

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. IPR2024-00384

U.S. Patent No. 9,320,536

PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE

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<i>Ormco Corp. v. Align Technology, Inc.</i> , 463 F.3d 1299 (Fed. Cir. 2006)	31, 32
<i>Phillips v. AWH Corp.</i> , 415 F.3d 1303 (Fed. Cir. 2005)	5
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EXHIBITS

Exhibit	Description
1001	U.S. Patent No. 9,320,536 (“the ’536 Patent”)
1002	Certified Copy of File Wrapper of the ’536 Patent
1003	[Corrected] Declaration of Dany Bérubé, Ph.D.
1004	U.S. Patent No. 8,608,737 to Mehta <i>et al.</i> (“ <u>Mehta</u> ”)
1005	International Patent Application Publication No. WO 2010/016848 by Na <i>et al.</i> (“ <u>Na</u> ’848”)
1006	[Reserved]
1007	Order No. 35 Construing Certain Terms of the Asserted Claims (Markman Claim Construction) from Related ITC Action
1008	[Reserved]
1009	[Reserved]
1010	Korean Registered Utility Model KR20-0441552 to Lee <i>et al.</i> (“ <u>Lee</u> ”)
1011	Certified Translation of Korean Registered Utility Model KR20-0441552 to Lee <i>et al.</i> (“ <u>Lee</u> ”)
1012	International Patent Application Publication No. WO 2008/005477 by Livneh (“ <u>Livneh</u> ”)
1013	Korean Registered Patent KR10-0719395 to Kang (“ <u>Kang</u> ”)
1014	Certified Translation of Korean Registered Patent KR10-0719395 to Kang (“ <u>Kang</u> ”)
1015	U.S. Patent No. 7,824,394 to Manstein (“ <u>Manstein</u> ”)
1016	U.S. Patent No. 7,618,429 to Mulholland (“ <u>Mulholland</u> ”)

Exhibit	Description
1017	U.S. Patent Application Publication No. 2007/0142885 by Hantash <i>et al.</i> (“ <u>Hantash</u> ”).
1018	U.S. Patent Application Publication No. 2009/0093749 by Shalev <i>et al.</i> (“ <u>Shalev</u> ”)
1019	U.S. Patent Application Publication No. 2009/0048557 by Yeshurun <i>et al.</i> (“ <u>Yeshurun</u> ”)
1020	U.S. Patent No. 9,775,774 to Na (“the ’774 patent”)
1021-1024	[Reserved]
1025	U.S. Provisional Patent Application No. 61/449,080 by Na
1026	Substitute Declaration of Jean Woloszko, Ph.D
1027	Serendia-Ilooda Settlement Agreement
1028	Excerpt from November 7, 2023 Evidentiary Hearing Transcript from related ITC proceeding
1029	Order No. 3 (Proposed Scheduling Order) from related ITC proceeding
1030	Order No. 2 (Ground Rules) from related ITC proceeding
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

Exhibit	Description
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
1039	Prime Journal Media Guide
1040	Supplemental Declaration of Dr. Jean Woloszko

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" should be given its plain and ordinary meaning, which distinguishes between needles that extend a *desired distance* as opposed to an *undesired distance* (Petition, 17-18; Ex.1003, ¶¶56-59)¹.

Serendia initially construed "desired distance" as "based on a user's selection" (PO's Preliminary Response ("POPR"), 33-37)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, 16), a "depth...programmed by the user" (*id.* 21), and "based on programming of this distance through user selection of the depth of needle insertion" (*id.*, 15). All PO's interpretations fail fact and law and regardless, all are disclosed in the prior art.

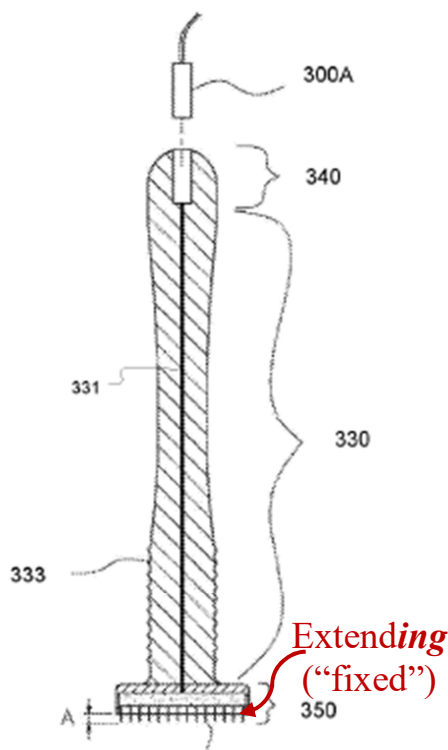
¹Petitioner's emphasis throughout unless otherwise indicated.

²POPR only mentions "program" to "support" this initial construction, not as part of the construction itself (POPR, 37), nor does it mention the device's **user** (i.e., operator) programming at all.

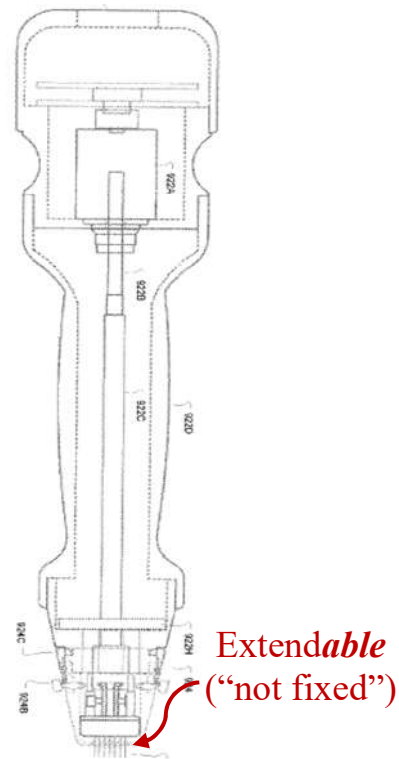
A. “Desired Distance” Has the Same Meaning in Claims Across Related Patents

It is presumed “the same claim term in the same patent **or related patents** carries the same construed meaning.” *Aventis Pharms. v. Amino Chems. Ltd.*, 715 F.3d 1363, 1380 (Fed. Cir. 2013) (internal quotations omitted). Related child U.S. Patent 9,775,774 (Ex.1020, “Related Patent”) claims make clear “desired distance” is the same distance either “**extending or extendable**” needles extend from a surface (Ex.1020, cl.1,11). PO asserts the ‘536 Patent claims “are limited in scope 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, 9-11, Ex.1007, 16)³:

³Petitioner's Figures annotations in red throughout.



