

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 IPR2024-00384
Patent 9,320,536

PATENT OWNER'S SUR-REPLY

¹ The Board, in IPR2024-00844, joined EndyMed Medical Ltd. and EndyMed Medical Inc. as petitioners to this proceeding.

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2004	Expert Report of Jean Woloszko, M.D., Ph.D., dated August 14, 2023 (PROTECTIVE ORDER MATERIAL AND REDACTED VERSIONS)
2005–2006	RESERVED
2007	Deposition transcript of Jean Woloszko, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C.), taken September 14, 2023 (excerpt)
2008	Deposition transcript of Jean Woloszko, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C.), taken September 15, 2023 (excerpt)
2009–2014	RESERVED
2015	Complainant's Rebuttal Post-Hearing Brief, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C. Jan. 5, 2024) (PROTECTIVE ORDER MATERIAL)
2016	Complainant's Public Interest Statement & Complaint of Serendia, LLC, Under Section 337 of the Tariff Action of 1930, as Amended, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C. Mar. 1, 2023)

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2017	Parties' Proposed Procedural Schedule and Notice of USPTO/PTO Proceedings and State and Federal Litigation Pursuant to Order No. 3, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C. Apr. 24, 2023)
2018	Order No. 6: Adopted Procedural Schedule, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C. Apr. 27, 2023)
2019	Respondents' Joint Reply Post-Hearing Brief, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C. Jan. 5, 2024) (excerpts)
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2021	Jeisys Medical Inc.'s and Cynosure, LLC's Response to the Complaint and Notice of Investigation, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C. May 1, 2023)
2022	Letter from Merle W. Richman, CKR Law, to Justin S. Cohen, Thompson & Knight LLP, Cutera, dated March 20, 2018
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], <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C. Oct. 19, 2023)
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2041	Direct Rebuttal Demonstratives of Vincent A. Thomas (CDX-0045C), <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C. Dec. 12, 2023) (PROTECTIVE ORDER MATERIAL)
2042–2051	RESERVED
2052	Email exchanges between SynKloud and Jeisys, transmitted December 6, 2021 through January 20, 2022, and Certified English Translations thereof (PROTECTIVE ORDER MATERIAL)
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2062	Presentation: Sylfirm X Clinical Training (2021) (PROTECTIVE ORDER MATERIAL)
2063–2065	RESERVED
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)
2067	World-Class Product of Korea 2020, Certificate to ViOL Co., Ltd., dated December 9, 2020 ("Sylfirm X Award")
2068–2069	RESERVED
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2071	Profit & Loss, January–December 2021 (Accrual Basis) (July 6, 2023, 2:31 PM) (PROTECTIVE ORDER MATERIAL)
2072–2078	RESERVED
2079	Sylfirm X (product information), ViOL (2022), https://violmedical.com/for_providers/product?idx=10 (last visited Feb. 25, 2023)
2080–2082	RESERVED
2083	ViOL, Sylfirm X User Manual (VO-UM-SFX-03), revised April 20, 2022
2084	Sylfirm X, Device Description (PROTECTIVE ORDER MATERIAL)
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2116	U.S. Patent No. 10,869,812 B2 (“’812 Patent”)
2117	U.S. Patent No. 8,540,705 B2 (“Mehta ’705”)
2118	File History for U.S. Patent No. 10,869,812
2119	U.S. Patent. No. 6,277,116 B1 (“Utely”)
2120	U.S. Patent Application Publication No. 2002/0120261 A1 (“Morris ’261”)
2121	RESERVED
2122	Cartessa Aesthetics, <i>Innovations in RF Microneedling: A Closer Look at VirtueRF</i> , Observations Aesthetics, Issue No. 1 (June 2021)
2123–2124	RESERVED
2125	Hearing transcripts, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C.), held November 7, 2023 and December 11, 2023 (Jean Woloszko testimony excerpts) (“Woloszko Hr’g Tr.”)

