

Filed on behalf of: Serendia, LLC

Entered: December 18, 2024

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

SERENDIA, LLC,
Patent Owner.

Case IPR2024-00845
Patent 10,869,812

PATENT OWNER'S PRELIMINARY RESPONSE

PUBLIC VERSION – REDACTED

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2002-2015	RESERVED
2016	Complainant's Public Interest Statement & Complaint of Serendia, LLC, Under Section 337 of the Tariff Action of 1930, as Amended, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C. Mar. 1, 2023)
2017-2036	RESERVED
2037	Brochure: Sylfirm X Dual Wave RF Microneedling System (2022)
2038	ViOL Patent List (Dec. 1, 2023), https://violmedical.com/about/patent
2039	Sylfirm X Video
2040	Transcript of Exhibit 2039 – Sylfirm X Video
2041	Direct Rebuttal Demonstratives of Vincent A. Thomas (CDX-0045C), <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C. Dec. 12, 2023) (PROTECTIVE ORDER MATERIAL)
2042–2053	RESERVED
2054	Complainant's Initial Validity Contentions, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C. June 16, 2023) (PROTECTIVE ORDER MATERIAL)
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2062	Presentation: Sylfirm X Clinical Training (2021) (PROTECTIVE ORDER MATERIAL)
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2066	Martin Braun, <i>Sylfirm X Revolutionises [sic] the Clinical Applications of RF Microneedling</i> , 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")
2068–2069	RESERVED
2070	Curriculum Vitae of Vincent A. Thomas
2071	Profit & Loss, January–December 2021 (Accrual Basis) (July 6, 2023, 2:31 PM) (PROTECTIVE ORDER MATERIAL)
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2079	Sylfirm X (product information), ViOL (2022), https://violmedical.com/for_providers/product?idx=10 (last visited Feb. 25, 2023)
2080–2082	RESERVED
2083	ViOL, Sylfirm X User Manual (VO-UM-SFX-03), revised April 20, 2022
2084	Sylfirm X, Device Description (PROTECTIVE ORDER MATERIAL)
2085	RESERVED
2086	Sylfirm X Product Photographs
2087–2096	RESERVED
2097	Sylfirm X Introduction Video 1

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2108	U.S. Patent Application Publication No. 2002/0120260 A1 (“Morris”)
2109-2113	RESERVED
2114	File History for U.S. Patent No. 9,320,536
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2116–2118	RESERVED
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)
2123–2124	RESERVED
2125	Hearing transcripts, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C.), held November 7, 2023 and December 11, 2023 (Jean Woloszko testimony excerpts) (“Woloszko Hr’g Tr.”)
2126	RESERVED
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)

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2131	RESERVED
2132	U.S. Patent Application Publication No. 2006/0036210 A1 ("Zhang")
2133–2135	RESERVED
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2137–2140	RESERVED
2141	Declaration of Vincent A. Thomas, dated December 13, 2024 ("Thomas Decl.") (PROTECTIVE ORDER MATERIAL AND REDACTED VERSIONS)
2142	U.S. Patent Application Publication No. 2004/0058882 A1 ("Eriksson")
2143	U.S. Patent Application Publication No. 2008/0091182 A1 ("Mehta 182")
2144	Disclaimer in a Patent Under 37 C.F.R. § 1.321(a) of U.S. Patent 10,869,812 ('812 Patent), including electronic payment receipt ("Disclaimer")
2145-2146	RESERVED
2147	Declaration of Peter Crosby, dated December 11, 2024 ("Crosby POR Decl.") (PROTECTIVE ORDER MATERIAL AND REDACTED VERSIONS)
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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, <i>Syneron Medical Buying Primaeva Medical</i> , VENTURE CAP. J. (Oct. 16, 2009), https://www.venturecapitaljournal.com/syneron-medical-buying-primaeva-medical/
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
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I. Introduction

Petitioners EndyMed Medical Ltd.'s and EndyMed Medical, Inc.'s (collectively "EndyMed") petition for *inter partes* review ("IPR") of U.S. Patent No. 10,869,812 ("812 Patent") should be denied for three reasons.

First, all but claims 8 and 19 recite a motor to cause the plurality needles to extend a desired distance. As properly construed, these claims require the motor to extend the needles a programmed distance. As the '812 Patent describes, 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, EndyMed's primary reference, Mehta is directed to an entirely different approach. Mehta does not disclose any way to program the distance the needles extend. Instead, Mehta discloses using different cartridge configurations (e.g., different needle lengths or angles) to reach different depths, and ways to tell whether the extended needles are at the right depth and for the physician to make adjustments if necessary, before delivering energy. And as EndyMed admits, Mehta does not disclose the limitations of claims 9 and 18.

Second, because Mehta fails to teach the claimed inventions, EndyMed relies on three other references (Lee, Na '848, and Livneh) to assert obviousness combinations. But Mehta and the other references are directed to different methods of treating skin. Mehta is concerned with delivering energy to the skin via needles

after confirming they are at the right depth. 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. Na '848 is an acupuncture-type device with no extendable needles that also fails to teach delivery of radio frequency via the needles. And Livneh teaches an integrated device with additional wiring and components, which add nothing but more complexity and cost to features already disclosed in Mehta. A person skilled in the art would not have been motivated to combine those references to achieve the claimed inventions nor have a reasonable expectation of success in doing so. Further, claims 9 and 18 require “a pin that is extendable in the same direction as the plurality of needles,” but EndyMed relies on Livneh's disclosure of a coil, which not a pin.

Third, substantial, uncontroverted evidence supports finding that objective indicia of non-obviousness, including commercial success and industry praise, demonstrate the non-obviousness of the '812 Patent. Despite being aware of Serendia's objective indicia evidence since the prior ITC proceedings, EndyMed failed to even try to rebut that evidence. Simply put, EndyMed'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 deny institution.

II. Background

A. Procedural History And Background Of The IPR Petitions

In August 2021, Patent Owner sued Sung Hwan E&B Co., Ltd. (“SHEnB”) and Cartessa Aesthetics, LLC (“Cartessa”) for infringing several patents, including the ’812 Patent. *SynKloud Techs., LLC v. SHEnB*, No. 6:21-cv-00811 (W.D. Tex. Aug. 6, 2021), ECF No. 1; *SynKloud Techs., LLC v. Cartessa*, No. 2:21-cv-04423 (E.D.N.Y. Aug. 6, 2021), ECF No. 1. In January 2022, Patent Owner sued Aesthetics Biomedical Incorporated (“ABM”) for infringing the ’812 Patent and others. *SynKloud Techs., LLC v. ABM*, No. 2:22-cv-00015 (D. Ariz. Jan. 4, 2022), ECF No. 1. In December 2021, Cartessa petitioned for IPR challenging the ’812 Patent claims, presenting a single invalidity ground based on U.S. Patent Application Publication Nos. 2002/0120260 to Morris, et al. (“Morris”) and 2006/0036210 to Zhang, et al. (“Zhang”). *Cartessa v. Serendia, LLC*, IPR2022-00377, Paper 1 (P.T.A.B. Dec. 28, 2021) (“*Cartessa IP*”); Ex.2108 (Morris); Ex.2132 (Zhang). The Board denied institution. *Cartessa II*, Paper 9.

B. The Current And Former Petitioners Fully Litigate The ’812 Patent’s Validity In The ITC

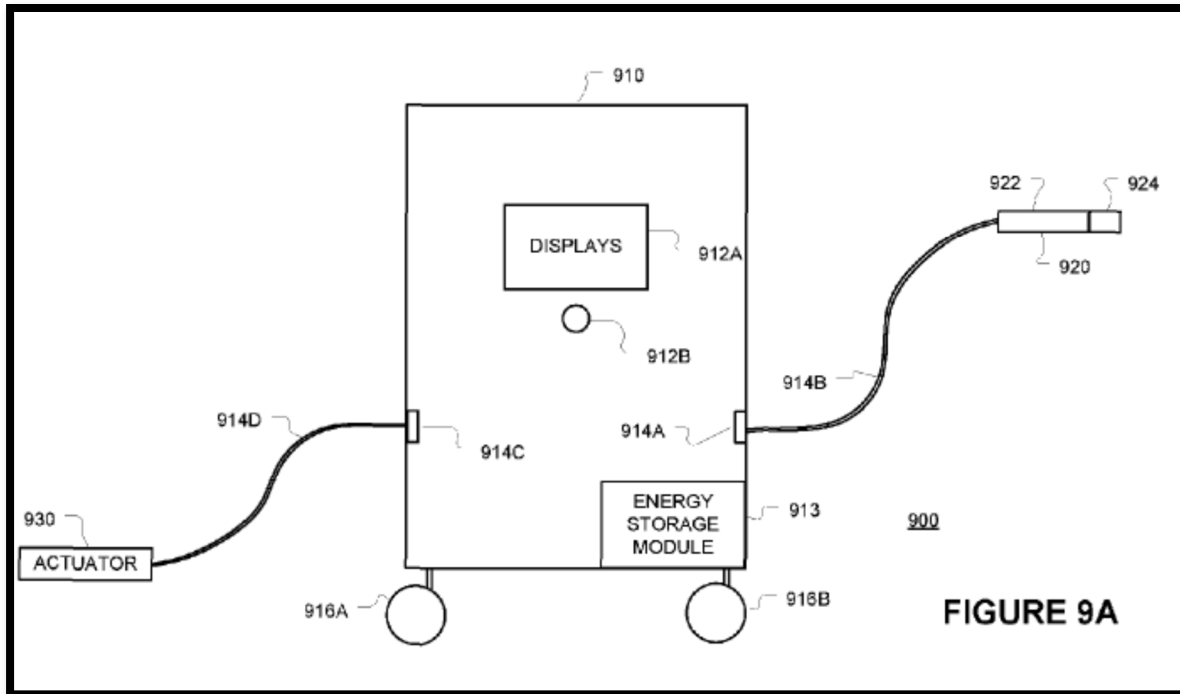
About nine months after the Board denied the first petition, in March 2023, Serendia filed additional District Court complaints alleging infringement of the ’812 Patent (and others), against various parties, including Cynosure, LLC (“Cynosure”). The same day, Serendia also filed an ITC complaint alleging infringement of the

'812 Patent (and others) against the named District Court defendants and Cynosure's Korean supplier: EndyMed, 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").

In November and December of 2023, evidentiary hearings were held in the ITC. On January 8, 2024, after the validity of the '812 Patent was fully litigated in the ITC, including the submission of all post-hearing briefings, Jeisys filed a second IPR petition, and the Board subsequently granted institution. *Jeisys Medical Inc. v. Serendia*, IPR2024-00463, Papers 1, 20 (Jan. 19, 2024) ("00463 IPR"). EndyMed then filed its own IPR petition against the '812 Patent, along with a motion for joinder, which is at issue here.

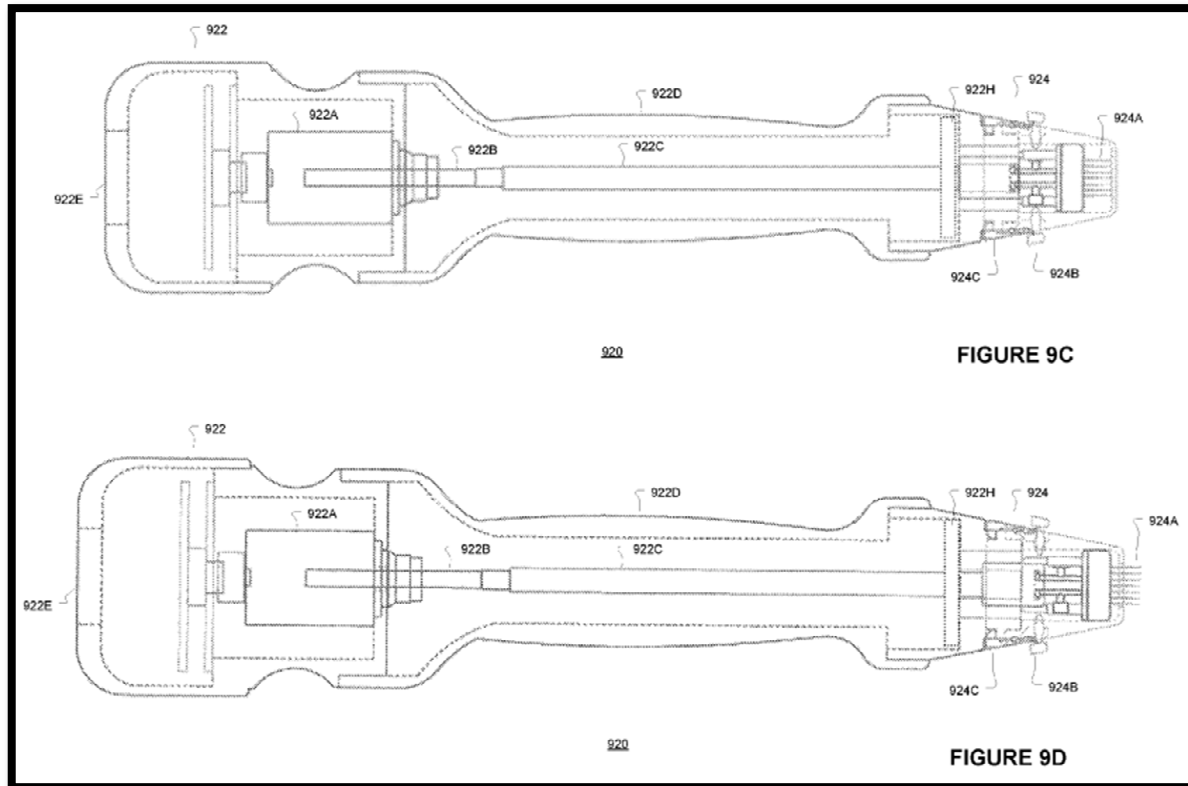
1. The '812 Patent (Ex.1001)

The '812 Patent claims 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 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, 9:40-44.