'536 Patent FIG.2B



'536 Patent FIG.9D

Regardless of whether the needles are **extending** (fixed) or **extendable** (not fixed), both types extend to the same “desired distance” (Ex.1020, cl.1,11).

Consistently construing “desired distance,” which is the same distance, for both extending and extendable needles therefore does not “contradict the language of the claims,” so *TIP Sys. v. Phillips & Brooks/Gladwin, Inc.* is irrelevant (POR, 9-10). Both PO and its expert neglect to consider claim consistency, rendering their analysis incomplete: PO misinterprets consistency as “inapplicable” across related patents (POPR, 37; contradicting *Aventis* above) and PO’s expert admits he simply did not consider whether PO’s construction is consistent with “extending” needles

in the Related Patent claims (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 the Related Patent claims, which are *fixed* relative to the surface and so, cannot be user-programmed (Ex.1007, 16; Ex.1040, ¶11). Because “desired distance” has the same meaning in related patent claims, it is likewise not user-programmed in the related ‘536 Patent claims.

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). In fact, selection appears nowhere in any ‘536 Patent claim (Ex.1001, all claims). “[D]esired distance” cannot require user-selection because PO's expert confirms a Related Patent claim reciting “desired distance” (Ex.1020, cl.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: “a user **may** select” (Ex.1001, 13:33-36, 13:58-61, *see also* 9:43-50, 10:9-13, 10:37-41). *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 ’536 Patent’s Examiner (Ex.1040, ¶8; Ex.1031, 87:14-88:1; POR, 16 and Ex.2147, ¶80, 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.1040, ¶8).

PO’s new construction, “based on a user programming this distance,” likewise improperly imports optional embodiments from the specification into the claims: POR, 14-15 citing Ex.1001, 10:9-13 (“may control”), 10:37-41 (“may employ the algorithm”), 9:31-34, 9:43-50 (“may include”), 13:33-36 (describing Fig.12: “may select...depth”), 13:39-41, 13:61-63, (“may enable”), 13:49-14:4 (“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** selection" (POR, 16, 29) contradicts PO's infringement position at the ITC:

[T]he desired distance that the needles extend is **predetermined** by the **mechanical adjustment** on the handpiece (Ex.1034, ¶182; Ex.1031, 158:8-159:10).

"[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 at least claims 1, 11, and 16 (Ex.1034, ¶¶40-49, 75-85) having a mechanical dial on the handpiece:



(Ex.1032, 1; Ex.1031, 136:11-137:3). PO's expert explained "the mechanism for adjusting the desired distance of needle extension" is "[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, ¶¶45, 49) that only allows "two positions" ("in or out") —i.e., a single fully extended ("out") position/distance (Ex.1033, 336:14-21; Ex.1031, 168:17-170:10; Ex.1040, ¶13). Because PO interpreted "desired distance" as selected entirely manually (mechanically rotating the handpiece's dial) for infringement, desired distance cannot require "a user programming this distance" that excludes manual selection for invalidity (POR, 16, 29). *L.A. Biomedical Research 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 selection (mechanical programming), e.g., rotating a hand-dial (in the accused Pixel8 device) or manually switching cartridges (as in Mehta) (Ex.1040, ¶¶13,16; POR, 11-12, 29). In either case, a motor that extends needles a desired distance is programmed to do so (Ex.1040, ¶12).

PO's expert confirmed these opinions from the ITC in this proceeding (Ex.1031, 143:9-147:22, 158:8-159:10). 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 Petitioner 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 depth control as discussed below.

PO’s expert contradicts PO by confirming Mehta’s cartridges do not have extending **ing** needles, but “extendable” needles (POR, 11-12; Ex.1031, 59:5-21). *See* “electrodes ... extendable 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, 12, PO’s emphasis) ignores that this embodiment refers to “a **particular** length,” not any length (POR, 11, 29, quoting Petition, 33)

PO’s issue that the claims rely on the user’s “mental state” (POR, 12-13) 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, 10-11). 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, 12-13). 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, ¶49,81).

Embodiment (3) also satisfies the “desired distance” limitation (POR, 13) because “manually” refers to “checking the needle location,” not “adjusting the needle depth” which is programmed in Mehta (see below). Regardless, PO confirmed manually selecting the desired distance is covered in the accused devices. Petitioner notes it identified embodiments (1)-(3) (POR, 11-13) as “**at least** three ways to meet the ‘desired distance’ limitation” (Petitioner’s Reply to POPR, 7; citing Ex.2125, 1151:2-18) and Mehta discloses others (discussed below).

