

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

**SUPPLEMENTAL DECLARATION OF DR. JEAN WOLOSZKO
IN SUPPORT OF PETITIONER'S REPLY TO PATENT OWNER'S
RESPONSE**

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I, Jean Woloszko, Ph.D., declare as follows:

I. INTRODUCTION

1. I submit this Supplemental Declaration at the request of EndyMed Medical Ltd., and EndyMed Medical, Inc. (“EndyMed” or “Petitioner”) in support of Petitioner’s Reply to Patent Owner’s Response in the matter of the *Inter Partes* Review IPR2024-00463 of U.S. Patent No. 10,869,812 (“the ’812 Patent”). I have been asked, by counsel for Petitioner, to respond to certain issues raised by Patent Owner in their Patent Owner’s Response. This Declaration supplements my original Substitute Declaration (Ex.1021), in which I explained that I have reviewed paragraphs 1-272 of Dr. Bérubé’s Declaration (Ex.1003) and Exhibits cited therein, and that I agree with and adopt paragraphs 17-269 (Ex.1021, ¶22). My opinions remain the same, which I incorporate by reference herein.

2. I am being compensated for my time in this matter at an hourly rate of \$600 per hour. I am also being reimbursed for reasonable and customary expenses associated with my work and testimony in this matter. My compensation is not contingent on the outcome of this matter or the specifics of my testimony. I have no personal or financial stake or interest in the outcome of the present proceeding. I am an independent consultant. All my opinions stated in this report are based on my own personal knowledge and professional judgment.

3. In the preparation of this Supplemental Declaration, I have read and considered:

- Materials referenced in paragraphs 17-269 of Dr. Bérubé's Declaration (Ex.1003);
- Materials referenced in my previous Substitute Declaration (Ex.1021);
- Patent Owner's Preliminary Response (Paper Nos. 14 (redacted version) and 16 (confidential version)) and its referenced Exhibits;
- Petitioner's Reply to Patent Owner's Preliminary Response (Paper No. 17);
- Patent Owner's Sur-Reply In Support of Patent Owner's Preliminary Response (Paper No. 18);
- Institution Decision (Paper No. 20);
- Patent Owner's Response (Paper Nos. 31 (redacted version) and 29 (confidential version)) and its referenced Exhibits; and
- Materials I cite in support of this Declaration

II. LEGAL STANDARDS

4. In forming my opinions I have applied the legal framework set forth in the Declaration of Dany Bérubé, Ph.D. (Ex. 1003), which I incorporated by reference

in my original Substitute Declaration (Ex.1021, ¶22), and which I incorporate by reference herein.

5. I understand the remaining claims challenged in this IPR are claims 2-6, 8, 9, 13-16 and 18 of the '812 Patent.

III. OPINIONS

6. In my opinion, for the reasons discussed in my original Substitute Declaration and this Supplemental Declaration, all remaining challenged claims 2-6, 8, 9, 13-16 and 18 of the '812 patent are unpatentable as being anticipated by and/or obvious over the prior art references.

A. Claim Construction of Desired Distance

7. I reiterate my opinion that the term “desired distance” should be given its plain and ordinary meaning, which simply distinguishes between needles extending or extendable a ***desired distance*** as opposed to an ***undesired distance*** (Ex.1003, ¶49; Ex.1021, ¶22).

8. I understand Patent Owner (“PO”) initially asserted the “desired distance” is “based on a user’s selection” (Patent Owner Preliminary Response (“POPR”), 35, 37). The term “desired distance” appears only in claims 2, 8 and 13 of the challenged claims (Ex.1001). In my opinion, there is nothing in the challenged claims that state the desired distance is selected, let alone state ***who*** selects the distance (Ex.1001, all claims). Therefore, even if there was a selection requirement,

which there is not, it could be selected by, for example, the device user (operator such as a physician or other medical practitioner interfacing with a patient), the device designer to a depth known to reach a desired layer of dermatological tissue, or by “automatic” control such as a current feedback algorithm (involving no person at all) cited during the grandparent patent’s prosecution history and by PO and PO’s expert in this IPR (POR, 15 and Ex.2147, ¶75, citing Ex. 2115, 10:11-20). Aside from optional embodiments that “may” be used (Ex.1001, 9:65-67 (“user may configure one or more operational parameters”), 10:32-37 (“user selected operational parameters...may determine the depth”), 10:61-63 (“may apply various therapies based on user selections”), 13:63-66, 14:21-24 (“a user may select”)), there is nothing in the Specification that restricts who selects the desired distance. Accordingly, I do not agree that the challenged claims require that the “desired distance” is “based on a **user’s** selection.”