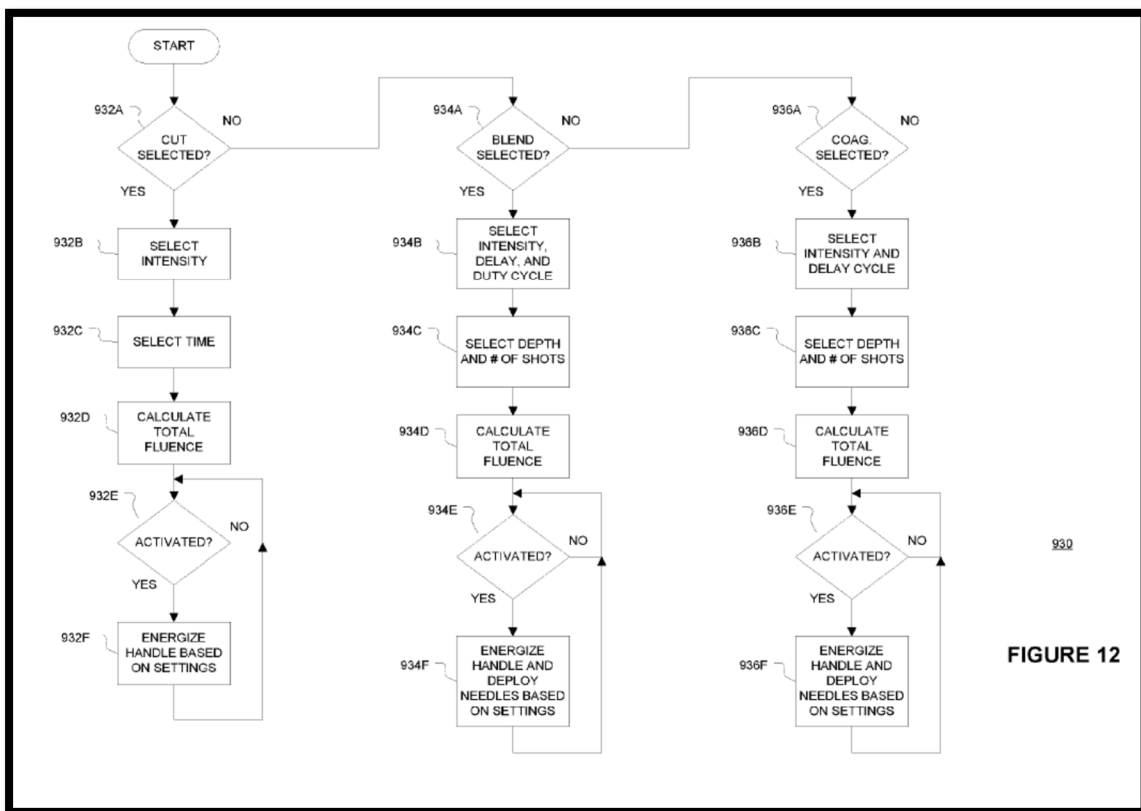
As shown above and in Figures 9C and 9D (copied below), the “handle module 920” may include (1) “a deployable needle module (DNM) 924” (which “may be a detachable cartridge module (DCM)”), and (2) “a motor and LED module [(MLM)] 922.” *Id.*, 9:47-52, 11:6-12. “[A] needle deployment motor controller (NDMC) module 911B” (shown above), “may control the deployment of one or more needles 924A” (shown below), of the deployable needle module 924 “based on one or more user selected operational parameters,” which include “the depth” of needle insertion. *Id.*, 9:67-10:5, 10:21-24, 10:32-37; *see also id.*, 9:65-10:5 (“a user may configure one or more operational parameters[,]” which include “needle deployment timing and depth(s)”). Accordingly, “needle deployment” “via one or more motors 922A” can be controlled by the user. *Id.*, 10:52-65. Figure 9C (below),

shows the “needles 924A retracted,” and Figure 9D (below), shows the “needles 924A deployed.” *Id.*, 10:66-11:5.



Needle extension 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.*, 11:15-24. 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.*, 11:24-28, 14:3-6, 14:24-26.

Accordingly, “a desired depth of needle 924A penetration within tissue” can be achieved “based on the operational parameters” the user selects. *Id.*, 14:14-20, 14:28-34. Figure 12 (below) is a flow diagram of algorithms for the DTA 900, which shows that in two operational modes (blend and coagulation), one of the steps 934C, 936C involves selecting needle deployment depth. *Id.*, 13:45-46, 13:51-55, 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.*, 9:65-10:5, 10:21-24, 10:32-37, 11:24-28, 14:3-6, 14:24-26; Ex.2147 ¶48.



2. Priority and Prosecution History

The '812 Patent was filed on October 3, 2017, and issued December 22, 2020. Ex.1001, 1(22), (45). It is a continuation of the '774 Patent, which in turn is a continuation of the '536 Patent. Serendia agrees that the proper priority date is March 3, 2011. Petitioner also challenged the '774 and '536 Patents.

During prosecution of the '812 Patent, the Examiner rejected the then-pending claims over WO 2005/096979 A1 ("Manstein") and KR 10-2011-00002210 ("Yang") (Ex.1002, 579-580), and issued a double patenting rejection in view of the '536 Patent. *Id.*, 580-582. In response, the Applicant initiated interviews, amended the claims to require that the electrical contacts be extendable, and filed a terminal disclaimer. *Id.*, 604-607, 614-622, 625-626. After the Applicant corrected the terminal disclaimer, the Examiner allowed the claims. *Id.*, 646-651, 682, 692-693.

3. Person of Ordinary Skill in the Art

For purposes of this preliminary response, Serendia accepts Petitioner's definition of a person of ordinary skill in the art ("POSITA"). Pet. 11; Ex.1003 ¶45.

III. Claim Construction

The prior art relied on in the Petition fails to disclose the subject matter of the challenged claims under any reasonable construction, including their plain meaning.¹ Serendia addresses construction of the relevant claim terms below.

- A. **Motor ... “to cause the plurality of needles to extend a desired distance from the releasably couplable deployable needle module end surface” / “to extend the plurality of needles a desired distance from the releasably couplable deployable needle assembly end surface”**

The crux of the parties' dispute centers on whether the construction of the “desired distance” limitation, which appears in all but claims 9 and 18 at issue, should reflect the limited scope of the claimed embodiments, which require a motor to extend a “plurality of needles a desired distance” either from the needle assembly end surface (Ex.1001, cls. 2-6, 8) or the needle module end surface. (*id.*, cls. 13-16). The answer is yes. Even EndyMed's expert, Dr. Woloszko, agrees that the claims are limited to extendable needles. Ex.2154, 183:15-18. EndyMed, however, 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

¹ Serendia reserves the right to advance claim constructions as appropriate in other proceedings.

distance.” ’00845 IPR, Paper 15 (“Jeisys’s Reply to POPR”) at 8.² By their plain language, the claims at issue apply only to needles that “extend”—not needles already “extending.”

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.1005, 16. Thus, the embodiments having extending needles, e.g., Figures 2A-2D, fall outside the scope of the claims. *See, e.g.,* Ex.1003 ¶51; *see also EndyMed Medical Inc. v. Serendia, LLC*, IPR2024-00843, Ex.1003 ¶51. This aligns 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

² All emphases added unless otherwise noted.

certain embodiments described in the specification but not claimed) (citation omitted).

The remaining question is the proper construction of a motor to cause the plurality of the needles to “extend” a “desired distance” from an end surface. Ex.1001, cls. 2-6, 8, 13-16. Serendia proposes the claimed “desired distance” means how far the needles extend from an end surface, based on a user’s selection, to penetrate the dermatological tissue. Serendia’s proposal is consistent with the claims’ plain language and the part of EndyMed’s proposed construction that applies to those claims.

According to the case EndyMed wishes to join, 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.” Jeisys’s Reply to POPR at 8.³ As explained below, the only part of this construction

³ In its Motion for Joinder, EndyMed “agrees to proceed solely on the grounds, claim constructions, evidence, and arguments advanced, or that will be advanced, in the 463 Proceeding” (i.e., ’00463 IPR). Mot., 2. Therefore, Serendia understands EndyMed to adopt Jeisys’s arguments in its reply to Serendia’s Patent Owner Preliminary Response (“POPR”) in the ’00463 IPR cited here.

that applies to the '812 patent claims is “(2) using a motor to extend the needles to a programmed distance.” *Id.*

EndyMed argues that the first alternative—“selecting a cartridge with needles of a particular length”—satisfies the claims based on “user selection of a cartridge having needle lengths corresponding to a desired distance.” *Id.* But this renders the “desired distance” limitation superfluous or makes infringement depend on the mental state of the user, either of which is erroneous. If EndyMed 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) (citations omitted).

If on the other hand EndyMed 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 EndyMed 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.

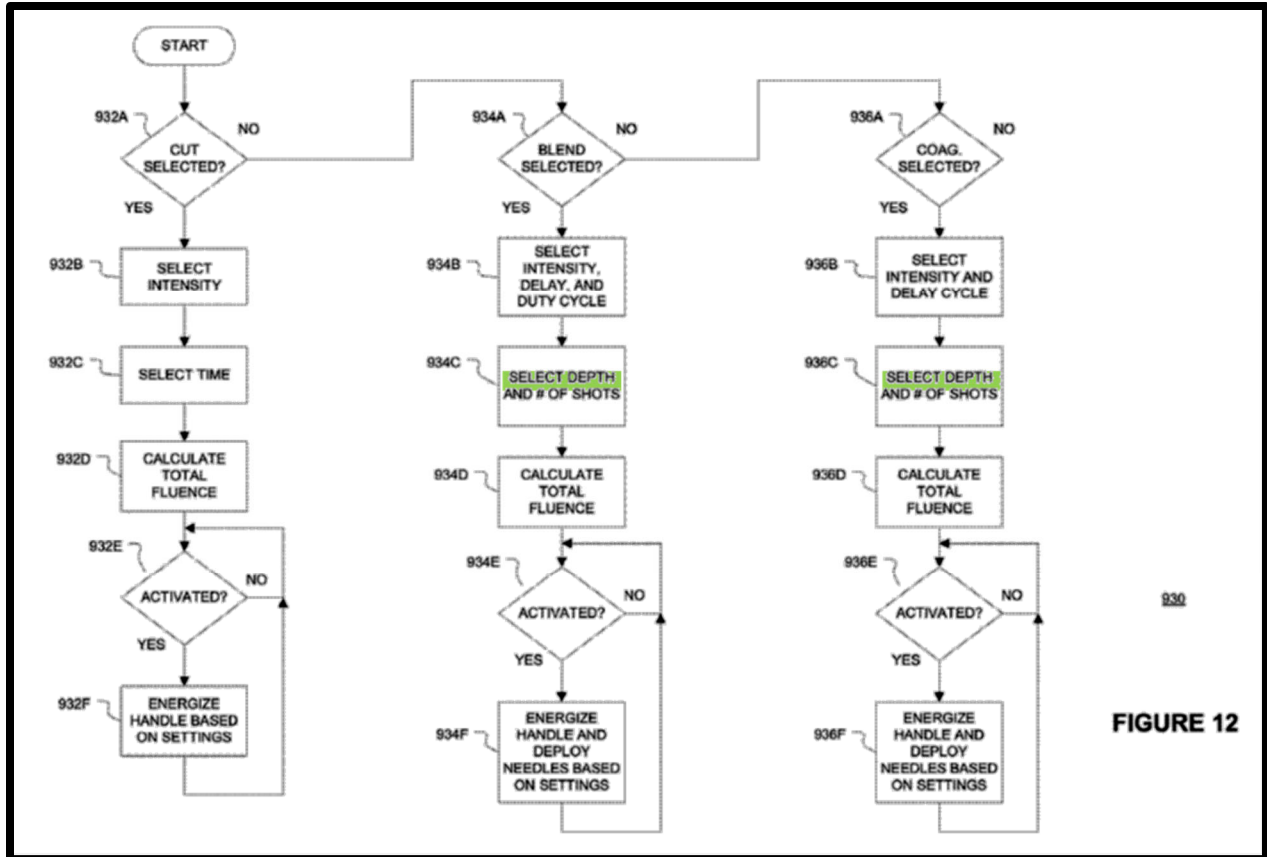
The claims also exclude the third alternative because they require “a motor” to cause the plurality of needles to “extend” a “desired distance” (*id.*, cls. 2-6, 8, 13-16), thus excluding “adjusting the needle depth by *manually* checking the needle location.” Jeisys’s Reply to POPR 8. Jeisys argues in its reply to the POPR for the ’00463 IPR that “*user* adjustment of the needle distance *after* an initial extension” is permitted (*id.*), but this is expressly excluded from the claims because they require using a “*motor*” to cause the “needles to *extend* a desired distance” (Ex.1001, cls. 2-6, 8, 13-16).

