

Filed on behalf of: Serendia, LLC

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

JEISYS MEDICAL INC. and ILOODA CO., LTD.,
Petitioner,

v.

SERENDIA, LLC,
Patent Owner.

Case IPR2024-00383
Patent 9,775,774

**DECLARATION OF PETER CROSBY
IN SUPPORT OF
PATENT OWNER'S PRELIMINARY RESPONSE**

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I. Introduction and Qualifications

1. I have been retained by Serendia, LLC (“Petitioner”) to provide my opinion concerning the validity of U.S. Patent No. 9,775,774 (Ex. 1001).

2. I have over 45 years of experience in the medical device industry. I earned my Bachelor’s degree in Electrical Engineering in 1974 and my Master’s degree in Engineering Science in 1976, both from the University of Melbourne, Australia. My M.Eng.Sci. degree was in Biomedical Engineering, and I took courses and received training in advanced engineering, anatomy, and physiology as part of my M.Eng.Sci. work.

3. I am a named inventor of over 50 issued U.S. patents and public applications (and foreign equivalents). Most of my patents are in the general field of medical devices. Some of my patents focus on RF ablation.

4. During my career I have worked as an engineer in Research and Development responsible for developing medical devices and have run the Research and Development function for several medical device companies. I spent approximately 15 years in product research and development, including participation in design, engineering, manufacturing ramp-up, clinical trial design and execution, and regulatory submissions. Since then, I have spent most of my career in general management.

5. I have served as the Chief Executive Officer of six medical device companies in four countries. In my career, I have brought over a dozen products from concept to market release, through Research and Development, manufacturing introduction, and clinical trials and regulatory approval in the United States as well as other markets worldwide, followed by development of a sales force and sales growth. I am keenly aware of the work and investment required to create a successful company in the medical device industry.

6. I have worked on the clinical trials and regulatory submission for multiple products, starting in 1984 when I was the primary author of the Pre-Market Approval Application (PMAA) for Cochlear (a multi-channel implantable hearing prosthesis). I have developed clinical trial protocols, analyzed clinical data, and written or co-authored applications to the FDA for 510(k) clearance and Pre-Market Approval (PMA) in multiple fields.

7. I have direct experience in radio frequency (RF) ablation and coagulation of tissue. As part of my work as Director of the Northern Region Biomedical Engineering Service, I was responsible for selection, purchasing, maintenance, and training on several types of RF electrosurgery equipment.

8. As part of my work at NeoVision, I co-developed equipment for RF ablation and cauterization of breast cancer tissue. I am an inventor on a patent in

this area – U.S. Patent No. 6,106,524 “Methods and apparatus for therapeutic cauterization of predetermined volumes of biological tissue.”

9. From July 2009 through October 2017, I was the CEO and Director of Mainstay Medical International PLC, a medical device company in the field of neurostimulation therapy for chronic lower back pain. I founded Mainstay and recruited key team members, designed the Feasibility Clinical Study and the clinical trial needed for marketing approval, and started the commercialization of a product in 2017. One aspect of therapy for treatment of chronic lower back pain is RF ablation of nerve tissue, and I am an inventor on a patent in this field – U.S. Patent No. 10,661,078 “Modular stimulator for treatment of back pain, implantable RF ablation system and methods of use.”

10. In 2022 I was engaged as an expert in a product liability lawsuit involving alleged injury during a plastic surgery procedure using RF electrosurgery.¹

11. I also served as an expert for Patent Owner in *Certain Dermatological Treatment Devices and Components Thereof*, Inv. No. 337-TA-1356 (the “1356 Investigation”) on a number of issues, including the validity and practice of several

¹ Case No. 21STCV30687 in the Superior Court for Los Angeles County, California.

of the patents at issue in that case. One of the patents I provided opinions on was the '774 Patent.

12. I have worked in several clinical specialties, including cardiology and cardiac surgery, clinical pathology, medical software, otolaryngology, ophthalmology, intensive care, orthopedics, pain management, gastroenterology, medical imaging, and clinical education and training.

13. I currently work as a consultant, board member, and expert witness through my consulting business, Biomedical Business Resources, LLC. I am the Chairman of the Board of two companies and a member of the Board of Directors of one other company.

14. I have been responsible for development and maintenance of the patent portfolios of several companies. I have presented to USPTO patent examiners and to the Appeals Board of the European Patent Office, and I have previously submitted a declaration to the PTAB in defense of an IPR. I have also testified in the International Trade Commission.

15. My resume is attached as Ex. 2136 (*Curriculum Vitae* of Peter Crosby).

II. Summary Of Materials Reviewed And Considered

16. All of the opinions contained in this Declaration are based on the documents I reviewed and my knowledge and professional judgment. In forming

the opinions expressed in this Declaration, while drawing on my experience, I reviewed the following documents:

Exhibit	Description
1001	U.S. Patent No. 9,775,774
1002	File History for U.S. Patent No. 9,775,774 (“’774 Patent File History”)
1004	U.S. Patent No. 8,608,737 (“Mehta”)
1006	July 21, 2023 Joint Claim Construction Chart
1007	Order No. 35, ITC’s Claim Construction
1011	Certified Translation of KR20-0441552
1003	Declaration of Dany Berube
1025	Substitute Declaration of Dr. Jean Woloszko
2037	Brochure: Sylfirm X Dual Wave RF Microneedling System (2022)
2062	Presentation: Sylfirm X Clinical Training (2021) (PROTECTIVE ORDER MATERIAL)
2066	Martin Braun, Sylfirm X Revolutionises [sic] the Clinical Applications of RF Microneedling, 12 PRIME INT’L J. AESTHETIC ANTI-AGEING [SIC] MED. 50 (2022)
2067	World-Class Product of Korea 2020, Certificate to ViOL Co., Ltd., dated December 9, 2020 (“Sylfirm X Award”)
2083	ViOL, Sylfirm X User Manual (VO-UM-SFX-03), revised April 20, 2022
2084	Sylfirm X, Device Description (PROTECTIVE ORDER MATERIAL)
2086	Sylfirm X Product Photographs
2097	Sylfirm X Introduction Video 1

Exhibit	Description
2098	Transcript - Sylfirm X Introduction Video 1
2114	File History for U.S. Patent No. 9,320,536
2115	U.S. Patent No. 6,890,319 B1 (“Crocker”)
2116	U.S. Patent No. 10,869,812 B2 (“’812 Patent”)
2117	U.S. Patent No. 8,540,705 B2 (“Mehta ’705”)
2118	File History for U.S. Patent No. 10,869,812
2119	U.S. Patent. No. 6,277,116 B1 (“Utely”)
2120	U.S. Patent Application Publication No. 2002/0120261 A1 (“Morris ’261”)
2122	Cartessa Aesthetics, <i>Innovations in RF Microneedling: A Closer Look at VirtueRF</i> , Observations Aesthetics, Issue No. 1 (June 2021)
2124	Declaration of Vincent A. Thomas (“Thomas Decl.”) (PROTECTIVE ORDER MATERIAL)
2125	Hearing transcript, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C.), held November 6, 2023 and December 12, 2023 (Jean Woloszko testimony excerpts) (“Woloszko Hr’g Tr.”)
2127	Sylfirm X RF Inspection Report of Peter Crosby
2128	Deposition transcript of Jongju Na, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C.), taken July 25, 2023 (excerpts)
2130	Sylfirm X Product Photographs
2136	<i>Curriculum Vitae</i> of Peter Crosby

17. My opinions are also guided by my appreciation of how a person of ordinary skill in the art would have understood the claims of the ’774 Patent.

III. LEGAL STANDARDS

18. I am not an attorney, and counsel for Serendia has instructed me as to the applicable legal standards relevant to my analysis in this declaration.

A. Claim Construction

19. I have been informed by counsel that claims should be given their ordinary and customary meaning as understood by a person of ordinary skill in the art (“POSITA”) in the context of the entire patent.

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

21. I understand that the claims themselves provide substantial guidance regarding the meaning of particular claim language, and the context in which a term is used in the asserted claim can be highly instructive. Similarly, I understand

that other claims of the patent at issue, whether or not they have been asserted, may show the scope and meaning of particular claim language.

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

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

24. I understand that extrinsic evidence may be used to construe claim language if the intrinsic evidence is inadequate to determine the meaning of

particular claim language. It is my understanding that extrinsic evidence may help explain the relevant art and consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.

25. It is also my understanding that when assessing expert testimony, it should be disregarded when it is conclusory or clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent. I also understand that expert testimony should only be given weight with respect to the particular claim language in dispute, if it identifies what the accepted meaning in the field is to a POSITA. I understand that testimony that simply recites how each expert would construe the term should receive little or no weight.

26. I understand that extrinsic evidence is less reliable than intrinsic evidence and is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence. I also understand that extrinsic evidence is considered last, if at all, because in cases where the public record unambiguously describes the scope of the patented invention, that ends the inquiry.

B. Anticipation

27. I understand that Respondents must prove—on a claim-by-claim basis—that specific claims of the Asserted Patents are invalid.

28. I am informed that for a claim to be anticipated, every limitation of the claimed invention must be found in a single prior art reference, either expressly or inherently, arranged as in the claim. I understand that the words in a reference are to be construed in light of the relevant surrounding circumstances in each case, and a reference in any event is good only for that which it discloses. I understand that a reference cannot anticipate if it is ambiguous as to whether it disclosed the respective claim limitations.

29. I further understand that anticipation cannot be established by multiple, distinct teachings that the artisan might combine to achieve the claimed invention. Additionally, I understand that when the reference does not disclose that the drawings are to scale and is silent as to dimensions, an accused infringer cannot infer dimensions to demonstrate invalidity.

30. I understand that an element may be inherently disclosed only if it is necessarily present, not merely probably or possibly present, in the prior art.

C. Obviousness

31. I understand that even if a patent is not anticipated, it is still invalid if it is shown by clear and convincing evidence that the differences between the

claimed subject matter and the prior art are such that the subject matter as a whole would have been obvious to a POSITA at the time the invention was made. I understand that, while obviousness can be based on one or more pieces of prior art, it is not sufficient that a collection of prior art references recite the various elements of a challenged patent claim. Rather, as I understand it, it must have been obvious to combine those elements in a manner that is consistent with their arrangement or use in the challenged claims.

32. It is my understanding that obviousness must be determined as of the date of the invention (i.e., the effective filing date or priority date of the patent). Thus, in considering the reason or motivation to combine references, it is essential to avoid using hindsight. I also understand that the problem that would have motivated a POSITA at the time that the invention was made can be any problem that would have motivated a particular solution, not the specific problem solved by the invention. I understand that defining the problem in terms of its solution reveals improper hindsight in the selection of the prior art relevant to obviousness. Further, I understand that an overly narrow statement of the problem can represent a form of hindsight, because an inventive contribution may lie in defining the problem in a new, revelatory way. Similarly, I understand that an assertion that a person of ordinary skill could combine the references, rather than that they would have been motivated to do so, is an impermissible form of hindsight.

33. I further understand that a POSITA is a hypothetical person who is presumed to have known the relevant art at the time the invention was made. I understand that the condition “at the time the invention was made” is imposed to rule out impermissible hindsight. I also understand that an expert is to analyze the prior art from the perspective of a POSITA and not simply to provide his/her own personal conclusions.

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

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

obviousness must be attributable to the claimed invention. I further understand that near simultaneous invention by two or more equally talented inventors working independently, may or may not be an indication of obviousness when considered in light of all the circumstances.

