

Filed on behalf of: Serendia, LLC

Entered: May 27, 2025

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ENDYMED MEDICAL LTD. AND ENDYMED MEDICAL, INC.,¹
Petitioner,

v.

SERENDIA, LLC,
Patent Owner.

Case IPR2024-00383
Patent 9,775,774

PATENT OWNER'S SUR-REPLY

¹ The Board, in IPR2024-00843, joined EndyMed Medical Ltd. and EndyMed Medical Inc. as petitioners to this proceeding.

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2016	Complainant's Public Interest Statement & Complaint of Serendia, LLC, Under Section 337 of the Tariff Action of 1930, as Amended, In re Certain Dermatological Treatment Devices & Components Thereof, No. 337-TA-1356 (U.S.I.T.C. Mar. 1, 2023)
2017	Parties' Proposed Procedural Schedule and Notice of USPTO/PTO Proceedings and State and Federal Litigation Pursuant to Order No. 3, In re Certain Dermatological Treatment Devices & Components Thereof, No. 337-TA-1356 (U.S.I.T.C. Apr. 24, 2023)
2018	Order No. 6: Adopted Procedural Schedule, In re Certain Dermatological Treatment Devices & Components Thereof, No. 337-TA-1356 (U.S.I.T.C. Apr. 27, 2023)
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2023	Letter from Keith K. Im, SynKloud Technologies, LLC, to Todd Tillemans, Cynosure, LLC, dated Nov. 29, 2021
2024	Order No. 33: Granting Parties' Joint Motion to Amend the Amended Procedural Schedule [Motion Docket No. 1356-027], In re Certain Dermatological Treatment Devices & Components Thereof, No. 337-TA-1356 (U.S.I.T.C. Oct. 19, 2023)

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2066	Martin Braun, Sylfirm X Revolutionises [sic] the Clinical Applications of RF Microneedling, 12 Prime Int'l J. Aesthetic Anti-Ageing [sic] Med. 50 (2022)
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2120	U.S. Patent Application Publication No. 2002/0120261 A1 (“Morris ’261”)
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2122	Cartessa Aesthetics, Innovations in RF Microneedling: A Closer Look at VirtueRF, Observations Aesthetics, Issue No. 1 (June 2021)
2123	Declaration of Peter Crosby, dated April 22, 2024 (“Crosby Decl.”) (PROTECTIVE ORDER MATERIAL AND REDACTED VERSIONS)
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2149	Primāeva Medical, Inc., Miratone Brochure (2009) (Bates nos. Berube-0000004-0000007)
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2151	Primāeva Medical, Inc., Miratone System Instructions for Use (Bates nos. Berube-0001071–0001097)
2152	VCF Staff, <i>Syneron Medical Buying Primaeva Medical</i> , VENTURE CAP. J. (Oct. 16, 2009), https://www.venturecapitaljournal.com/syneron-medical-buying-primaeva-medical/

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2153	Primāeva Medical, Inc., K082391 510(k) Summary (Aug. 24, 2009) and letter from Mark N. Melkerson, Department of Health & Human Services, Food & Drug Administration to Brian Grigsby, Primāeva Medical, Inc. (Sept. 1, 2009), https://www.accessdata.fda.gov/cdrh_docs/pdf8/K082391.pdf
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I. Introduction

Petitioner's reply confirms that Petitioner fails to show that claims 13 and 14 of U.S. Patent No. 9,775,774 ("774 Patent") are unpatentable because Petitioner's arguments rely on an incorrect claim interpretation and misinterpretation of the prior art. Petitioner not only advances a construction of the claim term "desired distance" that has no support in the intrinsic or extrinsic evidence, but also erroneously asserts that its principal reference, Mehta, permits the user to select the distance that needles extend. Nor would a POSITA have been motivated to modify in Mehta, as Petitioner proposes, to meet the claim requirements.