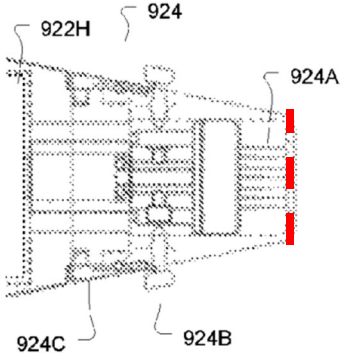
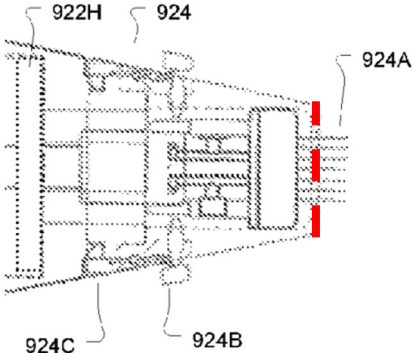
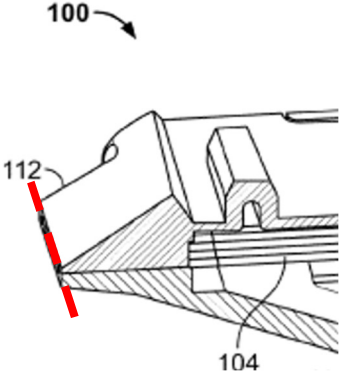
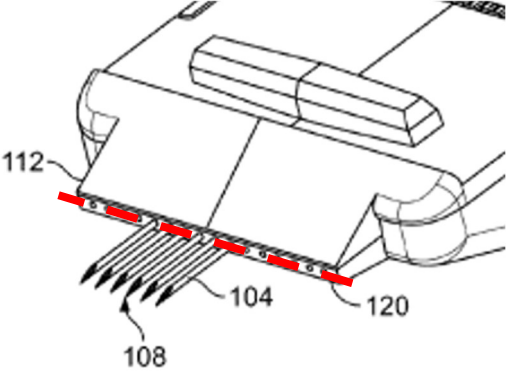
In sum, all PO’s constructions are unduly narrow and regardless, all are disclosed in the prior art as outlined below.

II. GROUND I: MEHTA ANTICIPATES CLAIMS 1-3, 6, 8, 11-13, 16, AND 18

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, 13, Board’s emphasis). To circumvent anticipation, all PO’s alleged distinctions over Mehta rely on new unclaimed optional embodiments imported from the Specification, as discussed above, to narrowly construct “desired distance” as “programmed by the user” (*see* POR, 20-21, 25-31). 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, ¶¶87, 89, 91-93), just like the “extendable needles” in the ’536 Patent’s Figs.9C-9D (POR, 6, 10):

'536 Patent Fig.9C (excerpt) ⁴ Retracted	'536 Patent Fig.9D (excerpt) Extended
 A schematic diagram of a device in a retracted state. It shows a rectangular frame with internal components. Labels 922H, 924, 924A, 924C, and 924B are present. Two vertical red dashed lines are positioned on the right side of the device.	 A schematic diagram of the same device in an extended state. The internal components are shifted to the right. Labels 922H, 924, 924A, 924C, and 924B are present. Two vertical red dashed lines are positioned on the right side of the device.
Mehta FIG.4C (excerpt) Retracted	Mehta Fig.4A (excerpt) Extended
 A perspective view of a device in a retracted state. Label 100 points to the top surface. Label 112 points to a red dashed line on the left side. Label 104 points to a component at the bottom. A red dashed line is also visible on the right side.	 A perspective view of the device in an extended state. Label 112 points to a red dashed line on the left side. Label 104 points to a component at the bottom. Label 108 points to a series of parallel lines at the bottom. Label 120 points to a component on the right side. A red dashed line is also visible on the right side.

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

⁴Red dashes illustrating the “end surface.”

to the **desired depth** of tissue” (Ex.1004, 21:8-10)⁵. 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, 13-14).

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

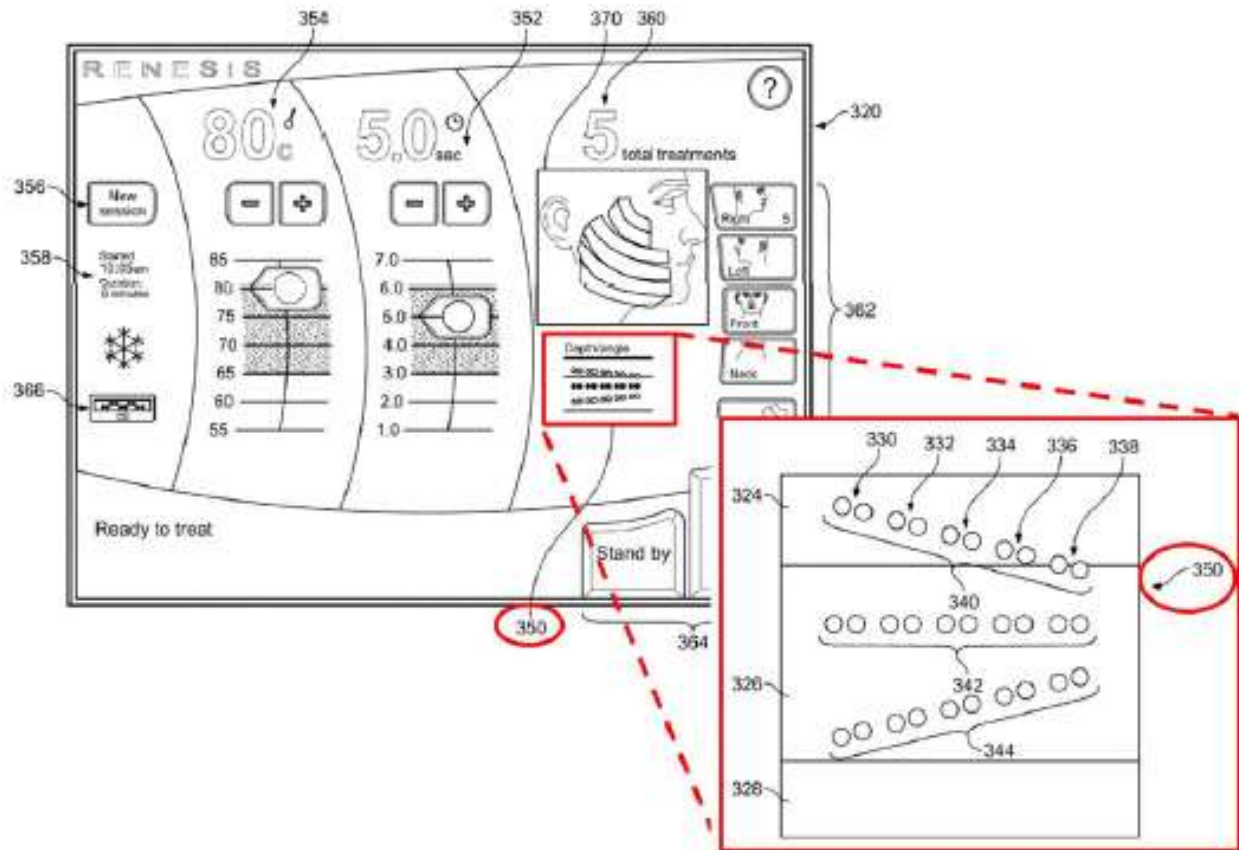
**1. Desired Distance: Based On A User’s Selection
(PO’s Original Construction)**

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, 11). 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, 15-16).