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

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

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

39. I understand that to demonstrate that a patent claim is obvious in view of a combination of references, a challenger must show that a POSITA would have been motivated to combine the references. Moreover, I understand that a POSITA must have a reasonable expectation of success when combining and/or modifying the cited references for a proper determination of obviousness.

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

claimed invention can provide a reason for combining the elements in the manner claimed.

IV. LEVEL OF SKILL IN THE ART

41. It is my opinion that a person of ordinary skill in the art (“POSITA”) for the ’774 Patent would have (1) 7-10 years of experience with developing and/or using treatment systems for delivery of electromagnetic radiation energy to skin or other tissues, and (2) a related graduate engineering degree or M.D. A POSITA may have worked as part of a multidisciplinary team and drawn upon not only his or her own skills, but also would have taken advantage of certain specialized skills of others on the team when solving a technical problem. On my opinion, additional education could substitute for professional experience and vice versa. The term “electromagnetic radiation energy” encompasses delivering electric current through electrodes inserted into tissue.

42. I understand the Petitioners apply the same level of skill.

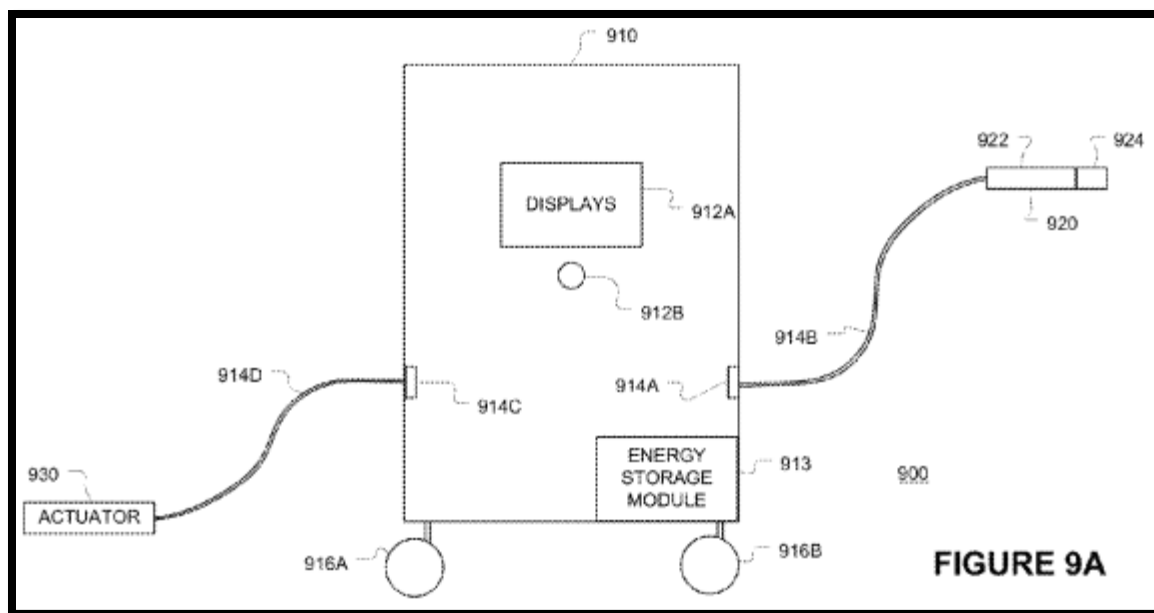
V. THE ’774 PATENT

A. Overview of the ’774 Patent

43. The ’774 Patent generally relates to dermatological treatment to improve the appearance of skin. Part of this dermatological treatment involves inserting microneedles into the skin and applying radiofrequency (“RF”) signals to the skin. This treatment is generally known as “RF microneedling.” This

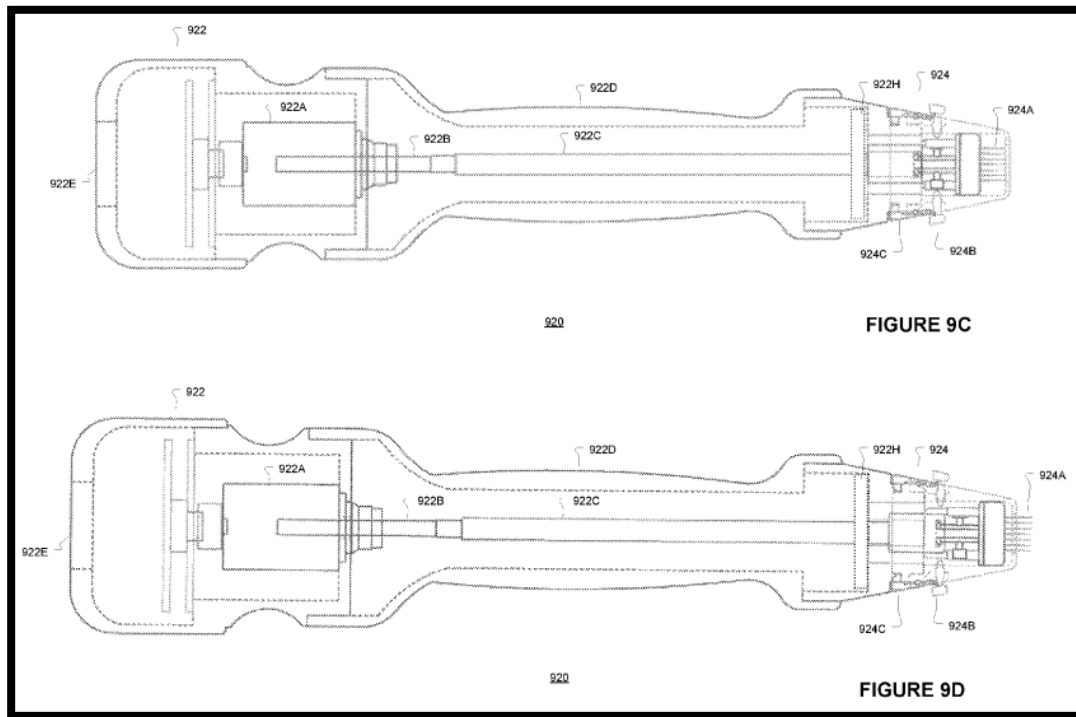
dermatological treatment apparatus is described in connection with Figures 9-11 of the '774 Patent.

44. An embodiment of the '774 Patent shown in Figure 9A (below) includes “a derma[to]logical treatment architecture (DTA) 900” with “a signal generation and control module (SGC) 910, a handle module 920, and an actuator module 930.” Ex. 1001 ('774 Patent), 9:39-43.



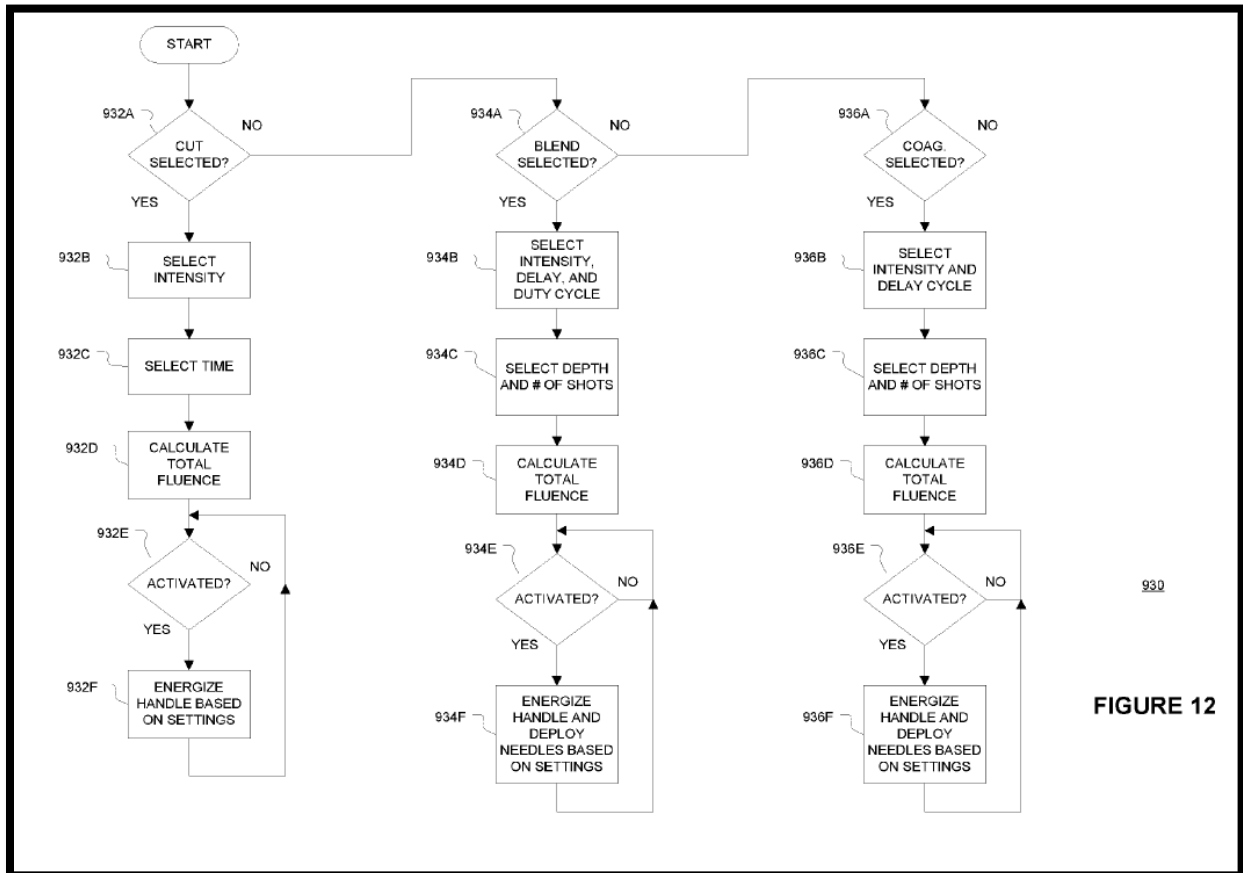
45. As shown in Figure 9A (copied above) and in Figures 9C and 9D (copied below), the “handle module 920 may include a deployable needle module 924 and a motor and LED module 922. *Id.*, 9:43-45. The '774 Patent also explains that “The CPU module **911** may include a radio frequency (RF) signal generator (RFSG) module **911A** [and] a needle deployment motor controller (NDMC) module **911B**” *Id.*, 10:20-21. “The NDMC 911B may control the deployment

of one or more needles 924A of the deployable needle module 924 [] based one or more user selected parameters,” which include “the depth” of needle insertion. *Id.*, 10:20-23, 10:31-36. The motor and LED module (MLM) 922 can include “one or more motors 922A, longitudinally extendable drive arm 922B, drive shaft 922C, outer casing 922D, signal interface 922E,” shown Figures 9C and 9D (below). *Id.*, 10:42-48, 10:57-11:2, 11:14-27, Figs. 9C, 9D. The drive shaft 922C may be moved to “deploy and retract one or more needles 924A when the MLM 922 is operatively coupled to the DNM 924” such that “the motor(s) 922A may enable precise needle extension (effective depth) control.” *Id.*, 10:57-11:2, 11:31-34, 12:39-41, Figs. 9C, 9D. Accordingly, “needle deployment” “via one or more motors 922A” can be controlled by the user. *Id.*, 10:51-59. The needles 924A in Figure 9C are retracted, and deployed in Figure 9D. *Id.*, 10:42-48.