9. I understand that, in its more recent Patent Owner Response (“POR”), PO interpreted that the “desired distance” is “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).

10. For the same reasons I disagree above that the desired distance is **user**-selected, I also disagree that the desired distance is **user**-programmed (e.g., it could

alternatively be programmed by the manufacturer, designer, or automatically as discussed above). There is nothing in the '812 Patent claims that require programming at the physician's office or at any particular time during the procedure or by any particular person. Aside from optional embodiments that "may" be used (POR, 13-16 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 ("may"), 14:12-34 ("may select")), there is nothing in the Specification that restricts who selects the desired distance.

11. I also disagree that the "desired distance" requires that the distance is "based on a user programming this distance" (POR, 16). I understand that, absent contrary evidence, claim terms are presumed to be consistent in "related" patents that includes U.S. Patent No. 9,775,774 (Ex.1012, "Related Patent"). The term "desired distance" applies in the '812 Patent's challenged claims to "extendable" needles that can be programmed, as well as in claim 11 of the Related Patent to "extending" needles that are "fixed and non-extendable relative to the surface" (Ex.1005, 16) and so, are not capable of user programming. Because it is presumed the meaning of "desired distance" is consistent across related patent claims, that meaning should cover the distance non-user-programmable "extending" needles extend, and so "desired distance" does not require user programming. This is consistent with the agreed construction: "needles 'extending' a desired distance from

the surface” (Ex.1005, 16). I am not aware of any evidence or reason to interpret the “desired distance” with a different meaning for extending and extendable needles in the claims of these related patents.

12. A motor that extends needles a distance must be programmed to control the needles to extend to, and stop at, this distance. PO’s expert confirms this is sufficient, opining that a “solenoid” (which he equated to a motor) extends needles the claimed desired distance, which under its interpretation is user-programmed, where the solenoid only allows “two positions” – retracted or extended (“in or out”) (Ex.1034, ¶182; Ex.1033, 336:14-21). Programming the desired distance is thereby broad enough to cover controlling needles to extend to a fully-extended distance.

13. If the “desired distance” were interpreted to require the device’s user (operator, such as a physician) to program the distance (which it does not as explained above), that would encompass any method to control the motor to extend the needles that distance. Programming the desired distance is not limited in the claims or specification to be done on-the-fly (e.g., during medical treatment) as opposed to during manufacturing. Programming the desired distance is also not limited in the claims or specification to be adjustable as opposed to programming a single extension distance (see solenoid discussion above). Programming the desired distance is also not limited in the claims or specification to any particular way of **how** the user selects the desired distance (see mechanical adjustment below).

Programming the desired distance is also not limited in the claims or specification to a user altering software, but can include any software, hardware, or any other ware, to command the motor to extend to that distance: I understand PO accused the Rohrer “Pixel8” device of infringing the challenged claims based on selecting/adjusting the desired distance by a user manually i.e., mechanically rotating the hand dial below:



Dialed-In Depth Control

(Ex.1032, 1; Ex.1031, 136:11-137:3; Ex.1034, ¶¶48, 181). The accused device uses a solenoid to extend its needles that only allows “two positions” (“in or out”) -i.e., a single fully extended (“out”) position (Ex.1034, ¶182; Ex.1033, 336:14-21). Accordingly, aside from its manual adjustment by rotating the hand-dial, the desired distance of the accused device cannot be otherwise programmed. This confirms my

understanding that programming the desired distance is broad enough to cover mechanical-only programming to adjust how far the motor/actuator extends the needles, such as, by rotating a hand-dial (as in the accused Pixel8 device) or manually switching between different cartridges (as in Mehta discussed below).

B. Ground I: Mehta Anticipated Claims 2-3, 6, 8, and 13-16

14. Even if “desired distance” requires “a user programming this distance” (POR, 16), Mehta discloses this. Mehta disclosed an actuator in the form of a “motor” controlled by a “control system/energy supply unit 90” driving a “shaft” with a distal tip to engage and move the needle assembly (Ex.1006, 10:38-39, 13:58-65). Mehta also disclosed a “step-motor” to move the electrode assembly to various “stepping” distances (Ex.1006, 15:34-40)¹:

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).

¹The step-motor can have a rotation-to-translation ratio that is any specific number of rotations per translation motion that a manufacturer desires. The value of this specific ratio is a design choice, any of which will achieve the desired translational motion.

