Filed on behalf of: Serendia, LLC

Entered: November 13, 2024

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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JEISYS MEDICAL INC.,
Petitioner,

v.

SERENDIA, LLC,
Patent Owner.

---

Case IPR2024-00383
Patent 9,775,774

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**PATENT OWNER'S RESPONSE**

***PUBLIC VERSION – REDACTED***

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| 2003 | Complainant's July 24, 2023 Supplemental Validity Contentions, In re Certain Dermatological Treatment Devices & Components Thereof, No. 337-TA-1356 (U.S.I.T.C. July 24, 2023) (PROTECTIVE ORDER MATERIAL AND REDACTED VERSIONS) |
| 2004 | Expert Report of Jean Woloszko, M.D., Ph.D., dated August 14, 2023 (PROTECTIVE ORDER MATERIAL AND REDACTED VERSIONS) |
| 2005–2006 | RESERVED |
| 2007 | Deposition transcript of Jean Woloszko, In re Certain Dermatological Treatment Devices & Components Thereof, No. 337-TA-1356 (U.S.I.T.C.), taken September 14, 2023 (excerpt) |
| 2008 | Deposition transcript of Jean Woloszko, In re Certain Dermatological Treatment Devices & Components Thereof, No. 337-TA-1356 (U.S.I.T.C.), taken September 15, 2023 (excerpt) |
| 2009–2014 | RESERVED |
| 2015 | Complainant's Rebuttal Post-Hearing Brief, In re Certain Dermatological Treatment Devices & Components Thereof, No. 337-TA-1356 (U.S.I.T.C. Jan. 5, 2024) (PROTECTIVE ORDER MATERIAL) |

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|---|---|
| 2016 | Complainant's Public Interest Statement & Complaint of Serendia, LLC, Under Section 337 of the Tariff Action of 1930, as Amended, In re Certain Dermatological Treatment Devices & Components Thereof, No. 337-TA-1356 (U.S.I.T.C. Mar. 1, 2023) |
| 2017 | Parties' Proposed Procedural Schedule and Notice of USPTO/PTO Proceedings and State and Federal Litigation Pursuant to Order No. 3, In re Certain Dermatological Treatment Devices & Components Thereof, No. 337-TA-1356 (U.S.I.T.C. Apr. 24, 2023) |
| 2018 | Order No. 6: Adopted Procedural Schedule, In re Certain Dermatological Treatment Devices & Components Thereof, No. 337-TA-1356 (U.S.I.T.C. Apr. 27, 2023) |
| 2019 | Respondents' Joint Reply Post-Hearing Brief, In re Certain Dermatological Treatment Devices & Components Thereof, No. 337-TA-1356 (U.S.I.T.C. Jan. 5, 2024) (excerpts) |
| 2020 | Ilooda's Response to the Complaint and Notice of Investigation, In re Certain Dermatological Treatment Devices & Components Thereof, No. 337-TA-1356 (U.S.I.T.C. May 1, 2023) |
| 2021 | Jeisys Medical Inc.'s and Cynosure, LLC's Response to the Complaint and Notice of Investigation, In re Certain Dermatological Treatment Devices & Components Thereof, No. 337-TA-1356 (U.S.I.T.C. May 1, 2023) |
| 2022 | Letter from Merle W. Richman, CKR Law, to Justin S. Cohen, Thompson & Knight LLP, Cutera, dated March 20, 2018 |
| 2023 | Letter from Keith K. Im, SynKloud Technologies, LLC, to Todd Tillemans, Cynosure, LLC, dated Nov. 29, 2021 |
| 2024 | Order No. 33: Granting Parties' Joint Motion to Amend the Amended Procedural Schedule [Motion Docket No. 1356-027], In re Certain Dermatological Treatment Devices & Components Thereof, No. 337-TA-1356 (U.S.I.T.C. Oct. 19, 2023) |

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| 2025–2036 | RESERVED |
| 2037 | Brochure: Sylfirm X Dual Wave RF Microneedling System (2022) |
| 2038 | ViOL Patent List (Dec. 1, 2023), https://violmedical.com/about/patent |
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| 2040 | Transcript of Exhibit 2039 – Sylfirm X Video |
| 2041 | Direct Rebuttal Demonstratives of Vincent A. Thomas (CDX-0045C), In re Certain Dermatological Treatment Devices & Components Thereof, No. 337-TA-1356 (U.S.I.T.C. Dec. 12, 2023) (PROTECTIVE ORDER MATERIAL) |
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| 2053 | Respondents' Notice of Prior Art, In re Certain Dermatological Treatment Devices & Components Thereof, No. 337-TA-1356 (U.S.I.T.C. May 24, 2023) ("1356 Investigation NOPA") |
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| 2066 | Martin Braun, Sylfirm X Revolutionises [sic] the Clinical Applications of RF Microneedling, 12 Prime Int'l J. Aesthetic Anti-Ageing [sic] Med. 50 (2022) |
| 2067 | World-Class Product of Korea 2020, Certificate to ViOL Co., Ltd., dated December 9, 2020 ("Sylfirm X Award") |
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| 2070 | Curriculum Vitae of Vincent A. Thomas |
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| 2103 | Deposition transcript of Peter Crosby, In re Certain Dermatological Treatment Devices & Components Thereof, No. 337-TA-1356 (U.S.I.T.C.), taken September 4, 2023 (excerpt) |
| 2104 | Deposition transcript of Peter Crosby, In re Certain Dermatological Treatment Devices & Components Thereof, No. 337-TA-1356 (U.S.I.T.C.), taken September 5, 2023 (excerpt) |
| 2105 | Statement Under 37 C.F.R. § 3.73(c) and Disclaimer in a Patent Under 37 C.F.R. § 1.321(a) of U.S. Patent 9,775,774 ('774 Patent) ("Disclaimer") |
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| 2108 | U.S. Patent Application Publication No. 2002/0120260 A1 ("Morris") |
| 2109 | U.S. Patent Application Publication No. 2003/0130711 A1 ("Pearson") |
| 2110 | Certified English translation of Korean Registered Patent Publication No. KR 10-0852500, dated August 18, 2008 ("Lee '500") |
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| 2116 | U.S. Patent No. 10,869,812 B2 ("'812 Patent") |

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| 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") |
| 2121 | RESERVED |
| 2122 | Cartessa Aesthetics, Innovations in RF Microneedling: A Closer Look at VirtueRF, Observations Aesthetics, Issue No. 1 (June 2021) |
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| 2126 | Hearing transcript, In re Certain Dermatological Treatment Devices & Components Thereof, No. 337-TA-1356 (U.S.I.T.C.), held December 12, 2023 (Peter Crosby testimony excerpts) ("Crosby Hr'g Tr.") |
| 2127 | Sylfirm X RF Inspection Report of Peter Crosby |
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| 2150 | Primāeva Medical, Inc., Primāeva Miratone System User Manual (Bates nos. Berube-0001098–0001136) |
| 2151 | Primāeva Medical, Inc., Miratone System Instructions for Use (Bates nos. Berube-0001071–0001097) |
| 2152 | VCF Staff, *Syneron Medical Buying Primaeva Medical*, VENTURE CAP. J. (Oct. 16, 2009), https://www.venturecapitaljournal.com/syneron-medical-buying-primaeva-medical/ |

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| 2153 | Primāeva Medical, Inc., K082391 510(k) Summary (Aug. 24, 2009) and letter from Mark N. Melkerson, Department of Health & Human Services, Food & Drug Administration to Brian Grigsby, Primāeva Medical, Inc. (Sept. 1, 2009), https://www.accessdata.fda.gov/cdrh_docs/pdf8/K082391.pdf |
| 2154 | Deposition transcript of Jean Woloszko, M.D., Ph.D., *Jeisys Medical Inc. v. Serendia, LLC*, IPR2024-00383, taken October 24, 2024 |

## I. Introduction

Claims 13 and 14 of U.S. Patent No. 9,775,774 ("'774 Patent") should be found patentable over the grounds raised in Petitioner Jeisys Medical Inc.'s ("Jeisys") petition for *inter partes* review ("IPR") for three reasons.

First, claims 13 and 14 are limited to "extendable needles" and as properly construed, these claims require using a "motor" or "mechanism" to extend needles a programmed distance. This approach provides precise control over the depth of needle insertion into dermatological tissue so that energy can be delivered to those needles to treat that target tissue. On the other hand, Jeisys's primary reference, Mehta is directed to an entirely different approach and does not disclose any way to program the distance the needles extend. Rather than disclose programming the distance that needles extend, Mehta discloses using different cartridge configurations (e.g., different needle lengths or angles), to reach different target depths, and ways to tell whether the extended needles are at the right depth, and for the physician to adjust the depth if appropriate before delivering energy.

Second, because Mehta fails to teach the inventions in claims 13 and 14 of the '774 patent, Jeisys relies on KR20-0441552 to Lee et al. ("Lee") to assert an obviousness combination. But Mehta and Lee are directed to a vastly different methods of treating skin. Mehta delivers energy to the skin via needles after taking the time to confirm that the needles are at the right depth, whereas Lee does not teach

delivering energy but rather focuses on rapidly creating hundreds to tens of thousands of holes in the skin at millisecond speeds. A POSITA would not have been motivated to combine those references to achieve the inventions of claims 13 and 14 of the '774 Patent nor would had a reasonable expectation of success in doing do.

Third, substantial, uncontroverted evidence supports finding that objective indicia of non-obviousness, including commercial success and industry praise, demonstrate the non-obviousness of the '774 Patent. Despite being aware of Patent Owner Serendia's objective indicia evidence since the prior ITC proceedings, Jeisys failed to even attempt to rebut that evidence. Simply put, Jeisys's hindsight obviousness arguments disregard the real-world evidence that the claimed inventions were far from obvious to those skilled in the art.

Serendia respectfully requests that the Board confirm the patentability of claims 13 and 14 of the '774 Patent.

## II. Background

### A. Procedural History And Background Of The IPR Petitions

On August 6, 2021, Patent Owner sued Cartessa Aesthetics, LLC ("Cartessa") in District Court for infringing multiple patents, including the '774 Patent. *See SynKloud Techs., LLC v. Cartessa*, No. 2:21-cv-04423 (E.D.N.Y. Aug. 6, 2021), ECF No. 1. On December 28, 2021, Cartessa petitioned for IPR challenging claims

1-7 and 9-19 of the '774 Patent. *Cartessa v. Serendia, LLC* ("*Serendia*"), IPR2022-00376, Paper 1 (P.T.A.B. Dec. 28, 2021) ("*Cartessa I*"). The single invalidity ground presented relied on U.S. Patent Application Publication Nos. 2002/0120260 to Morris, et al. and 2003/0130711 to Pearson, et al. Ex. 2108 (Morris); Ex. 2109 (Pearson). Patent Owner filed its Patent Owner Preliminary Response ("POPR") on April 18, 2022. *Cartessa I*, IPR2022-00376, Paper 8. On June 27, 2022, the Board denied institution. *Id.*, Paper 9.

### B. The Current And Former Petitioners Fully Litigate The '774 Patent's Validity In The ITC

About nine months after the Board denied the first petition, on March 1, 2023, Patent Owner filed additional District Court complaints alleging infringement of the '774 Patent (and others), against various parties, including Cynosure, LLC ("Cynosure"). The same day, Patent Owner also filed an ITC complaint alleging infringement of the '774 Patent (and others) against the named District Court defendants, as well as Cynosure's Korean supplier: Jeisys, the current Petitioner. *In re Certain Dermatological Treatment Devices and Components Thereof*, No. 337-TA-1356 (U.S.I.T.C. Mar. 1, 2023) ("1356 Investigation").

On November 1-2, November 6-7, and December 11-12, 2023, evidentiary hearings were held in the ITC. On January 8, 2024, after the validity of the '774 Patent was fully litigated in the ITC, including the submission of all post-hearing briefings, Jeisys filed the second IPR petition at issue here, and the Board

subsequently granted institution. EndyMed then filed its own IPR petition against the '774 Patent, along with a motion for joinder. *EndyMed Med. Ltd.* ("*EndyMed*") *v. Serendia*, IPR2024-00843, Papers 1, 2 (P.T.A.B. Aug. 1, 2024).

### C. The '774 Patent (Ex. 1001)

Claims 13 and 14 of the '774 Patent relate to a dermatological treatment to improve the appearance of skin that involves inserting needles into the skin and applying pulsed radiofrequency ("RF") signals to the needles. This dermatological treatment apparatus is described in connection with the embodiment of Figures 9-11. Figure 9A (copied below), shows "a dermatological treatment architecture (DTA) 900" with "a signal generation and control module (SGC) 910, a handle module 920, and an actuator module 930." Ex. 1001, 9:39-43.