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”

⁵Mehta’s needles are oriented as illustrated in the ‘536 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, 19; Ex.1004, Figs.10A-F, 32:46–33:43; Ex.1003, ¶102; Petition, 32-33).

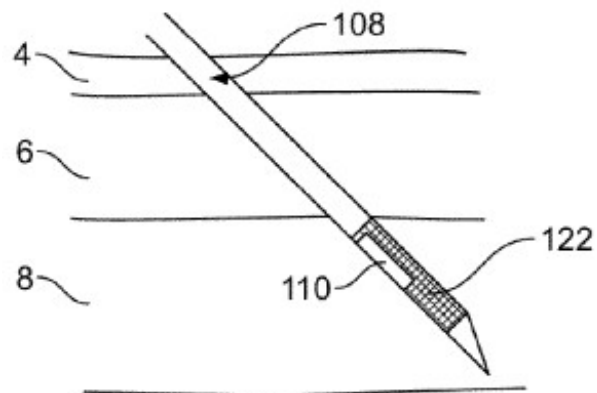
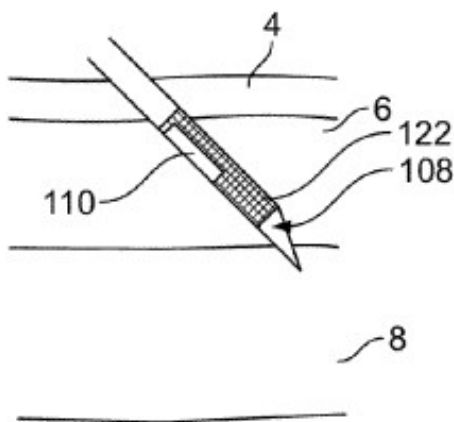
The “physician” –i.e. user– uses this information to control “advancement of the probes” to the “desired depth”:

[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):

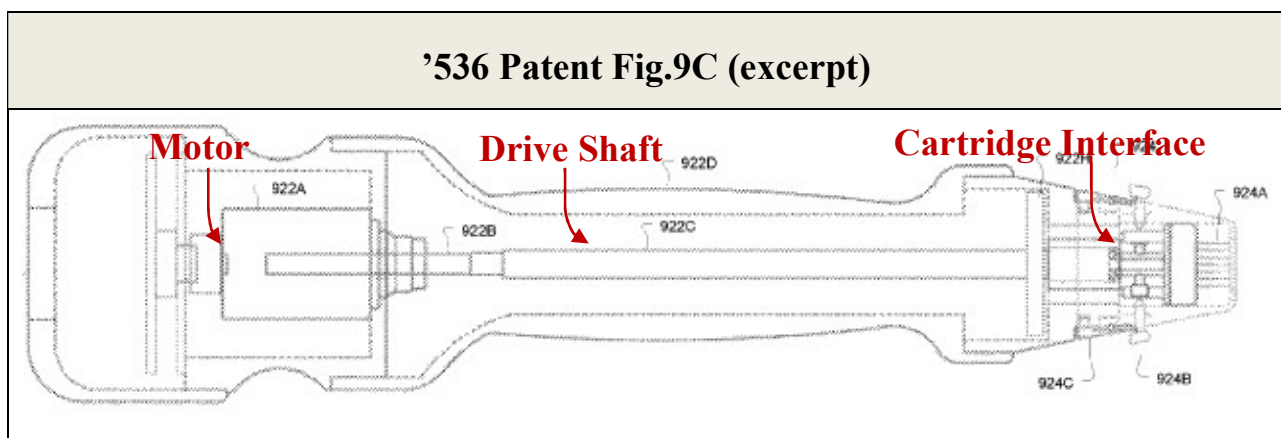


Mehta's disclosure of a "physician" or "user" operating a "system" that is motor-driven "adjusted to guide probe placement" to "precisely control" and "reposition" needles for their "further advancement" and "placement adjustment" to a "desired depth" is "based on a user's selection" (Ex.1004, 2:37-41, 21:8-10, 24:27-45, 24:61-25:2, 33:24-27).