Mehta's motor-driven "system" is "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.1003, ¶¶92-95). As I explained above, a motor that extends needles a desired distance is programmed to do so. Mehta's motor is thus programmed to extend needles the desired depth.

15. Mehta further disclosed "[o]ver-inserting and then partially retracting" the electrodes (Ex.1006 at 16:39-41; Ex.1003, ¶95). This embodiment includes at least two programmed distances: a first initial full-extension distance and a second partial retraction distance to "slightly retract" the needles (Ex.1006 at 16:34-36). For the needle to "partially retract[]," Mehta's motor must be programmed with a specific retraction distance and thus finally extends to the specific programmed second partial retraction distance that is between the fully-retracted and initially-extended state. Thus, Mehta's motor is programmed to extend the needles a first distance, which is the over-inserted distance, and then to retract to a second distance, which is the desired distance for treatment. As discussed above, Mehta's control system controls the motor's extension and retraction of the needles (Ex.1006, 10:38-39, 12:5-11, 13:58-65). As I explained above, a motor that extends needles a desired

distance is programmed to do so. Mehta's motor is thus programmed to extend needles the desired depth.

16. Mehta further disclosed selecting/replacing different extendable cartridge configurations with different needle lengths (Ex.1006, 8:13-18, 10:17-25, 12:31-46, 17:66-18:3; Ex.1003, ¶95-96) or angles (Ex.1004, 12:23-58, 20:56-21:13; Ex.1003, ¶95-96). Similar to rotating a dial in the accused "Pixel8" device, attaching or replacing a cartridge with a desired needle-extension distance is mechanical programming that causes a motor to extend its needles to the cartridge-programmed distance and stop. Because Mehta mentions that various cartridges have different configurations/lengths/angles (cited above), various cartridges will program the motor to stop at those different distances/depths: At least a first cartridge having a first needle length sufficient to reach first depth, selected and attached to the handpiece, will program the motor to extend the needles a first distance and a second cartridge having a second needle length sufficient to reach another depth, selected and attached to the handpiece, will program the motor to extend the needles to a second distance than if the first cartridge was attached to Mehta's handpiece (Ex.1006, 8:13-18, 10:17-25, 12:31-46, 17:66-18:3; Ex.1003, ¶95-96). As I explained above, a motor that extends needles a desired distance is programmed to do so. Mehta's motor is thus programmed to extend needles the desired depth.

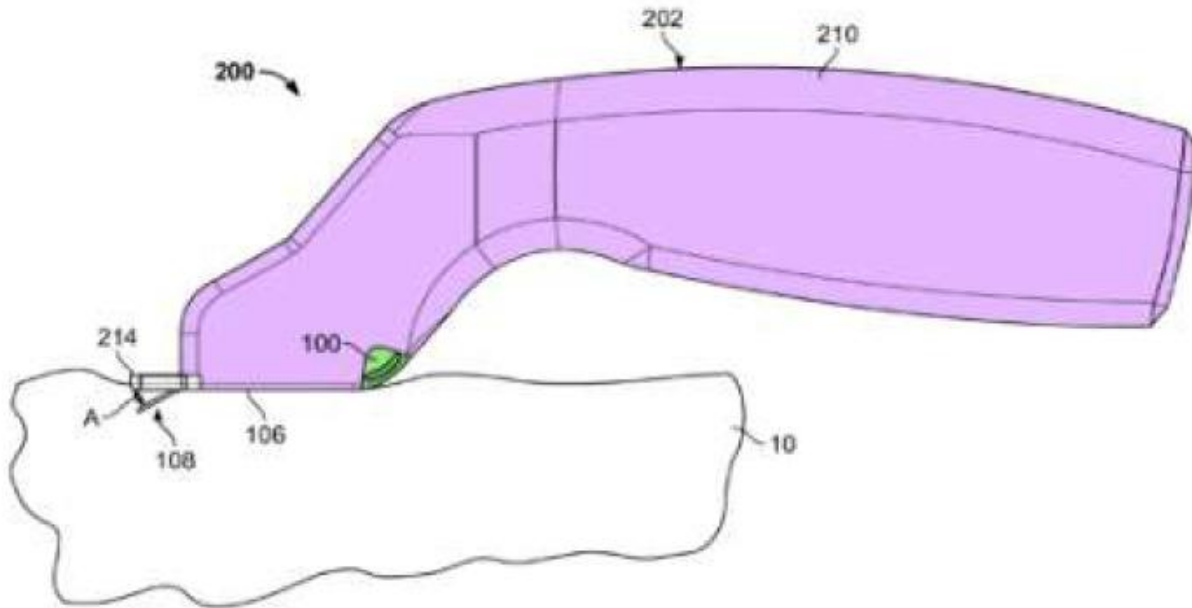
17. In all these ways, Mehta thus disclosed the desired distance “based on a user’s selection” (PO’s original construction) and “based on a user programming this distance” (PO’s new construction).

