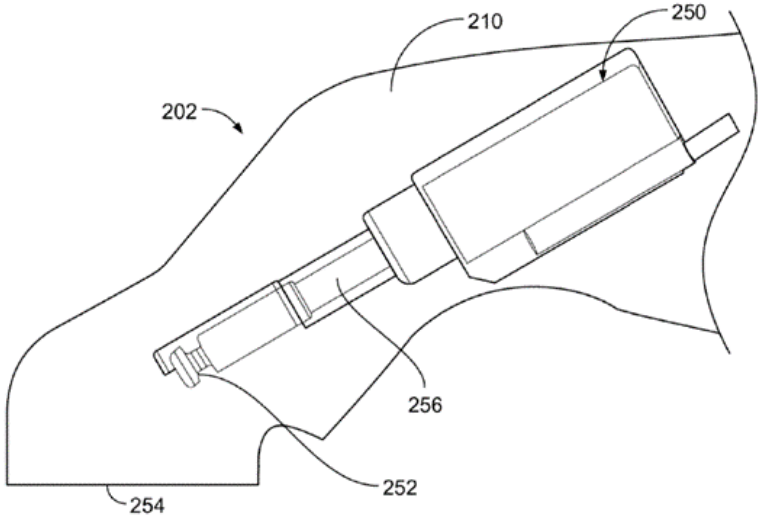
527. In view of the foregoing chart, claim 1 of the '812 Patent is rendered obvious by Na '848 in view of Mehta. Further, to the extent Complainant argues that any of the foregoing limitations is not explicitly or inherently disclosed by Na '848 in view of Mehta, such limitations would have been obvious given the knowledge of a POSITA. The teachings of Na '848 in view of Mehta are so similar to what is claimed that any alleged difference between the teachings of Mehta and what is claimed would not have been of patentable significance given the knowledge of a POSITA.

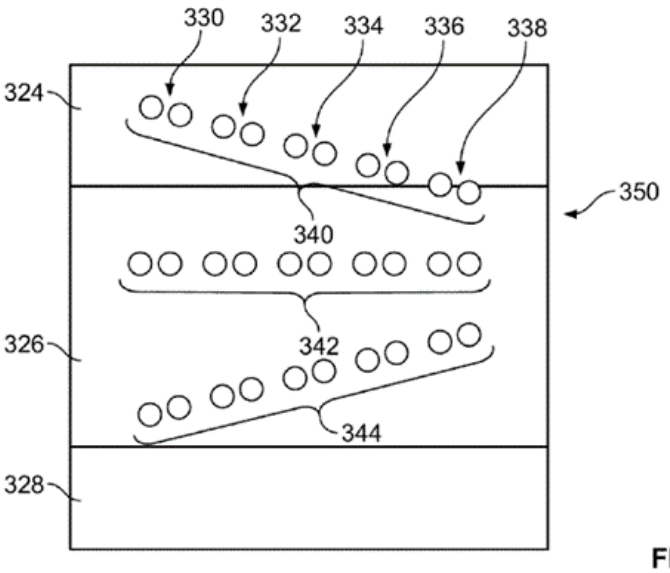
3. Claim 2 of the '812 Patent is Anticipated by or rendered Obvious by Mehta

528. Unasserted claim 2 of the '812 Patent depends on claim 1. It is my opinion that Mehta anticipates and/ or renders claim 1 of the '812 Patent obvious as detailed below:

'812 Patent Claim 2[41]		Mehta alone
2	2. The method of claim 1, further comprising energizing a motor coupled to the needle assembly to the plurality of the needles to extend a desired distance from the releasably couplable deployable needle module end surface.	***Claim 2 of the '812 Patent is anticipated and/or rendered obvious by Mehta.*** As noted above, Mehta discloses and/or renders obvious the method of treating dermatological tissue of claim 1. (*See* Claim 1, above). Mehta discloses energizing a motor coupled to the needle assembly to cause the plurality of the needles to extend a desired distance from the releasably couplable deployable needle module end surface. *See e.g.*, Mehta,; 4:63-5:2; 5:3-15; 6:64-65; 9:34-55; 10:33-39; 12:5-14; 12:31-46; 13:54-57;; 13:58-4; 15:27-33; 15:55-16:11; Fig. 4A; 16:42-58; 16:59-17:12; 18:21-37; Fig. 5; 23:55-24:4; Fig. 7E; 24:46-60; 32:46-62; Fig. 10B; 32:63-33:14; 33:15-29; 33:30-34; 33:57-13; Fig. 10E; 34:38-45; 35:8-22; Fig. 12A; Fig. 12B; 36:21-40. For example, Mehta discloses that "the cartridge and/or energy delivery elements can be coupled to an actuator, where movement of the actuator causes advancement or retraction of the first plurality of electrodes" (Mehta, at 4:63-5:2), and the "[e]xamples of such actuators include, but are not limited to … motors" "driven by the control system/energy supply unit 90" (*id*., at 10:33-39). *See also id*., at 12:5-14, 13:58-4 ("the actuator **250** comprises a motor"), 16:59-17:12, 18:21-

[41] Asserted claim 5 depends indirectly from unasserted claim 2.

‘812 Patent Claim 2[41]		Mehta alone
		37.  FIG. 3A  FIG. 5 *Id*., Fig. 5. Mehta discloses energizing a motor coupled to the needle assembly to cause the plurality of the needles to extend a desired distance from the releasably couplable deployable needle module end surface. For example, he describes that FIG. 5 illustrates a cross sectional view of a distal end of a

'812 Patent Claim 2[41]		Mehta alone
		variation of treatment unit **202** without a cartridge attached to a cartridge receiving surface **254** of the device body **210**. As shown, the device body 210 includes a moveable actuator **250** adjacent to the cartridge receiving Surface **254**. In this variation, a shaft **256** of the actuator **250** couples to a cartridge or probe assembly on a cartridge. The actuator 250 moves the shaft **256** where an engagement portion 252 on the shaft couples to the probe assembly (*e.g.*, via a coupling portion 118 shown above) to advance and retract the probes (not shown). In another example, Mehta discloses that the physician can check if the needles extended to the desired distance using a "virtual depiction **350** of the depth or location of the probe array," as shown in Fig. 10B, reproduced below. *Id*., at 32:46-62; *see also id*., at 32:63-33:14 ("desired probe location … represent the desired depth of placement for providing a treatment"), 33:15-29, 33:30-34 ("the system described herein can be adjusted to guide probe placement within the first or third layers **324** or **328** depending on the type of treatment being applied"), 33:57-34:13, 34:38-45, 35:8-22 ("The physician can use the information [displayed on the screen] to make decisions and then adjustments by using the actuators **612** and **614**"), 36:21-40 (desired distance relates to the depth of the 6 mm needle with it "enter[s] the epidermis at a 20° angle to the skin surface for a distance of 6 mm"), Fig. 10E.  FIG. 10B

'812 Patent Claim 2[41]		Mehta alone
		Id., Fig. 10B.

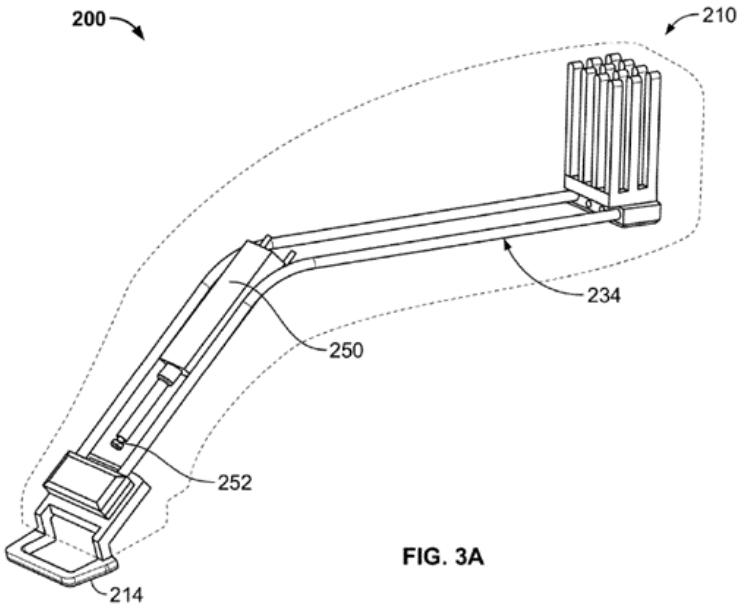
529. In view of the foregoing chart, claim 2 of the '812 Patent is anticipated by the teachings of Mehta. Further, to the extent Complainant argues that any of the foregoing limitations is not explicitly or inherently disclosed by Mehta, such limitations would have been obvious given the knowledge of a POSITA. The teachings of Mehta are so similar to what is claimed that any alleged difference between the teachings of Mehta and what is claimed would not have been of patentable significance given the knowledge of a POSITA.

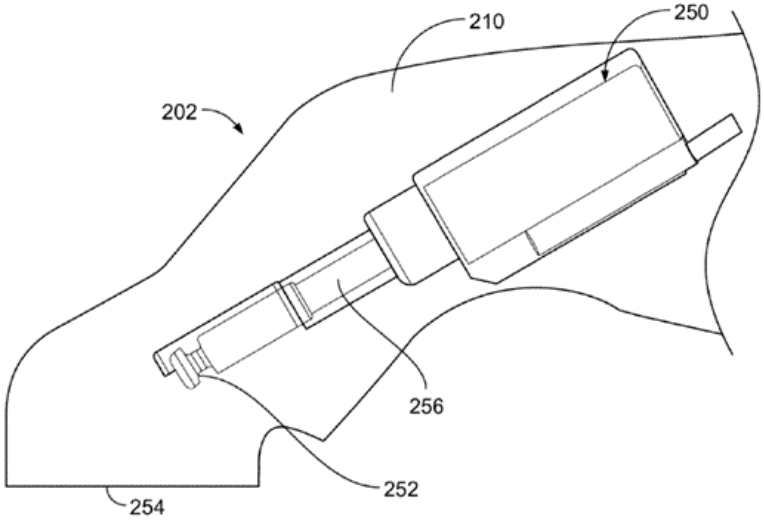
4. Claim 2 of the '812 Patent is rendered Obvious by Na '848 in view of Mehta

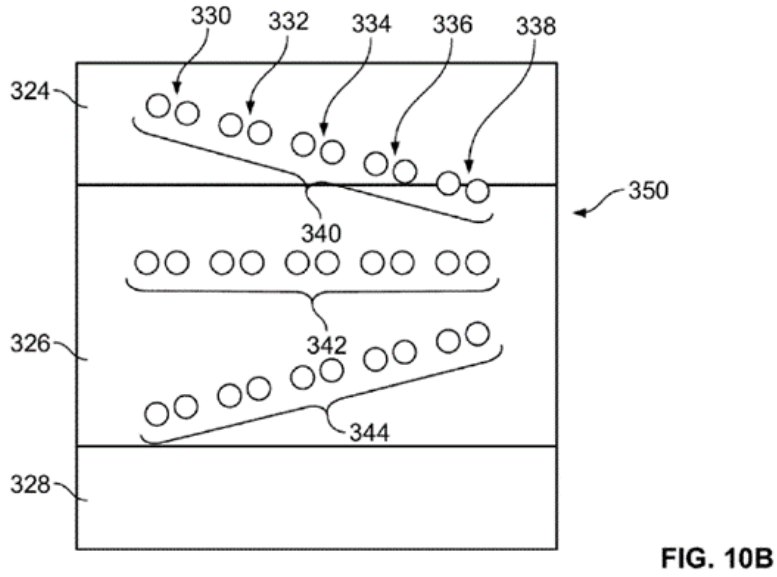
530. It is also my opinion that Na '848 in combination with Mehta renders claim 2 of the '812 Patent obvious as detailed below:

'812 Patent Claim 2[42]		Na '848 in view of Mehta
2	2. The method of claim 1, further comprising energizing a motor coupled to the needle assembly to cause the plurality of the needles to extend a desired distance from the releasably couplable deployable needle module end surface	***Claim 2 of the '812 Patent is rendered obvious by Na '848 in view of Mehta.*** For at least the reasons discussed above, Na '848 in view of Mehta renders the method of treating dermatological tissue of claim 1 of the '812 Patent obvious. *See* Claim 1, above. Mehta discloses energizing a motor coupled to the needle assembly to cause the plurality of the needles to extend a desired distance from the releasably couplable deployable needle module end surface. *See e.g.*, Mehta, at 3:29-39; 3:40-41; 4:63-5:2; 5:3-15; 6:64-65; 9:34-55; 10:33-39; 12:5-14; 12:31-46; 13:54-57; Fig. 3A; 13:58-4; 15:27-33; 15:55-16:11; Fig. 4A; 16:42-58; 16:59-17:12; 18:21-37; Fig. 5; 23:55-24:4; Fig. 7E; 24:46-60; 32:46-62; Fig. 10B; 32:63-33:14; 33:15-29; 33:30-34; 33:57-13; Fig. 10E; 34:38-45; 35:8-22; Fig. 12A; Fig. 12B; 36:21-40.

[42] Asserted claim 5 depends indirectly from unasserted claim 2.

'812 Patent Claim 2[42]		Na '848 in view of Mehta
		For example, Mehta discloses that **"**the cartridge and/or energy delivery elements can be coupled to an actuator, where movement of the actuator causes advancement or retraction of the first plurality of electrodes**"** (Mehta, at 4:63-5:2), and the **"**[e]xamples of such actuators include, but are not limited to … motors**"** **"**driven by the control system/energy supply unit 90**"** (*id*., at 10:33-39). *See also id*., at 12:5-14, 13:58-4 (**"**the actuator **250** comprises a motor**"**), 16:59-17:12, 18:21-37.  FIG. 3A *Id*., Fig. 3A.

'812 Patent Claim 2[42]		Na '848 in view of Mehta
		 FIG. 5 *Id*., Fig. 5. Mehta discloses energizing a motor coupled to the needle assembly to cause the plurality of the needles to extend a desired distance from the releasably couplable deployable needle module end surface. For example, Mehta discloses that the physician can check if the needles extended to the desired distance using a **"**virtual depiction **350** of the depth or location of the probe array,**"** as shown in Fig. 10B, reproduced below. *Id*., at 32:46-62; *see also id*., at 32:63-33:14 (**"**desired probe location … represent the desired depth of placement for providing a treatment**"**), 33:15-29, 33:30-34 (**"**the system described herein can be adjusted to guide probe placement within the first or third layers **324** or **328** depending on the type of treatment being applied**"**), 33:57-34:13, 34:38-45, 35:8-22 (**"**The physician can use the information [displayed on the screen] to make decisions and then adjustments by using the actuators **612** and **614"**), 36:21-40 (desired distance relates to the depth of the 6 mm needle with it **"**enter[s] the epidermis at a 20° angle to the skin surface for a distance of 6 mm**"**), Fig. 10E.

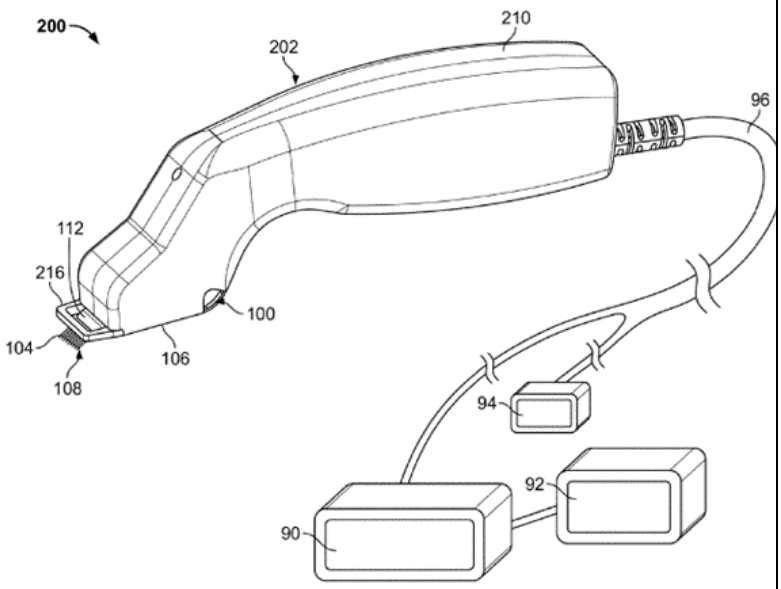
'812 Patent Claim 2[42]		Na '848 in view of Mehta
		 FIG. 10B *Id*., Fig. 10B.

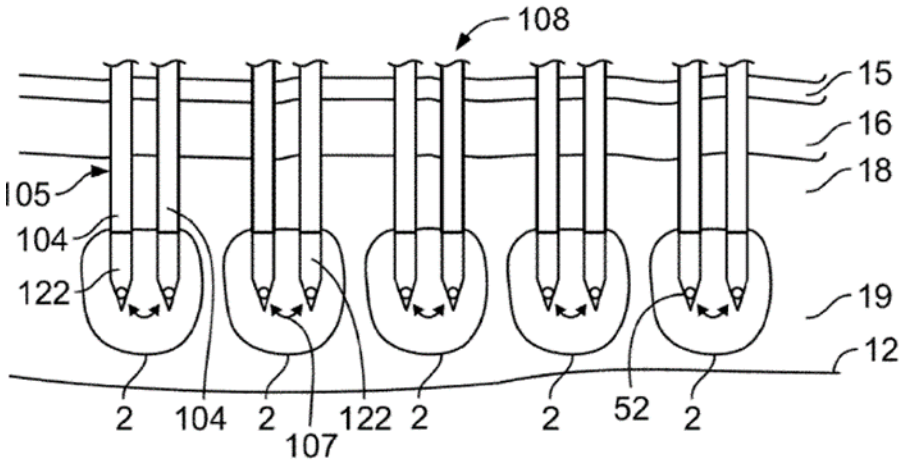
531. In view of the foregoing chart, Na '848 in view of Mehta render claim 2 of the '812 Patent obvious. Further, to the extent Complainant argues that any of the foregoing limitations are not explicitly or inherently disclosed by Na '848 in view of Mehta, such limitations would have been obvious given the knowledge of a POSITA.

5. Claim 3 of the '812 Patent is Anticipated and/or rendered Obvious by Mehta

532. Unasserted claim 3 of the '812 Patent depends on unasserted claim 2, which depends on claim 1. It is my opinion that Mehta anticipates claim 3 of the '812 Patent and/or Mehta alone renders claim 3 of the '812 Patent obvious as detailed below:

'812 Patent Claim 3		Mehta alone or in combination with one or more of ScarLet, Na '848, and/or Kang '395
3	3. The method of claim 2, further comprising energizing the plurality of	***Claim 3 of the '812 Patent is anticipated by Mehta and/or rendered obvious by Mehta alone.***

'812 Patent Claim 3		Mehta alone or in combination with one or more of ScarLet, Na '848, and/or Kang '395
	needles via a signal generator electrically coupled to the user holdable device proximal end.	Mehta discloses and/or renders obvious the method of treating dermatological tissue of claim 2. *See* Claim 2, above. Mehta discloses energizing the plurality of needles via a signal generator electrically coupled to the user holdable device proximal end. *See e.g.*, Mehta, at 2:58-62; 2:63-17; 3:40-56; 3:57-67; 4:1-18; 5:3-15; 5:16-25; 5:26-33; 5:49-57; 7:16-18; 8:13-23; 9:34-55; 10:17-25; 12:5-14; 10:53-65; Fig. 2A; 11:14-20; 11:21-52; 15:55-16:11; Fig. 4A; 17:59-18:3; 18:4-20; 18:64-19:8; 19:66-20:12; 20:13-29; 20:29-47; Fig. 6; 24:46-60; 25:30-55; 26:41-59; 26:60-27:22; 37:25-34; Fig. 13A; 40:39-44; 40:45-57; 41:40-43; 41:55-58; 42:9-15. As discussed above, regarding limitation 1.5, Mehta discloses energizing the plurality of needles via an electrical contact. Mehta also discloses that a signal generator (energy supply unit 90) is coupled to the proximal end of the user holdable device (treatment unit **202**). Mehta, at 10:53-65; *see also* 36:21-40 (RF "generator").  FIG. 2A *Id*., Fig. 2A. Mehta discloses energizing the plurality of needles via the signal generator electrically coupled to the user holdable device proximal end. *Id*. at 15:55-16:11 ("electrodes can be energized"), 24:46-60, 36:21-40, 37:25-35 ("passing current **107** between adjacent

'812 Patent Claim 3		Mehta alone or in combination with one or more of ScarLet, Na '848, and/or Kang '395
		electrodes **104** of opposite polarity in the electrode pair"), 41:55-58, 42:9-15.  FIG. 13A *Id*., Fig. 13A.

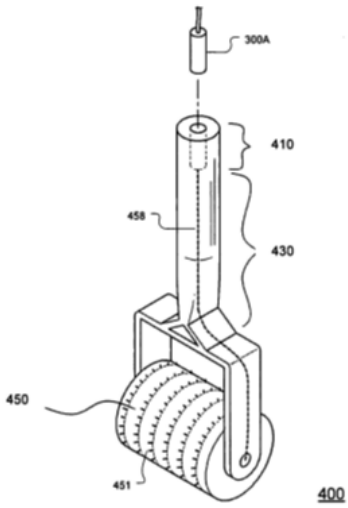
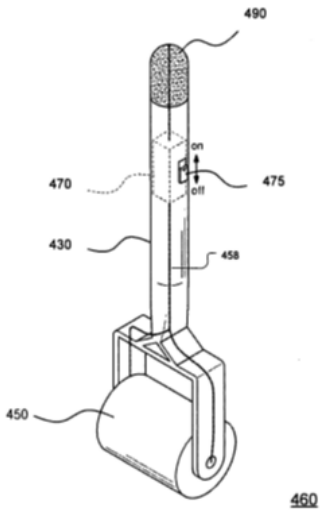
533. In view of the foregoing chart, claim 3 of the '812 Patent is anticipated by the teachings of Mehta. Further, to the extent Complainant argues that any of the foregoing limitations is not explicitly or inherently disclosed by Mehta, such limitations would have been obvious given the knowledge of a POSITA. The teachings of Mehta are so similar to what is claimed that any alleged difference between the teachings of Mehta and what is claimed would not have been of patentable significance given the knowledge of a POSITA.

6. Claim 3 of the '812 Patent is rendered Obvious by Na '848 in view of Mehta

534. It is my opinion that Na '848 in combination with Mehta renders claim 3 of the '812 Patent obvious as detailed below:

'812 Patent Claim 3[43]		Na '848 in view of Mehta
3	3. The method of claim 2, further comprising energizing the plurality of needles via a signal generator electrically coupled to the user holdable device proximal end.	***Claim 2 of the '812 Patent is rendered obvious by Na '848 in view of Mehta.*** Na '848 in view of Mehta renders obvious the method for treating dermatological tissue of claim 2. *See* Claim 2, above. Na '848 discloses energizing the plurality of extended needles via a signal generator electrically coupled to the plurality of extended needles. Na '848 discloses that the **"**[a]rchitecture **310** includes an acupuncture apparatus **320** and an electrical signal generation system **300**,**"** and that the **"**electrical signal generation system **300** may be electrically coupled to the acupuncture apparatus **320** via one or more wires **300A** and to a mammal **20** to be treated via one or more wires **300B**. Na '848 at [0026]. **"**The apparatus **320** may include a handle **330**, elastic section **333**, electrical interface **340**, internal wire(s) **33** land plate **350**.**"** *Id*. **"**The pins **351** may have a length A (0.3 mm to 2.1 mm in an embodiment) where at least one pin **351** is electrically coupled to the electrical interface **340** via the internal wire **331**.**"** *Id.; see also id*. at [0027] (**"**The signal generator **370** may be coupled to at least one pin **351** via internal wire **331** and coupled to the conductive interface **390**.**"**); [0028] **"**The signal generator or module **370** may generate a vary of signals (such as shown in FIGS. 5 A to 6) to vibrate one or more pins **351** electrically coupled to the system **300** via the internal wire **331** and the conductive interface **390**….The switch **375** coupled to the generator **370** may cause the generator to produce one or more electrical signals for a predetermined time interval or until the switch **375** is triggered again.**"**). Na '848 further discloses that the **"**signal generator **370** may be coupled to at least one pin **351** via internal wire **331** and coupled to at least one other pin **352** via internal wire **332**. *Id*. at [0029]. **"**The signal generator or module **370** may generate a vary of signals (such as shown in FIGS. 5A to 6) to vibrate one or more dipole pair or bipolar pins **351**, **352**.**"** *Id*. FIGS. 3A and 3B are simplified isometric diagrams of acupuncture apparatus **400**, **460** including at least one pin **451** that may be coupled to an electrical signal via an internal wire **458**.**"** *Id* at [0033]. **"**In apparatus **400**, the electrical lead wire **400A** may be coupled to an electrical interface **410** in the

[43] Asserted claim 5 depends indirectly from unasserted claim 3.

'812 Patent Claim 3[43]		Na '848 in view of Mehta
		apparatus handle **430** where the interface **410** is electrically coupled to the internal wire **458**." *Id*.  FIGURE 3A  FIGURE 3B *Id*. at FIGs 3A and 3B.

535. In view of the foregoing chart, claim 3 of the '812 Patent is rendered obvious by the Na '848 in view of Mehta. Further, to the extent Complainant argues that any of the foregoing limitations are not explicitly or inherently disclosed by Na '848 in view of Mehta, such limitations would have been obvious given the knowledge of a POSITA.

7. Claim 4 of the '812 Patent is Anticipated by Mehta and/or rendered Obvious by Mehta alone or Mehta in view of Na '848, ScarLet and/or Kang '395

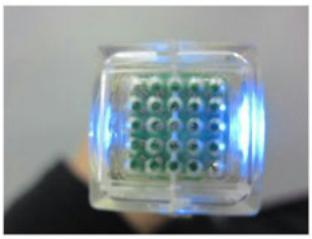
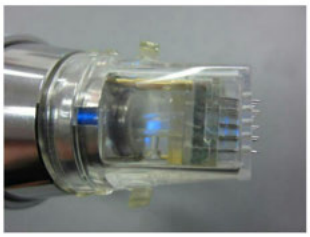
536. Unasserted claim 4 of the '812 Patent depends on unasserted claim 3, which depends on unasserted claim 2. In my opinion, Mehta anticipated and/or rendered obvious claim 4 of the '812 Patent as detailed below:

'812 Patent Claim 4[44]		Mehta alone or Mehta in view or more of ScarLet, Na '848, and/or Kang '395
4	4. The method of claim 3, wherein the user holdable device proximal end includes at least further one embedded LED therein and further including energizing the at least one embedded LED so the at least one embedded LED illuminates the releasably couplable deployable needle module.	***Claim 4 of the '812 Patent is anticipated by Mehta and/or rendered obvious by Mehta alone or Mehta in view of Na '848, ScarLet and/or Kang '395.*** Mehta discloses and/or renders obvious the method of treating dermatological tissue of claim 2. *See* Claim 3, above. Mehta discloses that the user holdable device proximal end further includes at least one embedded LED therein and further including energizing the at least one embedded LED so the at least one embedded LED illuminates the releasably couplable deployable needle module. Mehta explains that "the energy supply unit 90 may be a RF energy unit" and that "[a]dditional variations of energy supply units may include power supplies to provide … microwave energy, laser energy, pulsed light energy, and infrared energy." Mehta at 11:14-20. Mehta further discloses that "in addition to the use of RF energy, other therapeutic methods and devices can be used in combination with RF energy to provide additional or more efficacious treatments. For example, as shown in FIG. 2A, additional energy sources **90** can be delivered via the same or additional energy transfer elements located at the working end of a treatment unit **202**. Alternatively, the radiant energy may be supplied by the energy source/supply **90** that is coupled to **a diode**, fiber, or other **emitter** at the distal end of the treatment unit **202**." *Id*. at 11:21-30 (emphasis added). Mehta continues to disclose that "sources of light at the distal end of the treatment unit **202**. These transfer elements may be present on the cartridge **100**, on the device body **210**." *Id*. at 11:36-39; *see also id*. at 25:4-15 (disclosing that in some embodiments "the probe can employ light"). Mehta describes that a light source can be incorporated into the removable cartridge: "In the system **200** shown, the removable cartridge **100** contains a plurality of retractable probes **104** arranged in an array **108**. The term probes **104** (for purposes of this disclosure) is intended to include any electrode, energy transfer element (*e.g.*, thermal, electrical, electromagnetic, microwave, mechanical, ultrasound, **light**,

[44] Asserted claim 5 depends directly from unasserted claim 4.

'812 Patent Claim 4[44]		Mehta alone or Mehta in view or more of ScarLet, Na '848, and/or Kang '395
		radiation, monopolar RF, bipolar RF, chemical, radioactive, etc.), or source of therapeutic treatment." *Id.* at 9:41-48 (emphasis added). Na '848 discloses that "[i]n any of the above apparatus **10**, **320**, **350**, **360**, **400**, **460**, the plate or roller **200**, **350**, **450** may include a plurality of embedded LEDs **32A**, **32B**, a battery **52**, a controller **54,** and an antenna **56** as shown in FIG. **4A**." Na '848 at [0034]. "In an embodiment the LED **32A** may be configured to emit energy of a first particular frequency range and the LED **32B** may be configured to emit energy of a second particular frequency range." *Id*. "The controller 54 may be electrically coupled to the one or more LEDS 32A, 32B. The controller 54 may also be coupled to a battery 52." *Id*. at [0036]. "The controller **54** may be coupled to one or more LEDs **32A**, **32B** via one or more electric wires **106**," and the "controller **54** may generate one or more signals for LEDs **32A**, **32B** as a function of the user switch 56**."** *Id*. at [0037]. Na '848 further discloses that "[i]In any of the above apparatus **10**, **320**, **350**, **360**, **400**, **460**, the plate or roller **200**, **350**, **450** may include a plurality of embedded LED lens **536**, a fiber optic pathway **534**, and an LED **532**." *Id*. at [0038]. "In this embodiment the LED **532** may be coupled to lens **536** via the fiber optic pathway **534**," and the "controller **540** may generate an LED signal via the LED **532** that is transmitted to dermalogical cells via the lens **536** and the fiber optic pathway **534**." *Id*. ScarLet discloses that the user holdable device proximal end further includes at least one embedded LED therein and further including energizing the at least one embedded LED so the at least one embedded LED illuminates the releasably couplable deployable needle module.

'812 Patent Claim 4[44]		Mehta alone or Mehta in view or more of ScarLet, Na '848, and/or Kang '395
		 Ilooda-0010116 at 0:13.  Ilooda-0010141 at -148 (certified English translation of SERENDIA-00033705 at -711).

'812 Patent Claim 4[44]		Mehta alone or Mehta in view or more of ScarLet, Na '848, and/or Kang '395
		 Figure 4-12. Microneedle Tip skin contact surface.  Figure 4-13. After attaching the Microneedle Tip to the handpiece. Attaching the Microneedle tip to the handpiece is only possible in CARTRIDGE SETTING MODE. Press the jog dial under the bottom LCD of the Scarlet system to enter CARTRIDGE SETTING MODE and the handpiece will illuminate with a blue LED light. Ilooda-0011405 at -442 (SERENDIA-00073257 at -279). Kang '395 discloses that the user holdable device proximal end further includes at least one embedded LED therein and further including energizing the at least one embedded LED so the at least one embedded LED illuminates the releasably couplable deployable needle module. "Furthermore, the handpiece of the present invention is equipped with a light-emitting member so that the position of the heating part of the handpiece inserted into the skin can be easily discerned from outside of the skin as well." Kang '395 at col, 4, line 21. "Furthermore, by adopting and attaching various light-emitting members **250** of a fine size, such as a fiber or an LED, to the end of the heating part **200**, the heating part **220** of the handpiece **200** inserted into the skin emits a predetermined color at the same time as the high frequency is applied, so that the position of the heating part **220** of the

'812 Patent Claim 4[44]		Mehta alone or Mehta in view or more of ScarLet, Na '848, and/or Kang '395
		handpiece **200** can be easily discerned even from outside of the skin as well." Kang '395 at 4:51-53. "In addition, as for the heating part **230** of the handpiece **200**, which is inserted into the skin and heats the skin while moving in a reciprocating manner, its position cannot be identified because of the skin of the skin [*sic*], but since the light-emitting member **250** provided on one side of the heating part **230** emits light, it is possible to perform a procedure while accurately identifying the position of the heating part **230** with the naked eye even from outside of the thin skin." Kang '395 at 5:32-35. It is my opinion that to the extent it is asserted that Mehta does not disclose or suggest a user holdable device, including that feature, it would have nevertheless been obvious. It was known that it was advantageous to use an LED to illuminate the needle assembly when energized "so that the position of the heating part 220 of the handpiece 200 can be easily discerned even from outside of the skin as well" (Kang '395 at 4). "Furthermore, by adopting and attaching various light-emitting members 250 of a fine size, such as a fiber or an LED, to the end of the heating part 200, the heating part 220 of the handpiece 200 inserted into the skin emits a predetermined color at the same time as the high frequency is applied, so that the position of the heating part 220 of the handpiece 200 can be easily discerned even from outside of the skin as well." *Id*. This would assist with accuracy and safety. As Kang '395 taught, "as for the heating part 230 of the handpiece 200, which is inserted into the skin and heats the skin while moving in a reciprocating manner, its position cannot be identified because of the skin, but since the light-emitting member 250 provided on one side of the heating part 230 emits light, it is possible to perform a procedure while accurately identifying the position of the heating part 230 with the naked eye even from outside of the skin." *Id*. at 5. Like Kang '395, each of Mehta, Miratone, and ScarLet employ needles that are "inserted into the skin and heat[] the skin while moving in a reciprocating manner." *Id*. Therefore, the POSITA would have been motivated to incorporate the LED features of Kang '395 into Mehta to enable the POSITA to "perform a procedure while accurately identifying the heating part" with the "naked eye." *Id*.

'812 Patent Claim 4[44]		Mehta alone or Mehta in view or more of ScarLet, Na '848, and/or Kang '395
		In addition, Na '848 discloses that its apparatus "may include a plurality of embedded LEDs." Na '848 at [0034]. "The controller 54 may be electrically coupled to the one or more LEDs 32A, 32B via one or more electrical wires." *Id*. at [0035]. A signal waveform "may be applied to one or more LEDs" and the waveform "may be used to energize an LED." *Id*. The POSITA would have recognized the advantage of having direct visualization (via an LED) of energy being transferred to the needle module. *See, e.g.*, Mehta at 4:19–34 ("The device may also include a window located between the stabilization plate and the tissue engaging surface, where the window is configured to permit direct visualization of advancement of the energy transfer elements into the entry point."). Therefore, the POSITA would have been motivated to incorporate the LEDs disclosed in Na '848, ScarLet, and Kang '395 into Mehta and permit "direct visualization" of the transfer of energy to the patient's skin.

537. In view of the foregoing chart, claim 4 of the '812 Patent is anticipated by the teachings of Mehta. Further, to the extent Complainant argues that any of the foregoing limitations is not explicitly or inherently disclosed by Mehta, such limitations would have been obvious given the knowledge of a POSITA, and/or further in view of the teachings of ScarLet, Na '848, and/or Kang '395. The teachings of Mehta are so similar to what is claimed that any alleged difference between the teachings of Mehta and what is claimed would not have been of patentable significance given the knowledge of a POSITA. In addition, claim 4 of the '812 Patent is rendered obvious by Mehta in view of ScarLet, Na '848, and/or Kang '395.

8. Claim 4 of the '812 Patent is rendered Obvious by Na '848 in view of Mehta

538. It is my opinion that Na '848 in view of Mehta renders claim 4 of the '812 Patent obvious as detailed below:

'812 Patent Claim 4		Na '848 in view of Mehta
4.0	4. The method of claim 3, wherein the user holdable device proximal end further includes at least one embedded LED therein and further including energizing the at least one embedded LED so the at least one embedded LED illuminates the releasably couplable deployable needle module.	***Claim 4 of the '812 Patent is rendered obvious by Na '848 in view of Mehta.*** Na '848 in view of Mehta render obvious the method of treating dermatological tissue of claim 3. *See* claim 3 above Na '848 discloses that the user holdable device proximal end further includes at least one embedded LED therein and energizing the at least one embedded LED so the at least one embedded LED illuminates the needle module. Na '848 discloses that **"**[i]n any of the above apparatus **10**, **320**, **350**, **360**, **400**, **460**, the plate or roller **200**, **350**, **450** may include a plurality of embedded LEDs **32A**, **32B**, a battery **52**, a controller **54,** and an antenna **56** as shown in FIG. **4A**.**"** Na '848 at [0034]. **"**In an embodiment the LED **32A** may be configured to emit energy of a first particular frequency range and the LED **32B** may be configured to emit energy of a second particular frequency range.**"** *Id*. **"**The controller 54 may be electrically coupled to the one or more LEDS 32A, 32B. The controller 54 may also be coupled to a battery 52.**"** *Id*. at [0036]. **"**The controller **54** may be coupled to one or more LEDs **32A**, **32B** via one or more electric wires **106**,**"** and the **"controller 54** may generate one or more signals for LEDs **32A**, **32B** as a function of the user switch 56**."** *Id*. at [0037]. Na '848 further discloses that **"**[i]In any of the above apparatus **10**, **320**, **350**, **360**, **400**, **460**, the plate or roller **200**, **350**, **450** may include a plurality of embedded LED lens **536**, a fiber optic pathway **534**, and an LED **532**.**"** *Id*. at [0038]. **"**In this embodiment the LED **532** may be coupled to lens **536** via the fiber optic pathway **534**,**"** and the **"**controller **540** may generate an LED signal via the LED **532** that is transmitted to dermalogical (*sic*) cells via the lens **536** and the fiber optic pathway **534**.**"** *Id*.

539. In view of the foregoing chart, claim 4 of the '812 Patent is rendered obvious by Na '848 in view of Mehta. Further, to the extent Complainant argues that any of the foregoing limitations is not explicitly or inherently disclosed by Na '848 and Mehta, such limitations

would have been obvious given the knowledge of a POSITA. The teachings of Na '848 and Mehta are so similar to what is claimed that any alleged difference between the teachings of Na '848 and Mehta and what is claimed would not have been of patentable significance given the knowledge of a POSITA.

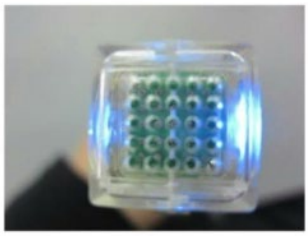
9. Claim 5 of the '812 Patent is Anticipated by Mehta and/or rendered Obvious by Mehta in view of Na '848, Kang '395 and/or ScarLet

540. Asserted claim 5 of the '812 Patent depends unasserted claim 4, which depends on unasserted claim 3, which depends on unasserted claim 2, which depends on asserted claim 1. In my opinion, Mehta anticipates and/or renders obvious claim 5 of the '812 Patent as detailed below:

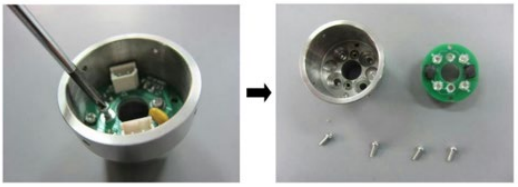
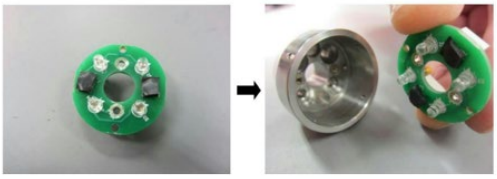
'812 Patent Claim 5		**Mehta alone or Mehta in view of ScarLet, Na '848, and/or Kang '395**
5	5. The method of claim 4, wherein the needle assembly includes a translucent section and further including energizing the least one embedded LED to illuminate the plurality of needles via the needle assembly translucent section.	***Claim 5 of the '812 Patent is anticipated by Mehta and/or rendered obvious by Mehta in view of Na '848, Kang '395 and/or ScarLet.*** Mehta discloses and/or renders obvious (alone or in view of ScarLet, Na '848, and Kang '395) the method of treating dermatological tissue of claim 4. *See* Claim 4, above. Mehta discloses that the needle assembly includes a translucent section and further including energizing the least one embedded LED to illuminate the plurality of needles via the needle assembly translucent section. Mehta discloses that the "device may also include a window located between the stabilization plate and the tissue engaging surface, where the window is configured to permit direct visualization of advancement of the energy transfer elements into the entry point." Mehta, at 4:19-34. Mehta further describes that "The window can comprise an opening in the stabilization plate or the window can comprise a transparent material having an outline or mark to denote the perimeter of the window." *Id*., at 4:31-34. In view of this disclosure, it would have been obvious to the skilled artisan based on Mehta to use a translucent section.

