

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. IPR2024-00463

U.S. Patent No. 10,869,812

PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE

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EXHIBITS

Exhibit	Description
1001	U.S. Patent No. 10,869,812 (“’812 Patent”)
1002	File History of the ’812 Patent
1003	Declaration of Dany Bérubé, Ph.D.
1004	<i>Curriculum Vitae</i> of Dany Bérubé, Ph.D.
1005	Order No. 35: Construing Certain Terms of the Asserted Claims, Inv. No. 337-TA-1356
1006	U.S. Patent No. 8,608,737 to Mehta <i>et al.</i> (“Mehta”)
1007	International Patent Application Publication No. WO 2010/016848 by Na <i>et al.</i> (“Na’848”)
1008	Korean Registered Utility Model KR20-0441552 to Lee <i>et al.</i> (“Lee”)
1009	Certified Translation of Korean Registered Utility Model KR20-0441552 to Lee <i>et al.</i> (“Lee”)
1010	International Publication Number WO 2008/005477 by Livneh (“Livneh”)
1011	U.S. Patent No. 8,540,705 to Mehta <i>et al.</i> (“Mehta’705”)
1012	U.S. Patent No. 9,775,774 to Na (“’774 Patent”)
1013	U.S. Patent Application Publication No. 2009/0093749 by Shalev <i>et al.</i> (“Shalev”)
1014	U.S. Patent Application Publication No. 2009/0048557 by Yeshurun <i>et al.</i> (“Yeshurun”)
1015	Korean Registered Patent KR10-0719395 to Kang (“Kang”)

Exhibit	Description
1016	Certified Translation of Korean Registered Patent KR10-0719395 to Kang ("Kang")
1017	U.S. Patent No. 7,824,394 to Manstein ("Manstein")
1018	U.S. Patent No. 7,618,429 to Mulholland ("Mulholland")
1019	U.S. Patent Application Publication No. 2007/0142885 by Hantash <i>et al.</i> ("Hantash")
1020	U.S. Application No. 61/449,080 by Na ("Na'080")
1021	Substitute Declaration of Dr. Jean Woloszko
1022	Serendia-Ilooda Settlement Agreement
1023	Excerpt from November 7, 2023 Evidentiary Hearing Transcript from related ITC proceeding
1024	Order No. 3 (Proposed Scheduling Order) from related ITC proceeding
1025	Order No. 2 (Ground Rules) from related ITC proceeding
1026-1029	[Reserved]
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 PiXeI8 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

Petitioner submits this 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, 11-12; Ex.1003, ¶¶49-52)¹.

Serendia initially construed "desired distance" as "based on a user's selection" (PO's Preliminary Response ("POPR"), 35,37)². However, after the Board confirmed Mehta discloses this (Institution Decision, 16-18), PO added the distance must be "based on a user programming this distance" (POR, 16), a "depth...programmed by the user" (*id.* 20), 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.

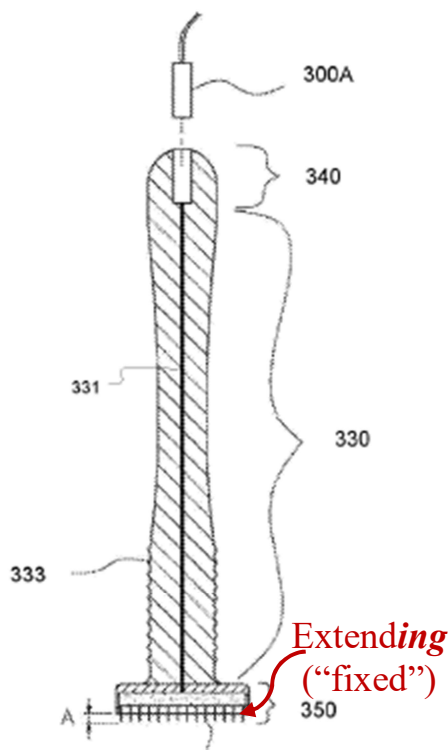
A. "Desired Distance" Has the Same Meaning in Claims Across Related Patents

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

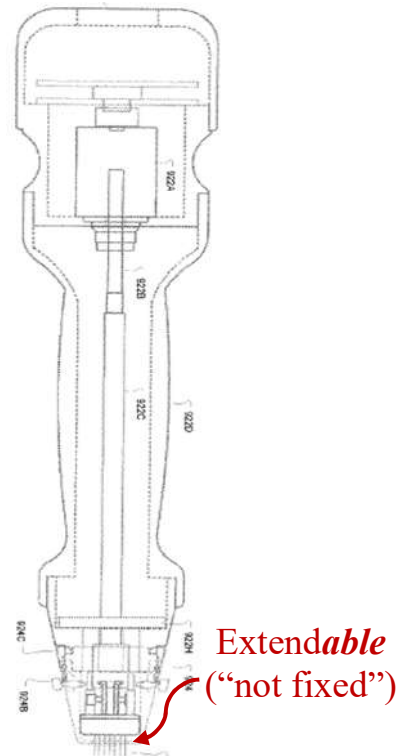
¹Petitioner's emphasis throughout unless otherwise indicated.

²POPR only mentions "program" to "support" this initial construction (POPR, 38), nor does it mention the device's **user** (i.e., operator) programming at all.

F.3d 1363, 1380 (Fed. Cir. 2013) (internal quotations omitted). Related parent U.S. 9,775,774 (Ex.1012, “Related Patent”) claims make clear “desired distance” is the same distance either “**extending or extendable**” needles extend from a surface (Ex.1012, cl.1,11). PO asserts the ‘812 Patent claims “are limited to **extendable** needles” that are “not fixed” and thus move 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, 9-10, Ex.1005, 16)³:



‘812 Patent FIG.2B



‘812 Patent FIG.9D

³Petitioner's Figures annotations in red throughout.

Regardless of whether the needles are extending^{*ing*} (fixed) or extendable (not fixed), both types extend to the same “desired distance” (Ex.1012, 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, 38; 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^{*ing*}” needles in the Related Patent claims, which are *fixed* relative to the surface and so, cannot be user-programmed (Ex.1005, 16; Ex.1030, ¶11). Because “desired distance” has the same meaning in related patent claims, it is likewise not user-programmed in the related '812 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, 14). In fact, selection

appears nowhere in any '812 Patent claim (Ex.1001, all claims). Likewise, the specification confirms all user-selections are optional: “a user **may** select” (Ex.1001, 13:63-66, 14:21-24, *see also* 9:65-10:5, 10:32-37, 10:61-63). *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 grandparent patent's Examiner (Ex.1030, ¶8; Ex.1031, 87:14-88:1; POR, 15-16 and Ex.2147, ¶75, 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, 13-15 citing Ex.1001, 10:32-37 (“may control”), 10:61-65 (“may employ the algorithm”), 9:53-54, 9:65-10:5 (“may include”), 13:63-66 (describing Fig.12: “may select...depth”), 14:3-6, 14:63-66 (“may”), 14:12-35 (“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, 16,30) 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).