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2126	Hearing transcript, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C.), held December 12, 2023 (Peter Crosby testimony excerpts) (“Crosby Hr’g Tr.”)
2127	Sylfirm X RF Inspection Report of Peter Crosby
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2132	U.S. Patent Application Publication No. 2006/0036210 A1 (“Zhang”)
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2134	Declaration of Peter Crosby, dated April 23, 2024 (“Crosby Decl.”) (PROTECTIVE ORDER MATERIAL AND REDACTED VERSIONS)
2135	Declaration of Vincent A. Thomas, dated April 23, 2024 (“Thomas Decl.”) (PROTECTIVE ORDER MATERIAL AND REDACTED VERSIONS)
2136	<i>Curriculum Vitae</i> of Peter A. Crosby
2137	Appendix 5 to Respondents’ Final Invalidity Contentions, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C. July 10, 2023)
2138	Statement Under 37 C.F.R. § 3.73(c) and Disclaimer in a Patent Under 37 C.F.R. § 1.321(a) of U.S. Patent 9,320,536 (’536 Patent) (“Disclaimer”)
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2140	Declaration of Charles H. Sanders in Response to Petitioner's Objections to Patent Owner's Evidence [<i>served, not filed</i>]
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2147	Declaration of Peter Crosby, dated November 12, 2024 (“Crosby POR Decl.”) (PROTECTIVE ORDER MATERIAL AND REDACTED VERSIONS)
2148	Deposition transcript of Jean Woloszko, M.D., Ph.D., <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C.), taken September 15, 2023 (excerpts)
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/
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
2154	Deposition transcript of Jean Woloszko, M.D., Ph.D., <i>Jeisys Medical Inc. v. Serendia, LLC</i> , IPR2024-00384, taken October 24, 2024

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2155	Declaration of Charles H. Sanders in Response to Petitioner's Objections to Patent Owner's Evidence [<i>served, not filed</i>]
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2158	INITIAL DETERMINATION ON VIOLATION OF SECTION 337 AND RECOMMENDED DETERMINATION ON REMEDY AND BOND, Administrative Law Judge MaryJoan McNamara (December 19, 2024) [Woloszko Dep. Ex. 1]
2159	NOTICE OF COMMISSION DETERMINATION TO REVIEW IN PART A FINAL INITIAL DETERMINATION FINDING A VIOLATION OF SECTION 337; REQUEST FOR WRITTEN SUBMISSIONS ON THE ISSUES UNDER REVIEW AND ON REMEDY, THE PUBLIC INTEREST, AND BONDING [Woloszko Dep. Ex. 2]

I. Introduction

Petitioner's reply confirms that Petitioner fails to show that the challenged claims are unpatentable. 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.

Petitioner fails to justify modifying Mehta in view of Lee to address Mehta's deficiencies. Further, Petitioner's combinations of Mehta (Ex.1004) with Na '848 (Ex.1005) and Livneh (Ex.1012), respectively, fail to meet the requirements of the challenged dependent claims.

For the reasons set forth below, and consistent with the ALJ's decision, the challenged claims should be found patentable over Petitioner's grounds.

II. Claim Construction

"Desired distance" refers to 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 extendable needles. POR 15. That is the only construction that aligns with and is supported by the intrinsic and extrinsic evidence. Contrary to Petitioner's contentions, Patent Owner's proposal has remained consistent. Indeed, before this IPR, both sides' experts agreed on this plain and ordinary meaning. As the ALJ noted in her final initial determination in the ITC: "***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, 204.²

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

First, Patent Owner's proposal applies across the related patents, including the claims of U.S. Patent 9,775,774 ("774 Patent") directed to "extending" and "extendable" needles. Ex.1031, 88:20-95:2; Ex.1020, cls. 5-6, 15.

² All emphasis added unless otherwise noted.

Second, Petitioner's argument that the claims do not specify who selects the desired distance (Reply 4-5), ignores that claims are 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 provided based on **user selection** of various parameters. Ex.1001, 13:16-14:4; Fig. 12. The ALJ agreed. Ex.2158, 203. In fact, Petitioner's expert also previously agreed, twice, that the specification supported user selection of the desired distance. Ex.1003, ¶59; Ex.2125, 1151:8-12; Ex.2158, 203.