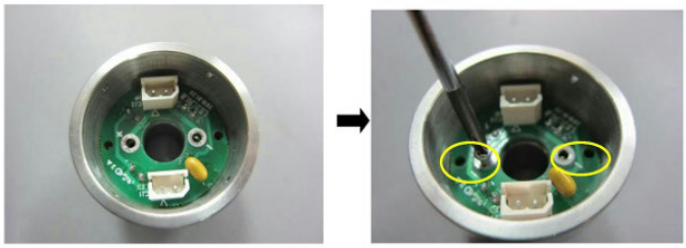
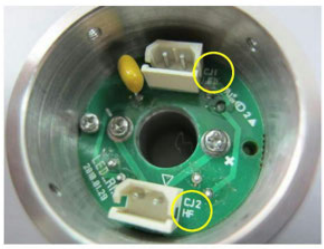
'812 Patent Claim 5		Mehta alone or Mehta in view of ScarLet, Na '848, and/or Kang '395
		Mehta explains that "the energy supply unit 90 may be a RF energy unit" and that "[a]dditional variations of energy supply units may include power supplies to provide … microwave energy, laser energy, pulsed light energy, and infrared energy." Mehta at 11:14-18. Mehta further discloses that "in addition to the use of RF energy, other therapeutic methods and devices can be used in combination with RF energy to provide additional or more efficacious treatments. For example, as shown in FIG. 2A, additional energy sources **90** can be delivered via the same or additional energy transfer elements located at the working end of a treatment unit **202**. Alternatively, the radiant energy may be supplied by the energy source/supply **90** that is coupled to **a diode**, fiber, or other **emitter** at the distal end of the treatment unit **202**." *Id*. at 11:21-30 (emphasis added). Mehta continues to disclose that "sources of light at the distal end of the treatment unit **202**. These transfer elements may be present on the cartridge **100**, on the device body **210**." *Id*. at 11:36-39; *see also id*. at 25:4-15 (disclosing that in some embodiments "the probe can employ light"). Na '848 discloses that the needle assembly includes a translucent section and further including energizing the least one embedded LED to illuminate the plurality of needles via the needle assembly translucent section. Na '848 discloses that "[i]n an embodiment the pin section **250**, **353**, may be translucent and comprised of a polyurethane, medical silicon, or other pliable, translucent, hypoallergenic material." Na '848 at [0035]. ScarLet discloses that the needle assembly includes a translucent section and further including energizing the least one embedded LED to illuminate the plurality of needles via the needle assembly translucent section.

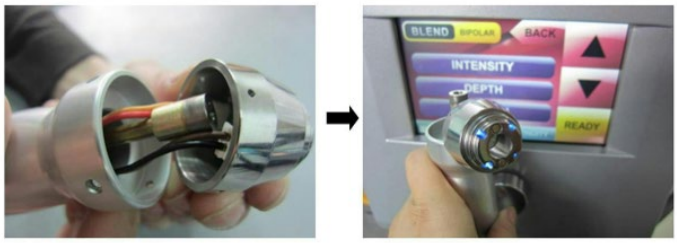
‘812 Patent Claim 5		Mehta alone or Mehta in view of ScarLet, Na ‘848, and/or Kang ‘395
		 Ilooda-0010116 at 0:13. 

'812 Patent Claim 5		Mehta alone or Mehta in view of ScarLet, Na '848, and/or Kang '395
		3) Combination of electrode and handpiece ① Scarlet Tip  Ilooda-0010141 at -148 (certified English translation of SERENDIA-00033705 at -711).  Figure 4-12. Microneedle Tip skin contact surface.  Figure 4-13. After attaching the Microneedle Tip to the handpiece. Attaching the Microneedle tip to the handpiece is only possible in CARTRIDGE SETTING MODE. Press the jog dial under the bottom LCD of the Scarlet system to enter CARTRIDGE SETTING MODE and the handpiece will illuminate with a blue LED light. Ilooda-0011405 at -1442 (SERENDIA-00073257 at -279).

'812 Patent Claim 5	Mehta alone or Mehta in view of ScarLet, Na '848, and/or Kang '395
	 Figure 4-15. Handpiece Status in CARTRIDGE SETTING MODE Ilooda-0011405 at -1443 (SERENDIA-00073257 at -280). SCARLET SOLUTION **7.3 Handpiece Issues** When the handpiece LED goes out and needs to be replaced 1) Disassemble the handpiece head using a screwdriver. 2) Disassemble the head carefully to avoid damaging the bolts when removing it. 3) Turn the small PCB inside the head with a screwdriver to remove the screws and take out the small PCB. 4) Insert the new LED's small PCB, insert the screws, and assemble. 5) There are two lines, the black line is the LED line, so connect it to the connector labeled LED on the small PCB. The other red line is the output line, so connect it to the connector labeled BAR. 6) After connecting the machine and before assembling the head, make sure the LEDs are lit and assemble. Ilooda-0011405 at -1499 (SERENDIA-00073257 at -317). **7.3.1 After-sales service** **If the LED light on your handpiece is off** 1) Loosen the four screws on the front of the handpiece   Ilooda-0011405 at -1499 (SERENDIA-00073257 at -317).

'812 Patent Claim 5		Mehta alone or Mehta in view of ScarLet, Na '848, and/or Kang '395
		SCARLET SOLUTION 2) After unscrewing the screws, disconnect the two connecting wires and it must look like the picture below.  3) Remove the PCB that is secured inside the head by unscrewing the four screws.  4) Replace the new PCB and insert it into the head of the handpiece. It is important that the LEDs fit into the grooves in the head.  Ilooda-0011405 at -1501 (SERENDIA-00073257 at -318).

'812 Patent Claim 5		Mehta alone or Mehta in view of ScarLet, Na '848, and/or Kang '395
		SCARLET SOLUTION 5) Screw the head with the new PCB to fasten it as shown below. There are four grooves in the PCB to insert the screws, but since the PCB is not perfectly aligned with the grooves in the head, typically only the three of them are fastened.  6) Plug the wire that connects to the handpiece into the fixed PCB board. If you look closely at the connectors on the PCB board, you will see LED on one side and HF on the other. Connect the red wire to the HF side and the black wire to the LED side. Check the RF and LED wires carefully before connecting them.  Ilooda-0011405 at -1502 (SERENDIA-00073257 at -319).

‘812 Patent Claim 5		Mehta alone or Mehta in view of ScarLet, Na ‘848, and/or Kang ‘395
		SCARLET SOLUTION 7) After connecting, plug the handpiece into the main unit to verify that the LED light is illuminated properly.  8) Once confirmed, screw the head onto the handpiece. Be careful not to gas the handpiece when tightening the screws.  Ilooda-0011405 at -1503 (SERENDIA-00073257 at -320). Kang ‘395 discloses and/or renders obvious the needle assembly includes a translucent section and further including energizing the least one embedded LED to illuminate the plurality of needles via the needle assembly translucent section. *See, e.g.*, Kang ‘395 at 4-5. “Furthermore, the handpiece of the present invention is equipped with a light-emitting member so that the position of the heating part of the handpiece inserted into the skin can be easily discerned from outside of the skin as well.” Kang ‘395 at 4:21-22. “Furthermore, by adopting and attaching various light-emitting members **250** of a fine size, such as a fiber or an LED, to the end of the heating part **200**, the heating part **220** of the handpiece **200** inserted into the skin emits a predetermined color at the same time as the high frequency is applied, so that the position of the heating part **220** of the

'812 Patent Claim 5		Mehta alone or Mehta in view of ScarLet, Na '848, and/or Kang '395
		handpiece **200** can be easily discerned even from outside of the skin as well." Kang '395 at 4: line 51-53. "In addition, as for the heating part **230** of the handpiece **200**, which is inserted into the skin and heats the skin while moving in a reciprocating manner, its position cannot be identified because of the skin of the skin [sic], but since the light-emitting member **250** provided on one side of the heating part **230** emits light, it is possible to perform a procedure while accurately identifying the position of the heating part **230** with the naked eye even from outside of the thin skin." Kang '395 at 5:line 32-35. It is my opinion that to the extend it is asserted that Mehta does not disclose or suggest a needle assembly it would have nevertheless been obvious to the POSITA. At the time of the invention, it was known that a physician would want "to directly observe insertion of the [needle] probe array" into the skin. Mehta, at 13:16-36. It was known that one way to allow direct observation was to employ a window "compris[ing] a transparent material." *Id*. at 4:31–34. It was also known that it was advantageous to use an LED to illuminate the needle assembly when energized "so that the position of the heating part 220 of the handpiece 200 can be easily discerned even from outside of the skin as well" (Kang '395 at 4). "Furthermore, by adopting and attaching various light-emitting members 250 of a fine size, such as a fiber or an LED, to the end of the heating part 200, the heating part 220 of the handpiece 200 inserted into the skin emits a predetermined color at the same time as the high frequency is applied, so that the position of the heating part 220 of the handpiece 200 can be easily discerned even from outside of the skin as well." *Id*. This would assist with accuracy and safety. As Kang '395 taught, "as for the heating part 230 of the handpiece 200, which is inserted into the skin and heats the skin while moving in a reciprocating manner, its position cannot be identified because of the skin, but since the light-emitting member 250 provided on one side of the heating part 230 emits light, it is possible to perform a procedure while accurately identifying the position of the heating part 230 with the naked eye even from outside of the skin." *Id*. at 5. Like Kang '395, each of Mehta, Miratone, and ScarLet employ needles that are "inserted into the skin and heat[] the skin while moving in a reciprocating manner." *Id*. Therefore, the POSITA would have been motivated to incorporate the LED features of

'812 Patent Claim 5		Mehta alone or Mehta in view of ScarLet, Na '848, and/or Kang '395
		Kang '395 into Mehta, Miratone, and ScarLet to enable the POSITA to "perform a procedure while accurately identifying the heating part" with the "naked eye." *Id*. In addition, Na '848 discloses that its apparatus "may include a plurality of embedded LEDs." Na '848 at [0034]. "The controller 54 may be electrically coupled to the one or more LEDs 32A, 32B via one or more electrical wires." *Id*. at [0035]. A signal waveform "may be applied to one or more LEDs" and the waveform "may be used to energize an LED." *Id*. The POSITA would have recognized the advantage of having direct visualization (via an LED) of energy being transferred to the needle module. *See, e.g.*, Mehta at 4:19–34 ("The device may also include a window located between the stabilization plate and the tissue engaging surface, where the window is configured to permit direct visualization of advancement of the energy transfer elements into the entry point."). Therefore, the POSITA would have been motivated to incorporate the LEDs disclosed in Na '848, Mehta, and Kang '395 into Miratone, Mehta, and ScarLet to permit "direct visualization" of the transfer of energy to the patient's skin. It was also known to put light emitting devices, such as LED, behind translucent material, not opaque material. *See, e.g.*, Mehta at 4:31–34 ("[T]he window can comprise a transparent material."). Translucent means the object allows light to pass through. The purpose of a light emitting device, such as an LED, is to transmit light at a source, which requires the light not to be blocked. In fact, ScarLet (available as early as June 1, 2010) implemented just that, an LED illuminating the needles via a translucent section as shown in Ilooda-0010116 at 0:13 or SERENDIA-00073257 at -278

541. In view of the foregoing chart, claim 5 of the '812 Patent is anticipated by the teachings of Mehta. Further, to the extent Complainant argues that any of the foregoing limitations is not explicitly or inherently disclosed by Mehta, such limitations would have been

obvious given the knowledge of a POSITA, and/or further in view of the teachings of ScarLet, Na '848, and/or Kang '395. The teachings of Mehta, ScarLet, Na '848, and/or Kang '395 are so similar to what is claimed that any alleged difference between the teachings of Mehta and what is claimed would not have been of patentable significance given the knowledge of a POSITA. Furthermore, in view of the overgoing chart, claim 5 of the '812 Patent is also rendered obvious by Mehta in view of Na '848, Kang '395 and/or ScarLet.

10. Claim 5 of the '812 Patent is rendered Obvious by Na '848 in view of Mehta.

542. In addition to being anticipated by Mehta, obvious over Mehta alone and obvious over Mehta in view of view of Na '848, Kang '395 and/or ScarLet, it is my opinion that Na '848 in view of Mehta renders claim 5 of the '812 Patent obvious as detailed below:

'812 Patent Claim 5		**Na '848 in combination with Mehta**
5.0	5. The method of claim 4, wherein the needle assembly includes a translucent section and further including energizing the least one embedded LED to illuminate the plurality of needles via the needle assembly translucent section.	***Claim 5 of the '812 Patent is rendered obvious by Na '848 in view of Mehta.*** Na '848 in view of Mehta renders obvious the method of treating dermatological tissue of claim 4. *See* Claim 4, above. Na '848 discloses that the needle assembly includes a translucent section and further including energizing the least one embedded LED to illuminate the plurality of needles via the needle assembly translucent section. Na '848 discloses that **"**[i]n an embodiment the pin section **250**, **353**, may be translucent and comprised of a polyurethane, medical silicon, or other pliable, translucent, hypoallergenic material.**"** Na '848 at [0035].

543. In view of the foregoing chart, claim 5 of the '812 Patent is rendered obvious by the teachings of Na '848 in view of Mehta. Further, to the extent Complainant argues that any of the foregoing limitations is not explicitly or inherently disclosed by Na '848 in view of Mehta, such limitations would have been obvious given the knowledge of a POSITA. The

teachings of Na '848 in view of Mehta are so similar to what is claimed that any alleged difference between the teachings of Na '848 in view of Mehta and what is claimed would not have been of patentable significance given the knowledge of a POSITA.

11. Claim 6 of the '812 Patent is Anticipated by Mehta and/or rendered Obvious by Mehta alone or Mehta in view of Na '848 and/or ScarLet

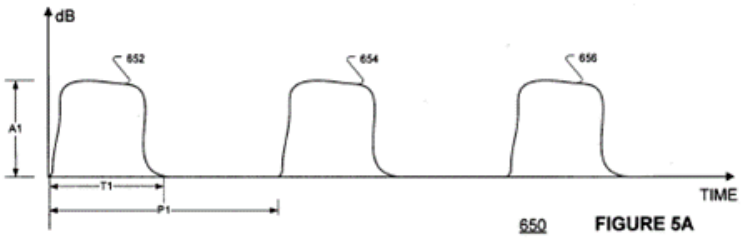
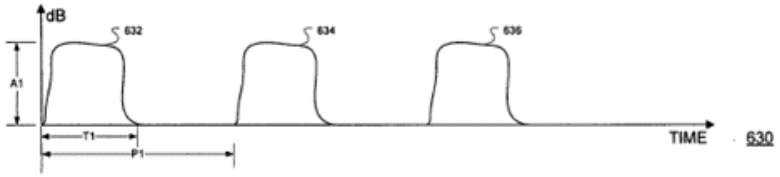
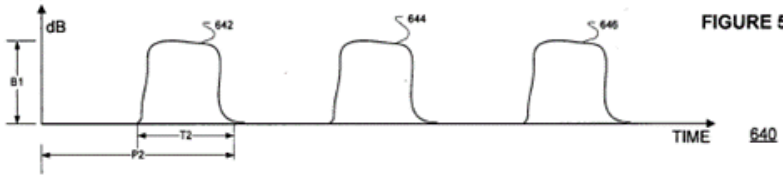
544. Asserted claim 6 of the '812 Patent depends on unasserted claim 3, which depends on unasserted claim 2, which depends on asserted claim 1. In my opinion, Mehta anticipates and/or renders obvious claim 6 of the '812 Patent as detailed below.

'812 Patent Claim 6		**Mehta alone or Mehta in view of one or more of ScarLet, Na '848, and/or Kang '395**
6	6. The method of claim 3, further comprising energizing the motor to deploy the plurality of needles to a predetermined depth and directing the signal generator to energize the plurality of needles at a predetermined intensity for a predetermined duty cycle.	***Claim 6 of the '812 Patent is anticipated by Mehta and/or rendered obvious by Mehta alone or Mehta in view of Na '848 and/or ScarLet.*** Mehta discloses and/or renders obvious the method of treating dermatological tissue of claim 3. *See* Claim 3, above. Mehta discloses energizing the motor to deploy the plurality of needles to a predetermined depth and directing the signal generator to energize the plurality of needles at a predetermined intensity for a predetermined duty cycle. *See e.g.*, Mehta, at 3:29-39; 3:40-41; 3:42-55; 3:57-67; 4:63-5:2; 5:3-15; 6:64-65; 10:33-39; 12:31-46; 13:54-57; Fig. 3A; 13:58-64; 15:55-16:11; Fig. 4A; 16:59-17:12; 18:21-37; Fig. 5; 18:64-19:8; 19:26-44; 19:45-65; 20:13-28; 20:29-55; Fig. 6; 23:55-24:4; Fig. 7E; 24:5-12; 25:24-29; 24:46-60; 25:24-29; 25:30-55; 26:41-59; 26:60-27:22; 27:66-28:6; 28:49-50; 32:46-62; Fig. 10B; 32:63-33:14; 33:15-29; 33:30-34; 33:57-13; Fig. 10E; 34:14-24; 34:38-45; 35:8-22; Fig. 12A; Fig. 12B; 36:21-40; 37:25-34; Fig. 13A; 40:5-38; 40:39-44; 40:45-57; 41:40-43; 41:55-58; 42:9-15. As discussed above, Mehta discloses energizing a motor coupled to the needle assembly to cause the plurality of the needles to extend a desired distance from the releasably couplable deployable needle module end surface. *See e.g.,* Mehta, at 10:33-39 ("motors" "driven by the control system/energy supply unit 90"), 12:5-14, 13:58-4, 16:59-17:12, 18:21-37, 32:46-33:34, 33:57-13, 33:57-13, 34:38-45, 35:8-22, 36:21-40, Figs. 10B, 10E.

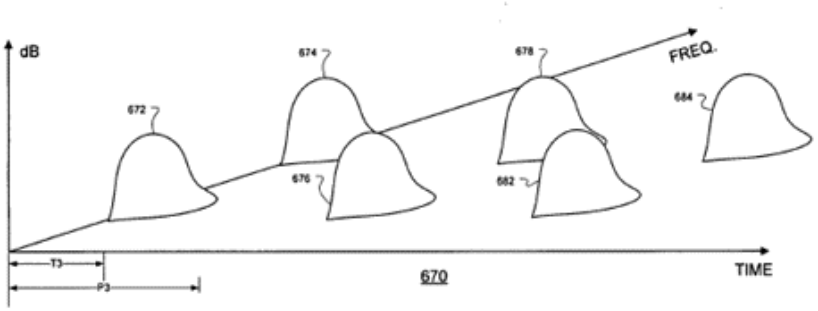
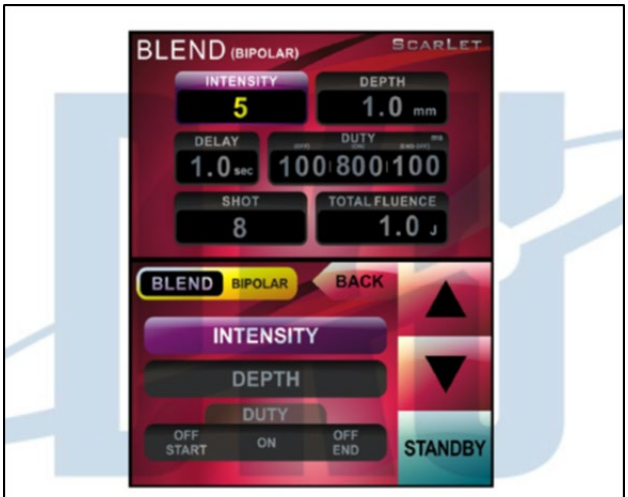
'812 Patent Claim 6		Mehta alone or Mehta in view of one or more of ScarLet, Na '848, and/or Kang '395
		Mehta discloses predetermining the depth of the plurality of needles before treatment. *See id*., at 32:46-33:34 ("The virtual depth/location depiction **350** can simply show the location of the probe array prior to treatment. Alternatively, the system can be configured to show (or the system can have an option to show) additional probe array information. For example, the virtual depth/location depiction **350** can also show a desired probe location (e.g., array **342** can represent the desired depth of placement for providing a treatment)."), 33:57-34:13, 34:38-45, 35:8-22. Mehta further discloses that the device "can also be configured to display a time setting **352** of the intended treatment, the target temperature setting **354** of the treatment tissue (or probes at the treatment site), as well as a counter **360** for the number of treatments." *Id*. at 34:14–18; *see also id*. at FIGs 10E and 10F. Mehta further discloses "applying energy to the electrode array from the energy source during a treatment cycle where the energy applied to each electrode pair is adjusted based upon the identified tissue layer." Mehta, at 3:42-55. Mehta discloses that the needles are energized at a predetermined intensity. *Id*., at 3:57-67 ("by selecting a set of controller parameters based on the identified tissue layer … the method further comprising supplying an initial energy level from the energy source between the electrodes … and modifying the initial energy level using the controller parameters to obtain a target temperature in the injured tissue"), 15:55-16:11 ("electrodes can be energized"). "Some examples of the pre-determined values include limiting energy delivery to [a predetermined intensity, such as] between 2 and 4 joules." *Id*., at 5:58-6:2; *see also id*., at 18:64-19:8 ("the controller can adjust the maximum parameters (maximum voltage, maximum current, maximum power, maximum impedance, maximum applied energy), and/or target parameters"), 19:26-44 ("maintaining that energy at a certain pre-determined level"), 25:24-29, 26:60-27:22, 27:66-28:6, 33:57-34:13. Mehta also discloses that the system delivers energy at a pre-set level: "When the impedance is between 300 and 1500 ohms the controller can provide energy at a first set of parameters, and when the tissue parameter is between 1500 and 3000 ohms the

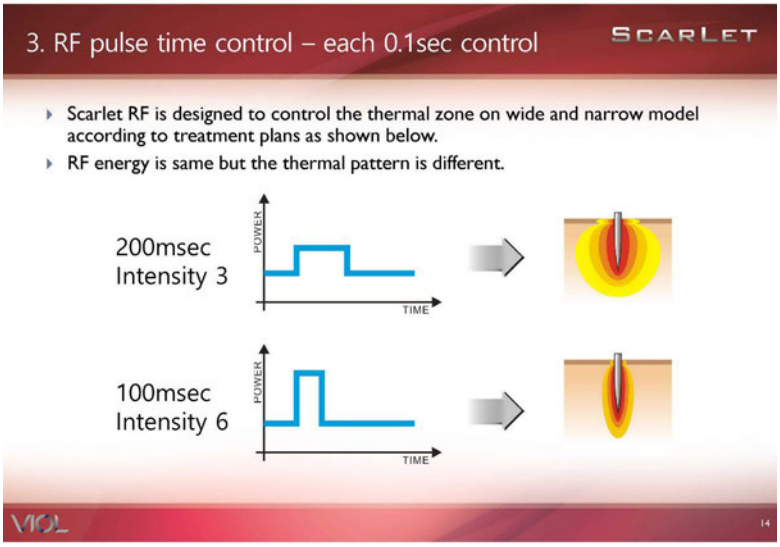
'812 Patent Claim 6		Mehta alone or Mehta in view of one or more of ScarLet, Na '848, and/or Kang '395
		controller can provide energy at a second set of parameters to account for the varying tissue." 5:43-48 . "The graphical user interface can be configured to allow a user to adjust at least one parameter of the energy supply unit." *Id*., at 3:40-41; *see also id*. "In addition, the graphical user interface can further comprise: a treatment counter indicator configured to show a number of treatment cycles applied by the energy supply unit." *Id*., at 3:29-39. Mehta also energizes the needles using RF energy "for a specific duty cycle to prevent stressing the components of that system." *Id*., at 20:13-28; *see also id*., at 19:26-44 ("pre-determined amount[s] of time" for the energizing the needles), 19:45-65 ("pre-determined cycle or dwell time … for precise control in maintaining the target site at the pre-determined temperature"), 27:66-28:6, 33:57-34:13, 34:14-24, Fig. 10E. Na '848 discloses energizing the plurality of extended needles via a signal generator electrically coupled to the plurality of extended needles. Na '848 discloses that the **"**[a]rchitecture **310** includes an acupuncture apparatus **320** and an electrical signal generation system **300**,**"** and that the **"**electrical signal generation system **300** may be electrically coupled to the acupuncture apparatus **320** via one or more wires **300A** and to a mammal **20** to be treated via one or more wires **300B**. Na '848 at [0026]. **"**The apparatus **320** may include a handle **330**, elastic section **333**, electrical interface **340**, internal wire(s) **33** land plate **350**.**"** *Id*. **"**The pins **351** may have a length A (0.3 mm to 2.1 mm in an embodiment) where at least one pin **351** is electrically coupled to the electrical interface **340** via the internal wire **331**.**"** *Id.; see also id*. at [0027] (**"**The signal generator **370** may be coupled to at least one pin **351** via internal wire **331** and coupled to the conductive interface **390**.**"**); [0028] **"**The signal generator or module **370** may generate a vary of signals (such as shown in FIGS. 5 A to 6) to vibrate one or more pins **351** electrically coupled to the system **300** via the internal wire **331** and the conductive interface **390**….The switch **375** coupled to the generator **370** may cause the generator to produce one or more electrical signals for a predetermined time interval or until the switch **375** is triggered again.**"**).

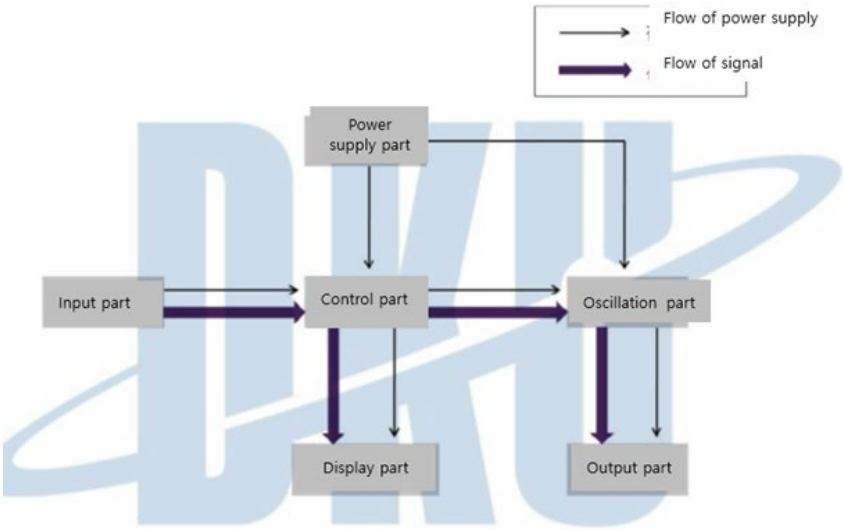
'812 Patent Claim 6		Mehta alone or Mehta in view of one or more of ScarLet, Na '848, and/or Kang '395
		Na '848 further discloses that the **"**signal generator **370** may be coupled to at least one pin **351** via internal wire **331** and coupled to at least one other pin **352** via internal wire **332**. *Id*. at [0029]. **"**The signal generator or module **370** may generate a vary of signals (such as shown in FIGS. 5A to 6) to vibrate one or more dipole pair or bipolar pins **351**, **352**.**"** *Id*. FIGS. 3A and 3B are simplified isometric diagrams of acupuncture apparatus **400**, **460** including at least one pin **451** that may be coupled to an electrical signal via an internal wire **458**.**"** *Id* at [0033]. **"**In apparatus **400**, the electrical lead wire **400A** may be coupled to an electrical interface **410** in the apparatus handle **430** where the interface **410** is electrically coupled to the internal wire **458**.**"** *Id*. Na '848 discloses directing the signal generator to energize the plurality of needles at a predetermined intensity for a predetermined duty cycle. Note: energizing for a for a predetermined duty cycle, means that it is activated cyclically or a predetermined time and then turned off for another predetermined amount of time. Na '848 discloses "diagrams of electrical signal waveforms **650**, **630**, **640** that may be applied to one or more LEDs **32A**, **32B**, **532** and to the pins **230**, **351**, **451** according to various embodiments." *Id*. at [0039]; *see* also, FIGs. 5A, 5B.

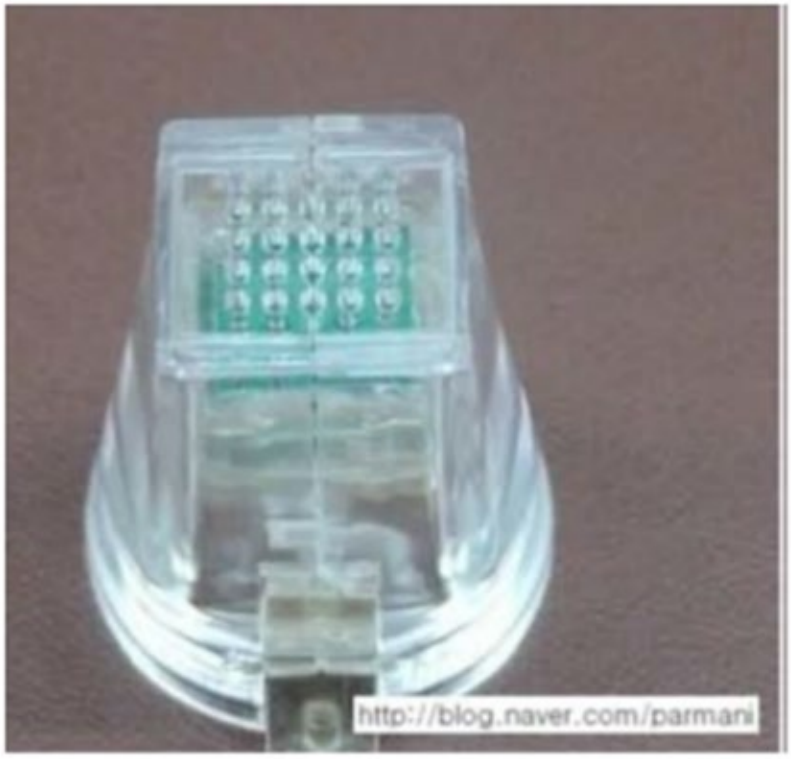
'812 Patent Claim 6	Mehta alone or Mehta in view of one or more of ScarLet, Na '848, and/or Kang '395
	 650 FIGURE 5A  630  640 FIGURE 5B *Id*. at FIGs. 5A, 5B. Na '848 further discloses that the **"**waveform **650** may be used to energize … the pins **230**, **351**, **451** periodically Pl for a predetermined interval Tl where each pulse **652**, **654**, **656** has a [*sic*] amplitude Al,**"** (*id*. at [0039]), and further that **"**a signal waveform **630** may be applied … to the pins **230**, **351**, **451** and a second waveform **640** may be applied or used to energize … the pins **230**, **351**, **451**, **352**,**"** (*id*. at [0040]). Na '848 continues to disclose that: The signal waveform **630** includes several square-wave pulses **632**, **634**, and **636** and the signal waveform **640** includes several square-wave pulses **642**, **644**, and **646**. Each pulse **632**, **634**, **636**, **642**, **644**, **646** may a have a similar magnitude and envelope. The waveform **630** may be used to energize a first LED **32A**, **32B**, **332** module and the pins **230**, **351**, **451** periodically Pl for a predetermined interval Tl where each pulse **632**, **634**, **636** has an amplitude Al. The waveform **640** may be used to energize a second LED **32A**, **32B**, **332** module and the pins **230**, **351**, **451** periodically P2 for a predetermined interval T2 where each pulse **642**, **644**, **646** has an amplitude Bl. The pulse width Tl, T2 may be about **100** microsecond (μs) to **500** μs and the

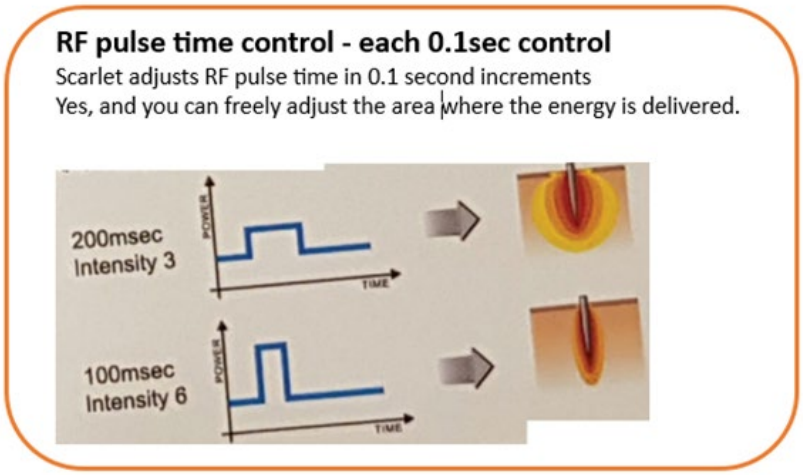
'812 Patent Claim 6	Mehta alone or Mehta in view of one or more of ScarLet, Na '848, and/or Kang '395
	period Pl, P2 may from **100** ms to **500** ms as a function of the energy to affect dermalogical cells or chemicals **22A**. In another embodiment, Al, A2 may be about 0.5 milliamperes (mA) to 5 mA, the pulse width Tl, T2 may be about **200** microsecond (μs) and the period Pl, P2 may about **250** ms as a function of the energy required to affect dermalogical cells or chemicals **22A**. In an embodiment the pulses **632**, **634**, **636** do not substantially overlap the pulses **642**, **644**, **646**. In an embodiment Tl > T2 and P2 is an integer multiple of Pl. *Id*. at [0040]. Na '848 further discloses: **"**In an embodiment each pulse **672**, **674**, **676**, **678**, **682**, and **684** may have a pulse width T3, and frequency spectrum width Fl and period P3. The pulse **672** is frequency offset from the pulse **674**, the pulse **676** is frequency offset from the pulse **678**, and the pulse **682** is frequency offset from the pulse **684**. The pulses **672**, **674**, **676**, **678**, **682**, and **684** may be applied to an LED module to affect dermalogical cells or chemicals **22A** and the pins **230**, **351**, **451**. Pulses **672**, **674** having different frequency spectrums may enable different LED stimulation. In an embodiment the pulses **672**, **676**, **682** may be applied to a first LED module and the pulses **674**, **678**, **684** may be applied to a second LED module. The frequency separation between the respective pulses may enable simultaneous energization of a first and a second LED module and the pins **230**, **351**, **451** and subsequent and independent spectrum generation." *Id*. at [0041].

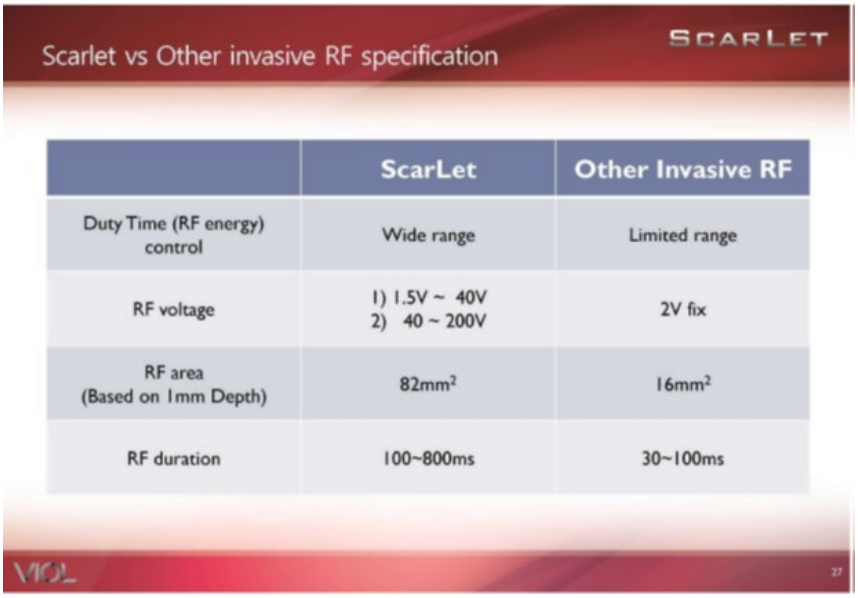
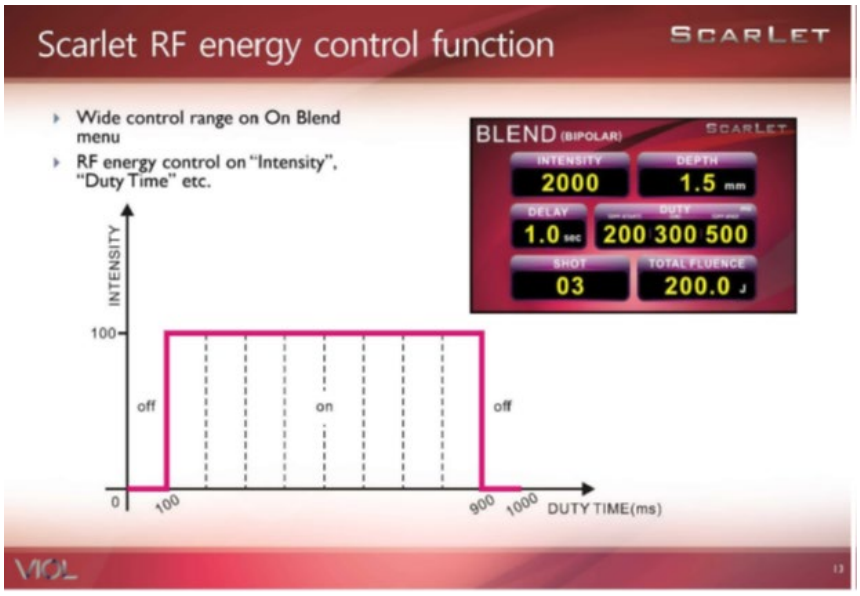
'812 Patent Claim 6	Mehta alone or Mehta in view of one or more of ScarLet, Na '848, and/or Kang '395
	 FIGURE 6 *Id*. at FIG 6. ScarLet discloses energizing the motor to deploy the plurality of needles to a predetermined depth and directing the signal generator to energize the plurality of needles at a predetermined intensity for a predetermined duty cycle.  Figure 2-3. An example of a lab display (touch screen) Ilooda-0006078 (#13_(Eng)_Shim 2010_DKU Thesis Dec 1 2010_Translated_Certified at 10)

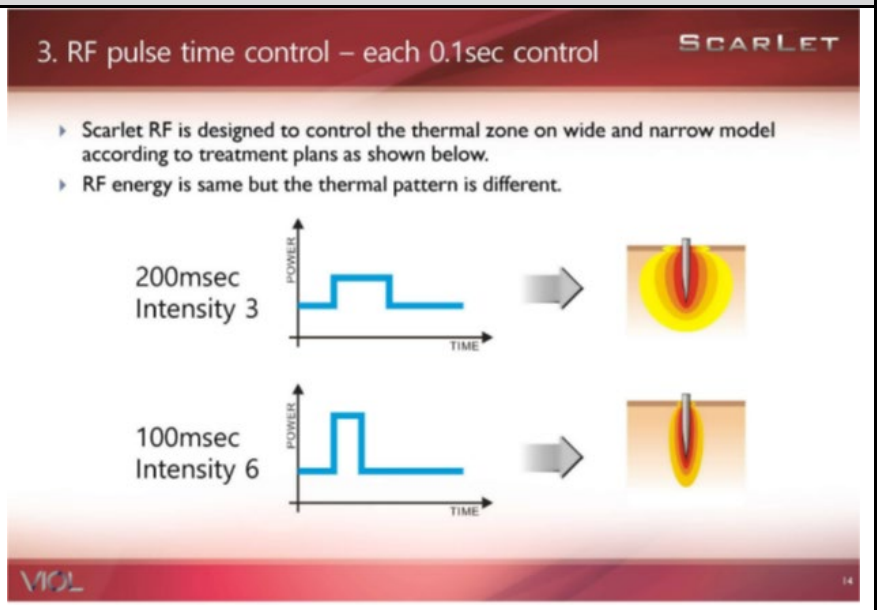
'812 Patent Claim 6	Mehta alone or Mehta in view of one or more of ScarLet, Na '848, and/or Kang '395
	 SERENDIA-00017306 at -319 "The block diagram of the device is shown in Figure 2-1. The power supply part supplies 220V power input from the outside and DC 24V to the control part, oscillation part, and output part. In the input part, select the function you want to use using the switch, and the signal is transmitted to the control part. The control part identifies the signal received from the input part, detects the connection of the output conductor, and delivers or blocks the signal to the oscillation part and the output part. The display part displays the output status. The oscillation part generates a signal of 2 MHz by the signal transmitted from the control part and transmits it to the output part. In the output part, the signal received from the oscillation part is amplified by the control signal and sent through the ceramic." Signal intensity and needles depth are controlled: "Intensity displays the intensity of the output and depth displays the distance the linear motor advances within the range 0.5-3.5mm. Delay displays the waiting time before the linear motor moves forward and then backward again. Duty displays the high frequency output time within the range of 0.3-1.0 seconds, where off start is the linear motor forward waiting time, on is the output time, and off end is the linear motor reverse waiting time. Shot counts the number of shots and total fluence displays the total amount of energy. Intensity, depth, and duty are adjustable on the device. The foot switch is used to interrupt the output, and the hand piece

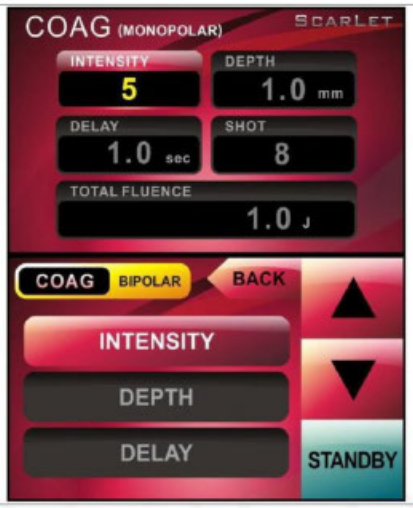
'812 Patent Claim 6	Mehta alone or Mehta in view of one or more of ScarLet, Na '848, and/or Kang '395
	connects the electrosurgical electrodes to the mating cap at the end of the hand piece to coagulate and incise through high-frequency current." Ilooda-0006078 (#13_(Eng)_Shim 2010_DKU Thesis Dec 1, 2010_Translated_Certified at 7).  Figure 2-1. Experiment Apparatus Block Diagram Ilooda-0006078 (#13_(Eng)_Shim 2010_DKU Thesis Dec 1, 2010_Translated_Certified at 8).

