

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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JEISYS MEDICAL INC. AND ILOODA CO., LTD.,  
Petitioners,

v.

SERENDIA, LLC,  
Patent Owner.

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U.S. Patent No. 9,320,536  
Filed: February 22, 2012  
Issued: April 26, 2016  
Inventor: Jongju Na

TITLE: METHOD, SYSTEM, AND APPARATUS  
FOR DERMATOLOGICAL TREATMENT

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*Inter Partes* Review No. IPR2024-00384

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**[CORRECTED] DECLARATION OF DANY BÉRUBÉ IN SUPPORT OF  
PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,320,536**

## TABLE OF CONTENTS

|       |                                                                                       |    |
|-------|---------------------------------------------------------------------------------------|----|
| I.    | INTRODUCTION .....                                                                    | 1  |
| II.   | QUALIFICATIONS AND PROFESSIONAL BACKGROUND .....                                      | 1  |
| III.  | INFORMATION CONSIDERED.....                                                           | 7  |
| IV.   | LEGAL STANDARDS .....                                                                 | 7  |
| A.    | Level of Ordinary Skill in the Art.....                                               | 8  |
| B.    | Claim Construction .....                                                              | 8  |
| C.    | Anticipation .....                                                                    | 9  |
| D.    | Obviousness.....                                                                      | 9  |
| V.    | FIELD OF TECHNOLOGY AND STATE OF THE ART .....                                        | 12 |
| A.    | Microneedling Devices in the Aesthetics Industry .....                                | 12 |
| B.    | Use of Disposable Needles in Microneedling Devices .....                              | 13 |
| C.    | Fine Control of Microneedle Insertion Depth.....                                      | 14 |
| D.    | Illumination of Treatment Areas .....                                                 | 15 |
| VI.   | THE '536 PATENT .....                                                                 | 16 |
| A.    | Overview of the '536 Patent.....                                                      | 16 |
| B.    | Priority date of the claims of the '536 Patent.....                                   | 22 |
| C.    | Prosecution History of the '536 Patent .....                                          | 26 |
| D.    | The Challenged Claims of the '536 Patent .....                                        | 27 |
| VII.  | LEVEL OF ORDINARY SKILL IN THE ART .....                                              | 27 |
| VIII. | CONSTRUCTION OF CLAIM TERMS .....                                                     | 28 |
| A.    | Agreed Constructions From The ITC Investigation .....                                 | 28 |
| B.    | “deployable needle assembly end surface” .....                                        | 29 |
| C.    | “a desired distance” / “predetermined depth” .....                                    | 29 |
| D.    | “separatably” .....                                                                   | 32 |
| E.    | “the deployable needle assembly mechanically separatably from the proximal end” ..... | 32 |
| F.    | “draft shaft” .....                                                                   | 32 |

|     |                                                                                                      |     |
|-----|------------------------------------------------------------------------------------------------------|-----|
| IX. | OVERVIEW OF THE PRIOR ART .....                                                                      | 33  |
| A.  | Mehta (EX1004).....                                                                                  | 33  |
| B.  | Na '848 (EX1005).....                                                                                | 36  |
| C.  | Livneh (EX1012).....                                                                                 | 37  |
| D.  | Lee (EX1011).....                                                                                    | 39  |
| X.  | THE CHALLENGED CLAIMS ARE UNPATENTABLE.....                                                          | 41  |
| A.  | Ground 1: Claims 1–3, 6, 8–9, 11–13, 16, and 18–19 are Anticipated<br>by Mehta.....                  | 41  |
| 1.  | Independent Claim 11 .....                                                                           | 41  |
| 2.  | Dependent Claim 12 .....                                                                             | 65  |
| 3.  | Dependent Claim 13 .....                                                                             | 68  |
| 4.  | Dependent Claim 16 .....                                                                             | 69  |
| 5.  | Dependent Claim 18 .....                                                                             | 70  |
| 6.  | Dependent Claim 19 .....                                                                             | 71  |
| 7.  | Independent Claim 1 .....                                                                            | 74  |
| 8.  | Dependent Claim 2 .....                                                                              | 80  |
| 9.  | Dependent Claim 3 .....                                                                              | 81  |
| 10. | Dependent Claim 6 .....                                                                              | 81  |
| 11. | Dependent Claim 8 .....                                                                              | 81  |
| 12. | Dependent Claim 9 .....                                                                              | 82  |
| B.  | Ground 2: Claims 1–9 and 11–19 are Obvious over Mehta in view of<br>the knowledge of a POSA .....    | 82  |
| 1.  | Independent Claims 1 and 11.....                                                                     | 82  |
| 2.  | Dependents Claims 2–3, 6, 8–9, 12–13, 16, and 18–19 .....                                            | 93  |
| 3.  | Dependent Claims 4–5 and 14–15 .....                                                                 | 94  |
| 4.  | Dependents Claims 7 and 17.....                                                                      | 101 |
| 5.  | Dependents Claims 9 and 19.....                                                                      | 105 |
| C.  | Ground 3: Claims 4-5 and 14-15 are Obvious over Mehta, Na '848,<br>and the Knowledge of a POSA ..... | 105 |
| 1.  | Motivation to Combine Mehta with Na '848.....                                                        | 105 |

|     |                                                                                                        |     |
|-----|--------------------------------------------------------------------------------------------------------|-----|
| 2.  | Dependent Claims 4 and 14 .....                                                                        | 111 |
| 3.  | Dependent Claims 5 and 15 .....                                                                        | 112 |
| D.  | Ground 4: Claims 7 and 17 are Obvious over Mehta in view of Livneh .....                               | 114 |
| 1.  | Motivation to Combine Mehta with Livneh .....                                                          | 114 |
| 2.  | Dependent Claims 7 and 17 .....                                                                        | 121 |
| E.  | Ground 5: Claims 1–3, 6, 8–9, 11–13, 16, and 18–19 are obvious over Mehta and Lee .....                | 122 |
| 1.  | Motivation to Combine Mehta and Lee .....                                                              | 122 |
| 2.  | Independent Claims 1 and 11 .....                                                                      | 126 |
| 3.  | Claims 2–4, 6, 8–9, 12–14, 16, and 18–19 .....                                                         | 127 |
| F.  | Ground 6: Claims 1-9 and 11-19 are obvious over Mehta and Lee in view of the Knowledge of a POSA ..... | 128 |
| G.  | Ground 7: Claims 4-5 and 14-15 are Obvious over Mehta, Lee, Na '848, and the knowledge of a POSA ..... | 129 |
| 1.  | Motivation to Combine Mehta, Lee and Na '848 .....                                                     | 129 |
| H.  | Ground 8: Claims 7 and 17 are Obvious over Mehta, Lee and Livneh .....                                 | 130 |
| 1.  | Motivation to Combine Mehta, Lee and Livneh .....                                                      | 130 |
| XI. | ACKNOWLEDGMENTS .....                                                                                  | 132 |

I, Dany Bérubé, Ph.D., declare as follows:

## **I. INTRODUCTION**

1. I have been retained by Jeisys Medical, Inc. (“Jeisys”) and Ilooda Co., Ltd. (“Ilooda”) (collectively, “Petitioners”) as a technical expert in connection with a petition for *inter partes* review (“IPR”) of U.S. Patent No. 9,320,536 (“the ’536 patent,” EX1001). I understand that the ’536 patent is assigned to Serendia, LLC (“Serendia” or “Patent Owner”).

2. I have been asked, by counsel for Petitioners, to provide opinions based on my experience with and expertise in skin treatment technologies for the aesthetics industry. In particular, I have been asked to offer opinions regarding the patentability of claims 1–20 of the ’536 patent (the “Challenged Claims”) in view of certain prior art references and the knowledge of a person of ordinary skill in the art (“POSA”).

3. I am being compensated for my time in this matter at an hourly rate. I am also being reimbursed for reasonable and customary expenses associated with my work and testimony in this matter. My compensation is not contingent on the outcome of this matter or the specifics of my testimony. I have no personal or financial stake or interest in the outcome of the present proceeding.

## **II. QUALIFICATIONS AND PROFESSIONAL BACKGROUND**

4. My qualifications and professional experience are described in my curriculum vitae, a copy of which is provided herewith as Appendix A. The

following is a brief summary of my relevant qualifications and professional experience.

5. I received a Bachelor's Degree in Engineering Physics from the Université Laval in 1993 and a Doctor of Philosophy in Biomedical Engineering from the École Polytechnique de Montréal in 1998. For my Ph.D. thesis, I developed and characterized ablation systems for treating cardiac arrhythmias with microwave frequency electromagnetic energy. The aim of my study was to overcome known issues and limitations with then current and traditional radiofrequency ablation systems.

6. During my studies, I received numerous Scholarships and Awards. I received a High Distinction for my Ph.D. thesis from the École Polytechnique de Montréal. My thesis was selected as a top three best thesis of the year. I received scholarships from the Canadian government during my Ph.D. and undergraduate studies, and from the government of Quebec during my Master studies. I was selected as member of the Table of Honor during my undergraduate engineering studies.

7. I have worked in the area of biomedical engineering for over 25 years and have extensive experience with the application of electromagnetic radiation, e.g. radiofrequency energy, and ultrasonic energy to biological tissues for the treatment of medical conditions. I have experience with the research and development of

medical devices, the use of Finite Elements Analysis to model interactions with biological tissue, and the use of RF and other energy modalities for the treatment of skin. I have written and published peer-reviewed articles on RF microneedling technology, science, and clinical results. In particular, I published a peer-reviewed article characterizing the thermodynamic aspects of collagen denaturation and its influence on clinical results for the treatment of facial wrinkles and skin laxity.

8. I worked in the cardiovascular space from 1998 to 2008. During that time, I developed the first surgical microwave ablation system to treat stand-alone atrial fibrillation (AF) on a beating heart without cardio-pulmonary bypass, using thoracoscopic or robotic access. I also worked with cardiac surgeons to develop the technical aspects of the surgical procedure and published several technical and clinical papers, as well as abstracts.

9. In 2008, I began working in the aesthetics industry. From 2008 to 2020, I worked as Vice President of Research and Development (Profound Division) and as Vice President of Global Business Development and Strategy for Candela Medical (f/k/a Syneron) and for Primaeva Medical before its acquisition by Syneron. I led the development of the company's bipolar RF microneedling technology (called "Profound") from inception to commercial release. The Profound product (which was also known by other names, including Renesis, Miratone, and ePrime) was the first FDA-cleared bipolar RF microneedling system. During my tenure, I

managed all products and software updates and developed and implemented an IP portfolio related to the Profound technology. I acted as a hands-on scientist and performed Finite Element Analysis to model various radiofrequency, laser, and cryoablation system interactions with biological tissues in order to investigate and/or improve treatment concepts. I also served as an “in-house expert” for Profound, traveling around the world to meet and train physicians and distributors on the features and advantages related to the Profound science and technology.

10. After leaving Candela Medical in 2020, I took the position of Vice President of Scientific Affairs and Innovations with Sofwave Medical, which I held from July 2021 to August 2023. In that position, I identified and developed strategies and products aimed at addressing existing and new market opportunities in the area of skin treatment technology in the aesthetic industry. In addition, I developed the company’s intellectual property portfolio, including IP related to the company’s skin treatment technology. While working for Sofwave Medical, I performed finite element analyses (FEA) to model tissue heating for skin treatment devices for the treatment of wrinkles and skin laxity in the aesthetic industry using different energy types, including ultrasound and radiofrequency (RF). I have also used FEA to model various competitive devices such as RF microneedling devices. I have extensive experience in thermal analysis, acoustic, RF, microwave, laser, and cryoablation modeling. I also have experience in using and reviewing histology results.

11. In August 2023, I assumed my current position as the Vice President of Advanced Research and Innovations for Lutronic Aesthetic, Inc., where I am responsible for high-level product strategy, for scientific aspects related to product development, and for intellectual property protection. I regularly deliver Proof-of-Feasibility studies for early innovative concepts and provide Scientific input during all product development phases.

12. In the past five years, I have testified, either at trial or by deposition, in the following matters:

- U.S. International Trade Commission: *In the Matter of Certain Radio Frequency Micro-Needle Dermatological Treatment Devices and Components Thereof*, Inv. No. 337-TA-112.
- U.S. International Trade Commission: *In the Matter of Certain Dermatological Treatment Devices and Components Thereof*, Inv. No. 337-TA-1356.<sup>1</sup>

13. I am a named inventor on a number of patents, including the following:

- *End-firing microwave ablation instrument with horn reflection device* (U.S. Patent No. 6,287,302).
- *Microwave ablation instrument with insertion probe* (U.S. Patent No. 6,325,796).

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<sup>1</sup> Hereinafter referred to as the “ITC investigation.”

- *Microwave ablation instrument with a directional radiation pattern* (U.S. Patent No. 6,471,696).
- *Flexible device for ablation of biological tissue* (U.S. Patent No. 6,817,999).
- *Ablation instrument having a flexible distal portion* (U.S. Patent No. 6,893,436).
- *Microwave ablation instrument with insertion probe* (U.S. Patent No. 6,962,586).
- *Catheter having improved steering* (U.S. Patent No. 7,099,717).
- *Microwave ablation instrument with flexible antenna assembly and method* (U.S. Patent No. 7,301,131).
- *Method of positioning a medical instrument* (U.S. Patent No. 7,303,560).
- *Monopole tip for ablation catheter* (U.S. Patent No. 7,346,399).
- *Vacuum-assisted securing apparatus for a microwave ablation instrument* (U.S. Patent No. 7,387,627).
- *Electrode arrangement for use in a medical instrument* (U.S. Patent No. 7,393,352).
- *Apparatus and method for assessing transmuralty of a tissue ablation* (U.S. Patent No. 7,497,858).

- *Devices and methods for creating continuous lesions* (U.S. Patent No. 7,736,360).
- *Delivery system for delivering a medical device to a location within a patient's body* (U.S. Patent No. 8,657,815).
- *Delivery system for delivering a medical device to a location within a patient's body* (U.S. Patent No. 10,932,848).

### **III. INFORMATION CONSIDERED**

14. In forming my opinions, I read and considered the '536 Patent and its prosecution history, the exhibits listed in the Exhibit Lists filed with the Petition for *Inter Partes* Review of the '536 Patent, as well as the other materials referenced herein.

### **IV. LEGAL STANDARDS**

15. I have been informed that the following legal principles apply to analysis of patentability based on 35 U.S.C. §§ 102 and 103. I also have been informed that, in an *inter partes* review proceeding, a patent claim may be deemed unpatentable if it is shown by a preponderance of the evidence that the claim was anticipated by a prior art patent or publication and/or rendered obvious by one or more prior art patents or publications.

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

16. It is my understanding that the claims and specification of a patent are to be read and construed through the eyes of a hypothetical person of ordinary skill in the art (i.e. “POSA”) at the time the invention was made. To determine the appropriate level of one of ordinary skill in the art, I have been informed that the following factors may be considered: (a) the types of problems encountered by those working in the field and prior art solutions thereto; (b) the sophistication of the technology in question, and the rapidity with which innovations occur in the field; and (c) the educational level of active workers in the field.

**B. Claim Construction**

17. I have also been informed that, in order to assess whether the prior art satisfies a certain claim element in an invalidity analysis, the claim element must first be construed, and then the prior art must be evaluated to determine whether it satisfies the properly-construed element of the claim. I have been informed that a patent claim is to be construed from the perspective of a POSA at the time the invention was made, taking into account the claim language, the teachings of the patent specification, and the prosecution history.

18. I have been informed that the claims in the ’536 Patent should generally be understood in accordance with their plain and ordinary meaning, in the context of the ’536 Patent, to a POSA at the time the invention was made. Unless otherwise

specifically noted, my opinions in this Declaration are consistent with that plain and ordinary meaning.

**C. Anticipation**

19. I have been informed that a patent claim is invalid as being anticipated if each limitation of the claim is disclosed explicitly or inherently in a single prior art reference. I further understand that a limitation is disclosed inherently if it is necessarily present in the prior art reference or is the natural result flowing from the disclosure of the prior art reference.

**D. Obviousness**

20. I have been informed that a patent claim is invalid as being obvious if the differences between the claimed subject matter and the prior art are such that the claimed subject matter as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made. I also understand that, in order to assess whether a claim would have been obvious in light of the prior art, I must step back in time and take the viewpoint of a POSA at the time the invention was unknown and just before it was made. I must then make a determination whether the claimed invention “as a whole” would have been obvious at that time to that POSA. My opinions in this declaration take the viewpoint of a POSA in the timeframe

immediately prior to the priority date of the challenged claims of the '536 Patent, i.e. March 3, 2011.<sup>2</sup>

21. I have been informed that the following facts are considered in determining whether a claimed invention is invalid as obvious over the prior art: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art and (4) any “secondary considerations” that may serve as evidence of nonobviousness, such as commercial success, long felt but unsolved needs, and failure of others.

22. I have been informed that a POSA is presumed to know all relevant prior art. I have been informed that a reference may be modified or combined with other references or with a POSA’s own knowledge if a POSA would have found the modification or combination obvious. In considering whether a claim is obvious, I can take account of inferences and creative steps that a POSA would employ, and the common knowledge of the art that a POSA would possess.

23. I have been told that there is no rigid rule that a reference or combination of references must contain a “teaching, suggestion, or motivation” to combine references. However, I have also been informed that the “teaching, suggestion, or motivation” test can be a useful guide in establishing a rationale for combining elements of the prior art. I have been informed that this test poses the

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<sup>2</sup> See *infra* Section VI.B.

question as to whether there is an express or implied teaching, suggestion or motivation to combine prior art elements in a way that realizes the claimed invention, and that it seeks to counter impermissible hindsight analysis.

24. I have also been informed that the combination of familiar elements disclosed in the prior art according to known methods is likely to be obvious when it does no more than yield predictable results. I understand that if a technique has been used to improve one product and a POSA would recognize that it would improve similar products in the same way, the use of that technique is obvious—unless its actual application is beyond the skill of a POSA. I have been informed that the proper obviousness analysis considers whether a POSA would have a “reasonable expectation of success”—and not an “absolute predictability” of success—in achieving the claimed invention by modifying and/or combining prior art references.

25. I have been informed that obviousness does not require that the prior art contain an express suggestion to combine known elements to achieve the claimed invention. A reason to combine known elements to achieve the claimed invention may come from the prior art as a whole or individually, as filtered through the knowledge of a POSA. A reason for combining the elements in the manner claimed may also come from any need or problem known in the field.

26. I have also been informed that if a POSA can implement a predictable variation and would see the benefit of doing so, that variation is likely to be obvious. I have been told that in many fields, there may be little discussion of obvious combinations in the scientific literature and market demand may drive design trends. I have been told that, when there is a design need or market pressure and a finite number of predictable solutions, it would be obvious to a POSA to pursue those known options.

## **V. FIELD OF TECHNOLOGY AND STATE OF THE ART**

27. For this declaration, I have assumed that the priority date of the challenged claims is March 3, 2011.<sup>3</sup> Thus, for purposes of this analysis, I assume that the time of the purported invention of the '536 patent was March 3, 2011 and have provided an overview of the background of the relevant technology at that time.

### **A. Microneedling Devices in the Aesthetics Industry**

28. Microneedling devices were well known in the aesthetics industry prior to March 3, 2011. For example, in 2008, Syneron began development of the ePrime system (also known by the names “ReneSis” and “Miratone” and now marketed by Candela Medical (who acquired Syneron) as the ProFound system). The ProFound system is a bipolar RF microneedle system designed to create fractional thermal injuries in the dermis and thereby elicit the production of new collagen, elastin, and

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<sup>3</sup> See *infra* Section VI.B.

hyaluronic acid. The Profound system (then known as ePrime) was cleared by the U.S. Food and Drug Administration (FDA) for hemostasis and electrocoagulation in 2007 and for the percutaneous treatment of facial wrinkles in 2009. The Profound system was fully commercialized and sold in the US by 2010.

29. In addition, Jeisys commercially released, in 2009, a bipolar RF microneedle system (i.e. the INTRAcel system) in Asia. The INTRAcel system utilized a rectangular array of multiple microneedles to create fractional thermal injuries in dermis, thereby providing for the percutaneous treatment of facial wrinkles.

30. Furthermore, microneedle systems had also been disclosed, prior to March 3, 2011, by Mehta (i.e. EX1004), Na '848 (i.e. EX1005), U.S. Patent No. 7,824,394 to Manstein ("Manstein") (i.e. EX1015), U.S. Patent No. 7,618,429 to Mulholland ("Mulholland") (i.e. EX1016), and U.S. Patent Application Publication No. 2007/0142885 by Hantash et al. ("Hantash") (i.e. EX1017).

#### **B. Use of Disposable Needles in Microneedling Devices**

31. Before March 3, 2011, it was well known to use disposable components in medical devices and, in particular, to use disposable cartridges in microneedling devices in the aesthetics industry. For example, the Profound system, which was commercialized and sold in the U.S. in 2010, utilized detachable, disposable needle cartridges designed for the Profound console and handpieces. The user manual for

the Profound system included warnings that cautioned against reusing the disposable needle cartridges to limit the risk of infection and patient-to-patient transmission of blood-based diseases. In addition, detachable, disposable needle cartridges were also disclosed by Mehta (*see, e.g.*, EX1004 at FIG. 2D), Hantash (*see, e.g.*, EX1017 at FIG. 14B, ¶72), and U.S. Patent Application Publication No. 2009/0093749 by Shalev et al. (“Shalev”) (*see, e.g.*, EX1018 at FIG. 8, ¶¶179-180).

### **C. Fine Control of Microneedle Insertion Depth**

32. Before March 3, 2011, it was known to provide for fine control of needle insertion depth in microneedling treatment.

33. Components suitable for producing fine translational control of microneedles, such as, step-motors, solenoids, pneumatic actuators, and other similar technologies, had been known for decades prior to March 3, 2011. Furthermore, the use of a step-motor in a microneedling device to control microneedle insertion depth in a microneedling treatment device was disclosed by Lee. *See* EX1011 at <21>, <44>, <50>, <60>-<61>, and <69>. The use of a step-motor in a microneedling device to provide translational movement of an electrode assembly containing RF microneedles was also disclosed by Mehta. *See* EX1004 at 15:36-40.

#### **D. Illumination of Treatment Areas**

34. Before March 3, 2011, it was generally known to illuminate medical devices. And it was known in the aesthetics industry to illuminate microneedling treatment devices and components thereof—as well as to illuminate an area of the skin being treated by a microneedling treatment device.

35. Prior to March 3, 2011, the Profound system was sold with a 3-color LED (red, green, blue) assembly provided on the top of the handpiece. The Profound system's LED assembly provided different colors of illumination to communicate the status of the device, or of a patient's tissue, to a physician (specifically, a red color was provided to indicate an error, a blue color was provided during application of RF energy to provide a visual indication of the application of the RF energy, and a green color was provided when the needles were retracted within the cartridge to provide a visual indication that it is safe to move the handpiece to a next adjacent treatment location). The same feature is still being used by the Profound system that is marketed and sold today. In addition, Shalev disclosed the use of an LED to provide a physician with a signal indicating that the temperature of a patient's skin has exceeded a threshold value in response to receiving RF energy. *See* EX1018 at ¶¶[0287]-[0288]. Korean Registered Patent KR10-0719395 to Kang (“Kang”) (i.e. EX1013, EX1014) teaches a dermatological radiofrequency device for cosmetic treatment and, specifically, a device in which a light-emitting member (*e.g.*, LED)

“emits a predetermined color at the same time as the high frequency is applied.” *See* EX1014 at 4; *see also id.* at Abstract, cl. 4.

36. Prior to March 3, 2011, it was also well known to provide illumination during the treatment of skin, e.g. using microneedling devices. Multiple types of light therapy for treating skin were well known and had been known for decades. Such light therapy includes, for example, using wavelengths in the infrared spectrum, provided, e.g., by a laser or light emitting diode (LED), to heat a region of the patient’s skin. Na ’848, for example, discloses the use of an LED to generate infrared radiation that is directed to skin tissue into which microneedles are to be inserted. *See, e.g.*, EX1005 at ¶¶[0044]-[0048]. As another example, U.S. Patent Application Publication No. 2009/0048557 by Yeshurun *et al.* (“Yeshurun”) (i.e. EX1019) discloses a hand-held device for providing dermabrasion treatment, the hand-held device having LEDs for providing illumination to the region of skin subject to dermabrasion. *See, e.g.*, EX1019 at ¶¶[0086], [0090], and [0094]. It was also well known to embed such LEDs into a handheld device, as evidenced by Yeshurun. *See, e.g., id.* at FIG. 8; [0094].

## **VI. The ’536 Patent**

### **A. Overview of the ’536 Patent**

37. I understand that the ’536 Patent is one of five issued U.S. patents and two pending U.S. patent applications that claim priority to an international patent

application published as International Patent Publication No. WO 2010/016848 to Na *et al.* (“Na ’848”), which I understand is Exhibit 1005 to the petition, and which claims priority to a Korean patent application filed on August 6, 2008.

38. The ’536 patent relates to systems and methods “used in treating dermatological tissue.” EX1001 at 1:25-27. The ’536 patent provides “a dermalogical [*sic*] treatment architecture (DTA) 900” that includes “a signal generation and control module (SGC) 910, a hand module 920, and an actuator module 930.” *Id.* at 9:18-22. The DTA 900 is illustrated in FIG. 9A (reproduced below).

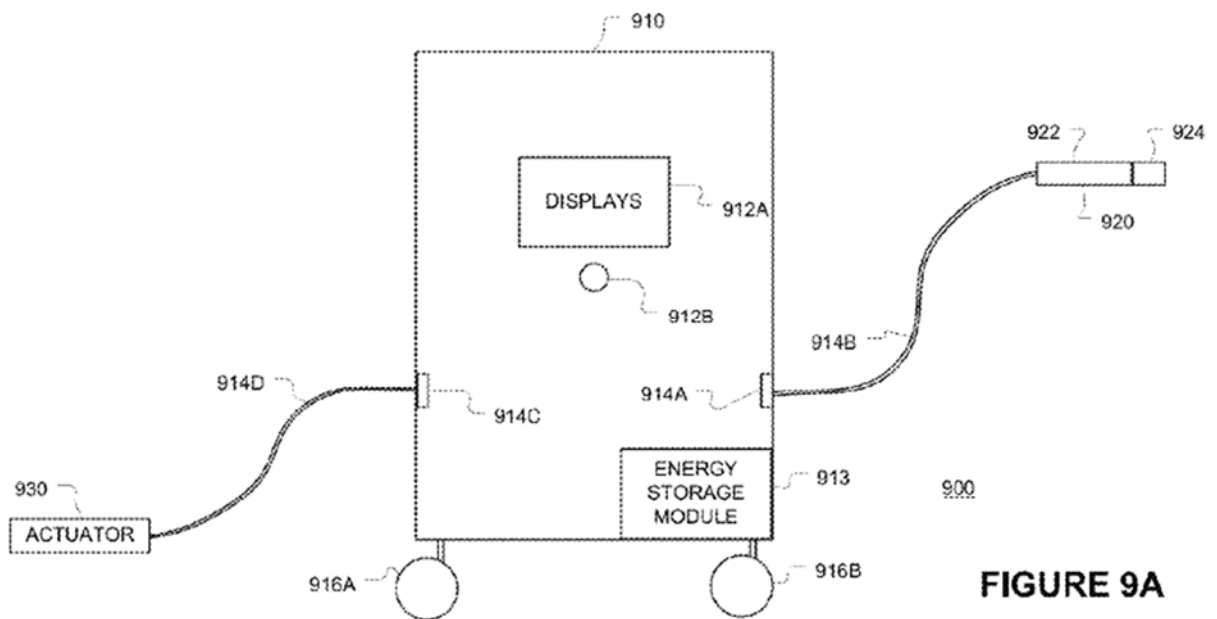
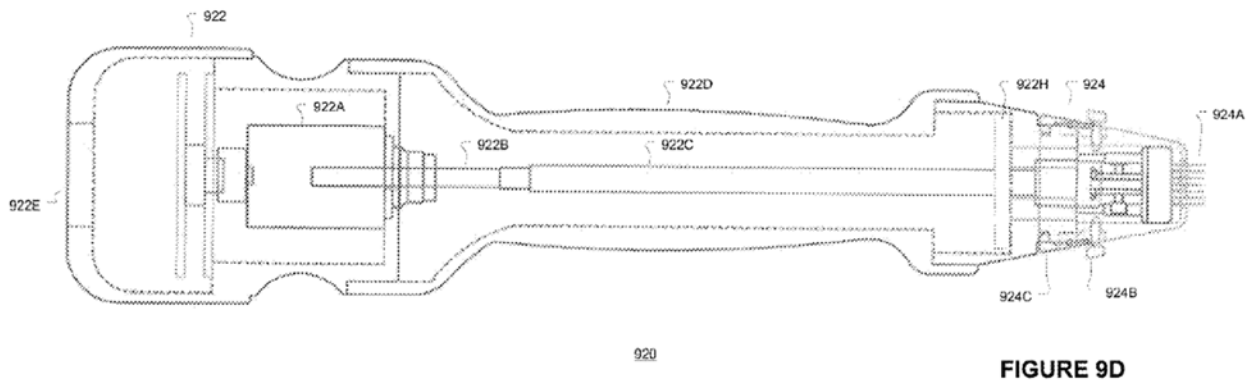
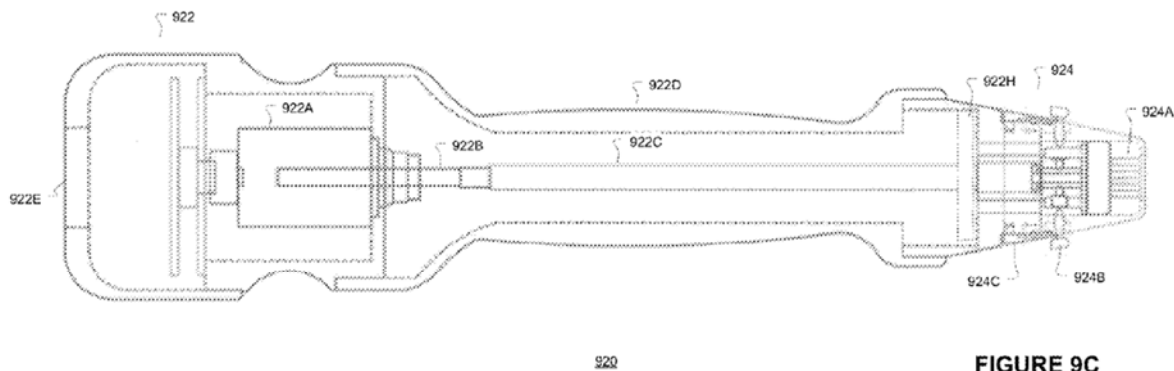


**FIGURE 9A**

**EX1001—FIG. 9A**

The DTA 900 specifically includes “cartridge based dermalogical [*sic*] treatment apparatus or hand module 920 with one or more needles 924A,” which is illustrated in FIGS. 9C and 9D (reproduced below). *Id.* at 10:42-45.