In fact, the parties litigated essentially these very issues before the U.S. International Trade Commission ("ITC"), and the Administrative Law Judge ("ALJ") construed "desired distance" consistent with Patent Owner's proposal here and rejected the same misinterpretation of Mehta that Petitioner advances here. The Board did not have the benefit of considering the ALJ's opinion when it instituted this proceeding because it issued on December 14, 2025, well after institution. Ex.2158. Although the Commission has decided to review-in-part the ALJ's determination, the Commission is not reviewing the ALJ's validity determinations. Ex.2159; Ex.2157, 99:180-100:8.

For the reasons set forth below, and consistent with the ALJ's decision, claims 13 and 14 of the '774 Patent should be found patentable over Petitioner's grounds.

II. Claim Construction

Petitioner misconstrues Patent Owner's explanation of the plain and ordinary meaning of "desired distance" in a failed attempt to rebut it. But what cannot be seriously disputed is that Patent Owner's proposed construction is the only construction that aligns with and is supported by the intrinsic and extrinsic evidence, whereas Petitioner's proposed construction wholly ignores it. Petitioner does even attempt to support its construction that "desired distance" means "needles extending or extendable a desired distance are distinguished from those that extend an undesired distance" (Reply to PORP 7), highlighting the lack of support for its meaningless proposal.

Contrary to Petitioner's contentions, Patent Owner's proposal throughout this IPR has remained consistent. "Desired distance" in the context of the claims refers to how far the extendable needles extend from the device's end surface based on programming of this distance through user selection of the depth of needle insertion extendable needles. POR 23. That is what the claims require and what the specification supports. *Id.* 20-23. Indeed, before this IPR, Petitioner's expert and Patent Owner's expert agreed on this plain and ordinary meaning. As the ALJ noted

in her final initial determination in the ITC involving Petitioner and Patent Owner:

“Both sides’ experts agreed that the plain and ordinary meaning of ‘desired distance,’ in the context of extendable needles that ‘extend a desired distance from’ the needle assembly end surface, refers to a distance that can be selected/programmed.” Ex.2158, 204 (emphasis added).²

Petitioner launches three main attacks on Patent Owner’s construction—none have merit.

First, Petitioner incorrectly argues that Patent Owner proposes different meanings for “desired distance” across all claims, including claim 11 which is directed to both extending and extendable needles. Petitioner is wrong.

The plain and ordinary meaning that Patent Owner proposes in this proceeding—on which both Petitioner’s and Patent Owner’s expert agreed before this proceeding—applies across all the claims including the term “desired distance.” Contrary to Petitioner’s assertions, Patent Owner’s expert also agrees, testifying that “**extending** needles extend a desired distance” (Ex.1031, 90:4-6; 88:20-89:6); disagreeing with Petitioner that “a user couldn’t select the **desired distance** for **extending needles**” as required in 11 (*id.*, 90:20-91:5), and explaining that he simply

² All emphasis added unless otherwise noted.

limited his opinions to the extendable needles of claims 13 and 14 because those were the claims at issue here. *Id.*, 93:17-95:2.

How far the needles extend from a device surface based on programming of the distance through user selection of the depth of needle insertion applies to all instances of the claimed “desired distance,” including in independent claim 11. Dependent claims not at issue in this proceeding make clear that the “extending” needles can be on an “inner surface,” and the distance that the needles extend from this inner surface can be selected or programmed. Ex.1001, cls. 5-6, 15. There is nothing inconsistent with Patent Owner’s proposal for the meaning of “desired distance” across the claims and Petitioner can point to none. Claims 13 and 14 at issue here, however, include two additional requirements, excluding “extending” needles: 1) that the needles be **extendable** and 2) that a mechanism or motor cause the **extendable** needles to extend the desired distance.

Second, Petitioner incorrectly contends that Patent Owner’s proposal that the desired distance be based on user programming or selection allegedly imports limitations from the specification into the claims. Reply 4-5. In essence, Petitioner argues, for the first time in its reply, that the claims do not specify who selects the desired distance such that it could be a “manufacturer, designer, programmer, or an ‘automatic’ feedback mechanism.” *Id.* at 5. Petitioner is wrong. Claims are to be construed in light of the specification. *Phillips v. AWH Corp.*, 415 F. 3d 1303, 1316

(Fed. Cir. 2005). The specification makes clear that the treatments are based on *user selection* of various parameters. Ex.1001, 10:29-64, 13:45-14-34; Fig. 12. The ALJ agreed, explaining that “the ‘desired distance’ the needles extend is determined based on the depth a *user selects* for the needle insertion, and an algorithm (i.e., software) executed by the CPU controls the needle deployment accordingly.” Ex.2158, 203.

