

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 No. IPR2024-00383

U.S. Patent No. 9,775,774

PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE

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EXHIBITS

Exhibit	Description
1001	U.S. Patent No. 9,775,774 (“the ’774 Patent”)
1002	Certified Copy of File Wrapper of the ’774 Patent
1003	Declaration of Dany Bérubé, Ph.D.
1004	U.S. Patent No. 8,608,737 to Mehta <i>et al.</i> (“Mehta”)
1005	International Patent Application Publication No. WO 2010/016848 by Na <i>et al.</i> (“Na ’848”)
1006	Post- <i>Markman</i> Hearing Joint Claim Construction Chart from related ITC proceeding
1007	Order No. 35 Construing Certain Terms of the Asserted Claims (Markman Claim Construction) from related ITC proceeding
1008	[Reserved]
1009	[Reserved]
1010	Korean Registered Utility Model No. KR20-0441552 to Lee <i>et al.</i> (“Lee”)
1011	Certified Translation of Korean Registered Utility Model No. KR20-0441552 to Lee <i>et al.</i> (“Lee”)
1012-1020	[Reserved]
1021	Korean Registered Patent No. KR10-1013581 to Ra Jong Joo
1022	Certified Translation of Korean Registered Patent No. KR10-1013581 to Ra Jong Joo
1023	U.S. Patent Application Publication No. US2011/0172745 A1 by Na <i>et al.</i>

Petitioner's Reply to Patent Owner's Response
U.S. Patent No. 9,775,774 | IPR2024-00383

Exhibit	Description
1024	U.S. Patent No. 9,320,536 to Na
1025	Substitute Declaration of Dr. Jean Woloszko
1026	Serendia-Ilooda Settlement Agreement
1027	Excerpt from November 7, 2023 Evidentiary Hearing Transcript from related ITC proceeding
1028	Order No. 3 (Proposed Scheduling Order) from related ITC proceeding
1029	Order No. 2 (Ground Rules) from related ITC proceeding
1030	Supplemental Declaration of Dr. Jean Woloszko
1031	Deposition transcript of Peter Crosby, in IPR2024-00383, IPR2024-00384, and IPR2024-00463, taken April 1, 2025
1032	Product Literature for Accused Rohrer PiXel8 RF-Microneedling Device
1033	Deposition transcript of Peter Crosby, from related ITC proceeding, taken September 4, 2023 (excerpts)
1034	Opening Expert Report of Peter Crosby Appendix (excerpts), from related ITC proceeding, filed August 14, 2023
1035	EDIS Confirmation of filing of Opening Expert Report of Peter Crosby, from related ITC proceeding, dated August 14, 2023
1036	Order No.: 65 Granting In-Part EndyMed Respondents' [Corrected] Motion To Declassify Portions of Documents Designated CBI by the Prior Rohrer Respondent, from related ITC proceeding
1037	Post- <i>Markman</i> Hearing Joint Claim Construction Chart, from related ITC proceeding, dated July 21, 2023
1038	Benev press release dated April 26, 2021

Petitioner's Reply to Patent Owner's Response
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Exhibit	Description
1039	Prime Journal Media Guide

Petitioner EndyMed Medical Ltd. and EndyMed Medical, Inc. ("EndyMed") submits this Petitioner's Reply to Serendia, LLC ("Serendia" or "PO")'s Patent Owner's Response ("POR").

I. CLAIM CONSTRUCTION FOR "DESIRED DISTANCE"

"[D]esired distance" has the same plain and ordinary meaning in all claims, which distinguishes between needles extending or extendable a *desired distance* as opposed to an *undesired distance* (Petition, 16; Ex.1003, ¶¶52-55)¹.

Serendia initially construed "desired distance" as "based on a user's selection" (PO's Preliminary Response ("POPR"), 33-38)². However, after the Board confirmed Mehta discloses this (Institution Decision, 13-16), PO added the distance must be "based on a user programming this distance" (POR, 24), a "depth ... programmed by the user" (*id.* 29), and "based on programming of this distance through user selection of the depth of needle insertion" (*id.*, 23). All PO's interpretations fail fact and law and regardless, all are disclosed in the prior art.

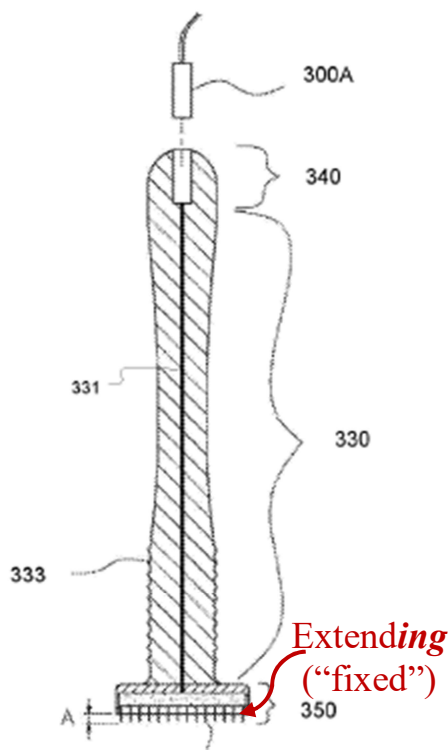
¹Petitioner's emphasis throughout unless otherwise indicated.

²POPR only mentions "program" to "support" this initial construction, not as part of the construction itself (POPR, 38), nor does it mention the device's **user** (i.e., operator) programming at all.

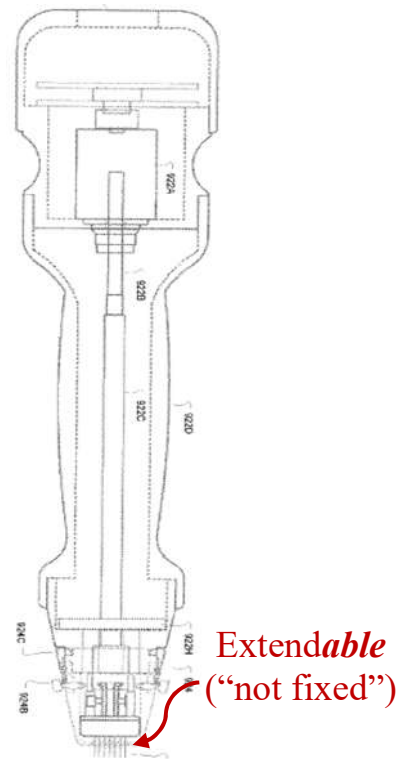
A. “Desired Distance” Has the Same Meaning in All Claims

It is presumed “desired distance” “should be given the same meaning” in all claims. *Paragon Sols., LLC v. Timex Corp.*, 566 F.3d 1075, 1087 (Fed. Cir. 2009). PO’s expert confirms “the desired distance in [claims] 13 and 14 should have the same meaning as in Claim 11” for extendable needles (Ex.1031, 77:5-78:7). Independent claim 11 makes clear “desired distance” is also the same distance either “**extending or extendable**” needles extend from a surface (Ex.1001, cl.11). Dependent claims 13 and 14 simply narrow the type of needles used to reach the desired distance to “**extendable** needles” that are “not fixed” and thus move relative to the surface to reach the desired distance, in contrast with “**extending**” needles that are “fixed and non-extendable relative to the surface” and thus stationary at the desired distance (POR, 17-18, Ex.1007, 16)³:

³Petitioner’s Figure annotations in red throughout.