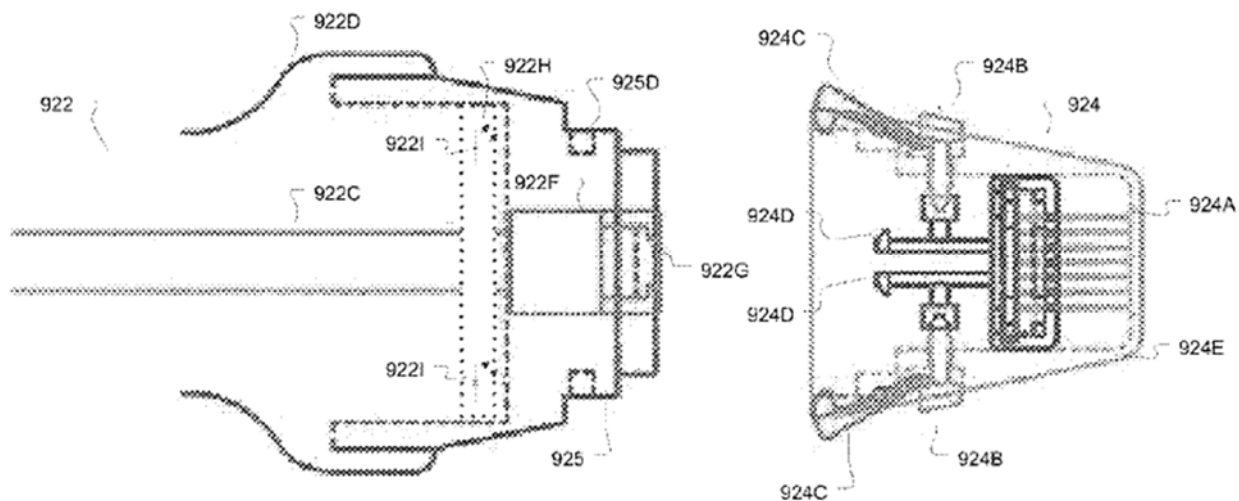


**EX1001—FIGS. 9C and 9D**

FIG. 9C illustrates the cartridge based hand module 920 with the needles 924A in a retracted position, while FIG. 9D illustrates the cartridge based hand module 920 with the needles 924A in an extended, or deployed, position.

39. The hand module 920 includes “a deployable needle module (DNM) 924 and a motor and LED module (MLM) 922,” the DNM 924 being a detachable

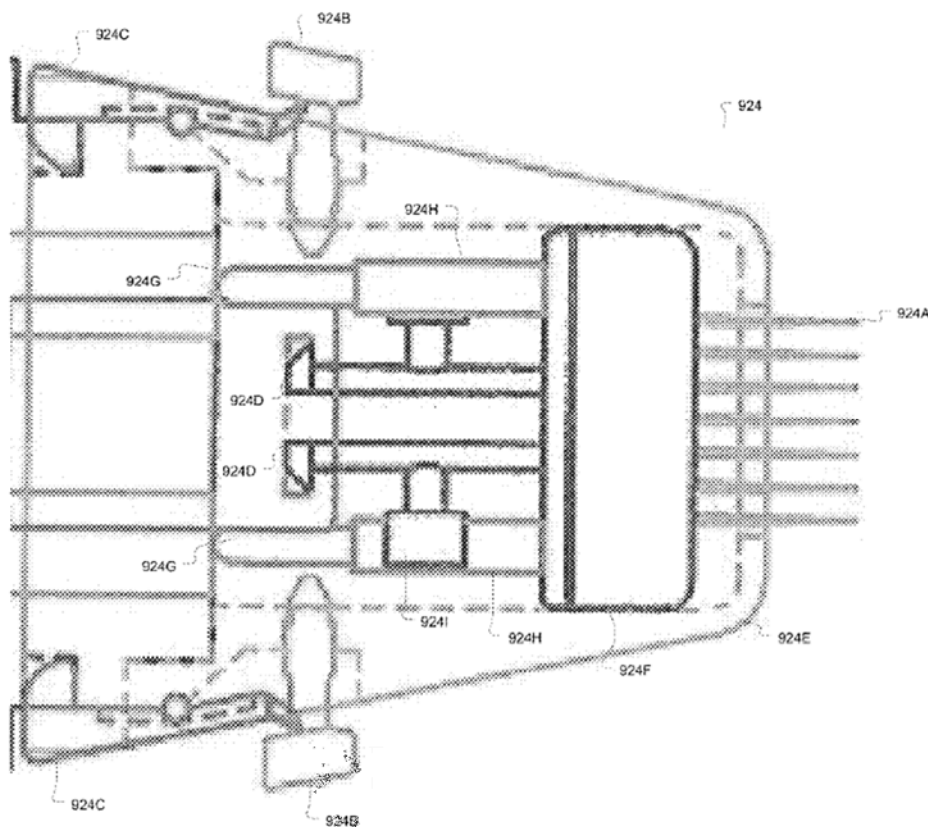
cartridge that “may be changed between therapy application(s) or client(s)” and “disposed after usage or cleaned via an autoclave or chemical process.” *Id.* at 10:48-56. FIG. 10A (reproduced below) illustrates the DNM 924 decoupled from the MLM 922.



**EX1001—FIG. 10A**

The MLM connecting/locking arms 924C facilitate coupling of the DNM 924 to the MLM 922, and the DNM 924 can be decoupled from the MLM 922 via depression of the drive coupling tabs 924B, which are configured to both disengage the MLM connecting/locking arms 924C and to displace the drive shaft connecting arms 924D. *See id.* at 11:3-21, 12:9-23. The drive shaft connecting arms 924D are configured to securely engage the recess 922G of the tip 922F of the drive shaft 922C, such that the motor(s) 922A of the MLM 922 may reliably

move the needles 924A between a retracted position and an extended, or deployed, position. *See id.* at 11:22-34. FIG. 11A (reproduced below) illustrates the needles 924A of the DNM in a deployed position.



**EX1001—FIG. 11A**

The needles 924A are provided as components of needle assembly 924F, which is illustrated in FIGS. 11B and 11C (reproduced below).

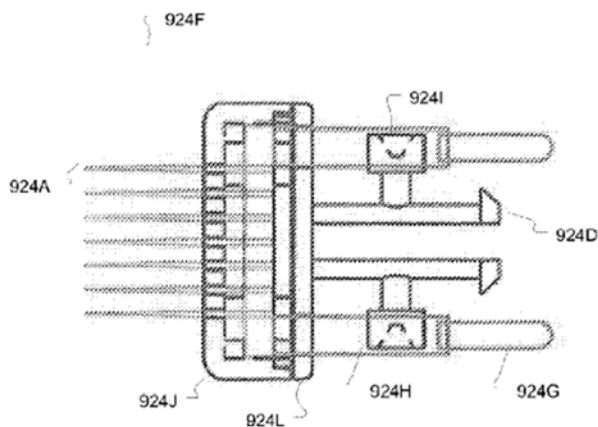


**FIGURE 11B**

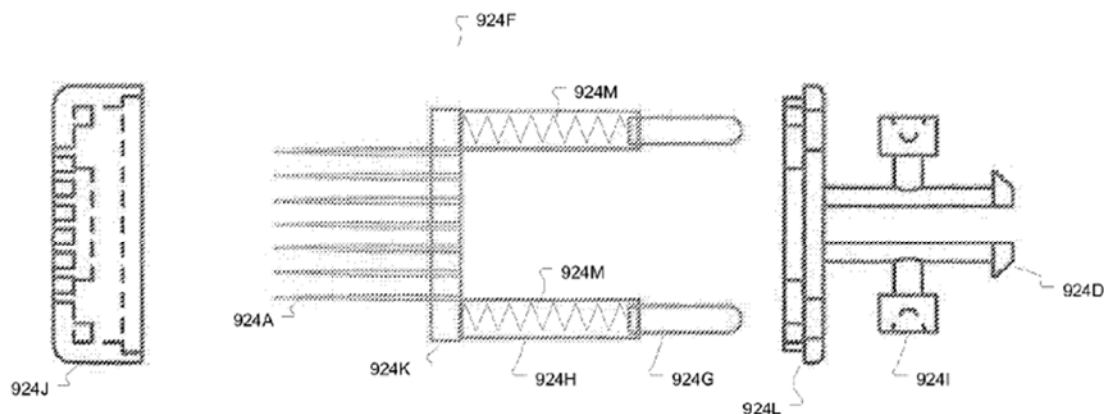


**FIGURE 11C**

**EX1001—FIGS. 11B and 11C**

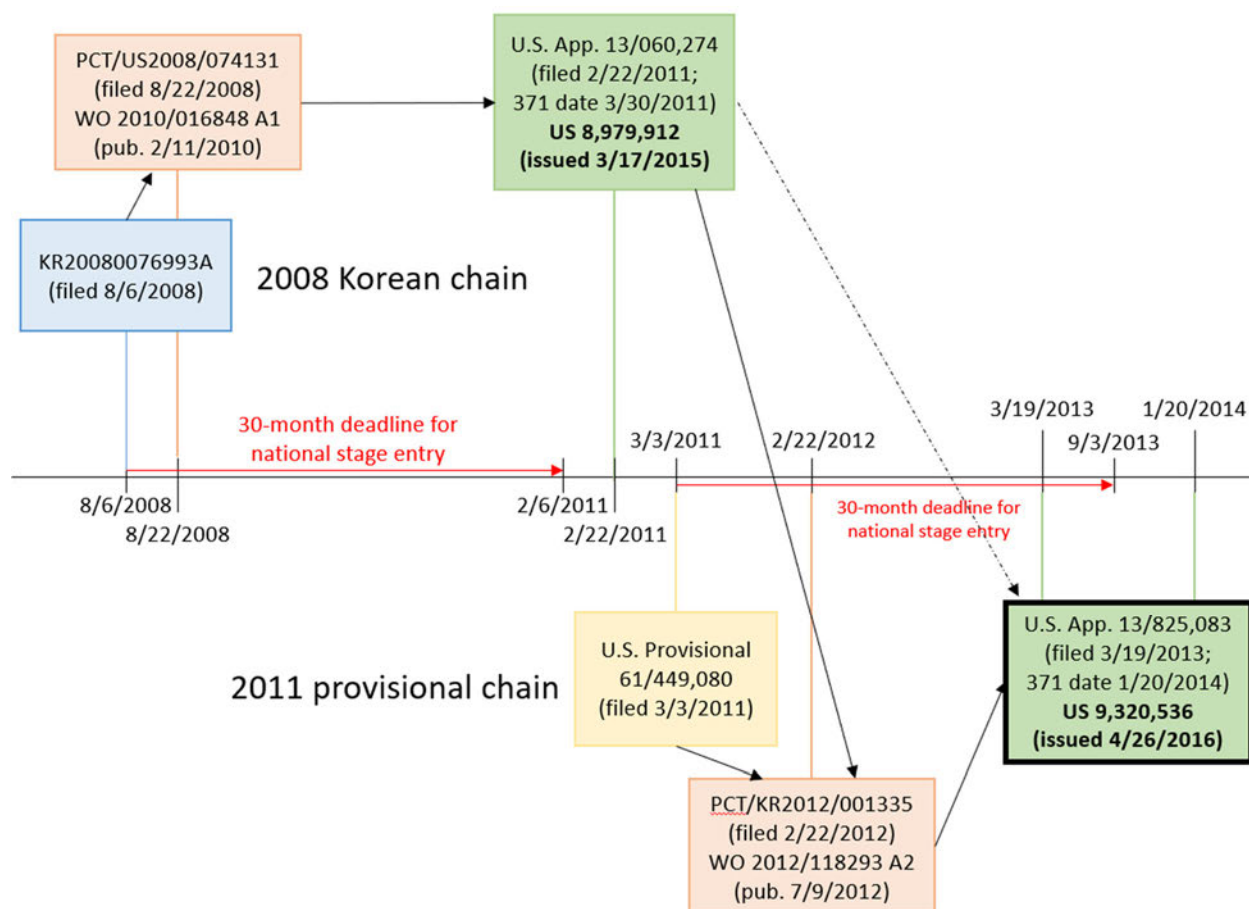
The needle assembly 924F includes a needle cover 924J, a drive arm module 924L, the drive shaft connecting arms 924D, and a needle printed circuit board (PCB) 924K that couples the needles 924A to electrical coupling pins 924G. *See id.* at 13:1-15. The electrical coupling pins 924G communicate electrical signals from a radio frequency (RF) signal generator (RFSG) 911A to the needles 924A. *See id.* at 12:38-40.

40. To apply treatment, a needle deployment motor controller (NDMC) module 911B generates signals to control deployment of the needles 924A, and the RFSG 911A generates one or more electrical signals to be applied to the needles to cause, e.g., “coagulation of the tissue in which the needles 924A are deployed.” *Id.* at 10:9-28. The NDMC 911B and the RFSG 911A are provided, for example, as components of a CPU module 911 of the SGC 910 of FIG. 9A. *See id.* at 9:62-10:8.

**B. Priority date of the claims of the '536 Patent**

41. I understand that the priority date of the claims of the '536 Patent depends on whether the features recited in the claims of the '536 Patent are disclosed in the documents to which priority is claimed. I also understand the claims of the '536 Patent only have priority to the earliest document in which claimed features are disclosed.

42. As depicted below, the '536 patent recites priority to a parent application which in turn claims priority to two separate chains: (1) the “2011 provisional chain” and (2) the “2008 Korean chain,” which includes Na '848 (i.e. EX1005).



I understand that a patent application may rely on the filing date of an earlier-filed application only if one or more claims have written description support in the earlier-filed application. I also understand that, in order to satisfy the written description requirement, the specification must reasonably convey to a POSA that the inventor had possession of the claimed subject matter.

43. Independent claim 1 of the '536 Patent recites “a plurality of needles extendable from the deployable needle assembly end surface,” and independent claim 11 recites “a plurality of extendable needles, a plurality of the extendable needles extendable from a deployable needle assembly end surface.” It is my

opinion that needles which are “extendable” are illustrated in the ’536 Patent in Figs. 9C–9D. In the Detailed Description regarding Figs. 9C–9D, the ’536 Patent describes that a motor is used to drive needles of the treatment apparatus between a retracted position, as illustrated in Fig. 9C, and a deployed position, as illustrated in Fig. 9D. EX1001 at 10:66–11:6, 11:22–27.

44. I have reviewed Na ’848, the international patent application from the 2008 Korean chain to which the ’536 Patent claims priority. Na ’848 includes figures and written descriptions regarding needles which are fixed and non-extendable, which are largely similar to the figures and written descriptions regarding fixed and non-extendable needles in the ’536 Patent. For example, Fig. 2B of Na ’848 is identical to Fig. 2B of the ’536 Patent. However, Na ’848 does not describe a treatment apparatus with needles which are “extendable.” Na ’848 does not include any depiction of a treatment apparatus resembling the apparatus illustrated in Figs. 9C–9D of the ’536 Patent. Nor does Na ’848 provide any illustration or written description of needles which are moveable between a retracted position and a deployed position, or even of a motor that could be used for moving needles. Based on the absence of disclosure in Na ’848 of “extendable” needles, it is my opinion that Na ’848 does not provide adequate disclosure to reasonably convey to a POSA that the inventor possessed the subject matter of “extendable” needles—as are recited by independent claims 1 and 11 of the ’536 Patent. It is therefore my

understanding that the claims of the '536 Patent do not have priority to the filing date of Na '848.

45. I have also reviewed U.S. Application No. 61/449,080 ("Na '080", EX1025), i.e. the progenitor application of the 2011 provisional chain, to which the '536 Patent also claims priority. Na '080 is a provisional application filed after Na '848 on March 3, 2011. In contrast to Na '848, Na '080 illustrates and describes needles which are extendable. Specifically, Na '080 describes a motor via which needles can be moved between retracted and deployed positions, and includes figures that are nearly identical to Figs. 9C–9D of the '536 Patent. Accordingly, it is my opinion that Na '080 provides adequate disclosure to reasonably convey to a POSA that the inventor possessed the subject matter of "extendable" needles—as are recited by independent claims 1 and 11 of the '536 Patent. It is therefore my understanding that the earliest possible priority date of the claims of the '536 Patent would be the filing date of Na '080, which is March 3, 2011. It is therefore also my understanding that the earliest possible priority date of the claims of the '536 with respect to prior art would also be March 3, 2011.<sup>4</sup>

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<sup>4</sup> I have been informed irregularities in both the 2008 Korean chain and the 2011 provisional chain may result in the priority date of certain claims of the '536 patent being as late as March 19, 2013, i.e. the filing date of the application that issued as the '536 patent. However, for the purposes of this declaration, I have assumed that the priority date of the claims of the '536 patent is March 3, 2011.

**C. Prosecution History of the '536 Patent**

46. The application leading to the '536 patent (U.S. Appl. No. 13/825,083) was filed on February 22, 2012, with 20 original claims. *See* EX1002 at 47-49, 170, 229-234. The Applicant submitted a Preliminary Amendment, on March 16, 2013, in which all 20 original claims were amended and submitted a further Preliminary Amendment, on April 23, 2013, in which certain ones of original claims 1-20 were amended and in which new claims 21-24 were added. *See id.* at 11-25, 239-245.

47. On August 27, 2015, the Patent Office issued an Office Action in which claims 1–2 and 11–12 were rejected as being anticipated by U.S. Patent No. 6,890,310 to Crocker (“Crocker”), claims 3–4, 10, 13–14, and 20–24 were rejected as being obvious over Crocker in view of U.S. Patent No. 7,618,429 to Mulholland (“Mulholland”), and claims 6–7, 9, 16–17, and 19 were objected to as being dependent upon a rejected base claim but indicated as being allowable if rewritten in independent form. *See id.* at 276-281. The Applicant did not argue against this rejection but instead filed, on September 20, 2015, a Response in which original independent claim 1 was amended so as to include limitations of original dependent claims 3 and 6 and in which original independent claim 11 was amended so as to include limitations of original dependent claims 13 and 16. *See id.* at 286-293.

48. After the filing of Applicant's September 20, 2015 Response, a Notice of Allowance was issued on January 14, 2016 and the '536 patent issued on April 26, 2016. *See id.* at 298-302, 335.

**D. The Challenged Claims of the '536 Patent**

49. The '536 Patent includes 20 claims. In this Declaration, I have considered the validity of claims 1-9 and 11-19. I have not considered the validity of claims 10 and 20. In my opinion, claims 1-9 and 11-19 of the '536 Patent are unpatentable as being anticipated by and/or obvious over prior-art references discussed below.

**VII. LEVEL OF ORDINARY SKILL IN THE ART**

50. In my opinion and based upon my background and experience, the level of skill of a POSA in the timeframe prior to March 3, 2011, would have been met by a person who had (1) 7-10 years of experience with developing and/or using treatment systems for delivery of electromagnetic radiation to skin or other tissues, and (2) a related graduate engineering degree or M.D. The POSA 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. Additional education could substitute for professional experience and vice versa.

## VIII. CONSTRUCTION OF CLAIM TERMS

51. For purposes of the Declaration, it is my understanding that I am to interpret the claim language according to the meaning that it would have to a POSA as of the priority date of the claims of the '536 patent. It is my understanding that, in interpreting the claim language, I am to take into consideration the teachings of the patent specification and any relevant prosecution history.

52. I discuss the meaning that certain terms used in the claims would have had to a POSA. For all other terms, I apply the plain and ordinary meaning.

### A. Agreed Constructions From The ITC Investigation

53. I understand that Patent Owner and Petitioners agreed to the following constructions of “extendable needles” and “extended needles”:

Plain and ordinary meaning:

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]

EX1007 at 15-16. Under these constructions, the claimed “extendable needles” would cover needles depicted, for example, in FIGS. 9C-9D and 10D-10E of the '536 patent and the claimed “extended needles” would cover those needles when they are in an extended position—as depicted, for example, in FIGS. 9D, 10E, and 11A of the '536 Patent.

54. I understand that Patent Owner and Petitioners also agreed that the preambles of the claims of the '536 patent are limiting, that “a particular signal,” as recited in claim 11 of the '536 patent, means “an electrical motor control signal,” and that “predetermined intensity,” as recited in claims 9 and 19 of the '536 patent, means “the electrical signal intensity selected for treatment.” *Id.*

**B. “deployable needle assembly end surface”**

55. I understand that the term “deployable needle assembly end surface,” which appears in the context of “a user holdable device releasably couplable deployable needle assembly end surface,” in claim 1 of the '536 patent, and in the context of “a deployable needle assembly end surface,” in claim 11 of the '536 patent, was construed in the ITC investigation 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

*Id.* at 16-17.

**C. “a desired distance” / “predetermined depth”**

56. In my opinion, the terms “a desired distance” (in claims 1 and 11) and “predetermined depth” (in claims 9 and 19) should be given their plain and ordinary meaning. The term “desired distance” simply distinguishes between needles which extend a desired distance as opposed to an undesired distance. For example, a POSA would understand in the context of the '536 patent that “a desired distance”

corresponds to a distance that is suitable for treatment of dermatological tissue (as opposed to an undesirable distance where the needles are too long or too short for the intended treatments). A POSA would have understood the plain and ordinary meaning of “predetermined depth” to be a depth that is determined beforehand.

57. I understand that Serendia may contend that the plain and ordinary meaning of the term “desired distance<sup>5</sup>” should be interpreted to require a user-selectable distance of needle extension along the axis of needle extension. I further understand that Serendia may contend that “desired distance” should be interpreted to exclude: (1) needles which are extendable by a “fixed,” predetermined distance; and (2) needles which are extendable to a distance chosen by selecting a particular angle of insertion. Serendia’s proposed interpretation of “desired distance” should be rejected because they are contrary to the plain meaning of that term.

58. Furthermore, Serendia’s proposed interpretation of “desired distance” is inconsistent with the context provided by the specification of the ’536 patent. The ’536 patent describes non-extendable needles or pins 351 of a dermatological treatment apparatus that may be placed in contact with skin to cause micro-wounds or cuts in the skin. *See* EX1001 at 3:38-41, 4:35-39. Indeed, in the related ’774

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<sup>5</sup> The term “desired distance” appears in the context of which appears in the context of “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.”

patent (EX1020), the term “desired distance” is used in claims 1 and 11 to refer to non-extendable needles extending a fixed distance from a surface. *See also* EX1007 at 16. Accordingly, the ’536 patent describes that a distance of needle extension may include a fixed or predetermined distance dictated by the length of needles. It is my opinion that a POSA would understand the plain meaning of “desired distance” to encompass such a fixed, predetermined, and/or manually selected distance, e.g. a distance dictated by the length of one or more needles.

59. The ’536 Patent describes that in the context of extendable (e.g., retractable and deployable) needles, the needles of a dermatological treatment device may be deployed “to a desired extension beyond [a detachable cartridge module] 924...to enable a desired depth of needle 924A penetration within tissue.” EX1001 at 13:51–57. This “desired extension” may be selected by a user and implemented by a central processing unit (CPU) 911 via control of a motor for deploying the needles. *Id.* at 13:58–14:4, Fig. 12. The “desired extension” of the needles is selected once along with other parameters selected by a user or the CPU, such as electrical signal intensity, signal start delay, number of shots per activation, and signal duty cycle. *Id.* at 13:33–36, 13:58–61, Fig. 12. The treatment apparatus is then repeatedly “activated” (e.g., caused to carry out its intended function by energizing and actuating its various components) based on the selected parameters. *Id.* at Fig. 12. Therefore, a POSA would understand the plain meaning of “desired distance” to also

encompass any user-selected and/or repeatedly implemented needle deployment distance.

**D. “separatably”**

60. I understand that the term “separatably,” which appears in the context of “the deployable needle assembly mechanically separatably from the proximal end,” in claims 1 and 11 of the ’536 patent, was construed in the ITC investigation to mean “separable.” EX1007 at 27.

**E. “the deployable needle assembly mechanically separatably from the proximal end”**

61. The term “the deployable needle assembly mechanically separatably from the proximal end,” which appears in claims 1 and 11 of the ’536 patent, was construed in the ITC investigation as follows:

|                                                                                                                                                                                                                                                         |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

*Id.* at 32.

**F. “draft shaft”**

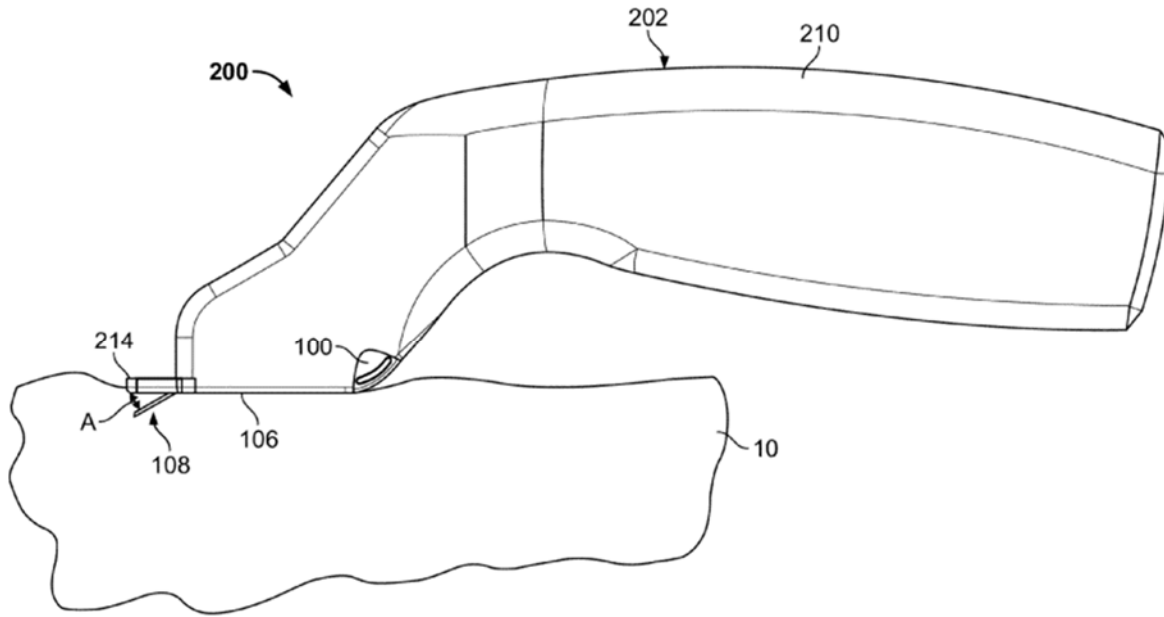
62. A POSA would have understood the term “draft shaft,” which appears in the context of “the motor including a draft shaft releasably couplable to the deployable needle assembly,” in claims 3 and 13 of the ’536 patent, to mean “drive shaft.”