PO accused Rohrer’s “Pixel8” device of infringing at least claims 1, 12-14 (Ex.1034, ¶¶180,193-202) having the following 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, ¶¶48,181). 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, ¶182) 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.1030, ¶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, 30). *L.A. Biomedical Research v. Eli Lilly & Co.*, 849 F.3d 1049, 1069 (Fed. Cir. 2017) ("that which infringes if later anticipates if earlier."). Desired distance that requires "user programming" must therefore be broad enough to encompass manual selection (mechanical programming), e.g., rotating a hand-dial (in the accused Pixel8) or manually switching cartridges (as in Mehta) (Ex.1030, ¶¶13,16; POR, 11-12). 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, 158:8-159:10, 162:14-163:19). 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** [Petitioner] 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 confirmed cartridges have “**extendable**” –“not extending”– needles (POR, 11-12; Ex.1031, 59:5-21). Cartridges are selected with “a **particular** length,” not *any* length, so this selection is not superfluous (POR, 11-12). PO’s issue that the claims rely on the user’s “mental state” (POR, 12) is a problem with the term “desired” appearing in the claims themselves, and selecting a cartridge with a desired extended needle distance is the same type of “user action” (*id.*) PO accused of infringement (“mechanical adjustment on the handpiece” Ex.1034, ¶130). Embodiment (3) also satisfies the “desired distance” limitation (POR, 12-13) 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. Embodiments (1)-(3) (POR, 11-13) are “**at least** three ways to meet the

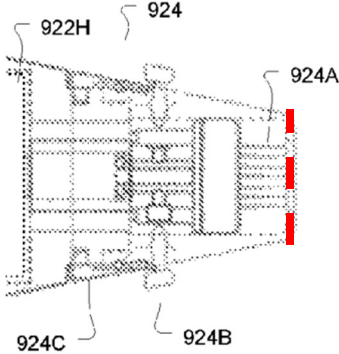
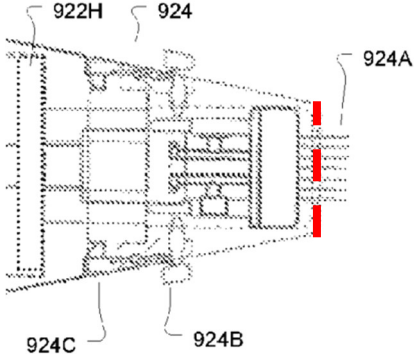
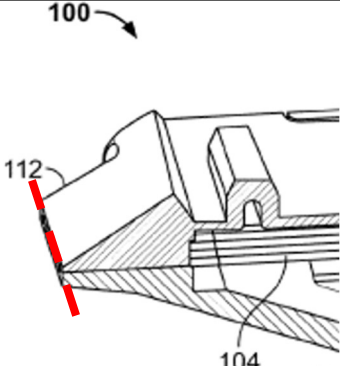
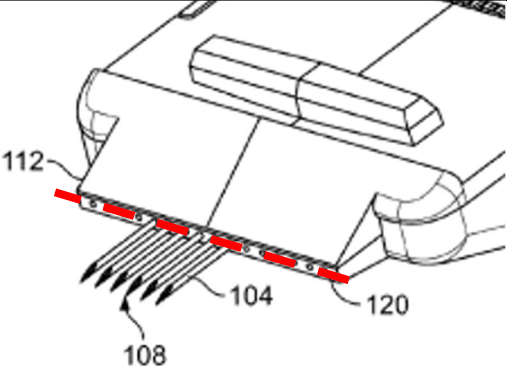
‘desired distance’ limitation” (Petitioner’s Reply to POPR, 7-8; citing Ex.2125, 1151:2-18) and Mehta discloses others (discussed below).

II. GROUND I: MEHTA ANTICIPATES CLAIMS 2-3, 6, 8, AND 13-16

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, 16, Board’s emphasis). To circumvent anticipation, PO relies on new unclaimed optional embodiments to narrowly construct “desired distance” as “programmed by the user” (POR, 20,24-31). 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.1006, 15:45-49, Figs.4C-4D; Ex.1031, 59:5-21, Ex.1003, ¶¶83-85), just like the “extendable needles” in the ’812 Patent’s Figs.9C-9D (POR, 5-6):

'812 Patent Fig.9C (excerpt) ⁴ Retracted	'812 Patent Fig.9D (excerpt) Extended
 A schematic diagram of a device in a retracted state. It shows a rectangular frame with internal components. Labels include 922H at the top left, 924 at the top center, 924A on the right side, 924C at the bottom left, and 924B at the bottom center. A red dashed line is on the right side.	 A schematic diagram of the same device in an extended state. The components are similar to Fig. 9C, but the right side is extended. Labels include 922H, 924, 924A, 924C, and 924B. A red dashed line is on the right side.
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 on the left 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 in the middle. Label 108 points to a series of lines at the bottom. Label 120 points to a component on the right. A red dashed line is on the left 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.1006, 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, 16).

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

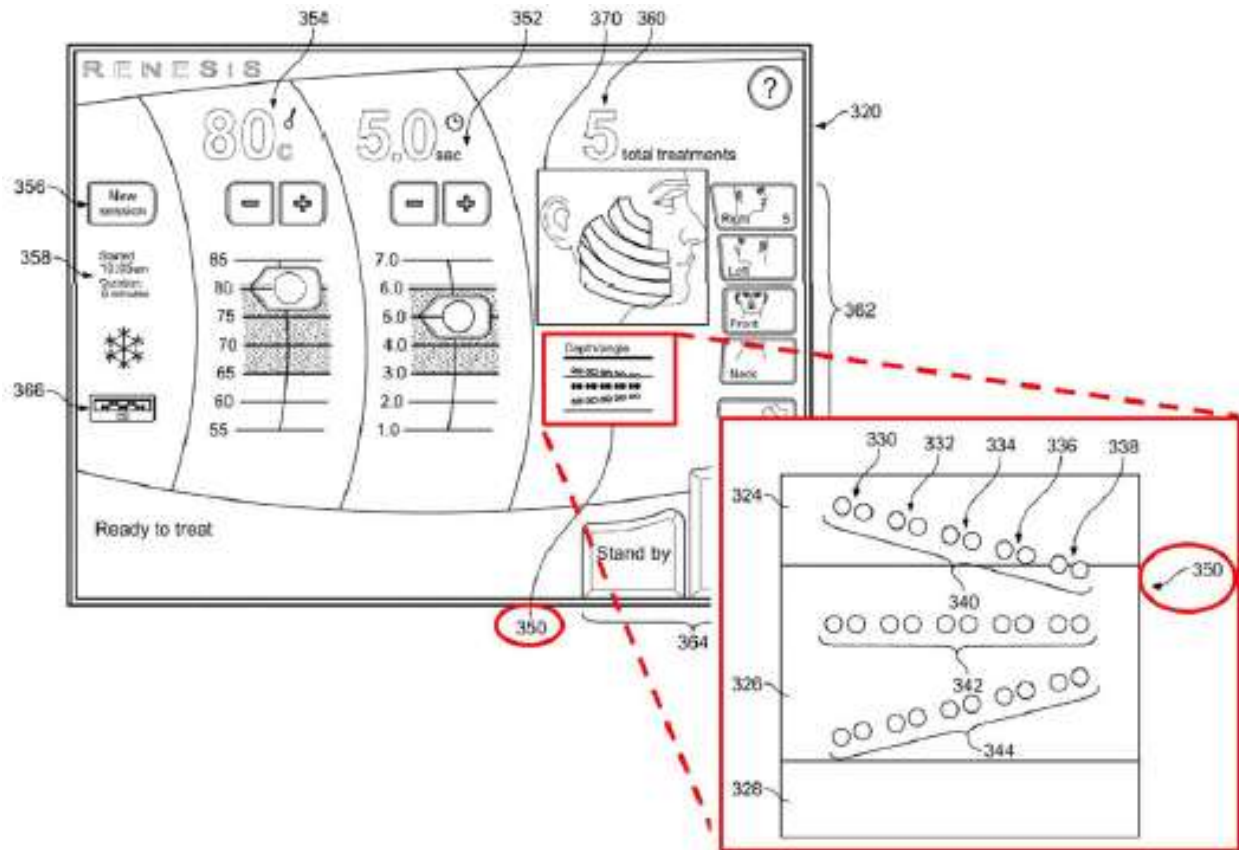
**1. Desired Distance: Based On A User’s Selection
(PO’s Original Construction)**

The Board concluded Mehta discloses the desired distance “even under Serendia’s proposed construction,” i.e., “based on a user’s selection” (Institution Decision, 14,18; *see* POR, 11,20). 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, 17-18).