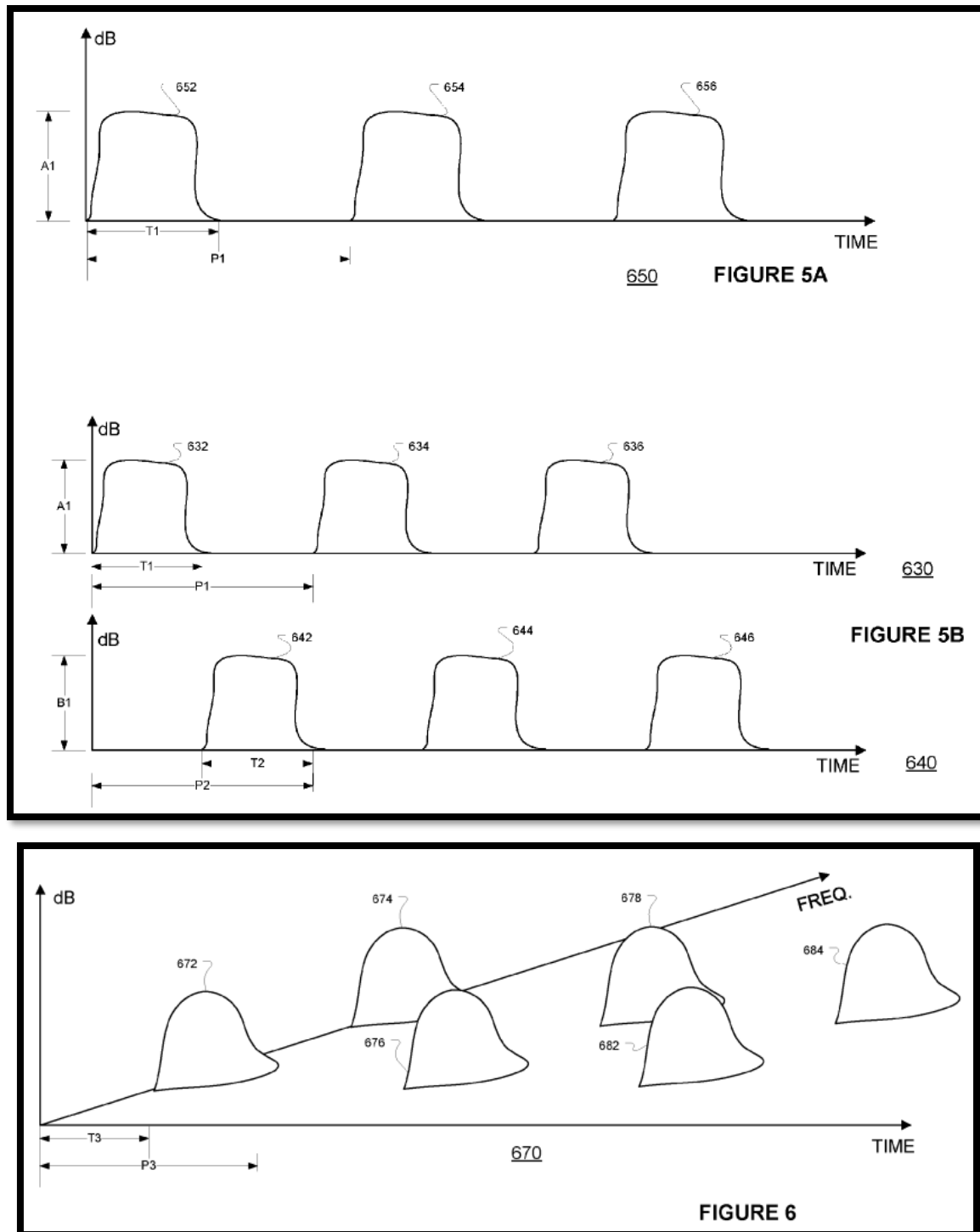


46. The “desired depth of needle 924 penetration within tissue” can be achieved “based on the operational parameters” selected by the user. *Id.*, 14:14-20, 14:28-34. For example, Figure 12 (reproduced below) is a flow diagram of the algorithm employed by DTA 900. *Id.*, 13:45-46. The DTA 900 can enable a user to “select a variety of operational parameters to deliver a desired combination of electrical, light (photonic), and mechanical (needle) therapy to dermatological tissue.” *Id.*, 13:47-51. One such parameter is the needle deployment depth. *Id.*, 13:65. Further, the DTA 900 of Figure 12 shows that in two operational modes (blend and coagulation) one of the steps 934C, 936C involves selecting the needle deployment depth. *Id.*, 13:45-46, 13:63-66, 14:21-24. Thus, the distance that the needles extend is determined based on a user-selected depth that is input into an

algorithm (*i.e.*, software) that controls a motor, providing precise control over the needle insertion depth. *Id.*; see also *id.*, 9:64-10:4, 10:20-23, 10:31-36, 11:23-26, 14:3-4, 14:24-26.



47. The '774 Patent discloses “radio frequency (RF) signal generator module (RFSG) 911A” that “may apply signals 650, 630, 640, 670 shown in FIGS. 5A, 5B, and 6.” *Id.*, 10:20-23, 10:48-50. Those radio frequency signals applied may take varying waveforms and as shown below, the signal waveforms 650, 630, 640, and 670 include pulses. *Id.*, 6:13-7:10.



B. Overview of the Prosecution of the '774 Patent

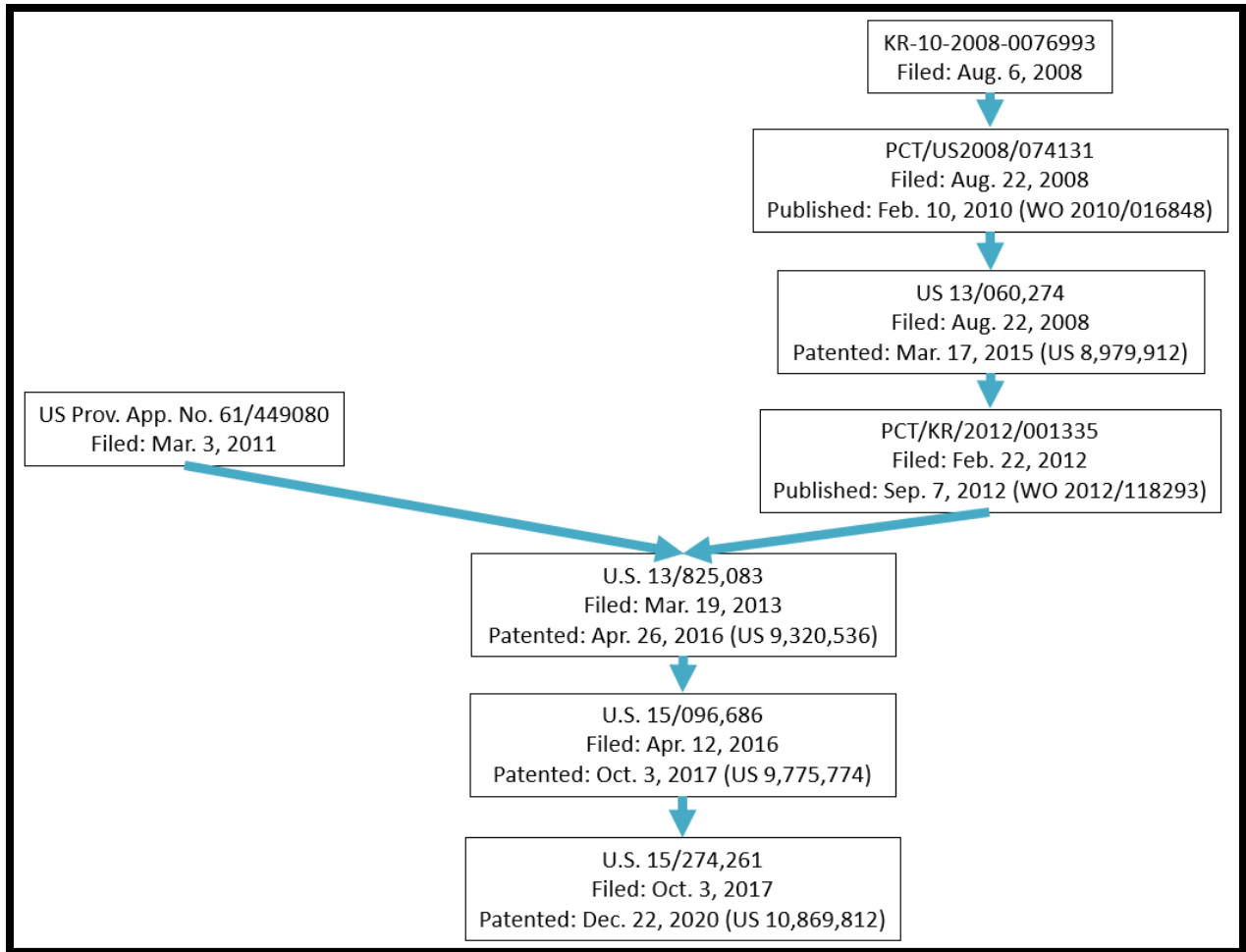
48. The '774 Patent was filed on April 12, 2016, as a continuation of the application for U.S. Patent No. 9,320,536 (the "'536 Patent"). All of the original

claims of the '774 patent were cancelled and new claims were added with the transmittal of the application. Ex. 1002 ('774 Patent File History), 72-75. The Examiner rejected the claims based on double patenting in view of the '536 Patent. *Id.*, 191-192. The applicant filed a terminal disclaimer (*id.*, 207), and after compliance with the disclaimer requirements (*id.*, 218, 233-235), the Examiner allowed the claims with no further comments. *Id.*, 253.

C. Priority date of the Claims of the '774 Patent

49. I understand Petitioners contend that the '774 Patent is entitled to a priority date of March 3, 2011, and I agree.

50. The application that became the '774 Patent is a continuation of the application that became the '536 Patent, which claims priority to U.S. Prov. App. No. 61/449,080, filed on March 3, 2011. The '536 Patent also claims priority to KR App. No. 10-2008-0076993 (filed on Aug. 6, 2008), priority thereto claimed in PCT App. No. PCT/US2008/074131 (filed on Aug. 22, 2008), which published as WO 2010/016848 and is the PCT application for the national stage entry of U.S. Pat. App. No. 13/060,274 (filed on Aug. 22, 2008), which became U.S. Pat. No. 8,979,912, priority thereto claimed in PCT App. No. PCT/KR/2012/001335 (filed on Feb. 22, 2012), which the application that became the '536 Patent claims priority to. Below is a figure showing the priority claims for the patents in the family of the '774 Patent.



51. The '774 Patent claims have written description support in U.S. Prov. App. No. 61/449,080, filed on March 3, 2011. I understand that Petitioners and their expert do not dispute as much.

VI. CLAIM CONSTRUCTION

52. I understand the language of the claims is given its plain and ordinary meaning to a POSITA as of the priority date of the '774 Patent in the context of the patent's disclosure. I also understand that certain terms were construed during the ITC investigation and others were not. I address them here.