'774 Patent FIG. 2B



'774 Patent FIG. 9D

Regardless of whether the needles are **extending** (fixed) or **extendable** (not fixed), both types extend to the same “desired distance” (Ex.1001, cl. 11).

Consistently construing “desired distance,” which is the same distance, for both extending and extendable needles therefore does not “contradict the language of the claims” (POR, 18; *see also* 16-19)⁴. PO’s construction analysis is incomplete

⁴*TIP Sys., LLC v. Phillips & Brooks/Gladwin, Inc.* (cited at POR, 18) is irrelevant because (1) Petitioner’s construction does not “contradict the language of the claims” and (2) *TIP* relates to importing limitations from the specification into the

as PO's expert admits he did not consider whether "user programming" is consistent with "extending" needles in claim 11 (Ex.1031, 83:9-84:10, 90:20-91:21, 101:15-102:8, 104:9-105:17, 109:8-17).

A proper construction of "desired distance" is consistent with "extending" needles in claim 11, which are *fixed* relative to the surface and so, cannot be user-programmed (Ex.1007, 16; Ex.1030, ¶11). Because "desired distance" has the same meaning in all claims, it is likewise not user-programmed in claims 13 and 14.

B. PO's Construction Impermissibly Imports Limitations From the Specification

As the Board noted, PO original construction, "based on a user's selection," relies on "a **particular** embodiment" (Institution Decision, 12). PO's expert confirms "Claim 11 doesn't specify *who* selects the desired distance" (Ex.1031, 80:12-17) and only identifies the selector as a "human," but does not differentiate between "a user as opposed to a manufacturer" (Ex.1031, 87:14-88:1). Likewise, the specification confirms all user-selections are optional embodiments: "a user **may** select" (Ex.1001, 13:63-66, 14:21-24, *see also* 9:64-66, 10:31-36, 10:60-62).

claims, not construing the same terms in different claims. *See* 529 F.3d 1364, 1373-1375 (Fed. Cir. 2008).

Who selects desired distance could be, and so is not limited to, the device's user (operator e.g., physician), manufacturer, designer, programmer, or an "automatic" feedback mechanism cited by PO, PO's expert and the parent patent's Examiner (Ex.1030, ¶8; Ex.1031, 87:14-88:1; POR, 23-24 and Ex.2147, ¶81, citing Ex. 2115, 10:11-20). This "automatic" "control of depth of penetration" is an "alternative[]" to "adjustment by an operator" and so, excludes the operator/user (Ex. 2115, 10:11-20, Ex.1030, ¶8).

PO's new construction, "based on a user programming this distance," likewise improperly imports optional embodiments from the specification into the claims: POR, 21-24 citing Ex.1001, 10:31-36 ("may control"), 10:60-64 ("may employ the algorithm"), 9:52-53, 9:64-10:4 ("may include"), 13:63-66 (describing Fig. 12: "may select ... depth"), 14:3-6 ("may"), 14:12-34 ("may select"). *Prima Tek II, L.L.C. v. Polypap*, 318 F.3d 1143, 1149-51 (Fed. Cir. 2003) (rejecting limiting claim scope when "[t]he written description only states ... 'may be' (not must be)" used).

The Federal Circuit "repeatedly warned against confining the claims to [described] embodiments" and "expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment," rendering both PO's constructions invalid. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1323 (Fed. Cir. 2005).

C. PO Applies its Construction Inconsistently

PO's construction that "desired distance" is "based on a user programming this distance" and excludes "**manual** adju[st]ment⁵" (POR, 19-20,36) contradicts PO's infringement position at the ITC:

[L]ike the subject claim limitation, ... the desired distance that the needles extend is **predetermined** by the **mechanical adjustment** on the handpiece" (Ex.1034, ¶130; Ex.1031, 153:17-154:17).

"[T]he element in the Rohrer device that enables that cause a plural -- plurality of the extendable needles to extend a desired distance is that **mechanical element** in the Rohrer handpiece. (Ex.1033, 331:5-332:5).

PO accused Rohrer's "Pixel8" device of infringing '774 Patent claims 13,14 (Ex.1034, ¶¶119,129) having the following handpiece:

⁵PO's misquote, Ex.2147, ¶106.



(Ex.1032, 1; Ex.1031, 136:11-137:3). PO's expert explained "the mechanism for adjusting the desired distance of needle extension" is that "[t]he end of the handpiece (proximal end) can be rotated relative to the body of the handpiece" (Ex.1034, ¶48). Aside from this manual adjustment, the accused device has no other way to control needle distance: it uses a "solenoid" to extend needles (Ex.1034, ¶121) that only allows "two positions" ("in or out") –i.e., a single fully extended ("out") position (Ex.1031, 168:17-170:10; Ex.1033, 336:14-21; *see also* Ex.1030, ¶13). Because PO interpreted "desired distance" as selected by entirely manual adjustment (mechanically rotating the handpiece's dial) for infringement, desired distance cannot require "a user programming this distance" that excludes manual adjustment for invalidity (POR, 24,36). *L.A. Biomedical Research Inst. at*

Harbor-UCLA Med. Ctr. v. Eli Lilly & Co., 849 F.3d 1049, 1069 (Fed. Cir. 2017)

(“that which infringes if later anticipates if earlier.”). To the extent desired distance requires “user programming,” “user programming” must be broad enough to encompass manual adjustment (mechanical programming), e.g., by rotating a hand-dial (as in the accused Pixel8 device) or manually switching between different cartridges (as in Mehta) (Ex.1030, ¶¶13,16). In either case, a motor that extends needles a desired distance is programmed to do so (Ex.1030, ¶12).

PO's expert confirmed these opinions from the ITC in this proceeding (Ex.1031, 146:16-147:16, 153:17-154:17). These opinions were submitted *after* the “Agreed Terms” I.A.2 related to “desired distance” was finalized (Ex.1035; Ex.1031, 134:7-15; Ex.1037, 2). The ITC held “Serendia, through its counsel, **intentionally evaded** EndyMed's requests” to allow Rohrer to grant permission to submit Exs.1033-1034 to the PTAB, and granted EndyMed emergency relief “to build a fulsome record before the PTAB” (Ex.1036, 2-3). Reconciling PO's inconsistent positions at the PTAB and ITC, because PO accused the Pixel8's manual depth control of infringement, Mehta's manual depth control invalidates. Additionally, Mehta also discloses electrical user-programming as discussed below.

