

Filed on behalf of: Serendia, LLC

Entered: May 22, 2024

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

JEISYS MEDICAL INC.,
Petitioner,

v.

SERENDIA, LLC,
Patent Owner.

Case IPR2024-00463
Patent 10,869,812

**PATENT OWNER'S
PRELIMINARY RESPONSE**

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	THE BOARD SHOULD EXERCISE ITS DISCRETION UNDER 35 U.S.C. § 314(A) AND DENY INSTITUTION BASED ON <i>GENERAL PLASTIC</i>	3
A.	Background The First IPR Petition Denial	3
B.	Petitioner Fully Litigated the Issues Here In The ITC	4
C.	Legal Standard.....	6
D.	The <i>General Plastic</i> Factors Favor of Denying Institution.....	7
1.	Factor 1	7
2.	Factor 2	10
3.	Factor 3	13
4.	Factor 4	18
5.	Factor 5	19
6.	Factors 6 and 7	21
7.	Factor 8	23
III.	THE BOARD SHOULD DENY INSTITUTION UNDER 35 U.S.C. § 325(D).....	24
A.	The Same or Substantially the Same Art Was Before Office	25
1.	Mehta.....	25
2.	Na '848.....	26
3.	Lee.....	26
4.	Livneh	27
B.	Petitioner Fails to Show the Office Materially Erred as to the Patentability of the Challenged Claims.....	28

IV.	PETITIONER FAILS TO SHOW A REASONABLE LIKELIHOOD OF PREVAILING AS TO ANY OF THE CHALLENGED CLAIMS.....	29
A.	Background	29
1.	The '812 Patent (Ex. 1001).....	29
2.	Priority and Prosecution History.....	33
3.	Person of Ordinary Skill in the Art.....	33
B.	Claim Construction.....	33
1.	Motor ... “to cause the plurality of needles to extend a desired distance from the releasably couplable deployable needle module end surface” / “to extend the plurality of needles a desired distance from the releasably couplable deployable needle assembly end surface”	34
C.	Relevant Summary of the Prior Art	38
1.	Mehta.....	38
2.	Lee.....	43
3.	Livneh	44
D.	Ground I: Petitioner fails to demonstrate that Mehta anticipates claims 2-5, 8, and 13-16	45
E.	Ground II: Petitioner fails to demonstrate that Mehta in view of the knowledge of a POSITA renders obvious claims 2-6, 8 and 13-16.....	50
F.	Ground III: Petitioner fails to demonstrate that Mehta in view of Na '848 and the knowledge of a POSITA renders obvious claims 4-5	53
G.	Ground IV: Petitioner fails to demonstrate that Mehta in view of Lee renders obvious claims 2-3, 6, 8, or 13-16	54
H.	Ground V: Petitioner fails to demonstrate that Mehta, Lee, Na '848 and the knowledge of a POSITA render obvious claims 4-5.....	57

I.	Ground VI: Petitioner fails to demonstrate that Mehta, Livneh and the knowledge of a POSITA render obvious claims 9 and 18.....	58
J.	Objective Indicia Of Nonobviousness Supports That Grounds II-VI Fail To Raise A Substantial Question Of Patentability	62
1.	The '812 Patent has achieved commercial success	64
2.	The '812 Patent has obtained industry praise	65
V.	CONCLUSION.....	66

TABLE OF AUTHORITIES**Page(s)****CASES**

<i>Abiomed, Inc. v. Maquet Cardiovascular, LLC</i> , IPR2017-02134, Paper 7 (P.T.A.B. Apr. 16, 2018)	19
<i>Adidas AG v. Nike, Inc.</i> , 963 F.3d 1355 (Fed. Cir. 2020), <i>cert. denied</i> , 141 S. Ct. 1376 (2021).....	54, 55
<i>Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH</i> , IPR2019-01469, Paper 6 (P.T.A.B. Feb. 13, 2020).....	24, 25
<i>Alloc, Inc. v. Int'l Trade Comm'n</i> , 342 F.3d 1361 (Fed. Cir. 2003)	37
<i>Am. Honda Motor Co. v. Intell. Ventures II, LLC</i> , IPR2018-00348, Paper 10 (P.T.A.B. June 27, 2018)	11, 12, 14
<i>Apple Inc. v. Corephotonics Ltd.</i> , IPR2018-01356, 2019 WL 462483 (P.T.A.B. Feb. 5, 2019)	20
<i>Cartessa Aesthetics, LLC (Cartessa) v. Serendia, LLC</i> , IPR2022-00376, Paper 9 (P.T.A.B. June 27, 2022)	4
<i>Cartessa v. Serendia, LLC</i> , IPR2022-00377, Paper 1 (P.T.A.B. Dec. 28, 2021)	4, 8, 15
<i>Cartessa v. Serendia, LLC</i> , IPR2022-00377, Paper 8 (P.T.A.B. Apr. 18, 2022)	4, 15
<i>Cartessa v. Serendia, LLC</i> , IPR2022-00377, Paper 9 (P.T.A.B. June 28, 2022)	4, 15
<i>Cartessa v. Serendia, LLC</i> , IPR2022-00378, Paper 9 (P.T.A.B. June 30, 2022)	4

<i>Cartessa v. Serendia, LLC</i> , IPR2022-00594, Paper 1 (P.T.A.B. Feb. 10, 2022).....	4
<i>Cartessa v. Serendia, LLC</i> , IPR2022-00594, Paper 9 (P.T.A.B. Aug. 12, 2022).....	4
<i>Coal. for Affordable Drugs V LLC v. Hoffman-LaRoche, Inc.</i> , IPR2015-01792, Paper 14 (P.T.A.B. Mar. 11, 2016).....	63
<i>Cuozzo Speed Techs., LLC v. Lee</i> , 579 U.S. 261 (2016).....	50
<i>Dropworks Inc. v. Bio Rad Laboratories Inc.</i> , IPR2021-00212, Paper 7 (P.T.A.B. June 1, 2021)	51, 54, 56
<i>Ford Motor Co. v. Neo Wireless LLC</i> , IPR2023-00763, Paper 28 (P.T.A.B. Mar. 22, 2024)	8, 10
<i>Gambro Lundia AB v. Baxter Healthcare Corp.</i> , 110 F.3d 1573 (Fed. Cir. 1997)	66
<i>Gen. Plastic Indus. Co. v. Canon Kabushiki Kaisha</i> , IPR2016-01357, Paper 19 (P.T.A.B. Sept. 6, 2017).....	<i>passim</i>
<i>Guangdong Boltpower Energy Co. v. Noco Co.</i> , IPR2021-00309, Paper 11 (P.T.A.B. May 10, 2021)	18, 19
<i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C. Mar. 1, 2023)	4
<i>Inline Plastics Corp. v. Lacerta Grp., LLC</i> , 97 F.4th 889 (Fed. Cir. 2024)	64
<i>Intel Corp. v. Inst. of Microelectronics Chinese Acad. of Scis.</i> , IPR2019-00834, Paper 14 (P.T.A.B. June 19, 2020)	19
<i>InTouch Techs., Inc. v. VGO Commc'ns, Inc.</i> , 751 F.3d 1327 (Fed. Cir. 2014)	63, 64
<i>KSR Int'l Co. v. Teleflex Inc.</i> , 550 U.S. 398 (2007).....	62

<i>Longi Green Energy Tech. Co. v. Hanwha Sols. Corp.</i> , IPR2020-00047, Paper 18 (P.T.A.B. Apr. 27, 2020)	11
<i>Merial Ltd. v. Virbac</i> , IPR2014-01279, Paper 13 (P.T.A.B. Jan. 22, 2015)	63
<i>Mitek Sys., Inc. v. United Servs. Auto. Ass'n</i> , IPR2020-00882, Paper 29 (P.T.A.B. Nov. 6, 2020).....	8, 14, 18, 19
<i>Nautilus Hyosung, Inc. v. Diebold, Inc.</i> , IPR2017-00426, Paper 17 (P.T.A.B. June 22, 2017)	14
<i>Nike, Inc. v. Adidas AG</i> , 812 F.3d 1326 (Fed. Cir. 2016), <i>aff'd</i> , No. 2021-1903, 2022 WL 4002668 (Fed. Cir. Sept. 1, 2022).....	62
<i>NVIDIA Corp. v. Samsung Elecs. Co.</i> , IPR2016-00134, Paper 9 (P.T.A.B. May 4, 2016)	7
<i>Omron Oilfield & Marine Inc. v. MD/TOTCO</i> , IPR2013-00265, Paper 11 (P.T.A.B. Oct. 31, 2013).....	63
<i>Phillips v. AWH Corp.</i> , 415 F.3d 1303 (Fed. Cir. 2005) (en banc)	35, 37
<i>Samsung Elecs. Co. v. Elm 3DS Innovations, LLC</i> , IPR2017-01305, Paper 11 (P.T.A.B. Oct. 17, 2017).....	14, 16, 18
<i>Samsung Elecs. Co. v. Netlist, Inc.</i> , IPR2022-00063, 2023 WL 5065223 (P.T.A.B. May 3, 2023)	53, 57, 61
<i>Semiconductor Component Indus., LLC v. Power Integrations, Inc.</i> , IPR2016-01588, Paper 15 (P.T.A.B. Feb. 17, 2017).....	62
<i>Shanghai Lunion Info. Techs., Ltd. v. Telefonaktiebolaget LM Ericsson</i> , IPR2018-00995, Paper 12 (P.T.A.B. Nov. 13, 2018).....	<i>passim</i>
<i>Shenzhen Silver Star Intelligent Tech. Co. v. iRobot Corp.</i> , IPR2018-00761, Paper 15 (P.T.A.B. Sept. 5, 2018).....	<i>passim</i>
<i>Shenzhen Silver Star Intelligent Tech. Co. v. iRobot Corp.</i> , IPR2018-00897, Paper 9 (P.T.A.B. Oct. 1, 2018).....	23, 24

<i>SynKloud Techs., LLC v. Sung Hwan E&B Co., Ltd. (SHEnB),</i> No. 6:21-cv-00811 (W.D. Tex. Aug. 6, 2021)	3
<i>SynKloud Techs., LLC v. Aesthetics Biomedical, Inc. (ABM),</i> No. 2:22-cv-00015 (D. Ariz. Jan. 4, 2022)	3
<i>SynKloud Techs., LLC v. Cartessa,</i> No. 2:21-cv-04423 (E.D.N.Y. Aug. 6, 2021)	3
<i>Trintec Indus., Inc. v. Top-U.S.A. Corp.,</i> 295 F.3d 1292 (Fed. Cir. 2002)	49
<i>Valve Corp. v. Elec. Scripting Prods., Inc.,</i> IPR2019-00062, Paper 11 (P.T.A.B. Apr. 2, 2019)	7, 9, 11, 21
<i>Valve Corp. v. Elec. Scripting Prods., Inc.,</i> IPR2019-00064, Paper 10 (P.T.A.B. May 1, 2019)	18, 19
<i>Videndum Prod. Sols., Inc. v. Rolight Ltd.,</i> IPR2023-01220, 2024 WL 266434 (P.T.A.B. Jan. 24, 2024)	20
<i>Vitronics Corp. v. Conceptronic, Inc.,</i> 90 F.3d 1576 (Fed. Cir. 1996)	35
<i>Vivint, Inc. v. Alarm.com Inc.,</i> 754 F. App'x 999 (Fed. Cir. 2018), <i>aff'd</i> , 856 F. App'x 300 (Fed. Cir. 2021)	53, 57, 61
<i>W. Digit. Corp. v. SPEX Techs., Inc.,</i> IPR2018-00082, 2018 WL 1990246 (P.T.A.B. Apr. 25, 2018)	22
<i>WBIP, LLC v. Kohler Co.,</i> 829 F.3d 1317 (Fed. Cir. 2016)	65, 66