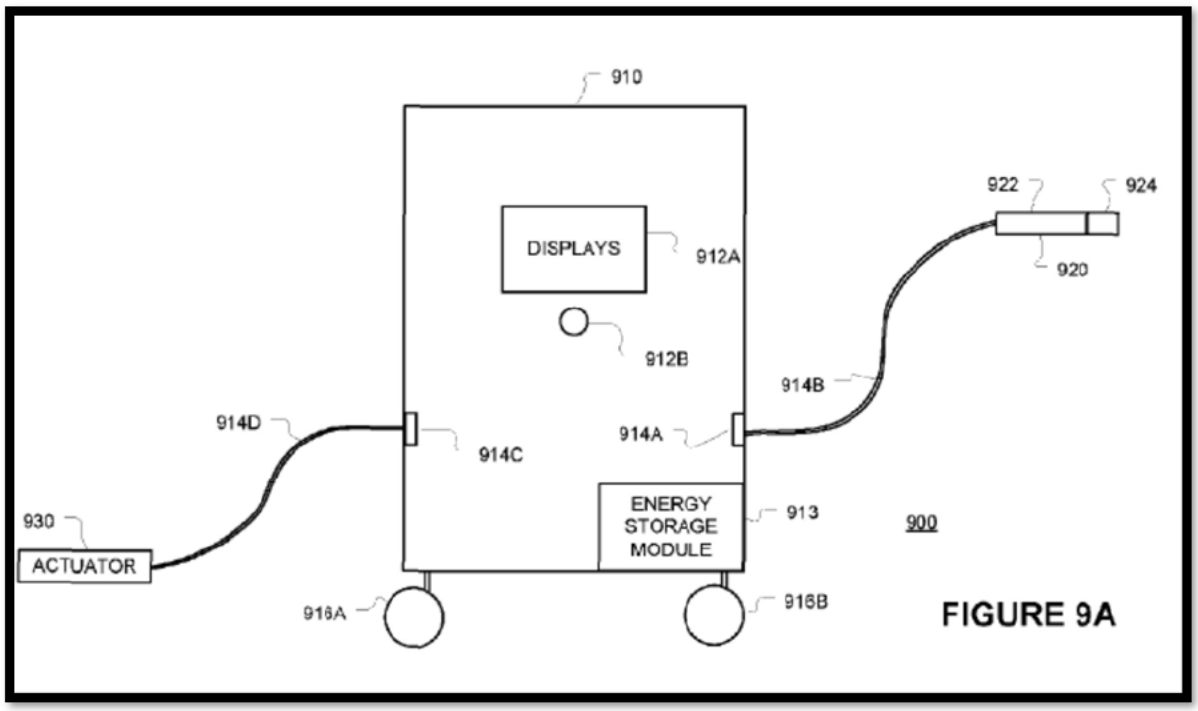



FIGURE 9A

As shown above and in Figures 9C and 9D (copied below), the "handle module 920" may include (1) "a deployable needle module (DNM) 924" (which "may be a detachable cartridge module (DCM)"), and (2) "a motor and LED module (MLM) 922." *Id.*, 9:43-45, 11:5-11. "[A] needle deployment motor controller (NDMC) module 911B" (shown above), "may control the deployment of one or more needles 924A" of the deployable needle module 924 "based one or more user selected operational parameters," one of which is "the depth" of needle insertion. *Id.*, 10:20-23, 10:31-36; *see also id.*, 9:64-10:4 ("a user may configure one or more operational parameters," which include "needle deployment timing and depth(s)"). Thus, "a desired depth of needle 924A penetration within tissue" is achieved "based on the operational parameters" selected by the user. *Id.*, 14:14-20, 14:28-34.

Extension of the needles to a particular depth based on the user's selection is performed by the MLM 922, which "may include one or more motors 922A, longitudinally extendable drive arms 922B, drive shaft 922C, outer casing 922D, [and] signal interface 922E" that receive "control signals and energy to operate [the] one or more motors 922A." *Id.*, 11:14-23. The drive shaft 922C may be moved "to deploy and retract one or more needles 924A" such that "the motor(s) 922A may enable precise needle extension (effective depth) control." *Id.*, 11:23-26, 14:3-4, 14:24-26. Figure 9C (below) shows the "needles 924A retracted," and Figure 9D (also below) shows the "needles 924A deployed." *Id.*, 10:65-11:4.

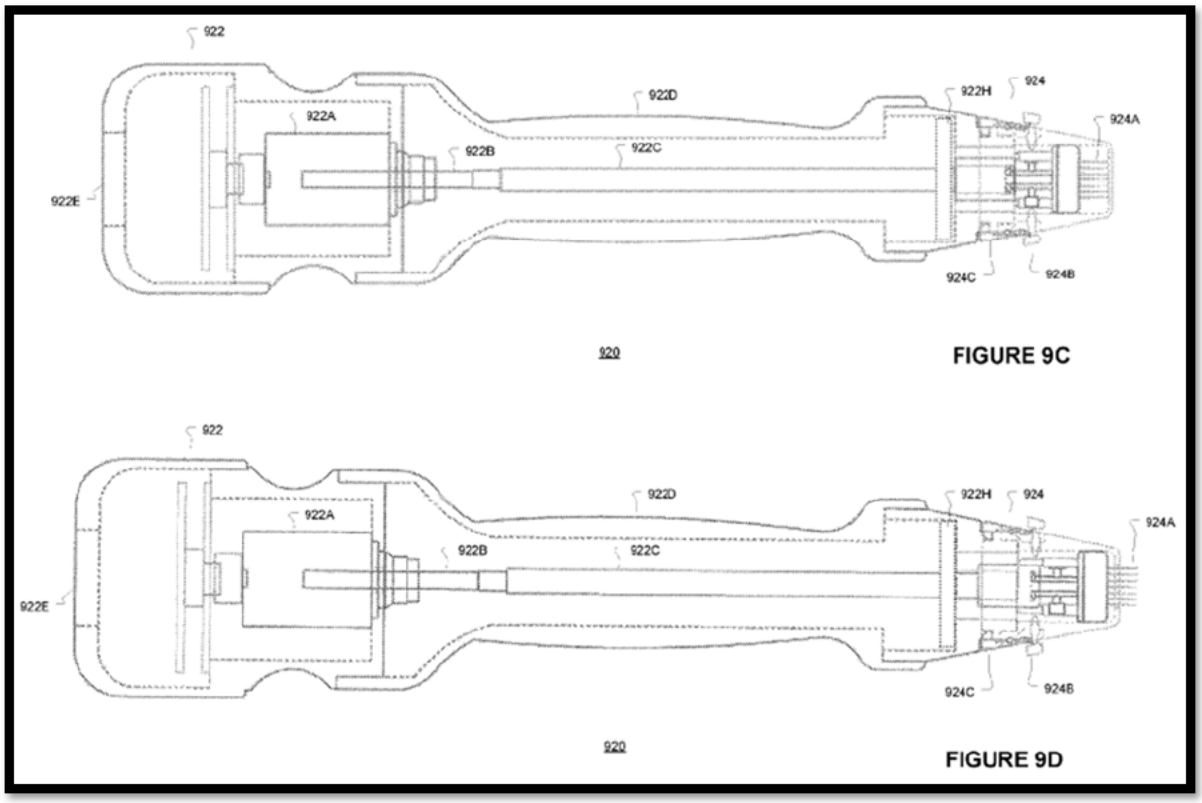



Figure 12 (copied below, annotated), is a flow diagram of algorithms for the system architecture (DTA 900) which shows that a step 934C, 936C in the treatment involves selecting needle deployment depth. *Id.*, 13:45-46, 13:63-66, 14:21-24. Thus, the distance the needles extend is determined based on a user-selected depth 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, 10:20-24, 10:31-36, 11:23-27, 14:3-4, 14:24-26; Ex. 2147 ¶47.

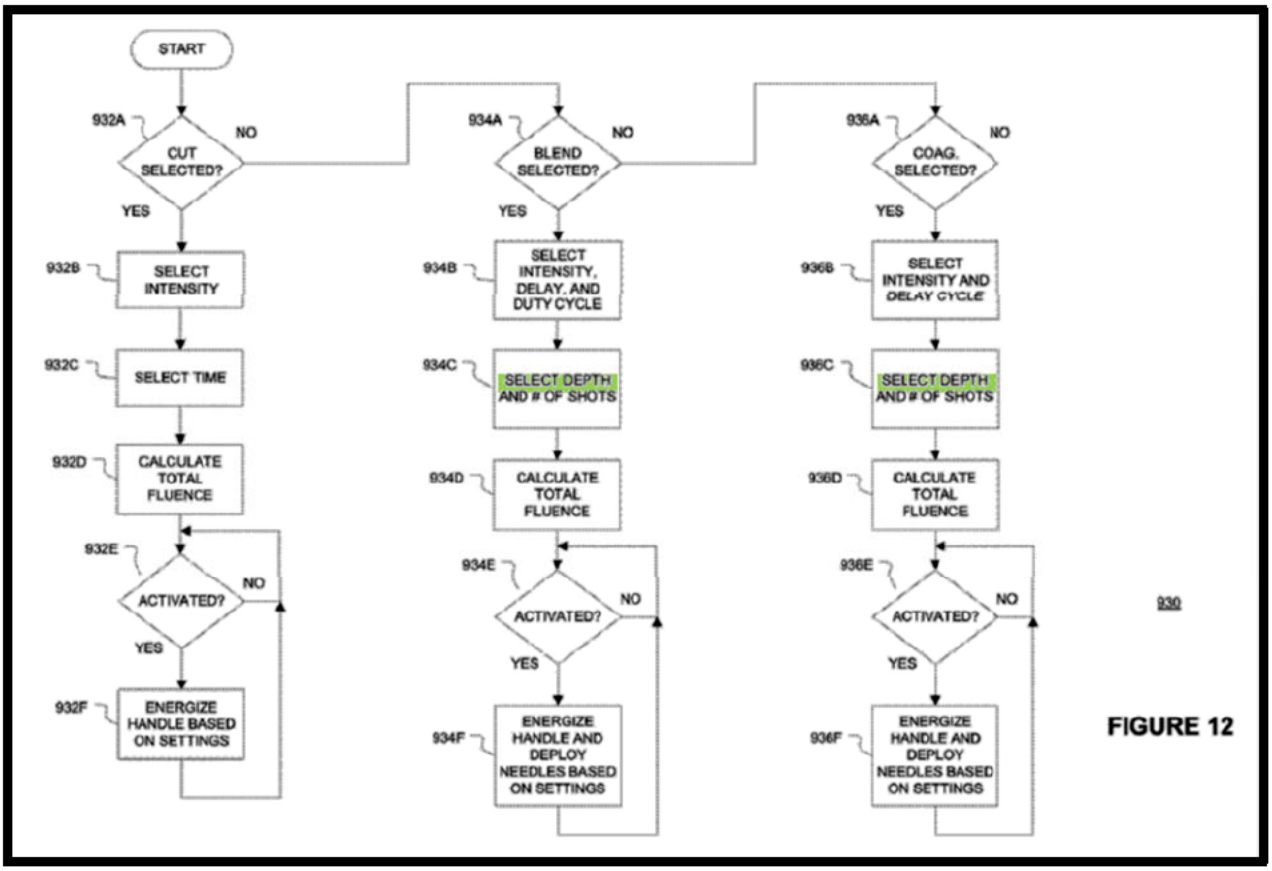
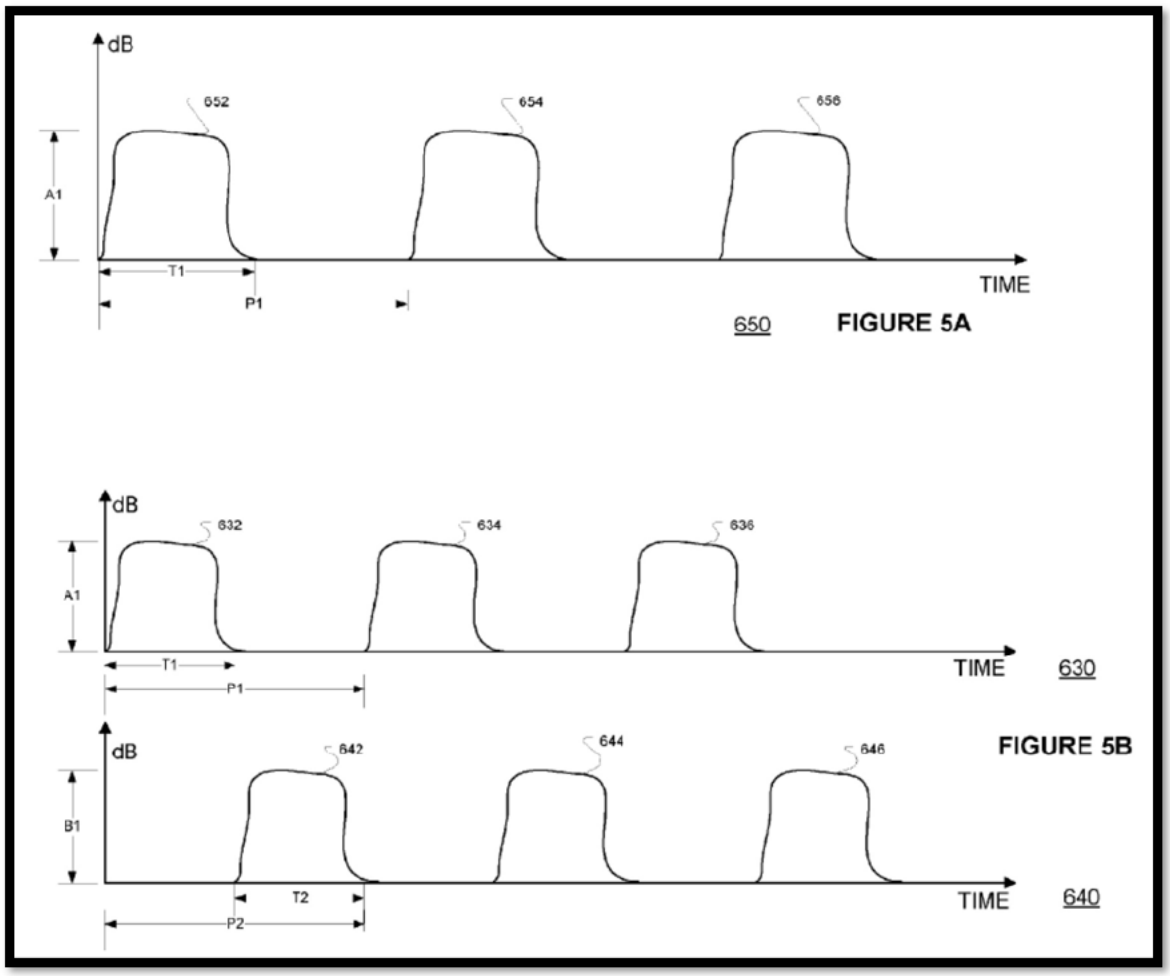
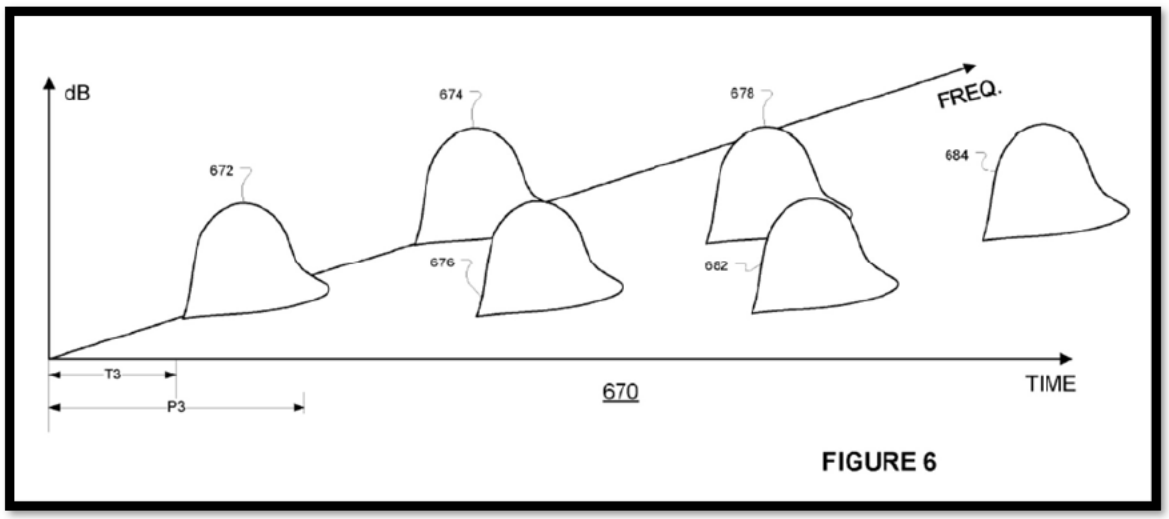