Contrary to POR, 19, PO's expert confirmed Mehta's cartridges do not have extending needles, but “**extendable**” needles (Ex.1031, 59:5-21). *See* “electrodes

... extend~~able~~ and retractable from ... the cartridge” (Ex.1004, 15:45-49). PO’s argument that “selection of *any* cartridge having *any* needle length” makes “desired distance” superfluous (POR, 19-20, PO’s emphasis) ignores that this embodiment refers to “a *particular* length,” not any length (POR, 36, quoting Petition, 27-29).

PO’s issue that the claims rely on the user’s “mental state” (POR, 19-20) is a problem with the term “desired” appearing in the claims themselves (PO critiques reliance on “the user’s desire,” POR, 20), not with Petitioner’s construction. Further, nothing in the claims exclude influence by a user's mental state, and, if Petitioner’s construction is based on a user’s mental state, so is PO’s own construction: “based on a user’s selection” (POR, 18). PO alleges the claims would not depend on a user’s mental state if the “desired distance” is “reflected by user action—selection of the ‘desired extension’/’desired depth.’” (POR, 20). Selecting a cartridge that extends a desired distance in Mehta is the same type of “user action” PO accused of infringement (“mechanical adjustment on the handpiece” Ex.1034, ¶130).

Embodiment (3) also satisfies the “desired distance” limitation (POR, 20-21) because “manually” refers to “checking the needle location,” not “adjusting the needle depth” which is programmed in Mehta (see below). Further, as discussed, PO confirms the claims cover manual adjustment of desired distance in the accused

device. Petitioner notes it identified embodiments (1)-(3) as “**at least** three ways,” not the only ways, “to meet the ‘desired distance’ limitation” (Petitioner’s Reply to POPR, 7-8; citing Ex.2125, 1151:2-18).

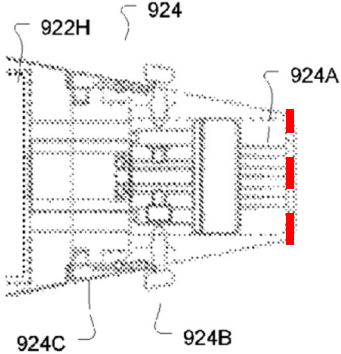
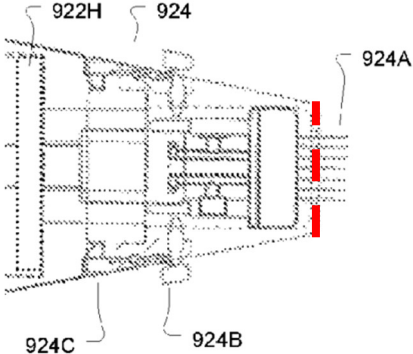
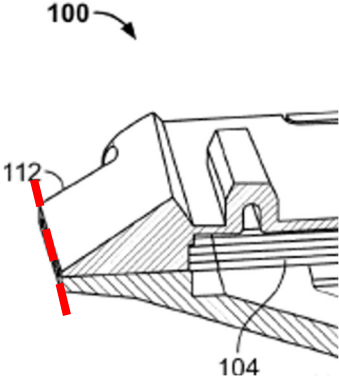
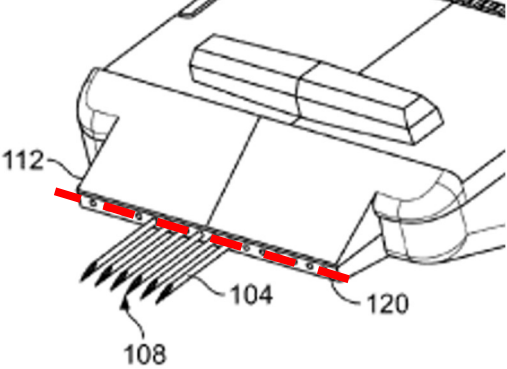
In sum, all PO’s constructions are unduly narrow and regardless, all are disclosed in the prior art as outlined below.

II. GROUND I: MEHTA ANTICIPATES CLAIMS 13 AND 14

The Board held: “Mehta discloses the ‘desired distance’ limitation even assuming Serendia’s construction of that limitation, i.e., that the needles are extendable to a depth *selected by the user*.” (Institution Decision, 14, Board’s emphasis). To circumvent Mehta’s anticipatory disclosure, all PO’s alleged distinctions over Mehta rely on newly asserted unclaimed optional embodiments imported from the Specification, as discussed above, to narrowly construct “desired distance” as being “programmed by the user” (*see* POR, 1, 29, 31-38). Although the claims are not so limited, Mehta discloses all these limitations:

A. Extendable Needles

Mehta discloses cartridges with needles that PO’s expert admits are “**extendable**” (“not extending”) relative to the device’s end surface (Ex.1004, 15:45-49, Figs. 4C-4D; Ex.1031, 59:5-21, Ex.1003, ¶¶81-83), just like the “extendable needles” shown in “FIGS. 9C-9D and 10D-10E of the ’774 patent” (POR, 17-18):

'774 Patent Fig. 9C (excerpt) ⁶ Retracted	'774 Patent Fig. 9D (excerpt) Extended
	
Mehta FIG. 4C (excerpt) Retracted	Mehta Fig. 4A (excerpt) Extended
	

B. Desired Distance

Mehta’s extendable needles extend a desired distance from the end surface:

“a user [can] place the device on the surface of tissue and advance the probes 104

⁶Figures annotated with red dashes indicating an “end surface.”

to the **desired depth** of tissue” (Ex.1004, 21:8-10)⁷. As the Board held: “although Mehta may not use the term ‘desired distance’ expressly, it comes about as close as one would expect from an anticipatory disclosure” (Institution Decision, 14).

Mehta also discloses “desired distance” under any of PO’s constructions:

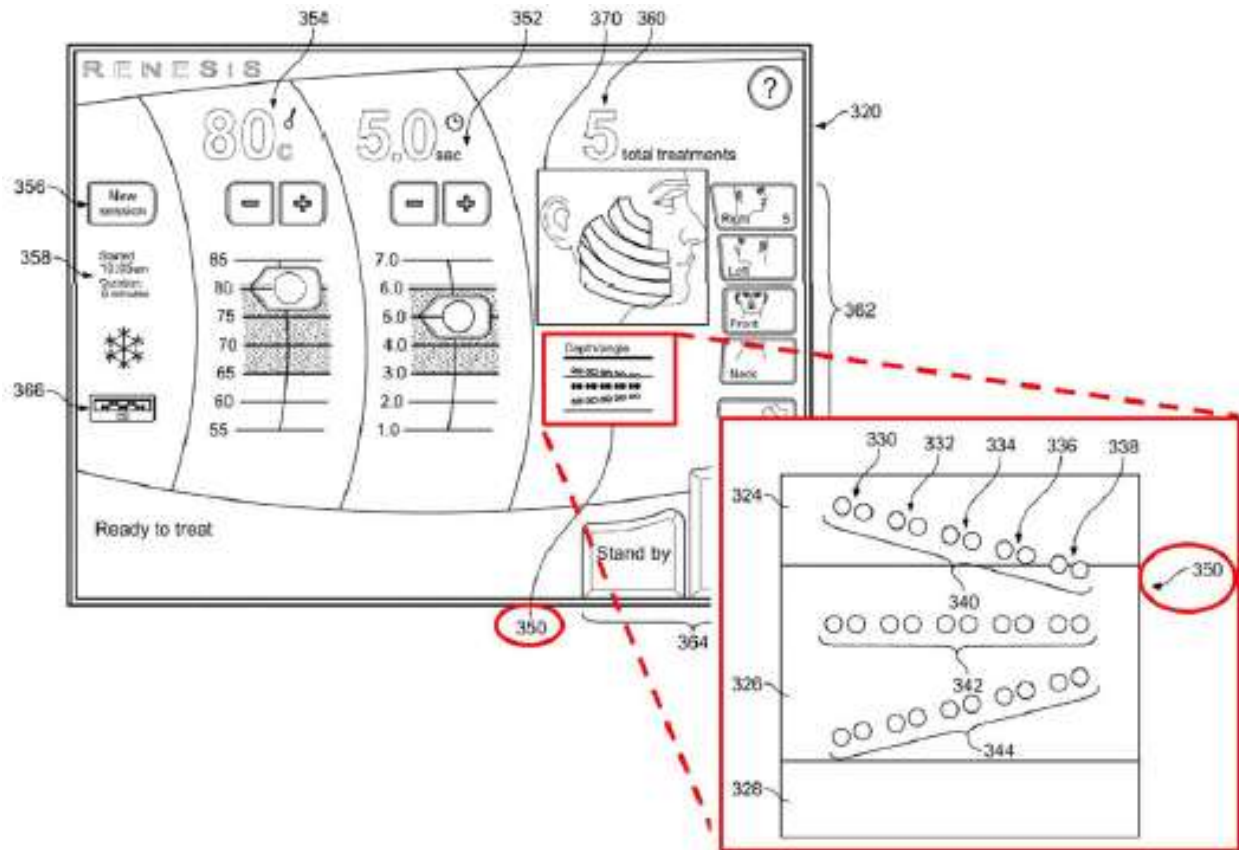
**1. Desired Distance: Based On A User’s Selection
(PO’s Original Construction)**

The Board concluded Mehta discloses the desired distance “even under Serendia’s narrower interpretation,” i.e., “based on a user’s selection” (Institution Decision, 12, 16; *see* POR, 18, 23-24, 29). The Board confirmed Mehta discloses “providing the user with the means to select and control the desired depth of the needles into the tissue” (Institution Decision, 16).

Indeed, Mehta discloses “the systems and methods enable a **physician** (or other medical practitioner) to **precisely control** the areas or region of tissue that receives energy” (Ex.1004, 2:37-41); “information can be provided to the **user for placement adjustment**” of needles (Ex.1004, 24:61-25:2). This information for the user to adjust the needles includes “virtual depth/location depiction 350”

⁷Mehta’s needles are oriented as illustrated in the ‘774 Patent figures when probes extend “at a more vertical angle to the target tissue like a pencil or pointer” (Ex.1004, 9:53-59; *see also* 12:36-41).

displaying “actual” and “desired” needle depths for the user to determine the “desired depth of placement”:



(POR, 28; Ex.1004, Figures 10A-F, 32:46–33:43; Ex.1003, ¶86; Petition, 26).

The “physician” –i.e. user– uses this information to control “advancement of the probes” to the “desired depth”:

[T]he virtual depth/location depiction 350 can illustrate an actual placement of the probe array 340... [and] a desired probe location (e.g., array 342 can represent the **desired depth** of placement for providing a treatment)... Therefore, the **physician** would be informed that **further advancement** of the probes is necessary to

place the probes within the second layer **326** (which corresponds to the dermal layer)...Naturally, the **desired target layer** of tissue can vary depending on the desired result of the treatment. For example, the **system** described herein can be **adjusted to guide probe placement** within the first or third layers 324 or 328 depending on the type of treatment being applied. (Ex.1004, 32:46–33:34).

Mehta's "system" that is motor-driven (Ex.1004, 13:58-64) is "adjusted to guide probe placement" to the "desired depth" as selected by the "physician" based on the "virtual depth/location depiction 350" (*id.*).

Mehta further discloses employing a sensor to "alert **the user** for the need to **reposition the probe**" to the "desired target region" (Ex.1004, 24:27–45). Mehta shows this user-repositioning in Figs. 8A-8B, where the needle initially deployed outside the desired target region 8 in Fig. 8A is further extended in Fig. 8B to reach a desired distance in desired target region 8 (Ex.1004, 24:37-45):

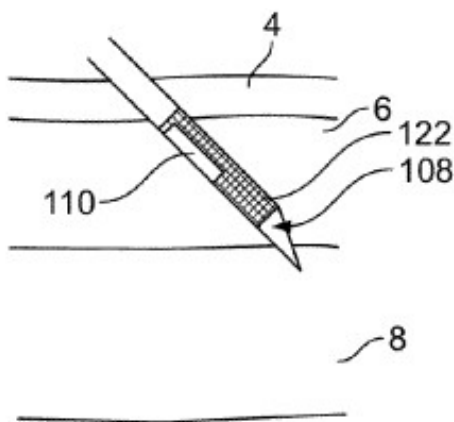


FIG. 8A

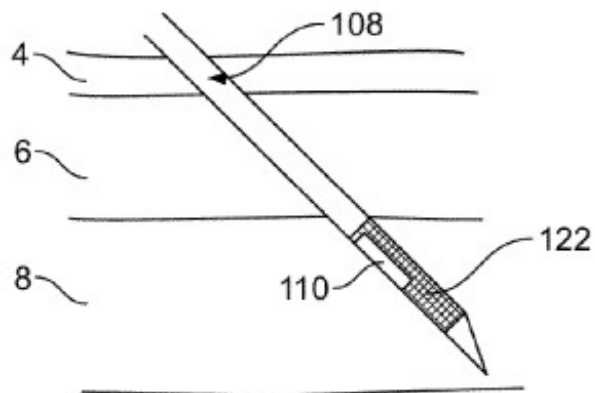
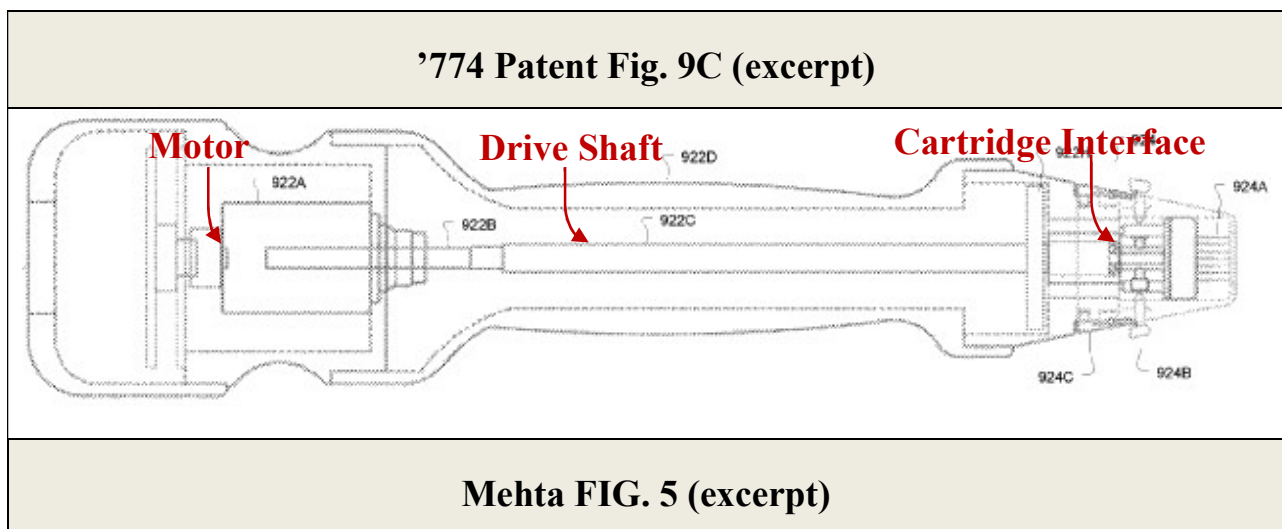