Even according to Jeisys, that leaves one way to meet the desired “distance” limitation: “using a motor to extend the needles to a programmed distance.” Jeisys’s Reply to POPR 8. That is consistent with Dr. Woloszko’s admission that a motor extending needles a predetermined distance would satisfy the claims “[a]s long as *you can program this distance*” (Ex.2125 (Woloszko Hr’g Tr.), 1151:8-12), and his opinion that, in the context of the embodiments covering “extendable” needles, “a POSA would understand the plain meaning of ‘a desired distance’ to also encompass any user-selected” distance. Ex.1003 ¶51.

In other words, the claims require using a motor to extend needles to a programmed distance. Ex.2147 ¶69; Ex.2154, 187:12-188:9. This construction is supported by 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, 10:61-65. One parameter is needle deployment depth. *Id.*, 9:65-10:5. The specification describes and illustrates a block diagram for the system architecture in Figure 9A, which includes a display and user input device. *Id.*, 9:53-54. The display “may be touch sensitive so a user may configure one or more operational parameters,” (*id.*, 9:65-66), or the input device may be a keypad, track ball, or other similar input device that allows the user to operate the system. *Id.*, 9:1-4.

The '812 patent also describes a central processing unit (CPU) employing an algorithm (shown in Figure 12 reproduced below, annotated), to control the system architecture, where a parameter inputted into the algorithm is the “selected depth” for the needles to extend.



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.*, 10:32-37; *see also id.*, 10:61-65, 14:63-66, 14:3-4, 14:21-26.

Thus, the specification confirms that the claimed “desired distance” 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.

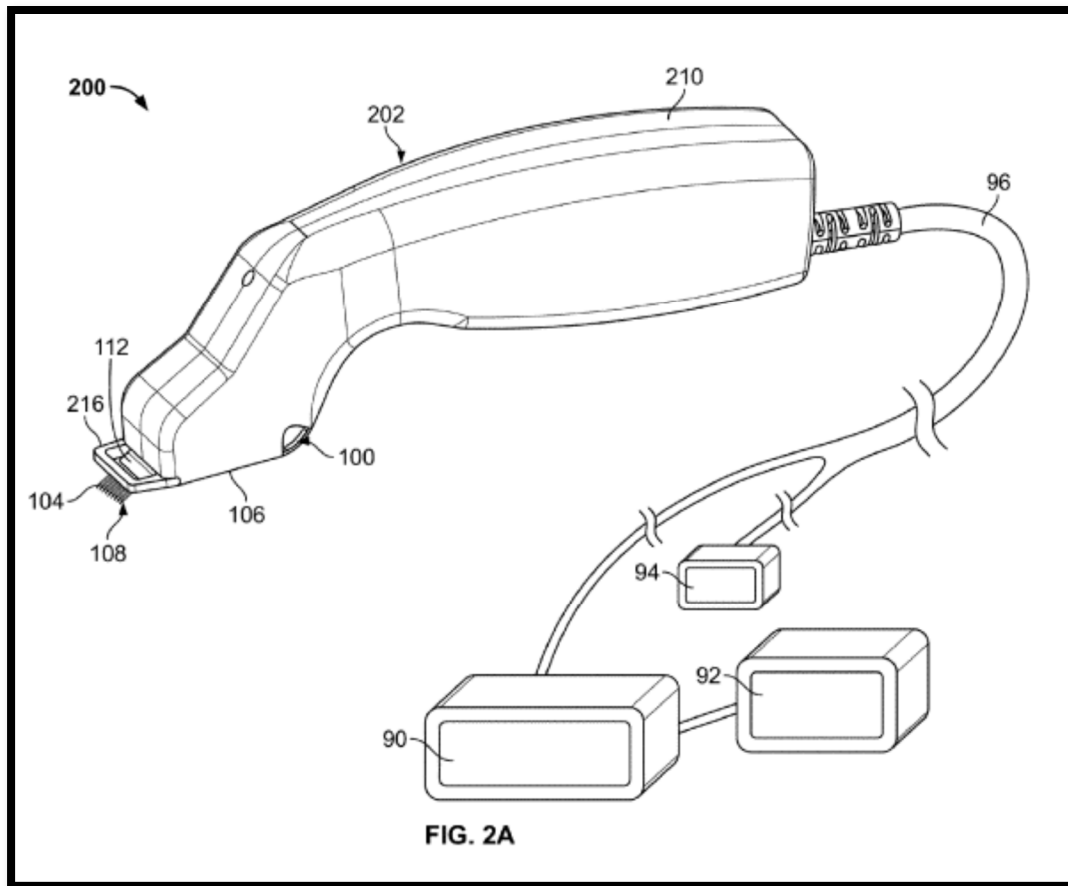
The prosecution history of the '536 Patent, the parent of the '812 Patent, reinforces this construction by “provid[ing] evidence” that this is “how the PTO ... understood the patent.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005) (citation omitted). During the prosecution of the '536 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, 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, 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 claimed “desired distance” is how far extendable needles extend from the device's end surface using a motor programming based on a user programming this distance.

IV. Summary of the Prior Art

A. Mehta

Mehta is a U.S. patent filed in 2009 and issued in 2013. Ex.1006. 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.

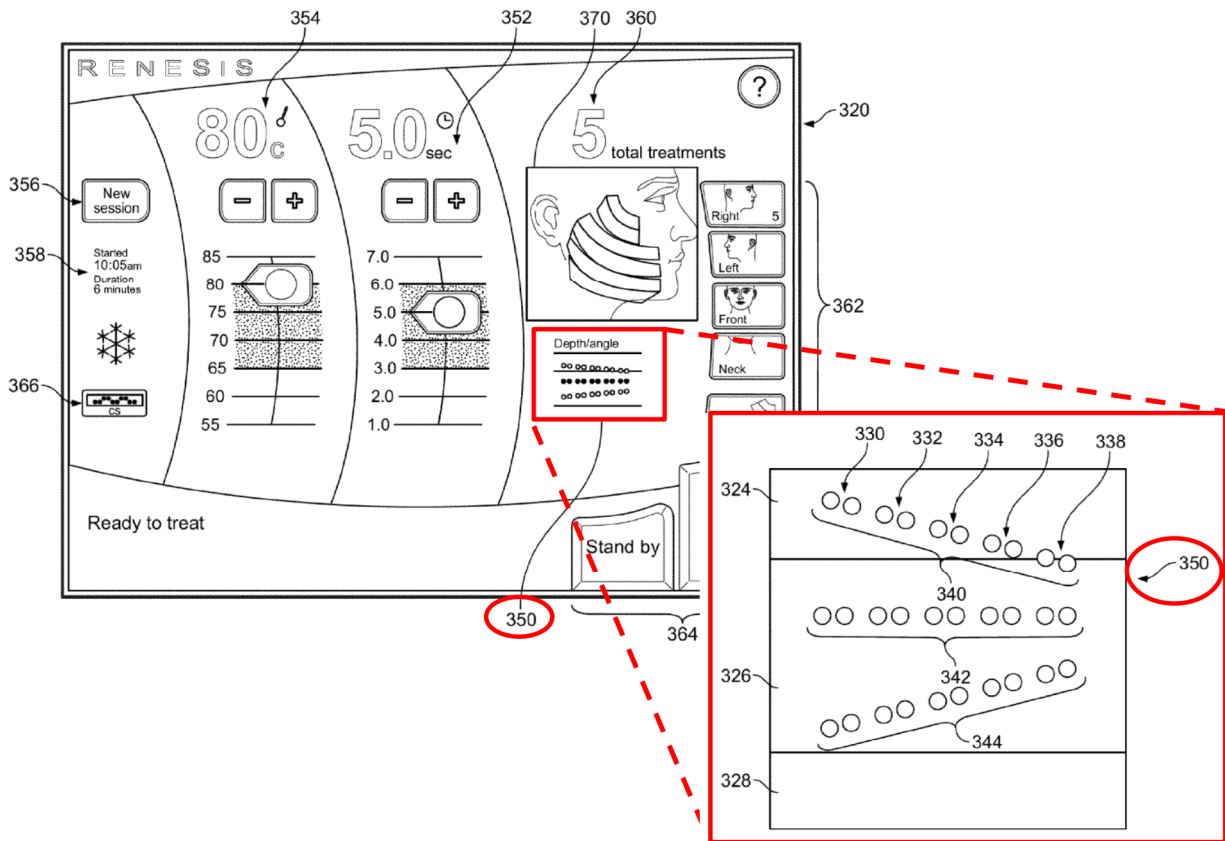


The “tissue engagement surface 106 provides a consistent starting point for the probes” 104 so that, “as the probes 104 advance from the device 202 they are driven to a uniform depth in the tissue” when they “enter the tissue at an oblique angle A as measured relative to the tissue engagement surface 106.” Ex.1006, 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 marking 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 (emphasis added). 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.”).

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.1006, 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. These are additional disclosures of adjusting needle position after the needles have been extended.

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

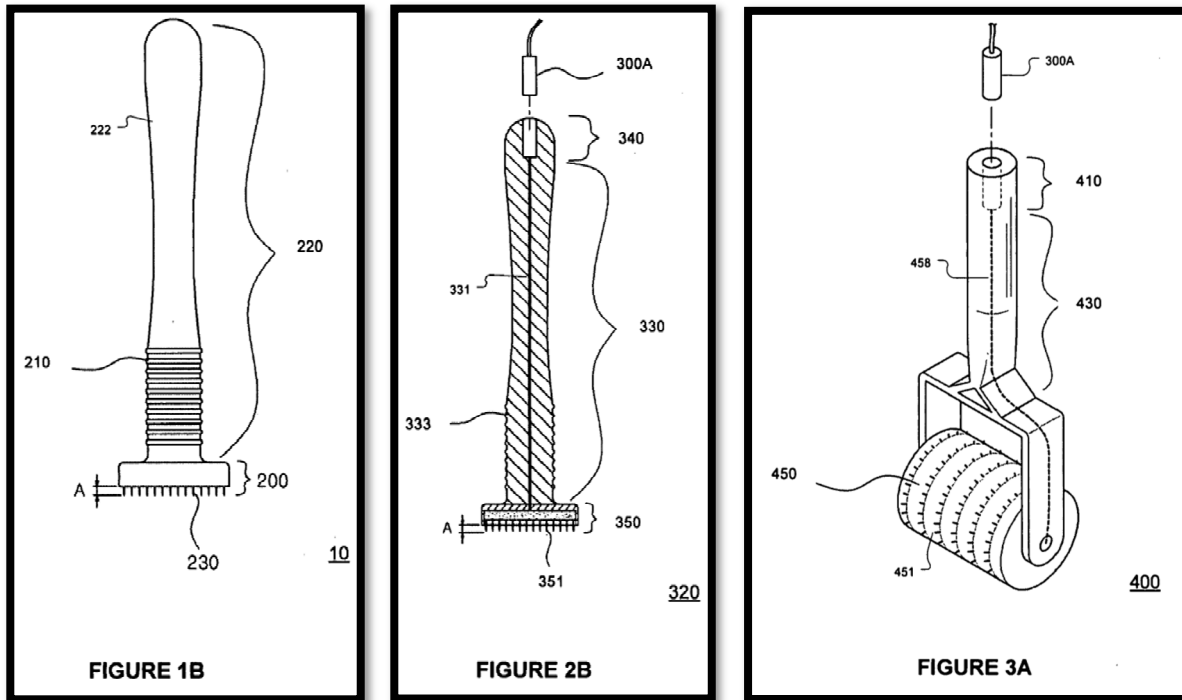
puncturing the tissue” and explains that “[t]he next action would then be an advancement of the probes so that they reach their intended target site.” *Id.*, 21:55-59. Mehta also discloses actuators to drive the probes, which can be “pneumatic cylinders, springs, linear actuators, or other such motors.” *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 a 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. Na '848

Na '848 is an international patent application filed on August 22, 2008, and published on February 11, 2010. It discloses an apparatus with a handle and either a

plate or roller with pins. Ex.1007 (Na '848) ¶¶22-38, Figs. 1A-4C. Figures 1B, 2B, and 3A below are representations of the devices disclosed.