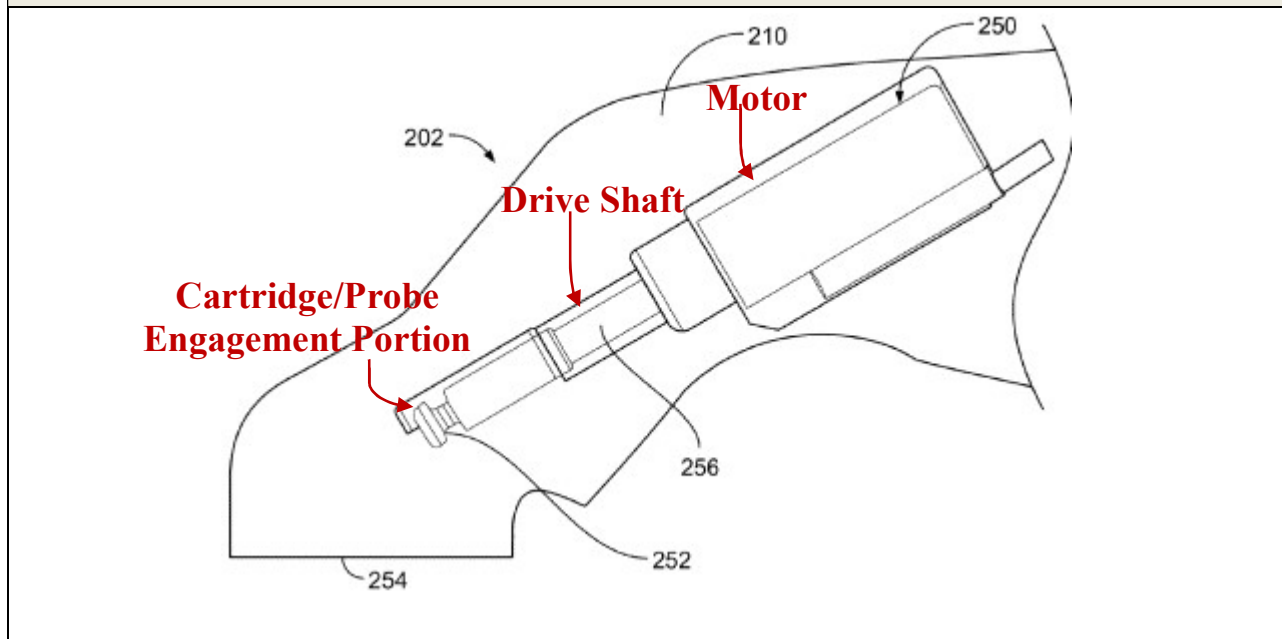
The Board confirmed "Mehta's clear and unambiguous teachings of [] means for selecting and controlling how far the needles are inserted into the tissue. ... [in which] **the user selectively actuates a motor** to cause insertion of the needles to the desired depth" (Institution Decision, 16).

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

Mehta's system comprises a "control system/energy supply unit 90" that actuates a "motor" to drive 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, ¶¶99-105), just like the '536 Patent (Ex.1001, 10:57-11:2):



Mehta FIG.5 (excerpt)



Mehta discloses a “step-motor” to move the electrode assembly to various “stepping” distances (Ex.1004, 15:34-40; Ex.1003, ¶¶102, 104), just like the ‘536 Patent (Ex.1001, 11:31-36):

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.1040, ¶14; Ex.1003, ¶¶102-105). 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.1040, ¶12,14; Ex.2154, 53:9-11).

Mehta further discloses “[o]ver-inserting and then partially retracting” the electrodes (Ex.1004 at 16:39-41; Ex.1003, ¶101; Ex.1040, ¶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.1040, ¶15). PO’s argument that partial insertion “simply ‘compensates for the movement and laxity of the skin...’ (POR, 29-30) does not negate its programming.

Selecting/replacing cartridges having different extendable needle lengths or angles (POR, 29-30; Ex.1004, 12:31-46, 17:66-18:3; Ex.1003, ¶101) also requires that Mehta’s motor is programmed to extend needles to the cartridge-programmed distance (Ex.1040, ¶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.1040, ¶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.1040, ¶¶12-17). To the extent PO asserts “a motor extending needles a predetermined distance” is inherently “programmed” in the claims (POR, 13, 17-21), it must also be so “programmed” in Mehta (POR, 20-21, 25-31).

PO criticizes that “Jeisys does not even contend that Mehta discloses programming the distance” in its original Petition (POR, 25). “Programming” however is not claimed, nor part of PO’s own original construction (POPR, 33).

PO reiterates (from POPR, 45-46) and relegates to footnote (POR, fn. 4, p. 25), 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 ‘536 Patent. The Board held:

“Mehta is *not*⁶ substantially the same as Mehta ’705 ... notably lacking from Mehta ’705 is **any disclosure of determining the**

⁶Board’s emphasis.

‘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.”
(IPR2024-00463, Institution Decision, 11-12)

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

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, 27-28, 30-31). 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, ¶102). Regarding “programming”
(POR, 20-21, 25-31), 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.1040, ¶¶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, 28-29, citing Ex.1003, ¶104). "[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.1040, 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 '536 Patent (only disclosing "motor(s) 922A may include steps," Ex.1001, 11:31-34).

Accordingly, Mehta anticipates claims 1-3, 6, 8, 11-13, 16, and 18 under Ground I.

III. GROUND II: MEHTA AND KNOWLEDGE OF POSA RENDER OBVIOUS CLAIMS 1-8 AND 11-18

A. Claims 1-3, 6-8, 11-13 and 16-18

Ground II provides reasoned explanation, supported by evidence, *why* a POSA would have been motivated to modify Mehta (POR, 31-35; Petition, 48-57; Ex.1003, ¶¶149-184). Ground II does not use the '536 Patent as a roadmap (POR, 35-36) because Mehta itself motivated "precision over **depth control**" for "controlled delivery of a specific thermal coagulation profile at a **particular depth**

in the dermis” and “ensured adequate sparing of normal tissue.” (Ex.1004, 37:7–11, 39:33–41). Additional motivations, e.g., “streamline treatment, improve the patient’s experience, and decrease treatment costs” (Petition, 48-49) are “universal” improvements motivated “even absent any hint of suggestion in the references themselves” (POR, 34-35). *Dystar Textilfarben GmbH v. C.H. Patrick Co.*, 464 F.3d 1356, 1368 (Fed. Cir. 2006).

Mehta does not seek to minimize variance in needle depth (POR, 32). A “consistent starting point” merely promotes uniform depth in a single extension (Ex.1004, 21:10-16). In general, Mehta provides needle depth **variation** to reach **different** target regions/depths: “the desired target layer of tissue can **vary** depending on the desired result of the treatment” (Ex.1004, 33:30-34). PO acknowledges Mehta’s needles extend “to reach different target depths” (POR, 1). PO further alleges Mehta teaches “a different approach” than “distance control” (POR, 32-33) that ignores this needle-depth variation in Mehta. Regardless, merely disclosing one solution does not teach away from alternative solutions. *Galderma Labs. v. Tolmar, Inc.*, 737 F.3d 731, 738 (Fed. Cir. 2013).