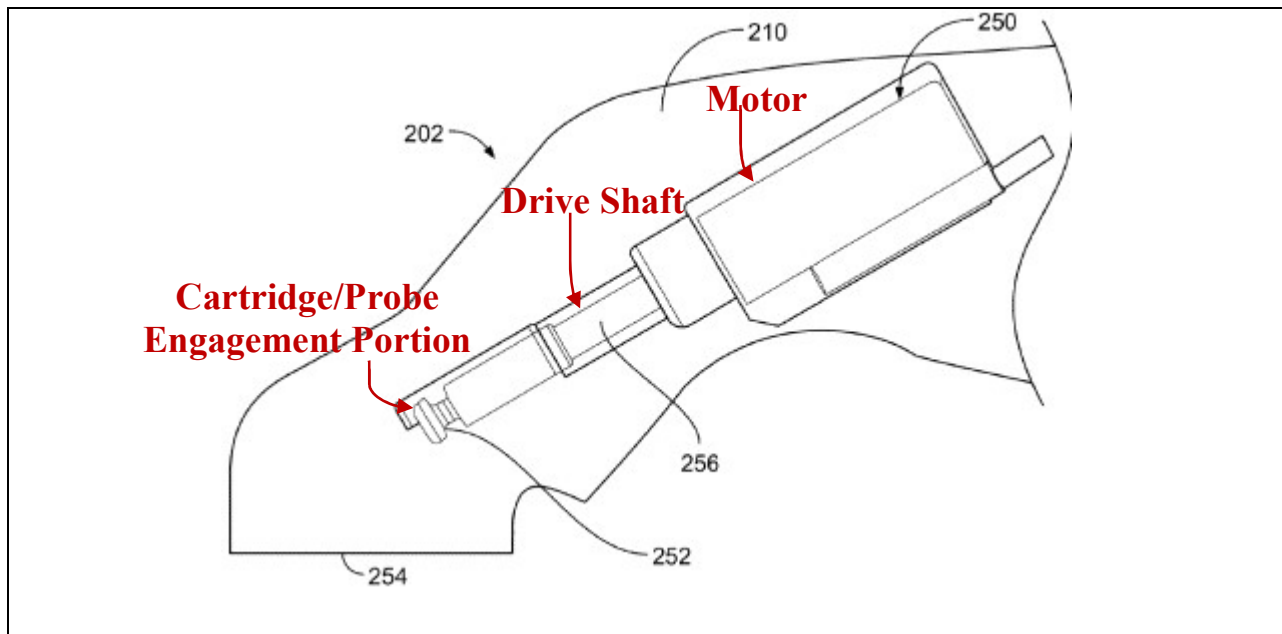
FIG. 8B

Mehta's disclosure of a "physician" or "user" operating a "system" that is motor-driven "adjusted to guide probe placement" to "precisely control" and "reposition" needles for their "further advancement" and "placement adjustment" to a "desired depth" is "based on a user's selection" (Ex.1004, 2:37-41, 21:8-10, 24:27-45, 24:61-25:2, 33:24-27). The Board confirmed "Mehta's clear and unambiguous teachings of [] means for selecting and controlling how far the needles are inserted into the tissue. ... [in which] **the user selectively actuates a motor** to cause insertion of the needles to the desired depth" (Institution Decision, 16).

2. Desired Distance: Based On A User Programming This Distance (PO's New Construction)

Mehta's system comprises a "motor" actuated by a "control system/energy supply unit 90" driving a "shaft" with a distal tip to engage and move the needle assembly (Ex.1004, 10:38-39, 13:58-65, 15:34-40, 18:21-37, Fig. 5; Ex.1003, ¶¶84-97), just like the '774 Patent (Ex.1001, 10:65-11:27):





Mehta discloses a “step-motor” to move the electrode assembly to various “stepping” distances (Ex.1004, 15:34-40; Ex.1003, ¶88), just like the ‘774 Patent (Ex.1001, 11:57-60):

The cartridge body 100 further includes an **electrode assembly 102 that is moveable or slidable within the cartridge body 100.**

The mode of movement of the actuator can include ... **stepping (via an step-motor).** (Ex.1004, 15:34-40)

Mehta discloses a motor-driven “system...adjusted to guide probe placement” to the user-selected “desired depth” (Ex.1004, 21:8-10, 32:46–33:34) and Mehta’s motor controls that electrode/needle movement, e.g. to precise “stepping” distances (Ex.1004, 13:58-65, 15:34-40), which together provides disclosure for a “desired depth” that is motor-controlled (Ex.1030, ¶14; Ex.1003,

¶¶84-88). Mehta's "motor" that extends needles the user-selected "desired depth" must be programmed to control the needles to extend to, and stop at, this distance (Ex.1030, ¶12,14; Ex.2154, 53:9-11).

Mehta further disclosed "[o]ver-inserting and then partially retracting" the electrodes (Ex.1004 at 16:39-41; Ex.1003, ¶90; Ex.1030, ¶15). Mehta's motor is thus programmed with at least two distances: an initial full-extension distance and a second partial retraction distance, which is the desired distance for treatment (Ex.1030, ¶15). PO's argument that partial insertion "simply 'compensates for the movement and laxity of the skin ...'" (POR, 36-37) does not negate its programming.