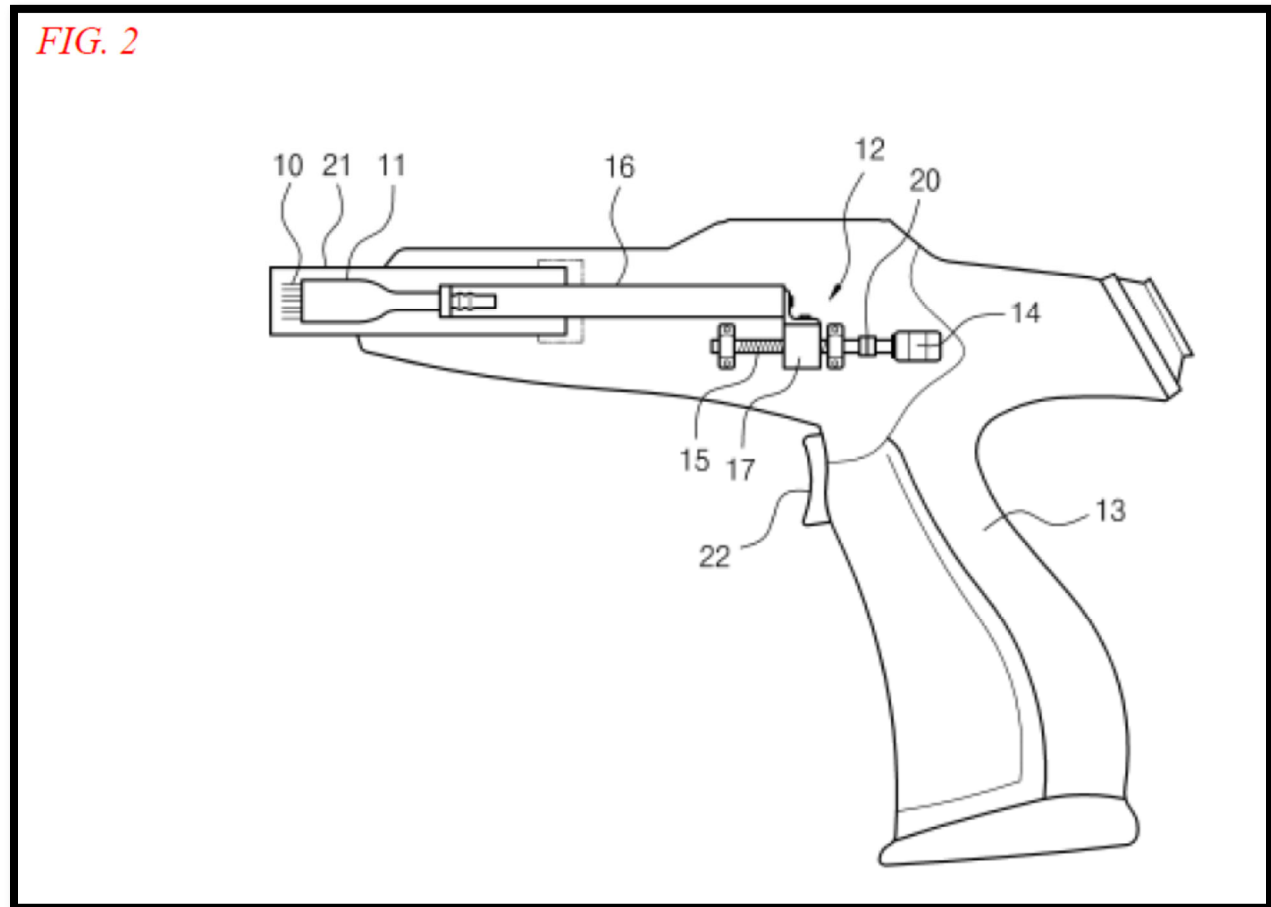


The needles in Na '848 are fixed, with a length A as shown in Figure 1B above. Ex.1007 ¶26. There is no motor to extend or deploy the needles, much less at a distance or depth that a user selects. Ex.2147 ¶90. Na '848 also discloses “FIGS.5A-5B are diagrams of electrical signal waveforms 650, 630, 640 that may be applied to one or more LEDs 32A, 32B, 532 and to the pins 230, 351, 451 according to various embodiments,” such as to “cause one or more pins 230, 351, 451 to vibrate.” *Id.* ¶39.

C. Lee

Lee is a Korean patent publication that published on August 25, 2008. Ex.1009. 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.”

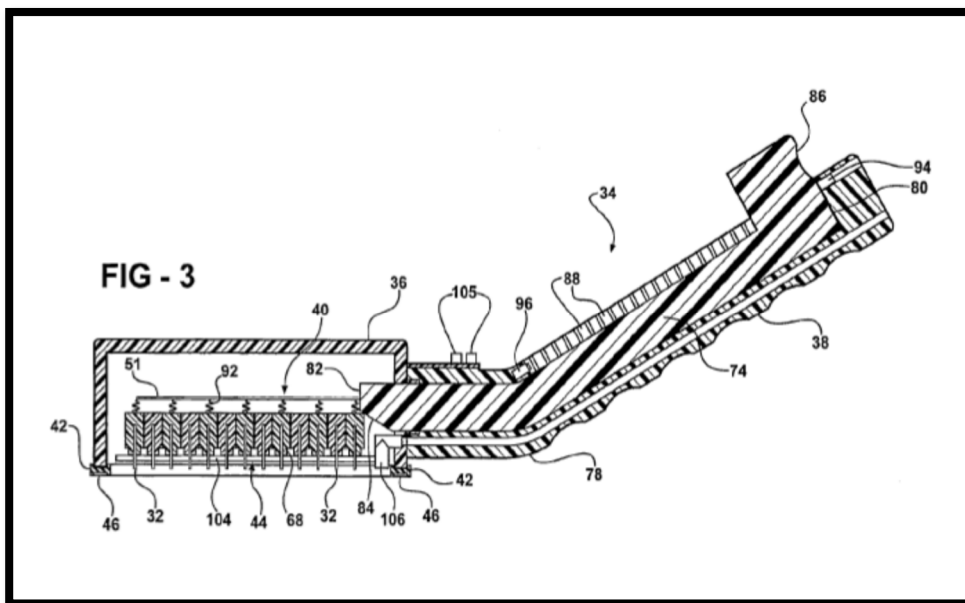
Id., Abstract. Lee's device is a "gun equipped with a plurality of microneedles," as illustrated in Figure 2 below. *Id.*

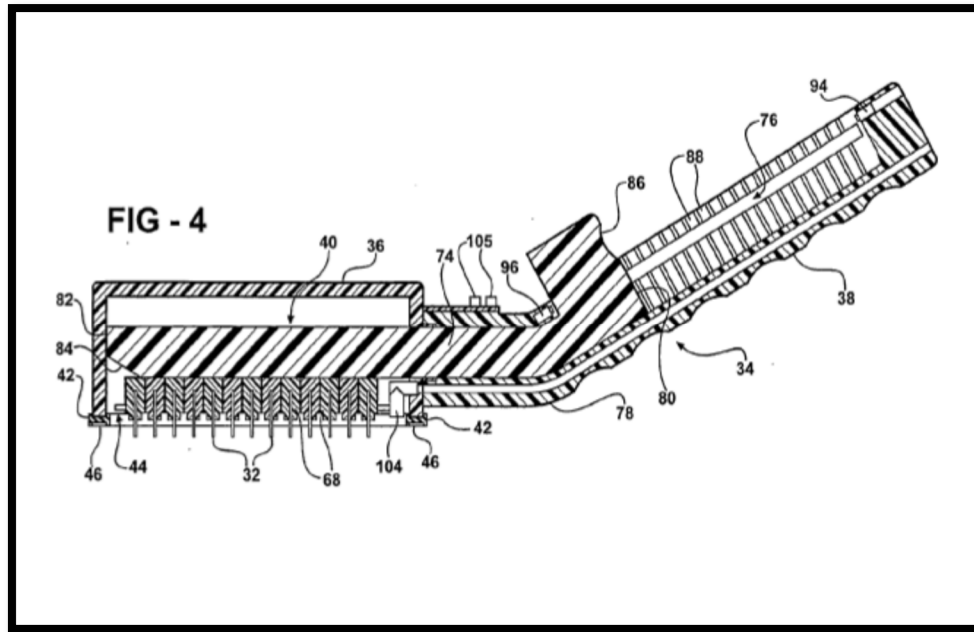


Lee seeks to create "hundreds to tens of thousands of tiny holes ... to regenerate tissue" "without removing or damaging the epidermis of the skin." *Id.* ¶¶15-16. "[T]he process of reciprocating operation of the microneedles is repeated multiple times by repetitively driving the motor back and forth, 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.

D. Livneh

Livneh is an international patent application filed on July 5, 2007, and published on January 10, 2008. It relates to “[a]n electro surgical apparatus” to “appl[y] electrical current to skin.” Ex.1010, Abstract. Livneh discloses an apparatus 30 with handheld unit 34 that includes a “housing 36 [that] is connected to handle portion 38.” *Id.*, [0033]. In Livneh, mechanism 74 fully extends (as shown in Figure 4) and fully retracts to move the electrodes between a first and a second position. *Id.*, [0042], [0046].





V. Ground I: Petitioner fails to demonstrate that Mehta anticipates claims 2, 3, 6, 8, and 13-16

Claims 2, 3, 6, 8, and 13-16 all recite a motor that causes the plurality of the needles to extend a “desired distance” from an end surface. Ex.1001, cls. 2, 8, 13. As discussed, that requires the motor to extend the needles a programmed distance. *See supra* Section III.A. Unlike the '812 patent, Mehta fails to disclose any programming to control how far the needles extend from the device's end surface. In fact, EndyMed does not even contend that Mehta discloses programming the distance that needles extend using a motor. Pet. 25-30. Therefore, as a matter of law,

Mehta cannot anticipate the claims as properly construed.⁴ *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295 (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.”) (citation omitted). That alone disposes of EndyMed’s anticipation argument.

There is no dispute that Mehta discloses an actuator such as a motor to drive the needles into tissue. *E.g.*, Ex.1006, 13:58-65. That alone, however, is insufficient to meet the requirements of the claims because they require a motor to extend the needles a programmed distance. *See supra* Section III.A

Even EndyMed’s expert agrees that distance has to be programmed, but he points to nothing in Mehta disclosing a program or algorithm to extend the needles

⁴ The prosecution of the ’812 Patent reinforces that Mehta does not disclose needles that extend the claimed “desired distance.” During prosecution, the Examiner considered U.S. Patent No. 8,540,705 (Mehta ’705, Ex. 1011), which contains the same disclosures Jeisys relies on here. Ex 1001, 2(56) (References Cited); Ex. 2117, 10:20-11:27, 15:63-17:19, 19:1-25; Ex. 2147 ¶98. But the Examiner did not reject those claims based on Mehta ’705. Ex. 1002, 577-582, 645-651. In other words, although the Examiner had same disclosures in Mehta that Jeisys relies on here, the Examiner did **not** contend that they disclose the claimed “desired distance.”

a desired distance. Ex.2125 (Woloszko Hr'g Tr.), 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 tissue (whether by a motor, actuator, or otherwise) and various means are used to determine whether needles that already penetrated the tissue have reached the desired treatment area (e.g., via needle markings and a virtual depiction system in a GUI).

EndyMed makes three main arguments to argue Mehta discloses the claimed desired distance limitation, but none support that Mehta teaches programming the distance needles extend using a motor as required.

First, EndyMed argues Mehta discloses an interface that shows the “desired depth of placement” to avoid placing the needles in an undesired region. Pet. 27 (citing Ex.1006, 32:63-33:3, 33:35-43). EndyMed 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. 28 (citations omitted). Thus, according to EndyMed, Mehta “discloses ‘[guiding] probe placement’ by ‘[adjusting]’ the system, and provides a stepper motor to support such adjustments. *Id.* (citations omitted).

The Board in the '00463 IPR 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." '00463 IPR, Paper 20 ('00463 ID) 16. 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 programming how far the needles extend using a motor or mechanism, which is what the claims require and Mehta fails to disclose. Ex.2147 ¶¶100-104.

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.1006, 32:63-33:43 (cited in Pet. 27). 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. Ex.2147 ¶101.

Also, providing feedback to the physician that “further advancement of the probes is necessary” after they have been extended into the tissue teaches nothing about programming a motor to extend the needles a desired distance, which even EndyMed’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.

Second, EndyMed relied on Mehta’s supply unit to argue that “Mehta discloses that the motor causes the needles to extend when energized with a particular signal” as required by claim 13. Pet. 29. The Board in the ’00463 IPR agreed, finding that “[a]long with the GUI, control system/energy supply unit 90 is provided for allowing the user to selectively control and adjust insertion of the needles based on feedback from the GUI.” ’00463 ID 17. But what EndyMed points to and Mehta discloses as “command signals” (Pet. 29 (citing to Ex.1006, 12:5-8)) has nothing to do with selecting a distance that the motor extends the needles. Ex.2147 ¶105. Mehta never discloses distance or depth as one of the “control and processing variables.” Ex.1006, 12:5-8; Ex.2147 ¶105. EndyMed invites error in arguing that the Board should treat those unspecified “command signals” as a signal controlling distance or depth. *Wasica Fin. GmbH v. Cont’l Auto. Sys., Inc.*, 853 F.3d 1272, 1284 (Fed. Cir. 2017) (“it has long been understood that ambiguous references

do not, as a matter of law, anticipate a claim”) (affirming the Board’s finding of patentability because the prior art reference was “at best ‘unclear’”).