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.1006, 2:37-41); “information can be provided to the **user for placement adjustment**” of needles (Ex.1006, 24:61-25:2). This information

⁵Mehta’s needles are oriented as illustrated in the ‘812 Patent figures when probes extend “at a more vertical angle to the target tissue like a pencil or pointer” (Ex.1006, 9:53-59; *see also* 12:36-41).

includes “virtual depth/location depiction 350” displaying “actual” and “desired” needle depths for the user to determine the “desired depth of placement”:



(POR, 19; Ex.1006, Figs.10A-F, 32:46–33:43; Ex.1003, ¶96; Petition, 27,40).

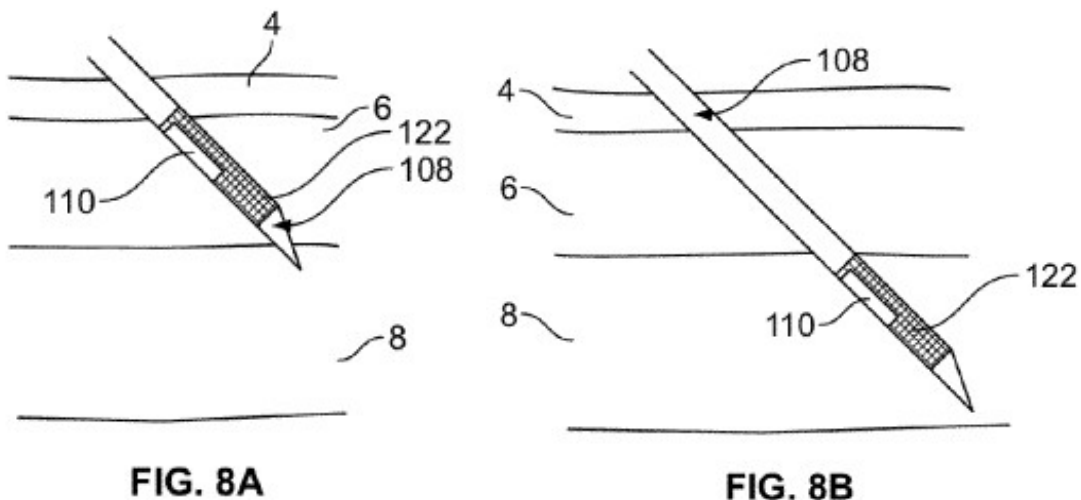
The “physician” –i.e. user– uses this information to control “advancement of the probes” to the “desired depth”:

[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.1006, 32:46–33:34).

Mehta's "system" that is motor-driven (Ex.1006, 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.*).

A user repositions needles from outside target region (Fig.8A) to further extend inside the desired target region (Fig.8B) (Ex.1006, 24:27-45):



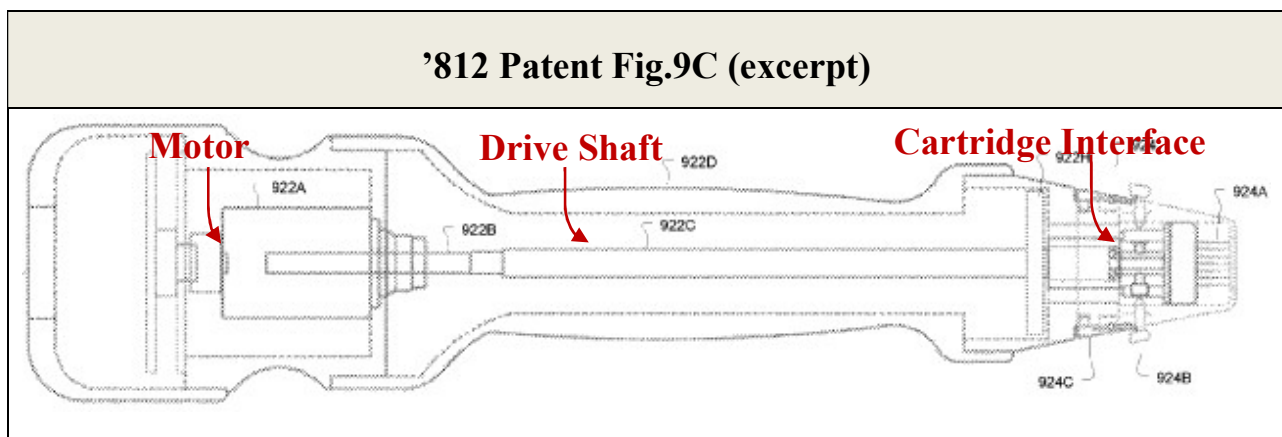
PO's interpretation that Mehta's only passively monitors "already-extended" needles "after the needles [are] extended" (POR, 19, 27-28, 30-31,33) ignores Mehta's disclosure that the user/physician actively controls distance to "precisely

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, ¶96).

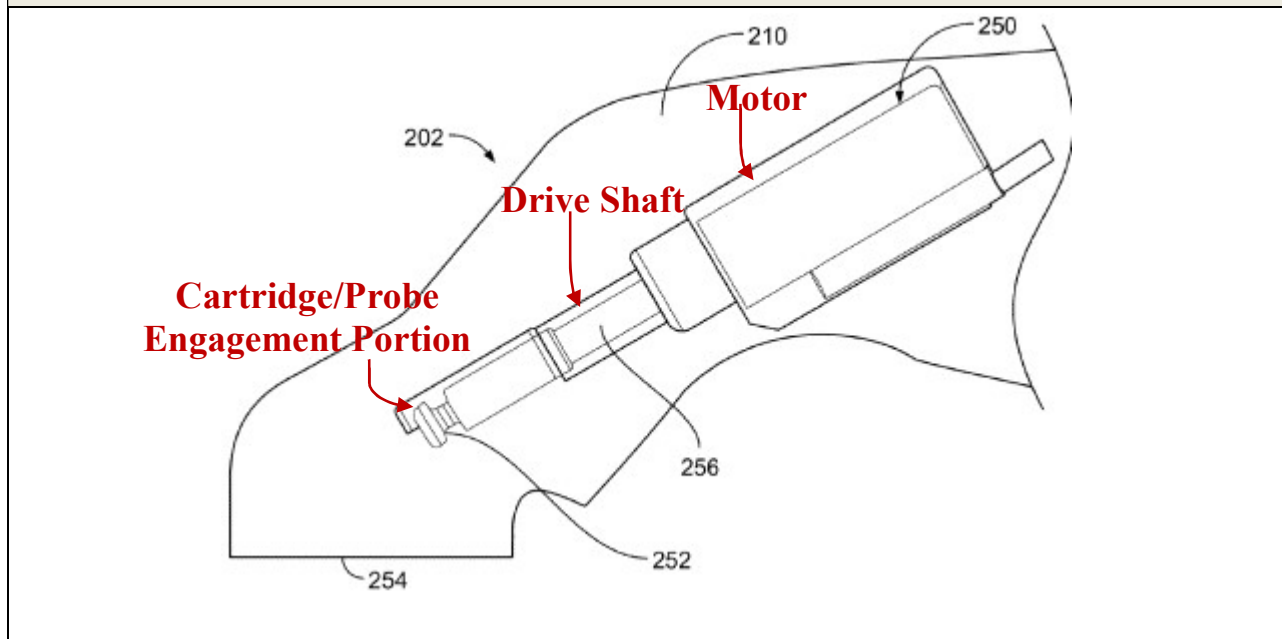
The Board confirmed “Mehta’s clear and unambiguous teachings of specific means for selecting and controlling how far the needles are inserted into the tissue, including...‘control system/energy supply unit 90’” (Institution Decision, 18).