1. Terms Construed or Disputed During the ITC

a. **pulsed radio frequency signals**

53. I understand that during the ITC investigation to which Petitioners and Patent Owner were parties, the Administrative Law Judge construed “pulsed radio frequency signals” to have its plain and ordinary meaning, which is “radio frequency signals that are normally off and suddenly on for a period of time (i.e., a rapid, transient change from a baseline to a different amplitude, followed by rapid return to baseline).” Ex. 1007 (Order No. 35, ITC’s Claim Construction), 36.

b. **“a plurality of needles one of extending or extendable . . . the plurality of [extended] needles”**

54. I understand that during the ITC investigation to which Petitioners and Patent Owner were parties, the parties agreed that “a plurality of needles one of extending or extendable . . . the plurality of [extended] needles” has its plain and ordinary meaning, which is “two or more extendable needles or extending needles . . . the two or more extended needles” and that the Administrative Law Judge adopted that construction. Ex. 1007 (Order No. 35, ITC’s Claim Construction), 16.

c. **mechanism for causing the plurality of the extendable needles to extend a desired distance from the end surface**

55. I understand that during the ITC investigation to which Petitioners and Patent Owner were parties, the parties proposed construing the “mechanism

for causing the plurality of the extendable needles to extend a desired distance from the end surface” phrase of claim 13, but ultimately dropped the construction as Patent Owner did not pursue claim 13.

56. I understand that all parties agreed that the term was a means-plus-function limitation, and agreed that the recited function is “causing the plurality of extendable needles to extend a desired distance from the end surface.” I also understand the parties had slightly different proposals for the corresponding structure.

57. Below is the corresponding structure proposed by Patent Owner and the respondents (including current Petitioners) in the ITC Investigation. *See* Ex. 1006 (July 21, 2023 Joint Claim Construction Chart).

Patent Owner	Respondents (including Petitioners)
A motor and LED module 922, depicted in Figs. 9A, 9C-D, 10A-E; and described at col. 13 lines 15-20, 22-26; col. 14 lines 14-20, 29-34; or A needle deployment motor controller (NDMC) module 911B, depicted in Fig. 9B; and described at col. 10 lines 31-36, 51-55; or One or more motors 922A, depicted in Figs. 9C-D; and described at col. 10 lines 36-39, 55-59; col. 11 lines 57-60; col. 14 lines 3-11, 24-26; or One or more drive shafts 922C, depicted in Figs. 9C-D and 10A-E; and described at col. 11 lines 23-27, 53-57.	A motor as described at col. 14, lines 3-11; col. 10, lines 36-39; col. 14, lines 24-26. Or, in the alternative One or more motors, one or more drive shafts, and a motor controller (NDMC) module operating in concert as described at col. 10, lines 31-39, 51-59; col. 11, lines 23-27, 53-60; col. 13, lines 15-26; col. 14, lines 3-11, 14-34. And equivalents thereof under 35 U.S.C. § 112(6).

Patent Owner	Respondents (including Petitioners)
And equivalents thereof.	

2. Terms Presented for Construction In This IPR

- a. **Causing / To Cause “the plurality of the extendable needles to extend a desired distance from the end surface”**

58. Claims 13 and 14 at issue in this Petition both recite “the plurality of the extendable needles to extend a desired distance from the end surface.” I understand that the term “desired distance” in that phrase is to be given its plain meaning in the context of the claims. Based on my review of the claim language, the specification, and the prosecution history, as well as my knowledge of the art and the field of the patented invention as a POSITA at the time of the invention of the '774 Patent, in my opinion the plain and ordinary meaning of “desired distance” is how far the needles extend from the device’s end surface, based on a user’s selection, to penetrate dermatological issue.

59. With respect to the language of the claims, dependent claims 13 and 14 respectively recite a mechanism or motor that causes “the plurality of the extendable needles to extend a desired distance from the end surface.” Ex. 1001 ('774 Patent), cl. 13 (“a mechanism for causing the plurality of the extendable needles to extend a desired distance from the end surface”), cl. 14 (“a motor coupled to the plurality of extendable needles that may be directed to cause the plurality of the extendable needles to extend a desired distance from the end

surface”). Further, dependent claims 13 and 14 depend from independent claim 11 which specifies that this “desired distance” is “selected to enable the plurality of needles to penetrate the dermatological tissue” (*id.*, cl. 11) and from dependent claim 12, which specifies that the desired distance is “from the end surface” of the device (*id.*, cl. 12). In my opinion, a POSITA reading the claims language would understand that the “desired distance” the extendable needles extend is selected by a user to enable the needles to penetrate the dermatological tissue (using a mechanism or motor).

60. With respect to the '774 Patent specification, the '774 Patent explains that, “upon activation (activity 934E, 934F) the DTA [dermatological treatment architecture] 900 may energize the MLM [motor and LED module] 922 based on the operational parameters and deploy the needle assembly 924F to a desired extension beyond the DNM [deployable needle module] 924 shell 924E to enable a desired depth of needle 924A penetration within tissue when the shell 924E is placed adjacent the tissue.” *Id.*, 14:14-20; *see also id.*, 14:28-34. In this manner, the motors “enable precise needle deployment depth or extension beyond the DNM 924 shell.” *Id.*, 11:57-60; *see also id.*, 14:3-6, 14:24-26. Therefore, in my opinion, the specification confirms that the “desired distance” in claims 13 and 14 is how far the needles extend from the device’s end surface, based on a user’s selection, to penetrate dermatological issue.

61. With respect to the prosecution history, during the prosecution of the '536 patent, which is the parent of the '774 Patent, the Examiner rejected claims 3, 4, 10, 13, 14, and 20-24 under 35 U.S.C. § 103 as unpatentable over U.S. Patent No. 6,890,319 to Croker ("Croker") in view of U.S. Patent No. 7,618,429 to Mulholland ("Mulholland"). Relevant to the meaning and scope of "desired distance" the Examiner relied on column 10, lines 11-20 in asserting that Croker disclosed that "[a] motor is energized to extend the needles a desired distance." Ex. 2114 ('536 Patent File History), 278. That passage of Croker states that "control of the depth" of needle insertion can be "electrical or mechanical" means "capable of adjustment by an operator" or that "control of the depth of penetration may alternatively be automatic" using feedback based on "current" measurements. Ex. 2115 (Croker), 10:11-20. In my opinion, the Examiner's reliance on this passage is indicative that the Examiner understood that the "desired distance" is based on a user's selection to provide control over the penetration depth (directly or automatically through a feedback mechanism).

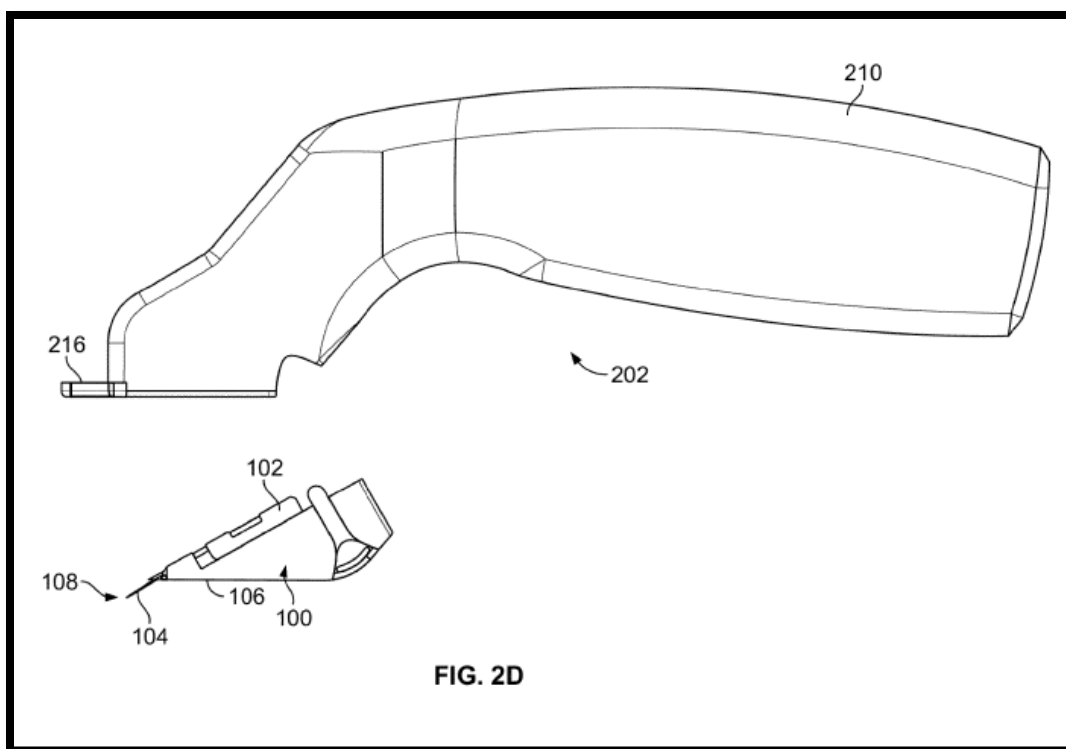
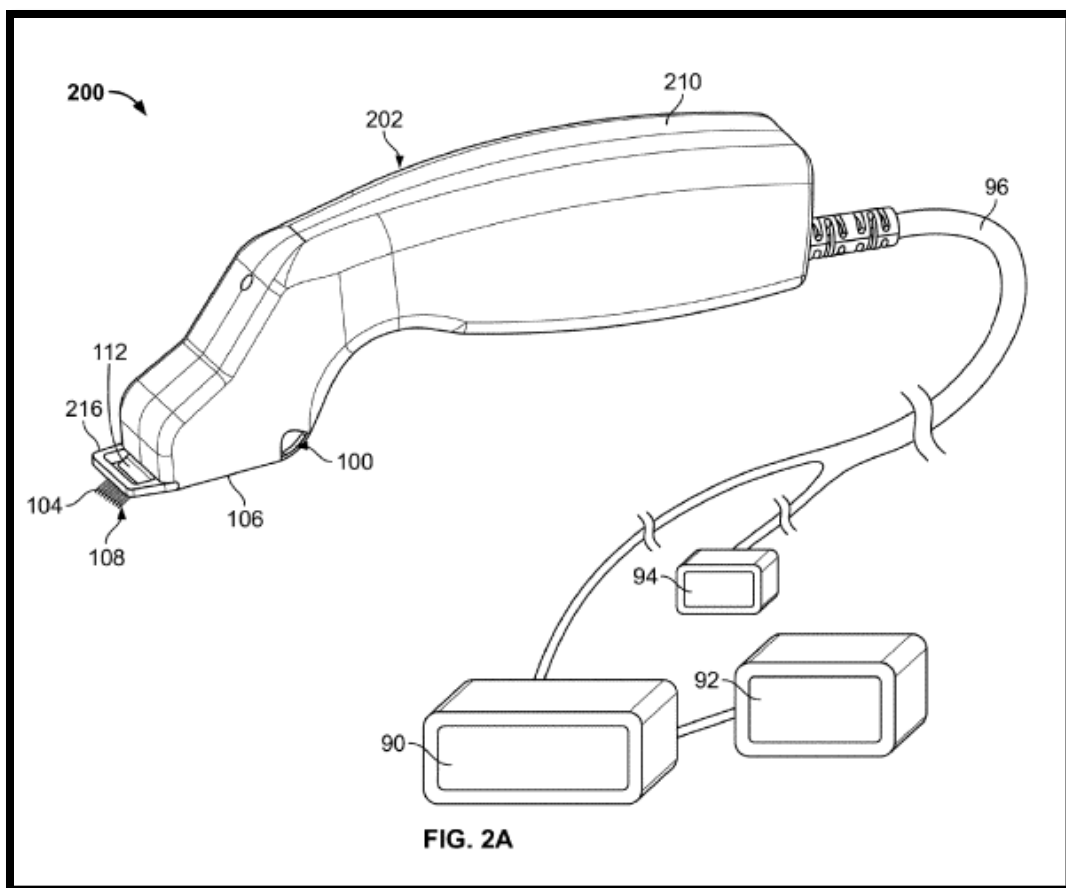
62. As to Petitioners' and their expert's assertion that a "desired distance" just means "a *desired distance* as opposed to an *undesired* distance" (Pet. 16), I disagree. The '774 Patent does not use the term "undesired." And to the extent it would have any meaning based on the intrinsic evidence, "undesired" would be a

different distance than the distance that the needles extend based on the depth that the user selected.