EndyMed’s reliance on Mehta’s disclosure of a “step-motor” also fails. In his declaration, EndyMed’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 ¶98. 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 using a motor to cause to extend/to extend the plurality of the needles “a desired distance,” which requires programming how far the needles extend using that motor, and Mehta simply fails to disclose this. Ex.2147 ¶105.

Third, EndyMed 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. 28-29. In its Petition, EndyMed 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.* 28. The Board in the ’00463 IPR did not seem to rely on these teachings as a basis for instituting Jeisys’s Petition. ’00463 ID 16-18. Regardless, Mehta’s selection of a cartridge with fixed length or angled needles is outside the scope of the claims under their proper

construction. *See supra* Section III.A. Moreover, “a user selecting a cartridge with a different array configuration would be akin to manual selection of how far the needles will extend to reach a target tissue,” which is outside the scope of the claims. Ex.2147 ¶100. Thus, EndyMed’s reliance on Mehta’s cartridge selection fails to meet the claims. As to Mehta’s disclosure of “[o]ver-inserting and then partially retracting” the needles (Pet. 28 (original alteration)), Mehta discloses this as an automated process that simply “compensates for the movement and laxity of the skin resulting in a more reliable insertion.” Ex.1006, 16:34-41; Ex.2147 ¶106. 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 ¶106; *see generally* Ex.2154, 71:8-15.

In its institution decision for the ’00463 IPR, 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.” ’00463 ID 17. 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.1006, 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.” 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 involves how to reach a target region. *Id.*

Because Mehta fails to disclose programming how far the needles extend using a motor, Mehta cannot and does not anticipate the claims 2, 3, 6, 8, and 13-16.

VI. Ground II: Petitioner fails to demonstrate that Mehta in view of the knowledge of a POSITA renders obvious claims 2-6, 8 and 13-16

Mehta fails to disclose several limitations of claims 2-6, 8 and 13-16, and EndyMed fails to show why a POSITA would have been motivated to modify Mehta to arrive at a system with those features, particularly in light of Mehta's contrary disclosures. EndyMed also ignores secondary considerations that rebut its obviousness arguments.

A. A POSITA would not be motivated to modify Mehta to include the claimed desired distance

As explained above with respect to Ground I (*see supra* Section V), Mehta does not teach the “desired distance” limitation. It also does not suggest this limitation, and EndyMed fails to meet its burden to establish that a POSITA would have been motivated to modify Mehta to include that feature.

Mehta recognized “a need to provide systems that can deliver energy to a predetermined target area while minimizing delivery of energy to undesired region of tissue.” Ex.1006, 2:9-12. To address that need, Mehta sought minimize the

variance associated with different needle insertions by using a “tissue engagement surface” that provides a “consistent starting point” for the needles. *Id.*, 21:10-16. Recognizing that variation in probe depth will still occur, Mehta discloses different means to compare “actual depth” to the “desired depth” and other ways of tracking insertion depth. Modifying Mehta to add a “distance setting” would increase not only the complexity of the system, but also the variation in the depth of the probes. Pet. 40, 41; Ex.2134 ¶89. Thus, the modification would not lead to “superior treatment outcomes” of treatment and “decrease treatment costs,” as EndyMed proposes. Pet. 40, 41; Ex.2147 ¶¶109-115.

Further, EndyMed ignores that Mehta was aware of distance control, but chose a different approach to delivering energy to a target location. As one example, in its Background Mehta cites U.S. Patent No. 6,277,116 to Utely (“Utely”), which 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 ’812 Patent petition for which the PTAB denied institution, discloses electrodes that can be “advanced to a selected deployment depth.” Ex.2120 (Morris ’261), Abstract. Thus, Mehta understood that selection of probe depth was known, but teaches 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.1006, 2:10-12, 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”); Ex.2134 ¶91. Mehta focuses on minimizing variation during needle extension and providing information to fine tune needle depth after the needles have been extended into the tissue. Ex.2147 ¶113.

EndyMed's reliance on Mehta's “step-motor” also fails. And even assuming, as EndyMed's expert contends, that a POSITA “would ... have known how to program a controller to cause the step-motor of Mehta to move the needles 104 to any specific intermediate step between a fully retracted position and a fully extended position[]” (Ex.1003 ¶148), EndyMed and its expert fail to explain *why* a POSITA would have been motivated to modify Mehta's step-motor to include such a feature, particularly in light of Mehta's system and operation. *See, e.g., 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 in view of contrary disclosures in that reference); *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[.]”).

EndyMed argues that a POSITA would be motivated to use a single cartridge to streamline treatments, and in that context argues that “[a]n additional motivation would be to facilitate compound treatments that target different layers of the skin” by moving needles from a first depth to a second depth. Pet. 41. But even EndyMed’s own expert agrees that Mehta only discloses reaching different target regions using a single cartridge by over-inserting and retracting the needles and changing the angle of the needles. Ex.2154, 71:8-15. And while neither meets the claim limitations (*see supra* Section V), they highlight that a POSITA would not be motivated to modify Mehta as EndyMed contends.

EndyMed’s obviousness analysis is woefully lacking and insufficient to show obviousness by a preponderance of the evidence. Aside from Mehta, EndyMed cites only its expert declaration and no other evidence to support that it would have been obvious to modify Mehta to supply the missing “desired distance” limitation. This is plainly insufficient. In similar situations, the Federal Circuit has repeatedly admonished against relying on so-called “common sense” to fill a missing limitation, stating that such analysis must be “supported by evidence and a reasoned explanation” and that the Board’s analysis “must be searching”—which is “particularly true where” as here “the missing limitation goes to the heart of [the] invention.” *Arendi SARL v.*

Apple Inc., 832 F.3d 1355, 1363 (Fed. Cir. 2016); *see also K/S HIMPP v. Hear-Wear Techs., LLC*, 751 F.3d 1362, 1366 (Fed. Cir. 2014) (“[T]he Board cannot accept general conclusions about what is ‘basic knowledge’ or ‘common sense’ as a replacement for documentary evidence for core factual findings in a determination of patentability.”) (citations omitted).

Additionally, EndyMed’s expert declaration makes multiple broad factual statements to support the hindsight-driven purported modification (*e.g.*, Ex.1003 ¶¶147, 148) without citation to any documentary evidence showing these to be true. It was EndyMed’s burden to provide evidence in support of these findings; EndyMed 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 ’536 Patent’s claims. *In re Van Os*, 844 F.3d 1359, 1361 (Fed. Cir. 2017) (original emphasis) (citation omitted). The Federal Circuit has similarly recognized that “to invoke ‘common sense’ or any other basis for extrapolating from prior art to a conclusion of obviousness, [the fact finder] must articulate its reasoning with sufficient clarity for review.” *Perfect Web Techs. Inc. v. InfoUSA Inc.*, 587 F.3d 1324, 1330 (Fed. Cir. 2009). EndyMed’s Petition and expert declaration fail to satisfy this standard.

EndyMed improperly uses the '812 patent claims as a roadmap for reconstructing the claimed invention without showing that a POSITA would have been motivated to modify Mehta to achieve it. *See Univ. of Strathclyde v. Clear-Vu Lighting LLC*, 17 F.4th 155, 165 (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. 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). Thus, EndyMed's obviousness arguments fail.

B. Nothing in Mehta discloses or suggests claims 4's and 17's "embedded LED" to illuminate the needle module/assembly "when energized"

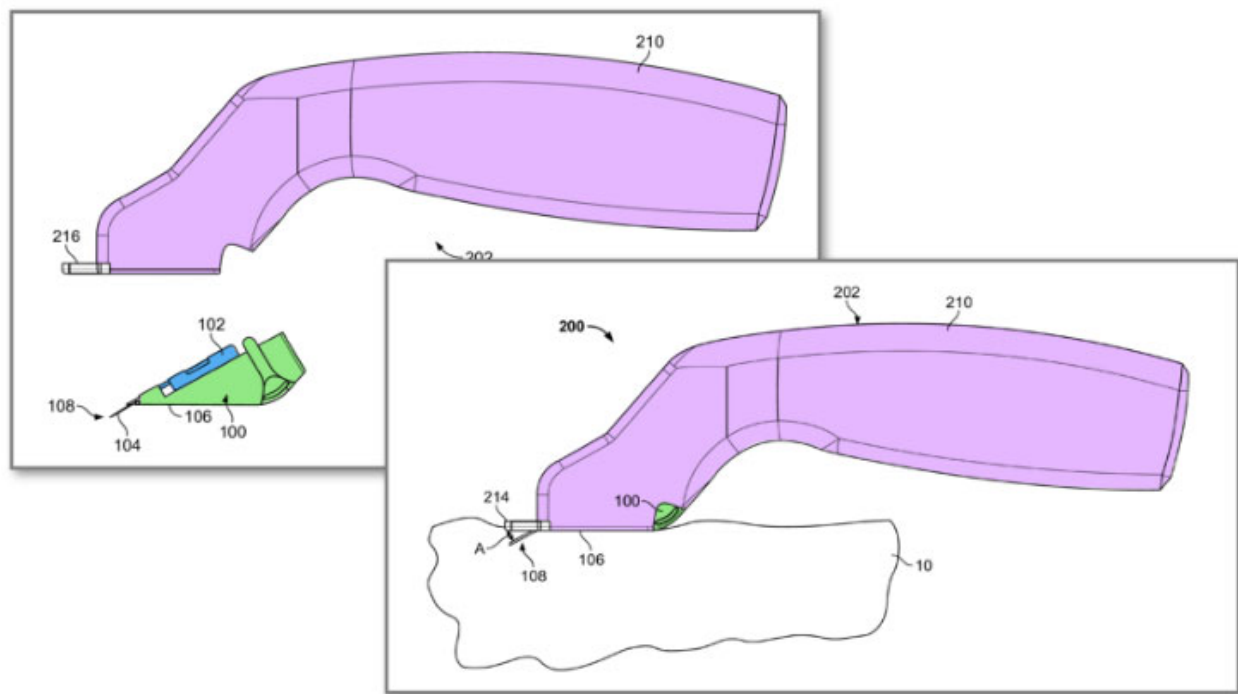
Claim 4 depends on claims 1-3, and claim 17 depends on claim 12. Claims 4 and 17 respectively require "the user holdable device proximal end further includes at least one embedded LED" that "illuminates the releasably couplable deployable

needle module” (claim 4) or is “capable of illuminating the needle assembly” (claim 17). Ex.1001, cls. 4, 17. Mehta, however, does not disclose an LED embedded in the proximal end of the user holdable device that illuminates the deployable needle assembly or module when energized. EndyMed’s obviousness arguments fail for at least two reasons.

First, EndyMed contends that a POSITA would be motivated “to illuminate the needles 104/needle assembly 102” in Mehta “to assist a physician in confirming the intended treatment area ... or to illuminate depth markings or other distinguishing features of the needles.” Pet. 44-45 (citations omitted). But Mehta already discloses different mechanisms for that purpose. For example, Mehta explains that the invention “allows marking of the treatment site” by including marking lumens to “allow[] the practitioner to place a mark at the treatment location to avoid excessive treatments.” Ex.1006, 23:36-42. As another example, Mehta discloses “a window located between the stabilization plate and the tissue engaging surface, where the window is configured to permit direct visualization of advancement of the energy transfer elements into the entry point.” *Id.*, 4:19-23. It also discloses a virtual depth/location depiction 350 system to confirm the location of the probe array before treatment. *Id.*, 32:63-33:3. Thus, Mehta already discloses several other mechanisms for the physician to confirm the intended treatment area. Ex.2147 ¶118.

Second, EndyMed's generic assertions that adding an LED would be routine engineering and a matter of design choice (Pet. 44), ignore that a POSITA would not add the LED at a location to illuminate the deployable needle assembly or module, as claims 4 and 17 require. The question is not whether adding an LED to Mehta would be routine engineering, but whether adding an LED to Mehta to illuminate the needle assembly or module would. The answer is no. Ex.2147 ¶119.

Mehta discloses an electrode assembly 102 (blue) within a removable cartridge 100 (green), both of which are inserted into the device body 210 (purple). Ex.1006, Figs. 2B, 2D (annotated below).