Petitioner's expert previously agreed that the specification supported user selection of the desired distance. In this proceeding, Petitioner's expert stated that, based on the specification's disclosure, “a POSA would understand the plain meaning of ‘a desired distance’ to also encompass any *user-selected* ... needle deployment distance.” Ex.1003, ¶55. And before this proceeding, in the ITC, Petitioner's expert testified that a motor could extend the needles the claimed “desired distance” “[a]s long as you can program this distance.” Ex.2125, 1151:8-12. This is all entirely consistent with Patent Owner's position and its expert's opinions. POR 16-24; Ex.2147 ¶¶73-81. The user selects the depth/programs the depth, the CPU executes the algorithm or software based on the user depth selection/programming to control the motor to extend the needles the claimed desired distance. *See also* POR 21-24 (citing to intrinsic evidence supporting construction); Ex.2158, 203.

Now, Petitioner sets up a straw man, arguing that “[t]here is nothing in the claims that require programming at the physician’s office or at any particular time during the procedure or by any particular person.” Ex.1030 ¶10. Petitioner misses the mark. The location where CPU that controls motor is programmed is not the issue. The issue is that the claims require selection of a “desired distance” the needles extend, and the intrinsic evidence only supports that the user selects that “desired distance.” Nowhere does the intrinsic record refer to a manufacturer, designer, or programmer selecting the desired distance. Patent Owner’s expert agrees that a manufacturer would not select the desired distance (Ex.1031, 88:11-19), as is not contemplated by the intrinsic evidence. As to an automatic feedback system that Petitioner proposes (which is not mentioned in the specification), the user would still have to select and program the desired distance, which could then be used by a feedback system to ensure the needles extend a desired distance based on that selection and programming. As Patent Owner explained, the Examiner’s citation to prior art that included such feedback system supports that the “desired distance” is based on a *user’s selection* to provide control over the penetration depth. POR 23-24.

Third, Petitioner’s reliance on infringement opinions presented before the parties’ crystallizing of the meaning of the claimed “desired distance” at the ITC is misplaced and does not support its position.

For background, the term “desired distance” was not proposed for construction by either party at the ITC. Ex.1037; Ex.1031, 256:12-257:7. As Mr. Crosby explained, at the beginning of the ITC proceeding many parties and products were at issue, but the parties refined and crystalized their positions by the time of the hearing. Ex.1031, 152:4-15. The Rohrer device was at issue at the beginning of the ITC proceeding, but not at the hearing. *Id.*, 257:8-11. And as Mr. Crosby, explained, his opinions on Rohrer device were based on what was identified as agreed and disputed at the time (*id.*, 258:2-10) which did not include the term “desired distance.”

In her order following the ITC hearing, the ALJ explained that “the ‘desired distance’ the needles extend is determined based on the depth a user selects for the needle insertion, and an algorithm (i.e., software) executed by the CPU controls the needle deployment accordingly.” Ex.2158, 203. This is consistent with Patent Owner’s proposed construction. And as Mr. Crosby explained, he did not analyze the Rohrer device under that understanding of “desired distance.” Ex.1031, 259:4-7. Petitioner attempts to disparage Patent Owner when relating the history of Petitioner’s motion to de-designate Rohrer ITC protective order materials for purpose of use in this IPR. But there is a settlement agreement between Rohrer and Patent Owner with confidential terms that must be respected, and Patent Owner had no right to de-designate any Rohrer confidential information or decide whether it qualified as confidential.

It is Petitioner that continues to tell government agencies different stories to suit its interests. Petitioner argued “contrary to statements and submissions [it] made to the FDA” to try to avoid infringement in the ITC and now—after its expert agreed with Patent Owner’s construction of “desired distance” in the ITC—argues here for a different construction to try to avoid the consequences of its infringement. Ex.2158, 85 n.39 & 204.