VII. PRIOR ART

A. U.S. Pat. No. 8,608,737 to Mehta

63. Mehta is a U.S. patent that was filed in 2009 and issued in 2013. Ex. 1004 (Mehta). Mehta sought to address a need for an “improved energy delivery system.” *Id.*, 2:3-4. Mehta discloses a “treatment system 200 [that] generally includes a treatment unit 202 having a hand-piece or device body 210. . . having one or more probes 104 extending from the body 210.” *Id.*, 9:34-39. “In some variations, the probes 104 are coupled to the body 210 via a removable cartridge 100.” *Id.*, 9:40-41, Figs. 2A and 2D. Mehta discloses that the “system 200 also includes an energy supply unit 90 coupled to the treatment unit 202 via a cable 96 or other mean” and “[i]n one variation the energy supply unit 90 may be a RF energy unit.” *Id.*, 10:53-57,11:14-15.



64. In Mehta, “[t]he tissue engagement surface 106 allows a user to place the device on the surface of tissue and advance the probes 104 to the desired depth of tissue. Because the tissue engagement surface 106 provides a consistent starting point for the probes, as the probes 104 advance from the device 202 they are driven to a uniform depth in the tissue” *Id.*, 21:10-16. Mehta also discloses preventing probes from delivering energy at “an unintended shallower location” other than “a specific depth in the target tissue that corresponds to the length of the extended electrode” by only coupling the probes to the power supply when “fully extended.” *Id.*, 15:62-16:8. But Mehta does not disclose any ability for a user to select the needle insertion depth; the stabilization plate provides a “consistent starting point” but does not offer any user control over the insertion depth.

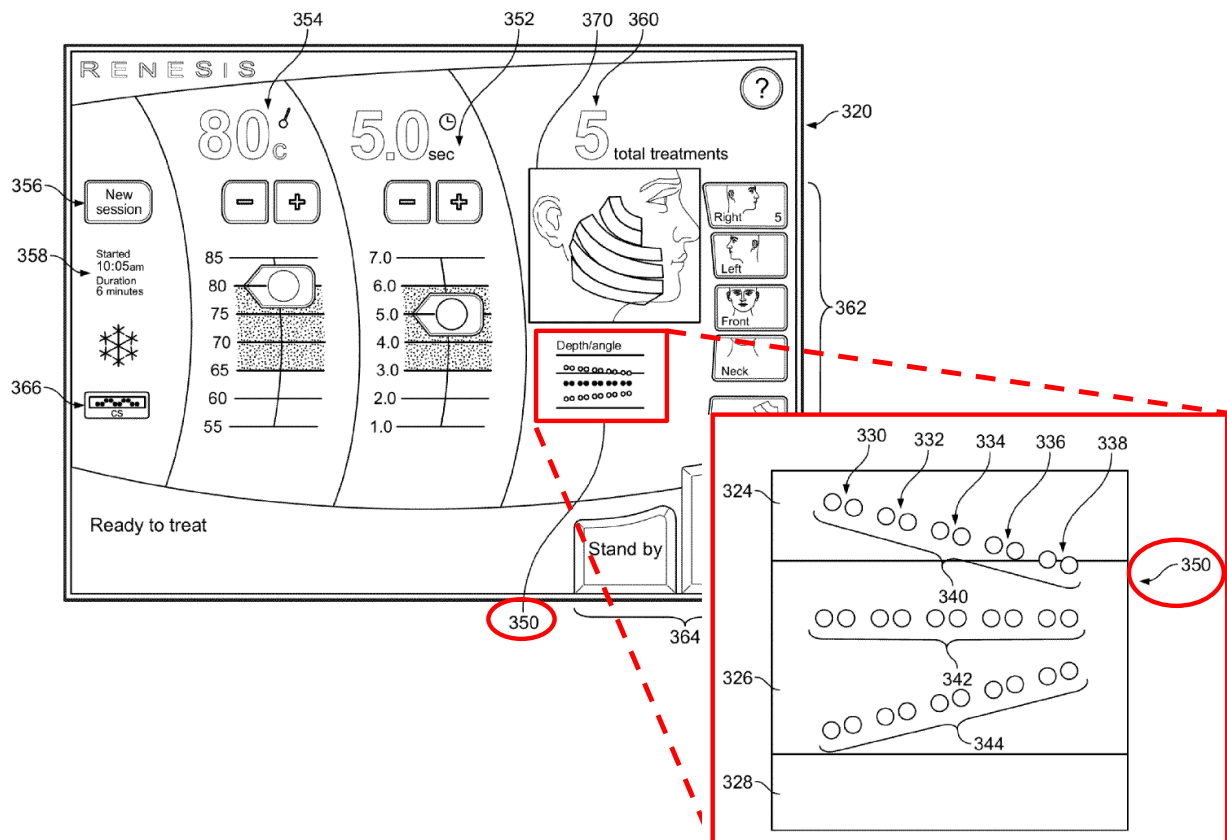
65. In Mehta, if the probes are not in the target tissue, a physician can manually adjust the placement of the device on the patient’s skin or can select a different cartridge with a different needle array configuration, e.g., a different length or angle for needle insertion. Specifically, Mehta explains that “[t]he present invention allows a physician to selectively change array configuration by attaching different cartridges.” *Id.*, 10:3-5. The device in Mehta “can include any number of arrays depending upon the intended treatment site” and “the target region of tissue drives the array configuration.” *Id.*, 9:65-10:3.

66. To confirm the probes reached the target tissue, Mehta discloses several ways of assessing penetration depth after the needles have been extended into the skin. For example, Mehta explains that “ultrasound energy can [] be used for imaging purposes . . . to assess the penetration depth of the electrodes, or to identify in which layer the electrodes are located.” *Id.*, 12:1-4. As another example, Mehta teaches that “[m]easurement of a tissue parameter by the sensor 110 provides information that can confirm whether the probe 108 is located in the desired target region. For example, when measuring impedance of the tissue, if the measured impedance is not within a range normally associated with tissue, the system can prevent treatment and alert the user for the need to reposition the probe 108. Accordingly, the probe 108 can ultimately be repositioned as shown in FIG. 8B (or the active area 122 of the probe 108 can be repositioned).” *Id.*, 24:37-45; *see also* Fig. 8A.

67. Mehta identifies a problem that the “physician can inadvertently place the array 108 of probes 104 at an angle relative to a tissue surface,” which would result in the probes not reaching target tissue as expected based on the length of the needles and their insertion angle. Ex. 1004 (Mehta), 32:20-22. “To address this problem,” Mehta discloses “measur[ing] tissue parameters to provide feedback to the physician,” so that the physician can appreciate if there was an inadvertently incorrect placement of the probe array. *Id.*, 32:23-25. This feedback can be “visual,

virtual, audible or other feedback[] allowing the user to identify whether the placement of the probes” is as it was “desired” or not. *Id.*, 32:46-50.

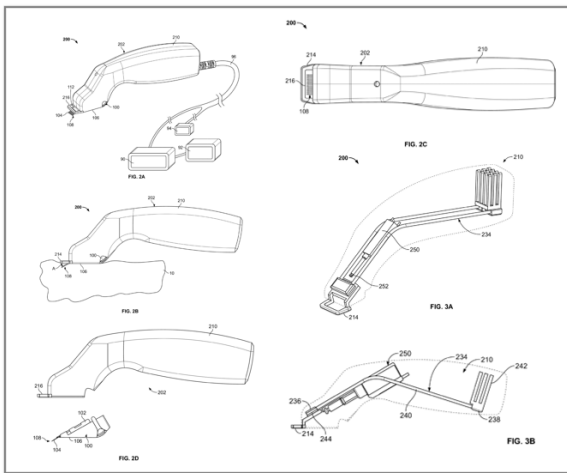
68. As an example, Mehta discloses a “virtual depth/location depiction 350” in a graphical user interface, as shown in Figure 10E and in a close-up view in Figure 10B (both copied and annotated below). Ex. 1004 (Mehta), 32:63-33:64.

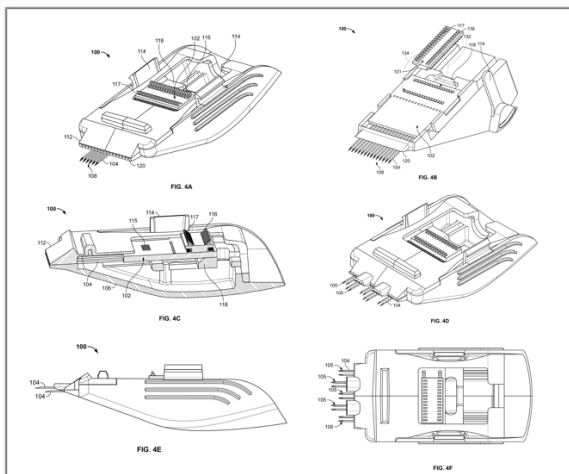


69. Virtual depth/location depiction 350 can “show the location of the probe array prior to treatment” (i.e., prior to energy application) and how it compares to the “desired probe location,” i.e., “the desired placement for providing treatment.” *Id.*, 32:63-33:3. Thus, a “physician would be informed” whether, for example, the probe array “is located in an undesired region” and “further

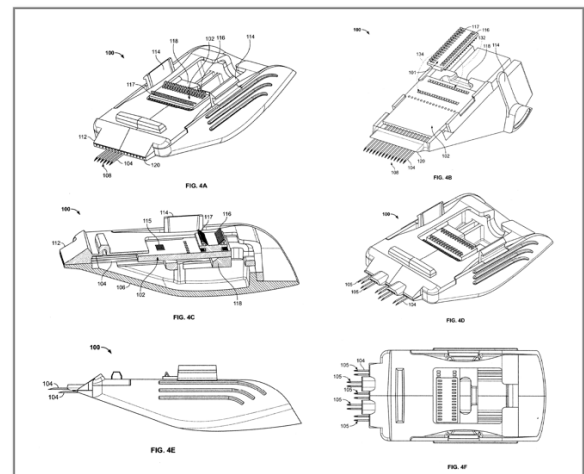
advancement of the probes is necessary” to reach “the desired tissue layer.” *Id.*, 33:14-40.

70. Mehta is substantially the same in relevant disclosures as U.S. Pat. App. No. 12/398,924 (U.S. Pat. No. 8,540,705) (“Mehta ’705”) that the USPTO considered during prosecution of the ’812 Patent. Both Mehta and Mehta ’705 were assigned to Syneron Medical Ltd., listed Bankim Mehta as a named inventor (Mehta also lists two other people), and were filed days apart in the spring of 2009 (Apr. 20, 2009, and Mar. 5, 2009, respectively). Many of the figures in Mehta that the Petitioners rely on are exactly the same as those in Mehta ’705. *See, e.g., compare* Ex. 1004 (Mehta), Figs. 2A-D, 3A, 3B, 4A-F *with* Ex. 2117 (Mehta ’705), Figs. 2A-D, 3A, 3B, 4A-F.