FIGURE 12

The '774 Patent describes providing pulsed RF signals to the needles when they are extended to affect the dermatological tissue near the needles. Along with the "needle deployment motor controller (NDMC) module 911B," "CPU module 911" also "may include a radio frequency (RF) signal generator module (RFSG) 911A." Ex. 1001, 10:20-24. "[T]he RFSG 911A may apply signals 650, 630, 640, 670 shown in FIGS. 5A, 5B, and 6" (copied below). *Id.*, 10:48-50. As shown below, the signal waveforms 650, 630, 640, and 670 include pulses. *Id.*, 6:13-7:10.


dB
652
654
656
A1
T1
P1
TIME
650
FIGURE 5A
dB
632
634
636
A1
T1
P1
TIME
630
dB
642
644
646
B1
T2
P2
TIME
640
FIGURE 5B


dB
674
678
FREQ.
672
684
676
662
T3
P3
670
TIME
FIGURE 6

### D. Prosecution History

The application for the '774 Patent was filed on April 12, 2016, as a continuation of the application for the '536 Patent, which Jeisys has also challenged, and claims priority to U.S. Provisional Application No. 61/449,080, filed on March 3, 2011. Ex. 1001, 1, 32. Serendia agrees that the proper priority date is March 3, 2011. The '812 Patent, which Petitioner has also challenged, is a continuation of the '774 Patent.

All the original claims of the '774 patent were cancelled, and new claims were added with the transmittal of the application. Ex. 1002, 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).

### E. Person of Ordinary Skill in the Art

For purposes of this response, Serendia accepts Petitioner's definition of a person of ordinary skill in the art ("POSITA"). Pet. 14-15.

## III. Serendia's Sylfirm X Patented Product Versus the Prior Art

The Sylfirm X, the product licensed under the '774 Patent, practices claims 13 and 14 at issue. Ex. 2147 ¶¶124-153. During the ITC investigation, Serendia relied on the Sylfirm X to establish a domestic industry, which is a requirement of a Section 337 investigation under which a complainant like Serendia must show it

made significant investments in the United States pertaining to articles protected by the asserted patents. 19 U.S.C. §1337(a). Jeisys presented no contrary evidence.

The Sylfirm X, like the embodiments of claims 13 and 14 of the '774 patent, includes a handpiece with a removable needle assembly with extendable needles. And as shown in the Sylfirm X photos below (Ex. 2130-002 and Ex. 2086-010), the needles extend and retract just as in the invention of the claimed embodiments of the '774 Patent copied below (Ex. 1001, Figs. 9C, 9D). Ex. 2147 ¶54.

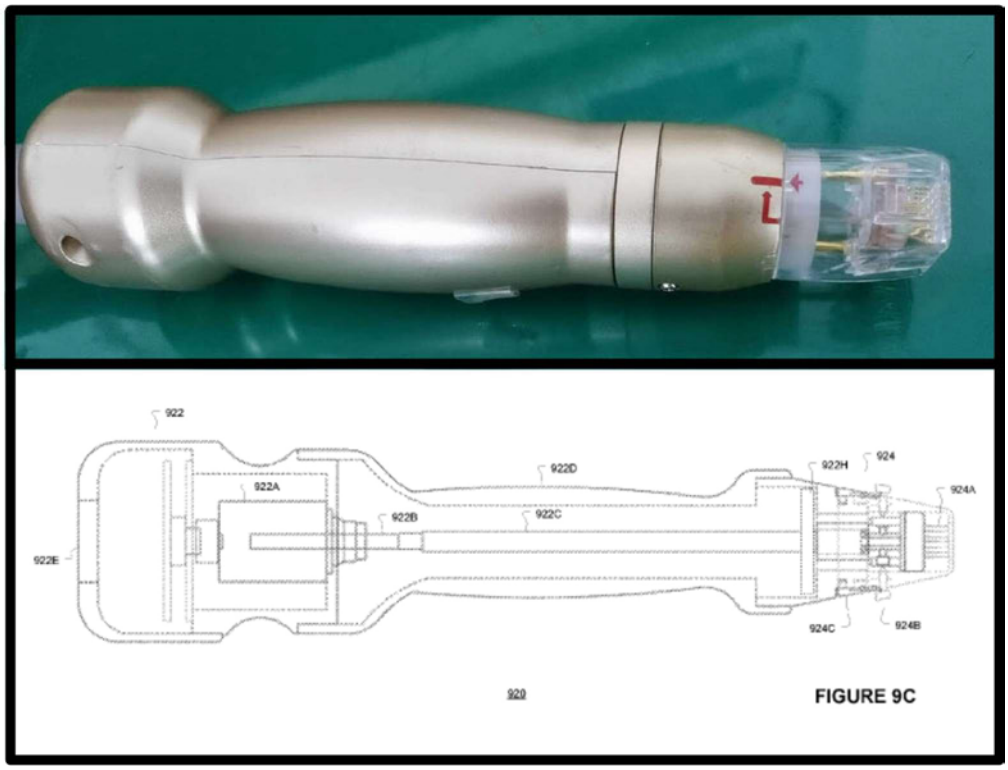



FIGURE 9C

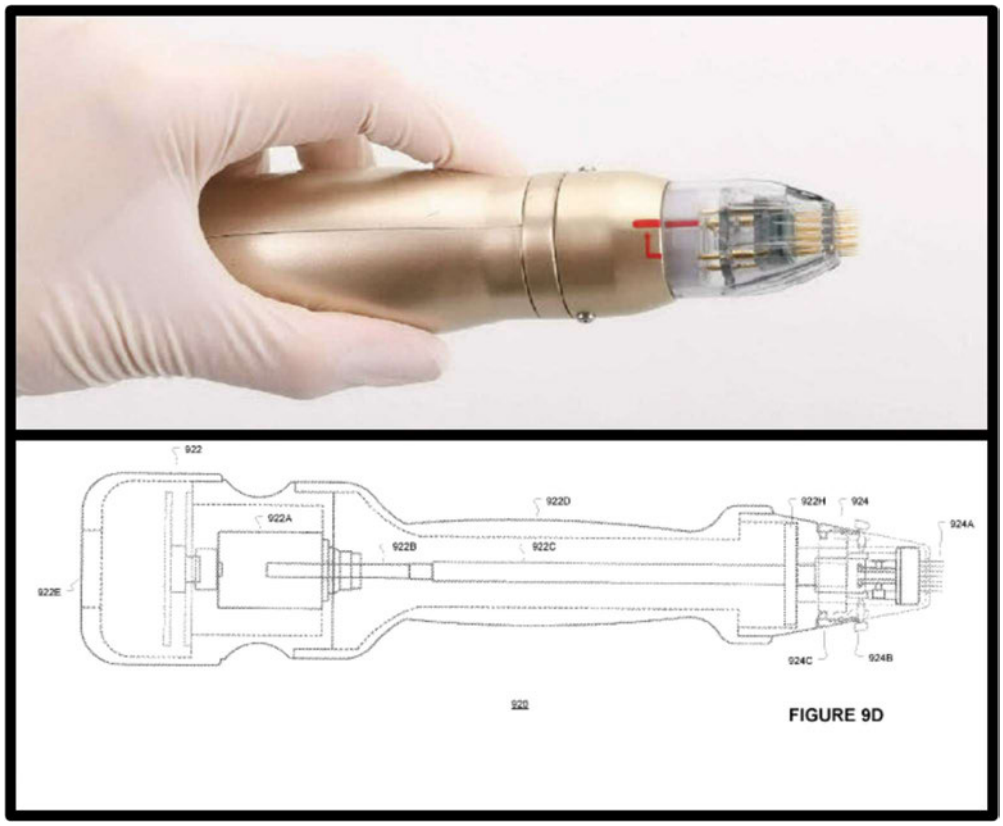


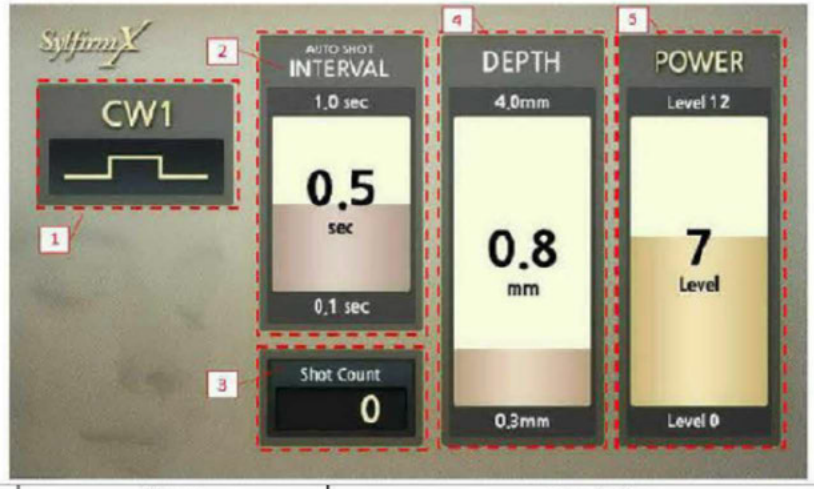

FIGURE 9D

Just as in the '774 Patent, how far the needles extend in the Sylfirm X is also based on user selection of a depth setting, which as shown below is included in the graphical user interface of the device. Ex. 2083-016; Ex. 2147 ¶55.

SylfirmX USER MANUAL

**3.3 User Interface (UI)**

i. Operation UI– Upper screen




| No. | Name | Description |
|---|---|---|
| 1 | Current operation mode display | The mode being operated |
| 2 | Auto Shot Interval display | Display of interval time between motor movements in Auto Shot (**0.1 ~ 1.0 sec**) |
| 3 | Shot Count display | Display total number of shot count |
| 4 | Depth display | Display microneedle penetration depth (**0.3 ~ 4.0 mm**) |
| 5 | Power display | Display RF output power level (**Level 0 ~ Level 12**)<br>- Level 0: No RF output<br>- Level 1 ~ 12: As the level increases, the output increases. |

In stark contrast, products like those in the prior art, do not include such depth settings and programming. The commercial product for the Mehta patent, is one such example. For background, Bankim Mehta, one of the named inventors of the Mehta

patent that Jeisys relies on, was the CEO of Primaeva Medical, Inc. prior to being acquired by Syneron Medical, Ltd. Ex. 2152; Ex. 2153, 1. Primaeva Medical developed the Miratone system, which is now marketed as Profound by Candela Medical (who acquired Syneron). Ex. 1003 (Berube Decl.) ¶¶9, 29.

In the ITC investigation, Jeisys at first relied on the Miratone system as prior art. Ex. 2053. One the materials Jeisys cited is the Miratone user manual, which identifies the treatment parameters to be set in the GUI. They are ***power***, ***energy***, ***temperature***, ***duty cycle***, and ***treatment time.*** Ex. 2150, 15 ("The treatment is controlled by maintaining the electrodes at a set temperature during the treatment. This requires the Power, Energy, Temperature (Temp), Duty Cycle, and Treatment Time (Time) parameters be set on the GUI."); *see also id*. 19, 20. The Miratone system included no depth setting. This aligns with a product brochure for the Miratone system (Ex. 2149, 2) reproduced on the left below, which shows the graphical user interface shown in Mehta (Ex. 1004, Fig. 10E) on the right below, in which again there is no input for the user to select the depth for needle deployment. Ex. 2147 ¶¶57-64.