Regardless, Petitioner’s attempt to equate the mechanical adjustment of Roher to manually exchanging cartridges as in Mehta (Reply 8), does not support its construction or serve to rebut Patent Owner’s. The Rohrer device includes a mechanical dial that can be used to adjust how far the needles in a single cartridge extend from a specific surface. Although there is no programming of a motor to extend the needles, the user selects the distance by using the dial. By contrast, in Mehta there is no user selection whatsoever of how far the needles extend. As the ALJ explained after considering the very evidence Petition relies on here, “having different cartridges with various probe configurations is distinct from probes in a particular cartridge extending a desired distance” because “[t]he penetration depth may change based on the length or angle of the needles in each cartridge, but the needles extend only a *fixed* distance.” Ex.2158, 209; Ex.2147 ¶82.

Petitioner also tries to equate the user selection of desired distance in Patent Owner’s proposal for the construction of “desired distance” as somehow relying on

the user mental state. Petitioner's arguments are again misplaced. The '774 Patent explains that user selected desired distance is a parameter implemented in the CPU to control the motor. Ex.1001, Fig. 12; 9:64-66; 10:31-36; 10:60-64, 13:63-66, 14:3-6, 14:12-34. That selected distance is the claimed "desired distance" even if it was selected by mistake. By contrast, Petitioner's proposed construction, which defines the "desired distance" as not being an "undesired distance" requires assessing what the user "desired," i.e., the user's mental state. Reply 1.

Lastly, Petitioner seems to rely on Mehta's manual post-insertion adjustment of a cartridge to construe the claims of the '774 Patent. But the claims of the '774 Patent are to be construed in light of the '774 Patent specification, not Mehta's. And in any event, manual post-insertion adjustment of a cartridge would not meet the limitations of the claims, which require a mechanism or motor to extend the needles the claimed desired distance. Ex.1001, cls. 13 and 14.

In sum, because no evidence supports Petitioner's proposed construction of the term "desired distance" and the intrinsic and extrinsic evidence of record support only Patent Owner's proposal, the term "desired distance" should be construed to mean how far the needles extend from the device's end surface based on programming of this distance through user selection of the depth of needle insertion.

III. Ground I: Petitioner Failed To Demonstrate That Mehta Anticipates Claims 13 Or 14 Of The '774 Patent

Mehta does not disclose a motor or mechanism for causing/to cause “the plurality of the extendable needles to extend a desired distance from the end surface,” as claims 13 and 14 require. As Patent Owner’s expert explained, the ’774 Patent and Mehta are “vastly different.” Ex.2147 ¶108. In the ’774 Patent, the user attaches a needle module to the handpiece, selects the depth the needles should extend, and based on that selection the motor controls how far the needles extend. *Id.* By contrast, in Mehta the user attaches a cartridge to the handpiece, the needles fully extend, the user is provided with information about the location of the needles (based on impedance measurements, depth markings, or a virtual depiction system), and if the needles cannot be manipulated into the correct location, then the user has to select a different cartridge and start the process all over again. *Id.* “These are two completely different ways to reach the result of reaching a target region of the tissue.” *Id.*

That an independent fact finder addressing the same argument Petitioner raises here has agreed with Patent Owner highlights the deficiencies in Petitioner’s arguments. The issue of whether Mehta invalidates claim 14 of the ’774 Patent was fully litigated before the ITC, and the ALJ unequivocally found that “the ’774 patent requires that needles extend ‘a desired distance’ from ‘a surface’ (claim 11) and an ‘end surface’ (claim 12) and “Mehta does not disclose needles extending a ‘desired

distance' from any surface." Ex.2158, 231. Petitioner and its expert relied on the same portions of Mehta at the ITC as they do here to argue that Mehta discloses the claimed desired distance, including Mehta's virtual depth/location depiction (*compare* Ex.2158, 207 *with* Reply 12-13), step-motor (*compare* Ex.2158, 207-08 *with* Reply 15-18), "[o]ver-inserting and then partially retracting" the electrodes (*compare* Ex.2158, 208-09 *with* Reply 17), and using different cartridges with different probe configurations (*compare* Ex.2158, 209 *with* Reply 17). As the ALJ found, nothing in those portions of Mehta discloses the claimed desired distance. Ex.2158, 207-09.