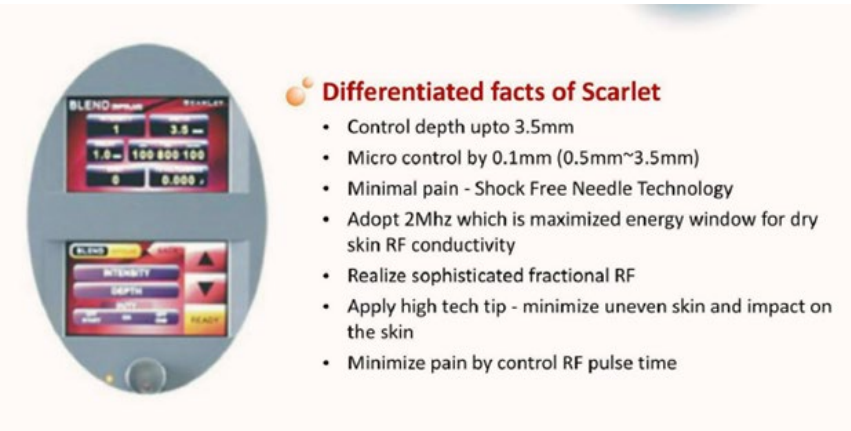
'812 Patent Claim 6	Mehta alone or Mehta in view of one or more of ScarLet, Na '848, and/or Kang '395
	 Ilooda-0006719 (#19-1_Naver Blog The H Jan 10, 2011_Translated_Certified at 5). 

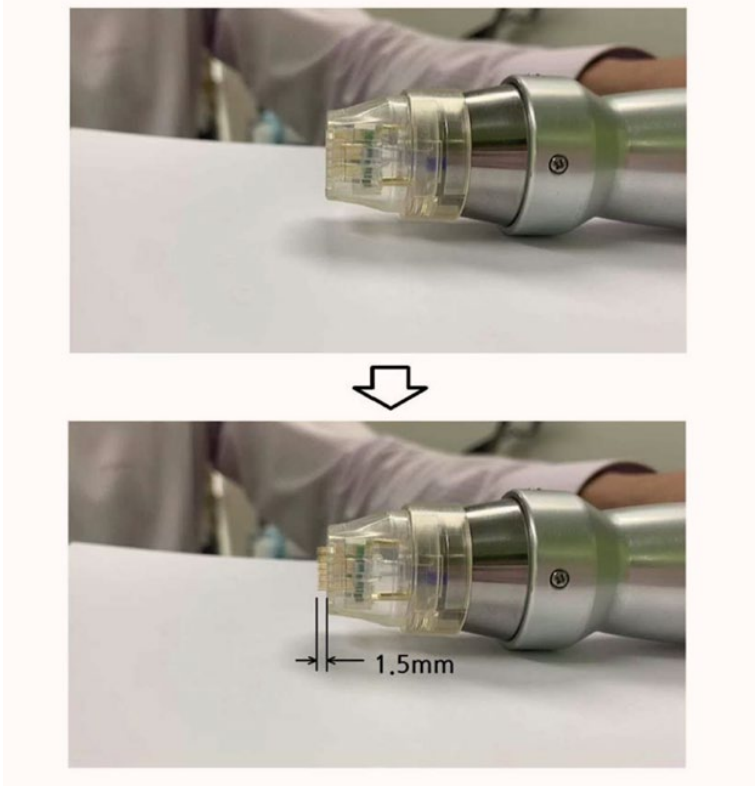
'812 Patent Claim 6	Mehta alone or Mehta in view of one or more of ScarLet, Na '848, and/or Kang '395
	Ilooda-0006770 (#18_D&PS Monthly Sept 2010_Translated_Certified at 4). 1. Specification of ScarLet Specification NEEDLE DEPTH: 0.5 mm ~ 3.5 mm (0.1 mm unit) RF CONDUCT. TIME: 100msec ~ 800msec (100msec unit) RF OUTPUT: 1) 1.5V ~ 40V 2) 40 ~ 200V RF E. FIELD WIDTH(at 1mm Depth): 82mm² RF FREQUENCY: 2MHz WEIGHT: 29Kg DIMENSION: 55cm(W) * 35cm(D) * 122cm(H) ELECTRODE NO.: 25 Pin SPOT SIZE: 1cm² Ilooda-0006075 (ScarLet intro at 2).  Ilooda-0006770 (#18_D&PS Monthly Sept 2010_Translated_Certified at 4). "Intensity displays the intensity of the output and depth displays the distance the linear motor advances within the range 0.5-3.5mm."

'812 Patent Claim 6		Mehta alone or Mehta in view of one or more of ScarLet, Na '848, and/or Kang '395
		Ilooda-0006078 (#13_(Eng)_Shim 2010_DKU Thesis Dec 1, 2010_Translated_Certified at 7).  SERENDIA-00017306 at -332.  SERENDIA-00017306 at -318.

'812 Patent Claim 6		Mehta alone or Mehta in view of one or more of ScarLet, Na '848, and/or Kang '395
		 SERENDIA-00017306 at -319.

'812 Patent Claim 6	Mehta alone or Mehta in view of one or more of ScarLet, Na '848, and/or Kang '395
	③ COAG mode  ⓐ Top Name / Description INTENSITY: Displays output intensity DEPTH: Displays the distance that the linear motor travels forward DELAY: Displays the delay time from the time of linear motor moving forward to the time of moving backward again SHOT: Counts the number of output shots TOTAL FLUENCE: Displays total energy amount ⓑ Bottom Name / Description BIPOLAR button: User may set the output choice of BIPOLAR/MONOPOLAR. INTENSITY button: Sets the INTENSITY value. In this state, press the down (▼) and the up (▲) buttons to adjust the INTENSITY value, and the INTENSITY value is displayed in the top figure DEPTH button: Sets the DEPTH value. In this state, press the down (▼) and the up (▲) buttons to adjust the DEPTH value, and the DEPTH value is displayed in the top figure. STANDBY button: Becomes the READY state. In this state, press the FOOT switch to generate output. In the READY state, other buttons cannot be operated; So, user must press the READY button again to make it go into the STANDBY state before operating any other buttons. BACK button: Return to the main screen. Ilooda-0010187 at -199 (certified English translation of SERENDIA-00061017 at -028).

'812 Patent Claim 6	Mehta alone or Mehta in view of one or more of ScarLet, Na '848, and/or Kang '395
	 Ilooda-0010031 at -033. **Performance** 1. Product configuration This product is a disposable electrode for a hand-operated electrosurgical device, and consists of an electrode that applies RF current to the human body and a cartridge cap. 2. Performance 1) Functional characteristics: Block RF electricity flow except in exposed areas. 2) RF leakage current: 1.16 mA 3) Length of the electrode exposed: 0.5 – 3.5mm (Adjustable in the Depth menu on the electrosurgical device) Ilooda-0010141 at -157 (certified English translation of SERENDIA-00033705 at -720).

'812 Patent Claim 6	Mehta alone or Mehta in view of one or more of ScarLet, Na '848, and/or Kang '395
	 [Plaintiff's Exhibits 22-10 and 22-11: 1.5 mm protrusion of the needles due to protrusion of the drive shaft]. Ilooda-0008178 at -234. "Intensity displays the intensity of the output and depth displays the distance the linear motor advances within the range 0.5-3.5mm. Delay displays the waiting time before the linear motor moves forward and then backward again. Duty displays the high frequency output time within the range of 0.3-1.0 seconds, where off start is the linear motor forward waiting time, on is the output time, and off end is the linear motor reverse waiting time. Shot counts the number of shots and total fluence displays the total amount of energy. Intensity, depth, and duty are adjustable on the device. The foot switch is used to interrupt the output, and the hand piece connects the electrosurgical electrodes to the mating cap at the end of the hand piece to coagulate and incise through high-frequency current." Ilooda-0006078 (#13_(Eng)_Shim 2010_DKU Thesis Dec 1 2010_Translated_Certified at 7).To the extent it is alleged that Mehta does not disclose a motor that is energized to extend the

'812 Patent Claim 6		Mehta alone or Mehta in view of one or more of ScarLet, Na '848, and/or Kang '395
		needles a desired distance, recited in claims 6 and 13, either expressly or inherently, it is my opinion that it would have been obvious to a POSITA as of the priority date of the '812 Patent to modify Mehta and/or combine the teaching of Mehta or ScarLet with the knowledge of a POSITA, or combine the teachings of Mehta with one of ScarLet and Na'848, in a manner that would have rendered the asserted claims invalid as obvious. For example, Mehta, ScarLet, and Na'848 disclose various mechanisms for causing a plurality of extendable needles to extend a desired distance from the end surface producing pulsed radio frequency signals across the plurality of needles, and at least Mehta, and ScarLet specifically disclose a motor coupled to the plurality of extendable needles that may be directed to cause the plurality of the extendable needles to extend a desired distance from the end surface. As of the priority date of the '812 Patent, it was well known that controlling the depth of penetration for the needles and being able to retract the needles was advantageous with respect to providing dermatological treatments. To the extent Mehta or ScarLet does not explicitly disclose that the needles of a dermatological treatment device are extendable using a motor, it would have been obvious to modify the dermatological treatment device to make the needles retractable and extendable to a desired depth using a motor connected to the needles to achieve enhanced safety (by having the needles retracted when not in use) and enhanced customizability of treatment (by specifying the needle penetration depth). Configuring a plurality of needles to be attached to a motor would have been a matter of routine engineering as of the priority date of the '812 Patent, as evidenced by the numerous dermatological treatment devices which included a motor for this purpose.

545. In view of the foregoing chart, claim 6 of the '812 Patent is anticipated by Mehta and/or rendered obvious by Mehta alone or Mehta in view of Na '848 and/or ScarLet. Further, to the extent Complainant argues that any of the foregoing limitations is not explicitly or inherently disclosed by Mehta alone or Mehta in view of Na '848 and/or ScarLet, such

limitations would have been obvious given the knowledge of a POSITA. The teachings of Mehta, Na '848 and/or ScarLet are so similar to what is claimed that any alleged difference between the teachings of Na '848 in view of Mehta and what is claimed would not have been of patentable significance given the knowledge of a POSITA.

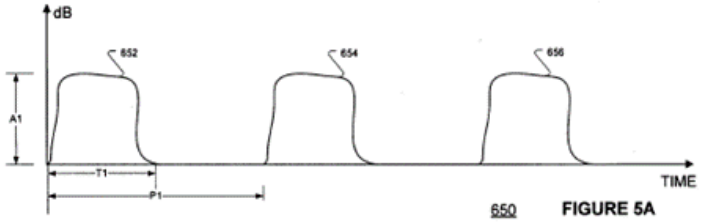
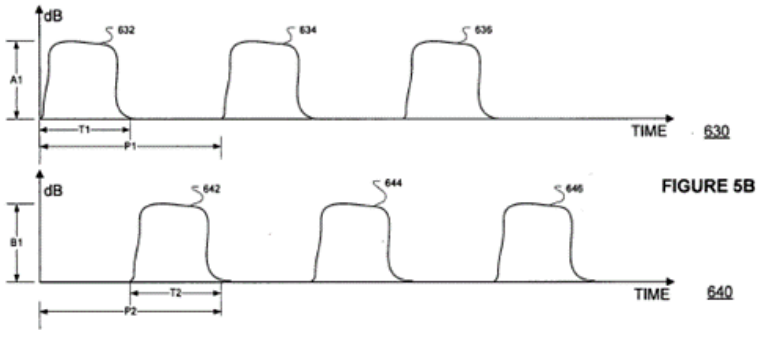
12. Claim 6 of the '812 Patent is rendered Obvious by Na '848 in view of Mehta

546. It is my opinion that claim 6 of the '812 Patent is rendered obvious over Na '848 in view of Mehta as detailed below:

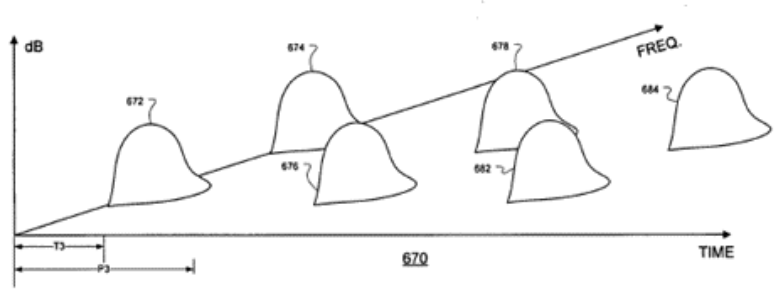
'812 Patent Claim 6		Na '848 in view of Mehta
6.0	6. The method of claim 3, further comprising energizing the motor to deploy the plurality of needles to a predetermined depth and directing the signal generator to energize the plurality of needles at a predetermined intensity for a predetermined duty cycle.	***Claim 6 of the '812 Patent is rendered obvious by Na '848 in view of Mehta.*** Na '848 in view of Mehta renders obvious the method of treating dermatological tissue of claim 3. *See* Claim 3, above. Mehta discloses energizing the motor to deploy the plurality of needles to a predetermined depth and directing the signal generator to energize the plurality of needles at a predetermined intensity for a predetermined duty cycle. *See e.g.*, Mehta, at 3:29-39; 3:40-41; 3:42-55; 3:57-67; 4:63-5:2; 5:3-15; 6:64-65; 10:33-39; 12:31-46; 13:54-57; Fig. 3A; 13:58-4; 15:27-33; 15:55-16:11; Fig. 4A; 16:59-17:12; 18:21-37; Fig. 5; 18:64-19:8; 19:26-44; 19:45-65; 20:13-28; 20:29-55; Fig. 6; 23:55-24:4; Fig. 7E; 24:5-12; 25:24-29; 24:46-60; 25:24-29; 25:30-55; 26:41-59; 26:60-27:22; 27:66-28:6; 28:49-50; 32:46-62; Fig. 10B; 32:63-33:14; 33:15-29; 33:30-34; 33:57-13; Fig. 10E; 34:14-24; 34:38-45; 35:8-22; Fig. 12A; Fig. 12B; 36:21-40; 37:25-34; Fig. 13A; 40:5-38; 40:39-44; 40:45-57; 41:40-43; 41:55-58; 42:9-15. As discussed above, Mehta discloses energizing a motor coupled to the needle assembly to cause the plurality of the needles to extend a desired distance from the releasably couplable deployable needle module end surface. *See e.g.,* Mehta, at 10:33-39 (**"**motors**"** **"**driven by the control system/energy supply unit 90**"**), 12:5-14, 13:58-4, 16:59-17:12, 18:21-37, 32:46-33:34, 33:57-13, 33:57-13, 34:38-45, 35:8-22, 36:21-40, Figs. 10B, 10E.

'812 Patent Claim 6		Na '848 in view of Mehta
		Mehta discloses predetermining the depth of the plurality of needles before treatment. *See id*., at 32:46-33:34 (**"**The virtual depth/location depiction **350** can simply show the location of the probe array prior to treatment. Alternatively, the system can be configured to show (or the system can have an option to show) additional probe array information. For example, the virtual depth/location depiction **350** can also show a desired probe location (e.g., array **342** can represent the desired depth of placement for providing a treatment).**"**), 33:57-34:13, 34:38-45, 35:8-22. Mehta further discloses that the devise **"**can also be configured to display a time setting **352** of the intended treatment, the target temperature setting **354** of the treatment tissue (or probes at the treatment site), as well as a counter **360** for the number of treatments.**"** *Id*. at 34:14–18; *see also id*. at FIGs 10E and 10F. Mehta further discloses **"**applying energy to the electrode array from the energy source during a treatment cycle where the energy applied to each electrode pair is adjusted based upon the identified tissue layer.**"** Mehta, at 3:42-55. Mehta discloses that the needles are energized at a predetermined intensity. *Id*., at 3:57-67 (**"**by selecting a set of controller parameters based on the identified tissue layer … the method further comprising supplying an initial energy level from the energy source between the electrodes … and modifying the initial energy level using the controller parameters to obtain a target temperature in the injured tissue**"**), 15:55-16:11 (**"**electrodes can be energized**"**). **"**Some examples of the pre-determined values include limiting energy delivery to [a predetermined intensity, such as] between 2 and 4 joules.**"** *Id*., at 5:58-6:2; *see also id*., at 18:64-19:8 (**"**the controller can adjust the maximum parameters (maximum voltage, maximum current, maximum power, maximum impedance, maximum applied energy), and/or target parameters**"**), 19:26-44 (**"**maintaining that energy at a certain pre-determined level**"**), 25:24-29, 26:60-27:22, 27:66-28:6, 33:57-34:13. **"**The graphical user interface can be configured to allow a user to adjust at least one parameter of the energy supply unit.**"** *Id*., at 3:40-41. **"**In addition, the graphical user interface can further comprise: a treatment counter indicator

'812 Patent Claim 6		Na '848 in view of Mehta
		configured to show a number of treatment cycles applied by the energy supply unit." *Id*., at 3:29-39. Mehta also energizes the needles using RF energy "for a specific duty cycle to prevent stressing the components of that system." *Id*., at 20:13-28; *see also id*., at 19:26-44 ("pre-determined amount[s] of time" for the energizing the needles), 19:45-65 ("pre-determined cycle or dwell time … for precise control in maintaining the target site at the pre-determined temperature"), 27:66-28:6, 33:57-34:13, 34:14-24, Fig. 10E. Na '848 discloses energizing the plurality of extended needles via a signal generator electrically coupled to the plurality of extended needles. Note: energizing for a for a predetermined duty cycle, means that it is activated cyclically or a predetermined time and then turned off for another predetermined amount of time. Na '848 discloses that the "[a]rchitecture **310** includes an acupuncture apparatus **320** and an electrical signal generation system **300**," and that the "electrical signal generation system **300** may be electrically coupled to the acupuncture apparatus **320** via one or more wires **300A** and to a mammal **20** to be treated via one or more wires **300B**. Na '848 at [0026]. "The apparatus **320** may include a handle **330**, elastic section **333**, electrical interface **340**, internal wire(s) **33** land plate **350**." *Id*. "The pins **351** may have a length A (0.3 mm to 2.1 mm in an embodiment) where at least one pin **351** is electrically coupled to the electrical interface **340** via the internal wire **331**." *Id.; see also id*. at [0027] ("The signal generator **370** may be coupled to at least one pin **351** via internal wire **331** and coupled to the conductive interface **390**."); [0028] "The signal generator or module **370** may generate a vary of signals (such as shown in FIGS. 5 A to 6) to vibrate one or more pins **351** electrically coupled to the system **300** via the internal wire **331** and the conductive interface **390**….The switch **375** coupled to the generator **370** may cause the generator to produce one or more electrical signals for a predetermined time interval or until the switch **375** is triggered again."). Na '848 further discloses that the "signal generator **370** may be coupled to at least one pin **351** via internal wire **331** and coupled to at least one other pin **352** via internal wire **332**. *Id*. at [0029]. "The signal generator or module **370** may generate

'812 Patent Claim 6		Na '848 in view of Mehta
		a vary of signals (such as shown in FIGS. 5A to 6) to vibrate one or more dipole pair or bipolar pins **351**, **352**." *Id*. FIGS. 3A and 3B are simplified isometric diagrams of acupuncture apparatus **400**, **460** including at least one pin **451** that may be coupled to an electrical signal via an internal wire **458**." *Id.* at [0033]. "In apparatus **400**, the electrical lead wire **400A** may be coupled to an electrical interface **410** in the apparatus handle **430** where the interface **410** is electrically coupled to the internal wire **458**." *Id*. Na '848 discloses directing the signal generator to energize the plurality of needles at a predetermined intensity for a predetermined duty cycle. Na '848 discloses "diagrams of electrical signal waveforms **650**, **630**, **640** that may be applied to one or more LEDs **32A**, **32B**, **532** and to the pins **230**, **351**, **451** according to various embodiments." *Id*. at [0039]; *see* also, FIGs. 5A, 5B.  650 FIGURE 5A  FIGURE 5B *Id*. at FIGs. 5A, 5B. Na '848 further discloses that the "waveform **650** may be used to energize … the pins **230**, **351**, **451** periodically Pl for a predetermined interval Tl where each pulse **652**, **654**, **656** has a [*sic*] amplitude Al," (*id*. at [0039]), and further that "a signal

'812 Patent Claim 6		Na '848 in view of Mehta
		waveform **630** may be applied … to the pins **230**, **351**, **451** and a second waveform **640** may be applied or used to energize … the pins **230**, **351**, **451**, **352**," (*id*. at [0040]). Na '848 continues to disclose that: The signal waveform **630** includes several square-wave pulses **632**, **634**, and **636** and the signal waveform **640** includes several square-wave pulses **642**, **644**, and **646**. Each pulse **632**, **634**, **636**, **642**, **644**, **646** may a have a similar magnitude and envelope. The waveform **630** may be used to energize a first LED **32A**, **32B**, **332** module and the pins **230**, **351**, **451** periodically Pl for a predetermined interval Tl where each pulse **632**, **634**, **636** has an amplitude Al. The waveform **640** may be used to energize a second LED **32A**, **32B**, **332** module and the pins **230**, **351**, **451** periodically P2 for a predetermined interval T2 where each pulse **642**, **644**, **646** has an amplitude Bl. The pulse width Tl, T2 may be about **100** microsecond (μs) to **500** μs and the period Pl, P2 may from **100** ms to **500** ms as a function of the energy to affect dermalogical cells or chemicals **22A**. In another embodiment, Al, A2 may be about 0.5 milliamperes (mA) to 5 mA, the pulse width Tl, T2 may be about **200** microsecond (μs) and the period Pl, P2 may about **250** ms as a function of the energy required to affect dermalogical cells or chemicals **22A**. In an embodiment the pulses **632**, **634**, **636** do not substantially overlap the pulses **642**, **644**, **646**. In an embodiment Tl > T2 and P2 is an integer multiple of Pl. *Id*. at [0040]. Na '848 further discloses: **"**In an embodiment each pulse **672**, **674**, **676**, **678**, **682**, and **684** may have a pulse width T3, and frequency spectrum width Fl and period P3. The pulse **672** is frequency offset from the pulse **674**, the pulse **676** is frequency offset from the pulse **678**, and the pulse **682** is frequency offset from the pulse **684**. The pulses **672**, **674**, **676**, **678**, **682**, and **684** may be applied to an LED module to affect dermalogical cells or chemicals **22A** and the pins **230**, **351**, **451**. Pulses

‘812 Patent Claim 6		Na ‘848 in view of Mehta
		672, **674** having different frequency spectrums may enable different LED stimulation. In an embodiment the pulses **672**, **676**, **682** may be applied to a first LED module and the pulses **674**, **678**, **684** may be applied to a second LED module. The frequency separation between the respective pulses may enable simultaneous energization of a first and a second LED module and the pins **230**, **351**, **451** and subsequent and independent spectrum generation. *Id*. at [0041].  FIGURE 6 *Id*. at FIG 6.

547. In view of the foregoing chart, claim 6 of the ‘812 Patent is rendered obvious by Na ‘848 in view of Mehta. Further, to the extent Complainant argues that any of the foregoing limitations is not explicitly or inherently disclosed by Na ‘848 in view of Mehta i, such limitations would have been obvious given the knowledge of a POSITA. The teachings of Na ‘848 and Mehta are so similar to what is claimed that any alleged difference between the teachings of Na ‘848 in view of Mehta and what is claimed would not have been of patentable significance given the knowledge of a POSITA.

13. Claim 10 of the '812 Patent is Anticipated by Mehta and/or rendered Obvious by Mehta

548. Asserted claim 10 of the '812 Patent depends from claim 1. It is my opinion that claim 10 is anticipated by Mehta and/or rendered obvious by Mehta alone as detailed below:

'812 Patent Claim 10		**Mehta alone or in combination with one or more of ScarLet, Na '848, and/or Kang '395**
10	10. The method of claim 1, wherein a first electrical contact of the at least one electrical contact is electrically coupled to a first plurality of the plurality of needles and a second electrical contact of the at least one electrical contact is electrically coupled to a second, different plurality of the plurality of needles.	***Claim 10 of the '812 Patent is anticipated by Mehta and/or rendered obvious by Mehta.*** Mehta discloses and/or renders obvious the method of treading dermatological tissue of claim 1. *See* Claim 1, above. Mehta discloses wherein a first electrical contact of the at least one electrical contact is electrically coupled to a first plurality of the plurality of needles and a second electrical contact of the at least one electrical contact is electrically coupled to a second, different plurality of the plurality of needles. *See e.g.*, Mehta, at 16:12-18; Fig. 4A; 16:59-17:9; Fig. 4C; 36:21-40. For example, Mehta discloses that "FIG. 4A also shows the electrodes 104 in the electrode assembly 102 as having connection or contact portions 116 that couple to a connection board on a treatment unit to provide an electrical pathway from the power supply to the electrodes 104." *Id.* at 15:55-59. In another example, Mehta discloses that, as shown in Fig. 4C, "the electrode assembly **102** can have multiple connection portions **116**, **117** per individual electrode." Mehta, at 16:59-17:12. Also, Mehta discloses multiple bipolar pairs of electrodes. *Id*., at 36:21-40. In one example, "[e]ach of the 5 electrode pairs were controlled independently by the generator," (*id*., at 36:21-40), which means that each of the pairs would has its own electrical contact that couples that pair to the generator because otherwise each electrode pair would receive the same amount of energy (and thus not be independently controlled by the generator).

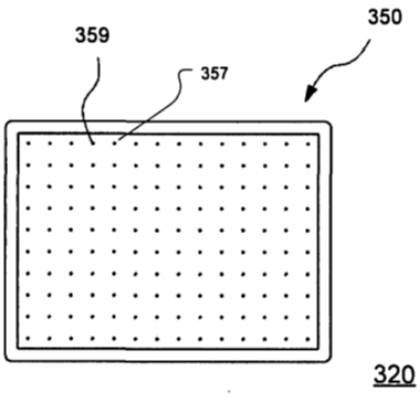
549. In view of the foregoing chart, claim 10 of the '812 Patent is anticipated by the teachings of Mehta. Further, to the extent Complainant argues that any of the foregoing

limitations are not explicitly or inherently disclosed by Mehta, such limitations would have been obvious given the knowledge of a POSITA. The teachings of Mehta are so similar to what is claimed that any alleged difference between the teachings of Mehta and what is claimed would not have been of patentable significance given the knowledge of a POSITA.

14. Claim 10 of the '812 Patent is rendered Obvious by Na '848 in view of Mehta

550. In my opinion claim 10 of the '812 Patent is obvious over Na '848 in view of Mehta as detailed below:

'812 Patent Claim 10		**Na '848 in combination with Mehta**
10.0	10. The method of claim 1, wherein a first electrical contact of the at least one electrical contact is electrically coupled to a first plurality of the plurality of needles and a second electrical contact of the at least one electrical contact is electrically coupled to a second, different plurality of the plurality of needles.	***Claim 10 of the '812 Patent is rendered obvious by Na '848 in view of Mehta.*** Na '848 in view of Mehta renders obvious the method of treating dermatological tissue of claim 1. *See* Claim 1, above. Na '848 discloses a first electrical contact of the at least one electrical contact being electrically coupled to a first plurality of the plurality of needles and a second electrical contact of the at least one electrical contact being electrically coupled to a second, different plurality of the plurality of needles. Na '848 discloses that the "apparatus **362** may include a handle **330**, an elastic section **333**, internal wire(s) **331**, **332**, signal generator **370**, switch **375**, and plate **350**. The signal generator **370** may be coupled to at least one pin **351** via internal wire **331** and coupled to at least one other pin **352** via internal wire **332**." Na '848 at [0029]. Na '848 further discloses that the "signal generator **370** may be coupled to at least one pin **351** via internal wire **331** and coupled to at least one other pin **352** via internal wire **332**." *Id.* Na '848 also discloses that the "acupuncture section **353** may include a plurality of acupuncture pins or needles **351** where at least one pin **351** is electrically coupled to the wire **331**." *Id.* at [0030]. "In a bipolar configuration a second wire **332** may be coupled to at least one other pin **351**." *Id.* "FIG. 2E is a simplified bottom view of the plate **350** showing the pins or needles **359**, **357** where the pins may be electrically

‘812 Patent Claim 10		Na ‘848 in combination with Mehta
		coupled to a first wire **331** and a second wire **332** to form dipole pair (bipolar pins).” *Id.*  **FIGURE 2E** *Id.* at FIG 2E.

551. In view of the foregoing chart, claim 10 of the ‘812 Patent is rendered obvious by Na ‘848 in view of Mehta. Further, to the extent Complainant argues that any of the foregoing limitations is not explicitly or inherently disclosed by Na ‘848 in view of Mehta, such limitations would have been obvious given the knowledge of a POSITA. The teachings of Mehta and Na ‘848 are so similar to what is claimed that any alleged difference between the teachings of Na ‘848 in view of Mehta and what is claimed would not have been of patentable significance given the knowledge of a POSITA.

15. Claim 12 of the ‘812 Patent is Anticipated and/or rendered Obvious by Mehta

552. Independent claim 12 is directed to an apparatus for treating dermatological tissue. The apparatus of claim 12 has the features of the apparatus recited in the method of treating dermatological tissue of claim 1. In my opinion, for at least the reasons discussed for

claim 1 above and as outlined below, claim 12 of the '812 Patent is anticipated by Mehta as detailed below:

'812 Patent Claim 12		Mehta alone
12.0	12. An apparatus for treating dermatological tissue, comprising:	***Claim 12 of the '812 Patent is anticipated by Mehta and/or rendered obvious by Mehta alone.*** Mehta discloses an apparatus for treating dermatological tissue. *See e.g.*, discussion of the preamble of claim 1.
12.1	a user holdable device including a proximal end and	Mehta discloses a user holdable device including a proximal end. *See e.g.*, discussion of claim element 1.2.
12.2	a releasably couplable deployable needle module, the releasably couplable deployable needle module mechanically separatably from the user holdable device proximal end and including a needle assembly including a plurality of needles,	Mehta discloses a releasably couplable deployable needle module, the releasably couplable deployable needle module mechanically separatably from the user holdable device proximal end and including a needle assembly including a plurality of needles. *See e.g.*, discussion of claim element 1.3.
12.3	the needle assembly movable within the releasably couplable deployable needle module to extend the plurality of needles from the releasably couplable deployable needle assembly end surface while at least one electrical contact of the needle assembly remains electrically coupled to at least one electrical contact of the user holdable device proximal end.	Mehta discloses the needle assembly movable within the releasably couplable deployable needle module to extend the plurality of needles from the releasably couplable deployable needle assembly end surface while at least one electrical contact of the needle assembly remains electrically coupled to at least one electrical contact of the user holdable device proximal end. *See e.g.*, discussion of claim element 1.4.

553. In view of the foregoing chart, claim 12 of the '812 Patent is anticipated by the teachings of Mehta. Further, to the extent Complainant argues that any of the foregoing limitations are not explicitly or inherently disclosed by Mehta, such limitations would have been obvious given the knowledge of a POSITA.

16. Claim 12 of the '812 Patent is rendered Obvious by Na '848 in view of Mehta

554. It is also my opinion that, for at least the reasons discussed for claim 1 above and as outlined below, claim 12 of the '812 Patent is rendered obvious by Na '848 in view of Mehta as detailed below:

'812 Patent Claim 12		**Na '848 in view of Mehta**
12.0	12. An apparatus for treating dermatological tissue, comprising:	***Claim 12 of the '818 Patent is rendered obvious by Na '848 in view of Mehta.*** To the extent the preamble is limiting, Na '848 discloses an apparatus for treating dermatological tissue. *See e.g.*, discussion of the preamble of claim 1.
12.1 & 12.2	a user holdable device including a proximal end and a releasably couplable deployable needle module, the releasably couplable deployable needle module mechanically separatably from the user holdable device proximal end and including a needle assembly including a plurality of needles,	Na '848 discloses a user holdable device including a proximal end and a needle module, the needle module including a needle assembly including a plurality of needles. *See e.g.*, discussion of claim elements 1.2 and 1.3.
12.3	the needle assembly movable within the releasably couplable deployable needle module to extend the plurality of needles	Mehta discloses the needle assembly movable within the releasably couplable deployable needle module to extend the plurality of needles from the releasably couplable deployable needle assembly end surface while at least one electrical contact of the needle assembly remains electrically coupled to

'812 Patent Claim 12		Na '848 in view of Mehta
	from the releasably couplable deployable needle assembly end surface while at least one electrical contact of the needle assembly remains electrically coupled to at least one electrical contact of the user holdable device proximal end.	at least one electrical contact of the user holdable device proximal end. *See e.g.*, discussion of claim element 1.4.

555. In view of the foregoing chart, claim 10 of the '812 Patent is rendered obvious by Na '848 in view of Mehta . Further, to the extent Complainant argues that any of the foregoing limitations is not explicitly or inherently disclosed by Na '848 in view of Mehta, such limitations would have been obvious given the knowledge of a POSITA. The teachings of Mehta and Na '848 are so similar to what is claimed that any alleged difference between the teachings of Na '848 in view of Mehta and what is claimed would not have been of patentable significance given the knowledge of a POSITA.

17. Claim 13 of the '812 Patent is Anticipated by Mehta

556. Claim 13 of the '812 Patent depends on claim 12. It is my opinion that claim 13 of the '812 Patent is anticipated by Mehta as detailed below:

'812 Patent Claim 13		Mehta alone
13	13. The apparatus of claim 12, further including a motor coupled to the needle assembly to extend the plurality of needles a desired distance from the releasably couplable deployable needle	***Claim 13 of the '812 Patent is anticipated by Mehta.*** Mehta discloses and/or renders obvious the apparatus for treating dermatological tissue of claim 12. *See* Claim 12, above. Mehta discloses a motor coupled to the needle assembly to extend the plurality of needles a desired distance from the releasably couplable deployable needle assembly end surface

'812 Patent Claim 13		Mehta alone
	assembly end surface when the motor is energized with a particular signal.	when the motor is energized with a particular signal. *See e.g.*, Mehta, at 3:29-39; 3:40-41; 4:63-5:2; 5:3-15; 6:64-65; 9:34-55; 10:33-39; 12:5-14; 12:31-46; 13:54-57; Fig. 3A; 13:58-4; 15:27-33; 15:55-16:11; Fig. 4A; 16:42-58; 16:59-17:12; 18:21-37; Fig. 5; 23:55-24:4; Fig. 7E; 24:46-60; 32:46-62; Fig. 10B; 32:63-33:14; 33:15-29; 33:30-34; 33:57-13; Fig. 10E; 34:38-45; 35:8-22; Fig. 12A; Fig. 12B; 36:21-40. As shown in the discussion of claim 2, Mehta discloses a motor coupled to the needle assembly to extend the plurality of needles a desired distance from the releasably couplable deployable needle assembly end surface when the motor is energized with a particular signal.

557. In view of the foregoing chart, claim 13 of the '812 Patent is anticipated by the teachings of Mehta. Further, to the extent Complainant argues that any of the foregoing limitations are not explicitly or inherently disclosed by Mehta, such limitations would have been obvious given the knowledge of a POSITA. The teachings of Mehta are so similar to what is claimed that any alleged difference between the teachings of Mehta and what is claimed would not have been of patentable significance given the knowledge of a POSITA.

18. Claim 13 of the '812 Patent is rendered Obvious by Na '848 in view of Mehta

558. Claim 13 of the '812 Patent depends on claim 12. In my opinion claim 13 of the '812 Patent is rendered obvious by Na '848 in view of Mehta as detailed below:

'812 Patent Claim 13		Na '848 in combination with Mehta
13	13. The apparatus of claim 12, further including a motor coupled to the needle assembly to extend the plurality of needles a desired distance from the releasably couplable	***Claim 13 of the '812 Patent is rendered obvious by Na '848 in view of Mehta.*** ***Na '848 in view of Mehta renders obvious the apparatus for treating dermatological tissue of claim 12.*** *See* Claim 12, above.