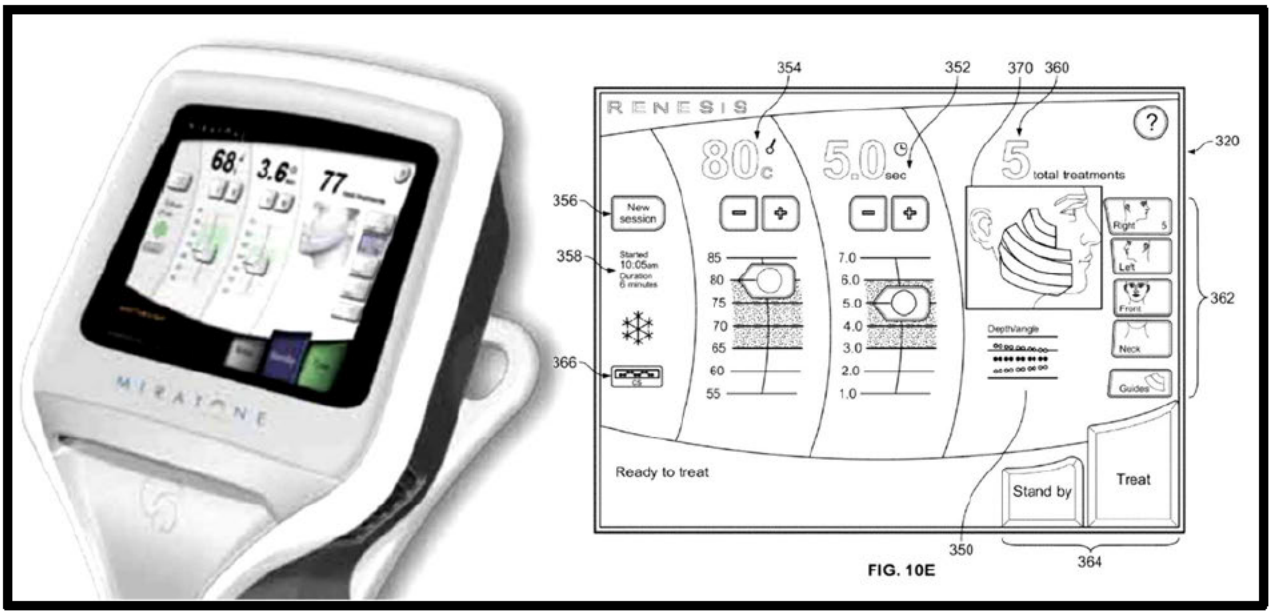
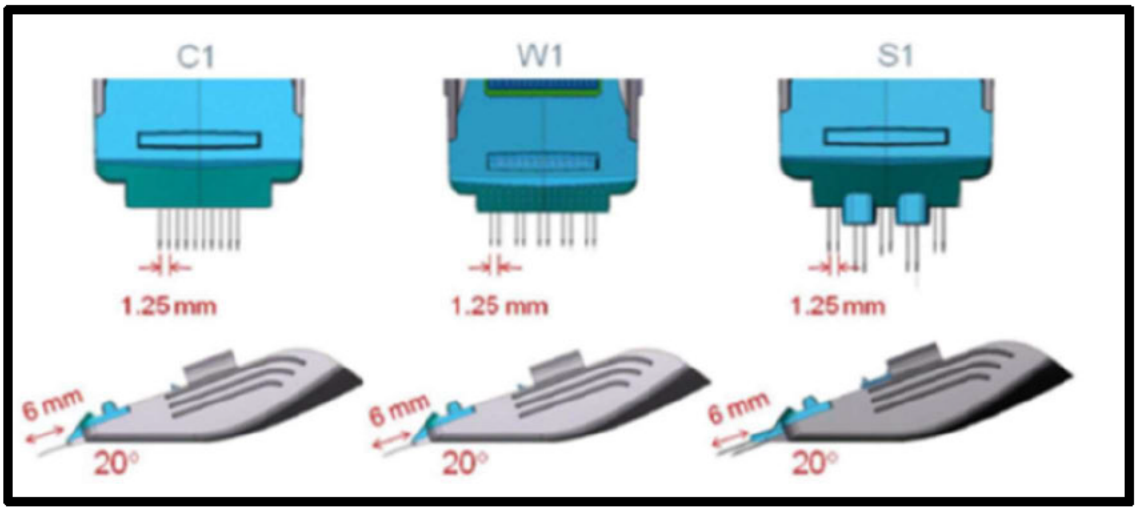
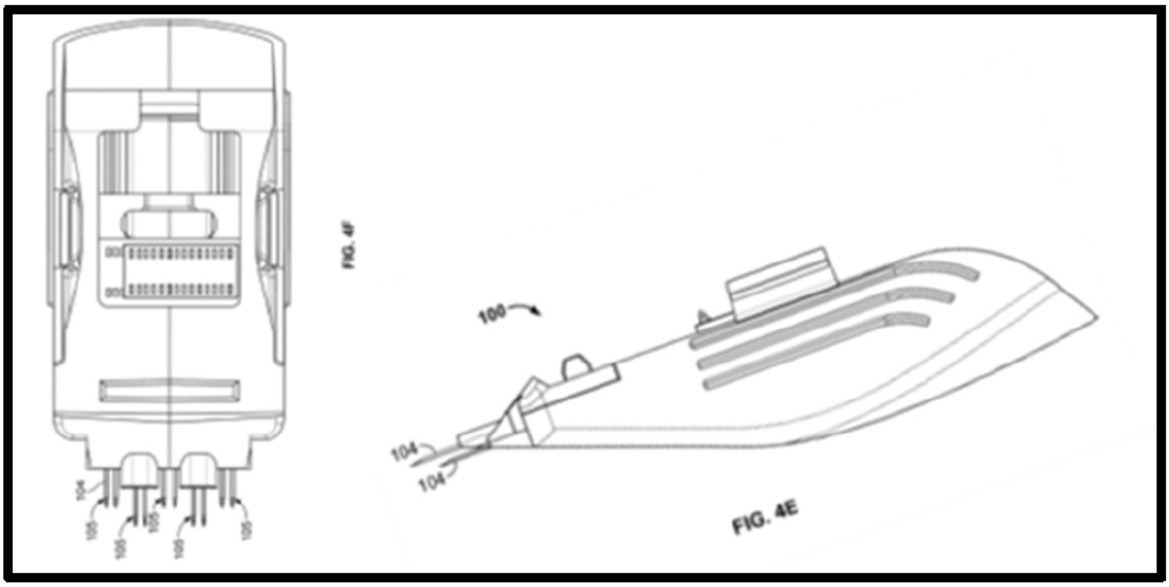



FIG. 10E

Jeisys also relied on the Miratone Instructions for Use, which illustrates cartridges for the system that are identical to those disclosed in Mehta. *Compare* Ex. 2151, 14 (illustrated below), *with* Ex. 1004, Figs. 4F, 4E (copied below).






The Miratone Instructions for Use further explain that "Each electrode of a pair ***is designed to penetrate 6 mm*** within the skin at an angle of 20° to the surface of the skin" (Ex. 2151, 14), further evidencing that the Miratone system included fixed non-adjustable needles of a particular length, rather than extendable needles as claimed in the '774 Patent.[1] This is an important distinction because "the scope of the claims at issue here differs from what was known in the prior art." Ex. 2147 ¶66.

## IV. Claim Construction

Neither Mehta alone nor in combination with Lee discloses the subject matter of the claims at issue—claims 13 and 14—under any reasonable construction,

[1] All emphases added unless otherwise noted.

including their plain and ordinary meaning.[2] Serendia addresses claim constructions relevant to those claims below.

### A. Causing / To Cause "the plurality of the extendable needles to extend a desired distance from the end surface" (claims 13 and 14)

The main dispute over this term is whether claims 13 and 14 are limited in scope to "extendable" needles, such that the construction of the "desired distance" limitation should reflect this claim scope. The answer is yes. By their plain language, claims 13 and 14 are limited to "extendable" needles. Jeisys ignores that important fact when contending that "[t]he term 'desired distance' has the same meaning in all claims, which is simply that needles extending or extendable a desired distance are distinguished from those that extend an undesired distance." Reply to POPR 7. But even its expert agrees that claims 13 and 14 are limited to extendable needles. Ex. 2154, 182:16-183:5.

Claims 13 and 14 (the only claims at issue) depend on claims 12 and 11, where claim 11 is the independent claim. Claim 11 recites "a device including a plurality of needles one of extending or extendable a desired distance from a surface," but dependent claims 12, 13, and 14 are narrower, requiring "***extendable***" needles.

[2] Serendia reserves the right to advance claim constructions as appropriate in other proceedings.

Ex. 1001, cls. 11-14. Specifically, claim 12 recites the apparatus 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." *Id*., cl. 12. And claims 13 and 14, which depend from claim 12, further recite the same "extendable" needles limitation. *Id*., 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").

Thus, by their plain language, claims 13 and 14 exclude embodiments disclosed in the specification with "extending" needles. The parties' agreed construction at the ITC for extending and extendable needles is instructive about which embodiments relate to which type of needles. At the ITC, the parties agreed that:

> needles one of extending or extendable: needles that are either extended or can be extended [from the device surface] (needles "extending" a desired distance from the surface covers non-extendable needles having a fixed length; "extendable" needles covers needles which are not fixed)[.]

Ex. 1007, 16. As Jeisys's expert agrees, "extending needles" "cover needles that are fixed and non-extendable relative to the surface as depicted, for example, in Figs.

2A–2D of the '774 patent" and "extendable needles" cover those embodiments "depicted, for example, in FIGS. 9C-9D and 10D-10E of the '774 patent." Ex. 1003 ¶51. Thus, because claims 13 and 14 do not claim extending needles, the embodiments that have extending needles, e.g., Figures 2A-2D, fall outside the scope of those claims. This is consistent with Federal Circuit law explaining that "the claims need not be construed to encompass all disclosed embodiments when the claim language is clearly limited to one or more embodiments." *TIP Sys., LLC v. Phillips & Brooks/Gladwin, Inc*., 529 F.3d 1364, 1375 (Fed. Cir. 2008) (affirming district court's claim construction which excluded certain embodiments described in the specification but not claimed). Here, because language of claims 13 and 14 makes clear that they do not include "extending" needles, "to construe the claim term to encompass [that] alternative embodiment in this case would contradict the language of the claims." *Id.* at 1373.

The remaining question is the proper construction of causing / to cause "the plurality of the extendable needles to extend a desired distance from the end surface" of claims 13 and 14. Serendia proposes the claimed "desired distance" means how far the needles extend from the device's end surface, based on a user's selection, to penetrate the dermatological tissue. Serendia's proposal is consistent with dependent claim 13 and 14's narrower scope and with the part of Jeisys's proposed construction that applies to claims 13 and 14.

According to Jeisys, the "desired distance" limitation can be met in three ways: "(1) selecting a cartridge with needles of a particular length; (2) using a motor to extend the needles to a programmed distance; and (3) adjusting the needle depth by manually checking the needle location." Reply to POPR 7. As explained below, the only part of this construction that applies to claims 13 and 14 is "(2) using a motor to extend the needles to a programmed distance." *Id.*

The first alternative, "selecting a cartridge with needles of a particular length" relates to "extending"—not "extendable"—needles, as Jeisys admits. Reply to POPR 7-8 (referring to "using by non-adjustable needles of 'a particular needle length'"); Ex. 1007, 16 ("needles 'extending' a desired distance from a surface cover needles that are fixed and non-extendable"). Jeisys's expert also agrees, opining that, in the context of "extending" needles "a POSA would understand the plain meaning of 'a desired distance' encompasses such a fixed, predetermined distance." Ex. 1003 ¶54. Thus, Jeisys's first alternative falls outside the scope of claims 13 and 14, which require "***extendable***" needles, rather than "***non-adjustable***" needles.

Jeisys's contention that "user selection of a cartridge having needle lengths corresponding to a desired distance" meets the claims (Reply to POPR 8), renders the "desired distance" limitation superfluous or makes infringement depend on the mental state of the user, either of which is erroneous. If Jeisys contends that user selection of *any* cartridge having *any* needle length meets the claim, then the "desired

distance" limitation is superfluous because simply using needles of any length would meet the claim. Thus, removing "a desired distance" from the claim would make no difference—the claim would have the same scope. But "[i]t is highly disfavored to construe terms in a way that renders them void, meaningless, or superfluous." *Intel Corp. v. Qualcomm Inc.*, 21 F.4th 801, 809-10 (Fed. Cir. 2021) (vacating and remanding to the Board to reconsider claim construction).

If on the other hand Jeisys contends that whether the "desired distance" limitation is met depends on whether the user selects a cartridge having a needle length matching the user's desire, then Jeisys is improperly making claim scope depend on a user's mental state. There is ***nothing*** in the intrinsic record to support making the claims depend on mental state. The specification never addresses the mental state of a user. Instead, the specification makes clear that whether a distance is "desired" is reflected by user ***action***—selection of the "desired extension"/"desired depth" as reflected in step 934C, 936C in Figure 12 (copied above and below). Ex. 1001, Fig. 12, 13:45-55, 13:63-66, 14:21-24.

Claims 13 and 14 also exclude the third alternative because they require "a mechanism" or "a motor" that "cause[s] the plurality of extendable needles to extend a desired distance," thus excluding "adjusting the needle depth by ***manually*** checking the needle location." Reply to POPR 7. Jeisys argues that "***user*** adjustment of the needle distance ***after*** an initial extension" is permitted (*id.* 8), but this is

expressly excluded from claims 13 and 14 because they require using a "***mechanism***" or "***motor***" to cause the "extendable needles to ***extend*** a desired distance" (Ex. 1001, cls. 13, 14).

Even according to Jeisys, that leaves one way to meet the desired "distance" limitation in claims 13 and 14: "using a motor to extend the needles to a programmed distance." Reply to POPR 7. That is consistent with Jeisys's expert admission that a motor extending needles a predetermined distance would satisfy the claims "***[a]s long as you can program this distance***" (Ex. 2125, 1151:8-12) and his opinion that in the context of "extendable" needles, "a POSA would understand the plain meaning of 'a desired distance' to also encompass any user-selected and/or repeatedly implemented needle deployment distance." Ex. 1003 ¶54.

In other words, as to claims 13 and 14, both Jeisys and Serendia (and their experts) agree that the claims require that the needles extend "to a programmed distance" using, according to the claims' plain language, a mechanism/motor. Ex. 2147 ¶77; Ex. 2154, 187:12-188:9. This construction is consistent with the intrinsic evidence, as explained below.