Furthermore, the relevant content of Mehta was before the Examiner during prosecution. As the testimony of Petitioner's expert confirms, the portions of Mehta he relies on to support his opinions that Mehta discloses the claimed "desired distance" are *all* disclosed in Mehta '705, which was before the Examiner in the '812 related Patent and which also claims the same "desired distance." *Compare* Ex.1030, ¶¶14-16 (citing Ex.1004, 15:34-40, 21:8-10, 13:58-65, 15:34-40, 16:39-41, 16:34-36, 10:38-39, 13:58-65, 8:13-18, 10:17-25, 12:31-46, 17:66-18:3, 12:23-58, 20:56-21:13) *with* Ex.2117, 16:3-10, 21:56-58, 14:27-34, 16:3-9, 17:16-18, 17:11-14, 11:24-25, 14:23-26, 8:54-59, 11:3-11, 13:1-16, 18:42-46, 12:60-13:27, 21:38-62, respectively. This was also true in the ITC, where "it was uncontested during the Hearing that both Mehta references have the same relevant disclosures." Ex.2158,

198. As the ALJ explained, “[t]he disclosures of Mehta and Mehta ’705 indicate that the operation of the handpiece and cartridges is the same for both, i.e., the needles extend a fixed distance, and manual adjustment or switching of cartridges is required to reposition the needles.” *Id.*, 200. The only portion of Mehta that Petitioner’s expert relies on that is not in Mehta ’705 (i.e., the virtual depiction system at 32:46-33:34), Petitioner’s expert admits is not necessary to meet the “desired distance” limitation. Ex.2157, 29:6-10. As the ALJ found, that disclosure is “not about how Mehta’s handpiece and cartridges operate.” Ex.2158, 200. The Examiner did not reject any of the claims which recite the “desired distance” limitation over Mehta ’705. Ex.2147 ¶¶90-91; Ex.2118, 577-582, 645-651.

A. Mehta does not disclose how far needles extend based on a user programming of the desired distance, as required by the claims

Petitioner tries to read out causing/to cause “the plurality of the extendable needles to extend a desired distance” out of the claims. First, Petitioner seek to equate providing information about the physical location of already inserted needles with user programming or selection of the desired distance that needles are to extend. They are not the same. Ex.2147 ¶¶101-104. Second, Petitioner assumes that disclosure of a “step-motor” and delivery of energy to a target region or desired depth is sufficient to teach the claimed “desired distance.” It is not. *Id.* ¶105. Lastly, Petitioner seems to equate Metha’s disclosure of extending needles to an undesired location and then extending to their full, fixed distance to somehow teaching the

“desired distance.” It does not. *Id.* ¶107. Mehta simply does not disclose or suggest user selection of the distance that the needles extend, or programming to cause a motor/mechanism to extend the needles that selected distance. Ex.2158, 205-207; Ex.2147 ¶96. Instead, as the ALJ found, “[b]ecause a user of Mehta’s device cannot select a desired distance for the needles to extend, Mehta teaches mechanisms to assess whether the already extended needles have reached the target tissue, so that the user can reposition them or change cartridges if needed.” Ex.2158, 205.

Petitioner’s reliance on Mehta’s disclosures of a physician’s controlling areas of tissue that receive energy, providing information to the user for post-insertion adjustment of the needles, and a virtual depiction system showing the actual location of the inserted probes does not show that Mehta discloses the claimed causing/to cause the “plurality of the extendable needles to extend a desired distance.” Reply 12-13; Ex.1001, cls. 13-14. As Petitioner admits, the virtual depth/location depiction 350 of Mehta simply shows the actual versus desired location of the probes. Reply 12-13. Mehta goes on to explain that based on that comparison, “the physician would be *informed* that further advancement of the probes is necessary to place the probes within the second layer 326.” Reply 13-14 (citing Ex.1004, 32:46–33:34). But nothing in those disclosures teaches using a motor to extend the needles a desired distance based on user selection and programming of that distance as the claims require. Ex.2147 ¶101; Ex.2158, 206 (“the visualization/measurement system

cannot change the distance the needles extend, and does not allow the physician to program the distance, as claimed”).