18. “[A] particular signal” (POR, 28-29): Mehta’s control system 90 communicates via “command signals” (Ex. 1006, 12:5-8) and also drives its motor/actuator (Ex.1006, 10:38-39, 13:58-65). A POSA would have understood those teachings, and because the only way controller 90 could communicate with motor/actuator 250 across a distance (cable 96) is via command signals (Ex.1006, Figures 2A,5), means control system 90 necessarily sends command signals to control its motor. Regardless, the agreed upon construction of “a particular signal” is “an electrical motor control signal,” which is satisfied by Mehta’s control system 90 electrically controlling its motor.

C. Ground III: Mehta, Na ‘848 And Knowledge Of POSA Render Obvious Claims 4-5

19. I reiterate my opinion that a POSA would have made portions of the cartridge 100 from transparent or translucent materials to allow light emitted by an embedded LED to be transmitted to an area targeted for illumination. (Ex.1003, ¶167; Ex.1021, ¶22). To illuminate target probe 108 insertion area (below 214) in Mehta’s figure below (Ex.1006, 13:16-19), only a bottom-facing portion of cartridge 100 directly in the path of (below) the embedded LED would have a

transparent/translucent opening to allow the LED's light to pass (Ex.1006, Fig. 2B, illustrating device body 210 purple and cartridge 100 green):



Mehta's device body 210 (covering all but the bottom-facing tissue engaging surface 106) is opaque (shown in purple above) and so, would not reveal internal components (Ex.1006, Fig. 2B). The transparent/translucent opening directly in front of the LED would only expose the LED, so no other internal components would be visible. If the light opening were somehow in front of other internal components (which there is no reason for), as I explained for claim 5, a POSA would have used a "translucent" material known to "scatter[] illumination" from the LED that would have further concealed any bottom-facing internal components (Ex.1003, ¶172).

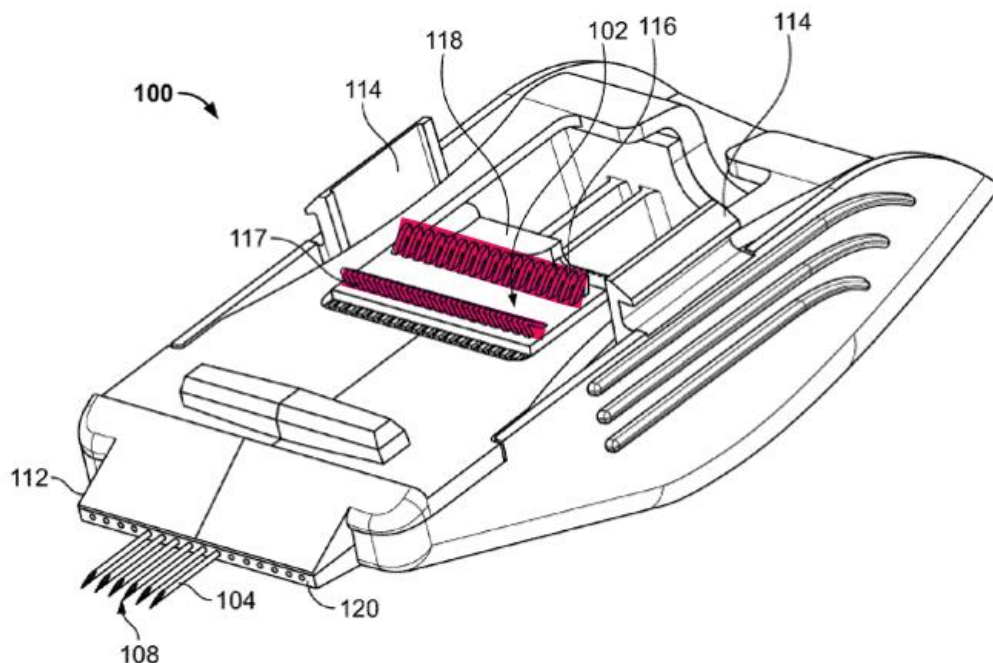
D. Ground VI: Livneh, Mehta And Knowledge Of POSA Render Obvious Claims 9 and 18

20. I reiterate my opinion that a POSA would have been motivated to modify Livneh to use a releasably couplable needle module, as in Mehta and known by a POSA (Ex.1003, ¶¶207-218; Ex.1021, ¶22).