STATUTES

35 U.S.C. § 314(a)	6
--------------------------	---

REGULATIONS

37 C.F.R.

§ 42.4(a)	6
§ 42.22(a)(2)	50
§ 42.104(b)(4)-(5)	50

OTHER AUTHORITIES

Manual of Patent Examining Procedure (MPEP) (9th ed. July 2022)

§ 2163.07(b)	26
--------------------	----

Exhibit List

Exhibit	Description
2001	[Proposed] Stipulated Protective Order
2002	Markup Comparison Showing Differences Between the [Proposed] Stipulated Protective Order and the Default Protective Order
2003	Complainant's July 24, 2023 Supplemental Validity Contentions, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C. July 24, 2023) (PROTECTIVE ORDER MATERIAL AND REDACTED VERSIONS)
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)

Exhibit	Description
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)
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)
2020	RESERVED
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	RESERVED
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)
2025–2036	RESERVED

Exhibit	Description
2037	Brochure: Sylfirm X Dual Wave RF Microneedling System (2022)
2038–2040	RESERVED
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)
2053	Respondents' Notice of Prior Art, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C. May 24, 2023) ("1356 Investigation NOPA")
2054	Complainant's Initial Validity Contentions, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C. June 16, 2023) (PROTECTIVE ORDER MATERIAL)
2055–2061	RESERVED
2062	Presentation: Sylfirm X Clinical Training (2021) (PROTECTIVE ORDER MATERIAL)
2063–2065	RESERVED
2066	Martin Braun, <i>Sylfirm X Revolutionises [sic] the Clinical Applications of RF Microneedling</i> , 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")

Exhibit	Description
2068–2069	RESERVED
2070	Curriculum Vitae of Vincent A. Thomas
2071	Profit & Loss, January–December 2021 (Accrual Basis) (July 6, 2023, 2:31 PM) (PROTECTIVE ORDER MATERIAL)
2072–2082	RESERVED
2083	ViOL, Sylfirm X User Manual (VO-UM-SFX-03), revised April 20, 2022
2084	Sylfirm X, Device Description (PROTECTIVE ORDER MATERIAL)
2085	RESERVED
2086	Sylfirm X Product Photographs
2087–2096	RESERVED
2097	Sylfirm X Introduction Video 1
2098	Transcript of Exhibit 2097 - Sylfirm X Introduction Video 1
2099–2102	RESERVED
2103	Deposition transcript of Peter Crosby, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C.), taken September 4, 2023 (excerpt)
2104	Deposition transcript of Peter Crosby, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C.), taken September 5, 2023 (excerpt)
2105–2107	RESERVED
2108	U.S. Patent Application Publication No. 2002/0120260 A1 (“Morris”)
2109	RESERVED

Exhibit	Description
2110	Certified English translation of Korean Registered Patent Publication No. KR 10-0852500, dated August 18, 2008 (“Lee ’500”)
2111	Respondents’ Amended Notice of Prior Art, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C. June 2, 2023)
2112	Rebuttal Expert Report of Peter Crosby, dated August 28, 2023 (PROTECTIVE ORDER MATERIAL)
2113	RESERVED
2114	File History for U.S. Patent No. 9,320,536
2115	U.S. Patent No. 6,890,319 B1 (“Crocker”)
2116–2118	RESERVED
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, Innovations in RF Microneedling: A Closer Look at VirtueRF, 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.”)

Exhibit	Description
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
2128	Deposition transcript of Jongju Na, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C.), taken July 25, 2023 (excerpts)
2129	RESERVED
2130	Sylfirm X Product Photographs
2131	RESERVED
2132	U.S. Patent Application Publication No. 2006/0036210 A1 (“Zhang”)
2133–2135	RESERVED
2136	Curriculum Vitae of Peter A. Crosby
2137–2138	RESERVED
2139	Appendix 7 – Summary Invalidity Claim Chart, U.S. Patent No. 10,869,812, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C.)
2140	Declaration of Peter Crosby, dated May 16, 2024 (“Crosby Decl.”) (PROTECTIVE ORDER MATERIAL AND REDACTED VERSIONS)
2141	Declaration of Vincent A. Thomas, dated May 20, 2024 (“Thomas Decl.”) (PROTECTIVE ORDER MATERIAL AND REDACTED VERSIONS)
2142	U.S. Patent Application Publication No. 2004/0058882 A1 (“Eriksson”)

Exhibit	Description
2143	U.S. Patent Application Publication No. 2008/0091182 A1 (“Mehta 182”)
2144	Disclaimer in a Patent Under 37 C.F.R. § 1.321(a) of U.S. Patent 10,869,812 (’812 Patent), including electronic payment receipt (“Disclaimer”)

I. INTRODUCTION

Petitioner Jeisys Medical Inc.'s ("Jeisys's") petition for *inter partes* review ("IPR") of U.S. Patent No. 10,869,812 (the "'812 Patent") should be denied for three reasons.

First, the Board should exercise its discretion to deny institution under *General Plastic*. Petitioner was aware of its alleged infringement before the filing of the first IPR petition and was a co-respondent with the prior Petitioners in parallel litigation in the U.S. International Trade Commission ("ITC"). Petitioner not only filed this second IPR petition long after the Board denied institution of the first petition, but also after tactically waiting **more than seven months** after being aware of the prior art presented here so it could learn as much as possible from Patent Owner by fully litigating that prior art at the ITC. Petitioner thus not only used Patent Owner's prior Preliminary Response and the Board's prior Institution Decision as a roadmap, but also delayed filing its petition until having the **full benefit** of seeing **all** the evidence and arguments Patent Owner presented in the ITC. This is the type of gamesmanship the Board's discretionary denial authority exists to prevent. Patent Owner respectfully requests that the Board exercise that authority to deny institution under § 314(a).

Second, substantially the same art as the art Petitioner relies on was before the Office during prosecution, and the Office allowed the claims despite that art. In

particular, Petitioner's primary reference in the second petition, U.S. Patent No. 8,608,737 ("Mehta"), was before the Office as U.S. Patent No. 8,540,705 ("Mehta '705"). The disclosures Petitioner relies on here are nearly identical, yet the Office did not view Mehta as invaliding the '812 Patent claims. And Petitioner fails to argue, much less show, that the Office materially erred in allowing the claims, and as such, discretionary denial is warranted under § 325(d).

Third, even if the Board were to reach the merits, the second IPR petition is at least as deficient as the first. Mehta, Petitioner's primary reference, is directed to an entirely different approach than claimed in the '812 Patent. The '812 Patent claims relate to a dermatological treatment device with a microneedle cartridge, where the needles are deployed a desired distance based on user selection, providing precise control over needle depth insertion to deliver energy to the correct target tissue. In contrast, Mehta's system does not permit the user to select the distance the needles extend. Instead, Mehta discloses a device that requires using different cartridges (with different needle lengths or angles), to reach different target depths. Rather than depth control, Mehta discloses a verification approach to check whether the already extended needles are in the correct tissue before applying energy. If not, the needles are repositioned manually or a different cartridge is selected.

Importantly, despite waiting until after receiving full exposition of Patent Owner's evidence on objective indicia of non-obviousness in the ITC, Petitioner

fails to controvert that evidence here—just as in the ITC. Petitioner's hindsight obviousness arguments disregard the real-world evidence that the claimed inventions were far from obvious to those skilled in the art.

Patent Owner respectfully requests that the Board deny institution.

II. THE BOARD SHOULD EXERCISE ITS DISCRETION UNDER 35 U.S.C. § 314(A) AND DENY INSTITUTION BASED ON *GENERAL PLASTIC*

A. Background The First IPR Petition Denial

On August 6, 2021, Patent Owner sued Sung Hwan E&B Co., Ltd. ("SHEnB") and Cartessa Aesthetics, LLC ("Cartessa") for infringing several patents, including the '812 Patent. *SynKloud Techs., LLC v. SHEnB*, No. 6:21-cv-00811 (W.D. Tex. Aug. 6, 2021), ECF No. 1; *SynKloud Techs., LLC v. Cartessa*, No. 2:21-cv-04423 (E.D.N.Y. Aug. 6, 2021), ECF No. 1. On January 4, 2022, Patent Owner also sued Aesthetics Biomedical Incorporated ("ABM") for infringing the '812 Patent and others. *SynKloud Techs., LLC v. ABM*, No. 2:22-cv-00015 (D. Ariz. Jan. 4, 2022), ECF No. 1. Patent Owner asserted U.S. Patent Nos. 9,320,536 (the "'536 Patent") and 9,480,836 (the "'836 Patent") in those suits, as well as U.S. Patent No. 9,775,774 (the "'774 Patent") in the suit against Cartessa.

On December 28, 2021, Cartessa petitioned for IPR challenging all claims of the '812 Patent, presenting a single invalidity ground based on U.S. Patent Application Publication Nos. 2002/0120260 to Morris, et al. ("Morris") and

2006/0036210 to Zhang, et al. (“Zhang”). *Cartessa v. Serendia, LLC*, IPR2022-00377, Paper 1 (P.T.A.B. Dec. 28, 2021) (“*Cartessa II*”); Ex. 2108 (Morris); Ex. 2132 (Zhang). After Patent Owner filed its Preliminary Response (“POPR”), the Board denied institution. *Cartessa II*, IPR2022-00377, Papers 8, 9.

On February 10, 2022, Cartessa petitioned for IPR challenging all claims of the ’836 Patent, including based on the same Mehta reference Petitioner now relies on. *Cartessa v. Serendia, LLC*, IPR2022-00594, Paper 1 (P.T.A.B. Feb. 10, 2022) (“*Cartessa IV*”). The Board denied IPR as to the ’836 Patent. *Id.*, Paper 9.

Cartessa also petitioned for IPR of the ’774 and ’536 Patents (which are related to the ’812 Patent), and the Board denied institution as to those patents. *Cartessa v. Serendia, LLC*, IPR2022-00376, Paper 9 (P.T.A.B. June 27, 2022) (“*Cartessa I*”); *Cartessa v. Serendia, LLC*, IPR2022-00378, Paper 9 (P.T.A.B. June 30, 2022) (“*Cartessa III*”).

B. Petitioner Fully Litigated the Issues Here In The ITC

About nine months after the Board denied the first IPR petition, Patent Owner filed additional complaints alleging infringement of the ’812 Patent (and others), against multiple parties, including Cynosure, LLC (“Cynosure”) and Cynosure’s Korean supplier, Jeisys, the current Petitioner. *In re Certain Dermatological Treatment Devices & Components Thereof*, No. 337-TA-1356 (U.S.I.T.C. Mar. 1, 2023) (the “1356 Investigation”).

On May 24, 2023, the respondents in the ITC, including the former and current Petitioners, filed a Notice of Prior Art identifying the art raised in this second IPR petition. Ex. 2053 (1356 Investigation NOPA). The Notice of Prior Art also identified a second Lee reference, KR 10-0852500 to Lee (“Lee ’500”), with similar disclosures to the Lee reference at issue here. *Compare* Ex. 2110 (Lee ’500), *with* Ex. 1009 (Lee). On June 2, 2023, the ITC respondents served an Amended Notice of Prior Art, removing the Lee reference on which Petitioners rely on here but keeping Lee ’500. Ex. 2111 (1356 Investigation Amended NOPA).

