

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

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

TABLE OF CONTENTS

I.	INTRODUCTION.....	1
II.	LEGAL STANDARDS	2
III.	OPINIONS.....	3
A.	Claim Construction of Desired Distance	3
B.	Grounds I-VIII Based On Mehta Anticipate or Render Obvious Claims 1-8 and 11-18.....	8
C.	Ground III: Mehta, Na ‘848 And Knowledge Of POSA Render Obvious Claims 4-5 and 14-15.....	11
IV.	CONCLUSION.....	12

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 IPR2024-00384 of U.S. Patent No. 9,320,536 (“the ’536 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.1026), in which I explained that I have reviewed paragraphs 1-226 of Dr. Bérubé’s Declaration (Ex.1003) and Exhibits cited therein, and that I agree with and adopt paragraphs 15-224 (Ex.1026, ¶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 15-224 of Dr. Bérubé's Declaration (Ex.1003);
- Materials referenced in my previous Substitute Declaration (Ex.1026);
- Patent Owner's Preliminary Response (Paper Nos. 12 (redacted version) and 14 (confidential version)) and its referenced Exhibits;
- Petitioner's Reply to Patent Owner's Preliminary Response (Paper No. 16);
- Patent Owner's Sur-Reply In Support of Patent Owner's Preliminary Response (Paper No. 17);
- Institution Decision (Paper No. 18);
- Patent Owner's Response (Paper Nos. 27 (redacted version) and 28 (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.1026, ¶22), and which I incorporate by reference herein.

5. I understand the remaining claims challenged in this IPR are claims 1-8 and 11-18 of the '536 patent.

III. OPINIONS

6. In my opinion, for the reasons discussed in my original Substitute Declaration and this Supplemental Declaration, all remaining challenged claims 1-8 and 11-18 of the '536 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, ¶56; Ex.1026, ¶22).

8. I understand Patent Owner (“PO”) initially asserted the “desired distance” is “based on a user’s selection” (Patent Owner Preliminary Response (“POPR”), 33-35, 37). In my opinion, there is nothing in the challenged claims that states the desired distance is selected, let alone ***who*** selects the distance (Ex.1001, cl. 1-8, 11-18). 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 ’536 patent’s prosecution history and by PO and PO’s expert in this IPR (POR, 16 and Ex.2134, ¶62, citing Ex. 2115, 10:11-20). Aside from optional embodiments that “may” be used (Ex.1001, 9:43-45 (“user may configure one or more operational parameters”), 10:9-13 (“user selected operational parameters...may determine the depth”), 10:37-40 (“may apply various therapies based on user selections”), 13:33-41, 13:58-61 (“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.* 21), 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 '536 Patent claims that requires 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, 14-16 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, 13:58-65 ("may enable"), 13:49-14:4 ("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.1020, "Related Patent"). The term "desired distance" applies in the '536 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.1007, 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.1007, 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, ¶49, 79, 81; 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, ¶¶48-49). 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, ¶49; 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. Grounds I-VIII Based On Mehta Anticipate or Render Obvious Claims 1-8 and 11-18

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.1004, 10:38-39, 13:58-65). Mehta also disclosed a “step-motor” to move the electrode assembly to various “stepping” distances (Ex.1004, 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.1004, 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 (Ex.1003, ¶104).

Mehta's motor-driven "system" is "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.1003, ¶¶102-105). 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.1004 at 16:39-41; Ex.1003, ¶101). 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.1004 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.1004, 10:38-39, 12:5-11, 13:58-65). As I explained above, a motor that extends needles a desired

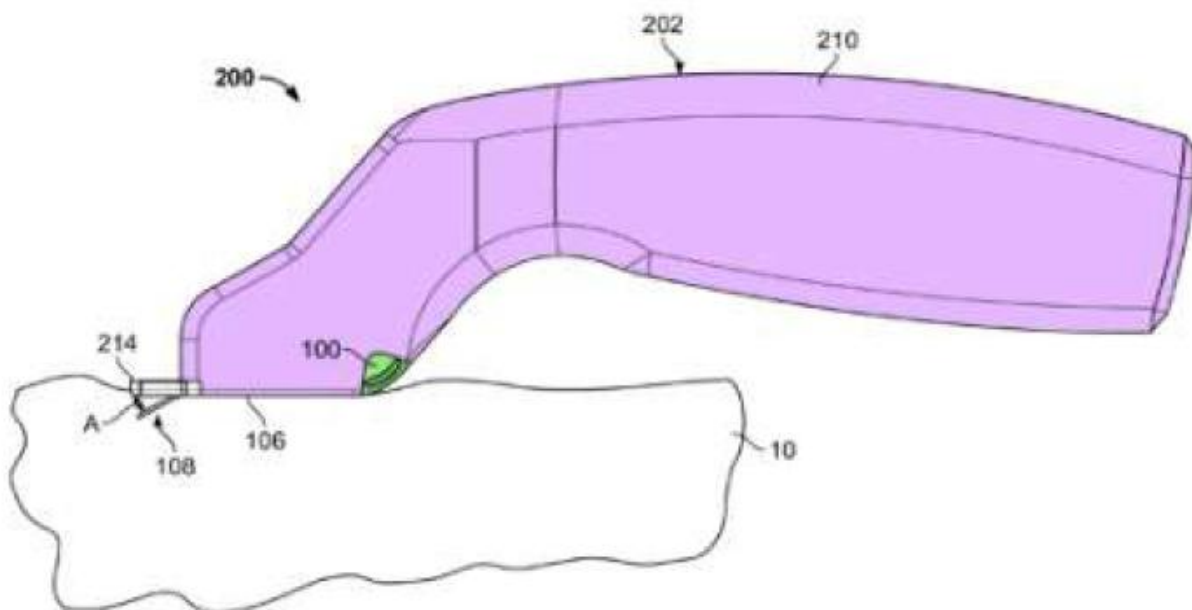
distance is programmed to do so. Mehta's motor is thus programmed to extend needles the desired depth.

16. Mehta further disclosed selecting/replacing different extendable cartridge configurations with different needle lengths (Ex.1004, 8:13-18, 10:17-25, 12:31-46, 17:66-18:3; Ex.1003, ¶101-102) or angles (Ex.1004, 12:23-58, 20:56-21:13; Ex.1003, ¶101-102). 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.1004, 8:13-18, 10:17-25, 12:31-46, 17:66-18:3; Ex.1003, ¶101-102). 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).

C. Ground III: Mehta, Na ‘848 And Knowledge Of POSA Render Obvious Claims 4-5 and 14-15

18. 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, ¶172; Ex.1026, ¶22). To illuminate target probe 108 insertion area (below 214) in Mehta’s figure below (Ex.1004, 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.1004, Fig. 2B, illustrating device body 210 purple and cartridge 100 green):



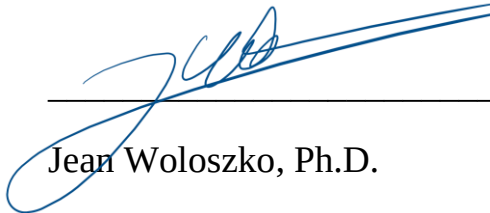
Mehta's device body 210 (covering all but the bottom-facing tissue engaging surface 106) is opaque (shown in purple above) and so, would not reveal internal components (Ex.1004, Fig. 2B). The transparent/translucent opening directly in front of the LED would only expose the LED, so no other internal 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, ¶177).

IV. CONCLUSION

19. 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 No. 9,320,536 | IPR2024-00384

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. 13, 2025