In describing the claimed embodiments, the specification discloses a system programmed to provide therapy based on user selection of operational parameters. Ex. 1001, 10:60-64. One of those parameters is needle deployment depth. *Id*., 9:64-10:4. For example, the specification describes and illustrates a block diagram for the

system architecture at Figure 9A, which includes a display and user input device. *Id.*, 9:52-53. The display "may be touch sensitive so a user may configure one or more operational parameters" (*id.*, 9:64-66), or the input device may be a keypad, track ball, or other similar input device that allows the user to operate the system. *Id.*, 9:1-3.

The '774 patent also describes a central processing unit (CPU) employing an algorithm (shown in Figure 12 reproduced below, annotated) to control the system architecture, where one of the parameters inputted into the algorithm is the "selected depth" for the needles to extend.

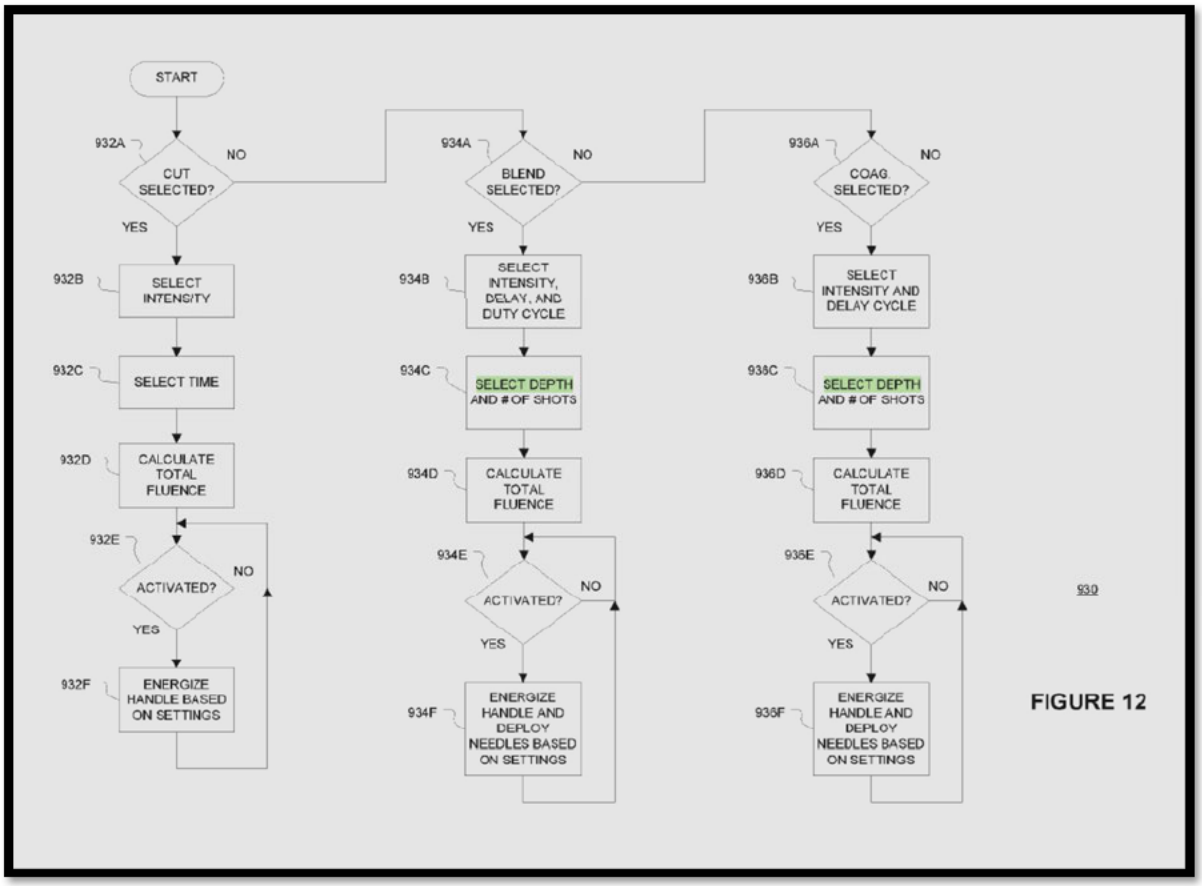



FIGURE 12

Ex. 1001, Fig. 12.

In addition, the specification describes a needle deployment motor controller (NDMC) module 911B that "may control the deployment of one or more needles 924A … based on one or more user selected operational parameters[,]" including "the depth" for "the needle(s) 924A deployment." *Id.*, 10:31-36; *see also id.*, 10:60-64, 13:63-66, 14:3-6, 14:12-34.

Thus, 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 programming of this distance through user selection of the depth of needle insertion.

The prosecution history of the parent of the '536 Patent, the parent of the '774 Patent, reinforces this construction by "provid[ing] evidence" that this is "how the PTO … understood the patent." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005). During the prosecution of the '536 Patent, the Examiner relied on U.S. Patent No. 6,890,319 to Crocker ("Crocker") to assert that it disclosed "[a] motor [] energized to extend the needles a desired distance." Ex. 2114 ('536 Patent File History), 278. The portion of Crocker on which the Examiner relied 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 (Crocker), 10:11-20. The Examiner's reliance on this passage shows 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). *Alloc, Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361, 1371-72 (Fed. Cir. 2003) (relying on the prosecution history of a parent application to determine the scope of limitations present in subsequent related applications).

Thus, consistent with the intrinsic evidence, the "desired distance" of claims 13 and 14 is how far extendable needles extend from the device's end surface using a motor/mechanism based on a user programming this distance.

**B. "pulsed radio frequency signals" (claims 13 and 14)**

Claim 11, on which claims 13 and 14 depend, recites "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." Ex. 1001, cl. 11. At the ITC, "pulsed radio frequency signals" was construed in the ITC to have "its plain and ordinary meaning" specifically "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, 36. Neither party proposes a different construction here. Therefore, Serendia respectfully submits that the ITC construction should govern.

### C. "a mechanism for causing the plurality of the extendable needles to extend a desired distance from the end surface" (claim 13)

Claim 13 recites "a mechanism for causing the plurality of the extendable needles to extend a desired distance from the end surface." In the ITC, the parties agreed the claims is a means-plus-function limitation where the recited function is "causing the plurality of extendable needles to extend a desired distance from the end surface" Ex. 1007, 4-5. Thus, how the Board construes the term "desired distance" for claims at issue in this IPR is relevant to the function claimed in claim 13. As to the corresponding structure, Jeisys agrees that whether the Board adopts Serendia's or Jeisys's proposal is not relevant to the validity issues to be decided. Pet. 18.

## V. Overview of the Prior Art Upon Which Petitioners Rely

### A. Mehta

Mehta is a U.S. patent filed in 2009 and issued in 2013. Ex. 1004. 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.*, 9:34-41, Figs. 2A, 2D (reproduced below). In Mehta, "system 200 also includes an energy supply unit 90 coupled to the treatment unit 202 via a cable 96 or other means," and "[i]n one variation, the energy supply unit 90 may be a RF energy unit." *Id.*, 10:53-57, 11:14-15.

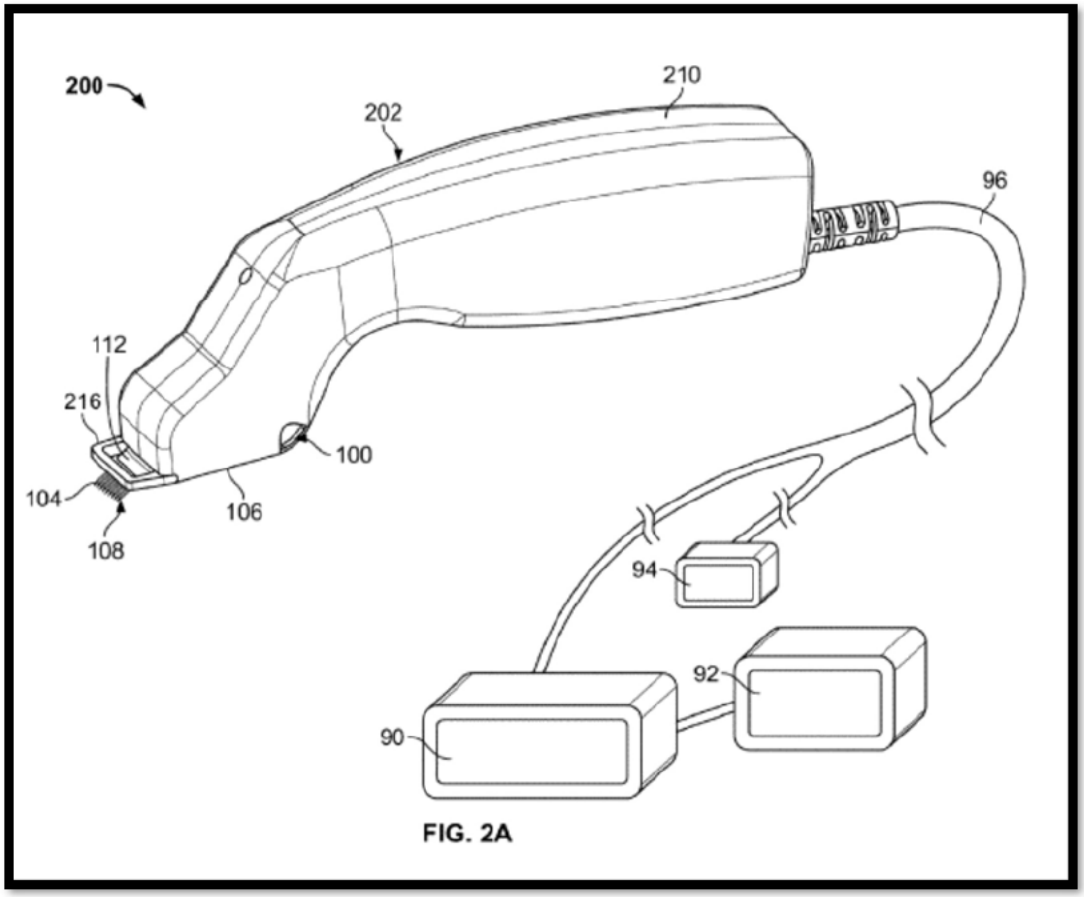


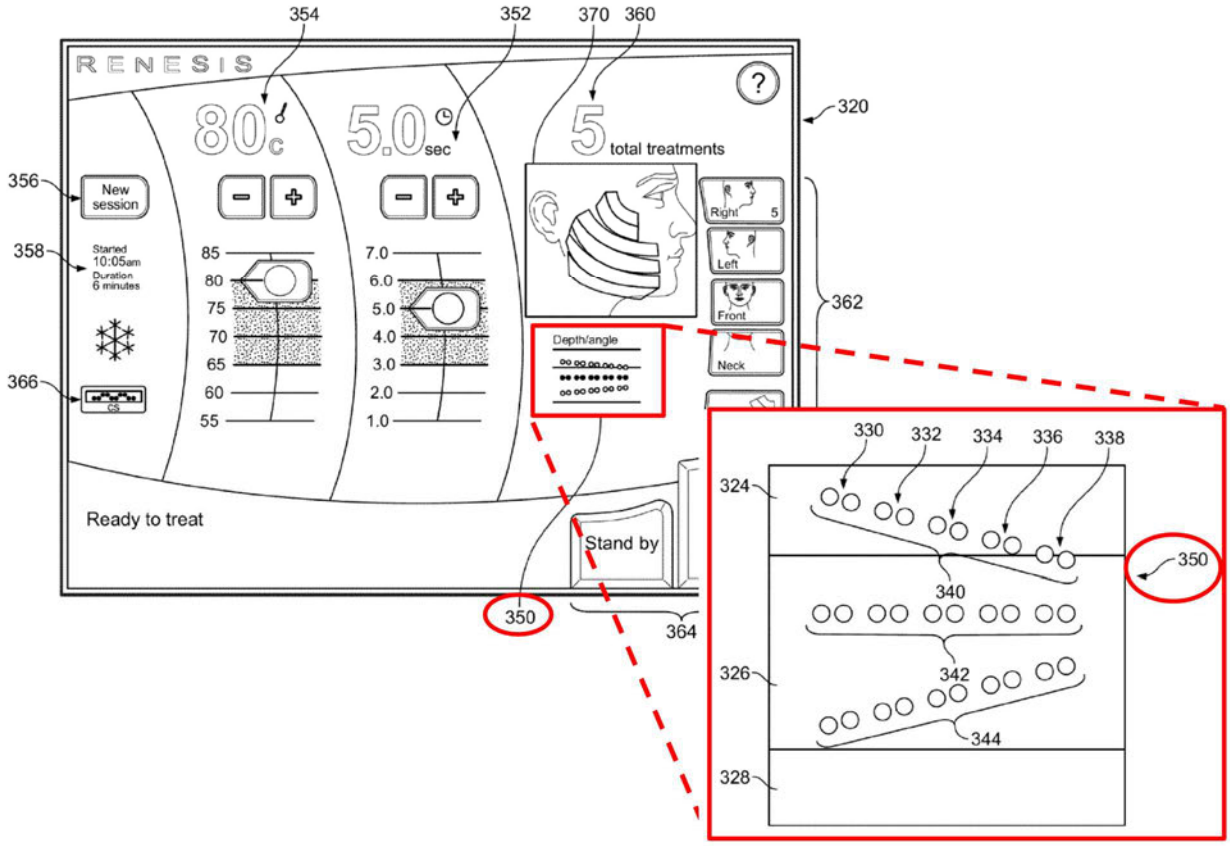

FIG. 2A

The "tissue engagement surface 106 provides a consistent starting point for the probes" 104 so that, "as the probes 104 advance from the device 202 they are driven to a uniform depth in the tissue" when they "enter the tissue at an oblique angle A as measured relative to the tissue engagement surface 106." Ex. 1004, 21:6-13; *see also id.*, Fig. 7A. By providing this "consistent starting point," the "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," rather than having "undesirable outcomes" where probes 104 "may be advanced too far or may not be

advanced far enough such that they would partially extend out of the skin." *Id.*, 21:6-16.