According to Dr. Woloszko, the LED would be around element 216. Ex.2148 (Woloszko ITC Dep. Tr.), 416:11-19. Even assuming a POSITA were motivated to

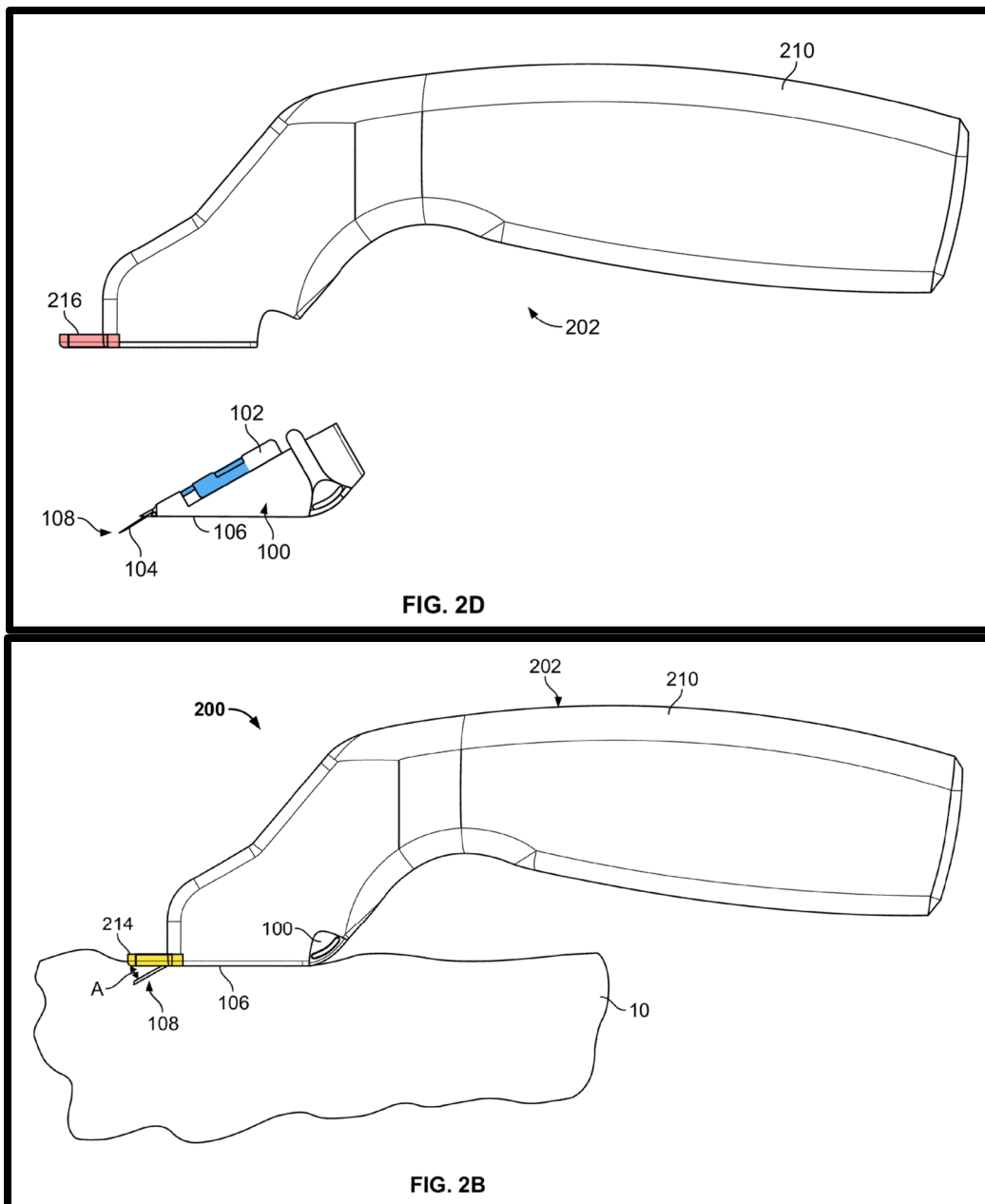
include an LED around element 216, such an LED would not illuminate the needle assembly 102 or the cartridge 100 because they are located entirely within the device body 210, and adding an LED on the device 210 around the window 216 would not illuminate either component. Ex.2147 ¶121.

EndyMed contends that a POSITA “would have been motivated to embed the LEDs to provide a visually appealing product (to both physicians, i.e., customers, and patients) with a sleek outer profile” (Pet. 44), but that ignores the realities of Mehta and requirements of the claims. To illuminate the needle assembly or cartridge of Mehta with an LED embedded in the handpiece, either those components would need to be transparent or the entire handpiece, needle assembly, and cartridge of Mehta would have to be redesigned. Ex.2147 ¶121. A POSITA would not be motivated to make the handpiece, needle assembly, or cartridge transparent because doing so would expose the internal components of the device, including the motor and wiring, which would lead to an aesthetically unpleasing and potentially scary looking device. *Id.* There would be no motivation to do so, particularly when Mehta already teaches other means to confirm the treatment area. *Id.* And redesigning Mehta to include the configuration of the '812 patent is nothing but impermissible hindsight. *See Univ. of Strathclyde*, 17 F.4th at 165.

C. Nothing in Mehta discloses or suggests the translucent section limitations of claim 5

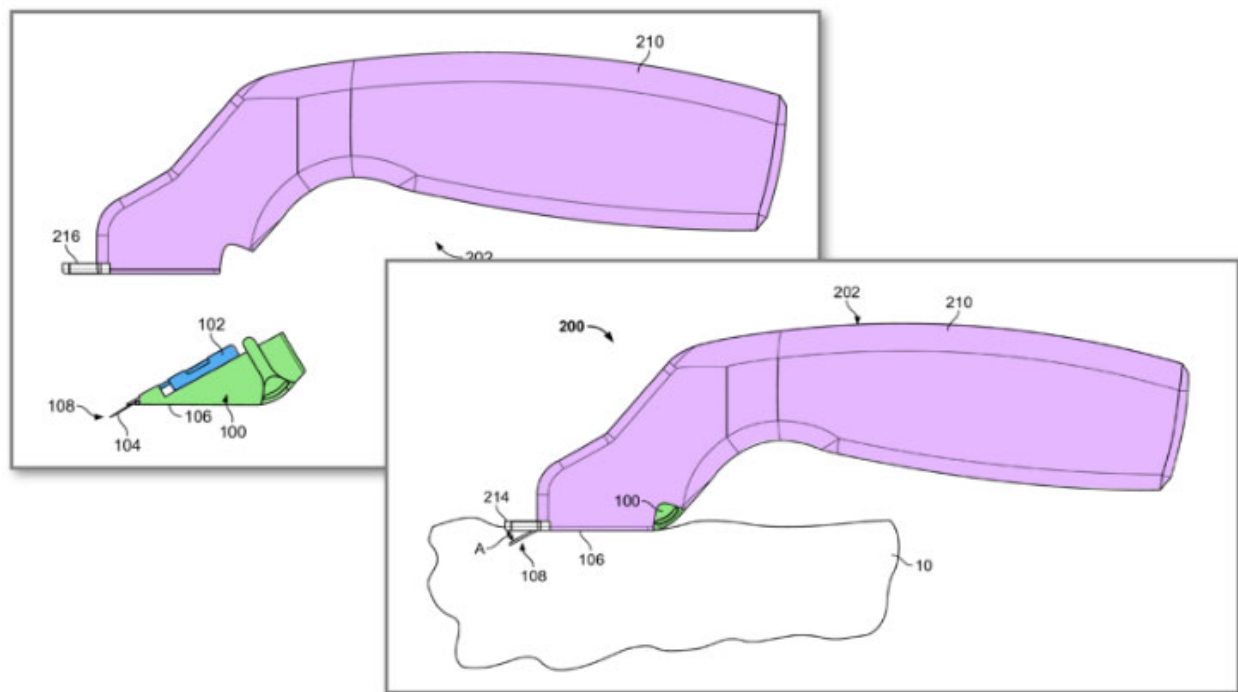
Claim 5, which depends on claims 1-4, recites “wherein the needle assembly includes a translucent section and further including energizing the at least one embedded LED to illuminate the plurality of needles via the needle assembly translucent section.” Ex.1001, cl. 5. Mehta nowhere discloses that limitation, and a POSITA would not be motivated to modify Mehta to include it.

To begin with, nowhere does Mehta describe the electrode assembly 102 or any portion of the removable cartridge 100 as transparent or translucent. EndyMed appears to admit as much as it only contends that “Mehta discloses that portions of the treatment device 202 are translucent.” Pet. 50 (citing Ex.1006, 22:65-23:10). But the portion of Mehta that EndyMed relies on refers to Mehta's cooling surface (Ex.1006, 22:65-23:10), which is *not* part of the needle assembly. As shown below in annotated Figures 2D and 2B of Mehta, neither the stabilization plate 214 (aka the cooling surface) (in yellow) nor feature 216 (in pink) are part of (or even exposed to) the electrode assembly 102 (in blue).



EndyMed offers two motivations to make the needle assembly translucent (1) to “prevent an opaque material from shading the tissue to be treated from illumination” and (2) to “further enhance the visual appearance of the device 202 by utilizing a material that would provide for diffuse reflection and transmission of the illuminating light provided by the LED and thereby create a visually-appealing

glow.” Pet. 46. EndyMed’s argument fails because simply making “needle assembly 102” “translucent” would not meet the requirements of claim 5. The electrode assembly 102 and cartridge 100 are entirely enclosed within the body portion 210 of the handle, which Mehta does not describe as—and EndyMed does not argue would be—transparent or translucent. Therefore, even if the electrode assembly 102 and cartridge 102 were transparent or translucent, illumination from an LED in the proximal end would be blocked by the opaque handle body (purple). Ex.2147 ¶123.



A POSITA would also not be motivated to make the electrode assembly 102, cartridge 10, or the body portion 210 of the handle transparent or translucent. First, doing so would not lead to an appealing device because the internal components of the handle would be visible, including the motor, wires, fasteners, etc. Ex.2147 ¶123.

Second, there would be no reason for making such components translucent or transparent. As explained above, Mehta already discloses a mechanism to confirm the treatment area (e.g., a window to see the entry point of the needles and using dyes and lumens to mark the treatment cite). A POSITA would not be motivated to redesign Mehta to include LEDs and transparent components that would lead to an unappealing device to arrive at the claimed invention. *Id.*

Mehta has its own solution to the issue of visualizing the treatment area. It simply does not meet the requirements of claim 5. EndyMed's obviousness argument is pure hindsight reconstruction of the claimed invention. *Univ. of Strathclyde*, 17 F.4th at 165.

VII. Ground III: Petitioner fails to demonstrate that Mehta in view of Na '848 and the knowledge of a POSITA renders obvious claims 4-5 and 17

The combination of Na '848 and Mehta fails to disclose or render obvious claims 4-5 and 17. EndyMed does not rely on Na '848 for the "desired distance" limitation, which as explained above Mehta fails to disclose or suggest. *See supra* Sections V, VI. Nor could it. Na '848 does not disclose a motor to extend needles. Ex.1007, [0022]; Ex.2147 ¶90; Ex.1003 ¶44. Because neither Mehta nor Na '848 disclose the "desired distance" limitation, the combination does not either.

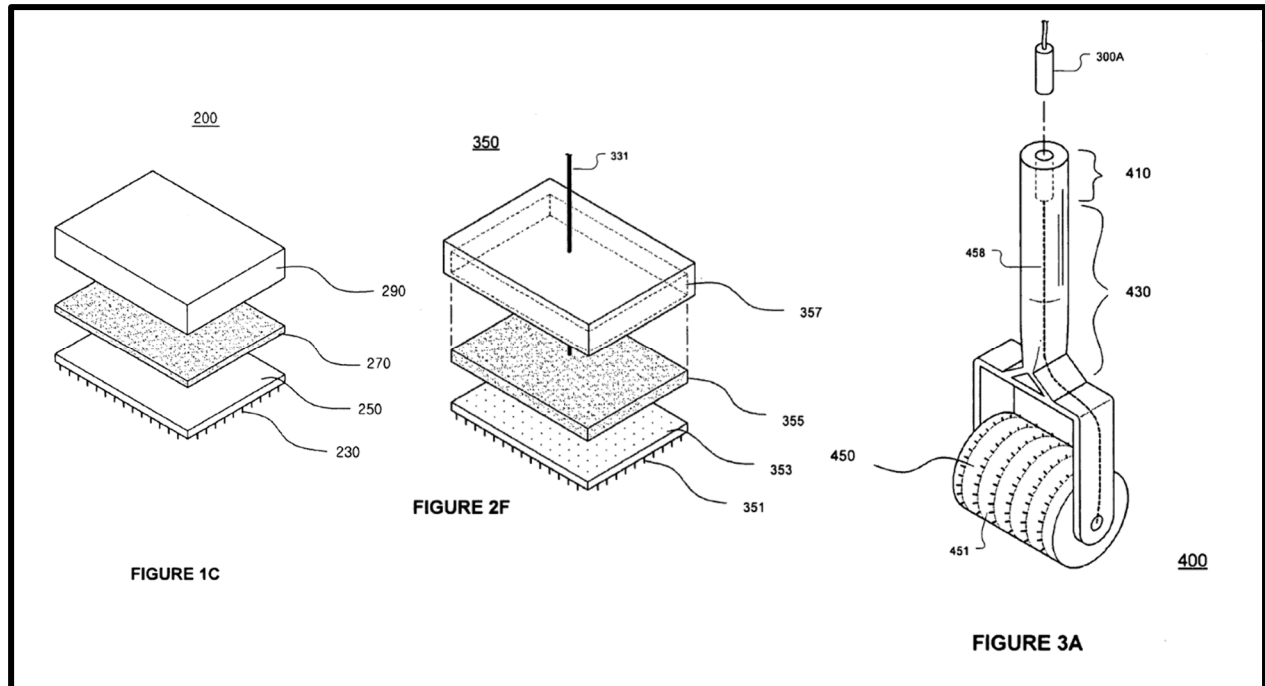
EndyMed relies on Na '848 only for the LED and translucent needle assembly section limitations that Mehta fails to teach or suggest (*see supra* Sections VI.B., VI.C). But EndyMed's arguments fail for at least two reasons. **First**, Na '848

discloses neither limitation. *Second*, a POSITA would not have been motivated to combine Mehta and Na '848 to achieve them.