On June 16, 2023, Patent Owner served its Initial Validity Contentions specifically addressing Petitioner’s allegations that the ’812 Patent claims were invalid in view of Mehta, Na ’848, Livneh, and Lee ’500. Ex. 2054 (Patent Owner’s Initial Validity Contentions). A month later, Patent Owner provided its Supplemental Validity Contentions, once again addressing the respondents’ contentions that the ’812 Patent claims were invalid over Mehta, Na ’848, Livneh, and Lee ’500. *See* Ex. 2003 (Patent Owner’s Supplemental Validity Contentions).

On August 14, 2023, the respondents in the ITC, including the current and former Petitioners, served the Expert Report of Dr. Woloszko in which he opined that certain ’812 Patent claims were invalid, including over Mehta and Na ’848. Ex. 2004 (Woloszko Expert Report). Dr. Woloszko did not present any invalidity opinions in view of Livneh or Lee ’500. Patent Owner then served the Rebuttal

Expert Report of Mr. Crosby explaining why Dr. Woloszko failed to show the '812 Patent claims were invalid. Ex. 2112 (Crosby Rebuttal Expert Report). Both experts were deposed. *See, e.g.*, Exs. 2007, 2008, 2103, 2104 (Woloszko and Crosby Deposition Transcripts).

In November and December 2023, an evidentiary hearing was held at the ITC. The respondents, including the current Petitioner, presented testimony from Dr. Woloszko, again alleging invalidity of the asserted '812 Patent claims in view of Mehta and Na '848. *See* Ex. 2125 (Woloszko Hr'g Tr.). And Patent Owner presented rebuttal testimony from Mr. Crosby. *See* Ex. 2126 (Crosby Hr'g Tr.). All experts were cross-examined. Exs. 2125, 2126.

On January 5, 2024, the parties submitted post-hearing briefing on validity. *See* Ex. 2015 (Patent Owner's Rebuttal Post-Hearing Brief); Ex. 2019 (Respondents' Post-Hearing Brief). Three days later, Petitioner filed the second IPR petition at issue here.

C. Legal Standard

The Director has discretion whether to institute IPR (*see* 35 U.S.C. § 314(a)), and that discretion has been delegated to the Board (*see* 37 C.F.R. § 42.4(a)). In determining whether to exercise discretion to deny institution under § 314(a), the Board considers a set of non-exhaustive factors. *Gen. Plastic Indus. Co. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 at 16-17 (P.T.A.B. Sept. 6, 2017)

(precedential) (citing *NVIDIA Corp. v. Samsung Elecs. Co.*, IPR2016-00134, Paper 9 at 6-7 (P.T.A.B. May 4, 2016)). Not all factors need to weigh against institution for the Board to exercise its discretion to deny institution. *Shenzhen Silver Star Intelligent Tech. Co. v. iRobot Corp.*, IPR2018-00761, Paper 15 at 16 (P.T.A.B. Sept. 5, 2018) (“*Shenzhen I*”). Instead, the central issue is balancing the equities between a petitioner and a patent owner. *Gen. Plastic*, IPR2016-01357, Paper 19 at 15-19. Here, the *General Plastic* factors heavily favor denying institution.

D. The *General Plastic* Factors Favor of Denying Institution

1. Factor 1

The first *General Plastic* factor considers “whether the same petitioner previously filed a petition directed to the same claims of the same patent[.]” IPR2016-01357, Paper 19 at 15-16.¹ This factor “is not limited solely to instances when multiple petitions are filed by the same petitioner[;]” rather, the Board “consider[s] **any** relationship between” the petitioners. *Valve Corp. v. Elec. Scripting Prods., Inc.*, IPR2019-00062, Paper 11 at 2, 9 (P.T.A.B. Apr. 2, 2019) (precedential) (“*Valve I*”).

¹ All emphases are added and internal quotation marks and citations are omitted unless stated otherwise.

While court-ordered case-management coordination alone does not create a “significant relationship” between petitioners, such coordination paired with “***other relevant or extenuating facts or circumstances***” may evidence a “significant relationship.” *Ford Motor Co. v. Neo Wireless LLC*, IPR2023-00763, Paper 28 at 10-11 (P.T.A.B. Mar. 22, 2024). For example, even where the petitioners were not involved in the same litigation, the Board has considered factors, such as awareness of the infringement allegations, sharing of information, and coordination among petitioners in separate litigations, to find a significant and meaningful relationship between them. *Mitek Sys., Inc. v. United Servs. Auto. Ass’n*, IPR2020-00882, Paper 29 at 17 (P.T.A.B. Nov. 6, 2020) (Factor 1 favored discretionary denial because “there [wa]s sufficient evidence indicating that Mitek was aware of USAA’s infringement allegations at the time Wells Fargo filed its two prior petitions.”).

Here, the current petition challenges the same claims as the prior petition. *Compare Cartessa II*, IPR2022-00377, Paper 1, with Pet. Petitioner Jeisys and prior Petitioner Cartessa were “co-defendants” in parallel proceedings. Ex. 2016 (1356 Investigation Public Complaint). And unlike in *Ford Motor Co. v. Neo Wireless*, the prior and current Petitioners ***jointly*** submitted a proposed schedule in the ITC, which the Administrative Law Judge adopted. Ex. 2017 (Joint Schedule Submission); Ex. 2018 (Schedule). Moreover, the level of coordination between the prior and current Petitioners goes significantly beyond presenting invalidity contentions and a claim

construction statement (as in *Ford Motor Co. v. Neo Wireless*). As co-respondents in the ITC, the current and former Petitioners submitted a joint validity expert report and presented a joint validity defense at the evidentiary hearing through their **shared** expert Dr. Woloszko—the same expert the current Petitioner relies on here. Ex. 2004; Ex. 2125.

Additional relevant and extenuating facts and circumstances exist warranting a finding of “a significant relationship between [the filers of the two petitions] with respect to [the] [p]atent [o]wner’s assertion of the [challenged] patent.” *Valve I*, IPR2019-00062, Paper 11 at 11. Petitioner Jeisys and prior Petitioner Cartessa are part of the same RF microneedling manufacturing and distribution community. Ex. 2021 (Jeisys 1356 Investigation ITC Complaint Response (Public)), ¶3.17. And, as in *Mitek Systems*, Petitioner Jeisys was on notice of its infringement of the ’812 Patent [REDACTED], before the first IPR petition was filed. Ex. 2023 (Notice Letter to Cynosure); [REDACTED]

Further, as discussed below, *supra* Section II.B, since the May 24, 2023 Notice of Prior Art filed in the 1356 Investigation, Petitioner was aware of the references it now relies on. Ex. 2053. Thus, Petitioner Jeisys tactically waited to file the present petition until **more than seven months** after being aware of the asserted prior art and **after** it had fully presented its joint invalidity case, working hand-in-

hand with prior Petitioner Cartessa throughout the ITC proceedings. *See supra* Section II.B. This tactical delay, paired with the significant coordination between the prior and current Petitioners throughout the parallel ITC proceedings, demonstrates “relevant or extenuating facts or circumstances” evidencing a “significant relationship” between the prior and current Petitioners. *Ford*, IPR2023-00763, Paper 28 at 11.

In short, this second Petition is directed to the same claims as the prior petition, and is filed by a Petitioner who: (i) was on notice of its potential infringement before the prior petition's filing; (ii) was aware of litigation filed against other RF microneedling manufacturers and distributors before the prior petition's filing; (iii) was a co-defendant with the prior petitioner in parallel litigation; (iv) worked closely with the prior petitioner to develop joint claim construction positions, invalidity and unenforceability contentions, invalidity expert reports, and testimony on invalidity in the parallel litigation; and (v) tactically delayed in filing this second petition until coordinated efforts with the prior petitioner were complete in the parallel litigation.

2. Factor 2

Under the second *General Plastic* factor, the Board considers “whether at the time of filing of the first petition the petitioner knew of the prior art asserted in the second petition or should have known of it.” *Gen. Plastic*, IPR2016-01357, Paper 19 at 16. This factor includes considering whether the prior art in the later petition

“could have been found with reasonable diligence.” *Id.* at 20; *see also Valve I*, IPR2019-00062, Paper 11 at 11.

In connection with Factor 2, the Board considers whether the petitioner would have reason to begin searching for prior art before the filing of the previous petition. *See, e.g., Am. Honda Motor Co. v. Intell. Ventures II, LLC*, IPR2018-00348, Paper 10 at 15-17 (P.T.A.B. June 27, 2018) (denying institution where the petitioner “would, at a minimum, have had some reason to begin searching for relevant prior art” when it was put on notice of potential infringement). Here, Petitioner was aware of its potential infringement [REDACTED]. Ex. 2023; Ex. 2052. Thus, as in *American Honda Motor*, here “[Petitioner] ... had the same motivation as the original petitioners in the Earlier IPRs ... to promptly conduct prior art searching” IPR2018-00348, Paper 10 at 15.

The Board also has found that Factor 2 favors denying institution when the newly asserted prior art: (i) consists of publicly available patent documents; (ii) has similar classifications or are in a related field to the challenged patent; and/or (iii) uses “common terms” as the challenged patent. *See, e.g., Shanghai Lunion Info. Techs., Ltd. v. Telefonaktiebolaget LM Ericsson*, IPR2018-00995, Paper 12 at 17 (P.T.A.B. Nov. 13, 2018) (the references were “U.S. patent documents having similar classifications as the [challenged patent]” and “presumably could have been uncovered with a reasonably diligent search”); *Longi Green Energy Tech. Co. v.*

Hanwha Sols. Corp., IPR2020-00047, Paper 18 at 9 (P.T.A.B. Apr. 27, 2020) (petitioner “should have known” of prior art that was published in a “well-known journal” and addressed a “related field” to the challenged patent); *Am. Honda Motor*, IPR2018-00348, Paper 10 at 16 (a reasonably diligent search would have likely identified at least some of the patent documents given the terms in common with the challenged patent).

Here, Petitioner relies on Mehta as its primary reference. Both Mehta and the '812 Patent include classifications as surgical patents (USPC classifications 606 and 607, respectively). *Compare* Ex. 1006 (Mehta), *with* Ex. 1001 ('812 Patent). As Petitioner admits, Mehta uses similar terminology as the '812 Patent, including terms like electrodes or needles that penetrate tissue or skin, and applying energy or signals to affect or injure tissue. *Id.* Because Mehta is a U.S. patent document in the same classification and field as the '812 Patent and uses similar terminology as the '812 Patent claims, Mehta “presumably could have been uncovered with a reasonably diligent search.” *Shanghai Lunion*, IPR2018-00995, Paper 12 at 17. In fact, during the prosecution of the '812 Patent, the Examiner considered Mehta as Mehta '705, which has the substantially same disclosures as Mehta. Ex. 2140 (Crosby Decl.), ¶¶66-67.

Similarly, Lee relates to a skin regeneration apparatus where microneedles are inserted into tissue. *See* Ex. 1009, Abstract. And again, Lee uses similar terminology

as the '812 Patent, such as needles inserted into tissue. *Id.* The same is also true of Na '848 (Ex 1007, [0025]) and Livneh (Ex. 1010, Abstract).