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

Mehta’s “control system/energy supply unit 90” actuates a “motor” to drive a “shaft” with a distal tip to engage and move the needle assembly (Ex.1006, 10:38-39, 13:58-65, 15:34-40, 18:21-37, Fig.5; Ex.1003, ¶¶93-99), just like the ‘812 Patent (Ex.1001, 10:66-11:28):



Mehta FIG.5 (excerpt)



Mehta discloses a “step-motor” to move the electrode assembly to various “stepping” distances (Ex.1006, 15:34-40; Ex.1003, ¶96-99), just like the ‘812 Patent (Ex.1001, 11:58-61):

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.1006, 15:34-40)

Mehta discloses a motor-driven “system...adjusted to guide probe placement” to the user-selected “desired depth” (Ex.1006, 21:8-10, 32:46–33:34) and Mehta’s motor controls that electrode/needle movement, e.g. to precise “stepping” distances (Ex.1006, 13:58-65, 15:34-40), which together provides

disclosure for a “desired depth” that is motor-controlled (Ex.1030, ¶14; Ex.1003, ¶¶96-99). 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 discloses “[o]ver-inserting and then partially retracting” the electrodes (Ex.1006 at 16:39-41; Ex.1003, ¶95; 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, 30) does not negate its programming.

Selecting/replacing cartridges having different extendable needle lengths or angles (POR, 29-30; Ex.1006, 12:31-46, 17:66-18:3; Ex.1003, ¶95) 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”, 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 all these embodiments, to the extent PO asserts “a motor extending needles a predetermined distance” is inherently “programmed” in the claims (POR, 12-13, 16-20), it must also be so “programmed” in Mehta (POR, 24-30).

“[P]articular signal”: Mehta’s control system 90 controls motor/actuator to extend needles from across a distance (over cable 96) (Ex.1006, 10:38-39, 13:58-65, Figs.2A,5), which requires “an electrical motor control signal” (Ex.1030, ¶18) —agreed construction (Ex.1005, 16). PO asserted a “particular signal” in the accused devices controls a solenoid (Ex.1034, ¶79,199-201) that can only extend needles “in or out” (Ex.1034, ¶79; Ex.1033, 336:14-21) and so cannot require any particular distance information.

III. GROUND II: MEHTA AND KNOWLEDGE OF POSA RENDER OBVIOUS CLAIMS 2-6, 8, AND 13-16

A. Claims 2-6, 8, and 13-16

Ground II provides reasoned explanation, supported by evidence, *why* a POSA would have been motivated to modify Mehta (POR, 33-35; Petition, 40-42; Ex.1003, ¶¶146–155). Ground II does not use the '812 Patent as a roadmap (POR, 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.1006, 37:7–11, 39:33–41). Additional motivations, e.g., “streamline treatment, improve the patient’s experience, and decrease treatment costs” (Petition, 41) 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, 31-32). A “consistent starting point” merely promotes uniform depth in a single extension (Ex.1006, 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.1006, 33:30-34). PO acknowledges Mehta’s needles extend “to reach different 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, 17⁶

1. Illuminating needles/needle assembly/module

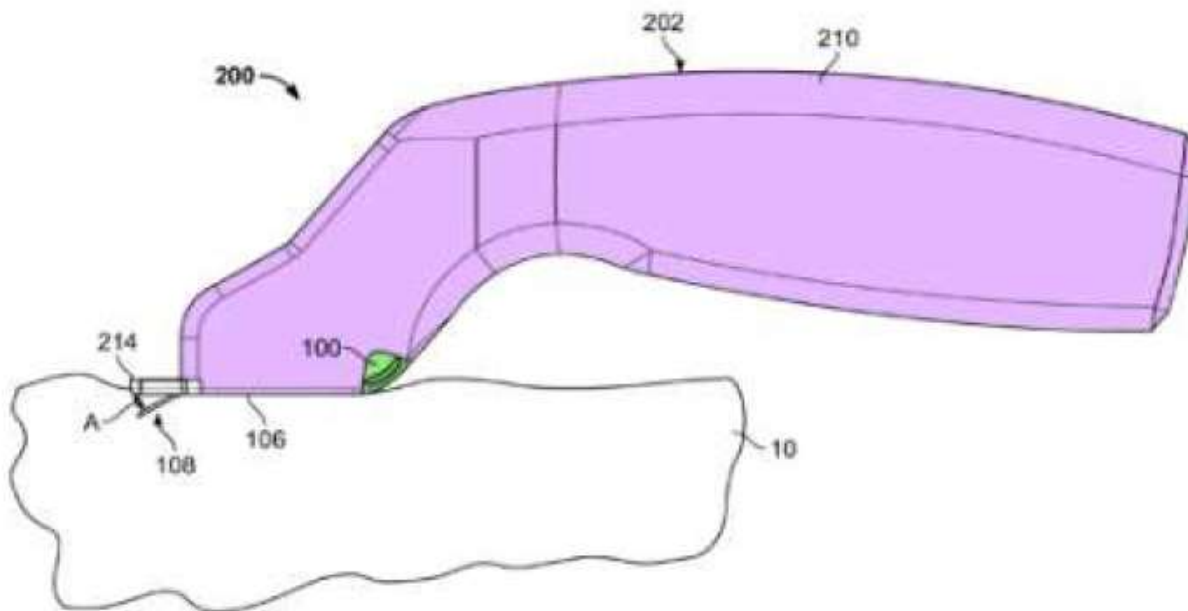
Mehta disclosed a “diode...emitter” of “light” (Ex.1006, 11:24-39) that PO does not dispute rendered obvious an LED. PO acknowledges Mehta discloses “several” mechanisms for, and so, explicitly motivated, “assist[ing] a physician in confirming the intended treatment area...or to illuminate depth markings 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.1006, 13:16-

⁶Claim 17 was statutorily disclaimed (Ex.2144, 3).

20), the inserted/extended needles would have been obvious to illuminate (Ex.1003, ¶166). Because “needles” are part of both the claimed “needle assembly” and “module” (Ex.1001, cl.1,12), illuminating Mehta’s inserted/extended needles necessarily illuminates the “needle assembly” and “module” (Ex.1001, cl.4-5,17). 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

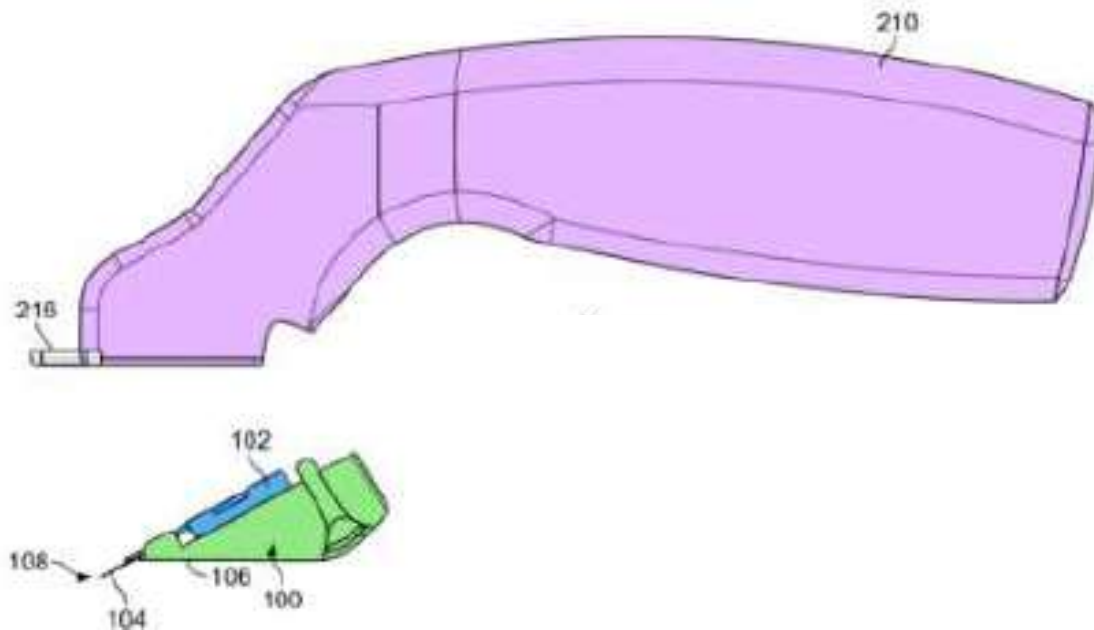
PO does not dispute the benefits that embedding LEDs “prevent them from protruding outward from the handpiece/device body 210” to provide “a sleek outer profile” (Petition, 44; Ex.1003, ¶167). Instead, PO argues embedding LEDs requires transparent exposed internal components that are “scary looking” (POR, 39,42). Mehta, however, motivated illuminating target probe 108 insertion area (Ex.1006, 13:16-20), so only the **bottom-facing** portion of cartridge 100 below, directly in the embedded LED’s illumination path, 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.1030, ¶19, Ex.1006, Figs.2B-2C):



A transparent/translucent opening directly in the LED illumination path would only expose the LED, not other internal components (Ex.1030, ¶19). Regardless, a POSA would have used “translucent” material that “scatter[s] illumination” from the LED, further concealing any bottom-facing internal components (Petition, 46; Ex.1003, ¶167,172; Ex.1030, ¶19).