Selecting/replacing cartridges having different extendable needle lengths or angles (POR, 32; Ex.1004, 12:31-46, 17:66-18:3; Ex.1003, ¶89, 91) also requires that Mehta's motor is programmed to extend needles to the cartridge-programmed distance (Ex.1030, ¶16). Similar to rotating a hand-dial in the accused "Pixel8" device, attaching or replacing a cartridge with a desired needle-extension distance in Mehta is mechanical user-programming that causes a motor to extend its needles to the cartridge-programmed distance and stop (Ex.1030, ¶12,16).

In sum, Mehta discloses a motor-driven system, comprising a step-motor that extends needles to various stepping distances, adjusted to guide probe placement for further advancement of the probes to a desired depth, a motor over-

inserting and partially retracting probes, as well as selecting motor-driven cartridges programmed to extend probes to particular extension distances and angles, all selected by a user/physician, as cited above. A motor requires a program to extend needles to the desired depth in all these cases and so, all these motor-driven extension distances are “programmed” (Ex.1030, ¶¶12-17). To the extent PO asserts “a motor extending needles a predetermined distance” is inherently “programmed” in the claims (POR, 21), it must also be so “programmed” in Mehta (POR, 32).

Mehta thus discloses the “desired distance” “based on a user’s selection” (PO’s original construction) and “based on a user programming this distance” (PO’s new construction) (POR, 1, 23-24, 29, 31-38; Ex.1030, ¶17).

PO criticizes that “Jeisys does not even contend that Mehta discloses programming the distance” in its original Petition (POR, 31). “Programming” however is not claimed, nor part of PO’s own original construction (POPR, 33).

PO reiterates (from POPR, 47) and relegates to footnote (POR, fn. 3, pp. 31-32), with no additional argumentation, that “Mehta ‘705” (Ex.2117, U.S. 8,540,705, another reference by the same author as Mehta Ex.1004) was considered by the Examiner in a continuation application of the ‘774 Patent’s that issued as US Patent 10,869,812. In this patent’s IPR2024-00463, the Board held:

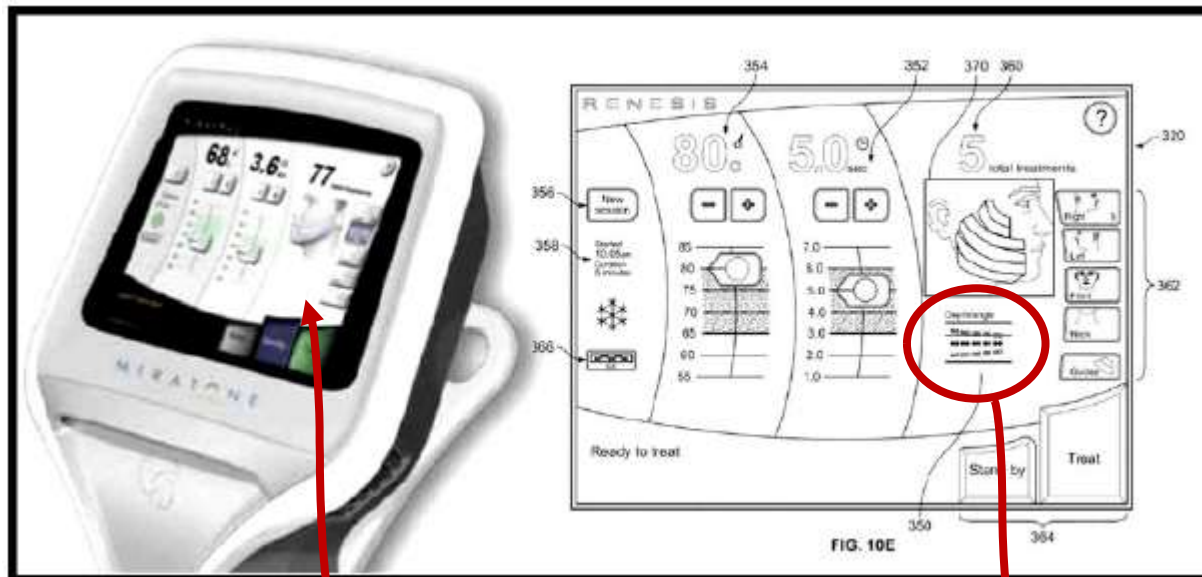
“Mehta is *not*⁸ substantially the same as Mehta '705 ... notably lacking from Mehta '705 is **any disclosure of determining the ‘depth’ and ‘location’ of the needle’s placement in the tissue,** let alone means for doing so, which Mehta discusses at length and upon which Jeisys relies to meet the ‘desired distance’ limitation.”
(Institution Decision, 11-12)

“Because Mehta includes disclosure relevant to the disputed ‘desired distance’ limitation that is absent from Mehta '705” (Institution Decision, 12), the Examiner not citing Mehta '705's for “desired distance” does not undermine its disclosure in Mehta.

Sylfirm X & Miratone Products: PO's comparison of Sylfirm X and Miratone product literature (POR, 9-15) is irrelevant –validity compares prior art to the claims: “[i]t is improper to limit the teachings of a prior art reference by focusing ... on commercial embodiments.” *Sherwin-Williams Co. v. Ppg Indus.*, No. 2:17-cv-01023-JFC, 2021 U.S. Dist. LEXIS 230994, at *21 (W.D. Pa. Oct. 21, 2021); *see also Invacare Corp. v. Sunrise Med. Holdings, Inc.*, No. 1:04 CV 1439, 2005 U.S. Dist. LEXIS 50519, at *7 (N.D. Ohio Jan. 21, 2005). Further, Miratone product materials omit, where Mehta includes, the same embodiment the Board found missing in Mehta '705 “relevant to the disputed ‘desired distance’

⁸Board's emphasis.

limitation”: Mehta’s “tissue characteristic indicator 350” a.k.a. “virtual depth/location depiction 350” that “allows a user to monitor the needle’s ‘location’ in the tissue so as to decide when the needle is placed at a ‘desired depth.’” (IPR2024-00463 Institution Decision, 11-12, citing Ex. 1004, 32:46–33:29, Figs 10A-10F). PO’s comparison (POR, 14, copied below) shows Mehta’s “virtual depth/location depiction 350” (circled right, Ex.1004, Figure 10E) is missing in Miratone product material display (omitted left, Ex.2149, 2):



Miratone's
Omission

Mehta's virtual depth/
location depiction 350

Miratone product materials further omit, where Mehta includes, at least a “step-motor” to extend needles to various “stepping” distances (Ex.1004, 15:34-40), “[o]ver-inserting and then partially retracting” probes (Ex.1004, 16:39-41), and a user/physician precisely controlling needle advancement (Ex.1004, 2:37-41, 21:8-

10, 24:27–45, 24:61-25:2, 33:24-27, Figures 8A-8B). Omission in Miratone product materials does not negate disclosure in Mehta. Because Miratone product materials omit the same relevant disclosure as Mehta '705, the Board should similarly conclude “Mehta includes disclosure relevant to the disputed ‘desired distance’ limitation that is absent from [Miratone product materials]” sufficient to prompt an independent determination of “desired distance” in Mehta (IPR2024-00463 Institution Decision, 11-12).