21. A POSA would have used materials to make the Modified Livneh Device with sufficient durability for its intended use as a medical device (POR, 56). Livneh's Mechanism 74 is disclosed to be made of an "elastomeric material" or "any other flexible material" (Ex.1010, ¶44). Flexible components, such as cables, links chains, or other components commonly used in flexible or steerable medical devices are known to be sufficiently durable. If extra durability was desired, a POSA would have simply used a sufficiently durable material for the angled surface 84 on the exposed tip of mechanism 74 (either durable and flexible throughout mechanism 74 or rigid only at the exposed tip to avoid impeding motion at bend 78) or mechanism 74 can be further recessed and/or covered with a cap or cover when uncoupled from the cartridge/module (Ex.1010, Figures 3-4; ¶44).

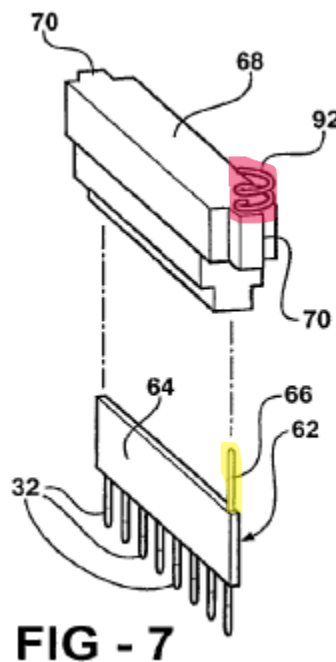
22. I reiterate my opinion that Livneh's coil 92 is a pin (Ex.1003, ¶237; Ex.1021, ¶22). All PO's alleged distinctions between the "pin" in claim 9 and 18 and Livneh's coils 92 are incorrect or not claimed: pin shape, "1 degree of freedom of movement," electrical contact when compressing vs. tensing, and pogo-pins (Ex.2147, ¶¶149-150).

23. The claimed “pin” can have various shapes and no particular pin shape or type is claimed (Ex.1001, claims 9 and 18). For example, a pin can be cylindrical, flat, straight, bent, coiled, or otherwise shaped. One such variety is shown in Mehta’s Fig. 4A depicting “spring pins” 116 that have a bent acute angled shape (Ex.1006, 16:12-18, Fig.4A):



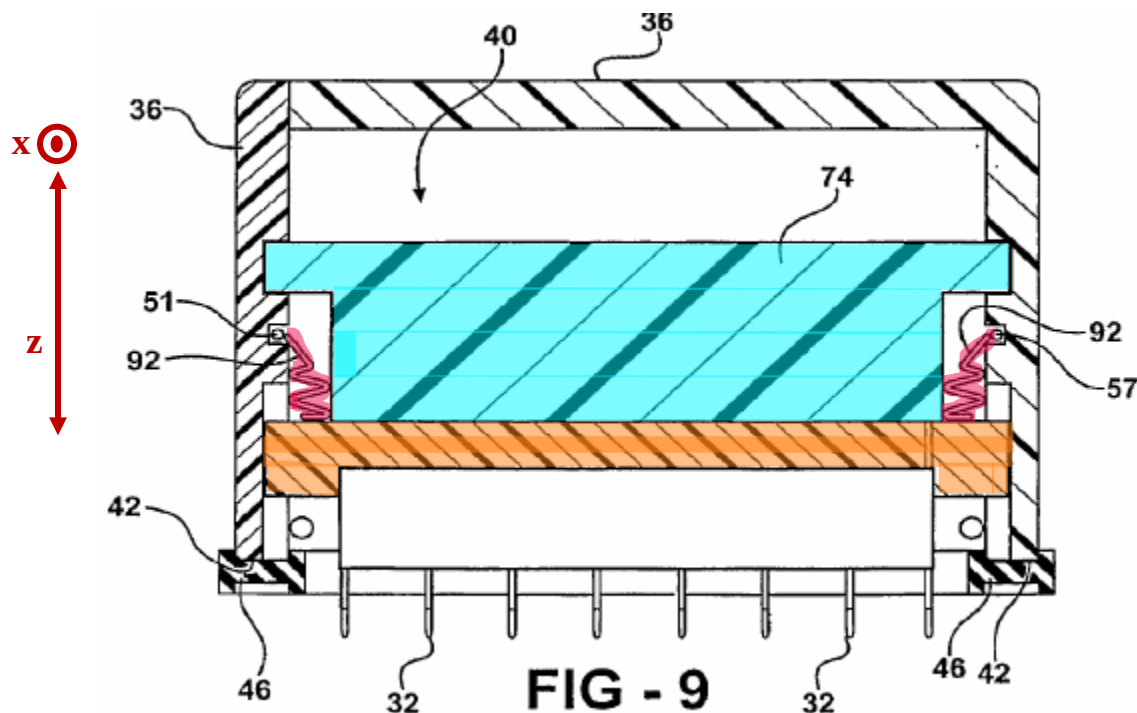
24. The claimed “pin” can have multiple parts. For example, PO’s expert identifies that the claimed “pin” depicted in the ‘812 Patent is a “pogo pin” (Ex.2147, ¶150) . This pogo pin, also known as “spring-loaded pin,” includes the combination of both a cylindrical-shaped plunger pin portion 924G and a spring loaded section 924H that contains an internal spring 924M (Ex.1001, 13:20-26). Because the spring