Mehta discloses several ways to confirm whether the probes are located at the correct target tissue before delivering energy to prevent delivering energy to an unintended location. *Id.*, 15:62-16:8. For example, Mehta discloses that the probes can include depth markings or lumens that "enable a physician to observe proper placement" to ensure "the probe is not driven too far into tissue." *Id*., 13:37-45; 23:36-39. But those markings only provide information to the physician about whether the already inserted probes are in the correct target tissue. Mehta also discloses measuring tissue parameters to "***confirm*** whether the probe 108 ***is located in the desired target region."*** *Id*., 24:37-39. Thus, Mehta discloses inserting the already extended probes and then using information to confirm whether they reached the target tissue before delivering energy. *Id*., 24:58-60 ("By measurement of the impedance adjacent to the sensor or active region 122 the ***positioning depth of the probe 108 can be confirmed*** or determined and treatment can be applied to the targeted tissue 8.") (emphasis added).

Mehta also discloses a GUI that can display a virtual depiction of the depth or location of the probes as shown in Figure 10E and in a close-up view in Figure 10B (both copied and annotated below). *Id.*, 32:63-33:64.




Mehta explains that the "virtual depth/location depiction 350 can illustrate the ***actual*** placement of the probe array 340" or "show a desired probe location" (Ex. 1004, 32:55-33:1), to allow the physician to identify "whether the array is located within the desired tissue layer." *Id.*, 33:15-18. If the probes are not in the correct location, the "the physician would be informed that further advancement of the probes is necessary." *Id.*, 33:24-25.

As for advancement into the tissue, Mehta discloses "[u]se of the spring force or impact mechanism to drive the probes may overcome the initial resistance in puncturing the tissue" and explains that "[t]he next action would then be an

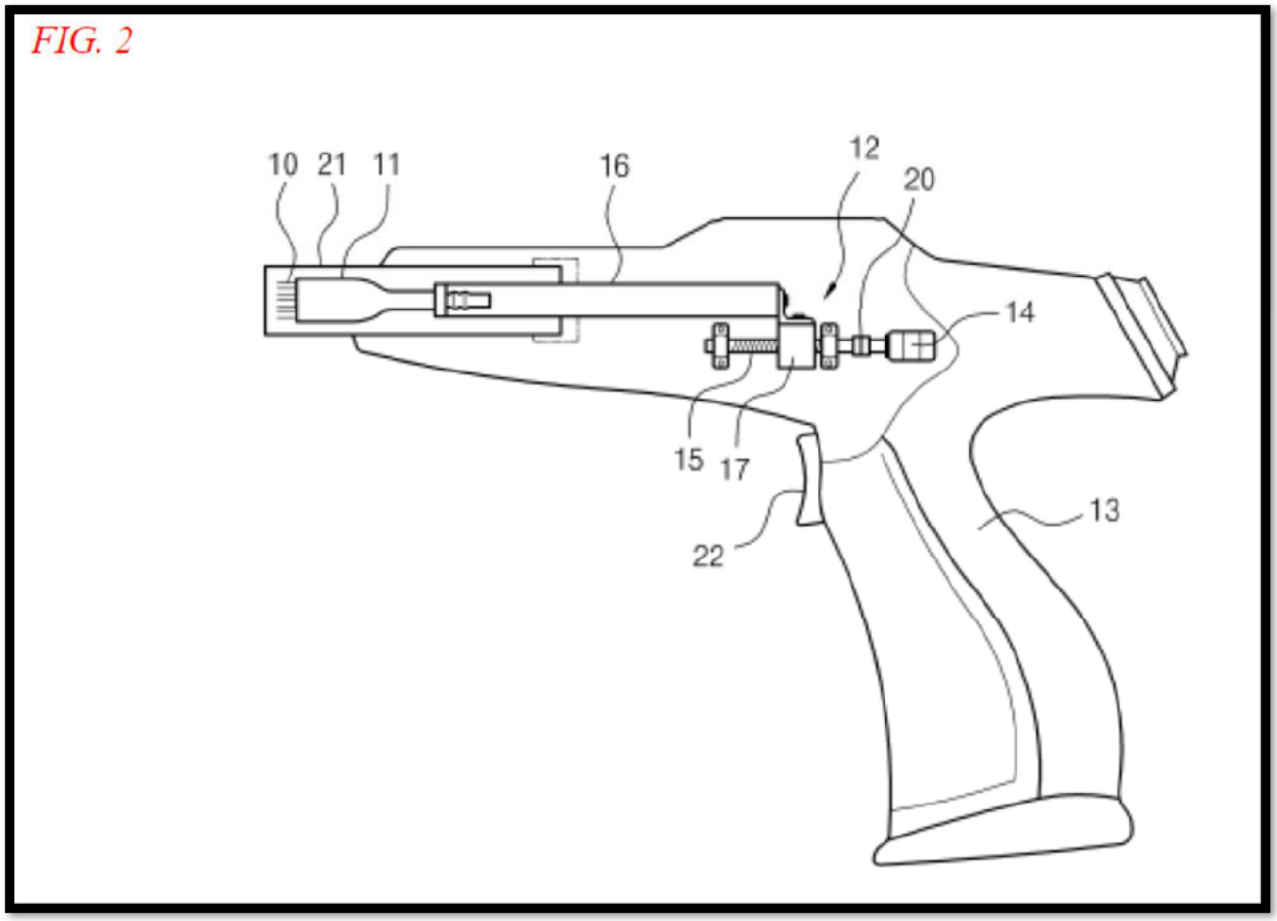
advancement of the probes so that they reach their intended target site." *Id*., 21:55-59. Mehta also discloses actuators to drive the probes, which can be "pneumatic cylinders, springs, linear actuators, or other such motors." *Id*., 10:37-39. It also explains that "[t]he mode of movement of the actuator can include those modes that are used in such similar applications. Examples of these modes include, sliding, rotation, incremental indexing (via a ratchet-type system), stepping (via an step-motor)." *Id*., 15:36-39.

Nowhere does Mehta disclose any programming so that probes advance a desired distance based on user selection or input. In fact, the only programming Mehta discloses is for applying voltage between the electrodes. For example, Mehta explains that "the system monitors the initial impedance of the tissue and uses an algorithm including a PID (Proportional, Integral, Derivative) control which controls the input voltage between a pair of electrode" and then provides exemplary algorithms to control the energy applied to the probes. *Id*., 25:63-66, 28:4-24. Nowhere is depth mentioned as a treatment parameter programmed by the user.

**B. Lee**

Lee is a Korean patent publication that published on August 25, 2008. Ex. 1011. 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."

*Id.*, Abstract. Lee teaches a "gun equipped with a plurality of microneedles[.]" as illustrated n Figure 2 below. *Id.*




The invention of Lee seeks to create "hundreds to tens of thousands of tiny holes … to regenerate tissue" "without removing or damaging the epidermis of the skin[]" and explains that medication applied to the area where the holes are created allows "the drugs to quickly permeate the skin through the tiny holes, thereby maximizing the efficacy of treatment." *Id.* ¶¶15-16. Lee's device "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 multiple

times by repetitively driving the motor back and forth, allowing creation of hundreds to tens of thousands of holes on the human skin[]" using Lee's gun-shaped device. *Id.* ¶63. Lee's gun performs this process "at a speed of about 66-420 times per minute." *Id.* ¶58.

## VI. Ground I: Petitioner failed to demonstrate that Mehta Anticipates Claims 13 Or 14 Of The '774 Patent

Mehta does not disclose a motor or mechanism for causing/to cause "the plurality of the extendable needles to extend a desired distance from the end surface," as claims 13 and 14 require.

As discussed above, under the claim construction proposed by both Jeisys and Serendia applicable to these claims, the claims require using a mechanism/motor to extend the needles to a programmed distance. *See supra* Section IV.A. Unlike the '774 patent, Mehta never discloses any kind of programming to determine how far the needles extend from the device's end surface. In fact, Jeisys does not even contend that Mehta discloses programming the distance that needles extend using a mechanism/motor. Pet. 21-29 (claim 1[a]), 34-35 (claims 3 and 4), 43 (referring to claims 3 and 4). Therefore, as a matter of law, Mehta cannot anticipate the claims as properly construed.[3] *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295

[3] The prosecution of the '812 Patent, which is a continuation of the '774 Patent, reinforces that Mehta does not disclose needles that extend the claimed "desired

(Fed. Cir. 2002) ("A single prior art reference anticipates a patent claim if it expressly or inherently describes each and every limitation set forth in the patent claim."). That alone disposes of Jeisys's anticipation argument.

There is no dispute that Mehta discloses an actuator such as a motor to drive the needles into the tissue. *E.g.*, Ex. 1004, 13:58-65. That alone, however, is insufficient to meet the requirements of claims 13 and 14. Those claims require using a mechanism/motor to extend the needles a programmed distance. *See supra* Section IV.A.

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distance." Claims of the '812 Patent, like those of the '774 Patent, recite needles that extend "a desired distance." Ex. 2116 ('812 Patent), cls. 2, 8, 13. During prosecution of the '812 Patent, the Examiner considered U.S. Patent No. 8,540,705 (Mehta '705), which contains the same disclosures that Petitioners rely on here. *Id.*, 2(56) (References Cited); Ex. 2117, 10:20-11:27, 15:63-17:19, 19:1-25; Ex. 2147 ¶¶90-91. But the Examiner did not reject any of those claims based on Mehta '705. Ex. 2118 ('812 Patent File History), 577-582, 645-651. In other words, although the Examiner of the application for the '812 Patent had before him the same disclosures in Mehta that Petitioners rely on here, the Examiner did ***not*** contend that they disclose the claimed "desired distance."

Even Jeisys's expert, Dr. Woloszko, agrees that distance has to be programmed, but he points to nothing in Mehta that discloses a program or algorithm to extend the needles a desired distance. Ex. 2125, 1151:8-12; Ex. 2154, 43:16-44:10. That is because Mehta does not disclose such a system. Rather, Mehta teaches a system where the needles are driven into the tissue (whether by a motor, actuator, or otherwise) and various means are used to determine whether needles that already penetrated the skin have reached the desired treatment area (e.g., via needle markings and a virtual depiction system in a GUI). That is not the programming of the distance that needles extend using a mechanism/motor that claims 13 and 14 require. Ex. 2147 ¶101.

Jeisys makes three main arguments to argue Mehta discloses the claimed desired distance, but none support that Mehta teaches programming the distance needles extend using a motor or mechanism as required under both Jeisys's and Serendia's proposed construction applicable to claims 13 and 14.

***First***, Jeisys argues Mehta discloses an interface that shows the "desired depth of placement" to avoid placing the needles in an undesired region. Pet. 26 (citing Ex. 1004, 32:63-33:43). Jeisys relies on Mehta's disclosure of a virtual depth/location depiction 350 to contend that:

> Mehta discloses indicating both an actual depth of placement of the needles and a desired depth of placement for the needles to "[allow] the physician to…identify whether the array is located within the desired tissue layer" and "be informed that further advancement of the probes is necessary."

*Id.* 27 (citations omitted). Thus, according to Jeisys, Mehta "discloses '[guiding] probe placement' by '[adjusting]' the system, and provides a stepper motor to support such adjustments. *Id.* (citations omitted).

The Board agreed with Jeisys, pointing to Mehta's disclosures of a graphical user interface (GUI) and finding it "incorporates a 'tissue characteristic indicator (whether visual, virtual, audible, or other feedback)' that allows the user to monitor the needle's actual location in the tissue and advance the needle a desired distance for providing treatment." ID 15. Serendia does not dispute that Mehta teaches monitoring the location of ***already-extended*** needles in tissue and providing that information to the user to make any necessary adjustment to reach the target area. But that is different from programing how far the needles ***extend*** using a motor or mechanism, which is what the claims require and Mehta fails to disclose. Ex. 2147 ¶101.

As to Mehta's disclosure of a virtual depiction system and GUI, Mehta only illustrates where the already-extended needles are located in the tissue. Mehta's "virtual depth/location depiction" "show[s] 'the desired depth of placement for

providing a treatment'" to compare it to the "location of the probe array" so that a user can confirm whether the probes are in the desired or "undesired region." Ex. 1004, 32:63-33:43 (cited in Pet. 26-27 & Ex. 1003 ¶¶86-87). As Dr. Woloszko agrees, that portion of Mehta is to allow verification and "observation of the location of the needles[.]" Ex. 2154, 73:6-15. Illustrating the location of the needles and comparing the "actual depth" to the "desired depth" of the needles (and other ways of tracking insertion depth, e.g., "depth markings") is not programming how far the needles extend using a motor or mechanism. Ex. 2147 ¶101.

Also, providing feedback to the physician that "further advancement of the probes is necessary" teaches nothing about how a ***motor*** or ***mechanism*** would be programmed to extend the needles a desired distance, which even Jeisys's expert agrees is necessary to satisfy the claims. Ex. 2125, 1151:8-12 (Dr. Woloszko admitting that a motor extending needles a predetermined distance would satisfy the claims "***[a]s long as you can program this distance***[.]"); Ex. 2154, 187:12-188:9.

Jeisys's reliance on Mehta's disclosure of a "step-motor" also fails. In his declaration, Jeisys's expert merely contends that a step-motor is "suitable" for controlling needle deployment and posits that a "rotation-to-translation mechanical conversion unit ***can be constructed*** in such a manner to provide a desired rotation-to-translation ratio[.]" Ex. 1003 ¶88. But the possibility of constructing such an undisclosed, hypothetical device is not anticipation as a matter of law. *Trintec Indus.,*

*Inc.*, 295 F.3d at 1295. The claims require causing the "plurality of the extendable needles to extend a desired distance from the end surface" using a motor or mechanism, which requires programming how far the needles extend using that motor or mechanism, and Mehta simply fails to disclose this. Ex. 2147 ¶105.