## **IX. OVERVIEW OF THE PRIOR ART**

### **A. Mehta (EX1004)**

63. Mehta is a U.S. patent that issued from an application filed on April 20, 2009, which was a continuation of a patent application filed on February 6, 2009. *See* EX1004 at p. 1. I understand that Mehta qualifies as prior art to the '536 Patent.

64. Mehta describes a microneedling device having an extendable array of probes. *See id.* at Abstract, 15:42–49. The probes are used to treat tissue in the human body by precisely delivering energy to regions beneath the surface of tissue without affecting the outer layer of skin. *See id.* at Abstract, 1:14–19, 2:37–57. The energy delivered by the probes can break down subcutaneous fat cells or other specifically targeted layers of tissue, allowing the device to aid in body contouring, reducing cellulite, and treating other skin surface imperfections and blemishes. *See id.* at 2:45–57.

**FIG. 2B**

65. Mehta uses the terms “needles,” “electrodes,” and “probes” interchangeably. *See id.* at 9:41–55 (“The term probes 104...is intended to include any electrode, energy transfer element...or source of therapeutic treatment.”), 12:54–58 (“The stabilization surface...can also be used to hold and therefore tension the skin at the insertion points to facilitate the needle insertion in the skin”), 14:13–19 (“the cartridge assembly 100 places the probes 104 in an array 108...to provide the probes 104 on a probe assembly 102”), 15:42–49 (“electrode assembly 102 includes any number of electrodes that form an array 108”), 17:6–8 (“needle assembly 102”). The needles or probes 104 of the device described in Mehta are extendable and retractable from a surface of the device, and may be arranged on or in a replaceable cartridge in the device. *See id.* at 4:63–5:2, 6:53–54, 9:41–43, 9:51–55, 15:42–49, 16:19–22, Figs. 2A, 2B, 2D, 4A, 4C.

66. The microneedling device of Mehta includes an energy supply unit 90, which may not only power actuators of the device, but also provide energy that is delivered to a patient's tissue via needles 104. *See id.* at 10:38–39, 10:19–55, 11:14–15. The energy supply unit 90 can be an RF energy unit that RF energy through the needles 104 that is then applied to a patient's tissue. *See id.* at 2:63–3:17, 11:14–15, 20:16–19. The RF energy can be delivered continuously or in pulses with a pulsed duty cycle that allows for improved temperature measurements in periods between pulsed energy deliveries. *See id.* at 20:16–47. The energy supply unit 90 can also be used to supply power necessary to provide or remove thermal energy, ultrasound energy, microwave energy, laser energy, pulsed light energy, infrared energy, and combinations thereof. *See id.* at 11:14–20.

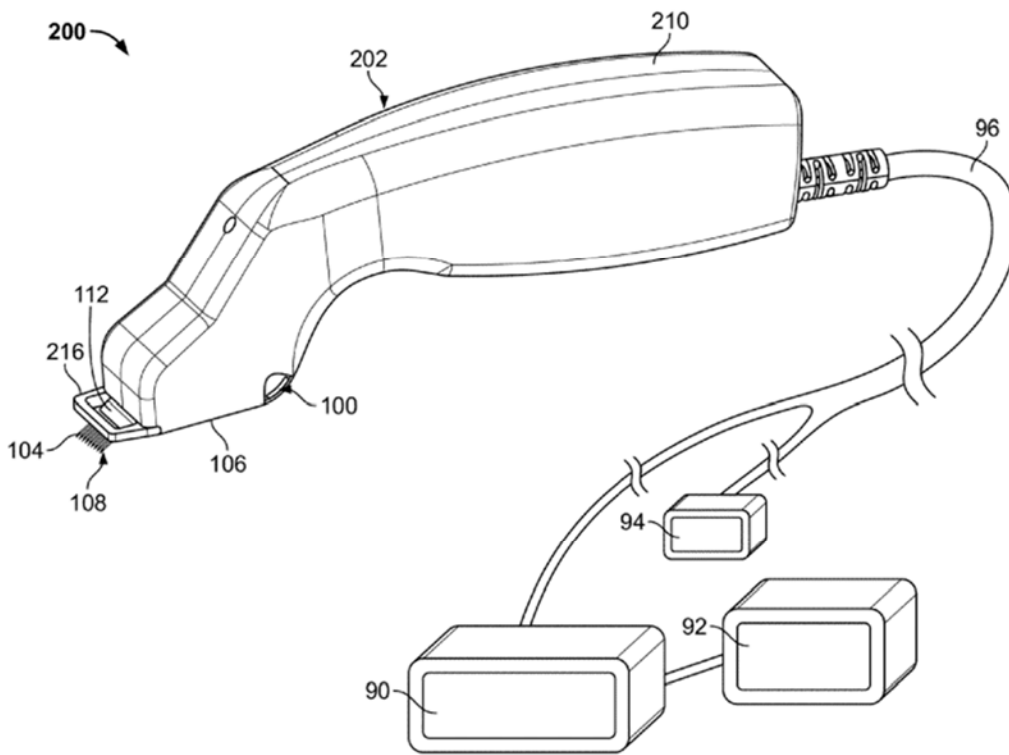


FIG. 2A

### B. Na '848 (EX1005)

67. Na '848 is an international patent publication that published on February 11, 2010. *See* EX1005 at p. 1. It is my understanding that Na '848 therefore qualifies as prior art to the '536 patent.

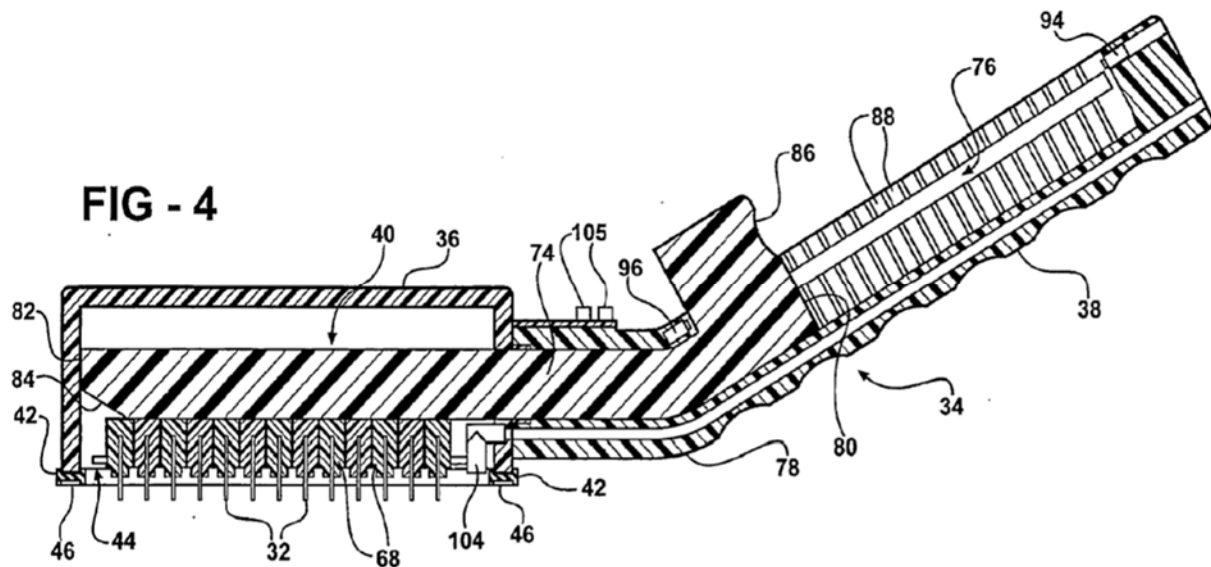
68. Much of Na '848 is identical or substantially identical to portions of the '536 patent. For example, Paragraphs [0002]-[0059] and Figs. 1-8 of Na '848 are substantially identical to cols. 1:25-2:14, cols. 2:51-9:17, cols. 14:5-15:14 and Figs. 1-8 of the '536 patent. The claims of Na '848 also have substantial overlap with the claims of the '536 patent.

69. Cols. 9:18–14:4 and Figs. 9A–12 of the '536 Patent contain matter which was not described or illustrated in Na '848. It is my understanding that the subject matter described in cols. 9:18–14:4 and illustrated in Figs. 9A–12 of the '536 patent thus contain new matter relative to Na '848. It is also my understanding that Na '848 was not considered as prior art during examination of the application that was the basis for issuance of the '536 patent.

**C. Livneh (EX1012)**

70. Livneh is a WIPO patent publication that published on January 10, 2008. *See* EX1012 at p. 1. It is my understanding that Livneh thus qualifies as prior art to the '536 patent.

71. Livneh describes “an electrosurgical apparatus 30” that is “capable of delivering electrical current to skin using a plurality of electrodes 32 which enter the skin.” *Id.* at [0032]; *see also id.* at [0005]. Livneh’s electrosurgical apparatus is intended to be used for “skin tightening procedures” and can be configured for either bipolar operation, in which a radiofrequency signal “is applied through a first set 54 of electrodes 32” while “a second set 56 of electrodes 32 [acts] as a return path to the power supply 50,” or for monopolar operation. *Id.* at [0032], [0039]. Livneh’s electrosurgical apparatus includes a handheld unit 34, illustrated in FIG. 4 (reproduced below).

**EX1012—FIG. 4**

The handheld unit includes a cavity 40 in which the electrodes 32 can be concealed when not in operation. *See d.* at [0034]. Each of the electrodes 32 “is preferably shaped like a needle,” i.e. “an end of each electrode forms a sharp, angled point allowing the electrode 32 to puncture the skin.” *Id.* at [0040].

72. Livneh describes that the electrodes are “arranged into a plurality of combs 62,” each of which is “supported by a holder 68.” *Id.* at [0040], [0048]. “At least one coil 92 extends from the top of each holder 68,” which forms an electrical connection between the electrodes of a comb and a wire 51. *Id.* at [0049]. In bipolar operation, illustrated in FIG. 10 (reproduced below), “the coil 92 of each holder 68 in successive rows alternates between the two wires 51, where one wire 51 provides a supply path from the power supply 50 and the other wire 51 provides a return path.” *Id.*

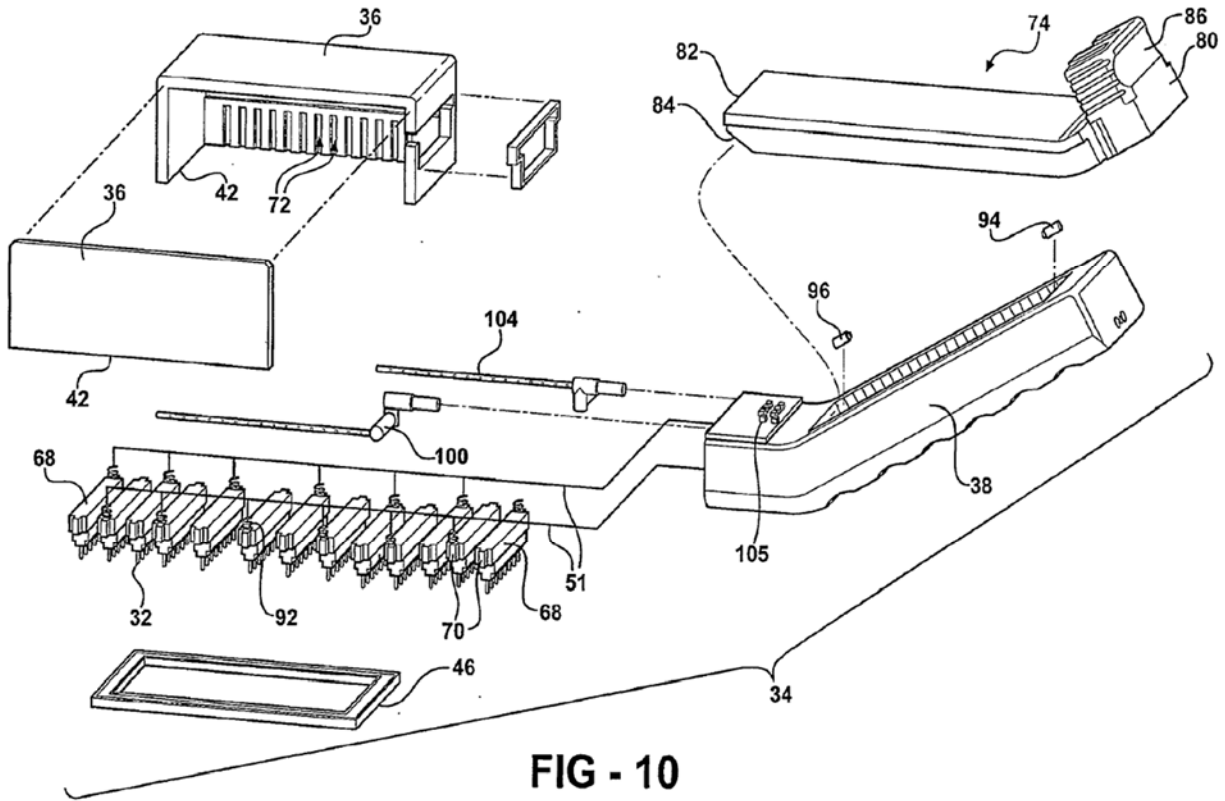


**FIG - 10**  
**EX1012—FIG. 10**

During utilization in skin tightening procedures, the electrodes 32 pierce the skin as a result electrode positioning mechanism 74 moving the electrodes 32 from a retracted position to an extended position. *Id.* at [0046], [0054]. While the electrodes 32 are extended into the skin, electric current is applied to the skin by supplying the electrodes 32 with an RF signal.

### D. Lee (EX1011)

73. Lee is a Korean patent publication that published on August 25, 2008. See EX1011 at p. 1. It is my understanding that Lee thus qualifies as prior art to the '536 patent.

74. Lee discloses a skin treatment device that uses microneedles. *See id.*, <13> (“The present invention relates to a skin regeneration apparatus capable of controlling the insertion depth of microneedles and, more particularly, to a skin regeneration apparatus capable of controlling microneedles that can provide effective multi-hole treatment as well as safety and precision as to the depth of microneedles by making it possible to automatically control the insertion depth of the microneedles during multi-hole treatment.”).

75. Lee discloses inserting the needles into skin to create perforations. *See id.*, <15> (“In this method, for example, hundreds to tens of thousands of tiny holes are created on the human skin to regenerate tissues by using its self-healing ability to heal the skin that is damaged in the process of making the tiny holes”).

76. Lee discloses an actuator and mode switch to control the precise insertion depth of the microneedles. *See id.*, <44> (“the present invention provides an actuator means that can control the insertion depth of the microneedles”); *id.*, <33> (“Pressing the mode switch changes the mode. The selected mode controls the speed of reciprocating insertions (number of repetitive insertions) and the insertion depth of the needles.”).

**X. THE CHALLENGED CLAIMS ARE UNPATENTABLE**

**A. Ground 1: Claims 1–3, 6, 8–9, 11–13, 16, and 18–19 are Anticipated by Mehta**

77. In my opinion, Mehta anticipates claims 1–3, 6, 8–9, 11–13, 16, and 18–19 of the '536 Patent.

**1. Independent Claim 11**

78. As discussed in more detail below, Mehta discloses each and every element of independent claim 11. Therefore, Mehta anticipates claim 11 of the '536 patent.

**a. [11pre] An apparatus for treating dermatological tissue**

79. Mehta discloses a microneedling device (i.e. apparatus) for treating dermatological tissue to, for example, enhance the appearance of a patient's skin. *See, e.g.*, EX1004 at 2:37-43. Microneedling treatment devices, like that described by Mehta, both (i) trigger the skin's natural healing response to stimulate collagen production and (ii) percutaneously deliver energy to cause contraction of existing collagen tissue in the skin's dermis. The result of a microneedling treatment provided by such devices is tightened and rejuvenated skin that has fewer visible fine lines and wrinkles.

80. Mehta teaches devices and methods to "treat cosmetic conditions affecting the skin of various body parts." *Id.* at 1:14–19. Mehta's devices and methods target specific layers of the skin for treatment. *See, e.g., id.* at 8:45–48

(“[W]hen applying cosmetic treatment to the skin for tightening or removal of wrinkles, it is desirable to deliver energy to the dermis.”); *see also id.* at 2:37–62, 3:42–56, 7:52–59; Treatment of the skin—and specific layers thereof—constitutes treatment of dermatological tissue.

81. Accordingly, Mehta discloses [11pre], i.e. an apparatus for the treatment of dermatological tissue.

**b. [11a] 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**

82. The microneedling apparatus disclosed by Mehta includes a handpiece with a handle that is designed to be grasped by a user, e.g. an aesthetician or dermatologist, during treatment of a patient’s skin. *See, e.g., id.* at 4:1-2, 9:34-39, 9:59-62. In addition, the microneedling apparatus disclosed by Mehta includes a removable cartridge having needles that are designed to penetrate a patient’s skin and apply subcutaneous treatments thereto. *See, e.g., id.* at 4:63-5:2; 9:40-64.

83. Mehta illustrates a microneedling apparatus, i.e. treatment system 200, in FIG. 2A.

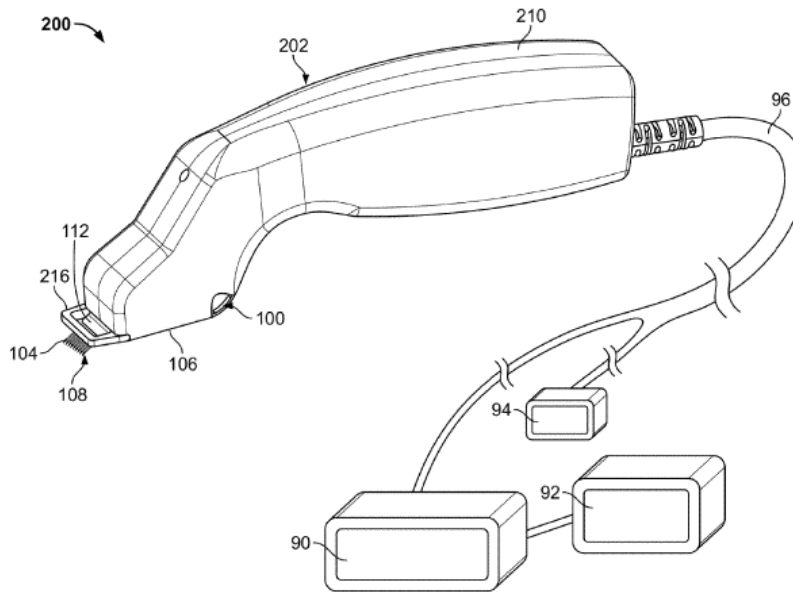
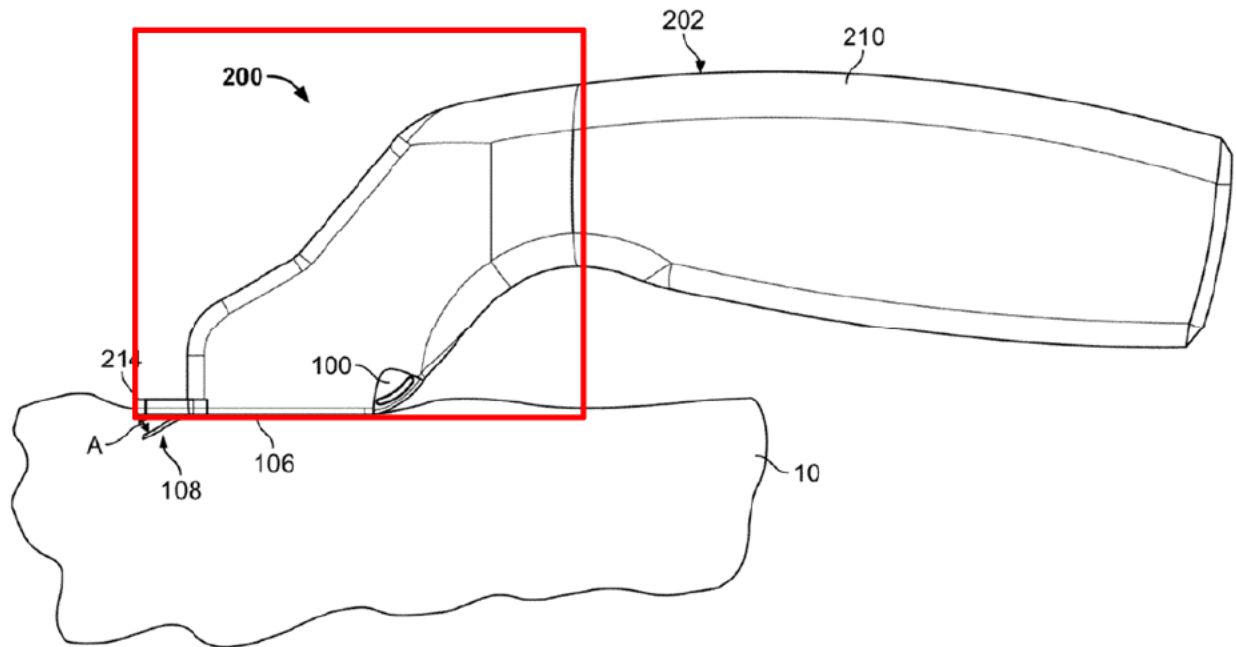


FIG. 2A

**Mehta—FIG. 2A**

The microneedling apparatus 200 includes “a treatment unit 202 having a hand-piece or device body 210,” which “facilitates...grasp[ing] by the hand” of a user, and “a plurality of retractable probes 104” that “are coupled to the body 210 via a removable cartridge 100.” *Id.* at 9:36-43, 9:56-64. During the application of treatment to a patient’s dermatological tissue, the treatment unit 202 is held, at the handpiece/device body 210, by a user (e.g. and aesthetician or dermatologist). *See id.* at 2:37-41, 9:56-64. Accordingly, the treatment unit 202 is a “user holdable device” as recited by claim 11 of the ’536 patent.

84. The microneedling treatment unit 202 includes a portion (designated by the red box in FIG. 2B of Mehta, reproduced below) that is designed to be positioned proximal to a patient’s dermatological tissue, i.e. tissue 10, during treatment.



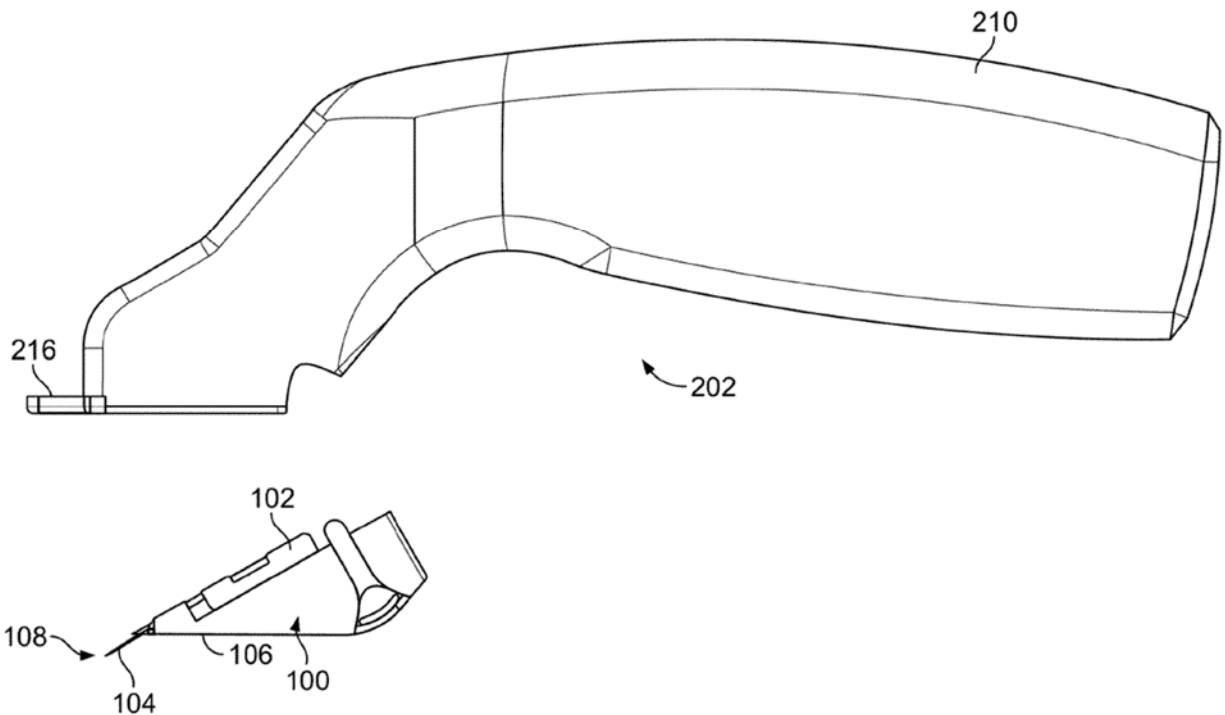
**Mehta—FIG. 2B**

Specifically, during treatment of a patient's dermatological tissue (e.g., skin on a patient's face or neck), a user would hold the handle portion, which is located at the right-hand side of the treatment unit 202 in FIG. 2B of Mehta, and position the proximal end of the microneedling treatment unit 202 near the dermatological tissue to be treated such that a tissue engaging surface 106 engages the dermatological tissue near a treatment region. *See, e.g., id.* at 12:23-30.

Accordingly, the treatment unit 202 includes a "proximal end" as recited by claim 11 of the '536 patent.

85. The microneedling treatment unit 202 also includes a cartridge 100 that has a needle assembly 102 with a plurality of microneedles 104 designed to penetrate a patient's skin and apply subcutaneous treatments thereto. *See id.* at 9:40-43, 14:15-

19. FIG. 2D of Mehta illustrates the microneedling treatment unit 202 with the cartridge 100 mechanically separated from the device body 210. *See id.* at 14:5-7.