Petitioner also relies on Mehta's disclosure of sensors to measure impedance, but again Mehta merely discloses that, based on those measurements, the user can be alerted to reposition the probes. Reply 14; Ex.2147 ¶103. Again, that the user is informed that already extended probes should be repositioned does not equate to disclosing user selection or programming of a distance the needles extend. Ex.2147 ¶104. The only disclosure in Mehta for pre-insertion probe adjustment is selection of a different cartridge, which involves no user selection or programming of how far needles extend, as the ALJ recognized. *Id.* ¶106; Ex.2158, 206 (“The only method Mehta discloses to adjust probe placement is to select a different cartridge.”); *see also id.*, 207 (“Mehta only discloses repositioning the probes manually or using different cartridges if initial probe advancement was unsuccessful.”).

Petitioner also relies on Mehta's disclosure of a “motor” and language in Mehta about needles needing to reach a desired depth prior to delivering energy to argue that the motor “*must* be programmed to control the needles to extend to, and stop at, this distance.” Reply 17. But that is simply not what Mehta teaches. The motor in Mehta instead fully extends the needles a fixed distance each time. Ex.2147 ¶97. In the ITC, Petitioner's expert, “Dr. Woloszko agreed, having a motor does not mean that the motor controls the desired distance of needle extension.” Ex.2158,

206-07. The claims require more than the presence of a motor programmed to fully extend the needles; they require that the motor be programmed based on user selection to extend the needles a desired distance. Petitioner's arguments erase the "desired distance" limitation of the '774 Patent claims. Petitioner points to nothing in Mehta disclosing any kind of user selection of the distance that the needles extend or programming to extend the needles that distance, which, as a matter of law, defeats Petitioner's anticipation grounds. *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295 (Fed. Cir. 2002) ("A single prior art reference anticipates a patent claim if it expressly or inherently describes each and every limitation set forth in the patent claim.") (citation omitted).

Petitioner's reliance on Mehta's disclosure of over-inserting and partially retracting the electrodes fares no better. Reply 17. As Mehta explains and Petitioner's expert agrees, that portion of Mehta addresses having a consistent and more reliable starting point for needle insertion due to skin laxity (Ex.2157, 31:10-32:3), which has nothing to do with programming a motor to extend needles a desired distance. Ex.2147 ¶107; POR 36-37. Mehta is designed to extend needles a fixed distance (Ex.2147 ¶96), and regardless of whether the needles are inserted to that distance initially or using a second step, e.g., partial retraction, that is not user selection of a distance to extend the needles. *Id.* ¶106. As the ALJ recognized,

“simply advancing and retracting the needles is not enough to disclose the claimed limitation.” Ex.2158, 208.

Finally, Petitioner's attempt to equate manually selecting a different cartridge with different needle configurations to a mechanical adjustment dial in the Pixel8 device does not support its argument that Mehta discloses the claimed desired distance. Patent Owner has not contended that the Pixel8 practices the claims at issue under the correct construction of “desired distance” that the experts agreed on, and the ALJ adopted, in the ITC. Ex.2158, 203-04. Regardless, the Pixel8 and Mehta are fundamentally different. Replacing a cartridge to select a different set of needle lengths to reach different target tissues is not the same as using a dial to adjust how far needles extend. Selecting a different cartridge does not meet the claim requirement of causing/to cause “extendable needles to extend a desired distance” using a motor/mechanism, as claims 13-14 require.

IV. Ground IV: Petitioner Failed To Demonstrate That Mehta And Lee Render Obvious Claims 13 Or 14 Of The '774 Patent

Petitioner ignores the vast and important differences between Mehta and Lee and mischaracterizes the goal of each reference to argue a POSITA would be motivated to combine them.