B. Claims 4-5 and 14-15

1. Illuminating Needle Assembly

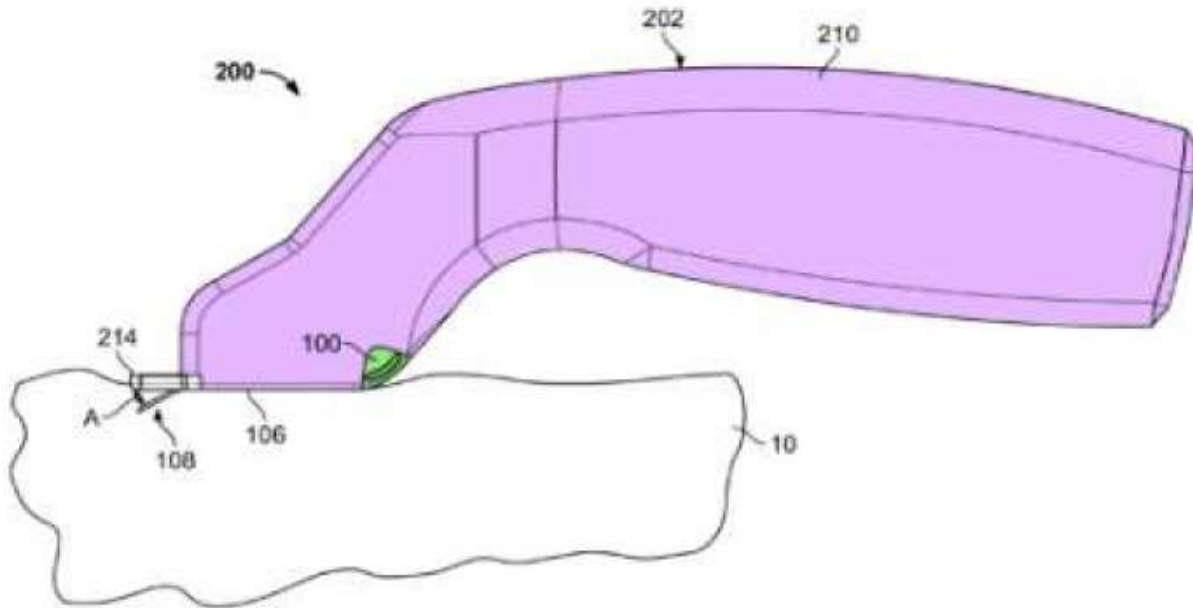
Mehta disclosed a “diode...emitter” of “light” (Ex.1004, 11:24-39) that PO does not dispute rendered obvious an LED. PO acknowledges Mehta discloses

“several” mechanisms for, and so, explicitly motivated, “assist[ing] a physician in confirming the intended treatment area...or to illuminate depth markings or other distinguishing features of the needles” (POR, 37). To improve the ability for “a physician to directly observe insertion of the probe array 108” (Ex.1004, 13:16-20), the inserted/extended needles would have been obvious to illuminate (Ex.1003, ¶171). Because “needles” are part of the claimed “needle assembly” (Ex.1001, cl.1,11), illuminating Mehta’s inserted/extended needles necessarily illuminates the “needle assembly” (Ex.1001, cl.4-5,14-15). PO’s argument that Mehta discloses “different mechanisms” for visualizing treatment (POR, 37, 43) does not teach away from alternative solutions. *Galderma*, 737 F.3d at 738.

2. Embedded

PO does not dispute the benefits that embedding LEDs provide “a sleek outer profile” by “prevent[ing] them from protruding outward from the handpiece/device body 210” (Petition 53; Ex.1003, ¶172). Instead, PO argues embedding LEDs requires transparent exposed internal components that are “scary looking” (POR, 39, 42). Mehta, however, motivated illuminating target probe 108 insertion area (Ex.1004, 13:16-20), so only the **bottom-facing** portion of cartridge 100 below, directly in the illumination path of the embedded LED, would have a transparent or translucent opening to allow light to pass (device body 210 is

otherwise opaque, concealing internal components, as illustrated in purple below)
(Ex.1040, ¶18, Ex.1004, Figs. 2B-2C):