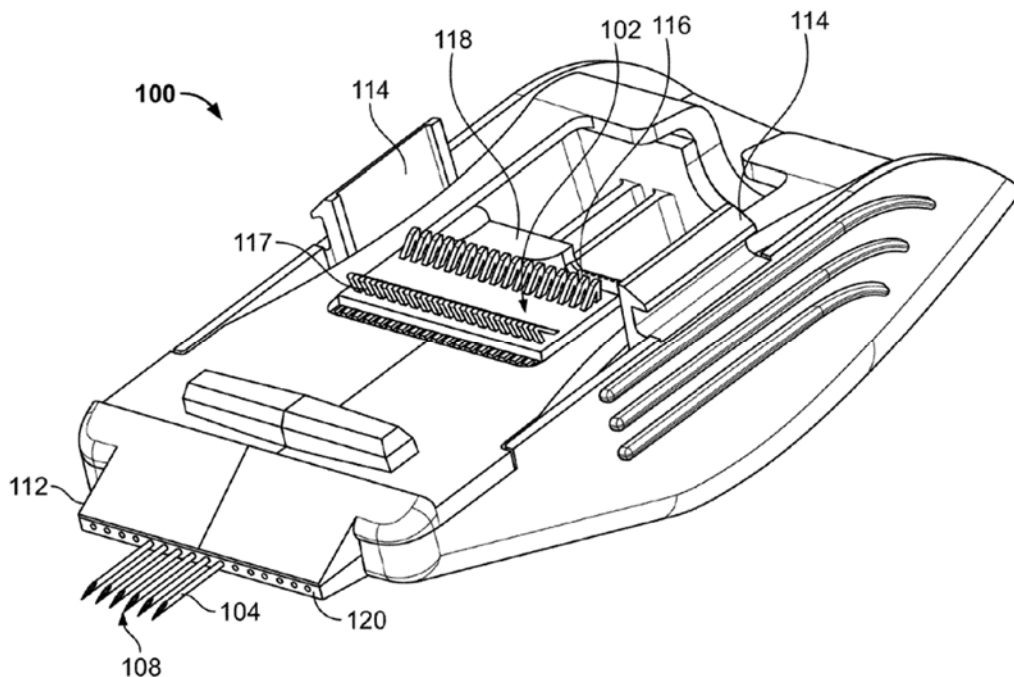
**EX1004—FIG. 2D**

Mehta interchangeably refers to elements 104 as “probes,” “electrodes,” and “needles” (*see, e.g., id.* at 9:41-55, 12:47-58, 21:34-38, 31:37-41, 37:7-16). For example, Mehta refers to the same assembly 102 as a probe assembly 102 (*see, e.g., id.* at 14:15-19), an electrode assembly 102 (*see, e.g., id.* at 15:34-36 and 15:42-49), and a needle assembly 102 (*see, e.g., id.* at 17:6-8). Mehta also repeatedly indicates that the term “needles” is intended to be interchangeable with “electrodes” and “probes.” *See, e.g., id.* at 17:6-12 (“upon distal advancement of the needle assembly 102 . . . the temperature of the electrodes can be continuously

monitored”), *id.* at 40:45-51 (“[w]hen used with a bi-polar RF energy modality, the use of minimally invasive micro-needle electrode pairs appears to have several clear advantages”), *id.* at 31:37-41 (“[w]hen more than 2 needles/probes have been placed in the tissue, sensing can be done between any two needles/probes to determine the tissue properties therebetween”). Moreover, Mehta states that “the term probe shall be used to refer to any electrode, energy transfer element or source of therapeutic treatment unless specifically noted otherwise,” and “is intended to include any electrode, energy transfer element (e.g., thermal, electrical, electromagnetic, microwave, mechanical, ultrasound, light, radiation, monopolar RF, bipolar RF, chemical, radioactive, etc.), or source of therapeutic treatment.” *Id.* at 9:43-51. Furthermore, the dermatological treatment device described by Mehta is a type of device commonly known in the skincare field as a “microneedling” device, and a POSA would have understood that the elements designated by reference numeral 104 throughout Mehta are needles—regardless of whether or not they are referred to as “probes” or “electrodes.”

86. In microneedling devices that include detachable cartridges, like the microneedling treatment unit 202, a user (e.g. an aesthetician or dermatologist) can customize the treatment provided by the microneedling device by selecting a particular cartridge with a particular microneedle configuration from a set of different cartridges having different microneedle configurations. *See, e.g., id.* at

9:40-55, 9:65-10:32. To fit a particular cartridge 100 to the proximal end of the handpiece/device body 210, Mehta teaches that “any number of structures can be incorporated into the device to permit removable coupling of the cartridge body 100,” for example “retention fasteners 114 allowing for coupling with the device body as well as removal from the device body.” *Id.* at 15:28-33. An example of retention fasteners 114 is provided in FIG. 4A of Mehta, reproduced below.



**EX1004—FIG. 4A**

Because the cartridge 100 can be attached, or coupled, to and detached, or removed, from the handpiece/device body 210—e.g. via the action of retention fasteners 114, both the cartridge 100 and the needle assembly 102—which is a part of the cartridge 100—are “releasably couplable” to the proximal end of the device

body 210. See, e.g., *id.* at FIGS. 2B, 2D, 4A<sup>6</sup> and 3:63-64, 6:41-42, 14:5-7, 15:28-33. Accordingly, the needle assembly 102 of Mehta is a “releasably couplable deployable needle assembly” that is “mechanically separatable from the proximal end,” as recited by claim 11 of the ’536 patent.

87. Mehta teaches that the needle assembly 102 is “slidable relative to the cartridge body 100 and the device body 210” to enable the needles 104 to “be driven into tissue.” *Id.* at 14:14-18. As a result, the needles 104 of the needle assembly 102 are configured to “advance and retract relative to the cartridge 100.” *Id.* at 16:19-22. Mehta also refers to the needles 104 as being “extendable and retractable.” *Id.* at 15:45-48. Accordingly, the needles 104 of Mehta are extendable needles, and, therefore, the needle assembly 102 includes “a plurality of extendable needles” as recited by claim 11 of the ’536 patent.

88. Mehta thus discloses a user holdable device (i.e. the treatment unit 202) including a proximal end (i.e. a portion of the device body 210 proximal to a patient’s tissue 10) and a releasably couplable deployable needle assembly (i.e. needle

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<sup>6</sup> Figs. 2A–2B of Mehta depict a system 200 generally, and Figs. 4A–4F and 7A–7E depict components included in that system 200 (e.g. in different variations thereof). EX1004 at 6:51-62, 7:1-12. For example, Fig. 4A depicts an exemplary implementation of a cartridge 100 that may be incorporated into the system 200 of Figs. 2A–2D, and Fig. 7A depicts a side view of how needles 104 of the cartridge 100 of Figs. 2A–2D would enter human tissue. Mehta also states “[i]t is expressly intended that, wherever possible, the invention includes combinations of aspects of the various embodiments described herein or even combinations of the embodiments themselves.” *Id.* at 6:3-6.

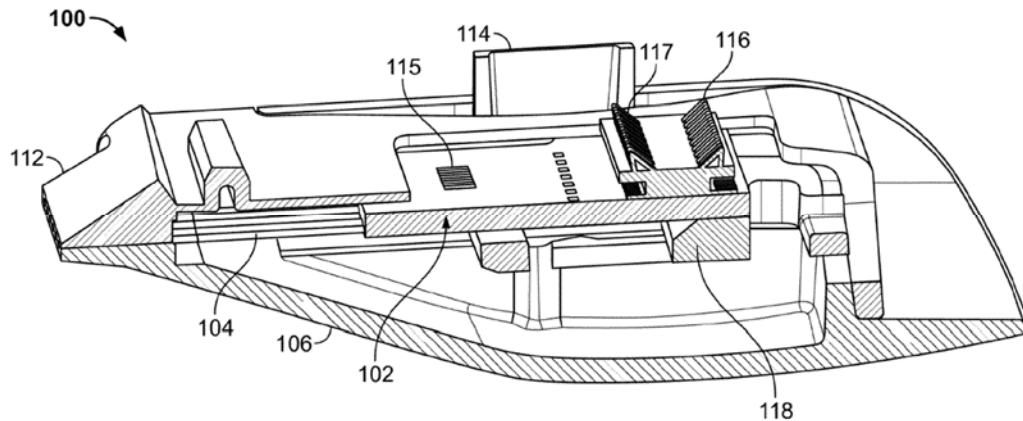
assembly 102), the deployable needle assembly mechanically separable from the proximal end and including a plurality of extendable needles (i.e. needles 104)—as is recited by claim 11 of the '536 patent. Therefore, Mehta discloses [11a].

**c. [11b] a plurality of the extendable needles extendable from a deployable needle assembly end surface**

89. The microneedling apparatus disclosed by Mehta includes a plurality of extendable needles that extend into a patient's skin and provide for percutaneous delivery of electromagnetic energy to dermatological tissue. *See, e.g., id.* at 2:37-43. In the microneedling apparatus of Mehta, the microneedles are extendable from a fully retracted position and from a front portion of a removable cartridge. *See, e.g., id.* at 14:14-18, 15:45-48, 16:19-22.

90. Mehta discloses a needle assembly 102, having a plurality of needles 104, that is “slidable relative to the cartridge body 100 and the device body 210” to enable the needles 104 to “be driven into tissue.” *Id.* at 14:14-18. As the needle assembly 102 slides relative to the cartridge body, the needles 104 move between an extended position and a retracted position.

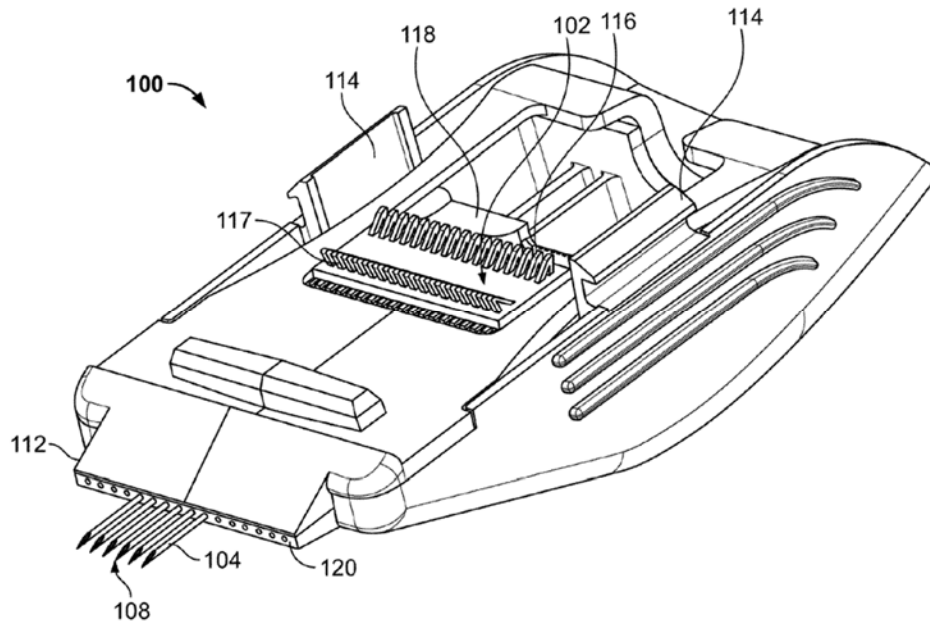
91. FIG. 4C of Mehta (reproduced below) illustrates the cartridge 100 with the needle assembly 102—and therefore the extendable needles 104—in a retracted position. *See id.* at 16:59-60.



**EX1004—FIG. 4C**

When the needle assembly 102 is in the retracted position, the tips of the needles 104 define a retracted tip plane, i.e. a plane that extends along the tip of each of the retracted needles. In FIG. 4C, that plane may correspond to the front portion 112 of the cartridge 100, or that plane may lie behind the front portion 112 of the cartridge.

92. FIG. 4A of Mehta (reproduced below) illustrates the removable cartridge 100 with the needle assembly 102 in an extended position.



**EX1004—FIG. 4A**

In the extended position illustrated in FIG. 4A, the needles 104 extend from both (i) the retracted tip plane, i.e. the plane that extends along the tips of the needles when they are in the retracted position, and (ii) the front portion 112 of the cartridge 100.

93. As discussed *supra* Section VIII.B., the term “a deployable needle assembly end surface” has been construed in the ITC investigation—in a manner consistent with the meaning that term would have had to a POSA—to mean:

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.

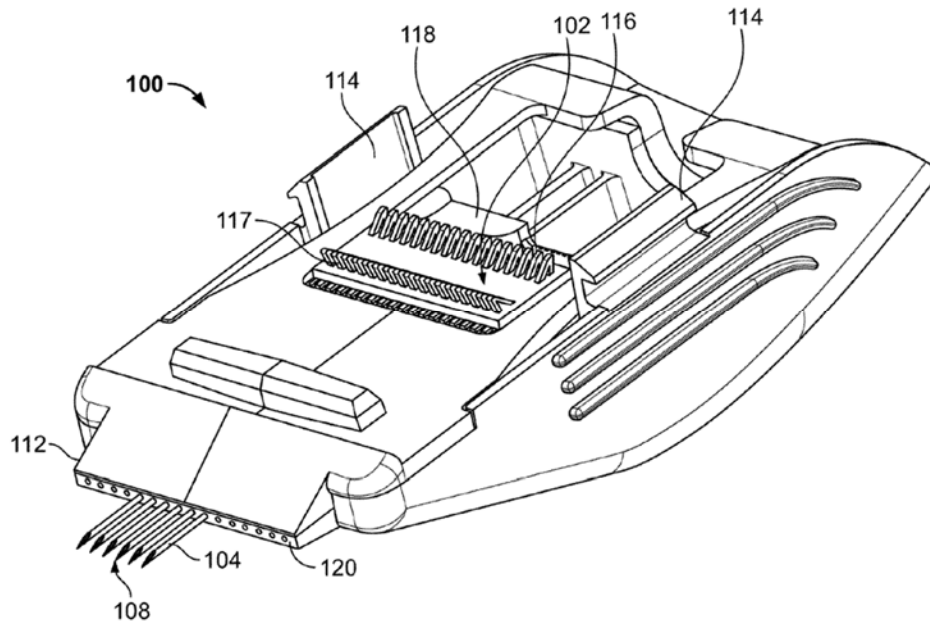
The definition of “deployable needle assembly end surface” provided in the ITC investigation corresponds to the retracted tip plane, i.e. the plane that extends along the tips of the needles when they are in the retracted position. Therefore, because the needles 104 are extendable from the retracted tip plane, as evidenced by FIGS. 4A and 4C of Mehta, the needles 104 are “extendable from a deployable needle assembly end surface,” as recited by claim 11 of the ’536 patent. Furthermore, as can be seen in FIG. 4A of Mehta, the needles 104 are also extendable from the front portion 112 of the cartridge 100.

**d. [11c] 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**

94. In the microneedling apparatus of Mehta, an electrical pathway is provided for transmitting electrical power from a power supply to the extendable needles, i.e. needles 104. *See, e.g.*, EX1004 at 15:55-59. Because (i) the extendable needles 104 are part of a needle assembly 102 that is a component of the removable cartridge 100 (*see, e.g., id.* at 9:40-43, 14:15-19) and (ii) the power supply is either connected to the handpiece/device body 210 via a cable 96 or provided in the handpiece/device body 210 itself (*see, e.g., id.* at 9:40-43, 10:53-65), the electrical pathway between the power supply and the extendable needles extends across the interface between the removable cartridge 100 and the handpiece/device body 210

in order for electrical power to be delivered from the power supply to the extendable needles. Accordingly, there must be a first electrical conductor (or set of electrical conductors) disposed on the removable cartridge 100 or a component thereof and a second electrical conductor (or set of electrical conductors) disposed on the handpiece/device body 210 such that, when the removable cartridge 100 is coupled to the handpiece/device body 210, the first and second electrical conductors (or first and second sets of electrical conductors) contact one another to provide an electrical connection therebetween.

95. Mehta discloses a set of electrical conductors, which are located on the removable cartridge 100 (specifically on needle assembly 102) at its interface with the proximal end of the handpiece/device body 210, provided in the form of restorably deflectable electrical contacts. *See, e.g., id.* at 16:12-18. Specifically, Mehta discloses that the extendable needles 104 of the needle assembly 102 of the removable cartridge 100 have “contact portions 116,” which “comprise spring contacts or spring pins,” and “couple to a connection board on a treatment unit to provide an electrical pathway from the power supply” to the extendable needles 104. *Id.* at 15:55-59 and 16:12-18. FIG. 4A of Mehta (reproduced below) illustrates the contact portions 116 in the form of spring contacts or spring pins.



**EX1004—FIG. 4A**

A spring, such as a spring contact or spring pin, exerts, when deformed, deflected, or bent from its original position, a restorative force that causes it to reassume that original position. For example, the connection portions 116 illustrated in FIG. 4A would, in response to being deflected downward toward the tissue engaging surface 106, exert a restorative force directed in an upward direction away from the tissue engaging surface. As a result of their resilient, or “restorably-deflectable,” nature, “the connection portions 116 can maintain contact with a corresponding contact point trace on a connection board during movement” of the needle assembly 102. *Id.* at 16:15-18. Each contact portion 116, provided in the form of a spring contact or spring pin, is therefore a “restorably deflectable electrical contact” as recited by claim 11 of the ’536 patent. Moreover, the “corresponding

contact point trace” is “at least one electrical conductor” included on “the proximal end” (i.e. of the handpiece/device body 210) as recited by claim 11 of the ’536 patent.

96. As noted *supra* ¶94, in order for an electrical pathway that provides for transmission of electrical power from the power supply to the extendable needs, there must be an electrical conductor (or set of electrical conductors) disposed on the handpiece/device body 210 such that, when the removable cartridge 100 is coupled thereto, said electrical conductor (or set of electrical conductors) contacts a corresponding conductor (or set of conductors) disposed on the cartridge, e.g. a component thereof. Thus, in the case of the contact portions 116 disposed on the needle assembly 102, there must be one or more corresponding electrical conductors disposed on the handpiece/device body 210 configured to electrically contact the contact portions 116. The corresponding one or more electrical conductors are “at least one electrical conductor” as recited by claim 11 of the ’536 patent.

97. Mehta discloses such corresponding electrical conductors. Specifically, Mehta discloses “a corresponding contact point trace on a connection board” to which the contact portions 116 “maintain contact” and “couple to” in order to establish “an electrical pathway from the power supply” to the extendable needles 104. EX1004 at 15:55-59, 16:15-18. Furthermore, because the removable cartridge 100 couples to the proximal end of the handpiece/device body 210, and because the

interface between the removable cartridge 100 and the handpiece/device body 210 is located at the proximal end thereof, the contact point trace/connection board is included on the proximal end of the handpiece/device body 210.

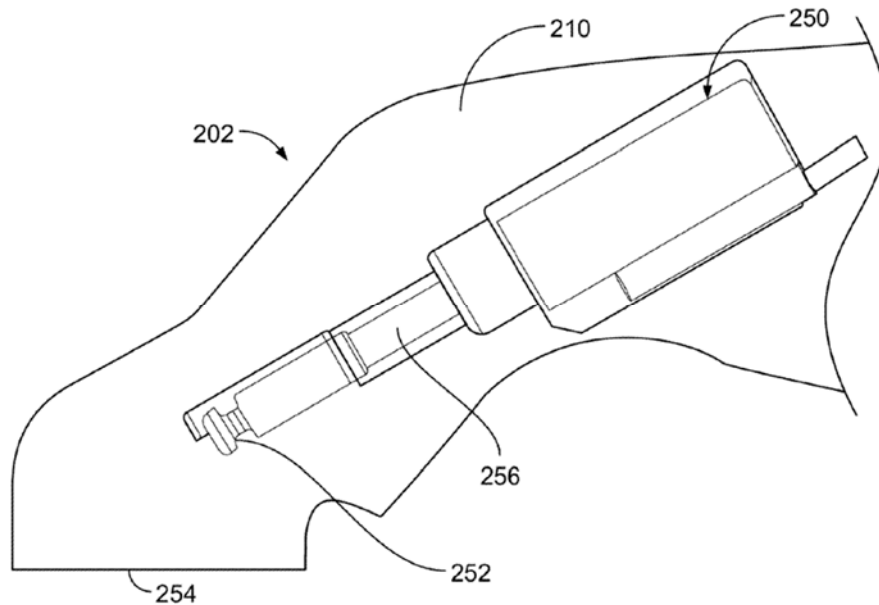
98. Accordingly, Mehta discloses one of the proximal end and the deployable needle assembly (i.e. the proximal end of the handpiece/device body 210) including at least one electrical conductor (i.e. at least one electrical conductor, e.g. the “corresponding contact point trace,” to which one or more of the contact portions 116 are couplable) and the other (i.e. the needle assembly 102) including at least one restorably deflectable electrical contact (i.e. at least one of the contact portions 116 in the form of spring contacts or spring pins) couplable to the one of the proximal end and the deployable needle assembly at least one electrical conductor—as is recited by claim 11 of the ’536 patent. Therefore, Mehta discloses [11c].

- e. **[11d] 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**

99. In the microneedling apparatus of Mehta, a motor is provided that couples to the needle assembly 102 in order slide the needle assembly towards a front portion 112 of the cartridge 100 and thereby cause the needles 104 of the needle assembly 102 to extend from the front portion of the cartridge 100. *See, e.g., id.* at

FIGS. 4A, 4C, 14:14-18, 15:34-40, 16:19-22, 16:59-64, 18:21-37. The motor is controlled by a control system. *See, e.g., id.* at 10:38-39.

100. Mehta discloses “a moveable actuator 250” which can be provided in the form of “any number of actuation means, including, but not limited to, pneumatic cylinders, springs, linear actuators, *or other such motors.*” *Id.* at 18:34-37 (emphasis added). Mehta provides “actuator 250” which “comprises a motor or drive unit that provides sufficient force, speed or impact to the probes to drive them into tissue.” EX1004 at 13:58-14:5. Accordingly, Mehta discloses an actuator provided in the form of a motor. Mehta further discloses that “[t]he mode of movement of the actuator can include...sliding, rotation, incremental indexing (via a ratchet-type system), [and] stepping (via an [*sic*] step-motor).” *Id.* at 15:36-40. Mehta further teaches that the “motor...provides sufficient force, speed or impact to” the needles “to drive them into tissue,” and that the motor “moves the shaft 256 where an engagement portion 252 on the shaft couples to” the needle assembly 102 “via a coupling portion 118...to advance and retract” the needles 104. *Id.* at 13:63-65, 18:27-30. The actuator 250 and the shaft 256 are illustrated in FIG. 5 of Mehta, which is reproduced below, while the coupling portion 118 is illustrated, e.g., in FIG. 4A of Mehta, which is also reproduced below.

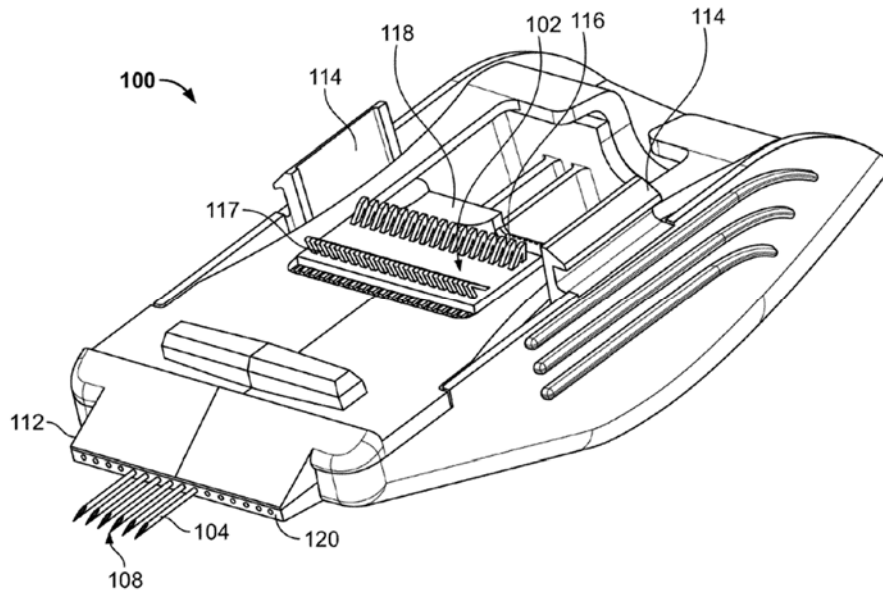


**EX1004—FIG. 5<sup>7</sup>**

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<sup>7</sup> Mehta describes FIG. 5 as illustrating "a cross sectional view of a distal end of a variation of treatment unit." EX1004 at 6:63-64; *see also id.* at 18:21-23.

However, Mehta uses the terms "proximal" and "distal" with reference to a user of the device. *See, e.g., id.* at 4:35-43, 6:63-65, 9:62-64, 18:21-23, 35:8-10, FIGS. 3A, 3B, 5, 12A, 12B. Accordingly, the "distal end" referred to by Mehta is an end of the handpiece 210 that is proximal to dermatological tissue to be treated, i.e. the proximal end recited by the claims of the '536 patent.



**EX1004—FIG. 4A**

Accordingly, Mehta discloses a motor (i.e. the actuator 250) coupled (via the shaft 256, the engagement portion 252 of the shaft, and the coupling portion 118 of the needle assembly 102) to a plurality of extendable needles (i.e. the extendable needles 104). Furthermore, as illustrated in FIG. 5 of Mehta, the motor (i.e. actuator 250) is positioned within the proximal end of the handpiece/device body 210.

101. Mehta also discloses that the motor causes the plurality of extendable needles to extend a desired distance from the needle assembly end surface. The distance by which the needles extend from the needle assembly end surface can be selected by a user, e.g. by choosing to couple a particular removable cartridge 100 having needles of a particular length to the proximal end of the handpiece/device

body 210. A distance that is selected by a user is a “desired distance” that, e.g., corresponds to a target tissue layer. A user may select the distance by which the needles extend from the needle assembly end surface by choosing a particular removable cartridge having needles of a particular length—e.g. a length that corresponds to deployment in the dermal region of a patient’s tissue when fully extended from the needle assembly end surface. Mehta specifically teaches that “the system can be provided with a number of electrode cartridges...for the physician to control treatment or placement of the electrodes[, i.e. needles,] by exchanging cartridges” (*id.* at 17:66-18:3), that “the individual probes[, i.e. needles,] 104 can have any number of shapes or profiles depending on the particular application” (*id.* at 10:17-19), that “for skin resurfacing, the length...is generally selected so that the energy delivery occurs in the dermis layer of the skin 10,” (*id.* at 10:21-23), and that “[s]electing probes[, i.e. needles,] having sufficient length to reach the subcutaneous fat layer allows for such probes[, i.e. needles,] to apply energy in the subcutaneous fat layer.” (*id.* at 8:16-18). Mehta teaches that “a more reliable insertion” can be achieved by “[o]ver-inserting and then partially retracting” the needles to the desired distance.” *Id.* at 16:34-41. And Mehta also indicates that a distance of needle extension can be selected by, e.g., choosing an angle A (*see* Mehta, FIG. 2B) “between nearly 0 and 90 degrees” such that the needles 104 are inserted at “a desired location in tissue.” *Id.* at 12:23-46. Accordingly, Mehta discloses that the

motor causes the plurality of extendable needles to extend a desired distance from the needle assembly end surface (i.e. a distance corresponding to a length of the needles of a removable cartridge selected by a user for a particular application).

102. Mehta discloses a user interface showing “depth/angle,” and states that this interface can “show a desired probe[, i.e. needle,] location (e.g. array 342 can represent the desired depth of placement for providing treatment).” *Id.* at 32:67-33:3, FIGS. 10B, 10E. In addition to showing the desired location, the user interface also shows “an actual placement of the probe[, i.e. needle,] array,” “probes that are not located in the target region via a specific color, flashing, or other visual indicator,” and “any number of prior probe locations,” e.g. “in a less prominent color (e.g., gray, faded, etc.) to clearly separate the previous treatment locations from the current location.” *Id.* at 32:52-57, 33:3-14. If a physician initially positions the needles too shallow into the tissue (i.e. into a “first layer”) for the intended treatment, “the physician would be informed that further advancement of the probes[, i.e. needles,] is necessary to place the probes within the second layer” of tissue. *Id.* at 33:24-27. Further advancement of the needles would entail a further extension thereof. In order to provide the capability of adjusting the amount of needle extension/needle insertion depth, and to provide for fine adjustments of needle position relative to previous treatment positions, Mehta provide a stepper-motor for advancing and retracting the needles 104. *See id.* at 10:33-39, 12:5-8, 15:34-42, 33:30-34.

103. Mehta's motor is driven by a control system/energy supply unit. *See, e.g., id.* at 10:38-39. Mehta also teaches that the control system/energy supply unit "may also include an input/output (I/O) device that allows the physician to input control and processing variables, to enable the controller to generate appropriate command signals." *Id.* at 12:5-8. Controlling the motor via a control system involves transmitting command signals from the control system to the motor, the command signals causing the motor to create a mechanical force that drives the shaft coupled to the needle assembly 102 to cause the needles 104 to extend from the needle assembly end surface. Such command signals are electrical motor control signals.

104. Stepper motors, such as the step-motor disclosed by Mehta, are electromechanical devices that convert electrical pulses into rotational motion. Unlike traditional electric motors, which spin continuously when voltage is applied, step motors move in discrete steps. Each step corresponds to a specific angular displacement, and the motor will move from one step to the next in response to electrical pulses. Step-motors are therefore suitable for applications where precise control of position and speed is crucial—as is the case in controlling the deployment of an array of RF microneedles. For a step-motor, like that disclosed by Mehta, the command signals are provided as electrical motor control signals in the form of a pulse train. A "rotation-to-translation" mechanical conversion unit, such as a gear assembly, is used between the motor and the array of needles to obtain the desired

translational movement. The rotation-to-translation mechanical conversion unit can be constructed in such a manner to provide a desired rotation-to-translation ratio, i.e. to provide a desired translational motion in response to a particular rotation of the step-motor.