loaded section 924H provides the pogo or spring action to make this a pogo pin, the spring loaded section 924H and its internal spring 924M are parts of the pogo-pin. Likewise, Livneh's electrical contact also comprises a multiple-part spring-pin combination including both cylindrical pin 66 (illustrated yellow) and coil 92 (illustrated pink), the combination of which is also covered by claims 9 and 18 (Ex.1010, Figure 7, ¶47):

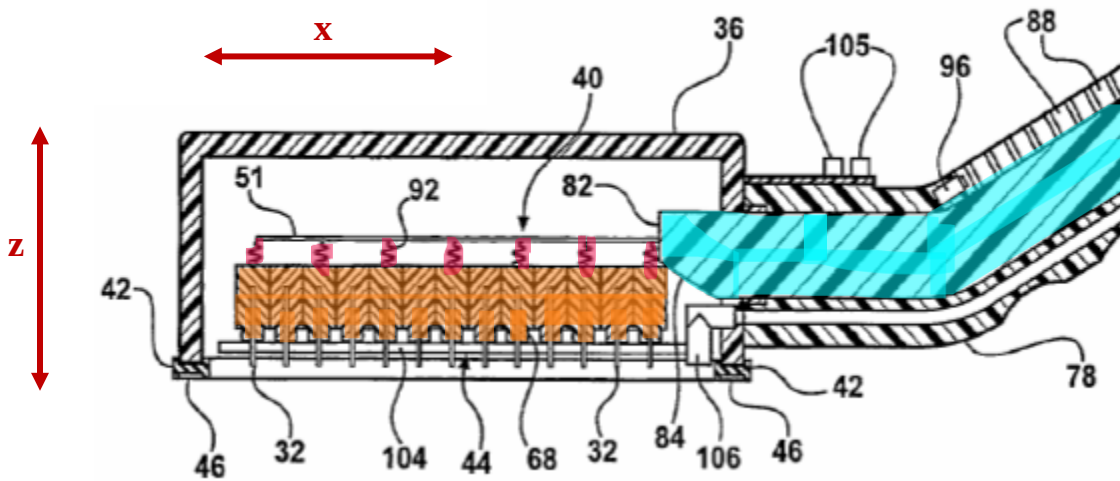


25. Livneh's coils 92 are extendable in the "same direction" as the needles 32 (Ex.1001, cl.9,18) and are extendable with "1 degree of freedom of movement" (Ex.2147, ¶149). PO's expert mischaracterized Livneh's coils 92 as having "3 degrees of freedom of movement" based on an error in his Declaration (Ex.2147, ¶149). Initially, he incorrectly stated coils 92 have "3 degrees of freedom of

movement” because “mechanism 74...push[es] on the coils as it deploys and retracts” (Ex.2147, ¶149). He later corrected this confirming, “mechanism 74 does **not** push on the springs” (Ex.1031, 204:4-205:4). Indeed, coils 92 only appear in-line with mechanism 74 because of Figures 3-4’s side-perspective. Livneh’s Figures 3-4 are side views of a first embodiment (Ex.1010, ¶¶12-13) and Fig. 9 is a front view of the same first embodiment (Ex.1010, ¶18). Livneh mechanism 74’s longitudinal left-right movements in Figures 3-4 (illustrated by an x-axis arrow) thus corresponds to its into/out-of the page movement in Figure 9 (illustrated by an x-axis circle with a dot in the center). Figure 9’s cross-sectional perspective clearly shows coils 92 (illustrated pink) are located on the side of, recessed from, and **not** in the path of, mechanism 74 (illustrated blue) (Ex.1010, Figure 9):