First, Petitioner tries to characterize Mehta as solving the problem of needle-depth control to argue that POSITA would have combined it with Lee. Petitioner's argument fails for at least two reasons. Mehta is concerned with delivery of energy

to a “predetermined target area while minimizing delivery of energy to undesired region of tissue.” Ex.1004, 2:9-12; *see also id.*, 2:37-41; 3:42-44. To do so, Mehta teaches inserting needles into the skin, confirming that the needles are in the target region of the tissue using several mechanisms (*e.g.*, ultrasound (Ex.1004, 2:10-12, 12:1-4), “virtual depiction ... of the depth” (*id.*, 32:46-57, impedance measurements (*id.*, 39:33-36)), and delivering energy for a period of time to target tissue. Ex.2147 ¶¶119, 141. Mehta was aware of distance control and chose a different approach. POR 43-45. Lee, on the other hand, teaches creating “hundreds to tens of thousands of holes on the human skin” (Ex.1011, Abstract), and “is concerned with speed—not with confirming the location of the needles after insertion because energy is not delivered via the needles.” Ex.2147 ¶116. These differences in Mehta and Lee “are central to [the] motivation to combine inquiry.” *Adidas AG v. Nike, Inc.*, 963 F.3d 1355, 1359 (Fed. Cir. 2020). Petitioner ignores them.

Second, that both systems deliver energy to the skin is not enough to combine them given their distinct designs, operations, and goals because a POSITA would have reasonable expectation of success in combining the references. To be clear, Patent Owner agrees that Mehta delivers mechanical energy since needles penetrate tissue. But Mehta requires more, as even the portions of Mehta that Petitioner cites show. Ex.1004, 8:66-9:6 (“the devices and methods described herein are not limited to the percutaneous delivery of thermal energy, but ***also include*** the percutaneous

delivery of mechanical energy or even reducing temperature of tissues beneath the epidermis”); cl. 1 (“applying energy to the electrode array from the energy source.”). By contrast, Lee does not disclose delivery of electrical or thermal energy as Mehta does. Nor could it, given the speed at which the needles in Lee are inserted into the skin. *Compare* Ex.1011 ¶58 (“the treatment procedure may be performed at a speed of about 66-420 times per minute.”) *with* Ex.1004, 37:17-24 (describing applying energy to reach temperatures for a duration of 1.5 to 25 seconds, or 1, 4, or 7 seconds); Ex.2154 (Woloszko Dep. Tr.), 66:1-13. Ex.2147 ¶144; *Trivascular, Inc. v. Samuels*, 812 F.3d 1056, 1068 (Fed. Cir. 2016) (finding nonobviousness where proposed modification would “destroy the basic objective” of the primary reference).

Petitioner ignores these important differences in improperly picking and choosing only so much of Lee’s teachings as support for its position, admitting that Petitioner “does not cite Lee for its treatment times, only Lee’s needle depth-control (Pet. 65-69).” Reply 24-25. Petitioner turns the obviousness inquiry on its head in arguing that “Mehta did **not** motivate **eliminating** delivering electrical RF energy, and thus, Mehta so modified by Lee would maintain Mehta’s RF treatment times.” Reply 25 (emphasis in original). The correct inquiry is whether a POSITA would have been motivated to modify Mehta as Petitioner proposes in view of Lee to arrive at the claimed invention. A POSITA would not have been motivated to do so. Ex.2147 ¶¶112-122. Petitioner’s approach is nothing more than cherry-picking

elements from different references and combining them without regard to what a POSITA would have been *motivated* to do. *Eli Lilly & Co. v. Actavis Elizabeth LLC*, 435 F. App'x 917, 921 (Fed. Cir. 2011) (affirming a finding of nonobviousness, explaining “it is impermissible to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art”) (citation omitted).

A. Evidence of Objective Indicia of Non-Obviousness

Petitioner's attorney argument fails to overcome the ample record evidence supporting non-obviousness. All of the record evidence supports that the Sylfirm X has enjoyed commercial success. PO's Response, 60-65; Ex.2147 ¶¶154-188; Ex.2135 (Thomas Decl.) ¶¶14-15. Petitioner argues that the fact that the Sylfirm X launched in the middle of 2021 makes the sales increase from 2021 to 2022 “inflat[ed].” Reply 32. But the record evidence shows that the sales of the Sylfirm X have totaled millions and have continued to grow each year. Ex.2135 (Thomas Decl.) ¶¶14-15; Ex.2071.