'812 Patent Claim 13		Na '848 in combination with Mehta
	deployable needle assembly end surface when the motor is energized with a particular signal.	Mehta discloses a motor coupled to the needle assembly to extend the plurality of needles a desired distance from the releasably couplable deployable needle assembly end surface when the motor is energized with a particular signal. *See e.g.*, Mehta, at 3:29-39; 3:40-41; 4:63-5:2; 5:3-15; 6:64-65; 9:34-55; 10:33-39; 12:5-14; 12:31-46; 13:54-57; Fig. 3A; 13:58-4; 15:27-33; 15:55-16:11; Fig. 4A; 16:42-58; 16:59-17:12; 18:21-37; Fig. 5; 23:55-24:4; Fig. 7E; 24:46-60; 32:46-62; Fig. 10B; 32:63-33:14; 33:15-29; 33:30-34; 33:57-13; Fig. 10E; 34:38-45; 35:8-22; Fig. 12A; Fig. 12B; 36:21-40. As shown in the discussion of claim 2, Mehta discloses a motor coupled to the needle assembly to extend the plurality of needles a desired distance from the releasably couplable deployable needle assembly end surface when the motor is energized with a particular signal.

559. In view of the foregoing chart, claim 13 of the '812 Patent is rendered obvious by Na '848 in view of Mehta. Further, to the extent Complainant argues that any of the foregoing limitations is not explicitly or inherently disclosed by Na '848 in view of Mehta, such limitations would have been obvious given the knowledge of a POSITA. The teachings of Mehta and Na '848 are so similar to what is claimed that any alleged difference between the teachings of Na '848 in view of Mehta and what is claimed would not have been of patentable significance given the knowledge of a POSITA.

19. Claim 14 of the '812 Patent is Anticipated by Mehta

560. Claim 14 of the '812 Patent depends on claim 13. In my opinion claim 14 of the '812 Patent is anticipated by Mehta as detailed below:

'812 Patent Claim 14		Mehta alone
14	14. The apparatus of claim 13, further including a signal generator electrically	***Claim 14 of the '812 Patent is anticipated by Mehta.***

'812 Patent Claim 14		Mehta alone
	coupled to the user holdable device proximal end to energize the plurality of needles.	***Mehta discloses or renders obvious the apparatus for treating dermatological tissue of claim 13.*** *See* Claim 13, above. Mehta discloses a signal generator electrically coupled to the user holdable device proximal end to energize the plurality of needles. *See e.g.*, Mehta, at 2:58-62; 2:63-17; 3:40-56; 3:57-67; 4:1-18; 5:3-15; 5:16-25; 5:26-33; 5:49-57; 7:16-18; 8:13-23; 9:34-55; 10:17-25; 12:5-14; 10:53-65; Fig. 2A; 11:14-20; 11:21-52; 15:55-16:11; Fig. 4A; 17:59-18:3; 18:4-20; 18:64-19:8; 19:66-20:12; 20:13-29; 20:29-47; Fig. 6; 24:46-60; 25:30-55; 26:41-59; 26:60-27:22; 37:25-34; Fig. 13A; 40:39-44; 40:45-57; 41:40-43; 41:55-58; 42:9-15. As shown in the discussion of the limitations of claim 3, Mehta discloses a signal generator electrically coupled to the user holdable device proximal end to energize the plurality of needles.

561. In view of the foregoing chart, claim 14 of the '812 Patent is anticipated by the teachings of Mehta. Further, to the extent Complainant argues that any of the foregoing limitations are not explicitly or inherently disclosed by Mehta, such limitations would have been obvious given the knowledge of a POSITA. The teachings of Mehta are so similar to what is claimed that any alleged difference between the teachings of Mehta and what is claimed would not have been of patentable significance given the knowledge of a POSITA.

20. Claim 14 of the '812 Patent is rendered Obvious by Na '848 in view of Mehta

562. In my opinion claim 14 of the '812 Patent is rendered obvious by Na '848 in view of Mehta as detailed below:

'812 Patent Claim 14		Na '848 in combination with Mehta
14	14. The apparatus of claim 13, further including a signal generator electrically	***Claim 14 of the '812 Patent is rendered obvious by Na '848 in view of Mehta.***

'812 Patent Claim 14		Na '848 in combination with Mehta
	coupled to the user holdable device proximal end to energize the plurality of needles.	Na '848 in view of Mehta renders obvious the apparatus for treating dermatological tissue of claim 13. *See* Claim 13, above. Na '848 discloses a signal generator electrically coupled to the user holdable device proximal end to energize the plurality of needles. *See, e.g.*, Na '848 at [0026]-[0029], [0033]. As shown in the discussion of the limitations of claim 3, Na '848 discloses a signal generator electrically coupled to the user holdable device proximal end to energize the plurality of needles.

563. In view of the foregoing chart, claim 14 of the '812 Patent is rendered obvious by Na '848 in view of Mehta. Further, to the extent Complainant argues that any of the foregoing limitations is not explicitly or inherently disclosed by Na '848 in view of Mehta, such limitations would have been obvious given the knowledge of a POSITA. The teachings of Mehta and Na '848 are so similar to what is claimed that any alleged difference between the teachings of Na '848 in view of Mehta and what is claimed would not have been of patentable significance given the knowledge of a POSITA.

21. Claim 16 of the '812 Patent is Anticipated by Mehta

564. Claim 16 of the '812 Patent depends from claim 13, which depends from claim 12. In my opinion claim 16 of the '812 Patent is anticipated by Mehta as shown below:

'812 Patent Claim 16		Mehta alone
16	16. The apparatus of claim 13, wherein the user holdable device proximal end includes the motor, the motor including a drive shaft releasably couplable to the needle assembly.	***Claim 16 of the '812 Patent is anticipated by Mehta.*** Mehta discloses and/or renders obvious the apparatus for treating dermatological tissue of claim 13. *See* Claim 13, above. Mehta discloses that the user holdable device proximal end includes the motor, the motor including a drive shaft

'812 Patent Claim 16		Mehta alone
		releasably couplable to the needle assembly. *See e.g.*, Mehta, at 4:63-5:2; 5:3-15; 6:64-65; 9:34-55; 10:33-39; 13:54-57; Fig. 3A; 13:58-4; 15:27-33; 15:55-16:11; Fig. 4A; 16:42-58; 16:59-17:12; 18:21-37; Fig. 5; 35:8-22; Fig. 12A; Fig. 12B. As shown in the discussion of claim 2, Mehta discloses an actuator that can be a motor. The motor **250** is part of the proximal end of the user holdable device **210 and** is "coupled to the [needle] array at a distal end of a [drive] shaft **252**. Mehta, at 13:58-14:4, *see also id*., at 13:54-57, 18:21-37, 35:8-22, Figs. 3A, 5, 12A, 12B. The "drive shaft" of the motor, releasably couplable to the needle assembly is also described in *id.*18:21-32: "FIG. 5 illustrates a cross sectional view of a distal end of a variation of treatment unit 202 without a cartridge attached to a cartridge receiving surface 254 of the device body 210. As shown, the device body 210 includes a moveable actuator 250 adjacent to the cartridge receiving Surface 254. In this variation, a **shaft 256 of the actuator** 250 couples to a cartridge or probe assembly on a cartridge. The actuator 250 moves the shaft 256 where an engagement portion 252 on the shaft couples to the probe assembly (*e.g.*, via a coupling portion 118 shown above) to advance and retract the probes (not shown)." As shown in the discussion of limitation 1.1, Mehta's needle assembly (needle cartridge) is releasably couplable to the user holdable device. Thus, Mehta's drive shaft, which is located in the user holdable device, is releasably couplable to the needle assembly.

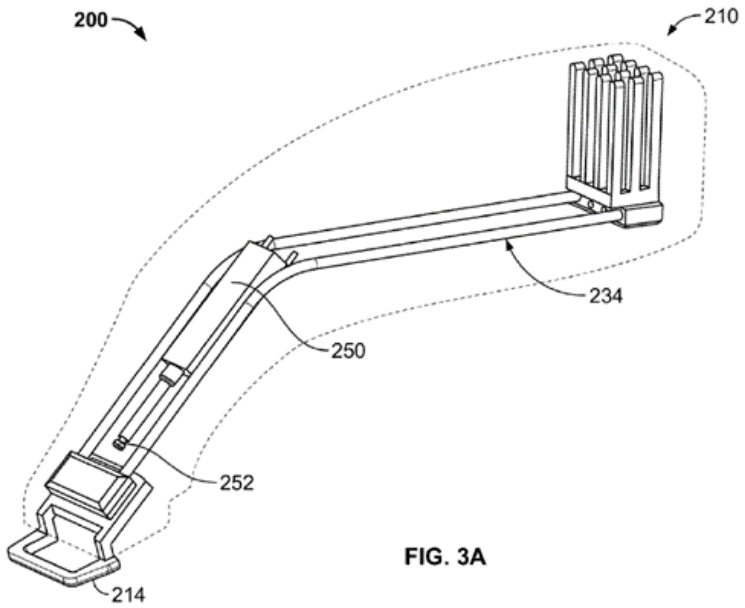
565. In view of the foregoing chart, claim 16 of the '812 Patent is anticipated by the teachings of Mehta. Further, to the extent Complainant argues that any of the foregoing limitations are not explicitly or inherently disclosed by Mehta, such limitations would have been obvious given the knowledge of a POSITA. The teachings of Mehta are so similar to what is

claimed that any alleged difference between the teachings of Mehta and what is claimed would not have been of patentable significance given the knowledge of a POSITA.

22. Claim 16 of the '812 Patent is rendered Obvious by Na '848 in view of Mehta.

566. It is my opinion that claim 16 of the '812 Patent is rendered obvious by Na '848 in view of Mehta as detailed below:

'812 Patent Claim 16		Na '848 in view of Mehta
16	16. The apparatus of claim 13, wherein the user holdable device proximal end includes the motor, the motor including a drive shaft releasably couplable to the needle assembly.	***Claim 16 of the '812 Patent is rendered obvious by Na '848 in view of Mehta.*** Na '848 in view of Mehta renders obvious the apparatus for treating dermatological tissue of claim 13. *See* Claim 13, above. Mehta discloses that the user holdable device proximal end includes the motor, the motor including a drive shaft releasably couplable to the needle assembly. *See e.g.*, Mehta, at 4:63-5:2; 5:3-15; 6:64-65; 9:34-55; 10:33-39; 13:54-57; Fig. 3A; 13:58-4; 15:27-33; 15:55-16:11; Fig. 4A; 16:42-58; 16:59-17:12; 18:21-37; Fig. 5; 35:8-22; Fig. 12A; Fig. 12B. The "drive shaft" of the motor, releasably couplable to the needle assembly is also described in *id.*18:21-32: "FIG. 5 illustrates a cross sectional view of a distal end of a variation of treatment unit 202 without a cartridge attached to a cartridge receiving surface 254 of the device body 210. As shown, the device body 210 includes a moveable actuator 250 adjacent to the cartridge receiving Surface 254. In this variation, a **shaft 256 of the actuator** 250 couples to a cartridge or probe assembly on a cartridge. The actuator 250 moves the shaft 256 where an engagement portion 252 on the shaft couples to the probe assembly (e.g., via a coupling portion 118 shown above) to advance and retract the probes (not shown)." As shown in the discussion of claim 2, Mehta discloses an actuator that can be a motor. The motor **250** is part of the proximal end of the user holdable device **210 and** is "coupled to the [needle] array at a distal end

‘812 Patent Claim 16		Na ‘848 in view of Mehta
		of a [drive] shaft **252**. Mehta, at 13:58-14:4, *see also id*., at 13:54-57, 18:21-37, 35:8-22, Figs. 3A, 5, 12A, 12B.  FIG. 3A As shown in the discussion of limitation 1.1, Mehta’s needle assembly (needle cartridge) is releasably couplable to the user holdable device. Thus, Mehta’s drive shaft, which is located in the user holdable device, is releasably couplable to the needle assembly.

567. In view of the foregoing chart, claim 16 of the ‘812 Patent is rendered obvious by Na ‘848 in view of Mehta. Further, to the extent Complainant argues that any of the foregoing limitations is not explicitly or inherently disclosed by Na ‘848 in view of Mehta, such limitations would have been obvious given the knowledge of a POSITA. The teachings of Mehta and Na ‘848 are so similar to what is claimed that any alleged difference between the teachings of Na ‘848 in view of Mehta and what is claimed would not have been of Patentable significance given the knowledge of a POSITA.

23. Claim 17 of the '812 Patent is Anticipated by and/or rendered Obvious by Mehta

568. Claim 17 depends from claim 12. In my opinion, claim 17 of the '812 Patent is anticipated by Mehta and/or rendered obvious by Mehta alone and/or Mehta in view of Na '848 as detailed below:

'812 Patent Claim 17		Mehta alone
17	17. The apparatus of claim 12, wherein the user holdable device proximal end further includes at least one embedded LED therein and the apparatus further including a photonic signal generator electrically coupled to the least one embedded LED, the at least one embedded LED capable of illuminating the needle assembly when energized.	***Mehta anticipates claim 17 of the '812 Patent and/or Mehta alone renders claim 17 of the '812 Patent obvious.*** *See* Claim 12, above. As shown in the discussion of claim 4, Mehta discloses that the user holdable device proximal end further includes at least one embedded LED therein and the apparatus further including a photonic signal generator electrically coupled to the least one embedded LED, the at least one embedded LED capable of illuminating the needle assembly when energized. Mehta explains that "the energy supply unit 90 may be a RF energy unit" and that "[a]dditional variations of energy supply units may include power supplies to provide … microwave energy, laser energy, pulsed light energy, and infrared energy." Mehta at 11:14-18. Mehta further discloses that "in addition to the use of RF energy, other therapeutic methods and devices can be used in combination with RF energy to provide additional or more efficacious treatments. For example, as shown in FIG. 2A, additional energy sources **90** can be delivered via the same or additional energy transfer elements located at the working end of a treatment unit **202**. Alternatively, the radiant energy may be supplied by the energy source/supply **90** that is coupled to **a diode**, fiber, or other **emitter** at the distal end of the treatment unit **202**." *Id*. at 11:21-30 (emphasis added). Mehta continues to disclose that "sources of light at the distal end of the treatment unit **202**. These transfer elements may be present on the cartridge **100**, on the device body **210**." *Id*. at 11:36-39; *see also id*. at 25:4-15 (disclosing that in some embodiments "the probe can employ light"). *See also*, Na '848 at [0034], [0036]-[0038].

569. In view of the foregoing chart, claim 17 of the '812 Patent is anticipated by the teachings of Mehta. Further, to the extent Complainant argues that any of the foregoing limitations are not explicitly or inherently disclosed by Mehta, such limitations would have been obvious given the knowledge of a POSITA, and/or further in view of the teachings of Na '848. The teachings of Mehta are so similar to what is claimed that any alleged difference between the teachings of Mehta and what is claimed would not have been of patentable significance given the knowledge of a POSITA.

24. Claim 17 of the '812 Patent is rendered Obvious by Na '848 in view of Mehta

570. In my opinion, claim 17 of the '812 Patent is rendered obvious by Na '848 in view of Mehta as outlined below.

'812 Patent Claim 17		**Na '848 in combination with Mehta**
17	17. The apparatus of claim 12, wherein the user holdable device proximal end further includes at least one embedded LED therein and the apparatus further including a photonic signal generator electrically coupled to the least one embedded LED, the at least one embedded LED capable of illuminating the needle assembly when energized.	***Claim 17 of the '812 Patent is rendered obvious by Na '848 in view of Mehta.*** Na '848 in view of Mehta renders obvious an apparatus for treating dermatological tissue of claim 12. *See* Claim 12, above. Na '848 discloses the user holdable device proximal end further including at least one embedded LED therein and the apparatus further including a photonic signal generator electrically coupled to the least one embedded LED, the at least one embedded LED capable of illuminating the needle assembly when energized. *See, e.g.*, Na '848 at [0034], [0036]-[0038].

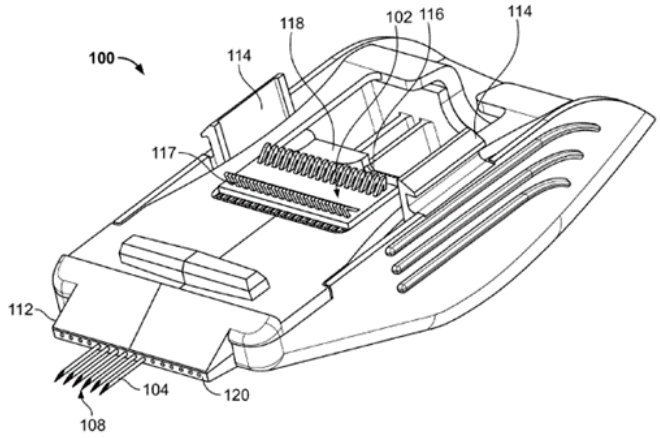
571. In view of the foregoing chart, claim 17 of the '812 Patent is rendered obvious by Na '848 in view of Mehta. Further, to the extent Complainant argues that any of the

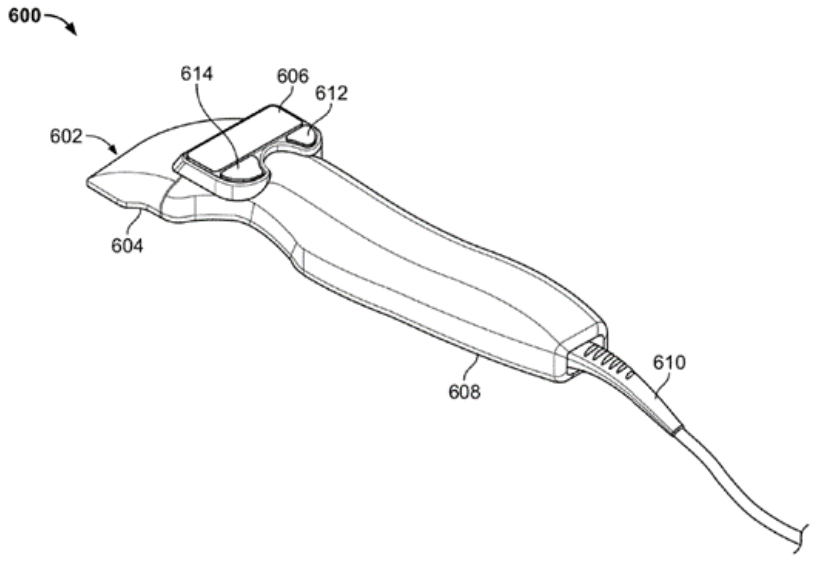
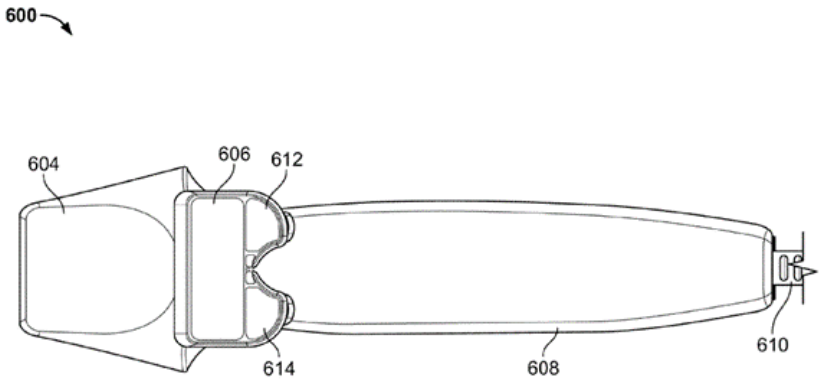
foregoing limitations is not explicitly or inherently disclosed by Na '848 in view of Mehta, such limitations would have been obvious given the knowledge of a POSITA. The teachings of Mehta and Na '848 are so similar to what is claimed that any alleged difference between the teachings of Na '848 in view of Mehta and what is claimed would not have been of Patentable significance given the knowledge of a POSITA.

25. Claim 18 of the '812 Patent is Anticipated by Mehta and/ or Obvious over Mehta or Mehta in view of ScarLet and/or DeÁge

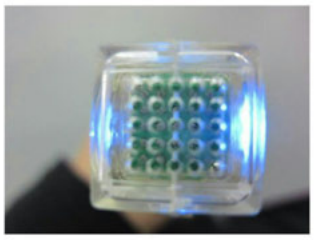
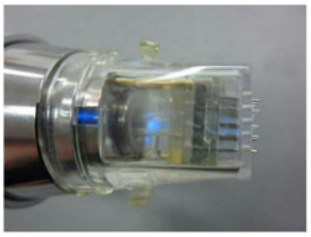
572. Claim 18 of the '812 Patent depends from claim 12. It is my opinion that claim 18 is anticipated by Mehta and/or rendered obvious by Mehta alone and/or Mehta in view of ScarLet and/or DeÁge as detailed below.

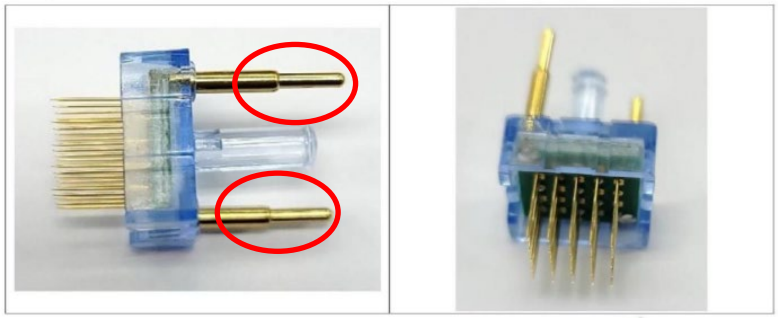
'812 Patent Claim 18		**Mehta alone or in combination with one or more of ScarLet, Na '848, and/or Kang '395**
18	18. The apparatus of claim 12, wherein one of the at least one electrical contacts includes a pin that is extendable in the same direction as the plurality of needles.	Mehta anticipates claim 18 of the '812 Patent and/or Mehta alone and/ or Mehta in view of ScarLet and/or DeÁge render claim 18 obvious. *See* Claim 12, above. Mehta discloses that one of the at least one electrical contacts includes a pin that is extendable in the same direction as the plurality of needles. *See* Mehta, at 15:55-16:11; 16:12-18; 16:42-58; 16:59-17:12. As discussed above in regard to limitation 1.4, Mehta discloses to extend the plurality of needles from the releasably couplable deployable needle assembly end surface while at least one electrical contact of the needle assembly remains electrically coupled to at least one electrical contact of the user holdable device proximal end. The needle assembly is movable, such that the needles can be extended while at least one electrical contact of the needle assembly remains electrically coupled to at least one electrical contact of the user holdable device proximal end. For example, as shown in Fig. 4A, reproduced below, "the electrodes **104** in the electrode assembly **102** as having connection or contact portions **116** that couple to a connection board on a treatment

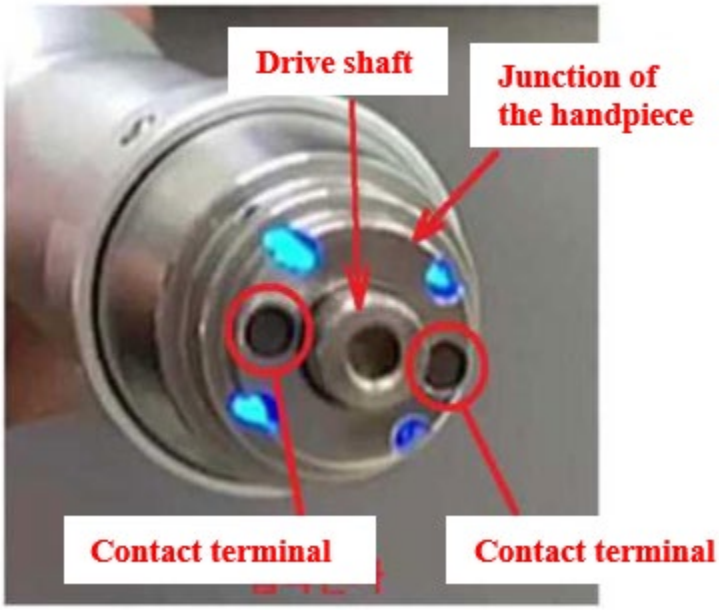
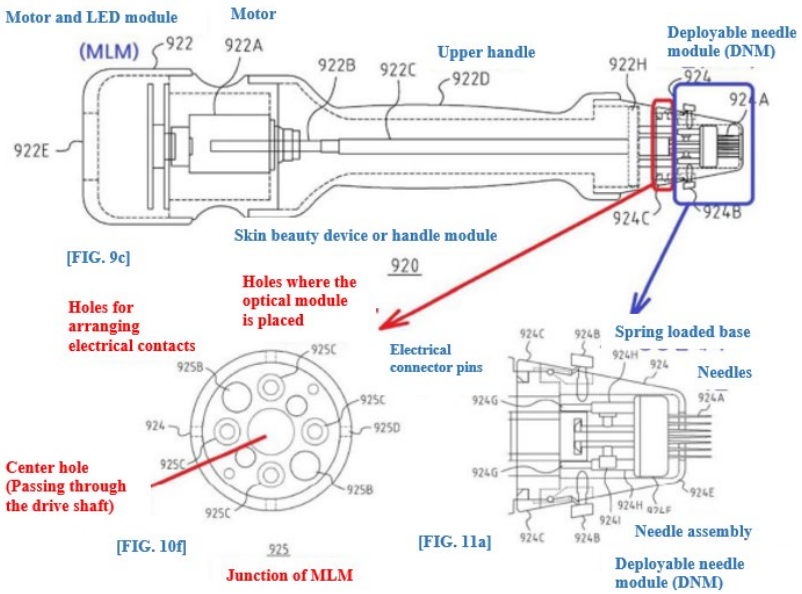
'812 Patent Claim 18		Mehta alone or in combination with one or more of ScarLet, Na '848, and/or Kang '395
		unit to provide an electrical pathway from the power supply to the electrodes **104**," and "the electrode assembly **102** as well as the connection portions **116** moves" so that the electrodes remain electrically connected to the "power supply" when extended. *Id*., at 15:55-16:11; *see also id*., at 16:12-18 (for example, by using "spring contacts or spring pins" for the electrical "connection portions **116**" so that "the connection portions **116** can maintain contact with a corresponding contact point trace on a connection board during movement of the electrode assembly **102**"), 35:8-22 ("electrical lead **610** on the proximal end"); *see also id*., at 10:53-65, 12:5-14,25:30-55, Fig. 2A.  FIG. 4A *Id*., Fig. 4A. "The connection portions 116 can be fabricated in any number of configurations as well. For example, as shown, the connection portions 116 comprise **spring contacts or spring pins** of the type shown. Accordingly, the connection portions 116 can maintain contact with a corresponding contact point trace on a connection board during movement of the electrode assembly." *Id.*16:12-19. The extendable contact (102), that can also be an extendable pin per Mehta's Patent specification, (pins (102)) in FIG. 4A shown above, deflect in the same plane as the needles (108). The specification of the patent mentions spring pins, that are extendable pins, and from Fig. 4, it would be obvious for a POSITA to install them in an axis parallel to the extendable needles.

'812 Patent Claim 18		Mehta alone or in combination with one or more of ScarLet, Na '848, and/or Kang '395
		 FIG. 12A *Id*., Fig. 12A.  FIG. 12B *Id*., Fig. 12B. Therefore, Mehta would have had extendable and depressible electrical contacts to connect the needles to the energy supply unit so that the energy can be transmitted to the needles when extended. This includes an extendable and depressible pin. ScarLet discloses and/or renders obvious one of the at least one electrical contacts includes a pin that is extendable in the same direction as the plurality of needles. *See, e.g.*,

'812 Patent Claim 18		Mehta alone or in combination with one or more of ScarLet, Na '848, and/or Kang '395
		 Ilooda-0006770 (#18_D&PS Monthly Sept 2010_Translated_Certified at 4).

'812 Patent Claim 18		Mehta alone or in combination with one or more of ScarLet, Na '848, and/or Kang '395
		 Figure 4-12. Microneedle Tip skin contact surface.  Figure 4-13. After attaching the Microneedle Tip to the handpiece. Attaching the Microneedle tip to the handpiece is only possible in CARTRIDGE SETTING MODE. Press the jog dial under the bottom LCD of the Scarlet system to enter CARTRIDGE SETTING MODE and the handpiece will illuminate with a blue LED light. Ilooda-0011405 at -442 (certified English translation of SERENDIA-00073257 at -279). 80).

'812 Patent Claim 18		Mehta alone or in combination with one or more of ScarLet, Na '848, and/or Kang '395
		2) Close-up of needles  3) Combination of electrode and handpiece  Ilooda-0010117 at -124 (certified English translation of SERENDIA-00033637 at -643). Ilooda-0008178 at -227. (the added red ovals show the two pins that are extendable in the same direction as the plurality of needle)

'812 Patent Claim 18		Mehta alone or in combination with one or more of ScarLet, Na '848, and/or Kang '395
		 Ilooda-0008178 at -230.  Ilooda-0008178 at -189. [redacted]

'812 Patent Claim 18	Mehta alone or in combination with one or more of ScarLet, Na '848, and/or Kang '395
	[redacted] [redacted] [redacted] To the extent it alleged that any of Mehta does not disclose that at least one electrical contacts includes a pin that is extendable in the same direction as the plurality of needles, recited in claim 18, either expressly or inherently, it would have been obvious to a POSITA as of the priority date of the '812 Patent to modify Mehta and/or combine the teaching of Mehta and ScarLet with the knowledge of a POSITA, or combine the teachings of Mehta with one of DeÁge and ScarLet in a manner that would have rendered the asserted claims invalid as obvious. [redacted]

'812 Patent Claim 18		Mehta alone or in combination with one or more of ScarLet, Na '848, and/or Kang '395
		[redacted] [redacted] A POSITA would have known that it is advantageous to use a pin to electrically connect the power source in a handpiece to a connectable needle cartridge with extendable needle electrodes. For example, it was known that using different needle array configurations for different treatment applications was useful, and, thus, it was desirable to "allow[] a physician to selectively change array configuration by attaching different [needle] cartridges." *See e.g.,* Mehta, at 9:65-10:5. It was also known that reusing needles can result in medical consequences for the patient, and thus disposable needle cartridges were also desirable to reduce medical consequences and reduce costs A pin contact would allow for the needle cartridges to be interchanged and electrically connected to the handpiece's energy source quickly and simply. Moreover, such extendable needles typically extend away from the handpiece, which is the same direction that the pin contact would need to extend to connect the needle cartridge and the needle assembly. *See, e.g.*, Livneh at [0047] ("A pin 66 extends from the flat section 64 opposite the electrodes 32 to allow electrical connection to the comb 62."). Configuring the at least one electrical contacts of a RF microneedling handpiece to include a pin that is extendable in the same direction as the plurality of needles would have been a

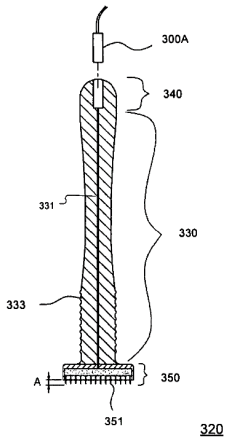
'812 Patent Claim 18		Mehta alone or in combination with one or more of ScarLet, Na '848, and/or Kang '395
		matter of routine engineering as of the priority date of the '812 Patent, as evidenced by the numerous dermatological treatment devices which included pins for this purpose.

573. In view of the foregoing chart, claim 18 of the '812 Patent is anticipated by the teachings of Mehta. Further, to the extent Complainant argues that any of the foregoing limitations are not explicitly or inherently disclosed by Mehta, such limitations would have been obvious given the knowledge of a POSITA, and/or further in view of the teachings of ScarLet and/or DeÁge. The teachings of Mehta are so similar to what is claimed that any alleged difference between the teachings of Mehta and what is claimed would not have been of patentable significance given the knowledge of a POSITA.

26. Claim 18 of the '812 Patent is rendered Obvious by Na '848 in view of Mehta

574. It is my opinion the claim 18 of the '812 Patent is obvious over Na '848 in view of Mehta as detailed below.

'812 Patent Claim 18		Na '848 in combination with Mehta
18.0	18. The apparatus of claim 12, wherein one of the at least one electrical contacts includes a pin that is extendable in the same direction as the plurality of needles.	***Na '848 in view of Mehta renders claim 18 of the '812 Patent obvious.*** Na '848 in view of Mehta renders obvious the apparatus for treating dermatological tissue of claim 12. *See* Claim 12, above.

'812 Patent Claim 18		Na '848 in combination with Mehta
		 FIGURE 2B In Figure 2B, Na shows an electrical connection between 300A and 340 that is in the same axis as the needles (351). Mehta discloses that one of the at least one electrical contacts includes a pin that is extendable in the same direction as the plurality of needles. *See* Mehta, at 15:55-16:11; 16:12-18; 16:42-58; 16:59-17:12. As discussed above in regard to limitation 1.4, Mehta discloses to extend the plurality of needles from the releasably couplable deployable needle assembly end surface while at least one electrical contact of the needle assembly remains electrically coupled to at least one electrical contact of the user holdable device proximal end. The needle assembly is movable, such that the needles can be extended while at least one electrical contact of the needle assembly remains electrically coupled to at least one electrical contact of the user holdable device proximal end. For example, as shown in Fig. 4A, reproduced below, "the electrodes **104** in the electrode assembly **102** as having connection or contact portions **116** that couple to a connection board on a treatment unit to provide an electrical pathway from the power supply to the electrodes **104**," and "the electrode assembly **102** as well as the connection portions **116** moves" so that the electrodes remain electrically connected to the "power supply" when extended. *Id*., at 15:55-16:11; *see also id*., at 16:12-18 (for example, by using "spring contacts or spring pins" for the electrical "connection

'812 Patent Claim 18		Na '848 in combination with Mehta
		portions **116**" so that "the connection portions **116** can maintain contact with a corresponding contact point trace on a connection board during movement of the electrode assembly **102**"), 35:8-22 ("electrical lead **610** on the proximal end"); *see also id*., at 10:53-65, 12:5-14,25:30-55, Fig. 2A.

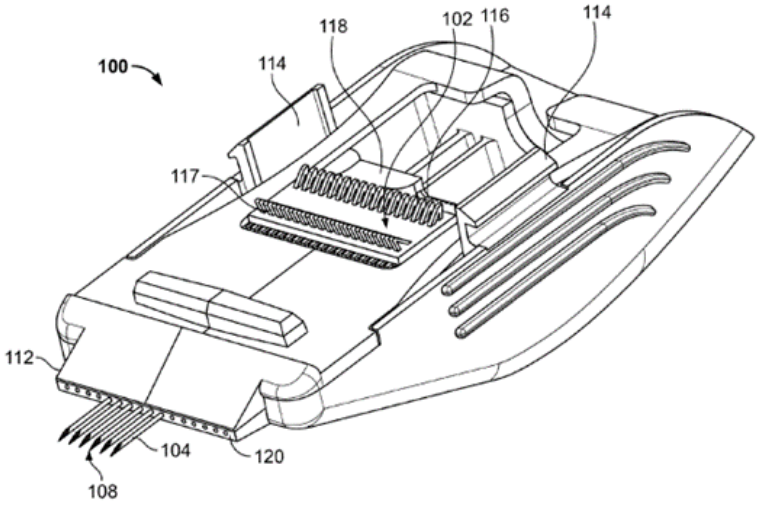
575. In view of the foregoing chart, claim 18 of the '812 Patent is rendered obvious by Na '848 in view of Mehta. Further, to the extent Complainant argues that any of the foregoing limitations is not explicitly or inherently disclosed by Na '848 in view of Mehta, such limitations would have been obvious given the knowledge of a POSITA. The teachings of Mehta and Na '848 are so similar to what is claimed that any alleged difference between the teachings of Na '848 in view of Mehta and what is claimed would not have been of patentable significance given the knowledge of a POSITA.

27. Claim 19 of the '812 Patent is Anticipated by Mehta and/or rendered obvious by Mehta

576. Claim 19 depends from claim 12. It is my opinion that claim 19 of the '812 Patent is anticipated by Mehta as detailed below.

'812 Patent Claim 19		Mehta alone
19	19. The apparatus of claim 12, wherein one of the user holdable device proximal end and the needle assembly includes at least two extendable electrical contacts and the other includes at least two electrical contacts couplable to the at least two extendable electrical contacts.	***Mehta anticipates claim 19 of the '812 Patent and/or Mehta alone renders claim 1 of the '812 Patent obvious.*** *See* Claim 12, above. Mehta discloses that one of the user holdable device proximal end and the needle assembly includes at least two extendable electrical contacts and the other includes at least two electrical contacts couplable to the at least two extendable electrical contacts. *See e.g.*, Mehta, at 2:58-62; 2:63-17; 3:29-39; 3:40-41; 3:57-67; 4:1-18; 4:63-5:2; 5:3-15; 5:16-25; 5:26-33; 5:49-57; 6:64-65; 7:16-18; 8:13-23; 9:34-55; 10:17-25; 10:33-39; 10:53-65; Fig. 2A; 11:14-20; 11:21-52; 12:5-14; 12:31-46; 13:54-57; Fig. 3A; 13:58-4; 15:27-33; 15:55-16:11; 16:12-18;

'812 Patent Claim 19		Mehta alone
		Fig. 4A; 16:42-58; 16:59-17:12; Fig. 4C; 36:21-40; 17:59-18:3; 18:4-20; 18:21-37; Fig. 5; 18:64-19:8; 19:66-20:12; 20:13-29; 20:29-47; Fig. 6; 23:55-24:4; Fig. 7E; 24:46-60; 25:30-55; 26:41-59; 26:60-27:22; 32:46-62; Fig. 10B; 32:63-33:14; 33:15-29; 33:30-34; 33:57-13; Fig. 10E; 34:38-45; 35:8-22; Fig. 12A; Fig. 12B; 36:21-40; 37:25-34; Fig. 13A; 40:39-44; 40:45-57; 41:40-43; 41:55-58; 41:55-58. As shown in the discussion of claim 10 above, Mehta discloses that each electrode needle pair has its own electrical contact that couples that pair to the generator to allow for independent control of the energy supplied to each pair. As shown in the discussion of limitations 1.1 and 1.4, Mehta's needle assembly is movable, such that the needles can be extended while the electrical contacts of the needle assembly remain electrically coupled to the electrical contacts of the user holdable device proximal end. For example, as shown in Fig. 4A, reproduced below, "the electrodes **104** in the electrode assembly **102** as having connection or contact portions **116** that couple to a connection board on a treatment unit to provide an electrical pathway from the power supply to the electrodes **104**," and "the electrode assembly **102** as well as the connection portions **116** moves" so that the electrodes remain electrically connected to the "power supply" when extended. *Id*., at 15:55-16:11. "The connection portions 116 can be fabricated in any number of configurations as well. For example, as shown, the connection portions 116 comprise **spring contacts or spring pins** of the type shown. Accordingly, the connection portions 116 can maintain contact with a corresponding contact point trace on a connection board during movement of the electrode assembly." *Id.*16:12-19.In other words the contacts are extendable, such as "spring contacts or spring pins" for the electrical "connection portions **116**" that allow "the connection portions **116** [to] maintain contact with a corresponding contact point trace on a connection board during movement of the electrode assembly **102**." *Id*., at 16:12-18. Fig. 4A shows that there are multiple (more than 2) extendable contacts (117).

‘812 Patent Claim 19		Mehta alone
		 FIG. 4A *Id*., Fig. 4A. Therefore, Mehta anticipates claim 19.

577. In view of the foregoing chart, claim 19 of the ‘812 Patent is anticipated by the teachings of Mehta. Further, to the extent Complainant argues that any of the foregoing limitations are not explicitly or inherently disclosed by Mehta, such limitations would have been obvious given the knowledge of a POSITA. The teachings of Mehta are so similar to what is claimed that any alleged difference between the teachings of Mehta and what is claimed would not have been of patentable significance given the knowledge of a POSITA.