PO alleges Mehta's user monitors the location of “already-extended” needles and “[o]bserving or determining needle placement” “after the needles are extended,” implying Mehta only passively monitors, but does not actively control, needle extension (POR, 33-34, 37-38). This ignores Mehta's disclosure that depth/location is monitored by the “physician” or “user” in order to “precisely control” and “reposition” needles for their “further advancement” and “placement adjustment” to a “desired depth” (Ex.1004, 2:37-41, 21:8-10, 24:27–45, 24:61-25:2, 33:24-27). **Repositioning**, **further** advancement and **adjustment** of needles all require user-action to control and change needle extension after the needles have already been initially extended (Ex.1003, ¶¶87-97). Regarding “programming” (POR, 35), Mehta's needles are extended by a “motor” (actuator) that is driven by “control system/energy supply unit 90” and so the motor is

programmed to extend needles by this user-selected desired depth (Ex.1030, ¶¶12-14; Ex.1004, 10:38-39).

PO misrepresents Petitioner's expert's testimony that conclusively describes how Mehta's step-motor advances needles the desired depth (POR, 35, citing Ex.1003, ¶88). "[C]an be constructed" refers only to the option to pick "a **desired** rotation-to-translation ratio," i.e., the number of rotations per translation motion (*id.*). The value of this specific ratio is a design choice, any of which will achieve the "desired translational motion" (desired distance) (Ex.1030, p.8:fn.1).

Regardless, this specific ratio is not claimed, and goes beyond the level of disclosure of, and therefore cannot be required to anticipate claims in, the '774 Patent (only disclosing "motor(s) 922A may include steps," Ex.1001, 11:57-60).

Accordingly, Mehta anticipates claims 13 and 14 under Ground I.

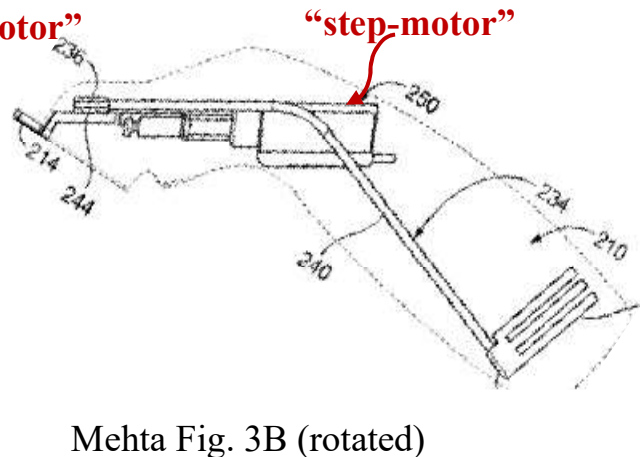
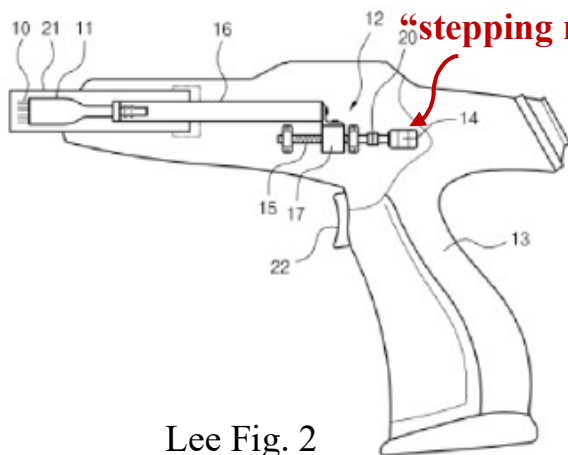
III. GROUND IV: MEHTA AND LEE RENDER CLAIMS 13 AND 14 OBVIOUS

PO does not dispute Lee disclosed the "desired distance" limitation and Mehta discloses all other limitations of claims 13 and 14. PO only disputes motivation to combine Mehta and Lee and whether secondary considerations render these claims non-obvious (POR, 38-46).

A. A POSA would have been Motivated to Combine Mehta and Lee

Both Mehta and Lee are directed to the same goal of inducing collagen production by puncturing skin with motor-driven needles (Ex.1004, 8:66-9:6;

Ex.1011, <14>; Ex.1003, ¶¶65-67,223). Both Mehta and Lee aim to solve the same problem of targeting and precisely controlling the desired location/depth of the needles (Ex.1004, 2:9-12, 2:37-41, 24:6-8; Ex.1011, <44>). Both Mehta's and Lee's devices use a step-motor to precisely step needle distance (Ex.1004, 15:34-40; Ex.1011, <24>; Ex.1003, ¶¶224-226):



Ground IV does not use the '774 Patent as a roadmap (POR, 45-46) because the cited motivation (Petition, 65-69; Ex.1003, ¶¶224, 232-233, 235) is “evidenced by the pertinent prior art,” not “found in the ['774] patent itself.” *See Univ. of Strathclyde v. Clear-Vu Lighting LLC* 17 F.4th 155, 165 (Fed. Cir. 2021): Mehta motivates solving “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.1004, 2:9-12) and Lee disclosed “**controlling the insertion depth** of microneedles” (Ex.1011, <13>) to “accomplish that goal.” *See Vivint, Inc. v. Alarm.com Inc.*, 754 F. App'x 999, 1007 (Fed. Cir. 2018).

PO alleges Mehta and Lee are uncombinable because Mehta's needles "deliver[] energy" and Lee's do not (POR, 39-41). This is false. Mehta explicitly defines "delivering ... energy" to encompass both electrical "thermal energy" (e.g., RF, Ex.1004, 39:28-30) and "percutaneous delivery of mechanical energy" (puncturing skin) as in Lee:

"[D]evices and methods described herein are **not limited to** the percutaneous delivery of **thermal energy**, **but also include** the percutaneous delivery of **mechanical energy**" (Ex.1004, 8:66-9:6, *see also* 9:43-48).

Mehta thus covers, and directs a POSA to consider and combine art disclosing, "delivery of mechanical energy" as in Lee.

PO alleges Lee's needle extension and retraction rate is too fast (at minimum every 0.9 seconds) for Mehta's treatment time (at minimum 1 second) (POR, 41-43). These times, however, are only examples ("For example," Ex.1011, <58>; "in the above example," Ex.1004, 37:17-24) and, in another example, Mehta discloses treatment times "between 0 and 6 seconds" (Ex.1004, 38:15-19), the lower range of which is within Lee's 0.9 second oscillation rate. Regardless, obviousness does not test if references can be "bodily incorporated" or "physically combin[ed]."

Allied Erecting & Dismantling Co. v. Genesis Attachments, LLC, 825 F.3d 1373, 1381 (Fed. Cir. 2016). Ground IV, further, does not cite Lee for its treatment times,

only Lee's needle depth-control (Petition, 65-69). While Mehta motivated incorporating Lee's needle depth-control, Mehta did **not** motivate **eliminating** delivering electrical RF energy, and thus, Mehta so modified by Lee would maintain Mehta's RF treatment times (Petition 65-69; Ex.1003, ¶¶223-241; Ex.1004, 11:14-15).