3. Translucent

PO argues Mehta’s opaque device body 210 (purple) would block a translucent needle assembly’s illumination (POR, 42), which is downward below (Ex.1030, ¶19), 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.1006, 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 and cartridge 100. Moreover, Serendia's expert confirmed changing LED location was not inventive (Ex.2126, 1547:8-25). *See Nano-Second Tech. 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, 17

A. Na '848 Disclosed LEDs (Claims 4, 17) and Translucent Needle Assembly Section (Claim 5):

All support in the '812 Patent for an “embedded LED” (Ex.1001, 5:12-15, 6:5-8) and “translucent” needle assembly section (Ex.1001, 5:31-34) is **identically**

disclosed in Na '848 (Ex.1007, ¶34-¶35⁷, 38). To the extent claims 4-5, 17 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 LEDs, not the light sources' location (Petition, 49-50,52; POR, 44-45,48), which PO does not contest is already disclosed at the proximal end of Mehta's handpiece/device body 210 (Ex.1006, 11:24-39; Ex.1003, ¶165).

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, 50-53; POR, 45,48). 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 traversing its path to illuminate the needles (POR, 44; Ex.1006, 9:53-59; Petition, 51; Ex.1003, ¶186).

B. Motivation to Combine Mehta and Na'848

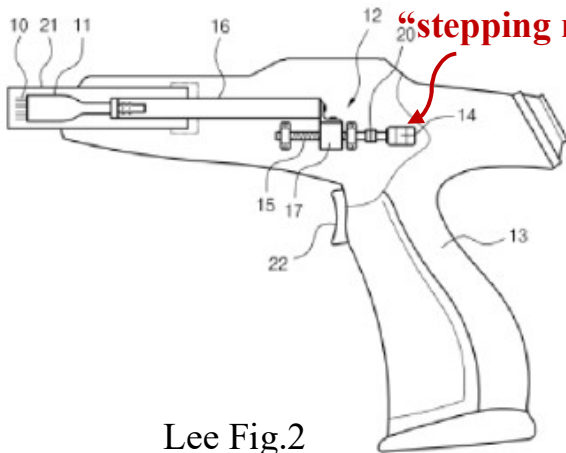
PO's rationale to not combine Mehta and Na '848 –that only Mehta (not Na '848) "deliver[s] energy"– is false (POR, 46-47; Ex.2147, ¶126). Both Mehta and

⁷Only translucent "outer casing 924E" is otherwise disclosed (Ex.1001, 12:61-64).

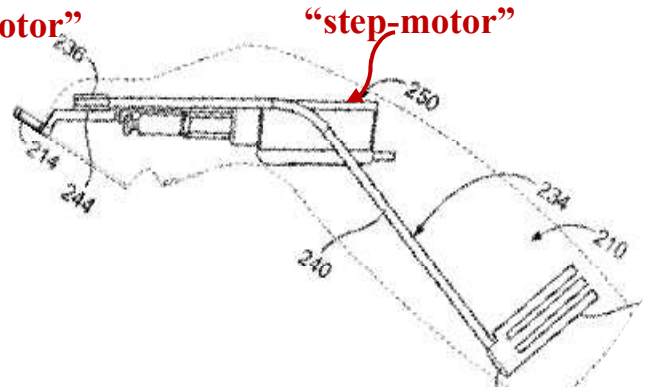
Na '848 deliver electrical *and* mechanical energy: Mehta explicitly defines delivering energy to encompass both “electrical” and “mechanical” energy (Ex.1006, 9:43-48). Likewise, Na '848 delivers both mechanical energy (“vibrate...pins”) and electrical energy (“the pins may be electrically coupled...to form dipole pair (bipolar pins)”) (Ex.1007, ¶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 (Ex.1001, 10:40-49, 13:37-40), through the skin (Ex.1031, 193:12-194:7).

**V. GROUND IV: MEHTA, LEE AND KNOWLEDGE OF POSA
RENDER OBVIOUS CLAIMS 2-3, 6, 8, AND 13-16**

Both Mehta and Lee are directed to the same goal of inducing collagen production by puncturing skin with motor-driven needles (Ex.1006, 8:66-9:6; Ex.1009, <14>; Ex.1003, ¶¶62-64,194). Both Mehta and Lee aim to solve the same problem of targeting and precisely controlling the needles' desired location/depth (Ex.1006, 2:9-12, 2:37-41, 24:6-8; Ex.1009, <44>). Both Mehta's and Lee's devices use a step-motor to precisely step needle distance (Ex.1006, 15:34-40; Ex.1009, <24>; Ex.1003, ¶¶145,194-200):



Lee Fig.2



Mehta Fig.3B (rotated)

Ground IV does not use the '812 Patent as a roadmap (POR, 54) because the cited motivation is in Mehta itself (Petition, 53-56; Ex.1003, ¶¶151-152, 195-196). 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.1006, 2:9-12) and Lee disclosed “**controlling the insertion depth** of microneedles” (Ex.1009, <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, 50-52). This is false. Mehta explicitly defines “delivering...energy” to encompass both electrical “thermal energy” (e.g., RF, Ex.1006, 39:28-30) and “percutaneous delivery of mechanical energy” (puncturing skin) as in Lee (Ex.1006, 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, 51-52). These times, however, are only examples ("For example," Ex.1009, <58>; "in the above example," Ex.1006, 37:17-24) and, in another example, Mehta discloses treatment times "between 0 and 6 seconds" (Ex.1006, 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, 53-56). 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, 53-56; Ex.1003, ¶¶194-203; Ex.1006, 11:14-15).

PO alleges Mehta teaches "a different approach" to "distance control" by confirming the location of "already-extended" probes (POR, 52-53). 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 .

VI. GROUND V: CLAIMS 4-5

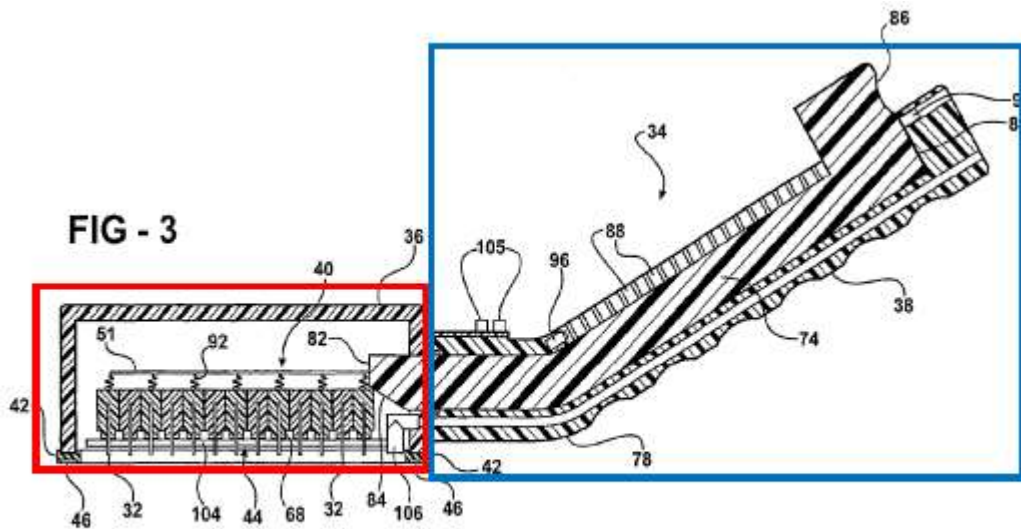
PO's only arguments against Ground V incorporate arguments for Grounds I-IV (POR, 54). PO is incorrect for the reasons above. *See supra* Sections II-V.