28. Claim 19 of the ‘812 Patent is rendered Obvious by Na ‘848 in view of Mehta

578. It is my opinion that claim 19 of the ‘812 Patent is obvious over Na ‘848 in view of Mehta as detailed below:

‘812 Patent Claim 19		Na ‘848 in combination with Mehta
19	19. The apparatus of claim 12, wherein one of the user holdable	***Na ‘848 in view of Mehta renders claim 19 of the ‘812 Patent obvious.***

'812 Patent Claim 19		Na '848 in combination with Mehta
	device proximal end and the needle assembly includes at least two extendable electrical contacts and the other includes at least two electrical contacts couplable to the at least two extendable electrical contacts.	Na '848 in view of Mehta render obvious the apparatus for treating dermatological tissue of claim 12. *See* Claim 12, above. Mehta discloses that one of the at least one electrical contacts includes a pin that is extendable in the same direction as the plurality of needles. *See* Mehta, at 15:55-16:11; 16:12-18; 16:42-58; 16:59-17:12. As discussed above in regard to limitation 1.4, Mehta discloses to extend the plurality of needles from the releasably couplable deployable needle assembly end surface while at least one electrical contact of the needle assembly remains electrically coupled to at least one electrical contact of the user holdable device proximal end. The needle assembly is movable, such that the needles can be extended while at least one electrical contact of the needle assembly remains electrically coupled to at least one electrical contact of the user holdable device proximal end. For example, as shown in Fig. 4A, reproduced below, "the electrodes **104** in the electrode assembly **102** as having connection or contact portions **116** that couple to a connection board on a treatment unit to provide an electrical pathway from the power supply to the electrodes **104**," and "the electrode assembly **102** as well as the connection portions **116** moves" so that the electrodes remain electrically connected to the "power supply" when extended. *Id*., at 15:55-16:11; *see also id*., at 16:12-18 (for example, by using "spring contacts or spring pins" for the electrical "connection portions **116**" so that "the connection portions **116** can maintain contact with a corresponding contact point trace on a connection board during movement of the electrode assembly **102**"), 35:8-22 ("electrical lead **610** on the proximal end"); *see also id*., at 10:53-65, 12:5-14,25:30-55, Fig. 2A.

579. In view of the foregoing chart, claim 19 of the '812 Patent is rendered obvious by Na '848 in view of Mehta. Further, to the extent Complainant argues that any of the foregoing limitations is not explicitly or inherently disclosed by Na '848 in view of Mehta, such limitations would have been obvious given the knowledge of a POSITA. The teachings of

Mehta and Na '848 are so similar to what is claimed that any alleged difference between the teachings of Na '848 in view of Mehta and what is claimed would not have been of patentable significance given the knowledge of a POSITA.

XIV. INVALIDITY UNDER 35 U.S.C. § 112

580. As will be explained in detail below, it is my opinion that the asserted claims in the Asserted Patents are invalid under 35 U.S.C. § 112 for indefiniteness, lack of enablement, and/or lack of written description.

581. My opinion is summarized in the Tables below. Where a certain claim term or limitation in one claim is identified as indefinite, it is my position that the same claim term or limitation is indefinite in every instance the term or limitation is recited throughout the Asserted Claims. Where I have identified a phrase as indefinite, I also contend that the subparts of the phrase are indefinite within the context recited in the Asserted Claim. The same rationale applies to claims that I believe lack enablement and/or written description.

A. The Asserted Claims of the '836, '379, and '444 Patents lack written description

582. It is my opinion that the Asserted Claims of the '836, '379, and '444 Patents, all of which require obtaining the so-called "Na Effect" or other similar result, lack sufficient written description and are therefore invalid under pre-AIA 35 U.S.C. § 112, ¶ 1 or AIA 35 U.S.C. § 112

583. It is my opinion, the following claim elements lack sufficient written description and are therefore invalid under pre-AIA 35 U.S.C. § 112, ¶ 1 or AIA 35 U.S.C. § 112:

Asserted Patent(s)	Asserted Claim(s)	Term(s) and/or Phrase(s) Lacking Written Description
'836 Patent	1, 14	"coagulation around each electrode rather than coagulating between the electrodes"
'836 Patent	1	"a radio frequency (RF) generation module … configured to provide an Alternating Current (AC) RF signal to the plurality of electrodes to cause coagulation around each electrode rather than coagulating between the electrodes"
'379 Patent	1	"apply energy to body segments around each electrode rather than body segments between the electrodes"
'379 Patent	1	"a radio frequency (RF) generation module … configured to provide an RF signal with oscillating current to the plurality of electrodes to apply energy to body segments around each electrode rather than to body segments between the electrodes."
'444 Patent	1	"cause(s) energy to be substantially applied to body segments around each electrode"
'444 Patent	1	"a radio frequency (RF) generation module, the RF generation module electrically coupled to the plurality of electrodes and configured to provide an RF signal with oscillating current to the plurality of electrodes to cause energy to be substantially applied to body segments around each electrode."

1. "coagulation around each electrode rather than coagulating between the electrodes" ('836 Patent Claims 1 and 14)

584. It is my opinion that claims 1 and 14 of the '836 Patent are invalid because there is no written description support for "coagulation around each electrode rather than coagulating

between the electrodes." The specification uses the term "coagulation" just four times, and none of the references refer to, describe, or explain how to effect coagulation "around each electrode rather than coagulating between the electrodes." *See* '836 Patent at 2:62-65 (referring to three phenomena, carbonization, vaporization, and coagulation); 3:3-4 (referring to raising temperature by applying energy to achieve coagulation). Nor does the specification adequately describe the meaning of the phrases "around each electrode" and "between the electrodes" in the context of the claimed invention.

585. First, the claims of the '836 Patent lack written description support because there is no description of how a POSITA measures or determines whether there is coagulation "around each electrode rather than between the electrodes." In fact, the specification for the'836 Patent does not show a single example of "coagulation around" but not "between the electrodes." For example, Figures 5 and 9B show shading [909 and 949] around the tips of electrodes. But that shading is not identified as coagulation around the electrodes. Rather, that shading is disclosed as the "desired energy field" around the electrodes. *See, e.g.*, 836 Pat at 9:58-61. But the applied energy is what causes coagulation, and is not the coagulation itself. Dr. Na admitted that "coagulation, that occurs as a result of the heat applied." Na Dep. Tr. at 476:5-7. He then admitted that the area where coagulation occurs may be different than the area where energy is applied. Na Dep. Tr. at 485:4-11. As a result, the '836 Patent does not disclose or describe any embodiment where coagulation "around each electrode rather than between the electrodes." Even if it did, the '836 Patent does not describe any method, process or analysis for determining whether there is coagulation "around each electrode rather than between the electrodes."

586. Second, the specification still does not disclose or explain how to achieve or effect coagulation "around each electrode rather than coagulating between the electrodes." The specification states that numerous parameters will impact whether the desired field will be achieved. For example, the '836 Patent states that:

- "several parameters … control the energy field 909 generated about needles 300 … including the voltage, current, and the 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." '836 Pat. at 5:36-41.
- "The RF generator 14 may generate signal or signal(s) having a desired voltage, current, energy, resistance, RF frequency, on cycle, off cycle, and other parameters according to various embodiments." '836 Pat. at 5:53-57.
- In various embodiments, achieving a desired therapy may be related to the distance between deployed needles." '836 Pat. at 6:56-57.
- "[E]mbodiments may employ an AC signal having a frequency from 0.5 to 10 MHz…" '836 Pat. at 6:24-25.
- "In an embodiment, a needle 300 cross-section may be configured in a square shape 100…. The shape of a rhombus, rectangle, circle, oval, or quadrangle." '836 Pat. at 7:42-45.
- "A variety of needle 300 polarity combinations , placements, and needle shapes 100 may be used in designing a device that generates a desired energy field about a needle 300 including the configurations shown in FIG. 6 and FIG. 10." '836 Pat. at 7:63-67.
- "In order to generate a desired energy field 909 (FIG 5), 949 (FIG. 9) 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." '836 Pat. at 8:9-14.

- "It is noted that the applied voltage may be directedly related to the amount of energy created at a needle. In an embodiment, the voltage applied to a needle or electrode may not exceed 100V with a recommend operation range between 10 to 60V." '836 Pat. at 8:29-34.
- "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 cycles." '836 Pat. at 8:54-56.
- "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 employe needles having a desired distance and shape including the shapes shown in FIG. 11." '836 Pat. at 9:58-61.Additional parameters that will impact the energy field include needle resistance and skin resistance. '836 Pat. at 10:23-40.

587. While the '836 Patent does disclose some broad ranges for some of these parameters, the guidance in the written description for selecting each of the required parameters to achieve coagulation "around each electrode rather than coagulating between the electrodes" is insufficient to show that Dr. Na had possession of the apparatus and methods as claimed in the '836 Patent at the time of filing. The number of options that could be employed using the range of parameters disclosed (where ranges even are disclosed) is endless. And it is impossible to know which of those combinations of parameters will achieve coagulation around the needles but not between them in a way that achieves the claimed goal of "skin treatment".

588. Making matters worse, there is not a single example setting forth the various values of all relevant parameters that achieved coagulation around but not between the needles. One simply cannot discern the full scope of the invention from the written description without further guidance, nor that the named inventor possessed the full scope of the invention based on this limited disclosure in the specification.

589. A POSITA knows that the local temperature is the result of the rate of energy dissipated, the time and timing of application and the rate of convection cooling. No relationship is shown in the patent specification between the esoteric "energy field," electrical parameters and tissue coagulation that occurs only in a specific temperature range. A POSITA also knows that the zone of coagulated tissue around the tip of the electrode will, over time, grow up to a limit and does not represent a "fixed energy field." Thus, the specification fails to provide written description support that demonstrates that the inventor possessed the full scope of the claimed invention.

2. "a radio frequency (RF) generation module … 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" ('836 Patent Claim 1)

590. It is also my opinion that claim 1 of the '836 Patent is invalid because there is no written description support for "a radio frequency (RF) generation module … 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." As discussed above, there is no written description support for the "coagulation around each electrode rather than coagulating between the electrodes," and thus, there is no written description support for "caus[ing]" this coagulation using an RF generation module configured to provide an Alternating Current (AC) RF signal to the electrodes configured to cause the

coagulation around each electrode. As recited in claim 1, the "plurality of electrodes" is the element that is "configured to . . . cause coagulation," *see* '836 Patent Claim 1. There is inadequate description of how that configuration of the plurality of electrodes is achieved and, importantly, the description that appears in the specification strongly indicates that Dr. Na did not have possession of that knowledge at the time of filing the application.

591. The common specification to the '836, '379, and '444 Patents explains that "to achieve a desired energy field about the needle(s)," one must tune multiple variables, such as "distance between needles," "energy level (current, voltage)," "needle's thickness," "system resistance, AC frequency rate, high frequency rate, timing" "needle length or needle depth," and a "proportional constant" somehow related to "Device resistance, needle resistance," and "skin resistance." '836 Patent, at 10:1-41; '379 Patent, at 10:1-43; '444 Patent, at 10:13-54. Notably, the common specification of the '836, '379 and '444 Patents purports to include formulae for determining "the distance between adjacent needles." '836 Patent at 10:19-40. These formulae are shown below:

$$\text{Distance} = \text{N} * \ (\text{Power} - \text{energy}) * (\text{Needle Thickness}) * (\text{Conductivity}) \div (\text{Resistance}) * (\text{AC Frequency}) * (\text{High Frequency}) * (\text{Penetrated Needle Depth})$$

Substituting V*I*t into this equation gives

$$\text{Distance} = \text{N} * \ \text{V} * I * t * (\text{Needle Thickness}) * (\text{Conductivity}) \div (\text{Resistance}) * (\text{AC Frequency}) * (\text{High Frequency}) * (\text{Penetrated Needle Depth})$$

592. These formulae attempt to model the growth of a lesion around each electrode in the x/y plane and calculate the distance between the two electrodes such that the lesions do not overlap. At first glance, it appears that the formulae are not a particularly good approximation, as they specify that the distance is proportional to the amount of energy. The fact that the

formulae are inaccurate confirm to me that Dr. Na did not have possession of the full claimed subject matter at the time he filed the applications that contained those formulae.

593. The formulae can be simplified, and for easier understanding let's ignore the convective cooling effect of blood flow in tissue that would slow down the growth of the coagulated lesion. It is well known that 4.184 Joules are equivalent to 1 calorie, and that 1 calorie is the amount of energy required to elevate the temperature of 1 gram of water by 1 degree (Celsius). Tissue has a different specific heat (amount of energy required to elevate the temperature of 1 gram of tissue by 1°C), but the principles of physics are the same. It therefore takes twice the amount of energy to elevate the temperature of twice the volume of tissue by the same level. During RF microneedling, a lesion is created when a given volume of tissue has its temperature elevated to a certain level for a certain time (depending on the actual tissue composition, it should be over 60-65°C for, by way of example,1 second). Thus, each volume of tissue needs to receive a certain number of calories (energy) to reach a temperature over 60°C to achieve tissue "coagulation". For simplicity, assume that the lesion is spherical, with a diameter "D"; the volume of that spherical lesion can be calculated by the equation $V = 1/6 \cdot \pi \cdot D^3$. Thus, if the volume is proportional to D^3, then the diameter of the sphere is growing with the cubic root of the amount of energy: $D = a + b. \sqrt[3]{E}$.

594. In other words, in the formulae given by Dr. Na, the distance should not be proportional to the amount of energy but to the cubic value E^3 ($\sqrt[3]{E}.$) of the energy dissipated. Even this is greatly simplified, as tissue impedance changes when it is heated (impedance goes down for small temperature elevation as warmer salt water [extracellular fluid] has a lower impedance, when desiccation starts to occur prior to coagulation, impedance goes up). When the tissue reaches a level of coagulation, it has a higher impedance, forcing the lesion to grow in

another direction, and therefore the growth of the lesion over its x and y direction is slowed down, because the lesion grows in the Z direction (along the needle: the difference of impedance value between the epidermis and coagulated dermis at the tip of the needle gets smaller). The lesion is not spherical anymore and takes an oblong shape; it will also stops growing after a certain amount of time.

595. In my opinion not only are these formulae incorrect, but they only describe well known and documented natural phenomena.

Looking again at these formulae:

$$\text{Distance} = \text{N} * \text{V} * I * t * (\text{Needle Thickness}) * (\text{Conductivity}) \div (\text{Resistance}) * (\text{AC Frequency}) * (\text{High Frequency}) * (\text{Penetrated Needle Depth})$$

If one defines the following variables: d: depth of needle

L : distance between needles

D : needle diameter

E : energy = V.I.t

σ : tissue conductivity

Then:

$$L = N.\frac{E.D.\sigma.}{R.F_{ac}.F_{rf}.d} \quad (1)$$

The POSITA would have recognized that the resistance (it should really be the impedance, as we are dealing with AC current, not DC) of the circuit includes two major components: the resistance of the needle combined with needle tissue interface impedance (R_n) and the tissue impedance R_t that in conductors the resistance is given by the equation (the internal impedance of the generator is not relevant and that of the cables is usually insignificant) .

$$R = R_n + R_t$$

the resistance of the needle and its interface is inversely proportional to the exposed area of the needle:

$$R_n = K_n/(L*D*\pi)$$

R_n is also a function of the frequency, the work function of the metal comprising the electrodes as well as its surface texture and therefore cannot be considered a constant value as assumed by Dr. Na. As this resistance is already a function of the exposed length of the needle and the needle diameter, it is unclear if this should be counted twice in Dr. Na's formula.

596. The impedance of the tissue between two needles can be approximated by

$$R_t = L/(\sigma \, . \, S),$$

Where L is the length of conductor (distance between 2 needles) and S the cross section of the tissue separating the 2 needles. We can approximate $S = D.L$

So:

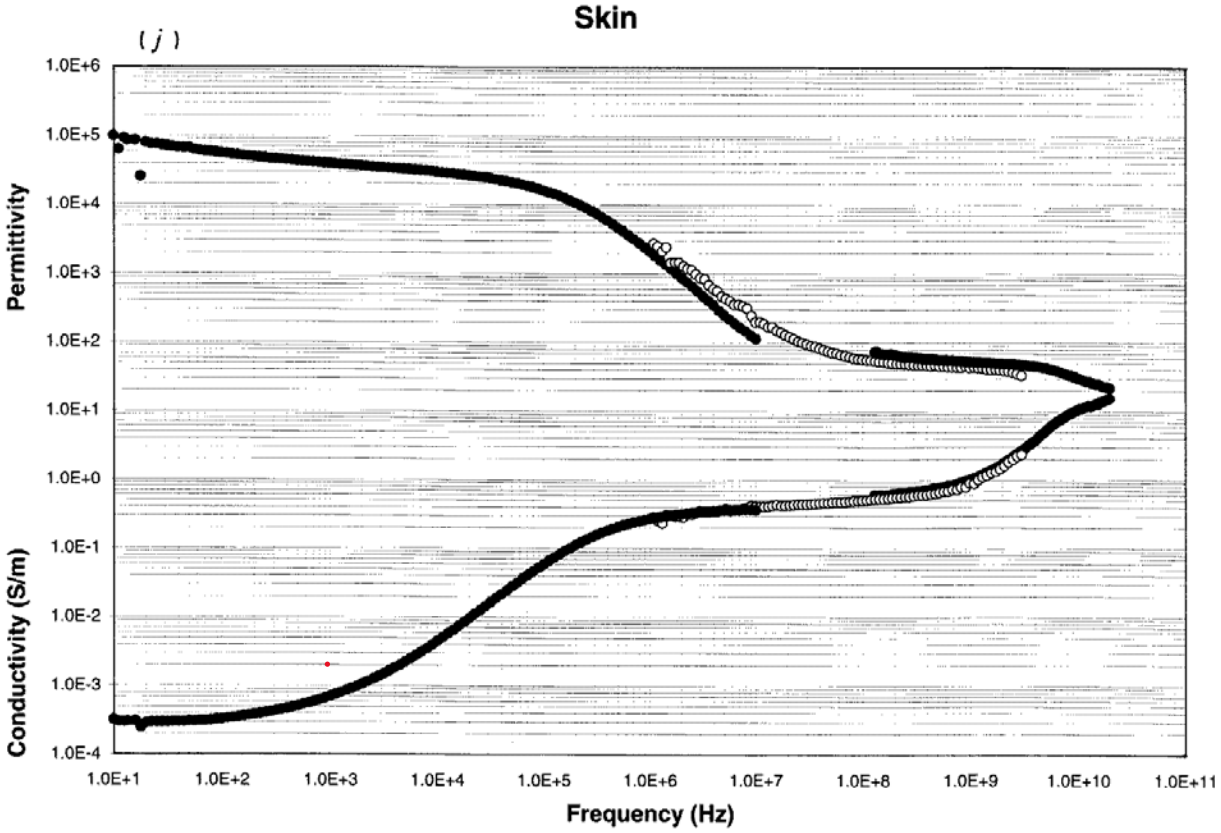
$$R = \frac{K_n}{L \, . D . \pi} + \frac{L}{\sigma . D . L} = \frac{K_n . \sigma + L \, . \pi}{\sigma . D . L . \pi}$$

Replacing R in equation (1) with equation (2) results in equation (3).

$$L = N . \pi . \frac{E . D^2 . \sigma^2}{(K_n . \sigma + L \, . \pi) . F_{ac} . F_{rf} . d} \quad (3)$$

597. In actuality, the conductivity of tissue σ is already a function of frequency; Gabriel showed in 1996 that conductivity for tissue varies with frequency. The figure below (from Gabriel, 1996) shows human skin impedance as a function of the frequency. Below 100Hz (AC as stated by Dr. Na is 50-60Hz) the conductivity is almost constant. However, given

the logarithmic scale of this graph, the resistivity increases almost linearly between 1kHz (1.0E+3) and 2 MHz (1 MHz = 2.0E+06)



598. It is unclear in the formula presented by Dr. Na if the conductivity is the value of DC current or if it is already corrected for a specific frequency. As the conductivity of tissue is also dependent on the tissue temperature, and therefore the amount of energy delivered over time, this equation becomes a very complex differential equation. Thus, the seemingly simple linear formula proposed by Dr. Na is not that linear, and while each of the parameters proposed by Dr. Na in his formula may have some level of correlation with the distance L, each of these parameters does not have a direct proportional relationship with the distance between the two needles.

599. At best, a POSITA could conclude that to prevent lesions from overlapping when: (1) the needle diameter, (2) the amount of energy delivered , or (3) the length of exposed needle increase, the distance between the needle electrodes should increase; and when (4) the RF frequency increases, the distance between needles can decrease. However, the relationship of each of these parameters with the distance between the needle is not linear as proposed by Na. Furthermore, the conductivity of tissue is not a variable that can be controlled, and its actual value may vary between patients as well. It is only relevant when doing experimental work on various types of tissue using living or dead animal tissue, often non dermatological tissue which is not relevant to this series of patents. It is known however that tissue conductivity varies with the signal frequency, and this is a main reason why the frequency has an impact on the needle distance. In conclusion, the formulae provided in the '836, '379, and '444 Patents do not provide any guidance in selecting values for the laundry list of parameters provided in the patent specification, and they are not of any help for a POSITA to put the invention into practice. Furthermore, if the formulae were a true model of a system disclosed in the '836, '379 and '444 Patents, multivariable statistical analysis of the experimental data (when properly conducted) would allow assignment of a value to the constant N and provide useful guidance to determine the minimum distance between needles to achieve the Na effect. However, none of this is disclosed, and it does not appear that any such analysis has been performed. It is my opinion that the formulae provided in the '836, '379, and '444 Patents are of no use in actually determining the distance between needles for obtaining the so-called "Na Effect," the "Na-Plus Effect" or any other similar desired result.

600. Dr. Na testified that the proportional constant N "doesn't have a meaning." Transcript of Dr. Jongju Na, Volume 3, at 426:20-427:11. Dr. Na could not answer whether the proportional

constant N had units (*Id*., at 429:1-8), and was not sure how to "calculate the value of N" (*Id*., at 438:8-439:12).

> Q And going back a second to N, the proportional constant.
> Does the proportional constant have units?
> A Sir, as I stated earlier, those equations represent correlations.
> Q What do you mean by that?
> A This is an equation that shows the correlations of the things shown there.
> *Id*., at 429:1-8.
>
> Q Where does the patent disclose the value of N?
> A It says N is a constant.
> Q What is that constant?
> A That means it's a number that is not variable.
> Q Right. So gravity, for example, is 9.81 meters a second squarred.
> What is the value of N?
> A Sir, I am not quite sure how you are suggesting that I calculate the value of N.
> Q You're telling me it's a constant and it has a constant value. What is that value?
> A Again, sir, N is a number that does not change, and this equation represents the correlations amongst those parameters.
> Q Is N equal to 1?
> A Sire?
> Q Is N equal to 1?
> A It says N is a constant.
> …..
> Q What is the value of N?
> A Sir – sire, it says here N is a constant, and this equation shows the correlation.
>
> *Id*., at 438:8-439:12.

601. The formulae also include a variable for conductivity. '836 Pat. at 10:10-45. When asked, Dr. Na was unable to figure out to what material the conductivity variable in the formulae were referring. Transcript of Dr. Jongju Na, Volume 3, at 429:18-432:8.

> Q The next term is conductivity. What is conductivity?
> A Whether electricity conduct well or not.
> Q The conductivity – scratch that.
> This refers to the conductivity of what?
> A Essentially a conductivity is – refers to whether electricity is conducted well or not.

Q In this equation, how would you know what material's conductivity to look at?
A I don't quite understand your question, sir.
Q Does this refer to the conductivity of the needles?
A This is an equation showing the correlations of the parameters listed here.
Q So it doesn't refer to conductivity of needles?
A This is an equation that means there's a correlation between the distance and conductivity.
…
Q Does this refer to the conductivity of the skin?
A Again, sir, distance means needle distance, and it means the correlations between distance and conductivity that affects the distance.
Q That doesn't answer my question.
Conductivity of what?
A Again, sir, this is between needles. I mean needle distance. And this is the conductivity that affects a needle distance.
Q How would I measure conductivity to use this equation?
A This equation is not a measure or compute the conductivity. Rather it represents the correlation between the needle distance and conductivity.
…
Q What material's conductivity is referred to by this equation?
A This equation is an equation to describe the correlation between conductivity and needle distance.

Transcript of Dr. Jongju Na, Volume 3, at 429:18-432:8.

602. The formula also includes a variable for resistance. '836 Pat. at 10:10-45. When asked, Dr. Na was unable to figure out what material the resistance variable in the formula was referring to (e.g., does it refer to device resistance, needle resistance, skin resistance, or a combination of these resistances?). Transcript of Dr. Jongju Na, Volume 3, at 432:9-437:2.

Q The next term in the equation is "resistance."
What material's resistance does this refer to?
A Similar to my other answer. This represents the correlation between needle distance and resistance.
Q Resistance of what?
A This is an equation that represent a correlation with the resistance that affect the needle distance.
Q What resistance is that?
A So resistance is the term in terms of whether electricity is conducted well or not. So it – it's a term used to express the degree which the electricity is not conducted very well.
Q Does this refer to needle resistance?

A This is an equation that represents the correlation with the resistance that affects the needle distance.
Q Is it the skin resistance?
A Sir, as I mentioned, this represents the correlation with the – with the resistance that affect needle distance.
Q What resistance affects needle distance?
A So just like conductivity we looked at earlier, resistance over here represents the distance between the needles.
So the correlation is that if the resistance is strong, and also if the resistance – of course there will be a weak resistance, too.
But if the resistance is high and strong, then the distance should be smaller.
So this is an equation that represents that correlation.
…
Q It says, "Where N: A proportional constant, Resistance: Device resistance, needle resistance, skin resistance."
A Okay.
Q. What is device resistance?
A It means what is the resistance when electrical signal – signals that are emitted from the device.
Q So does resistance in the equation refer to device resistance?
A Come again, sir?
Q Does resistance in the equation refer to device resistance?
A I believe that it's rather unclear phrasing. If you just say that resistance is – refers to device resistance, I believe it is misspoken.
Q Does resistance in the question refer to some kind of combination between device resistance, needle resistance, and skin resistance?
A This is an equation that describes a – describes the correlation between the needle distance and resistance, and it – here it just lists – lists the examples of resistance.
Q How would you know which value of resistance to pick from the examples?
A I don't quite understand. If you could clarify your question, please.
Q What's unclear about my question?
A Oh, well … I'm not sure, sir.
Q What is an example of low resistance?
A I don't quite know, sire.
Q What is device resistance?
A I don't know what you mean by the term sir.
…
A It means what is the resistance when electric signal – signals that are emitted from the device.
Q So does resistance in the question refer to device resistance?
A Come again, sir?
Q Does resistance in the equation refer to device resistance?
A I believe that it's rather unclear phrasing. If you just say that resistance is – refers to device resistance, I believe it is misspoken.

Q Does resistance in the equation refer to some kind of combination between device resistance, needle resistance, and skin resistance?
A This is an equation that describes a – describes the correlation between the needle distance and resistance, and it – here it just lists – lists the examples of resistance.
Q How would you know which value of resistance to pick from the examples?
A I don't quite understand. If you could clarify your question, please.
Q What's unclear about my question?
A May I have the question one more time please?
Not the interpretation, but can you re-ask the question, please.
Q How would you know which value of resistance to pick from the examples?
…
A Did I say "for example"?
Q Dr. Na, you testified that the patent lists examples of resistance which include device resistance, needle resistance, and skin resistance.
How would you know which value of resistance to pick from the examples?
…
A I never said that. I guess I don't remember. I don't have recollection of saying that examples are listed here.
So if there's any misunderstanding about what I said, let me correct myself.
So as I recall, I said resistance, device resistance, skin resistance. That's how I remember as to what I said.

Transcript of Dr. Jongju Na, Volume 3, at 432:9-437:2.

603. The formula also includes separate variables for "AC Frequency" and "High Frequency" to be multiplied by each other. '836 Pat. at 10:10-45. However, Dr. Na could not tell if the "AC Frequency in this equation" refers to "an AC frequency rate." Transcript of Dr. Jongju Na, Volume 3, at 445:14-18. Nor could Dr. Na explain what the separate high frequency variable was for. Transcript of Dr. Jongju Na, Volume 3, at 446:6-447:5.

Q So is the AC frequency in this equation an AC frequency rate?
...
A (In English) I don't know.
Transcript of Dr. Jongju Na, Volume 3, at 445:14-18.

Q What does high frequency refer to in the equation?
A High frequency means high frequency.
Q Does it refer to an RF frequency rate?
A High frequency sometimes is used as the same as other frequency in terms of meaning, but then it can be defined differently in electrical engineering, and so if you look at the books and different things, how to define can be different. There are many different ones.

Q What did you mean by high frequency in this equation?
A (In English) High frequency is – high frequency.
(Through interpreter) High frequency is – high frequency.
Q Just to clarify, your answer is to define high frequency is high frequency?
A (In English) High frequency is a high frequency – (speaking Korean).
(Through interpreter) I said high frequency is a high frequency.
Transcript of Dr. Jongju Na, Volume 3, at 446:6-447:5

604. Dr. Na also could not explain why "both AC frequency and high frequency [are] recited in this equation." Transcript of Dr. Jongju Na, Volume 3, at 448:4-450:8.

Q Why are both AC frequency and high frequency recited in this equation?
A That is to show the correlation with the needle distance. So the – what shows the correlation with the needle distance, there's an AC frequency, and there's also high frequency. That's why they are listed here.
Q What is the correlation between needle distance and high frequency?
A I believe your question is incomplete.
Q Why?
A Because there is no definition which coagulation has relation with which frequency. That is not defined. So it's impossible for me to answer.
Q What's the correlation with the needle distance when there's an AC frequency and there's also high frequency?
…
A As I already answered, sir, it's an incomplete question.
Q Sir, you just testified, and I quote, "So what shows the correlation with the needle distance. There's an AC frequency and there's also a high frequency." End quote. I'm trying to understand your statement there. Can you please clarify what that means?
A So this is an equation that shows a correlation between the needle distance and AC frequency. So it means is that if AC frequency increases so they are in invert – well, it's hard to put it in word. So what I meant was that when AC frequency's high, then needle distance is low.
Q Can AC frequency and high frequency change independent of one another?
…
A So AC frequency rate and high frequency rate can be the same or can be different, and AC frequency gets to high frequency by using alternating current. AC alternating current, right.

605. Transcript of Dr. Jongju Na, Volume 3, at 448:4-450:8.Dr. Na admits that the formulae cannot be used to "obtain a value" for the "distance between needles" to achieve the claimed effect. Transcript of Dr. Jongju Na, Volume 3, at 431:12-16; *see also id*., at 437:3-6, 439:13-17.

Q Is this equation used to determine a distance between needles?
A **It is not used to obtain a value that's in numbers**, but rather it's an equation to show a correlation.

Transcript of Dr. Jongju Na, Volume 3, at 431:12-16 (emphasis added).

Q So this equation can't be used to calculate a value for needle distance, correct?
A Again, sir, this represents correlations between needle distance and a number of things.
…
Q So you can't get a value for needle distance from this equation; correct?
A

Transcript of Dr. Jongju Na, Volume 3, at 437:3-12

606. Further, the term "radio frequency [or RF] generation module" is not used in the specification, which refers only to a "radio frequency (RF) generator" (*see* '836 Patent at 5:34-35. The RF generator is described only as being supplied with power by a power supply (*see id.*) and that it "may generate signal or signal(s) having a desired voltage, current, energy, resistance, RF frequency, on cycle, off cycle, and other parameters according to various embodiments." *Id.* at 5:53-57. Notably, the specification does not describe the specific configuration for an RF generator to be capable of providing "an Alternating Current (AC) RF signal" as required under Respondents' construction of this term. In particular, in col. 10:25-28 and 10:37-39, the specification clearly differentiates between AC frequency and RF frequency. However, the specification provides no written description of how to implement a signal having both an AC frequency and an RF frequency. There is also no description of how this signal is "provide[d] . . . to cause coagulation." Thus, the specification fails to provide written description support that demonstrates that the inventor possessed the full scope of the claimed invention.

3. apply energy to body segments around each electrode rather than to body segments between the electrodes" ('379 Patent Claim 1)

607. In my opinion, claim 1 of the '379 Patent is invalid because there is no written description support for "apply[ing] energy to body segments around each electrode rather than to body segments between the electrodes." The specification's references to "around" the needle refer to heat or temperature occurring "around" the needle- not energy being applied "around" rather than "between" the needle. *See* '379 Patent at 2:24-27; 3:25-29. The specification's references to "between" generally refer to *heat or temperature* between the needles or the *distance* between needles- not that energy is not applied between the needles. *See, e.g., id.* at 2:14-17; 3:27-28; 3:30-34; 3:48-51. The generator applies electrical energy between the electrodes, the electrodes configuration in conjunction with the tissue characteristics and the RF signal convert some of the RF energy to heat in various locations of the body segments. Thus, the specification fails to provide written description support that demonstrates that the inventor possessed the full scope of the claimed invention." The only definition of "energy" in the specification of the '379, '836 or '444 Patents is in 10:25-40 that the energy dissipated is V*I*t, but this defines the total amount of energy dissipated in tissue without any indication of how or where this energy is dissipated.

608. In addition, the specification states that numerous parameters will impact whether the desired field will be achieved. For example, the '379 Patent states that:

- "several parameters … control the energy field 909 generated about needles 300 … including the voltage, current, and the 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." '379 Pat. at 5:37-42.

- "The RF generator 14 may generate signal or signal(s) having a desired voltage, current, energy, resistance, RF frequency, on cycle, off cycle, and other parameters according to various embodiments." '379 Pat. at 5:55-59.
- In various embodiments, achieving a desired therapy may be related to the distance between deployed needles." '379Pat. at 6:58-59.
- "[E]mbodiments may employ an AC signal having a frequency from 0.5 to 10 MHz…" . '379 Pat. at 6:26-27.
- "In an embodiment, a needle 300 cross-section may be configured in a square shape 100…. The shape of a rhombus, rectangle, circle, oval, or quadrangle." '379 Pat. at 7:44-47.
- "A variety of needle 300 polarity combinations , placements, and needle shapes 100 may be used in designing a device that generates a desired energy field about a needle 300 including the configurations shown in FIG. 6 and FIG. 10." 379 Pat. at 7:66-8:3.
- "In order to generate a desired energy field 909 (FIG 5), 949 (FIG. 9) 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." '378 Pat. at 8:12-16.
- "It is noted that the applied voltage may be directedly related to the amount of energy created at a needle. In an embodiment, the voltage applied to a needle or electrode may not exceed 100V with a recommend operation range between 10 to 60V." '379 Pat. at 8:31-35.

- "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 cycles." '379 Pat. at 8:55-57.
- "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 employe needles having a desired distance and shape including the shapes shown in FIG. 11." '379 Pat. at 9:58-61.

609. Additional parameters that will impact the energy field include needle resistance and skin resistance. '379 Pat. at 10:25-42. While the '379 Patent does disclose some broad ranges for some of these parameters, the amount of guidance for selecting parameters that generate the energy applied to body segments around each electrode is minimal at best. The number of options that could be employed using the range of parameters disclosed (where ranges even are disclosed) is endless. And it is impossible to know which of those combinations of parameters will achieve energy applied to body segments around the needles but not between them. The specification provides insufficient guidance and written description for a POSITA to identify and appreciate which of the options for each relevant parameter will achieve energy applied to body segments around but not between needles.

610. Making matters worse, there is not a single example setting forth the various values of all relevant parameters that achieved coagulation around but not between the needles. One simply cannot discern the full scope of the invention from the written description without further guidance, nor that the named inventor possessed the full scope of the invention based on this limited disclosure in the specification.

611. A POSITA would know that most of the energy is dissipated into heat, but no indication is given about why energy is only dissipated around the electrodes.

4. "a radio frequency (RF) generation module … configured to provide an RF signal with oscillating current to the plurality of electrodes to apply energy to body segments around each electrode rather than to body segments between the electrodes." ('379 Patent Claim 1)

612. Furthermore, it is my opinion that claim 1 of the '379 Patent is invalid because there is no written description support for "a radio frequency (RF) generation module … configured to provide an RF signal with oscillating current to the plurality of electrodes to apply energy to body segments around each electrode rather than to body segments between the electrodes." The term "radio frequency [or RF] generation module" is not used in the specification, which refers only to a "radio frequency (RF) generator" (*see* '379 Patent at 5:30-32). The RF generator is described only as being supplied with power by a power supply (*see id.*) and that it "may generate signal or signal(s) having a desired voltage, current, energy, resistance, RF frequency, AC Frequency, on cycle, off cycle, and other parameters according to various embodiments." *Id.* at 5:55-59. However, the specification does not include a disclosure of a set of the desired voltage, current energy, resistance, RF frequency, AC frequency, on cycle, off cycle, and other parameters.

613. Notably, the specification does not describe the RF generator providing an RF signal with oscillating current "to apply energy . . . around each electrode rather than . . . between the electrodes." In particular, in col. 10:25-28 and 10:40-42, the specification clearly differentiates between AC frequency and RF frequency. I understand that the parties have agreed that RF signal with oscillating current has the same meaning as Alternating Current (AC) RF signal and Alternating Current (AC) Radio Frequency (RF) signal. Under Respondents construction of this term, the specification provides no written description of how to implement

a signal having both an AC frequency and an RF frequency. Thus, the specification fails to provide written description support that demonstrates that the inventor possessed the full scope of the claimed invention. .

5. "a radio frequency (RF) generation module, the RF generation module electrically coupled to the plurality of electrodes and configured to provide an RF signal with oscillating current to the plurality of electrodes to cause energy to be substantially applied to body segments around each electrode." ('444 Patent Claim 1)

614. It is my opinion that claim 1 of the '444 Patent is invalid because there is no written description support for "a radio frequency (RF) generation module, the RF generation module electrically coupled to the plurality of electrodes and configured to provide an RF signal with oscillating current to the plurality of electrodes that causes energy to be substantially applied to body segments around each electrode." The term "radio frequency [or RF] generation module" is not used in the specification, which refers only to a "radio frequency (RF) generator" (*see* '444 Patent at 5:46-48). The RF generator is described only as being supplied with power by a power supply (*see id.*) and that it "may generate signal or signal(s) having a desired voltage, current, energy, resistance, RF frequency, AC Frequency, on cycle, off cycle, and other parameters according to various embodiments." *Id.* at 5:55-59. However, the specification does not include a disclosure of a set of the desired voltage, current energy, resistance, RF frequency, AC frequency, on cycle, off cycle, and other parameters. As there is no written description support for "a radio frequency (RF) generation module … configured to provide an RF signal with oscillating current to the plurality of electrodes" from claim 1 of the '379 Patent, which shares a specification with the '444 Patent, and there is no written description support for the additional limitation "causes energy to be substantially applied to body segments around each electrode" (*see supra*), the specification fails to provide written

description support that demonstrates that the inventor "possessed the full scope of the claimed invention.".

615. In addition, in col. 10:37-39 and 10:51-43, the specification clearly differentiates between AC frequency and RF frequency. I understand that the parties have agreed that RF signal with oscillating current has the same meaning as Alternating Current (AC) RF signal and Alternating Current (AC) Radio Frequency (RF) signal. Under Respondents construction of this term, the specification provides no written description of how to implement a signal having both an AC frequency and an RF frequency. Thus, the specification fails to provide written description support that demonstrates that the inventor possessed the full scope of the claimed invention.

6. "cause[s] energy to be substantially applied to body segments around each electrode" ('444 Patent Claim 1)

616. Claim 1 of the '444 Patent recites "[causes/to cause] energy to be substantially applied to body segments around each electrode." In my opinion, the specification does not provide adequate written description for the term "substantially applied". The specification does not provide any standard for determining the bounds of substantially applying energy. There is no disclosure in the '444 Patent that would help a POSITA know how much or little overlap is needed to be considered substantial application around an electrode. For example, there is no way to tell at what point does too much overlap between energy fields of different electrodes results in the energy fields being classified as not being substantially applied around the individual electrodes.

7. The Specification does not provide sufficient written description for the "Na effect" claimed in the asserted claims of the '836, '379, and '444 Patents .