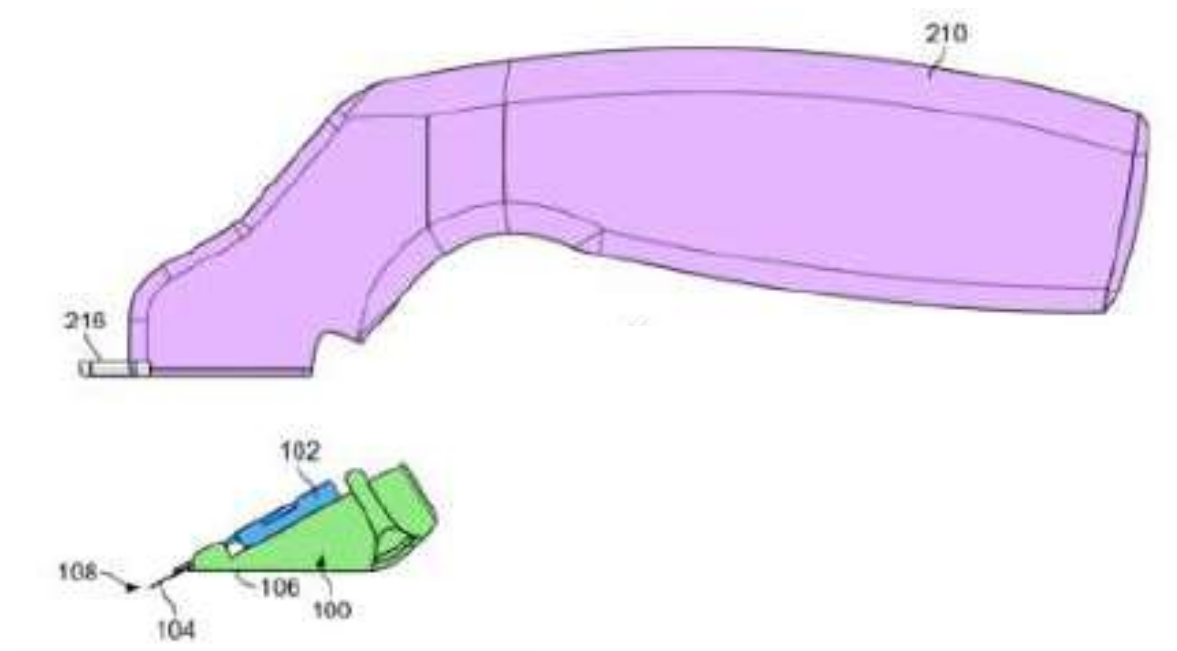


A transparent/translucent opening directly in the LED illumination path would only expose the LED, not other internal components (Ex.1040, ¶18). Regardless, a POSA would have used “translucent” material that “scatter[s] illumination” from the LED, further concealing any bottom-facing internal components (Petition 55; Ex.1003, ¶177; Ex.1040, ¶18).

3. Translucent

PO argues Mehta's opaque device body 210 (purple) would block a translucent needle assembly's illumination (POR, 41-42), which is downward below (Ex.1040, ¶18), but Mehta's device body 210 cannot cover the downward

bottom-facing surface or it would be impossible to attach/exchange cartridges 100 (green) (Ex.1004, Fig.2D):



Regarding LED placement (POR, 38-39), an LED at a proximal part of the handle near 216 (Ex.2148, 416:11-19) that is embedded would be interior to device body 210, and thus necessarily illuminate, needle assembly 102 that extends to the device's proximal end. Moreover, Serendia's expert confirmed changing LED location was not inventive (Ex.2126, 1547:8-25). *See Nano-Second Tech. Co. v. Dynaflex Int'l*, 944 F. Supp. 2d 855, 864 (C.D. Cal. 2013) (“[t]he location of the...LEDs is merely a matter of design choice”).

**IV. GROUND III: MEHTA, NA '848 AND KNOWLEDGE OF POSA
RENDER OBVIOUS CLAIMS 4-5 AND 14-15**

**A. Na '848 Disclosed Embedded LEDs (Claims 4, 14) and
Translucent Needle Assembly Section (Claims 5, 15):**

All support in the '536 Patent for an “embedded LED” (Ex.1001, 4:63-66, 5:55-60) and “translucent” needle assembly section (Ex.1001, 5:15-18) is **identically** disclosed in Na '848 (Ex.1005, ¶34-¶35⁷, 38). To the extent claims 4-5, 14-15 contain written description for an embedded LED and translucent needle assembly section, they are identically disclosed in Na '848.

Embedded LEDs: Ground III relies on Na '848 for embedded LEDs, not the location of light sources (Petition, 59-60,62; POR, 44-45,48), which PO does not contest is already disclosed at the proximal end of Mehta's handpiece/device body 210 (Ex.1004, 11:24-39; Ex.1003, ¶170).

Translucent: Ground III relies on Na '848 for the needle assembly having a translucent section, not its mechanical separability, which PO does not contest is already disclosed in Mehta (Petition, 60-63; POR, 45-46,48). PO also ignores Mehta's configuration when needles extend “at a more vertical angle like a pencil or pointer,” i.e., so embedded LEDs are behind the needle assembly, particularly motivating making Na '848' needle assembly section translucent to allow light

⁷Only translucent “outer casing 924E” is otherwise disclosed (Ex.1001, 12:32-35).

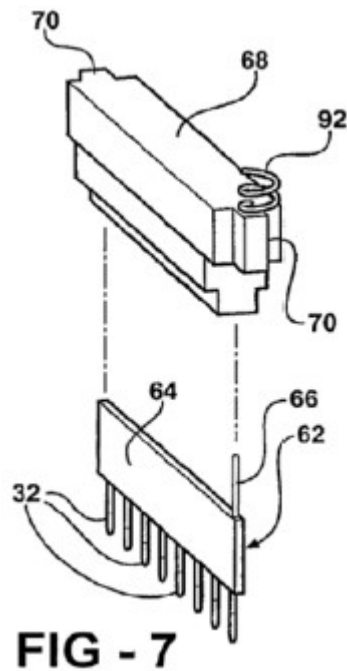
traversing its path to illuminate the needles (Ex.1004, 9:53-59; Petition 61; Ex.1003, ¶192).

B. Motivation to Combine Mehta and Na'848

PO's rationale to not combine Mehta and Na '848 –that only Mehta (not Na '848) “deliver[s] energy”– is false (POR, 46-47; Ex.2147, ¶133). Both Mehta and Na '848 deliver electrical *and* mechanical energy: Mehta explicitly defines delivering energy to encompass both “electrical” and “mechanical” energy (Ex.1004, 9:43-48). Likewise, Na '848 delivers both mechanical energy (“vibrate...pins”) and electrical energy (“the pins may be electrically coupled...to form dipole pair (bipolar pins)”) (Ex.1005, ¶28-30). PO's expert confirmed Na '848's bipolar pins deliver “electrical current that travels from at least one pin to at least another,” i.e. electrical energy, through the skin (Ex.1031, 193:12-194:7).