Third, Petitioner's reliance on infringement opinions presented before the parties' crystallizing of the meaning of "desired distance" at the ITC is misplaced and does not support its position. Because "desired distance" was not proposed for construction at the ITC (Ex.1037; Ex.1031, 256:12-257:7), Mr. Crosby did not analyze the Rohrer device under the construction the ALJ ultimately applied, which is consistent with the meaning Patent Owner proposes here. Ex.1031, 259:4-7; Ex.2158, 203 ("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"). And regardless, the mechanical dial in the Rohrer device used to adjust how far the needles extend is different from Mehta, where there is no user selection whatsoever of how far the needles extend. As the ALJ explained, "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’s argument that user selection somehow relies on the user’s mental state is also misplaced. The ’536 Patent explains that user-selected distance is a parameter implemented in the CPU to control the motor. Ex.1001, 13:16-17, 13:33-36; 13:51-57, 13:65-14:4; Fig. 12. By contrast, Petitioner’s proposed construction, which defines “desired distance” as not being an “undesired distance,” requires assessing what the user “desired,” i.e., the user’s mental state. Reply 1, 8-9.

Lastly, Petitioner’s reliance on Mehta’s manual post-insertion adjustment of a cartridge ignores that the claims require a motor to extend the needles the claimed desired distance. Ex.1001, cls. 1 and 11.

III. Ground I: Mehta Does Not Anticipate Claims 1-3, 6, 8, 11-13, 16, And 18

Mehta does not disclose a motor that causes extendable needles to extend a desired distance. As Patent Owner’s expert explained, the ’536 Patent and Mehta are “vastly different.” Ex.2147 ¶112. In the ’536 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 needles' location (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 considering the same arguments Petitioner raises here agreed with Patent Owner highlights the deficiencies in Petitioner's positions. Whether Mehta invalidates the claims of the '536 Patent was fully litigated before the ITC, and the ALJ unequivocally found that "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, including Mehta's virtual depth/location depiction (*compare* Ex.2158, 207 *with* Reply 12-14), step-motor (*compare* Ex.2158, 207-08 *with* Reply 16-20), "[o]ver-inserting and then partially retracting" the electrodes (*compare* Ex.2158, 208-09 *with* Reply 18), and using different cartridges with different probe configurations (*compare* Ex.2158, 209 *with* Reply 17-18). 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 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.1040, ¶¶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 at 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 of the '812 Patent which recite the same “desired distance” limitation over Mehta '705. Ex.2147 ¶¶89-90, 103; Ex.2118, 577-582, 645-651.

A. Mehta does not disclose the claimed “desired distance”

Petitioner reads extending the plurality of the extendable needles a “desired distance” out of the claims. Mehta simply does not disclose or suggest user selection of the distance the needles extend, or programming to cause a motor/mechanism to extend the needles that selected distance. Ex.2158, 205-207; Ex.2147 ¶¶101, 111. 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 is insufficient to show that Mehta discloses the claimed “desired distance.” Reply 12-20. As Petitioner admits, the virtual depth/location depiction of Mehta simply shows the actual versus desired location of the probes (*id.*, 12-13), and 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 ¶106; Ex.2158, 206.

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. The user being 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 ¶108. 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.*, ¶105; Ex.2158, 206-7 ("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 (emphasis added). But that is 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 "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; they require programming a motor based on user

selection to extend the needles a desired distance. 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).

Petitioner's reliance on Mehta's over-inserting and partially retracting the electrodes fares no better. Reply 17-18. 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 ¶111; POR 29-30. Mehta is designed to extend needles a fixed distance (Ex.2147 ¶102) 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.* ¶112. As the ALJ recognized, "simply advancing and retracting the needles is not enough to disclose the claimed limitation." Ex.2158, 208.

Finally, regarding the Pixel8, Patent Owner has not contended it practices the claims at issue under the 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 as noted above.