A. Na '848 does not disclose the claimed LED (claims 4 and 17) or the claimed a translucent section (claim 5)

Serendia does not dispute that Na '848 discloses LEDs on the needle plate or roller, and that the needle section may be translucent. Ex.1007 ¶¶34, 35, 38, Figs. 1A-4C. But the claims of the '812 Patent require more. Claims 4 and 17 require an embedded LED in the *user holdable device proximal end*. Ex.1001, cls. 4, 17. And claims 5 and 15 further require that the “*needle assembly* include[] a translucent section” and “illuminat[ing] the plurality of [extendable] needles via the needle assembly translucent section.” Na '848 discloses neither, and EndyMed fails to contend otherwise.

As for claims 4 and 17, EndyMed does not argue that Na '848 discloses an LED on the proximal end of the handpiece. *See, e.g.*, Pet. 52. The LEDs in Na '848 are on plate or roller 200, 350, or 450 (Ex.1007 ¶34), which as shown below is *not* part of the handpiece (Ex.2147 ¶125), as the claims require.



As for claim 5, EndyMed contends that “Na ’848 discloses a needle assembly in the form of a plate that includes a plurality of needles and a translucent section.” Pet. 52. EndyMed is wrong. The claims require that the needle assembly be “mechanically separabl[e] from the user holdable device proximal end” and that it include “a plurality of needles” that extend from the deployable needle assembly end surface. Ex.1001, cl. 1. “[N]owhere does Na ’848 disclose that the plate or roller can be mechanically separable from the handle or that the plate or roller includes needles that extend from an end surface.” Ex.2147 ¶125. EndyMed’s expert agrees. Ex.1003 ¶44; Ex.2148 (Woloszko ITC Dep. Tr.), 439:19-440:7; Ex.2125 (Woloszko Hr’g Tr.), 1046:23-1047:2. That a portion of Na ’848’s plate can be translucent is not enough to meet claim 5. Ex.2147 ¶125. EndyMed points to the figures of the ’812 Patent illustrating the same acupuncture-type apparatus as Na ’848 (Pet. 52-53), but

those embodiments are not claimed in the '812 Patent. *See supra* Section III. EndyMed's reliance on unclaimed embodiments does not support that Na '848 includes the limitation of claim 5.

B. A POSITA would not have been motivated to combine Mehta with Na '848 to arrive at the claimed invention

EndyMed presents bare and generic assertions of a motivation to combine Mehta and Na '848, which fail to support obviousness. *See generally ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1328 (Fed. Cir. 2012) (affirming non-obviousness because the Verizon's experts' testimony was 'generic and b[ore] no relation to any specific combination of prior art elements' and failed "to explain why a person of ordinary skill in the art would have combined elements from specific references in the way the claimed invention does") (citation omitted).

First, EndyMed's assertions that "Mehta and Na '848 are readily combinable because both references are directed to systems and methods of treating dermatological tissue using energized microneedles" (Pet. 48), are not only too conclusory to support obviousness but also wrong. *Securus Techs., Inc. v. Glob. Tel*Link Corp.*, 701 F. App'x 971, 977 (Fed. Cir. 2017) (affirming finding that broad characterization of the prior art "as both falling within the same ... field ... without more, is not enough for [the patent challenger] to meet its burden of presenting a sufficient rationale to support an obviousness conclusion") (citation omitted). Mehta

and Na '848 tackle different problems, and their distinct design and operation would not have motivated a POSITA to combine them.

Mehta aims to provide “improved systems and methods of percutaneously **delivering energy** to tissue where the systems and methods enable a physician (or other medical practitioner) to precisely control the areas or region of tissue that receives energy.” Ex.1006, Title, 2:37-41; *see also id.*, 3:42-44. To do so, Mehta discloses several means to confirm the location of the already-inserted needles (*e.g.*, *id.*, 12:1-4 (“ultrasound”), 21:10-12 (“a consistent starting point”), 32:46-57 (“virtual depiction”), 39:33-36 (“impedance measurements”)), to ensure energy is not delivered to an unintended location. *Id.*, 15:65-16:11.

In contrast, Na '848 is an acupuncture-type device used “to create a plurality of micro-wounds or holes in dermalogical [*sic*] layers of” skin. Ex.1007 ¶25. Na '848 is a simple device that is not concerned with confirming the location of the needles once they penetrate tissue because Na '848 does not deliver electrical energy to skin via the needles. Ex.2147 ¶126. Na '848 instead only discloses using electrical energy to vibrate the needles themselves. Ex.1007 ¶¶28-29. In fact, as Dr. Woloszko admits, Na '848 does not mention supplying radiofrequency to the needles at all. Ex.2125, 1046:5-10.

Second, EndyMed glosses over the requirements of the claims and the realities of Mehta and Na '848 to the claimed device. But as the Federal Circuit has

found “[o]bviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention.” *Univ. of Strathclyde*, 17 F.4th at 162 (quoting *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 546 (Fed. Cir. 1998)). Yet, that is exactly what EndyMed proposes, improperly engaging in hindsight reconstruction of the claimed invention.

As for the LED limitation of claims 4 and 17, as explained above (*supra* Section VI.B), there would be no motivation to embed an LED in the proximal end of the handle in Mehta to illuminate the needle assembly or module. Ex.2147 ¶¶117-121, 127. And resorting to Na '848 which discloses neither an LED in the required location nor a needle assembly at all would not provide a POSITA with a motivation to modify Mehta to arrive at the claimed invention. *Id.* ¶¶126-127. The same is true for claim 5, since again, neither Mehta nor Na '848 teach or suggest an “embedded LED to illuminate the plurality of needles via the needle assembly translucent section.” *See supra* Sections VI.C, VII.A. And even if the electrode assembly in Mehta were translucent (it is not), a POSITA would not have combined Mehta and Na '848 to achieve the claimed invention because the electrode assembly is encased within other components—the cartridge and the device body. Ex.2147 ¶¶116-121, 127. No light from an LED would travel through a translucent section of the needle assembly to illuminate the needles, as claim 5 requires. *Id.* ¶¶122-123, 127; *see supra* Section VI.C.

Accordingly, EndyMed fails to show that claims 4-5 and 17 would have been obvious in view of Mehta and Na '848.

VIII. Ground IV: Petitioner fails to demonstrate that Mehta in view of Lee renders obvious claims 2-3, 6, 8, or 13-16

EndyMed relies on Lee only for the “desired distance” limitation and the “predetermined depth” limitation of claim 6 and contends it would have been obvious to combine Lee with Mehta. Pet. 53 But EndyMed ignores the purpose, design, and operation of both references, which would not have motivated a POSITA to combine them. EndyMed also ignores secondary considerations that rebut its obviousness arguments.

EndyMed 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.” *Id.* 54 (citing Ex.1003 ¶194). This superficial assertion fails to justify the combination. 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.”) (internal quotation marks and citations omitted), *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. 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.1006, 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), 21:10-12 (“a consistent starting point”), 32:46-57 (“virtual depiction ... of the depth”), 39:33-36 (“impedance measurements”)), to ensure energy is not delivered to an unintended location. *Id.*, 15:65-16:11; Ex.2147 ¶¶130-131.

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.1009 (Lee), Abstract; *see id.* ¶15. Nowhere does Lee teach delivering energy. 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.1009 ¶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.1006, 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; Ex.2147 ¶130-131

Second, a POSITA would not have a high likelihood of success in combining Lee with Mehta to use the techniques Mehta discloses for assessing needle depth, which is another reason a POSITA would not have been motivated to combine them. Mehta and Lee have distinct design and operation because they have 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 ¶132. Lee’s goal, on the other hand, is creating “hundreds to tens of thousands of holes on the human skin.” Ex.1009, Abstract; Ex.2147 ¶132. 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 ¶132.

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.1006, 19:17-19, 19:45-51. Thus, energy is applied to reach a particular temperature and maintained for a period of time. Ex.2147 ¶¶133-134; Ex.1006, 37:17-24, Figs. 10E, 10F; Ex.2154, 66:1-13. In contrast, in Lee “the

treatment procedure may be performed at a speed of about 66-420 times per minute.”

Ex.1009 ¶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 ¶135. Modifying Mehta in view of Lee simply would not leave enough time to check the location of the already-inserted needles using the means Mehta discloses for doing so, adjust their location if needed, and 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 EndyMed proposes. Ex.2147 ¶¶136-140. *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.1006, 2:10-12, *see supra* Section VI.A. 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.1006, 12:1-4 (ultrasound), 21:10-12 (“a consistent starting point”), 32:46-57 (virtual depiction), 39:33-36 (impedance measurements); Ex.2147 ¶141. “[A]ssuming that rapidly inserted needles would be inserted to the right depth before delivering energy would conflict with Mehta's

teachings.” Ex.2147 ¶141. 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 useless because there would be no time to use them. *Id.* Therefore, a POSITA would not have looked to Lee to modify Mehta as EndyMed proposes. *See 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”) (citation omitted).

EndyMed relies on broad, generic references to “routine programming” and “common sense” to argue a POSITA would have modified Mehta in view of Lee to include a step motor or to modify Mehta’s GUI, but EndyMed’s generic assertions improperly ignore the teachings of these references. Mehta itself already discloses a stepper motor, as EndyMed admits. Pet. 54; Ex.1006, 15:34-40. EndyMed provides no reason a POSITA would be motivated to substitute Lee’s step motor in Mehta, particularly in light of Lee’s vastly different function and operation. EndyMed also fails to explain why a POSITA would have been motivated to modify Mehta’s control system to provide the programming necessary to extend needles a desired distance, especially in view of Mehta’s teachings about instead using the GUI to

check the position of the already-extended probes. Pet. 56; *Virtek*, 97 F.4th at 887 (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.").

EndyMed improperly uses the '812 Patent claims as a roadmap for reconstructing the claimed invention without showing that a POSITA would have been motivated to combine Mehta with Lee to achieve the claimed inventions. EndyMed thus fails to meet its burden. *See Univ. of Strathclyde*, 17 F.4th at 165; *Netlist*, 2023 WL 5065223, at *18; *Vivint*, 754 F. App'x at 1006-07.

IX. Ground V: Petitioner fails to demonstrate that Mehta, Lee, Na '848 and the knowledge of a POSITA render obvious claims 4-5

For Ground V, EndyMed merely incorporates by reference its arguments for the Mehta-Lee and Mehta-Na '848 combinations in a single paragraph to conclusorily argue that "the combination of these [three] references would have been a matter of routine engineering and would have yielded predictable results." Pet. 57-58. Petitioner's arguments fail for the same reasons discussed above. *See supra* Sections V-VIII.

X. Ground VI: Petitioner fails to demonstrate that Mehta, Livneh, and the knowledge of a POSITA render obvious claims 9 and 18

The combination of Livneh, Mehta, and the knowledge of a POSITA does not render claims 9 and 18 obvious for at least two reasons.

First, claims 9 and 18 (by their dependency on claims 1 and 12) require a “releasably couplable deployable needle module” that is “mechanically separabl[e] from the user holdable device.” Ex.1001, cls. 1, 12. Nothing in Livneh teaches those limitations. In fact, Livneh teaches that “housing 36” (which Petitioners map to the needle module of the '812 Patent) is “**connected**” to a “handle portion 38” (which Petitioner maps to the user holdable device). Ex.1010, [0033]; Pet. 60. Livneh neither teaches nor suggests that housing 36 is releasably couplable or mechanically separable from handle portion 38. Ex.2154, 128:8-21. Knowing as much, EndyMed proposes a “Modified Livneh Device” and “Modified Livneh Method” arguing, “A POSA would have been motivated to make the connection between the housing and the handle portion in Livneh releasably couplable, as taught by Mehta.” Pet. 61. EndyMed is wrong. Ex.2147 ¶144.

EndyMed relies on “retention fasteners 114” in Mehta’s cartridge to argue that a POSITA would modify Livneh to “make the connection between the needle module and the handle portion releasably couplable in light of Mehta’s teaching of a removable needle module.” Pet. 60-61. But the opposite is true. The “retention fasteners” would have to be included where housing 36 connects to handle portion 38 (noted in red below). Ex.2147 ¶145.