V. GROUND IV: MEHTA IN VIEW OF LIVNEH RENDER OBVIOUS CLAIMS 7 AND 17

Contrary to POR 49-50, Ground IV provides detailed and reasoned explanation why a POSA would have been motivated to provide electrical contacts to first and second needle groups, instead of individual needles (Ex.1003, ¶¶204-206). *See e.g.*, Livneh's coil 92 electrically contacting group of needles 32 below, Ex.1012, Figure 7) (in contrast to Mehta's needle-specific individual contacts 116, Ex.1004, Fig. 4A):

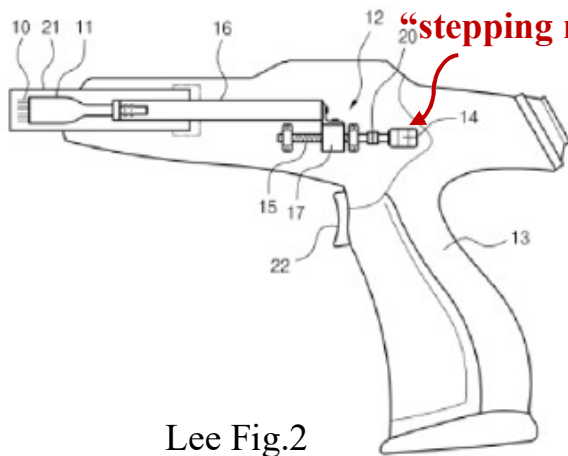


Whereas energizing needles in groups, instead of individually, clearly **reduces** the number of electrical components, cost and complexity (Ex.1003, ¶¶205-206), PO's expert states the opposite without any explanation (Ex.2147, ¶136; cited at POR, 50). Petitioner's motivation is not "hindsight analysis" (POR, 49-50) since reducing cost and complexity are "universal" improvements motivated "even absent any hint of suggestion in the references themselves." *Dystar*, 464 F.3d at 1368.

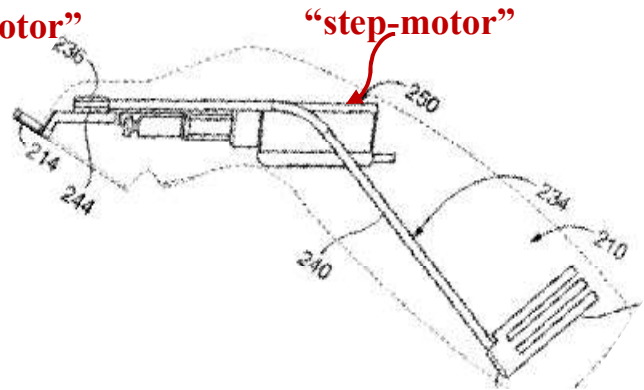
VI. GROUND V: MEHTA AND LEE RENDER OBVIOUS 1-3, 6, 8, 11-13, 16 AND 18

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, ¶¶74-76,211). Both Mehta and Lee aim to solve the same

problem of targeting and precisely controlling the needles' desired location/depth (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, ¶¶152, 211-214):



Lee Fig.2



Mehta Fig.3B (rotated)

Ground V does not use the '536 Patent as a roadmap (POR, 56) because the cited motivation is in Mehta itself (Petition, 70-71; Ex.1003, ¶¶158-159, 213-214). 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, 52-53). 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 (Ex.1004, 8:66-9:6, *see also* 9:43-48). Mehta thus disclosed, and directs a POSA to consider and combine art disclosing, “delivery of mechanical energy” as in Lee.

PO alleges Lee's needle extension/retraction rate is too fast (at minimum every 0.9 seconds) for Mehta's treatment time (at minimum 1 second) (POR, 53-54). 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 V, further, does not cite Lee for its treatment times, only Lee's needle depth-control (Petition, 70). While Mehta motivates incorporating Lee's needle depth-control, Mehta does **not** motivate **eliminating** delivering electrical RF energy, and thus, Mehta so modified by Lee would maintain Mehta's RF treatment times (Petition, 68-71; Ex.1003, ¶¶211-214; Ex.1004, 11:14-15).

PO alleges Mehta teaches “a different approach” to “distance control” by confirming the location of “already-extended” probes (POR, 54-56). 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*, 737 F.3d at 738 .

VII. GROUND VI: MEHTA IN VIEW OF LEE AND KNOWLEDGE OF POSA RENDERS OBVIOUS CLAIMS 1-8 AND 11-18

PO’s only arguments against Ground VI incorporate arguments for Grounds II and V (POR, 56). PO is incorrect for the reasons above. *See supra* Sections III and VI.

VIII. GROUND VII & VIII: CLAIMS 4-5, 7, 14-15 AND 17

PO’s only arguments against Grounds VII and VIII incorporate arguments for Grounds III and IV (POR, 57). PO is incorrect for the reasons above. *See supra* Sections IV-V.

IX. SECONDARY CONSIDERATIONS

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 ’536 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 '536 Patent but instead goes to the heart of another one of Serendia's patents." (Institution Decision, 17); citing PO: "The Sylfirm X has achieved commercial success **due in part** to implementation of the inventions claimed in the '536 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 '536 Patent (IPR2024-00842 Institution Decision, 11, Board's emphasis). Because PO's different patents cover different inventions: U.S. 9,480,836 allegedly covers the "Na effect" (IPR2024-00386, POPR, 61-63), whereas the '536 Patent instead covers needle depth control (Ex.2147, ¶189; Ex.2135, ¶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 correctly concludes PO has failed to explain “how its evidence of commercial success is the ‘direct result of the unique characteristics of the claimed invention,’ as opposed to those of the claimed invention at the heart of Serendia’s other patent.” (Institution Decision, 18).

2. PO Fails to Show Commercial Success

PO’s only cited year-to-year sales comparison –2021 vs. 2022 (POR, 62-63)– 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 (POR, 65) 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

article⁸ (Ex.1039, 11). PO confirms Ex.2066 is “marketing” material (POR, 64).

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).

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 Grounds II-VIII.

X. CONCLUSION

In view of the foregoing, Petitioner respectfully requests the Board find claims 1-8 and 11-18 of the '536 Patent unpatentable.

Respectfully submitted,

Date: April 15, 2025

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

⁸2025 rate.

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 to be no more than 5,600 words. As calculated by the word count feature of the word-processing system used to prepare this reply, it contains 5,490 words, excluding the parts of this reply that are exempted by 37 C.F.R. § 42.24(c) ("The word counts or page limits do not include a table of contents; a table of authorities; a listing of facts that are admitted, denied, or cannot be admitted or denied; a certificate of service or word count; or an appendix of exhibits").

Date: April 15, 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 for U.S. Patent No. 9,320,536 and supporting Exhibits, is being served via electronic mail, on April 15, 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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