IV. Ground II: Mehta In View Of The Knowledge Of A POSITA Does Not Render Obvious Claims 1-8 And 11-18**A. A POSITA would not be motivated to modify Mehta to arrive at the claimed desired distance**

Petitioner's reply fails to address Patent Owner's arguments rebutting an alleged motivation to modify Mehta as Petitioner proposes. Petitioner's obviousness challenge in Ground II assumes that Mehta does not disclose "caus[ing] a plurality of the extendable needles to extend a desired distance from the needle assembly end surface" and contends that it would have been obvious to modify Mehta in view of the knowledge of a POSITA to meet this limitation. Pet. 45. But nowhere does Petitioner meet its burden of showing why a POSITA would have been motivated to make those changes.

Patent Owner does not dispute that Mehta is concerned with "deliver[ing] energy to a predetermined target area while minimizing delivery of energy to undesired region of tissue." Ex.1004, 2:9-12. To do so, Mehta discloses different means to ensure that the needles are in the correct location before delivering energy, e.g., "virtual depth/location depiction" showing the actual location of the probes (Ex.1004, 32:63-33:43), measuring tissue parameters to confirm probe location (*id.*, 24:37-39), and "depth markings ... to observe proper placement" and "determine the depth of insertion of the probe." *Id.*, 13:37-45. These means all serve Mehta's goal of minimizing energy to an unintended location. Even petitioner's expert agrees that

“the goal is to deliver it in the desired location and therefore reduce the -- and reduce the chance of delivered energy in an undesired location, ... we don't disagree on that.” Ex.2154, 58:7-11.

Modifying Mehta to add depth control would not serve Mehta's goals. Ex.2147 ¶¶116-117. Mehta seeks to avoid, rather than promote insertion depth variability, and instead relies on post-needle assertion adjustment using Mehta's GUI/virtual depiction system, tissue parameter measurements, or probe marking to confirm that the already inserted needles are in the intended location prior to delivering energy. *Id.*; Ex.1004, 10:49-52, 16:36-37. Rather than trying to achieve insertion at a precise depth through pre-insertion depth control, Mehta teaches inserting the needles as consistently as possible and then using post-insertion observation and adjustment to ensure the desired depth has been reached. Ex.2147 ¶¶116-117. The modifications Petitioner proposes would add an additional step to the treatment (setting depth control before needle insertion), as well as variability, complexity, and cost to the system and would not address Mehta's goal. *Id.* Petitioner responds that “the desired target layer of tissue can **vary** depending on the desired result,” but this is a disclosure that the target can vary—not that introducing variation in insertion depth before insertion is desirable. Reply 21 (quoting Ex.1004, 33:30-34).

Thus, adding depth control would conflict with the motivations Petitioner relies on—“streamlin[ed] treatment, improv[ing] the patient’s experience, and decreas[ing] treatment costs.” Reply 21. As the ALJ found evaluating the same Mehta reference and consistent opinions from Petitioner’s expert, “[t]he mechanisms in Mehta and the [’536 Patent] for reaching a target tissue are, as Mr. Crosby described, ‘apples and oranges’” and a POSITA “would not been motivated to modify Mehta to arrive at the ‘desired distance’ limitation.” Ex.2158, 212; Ex.2157 (Woloszko Dep. Tr.), 58:16-10;102:19-103:9

B. Mehta in view of the knowledge of a POSITA does NOT render obvious claims 4-5 or 14-15

Petitioner’s obviousness arguments fail for two main reasons. *First*, Mehta discloses mechanisms for the physician to confirm the intended treatment area such that modifying Mehta to include an embedded LED to illuminate a deployable needle assembly, as Petitioner proposes, would be unnecessary; thus, a POSITA would not be motivated to make those modifications. *Stryker Corp. v. Karl Storz Endoscopy Am., Inc.*, IPR2015-00764, Paper 13 at 13 (P.T.A.B. Sept. 2, 2015). *Second*, as detailed below, the modifications Petitioner proposes ignore Mehta’s teachings and still fail to meet the claim limitations. Although Petitioner groups claims 4-5 and 14-15 in its Reply, it is important to evaluate claims 4 and 14 separately from claims 5 and 15 because each pair of claims includes different limitations, which Petitioner glosses over.