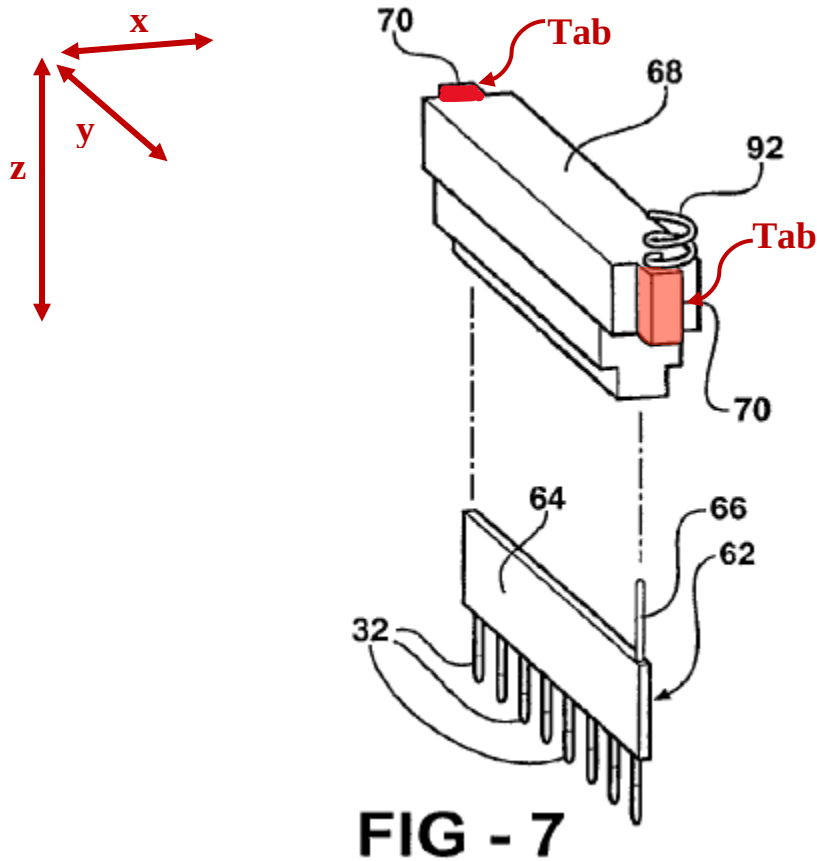


Thus, when mechanism 74 moves longitudinally along x-axis to extend needles (right-left in Figure 3 / into-out of the page in Figure 9), mechanism 74 can only directly push needle holder 68 (illustrated orange) in its path, but not coils 92 (illustrated pink) that are recessed to its side (Ex.1010, Figures 3-4, 9, ¶42):