Further, Petitioner's May 24, 2023 Notice of Prior Art indisputably shows it was aware of these references ***more than seven months*** before filing its Petition. *See* Ex. 2053.

In short, at the time of the filing of the prior petition, Petitioner Jeisys (co-defendant of prior Petitioner Cartessa), either explicitly knew of the prior art being asserted in its second petition or "presumably could have been uncovered with a reasonably diligent search." *Shanghai Lunion*, IPR2018-00995, Paper 12 at 17. Thus, Factor 2 favors denying institution.

3. Factor 3

Under the third *General Plastic* factor, the Board considers "whether at the time of filing of the second petition the petitioner already received the patent owner's preliminary response to the first petition or received the Board's decision on whether to institute review in the first petition." *Gen. Plastic*, IPR2016-01357, Paper 19 at 16. "[F]actor 3 is directed to Petitioner's potential benefit from receiving and having the opportunity to study Patent Owner's Preliminary Response, as well as our institution decisions on the first-filed petitions, prior to its filing of follow-on petitions." *Id.* at 17-18.

Thus, the Board has ***routinely*** exercised its discretion to deny institution where, as here, the petitioner had an opportunity to review the prior Patent Owner's Preliminary Responses and the Board's Decisions. *See, e.g., Shanghai Lunion*, IPR2018-00995, Paper 12 at 18 (denying institution where the petitioner had ample opportunity to study Patent Owner's arguments and the Board's findings of fact and conclusions of law); *Mitek Sys.*, IPR2020-00882, Paper 29 at 24-28, 34 (same); *Shenzhen I*, IPR2018-00761, Paper 15 at 11-13 (same); *Am. Honda Motor*, IPR2018-00348, Paper 10 at 17-18, 21-22 (same); *Samsung Elecs. Co. v. Elm 3DS Innovations, LLC*, IPR2017-01305, Paper 11 at 20-21 (P.T.A.B. Oct. 17, 2017) (same); *Nautilus Hyosung, Inc. v. Diebold, Inc.*, IPR2017-00426, Paper 17 at 14, 17 (P.T.A.B. June 22, 2017) (same).

Indeed, this factor weighs “***strongly***” against institution when the petitioner adjusted its arguments in the subsequent petition to account for those made in the prior Patent Owner Preliminary Response and for the Institution Decision. For example, in *Shenzhen I*, the Board noted that in the second petition the petitioner preempted a claim construction argument based on Patent Owner's Preliminary Response to the first petition. IPR2018-00761, Paper 15 at 12. The petitioners thus “took advantage of ‘the opportunity to strategically stage their prior art and arguments,’ to account for positions taken by Patent Owner in its Preliminary Response.” *Id.* (quoting *Gen. Plastic*, IPR2016-01357, Paper 19 at 17-18).

Here, review of the first and second petitions shows that the current Petitioner adjusted its positions in view of the Patent Owner Preliminary Response and the Board's earlier conclusions addressing the prior petition. For example, in the original petition, Petitioner Cartessa relied on references directed to, for example, "apparatus and method for the minimally invasive treatment and ablation of tissue masses such as tumors[.]" *Cartessa II*, IPR2022-00377, Paper 1 at 20-21 (describing Morris). In the POPR, Patent Owner explained that Petitioner's proposed combination fails to meet several limitations, including "a method or apparatus for 'treating dermatological tissue,'" in part because the "prior art relates to killing (ablating) cancer cells (tumors), not treating healthy dermatological tissue." *Id.*, Paper 8 at 1-2. The Board agreed and denied institution on the merits. *Id.*, Paper 9 at 5-13. Informed by Patent Owner's argument and the Board's agreement, the current Petitioner relies on Mehta, Na '848, Livneh, and Lee, which are directed toward treatment of dermatological tissue.

As in *Shenzhen I*, Petitioner adjusted its arguments in this second petition in view of the first petition, strongly indicating that Petitioner impermissibly took "the opportunity to strategically stage their prior art and arguments in multiple petitions," to account for positions taken by Patent Owner in its Preliminary Response. *Gen. Plastic*, IPR2016-01357, Paper 19 at 17.

Moreover, not only did Petitioner use Patent Owner's Preliminary Response and the Board's prior Institution Decision to inform its positions in the second petition, it *also* tactically delayed filing its second petition to benefit from studying Patent Owner's validity positions ***all the way through the evidentiary hearing***. See, e.g., Ex. 2024 (Order No. 33). Indeed, Petitioner waited to file its Petition until ***after*** receiving Patent Owner's post-hearing brief explaining why Mehta does not invalidate the claims, taking into account expert testimony on validity. Ex. 2015.

When, as here, a party has waited to file a subsequent petition until after validity positions have been disclosed in a related proceeding, the Board has held this weighs "***strongly***" in favor of denying institution. See, e.g., *Samsung*, IPR2017-01305, Paper 11 at 21 ("The availability of the Patent Owner's Response ***and Patent Owner's expert testimony from other proceedings*** also weighs ***strongly*** in favor of exercising our discretion, as does Petitioner's use of such information in its Petition."); see also *Shanghai Lunion*, IPR2018-00995, Paper 12 at 18 (Factor 3 favored denial of institution where "Petitioner also had the Patent Owner's Responses ***and Patent Owner's expert testimony in the other related proceedings*** when the Petition was filed.").

Here, Petitioner not only waited to file this second petition until ***after*** having the benefit of Patent Owner's evidentiary presentation on validity and exposition of

its validity positions in post-hearing briefing, but also used this information to inform the arguments in its Petition.

For example, in the ITC, the parties did not propose a construction for “desired distance” because the meaning of the term was not initially in dispute. During the hearing, when addressing why Mehta does not meet this claim limitation, Patent Owner’s expert Mr. Crosby explained that “the distance at which the probes extend in Mehta is ***fixed***” and “the only mechanism Mehta discloses for adjusting the probe placement is selecting a different cartridge.” Ex. 2126, 1506:2-4, 1515:17-20. Petitioner now expressly seeks to preempt the plain meaning interpretation, arguing that “[Patent Owner’s] interpretation should be rejected.” Pet. 11-13. Thus, Petitioner is making direct use of Patent Owner’s expert testimony in framing the arguments in its Petition.

As another example, in its invalidity contentions in the ITC, Petitioner presented ***12 different invalidity grounds*** for claim 5 (including based on Mehta and Na ’848) and ***15 different invalidity grounds*** for claim 18 (including based on Mehta and Livneh). Ex. 2139 (Appendix 7 to Respondents’ Final Invalidity Contentions). After having the benefit of Patent Owner’s responses, Petitioner dropped all but two of those grounds (obviousness based on Mehta for the remaining claims and obviousness based on Mehta and Na ’848 for claim 5 only).

In short, in crafting the arguments in their petition, Petitioner not only leveraged the Patent Owner's Preliminary Response and the Board's Institution Decision on the first petition, but also Patent Owner's full evidentiary presentation and briefing in the ITC. As such, this factor “**strongly**” favors denying institution. *See, e.g., Samsung*, IPR2017-01305, Paper 11 at 21.

4. Factor 4

Under the fourth *General Plastic* factor, the Board considers “the length of time that elapsed between the time the petitioner learned of the prior art asserted in the second petition and the filing of the second petition[.]” *Gen. Plastic*, IPR2016-01357, Paper 19 at 16. Because Factor 4 does not consider the reason for the delay, the Board has **repeatedly** found that Factor 4 favors denying institution where the petitioner waited five months or more between learning of the prior art asserted and filing the subsequent petition. *See, e.g., Valve Corp. v. Elec. Scripting Prods., Inc.*, IPR2019-00064, Paper 10 at 13-15 (P.T.A.B. May 1, 2019) (precedential) (“*Valve II*”) (delay of five months favored denial of institution); *Shenzhen I*, IPR2018-00761, Paper 15 at 13 (Factor 4 “**strongly**” favored denying institution where “Petitioner knew of the majority of the asserted art for at least five and a half months before filing this Petition.”); *Guangdong Boltpower Energy Co. v. Noco Co.*, IPR2021-00309, Paper 11 at 9-12 (P.T.A.B. May 10, 2021) (seven-month delay favored denying institution); *Mitek Sys.*, IPR2020-00882, Paper 29 at 31 (“waiting five

months to file its own petition still, by itself, is unreasonable and weighs in favor of discretionary denial"); *Intel Corp. v. Inst. of Microelectronics Chinese Acad. of Scis.*, IPR2019-00834, Paper 14 at 10-12 (P.T.A.B. June 19, 2020) (six-month delay favored denying institution); *Abiomed, Inc. v. Maquet Cardiovascular, LLC*, IPR2017-02134, Paper 7 at 11-13 (P.T.A.B. Apr. 16, 2018) ("nearly six months" delay favored denying institution).

Here, Petitioner indisputably was aware of the asserted prior art no later than May 24, 2023, when it filed its Notice of Prior Art in the ITC. *See* Ex. 2053. Petitioner thus was aware of these references ***at least seven months*** before filing its Petition. This lengthy delay alone "***strongly***" favors denial of institution—it is substantially longer than other delays supporting denial of institution. *Shenzhen I*, IPR2018-00761, Paper 15 at 13 ("at least five and a half month[]" delay); *see also*, *e.g.*, *Guangdong Boltpower Energy*, IPR2021-00309, Paper 11 at 9-12 (seven-month delay); *Mitek Sys.*, IPR2020-00882, Paper 29 at 31 (five-month delay); *Intel*, IPR2019-00834, Paper 14 at 10-12 (six-month delay); *Valve II*, IPR2019-00064, Paper 10 at 13-15 (five-month delay); *Abiomed*, IPR2017-02134, Paper 7 at 11-13 ("nearly six months" delay).

5. Factor 5

Under the fifth *General Plastic* factor, the Board considers "whether the petitioner provides adequate explanation for the time elapsed between the filings of

multiple petitions directed to the same claims of the same patent[.]” *Gen. Plastic*, IPR2016-01357, Paper 19 at 16. Factor 5 favors denying institution where the petitioner fails to provide an adequate explanation for the delay. *See, e.g., Videndum Prod. Sols., Inc. v. Rolight Ltd.*, IPR2023-01220, 2024 WL 266434, at *7 (P.T.A.B. Jan. 24, 2024) (“Although Petitioner is correct that it was not obligated under 35 U.S.C. § 315(b) to file this Petition sooner, that does not constitute an adequate explanation” for delaying filing its petition.). Indeed, when such a delay exists, it is incumbent on the petitioner to provide an explanation for it. *See, e.g., Apple Inc. v. Corephotonics Ltd.*, IPR2018-01356, 2019 WL 462483, at *3 (P.T.A.B. Feb. 5, 2019) (“To the extent a reasonable explanation exists for Petitioner’s delay, it was incumbent upon Petitioner to identify those circumstances in its Petition.”); *Shenzhen I*, IPR2018-00761, Paper 15 at 13 (same).

Here, Petitioner provides ***no explanation*** for its lengthy delay, let alone an “adequate” explanation. This heavily favors denying institution. *See, e.g., Videndum Prod. Sols.*, 2024 WL 266434, at *7 (lack of explanation supported denial of institution).

Accordingly, Factors 4 and 5 are particularly significant here in view of Petitioner’s long delay and lack explanation for it, favoring denial of institution.