1. Nothing in Mehta discloses the limitations of claims 4 and 14

Claims 4 and 14 require an “embedded LED” in “the proximal end” that “illuminat[es] the deployable needle assembly when energized.” Ex.1001, cls. 4, 14.

Petitioner relies on Mehta at 13:16-20 to argue that a POSITA would be motivated to illuminate the needle assembly. Reply 22. But that passage explains that “the stabilization plate 214 includes a feature 216 such as (a window or an opening) that permits a physician to directly observe insertion of the probe array 108 through the stabilization plate 214.” Ex.1004 at 13:16-20; *see also id.*, 4:19-23. In other words, the physician looking down through window 216 of the stabilization plate 214 would see the probe array 108 inserted beneath. *Id.* Thus, as Petitioner’s expert admits, an LED would be near window 216 to illuminate the area beneath it, where probe array 108 is inserted. Ex.2148 (Woloszko ITC Depo Tr.), 416:11-19. That would not meet the claim limitation because the LED would neither be “embedded” nor “illuminat[e] the deployable needle assembly when energized.” Ex.1001, cls. 4, 14. Instead, the LED would be to the left of, and outside, the handpiece, which Petitioner admits is “*opaque*” and thus “*conceal[s] internal components*,” such as the needle assembly. Reply 22-23; Pet. 24 (identifying 102 as the needle assembly).

Petitioner nowhere explains what would motivate a POSITA to modify Mehta to include an embedded LED to illuminate the needle assembly, as the claims require.

In fact, the opposite is true. Petitioner argues—citing no supporting evidence—that the LED would be “embedded ... interior to the device body.” but then it would not illuminate where the probe assembly 108 is inserted beneath window 216 due to the undisputedly “opaque” housing of the handpiece. Reply 22-24. Petitioner argues for implementing a “transparent or translucent opening” in “cartridge 100,” but light from an LED somewhere “interior” the undisputedly “opaque” handpiece cannot illuminate the area below window 216 where the probe array 108 is inserted. *See, e.g., Ex.1004, Figs. 2B-2C.* Petitioner’s proposed modification serves no purpose, is a hindsight attempt to reconstruct the claimed invention, and is an improper new argument to the extent raised against claims 4 and 14 because Petitioner made no such argument against those claims in its Petition. Pet. 51-54; *Univ. of Strathclyde v. Clear-Vu Lighting LLC*, 17 F.4th 155, 165 (Fed. Cir. 2021).

Petitioner also misconstrues Mr. Crosby’s testimony and cites inapplicable case law to argue the location of the LED is not inventive. Reply 24. Mr. Crosby testified that placing an LED on the handpiece “with a hole” versus “located on a motherboard” was not inventive. Ex.2126, 1547:8-25. That has nothing to do with Petitioner’s proposed modification. In *Nano-Second Technology Co. v. Dynaflex Int’l*, 944 F. Supp. 2d 855, 864 (C.D. Cal. 2013), which Petitioner cites, both the prior art and the patent at issue disclosed LEDs and the parties did not identify how the location of the LED in the prior art led to a different result from the patent. Here,

Mehta does not disclose an LED, and the location of the LED is important because it affects what the LED will illuminate and whether the LED will serve a useful purpose.

Thus, Petitioner has failed to show that claims 4 and 14 would have been obvious in view of Mehta and the knowledge of a POSITA.