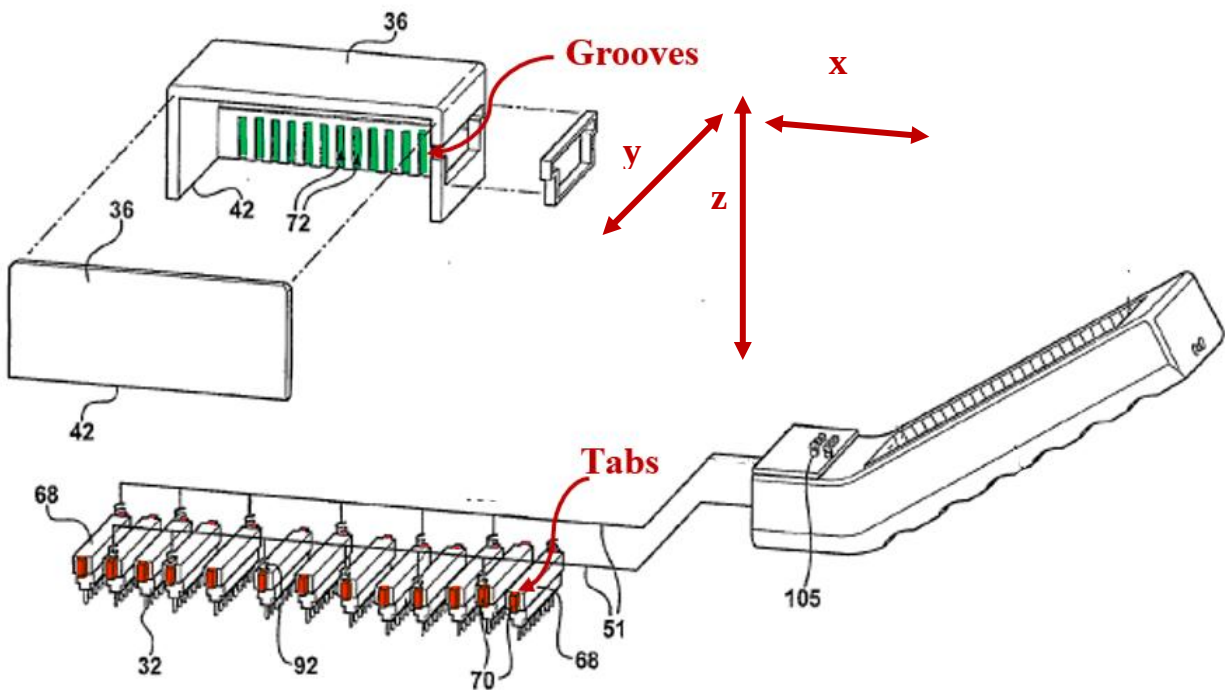


Because mechanism 74 only pushes holder 68, and not coils 92 or needles 32 directly, coils 92 and needles 32 only move by virtue of their connection to holder 68 (Ex.1010, Figures 3-4, 9). Thus, coils 92 and needles 32 both move together with holder 68, so coils 92's motion is inextricably in the "same direction" as needles 32 extendable motion (as claimed in claims 9 and 18). Though not claimed, Livneh's coils move only vertically (illustrated by a z-axis arrow) with "1 degree of freedom of movement" (Ex.2147, ¶149), explained as follows. While mechanism 74 pushes holder 68 via the angled surface 84, translating movement from a longitudinal (x-axis) direction into a vertical (z-axis) direction, holder 68 contains tabs 70

(illustrated red) that engage in grooves 72 to prevent its longitudinal (x-axis) and lateral (y-axis) movements (Ex.1010, Figures 3-4,9, ¶¶45,48, cl.5):



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



Thus, when mechanism 74 extends and pushes longitudinally (x-axis) (right-to-left above), the notched joint between tabs 70 and grooves 72 fix holder 68 longitudinally (in x-axis), thereby preventing holder 68's longitudinal (x-axis) movement (Ex.1010, ¶48, Figures 3-4, 9-10). Further, Figure 9 above shows the width of tabs 70 of holder 68 (illustrated orange above) in the lateral direction (illustrated y-axis) are sized to fit into grooves 72 to also fix holder 68, and prevent its movement, in the lateral (y-axis) direction. Because holder 68 cannot move longitudinally (along x-axis) or laterally (along y-axis), it can only move vertically (along z-axis). Likewise, because coils 92 and needles 32 only move by virtue of their connection to holder 68, coils 92 and needles 32 can also only move vertically (not longitudinally or laterally). Thus, Livneh's coils 92 do not allow "3 degrees of

freedom of movement,” but rather extend with the same “1 degree of freedom of movement” as needles 32. Though not claimed, this “1 degree of freedom of movement” matches how PO’s expert characterizes the claimed “pin” (Ex.2147, ¶149).

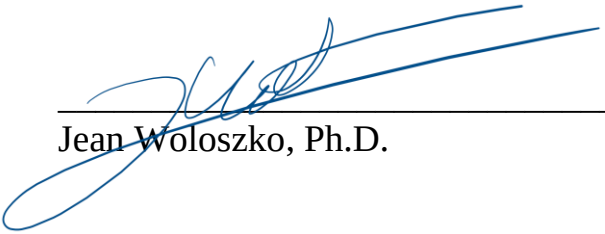
26. The claimed “pin” does not require that it is compressed to maintain an electrical connection (Ex.2147, ¶150). A “pin” can complete a circuit regardless of whether it is being pushed or pulled by compression *or* tension forces. For example, Livneh’s pin 66 maintains electrical contact when coil 92 is under tension (stretched) (Ex.1010, Figure 9, ¶63).

IV. CONCLUSION

27. I declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001.

Supplemental Declaration of Dr. Jean Woloszko
U.S. Patent 10,869,812 | IPR2024-00463

I, Jean Woloszko, Ph.D., declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.



Jean Woloszko, Ph.D.

Executed on Apr. 11, 2025