VII. GROUND VI: LIVNEH, MEHTA AND KNOWLEDGE OF POSA RENDER OBVIOUS CLAIMS 9 AND 18

A. Releasably Couplable Module

Disposable (i.e., releasably couplable) needle cartridges were well-known and advantageous for sanitary/sterile use and replacing dull needles (Ex.1003, ¶210). While Livneh replaces needles individually (Ex.1010, Figs.12–18, ¶¶61–63), because needles are co-contaminated and dull at around the same time, a POSA would have been motivated to use replaceable needle cartridges to more efficiently and cost-effectively replace all needles together (Ex.1003, ¶211). PO's alleged cost-effectiveness of replacing a single needle vs. all needles ignores this fact (POR, 57).

In Ground VI's Modified Livneh Device, all patient-touching surfaces are in the disposable proximal portion (red box, left-below) that is sterile, and all reusable surfaces (e.g., Mehta's stabilization plate 214) are in the handpiece (blue box, right-above) that would have been "cleanable or...covered with a sterile plastic wrap so that they do not have to be sterilized" (Ex.1003, ¶208-210; Ex.2147, ¶148).



Livneh—Fig. 3

PO argues making Livneh's housing 36 releasably couplable would expose mechanism 74 (POR, 56) made of an "elastomeric material" or "any other flexible material" (Ex.1010, ¶44). Flexibility, however, does not indicate fragility (Ex.1030, ¶21). Flexible durable materials were known and, if extra durability was desired, a POSA would have simply used a sufficiently durable material for angled surface 84 on the exposed tip of mechanism 74 and/or further recessed or enclosed mechanism 74 with a cap/cover when uncoupled from the cartridge/module (*id.*; Ex.1010, Fig.3-4). Simply, a POSA would have used materials to make the Modified Livneh Device sufficiently durable for its intended use (Ex.1030, ¶21).

Ground VI also outlines Livneh's electrical modification (POR, 56-57; Petition, 71-72). Separating Livneh's housing 36 and handle 38 would have obviously bisected "wires 51" "to make these electrical connections releasably

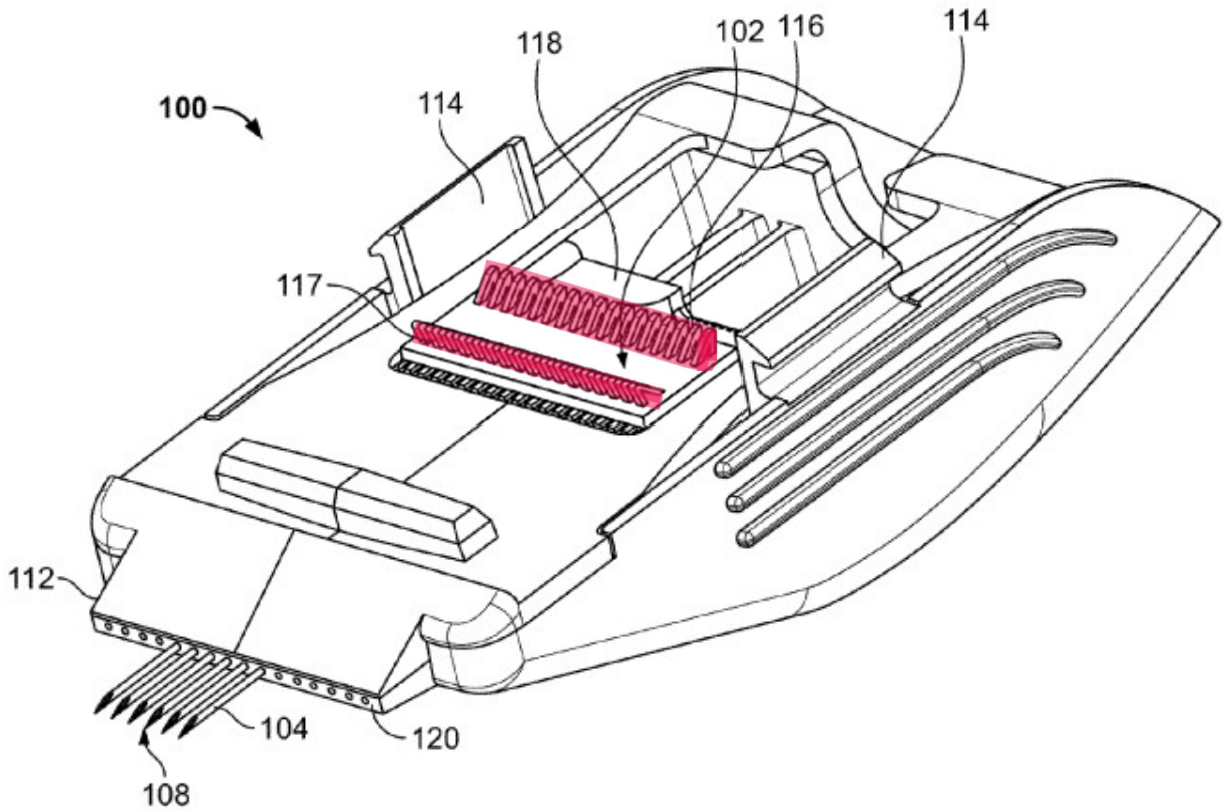
couplable at the connection point” “e.g., by using electrical standard off-the-shelf connectors” (Ex.1003, ¶213).

B. Pin

All PO's alleged distinctions between the claimed “pin” and Livneh's coils 92 –pin shape, “1 degree of freedom of movement,” electrical contact under compression vs. tension, and pogo-pins (Ex.2147, ¶¶149-150)– are incorrect and/or not claimed:

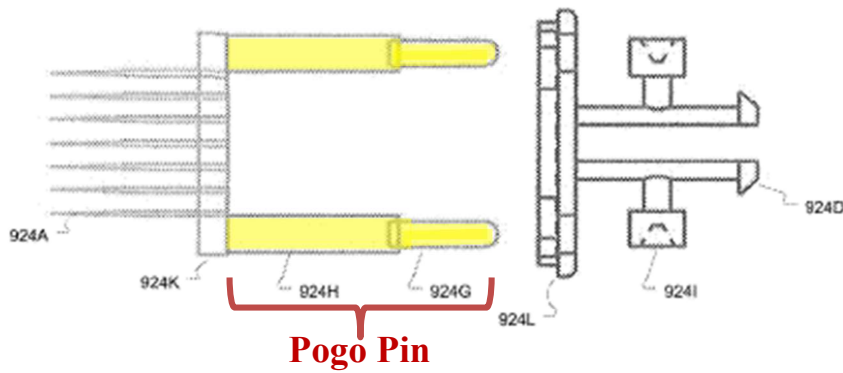
1. A “Pin” Does Not Require A Particular Shape

Claims 9 and 18 do not restrict the claimed “pin” to any particular shape or type. Pins can be shaped, and so cannot be limited to, cylindrical, flat, straight, bent, coiled, etc. (Ex.2154, 74:22-77:16; Ex.1030, ¶23). E.g., Mehta's “spring pins” 116 (illustrated pink) are bent in an **acute-angular** shape (Ex.1006, 16:12-18, Fig.4A):