Ex. 1004 (Mehta), Figs. 4A-F.

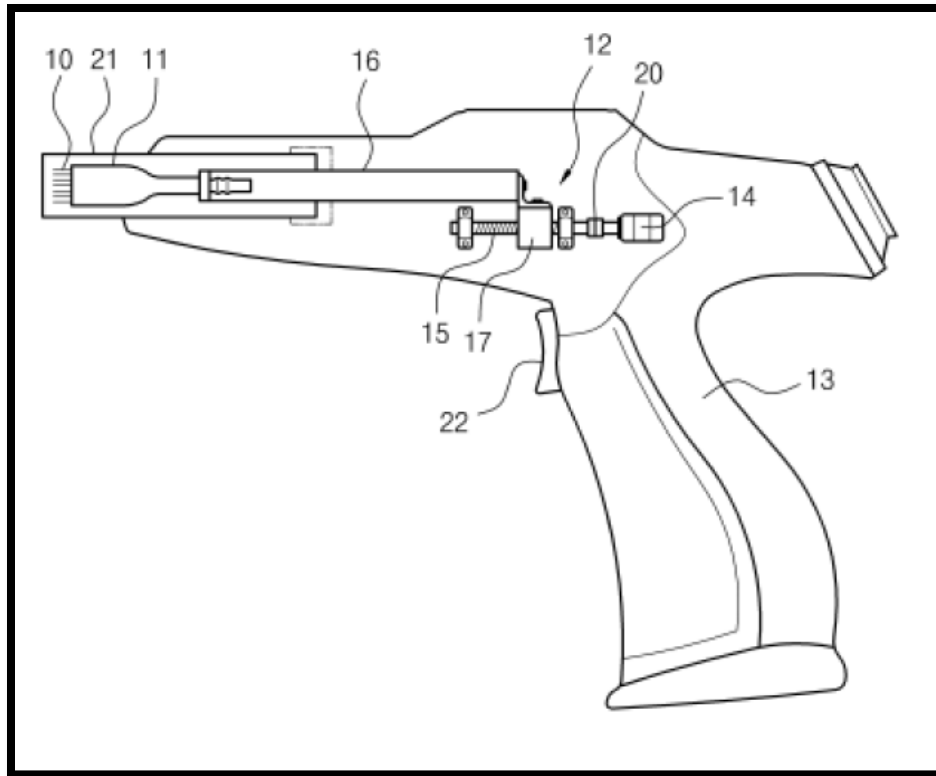


Ex. 2117 (Mehta '705), Figs. 4A-F

71. The descriptions of those figures are substantially the same, if not identical, in Mehta and Mehta '705. *See, e.g., compare* Ex. 1004 (Mehta), 9:34-10:39 (description of Fig. 2A), 15:27-16:41 (description of Fig. 4A), 18:21-45 (description of Fig. 5) *with* Ex. 2117 (Mehta '705), 10:20-11:25 (description of Fig. 2A), 15:63-17:18 (description of Fig. 4A), 19:1-25 (description of Fig. 5); *see also compare* Ex. 1004 (Mehta), 36:20-37:24 (description of experiment) *with* Ex. 2117 (Mehta '705), 31:10-32:16 (description of experiment).

B. KR20-0441552 (“Lee”)

72. Lee is a Korean patent publication that was published on August 25, 2008. It “relates to a skin regeneration apparatus used for performing multi-hole procedures to remove or treat stretch marks, calluses, wrinkles, hair loss, scars, etc.” Ex. 1011 (Lee), 2. Lee’s device is a “gun equipped with a plurality of microneedles” as illustrated in Figure 2 below.



73. The invention of Lee seeks to create “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” and apply medication on “the area where tiny holes are created, allowing the drugs to quickly permeate the skin through the tiny holes, thereby maximizing the efficacy of treatment.” Ex. 1011 (Lee), ¶15.

74. Lee “provides an actuator means that can control the insertion depth of the microneedles.” *Id.*, ¶44. “[T]he process of reciprocating operation of the microneedles is repeated many times by repetitively driving the motor back and forth, allowing creation of hundreds to tens of thousands of holes on the human

skin.” *Id.*, ¶63. The treatment method [of Lee] allows repetitive insertion of needles at a constant speed and at a constant depth.” *Id.*, ¶57.

VIII. None of the Grounds in the Petition Show that Claims 13 or 14 are Unpatentable

A. GROUND I – Claims 13 and 14 of the '774 patent are not anticipated by Mehta

75. I understand that Patent Owner has disclaimed all claims other than claims 13 and 14 of the '774 Patent. Therefore, my opinions are limited to claims 13 and 14. Claim 13 recites “a mechanism for causing the plurality of the extendable needles to extend a desired distance from the end surface” and claim 14 recites a “motor coupled to the plurality of extendable needles that may be directed to cause the plurality of the extendable needles to extend a desired distance from the end surface.” Therefore, both claims recite needles that are extendable a “desired distance,” and as discussed in the claim construction section (*see supra* Section VI), the “desired distance” in these claims is how far the needles extend from the device’s end surface, based on a user’s selection, to penetrate dermatological issue. Mehta fails to disclose the claimed “desired distance,” and in my opinion, for at least that reason, it fails to anticipate claims 13 and 14 of the '774 Patent.

76. In Mehta, the user does not select a desired depth for the needles extend to penetrate dermatological tissue. Instead, Mehta discloses selecting

cartridges having different probe *lengths* or *angles*, not selecting *how far* the probes in a given cartridge extend when used in Mehta's system. Mehta discloses "[s]electing probes having sufficient length to reach" different layers of the dermis (*id.*, 2:47-49, 8:16-18) and explains that "the length of the probes 104 is generally selected so that the energy delivery occurs is in the dermis layer of the skin 10" *Id.*, 10:21-23. But Mehta does not disclose any selection by a user of how far the needles extend from the device's end surface to penetrate the skin.

77. Also, the system in Mehta is designed for insertion of the needles a *fixed distance*. Ex. 1004 (Mehta), 10:2-7, 10:19-25, 12:31-34, 16:1-8. Thus, in Mehta, the distance that the needles extend when using a particular cartridge is not selected by the user but rather is determined by the "fixed length" of the needles. *Id.*

78. As I noted above, I understand that during prosecution of the '812 Patent, a continuation of the '774 Patent that includes claims that also recite the same "desired distance" limitation (Ex. 2116 ('812 Patent), cls. 2, 8, 13), the Examiner considered Mehta '705. As I explained above, Mehta '705 contains the same disclosures as the Mehta that Petitioners rely on here. Ex. 2116 ('812 Patent), pg. 2 ("References Cited"); Ex. 2117 (Mehta '705), 10:20-11:25, 15:63-17:18, 19:1-25. I understand that the Examiner did not reject the claims of the '812 Patent, including those requiring a "desired distance" based on Mehta '705. Ex. 2118 ('812

Patent File History), 577-582, 645-651. This further confirms my opinion that Mehta does not disclose the claimed “desired distance” of claims 13 and 14 of the '774 Patent.

79. Based on my review of the Petition and the Petitioners’ expert declaration, both fail to cite any disclosure in Mehta of user selection of the distance that the needles extend, and that is because there is none.

80. Petitioners assert that “[c]ontrol of the actuator 250 [in Mehta] confers the ability of the needles 104 to be extendable a desired distance from the surface” and “the needles are extendable to a distance selected by a user.” Pet. 26. While Petitioners cite to disclosure in Mehta of using an actuator to extend the needles, they do not identify any disclosure of a user selecting a distance that the needles extend. *Id.* (citing Ex. 1004 (Mehta), 18:26-37); Ex. 1003 (Berube Decl.), ¶86.² The portion Petitioners cite to refers to using a tissue engaging surface to ensure that actuator 250 extends the needles from a consistent starting point.

81. Petitioners also cite to the “virtual depth/location depiction” system of Mehta to contend Mehta discloses a desired depth. But that is not a “desired depth” that a user selects for the needles to extend. Rather, it is a displayed depth

² I understand that Dr. Woloszko submitted a substitute declaration (Ex. 1025) adopting the opinions in Ex. 1003.

to confirm where the needles were extended. Specifically, Mehta's "virtual depth/location depiction" "show[s] 'the desired depth of placement for providing treatment'" to compare it to the "location of the probe array" so that a user can determine whether the probes are in the desired region or "an undesired region." Ex. 1004 (Mehta), 32:63-33:43 (cited in Pet. 26-27 & Ex. 1003 (Berube Decl.), ¶¶86-87); Pet. 26. That Mehta discloses a virtual display for **comparing** "actual depth" to the "desired depth" (and other ways of tracking insertion depth, e.g., "depth markings"), as Petitioners concede (see Pet. 27-28), in my opinion reinforces that Mehta does not disclose extending the needles "a desired distance."

82. Regarding Mehta's disclosure of a "step-motor" as one of the possible "mode[s] of movement of the actuator" that Petitioners cite (Ex. 1004 (Mehta), 15:36-40 (cited in Pet. 27)), this disclosure is only of how the actuator can be implemented. Nothing in Mehta, including the disclosure of a step-motor, discloses selecting how far the needles extend. And, as the Petitioner's own expert admits, a motor that extends a plurality of needles a predetermined distance only meets the claims "**[a]s long as you can program this distance**" and otherwise "does not" meet the claims. Ex. 2125, (Woloszko Hr'g Tr.), 1151:8-12, 1151:23-1152:3. There is no disclosure in Mehta of programming the distance that the needles extend and, based on my review of the Petition and supporting declaration, Petitioners do not contend otherwise.

83. Petitioners also cite to the disclosure in Mehta “***selecting a cartridge*** having needles of a particular length and coupling that to the proximal end of the handpiece” or “choosing” one having a particular insertion “angle.” Pet. 27-28; *see also* Ex. 1003 (Berube Decl.), ¶89 (“a user may select the distance by which the needles extend from the tissue engaging surface 106 by choosing a particular removable cartridge having needles of a particular length”). But, neither of those selections are a selection by a user of how far the needles extend from the device’s end surface to penetrate the skin. In fact, nothing in those passages in Mehta discloses how far needles extend based on user selection.

84. Petitioners also rely on Mehta’s disclosure of “[o]ver-inserting and then partially retracting” the needles. Pet. 27-28. But as Mehta explains, “[o]ver inserting and then partially retracting the electrodes compensates for the movement and laxity of the skin resulting in a more reliable insertion.” Ex. 1004 (Mehta), 16:34-41. Mehta does not disclose a user making a selection that determines how far the needles extend, over-insert, or retract. Mehta’s display includes no such option.

85. In my opinion, the invention of the ’774 Patent is vastly different from the system described in Mehta. In the ’774 Patent, the user attaches a needle cartridge or module to the handpiece and then selects the depth the needles should extend before the needles extend and that selection is used to control how far the

motor extends the needles. In contrast, in Mehta, the user attaches a cartridge to the handpiece, the needles extend into the tissue, and the user is informed whether the needles are located at the proper depth via, for example, a virtual depiction system, and if they are not, the user then selects a different cartridge to use. The process would need to be repeated until the user is informed the needles are in the correct depth. These are two completely different ways to reach the result of reaching a target region of the tissue.