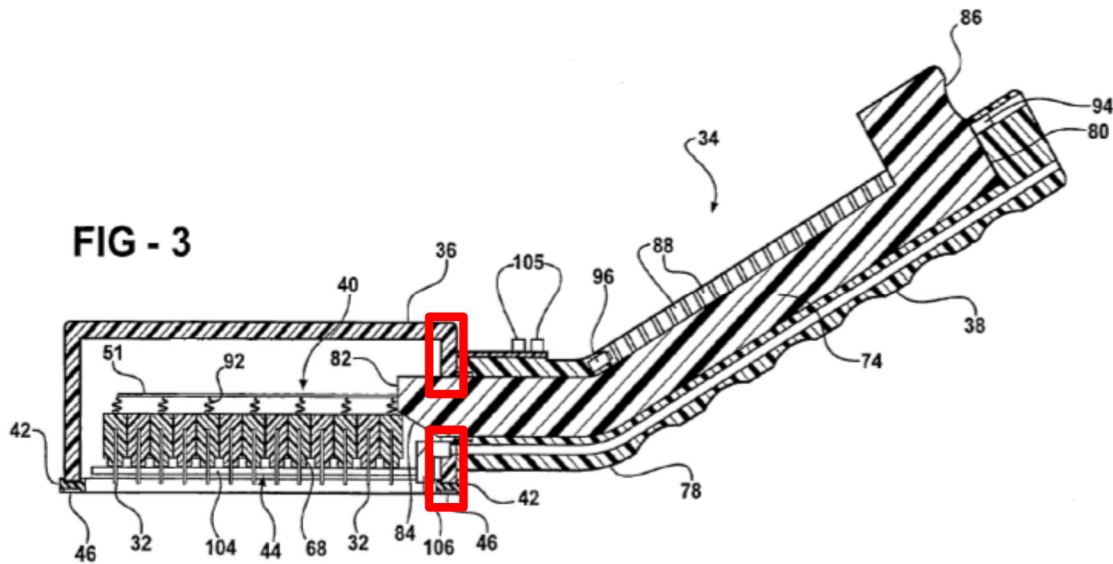


Figure 1 - Figure 3 of Ex.1010 (Livneh) (annotated)

Making housing 36 releasably couplable as EndyMed contends would leave mechanism 74 exposed, risking potential damage to mechanism 74 and therefore lack of engagement with the electrodes to move them from a first to a second position as Livneh teaches. Ex.2147 ¶146; Ex.1010, [0044], [0045]. Therefore, a POSITA would not be motivated to modify Livneh as EndyMed contends. Ex.2147 ¶146.

Even if “retention fasteners” were included, housing 36 and handle portion 38 would still be electrically connected. EndyMed admits as much, acknowledging the electrical connections between the needle module and the handle portion of Livneh. Pet. 61; Ex.1010, [0049], Figs. 10, 11. Other than summarily contending that “[m]aking the needle module in Livneh releasably couplable to the handle portion would have been a matter of routine engineering” (Pet. 63), EndyMed fails to explain

how a POSITA would modify the wires and electrical connections in Livneh to arrive at the claimed invention. That is particularly relevant to the claim limitation requiring that “at least one electrical contact of the needle assembly remains electrically coupled to at least one electrical contact of the user holdable device proximal end” while the needle assembly moves within the needle module. Ex.1001, cls. 1, 12. EndyMed brushes past that limitation. Pet. 71-72. EndyMed fails to explain why the electrical contact would be located in the proximal end of the user holdable device versus elsewhere. *Id.* And EndyMed does not explain what modifications would need to be made to housing 36 and handle portion 38, the electrode carrier and its components (including wires 51, coils 92, combs 62, holder 68, and others), the coolant, and the vacuum disclosed in Livneh. Ex.1010, [0048]-[0049], [0051]-[0052]; Ex.2147 ¶147.

EndyMed also argues that “[a] POSA would also have been motivated to use detachable needle cartridges to easily replace damaged or contaminated needles” (Pet. 61), but even EndyMed acknowledges that Livneh already discloses replaceable needles in a *non*-releasably couplable needle module. *Id.* Replacing a single needle or needle holder if damaged would be more cost effective than replacing an entire needle module with the full array of needles. Ex.2147 ¶148.

Second, modifying Livneh as EndyMed proposes would not lead to claims 9 and 18, which require that at least one of the electrical contacts include a “*pin* that

is extendable in the same direction as the plurality of needles.” Ex.1001, cls. 9, 18. Nowhere does EndyMed argue that Mehta satisfies that limitation. *See, e.g.*, Grounds I & II. Instead, EndyMed relies on Livneh’s coil 92 (Pet. 72-75), but a coil is not a pin. Petitioner simply argues that coil 92 of Livneh “operates in the same manner and performs the same function” as the pin illustrated in the Figures of the ’812 Patent. *Id.* 75. But that too is incorrect, and irrelevant to the obviousness analysis. EndyMed does not argue that a POSITA would have been motivated to use a pin instead of Livneh’s coil. *Id.* 72-75. Regardless, a POSITA would not have been motivated to replace Livneh’s coils with pins. Ex.2147 ¶¶149-150; Ex.1010, [0046] & Figs. 3-4.

EndyMed thus fails to explain why a POSITA would have modified Livneh in view of Mehta to achieve the inventions of claims 9 and 18. *Netlist*, 2023 WL 5065223, at *18; *Vivint*, 754 F. App’x at 1006-07.

XI. Strong Evidence of Objective Indicia Rebutts EndyMed’s Obviousness Challenges

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) (citations omitted); *see also 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) (citations omitted).

Here, EndyMed'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 '812 Patent claims were far from obvious.

1. EndyMed'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 the underlying four *Graham* factors, which include 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) (citation omitted).

Here, evidence of secondary considerations is present, and EndyMed has been on notice of that evidence since at least June 2023, when Serendia served its initial validity contentions in the ITC. Ex.2054. Indeed, because EndyMed waited until after the evidentiary hearing in the ITC and post-hearing briefing to file its Petition, EndyMed filed it with knowledge of the full evidentiary record on secondary considerations developed in the ITC. *See, e.g.,* Ex.2154, 24:19-25:14 (Dr. Woloszko admitting that he saw Serendia's presentation of evidence on secondary considerations of non-obviousness at the ITC evidentiary hearing). Yet Respondents failed to address this evidence at the ITC, and EndyMed's obviousness arguments suffer from the same glaring omission here. *See, e.g., id.*, 19:1-20:11 (Dr. Woloszko admitting that he, once again, did not address secondary considerations). This alone is enough to reject EndyMed's invalidity arguments. *See, e.g., Semiconductor Component Indus., LLC v. Power Integrations, Inc.*, IPR2016-01588, Paper 15 at 29 (P.T.A.B. Feb. 17, 2017) (denying institution when the “Petitioner was well aware of the evidence of objective considerations from the prior litigations, and elected not to address them in the Petition”); *Coal. for Affordable Drugs V LLC v. Hoffman-LaRoche, Inc.*, IPR2015-01792, Paper 14 at 17-18 (P.T.A.B. Mar. 11, 2016) (denying institution where petitioner failed to address objective indicia presented

during prosecution); *Merial Ltd. v. Virbac*, IPR2014-01279, Paper 13 at 27 (P.T.A.B. Jan. 22, 2015) (denying institution for failure to address objective indicia, noting “Merial was aware of the unexpected results showing which the Examiner found persuasive.... Merial should have addressed unexpected results in the first instance[.]”); *Omron Oilfield & Marine, Inc. v. MD/TOTCO*, IPR2013-00265, Paper 11 (P.T.A.B. Oct. 31, 2013) (denying institution for failure to address objective indicia); *Robert Bosch Tool Corp. v. SD3, LLC*, IPR2016-01753, 2017 WL 1096548, at *16 (P.T.A.B. Mar. 22, 2017) (“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) (evidence of objective indicia “must always when present be considered en route to a determination of obviousness”) (citations omitted).

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). Because EndyMed's expert failed to consider all four *Graham* factors (Ex.1003 ¶21), 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*, No. 2022-1954, 2024 WL 1292741 (Fed. Cir. Mar. 27, 2024).

2. The Claimed Invention Has Been Commercially Successful

The Sylfirm X was designed by the inventor of the '812 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 ¶¶151-200.

The Sylfirm X is an RF microneedling system for “treating dermatological tissue.” Ex.1001, cls. 1[pre], 12[pre]; Ex.2147 ¶¶152-155, 177-179; Ex.2083 (Sylfirm X User Manual), 4 (“Th[e] device is intended for coagulating skin tissue”); Ex.2037 (Sylfirm X Brochure). To so do, the user “plac[es] a user holdable device releasably couplable deployable needle module end surface on or near dermatological tissue to be treated, the user holdable device including a proximal end and the releasably couplable deployable needle module.” Ex.1001, cl. 1[a1]; *see also id.*, cl. 12[a], 12[b1]; Ex.2147 ¶¶156-159, 181-188; Ex.2097 (Sylfirm X Instructional Video).

The Sylfirm X has a “releasably couplable deployable needle module mechanically separatably from the user holdable device proximal end and including a needle assembly including a plurality of needles.” Ex.1001, cl. 1[a2]; *see also id.*, cl. 12[a], 12[b1], 12[b2]; Ex.2147 ¶¶160-164, 181-192; Ex.2086 (Sylfirm X Photos), 7-11; Ex.2037 (Sylfirm X Brochure), 4, 11, 13; Ex.2084 (Sylfirm X Device Description), 7; Ex.2086 (Sylfirm X Photos), 2. It also has “needle assembly [that is] movable within the releasably couplable deployable needle module to extend the plurality of needles from the releasably couplable deployable needle assembly end surface while at least one electrical contact of the needle assembly remains electrically coupled to at least one electrical contact of the user holdable device proximal end.” Ex.1001, cls. 1[a3], 12[b3]; Ex.2147 ¶¶165-167, 193-195; Ex.2086 (Sylfirm X Photos), 6-11. Specifically, the user holdable device of the Sylfirm X includes an electrical contact, and the deployable needle assembly includes an electrical contact (i.e., Pogo pin), which is couplable to the electrical contact in the proximal end. *See* Ex.2086 (Sylfirm X Photos), 6-11. In use, the needle assembly moves within the releasably couplable deployable needle module to extend the plurality of needles from the needle assembly end surface while the electrical contacts remain electrically coupled. Ex.2147 ¶¶166, 194.

When treating dermatological tissue with the Sylfirm X, “electrical signals from the user holdable device proximal end” are communicated “to the needle

assembly via the electrical contacts.” Ex.1001, cls. 1[b], 12[b3]; Ex.2147 ¶¶168-171, 193-195. Ex.2037 (Sylfirm X Brochure), 2 (describing use of Pulsed Wave (PW) radio frequency signals or Continuous Wave (CW) radio frequency signals); Ex.2086 (Sylfirm X Photos), 4; Ex.2083 (Sylfirm X User Manual), 18. Further, the Sylfirm X’s method of treating dermatological tissue involves “energizing a motor coupled to the needle assembly to cause the plurality of the needles to extend a desired distance from the releasably couplable deployable needle module end surface.” Ex.1001, cl. 2 *see also id.*, cl. 13; Ex.2147 ¶¶172-176, 196-200. The Sylfirm X includes a motor coupled to the needle assembly. Ex.2130 (Sylfirm X Photos), 3, 4; Ex.2147 ¶¶172-176, 196-200. In the Sylfirm X, the desired distance is configured via the “Depth” setting in the user interface/control panel. Ex.2147 ¶¶172-176, 196-200; Ex.2086 (Sylfirm X Photos), 2-3; Ex.2084 (Sylfirm X Device Description), 8, 16. Thus, the Sylfirm X practices the claimed invention.

As Serendia’s economic expert, Mr. Thomas explains, the Sylfirm X has been commercially successful. Ex.2141 (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), [REDACTED]. *Id.* In just the first quarter of 2023, Sylfirm X made [REDACTED] in sales, which annualizes to [REDACTED]. *Id.*

a. A Strong Nexus Exists 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 be 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 ¶¶201-203. 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 '812 Patent and Sylfirm X's commercial success.

3. The Claimed Invention Has Received Industry Praise And Recognition

The depth control claimed by the '812 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 '812 Patent has become widely recognized and praised, and “recognition 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 the '00463 IPR

In its Institution Decision in the '00463 IPR, 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.” '00463 ID 19-20.

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. *Id.* at 1212. The Federal Circuit disagreed, finding that the Board's determination was not supported by substantial evidence. *Id.* As the Federal Circuit explained, the patent owner cited documents showing 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.

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.* at 1212.

XII. Conclusion

For the reasons set forth above, the Board should deny institution of *Inter Partes* Review.

Respectfully submitted,

Dated: December 18, 2024

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

I hereby certify that this Patent Owner's Preliminary Response complies with the word count limitation of 37 C.F.R. § 42.24(b)(1) because the Patent Owner's Preliminary Response contains 13,964 words using Microsoft Word's counting feature, excluding the cover page, signature block, and the parts of the Patent Owner's Preliminary Response exempted by 37 C.F.R. § 42.24(b)(1).

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that on this 18th day of December, 2024, a true and correct copy of the foregoing **Patent Owner's Preliminary Response and all Exhibits** were served by electronic mail on Petitioner's lead and backup counsel at the following email addresses:

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