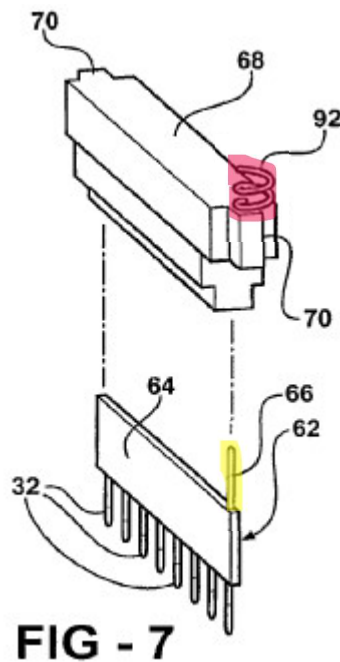


2. A “Pin” Can Have Multiple Parts

PO's expert identifies the "pin" in the '812 Patent as a "pogo pin" (Ex.2147, ¶150). A "pogo pin" a.k.a. a "spring-loaded pin" (illustrated yellow) combines **both** pin 924G **and** spring loaded based 924H (both required for "pogo" spring-action) (Ex.1030, ¶24; Ex.1001, 13:20-26; Fig.11C(excerpt)):



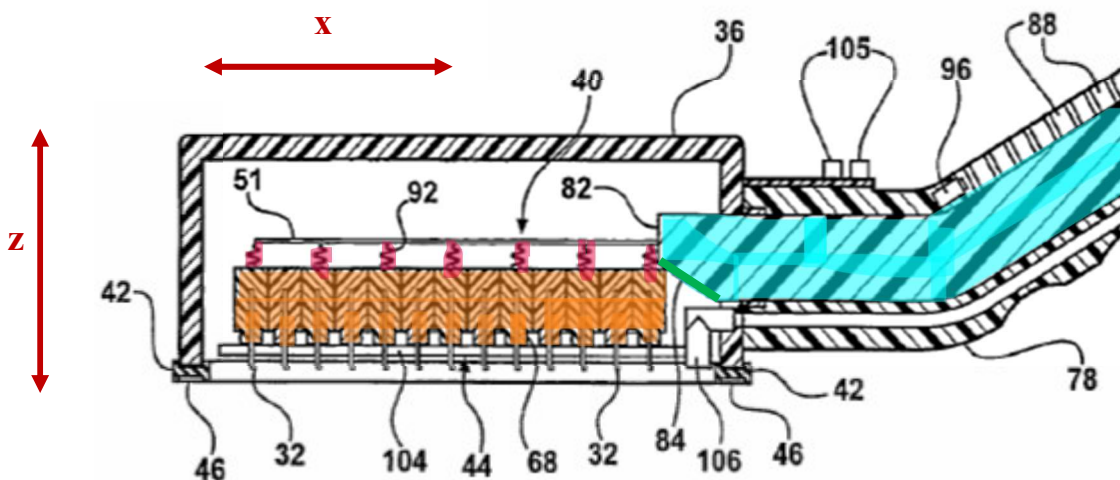
To the extent PO asserts the claimed “pin” covers a multiple-part spring-pin combination, Livneh’s electrical contact also comprises a cylindrical pin 66 (illustrated yellow) combined with coil 92 (illustrated pink), that together are extendable in the same direction as needles 32, satisfying claims 9 and 18 (Ex.1010, Fig.7, ¶47; Ex.1030, ¶24):



3. One vs. Three Degree of Freedom

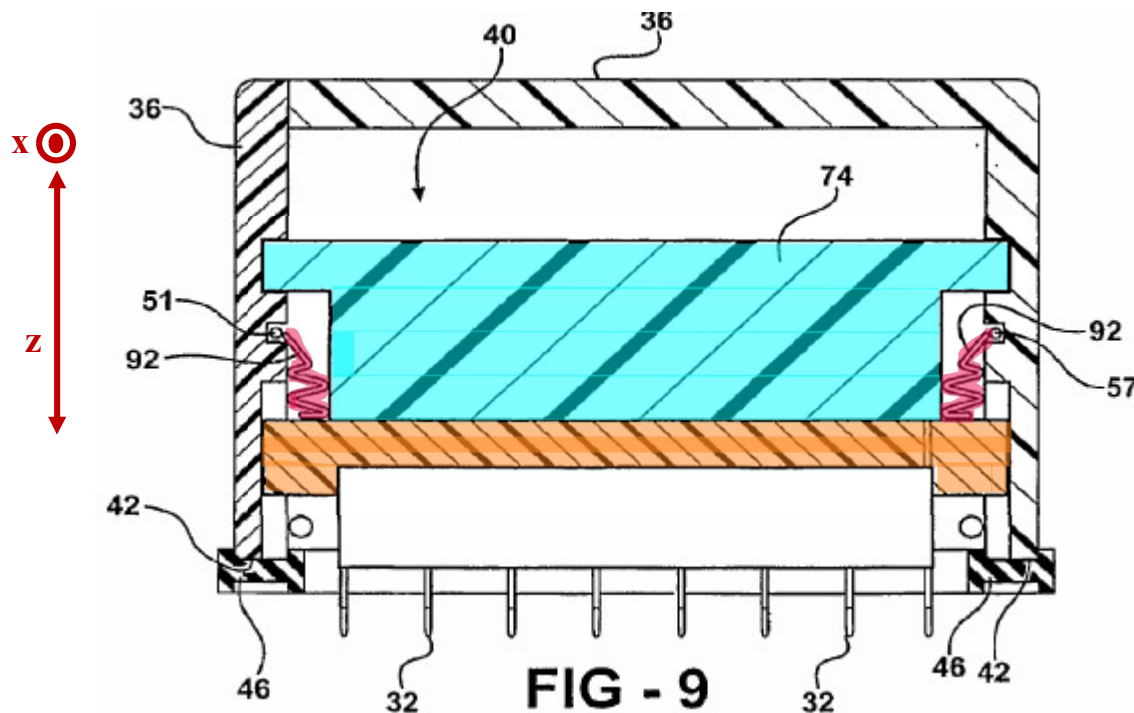
The claimed “pin” does not require “1 degree of freedom of movement,” only movement in the “same direction” as needles (Ex.2147, ¶149; Ex.1001, cl.9,18). Regardless, Livneh's coils 92 satisfy both conditions:

To extend needles, Livneh's mechanism 74 (illustrated blue below) moves longitudinally along x-axis (right-left in Fig.3 (illustrated by an x-axis arrow) and into/out-of the page in Fig.9 (illustrated by an x-axis circle with a dot in the center)) (Ex.1010, Figures 3-4,9, ¶¶12-13,18,42; Ex.1030, ¶25):



While mechanism 74 moves longitudinally along x-axis, it pushes holder 68 at angled surface 84 (illustrated green above), translating movement from longitudinal (x-axis) direction downward into vertical (z-axis) direction (Ex.1010, Figures 3-4, 9, ¶45, cl.5; Ex.1030, ¶25).

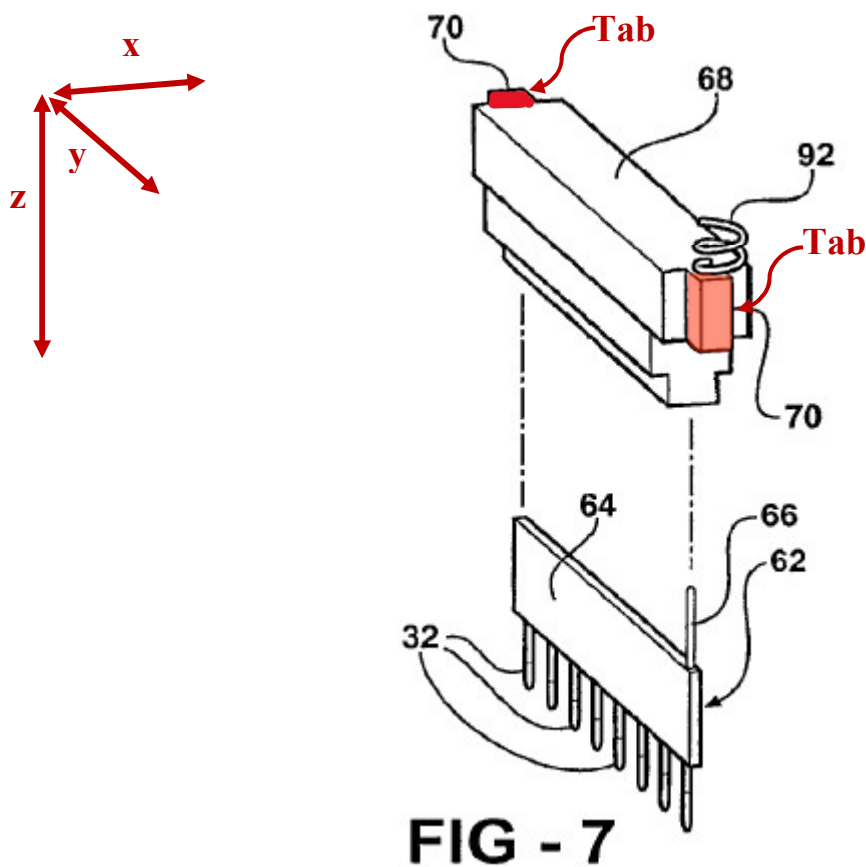
Figure 9 shows coils 92 (illustrated pink) are located on the side of, recessed from, and **not** in the path of, mechanism 74 (illustrated blue) that moves into/out-of the page (Ex.1010, Fig.9; Ex.1030, ¶25):