2. Nothing in Mehta discloses the translucent section limitations of claims 5 and 15

Claims 5 and 15, which depend on claims 4 and 14 respectively, require that the needle assembly include a translucent section to communicate illumination from the embedded LED to the needles. Ex.1001, cls. 5 and 15. Again, Mehta nowhere discloses these limitations, and a POSITA would not be motivated to modify Mehta to include them. To begin with, nowhere does Mehta describe the electrode assembly 102 or any portion of the removable cartridge 100 as transparent or translucent. Petitioner admits as much. Pet. 55 (citing Ex.1004, 22:65-23:10 (referring to Mehta's cooling surface, which is *not* part of the needle assembly)). In its reply, Petitioner relies on its new argument that the LED would be located on the inside of the device body and that "only the **bottom-facing** portion of cartridge 100 ... would have a transparent or translucent opening to allow light to pass." Reply 22; Ex.1040 ¶18. But even if an LED were placed inside the device body and the bottom-facing portion of cartridge were transparent or translucent, as discussed above the light from such an LED would not be communicated to illuminate the needles because

the undisputedly “opaque” housing would block such light from reaching the probe array 108, which is on the opposite side of the handpiece. Reply 22-23. During his deposition, Petitioner's expert attempted to provide yet another modification to Mehta, which is to make Mehta's window 216 part of the cartridge, not the device body as described. Ex.2157, 94:14-96:5. But other than conclusorily saying it would be obvious, neither Petitioner nor its expert provide any support or basis for such a modification. *Id.*

Further, as discussed above, because Mehta already discloses mechanisms to confirm the treatment area (e.g., a window to see the entry point of the needles and using dyes and lumens to mark the treatment cite), Petitioner's obviousness argument is pure hindsight reconstruction. *Univ. of Strathclyde*, 17 F.4th at 165.

V. Grounds III: The Combination Of Metha And Na '848 Would Not Lead To The Limitations Of Claims 4-5 Or 14-15

Petitioner concedes that it does *not* rely on Na '848 for “the location” of embedded LEDs and, as discussed above, Petitioner's arguments for embedding an LED within the handpiece's opaque housing would not meet the claim requirements. That is dispositive.

Petitioner argues that Patent Owner ignores Mehta's configuration when the device be held “at a more vertical angle like a pencil or pointer.” Reply 25 (citing Ex.1004, 9:53-59). Not so. Petitioner argued “to modify Mehta to provide the needle assembly 102 in the form of Na '848's plate.” Pet. 61. Petitioner does not propose

modifying Na '848's plate to be a *releasably couplable deployable needle assembly*, as the claims require, let alone contend that it would have been obvious to do so. Na '848 does not disclose that the plate can be mechanically separable from the handle or includes needles that extend from an end surface. Ex.2147 ¶132. Petitioner's expert agrees. Ex.1003 ¶44; Ex.2148, 439:19-440:7; Ex.2125, 065 (1046:23-1047:2); Ex.2154, 138:13-21. Thus, Petitioner's proposed combination fails to meet the claim requirements, no matter where any LED is located. Furthermore, in Na '848, the LEDs are on the plate (Ex.1005 ¶34), which is *not* part of the handpiece, and Petitioner does not justify moving Na '848's LEDs to some other location. Ex.2147 ¶132; Ex.2158, 267 (in the context of related '812 Patent which includes similar limitations, the ALJ finding that "Na '848 does not disclose an LED in a handpiece (proximal end) or a needle assembly, which further removes a motivation to modify Mehta to include such features.")

In addition, Petitioner fails to justify using Na '848's plate in Mehta's device. Petitioner merely states that it "would have been a matter of routine engineering" to "[p]rovid[e] Mehta's needle assembly 102 in the form of a plate ..., as disclosed by Na '848" (Pet. 61), but this "conclusory" assertion fails to "address why or whether a skilled artisan would have been motivated to combine" the references." *Virtek Vision Int'l ULC v. Assembly Guidance Sys., Inc.*, 97 F.4th 882, 889 (Fed. Cir. 2024) (affirming the Board's non-obviousness determination). Petitioner offers no further

explanation of why or whether a POSITA would have been motivated to combine Mehta and Na '848, as Petitioner proposes, in its Reply. Instead, Petitioner merely asserts that both involve delivery of electrical and mechanical energy. Reply 26.