6. Factors 6 and 7

Under the sixth and seventh *General Plastic* factors, the Board considers “the finite resources of the Board[]” and “the requirement under 35 U.S.C. § 316(a)(11) to issue a final determination not later than 1 year after the date on which the Director notices institution of review.” *Gen. Plastic*, IPR2016-01357, Paper 19 at 16. “The sixth and seventh factors are efficiency considerations.” *Valve I*, IPR2019-00062, Paper 11 at 15.

The Board has explained that “multiple, staggered petition filings ... are an inefficient use of the *inter partes* review process and the Board’s resources.” *Shanghai Lunion*, IPR2018-00995, Paper 12 at 20 (quoting *Gen. Plastic*, IPR2016-01357, Paper 19 at 21). This efficiency consideration applies here because the second Petition was tactically staggered in time and seeks to have the Board consider anew the same claims already addressed in deciding whether to institute the first Petition.

Petitioner argues that reviewing this petition would further “the Board’s mission to improve patent quality[]” (Pet. 84-85), but the Board already has served this mission by considering the first petition on the merits. Petitioner’s second Petition, which is a “sequential attack[] against the same claims” challenged in the first Petition, where Petitioner took advantage of “the opportunity to morph positions along the way” “imposes inequities on [Patent Owner].” *Gen. Plastic*, IPR2016-

01357, Paper 19 at 11; *see also id.* at 17 (“Multiple, staggered petitions challenging the same patent and same claims raise the potential for abuse. The absence of any restrictions on follow-on petitions would allow petitioners the opportunity to strategically stage their prior art and arguments in multiple petitions, using our decisions as a roadmap, until a ground is found that results in the grant of review.”) (footnote omitted).

Petitioner relies on *Western Digital* to assert its Petition “employ[ing] entirely different art, different arguments and a different expert[,]” and “cannot be said to be wasteful of resources of the Board.” Pet. 86 (quoting *W. Digit. Corp. v. SPEX Techs., Inc.*, IPR2018-00082, 2018 WL 1990246, at *9 (P.T.A.B. Apr. 25, 2018)). *Western Digital* is inapposite. Unlike here, in that case there was no evidence of undue delay in filing of the subsequent petition, or evidence that the subsequent petitioner tactically waited to file its petition. *W. Digit.*, 2018 WL 1990246, at *8-9 (finding that the Patent Owner did not point to any evidence of “extenuating circumstances” relating to tactical delays or “staggered petitions”).

Here, substantial evidence shows that Petitioner tactically waited to file this subsequent petition—***at least seven months after being aware of the prior art***—to have the benefit of not only reviewing Patent Owner’s prior Preliminary Response and the Board’s Institution Decision but also Patent Owner’s evidentiary presentation and briefing on validity in a related litigation. This behavior is “of

particular concern” and weighs heavily against institution. *Gen. Plastic*, IPR2016-01357, Paper 19 at 11.

In short, Petitioner's second attack against the '812 Patent claims—purposely staggered to game the system and benefit from earlier IPR filings and fully litigating the invalidity challenges raised here—abuses the IPR process and imposes inequities on Patent Owner. *Id.* at 11, 17. This factor favors denying institution.

7. Factor 8

In certain circumstances the Board has considered an additional factor 8, which takes into account “the extent to which the petitioner and any prior petitioner(s) were similarly situated defendants or otherwise realized a similar-in-time hazard regarding the challenged patent.” *Shenzhen Silver Star Intelligent Tech. Co. v. iRobot Corp.*, IPR2018-00897, Paper 9 at 12 (P.T.A.B. Oct. 1, 2018) (“*Shenzhen II*”) (quoting *Shenzhen I*, IPR2018-00761, Paper 15 at 15, 18). The Board explained that “[t]he purpose of proposed Factor 8 is to discourage tactical filing of petitions over time by parties that faced the same litigation threat at the same time.” *Shenzhen II*, IPR2018-00897, Paper 9 at 12 (footnote omitted).

In *Shenzhen II*, the current and prior petitioners were co-respondents in the ITC and filed their invalidity contentions at the same time; thus, the Board found they “faced a similar-in-time hazard” regarding the asserted patent. *Id.* at 12. Yet, the second petitioner waited until after the Denial of Institution of the first petition

to file the second petition. The Board explained that “[a]bsent mitigating explanation, of which we have none, this suggests an attempt to secure a tactical advantage” *Id.* at 11-12. Similarly, here Petitioner was on notice of the ’812 Patent before the prior Petition was filed, was a co-respondent with the prior petitioners at the ITC, and not only waited until after the Denial on Institution of the prior petition, but also months after being aware of the prior art asserted here. Petitioner tactically delayed to have the benefit of Patent Owner’s fully developed record at the ITC. *See supra* Sections II.A, II.B, and II.D.1 and 2. Therefore, for the same reasons as in *Shenzhen II*, proposed Factor 8 favors denial of institution.

III. THE BOARD SHOULD DENY INSTITUTION UNDER 35 U.S.C. § 325(D)

The Board analyzes § 325(d) using a two-part framework, first considering whether the same or substantially the same art or was before the Office and then whether the petitioner showed the Office “erred in a manner material to the patentability of challenged claims.” *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8 (P.T.A.B. Feb. 13, 2020) (precedential) (footnote omitted). Because the Petition presents substantially the same art the Office previously analyzed and fails to show the Office materially erred during prosecution, the Board should deny institution under § 325(d).

A. The Same or Substantially the Same Art Was Before Office**1. Mehta**

The Examiner had Mehta as Mehta '705² during prosecution, and allowed the claims. Ex. 1002, 577-582, 645-651; Ex. 1001, 2(56) (References Cited); Ex. 2125 (Woloszko Hr'g Tr.), 1043:4-9 (Q. *You understand that the Mehta reference was considered by the Patent Office, right?* A. I believe so, *yes.*”). Mehta '705 was cited in an IDS filed before any substantive prosecution (Ex. 1002, 434), and Petitioner concedes that Mehta '705 is on the face of the '812 Patent. Pet. 87. *See Advanced Bionics*, IPR2019-01469, Paper 6 at 7-8 (“Previously presented art” includes “art provided to the Office by an applicant, such as on an Information Disclosure Statement (IDS)[.]”).

² The disclosures in Mehta and Mehta '705 are nearly identical, particularly with respect to the portions Petitioner relies on here. Ex. 2140 ¶¶61, 66; *compare* Ex. 1006, Figs. 2A, 2B, 2D, 4A, 4C, 6:41-42, 9:36-55, 14:5-7, 14:14-19, 15:27-33, 15:40-42, 15:45-49, 15:55-59, 16:12-22, 16:59-60, 16:65-66, *with* Ex 1011 (Mehta '705), Figs. 2A, 2B, 2D, 4A, 4C, 7:14-15, 10:20-41, 14:41-43, 14:48-54, 15:63-16:2, 16:9-11, 16:14-18, 16:24-28, 16:56-17:2, 17:36-37, 17:42-43. Indeed, Petitioner made no effort to differentiate Mehta from Mehta '705, nor could they given their similarities. *See* Pet. 87.

2. Na '848

Na '848 is International Application No. PCT/US2008/074131, which is listed and incorporated by reference in the specification of the '812 Patent (Ex. 1001, 1:7-29), and thus was before the Office during prosecution. Information incorporated by reference “is as much part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed.” MPEP 2163.07(b).

3. Lee

Substantially the same art as Lee was before the Office during prosecution. Petitioner relies on Lee's disclosure of a step-motor for the purported teaching of needles extending a “desired distance.” Pet. 53-58. Specifically, Petitioner contends that “Lee teaches a step-motor 14 that rotates to move a slider 17 and needle mount 11, and controlling the step-motor 14 by setting an operational parameter that corresponds to an amount of rotation of the motor to determine an insertion depth.” *Id.* 56. Substantially similar disclosure was considered by the Office in U.S. Patent Application Publication No. US2004/0058882 (“Eriksson”) (Ex. 2142), which is cited on the face of the '812 Patent. Ex. 1001, 2(56) (References Cited); *see also* Ex. 1002, 118.

Eriksson discloses a device to facilitate delivery to target tissue via microneedles. Ex. 2142, [0041]. The microneedles are “driven by a power source,”

which can be an “electric motor” connected to a piston. *Id.*, [0042]. When energized, the piston can oscillate the microneedles and “[t]he amplitude of the oscillating microneedles ... can vary ... depending on the ... desired penetration path.” *Id.*, [0124]. The amplitude is configured by the internal components of the drive body, including shafts that Eriksson explains “translate rotational motion to linear oscillating motion[.]” *Id.*, [0125]. The oscillation frequency may be controlled via a control module. *Id.*, [0135].

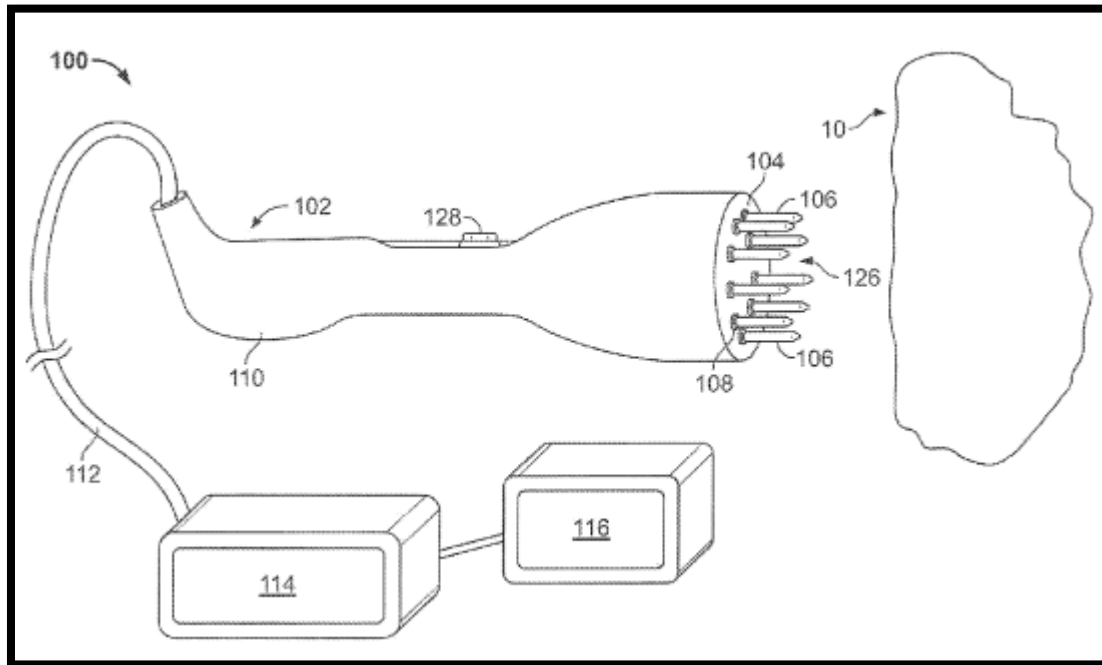
Therefore, the portions of Lee that Petitioner relies on are substantially the same as the disclosures in Eriksson.

4. Livneh

Substantially the same disclosures that Petitioner relies on from Livneh were also before the Office. Petitioner relies on Livneh for all aspects of claims 9 and 18 of the '812 Patent except for the needle module being releasably couplable and mechanically separable from the user holdable device. *See* Pet. 63-64, 67-68, 80. Those same teachings were previously before the Office in U.S. Patent Application Publication No. 2008/0091182 (“Mehta '182”) (Ex. 2143), which was included an IDS filed before any substantive prosecution of the '812 Patent. Ex.1002, 118.