The same is true for the Sylfirm X's industry praise. PO's Response 65. Petitioner tries to discredit the unrebutted evidence of industry praise contending that it does not refer to depth control, but ignores that the praise is connected to the patented product. *See* Ex.2038 (expressly identifying the '774 Patent in “Viol Patent

list”) and Ex.2067 (recognizing the Sylfirm X as a world-class product). Petitioner’s attack specific to the Prime Journal Article also fails. **First**, the article Patent Owner relies on is from 2022 (Ex.2066), but Petitioner relies on information from 2025 to attack it without evidence showing the sponsorship applicable in 2025 applied in 2022. Ex.1039. **Second**, Petitioner relies on *Amarin Pharma v. Hikma Pharmaceutical USA, Inc.*, 449 F. Supp. 3d 967, 998 (D. Nev. 2020), where an article plaintiff sponsored citing a party who submitted supporting declarations during prosecution was found not to be persuasive evidence of industry praise. That case is inapt to the facts here. Here, the Prime Journal Article refers to a third-party Medical Director who “discusses his experience using the SYLFIRM X,” and he did not submit any declarations during the prosecution. Ex.2066.

Petitioner’s main attack on the unrebutted evidence of secondary considerations focuses on nexus. Petitioner cites *Ormco Corp. v. Align Technology, Inc.*, but in that case, the commercial success was due to features that were not new. 463 F.3d 1299, 1313 (Fed. Cir. 2006). Here, that is not the case. Petitioner also cites *Fox Factory, Inc. v. SRAM, LLC*, but that case addressed the presumption of nexus when a product is not coextensive with a patented claim. 944 F.3d 1366, 1372-73 (Fed. Cir. 2019). Regardless of whether a presumption of nexus applies, the evidence here is enough to show a strong nexus between the commercial success of the Sylfirm X and the claimed invention.

The Federal Circuit has explained that, when determining whether a nexus exists, it is important to consider “the invention as a whole,” rather than on a “limitation-by-limitation” basis. *Volvo Penta of the Ams., LLC v. Brunswick Corp.*, 81 F.4th 1202, 1210 (Fed. Cir. 2023) (citing *Chemours Co. FC, LLC v. Daikin Indus. Ltd.*, 4 F.4th 1370, 1377 (Fed. Cir. 2021); *Yita LLC v. MacNeil IP LLC*, 69 F.4th 1356, 1364 (Fed. Cir. 2023) (discussing *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317 (Fed. Cir. 2016)). Here, the “inventive combination” of features drove the commercial success of the Sylfirm X. *Chemours*, 4 F.4th at 1378; Ex.2147 ¶¶189-191; Ex.2037, 2, 13; Ex.2066, 2-3; Exs.2039, 2079, 2083, 2084. The '774 Patent is also cited in the Sylfirm X marketing materials. Ex.2038.

The un rebutted evidence of secondary considerations along with evidence showing a nexus between commercial success and industry praise to the patented features are sufficient to rebut any *prima facie* case of obviousness.

V. Conclusion

For the reasons set forth above, the Board should confirm the patentability of claims 13 and 14.

Respectfully submitted,

Dated: May 27, 2025

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CERTIFICATE OF COMPLIANCE WITH 37 C.F.R. § 42.24

I hereby certify that this Patent Owner's Sur-Reply complies with the word count limitation of 37 C.F.R. § 42.24(c)(4) because the Patent Owner's Sur-Reply contains 4,888 words using Microsoft Word's counting feature, excluding the cover page, signature block, and the parts of the Patent Owner's Sur-Reply exempted by 37 C.F.R. § 42.24(c)(4).

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that on this 27th day of May, 2025, a true and correct copy of the foregoing **Patent Owner's Sur-Reply and all Exhibits** were served by electronic mail on Petitioner's lead and backup counsel at the following email addresses:

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