VI. Ground IV: Mehta In View Of Livneh Does Not Render Obvious Claims 7 And 17

Petitioner's proposed Ground IV contradicts Mehta's teachings. Petitioner conclusorily contends that a POSITA "would have been motivated to provide electrical contacts to first and second needle groups, instead of individual needles." Reply 26. Petitioner points to the individual electrical contacts 116 of Mehta and argues that a POSITA would replace them with the coils in Livneh, which contact a group of needles rather than individual needles. *Id.* But doing so would eliminate functionality that Mehta discloses is advantageous.

Mehta explains that "the electrode assembly 102 can have multiple connection portions 116, 117 per individual electrode" to "increase the number of configurations possible with the electrode assembly." Ex.1004, 16:65-17-3. Mehta also explains that "the ability *to control each electrode* pair on a separate channel from the power supply *provides additional benefits* based on the impedance or other characteristic of the tissue being treated." *Id.*, 18:5-8. For example, such a configuration allows for monitoring of the treatment site via a thermocouple, selectively firing electrode pairs to "minimize the chance that a significant amount of current flows between the separate electrode pairs," and more. *Id.*, 18:8-18; *see also id.*, 17:3-12. Monitoring

the treatment site in Mehta is a fundamental feature of its operation as Mehta relies on temperature, impedance, and other tissue measurements to deliver the proper amount of energy. Ex.1004, Fig. 9E; 3:57-67; 5:58-6:2; 19:45-53; 20:35-45.

Because Petitioner's proposed Mehta-Livneh combination conflicts with Mehta's teachings, Petitioner's obviousness argument fails. *See generally, Plas-Pak Indus., Inc. V. Sulzer Mixpac AG*, No. 2014-1447 (Fed. Cir. Jan. 27, 2015) (affirming the Board's holding that claims were not obvious because the combination proposed would alter the principle of operation of one of the references) (non-precedential) (citing *In re Ratti*, 270 F.2d 810, 813 (C.C.P.A. 1959)). The only support for an alleged Livneh-Mehta motivation that Petitioner and its expert propose is an alleged reduction in the complexity and cost of the system. Reply 26 (citing Ex.1003, ¶¶204-206). But even if the combination resulted in fewer wire connections, neither Petitioner nor its expert provide any evidence that such minimal cost reduction would be significant or motivate a POSITA to abandon the "additional benefits" of multiple electrical connections that Mehta describes. Ex.1004, 18:5-8. Thus, a POSITA would not be motivated to combine the references.

VII. Ground V: Petitioners Failed To Demonstrate That Mehta In View Of Lee Renders Obvious Claims 1-3, 6, 8, 11-13, 16, And 18

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 delivering 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, confirming they 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 . Ex.2147 ¶119, 141. Mehta was aware of distance control and chose a different approach. POR 32-33. 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 ¶141. These differences in Mehta and Lee "are central to [the] motivation to combine inquiry." *Adidas AG v. Nike, Inc.*, 963 F.3d 1359 (Fed. Cir. 2017). 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. 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. 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, 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 its position, admitting that Petitioner “does not cite Lee for its treatment times, only Lee’s needle depth-control (Petition 70).” Reply 29; *Eli Lilly & Co. v. Actavis Elizabeth LLC*, 435 F. App’x 917, 921 (Fed. Cir. 2011).

VIII. Grounds VI, VII, And VIII: Petitioner’s Grounds Fail

For the reasons above, a POSITA would not have been motivated to combine Mehta with Lee, Na ’848, or Livneh, as well as with and his/her knowledge to arrive at the claims as Petitioner argues. *See supra* Sections VI, IX, VII, VIII.

IX. Strong Evidence Of Objective Indicia Rebutts Petitioner's Obviousness Challenges

Petitioner's attorney argument fails to overcome the ample record evidence supporting non-obviousness. All 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 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 '536 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 Pharmaceuticals 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 inapplicable 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 un rebutted 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) (quoting *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 '536 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.

X. Conclusion

For the reasons set forth above, the Board should confirm patentability of the challenged claims.

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 5,520 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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