617. The asserted claims of the '836, '379, and '444 Patents broadly claim the "Na-effect" in terms of a result without specifying how to achieve the result, *i.e.*

- "... to cause coagulation around each electrode rather than coagulating between the electrodes." '836 Patent at claims 1 and 14.
- "… to apply energy to body segments around each electrode rather than to body segments between the electrodes." '379 Patent at claims 1 and 10.
- "… that causes energy to be substantially applied to body segments around each electrode." - '444 Patent at claim 1 and 10.

The asserted dependent claims of the '836, '379, and '444 Patents also do not provide sufficient parameters as to how to achieve this result.

618. Dr. Na testified that, even if he knew all the values for the relevant parameters for an RF microneedling device, he would not have been able to predict, with a high degree of confidence, whether a RF microneedling device would achieve his alleged invention. *See* Transcript of Dr. Jongju Na, Volume 4, at, 516:3-15, 510:4-15.

> Q. Okay. So I just went over some of the different parameters that might – that are options disclosed in your patent.
> And my question is, not every bipolar microneedling device that can be made using the various options for each of those parameters will achieve your invention, correct?
> …
> A (In English.) I don't know.
> (Through interpreter.) Right, I do not know because what you described is incomplete hypothetical. So I do not know.
>
> Transcript of Dr. Jongju Na, Volume 4, at, 516:3-15.

> Q. What would you need to know about an RF microneedling device that has bipolar electrodes to be able to conclude with a high degree of confidence that your invention will be observed?
> CHECK INTERPRETER: (rendering interpretation.)

(The interpreters conferred.)
LEAD INTERPRETER: Why don't you go ahead.
CHECK INTERPRETER: (Rendering interpretation.)
A. **That's too difficult a question**.

Transcript of Dr. Jongju Na, Volume 4, at, 510:4-15. (emphasis added.)

619. Dr. Na testified that, after applying energy to the electrodes, he would need to cut into the tissue cross-sectionally to determine whether his alleged invention was implemented. *See* Transcript of Dr. Jongju Na, Volume 4, at,482:3-19, 483:16-484:19; Transcript of Dr. Jongju Na, Volume 1, at 87:12-88:7

Q I'm just asking you, how would you go about determining whether there has been energy applied around the needles but not between the needles?
A Usually, to ensure accuracy, we conduct experiments and then publish papers. And after that, we would – well, I'm not sure whether this is the correct expression, but **we cut it cross-sectionally**.
Q Are there any other ways that you can determine whether there has been energy applied around the needles but not between the needles?
….
A Right. Not that – anything particular that comes to my mind that I can present at this moment.
Transcript of Dr. Jongju Na, Volume 4, at,482:3-19. (emphasis added.)

Q My questions is, you've mentioned that one way to determine if there is energy around the needles but not between them is to perform experiments.
Do you remember that?
A Yes.
Q An I'm asking you to describe those experiments that you would perform.
A So usually, it's performed in accordance with the **tissue** used, and so – as I told you earlier, and then **the cut, it would be cut cross-sectionally**.
But we watch the appearance of where electrode is inserted.
CHECK INTERPRETER: "Whether or not there is any kind of change occurring such as any markings visible."
(The interpreters conferred.)
LEAD INTERPRETER: "Marking" was not mentioned.
(The witness and check interpreter conferred in Korean.)
Q And what is it about the appearance of where the electrode is inserted that would allow you to understand where the energy was actually applied during the treatment?
A So around where the electrode was inserted **we would observe for any coagulation or any changes in the tissue**, as I mentioned earlier. And so we would observe the tissue and any changes there. And so **if there's any change, that means that was caused by the application of energy**.
Transcript of Dr. Jongju Na, Volume 4, at, 483:16-484:19. (emphasis added.)

Q. So when did you discover the so-called Na effect?
A I discovered it during my experiments in 2010, 2011. Around then.
Q Could you please explain the experiment?
A Using bipolar AC RF, I experimented on animal tissue using electrode, changing a conduction time, frequencies, and power levels. So that's how I conducted my experiment. In the course of doing that, I invented Na effect.
Q. So when you used the animal tissue, how did you know that there was a coagulation around each electrode?
A. (In English) Animal tissue –
(Through Interpreter) **You stick the needles in the animal tissue and then change the various parameters, and then after that you slice it**.
Transcript of Dr. Jongju Na, Volume 1, at 87:12-88:7. (emphasis added.)

620. When asked if "the area where coagulation occurred fully" was "representative of the area in which energy was applied to the tissue," Dr. Na testified "I reckon it could be the same, and it could be different." Transcript of Dr. Jongju Na, Volume 4, at 485:4-13. "In the case where it may be different," Dr. Na could not answer how he would be able to "determine the full extent of the area that energy was applied to the tissue." Transcript of Dr. Jongju Na, Volume 4, at 485:14-486:6.

Q In the case where it may be different how would you determine the full extent of the area that energy was applied to the tissue?
A I believe if you ask the specialist, I mean, the energy specialist, I believe they would be able to answer you better.
Q But you can't provide an answer to that question today?
A Because I do not want to wish – I do not wish to give you an inaccurate answer, that's why I'm not answering here today.
Q The '836 patent does not answer that question, does it?
...
A (In English.) I don't know.
Transcript of Dr. Jongju Na, Volume 4, at 485:14-486:6.

621. The specification also asserts that whether a user "generate[s] a desired energy field" also depends on the shape of the needles ('836 Patent, at 9:58-63; '444 Patent, at 10:2-12; '379 Patent, at 9:58-67); however, based on my review, the specification does not explain how one must adjust all the other variables to achieve the desired effect for a given needle shape.

622. Nor does the specification limit the tunable parameters to just those enumerated. *See* '836 Patent, at 10:10-18 ("including"); 10:40-41 ("Other distance calculations are possible"); '444 Patent, at 10:22-30, 10:55-56; '379 Patent, at 10:10-18, 10:43-44.

623. Based on my review, the common specification does not provide a single example of a full set of parameters necessary to achieve the claimed coagulation. The specification merely includes two Figures illustrating the claimed invention without further explanation and does not provide any working examples. The claims and specification of the '836, '379, and '444 Patents also provide some guidance on some of the parameters such as RF frequency (2MHz), needle diameter (0.25-0.30 mm), treatment duration (0.05 - 0.8 s), voltage (20-60 V), needle distance (2 mm) but no guidance as to what level of energy, power output, AC frequency, duty cycle, number of pulses should be applied.

624. As I discussed above, the specifications includes a laundry list of variables (at least 8), such as "distance between needles," "energy level (current, voltage, instantaneous and average power)," "needle's thickness," "system resistance, AC frequency rate, high frequency rate," "needle length or needle depth," and an a "proportional constant" somehow related to "Device resistance, needle resistance," and "skin resistance" that must all be tuned in relation to each other to achieve the desired result. '836 Patent, at 10:1-41. For example, Dr. Na testified that "it's not like that you just use a certain conduction time, but rather" it "depend[s] on the various parameter settings," and "you actually use many different parameters." Transcript of Dr. Jongju Na, Volume 1, at 101:3-19; *see also* Transcript of Dr. Jongju Na, Volume 2 at 230:21-231:15.

> Q So when you observed the so-called Na effect, what level of power and what level of conduction time did you use?
> A So if you look at the specification of my patent, you will see the definition which describes Na effect, of course, in so and so situations. And to see this

phenomenon, for example, **it's not like that you just use a certain conduction time, but rather depending on the various parameter settings that you have phenomenon** or phenomenons and the – **it's not like you use a set value for one component – one component of single value, but rather you actually use many different parameters**.

So it's like – it's kind of relative to the values. It's almost like mathematical equation.

Transcript of Dr. Jongju Na, Volume 1, at 101:3-19. (emphasis added.)

Q Does applying ACRF to tissue via the electrodes in the Sylfirm X cause coagulation around the electrodes?
A Well, rather than saying the Sylfirm X do that, well, I'll just say it depends on which setting you select in Sylfirm X. It could or it could not.
Q **In what setting would it – would applying ACRF to tissue via the electrodes cause coagulation around the electrodes**?
A **So it's not like there's one parameter for one -- each setting. There are many parameters that correlated**. So you will have to understand the correlation. For example, in Sylfirm X in CW mode, coagulation can form around each electrode, but in the case of pulsed wave, coagulation around each electrode can occur or not – cannot occur.

Transcript of Dr. Jongju Na, Volume 2 at 230:21-231:15. (emphasis added.)

625. Dr. Na testified that "it is impossible for me to answer" under what conditions the "Na effect" "is not observed" because changing the value of one variable effects all the other variables. Transcript of Dr. Jongju Na, Volume 4, at 493:19-495:3.

Q. So you were able to verify the conditions in which the Na effect was not observed?
A. … So I did observe, during the experiments, under certain conditions, my invention that's described here was not observed.
Q What are some of the conditions that you referred to where your invention was not observed?
A Sir, if you read the descriptions in my invention, there are parameters, conditions that affect. And so among the parameters – **between the parameters, there are correlations**. So **if one condition changes, then that can affect other conditions, and it means another condition can change as well. … So if you ask me under what condition it is not observed, it is impossible for me to answer**...
Q. So you testified that **if one condition changes, that can affect other conditions**, right?
A. **Yes**. I believe they are – there is a correlation.

Transcript of Dr. Jongju Na, Volume 4, at 493:19-495:3. (emphasis added.)

626. The specification also does not identify what material the needles are constructed from or the surface condition of the needles. . The needle material and surface condition are significant parameters a POSITA would need to know as those determines how energy is transferred into the dermis.

627. As previously addressed, the specification and claims do not instruct how to adjust the various parameters that the specification says must be tuned in relation to each other to achieve the desired results that are claimed, but rather, for example, the '836 Patent's independent claims just require applying "Alternating Current (AC) RF signal to the plurality of electrodes configured to cause coagulation around each electrode rather than coagulating between the electrodes" ('836 Patent, at claims 1 and 14). Similarly, the '379 and '444 Patents' independent claims also simply require a desired effect (to apply energy to body segments around each electrode rather than to body segments between the electrodes," '379 Patent at claim 1, and "… that causes energy to be substantially applied to body segments around each electrode," '444 Patent at claim 1) without referencing any of the parameters that the specification says must be tuned in relation to each other to achieve that desired result.

628. For at least the foregoing reasons, I believe that the common specification for the '836, '379, and '444 Patents does not provide sufficient written description for the full scope of the invention as defined by its claims, particularly if such claims are broadly construed.

B. The Asserted Claims of the '836, '379, and '444 Patents are not enabled.

629. For the reasons discussed above, which are incorporated by reference here, as well as the reasons set forth below, it is my opinion that the asserted claims of the '836, '379, and '444 Patents, all of which require obtaining the so-called "Na Effect" or other similar result,

are not enabled because the specification does not enable the full scope of obtaining such result or outcome.

630. Furthermore, for the reasons set forth with respect to written description, above as well as the reasons set forth below, it is my opinion that the following claim elements lack enablement and are therefore invalid under pre-AIA 35 U.S.C. § 112, ¶1:45

Asserted Patent	Asserted Claim(s)	Term(s) and/or Phrase(s) Lacking Enablement
'836, '379, and '444 Patents	All	"plurality of electrodes"
'836 Patent	1, 14	"coagulation around each electrode rather than coagulating between the electrodes"
'379 Patent	1	"apply energy to body segments around each electrode rather than body segments between the electrodes"
'444 Patent	1	"cause(s) energy to be substantially applied to body segments around each electrode"

1. The Specification does not enable the skilled artisan to practice the Na effect claimed in the asserted claims of the '836, '379, and '444 Patents .

631. In my opinion the asserted claims of the '836, '379, and '444 Patents, all of which require obtaining the so-called "Na Effect" or other similar result, are not enabled because the specification does not enable the full scope of obtaining such result or outcome. As I will explain in detail below, I reached this conclusion based on a factual analysis of the *Wands* factors, including "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

[45] To extent that any of the patents are determined to be AIA patents, they are invalided under 35 U.S.C. § 112(a).

632. As noted above, the asserted claims of the '836, '379, and '444 Patents broadly claim the "Na-effect" in terms of a result without specifying how to achieve the result, *i.e.*

- "... to cause coagulation around each electrode rather than coagulating between the electrodes." '836 Patent at claims 1 and 14.
- "… to apply energy to body segments around each electrode rather than to body segments between the electrodes." '379 Patent at claims 1 and 10.
- "… that causes energy to be substantially applied to body segments around each electrode." - '444 Patent at claim 1 and 10.

The asserted dependent claims of the '836, '379, and '444 Patents also do not provide sufficient parameters as to how to achieve this result. As such, the asserted claims of 836, '379, and '444 Patents are overly broad (*Wands* factor 8). As will be explained below, achieving the claimed effect requires manipulation of many factors in the formulae provided by the specification and, as such, the nature of the invention is complex (*Wands* factor 4).

633. The common specification to the '836, '379, and '444 Patents explains that "to achieve a desired energy field about the needle(s)," one must tune multiple variables, such as "distance between needles," "energy level (current, voltage)," "needle's thickness," "system resistance, AC frequency rate, high frequency rate, timing" "needle length or needle depth," and a "proportional constant" somehow related to "Device resistance, needle resistance," and "skin resistance." '836 Patent, at 10:1-41; '379 Patent, at 10:1-43; '444 Patent, at 10:13-54. Notably, the common specification of the '836, '379 and '444 Patents purports to include formulae for determining "the distance between adjacent needles." '836 Patent at 10:19-40. These formulae are shown below:

$$\text{Distance} = \text{N} * \ (\text{Power} - \text{energy}) * (\text{Needle Thickness}) * (\text{Conductivity}) \div (\text{Resistance}) * (\text{AC Frequency}) * (\text{High Frequency}) * (\text{Penetrated Needle Depth})$$

Substituting V*I*t into this equation gives

$$\text{Distance} = \text{N} * \ \text{V} * I * t * (\text{Needle Thickness}) * (\text{Conductivity}) \div (\text{Resistance}) * (\text{AC Frequency}) * (\text{High Frequency}) * (\text{Penetrated Needle Depth})$$

634. These formulae attempt to model the growth of a lesion around each electrode in the x/y plane and calculate the distance between the two electrodes such that the lesions do not overlap. At first glance, it appears that the formulae are not a particularly good approximation, as they specify that the distance is proportional to the amount of energy. As detailed previously and described below, not only are values for the parameters in the formulae provided but the formulae are also inaccurate. Thus, the specifications do not enable a POSITA to calculate the distance between needles that is required to achieve the desired effect.

635. The formulae can be simplified, and for easier understanding, ignore the convective cooling effect of blood flow in tissue that would slow down the growth of the coagulated lesion. It is well known that 4.184 Joules are equivalent to 1 calorie, and that 1 calorie is the amount of energy required to elevate the temperature of 1 gram of water by 1 degree (Celsius). Tissue has a different specific heat (amount of energy required to elevate the temperature of 1 gram of tissue by 1°C), but the principles of physics are the same. It therefore takes twice the amount of energy to elevate the temperature of twice the volume of tissue by the same level. During RF microneedling, a lesion is created when a given volume of tissue has its temperature elevated to a certain level for a certain time (depending on the actual tissue composition, it should be over 60-65°C for, by way of example,1 second). Thus, each volume of tissue needs to receive a certain number of calories (energy) to reach a temperature over 60°C to

achieve tissue "coagulation". For simplicity, assume that the lesion is spherical, with a diameter "D"; the volume of that spherical lesion can be calculated by the equation V = 1/6 . □ . D^3. Thus, if the volume is proportional to D^3, then the diameter of the sphere is growing with the cubic root of the amount of energy: D = a + b. $\sqrt[3]{E}$.

636. In other words, in the formulae given by Dr. Na, the distance should not be proportional to the amount of energy but to the cubic value E^3 ($\sqrt[3]{E}$.) of the energy dissipated. Even this is greatly simplified, as tissue impedance changes when it is heated (impedance goes down for small temperature elevation as warmer salt water [extracellular fluid] has a lower impedance, when desiccation starts to occur prior to coagulation, impedance goes up). When the tissue reaches a level of coagulation, it has a higher impedance, forcing the lesion to grow in another direction, and therefore the growth of the lesion over its x and y direction is slowed down, because the lesion grows in the Z direction (along the needle: the difference of impedance value between the epidermis and coagulated dermis at the tip of the needle gets smaller). The lesion is not spherical anymore and takes an oblong shape; it will also stops growing after a certain amount of time.

637. In my opinion not only are these formulae incorrect, but they only describe well known and documented natural phenomena.

Looking again at these formulae:

$$\text{Distance} = \text{N} * \text{V} * I * t * (\text{Needle Thickness}) * (\text{Conductivity}) \div (\text{Resistance}) * (\text{AC Frequency}) * (\text{High Frequency}) * (\text{Penetrated Needle Depth})$$

If one defines the following variables: d: depth of needle

L : distance between needles

D : needle diameter

E : energy = V.I.t

σ : tissue conductivity

Then:

$$L = N.\frac{E.D.\sigma.}{R.F_{ac}.F_{rf}.d} \quad (1)$$

The POSITA would have recognized that the resistance (it should really be the impedance, as we are dealing with AC current, not DC) of the circuit includes two major components: the resistance of the needle combined with needle tissue interface impedance (R_n) and the tissue impedance R_t that in conductors the resistance is given by the equation (the internal impedance of the generator is not relevant and that of the cables is usually insignificant) .

$$R = R_n + R_t$$

the resistance of the needle and its interface is inversely proportional to the exposed area of the needle:

$$R_n = K_n/(L*D*\pi)$$

R_n is also a function of the frequency, the work function of the metal comprising the electrodes as well as its surface texture and therefore cannot be considered a constant value as assumed by Dr. Na. As this resistance is already a function of the exposed length of the needle and the needle diameter, it is unclear if this should be counted twice in Dr. Na's formula.

638. The impedance of the tissue between two needles can be approximated by

$$R_t = L/(\sigma \, . \, S),$$

Where L is the length of conductor (distance between 2 needles) and S the cross section of the tissue separating the 2 needles. We can approximate S = D.L

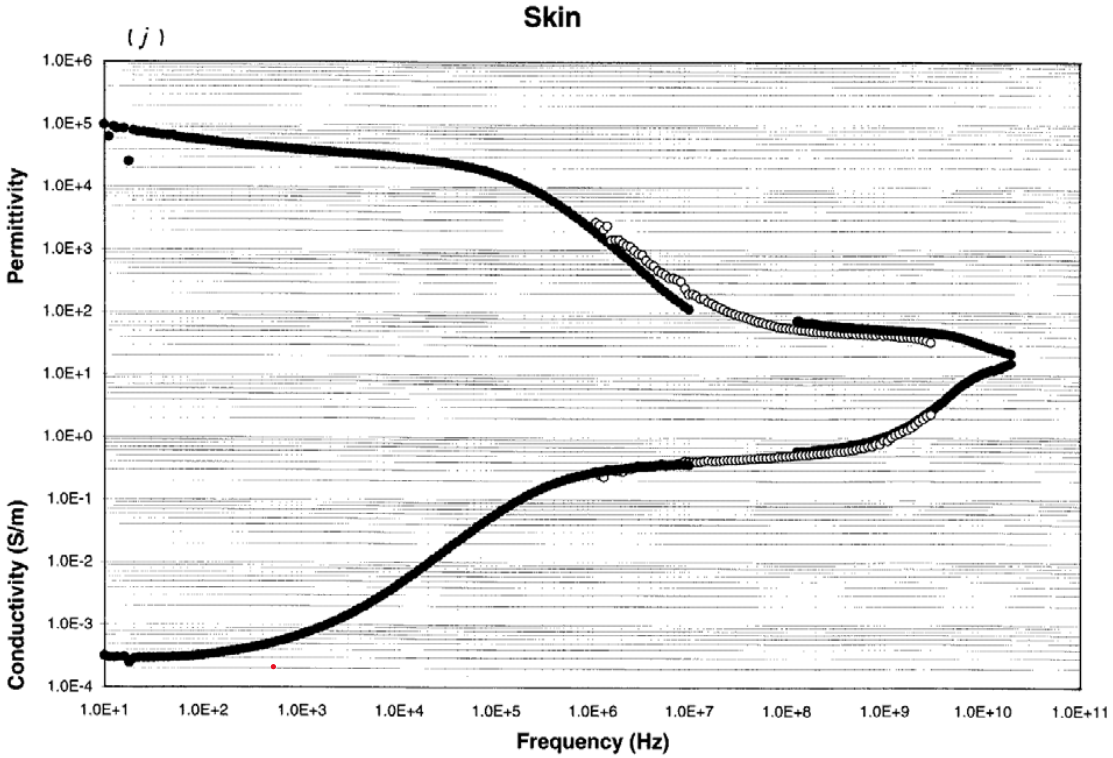
So:

$$R = \frac{K_n}{L\,.D.\pi} + \frac{L}{\sigma.D.L} = \frac{K_n.\sigma + L\,.\pi}{\sigma.D.L.\pi}$$

Replacing R in equation (1) with equation (2) results in equation (3).

$$L = N.\pi.\frac{E.D^2.\sigma^2}{(K_n.\sigma + L\,.\pi).F_{ac}.F_{rf}.d} \quad (3)$$

639. In actuality, the conductivity of tissue σ is already a function of frequency; Gabriel showed in 1996 that conductivity for tissue varies with frequency. The figure below (from Gabriel, 1996) shows human skin impedance as a function of the frequency. Below 100Hz (AC as stated by Dr. Na is 50-60Hz) the conductivity is almost constant. However, given the logarithmic scale of this graph, the resistivity increases almost linearly between 1kHz (1.0E+3) and 2 MHz (1 MHz = 2.0E+06)



640. It is unclear in the formula presented by Dr. Na if the conductivity is the value of DC current or if it is already corrected for a specific frequency. As the conductivity of tissue is also dependent on the tissue temperature, and therefore the amount of energy delivered over time, this equation becomes a very complex differential equation. Thus, the seemingly simple linear formula proposed by Dr. Na is not that linear, and while each of the parameters proposed by Dr. Na in his formula may have some level of correlation with the distance L, each of these parameters does not have a direct proportional relationship with the distance between the two needles. At best, a POSITA could conclude that to prevent lesions from overlapping when: (1) the needle diameter, (2) the amount of energy delivered , or (3) the length of exposed needle increase, the distance between the needle electrodes should increase; and when (4) the RF frequency increases, the distance between needles can decrease.

641. However, the relationship of each of these parameters with the distance between the needle is not linear as proposed by Na. Furthermore, the conductivity of tissue is not a variable that can be controlled, and its actual value may vary between patients as well. It is only relevant when doing experimental work on various types of tissue using living or dead animal tissue, often non dermatological tissue which is not relevant to this series of patents. It is known however that tissue conductivity varies with the signal frequency, and this is a main reason why the frequency has an impact on the needle distance.

642. In conclusion, the formulae provided in the ‘836, ‘379, and ‘444 Patents do not provide any guidance in selecting values for the laundry list of parameters provided in the patent specification, and they are not of any help for a POSITA to put the invention into practice. Furthermore, if the formulae were a true model of a system disclosed in the ‘836, ‘379 and ‘444 Patents, multivariable statistical analysis of the experimental data (when properly

conducted) would allow assignment of a value to the constant N and provide useful guidance to determine the minimum distance between needles to achieve the Na effect.

643. However, none of this is disclosed, and it does not appear that any such analysis has been performed. It is my opinion that the formulae provided in the '836, '379, and '444 Patents are of no use in actually determining the distance between needles for obtaining the so-called "Na Effect," the "Na-Plus Effect" or any other similar desired result. As such, the specification of '836 , '379, and '444 Patents do not provide sufficient guidance as to how to achieve the claimed effect (*Wands* factor 2).

644. For at least the reason discussed above, it is my opinion that solving these equations would require extensive experimentation (*Wands* factor 1). This conclusion is supported by statements of Dr. Na in his deposition.

645. Dr. Na testified that the proportional constant N "doesn't have a meaning." Transcript of Dr. Jongju Na, Volume 3, at 426:20-427:11. Dr. Na could not answer whether the proportional constant N had units (*Id*., at 429:1-8), and was not sure how to "calculate the value of N" (*Id*., at 438:8-439:12).

> Q And going back a second to N, the proportional constant.
> Does the proportional constant have units?
> A Sir, as I stated earlier, those equations represent correlations.
> Q What do you mean by that?
> A This is an equation that shows the correlations of the things shown there.
> *Id*., at 429:1-8.

> Q Where does the patent disclose the value of N?
> A It says N is a constant.
> Q What is that constant?
> A That means it's a number that is not variable.
> Q Right. So gravity, for example, is 9.81 meters a second squarred.
> What is the value of N?
> A Sir, I am not quite sure how you are suggesting that I calculate the value of N.

Q You're telling me it's a constant and it has a constant value. What is that value?
A Again, sir, N is a number that does not change, and this equation represents the correlations amongst those parameters.
Q Is N equal to 1?
A Sire?
Q Is N equal to 1?
A It says N is a constant.
…..
Q What is the value of N?
A Sir – sire, it says here N is a constant, and this equation shows the correlation.

Id., at 438:8-439:12.

646. The formulae also include a variable for conductivity. '836 Pat. at 10:10-45. When asked, Dr. Na was unable to figure out to what material the conductivity variable in the formulae were referring. Transcript of Dr. Jongju Na, Volume 3, at 429:18-432:8.

Q The next term is conductivity. What is conductivity?
A Whether electricity conduct well or not.
Q The conductivity – scratch that.
This refers to the conductivity of what?
A Essentially a conductivity is – refers to whether electricity is conducted well or not.
Q In this equation, how would you know what material's conductivity to look at?
A I don't quite understand your question, sir.
Q Does this refer to the conductivity of the needles?
A This is an equation showing the correlations of the parameters listed here.
Q So it doesn't refer to conductivity of needles?
A This is an equation that means there's a correlation between the distance and conductivity.
…
Q Does this refer to the conductivity of the skin?
A Again, sir, distance means needle distance, and it means the correlations between distance and conductivity that affects the distance.
Q That doesn't answer my question.
Conductivity of what?
A Again, sir, this is between needles. I mean needle distance. And this is the conductivity that affects a needle distance.
Q How would I measure conductivity to use this equation?
A This equation is not a measure or compute the conductivity. Rather it represents the correlation between the needle distance and conductivity.
…

Q What material's conductivity is referred to by this equation?
A This equation is an equation to describe the correlation between conductivity and needle distance.

Transcript of Dr. Jongju Na, Volume 3, at 429:18-432:8.

647. The formula also includes a variable for resistance. '836 Pat. at 10:10-45. When asked, Dr. Na was unable to figure out what material the resistance variable in the formula was referring to (e.g., does it refer to device resistance, needle resistance, skin resistance, or a combination of these resistances?). Transcript of Dr. Jongju Na, Volume 3, at 432:9-437:2.

Q The next term in the equation is "resistance."
What material's resistance does this refer to?
A Similar to my other answer. This represents the correlation between needle distance and resistance.
Q Resistance of what?
A This is an equation that represent a correlation with the resistance that affect the needle distance.
Q What resistance is that?
A So resistance is the term in terms of whether electricity is conducted well or not. So it – it's a term used to express the degree which the electricity is not conducted very well.
Q Does this refer to needle resistance?
A This is an equation that represents the correlation with the resistance that affects the needle distance.
Q Is it the skin resistance?
A Sir, as I mentioned, this represents the correlation with the – with the resistance that affect needle distance.
Q What resistance affects needle distance?
A So just like conductivity we looked at earlier, resistance over here represents the distance between the needles.
So the correlation is that if the resistance is strong, and also if the resistance – of course there will be a weak resistance, too.
But if the resistance is high and strong, then the distance should be smaller.
So this is an equation that represents that correlation.
…
Q It says, "Where N: A proportional constant, Resistance: Device resistance, needle resistance, skin resistance."
A Okay.
Q. What is device resistance?
A It means what is the resistance when electrical signal – signals that are emitted from the device.
Q So does resistance in the equation refer to device resistance?
A Come again, sir?

Q Does resistance in the equation refer to device resistance?
A I believe that it's rather unclear phrasing. If you just say that resistance is – refers to device resistance, I believe it is misspoken.
Q Does resistance in the question refer to some kind of combination between device resistance, needle resistance, and skin resistance?
A This is an equation that describes a – describes the correlation between the needle distance and resistance, and it – here it just lists – lists the examples of resistance.
Q How would you know which value of resistance to pick from the examples?
A I don't quite understand. If you could clarify your question, please.
Q What's unclear about my question?
A Oh, well … I'm not sure, sir.
Q What is an example of low resistance?
A I don't quite know, sire.
Q What is device resistance?
A I don't know what you mean by the term sir.
…
A It means what is the resistance when electric signal – signals that are emitted from the device.
Q So does resistance in the question refer to device resistance?
A Come again, sir?
Q Does resistance in the equation refer to device resistance?
A I believe that it's rather unclear phrasing. If you just say that resistance is – refers to device resistance, I believe it is misspoken.
Q Does resistance in the equation refer to some kind of combination between device resistance, needle resistance, and skin resistance?
A This is an equation that describes a – describes the correlation between the needle distance and resistance, and it – here it just lists – lists the examples of resistance.
Q How would you know which value of resistance to pick from the examples?
A I don't quite understand. If you could clarify your question, please.
Q What's unclear about my question?
A May I have the question one more time please?
Not the interpretation, but can you re-ask the question, please.
Q How would you know which value of resistance to pick from the examples?
…
A Did I say "for example"?
Q Dr. Na, you testified that the patent lists examples of resistance which include device resistance, needle resistance, and skin resistance.
How would you know which value of resistance to pick from the examples?
…
A I never said that. I guess I don't remember. I don't have recollection of saying that examples are listed here.
So if there's any misunderstanding about what I said, let me correct myself. So as I recall, I said resistance, device resistance, skin resistance. That's how I remember as to what I said.

Transcript of Dr. Jongju Na, Volume 3, at 432:9-437:2.

648. The formula also includes separate variables for "AC Frequency" and "High Frequency" to be multiplied by each other. '836 Pat. at 10:10-45. However, Dr. Na could not tell if the "AC Frequency in this equation" refers to "an AC frequency rate." Transcript of Dr. Jongju Na, Volume 3, at 445:14-18. Nor could Dr. Na explain what the separate high frequency variable was for. Transcript of Dr. Jongju Na, Volume 3, at 446:6-447:5.

Q So is the AC frequency in this equation an AC frequency rate?
...
A (In English) I don't know.
Transcript of Dr. Jongju Na, Volume 3, at 445:14-18.

Q What does high frequency refer to in the equation?
A High frequency means high frequency.
Q Does it refer to an RF frequency rate?
A High frequency sometimes is used as the same as other frequency in terms of meaning, but then it can be defined differently in electrical engineering, and so if you look at the books and different things, how to define can be different. There are many different ones.
Q What did you mean by high frequency in this equation?
A (In English) High frequency is – high frequency.
(Through interpreter) High frequency is – high frequency.
Q Just to clarify, your answer is to define high frequency is high frequency?
A (In English) High frequency is a high frequency – (speaking Korean).
(Through interpreter) I said high frequency is a high frequency.
Transcript of Dr. Jongju Na, Volume 3, at 446:6-447:5

649. Dr. Na also could not explain why "both AC frequency and high frequency [are] recited in this equation." Transcript of Dr. Jongju Na, Volume 3, at 448:4-450:8.

Q Why are both AC frequency and high frequency recited in this equation?
A That is to show the correlation with the needle distance. So the – what shows the correlation with the needle distance, there's an AC frequency, and there's also high frequency. That's why they are listed here.
Q What is the correlation between needle distance and high frequency?
A I believe your question is incomplete.
Q Why?
A Because there is no definition which coagulation has relation with which frequency. That is not defined. So it's impossible for me to answer.
Q What's the correlation with the needle distance when there's an AC frequency and there's also high frequency?

…
A As I already answered, sir, it's an incomplete question.
Q Sir, you just testified, and I quote, "So what shows the correlation with the needle distance. There's an AC frequency and there's also a high frequency." End quote. I'm trying to understand your statement there. Can you please clarify what that means?
A So this is an equation that shows a correlation between the needle distance and AC frequency. So it means is that if AC frequency increases so they are in invert – well, it's hard to put it in word. So what I meant was that when AC frequency's high, then needle distance is low.
Q Can AC frequency and high frequency change independent of one another?
…
A So AC frequency rate and high frequency rate can be the same or can be different, and AC frequency gets to high frequency by using alternating current. AC alternating current, right.

650. Transcript of Dr. Jongju Na, Volume 3, at 448:4-450:8.Dr. Na admits that the formulae cannot be used to "obtain a value" for the "distance between needles" to achieve the claimed effect. Transcript of Dr. Jongju Na, Volume 3, at 431:12-16; *see also id*., at 437:3-6, 439:13-17.

Q Is this equation used to determine a distance between needles?
A **It is not used to obtain a value that's in numbers**, but rather it's an equation to show a correlation.
Transcript of Dr. Jongju Na, Volume 3, at 431:12-16. (emphasis added.)

Q So this equation can't be used to calculate a value for needle distance, correct?
A Again, sir, this represents correlations between needle distance and a number of things.
…
Q So you can't get a value for needle distance from this equation; correct?
A

651. Dr. Na testified that, even if he knew all the values for the relevant parameters for an RF microneedling device, he would not have been able to predict, with a high degree of confidence, whether a RF microneedling device would achieve his alleged invention. *See* Transcript of Dr. Jongju Na, Volume 4, at, 516:3-15, 510:4-15.

Q. Okay. So I just went over some of the different parameters that might –

that are options disclosed in your patent.

And my question is, not every bipolar microneedling device that can be made using the various options for each of those parameters will achieve your invention, correct?

…

A (In English.) I don't know.

(Through interpreter.) Right, I do not know because what you described is incomplete hypothetical. So I do not know.

Transcript of Dr. Jongju Na, Volume 4, at, 516:3-15.

Q. What would you need to know about an RF microneedling device that has bipolar electrodes to be able to conclude with a high degree of confidence that your invention will be observed?

CHECK INTERPRETER: (rendering interpretation.)

(The interpreters conferred.)

LEAD INTERPRETER: Why don't you go ahead.

CHECK INTERPRETER: (Rendering interpretation.)

A. **That's too difficult a question**.

Transcript of Dr. Jongju Na, Volume 4, at, 510:4-15. (emphasis added.)

652. Dr. Na testified that, after applying energy to the electrodes, he would need to cut into the tissue cross-sectionally to determine whether his alleged invention was implemented. *See* Transcript of Dr. Jongju Na, Volume 4, at,482:3-19, 483:16-484:19; Transcript of Dr. Jongju Na, Volume 1, at 87:12-88:7.

Q I'm just asking you, how would you go about determining whether there has been energy applied around the needles but not between the needles?

A Usually, to ensure accuracy, we conduct experiments and then publish papers. And after that, we would – well, I'm not sure whether this is the correct expression, but **we cut it cross-sectionally**.

Q Are there any other ways that you can determine whether there has been energy applied around the needles but not between the needles?

….

A Right. Not that – anything particular that comes to my mind that I can present at this moment.

Transcript of Dr. Jongju Na, Volume 4, at,482:3-19. (emphasis added.)

Q My questions is, you've mentioned that one way to determine if there is energy around the needles but not between them is to perform experiments.

Do you remember that?

A Yes.

Q An I'm asking you to describe those experiments that you would perform.
A So usually, it's performed in accordance with the **tissue** used, and so – as I told you earlier, and then **the cut, it would be cut cross-sectionally**.
But we watch the appearance of where electrode is inserted.
CHECK INTERPRETER: "Whether or not there is any kind of change occurring such as any markings visible."
(The interpreters conferred.)
LEAD INTERPRETER: "Marking" was not mentioned.
(The witness and check interpreter conferred in Korean.)
Q And what is it about the appearance of where the electrode is inserted that would allow you to understand where the energy was actually applied during the treatment?
A So around where the electrode was inserted **we would observe for any coagulation or any changes in the tissue**, as I mentioned earlier. And so we would observe the tissue and any changes there. And so **if there's any change, that means that was caused by the application of energy**.
Transcript of Dr. Jongju Na, Volume 4, at, 483:16-484:19. (emphasis added.)

Q. So when did you discover the so-called Na effect?
A I discovered it during my experiments in 2010, 2011. Around then.
Q Could you please explain the experiment?
A Using bipolar AC RF, I experimented on animal tissue using electrode, changing a conduction time, frequencies, and power levels. So that's how I conducted my experiment. In the course of doing that, I invented Na effect.
Q. So when you used the animal tissue, how did you know that there was a coagulation around each electrode?
A. (In English) Animal tissue –
(Through Interpreter) **You stick the needles in the animal tissue and then change the various parameters, and then after that you slice it**.
Transcript of Dr. Jongju Na, Volume 1, at 87:12-88:7. (emphasis added.)

653. When asked if "the area where coagulation occurred fully" was "representative of the area in which energy was applied to the tissue," Dr. Na testified "I reckon it could be the same, and it could be different." Transcript of Dr. Jongju Na, Volume 4, at 485:4-13. "In the case where it may be different," Dr. Na could not answer how he would be able to "determine the full extent of the area that energy was applied to the tissue." Transcript of Dr. Jongju Na, Volume 4, at 485:14-486:6.

Q In the case where it may be different how would you determine the full extent of the area that energy was applied to the tissue?
A I believe if you ask the specialist, I mean, the energy specialist, I believe they would be able to answer you better.

Q But you can't provide an answer to that question today?
A Because I do not want to wish – I do not wish to give you an inaccurate answer, that's why I'm not answering here today.
Q The '836 patent does not answer that question, does it?
...
A (In English.) I don't know.
Transcript of Dr. Jongju Na, Volume 4, at 485:14-486:6.

654. The specification also asserts that whether a user "generate[s] a desired energy field" also depends on the shape of the needles ('836 Patent, at 9:58-63; '444 Patent, at 10:2-12; '379 Patent, at 9:58-67); however, based on my review, the specification does not explain how one must adjust all the other variables to achieve the desired effect for a given needle shape.

655. Nor does the specification limit the tunable parameters to just those enumerated. *See* '836 Patent, at 10:10-18 ("including"); 10:40-41 ("Other distance calculations are possible"); '444 Patent, at 10:22-30, 10:55-56; '379 Patent, at 10:10-18, 10:43-44.

656. Based on my review, the common specification does not provide a single example of a full set of parameters necessary to achieve the claimed coagulation. The specification merely includes two Figures illustrating the claimed invention without further explanation and does not provide any working examples (*Wands* factor 3). The claims and specification of the '836, '379, and '444 Patents also provide some guidance on some of the parameters such as RF frequency (2MHz), needle diameter (0.25-0.30 mm), treatment duration (0.05 - 0.8 s), voltage (20-60 V), needle distance (2 mm) but no guidance as to what level of energy, power output, AC frequency, duty cycle, number of pulses should be applied.

657. As I discussed above, the specifications includes a laundry list of variables (at least 8), such as "distance between needles," "energy level (current, voltage, instantaneous and average power)," "needle's thickness," "system resistance, AC frequency rate, high frequency rate," "needle length or needle depth," and an a "proportional constant" somehow related to

"Device resistance, needle resistance," and "skin resistance" that must all be tuned in relation to each other to achieve the desired result. '836 Patent, at 10:1-41. For example, Dr. Na testified that "it's not like that you just use a certain conduction time, but rather" it "depend[s] on the various parameter settings," and "you actually use many different parameters." Transcript of Dr. Jongju Na, Volume 1, at 101:3-19; *see also* Transcript of Dr. Jongju Na, Volume 2 at 230:21-231:15.