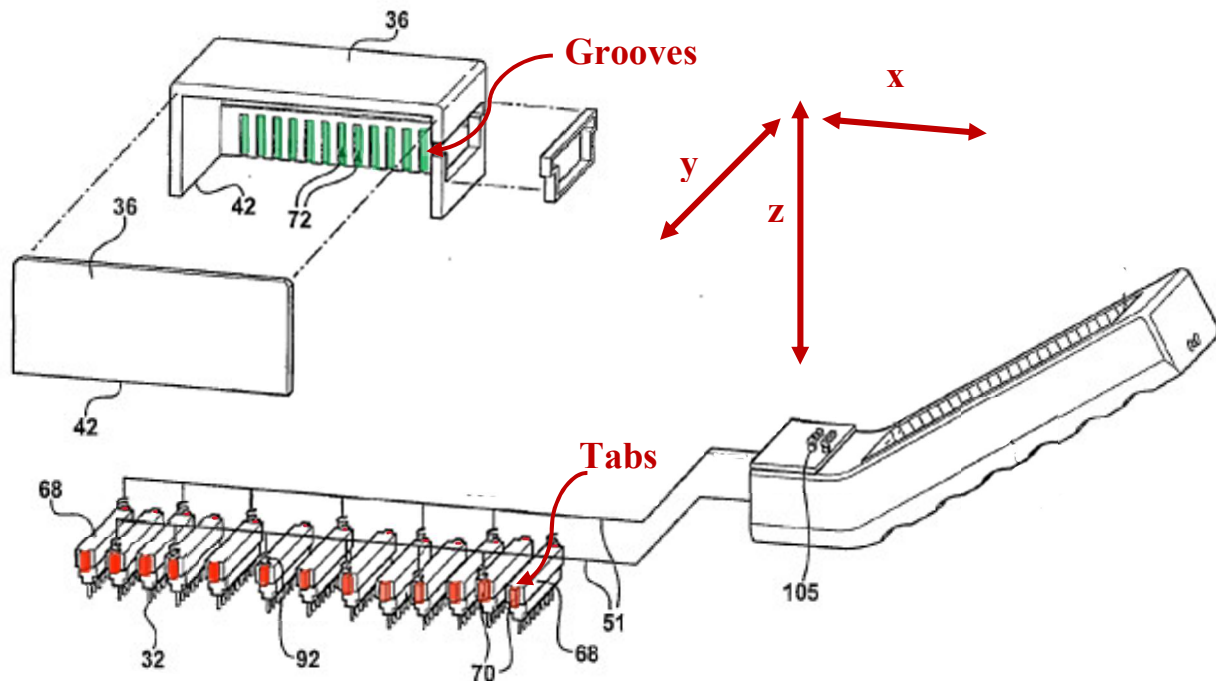
Thus, when mechanism 74 moves longitudinally along the x-axis (right-left in Fig.3; into-out of the page in Fig.9), mechanism 74 can only directly push needle holder 68 (illustrated orange) in its path, **not** coils 92 (illustrated pink) recessed to its side (Ex.1010, Figures 3-4,9; Ex.1030, ¶25; PO's expert's confirmed mistake: Ex.1031, 204:4-205:4). Because mechanism 74 only pushes holder 68, and not coils 92 or needles 32 directly, coils 92 and needles 32 only move by virtue of their connection to holder 68 (Ex.1010, Fig.7; Ex.1030, ¶25). Thus, coils 92 and needles

32 both move **together** with holder 68, so coils 92's motion is inextricably in the “**same** direction” as needles 32 extendable motion (as claimed) (Ex.1030, ¶25).

Livneh's Coils Only Move Vertically in One-Dimension: Livneh's needle holder 68 contains tabs 70 (illustrated red) that notch into housing 36 to prevent its lateral movement (Ex.1010, ¶48, Fig.7; Ex.1030, ¶25):



Livneh's holder tabs 70 (illustrated red) fit into matching grooves 72 (illustrated green) in housing 36 (Ex.1010, ¶48, Fig.10 (excerpt)):



Thus, when mechanism 74 pushes longitudinally along x-axis (right-to-left above), the notched joint between tabs 70 and grooves 72 fit to fix holder 68 longitudinally (in x-axis), which prevents holder 68's longitudinal (x-axis) movement (Ex.1010, ¶48, Figures 3-4,9-10; Ex.1030, ¶25). Figure 9 above also shows the width of tabs 70 of holder 68 (illustrated orange above) are sized in the lateral direction (illustrated y-axis) to closely fit into grooves 72, thereby fixing holder 68 and preventing its movement in the lateral (y-axis) direction (*id.*). Because holder 68 cannot move longitudinally (along x-axis) or laterally (along y-axis), it can only move vertically (along z-axis) (*id.*). Similarly, because coils 92 and needles 32 only move by virtue of their connection to holder 68, as explained above, coils 92

and needles 32 can also only move vertically (not longitudinally or laterally) (*id.*). Thus, Livneh's coils 92 do not have "3," but "1 degree of freedom of movement" as PO's expert characterizes the claimed "pin" (Ex.2147, ¶149; Ex.1030, ¶25).

4. A "Pin" Does Not Require Conduction During Compression

Contrary to Ex.2147, ¶150, a "pin" can complete a circuit while either pushed/pulled by compression *or* tension (e.g., Livneh's pin 66 maintains electrical contact when coil 92 is tensed/stretched) (Ex.1030, ¶26; Ex.1010, Fig.9, ¶63).

Accordingly, Livneh's coils 92 satisfy all requirements of the claimed "pin."

VIII. 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 '812 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 '812 Patent but instead goes to the heart of another one of Serendia's patents." (Institution Decision, 19); citing PO: "The Sylfirm X has achieved commercial success **due in part** to implementation of the inventions claimed in the '812 Patent." (POPR, 65). 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 ‘812 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 ‘812 Patent instead covers needle depth control (Ex.2147, ¶201; Ex.2141, ¶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.”” (IPR2024-00386, Institution Decision, 19-20).

2. PO Fails to Show Commercial Success

PO’s only cited year-to-year sales comparison –2021 vs. 2022 (POR, 64)—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 article⁸ (Ex.1039, 11). PO confirms Ex.2066 is “marketing” material (POR, 65). 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

⁸2025 rate.

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-VI.

IX. CONCLUSION

In view of the foregoing, Petitioner respectfully requests the Board find claims 2-6, 8-9, 13-16 and 18 of the '812 Patent unpatentable.

Respectfully submitted,

Date: April 14, 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 5442 words, excluding the parts of this reply that are exempted by 37 C.F.R. § 42.24(c).

Date: April 14, 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 14, 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 27, 2024 Updated Mandatory Notices, as follows:

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