***Second***, Jeisys argues "[a] user can also achieve a desired distance of needle extension by, e.g., selecting a cartridge having needles of a particular length" or "choosing an angle A." Pet. 27-28. In its Petition, Jeisys also conclusorily argues that "Mehta discloses '[o]ver-inserting and then partially retracting' the needles to the desired distance in order to provide 'a more reliable insertion.'" *Id.* The Board did not seem to rely on these teachings as a basis for instituting Jeisys's Petition. ID 16. Regardless, Mehta's selection of a cartridge with fixed length or angled needles is outside the scope of claims 13 and 14 under their proper construction, as Serendia and Jeisys agree, because those claims require extendable needles that a motor/mechanism causes to extend. *See supra* Section IV.A. Moreover, "a user selecting a cartridge with a different array configuration would be akin to manual adjudgment to reach a target tissue, which is also outside the scope of claims 13 and 14" for the same reason. Ex. 2147 ¶106. Thus, Jeisys's reliance on Mehta's cartridge selection fails. As to Mehta's disclosure of "'[o]ver-inserting and then partially retracting" the needles (Pet. 27-28 (original alteration)), Mehta discloses this as a process that simply "compensates for the movement and laxity of the skin resulting

in a more reliable insertion." Ex. 1004, 16:34-41; Ex. 2147 ¶107. Mehta does not disclose a user making a selection that determines how far the needles extend in the first place, over-insert, or retract—or programming a motor to do so. Ex. 2147 ¶107; *see generally* Ex. 2154, 71:8-15.

***Third***, Jeisys relies on Mehta's disclosure of needles with "distinguishing features (e.g., depth markings, colors, shades, etc.) that enable a physician to observe proper placement' to ensure, e.g., the needles are 'not driven too far into tissue.'" Pet. 28 (internal citations omitted). The Board also agreed with Jeisys, finding that was one of the means Mehta discloses for "selecting and controlling how far the needles are inserted into the tissue." ID 14, 16. But this disclosure is only about a physician's assessing needle placement: "The electrodes of the probe array can also include any number of visually distinguishing features (e.g., depth markings, colors, shades, etc.) that enable a physician to ***observe proper placement***" and probes can have distinguishing features to "allow the physician to ***determine*** the depth of insertion of the probe." Ex. 1004, 13:37–45. Even Dr. Woloszko agrees. Ex. 2154, 35:9-15, 36:15-22. Observing or determining needle placement, however, simply is not programming a distance that the needles will extend using a motor or mechanism. Ex. 2147 ¶102.

In its decision, the Board also found that "Mehta discloses that the needle may employ a sensor to assist the user in positioning the needle to the desired depth." ID

15. Specifically, Mehta teaches using sensors to measure tissue parameters to "provide[] information that can confirm whether the probe 108 is located in the desired target region." Ex. 1004, 24:37-39. If the probe is not in the correct region, "the system can prevent treatment and alert the user for the need to reposition the probe 108." *Id*., 24:41-43. But measuring tissue parameters after the needles are extended has nothing to do with programming how far needles extend using a motor or mechanism, as claims 13 and 14 require. Ex. 2147 ¶103. "Measuring tissue parameters involves obtaining information about a target region once it has been reached, while programming how far needles extend using a motor/mechanism involves how to reach a target region." *Id*.

Because Mehta fails to disclose programming how far the needles extend using a motor or mechanism, Mehta does not anticipate claims 13 and 14.

## VII. Ground IV: Petitioner failed to demonstrate that Mehta and Lee Render Obvious Claims 13 Or 14 Of The '774 Patent

In its Petition, Jeisys relies on Lee ***only*** for the claimed "desired distance" limitation and contends it would have been obvious to combine Mehta and Lee to arrive at the claimed invention. Pet. 65. But, Jeisys ignores the purpose, design, and operation of both Mehta and Lee, which would not motivate a POSITA to combine them. Jeisys also ignores secondary considerations that rebut its obviousness argument.

### A. A POSITA would not have been motivated to combine Mehta and Lee

Jeisys asserts, "A POSA would have been motivated to combine Mehta and Lee because they are directed to similar technologies and a skilled artisan would have understood the benefits of combining these two references." Pet. 65 (citing Ex. 1003 ¶223). This superficial assertion fails to justify combining Mehta and Lee. Even assuming Mehta and Lee relate to "similar technologies," that merely supports that they ***could*** be combined; it is not a ***reason*** to do so. *Adidas AG v. Nike, Inc.*, 963 F.3d 1355, 1359 (Fed. Cir. 2020) ("The obviousness inquiry does not merely ask whether a skilled artisan could combine the references, but instead asks whether they would have been motivated to do so."), *cert. denied*, 141 S. Ct. 1376 (2021). Moreover, while both Mehta and Lee are both directed to the treatment of skin, they tackle different problems in vastly different ways, and their design and operation would not motivate a POSITA to combine them or provide a POSITA with reasonable likelihood of success in doing so.

***First***, Mehta and Lee teach different mechanisms for treating skin, which would not lead a POSITA to combine them. Specifically, Mehta is directed to "Methods for ***Applying Energy*** to Tissue Using a Graphical User Interface" and aims to provide "improved systems and methods of percutaneously ***delivering energy*** to tissue." Ex. 1004, Title, 2:37-41; *see also id*., 3:42-44. Mehta also discloses several ways to confirm the location of the probes once they are inserted

into the skin (*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")), to ensure energy is not delivered to an unintended location. *Id.*, 15:65-16:11.

Lee, on the other hand, teaches "***performing multi-hole procedures***" at rapid speeds where the system "can create hundreds to tens of thousands of holes on the human skin with a gun equipped with a plurality of microneedle." Ex. 1011, Abstract; *see id*. ¶15. Nowhere does Lee teach delivering energy—one of the requirements of the claims (i.e., "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[]"). Ex. 1001, cl. 11; Ex. 2154, 98:15-21. While Lee teaches a mechanical treatment method that is "simple and safe as well as free of side effects" (Ex. 1011 ¶17), Mehta by contrast is directed toward delivery of RF energy, which Mehta explains "creates the risk of unwanted collateral damage to the skin" (Ex. 1004, 2:1-2), such as "burns and/or scars." *Id*., 8:52-53. Such "[f]undamental differences between the references are central to [the] motivation to combine inquiry." *Adidas AG*, 963 F.3d 1359; *see also Chemours Co, FC, LLC v. Daikin Indus., Ltd.*, 4 F.4th 1370, 1376 (Fed. Cir. 2021) (reversing the Board's obviousness analysis where the Board "did not adequately grapple" with

why a POSITA would have found it obvious to modify a prior art reference to include the claim limitation in view of contrary critical features discloses in that reference).

***Second***, a POSITA would not have a high likelihood of success to arrive at the claimed invention when combining Mehta and Lee based on their design and operation because they are directed to different goals. Mehta is concerned with inserting needles into the skin, confirming that the needles are in the target region of the tissue, and delivering energy for a period of time to target tissue. Ex. 2147 ¶114. Lee's goal, on the other hand, is creating "hundreds to tens of thousands of holes on the human skin." Ex. 1011, Abstract; Ex. 2147 ¶115. "Lee is concerned with speed—not with confirming the location of the needles after insertion because energy is not delivered via the needles." Ex. 2147 ¶115.

Mehta explains that therapeutic treatments involve "thermally denaturing the collagen in the dermal layer of a target area[;]"to do so the system applies energy to a target cite to reach a predetermined temperature and "[o]nce the target site reaches the treatment temperature, the system then maintains this condition for the cycle or dwell time." Ex. 1004, 19:17-19, 19:45-51. Thus, energy is applied to reach a particular temperature and maintaining it for a period of time. Ex. 2147 ¶116. One study Mehta describes for this therapeutic treatment involved adjusting the

temperature and time, using at least 1 second just for treatment—after the needles were inserted and adjusted as needed:

> The temperature in the above example was adjusted from 60 to 80° C. and the time-at-temperature was adjusted from 1.5 to 25 seconds. During a later phase of the study, the treatment temperature was held at 70° C. using the system described above and the time-at-temperature was set to 1, 4, or 7 second(s). A higher temperature setting of 78°C. for 4 seconds was also used toward the end of the study with excellent clinical results and safety profile[.]

Ex. 1004, 37:17-24; *see also* Ex. 2147 ¶¶117, 118; Ex. 2154, 66:1-13. Mehta's figures are consistent, showing treatment times of 5 seconds. Ex. 1004, Figs. 10E, 10F.

In contrast, in Lee "the treatment procedure may be performed at a speed of about 66-420 times per minute." Ex. 1011 ¶58. Thus, in the slowest setting, Lee's needles penetrate skin every 0.9 seconds and at the fastest setting every 0.14 seconds. Ex. 2147 ¶119. Modifying Mehta in view of Lee simply not enough time to check the location of the already-inserted needles with the observation or measurement means, adjust their location if needed, and then deliver RF energy before retracting the needles, as Mehta teaches. *Id.*; Ex. 2154, 102:17-104:1, 107:17-22.

Therefore, the teachings of Lee conflict with those of Mehta and a POSITA would not look to Lee to modify Mehta as Jeisys proposes. Ex. 2147 ¶120. *Trivascular, Inc. v. Samuels*, 812 F.3d 1056, 1068 (Fed. Cir. 2016) (finding

nonobviousness where proposed modification would "destroy the basic objective" of the primary reference).

***Third***, Mehta was aware of distance control, but teaches a different approach to ensure energy is delivered to "a predetermined target area." Ex. 1004, 2:10-12. As one example, Mehta cites U.S. Patent No. 6,277,116 to Utely ("Utely") in its Background, and it discloses a controller that can "establish and maintain a control depth" that can be "set by the physician." Ex. 2119 (Utely), 11:26-30. As another example, U.S. Patent Application Publication No. 2002/0120261 to Morris ("Morris '261"), which Mehta cites and is a continuation of the Morris reference cited in the petition on the '774 Patent for which the PTAB denied institution, discloses electrodes that can be "advanced to a selected deployment depth." Ex. 2120 (Morris '261), Abstract.

Rather than rely on depth control, Mehta discloses various means to confirm the location of the already-extended probes to ensure energy is delivered to the intended region. *E.g.*, Ex. 1004, 12:1-4 (using 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"); Ex. 2147 ¶122. "Assuming that rapidly inserted needles would be inserted to the right depth before delivering energy would conflict with Mehta's teachings." *Id*. Further, if

Mehta were modified in view of Lee, the many teachings in Mehta to confirm the location of the already-inserted probes would be rendered meaningless because there would be no time to use them. *Id.* Therefore, a POSITA would not have looked to Lee to modify Mehta as Jeisys proposes. *Trivascular*, 812 F.3d at 1068; *Eli Lilly & Co. v. Actavis Elizabeth LLC*, 435 F. App'x 917, 921 (Fed. Cir. 2011) (affirming a finding of nonobviousness, explaining "it is impermissible to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art").

Jeisys relies on broad references to "routine programming" and "design choice" to argue a POSITA would have modified Mehta in view of Lee to include a step motor or to modify Mehta's GUI, but Jeisys's generic assertions improperly ignore the teachings of these references. Mehta itself already discloses a stepper motor, as Jeisys admits. Pet. 27 ("Mehta … provides a stepper motor"); *id.* 67-68 ("a stepper motor as disclosed in Mehta and as also disclosed in Lee"); Ex. 1004, 15:34-40 ("[t]he mode of movement of the actuator can include … stepping (via an step-motor)"). Jeisys provides no reason a POSITA would be motivated to substitute Lee's step motor in Mehta, particularly in light of the references vastly different function and operation as described above. Jeisys also fails to explain why a POSITA would be motivated to "provide a distance setting on Mehta's I/O interface,"

especially in view of Mehta's teachings about using the GUI instead to check the position of the already-extended probes. Pet. 68; *Virtek Vision Int'l. ULC v. Assembly Guidance Sys., Inc*., 97 F.4th 882, 887 (Fed. Cir. 2024) (reversing the Board's obviousness determination because "[t]here was no argument in the petition regarding why a skilled artisan would" substitute one prior art system for another other than they were "known to be used").

Jeisys's expert declaration fares no batter. In his declaration, Jeisys's expert makes multiple broad factual statements to support the hindsight-driven purported modification (*e.g*., Ex. 1003 ¶228) without citation to any documentary evidence showing these to be true. It was Jeisys's burden to provide evidence in support of these findings; Jeisys did not. An expert's bare testimony, devoid of any evidentiary support, amounts to little more than a "conclusory assertion" which "tracks the ex post reasoning KSR warned of and fails to identify any actual *reason* why a skilled artisan" would have modified Mehta to satisfy the missing limitation of the '774 Patent's claims. *In re Van Os*, 844 F.3d 1359, 1361 (Fed. Cir. 2017) (italics in original). Jeisys's Petition and expert declaration fail to satisfy this standard.

Jeisys improperly uses the '774 patent as a roadmap for reconstructing the claimed invention without showing that a POSITA would have been motivated to modify Mehta to achieve the claimed inventions. *See Univ. of Strathclyde v. Clear-Vu Lighting LLC*, 17 F.4th 155, 162 (Fed. Cir. 2021) (reversing the Board's

obviousness determination, in part, because the "only support for such a finding is pure conjecture coupled with hindsight reliance on the teachings in the [challenged] patent."); *Samsung Elecs. Co., Ltd. v. Netlist, Inc.*, IPR2022-00063, 2023 WL 5065223, at *18 (P.T.A.B. May 3, 2023) (finding the petitioner did not show the claims to be unpatentable and that "that Petitioner's specific modifications were driven by hindsight view of the roadmap provided by the claim limitations"); *Vivint, Inc. v. Alarm.com Inc.*, 754 F. App'x 999, 1006-07 (Fed. Cir. 2018), *aff'd*, 856 F. App'x 300 (Fed. Cir. 2021) (affirming the Board's patentability finding where the prior art taught status messages relayed information about the communication path but did not confirm whether the equipment was working properly, and the claims required normal status messages that conveyed information about the monitored equipment).