> Q So when you observed the so-called Na effect, what level of power and what level of conduction time did you use?
> A So if you look at the specification of my patent, you will see the definition which describes Na effect, of course, in so and so situations. And to see this phenomenon, for example, **it's not like that you just use a certain conduction time, but rather depending on the various parameter settings that you have phenomenon** or phenomenons and the – **it's not like you use a set value for one component – one component of single value, but rather you actually use many different parameters**.
> So it's like – it's kind of relative to the values. It's almost like mathematical equation.
>
> Transcript of Dr. Jongju Na, Volume 1, at 101:3-19. (emphasis added.)

> Q Does applying ACRF to tissue via the electrodes in the Sylfirm X cause coagulation around the electrodes?
> A Well, rather than saying the Sylfirm X do that, well, I'll just say it depends on which setting you select in Sylfirm X. It could or it could not.
> Q **In what setting would it – would applying ACRF to tissue via the electrodes cause coagulation around the electrodes**?
> A **So it's not like there's one parameter for one -- each setting. There are many parameters that correlated**. So you will have to understand the correlation. For example, in Sylfirm X in CW mode, coagulation can form around each electrode, but in the case of pulsed wave, coagulation around each electrode can occur or not – cannot occur.
>
> Transcript of Dr. Jongju Na, Volume 2 at 230:21-231:15. (emphasis added.)

658. Dr. Na testified that "it is impossible for me to answer" under what conditions the "Na effect" "is not observed" because changing the value of one variable effects all the other variables. Transcript of Dr. Jongju Na, Volume 4, at 493:19-495:3.

> Q. So you were able to verify the conditions in which the Na effect was not

observed?
A. … So I did observe, during the experiments, under certain conditions, my invention that's described here was not observed.
Q What are some of the conditions that you referred to where your invention was not observed?
A Sir, if you read the descriptions in my invention, there are parameters, conditions that affect. And so among the parameters – **between the parameters, there are correlations**. So **if one condition changes, then that can affect other conditions, and it means another condition can change as well. … So if you ask me under what condition it is not observed, it is impossible for me to answer**...
Q. So you testified that **if one condition changes, that can affect other conditions**, right?
A. **Yes**. I believe they are – there is a correlation.

Transcript of Dr. Jongju Na, Volume 4, at 493:19-495:3. (emphasis added.)

659. The specification also does not identify what material the needles are constructed from or the surface condition of the needles. . The needle material and surface condition are significant parameters a POSITA would need to know as those determines how energy is transferred into the dermis.

660. As previously addressed, the specification and claims do not instruct how to adjust the various parameters that the specification says must be tuned in relation to each other to achieve the desired results that are claimed, but rather, for example, the '836 Patent's independent claims just require applying "Alternating Current (AC) RF signal to the plurality of electrodes configured to cause coagulation around each electrode rather than coagulating between the electrodes" ('836 Patent, at claims 1 and 14). Similarly, the '379 and '444 Patents' independent claims also simply require a desired effect (to apply energy to body segments around each electrode rather than to body segments between the electrodes," '379 Patent at claim 1, and "… that causes energy to be substantially applied to body segments around each electrode," '444 Patent at claim 1) without referencing any of the parameters that the specification says must be tuned in relation to each other to achieve that desired result. Thus,

despite an extensive state of the art as described above (*Wands* factor 5), and a high level of skill (*Wands* factor 4), a POSITA would not be able to predict whether they would achieve the claimed results selecting values for the various parameters without any guidance provided by the disclosure of the 836, '379, and '444 Patents (*Wands* factor 7).

661. For at least the foregoing reasons balancing the *Wands* factors, I believe that the common specification for the '836, '379, and '444 Patents does not enable the full scope of the invention as defined by its claims, particularly if such claims are broadly construed.

2. "plurality of electrodes" ('836 Patent Claims 1 and 14, '379 Patent Claim 1, and '444 Patent Claim 1)

662. It is my opinion that the specification is not enabling with respect to a "plurality of electrodes" that encompasses insulated electrodes. Based on my assessment, the factual considerations provided by the *Wands* factors, including "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims," counsel in favor of finding a lack of enablement for this claim term.

663. In my opinion, a POSITA, having read the specification at the time of the invention, would not be able to make and use the claim elements set forth above. As already stated, the '836, '379, and '444 Patents, through at least incorporation by reference of the translated Korean priority application, indicate that embodiments containing a "plurality of electrodes" that are insulated can in fact "prevent Na-effect and Na-Plus effect" from taking place. Complaint Appendix A at pp. 24-25, ¶ [41]. This disclosure, together with repeated disparagement of embodiments containing insulated electrodes, would require a POSITA to conduct undue experimentation to discover how the claimed effects would occur.

664. With respect to the *Wands* factors, in my assessment balancing various factors points to a lack of enablement:

- The quantity of experimentation needed to achieve the claimed effects would be extremely high, and potentially impossible. (Factor 1). Because the patent does not clearly the define the end result being achieved, *i.e.* in the context of a "treatment"[46] what is coagulation, energy applied to body segments around electrodes but not between them, energy substantially to body segments around each electrode, a POSITA would have to conduct numerous experiments to discover how the claimed Na-effect and Na-Plus effect work with insulated or even non-insulated electrodes. This is undue experimentation.
- The specification provides no guidance or direction for how to achieve the claimed Na-effect and Na-Plus effect with insulated electrodes (Factor 2). Indeed, the translated Korean PCT application, which is incorporated by reference into the specification of the '836, '379, and '444 Patents, instructs that a "required component" to achieve the claimed Na-effect and Na-Plus effect is "the use of non-insulated needles." Complaint Appendix A, p. 23 ([34]). Without guidance, the specification, at best, offers a starting point for a POSITA to conduct further research.
- The specification provides no working examples of embodiments containing insulated electrodes that also achieve the claimed Na-effect and Na-Plus effect (Factor 3). Figures 4, 9A, and 9B include labels corresponding to "700: insulated area of needle." '836 pat., 5:13. While the '836 specification refers to Fig. 4 as "a simplified diagram of treatment architecture using bipolar needles that are insulated except at the needle tip according to

[46] As set forth in the claim construction section above, the Parties have agreed that the preambles of the claims, which contain the term "treatment" is limiting and I should therefore treat this as a limitation of the claims.

an embodiment of the present invention," the translated Korean PCT application makes clear that Fig. 4 in fact shows a prior art system. *See* Complaint Appendix A, p. 22 ([21]). In any case, Fig. 4 also shows an area where temperature is raised between the electrodes (see, *e.g.*, ''836 pat., 5:16-17), which is not the claimed "Na-Effect." Figure 9B, which was added during prosecution, at best shows the use of "non-electrical insulation coating," which is distinct from electrical insulation. '836 pat., 7:7-11. None of these purported embodiments constitute working examples of the use of insulated electrodes to achieve the claimed Na-effect and Na-Plus effect.

- The nature of the invention (Factor 4). All the claims recite an apparatus and method for treating skin, which involves employing bipolar electrodes, alternating current (AC) signals, and high frequency signals where the bipolar electrodes (or needles) are inserted into the skin and energized to cause coagulation around each electrode (Factor 4). Given the nature of the invention, the specification should provide guidance regarding the manner of achieving the claimed effect with insulated or non-insulated electrodes. But the specification fails to do so.
- The state of the prior art in the area of the invention is well-known and extensive (Factor 5). Although a POSITA would be familiar with the prior art, a POSITA would still need to conduct confirmatory tests to ensure the claimed Na effect and Na-plus effect was achieved with insulated electrodes.
- The relative skill of those in the art (Factor 6) is high, with a POSITA holding an advanced degree and relevant work experience. Given the state of the prior art (Factor 5), a POSITA would be familiar with the techniques underlying the claimed invention

but could not predict in advance the values to be used for the various parameters with a device having insulated electrodes to achieve the claimed effects.

- The invention is a "treatment" and therefore requires a healing effect. The selection of parameters to achieve the claimed effect as a treatment would require considerable trial-and-error as a result of the lack of guidance as to the parameters, including how to use insulated electrodes (Factor 7).
- The breadth of the claims is broad, covering many types of electrodes such as insulated, non-insulated, and partially insulated (Factor 8). The specification does not allow a POSITA to make and use the full scope of the claims, which includes different electrode preparations, without undue experimentation.

665. Accordingly, I believe that the specification fails to enable a POSITA to practice the asserted claims of the '836, '379, and '444 Patents.

C. The Asserted Claims of the '836, '379, and '444 Patents are indefinite

666. It is my understanding that claims are indefinite under pre-AIA 35 U.S.C. § 112, ¶ 2 or AIA 35 U.S.C. § 112(b) when they fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention. Furthermore, claims are invalid under pre-AIA or 35 U.S.C. § 112, ¶ 6 or AIA 35 U.S.C. § 112(f) for failing to adequately describe all claimed structure that corresponds to the claimed function(s). As will be discussed in detail, it is my opinion that: the Asserted Patents are invalid under pre-AIA 35 U.S.C. § 112, ¶ 2 or AIA 35 U.S.C. § 112(b); the Asserted Patents are invalid under pre-AIA or 35 U.S.C. § 112, ¶ 6 or AIA 35 U.S.C. § 112(f).

667. The Asserted Claims identified below are invalid under pre-AIA 35 U.S.C. § 112, ¶ 2 /AIA 35 U.S.C. § 112(b) and/or pre-AIA or 35 U.S.C. § 112, ¶ 6/AIA 35 U.S.C. §

112(f) because they fail to inform, with reasonable certainty, the POSITA about the scope of the claimed invention(s) and/or fail to adequately describe all claimed structure that corresponds to the claimed function(s):

Asserted Patent(s)	Asserted Claim(s)	Indefinite Term(s) and/or Phrase(s)
'444 Patent	1	"cause[s] energy to be substantially applied to body segments around each electrode"
'836 Patent	1	"a radio frequency (RF) generation module,… configured to provide an Alternating Current (AC) RF signal to the plurality of electrodes."
'444 Patent	1	"a radio frequency (RF) generation module,… configured to provide an RF signal with oscillating current to the plurality of electrodes."

1. "cause[s] energy to be substantially applied to body segments around each electrode" ('444 Patent Claim 1)

668. Claim 1 of the '444 Patent recites "[causes/to cause] energy to be substantially applied to body segments around each electrode." In my opinion, the term "substantially applied" renders the independent claims indefinite. The specification does not provide any standard for determining the bounds of substantially applying energy. There is no disclosure in the '444 Patent that would help a POSITA know how much or little overlap is needed to be considered substantial application around an electrode. For example, there is no way to tell at what point does too much overlap between energy fields of different electrodes results in the energy fields being classified as not being substantially applied around the individual electrodes.

669. In addition, the '444 specification only describes two energy field formations: (1) embodiments with "overlapping or intersecting energy fields," such as Fig. 9A, and (2) embodiments "with non-overlapping or non-intersecting energy fields," such as Fig. 9B.

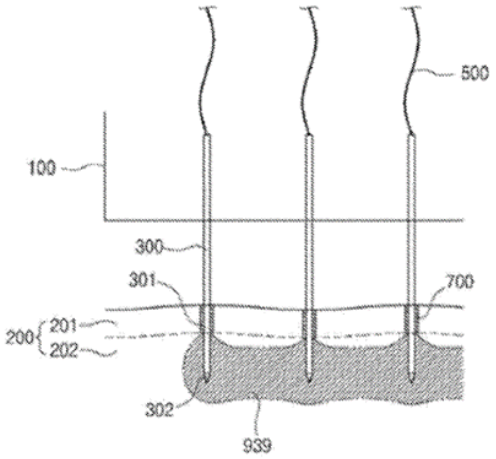


FIGURE 9A

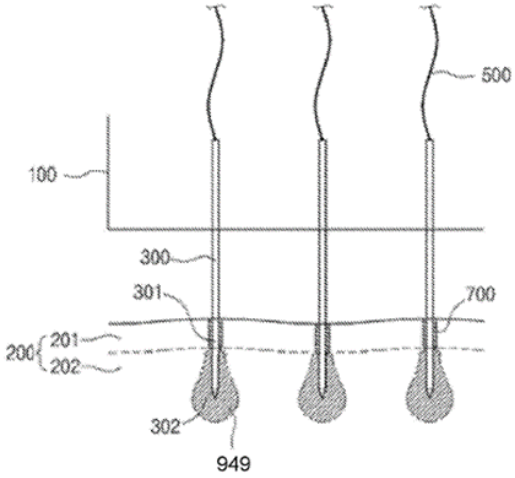


FIGURE 9B

670. In the Patent Owner's Preliminary Response to the petition for Inter Partes Review of the '379 Patent in IPR2022-00593, Serendia argued that Figs. 2, 5, and 9B, "illustrat[e] energy fields focused around each needle, without connection or intersection between the electrodes," while Figs. 4, 7 and 8 are the embodiments with connected energy fields. (*See* Patent Owner's Preliminary Response in IPR2022-00593, at pgs.9-12). The only other relevant figure is fig. 3, which shows overlapping energy fields. Other than the two embodiments of completely overlapping energy fields and non-overlapping energy fields, no other energy field formation is described in the specification or shown in its drawings.

671. In IPR2022-00593, Serendia argued that the non-overlapping/non-intersecting energy field embodiments (*e.g.*, Figs. 2, 5, and 9B) require that the energy field for each electrode is only applied around the electrode (absolutely no energy is transferred between electrodes) (*See* Patent Owner's Preliminary Response in IPR2022-00593, at pg. 12).

672. Because the term "substantially applied to body segments around the electrodes" connotes that not all of the energy is applied around the electrodes and, instead, some of the

energy is applied elsewhere, and there is absolutely no energy transferred between electrodes in the non-overlapping/non-intersecting energy field embodiments, that claim limitation is not directed to the non-overlapping/non-intersecting energy field embodiments.

673. Accordingly, that only leaves the overlapping/intersecting energy field embodiments as potential support for understanding what substantially applying an energy field around an electrode means. However, the prosecution history of the application for the '444 Patent shows that at least the Examiner did not believe that the overlapping/intersecting energy field embodiments were covered by the independent claims of the '444 Patent. Specifically, the Examiner allowed the claims because the Examiner believed the independent claim required absolutely no overlap in energy fields (that each electrode complete the positive/negative flow path itself). '444 Patent Prosecution History, March 23, 2022, Notice of Allowance, at pg. 2.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance: The applicant included the allowable subject matter requiring the RF signal to be oscillating current. This is illustrated in figure 6 of the applicant's drawings in which each individual needle changes polarity rapidly from negative to positive and vice versa. This produces the effect illustrated in figures 5 and 9B where the RF energy flows around individual needles rather than between needles as each individual needle is completing the positive/negative flow path itself. This subtle distinction does not appear to be disclosed in the Manstein reference.

Id.

674. As a result of the arguments presented to the Patent Office, there is no disclosure in the '444 Patent that relates to the "substantially applied to body segments around the electrodes" and therefore it is unclear what that limitation covers, thereby rendering it indefinite.

Serendia intentionally chose different wording for the ‘444 Patent than the rest of its asserted family members, presumably, to achieve a broader claim scope. Specifically, in my assessment, Serendia knew how to claim absolutely no overlap in energy fields, which is shown by the claim language for the independent claims of the ‘379 Patent: “apply energy to body segments around each electrode rather than body segments between the electrodes,” and chose not to for the ‘444 Patent.

2. “a radio frequency (RF) generation module …configured to provide an Alternating Current (AC) RF signal to the plurality of electrodes” (‘836 Patent Claim 1) and “a radio frequency (RF) generation module… configured to provide an RF signal with oscillating current to the plurality of electrodes.” (‘444 Patent Claim 1)

675. In my opinion, claim 1 of the ‘836 Patent and claim 1 of the ‘444 Patent are invalid because the “radio frequency (RF) generation module” limitation renders the claim indefinite. The term “radio frequency (RF) generation module” is purely functional. Although the term “radio frequency (RF) generation module” does not use the term “means” and is therefore entitled to a presumption that § 112, ¶ 6 does not apply, that presumption is overcome here because the term “radio frequency (RF) generation module” does not connote specific structure to a POSITA and this limitation is recited entirely using functional language (“to provide an RF signal with oscillating current”) insofar as the use of “module” here simply replaces “means” with the term “device.”

676. Based on my review, the term “Module” has no structural significance, and the surrounding language does not provide any structure whatsoever. *“*[R]adio frequency (RF) generation” provides no structure and neither does “to provide an RF signal with oscillating current.” Pairing the nonce word “module” with the purely functional modifier “radio frequency (RF) generation,” as the disputed claim term, does not confer any structure on the claim limitations even when considering all the functional language following that claim element. In

my assessment, "radio frequency (RF) generation" only describes the function the "module" performs and not its structure.

677. A POSITA reviewing the specification, however, would recognize that a corresponding structure is not disclosed. As set forth above, the term "radio frequency (RF) generation module," appears nowhere in the specification. Thus, it is not surprising that corresponding structure is not disclosed. In fact, the only box diagram that purportedly shows an "RF generator" (*see* '836 Patent at Fig. 1) does not even hint at a structure that performs the claimed function. Accordingly, I believe that claim 1 of the '836 Patent and claim 1 of the '444 Patent are invalid.

D. The Claims of the '536, '774, and '812 Patents lack written description.

678. It is my opinion that the following claim elements of the claims of the '536, '774, and '812 Patents lack sufficient written description and are therefore invalid under pre-AIA 35 U.S.C. § 112, ¶ 1:

Asserted Patent	Asserted Claim(s)	Term(s) and/or Phrase(s) Lacking Written Description
'774 Patent	All	"pulsed radio frequency signals"
'536 Patent	1, 11	"the releasably couplable deployable needle assembly, the deployable needle assembly mechanically separatably from the proximal end"
'536 Patent	1, 11	"a plurality of needles extendable from the deployable needle assembly end surface"
'536 Patent	1	"communicating electrical signals from the proximal end to the plurality of the extendable needles… energizing the plurality of extended needles via a signal generator electrically

Asserted Patent	Asserted Claim(s)	Term(s) and/or Phrase(s) Lacking Written Description
		coupled to the plurality of extended needles"
'536 Patent	13	"draft shaft"
'812 Patent	1, 12	"the releasably couplable deployable needle module mechanically separatably from the user holdable device proximal end"
'812 Patent	1, 12	"releasably couplable deployable needle assembly"
'812 Patent	1, 12	"the needle assembly movable within the releasably couplable deployable needle module to extend the plurality of needles from the releasably couplable deployable needle assembly end surface while at least one electrical contact of the needle assembly remains electrically coupled to at least one electrical contact of the user holdable device proximal end"

1. "pulsed radio frequency signals" (All claims of the '774 Patent)

679. It is my opinion that the phrase "pulsed radio frequency signals" renders all asserted claims of the '774 Patent invalid for lack of written description to the extent this phrase is construed consistent with the construction Serendia has proposed. Serendia proposes that this term be construed simply to mean "radio frequency signals that are normally off and suddenly on for a period of time (*i.e.*, a rapid, transient change from a baseline to a different amplitude, followed by rapid return to baseline)." Serendia's construction is overly broad and is not supported by the '774 Patent specification.

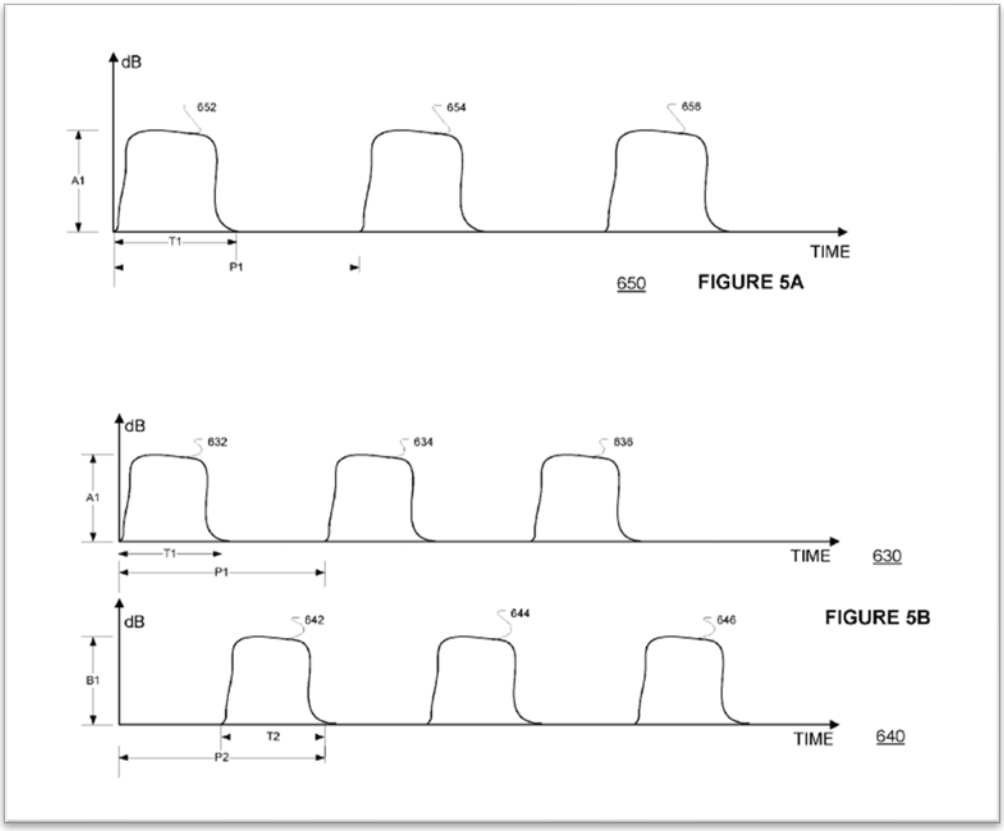
680. The patent specification describes, in detail, pulses to power LEDs ('774 Patent at 6:18-30) or vibrate the pins (needles), but does not describe either of these pulses as being an

RF signal. Radio Frequency is only mentioned once in the specification (*id.* at 10:20) without specifying how that signal is applied, *e.g.*, continuous, pulsed, etc. (*see id*.). The '774 Patent describes different operational modes (*e.g.*, "blend operational mode" and "coagulation mode"), but no description is provided for the different signals used in blend (*id.* at 13:63) or coagulation mode (*id.* at 14:21-25). Although "duty cycle" (*id.* at 13:64-65) and "number of shots per activation" (*id.* at 14:23-24) are mentioned, there is no indication that RF pulses are produced. Conventional electrosurgery uses various types of amplitude and frequency modulation to achieve coagulation and blend modes, without using any actual pulse.

681. In my opinion, if Serendia's claim construction is adopted, then there is no written description for claim 11 of the '774 Patent and that claim is invalid. As an initial matter, the '774 Patent contains only a single disclosure of the use of radiofrequency signals. 774 patent at 10:20-23 ("The CPU module 911 may include a radio frequency (RF) signal generator (RFSG) module 911A , a needle deployment motor controller (NDMC) module 911B, and a photonic signal generator module (PSG) 911C"). The '774 Patent describes only "square-wave" pulses that can be applied to LEDs; however, nowhere in the '774 specification is it mentioned that the pulses can also be the envelope of the RF signal. To the extent Serendia is contending that the pulse can take on any shape as long as the signal amplitude changes quickly, that has no support in the '774 Patent.

682. To the extent Serendia argues that the claim language merely requires "appl[ying]" radio frequency signals in pulses, it is my opinion that such an interpretation is not supported. Rather, the specification clearly shows pulses that occur at frequencies far below radio frequency. Even if the pulse width of 200 microseconds ('774 Patent at 6:53) is in the lower range of radio frequency, the period of 100-250 ms between pulses ('774Patent 6:48-50)

corresponds to a frequency of 4-10 Hz which is far below the lowest end of what is considered to be radio frequency much less the 100kHz considered as the lowest end of radio frequency for medical use).



683. Every embodiment described in the specification demonstrates that the pulses shown in Figures 5A and 5B occur at low frequency. The entirety of the relevant description provides:

> FIGS. 5A-5B are diagrams of electrical signal waveforms 650, 630, 640 that may be applied to one or more LEDs 32A, 32B, 532 and to the pins 230, 351, 451 according to various embodiments. The signal waveform 650 includes several square-wave pulses 652, 654, 656 that may be applied to an LED 32A, 32B, 532. Each pulse 652, 654, 656 may a have a similar magnitude and envelope. The waveform 650 may be used to energize an LED 32A, 32B, 532 and to the pins 230, 351, 451 periodically P1 for a predetermined interval T1 where each pulse 652, 654, 656 has

> a[n] amplitude A1. In an embodiment, A1 may be about 0.1 milliamperes (mA) to 10 mA, the pulse width T1 may be about 100 microseconds (μs) to 500 μs and the period P1 may from 100 ms to 500 ms as a function of the energy required to create capacitance in a liquid.

'774 Patent, 6:13-27.

> In FIG. 5B a signal waveform 630 may be applied to a first LED 32A, 32B, 532 module or group and to the pins 230, 351, 451 and a second waveform 640 may be applied or used to energize a second LED 32A, 32B, 532 module and the pins 230, 351, 451, 352. The signal waveform 630 includes several square-wave pulses 632, 634, and 636 and the signal waveform 640 includes several square-wave pulses 642, 644, and 646. Each pulse 632, 634, 636, 642, 644, 646 may a have a similar magnitude and envelope. The waveform 630 may be used to energize a first LED 32A, 32B, 332 module and the pins 230, 351, 451 periodically P1 for a predetermined interval T1 where each pulse 632, 634, 636 has an amplitude A1. The waveform 640 may be used to energize a second LED 32A, 32B, 332 module and the pins 230, 351, 451 periodically P2 for a predetermined interval T2 where each pulse 642, 644, 646 has an amplitude B1. The pulse width T1, T2 may be about 100 microseconds (μs) to 500 μs and the period P1, P2 may [be] from 100 ms to 500 ms as a function of the energy to affect dermatological cells or chemicals 22A.

Id. at 6:32-51.

684. Serendia's Patent Owner's Preliminary Response took the position that "pulsed radio frequency signals" is "a radio frequency signal that is normally off and suddenly on for a portion of time." POPR IPR2022-00376 at 16. Serendia's definition says nothing about "applied" pulses of RF signal because there is no disclosure of an embodiment where an RF signal is applied in pulses.

685. Based on my review, Serendia argues in various places in its Validity Contentions that Na '848 discloses only signals for vibrating pins, not pulsed radio frequency signals, and Figures 5A, 5B, and 6 are only about vibrating pins, not about pulsed radio frequency signals. However, I understand that Na '848 is part of the same patent family as the

‘774 Patent, and the disclosures of the “pulsed signals” in Na ‘848 are identical to those in the ‘774 Patent. It is my opinion that, to the extent Serendia contends Figs. 5A, 5B, and 6 do not disclose pulsed radiofrequency signals in Na ‘848, the ‘774 Patent lacks written description for “pulsed radio frequency signals” because the term “pulse” does not appear anywhere in the new disclosure added to the ‘774 Patent specification relative to Na ‘848.

2. “the releasably couplable deployable needle assembly, the deployable needle assembly mechanically separatably from the proximal end” (claims 1 and 11 of the ‘536 Patent)

686. Based on my review, the term “mechanically separatably” does not appear anywhere in the ‘536 Patent specification, and the ‘536 specification does not set forth any description or depictions that support the claim language “deployable needle assembly mechanically separatably from the proximal end.” It is my understanding that Complainant has admitted that the word “separatably” as it appears in the claims is an error (*see* Complainant’s Proposed Constructions of Disputed Claim Terms dated May 19, 2023), and Respondents contend that claim errors are not correctable in an ITC proceeding. Thus, under Respondents construction, the expression “the deployable needle assembly mechanically separatably from the proximal end,” as recited in claims 1 and 11 of the ‘536 Patent, lacks support in the ‘536 specification.

687. To the extent that Serendia’s proposed construction for “deployable needle assembly mechanically separatably from the proximal end” is adopted, and Serendia argues that this means the assembly does not itself need to be mechanically separatably from the proximal end and that this limitation can be satisfied by the assembly being indirectly separable based on the module being mechanically separatably from the proximal end, claims 1 and 11 of the ‘536 Patent lack written description. Based on my review, there is no disclosure in the ‘536 specification which depicts or describes an assembly being mechanically separatably from the

proximal end based on only the module, and not the assembly, being mechanically separatably from the proximal end.

3. "a plurality of needles extendable from the deployable needle assembly end surface" (claims 1 and 11 of the '536 Patent)

688. In my assessment, the '536 specification does not describe or depict a plurality of needles which are extendable from a deployable needle assembly end surface. As can be seen, for example, in Figures 10A-10E and Figs. 11A-11B of the '536 Patent, the end surface of the needle assembly 924 has a fixed relationship relative to the plurality of needles, and the '536 specification does not describe that the needles are *extendable from* this surface. Rather, the '536 specification depicts the needles being extendable from the module end surface. *See, e.g.*, Figs. 9C-9D.

4. "communicating electrical signals from the proximal end to the plurality of the extendable needles… energizing the plurality of extended needles via a signal generator electrically coupled to the plurality of extended needles" (claim 1 of the '536 Patent)

689. In my opinion, the '536 specification does not describe or depict a step of "communicating electrical signals from the proximal end to the plurality of the extendable needles" as being a separate step relative to "energizing the plurality of extended needles via a signal generator electrically coupled to the plurality of extended needles" in the context of a method of treating dermatological tissue. The '536 specification does not describe a step of communication of electrical signals from the proximal end to the plurality of extendable needles separate from energizing the plurality of extended needles via a signal generator electrically coupled to the plurality of extended needles. *See, e.g.*, '536 Pat. at col. 6:13-58, Figs. 5A-5B. Thus, the '536 specification does not support an embodiment where these two operations are separated from one another into distinct steps of a method of treating dermatological tissue.

5. "draft shaft" (claim 13 of the '536 Patent)

690. It is my understanding that Complainant has admitted that the phrase "draft shaft" as it appears in claim 13 of the '536 Patent is an error (*see* Complainant's Proposed Constructions of Disputed Claim Terms dated May 19, 2023), and Respondents contend that errors are not correctable in an ITC proceeding. Based on my review, the words "draft shaft," as recited in claim 13 of the '536 Patent, are not found in the '536 specification, as the '536 specification does not use this language. If Respondents' claim construction is adopted, there are no disclosed embodiments that correspond to this language.

6. "the releasably couplable deployable needle module mechanically separatably from the user holdable device proximal end" (claims 1 and 12 of the '812 Patent)

691. Based on my review, the term "mechanically separatably" does not appear anywhere in the '812 Patent specification, and the '812 specification does not set forth any description or depictions that support the claim language "the releasably couplable deployable needle module mechanically separatably from the user holdable device proximal end." It is my understanding that Complainant has admitted that the word "separatably" as it appears in the claims is an error (*see* Complainant's Proposed Constructions of Disputed Claim Terms dated May 19, 2023), and Respondents contend that errors are not correctable in an ITC proceeding. Thus, if Respondents' claim construction is adopted, the expression "the releasably couplable deployable needle module mechanically separatably from the user holdable device proximal end," as recited in claims 1 and 12 of the '812 Patent, lacks support in the '812 specification.

7. "the needle assembly movable within the releasably couplable deployable needle module to extend the plurality of needles from the releasably couplable deployable needle assembly end surface while at least one electrical contact of the needle assembly remains electrically coupled to at least one electrical contact of the user holdable device proximal end" (claims 1 and 12 of the '812 Patent)

692. It is my opinion that the '812 specification does depict and describe that the needle assembly is movable within the releasably couplable deployable needle module, but the '812 specification fails to depict or describe that such movement *is to extend the plurality of needles from the releasably couplable deployable needle assembly end surface while at least one electrical contact of the needle assembly remains electrically coupled to at least one electrical contact of the user holdable device proximal end*. As can be seen, for example, in Figures 10A-10E and Figs. 11A-11B of the '812 Patent, the end surface of the needle assembly 924F has a fixed relationship relative to the plurality of needles, and the '812 specification does not describe that movement of the assembly causes extension of the needles relative to the end surface of the needle assembly. Rather, the '812 specification depicts the needle assembly being movable within the module to extend the needles from the module 924 end surfaced. *See, e.g.*, Figs. 9C-9D.

E. The claims of the '536, '774, and '812 Patents lack enablement.

693. For at least the reasons set forth above with respect to written description, as well as the reasons set forth below, the following claim elements lack enablement and are therefore invalid under pre-AIA 35 U.S.C. § 112, 1¶:

Asserted Patent	Asserted Claim(s)	Term(s) and/or Phrase(s) Lacking Enablement
'774 Patent	All	"pulsed radio frequency signals"
'536 Patent	1, 11	"the deployable needle assembly mechanically separatably from the proximal end"

Asserted Patent	Asserted Claim(s)	Term(s) and/or Phrase(s) Lacking Enablement
'536 Patent	13	"the motor including a draft shaft releasably couplable to the deployable needle assembly"
'812 Patent	1, 12	"the releasably couplable deployable needle module mechanically separatably from the user holdable device proximal end"

694. In my opinion, a POSITA, having read the specification at the time of invention, would not be able to make and use the claim elements set forth above. With respect to the *Wands* factors, in my opinion at least that the quantity of experimentation to make and use the claimed invention was high, there were no working examples developed by the Applicants at the time of invention, and there is no disclosure of these elements.

1. "pulsed radio frequency signals (all claims of the '774 Patent)

695. For the same reasons discussed for lack of written description, it is my opinion that the specification is not enabling with respect to a "pulsed radio frequency signals" to the extent this term is not construed consistently with the specification, including the fact that the pulses occur at frequencies below radiofrequency. As an initial matter, the '774 Patent contains only a single disclosure of the use of radiofrequency signals. '774 Patent at 10:20-23 ("The CPU module 911 may include a radio frequency (RF) signal generator (RFSG) module 911A , a needle deployment motor controller (NDMC) module 911B, and a photonic signal generator module (PSG) 911C"). The '774 Patent describes only "square-wave" pulses that can be applied to LEDs; however, nowhere in the '774 specification is it mentioned that the pulses can also be the envelope of the RF signal. The factual considerations provided by the *Wands* factors, including "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the

predictability or unpredictability of the art, and (8) the breadth of the claims," counsel in favor of finding a lack of enablement for this claim term.

696. A POSITA, having read the specification at the time of invention, would not be able to make and use the claim elements set forth above. The specification does not provide any discussion of "apply[ing]" or "pulsing" radiofrequency signals on the electrodes. Accordingly, it is my opinion that a POSITA would essentially have to invent through undue experimentation a mechanism for taking a radio frequency signal and "appl[ying]" or "puls[ing]" it to practice the claims.

697. With respect to the *Wands* factors, each factor points to a lack of enablement:

- The quantity of experimentation needed to achieve the claimed effects would be extremely high and potentially impossible (Factor 1). A POSITA would have to conduct numerous experiments to determine how and to what extent radio frequency (RF) signals should be applied in pulses to meet the claims. This is undue experimentation.
- The specification provides no guidance or direction for how RF is applied in pulses (Factor 2). Without guidance, the specification, at best, offers a starting point for a POSITA to conduct further research.
- The specification provides no working examples of embodiments containing RF signals applied in pulses (Factor 3).
- The nature of the invention is complex (Factor 4). All the claims are directed to a handheld dermatological treatment apparatus having an electrical signal generator coupled to electrode needles which extend into the skin, and having a disposable needle electrode cartridge module that can be removed and disposed after treatment.

Given the nature of the invention, the specification should provide guidance regarding the RF signals applied in pulses from the electrical signal generator. But the specification fails to do so.

- The state of the prior art in the area of the invention is well-known and extensive (Factor 5). Although a POSITA would be familiar with the prior art, a POSITA would still need to conduct confirmatory tests to ensure the presence of RF signals applied in pulses.
- The relative skill of those in the art (Factor 6) is high, with a POSITA holding an advanced degree and relevant work experience. Given the state of the prior art (Factor 5), a POSITA would be familiar with the techniques underlying the claimed invention but could not predict in advance the parameters for applying RF signals in pulses.
- The field of the claimed invention includes medical devices, biology, and biological processes, which can be unpredictable (Factor 7). This unpredictability is compounded here by the lack of guidance as to how to apply RF signals in pulses to achieve the claimed effect other than by trial-and-error.
- The breadth of the claims is broad, covering many parameters for potentially applying RF signals in pulses (Factor 8). The specification does not allow a POSITA to make and use the full scope of the claims, which includes pulsed RF signals, without undue experimentation.

698. Further, it is my understanding that Serendia argues in various places in its Validity Contentions that Na '848 discloses only signals for vibrating pins, not pulsed radio frequency signals, and Figures 5A, 5B, and 6 are only about vibrating pins, not about pulsed

radio frequency signals. *See, e.g.*, 2023.06.16 Serendia Initial Validity Contentions at 241 ("Na '848 discloses only signals for vibrating pins—not pulsed radio frequency signals across a plurality of needles to affect dermatological tissue near the plurality of needles. *See, e.g.*, Na '848 at ¶¶ 26-29, 33, 39-44, Figs. 5A, 5B, and 6."); *see also id.* at 242, 243.

699. Figures 5A, 5B, and 6 of Na '848 are identical to Figures 5A, 5B, and 6 of the '774 Patent, and paragraphs [0039]–[0041] of Na '848 are the identical description for Figs. 5A, 5B, and 6 as in the '774 Patent specification. *Compare* Na '848, [0039]–[0041] with '774 Patent, 6:13-7:10.

700. To the extent Serendia contends Figs. 5A, 5B, and 6 do not disclose pulsed radiofrequency signals, in my opinion the '774 Patent lacks enablement for "pulsed radio frequency signals" because the term "pulse" does not appear anywhere in the new disclosure added to the '774 Patent specification relative to Na '848.

701. For these reasons and others expected to be elucidated during fact and expert discovery, the specification fails to enable a POSITA to practice the claims of the '774 Patent.

2. "the releasably couplable deployable needle assembly, the deployable needle assembly mechanically separatably from the proximal end" (claims 1 and 11 of the '536 Patent)

702. It is my understanding that Complainant has admitted that the phrase "separatably" as it appears in the claims of the '536 Patent is an error (*see* Complainant's Proposed Constructions of Disputed Claim Terms dated May 19, 2023), and Respondents contend that errors are not correctable in an ITC proceeding. In my opinion, a POSITA would not be able to read the specification and practice the claimed invention with respect to the feature "the deployable needle assembly mechanically separatably from the proximal end," as recited in claims 1 and 11 of the '536 Patent.

703. For the same reasons discussed for lack of written description, as well as the reasons below, the specification is not enabling with respect to "the releasably couplable deployable needle assembly" being "mechanically separatably from the proximal end." The factual considerations provided by the *Wands* factors, including "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims," counsel in favor of finding a lack of enablement for this claim term.

704. A POSITA, having read the specification at the time of invention, would not be able to make and use the claim elements set forth above. The specification does not provide any discussion of any mechanism by which the needle assembly is "mechanically separatably" from the proximal end. Accordingly, a POSITA would essentially have to invent through undue experimentation a needle assembly that is "mechanically separatably from the proximal end" to practice the claims.

705. With respect to the *Wands* factors, each factor points to a lack of enablement:

- The quantity of experimentation needed to achieve the claimed effects would be extremely high and potentially impossible (Factor 1). A POSITA would have to conduct numerous experiments to determine how the needle assembly can be "mechanically separatably from the proximal end" to meet the claims. This is undue experimentation.
- The specification provides no guidance or direction for the mechanism behind how the needle assembly can be "mechanically separatably from the proximal end"

(Factor 2). Without guidance, the specification, at best, offers a starting point for a POSITA to conduct further research.