B. GROUND II – Patent Owner Disclaimed Claims 8, 19, And 20, The Only Claims Pertinent To This Ground

86. I have been informed by counsel that the Patent Owner has disclaimed claims 8, 19, and 20 of the '774 Patent such that their patentability will not be at issue if the Petition is instituted. Thus, I have not formed any opinions as to the patentability of those as to those claims.

C. GROUND III – Patent Owner Disclaimed Claims 1, 5-11, And 15-20, The Only Claims Pertinent To This Ground

87. I have been informed by counsel that the Patent Owner has disclaimed claims 1, 5-11, and 15-20 of the '774 Patent such that their patentability will not be at issue if the Petition is instituted. Thus, I have not formed any opinions as to the patentability of those as to those claims.

D. GROUND IV – Claims 13 and 14 of the '774 Patent are not obvious over Mehta and Lee

88. I understand that Patent Owner has disclaimed all claims other than claims 13 and 14 of the '774 Patent. Therefore, my opinions are limited to claims 13 and 14. In my opinion, Mehta in combination with Lee does not render claims 13 and 14 of the '774 Patent obvious at least because a POSITA would not have combined those references to achieve “a mechanism for causing the plurality of the extendable needles to extend a desired distance from the end surface” (claim 13) or “motor coupled to the plurality of extendable needles that may be directed to cause the plurality of the extendable needles to extend a desired distance from the end surface” (claim 14).

89. Petitioners argue “[a] POSA would have been motivated to use and configure the Mehta system in view of Lee to include the stepper motor taught by Lee to precisely control a needle extension distance. . . .” (Pet. 66); that “[a] POSA would have been motivated to modify Mehta with the Lee motor to gain the benefits of being able to control needle insertion. . . .” (*id.*, 67); and that “[m]odifying Mehta to use the motor in the manner taught by Lee would have yielded predictable results. . . .” *Id.* I disagree.

90. Modifying Mehta to include Lee’s stepper motor would not meet the claim requirements. As an initial matter, Mehta itself already discloses a stepper motor. Ex. 1004 (Mehta), 15:34-40 (“[t]he mode of movement of the actuator can

include ... stepping (via an step-motor)"). And as I opine when addressing Ground I (*see infra* Section VIII.A), Mehta does not teach or suggest a user selecting how far the needles extend and replacing Mehta's stepper motor with Lee's stepper motor also does not meet the claims because this combination lacks any teaching of a user selecting how far the needles extend.

91. Specifically, the invention described in Lee relates to creating holes in tissue using a "gun" that can "vertically insert the microneedles" at a very high "speed of about 66-420 times per minute" at a particular insertion depth. Ex. 1011 (Lee), ¶¶56-58. There is no "distance setting" in Lee that Petitioners' propose to include in Mehta. The only disclosure in Lee regarding user selection is a "mode switch" which "controls the speed of reciprocating insertions (number of repetitive insertions) and the insertion depth of the needles." *Id.*, ¶33. While Lee's modes include the number of insertions and insertion depth, Lee does not disclose user selection of distance specifically or teach how to configure a controller to provide a distance control signal. To the extent Petitioners rely on Lee's disclosure of a "mode switch," they fail to explain why that disclosure would have motivated a POSITA to implement a distance setting in Mehta. In my opinion, a POSITA would not have been motivated to implement a "distance setting" in Mehta based on Lee's disclosure of a "mode switch."

92. Importantly, Mehta is directed to minimizing variance in needle insertion. Mehta recognizes that this variation affects the actual insertion depth of the needles and teaches a way to provide information to the physician to compare the actual to desired depth so that the physician can react accordingly. Specifically, Mehta discloses a “tissue engagement surface” that provides a “consistent starting point” to try to minimize “undesirable outcomes” where probes 104 “may be advanced too far or may not be advanced far enough.” Ex. 1004 (Mehta), 21:10-16. Recognizing that variation in probe depth will still occur, Mehta discloses a number of ways for a physician to compare “actual depth” to the “desired depth” and other ways of tracking insertion depth. Adding a “distance setting” to Mehta in view of Lee would only increase the variation in “actual depth” by, for example, adding another variable to needle insertion, and thus would increase the likelihood that the probes would not be at the “desired depth” that the physician intended to achieve based on the physician’s choice of cartridge.

93. Lee is directed toward “a method of creating holes on the skin by using the repetitive, reciprocating operation of the actuator” Ex. 1011 (Lee), ¶20 “at a speed of about 66-420 times per minute.” Ex. 1011 (Lee), ¶58. At the lowest speed in that range, that is less than a second between insertions, and at the highest speed there is 1/7th of a second (about 140 ms) between insertions.

94. Mehta is directed towards treating tissue with a method to verify the probes are in the target tissue to be treated for each insertion. In Mehta, the probes are inserted to a constant distance (determined by the choice of probe cartridge), measurements are obtained after the probes are inserted and the results are displayed on a screen, and then the probes are retracted. The physician would use the measurements to reposition the probe if necessary prior to the next insertion. In my opinion, it would be impossible to make the measurements, display the results, have the physician make a decision on those results, and if necessary, reposition the probe in less than a second – and certainly not in 140 ms.

95. Therefore, a POSITA would not be motivated to combine a repetitive reciprocating mechanism to provide a controlled depth of needle insertion with a method to verify the needle depth at every insertion. Despite the lack of motivation, even if the mechanisms were combined, there is no reasonable expectation of success for the reasons discussed above. Further, even if the depth of the probe insertion could be controlled in Mehta, doing so would not have addressed the problem Mehta was attempting to solve because there would still be a need to determine if those probes reached the target region to ensure energy would not be delivered to an undesired location as Mehta explains. The purpose is to minimize energy delivery to unintended regions of the tissue. Thus, a POSITA would not have been motivated to combine the already complex system of Mehta with the

depth control mechanism of Lee. Doing so would have increased the cost of the system due to, for example, additional parts to control and program the motor even though the mechanisms in Mehta for probe location would still have to be utilized to perform its intended function.

96. Mehta was aware of distance control but did not rely on that approach. For example, Mehta cites a number of prior art references that disclosed distance control, including U.S. Patent. No. 6,277,116 to Utely (“Utely”), cited in the Background of Mehta, and U.S. Patent Application No. 2002/0120261 to Morris (“Morris ’261”). Ex. 2119 (Utely); Ex. 2120 (Morris ’261). Utely discloses a controller that can “establish and maintain a control depth” that can be “set by the physician.” Ex. 2119 (Utely), 11:27-31. Morris discloses electrodes that can be “advanced to a selected deployment depth.” Ex. 2120 (Morris ’261), Abstract. Notably, these references like Mehta relate to application of energy to the electrodes, unlike Lee which relates to rapidly creating a large number of holes. *Compare* Ex. 2119 (Utely), 4:38-41, *and* Ex. 2120 (Morris ’261), ¶84, *with* Ex. 1011 (Lee), ¶58. Rather than relying on distance control, Mehta teaches using a different approach to minimize depth variation in the first instance and allows the physician to address undesired insertion depth.

97. Understanding that selection of probe depth was known, Mehta chose to teach a different approach to ensure that energy would be delivered to “a

predetermined target area while minimizing delivery of energy to undesired region of tissue.” Ex. 1004 (Mehta), 2:10-12. Specifically, Mehta teaches how to insert probes consistently and how to measure and validate probe placement before delivering energy, to ensure it is delivered at the intended location in the tissue. *E.g., id.*, 12:1-4 (ultrasound “to assess the penetration depth of the electrodes”), 21:10-12 (“a consistent starting point for the probes”), 32:46-57 (“virtual depiction ... of the depth”), 39:33-36 (“impedance measurements to precisely determine depth of placement of the active electrode portion”). Mehta thus addressed the problem of inserting needles at a particular depth in a different way than the prior art methods of selecting among variable insertion depths for a particular set of needles.

E. GROUND V – Patent Owner Disclaimed Claims 8, 19, and 20, The Only Claims Pertinent To This Ground

98. I have been informed by counsel that the Patent Owner has disclaimed claims 8, 19, and 20 of the '774 Patent such that their patentability will not be at issue if the Petition is instituted. Thus, I have not formed any opinions as to the patentability of those as to those claims.

IX. OBJECTIVE INDICIA OF SECONDARY CONSIDERATIONS

A. The Sylfirm X practices claims 13 and 14 of the '774 Patent

99. I served as an expert for Patent Owner during the 1356 Investigation, where I provided opinions on a number of issues, including validity of the '774

Patent as well as practice of that patent by various products. One of those products is the Sylfirm X, [REDACTED]

[REDACTED] As part of my analysis and rendering of my opinions regarding the Sylfirm X, I reviewed numerous documents for the product such as the user manual, brochures and other marketing and advertising documents, instructional videos, the 510k, and others. I also personally inspected the Sylfirm X and prepared an inspection report. *See generally* Ex. 2127 (Inspection Report). In my opinion, the Sylfirm X practices claims 13 and 14 of the '774 Patent.

100. Because claims 13 and 14 depend on claims 11 and 12 of the '774 Patent, I provide an analysis of those claims as well.

1. '774 Patent, Claim 11

a. **“11[pre] An apparatus for treating dermatological tissue, comprising:”**

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

102. Patent Owner's documents confirm that the Sylfirm X practices this limitation. For example, a Sylfirm X User Manual shows it is an RF microneedling system used to treat dermatological tissue. *See* Ex. 2083 (Sylfirm X User Manual), 4 (“The device is intended for coagulating skin tissue”); Ex. 2037 (Sylfirm X Brochure), 2 (“The world's first & only FDA registered Pulse Wave (PW) and Continuous Wave (CW) Radio Frequency Micro Needling device featuring 300

Micron depth targeting both skin laxity and pigmentation for ultimate skin rejuvenation.”)

103. Deposition testimony of the '774 Patent inventor, Dr. Jongju Na, confirms the Sylfirm X practices this limitation. For example, Dr. Na testified that the Sylfirm X “is one of [the] RF microneedling device.” *See, e.g.*, Ex. 2128 (July 25, 2023 Na Dep. Tr.), 202:13-15.

104. I personally inspected the Sylfirm X and confirmed it practices this limitation. *See* Ex. 2127 (Inspection Report).

- b. **“11[a] a device including a plurality of needles one of extending or extendable a desired distance from a surface, the desired distance selected to enable the plurality of needles to penetrate dermatological tissue; and”**

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

106. I understand that in the 1356 Investigation, the parties agreed that the term “needles one of extending or extendable” means “needles that are either extended or can be extended [from the device surface] (needles ‘extending’ a desired distance from the surface covers non-extendable needles having a fixed length; ‘extendable’ needles covers needles which are not fixed).” *See* Ex. 1006 (July 21, 2023 Joint Claim Construction Chart).

107. I also understand that in the 1356 Investigation the parties agreed that the term “a plurality of needles one of extending or extendable . . . the plurality of

[extended] needles” means “Plain and ordinary meaning: two or more extendable needles or extending needles . . . the two or more extended needles.” *See* Ex. 1006 (July 21, 2023 Joint Claim Construction Chart).