### B. Evidence of Objective Indicia of Non-Obviousness

Objective evidence of a patented invention's non-obviousness—such as commercial success and industry praise—"may often be the most probative and cogent evidence in the record" and "must be considered in ***every*** case." *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1328-37 (Fed. Cir. 2016) (original emphasis); *see also, e.g.*, *Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1071-72 (Fed. Cir. 2018). Such evidence serves "to 'guard against slipping into use of hindsight' … and

to resist the temptation to read into the prior art the teachings of the invention." *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 36 (1966).

Here, Jeisys's and its expert's failure to address secondary considerations of non-obviousness render their obviousness arguments deficient as a matter of law. This omission is particularly glaring because significant objective indicia support non-obviousness. The products practicing the patented invention garnered significant commercial success and industry praise. This evidence confirms that the '774 Patent was far from obvious.

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

Whether patent claims would have been obvious to a POSITA is a legal question assessed based on underlying factual findings, known as the *Graham* factors: (1) the level of ordinary skill in the pertinent art; (2) the scope and content of the prior art; (3) the differences between the prior art and the claims at issue; and (4) secondary considerations of non-obviousness such as commercial success, long-felt but unsolved needs, failure of others, etc. *See generally KSR Int'l Co. v. Teleflex Inc*., 550 U.S. 398, 406 (2007). The Federal Circuit has "repeatedly emphasized that an obviousness inquiry requires examination of ***all four*** *Graham* factors and that an obviousness determination can be made only after consideration of each factor." *Nike, Inc. v. Adidas AG*, 812 F.3d 1326, 1335 (Fed. Cir. 2016), *aff'd*, No. 2021-1903,

2022 WL 4002668 (Fed. Cir. Sept. 1, 2022). And, "when secondary considerations are present … it is error not to consider them." *Id*. at 1339 (original alteration).

Here, evidence of secondary considerations is present, and Jeisys has been on notice of that evidence since at least June 16, 2023, when Patent Owner served its initial validity contentions in the 1356 ITC Investigation. Ex. 2054. Indeed, because Jeisys waited until after the evidentiary hearing in the ITC and post-hearing briefing to file its Petition, Jeisys filed its Petition with knowledge of the full evidentiary record on secondary considerations that was developed in the ITC. *See, e.g*., Ex. 2154, 24:19-25:14 (Dr. Woloszko admitting that he saw Serendia's presentation of evidence regarding secondary considerations of non-obviousness at the ITC evidentiary hearing). Yet, Respondents failed to address Patent Owner's evidence of secondary considerations at all in the ITC, and Jeisys's obviousness arguments suffer from the same glaring omission here. *See, e.g*., *id.*, 22:20-23:13 (Dr. Woloszko admitting that he, once again, did not address secondary considerations).

Despite being aware of the substantial evidence of secondary considerations, Jeisys and its expert disregard it. This alone is sufficient to reject Jeisys's invalidity arguments. *See, e.g., Robert Bosch Tool Corp. v. SD3, LLC*, IPR2016-01753, 2017 WL 1096548, at *16 (P.T.A.B. Mar. 22, 2017) (finding that "the evidence of secondary considerations weighs decisively toward non-obviousness"); *id*. at *12 ("Although we are mindful that at this stage of a proceeding a petitioner may be

unaware of a patent owner's potential objective indicia of nonobviousness, in the case before us Patent Owner relies upon evidence that was introduced during the related ITC proceeding against Petitioner."); *In re Nat. Alts., LLC*, 659 F. App'x 608, 614-15 (Fed. Cir. 2016) (explaining that evidence of objective indicia "must always when present be considered en route to a determination of obviousness").

Indeed, as the Federal Circuit has explained, when, as here, an expert "fail[s] to account for objective evidence of nonobviousness, [his or her] analysis [i]s incomplete, and ultimately insufficient to establish obviousness," and thus the expert cannot offer an "ultimate question of obviousness" because the "expert must consider all factors relevant to that ultimate question" to render an opinion on it. *InTouch Techs., Inc. v. VGO Commc'ns, Inc.*, 751 F.3d 1327, 1352 & n.8 (Fed. Cir. 2014). Jeisys's expert was properly informed that he needed to consider evidence of secondary considerations (Ex. 1003 ¶21), but he failed to do so. Because Jeisys's expert failed to consider all four *Graham* factors, his analysis is incomplete and his opinion on the ultimate issue of obviousness is not competent. *InTouch Techs.*, 751 F.3d at 1352 & n.8; *see also Inline Plastics Corp. v. Lacerta Grp., LLC*, 97 F.4th 889 (Fed. Cir. 2024).

**2. The Claimed Invention Has Been Commercially Successful**

The Sylfirm X was designed by the inventor of the '774 Patent, Dr. Jung Ju Na, (Ex. 2037 (Sylfirm X Brochure), 4), and as Mr. Crosby explains, the Sylfirm X practices the claimed invention. Ex. 2147 ¶¶124-153.

The Sylfirm X is an RF microneedling system for "treating dermatological tissue." Ex. 1001, cl. 11[pre]; Ex. 2147 ¶¶126-129; Ex. 2083 (Sylfirm X User Manual), 4 ("The device is intended for coagulating skin tissue …."); Ex. 2037 (Sylfirm X Brochure). The Sylfirm X includes "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." Ex. 1001, cl. 11[a]; Ex. 2147 ¶¶130-135. Serendia's documents confirm as much. Ex. 2147 ¶133. 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. Ex. 2147 ¶133.

The Sylfirm X includes "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." Ex. 1001, cl. 11[b]; Ex. 2147 ¶¶136-141. 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); *see also* Ex. 2097; Ex. 2147 ¶139.

The Sylfirm X further "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." Ex. 1001, cl. 12; Ex. 2147 ¶¶142-145. 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); *see also* Ex. 2037 (Sylfirm X Brochure), Ex. 2130 (Sylfirm X Photos), 2, 4.

The Sylfirm X also meets the "mechanism for causing the plurality of the extendable needles to extend a desired distance from the end surface" and "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"

limitations of claims 13 and 14, respectively. Ex. 1001, cls. 13, 14; Ex. 2147 ¶¶146-153. Serendia's documents confirm as much. 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; Ex. 2147 ¶¶129, 152.

[redacted].

Moreover, as Serendia's economic expert, Mr. Thomas explains, the Sylfirm X has been commercially successful. Ex. 2124 (Thomas Decl.) ¶¶14-15. For example, its sales "have grown significantly" each year. *Id*. ¶15. In its first year on the market (2021), sales were [redacted]; the next year (2022), sales almost tripled to [redacted]. *Id*. In just the first quarter of 2023, Sylfirm X made [redacted] in sales, which annualizes to [redacted]. *Id*.

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

There is a strong nexus between the commercial success of the Sylfirm X and the claimed invention. For objective evidence of secondary considerations to be relevant, there must be a nexus between the merits of the claimed invention and the objective evidence. Absent a presumption of nexus, "the patent owner is still afforded an opportunity to prove nexus by showing that the evidence of secondary considerations is the 'direct result of the unique characteristics of the claimed invention.'" *Volvo Penta of the Ams., LLC v. Brunswick Corp*., 81 F.4th 1202, 1210 (Fed. Cir. 2023) (citing *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373-74 (Fed. Cir. 2019) (quoting *In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996))). Importantly, a nexus analysis is not limited to the allegedly novel features. *Id*. (citing *WBIP*, 829 F.3d at 1330 (stating that "proof of nexus is not limited to only when objective evidence is tied to the supposedly 'new' feature(s)")). Instead, it is important to consider "the invention as a whole," rather than on a "limitation-by-limitation" basis. *Id*. (citing *Chemours*, 4 F.4th at 1377; *Yita LLC v. MacNeil IP LLC*, 69 F.4th 1356, 1364 (Fed. Cir. 2023) (discussing *WBIP*)).

The evidence shows that the "inventive combination" of features drove the commercial success of the Sylfirm X. *Chemours*, 4 F.4th at 1378; Ex. 2147 ¶¶154-156. Dr. Na patented his invention, and then developed the Sylfirm X to implement it. Advertisements for the Sylfirm X tout the benefit of the '812 Patent technology.

Ex. 2037 (Sylfirm X Brochure), 2, 13 (Sylfirm X "enables the treatment by targeting the papillary dermis layers by adjusting the needle depth in the range of 0.3 to 4.0 mm" and ""[t]reatment depth" is a parameter that is "adjustable by the user."). Other marketing and training materials likewise focus on the treatment benefits associated with implementing the claimed technology. Ex. 2066, 2-3 ("needle depth can be adjusted from 0.3-4.0mm so we can treat thin skin, as well as the body" and that "Sylfirm X appears to be the only RF device that accurately targets and treats at 0.3mm of skin depth."); Exs. 2039, 2079, 2083, 2084. The '812 Patent is also cited in the Sylfirm X marketing materials. Ex. 2038 (Patent List). "Th[is] prominence of the patented technology in … advertising creates an inference that links the … invention to this success." *Gambro Lundia AB v. Baxter Healthcare Corp*., 110 F.3d 1573, 1579 (Fed. Cir. 1997)..

Thus, there is a strong nexus between the '774 Patent and Sylfirm X's commercial success.

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

The depth control claimed by the '774 Patent has also received industry praise and recognition. *WBIP*, 829 F.3d at 1334. For example, medical providers have praised the Sylfirm X for its ability to "accurately target and treat[]" at the desired skin depth. Ex. 2066 (Sylfirm X Revolutionises [sic] the Clinical Applications of RF Microneedling), 3. That former respondents have praised the patented technology

also supports non-obviousness. Ex. 2122 (Cartessa Aesthetics, Innovations in RF Microneedling), 2; *WBIP*, 829 F.3d at 1334 ("competitors, are not likely to praise an obvious advance over the known art"). Further, in 2020, ViOL also received a world-class product award for the Sylfirm X in Korea. Ex. 2067 (Sylfirm X Award).

Thus, the technology claimed in the '774 Patent has become widely recognized and praised, and "[r]ecognition of the importance of this advance is relevant to a determination of nonobviousness." *Gambro Lundia*, 110 F.3d at 1579.

**4. The Board's Institution Decision**

In its Institution Decision, the Board concluded that Serendia's Preliminary Response "fails to explain the criticality of the unclaimed 'Na effect' to the functionality of the Sylfirm X product" and "how its evidence of commercial success is the direct result of the claimed invention here, as opposed to the claimed invention at the heart of Serendia's other patent." ID 18.

As the Federal Circuit has explained, it is important to consider "the invention as a whole," rather than on a "limitation-by-limitation" basis. *Volvo*, 81 F.4th at 1212 (citing *Chemours*, 4 F.4th at 1377). For example, in *Volvo*, the Board determined that the patent owner did not demonstrate a nexus to certain objective indicia. *Id*. The Federal Circuit disagreed however, finding that the Board's determination was not supported by substantial evidence. *Id*. As the Federal Circuit explained, the patent owner cited documents demonstrating a connection between claimed

elements of the invention and the objective evidence of non-obviousness. *Id.* This included evidence highlighting what made aspects of the claimed invention valuable and useful. *Id*. This further included evidence that "[t]he inventive combination of [claimed elements] provided certain benefits praised in the industry and not achieved [] in the prior art," as well as evidence that potential customers "strongly desired" the claimed features. *Id*. Thus, the Federal Circuit concluded that "[t]here is therefore a nexus between the unique features of the claimed invention … and the evidence of secondary considerations." *Id*. That was the case even though the product at issue included unclaimed features that fell within the scope of other patents.

As explained above, the same kind of evidence is available here, and, thus, just as in *Volvo*, "[t]here is therefore a nexus between the unique features of the claimed invention … and the evidence of secondary considerations." *Id.*

## VIII. Conclusion

For the reasons set forth above, the Board should confirm the patentability of claims 13 and 14.

Respectfully submitted,

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By: / Charles H. Sanders /

Charles H. Sanders (Reg. No. 47,053)
charles.sanders@lw.com
Latham & Watkins LLP
200 Clarendon Street
Boston, MA 02116
Telephone: 617.948.6000
Fax: 617.948.6001

*Counsel for Patent Owner*
*Serendia LLC*

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

I hereby certify that this Patent Owner's Response complies with the word count limitation of 37 C.F.R. § 42.24(b)(2) because the Patent Owner's Response contains 11,186 words using Microsoft Word's counting feature, excluding the cover page, signature block, and the parts of the Patent Owner's Response exempted by 37 C.F.R. § 42.24(b)(2).

By: / Charles H. Sanders /

Charles H. Sanders (Reg. No. 47,053)
charles.sanders@lw.com
Latham & Watkins LLP
200 Clarendon Street
Boston, MA 02116
Telephone: 617.948.6000
Fax: 617.948.6001

*Counsel for Patent Owner*
*Serendia LLC*

## CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that on this 13th day of November, 2024, a true and correct copy of the foregoing **Patent Owner's Response and all Exhibits** were served by electronic mail on Petitioner's lead and backup counsel at the following email addresses:

Wesley O. Mueller
Leonard Z. Hua
Paul J. Filbin
Brent A. Chatham
LEYDIG, VOIT & MAYER, LTD.
Two Prudential Plaza, Suite 4900
180 North Stetson Avenue
Chicago, Illinois 60601-6731
Tel.: 312.616.5600
Fax: 312.616.5700
wmueller@leydig.com
lhua@leydig.com
pfilbin@leydig.com
bchatham@leydig.com
Jeisys-IPR@leydig.com

By: / Charles H. Sanders /

Charles H. Sanders (Reg. No. 47,053)
charles.sanders@lw.com
Latham & Watkins LLP
200 Clarendon Street
Boston, MA 02116
Telephone: 617.948.6000
Fax: 617.948.6001

*Counsel for Patent Owner*
*Serendia, LLC*