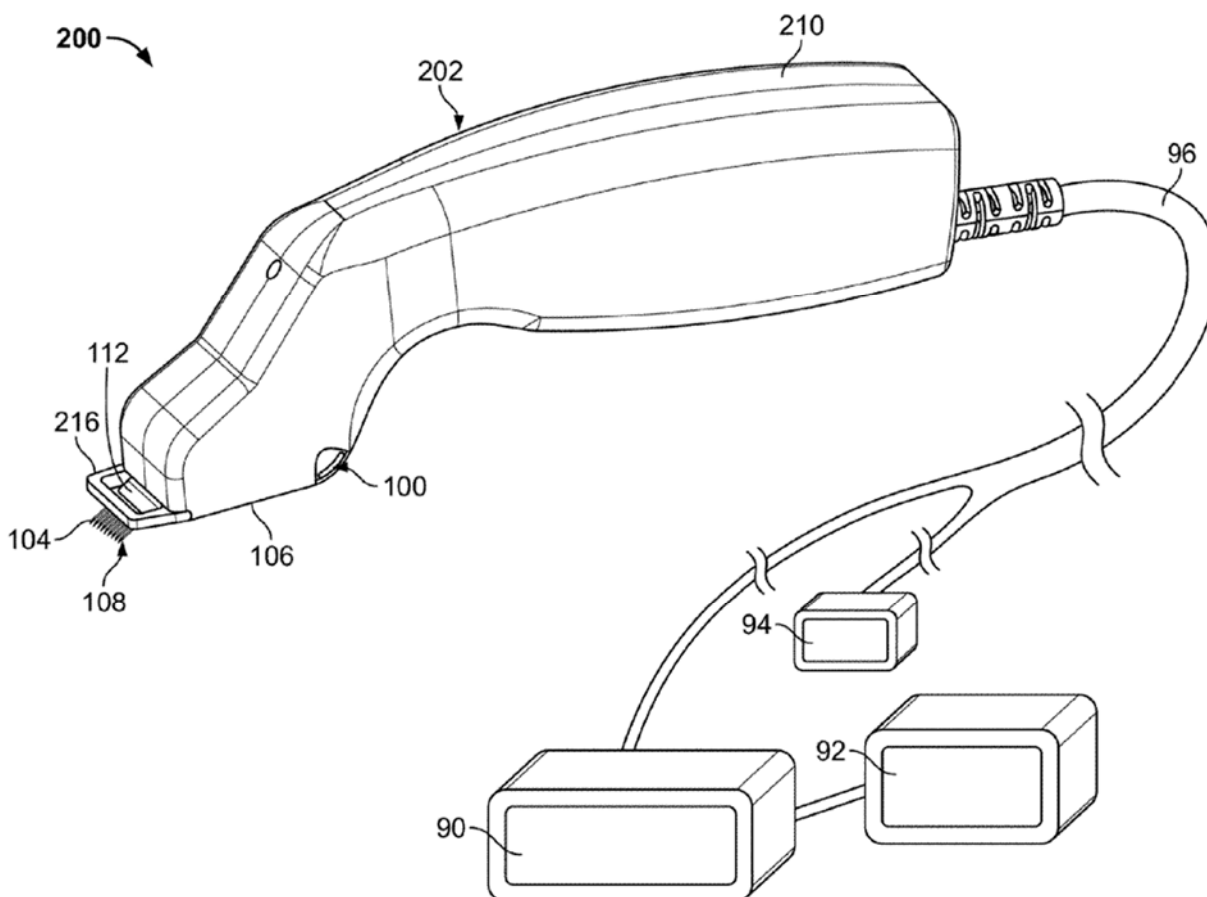
105. Accordingly, Mehta discloses a motor (i.e. actuator 250) coupled (via the shaft 256 and the coupling portion 118 of the assembly 102) to a plurality of extendable needles (i.e. the needles/electrodes/probes 104) that causes the plurality of extendable needles to extend a desired distance from the needle assembly end surface when the motor is energized with a particular signal (i.e. an appropriate command signal from control system/energy supply unit 90)—as is recited by claim 11 of the '536 patent. Therefore, Mehta discloses [11d] regardless of which interpretation of “desired distance” is applied.

**f. [11e] a signal generator electrically coupled to the plurality of extended needles to energize the plurality of extended needles**

106. In Mehta's microneedling apparatus, a signal generator is electrically coupled to the needles when they are extended from the needle assembly end surface and provides energy to, i.e. energizes, the extended needles to percutaneously deliver energy to the patient's skin and thereby provide treatment. *See, e.g., id.* at 2:37-62, 10:53-65, 15:55-59, and 17:3-12.

107. Mehta discloses that “[t]he system 200 also includes an energy supply unit 90 coupled to the treatment unit 202 via a cable 96 or other means.” *Id.* at 10:53-

55. FIG. 2A of Mehta, reproduced below, illustrates the system 200—including the treatment unit 202, cable 96, and energy supply unit 90.



**EX1004—FIG. 2A**

Mehta teaches that “the energy supply unit 90 contains the software and hardware required to control energy delivery” (*id.* at 10:57-59) and that the “electrodes 104 in the electrode assembly 102” have “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[, i.e. needles,] 104” (*id.* at 15:55-59).

Mehta further teaches that “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” (*id.* at 15:62-65), while in other variations “the system can be configured so that the electrodes can be energized whether in the treatment or retracted positions” (*id.* at 16:8-11). In Mehta, the energy is delivered in the form of parameterized RF pulse signals—which are generated by the power supply. *See id.* at 20:13-55. As an alternative to the externally-located energy supply unit 90 depicted in FIG. 2A, Mehta discloses that “the CPU, software and other hardware control systems,” as well as “the power supply necessary to deliver treatment,” may “reside in the handpiece 210.” *Id.* at 10:53-65.

108. Accordingly, Mehta discloses a signal generator (i.e. energy supply unit 90 or power supply residing in the handpiece) electrically coupled to the plurality of extended needles (i.e. needles 104) to energize the plurality of extended needles—as recited by claim 11 of the ’536 patent. Therefore, Mehta discloses [11e].

## **2. Dependent Claim 12**

109. Claim 12 recites the apparatus of claim 11, including the additional limitation of “wherein the device proximal end includes an electrical connector couplable to the signal generator.” In my opinion, Mehta discloses the additional

limitation of claim 12 of the '536 patent. Therefore—and for the reasons set forth *supra* Section X.A.1.—Mehta anticipates claim 12.

110. In order for electrical power to be delivered from the power supply to the needles, there must be a continuous, uninterrupted electrical connection from the power supply to the needles. Due to the geometry of Mehta's microneedling apparatus and its various components, that continuous, uninterrupted electrical connection must extend from (a) the power supply, through (b) the device proximal end, (c) an electrical conductor on the device proximal end configured to electrically contact the contact portions 116, (c) the contact portions 116 themselves, and (d) the needles 104. Such pathway must necessarily include an electrical connector in the device proximal end that is couplable to a signal generator (i.e. the power supply), as recited by claim 12 of the '536 patent.

111. As discussed *supra* ¶90, (i) the extendable needles 104 are part of a needle assembly 102 that is a component of the removable cartridge 100 (*see, e.g.*, EX1004 at 9:40-43, 14:15-19) and (ii) the power supply is either connected to the handpiece/device body 210 via a cable 96 or provided in the handpiece/device body 210 itself (*see, e.g., id.* at 9:40-43, 10:53-65). The electrical pathway between the power supply and the extendable needles must necessarily—in order for electrical power to be delivered from the power supply to the extendable needles—extend across the interface between the removable cartridge 100 and the handpiece/device

body 210. As discussed *supra* ¶¶94, 96, there must be (a) a first electrical conductor (or set of electrical conductors) disposed on the removable cartridge 100 or a component thereof and (b) a second electrical conductor (or set of electrical conductors) disposed on the handpiece/device body 210 such that, when the removable cartridge 100 is coupled to the handpiece/device body 210, the first and second electrical conductors (or first and second sets of electrical conductors) contact one another to provide an electrical connection therebetween. Moreover, in order for electrical power to be transmitted from the power supply to the extendable needles, there must be (c) an electrical conductor (or set of electrical conductors) that is electrically connected to the power supply in order to transmit power from the power supply to (b) the second electrical conductor (or set of electrical conductors) referenced in the preceding sentence.

112. As discussed *supra* ¶¶95, 97, the proximal end of the handpiece/device body 210 includes an electrical conductor (or set of electrical conductors) (e.g. the “corresponding contact point trace,” EX1004 at 16:15-18) corresponding to and configured to contact the contact portions 116 disposed on the needle assembly 102. And as discussed *supra* ¶107, an electrical pathway is provided from the power supply to the electrodes 104. That electrical pathway includes an electrical connector in the proximal end that is couplable to the signal generator. In order for electrical power to be transmitted from the power supply to the needles 104, the electrical

conductor (or set of electrical conductors) on the proximal end of the handpiece/device body 210 must be electrically connected to the power supply. Therefore, there necessarily must be an electrical connector, located in the proximal end of the handpiece/device body 210, couplable to the signal generator and to the one or more electrical conductors that contact the contact portions 116. Absent such an electrical connector, energy could not flow from the signal generator to the needles 104.

113. Accordingly, Mehta discloses that the device proximal end (i.e. of the handpiece/device body 210) includes an electrical connector couplable to the signal generator (i.e. energy supply unit 90 or power supply residing in the handpiece), as recited by claim 12 of the '536 patent. Therefore, Mehta anticipates claim 12.

### **3. Dependent Claim 13**

114. Claim 13 recites the apparatus of claim 11, including the additional limitation of “wherein the proximal end includes the needle deploying motor, the motor including a draft shaft releasably couplable to the deployable needle assembly.” In my opinion, Mehta discloses the additional limitation of claim 13 of the '536 patent. Therefore—and for the reasons set forth *supra* Section X.A.1.—Mehta anticipates claim 13.

115. As discussed *supra* Section VIII.F., the term “draft shaft,” recited by claim 13 of the '536 patent, would have been understood by a POSA as a “drive

shaft.” As discussed *supra* ¶100, Mehta discloses a motor (i.e. the actuator 250) and a drive shaft (i.e. the shaft 256) couplable to the deployable needle assembly (i.e. via the coupling portion 118 of the needle assembly 102) positioned within the proximal end of the handpiece/device body 210. A POSA would understand the drive shaft 256 to be a component of the motor (i.e. actuator 250). Furthermore, because the cartridge 100 is attachable and detachable from the handpiece/device body 210, the connection between the drive shaft 256 and the coupling portion 118 of the needle assembly 102 can be interrupted by detaching the cartridge from the handpiece/device body 210. The drive shaft 256 is thus releasably couplable to the deployable needle assembly.

116. Accordingly, Mehta discloses that the proximal end (i.e. of the handpiece/device body 210) includes the needle deploying motor (i.e. the actuator 250), the motor including a drive shaft (i.e. the shaft 256) releasably couplable (via engagement of the engagement portion 252 with the coupling portion 118 of the needle assembly 102) to the deployable needle assembly (i.e. the assembly 102), as recited by claim 13 of the '536 patent. Therefore, Mehta anticipates claim 13.

#### **4. Dependent Claim 16**

117. Claim 16 recites the apparatus of claim 11, including the additional limitation of “wherein at least one restorably deflectable electrical contact includes a depressible pin.” In my opinion, Mehta discloses the additional limitation of claim

16 of the '536 patent. Therefore—and for the reasons set forth *supra* Section X.A.1.—Mehta anticipates claim 16.

118. As discussed *supra* ¶95, the needle assembly 102 of the removable cartridge 100 of the microneedling apparatus of Mehta includes “connection or contact portions 116” in the form of “spring contacts or spring pins.” EX1004 at 15:55-59, 16:12-15. A spring pin is a “depressible pin,” as recited by dependent claim 16. Thus, the connection or contact portions 116, as disclosed in Mehta, include depressible pins. Therefore, Mehta anticipates claim 16.

## **5. Dependent Claim 18**

119. Claim 18 recites the apparatus of claim 11, including the additional limitation of “wherein the signal generator energizes the plurality of extended needles with energy to one of cut, blend, or coagulate dermatological tissue.” In my opinion, Mehta discloses the additional limitation of claim 18 of the '536 patent. Therefore—and for the reasons set forth *supra* Section X.A.1.—Mehta anticipates claim 18.

120. The microneedling apparatus of Mehta is designed to coagulate collagen in a patient's skin in order to reduce the visibility of fine lines and wrinkles. *See, e.g.*, EX1004 at 1:27-31, 24:46-47, 37:25-34. As discussed *supra* Section X.A.1.f., Mehta discloses a signal generator (i.e. energy supply unit 90) electrically coupled to the plurality of extended needles (i.e. the needles 104) to energize the

plurality of extended needles. Mehta further teaches that the extended needles “can employ an RF energy mode to denature or coagulate collagen in a dermal layer.” EX1004 at 24:46-47. Accordingly, Mehta discloses that the signal generator (i.e. energy supply unit 90) energizes the plurality of extended needles (i.e. probes/electrodes 104 and/or 108) with energy (i.e. RF energy) to one of cut, blend, or coagulate (i.e. coagulate) dermatological tissue, as recited by claim 18 of the ’536 patent. Therefore, Mehta anticipates claim 18.

## **6. Dependent Claim 19**

121. Claim 19 recites that the apparatus of claim 11 further includes the additional limitation of “the motor deploying the plurality of extendable needles to a predetermined depth and the signal generator energizing the plurality of extended needles to a predetermined intensity for a predetermined duty cycle.” In my opinion, Mehta discloses the additional limitation of claim 19 of the ’536 patent. Therefore—and for the reasons set forth *supra* Section X.A.1.—Mehta anticipates claim 19.

122. Mehta discusses measuring tissue parameters prior to the delivery of treatment to the tissue to be treated, and controlling aspects of the treatment based on the measured tissue parameters. *See, e.g.*, EX1004 at 24:5-12. Specifically, Mehta teaches (i) measuring, prior to the delivery of RF treatment to a patient’s dermatological tissue, (a) the temperature of a patient’s dermatological tissue in the vicinity of a microneedle and/or (b) the impedance between a pair of microneedles

inserted into the patient's dermatological tissue, and (ii) controlling, based on measured temperature and/or impedance values, the manner in which RF energy is delivered to the patient's dermatological tissue. *See, e.g., id.* at 3:42-67, 24:5-12. Mehta specifically teaches that RF energy can be provided in pulses, that the RF energy can be delivered with a specific duty cycle, and that an amplitude (i.e. intensity) and duration (which is related to duty cycle) of the pulses is predetermined prior to the delivery of the RF energy. *See, e.g., id.* at 20:13-55.

123. As discussed *supra* (Section X.A.1.e.), Mehta discloses a motor (i.e. actuator 250) coupled (via the shaft 256 and the coupling portion 118 of the assembly 102) to a plurality of extendable needles (i.e. the needles/electrodes/probes 104) that causes the plurality of extendable needles to extend a desired distance from the needle assembly end surface. Causing the extendable needles to extend a desired distance deploys them to a predetermined depth in a patient's tissue.

124. As further discussed *supra* (Section X.A.1.f.), Mehta also discloses a signal generator (i.e. energy supply unit 90) electrically coupled to the plurality of needles (i.e. the probes/electrodes 104) to energize the plurality of needles. Mehta teaches that "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."

EX1004 at 20:21-24.

125. Mehta teaches predetermining pulse parameters—including duration (which corresponds to duty cycle) and amplitude (which corresponds to intensity)—prior to providing a pulse and then predetermining modified pulse parameters again prior to a subsequent pulse. Specifically, Mehta teaches that (i) “[p]ulsing the energy delivery allows for an improved temperature measurement in the period between energy deliveries and provides precise control of energy delivery” (*id.* at 20:24-27, (ii) “[e]ach pulse has a parameter, including amount of energy, duration, maximum energy delivered, energy wave form or profile (square wave, sinusoidal, triangular, etc.), current, voltage, amplitude, frequency, etc.” (*id.* at 20:31-35), and (iii) “[t]he 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” (*id.* at 20:39-42). Mehta teaches predetermining pulse parameters—which include intensity and duration—prior to providing a pulse and then predetermining modified pulse parameters again prior to a subsequent pulse. Mehta also teaches that the present system can be pulsed with varying duty cycles so that temperature measurements can be taken between the pulsed deliveries of energy. *See id.* at 20:21-24. Mehta also teaches that a “control system can be adjusted to control the amount or a rate of energy deposition depending on a measured parameter, such as a tissue impedance for example.” *Id.* at 20:48-55. The rate of energy deposition

is proportional to the duration of the pulse parameter disclosed by Metha (*id.* at 20:29-35), which is directly related to the duty cycle.

126. Accordingly, Mehta discloses the motor (i.e. actuator 250) deploying the plurality of extendable needles (i.e. probes/electrodes 104) to a predetermined depth (i.e. a desired depth for treatment, determined beforehand, e.g. through selection of a particular cartridge 100) and the signal generator (i.e. the energy supply unit 90) energizing the plurality of extended needles (i.e. probes/electrodes 104) to a predetermined intensity for a predetermined duty cycle (i.e. a duty cycle and an amplitude determined by a controller prior to delivery of a pulse and a specific duty cycle), as recited by claim 19 of the '536 patent. Mehta also discloses predetermination of treatment parameters, such as intensity and duty cycle, through user selection or adjustment. *See, e.g.*, EX1004 at 35:8-22 (physician adjustment of treatment settings); 37:35-41 (adjusting time-at-temperature); 3:40-41 (adjusting parameters of energy supply unit). Therefore, Mehta anticipates claim 19.

## **7. Independent Claim 1**

127. As discussed in more detail below, Mehta discloses each and every element of independent claim 1. Therefore, Mehta anticipates claim 1 of the '536 patent.

**a. [1pre] A method of treating dermatological tissue, comprising:**

128. Mehta discloses microneedling methods for treating dermatological tissue to, for example, enhance the appearance of a patient's skin. *See, e.g.*, EX1004 at 2:37-45. Microneedling methods, like those described by Mehta, both (i) trigger the skin's natural healing response to stimulate collagen production and (ii) percutaneously deliver energy to cause contraction of existing collagen tissue in the skin's dermis. The result of such microneedling treatment methods is tightened and rejuvenated skin with fewer visible fine lines and wrinkles.

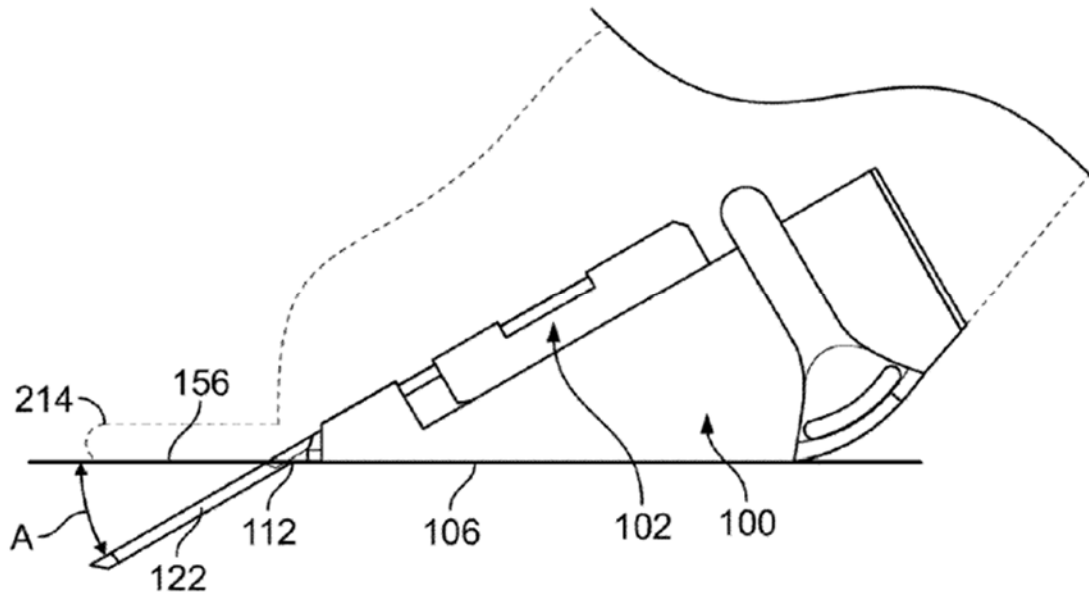
129. Mehta teaches devices and methods to “treat cosmetic conditions affecting the skin of various body parts.” *Id.* at 1:14–19. Mehta's devices and methods target specific layers of the skin for treatment. *See, e.g., id.* at 8:45–48 (“[W]hen applying cosmetic treatment to the skin for tightening or removal of wrinkles, it is desirable to deliver energy to the dermis.”); *see also id.* at 2:37–62, 3:42–56, 7:52–59. Treatment of the skin—and specific layers thereof—constitutes treatment of dermatological tissue.

130. Accordingly, Mehta discloses [1pre], i.e. a method of treating dermatological tissue.

**b. [1a] placing a user holdable device releasably couplable deployable needle assembly end surface on or near dermatological tissue to be treated,**

131. Mehta's methods for treating dermatological tissue involve placing a microneedling device, which is holdable by a user, against a patient's skin and inserting microneedles into the patient's skin to apply treatment thereto.

132. Mehta discloses "placing a tissue engaging surface of an energy delivery device against a surface of the tissue." *Id.* at 5:3-6. Mehta's energy delivery device includes a user holdable device releasably couplable deployable needle assembly end surface (i.e. either of (a) the front portion 112 of the removable cartridge 100 or (b) the retracted position tip plane of the needle assembly 102) (*see supra* Sections X.A.1.b. and X.A.1.c.)), and a POSA would understand that using Mehta's skin treatment apparatus 200 would necessarily entail placing both (a) the front portion 112 of the removable cartridge 100 and (b) the retracted position tip plane of the needle assembly 102 on or near dermatological tissue to be treated. For example, FIG. 7A of Mehta, reproduced below, illustrates the front portion 112 of the removable cartridge 100 placed on an area of tissue 156 directly above a region treated by an active area 122 of a needle 104.



**EX1004—FIG. 7A**

Accordingly, Mehta's microneedling treatment method involves placing a user holdable device releasably couplable deployable needle assembly end surface (i.e. an end surface of the needle assembly 102) on or near dermatological tissue to be treated, as recited by claim 1 of the '536 patent. Therefore, Mehta discloses [1a].

- c. [1b] the holdable device including a proximal end and the releasably couplable deployable needle assembly,**

133. Mehta discloses [1b]. *Supra* Section X.A.1.b.

- d. [1c] the deployable needle assembly mechanically separatably from the proximal end and including a plurality of needles extendable from the deployable needle assembly end surface,**

134. Mehta discloses [1c]. *Supra* Sections X.A.1.b. and X.A.1.c.

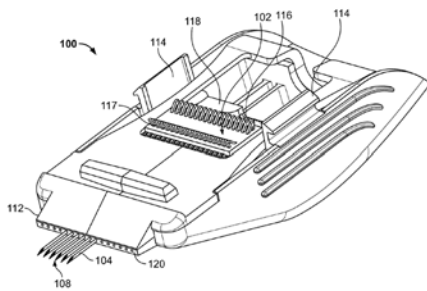
- e. [1d] one of the proximal end and the deployable needle assembly including at least one electrical conductor and the other including at least one restorably deflectable electrical contact couplable to the one**

**of the proximal end and the deployable needle assembly at least one electrical conductor;**

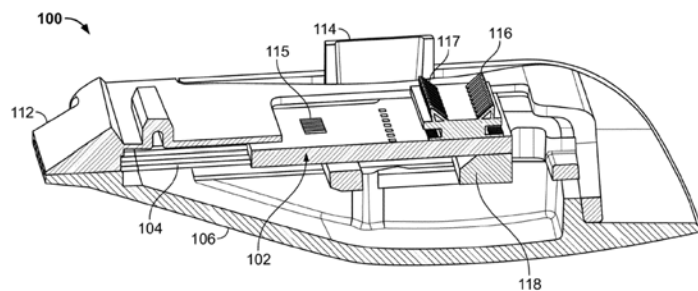
135. Mehta discloses [1d]. *Supra* Section X.A.1.d.

**f. [1e] communicating electrical signals from the proximal end to the plurality of the extendable needles;**

136. Mehta discloses [1e]. Mehta teaches that each extendable needle 104 of the needle assembly 102 “can have multiple connection portions 116, 117,” and “in one possible variation, the proximal connection portion 116 can electrically couple to a temperature detecting circuit on the hand unit” while “distal connection portion 117 can connect to a power delivery circuit.” EX1004 at 16:62-17:7. FIGS. 4A and 4C of Mehta, which depict the multiple connection portions 116 and 117 of the assembly 102, are depicted below.



EX1004—FIG. 4A



Ex 1004—FIG. 4C

Mehta additionally teaches that “[i]n such an example, the temperature of the electrodes can be continuously monitored while the power delivery to the electrodes can be limited to distal advancement of the assembly.” *Id.* at 17:8-11.

Continuously monitoring the temperature of the electrodes—via an electrical

coupling of the proximal connection portion 116 to a temperature detecting circuit on the hand unit (i.e. the device body 210)—requires communicating signals, i.e. electrical signals, from the proximal end (i.e. of the handpiece/device body 210) to the plurality of the extendable needles (via the proximal connection portion 116 of the extendable needles 104).

137. Furthermore, as noted *supra* Section X.A.6., Mehta teaches (i) measuring, prior to the delivery of RF treatment to a patient's dermatological tissue, the impedance between a pair of microneedles inserted into the patient's dermatological tissue. *See, e.g.*, EX1004 at 24:57-60. Measuring the impedance between a pair a microneedles inserted into the patient's dermatological tissue requires sending electrical signals to the microneedles in order to carry out the measurement.

138. Accordingly, Mehta discloses communicating electrical signals (i.e. those necessary to carry out and communicate the results of temperature and impedance measurements) from the proximal end (i.e. of the handpiece/device body 210) to the plurality of the extendable needles (i.e. needles 104). Therefore, Mehta discloses [1e].

**g. [1f] 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**

139. Mehta discloses [1f]. *Supra* Section X.A.1.e.

**h. [1g] energizing the plurality of extended needles via a signal generator electrically coupled to the plurality of extended needles.**

140. Mehta discloses [1g]. *Supra* Section X.A.1.f.

**8. Dependent Claim 2**

141. Claim 2 recites that the method of claim 1 further includes the limitation of “placing a dermatological chemical one of on at least a portion of the dermatological tissue, at least a portion of the end surface, and the plurality of the extendable needles.” In my opinion, Mehta discloses the additional limitation of claim 2 of the ’536 patent. Therefore—and for the reasons set forth *supra* Section X.A.1.—Mehta anticipates claim 2 of the ’536 patent.

142. Mehta teaches that “[t]he treatment methods and device can also include the use of additives, medicines, bioactive substances, or other substances intended to create a therapeutic effect on their own or augment a therapeutic effect created by any one of the energy modalities discussed herein.” EX1004 at 9:7-11. As a specific example of such a substance, Mehta teaches that “anesthetic or numbing agents can be delivered to reduce the patient’s sensation of pain” by being “applied on the epidermal layer” or “injected into the dermal layer of the skin.” EX1004 at 9:19-22. Each of an anesthetic or numbing agent—as well as other substances intended to create a therapeutic effect—is a “dermatological chemical” as recited by claim 2 of the ’536 patent. Accordingly, Mehta discloses placing a dermatological chemical (e.g. an anesthetic or numbing agent) one of on at least a

portion of the dermatological tissue, at least a portion of the end surface, and the plurality of the extendable needles (i.e. on the epidermal layer or into the dermal layer). Therefore, Mehta anticipates claim 2 of the '536 patent.

### **9. Dependent Claim 3**

143. Claim 3 recites the method of claim 1, including the additional limitation of “wherein the proximal end includes the needle deploying motor, the motor including a draft shaft releasably couplable to the deployable needle assembly.” For the reasons set forth *supra* Section X.A.3., Mehta discloses the additional limitation of claim 3. Therefore—and for the reasons set forth *supra* Section X.A.1.—Mehta anticipates claim 3.