108. Patent Owner’s documents confirm that the Sylfirm X practices this limitation. For example, a Sylfirm X instructional video shows how when treating dermatological tissue, a surface is placed on or near dermatological tissue to be treated. *See* Ex. 2097 (Sylfirm X Instructional Video). The Sylfirm X Manual and photos of the Sylfirm X show the plurality of extendable needles extend a desired distance from the surface with a force sufficient to cause the plurality of needles to penetrate the dermatological tissue, and the desired distance is configured via the “Depth” setting in the user interface/control panel. *See* Ex. 2086 (Sylfirm X Photos), 2-3; Ex. 2083 (Sylfirm X User Manual), 16. The desired distance correlates to the distance the user selects with the “Depth” setting.

109. Deposition testimony of the inventor, Dr. Jongju Na, confirms the Sylfirm X practices this limitation. For example, Dr. Na testified that the Sylfirm X has needles that extend from the surface. *See, e.g.*, Ex. 2128 (July 25, 2023 Na Dep. Tr.), 249:7-22.

110. I personally inspected the Sylfirm X and confirmed it practices this limitation. *See* Ex. 2127 (Inspection Report).

- c. **“11[b] a signal generator electrically coupled to the plurality of extended needles to produce pulsed**

radio frequency signals across the plurality of needles to affect dermatological tissue near the plurality of needles.”

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

112. I understand that in the 1356 Investigation the term “pulsed radio frequency signals” was construed to have its plain and ordinary meaning, which is “radio frequency signals that are normally off and suddenly on for a period of time (i.e., a rapid, transient change from a baseline to a different amplitude, followed by rapid return to baseline.” Ex. 1007 (Order No. 35, ITC’s Claim Construction). The Sylfirm X practices this limitation literally because the products emit radio frequency signals that are normally off and suddenly on for a period of time—there is a rapid, transient change from a baseline to a different amplitude, followed by a rapid return to baseline.

113. I understand that in the 1356 Investigation the parties agreed that the term “a plurality of needles one of extending or extendable . . . the plurality of [extended] needles” means “Plain and ordinary meaning: two or more extendable needles or extending needles . . . the two or more extended needles.” See Ex. 1006 (July 21, 2023 Joint Claim Construction Chart).

114. Patent Owner’s documents confirm that the Sylfirm X practices this limitation. For example, a Sylfirm X brochure shows the products communicate electrical signals (using Pulsed Wave (PW) radio frequency signal or Continuous

Wave (CW) radio frequency signals) from the proximal end of the user holdable device to the plurality of the extendable needles to treat dermatological tissue and maximize treatment results. *See* Ex. 2037 (Sylfirm X Brochure), 2. A Sylfirm X introduction video shows the RF signal generator is directed to produce pulsed radio frequency signals across the plurality of needles to affect dermatological tissue near the plurality of needles. *See* Ex. 2097 (Sylfirm X Instructional Video). The Sylfirm X Manual and photos of the Sylfirm X show the production of pulsed radio frequency signals across the plurality of needles are controlled via a user interface/control panel, and the parameters of the signal can be configured (e.g. “Power” and “Interval” settings on the control panel). *See* Ex. 2086 (Sylfirm X Photos), 2; Ex. 2083 (Sylfirm X User Manual), 16.

115. Deposition testimony of the inventor, Dr. Jongju Na, confirms the Sylfirm X practices this limitation. For example, Dr. Na testified that the Sylfirm X generates a 2 MHz signal that is “delivered to the needles.” *See, e.g.*, Ex. 2128 (July 25, 2023 Na Dep. Tr.), 202:9-12, 205:22-206:5.

116. I personally inspected the Sylfirm X and confirmed it practices this limitation. *See* Ex. 2127 (Inspection Report).

2. '774 Patent, Claim 12

- a. **“The apparatus for treating dermatological tissue of claim 11, wherein the device includes an end surface configured to be placed on or near dermatological tissue to be treated, the end surface including a**

**plurality of needles extendable a desired distance
from the end surface.”**

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

118. Patent Owner's documents confirm that the Sylfirm X practices this limitation. For example, a Sylfirm X instructional video shows how when treating dermatological tissue, an end surface is placed on or near dermatological tissue to be treated. *See* Ex. 2097 (Sylfirm X Instructional Video). A Sylfirm X brochure shows that in the product, the end surface includes a plurality of needles extendable a desired distance from the end surface. *See* Ex. 2037 (Sylfirm X Brochure), 11; *see also* Ex. 2130 (Sylfirm X Photos), 2, 4. Photos of the Sylfirm X show the plurality of the extendable needles extend a desired distance from the end surface, and the desired distance is configured via the “Depth” setting in the user interface/control panel. *See* Ex. 2086 (Sylfirm X Photos), 2-3.

119. Deposition testimony of the inventor, Dr. Jongju Na, confirms the Sylfirm X practices this limitation. For example, Dr. Na testified that the Sylfirm X has needles extend from the surface. *See, e.g.*, Ex. 2128 (July 25, 2023 Na Dep. Tr.), 249:7-22.

120. I personally inspected the Sylfirm X and confirmed it practices this limitation. *See* Ex. 2127 (Inspection Report).

3. ’774 Patent, Claim 13

- a. “The apparatus for treating dermatological tissue of claim 12, further including a mechanism for causing the plurality of the extendable needles to extend a desired distance from the end surface.”

121. It is my opinion that the Sylfirm X practices this limitation. See discussion for ’774 Patent, Claim 12 above.

122. I understand that in the 1356 Investigation the parties initially disputed the construction of the term “mechanism for causing the plurality of the extendable needles to extend a desired distance from the end surface” but all parties agreed that the term a means-plus-function limitation subject to 35 U.S.C. § 112(6) and that the recited function is “causing the plurality of the extendable needles to extend a desired distance from the end surface.” My understanding is that the parties disputed the proposed corresponding structure. Below is the corresponding structure proposed by Patent Owner and the respondents in the ITC, including current Petitioners. See Ex. 1006 (July 21, 2023 JCCC).

Patent Owner	Respondents (including Petitioners)
A motor and LED module 922, depicted in Figs. 9A, 9C-D, 10A-E; and described at col. 13 lines 15-20, 22-26; col. 14 lines 14-20, 29-34; or A needle deployment motor controller (NDMC) module 911B, depicted in Fig. 9B; and described at col. 10 lines 31-36, 51-55; or	A motor as described at col. 14, lines 3-11; col. 10, lines 36-39; col. 14, lines 24-26. Or, in the alternative One or more motors, one or more drive shafts, and a motor controller (NDMC) module operating in concert as described at col. 10, lines 31-39,

Patent Owner	Respondents (including Petitioners)
One or more motors 922A, depicted in Figs. 9C-D; and described at col. 10 lines 36-39, 55-59; col. 11 lines 57-60; col. 14 lines 3-11, 24-26; or One or more drive shafts 922C, depicted in Figs. 9C-D and 10A-E; and described at col. 11 lines 23-27, 53-57. And equivalents thereof.	51-59; col. 11, lines 23-27, 53-60; col. 13, lines 15-26; col. 14, lines 3-11, 14-34. And equivalents thereof under 35 U.S.C. § 112(6).

123. Regardless of the corresponding structure, it is my opinion that the Sylfirm X practices this limitation because it includes a motor to cause the plurality of extendable needles to extend a desired distance from the end surface.

124. Patent Owner’s documents confirm that the Sylfirm X practices this limitation. For example, photos of the Sylfirm X show that it includes a motor, and that the product energizes the motor coupled to the plurality of extendable needles to cause them to extend a desired distance from the end surface. *See* Ex. 2130 (Sylfirm X Photos), 3; *see also* Ex. 2086 (Sylfirm X Photos), 9-10. Photos of the Sylfirm X show the desired distance is configured via the “Depth” setting in the user interface/control panel. *See* Ex. 2086 (Sylfirm X Photos), 2-3. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

125. I personally inspected the Sylfirm X and confirmed it practices this limitation. *See* Ex. 2127 (Inspection Report).

4. '774 Patent, Claim 14

- a. **“The apparatus for treating dermatological tissue of claim 12, further including a motor coupled to the plurality of extendable needles that may be directed to cause the plurality of the extendable needles to extend a desired distance from the end surface.”**

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

127. Patent Owner's documents confirm that the Sylfirm X practices this limitation. For example, photos show the Sylfirm X includes a motor, and the product energizes the motor coupled to the plurality of extendable needles via a drive shaft that may be directed to cause the plurality of the extendable needles to extend a desired distance from the end surface. *See* Ex. 2130 (Sylfirm X Photos), 3; *see also* Ex. 2086 (Sylfirm X Photos), 9-10. Photos of the Sylfirm X show the desired distance is configured via the “Depth” setting in the user interface/control panel. *See* Ex. 2086 (Sylfirm X Photos), 2-3. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

128. I personally inspected the Sylfirm X and confirmed it practices this limitation. *See* Ex. 2127 (Inspection Report).

B. The Claims at Issue Of The '774 Patent has achieved commercial success

129. The Sylfirm X has achieved great commercial success due to the claimed invention of the '774 Patent. Specifically, the '774 Patent claims 13 and 14 at issue here involve extending a plurality of needles into the skin a desired distance based on user selection and applying energy to the dermatological tissue through the needles. The '774 Patent discloses how the motors of the system enable such precise needle extension depth control based on the distance the user selects. This is one of the main features of the '774 Patent and one of the features that is highlighted and touted in advertising and training materials for the Sylfirm X. For example, the Sylfirm X brochure highlights that “[t]reatment depth . . . [is] adjustable by the user” to deliver the “most accurate energy into the skin without any thermal damage to the skin surface” and also treating different medical indications such as rosacea, melasma, and others. Ex. 2037 (Sylfirm X Brochure), 10, 13. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

130. Whether a particular treatment is successful depends on precise placement of the coagulation in the tissue, which is achieved by the RF energy delivered through the needles. Thus, needle placement is crucial. If the needles are inserted too deeply, the treatment could have an adverse consequence. Thus, “the desired distance” as claimed in the '774 Patent allows more indications for these products to treat more types of patients, which is a deciding factor in purchasing decisions.

131. I reviewed the declaration of Vince Thomas and I understand that the Sylfirm X has been commercially successful. Ex. 2124 (Thomas Decl.) ¶¶ 1, 14-15. In my opinion, these products have achieved commercial success due in part to implementation of the '774 Patent inventions of claims 13 and 14.

C. The Inventions of Claims 13 and 14 of the '774 Patent have received industry praise

132. Mechanisms for extending needles a desired distance and precise needle depth control as claimed by claims 13 and 14 the '774 Patent and the products implementing the claimed inventions have received industry praise and recognition. For example, medical providers have praised the products that use this technology for their ability to “accurately target and treat[]” at the desired skin depth. Ex. 2066 (Sylfirm X Revolutionises [sic] the Clinical Applications of RF Microneedling), 3; Ex. 2122 (Cartessa Aesthetics, *Innovations in RF Microneedling*), 2. That former respondents such as Cartessa have praised the

patented technology in their brochures and magazine placements indicates non-obviousness. Further, in 2020, [REDACTED] also received a world-class product award for the Sylfirm X in Korea. Ex. 2067 (Sylfirm X Award).

133. Thus, the technology claimed in claims 13 and 14 of the '774 Patent has become widely recognized and praised.

X. CONCLUSION

All statements made herein of my own knowledge are true, and all statements made on information and belief are believed to be true. Further, I am aware that these statements are made with the 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 declare under penalty of perjury that the foregoing is true and correct.

Executed on April 22, 2024, in Marthon, France.

A handwritten signature in black ink that reads "Peter Crosby". The signature is written in a cursive, flowing style.

Peter Crosby