Mehta '182 discloses a skin treatment system, which includes (1) a treatment unit 102 with handpiece 110, electrode array 126 with electrodes 108 that extend from a faceplate 104, and an actuator 128 for driving the electrodes 108 and (2) an

energy supply unit 114. Ex. 2143, Fig. 1 (below), [0047], [0053], [0055], [0058], [0061], [0069].



Id., Figs. 2A, 2B, 2C.

Like Livneh, there is no releasably couplable or mechanically separable needle module. No portion of treatment unit 102 in Mehta '182 separates from another portion. *See id.*, [0047]-[0072] (describing Figures 1-2F). This is the same or substantially the same alleged deficiency in Livneh according to Petitioner. Pet. 58-64.

B. Petitioner Fails to Show the Office Materially Erred as to the Patentability of the Challenged Claims

Petitioner has not shown the Office erred in the patentability of the challenged claims. In a single paragraph devoted to discretion under § 325(d), Petitioner merely

argues that none of the references were of record. But as shown above, the same or substantially the same art was presented to the Office during prosecution. Nowhere has Petitioner argued, much less shown, that the Office materially erred in allowing the claims based on those references. Nor could it because, as shown below, none of Mehta, Na '848, Lee, or Livneh alone or in combination render the challenged claims invalid.

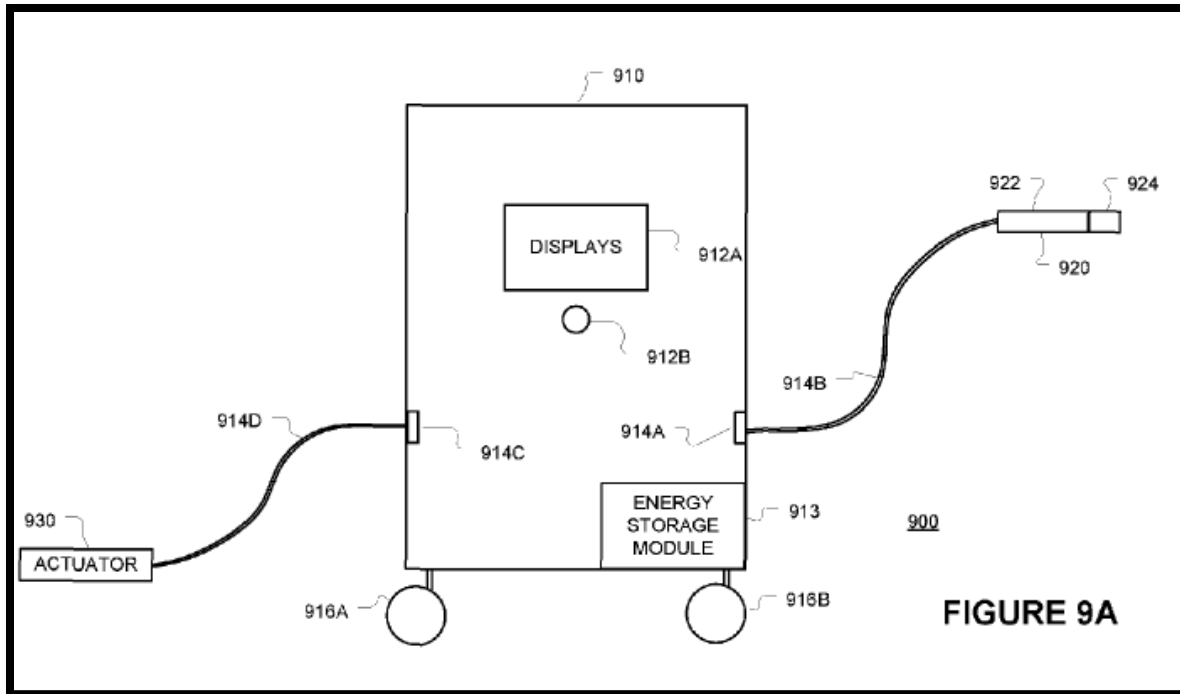
Thus, the Board should thus exercise its discretion under § 325(d) and deny institution.

IV. PETITIONER FAILS TO SHOW A REASONABLE LIKELIHOOD OF PREVAILING AS TO ANY OF THE CHALLENGED CLAIMS

A. Background

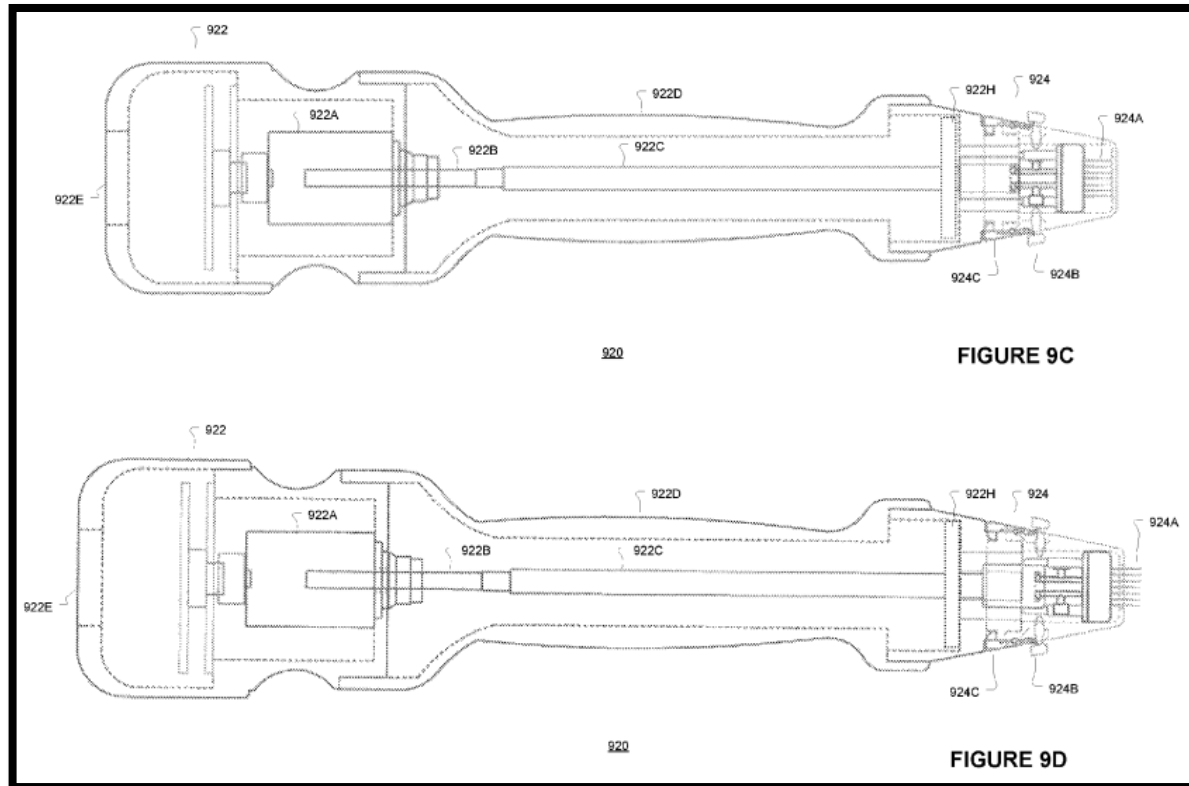
1. The '812 Patent (Ex. 1001)

The '812 Patent claims relate to a dermatological treatment to improve the appearance of skin that involves inserting needles into the skin and applying pulsed radiofrequency (“RF”) signals to the needles. This dermatological treatment apparatus is described in connection with Figures 9-11. Figure 9A (copied below), shows “a dermatological treatment architecture (DTA) 900” with “a signal generation and control module (SGC) 910, a handle module 920, and an actuator module 930.” Ex. 1001, 9:40-44.



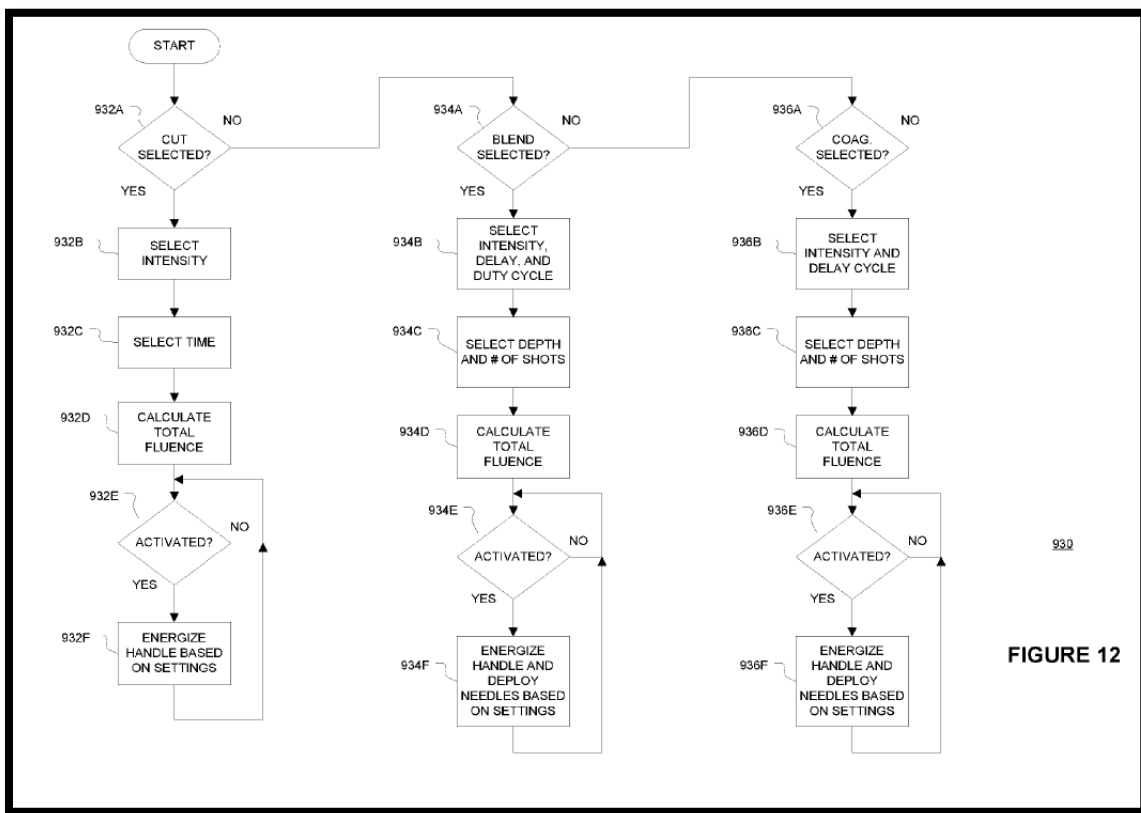
As shown above and in Figures 9C and 9D (copied below), the “handle module 920” may include (1) “a deployable needle module (DNM) 924” (which “may be a detachable cartridge module (DCM)”), and (2) “a motor and LED module [(MLM)] 922.” *Id.*, 9:47-52, 11:6-12. “[A] needle deployment motor controller (NDMC) module 911B” (shown above), “may control the deployment of one or more needles 924A” (shown below), of the deployable needle module 924 “based on one or more user selected operational parameters,” which include “the depth” of needle insertion. *Id.*, 9:67-10:5, 10:21-24, 10:32-37; *see also id.*, 9:65-10:5 (“a user may configure one or more operational parameters[,]” which include “needle deployment timing and depth(s)”). Accordingly, “needle deployment” “via one or more motors 922A” can be controlled by the user. *Id.*, 10:52-65. Figure 9C (below),

shows the “needles 924A retracted,” and Figure 9D (below), shows the “needles 924A deployed.” *Id.*, 10:66-11:5.