### **10. Dependent Claim 6**

144. Claim 6 recites the method of claim 1, including the additional limitation of “wherein the at least one restorably deflectable electrical contact includes a depressible pin.” For the reasons set forth *supra* Section X.A.4., Mehta discloses the additional limitation of claim 6. Therefore—and for the reasons set forth *supra* Section X.A.1.—Mehta anticipates claim 6.

### **11. Dependent Claim 8**

145. Claim 8 recites that the method of claim 1, including the additional limitation of “employing the signal generator to energize the plurality of extended needles with energy to one of cut, blend, or coagulate dermatological tissue.” For the reasons set forth *supra* Section X.A.5., Mehta discloses the additional limitation

of claim 8. Therefore—and for the reasons set forth *supra* Section X.A.1.—Mehta anticipates claim 8.

## **12. Dependent Claim 9**

146. Claim 9 recites that the method of claim 1 further includes the additional limitation of “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.” For the reasons set forth *supra* Section X.A.6., Mehta discloses the additional limitation of claim 9. Therefore—and for the reasons set forth *supra* Section X.A.1.—Mehta anticipates claim 9.

## **B. Ground 2: Claims 1–9 and 11–19 are Obvious over Mehta in view of the knowledge of a POSA**

147. In my opinion, claims 1–9 and 11–19 of the ’536 patent are obvious over Mehta in view of the knowledge of a POSA.

### **1. Independent Claims 1 and 11**

#### **a. Independent Claim 11**

148. As discussed in Sections X.A.1.a., X.A.1.b., X.A.1.c., X.A.1.d., X.A.1.e., and X.A.1.f., Mehta discloses elements [11pre], [11a], [11b], [11c], [11d], and [11e].

149. To the extent that Patent Owner argues that any of elements [11pre], [11a], [11b], [11c], [11d], and [11e] is not disclosed by Mehta, either explicitly or

inherently, it would have been obvious, in view of the knowledge of a POSA, to modify the microneedling apparatus of Mehta to provide any such element. For example, with respect to element [11c], it would have been obvious to a POSA to provide at least one electrical conductor on the proximal end of the handpiece 210 to contact the contact portions 116 of the needle assembly 102 and thereby form an electrical pathway extending from the power supply (i.e. energy supply unit 90/power supply residing in handpiece 210) to the needles 104. The motivation would have been to provide such an electrical pathway while simultaneously allowing one cartridge 100 to be disposed after a first patient is treated and another cartridge 100 attached to the handpiece 210 prior to a second patient being treated. With respect to element [11f], it would have been obvious to a POSA to provide a signal generator to supply an RF signal to the needles 104 in order to effectuate treatment of a patient's skin.

150. I also note that, although Mehta describes and illustrates slight variations or so-called “embodiments” throughout, they are nonetheless not entirely distinct and separate alternatives to one another. For example, Figs. 2A–2B of Mehta depict a system 200 generally, and Figs. 4A–4F and 7A–7E depict a variety of exemplary implementations of components that could be included in the system 200. EX1004 at 6:51-62, 7:1-12. In a more specific example, Fig. 4A depicts an exemplary implementation of a cartridge 100 that may be incorporated into the

system 200 of Figs. 2A–2B, and Fig. 7A depicts a side view of how needles 104 of the cartridge 100 of Figs. 2A–2B would enter human tissue. I also note that Mehta states “[i]t is expressly intended that, wherever possible, the invention includes combinations of aspects of the various embodiments described herein or even combinations of the embodiments themselves.” *Id.* at 6:3-6. Accordingly, a POSA would have understood that the microneedling apparatuses and methods disclosed by Mehta include combinations of what Mehta refers to as embodiments as well as combinations of certain aspects of what Mehta refers to as embodiments. Furthermore, it would have been obvious to a POSA to combine both embodiments of Mehta and aspects thereof.

151. With respect to element [11d], I understand Serendia may contend that the term “desired distance” should be interpreted so as to specifically require a user-settable distance of needle extension along the axis of extension. For the reasons set forth *supra* Section VIII.C., Serendia’s proposed interpretation is unduly narrow and should be rejected as contrary to the plain meaning of the term “desired distance.” Nevertheless, even if Serendia’s unduly narrow interpretation were to be adopted, independent claim 11 would have been obvious over Mehta and the knowledge of a POSA.

152. As discussed *supra* Section X.A.1.e., Mehta discloses a microneedling apparatus that includes a motor (i.e. actuator 250) coupled (via the shaft 256 and the

coupling portion 118 of the assembly 102) to a plurality of extendable needles (i.e. the needles/electrodes/probes 104) 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 (i.e. an appropriate command signal from control system/energy supply unit 90)—as is recited by claim 11 of the '536 patent. Mehta teaches that motor provides for a “mode of movement” of the needles that can include “incremental indexing (via a ratchet-type system), [and] stepping (via an [*sic*] step-motor).” EX1004 at 15:36-40. With either a ratchet-type system or a step-motor, the needles 104 of Mehta would move between two terminal positions (one corresponding to a fully retracted position of the needle assembly 102/needles 104, and the other corresponding to a fully extended position of the needle assembly 102/needles 104) by traversing a number of intermediate positions, each intermediate position separated by a single, incremental step.

153. A POSA would also have understood that, in the microneedling apparatus of Mehta where the actuator 250 is provided in the form of a step-motor, a gear mechanism must necessarily be present that converts the rotational movements of the step-motor into translational movements of the shaft 256—and therefore of the needles 104 (which are coupled to the shaft via the coupling portion 118 of the needle assembly 102)—in order for the needles 104 to extend and retract.

154. At the time of the invention, a POSA would have been familiar with step-motors and gear mechanisms capable of moving the needle assembly 102/needles 104 of Mehta's microneedling device in steps of approximately 100  $\mu\text{m}$ . Specifically, a POSA would have known that providing the actuator 250 of Mehta's microneedling apparatus in the form of a step-motor would allow fixed angle rotations of the step-motor that cause fixed, approximately 100  $\mu\text{m}$  translational movements of the shaft 256 (coupled via the coupling portion 118 of the needle assembly 102) and, therefore, of the needles 104.

155. Moreover, a POSA would have known how to provide control signals to a step-motor to cause the step-motor to assume a particular intermediate position between two terminal positions. For example, a POSA would have known that a step-motor can be controlled by providing a train of input pulses (e.g. in the form of a square wave) to the step-motor, where each pulse of the pulse train is tailored (i.e. through selection of proper parameters, such as period and amplitude) to cause a single, fixed-angle rotation of the shaft of the step-motor. A POSA would also have known how to program a controller to track a current position of the step-motor (or alternatively, to track a current position of an associated gear mechanism) and to generate a pulse train having a number of pulses equal to a number of steps between that current position and a desired position (i.e. for the step motor or the associated gear mechanism). A POSA would therefore have known how to program a controller

to cause the step-motor of Mehta to move the needles 104 to any specific intermediate step between a fully retracted position and a fully extended position.

156. As also discussed *supra* Section X.A.1.e., the motor of Mehta's microneedling device is driven by a control system/energy supply unit (*see, e.g.*, EX1004 at 10:38-39), and the control system/energy supply unit "may also include an input/output (I/O) device that allows the physician to input control and processing variables, to enable the controller to generate appropriate command signals" (EX1004 at 12:5-8). To the extent that Mehta does not explicitly disclose controlling the motor to provide for needle extension by a distance that is user-settable, it would have been obvious to a POSA to modify Mehta to provide such control. Providing such control would streamline the treatment process, decrease the time required for treatment, and limit treatment cost and waste generated during treatment. In addition, providing such control would allow more precise targeting of treatment within the dermis, thereby providing improved treatment outcomes.

157. Proper needle depth may vary from one location on a patient's face to another. For example, when a user moves the microneedling device of Mehta from a patient's forehead to cheeks (the dermis is typically thinner on the forehead) or between different regions of a patient's cheek (the dermis is typically thinner on top of the cheek bones immediately beneath the eye sockets than it is above the facial cheek muscles), it may be necessary to adjust, or fine-tune, needle deployment depth.

If only two positions—extended and retracted—were provided for the needles 104, it might be necessary to swap cartridges when treating different facial regions or when treating the face and the neck. By modifying Mehta to (i) allow a user to select a particular extension distance or insertion depth of the needles 104 (corresponding to a specific intermediate step of a step-motor) and/or (ii) allow an incremental increase or decrease, by one or more steps of a step-motor, of the extension distance and/or insertion depth of the needles 104, a user would be provided with flexibility necessary to rapidly adapt needle deployment and depth to different facial regions.

158. Mehta teaches that, by “detect[ing] the layer of skin in which the needles were deployed,” “real-time information” can be provided “to the physician...to confirm proper needle deployment and needle depth.” EX1004 at 37:7-11. For example, Mehta discloses a “tissue characteristic indicator” that provides “a virtual depiction 350 of the depth or location” of the needles to “illustrate an actual placement” of the needles, which “allows the physician to...identify whether the array [of needles] is located within the desired tissue layer.” EX1004 at 32:46-50, 32:52-59, 33:14-19. In the event the tissue characteristic indicator indicated an improper needle depth, incrementally increasing or decreasing needle deployment depth (e.g. by  $\sim 100\mu\text{m}$  steps of a step-motor) would allow a user, e.g. an aesthetician or dermatologist, to fine-tune needle extension to precisely and expeditiously achieve proper needle deployment and depth—in both different facial

regions as well as on both the face and the neck—with a single cartridge. As a result, patients could be treated in less time, and clinicians and physicians could treat more patients per day. Furthermore, because it would not be necessary to use multiple cartridges when treating the same patient, fewer cartridges would be discarded (as compared to the case of swapping cartridges when treating different regions of the patient's skin) thereby resulting in less waste and lower costs.

159. Mehta also teaches that “precisely determin[ing] depth of placement” of the needles “allowed tunable dosimetry permitting controlled delivery of a specific thermal coagulation profile at a particular depth in the dermis” and “ensured adequate sparing of normal tissue.” EX1004 at 39:33-41. Allowing a user to (i) select a particular extension distance or insertion depth of the needles 104 (corresponding to a specific intermediate step of a step-motor) and/or (ii) incrementally increasing or decreasing, by one or more steps of a step-motor, an extension distance and/or insertion depth of the needles 104 would enable more precise control over needle depth (as compared to providing only retracted and extended positions combined with different cartridges with different needles lengths/sizes) would provide a user, e.g. an aesthetician or dermatologist, with both (i) an enhanced ability to precisely control needle depth and thereby the thermal coagulation profile and (ii) more flexibility in spacing fractional lesions (i.e. at

different depths within the dermis) to ensure adequate sparing of normal tissue, thereby improving treatment outcomes.

160. Furthermore, allowing a clinician select a particular extension distance or insertion depth of the needles 104 (corresponding to a specific intermediate step of a step-motor) would facilitate compound treatments that target different layers of the skin—without necessarily requiring cartridges to be swapped. Mehta teaches that the skin treatment apparatus, “with its use of penetrating devices lends itself to the delivery of agents and materials directly to a specific region of tissue” (EX1004, 35:61-63), that “anesthetic agents such as lidocaine can be delivered through the probe” (EX1004, 35:63-65), that “[c]ollagen or other filler material can be delivered prior to, during, or after energy delivery” (EX1004, 35:66-36:4), and that “Botulinum Toxin type A (Botox®) can also be delivered to the dermis or to the muscular layer below the dermis by further inserting the access probe” (EX1004, 9:22-25). Modifying Mehta to enable a clinician to variably select a needle extension distance would allow the clinician to move the needles from a first treatment depth (corresponding, e.g., to a thermal treatment designed to cause coagulation of collagen in the dermis of a patient’s skin) to a second treatment depth (corresponding, e.g., to a depth for the delivery of Botox®, collagen, or an anesthetic agent). Such modifications of would shorten the duration of such compound treatments, thereby allowing patients to spend less time in a clinical setting, allowing

clinicians to treat more patients in a given amount of time, and decreasing the cost of treatment.

161. Accordingly, a POSA would have been motivated, by a desire to both (i) streamline treatment and decrease treatment costs and (ii) improve treatment outcomes for patients, modify Mehta to allow a user to set, e.g. via a user interface, a distance of needle extension along the axis of extension, i.e. by providing the functionality necessary to allow a user to select a particular extension distance or insertion depth of the needles 104 and/or incrementally increasing or decreasing, by one or more steps of a step-motor, an extension distance and/or insertion depth of the needles.

162. Modifying Mehta to enable the variable selection of a needle extension distance ranging from a fully retracted position to a fully extended position would be straightforward and within the capability of a POSA. As discussed *supra* ¶155, a POSA would have known how to provide control signals to a step-motor to cause the step-motor to assume a particular intermediate position between two terminal positions. The only modifications necessary to enable variable selection of a needle extension distance would have been (i) augmenting the I/O device (i.e. to include an input element that allows for selection of a particular extension distance or insertion depth of the needles 104 and/or a command to incrementally increase or decrease an extension distance and/or insertion depth of the needles) and (ii) configuring the

control system/energy supply unit 90 to provide the functionality to convert the user-selected needle extension distance/insertion depth and/or incremental needle movement command to a control signal for the step-motor (e.g. a pulse train). Both modifications would have been within the skill of a POSA as of the effective date of the '536 patent.

**b. Independent Claim 1**

163. With respect to independent claim 1, as discussed *supra* Sections X.A.7.a., X.A.7.b., X.A.7.c., X.A.7.d., X.A.7.e., X.A.7.f, X.A.7.g., and X.A.7.h, Mehta discloses elements [1pre], [1a], [1b], [1c], [1d], [1e], [1f], and [1g]. Furthermore, to the extent that Patent Owner argues that any of elements [1pre], [1a], [1b], [1c], [1d], [1e], [1f], and [1g] is not disclosed by Mehta, either explicitly or inherently, it would have been obvious, in view of the knowledge of a POSA, to modify the methods disclosed by Mehta to provide any such element. *Supra* Section X.B.1.a.

164. With respect to element [1f], for the foregoing reasons set forth *supra* Section X.B.1.a., it would have been obvious to modify Mehta to enable a user to set, e.g. via a user interface, a distance of needle extension along the axis of extension, i.e. by providing the functionality necessary to allow a user to select a particular extension distance or insertion depth of the needles 104 and/or incrementally increasing or decreasing, by one or more steps of a step-motor, an

extension distance and/or insertion depth of the needles. Therefore, even if Serendia's unduly narrow interpretation of "desired distance" (*see supra* Section VIII.C.) were to be adopted, independent claim 11 would have been obvious over Mehta and the knowledge of a POSA.

## **2. Dependents Claims 2–3, 6, 8–9, 12–13, 16, and 18–19**

165. Mehta discloses the features recited by claims 2–3, 6, 8–9, 12–13, 16, and 18–19. *Supra* Sections X.A.2.–X.A.6. and X.A.8.–X.A.12. Accordingly, for the reasons set forth *supra* Sections X.A.1.–X.A.12. and those set forth *supra* Section X.B.1., dependent claims 2–3, 6, 8–9, 12–13, 16, and 18–19 are obvious over Mehta in view of the knowledge of a POSA.

166. To the extent that Patent Owner argues that any additional element of any of claims 2–3, 6, 8–9, 12–13, 16, and 18–19 is not disclosed by Mehta, either explicitly or inherently, it would have been obvious, in view of the knowledge of a POSA, to modify the microneedling apparatus of Mehta to provide such element(s). For example, with respect to the additional element of claim 12, it would have been obvious to a POSA to provide, in the proximal end of the handpiece 210, an electrical connector couplable to the signal generator to form an electrical pathway extending from the power supply (i.e. energy supply unit 90/power supply residing in handpiece 210)—through the handpiece 210/the proximal end thereof—to the needles 104. The motivation would have been to provide such an electrical pathway

while simultaneously allowing one cartridge 100 to be disposed after a first patient is treated and another cartridge 100 attached to the handpiece 210 prior to a second patient being treated.

167. For the reasons set forth *supra* Sections X.B.1.a. and X.B.1.b., it would have been obvious to modify Mehta to enable a user to set, e.g. via a user input, a depth of needle deployment along the axis of extension, i.e. by providing the functionality necessary to allow a user to select a particular extension distance or insertion depth of the needles 104 and/or incrementally increasing or decreasing, by one or more steps of a step-motor, an extension distance and/or insertion depth of the needles. Therefore, it would have been obvious to deploy the needles to a “predetermined depth” in the form of a user-settable depth, and claims 9 and 19 would have been obvious over Mehta in view of the knowledge of a POSA for this additional reason.

### **3. Dependent Claims 4–5 and 14–15**

#### **a. Dependent Claims 4 and 14**

168. Claim 14 recites the apparatus of claim 11, including the additional limitation of “wherein the 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 illuminating the deployable needle assembly when energized.” Claim 4 recites the method of

claim 1, including the additional limitation of “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 needle assembly when energized.”

169. In my opinion, it would have been obvious, in view of the knowledge of a POSA, to modify the microneedling apparatus and the microneedling methods disclosed by Mehta to include the additional limitations of claims 4 and 14 of the ’536 patent. Therefore—and for the reasons set forth *supra* Sections X.B.1.a. and X.B.1.b.—claims 4 and 14 are obvious over Mehta in view of the knowledge of a POSA.

170. Mehta discloses providing light sources at the proximal end of the handpiece/device body 210. Specifically, Mehta discloses “additional energy transfer elements located at the working end of a treatment unit 202,” that “may comprise sources of light,” and that “may be present on the cartridge 100, [or] on the [handpiece/]device body 210.” EX1004 at 11:24-39. Mehta does not explicitly state that the light sources are LEDs. However, a POSA would have known that one or more LEDs could be used as the light sources at the proximal end of the handpiece/device body 210. Mehta also discloses a source of energy for providing photonic radiation, i.e. a photonic signal generator as recited by claims 4 and 14. Specifically, Mehta discloses that “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<sup>8</sup> of the treatment unit” and further discloses that “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).” *Id.* at 11:27-33.

171. LEDs were, as of the priority date of the '536 patent, known to be highly energy efficient, relatively low cost, and readily available sources of light. A POSA would be motivated use one or more LEDs for Mehta's light sources in order to provide a cost-effective source of illumination (e.g. to illuminate a tissue region into which the needles are to be inserted and thereby assist an aesthetician or dermatologist in confirming the intended treatment area (*see id.* at 13:20-35), or to illuminate depth markings or other distinguishing features of the needles that allow the aesthetician or dermatologist to confirm that the needle is not driven too far into the patient's tissue (*see id.* at 13:37-45)). Furthermore, using an LED to provide illumination during operation of Mehta's microneedling apparatus, i.e. during the transmission of RF energy to a patient's dermis, would also provide an aesthetician or dermatologist with a visual indication of the operational status of the microneedling device, thereby reducing the risk of an unintentional overdose of RF

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<sup>8</sup> Mehta uses the terms “proximal” and “distal” with reference to a user of the device. *See* EX1004 at 4:35-43, 6:63-65, 9:62-64, 18:21-23, 35:8-10, FIGS. 3A, 3B, 5, 12A, 12B. Accordingly, the “distal end” referred to by Mehta is an end of Mehta's handpiece 210 that is proximal to dermatological tissue to be treated, i.e. the proximal end recited by the claims of the '536 patent.

energy. *See, e.g.*, EX1014 at 4 (describing that an LED “emits a predetermined color at the same time as the high frequency is applied”). A POSA would have been motivated to provide for control of the photonic signal generator (i.e. the energy source/supply 90 or the energy source/supply 94), so as to energize the LED during the transmission of RF energy, and doing so (e.g. by programming a controller of the energy source/supply and providing a pathway for supplying power from the energy source/supply to the LEDs) would have been a matter of routine engineering within the skill of a POSA.

172. A POSA would also have known, as of the priority date of the '536 patent, that the one or more LEDs could be embedded in the proximal end of the handpiece/device body 210. A POSA would also have known that portions of the cartridge 100 and the handpiece/device body 210 could be made from transparent or translucent materials to allow light emitted by an embedded LED to be transmitted to an area targeted for illuminations. Choosing to embed the one or more LEDs in the proximal end of the handpiece/device body 210 would have been an obvious design choice—as would have been the use of transparent or translucent materials for portions of the cartridge 100 and the handpiece/device body 210. A POSA would have appreciated that embedding the one or more LEDs would prevent them from protruding outward from the handpiece/device body 210, thereby allowing the handpiece/device body 210 to retain a sleek and appealing outer profile, making it

more attractive to customers of the device manufacturer as well as to patients. A POSA would also have appreciated that the one or more LEDs in the handpiece/device body 210 would allow the LEDs to illuminate the treatment area—and the needles 104 (which are part of the needle assembly 102) extending into that treatment area—in an unobstructed fashion (e.g. by providing a transparent window between the LEDs and the treatment area) or to illuminate the needles 104/needle assembly 102 and thereby provide a visually appealing glow of the proximal end of the handpiece/device body 210, the cartridge 100, and/or the needle assembly 102 during operation of the microneedling device (e.g. by providing a translucent section between the LEDs and the treatment area). Embedding one or more LEDs in the handpiece/device body 210 would have been a matter of routine engineering within the skill of a POSA.

173. For the foregoing reasons, it would have been obvious to use LEDs as the light sources at the proximal end of the handpiece/device body 210 of Mehta, e.g. to provide a cost-effective and reliable source of illumination for illuminating the treatment area. Furthermore, modifying Mehta to use LEDs as the light sources would be a straightforward and predictable use of LEDs according to their established function, and would have been a matter of routine engineering within the skill of a POSA.

174. In the modified device of Mehta, the proximal end further includes at least one embedded LED therein (i.e. the light sources—in the form of at least one LED—at the proximal end of the handpiece/device body 210) and the apparatus further including a photonic signal generator (i.e. the energy source/supply 90 or the energy source/supply 94) electrically coupled to the least one embedded LED, the at least one embedded LED illuminating the deployable needle assembly (e.g. the needles 104 of the needle assembly 102 or the entire needle assembly 102) when energized. Therefore, dependent claims 4 and 14 of the '536 patent are obvious over Mehta in view of the knowledge of a POSA.

**b. Dependent Claims 5 and 15**

175. Claim 15 recites the apparatus of claim 14, including the additional limitation of “wherein the releasably couplable deployable needle assembly includes a translucent section that communicates illumination from the least one embedded LED to the plurality of extendable needles.” Claim 5 recites the method of claim 4, including the additional limitation of “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.”

176. In my opinion, it would have been obvious, in view of the knowledge of a POSA, to modify the microneedling apparatus and the microneedling methods disclosed by Mehta to include the additional limitations of claims 5 and 15 of the

'536 patent. Therefore—and for the reasons set forth *supra* Sections X.B.1.a., X.B.1.b., and X.B.3.a.—claims 5 and 15 are obvious over Mehta in view of the knowledge of a POSA.

177. Mehta discloses the use of translucent materials for components of the microneedling apparatus so as “not to obscure a view of the surface tissue above the region of treatment.” EX1004 at 22:65-23:2. Furthermore, translucent materials were, as of the priority date of the '536 patent, well known to a POSA. It would have been obvious to a POSA to provide at least a section of the needle assembly 102 from a translucent material (as opposed to from an opaque material) in order to allow the light emitted by one or more embedded LEDs to be communicated to the needles 104. For example, a POSA would have been aware of the availability of translucent printed circuit boards (PCBs), e.g. made from glass or polyimide, and would have appreciated that such a PCB could be used to construct a portion of the needle assembly 102, e.g. a portion from which connection portions 116 protrude. Furthermore, a POSA would have known that sections of the needle assembly 102—as well as of cartridge 100 and/or handpiece 210 located around the needle assembly 102—could be formed from translucent materials such as frosted glass, polyethylene, or polypropylene. Using a translucent material for a section of the needle assembly 102 of Mehta would have been an obvious design choice—and one that would create (as compared with an opaque material) a visually appealing glow

of the needle assembly 102 (by scattering illumination provided by an LED embedded in the proximal end of the handpiece/device body 210) during operation of the microneedling device. Furthermore, Mehta teaches that it is beneficial for a physician to visualize aspects of the needles 104 during treatment (*see, e.g., id.* at 13:37-45), and communicating illumination to the needles 104, e.g. via a translucent section of the needle assembly 102, during application of RF energy by the needles would provide a physician with a visual indication of the radiative status of the needles.

178. For the foregoing reasons, it would have been obvious to construct a portion of the needle assembly 102 from a translucent material to provide a translucent section that communicates illumination from the least one embedded LED to the plurality of extendable needles, as recited by claims 5 and 15 of the '536 patent. Furthermore, modifying Mehta to form a portion of the needle assembly 102 from a translucent material would be a straightforward and predictable use of translucent materials according to their established function. Therefore, dependent claims 5 and 15 of the '536 patent are obvious over Mehta in view of the knowledge of a POSA.

#### **4. Dependents Claims 7 and 17**

179. Dependent claim 17 recites the apparatus of claim 11, including the additional limitation of “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.” Dependent claim 7 recites the method of claim 1, including the additional limitation of “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.”

180. In my opinion, it would have been obvious, in view of the knowledge of a POSA, to modify the microneedling apparatus and the microneedling methods disclosed by Mehta to include the additional limitations of claims 7 and 17 of the ’536 patent. Therefore—and for the reasons set forth *supra* Sections X.B.1.a. and X.B.1.b.—claims 7 and 17 are obvious over Mehta in view of the knowledge of a POSA.

181. Mehta discloses a microneedling apparatus and microneedling treatment methods that involve what is known as “bipolar operation.” In bipolar operation, electromagnetic, e.g. RF, radiation is transmitted between pairs of microneedles: one microneedle of the pair acts as a transmitter, and the other microneedle of the pair acts as a receiver. *See, e.g.*, EX1004 at 17:59-61, 37:25-34 (describing pairs of an “active” and a “return” needle and passing current between needles “of opposite polarity”). Mehta teaches both (i) providing every pair of

microneedles with an “independent and electrically isolated” power supply channel (*id.* at 25:45-49) and (ii) coupling multiple pairs of microneedles to the same power supply channel (*see id.* at 18:18-20).

182. A POSA would have appreciated that, when coupling multiple pairs of microneedles to the same power supply channel, it would not be necessary to provide an individual contact portion 116 in the form of a spring contact or spring pin for every needle. Instead, reducing the number of contact portions between needle assembly 102 and the handpiece/device body 210 would decrease the cost and overall complexity of both the removable cartridges 100 and the handpiece/device body 210. Accordingly, a POSA would have been motivated, by a desire to reduce cost and complexity, to replace the plurality of connection portions 116 provided for every needle 104 (as illustrated, e.g., in FIG. 4A of Mehta) with only two connection portions 116: a first spring contact or spring pin electrically coupled (e.g. by one or more wires or conductors) to a first set of needles (i.e. to the transmitter microneedle of each microneedle pair) and a second spring contact or spring pin electrically coupled (by one or more other wires or conductors) to a second set of needles (i.e. to the receiver microneedle in each microneedle pair).

183. Such a modification would have been a straightforward and predictable use of electrical conductors, e.g. wires, according to a well-established function, i.e. providing multiple, parallel transmission paths within a single power supply channel,

and would have been a matter of routine engineering with the skill of a POSA. Specifically, such a modification could be achieved by providing multiple, parallel metal traces branching off from a single contact portion 116 and connecting to individual ones of the needles 104. Therefore, dependent claims 7 and 17 of the '536 patent are obvious over Mehta in view of the knowledge of a POSA.

184. While Mehta discusses a number of advantages that can be realized by providing every pair of microneedles with an “independent and electrically isolated” power supply channel, a POSA would not have understood such a configuration to be essential to the microneedling devices of Mehta. Instead, a POSA would have appreciated that there would be, for at least some segments of the aesthetics market, considerable advantages to a single power supply channel device. For example, a POSA would have appreciated that a multi-channel device would require highly complicated controller circuitry, an expensive, multi-channel power supply, and complicated transmission pathways—and be far more expensive than a single channel device as a result. During my time at Primaeva/Syneron, our multi-channel microneedling devices had a list price of about \$120k per device, while our competitors’ list prices for their single channel microneedling devices were about \$50k. The disposable cartridges demonstrated a similar price disparity: ~\$350/cartridge for our multi-channel devices and ~\$50 for our competitors’ single-channel devices. Accordingly, a POSA would have been motivated by significant

cost savings to provide a more affordable, single-channel microneedling device that appeals to a cost-sensitive segment of the aesthetics market.