- The specification provides no working examples of embodiments showing the mechanisms behind how the needle assembly is "mechanically separatably from the proximal end" (Factor 3).
- The nature of the invention is complex (Factor 4). All the claims are directed to a handheld dermatological treatment apparatus having an electrical signal generator coupled to electrode needles which extend into the skin, and having a disposable needle electrode cartridge module that can be removed and disposed after treatment. Given the nature of the invention, the specification should provide guidance regarding the claim elements related to the needle assembly. But the specification fails to do so.
- The state of the prior art in the area of the invention is well-known and extensive (Factor 5). Although a POSITA would be familiar with the prior art, a POSITA would still need to conduct confirmatory tests to ensure the needle assembly is "mechanically separatably from the proximal end."
- The relative skill of those in the art (Factor 6) is high, with a POSITA holding an advanced degree and relevant work experience. Given the state of the prior art (Factor 5), a POSITA would be familiar with the techniques underlying the claimed invention but could not predict in advance the parameters for creating a needle assembly that is "mechanically separatably from the proximal end."
- The field of the claimed invention includes medical devices, biology, and biological processes, which can be unpredictable (Factor 7). This unpredictability is

compounded here by the lack of guidance as to the mechanisms behind the claimed needle assembly other than by trial-and-error.

- The breadth of the claims is broad and covers potentially many methods for creating a needle assembly that is "mechanically separatably from the proximal end." (Factor 8). The specification does not allow a POSITA to make and use the full scope of the claims without undue experimentation because it fails to offer any guidance on these claim elements.

706. Accordingly, it is my opinion, that the specification fails to enable a POSITA to practice the claims of the '536 Patent.

3. "the motor including a draft shaft releasably couplable to the deployable needle assembly" (claim 13 of the '536 Patent)

707. It is also my understanding that Complainant has admitted that the phrase "draft shaft" as it appears in claim 13 of the '536 Patent is an error (*see* Complainant's Proposed Constructions of Disputed Claim Terms dated May 19, 2023), and Respondents contend that errors are not correctable in an ITC proceeding. In my assessment, a POSITA would not be able to read the specification and practice the claimed invention with respect to the feature "the motor including a draft shaft releasably couplable to the deployable needle assembly," as recited in claim 13 of the '536 Patent.

708. For the same reasons discussed for lack of written description, the specification is not enabling with respect to "the motor including a draft shaft releasably couplable to the deployable needle assembly." The factual considerations provided by the *Wands* factors, including "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the

predictability or unpredictability of the art, and (8) the breadth of the claims," counsel in favor of finding a lack of enablement for this claim term.

709. A POSITA, having read the specification at the time of invention, would not be able to make and use the claim elements set forth above. The specification does not provide any discussion of any mechanism describing the motor and a draft shaft that is "releasably couplable to the deployable needle assembly." Accordingly, a POSITA would essentially have to invent through undue experimentation a "motor including a draft shaft releasably couplable to the deployable needle assembly."

710. With respect to the *Wands* factors, each factor points to a lack of enablement:

- The quantity of experimentation needed to achieve the claimed effects would be extremely high and potentially impossible (Factor 1). A POSITA would have to conduct numerous experiments to assemble a "motor including a draft shaft releasably couplable to the deployable needle assembly." This is undue experimentation.
- The specification provides no guidance or direction for how to assemble a "motor including a draft shaft releasably couplable to the deployable needle assembly" (Factor 2). Without guidance, the specification, at best, offers a starting point for a POSITA to conduct further research.
- The specification provides no working examples of embodiments showing "the motor including a draft shaft releasably couplable to the deployable needle assembly" (Factor 3).
- The nature of the invention is complex (Factor 4). All the claims are directed to a handheld dermatological treatment apparatus having an electrical signal generator

coupled to electrode needles which extend into the skin, and having a disposable needle electrode cartridge module that can be removed and disposed after treatment. Given the nature of the invention, the specification should provide guidance how "the motor including a draft shaft releasably couplable to the deployable needle assembly." But the specification fails to do so.

- The state of the prior art in the area of the invention is well-known and extensive (Factor 5). Although a POSITA would be familiar with the prior art, a POSITA would still need to conduct confirmatory tests to ensure draft shaft of the motor is releasably couplable to the deployable needle assembly.
- The relative skill of those in the art (Factor 6) is high, with a POSITA holding an advanced degree and relevant work experience. Given the state of the prior art (Factor 5), a POSITA would be familiar with the techniques underlying the claimed invention but could not predict in advance the parameters for how the motor would include a draft shaft releasably couplable to the deployable needle assembly.
- The field of the claimed invention includes medical devices, biology, and biological processes, which can be unpredictable (Factor 7). This unpredictability is compounded here by the lack of guidance as to how to assemble "the motor including a draft shaft releasably couplable to the deployable needle assembly" other than by trial-and-error.
- The breadth of the claims is broad, covering many parameters for potentially assembling a motor including a draft shaft releasably couplable to the deployable needle assembly (Factor 8). The specification does not allow a POSITA to make and use the full scope of the claims without undue experimentation because it fails to

provide any guidance regarding the motor and how the draft shaft is releasably couplable to the deployable needle assembly.

711. Accordingly, in my opinion, the specification fails to enable a POSITA to practice the claims of the '536 Patent.

4. "the releasably couplable deployable needle module mechanically separatably from the user holdable device proximal end" (claims 1 and 12 of the '812 Patent)

712. It is my understanding Complainant has admitted that the word "separatably" as it appears in the claims is an error (*see* Complainant's Proposed Constructions of Disputed Claim Terms dated May 19, 2023), and Respondents contend that errors are not correctable in an ITC proceeding. A POSITA would not be able to read the specification and practice the claimed invention with respect to the feature "the releasably couplable deployable needle module mechanically separatably from the user holdable device proximal end," as recited in claims 1 and 12 of the '812 Patent.

With respect to the *Wands* factors, each factor points to a lack of enablement:

- The quantity of experimentation needed to achieve the claimed effects would be extremely high and potentially impossible (Factor 1). A POSITA would have to conduct numerous experiments to determine how the needle module can be "mechanically separatably from the user holdable device proximal end" to meet the claims. This is undue experimentation.
- The specification provides no guidance or direction for the mechanism behind how the needle assembly can be "releasably couplable," "deployable," and "mechanically separatably from the proximal end from the user holdable device proximal end"

(Factor 2). Without guidance, the specification, at best, offers a starting point for a POSITA to conduct further research.

- The specification provides no working examples of embodiments showing the mechanisms behind how the needle assembly is "releasably couplable," "deployable," and "mechanically separatably from the proximal end from the user holdable device proximal end" (Factor 3).
- The nature of the invention is complex (Factor 4). All the claims are directed to a handheld dermatological treatment apparatus having an electrical signal generator coupled to electrode needles which extend into the skin, and having a disposable needle electrode cartridge module that can be removed and disposed after treatment. Given the nature of the invention, the specification should provide guidance regarding the claim elements related to the needle module. But the specification fails to do so.
- The state of the prior art in the area of the invention is well-known and extensive (Factor 5). Although a POSITA would be familiar with the prior art, a POSITA would still need to conduct confirmatory tests to ensure the needle assembly is "releasably couplable," "deployable," and "mechanically separatably from the proximal end from the user holdable device proximal end."
- The relative skill of those in the art (Factor 6) is high, with a POSITA holding an advanced degree and relevant work experience. Given the state of the prior art (Factor 5), a POSITA would be familiar with the techniques underlying the claimed invention but could not predict in advance the parameters for creating a needle

module that is "mechanically separatably from the proximal end from the user holdable device proximal end."

- The field of the claimed invention includes medical devices, biology, and biological processes, which can be unpredictable (Factor 7). This unpredictability is compounded here by the lack of guidance as to the mechanisms behind the claimed needle module other than by trial-and-error.
- The breadth of the claims is broad and covers potentially many methods for creating a needle assembly that is "releasably couplable," "deployable," and mechanically separatably from the proximal end from the user holdable device proximal end" (Factor 8). The specification does not allow a POSITA to make and use the full scope of the claims without undue experimentation because it fails to offer any guidance on these claim elements.

F. Certain Claims of the '536, '774, and '812 Patents are indefinite.

713. In my opinion, the Asserted Claims identified below are invalid under pre-AIA 35 U.S.C. § 112, ¶ 2 because they fail to inform, with reasonable certainty, those skilled in the art about the scope of the claimed invention(s):

Asserted Patent	Asserted Claim(s)	Indefinite Term(s) and/or Phrase(s)
'536 Patent	1, 11	"a [user holdable device releasably couplable] deployable needle assembly end surface" / "the deployable needle assembly mechanically separatably from the proximal end" /
'812 Patent	1, 12	"the releasably couplable deployable needle assembly end surface"

Asserted Patent	Asserted Claim(s)	Indefinite Term(s) and/or Phrase(s)
'812 Patent	1, 12	"the releasably couplable deployable needle module mechanically separatably from the user holdable device proximal end"
'536 Patent	13	"draft shaft"
'774 Patent	11[47]	"a plurality of needles one of extending or extendable... the plurality of extended needles"

1. "the releasably couplable deployable needle assembly, the deployable needle assembly mechanically separatably from the proximal end" (claims 1 and 11 of the '536 Patent)

714. Based on my review, the term "mechanically separatably" does not appear anywhere in the '536 Patent specification, and the '536 specification does not set forth any description or depictions that support the claim language "deployable needle assembly mechanically separatably from the proximal end." It is my understanding that Complainant has admitted that the word "separatably" as it appears in the claims is an error (*see* Complainant's Proposed Constructions of Disputed Claim Terms dated May 19, 2023), and Respondents contend that claim errors are not correctable in an ITC proceeding. Thus, under Respondents construction, the expression "the deployable needle assembly mechanically separatably from the proximal end," as recited in claims 1 and 11 of the '536 Patent, lacks support in the '536 specification.

715. To the extent that Serendia's proposed construction for "deployable needle assembly mechanically separatably from the proximal end" is adopted, and Serendia argues that this means the assembly does not itself need to be mechanically separatably from the proximal

[47] It is my understanding that Serendia is no longer asserting claim 11 of the '774 Patent. However, Serendia is asserting claim 13, which depends on claim 11 and 12. Accordingly, claim 11 is included in this analysis.

end and that this limitation can be satisfied by the assembly being indirectly separable based on the module being mechanically separatably from the proximal end, claims 1 and 11 of the '536 Patent lack written description. Based on my review, there is no disclosure in the '536 specification which depicts or describes an assembly being mechanically separatably from the proximal end based on only the module, and not the assembly, being mechanically separatably from the proximal end.

2. "a [user holdable device releasably couplable] deployable needle assembly end surface" (claims 1 and 11 of the '536 Patent) / "the deployable needle assembly mechanically separatably from the proximal end" (claims 1 and 11 of the '536 Patent) / "the releasably couplable deployable needle assembly end surface" (claims 1 and 12 of the '812 Patent)

716. It is my understanding that Complainant has admitted that the word "separatably" as it appears in the claims is an error (*see* Complainant's Proposed Constructions of Disputed Claim Terms dated May 19, 2023), and Respondents contend errors are not correctable in an ITC proceeding. To the extent Respondents claim construction is adopted, the phrase "the deployable needle assembly mechanically separatably from the proximal end," as recited in claims 1 and 11 of the '536 Patent, is not clear to a POSITA and fails to inform a POSITA with reasonable certainty of the scope of the invention.

717. Further, in my opinion, the phrase "the releasably couplable deployable needle assembly end surface" as recited in claims 1 and 12 of the '812 Patent is unclear as to what "releasably couplable deployable" means in relation to the needle assembly, as neither the context of the claim language nor the specification contains any indication as to what other element(s) the needle assembly is to be coupled to and how it is to be releasably coupled and deployed. A POSITA would thus not be able to ascertain with reasonable certainty whether or not these limitations with respect to the needle assembly are met.

3. "draft shaft" (claim 13 of the '536 Patent)

718. It is my understanding that Complainant has admitted that the phrase "draft shaft" as it appears in claim 13 of the '536 Patent is an error (*see* Complainant's Proposed Constructions of Disputed Claim Terms dated May 19, 2023), and Respondents contend that errors are not correctable in an ITC proceeding. In my assessment, the phrase "draft shaft," as recited in claim 13 of the '536 Patent, is not clear to a POSITA and fails to inform a POSITA with reasonable certainty of the scope of the invention.

4. "a plurality of needles one of extending or extendable... the plurality of extended needles" (claim 11 of the '774 Patent)

719. It is my opinion that there is no antecedent basis for "the plurality of extended needles" in claim 11 of the '774 Patent. There is a previous reference in claim 11 to "a plurality of needles one of extending or extendable a desired distance from a surface," but a POSITA would not be able to ascertain with reasonable certainty, from this claim language, whether "the plurality of extended needles" is referring back to a plurality of needles extending a desired distance from a surface or a plurality of needles extendable a desired distance from a surface, and further in the case of the plurality of needles extendable a desired distance from a surface, whether "the plurality of extended needles" is only referring to the plurality of extendable needles being in a retracted state, a fully extended state, and/or a partially extended state. Claim 7 may also state that the signal generator is only electrically coupled to the needles when they are in their extended position, which is not supported by the patent specification. Thus, in my assessment, this claim language fails to inform a POSITA with reasonable certainty of the scope of the invention.

XV. INVENTORSHIP

A. [redacted]

720. It is my understanding that Respondents assert that the Asserted Patents fail to name [redacted]

721. I have been informed that [redacted] However, [redacted]

722. Based on my review, [redacted] I understand that [redacted]

[redacted] I also understand that [redacted]

723. I also understand [redacted]. In particular, [redacted]

724. Furthermore, I have been informed that [redacted]

725. I understand [redacted]

[48] [redacted]

[redacted] I understand [redacted]

726. On the other hand, I understand from his deposition that Dr. Na testified that prior to 2010, he knew that there was an aesthetic device designed to transmit an RF signal to the skin but did not know the internal structure of the device because he was "not an engineer . . . just a doctor." Na Tr. 219:17–220:1. He still "[does] not have ample knowledge in that area" as to what would supply the RF signal to the electrodes. *Id.* Dr. Na also testified that he does not know whether AC current was used in conjunction with bipolar needle electrodes before 2010" because he is "not an engineer," "[does] not have ample knowledge in that area," and "[does] not know about the internal structure of such devices." Na Tr. 248:18–249:2.

727. I also understand that Serendia failed to provide any documents actually showing that Dr. Na conceived all of the ideas about the RF microneedling product prior to the meeting [redacted]

728. I also understand that Dr. Na asserts that he lost all electronic files and hard-copy documents around 2013 or 2014, and does not remember whether he kept his lab notebooks. *Id.* 98:3–99:11.

729. To the extent the ALJ finds [redacted]

[redacted]

730. Based on my review, [redacted]

XVI.INEQUITABLE CONDUCT

A. Failure to cite Hantash – *Lasers in Surgery* and Berube – *Lasers in Surgery*

731. It is my understanding that Respondents are asserting that at least the Asserted Patents are unenforceable as a result of the failure of at least the named inventor, Dr. Na, to cite the article Hantash, B., *et al*, "Pilot Clinical Study of a Novel Minimally Invasive Bipolar Microneedle Radiofrequency Device," *Lasers in Surgery and Medicine*, 41:87-95 (2009) ("Hantash – Lasers in Surgery"), and/or the article Berube *et al.*, "A Predictive Model of Minimally Invasive Bipolar Fractional Radiofrequency Skin Treatment," *Lasers in Surgery and Medicine*, 41:473-478 (2009) ("Berube"), during prosecution of those patents.

732. Dr. Na cited Hantash-Lasers in Surgery and Berube in his article entitled "Electromagnetic Initiation and Propagation of Bipolar Radiofrequency Tissue Reactions via Invasive Non-Insulated Microneedle Electrodes , which published on November 13, 2015. Na

et al., *Sci. Rep.* 5:16735 at 8 (Nov. 13, 2015) (the "Na article"). It is my understanding that each of the applications that resulted in the '836, '379, '444, '536, '774, and '812 Patents were either still pending or had not yet been filed as of the date of publication of the Na article.

733. I have reviewed Hantash-Lasers in Surgery and Berube and it is my opinion that Hantash-Lasers in Surgery and Berube are references that a reasonable examiner would have wanted to know about during the prosecution of each of the Asserted Patents. I reached my conclusion based, in part, on my review of Hantash-Lasers in Surgery and Berube claim charts for Hantash – Lasers in Surgery and Miratone submitted as part of the Final Invalidity Contentions.

734. Hantash describes a microneedle apparatus with releasable couplable deployable needles, driven by a motor to a predetermined depth, connected to a pulsed RF generator via extendable electrical contacts. He also describes how to accomplish fractional or patterned heat lesion in the dermis, or the epidermis and dermis, and provides concrete examples of parameter sets to generate oval shaped lesions around each electrode pair comparable to what is described in the Na and Na+ Effects. Yet, in his 2015 article, citing three different references including Hantash, Dr. Na states that "due to differences in the tissue impedances of skin layers, a water drop-shaped zone of electrothermal coagulation in the dermis is reportedly observed upon the delivery of RF energy to the skin through penetrating electrodes" Na at 5. In my opinion, the water drop-shaped zone described by Dr. Na is comparable to the coagulation around the electrode feature claimed in the '836, '379, and '444 Patents. As such, it is my opinion, that by Dr. Na's admission that Hantash discloses the comparable discrete coagulation zones features to the '836, '379, and '444 Patents, for which, as acknowledged during the prosecution, the

Examiner could not find any art. Thus, in my opinion, Hantash is not cumulative over any other reference cited during the prosecution of the '536, '774, and '812 Patents.

735. Berube discloses "a FEA model capable of accurately predicting the in vivo energy deposition pattern in human skin under various clinically relevant conditions." Berube at 474. Berube discloses that "[t]he thermal profile remained confined between the proximal and distal end of the electrodes." Berube at Abstract. In my opinion, the model described by Berube includes many of the aspects of the coagulation phenomenon claimed in the '836, '379, and '812 Patents. Thus, like Hantash, Berube is also not cumulative – it is prior art reading on an embodiment for which the USPTO did not find any prior art.

736. As explained above, Hantash – Lasers in Surgery and Berube provide disclosure of RF micro needling devices in which at least at some stage of the operation there is coagulation around and not between the electrodes pairs as is required by the "Na effect." As discussed in Section VIII, the claims of the '836, '379 and '444 Patents were distinguished, in part, based on the argument by Applicant that the claims required energy surrounding the electrodes but no energy passing between the electrodes. The Patent Examiner cited this argument in allowing these Patents. Given that this alleged distinguishing feature is disclosed in the Hantash- Lasers in Surgery and Berube references, both of which disclose RF Microneedling devices with biopolar electrodes, it is my opinion that a reasonable examiner would have wanted to know about these references in allowing these patents.

737. As set forth in the claim charts submitted by Respondents in their Final Invalidity Contentions, which I have reviewed and considered in forming my opinions, with respect to the '536, '774 and '812 Patents, it is my opinion that Hantash – Lasers anticipates and/or renders obvious claims 1, 4, 5, 9, 11, 13, 16 and 17 of the '536 Patent, anticipates and/or

renders obvious claims 11, 13 and 14 of the '774 Patent, and anticipates and/or renders obvious claims 1, 5, 6, 10, 12-14, 16, 17, 18 and 19 of the '812 Patent. Furthermore, it is my opinion that, like Hantash, Berube, alone or in conjunction with Hantash – Lasers in Surgery, renders obvious claims 1, 5, 9, 11, and 13 of the '536 Patent, claims 11, 13 and 14 of the '774 Patent and claims 1, 5, 6, 10, 12-14, 16, 17, 18 and 19 of the '812 Patent.

738. Therefore, those references are each material to the issue of patentability and should have been disclosed to the USPTO during prosecution. Dr. Na knew of the Hantash-Lasers in Surgery and Berube references, because he had cited them in the 2015 Na article and knew or should have known of their relevance to the patent applications on which he was the named inventor.

B. Addition of new matter

739. It is my understanding that Respondents are asserting that at least the '836 Patent is unenforceable because it introduced new matter into the specification. It is also my understanding, as a U.S. national phase of PCT/KR2012/004695 ("the '695 PCT application"), no new matter was permitted to be added to the specification, but a substitute specification was presented on September 23, 2013. As noted above and contrary to merely "correcting grammatical and language issues," as stated in the supplemental preliminary amendment filed on September 24, 2013, the substitute specification contains deletions, substitutions, additions, and recharacterizations of the invention and the prior art.

740. It is my opinion that an accurate translation of the '695 PCT specification would have been material to the patentability of the '836 Patent in particular because the as-filed translation of the '695 PCT specification places certain requirements on the Na-effect.

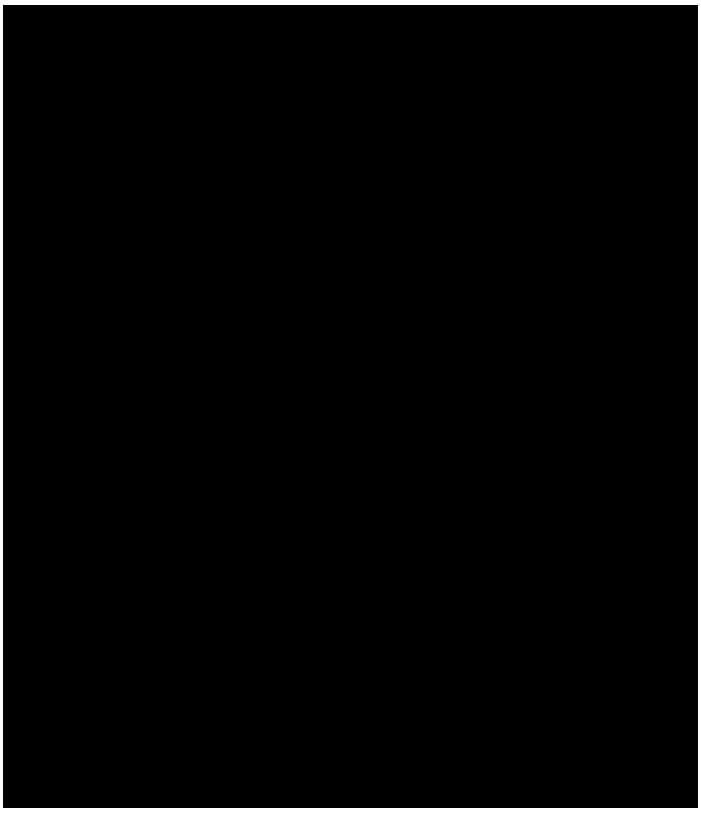
C. Failure to cite INTRAcel

741. It is my understanding that Respondents are asserting that at least the '812 Patent is unenforceable as a result of the failure to cite an April 8, 2011, INTRAcel video that was cited and relied upon by the Patent Trial and Appeal Board of the Korean Patent Office in invalidating the claims in a corresponding Korean patent. It is my understanding that as asserted in the Korean Patent Trial and Appeal Board proceeding, and as evidenced by the article "Evaluation of the wound healing response post-deep dermal heating by fractional RF: INTRAcel" by Yeo, 12th Symposium of the Association of Korean Dermatologists (2009), the INTRAcel product is believed to have been publicly available at least as early as October 9, 2009.

742. On November 30, 2018, the Patent Trial and Appeal Board of the Korean Patent Office issued a decision invalidating KR101181870B1 ("the Korean '870 Patent") (one of the priority documents to the '444 Patent) over, a video showing operation of the INTRAcel device. The invalidated claims of the Korean '870 Patent, which also lists Dr. Na as an inventor, were similar to claims of the '812 Patents. As provided in M.P.E.P. § 2001.06, "[t]he inference that such prior art or other information is material is especially strong where it has been used in rejecting the same or similar claims in the foreign application or where it has been identified in some manner as particularly relevant."

743. Notwithstanding that the Korean Patent Trial and Appeal Board decision includes stills of the INTRAcel video, it is my understanding that Dr. Na did not cite the Korean Patent Trial and Appeal Board decision, the INTRAcel video or any of the stills from that video during the prosecution of the'812 Patent. Dr. Na omitted citing the video despite being listed as the sole inventor on both the '444 and the '812 Patents and having cited both the '836 Patent

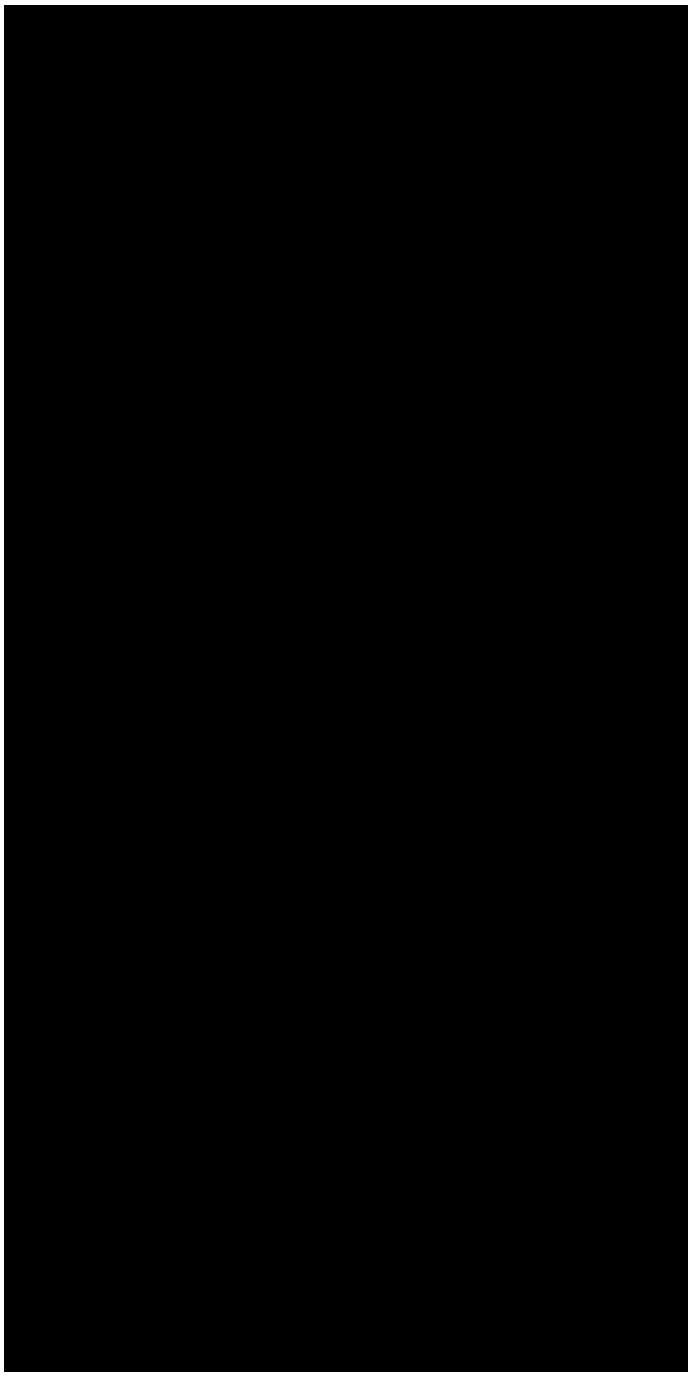
and the search report of the corresponding PCT application in the '812 Patent.[49] Claim 11 of '812 Patent is directed to an apparatus for treating dermatological tissue which requires: "a user holdable device including a proximal end", a "releasably couplable deployable needle module mechanically separatably from the user holdable device proximal end and including a needle assembly including a plurality of needles"; and a movable needle assembly "to extend the plurality of needles from the releasably couplable deployable needle assembly" into tissue "while at least one electrical contact of the needle assembly remains electrically coupled to at least one electrical contact of the user holdable device proximal end." It is my opinion that these features are shown in the video captures below from the Korean invalidation decision:



[49] In his deposition, Dr. Na admitted that he has known about the INTRAcel device since April 30, 2010.

Q. Is it fair to say that you knew of INTRAcel on or around 2010, 04/30?
A. Yes.

Transcript of Dr. Jongju Na, Volume 2, at 288:17-19.



744. Furthermore, while the invalidation decision was issued in 2018, the invalidation trial was requested on October 11, 2016. To the extent that Dr. Na was aware of the INTRAcel video before the October 3, 2017 issue date of the ‘774 Patent, Dr. Na should have also submitted the INTRAcel video or any of the stills from that video during the prosecution of the ‘774 Patent. The claims 13 and 14 of the ‘774 Patent require features that are disclosed in the

INTRAcel video or any of the stills from that video.

745. Specifically, it is my opinion that INTRAcel anticipates and/or renders obvious: claims 13 and 14 of the '774 Patent; and claims 1, 5, 6, 12, 13, 14, and 17 of the '812 Patent.

746. During the prosecution of the '774 Patent, the USPTO did not cite any prior art other than the '534 patent. As such, INTRAcel shows features that were not considered by the USPTO when allowing the '774 Patent. During the prosecution of the application that issued as the '812 Patent, in the response filed October 30, 2018, Mr. Richman stated that "the Examiner indicated that if the claims were amended to note the needles move independently of the entire disposable section, the[y] may be allowable." Based my review INTRAcel discloses this feature. Thus, INTRAcel also shows features that were not of record during the prosecution of the '812 Patent.

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747. On their faces, the '536, '774, and '812 Patents claim priority to Korean Patent Application No. 10-2008-0076993 ("'993 Application") filed by Dr. Na.[50] On August 22, 2008, Dr. Na and Mr. Richman, both the prosecuting attorney and co-inventor, filed a PCT application (PCT/US2008/074131; "'131 Application"), which claims priority to the '993 Application.[51] I have been informed that on March 3, 2011, Applicants, Dr. Na and Mr. Richman, subsequently filed a national stage application in Korea (Korea Patent Application No. 10-2011-7005052; "'052 Application"), which claims priority to the '131 application. Applicants newly added three paragraphs in the '052 Application, which among other things, explained that "the high-

[50] It is my understanding that the priority claim to the '993 patent on the face of '536, '774, and '812 Patents is ineffective.
[51] The '131 Application published as Na '848.

frequency, such as radio waves, are basically alternating current." ('052 Application at [0016]). Thus, the '052 Korean Application makes clear that high frequency waves, *e.g.*, radiofrequency waves, are alternating current.

748. On September 23, 2013, Dr. Na filed U.S. Application No. 14/006,930 ("'930 Application") which ultimately issued as the '836 Patent. Dr. Na was the sole inventor, and Mr. Richman was the prosecuting attorney for the '930 Application. Early in the prosecution of the '930 Application, Dr. Na and Mr. Richman amended the claims to recite "a signal generation module . . . coupled to the set of electrodes and providing high frequency signals to the bipolar electrodes." Complaint, Appendix A ('836 FH), Response Under 37 CFR 1.111 (July 7, 2015) at 3.

749. The USPTO rejected the claims under § 102(b) as being anticipated by U.S. Patent Publication No. 2005/0222565 ("Manstein"), citing Manstein's disclosure of needles operating "in bipolar mode . . . delivering RF." (Manstein at [0043]); Complaint, Appendix A ('836 FH), Detailed Action (Aug. 4, 2015) at 4.

750. Manstein describes an energy source 320 as supplying power to bipolar electrodes. Manstein at [0041]-[0042]. Manstein also describes this energy source 320 as "a radio frequency (RF) device capable of outputting signals having frequencies in a desired range." Manstein at [0032]. As Dr. Na admitted in his own publication, it was well-known in the art that radiofrequency (also called as high frequency) energy is generated from alternating current (AC). Electromagnetic Initiation and Propagation of Bipolar Radiofrequency Tissue Reactions via Invasive Non-Insulated Microneedle Electrodes, Na, J. *et al.*, *Scientific Reports* (2015) 5:16735 at 1 ("[R]adiofrequency (RF) refers to high frequency alternating electrical current at the frequency range traditionally used for radio-wave communication."); *see also*

Radiofrequency Catheter Ablation for Cardiac Tachyarrhythmias, Manolis, A.S., *et al.*, *Ann Intern Med.* (1994) 121:452-461 at 452 ("Radiofrequency energy is a form of electrical energy, generated from low-power (15 to 60 V), high-frequency (30 KHz to 300 MHz) alternating current.") and IEC 60601-2-2 (section 201.8.4.102). As such, a POSITA would have recognized that the radiofrequency signals in Manstein are alternating current signals. Manstein therefore described, in a single embodiment, the application of radio frequency alternating current signals to bipolar electrodes.

751. In responding to the USPTO's rejections, Dr. Na and Mr. Richman amended the claims to specify that the claimed "signal generation module" provides "a high frequency Alternating Current (AC) . . . to . . . the . . . electrodes." *Id.*, Response Under 37 CFR 1.111 (Oct. 18, 2015) at 2. To overcome the USPTO's rejections, Dr. Na and Mr. Richman further stated that "the Manstein reference does not teach applying a high frequency Alternating Current signal to bipolar electrodes." *Id.*, Response Under 37 CFR 1.111 (Oct. 18, 2015) at 9.

752. After the USPTO then rejected the claims again based on Manstein, Dr. Na and Mr. Richman again stated that Manstein does not disclose the claimed "a radio frequency (RF) generation module . . . configured to provide an Alternating Current RF signal to the plurality of electrodes" because "Manstein clearly does not teach or suggest providing a high frequency AC signal to bipolar electrodes." *Id.*, Response Under 37 CFR 1.111 (Mar. 1, 2016) at 2, 8. In the remarks, Dr. Na and Mr. Richman distinguished between RF "in one embodiment" and AC in "another embodiment".

753. To the extent Complainant's proposed claim construction for the "Alternating Current (AC) RF signal," "Alternating Current (AC) Radio Frequency (RF) signal," and "RF signal with oscillating current" is adopted, the factual representations made to the USPTO by

Dr. Na and Mr. Richman to distinguish Manstein from the then-pending claims were false. Manstein in fact teaches, suggests, and describes, in a single embodiment, the application of high frequency AC signals to a plurality of electrodes operating in a bipolar mode. (Manstein, 4:25-29: "Radio frequency pulses of electrical current are then applied to one or more of the needles, which can function as electrodes in monopolar or bipolar modes to create regions of thermal damage and/or necrosis in the tissue surrounding the tips of the needles.")

754. Specifically, as noted, Dr. Na and Mr. Richman knew that, in a single embodiment of Manstein, the radio frequency signals applied to electrodes operating in a bipolar mode were high frequency alternating current signals. Dr. Na demonstrated this knowledge in the '052 application, which discloses that "high-frequency, such as radio waves, are basically alternating current." ('052 Application at [0016]).

755. The statements repeatedly made by Dr. Na and Mr. Richman to the USPTO clearly contradict Dr. Na and Mr. Richman's prior disclosure to the Korean Patent Office that a high-frequency signal, such as an RF signal, is "basically alternating current." And it was well known in the art that radiofrequency energy is generated from alternating current; this is also the only way to follow the international regulation (*see* above). Both Dr. Na and Mr. Richman had been aware of this fact at least since 2008 when they submitted the '052 Application to the Korean Patent Office. Consistent with the incorrect assertions made by Dr. Na and Mr. Richman, they also omitted from the '930 Application the disclosure they had made to the Korean Patent Office that high-frequency signals, such as RF signal, is "basically alternating current."

756. The USPTO relied upon the representations made by Dr. Na and Mr. Richman. In its Notice of Allowability, the USPTO stated "[t]he examiner agrees that with the applicant's

argument that the AC signal and RF signal are applied in different embodiments in the prior art (*e.g., see* [0032] of Manstein) and that there would be no motivation to combine the embodiments. [0052] of the applicant's specification is where the applicant discloses the RF AC signal being implemented in one embodiment." Complaint, Appendix A ('836 FH), Notice of Allowability (May 18, 2016) at 2. Based on my review, if Dr. Na and Mr. Richman's position was that Manstein did not disclose an AC signal with a radiofrequency, the Examiner was incorrect and neither Dr. Na nor Mr. Richman made any effort to correct the Examiner's statements.

757. Therefore, to the extent Serendia's construction is adopted, I believe that Dr. Na, as the applicant, and Mr. Richman, as the prosecuting attorney, misrepresented the facts concerning Manstein's disclosure of the claimed limitations and/or failed to correct the examiner's misunderstanding to obtain allowance of the '930 application. Accordingly, if Serendia's construction of the AC RF signal terms is adopted, I believe that the '836 Patent should be found unenforceable under the doctrine of inequitable conduct.

758. As will be explained, it is my opinion that the '379 and '444 Patents are also unenforceable for inequitable conduct. The '379 Patent is a continuation of the '836 Patent, and the '444 Patent is a continuation that traces of its lineage back to the '836 Patent. Dr. Na filed applications that issued as the '379 and '444 Patents as the sole inventor and applicant. Mr. Richman was the prosecuting attorney for both applications. Both the '379 and '444 Patents were examined by the same Assistant Examiner, Philip C. Edwards, that examined the '836 Patent.

759. Moreover, to the extent Serendia argues that the claims do not require energy to form around the needles but not between the needles, contrary to what was asserted to the

Patent Office during prosecution and in response to the petition for IPR, it is my opinion the '379 Patent would not have been issued but for Dr. Na and Mr. Richman's material omission in correcting the Examiner's misunderstanding of the arguments presented. In the "Reasons for Allowance," the Examiner concluded that "applying an RF signal with an oscillating current at an extremely high frequency which causes each needle to change polarity many times per second" and "[t]his results in the current or energy forming around each needle rather than between needles as is disclosed in the prior art." Complaint, Appendix B ('379 FH), Notice of Allowability (June 18, 2018) at 2.

760. Similar to the '379 Patent, to the extent Serendia takes a position that the claims do not require energy to form around the needles but not between the needles, the '444 Patent would not have been issued but for Dr. Na and Mr. Richman's material omission in correcting the Examiner's misunderstanding of the arguments presented during prosecution. In the "Reasons for Allowance," the Examiner specifically stated that "the allowable subject matter [was] requiring the RF signal to be oscillating current. . .. This produces the effect . . . where the RF energy flows around individual needles rather than between needles as each individual needle is completing the positive/negative flow path itself." Complaint, Appendix C ('444 FH), Notice of Allowability (March 23, 2022) at 2.

761. I believe that at the time of the invention of the '836 Patent, a POSITA would have known that an alternating current is a type of oscillating current that has no damping and zero as the neutral value around which it oscillates. As such, I believe that Dr. Na and/or Mr. Richman should have known this, yet Applicant omitted the information that the RF current, which is an alternating current, is an oscillating current by nature. *See, e.g.*, Catheter Ablation Using Radiofrequency Energy, Borggrefe, M., *et al.*, *Clin. Cardiol.* (1990) 13: 127-131 at 128,

Fig. 1 (showing oscilloscopic recordings of current wave forms of radiofrequency current). Both Dr. Na and Mr. Richman had been aware of the fact that an RF signal is an oscillating current at least since 2008 when they submitted to the Korean Patent Office the '052 Application, which disclosed that "high-frequency, such as radio waves, are basically alternating current."

XVII. HEARING EXHIBITS

762. I have not yet prepared any exhibits or demonstrative evidence for the Hearing set in this Investigation, but I may intend to do so pursuant to the schedule set by the Commission.

XVIII. SUPPLEMENTATION

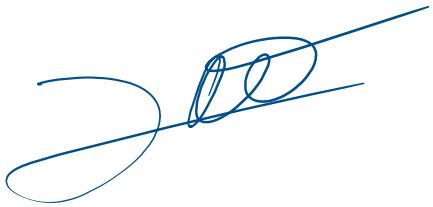
763. In preparing this report I have endeavored to identify all arguments for each claim of the Asserted Patents and to have consistency in the arguments relating to corresponding features in related Asserted Patents. To the extent an argument is presented with respect to a claim, or an element of a claim, of one Asserted Patent, and that argument is not presented with respect to that feature when found in an Asserted Claim of a related Asserted Patent, and unless otherwise indicated, I hereby incorporate that argument by reference. I reserve the right to amend or supplement this report based on further discovery and preparation in this action, including my review of any expert report submitted on behalf of Complainant, by any fact or expert witness, or any ruling on claim construction by the Commission.

XIX.CONCLUSION

764. I do hereby declare and state, that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be

true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that willful false statements may jeopardize the outcome of these proceedings. Accordingly, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Dated: August 14th, 2023



Jean Woloszko