Needle extension to a particular depth based on the user's selection is performed by the MLM 922, which “may include one or more motors 922A, longitudinally extendable drive arms 922B, drive shaft 922C, outer casing 922D, [and] signal interface 922E” that receive “control signals and energy to operate [the] one or more motors 922A.” *Id.*, 11:15-24. The drive shaft 922C may be moved “to deploy and retract one or more needles 924A” such that “the motor(s) 922A may enable precise needle extension (effective depth) control.” *Id.*, 11:24-28, 14:3-6, 14:24-26.

Accordingly, “a desired depth of needle 924A penetration within tissue” can be achieved “based on the operational parameters” the user selects. *Id.*, 14:14-20, 14:28-34. Figure 12 (below) is a flow diagram of algorithms for the DTA 900, which shows that in two operational modes (blend and coagulation), one of the steps 934C, 936C involves selecting needle deployment depth. *Id.*, 13:45-46, 13:51-55, 13:63-66, 14:21-24. Thus, the distance the needles extend is determined based on a user-selected depth that is input into an algorithm (i.e., software), that controls a motor, providing precise control over the needle insertion depth. *Id.*; *see also id.*, 9:65-10:5, 10:21-24, 10:32-37, 11:24-28, 14:3-6, 14:24-26; Ex. 2140 ¶47.



2. Priority and Prosecution History

The '812 Patent was filed on October 3, 2017, and issued December 22, 2020. Ex. 1001, 1(22), (45). It is a continuation of the '774 Patent, which in turn is a continuation of the '536 Patent. The Patent Owner agrees that the proper priority date for the claims of the '536 Patent is March 3, 2011. Petitioners have also challenged the '774 and '536 Patents.

During prosecution of the '812 Patent, the Examiner rejected the then-pending claims over WO 2005/096979 A1 ("Manstein") and KR 10-2011-00002210 ("Yang") (Ex. 1002, 579-580), and issued a double patenting rejection in view of the '536 Patent. *Id.*, 580-582. In response, the Applicant initiated interviews, amended the claims to require that the electrical contacts be extendable, and filed a terminal disclaimer. *Id.*, 604-607, 614-622, 625-626. After the Applicant corrected the terminal disclaimer, the Examiner allowed the claims. *Id.*, 646-651, 682, 692-693.

3. Person of Ordinary Skill in the Art

For purposes of this preliminary response, Patent Owner accepts Petitioners' definition of a person of ordinary skill in the art ("POSITA"). Pet. 11; Ex. 1003 ¶45.

B. Claim Construction

The prior art Petitioner relies on fails to disclose the subject matter of the claims under any reasonable construction, including their plain and ordinary meaning.

1. **Motor ... “to cause the plurality of needles to extend a desired distance from the releasably couplable deployable needle module end surface” / “to extend the plurality of needles a desired distance from the releasably couplable deployable needle assembly end surface”**

The term “desired distance” appears in the claims at issue, except for claims 9 and 18. Specifically, claim 2 recites “a motor coupled to the needle assembly to cause the plurality of the needles to extend **a desired distance** from the releasably couplable deployable needle module end surface” (Ex. 1001, cl. 2) and claims 3-6 depend on claim 2. *Id.*, cls. 3-6. Claim 8, which depends on claim 1, recites “energizing the motor via the drive shaft to the needle assembly to cause the plurality of needles to extend **a desired distance** from the releasably couplable deployable needle module end surface.” *Id.*, cl. 8. And claim 13, on which claims 14-16 depend, recites “a motor coupled to the needle assembly to extend the plurality of needles **a desired distance** from the releasably couplable deployable needle assembly end surface.” *Id.*, cls. 13-16.

The “desired distance” in each of these claims should be construed to have its plain meaning in the context of the claims.³ The particular distance is “desired”

³ Petitioners propose a construction for “predetermined depth” (Pet. 11-12), but that term appears only on claim 6, which Patent Owner has disclaimed. Ex. 2144 (Disclaimer). Thus, the construction is moot.

because it is the distance a user decided to select to achieve a particular penetration depth. The “distance” itself is how far the needles extend from an end surface to penetrate dermatological tissue. Accordingly, the “desired distance” is how far the needles extend from the device’s needle module or needle assembly end surface, based on a user’s selection, to penetrate dermatological issue. Ex. 2140 ¶¶54-55. This construction is supported by the claims, the specification’s description of the claimed invention, the prosecution history relating to the “desired distance.”

Here “the claims themselves provide substantial guidance as to the meaning of” the claim term “desired distance.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc). The claims recite a motor that causes the plurality of the extendable needles to extend a “desired distance” from an end surface, whether that be the needle module or the needle assembly end surface. Ex. 1001, cls. 2, 8, 13. Accordingly, by their plain language, the claims instruct that the “desired distance” is a distance that extendable needles extend, from the needle module end surface for claims 2-6 and 8 or from the needle assembly end surface for claims 13-16, into tissue to treat dermatological tissue. Ex. 2140 ¶55.

The specification, which “is the single best guide to the meaning of a disputed term,” confirms that the claimed “desired distance” is how far the needles extend from an end surface, based on a user’s selection, to penetrate the dermatological issue. *Phillips*, 415 F.3d at 1315 (quoting *Vitronics Corp. v. Conception, Inc.*, 90

F.3d 1576, 1582 (Fed. Cir. 1996)). The '812 Patent explains that the user may configure several operational parameters, including needle deployment depth. Ex. 1001, 9:63-10:8. The step of selecting the needle deployment depth 934C, 936C is shown in Figure 12 (copied above). *Id.*, 13:45-46, 13:51-55, 13:63-66, 14:21-24. The specification describes a needle deployment motor controller (NDMC) module 911B that “may control the deployment of one or more needles 924A ... based on one or more user selected operational parameters[,]” including “the depth” for “the needle(s) 924A deployment.” *Id.*, 10:32-37; *see also id.*, 10:63-65, 14:14-20, 14:28-34. This is how “needle deployment” “via one or more motors 922A” is controlled by the user. *Id.*, 10:52-65.

Specifically, the '812 Patent explains that,

upon activation (activity 934E, 934F) the DTA 900 [dermatological treatment architecture] may energize the MLM [motor and LED module] 922 based on the operational parameters and deploy the needle assembly 924F to a desired extension beyond the DNM [deployable needle module] 924 shell 924E to enable a desired depth of needle 924A penetration within tissue when the shell 924E is placed adjacent the tissue.

Id., 14:14-20; *see also id.*, 14:28-34. Thus, the motors “enable precise needle deployment depth or extension beyond the DNM [deployable needle module] 924 shell.” *Id.*, 11:58-61; *see also id.*, 14:3-6, 14:24-26.

The specification thus confirms that the “desired distance” is how far the needles extend from the needle module or needle assembly end surface, based on a user’s selection, to penetrate dermatological issue. Ex. 2140 ¶56.

The prosecution history of the ’536 Patent, the parent of the ’812 Patent, reinforces this construction by “provid[ing] evidence” that this is “how the PTO ... understood the patent.” *Phillips*, 415 F.3d at 1317. During the prosecution of the ’536 Patent, the Examiner relied on column 10, lines 11-20, in asserting that Crocker disclosed that “[a] motor is energized to extend the needles a desired distance.” Ex. 2114 (’536 Patent FH), 278. That passage of Crocker states that “control of the depth” of needle insertion can be “electrical or mechanical” means “capable of adjustment by an operator” or that “control of the depth of penetration may alternatively be automatic” using feedback based on “current” measurements. Ex. 2115 (Crocker), 10:11-20. The Examiner’s reliance on this passage shows he understood that the “desired distance” is based on a user’s selection to provide control over the penetration depth (directly or automatically through a feedback mechanism). Ex. 2140 ¶57; *Alloc, Inc. v. Int’l Trade Comm’n*, 342 F.3d 1361, 1371-72 (Fed. Cir. 2003) (relying on the prosecution history of a parent application to determine the scope of limitations present in subsequent related applications).

Petitioner fails to address **any** of this intrinsic evidence in arguing that the term “a desired distance” just means “a ***desired distance*** as opposed to an ***undesired***

distance.” Pet. 11-12 (original emphasis). Petitioner’s construction, which merely states that a claim term is different than its opposite, is meaningless. It sheds no light on the meaning of the term “desired distance.” Petitioner’s proposed construction also has no support in the intrinsic record as the term “undesired” appears nowhere in the ’812 Patent. To the extent it would have any meaning, “undesired” would be a different distance than the distance the needles extend based on the depth the user selected. *Id.*; Ex. 2140 ¶58.

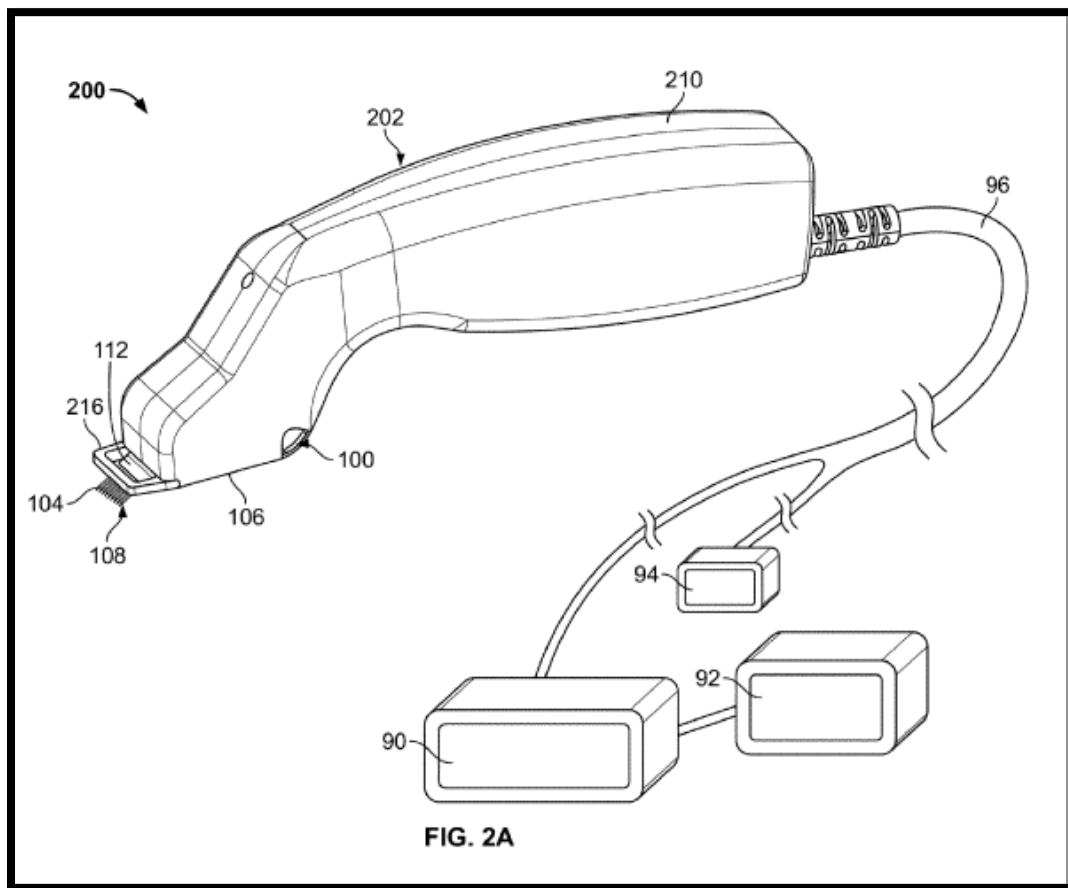
Furthermore, Petitioner’s contention regarding some claims of the ’774 Patent is inapplicable here since needles “extending” is not in the ’812 Patent claims. Pet. 12. And the ’812 Patent further requires a motor to cause the needles to extend a “desired distance,” which by their plain language exclude “fixed, non-extendable needles.” Ex. 1001, cls. 2, 8, 13. Indeed, Petitioner’s argument here conflicts with its current expert’s, Dr. Woloszko’s, testimony in the ITC about what is required to meet the claims. Dr. Woloszko testified that a motor extending needles a predetermined distance would satisfy the claims “[a]s long as you can program this ***distance***[.]” Ex. 2125, 1151:8-12.