## **5. Dependents Claims 9 and 19**

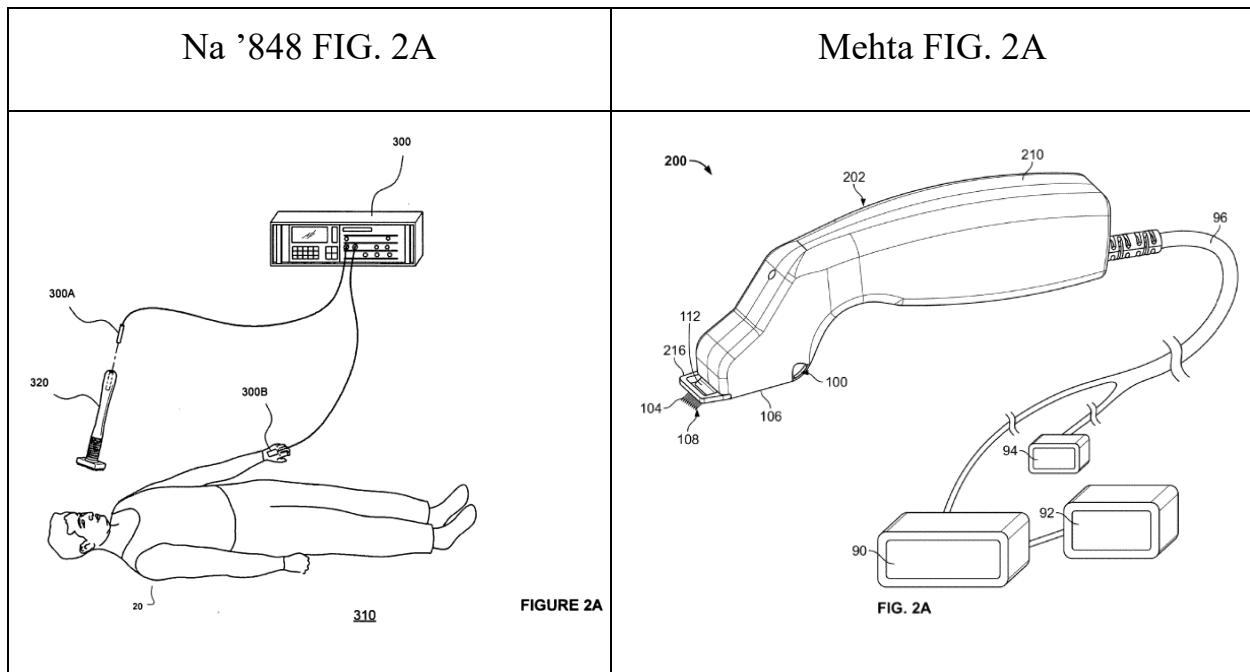
185. It would have been obvious (for the reasons set forth *supra* Section X.B.1.), in view of the knowledge of a POSA, to modify Mehta to provide allow a user to set—e.g. via a user interface—a distance for the needles to extend from the needle assembly end surface and/or a depth for the needles to extend into the patient’s skin. Therefore, it would have been obvious to deploy the needles to a “predetermined depth” in the form of a user-settable depth, and claims 9 and 19 would have been obvious over Mehta in view of the knowledge of a POSA for this additional reason

### **C. Ground 3: Claims 4-5 and 14-15 are Obvious over Mehta, Na ’848, and the Knowledge of a POSA**

186. In my opinion, claims 4-5 and 14-15 of the ’536 patent are obvious over Mehta in view of Na ’848 and the knowledge of a POSA.

#### **1. Motivation to Combine Mehta with Na ’848**

187. Na ’848 is readily combinable with Mehta because Na ’848—like Mehta—is directed to systems and methods for treating dermatological tissue using RF energy to improve the cosmetic condition of a patient’s skin. *See, e.g.*, EX1005, ¶¶25-27; EX1004 at 2:37-41; FIG. 2A.



It therefore would have been obvious, because both references are directed to similar technologies and a POSA would have understood the benefits of combining the two references, to apply advantageous teachings of Na '848 to Mehta's microneedling apparatus and method. Specifically, it would have been obvious to utilize the LEDs described by Na '848 for Mehta's light sources and to use the translucent materials described by Na '848 to form at least a section of the needle assembly 102 of Mehta. Such modifications would have been a matter of routine engineering within the skill of a POSA, and a POSA would have had a high likelihood of success in implementing such modifications.

188. Mehta discloses light sources at the proximal end of handpiece 210 and a photonic signal generator electrically coupled to those light sources. Na '848 teaches that, for energized microneedling treatment, the application of "LED light

of specific frequencies” to dermatological tissue can “decreas[e] treatment time and facilitate healing.” EX1005, ¶46. Na ’848 also teaches several “optimal LED wavelengths for skin repair.” *Id.*, ¶47. And Na ’848 teaches that “generat[ing] one or more signals for LEDs” by a controller coupled to the LEDs “via one or more electric wires 106.” *Id.*, ¶37.

189. A POSA would have been motivated to utilize LEDs in Mehta’s treatment system in order to provide illumination of Mehta’s needles 104 and the tissue into which they are inserted during treatment with actinic light of optimal wavelengths for skin repair—as taught by Na ’848. It would also have been obvious, based on the teachings of Na ’848, to energize the LEDs, e.g. by “generat[ing] one or more signals for the LEDs” (EX1005, ¶37) by a controller, e.g. “the energy source/supply 94” of Mehta. Utilizing LEDs, as taught by Na ’848, in Mehta’s system would have been straightforward and well within the capability of a POSA.

190. Furthermore, as discussed *supra* Section X.B.3., embedding LEDs in a handpiece, such as the handpiece 210 of Mehta, was well known to a POSA, and it would have been an obvious design choice to embed LEDs, such as those disclosed by Na ’848, in the proximal end of the handpiece 210 of Mehta.

191. As also discussed *supra* Section X.B.3., Mehta discloses that portions of the treatment device 202 are translucent. *See* EX1004 at 22:65-23:10. Na ’848 discloses an acupuncture plate 200 of a dermatological treatment apparatus 10

having an acupuncture section 250 that “include[s] a plurality of acupuncture pins or needles” and that can be “translucent” and formed of a “polyurethane, medical silicon, or other pliable, translucent, hypoallergenic material.” EX1005, ¶¶23, 35. Notably, the only disclosure in the ’536 patent of a needle assembly that includes a translucent section is from the portion of the ’536 patent that corresponds to Na ’848. *See supra* ¶68; *see also* EX1001 at 5:15-18 (“pin section 250, 353, may be translucent”), FIGS. 1C (element 250), 2F (element 353); EX1005 at [0035], FIGS. 1C, 2F. While the ’536 patent also discloses a translucent material in connection with the description of outer casing 924E of the deployable needle module 924 (see EX1001, 12:32-35), the outer casing 924E is a component that is separate and distinct from the needle assembly 924F (see EX1001, 12:53-13:5, FIGS. 11A, 11B).

192. It would have been obvious for a POSA to modify Mehta to provide the needle assembly 102 in the form of Na ’848’s plate including a plurality of needles and a translucent section—particularly for variations of Mehta’s device “that can be held at a more vertical angle to the target tissue like a pencil or pointer” (EX1004 at 9:57-59) and that include needle assembly 102 with an MxN array of needles 104 (*see* EX1004 at 15:49-54), where both M and N have relatively large values, e.g. ~5-10. A POSA would have understood that, in order to provide a treatment device held at a vertical angle, the plane defining the front portion of the cartridge 112 (i.e. the plane from which needles 104 protrude) would be rotated relative to the orientation

shown in Mehta's figures, such that it would extend approximately parallel to the tissue engaging surface 106. A POSA would have appreciated that in some variations described by Mehta (i.e. variations designed to be held at a vertical angle), the plane defining the front portion of the cartridge 112 would be the same as the plane defining the tissue engaging surface 106. A POSA would also have appreciated that, in variations of Mehta's device having an  $M \times N$  array of needles 104 (where both  $M$  and  $N$  have relatively large values, e.g.  $\sim 5$ -10), the needle assembly 102—as well as the plane defining the front portion of the cartridge 112 and the retracted tip plane—would occupy a larger area than that shown in Mehta's figures. Thus, a POSA would have understood that, in some variations of Mehta's treatment device (i.e. those variations designed to be held at a vertical angle and having an  $M \times N$  array of needles 104 for relatively large values of  $M$  and  $N$ ), the geometric arrangement of the components in the proximal end of the handpiece would vary somewhat from the geometric arrangement depicted in Mehta's figures. It would have been a matter of routine engineering and well within the skill of a POSA to provide such geometric arrangements of components.

193. Forming at least a section of the needle assembly 102 of Mehta from the “polyurethane, medical silicon, or other pliable, translucent, hypoallergenic material,” as described by Na '848, would facilitate transmission of light, from an LED embedded in the proximal end of handpiece 210, to the tissue into which the

needles 104 are inserted during treatment. For example, in variations designed to be held at a vertical angle and having an MxN array of needles 104 for relatively large values of M and N, the needle assembly 102 would occupy a relatively large area at the far proximal end of the handpiece 210. In such variations, it would be geometrically convenient to provide a section of the needle assembly 102 between the tissue to be treated and an LED embedded in the proximal end of the handpiece 210. A POSA would have understood that, in such variations of Mehta's device, an acupuncture plate having a translucent section—such as that disclosed by Na '848, could be coupled to the motor of Mehta. A POSA would further have understood that the translucent section of that acupuncture plate would communicate illumination from an embedded LED in the proximal end of the handpiece 210 to the needles.

194. In addition, it would have been within the skill of a POSA to provide Mehta's needle assembly 102 in the form of a plate that includes a plurality of needles and a translucent section, as disclosed by Na '848. Specifically, it would have been a matter of routine engineering to provide an acupuncture plate as disclosed by Na '848 in the device of Mehta—e.g. in a variation designed to be held at a vertical angle and having an MxN array of needles 104 for relatively large values of M and N. It also would have been a matter of routine engineering to geometrically rearrange the components of Mehta—to provide such a variation—so that the

translucent section of the acupuncture plate would lie between the embedded LED and the needles.

## **2. Dependent Claims 4 and 14**

195. Claim 14 recites the apparatus of claim 11, including the additional limitation of “wherein the 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 illuminating the deployable needle assembly when energized.” Claim 4 recites the method of claim 1, including the additional limitation of “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 needle assembly when energized.”

196. In my opinion, it would have been obvious, in view the teachings of Na ’848 and the knowledge of a POSA, to modify the microneedling apparatus and the microneedling methods disclosed by Mehta to include the additional limitations of claims 4 and 14 of the ’536 patent. A POSA would have been motivated to modify Mehta based on the teachings of Na ’848 and the knowledge of a POSA for the reasons set forth *supra* Sections X.B.3. and X.C.1. Therefore—and for the reasons set forth *supra* Sections X.B.1.a. and X.B.1.b.—claims 4 and 14 are obvious over Mehta in view of Na ’848 and the knowledge of a POSA.

197. The microneedling apparatus of Mehta, as modified by Na '848 and the knowledge of a POSA, has a proximal end (i.e. of the handpiece/device body 210) including at least one embedded LED therein (i.e. the LED taught by Na '848) and further includes a photonic signal generator (i.e. Mehta's control system/energy supply unit 90 and/or additional power supply unit 94) coupled to the at least one embedded LED, the at least one embedded LED illuminating the deployable needle assembly (i.e. the needles 104 of the needle assembly 102 of Mehta) when energized (e.g. to (i) provide illumination of Mehta's needles 104 and the tissue into which they are inserted/to-be-inserted with actinic light of optimal wavelengths for skin repair, (ii) visualize the application of energy, and/or (iii) assist a physician in observing the needles at their point of insertion during treatment). Therefore, the microneedling apparatus and methods of Mehta, as modified in view of the teachings of Na '848 and the knowledge of a POSA, provide the additional limitations of claims 4 and 14 of the '536 patent.

### **3. Dependent Claims 5 and 15**

198. Claim 15 recites the apparatus of claim 14, including the additional limitation of "wherein the releasably couplable deployable needle assembly includes a translucent section that communicates illumination from the least one embedded LED to the plurality of extendable needles." Claim 5 recites the method of claim 4, including the additional limitation of "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.”

199. In my opinion, it would have been obvious, in view the teachings of Na ’848 and the knowledge of a POSA, to modify the microneedling apparatus and the microneedling methods disclosed by Mehta to include the additional limitations of claims 5 and 15 of the ’536 patent. A POSA would have been motivated to modify Mehta based on the teachings of Na ’848 and the knowledge of a POSA for the reasons set forth *supra* Sections X.B.3. and X.C.1. Therefore—and for the reasons set forth *supra* Sections X.B.1.a. and X.B.1.b.—claims 5 and 15 are obvious over Mehta in view of Na ’848 and the knowledge of a POSA.

200. The microneedling apparatus of Mehta, as modified by Na ’848 and the knowledge of a POSA, includes a releasably couplable deployable needle assembly (i.e. the needle assembly 102 of Mehta—as modified to include an acupuncture plate as disclosed by Na ’848 and thereby provide a variation with an MxN array of needles and designed to be held at a vertical angle) including a translucent section (i.e. the translucent section of Na ’848’s acupuncture plate) that communicates illumination (e.g. the actinic light taught by Na ’848) from the least one embedded LED to the plurality of extendable needles (as taught by Mehta). Therefore, the microneedling apparatus and methods of Mehta, as modified by Na ’848 and the

knowledge of a POSA, provide the additional limitations of claims 5 and 15 of the '536 patent.

**D. Ground 4: Claims 7 and 17 are Obvious over Mehta in view of Livneh**

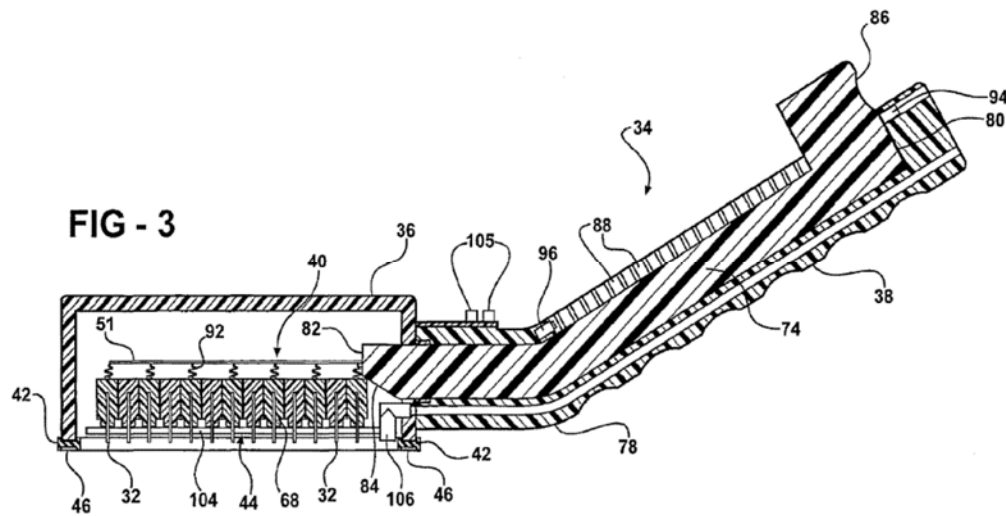
201. In my opinion, claims 7 and 17 of the '536 patent are obvious over Mehta in view of Livneh.

**1. Motivation to Combine Mehta with Livneh**

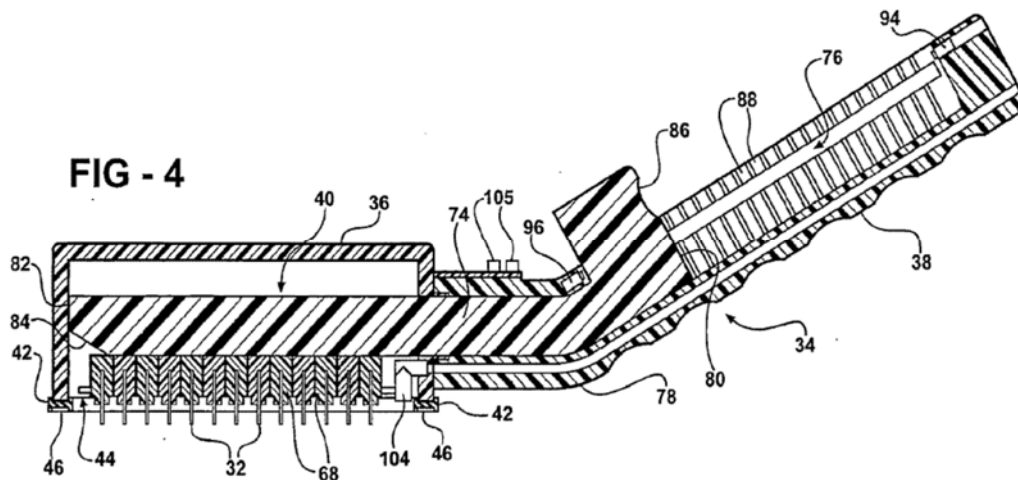
202. Mehta and Livneh are readily combinable because both references are directed to systems and methods of treating dermatological tissue using energized microneedles. EX1012, ¶¶5, 40-42, FIG. 3; EX1004 at 2:37-41, FIG. 2A. It therefore would have been obvious, because both references are directed to similar technologies and a POSA would have understood the benefits of combining the two references, to apply advantageous teachings of Livneh to Mehta's microneedling apparatus and methods. Specifically, it would have been obvious to utilize Livneh's wiring architecture (for transmitting power from a power supply to microneedles in bipolar operation) in Mehta's microneedling apparatus. Such modifications would have been a matter of routine engineering within the skill of a POSA, and a POSA would have had a high likelihood of success in implementing such modifications.

203. Both Mehta and Livneh describe systems and methods of treating dermatological tissue using extendable and retractable microneedles. As discussed *supra* Section X.A.1.b., Mehta discloses a microneedling apparatus with a

removable cartridge 100 that includes a needle assembly 102 with a plurality of microneedles 104. And as discussed *supra* Section X.A.1.c., Mehta discloses that the needle assembly 102 slides relative to the cartridge body to allow the needles 104 to move between an extended position and a retracted position. Livneh similarly discloses a microneedling apparatus that allows needles to move between an extended position and a retracted position—as illustrated in FIGS. 3 and 4 of Livneh (reproduced below).

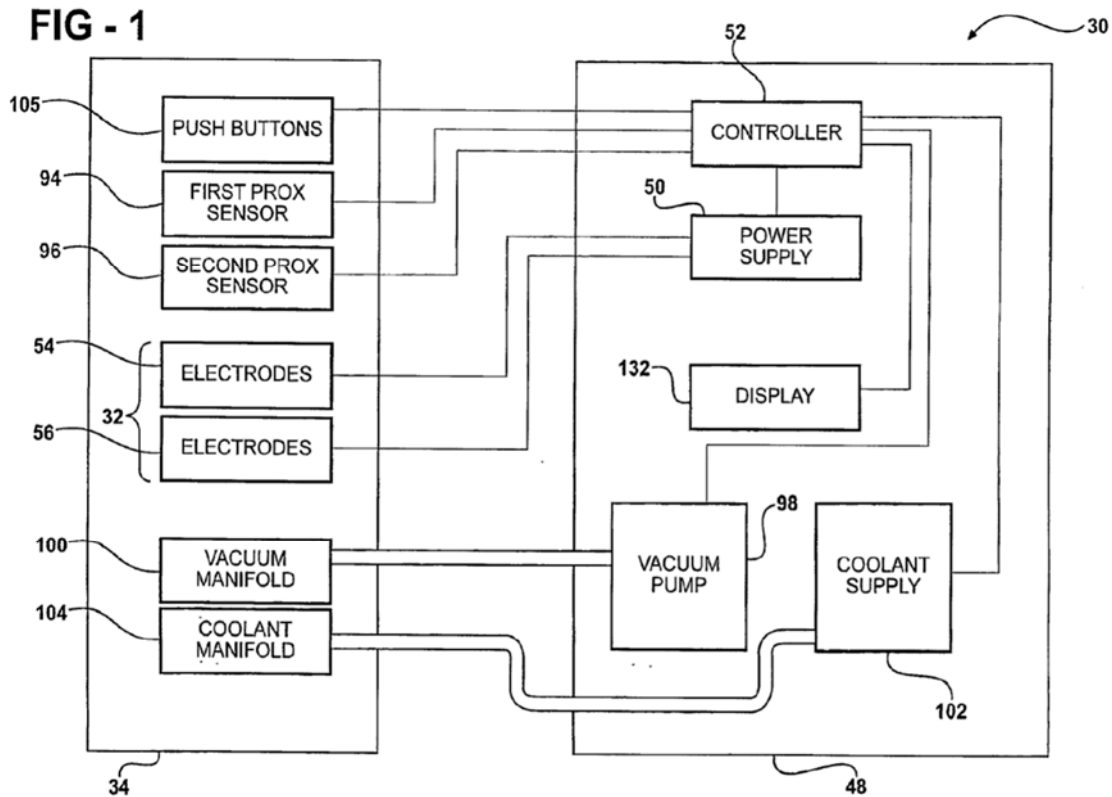


**EX1012—FIG. 3 (needles retracted)**



**EX1012—FIG. 4 (needles extended)**

Furthermore, both Mehta (*see supra* Section X.B.4.) and Livneh disclose energizing their respective microneedles to provide RF energy to a patient's dermatological tissue in a bipolar mode of operation. Specifically, Livneh discloses that "in bipolar operation, as shown in Figure 1," which is reproduced below, "the RF signal is applied through a first set 54 of the electrodes 32 and utilizes a second set 56 of electrodes as a return path to the power supply 50." EX1012, ¶39.

**EX1012—FIG. 1**

Livneh's electrodes are needles. *See, e.g.,* EX1012, ¶40 ("Each electrode 32 is preferably shaped like a needle.").

204. Both Mehta (*see supra* Section X.B.4.; *see also* EX1004 at 18:18-20) and Livneh disclose supplying RF energy to pairs of microneedles in bipolar operation by coupling multiple pairs of microneedles to the same power supply channel. Livneh discloses a power transmission architecture for transmitting power from a single-channel power supply to numerous pairs of microneedles configured for bipolar operation. Livneh's microneedle pairs are "arranged into a plurality of

combs 62” (EX1012, ¶47), each of which is “supported by a holder 68” (*id.*, ¶48), as shown in FIG. 7 (reproduced below).

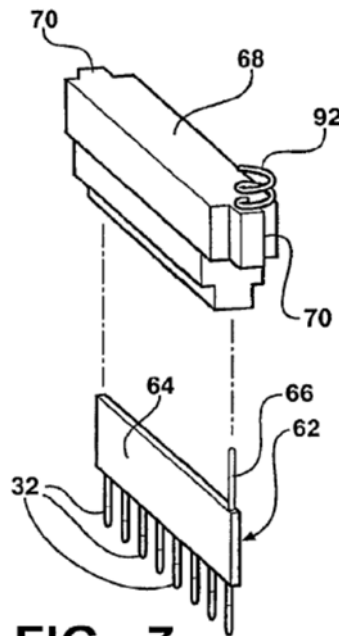
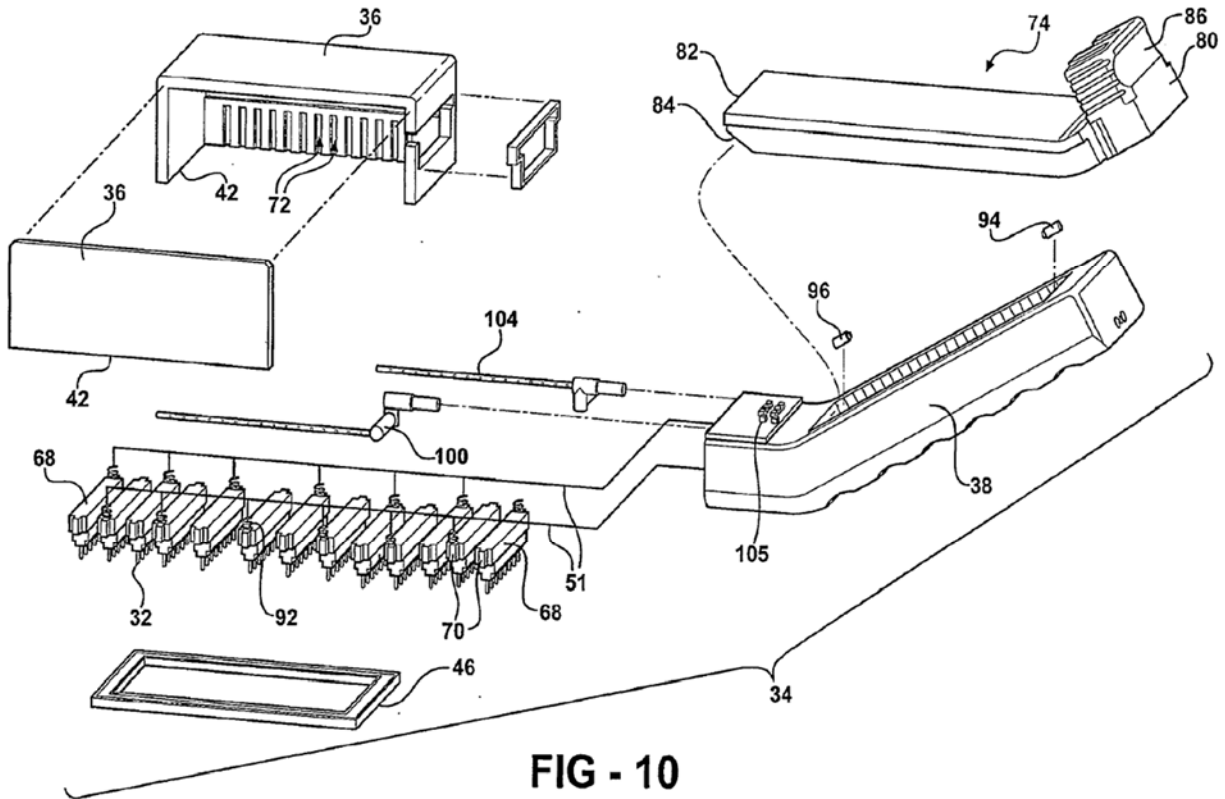


**FIG - 7**

**EX1012—FIG. 7**

“At least one coil 92 extends from the top of each holder 68,” (*id.*, ¶49), each coil being elastically deformable to allow the needle-shaped electrodes to remain connected to the power supply when being moved between their retracted and extended positions. Livneh further teaches that “[i]n the bipolar configuration, as shown in Figure 10,” which is reproduced below, “the coil 92 of each holder 68 in successive rows alternates between the two wires 51, where one wire 51 provides a supply path from the power supply 50 and the other wire 51 provides a return path.” EX1012, ¶49.

**FIG - 10****EX1012—FIG. 10**

Therefore, Livneh discloses a first deflectable electrical contact (i.e. a first coil 92 connected to the wire 51 that provides a supply path from the power supply) coupled to a first plurality of extendable needles (those of a first comb 62 to which the first coil 92 is connected), and a second deflectable electrical contact (i.e. a second coil 92 connected to the wire 51 that provides the return path) coupled to a first plurality of extendable needles (those of a second comb 62 to which the second coil 92 is connected).

205. It would have been obvious to a POSA to have combined Mehta with Livneh to arrive at the subject matter of claims 7 and 17. Specifically, it would have

been obvious to a POSA to connect multiple electrode pairs in Mehta to a single channel of a power supply, as Mehta discloses (*see* EX1004 at 18:18-20), by using a single deflectable electrical contact to connect a power supply line to first polarity needles of multiple needle pairs and by using a second deflectable electrical contact to connect a return line to second polarity needles of those same needle pairs—as disclosed by Livneh. Specifically, a POSA would have been motivated, by a desire to reduce cost and complexity, to implement Livneh’s wiring architecture for bipolar operation by replacing the plurality of connection portions 116 provided for every needle 104 (as illustrated, e.g., in FIG. 4A of Mehta) with only two connection portions 116: a first spring contact or spring pin electrically coupled to a first set of needles (i.e. to the transmitter microneedle of each microneedle pair) and a second spring contact or spring pin electrically coupled (by one or more other wires or conductors) to a second set of needles (i.e. to the receiver microneedle in each microneedle pair).