PO alleges Mehta teaches "a different approach" to "distance control" by confirming the location of "already-extended" probes (POR, 43-45). This ignores Mehta's disclosure for user-controlling the needle's distance (shown above). Regardless, merely disclosing one solution does not teach away from alternative solutions. *Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 738 (Fed. Cir. 2013).

Ground IV does not "substitute Lee's step motor in Mehta" (POR, 44) because Mehta already discloses a "step-motor" (Ex.1004, 15:34-40). Mehta does not promote, but warns against, "unwanted skin damage" (Ex.1004, 2:1-2) and so does not teach away from the combination (POR, 40). The sections of Mehta that PO quotes explain what not to do (Ex.1004, at 2:1-2, 8:45-53). In contrast, Mehta explains it avoids these problems ("[s]ome of the benefits associated with this ... invention consist of being capable of safely ... delivering the ablative energy ... while protecting adjacent structure," Ex.1004, 38:58-67; *see also* 37:65-38:15).

Petitioner clearly explains the motivation to “provide a distance setting on Mehta’s I/O interface” (POR, 44-45): Mehta’s motor is driven by control system/energy supply unit (Ex.1004, 10:38-39, 13:63-65) that has an I/O interface that “allows the physician to input control and processing variables” (Ex.1004, 12:5-8) and Lee “pre-programmed” a motor to control the needles “insertion depth” (Ex.1011, <50>) which thus would have been obvious to control via Mehta’s I/O interface (Petition 68-69, Ex.1003, ¶¶237-238).

Accordingly, a POSA would have been motivated to combine Mehta and Lee under Ground IV.

B. Objective Indicia of Non-Obviousness

1. PO Fails to Show a Nexus Between the Claimed Invention and Evidence of Alleged Commercial Success and Industry Praise

As the Board correctly found, “Serendia acknowledges that the success of the Sylfirm X product is due **only ‘in part’** to the technology claimed in the ’774 patent... Indeed, in another proceeding, Serendia contends that the commercial success of the Sylfirm X product is due to the so-called ‘Na effect,’ which is not claimed in the ’774 Patent but instead goes to the heart of another one of Serendia’s patents.” (IPR2024-00383 Institution Decision, 18); citing PO: “The Sylfirm X has achieved commercial success **due in part** to implementation of the inventions claimed in the ’774 Patent.” (POPR, 62). PO’s nexus showing is insufficient when PO “itself only argues that the commercial success [and industry

praise] is due 'partially' to claimed features.” *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1313 (Fed. Cir. 2006).

Indeed, as per the Board, “Serendia references the *same evidence* as providing evidence of nonobviousness for *four different patents*” including the '774 Patent (IPR2024-00842 Institution Decision, 11, Board's emphasis). Because PO's different patents cover different inventions: US 9,480,836 allegedly covers the “Na effect” (IPR2024-00386, POPR, 61-63), whereas the '774 Patent instead covers needle depth control (Ex.2147, ¶154; Ex.2124, ¶14), PO errs in submitting the same evidence of secondary considerations for patents that do not “generally cover the same invention.” *Fox Factory*, 944 F.3d at 1377 (“The same evidence of secondary considerations cannot be presumed to be attributable to two different combinations of features... In such situations, the patentee retains the burden of proving the degree to which evidence of secondary considerations tied to a product is attributable to a particular claimed invention.” (*Id.*, 1378). Where the Board confirms “Patent Owner fails to set forth which patents ‘generally cover’ the Sylfirm X device” (IPR2024-00386 Institution Decision, 18), or to which degree, it is impossible to know to which invention PO's evidence pertains. That evidence, attributable at least partially to the “Na effect” is irrelevant here. *Ormco*, 463 F.3d at 1312 (“if the commercial success is due to an unclaimed feature of the device, the commercial success is irrelevant”). The Board thus concludes PO has failed to

explain ‘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 [PO]’s other patent.’” (IPR2024-00386, Paper 27, Institution Decision, 18).

2. PO Fails to Show Commercial Success

PO’s only cited year-to-year sales comparison –2021 vs. 2022 (POR, 52)– appears incomplete because Sylfirm X was launched in the U.S. mid-2021 (Ex.1038). If the Sylfirm X was sold for only part of 2021, its 2021 annual revenue would be artificially deflated, thereby artificially inflating sales growth in 2022 by comparison.

3. PO Fails to Show Industry Praise

PO’s only alleged evidence of industry praise that specifically mentions SylfirmX or needle depth-control, Ex.2066, is paid promotional material: *See* “PRIME PROMOTION” (Ex.2066, p.2 header). Prime Journal sells these “PROMOTION ARTICLES” as paid “Advertising” costing £6,000 for a 2-page article⁹ (Ex.1039, 11). PO confirms Ex.2066 is “marketing” material (POR, 54). Industry praise cannot rely on a “[PO]-sponsored article” as “The Federal Circuit has made clear... that such self-referential commendation also falls well short of demonstrating true industry praise.” *Amarin Pharma v. Hikma Pharms. United States*, 449 F. Supp. 3d 967, 998 (D. Nev. 2020) (internal quotations omitted)

⁹2025 rate.

quoting *Bayer Healthcare Pharms., Inc. v. Watson Pharms., Inc.*, 713 F.3d 1369, 1377 (Fed. Cir. 2013).

PO's remaining alleged evidence of industry praise –Ex.2067 and Ex.2122– are both entirely silent regarding needle depth-control and do not identify SylfirmX.

Thus, PO does not overcome the strong *prima facie* case of obviousness in Ground IV.

IV. CONCLUSION

In view of the foregoing, Petitioner respectfully requests the Board find claims 13 and 14 of the '774 Patent unpatentable.

Respectfully submitted,

Date: April 11, 2025

/ Guy Yonay /
Guy Yonay
Registration No. 52,388

CERTIFICATE OF WORD COUNT COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), I hereby certify that Petitioner's Reply to Patent Owner's Response complies with the type-volume limits of 37 C.F.R. § 42.24(c)(1) requiring this reply not exceed 5,600 words. As calculated by the word count feature of the word-processing system used to prepare this reply, it contains 4957 words, excluding the parts of this reply that are exempted by 37 C.F.R. § 42.24(c).

Date: April 11, 2025

/ Guy Yonay /
Guy Yonay
Registration No. 52,388

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e)(1), the parties have agreed that service may be made electronically. I hereby certify that, pursuant to 37 C.F.R. § 42.6(e), a complete copy of the attached Petitioner's Reply to Patent Owner's Response and supporting Exhibits, is being served via electronic mail, on April 11, 2025, the same day as the filing of the above-identified document in the USPTO with the Patent Trial and Appeal Board, to lead and back-up counsel of record for Patent Owner, pursuant to its November 25, 2024 Updated Mandatory Notices, as follows:

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