206. The motivation for incorporating Livneh’s wiring architecture into Mehta’s treatment device would be to provide a simple and cost-effective technique to connect multiple needle pairs to a single channel power supply. A POSA would have been motivated, as discussed *supra* Section X.B.4., by a desire to provide a more affordable, single-channel microneedling device that appeals to the cost-sensitive segment of the aesthetics market, to incorporate Livneh’s wiring

architecture into Mehta's treatment device—particularly for larger needle arrays (Mehta discloses that the array of needles “can comprise any dimension of MxN electrodes where the limits are driven by the nature of the treatment site as well as the type of energy delivery required,” EX1004 at 15:49-54). Such a modification would have been a matter of routine engineering and would have yielded predictable results. *See supra* Section X.B.4.

## **2. Dependent Claims 7 and 17**

207. Claim 17 recites 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.” Claim 7 recites the method of claim 1, “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.”

208. In my opinion, it would have been obvious, in view the teachings of Livneh, to modify the microneedling apparatus and the microneedling methods disclosed by Mehta to include the additional limitations of claims 7 and 17 of the '536 patent. Therefore—and for the reasons set forth *supra* Sections X.A.1. and X.A.7.—claims 7 and 17 are obvious over Mehta in view of Livneh.

209. The microneedling apparatus of Mehta, as modified by Livneh, includes a first deflectable electrical contact (i.e. a connection portion 116 in the form of a spring contact or spring pin) coupled to a first plurality of the plurality of extendable needles (i.e. to the microneedles of each microneedle pair in the supply path as taught by Livneh) needles and a second deflectable electrical contact (i.e. a second connection portion 116 in the form of a spring contact or spring pin) is coupled to a second, different plurality of the plurality of extendable needles (i.e. to the microneedles of each microneedle pair in the return path as taught by Livneh).

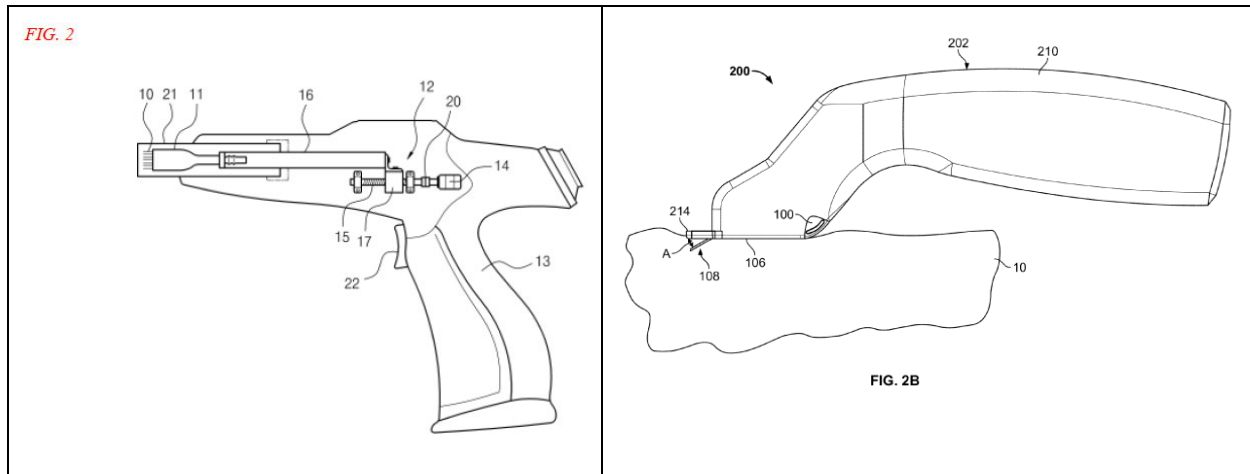
**E. Ground 5: Claims 1–3, 6, 8–9, 11–13, 16, and 18–19 are obvious over Mehta and Lee**

210. In my opinion, claims 1–3, 6, 8–9, 11–13, 16, and 18–19 of the '536 patent are obvious over Mehta in view of Lee.

**1. Motivation to Combine Mehta and Lee**

211. Mehta and Lee are readily combinable because both references are directed to systems and methods for treating dermatological tissue using needles driven into skin tissue by a step-motor. *See, e.g.*, EX1011 at <23>–<26>, <45>–<53>, <60>–<63>, FIGS. 2-4b; EX1004 at 15:34-40, FIG. 2B.

|            |               |
|------------|---------------|
| Lee FIG. 2 | Mehta FIG. 2B |
|------------|---------------|



It would have been obvious to apply advantageous principles discussed in Lee to Mehta's treatment system because both references are directed to similar technologies and a POSA would have understood the benefits of combining the two references. Specifically, it would have been obvious to a POSA to modify Mehta, based on the teachings of Lee, to allow a user to select a particular extension distance or insertion depth of the needles 104 and/or incrementally increase or decrease, by one or more steps of a step-motor, an extension distance and/or insertion depth of the needles. Such modifications would have been a matter of routine engineering within the skill of a POSA, and a POSA would have had a high likelihood of success in implementing such modifications.

212. Lee expressly teaches the use of a step-motor for precise control of needle insertion depth along the axis of needle extension. EX1011 at <45>, <50>, <69>, FIGS. 4a-4b. Lee teaches a "position-controllable" motor 14, which may be a "stepping motor," that rotates to move a slider 17 and needle mount 11, which allows

for precise control of an insertion depth of the needles along the axis of needle extension. EX1011 at <46>, <50>, <69>, Figs. 4a-4b. Lee further teaches that the extendable needles are extended and reciprocally retracted multiple times by repetitively driving the motor back and forth for dermatological treatment. EX1011 at Figs. 4a-4b, <58>, <62>–<63>.

213. A POSA would have been motivated to utilize Mehta's motor in this manner taught by Lee, as both Mehta and Lee recognize the benefits of being able to control needle insertion to a specific target depth and location. EX1004 at 12:41-13:4 (avoiding burns), 21:14–21 (uniformity; avoiding undesirable cosmetic outcomes and insufficient treatment), 33:30-31; EX1011 at 69 (minimizing pain; low cost; customized treatment; safety). A POSA would also have been motivated to utilize Mehta's motor in the manner taught by Lee for the reasons discussed *supra* Section X.B.1.a. (e.g. streamlining the treatment process, decreasing time required for treatment, limiting treatment cost and waste generated during treatment, and allowing more precise targeting of treatment within the dermis, thereby providing improved treatment outcomes). Thus, to the extent that Mehta does not teach controlling the needle extension along the axis of extension, a POSA would have been motivated to improve upon Mehta by providing for the type of control taught by Lee to achieve an even more precise and flexible manner of inserting needles to a desired target depth and location.

214. Utilizing Mehta's motor in the manner taught by Lee would have been straightforward and predictable to a POSA, and would merely involve operating a known component (a stepper motor as disclosed in Mehta and as also disclosed in Lee) according to its established function (providing step-based actuation of needles along the axis of needle extension as expressly disclosed in Lee). The only modifications of Mehta that would be necessary to utilize Mehta's motor in the manner taught by Lee are those discussed *supra* Section X.B.1.a. (i.e. (i) providing an input element that allows for selection of a particular extension distance or insertion depth of the needles 104 and/or for a command to incrementally increase or decrease an extension distance and/or insertion depth of the needles and (ii) augmenting the software and/or firmware of the control system/energy supply unit 90 to provide the functionality to convert the input to a control signal for the step-motor). Lee specifically teaches one possible scheme for programming a motor to advance needles to extend by a desire distance. *See* EX1011 at <50> ("motor 14 rotates to the extent of the pre-programmed setting in accordance with the mode selected" and "therefore, ... the insertion depth of the microneedles can be controlled to fit in with the parameters"), <61> ("for the method of setting the mode such as the operational parameter of the motor, any method typically known in the convention art...may be adopted"), <33> ("[p]ressing the mode switch changes the mode" and "[t]he selected mode controls...the insertion depth of the needles.").

Such modifications would have been a matter of routine engineering/programming, and would have been within the skill of a POSA.

## **2. Independent Claims 1 and 11**

### **a. Independent Claim 11**

215. As discussed in Sections X.A.1.a., X.A.1.b., X.A.1.c., X.A.1.d., X.A.1.e., and X.A.1.f., Mehta discloses elements [11pre], [11a], [11b], [11c], [11d], and [11e]. With respect to element [11d], I understand Serendia may contend that the term “desired distance” should be interpreted so as to specifically require a user-settable distance of needle extension along the axis of extension. For the reasons set forth *supra* Section VIII.C., Serendia’s proposed interpretation is unduly narrow and should be rejected as contrary to the plain meaning of the term “desired distance.” Nevertheless, even if Serendia’s unduly narrow interpretation were to be adopted, independent claim 11 would have been obvious over Mehta in view of Lee.

216. As discussed *supra* Section X.A.1.e., Mehta discloses a microneedling apparatus that includes a motor (i.e. actuator 250) that provides for a “mode of movement” of the needles 104 that can include “stepping (via an [*sic*] step-motor).” EX1004 at 15:36-40. As discussed *supra* Section X.E.1., Lee expressly teaches the use of a stepper motor for precise control of needle insertion depth along the axis of needle extension. EX1011 at <45>, <50>, <69>, FIGS. 4a-4b. It would have been obvious to modify Mehta, in view of the teachings of Lee, to enable a user to set,

e.g. via a user interface, a depth of needle deployment along the axis of extension. Therefore, even if Serendia's unduly narrow interpretation of "desired distance" (*see supra* Section VIII.C.) were to be adopted, claim 11 would have been obvious over Mehta in view of Lee.

### **b. Independent Claim 1**

217. With respect to independent claim 1, as discussed *supra* Sections X.A.7.a., X.A.7.b., X.A.7.c., X.A.7.d., X.A.7.e., X.A.7.f, X.A.7.g., and X.A.7.h., Mehta discloses elements [1pre], [1a], [1b], [1c], [1d], [1e], [1f], and [1g]. With respect to element [1f], for the foregoing reasons set forth *supra* Section X.E.1. and X.E.2.a., it would have been obvious to modify Mehta, in view of the teachings of Lee, to enable a user to set, e.g. via a user-interface, a depth of needle deployment along the axis of extension. Therefore, even if Serendia's unduly narrow interpretation of "desired distance" (*see supra* Section VIII.C.) were to be adopted, independent claim 1 would have been obvious over Mehta in view of Lee.

### **3. Claims 2–4, 6, 8–9, 12–14, 16, and 18–19**

218. Mehta discloses the features recited by claims 2–4, 6, 8–9, 12–14, 16, and 18–19. *Supra* Sections X.A.2.–X.A.6. and X.A.8.–X.A.12. Accordingly, for the reasons set forth *supra* Sections X.A.1.–X.A.12. and those set forth *supra* Sections X.E.1.–X.E.2., dependent claims 2–4, 6, 8–9, 12–14, 16, and 18–19 are obvious over Mehta in view of Lee.

219. For the reasons set forth *supra* Sections X.E.1. and X.E.2., it would have been obvious to modify Mehta, in view of the teachings of Lee, to enable a user to set, e.g. via a user interface, a depth of needle deployment along the axis of extension. Therefore, it would have been obvious to deploy the needles to a “predetermined depth” in the form of a user-settable depth, and claims 9 and 19 would have been obvious over Mehta in view of Lee for this additional reason.

**F. Ground 6: Claims 1-9 and 11-19 are obvious over Mehta and Lee in view of the Knowledge of a POSA**

220. As discussed above in Section X.B., claims 1-9 and 11-19 are obvious over Mehta in view of the knowledge of a POSA. However, to the extent that Serendia’s interpretation of “desired distance” is adopted *and* to the extent that needles extendable “a desired distance” are not found obvious over Mehta in view of the knowledge of a POSA, claims 1-9 and 11-19 would have been obvious over Mehta and Lee in view of the knowledge of a POSA. A POSA would have been motivated, for the reasons set forth *supra* Sections X.B. and X.E., to apply advantageous teachings of Lee (i.e. regarding precise control of needle insertion depth and the structures to achieve the same) in modifying Mehta (i.e. to provide for a user-selectable needle extension distance along the axis of extension). Accordingly, for the reasons set forth *supra* Sections X.B. and X.E., the combination of Mehta, Lee, and the knowledge of a POSA renders claims 1-9 and 11-19 obvious.

**G. Ground 7: Claims 4-5 and 14-15 are Obvious over Mehta, Lee, Na '848, and the knowledge of a POSA**

221. It is my opinion that, for the reasons set forth *supra* Sections X.E.1. and X.E.2., it would have been obvious to a POSA to modify Mehta based on the teachings of Lee to enable a user to set, e.g. via a user interface, a distance of needle extension along the axis of extension. It is also my opinion that, for the reasons set forth *supra* Sections X.C.1., X.C.2., and X.C.3., it would have been obvious to a POSA to modify Mehta in view of Na '848 and the knowledge of a POSA to provide the additional features of claims 4-5 and 14-15 of the '536 patent. Therefore, if Serendia's proposed interpretation of "desired distance" (*see supra* Section VIII.C.) is adopted, it is my opinion that claims 4-5 and 14-15 of the '536 patent are obvious over Mehta, Lee, Na '848, and the knowledge of a POSA.

**1. Motivation to Combine Mehta, Lee and Na '848**

222. A POSA would have been motivated to combine Mehta with Lee for the reasons set forth *supra* Section X.E.1., and a POSA would have been motivated to add Na '848 to this combination of Mehta and Lee for the reasons set forth *supra* Section X.C.1. Mehta, Lee, and Na '848 are all directed to systems and methods of treating dermatological tissue, and a POSA would have been motivated to apply, to Mehta's microneedling apparatus and methods, both (i) advantageous teachings of Lee regarding precise control of needle insertion depth, and (ii) advantageous teachings of Na '848 regarding the use of LEDs to illuminate a treatment device. *See*

*supra* Sections X.C.1, X.E.1. The combination of these three references would have been a matter of routine engineering and would have yielded predictable results. *See id.*

**H. Ground 8: Claims 7 and 17 are Obvious over Mehta, Lee and Livneh**

223. It is my opinion that, for the reasons set forth *supra* Sections X.E.1. and X.E.2., it would have been obvious to a POSA to modify Mehta based on the teachings of Lee to enable a user to set, e.g. via a user interface, a distance of needle extension along the axis of extension. It is also my opinion that, for the reasons set forth *supra* Sections X.D.1. and X.D.2., it would have been obvious to a POSA to modify Mehta based on the teachings of Livneh to provide the additional features of claims 7 and 17 of the '536 patent. Therefore, if Serendia's proposed interpretation of "desired distance" (*see supra* Section VIII.C.) is adopted, it is my opinion that claims 7 and 17 of the '536 patent are obvious over Mehta, Lee, and Livneh.

**1. Motivation to Combine Mehta, Lee and Livneh**

224. A POSA would have been motivated to combine Mehta with Lee for the reasons set forth *supra* Section X.E.1., and a POSA would have been motivated to add Livneh to this combination of Mehta and Lee for the reasons set forth *supra* Section X.D.1. Mehta, Lee, and Livneh are all directed to systems and methods of treating dermatological tissue using energized microneedles, and a POSA would have been motivated to apply, to Mehta's microneedling apparatus and methods, (i)

advantageous teachings of Lee regarding precise control of needle insertion depth and (ii) advantageous teachings of Livneh relating to transmission of power from a power supply to microneedles in bipolar operation. *See supra* Sections X.D.1, X.E.1. The combination of these three references would have been a matter of routine engineering and would have yielded predictable results. *See id.*

**XI. ACKNOWLEDGMENTS**

225. In signing this declaration, I understand that the declaration will be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I acknowledge that I may be subject to cross-examination in the case and that cross-examination will take place within the United States. If cross-examination is required of me, I will appear for cross-examination within the United States during the time allotted for cross-examination.

226. I declare that all statements made herein of my 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 knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001.

I, DANY BERUBE declare under penalty of perjury under the laws of the United States of America that the foregoing is true and current.

A handwritten signature in black ink, appearing to read 'Dany Berube', is written over a horizontal line.

Executed on JANUARY 18<sup>th</sup>, 2024

# **APPENDIX A**

# DANY BÉRUBÉ, Ph.D.

## Professional experience

August 2023 – Present **Lutronic Corporation**

Milpitas, CA

***Vice President of Advanced Research & Innovations***

- Deliver Proof-of-Feasibility for early innovative concept.
- Provide Scientific inputs for during all product development phases.
- Responsible for all scientific aspects related to product development.
- Develop high-level strategies for product pipelines, and IP protection.

June 2021 – August 2023 **Sofwave Medical**

Milpitas, CA

***Vice President of Scientific Affairs & Innovations***

- Identify and develop strategies/products aimed at addressing existing and new market opportunities to position the company as the market leader in the field.
- Develop and manage the patent portfolio.
- Deliver “Proof of Concepts” related to product enhancements, new technologies, and new procedures.
- Responsible to provide scientific competitive intelligence to the company in order to optimally define and position Sofwave offerings.
- Publish papers in peer-reviewed Journals.
- Present the science and key benefits of Sofwave technology to Key Opinion Leaders (KOLs) and salesforce during various meetings.

2020 – June 2021 **Self-Employed**

Milpitas, CA

***Consultant for Sofwave Medical and Healium Medical (Israel)***

- Perform FEA analysis with Comsol to model tissue heating with an unfocused ultrasonic device for the treatment of wrinkles and skin laxity in the esthetic industry, and to model an ultrasonic catheter for the pulmonary veins isolation to treat atrial fibrillation in the electrophysiology industry.
- Extensive experience in thermal analysis, acoustic, RF, microwave, and laser modeling. Experienced using PDE and moving mesh modules with Comsol, as well as Ansys, Matlab, and Solidworks.

2008 – 2020 **Candela Medical (Primaeva Medical, Syneron Candela)**

Milpitas, CA

***Vice President R&D – Profound Division, and Vice President of Global Business Development and Strategy – R&D***

**Key Achievements**

- Designed, presented, and implemented a patent portfolio strategy which led to \$20M in upfront payments and 2-6% royalty streams from all RF needle-based competitive products in the US. The concept was presented to the Chairman of the Board in 2010, and the ITC lawsuit successfully completed in 2019.
- Developed new market opportunities for the treatment of cellulite and submental fat reduction. Proposed and develop new sterile single-used cartridges, which now represent about 30% of Profound recurring revenues. Led all clinical and data collection activities to obtain FDA 510k clearance for the treatment of cellulite. Trained physicians and on-staff nurses on the new clinical procedures and technology.
- Led the development of a new proprietary platform technology to compete with Cryolipolysis (CoolSculpt). Identified a missing key technological feature needed for success, and successfully

completed a proof of concept study with a major US university. Led the internal patent portfolio development to protect the concept.

- Wrote and published 5 peer-reviewed articles related to Profound technology, clinical results, and science in scientific Journals.
- Trained the direct US salesforce and international distributors on Profound technology, clinical procedures, science, as well as competitive positioning.
- Led the development of Profound (ePrime/Miratone) from inception to commercial release. Lead the R&D team in the design, V&V, 510k clearance, and commercial release of a system for the treatment of rhytids and skin laxity. Led the transfer to manufacturing from the US to Israel and China. The system is commercially available and called “Profound” (see: <https://candelamedical.com/na/provider/product/profound>). Manage all product and software updates since the commercial release.
- Develop and implement a strong IP portfolio related to Profound technology before the acquisition of Primaeva Medical by Syneron (now called Candela Medical).
- Filed 9 patents application in 5 months in 2009 as requested by the CEO.
- Act as a hands-on scientist and performed Finite Element Analysis (FEA) to model the radiofrequency and laser interactions with biological tissues in order to investigate and/or improve several treatment concepts.

#### **Key Roles**

- Identify and develop strategies aimed at addressing existing or new market opportunities to position the company as market leader, and create value for all stakeholders.
- Develop/maintain professional connections and alliances with major research laboratories in the industry to better address clinical needs. Act as a liaison between major research laboratories and the company.
- Develop both defensive and offensive IP strategies to optimize investment returns in key market segments occupied by the company.
- Develop a strong relationship with all Research and Clinical functions to ensure insightful inputs and strategies are generated for product and procedural development.
- Work directly with R&D to deliver “Proof of Concepts” related to product enhancements, new technologies, and new procedures.
- Work directly with Product Development, Engineering, Regulatory, and Marketing to guide product development, and optimize product launch.
- Act as a Technology Leader to guide Executive Leadership in potential asset acquisitions.
- Stay current with scientific and medical literature to ensure the latest innovations, knowledge and trends are applied in the company product and IP portfolio.
- Leading by example, create a culture where Innovation, Quality and Excellence are expected and rewarded.

2005 – 2008 **MicroCube, LLC**

Fremont, CA

#### ***Program Manager***

- Lead a full-fledged business project within the incubator. Responsible for all aspects of the project including clinical and market needs identification, staffing, R&D, IP, Quality, Regulatory, and Clinical. The project was to design a catheter-based procedure for the treatment of atrial fibrillation.
- Identify various market opportunities in medical fields for startup projects, and serve as a Board Director for the other active projects (3) within the incubator.
- Serve as a Quality Manager and implement a Quality System from the ground up. Lead all activities, and obtained ISO 13485 certification.

2004 - 2005 **Guidant**

Santa Clara, CA

#### ***Consultant***

- Along with 2 other executives from AFx, delivered \$65 MM of Milestone Payments related to the acquisition of AFx by Guidant.

- Responsible to transfer AFx microwave ablation technology and “know-how” to Guidant.

1997 - 2004      **AFx inc.**

Fremont, CA

***Program Manager***

- Lead the initial development of all the AFx surgical microwave ablation products released in the market. Three surgical devices were commercially released, and two catheter were under IDE.
- Developed products and procedures to perform first worldwide off-pump ablation of AF on beating heart, as well as first worldwide minimally invasive ablation procedure for AF.
- Brought the first worldwide minimally-invasive microwave ablation surgical product for the treatment of atrial fibrillation (FLEX 10) to a full market release.
- Developed and straightened AFx IP portfolio - named in 23 issued US patents, and 34 US pending applications.
- Lead all activities to publish technical and clinical results in Scientific Peer-Reviewed Journals.
- Provided technical support to physicians in the surgical operation room and electrophysiology laboratory.
- Worked closely with CEO and Board of Director to define acceptable terms during the acquisition of AFx by Guidant.
- Established strong relationships with key international Opinion Leaders to develop and promote AFx technology.
- Analyzed competitive technologies. Defined and lead company’s response in term of technology and positioning to make sure that AFx was considered as the Leader in the field.
- Managed the Faculty of major International Conferences in Cardiac Surgery and Electrophysiology to insure optimal coverage of AFx technology.
- Maintained all responsibilities of a Program Manager position, including all R&D, Engineering, Operational, IP, Quality and Finance aspects. Reported directly to the CEO.

## **Areas of Expertise**

R&D, Medical Device, Scientific Affairs, Patent Strategy, Company Liaison with External Research Centers, Product Development, Technology Evaluation, Product Portfolio Development, Scientific Publications, Team Management, Leadership Development, Quality System, Competitive Positioning, Electromagnetic Energy Interaction with Biological Tissues, Finite Element Analysis (FEA), Treatment of Arrhythmia, Atrial Fibrillation, Esthetic Procedures, Skin Treatment, Fat Removal Procedures, Cellulite Treatment, Faculty Management, Technical Writing, V&V, Product Commercialization, Biomedical Engineering, Microwave and RF Ablation, Regulatory Clearance.

## **List of Publications**

Berube D (1998) - PhD Thesis - Traitement des arythmies cardiaques par ablation micro-onde. Ph.D, Ecole Polytechnique de Montreal.

Berube D, Ghannouchi FM, Savard P. A comparative study of four open-ended coaxial probe models for permittivity measurements of lossy dielectric/biological materials at microwave frequencies. IEEE Trans. Microwave Theory Tech. vol. 44, no. 10, pp. 1928-34, Oct. 1996. DOI: 10.1109/22.539951.

Williams MR, Knaut M, Bérubé D, Oz MC. Application of microwave energy in cardiac tissue ablation: from in vitro analyses to clinical use. Ann Thorac Surg. 2002 Nov;74(5):1500-5. doi: 10.1016/s0003-4975(02)03951-6. PMID: 12440599.

Keane D, Ruskin J, Norris N, Chapelon PA, Bérubé D. In vitro and in vivo evaluation of the thermal patterns and lesions of catheter ablation with a microwave monopole antenna. *J Interv Card Electrophysiol.* 2004 Apr;10(2):111-9. doi: 10.1023/B:JICE.0000019264.14661.8e. PMID: 15014211.

Gaynor SL, Byrd GD, Diodato MD, Ishii Y, Lee AM, Prasad SM, Gopal J, Berube D, Schuessler RB, Damiano RJ Jr. Dose response curves for microwave ablation in the cardioplegia-arrested porcine heart. *Heart Surg Forum.* 2005;8(5):E331-6. doi: 10.1532/HSF98.20051011. PMID: 16099735.

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Alexiades M, Munavalli G, Goldberg D, Berube D. Prospective Multicenter Clinical Trial of a Temperature-Controlled Subcutaneous Microneedle Fractional Bipolar Radiofrequency System for the Treatment of Cellulite. *Dermatol Surg.* 2018 Oct;44(10):1262-1271. doi: 10.1097/DSS.0000000000001593. PMID: 30222637.

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Berube D, Amir R. Energy deposition and thermal profile of a novel non-invasive synchronous ultrasound parallel beam technology for skin treatment. *ASLMS, Orlando, FL, Apr. 21-25 2021.*

## List of Patents and Patent Applications

|                 |                                                                                      |
|-----------------|--------------------------------------------------------------------------------------|
| EP 1 240 876 A1 | Directional ablation catheter with myopotential sensing electrodes                   |
| EP 1 608 279 B1 | A tissue ablation system with a sliding ablating device                              |
| EP 2 309940 A4  | A positionable medical system for positioning medical components on or within a body |
| US 6,325,796B1  | Microwave ablation instrument with insertion probe                                   |
| US 6,471,696 B1 | Microwave ablation instrument with a directional radiation pattern                   |
| US 6,527,768B2  | End-firing microwave ablation instrument with horn reflection device                 |
| US 6,817,999 B2 | Flexible device for ablation of biological tissue                                    |
| US 6,893,436 B2 | Ablation instrument having a flexible distal portion                                 |
| US 7,099,717B2  | Catheter having improved steering                                                    |
| US 7,156,841 B2 | Electrode arrangement for use in a medical instrument                                |
| US 7,301,131 B2 | Microwave ablation instrument with flexible antenna assembly and method              |
| US 7,303,560 B2 | Method of positioning a medical instrument                                           |
| US 7,346,399 B2 | Monopole tip for ablation catheter                                                   |
| US 7,387,627B2  | Vacuum-assisted securing apparatus for a microwave ablation instrument               |
| US 7,393,352B2  | Electrode arrangement for use in a medical instrument                                |
| US 7,497.858 B2 | Apparatus and method for assessing transmuralty of a tissue ablation                 |

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|--------------------|---------------------------------------------------------------------------------------|
| US 7,736,360B2     | Devices and methods for creating continuous lesions                                   |
| US 8,657,815B2     | Delivery system for delivering a medical device to a location within a patient's body |
| US 10,932,848 B2   | Delivery system for delivering a medical device to a location within a patient's body |
| US 11,065,055 B2   | Devices and methods for creating continuous lesions                                   |
| US 2003/0083654A1  | Tissue ablation system with a sliding ablating device and method                      |
| US 2004/0106937A1  | Clamp accessory and method for an ablation instrument                                 |
| US 2006/0116672A1  | Microwave ablation instrument with insertion probe                                    |
| US 2007/0203480 A1 | Surgical microwave ablation assembly                                                  |
| US 2010/0262135 A1 | Controlled delivery of therapeutic energy to tissue                                   |
| AU2003209157A8     | Ablation instrument having a flexible distal portion                                  |
| AU2020245366A1     | Device and method for treating tissue                                                 |
| AU2021211369A1     | Skin tightening system                                                                |
| WO 2004073535A2    | Apparatus and method for assessing tissue ablation transmural                         |
| WO 2020171995A1    | Monopolar RF subcutaneous fat treatment systems and methods                           |
| WO2021222372A1     | Treatment apparatus                                                                   |
| WO 2023089625A1    | Vector tightening                                                                     |