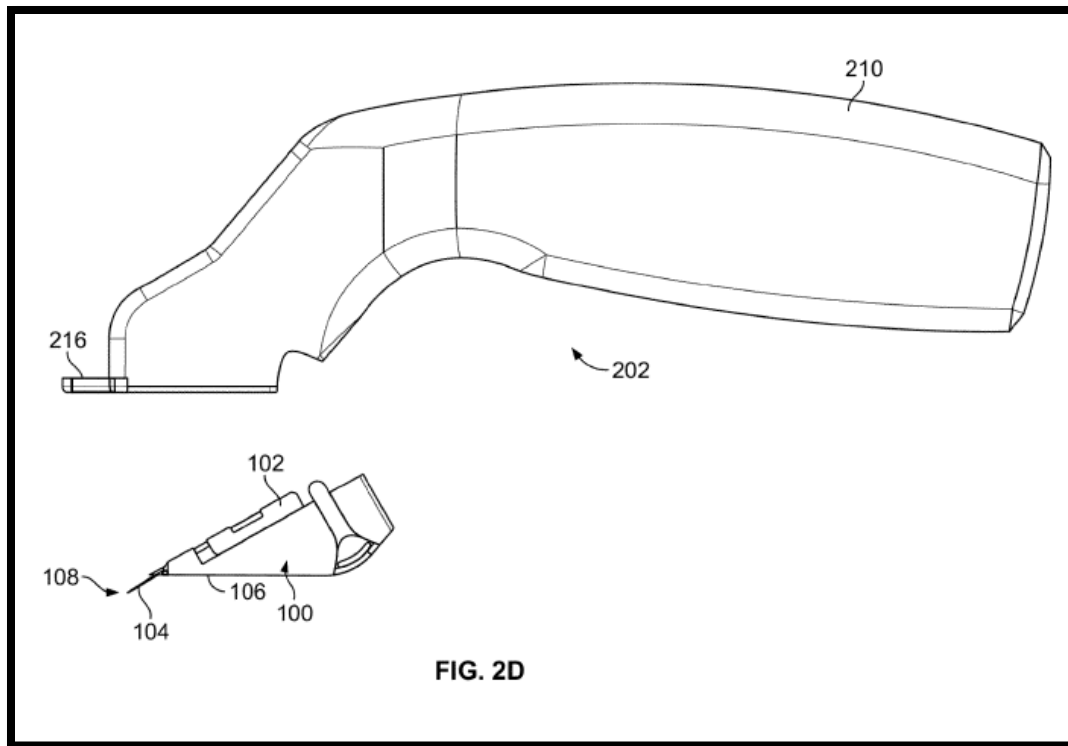
C. Relevant Summary of the Prior Art

1. Mehta

Mehta is a U.S. patent that was filed in 2009 and issued in 2013. Ex. 1006. Mehta sought to address a need for an “improved energy delivery system.” *Id.*, 2:3-

4. Mehta discloses a “treatment system 200 [that] generally includes a treatment unit 202 having a hand-piece or device body 210 ... having one or more probes 104 extending from the body 210.” *Id.*, 9:34-41, Figs. 2A, 2D (reproduced below). In Mehta, “system 200 also includes an energy supply unit 90 coupled to the treatment unit 202 via a cable 96 or other means[]” and “[i]n one variation, the energy supply unit 90 may be a RF energy unit.” *Id.*, 10:53-57, 11:14-15.





The “tissue engagement surface 106 provides a consistent starting point for the probes” 104 so that, “as the probes 104 advance from the device 202 they are driven to a uniform depth in the tissue[]” when they “enter the tissue at an oblique angle A as measured relative to the tissue engagement surface 106.” *Id.*, 21:6-13; *see also id.*, Fig. 7A. By providing this “consistent starting point,” the “tissue engagement surface 106 allows a user to place the device on the surface of tissue and advance the probes 104 to the desired depth of tissue,” as opposed to having “undesirable outcomes” where probes 104 “may be advanced too far or may not be advanced far enough such that they would partially extend out of the skin.” *Id.*, 21:6-16. Mehta also discloses preventing probes from delivering energy at “an unintended shallower location” other than “at specific depth in the target tissue that corresponds

to the length of the extended electrode” by only coupling the probes to the power supply when “fully extended.” *Id.*, 15:62-16:8. But Mehta does not disclose any ability for a user to select the needle insertion depth; the stabilization plate provides a “consistent starting point” but does not offer any user control over the insertion depth. Ex. 2140 ¶60.

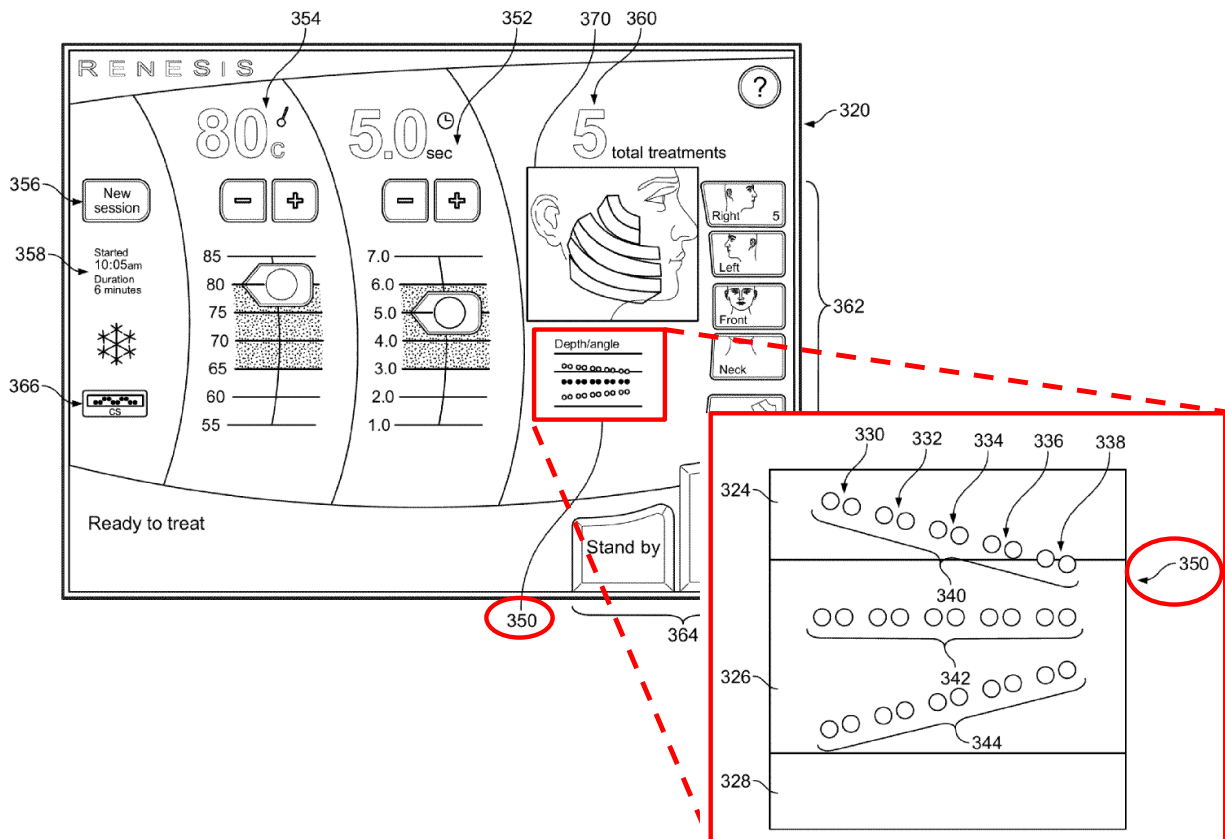
Other than manual adjustment of the placement of the device on the patient's skin by the physician, the only way to adjust probe placement in Mehta is to select a different cartridge with a different needle array configuration, e.g., a different length or angle for needle insertion. Mehta teaches that the device “can include any number of arrays depending upon the intended treatment site[]” and that “the target region of tissue drives the array configuration.” Ex. 1006, 9:65-10:3. Mehta further explains that “[t]he present invention allows a physician to selectively change array configuration by attaching different cartridges.” *Id.*, 10:3-5.

To determine whether the probes reached the target tissue, Mehta discloses ways of assessing penetration depth after the needles have been extended into the skin. For example, Mehta explains that ultrasound energy can be “used to assess the penetration depth of the electrodes, or to identify in which layer the electrodes are located.” *Id.*, 12:1-4. As another example, a sensor 110 can be used to measure the impedance of the tissue to determine whether the “measured impedance” is “within

a range normally associated with tissue,” so that the probe can be “repositioned” if that is not the case. *Id.*, 24:37-45; *see also id.*, Fig. 8A.

Mehta identifies a problem that the “physician can inadvertently place the array 108 of probes 104 at an angle relative to a tissue surface[,]” which would result in the probes not reaching target tissue as expected based on the length of the needles and their insertion angle. *Id.*, 32:20-22; Ex. 2140 ¶63. “To address this problem,” Mehta discloses “measur[ing] tissue parameters to provide feedback to the physician[,]” so that the physician can appreciate if there was an inadvertently incorrect placement of the probe array. Ex. 2140 ¶63 (quoting Ex. 1006, 32:23-25). This feedback can be “visual, virtual, audible or other feedback[] allowing the user to identify whether the placement of the probes” is as it was “desired” or not. Ex. 1006, 32:46-50.

As an example, Mehta discloses a “virtual depth/location depiction 350” in a graphical user interface, as shown in Figure 10E and in a close-up view in Figure 10B (both copied and annotated below). *Id.*, 32:63-33:64.



This virtual depth/location depiction 350 can “show the location of the probe array prior to treatment” (i.e., prior to energy application) and how it compares to the “desired probe location,” i.e., “the desired depth of placement for providing treatment.” *Id.*, 32:63-33:3. Thus, a “physician would be informed” whether, for example, the probe array “is located in an undesired region” and “further advancement of the probes is necessary” to reach “the desired tissue layer.” *Id.*, 33:14-40.

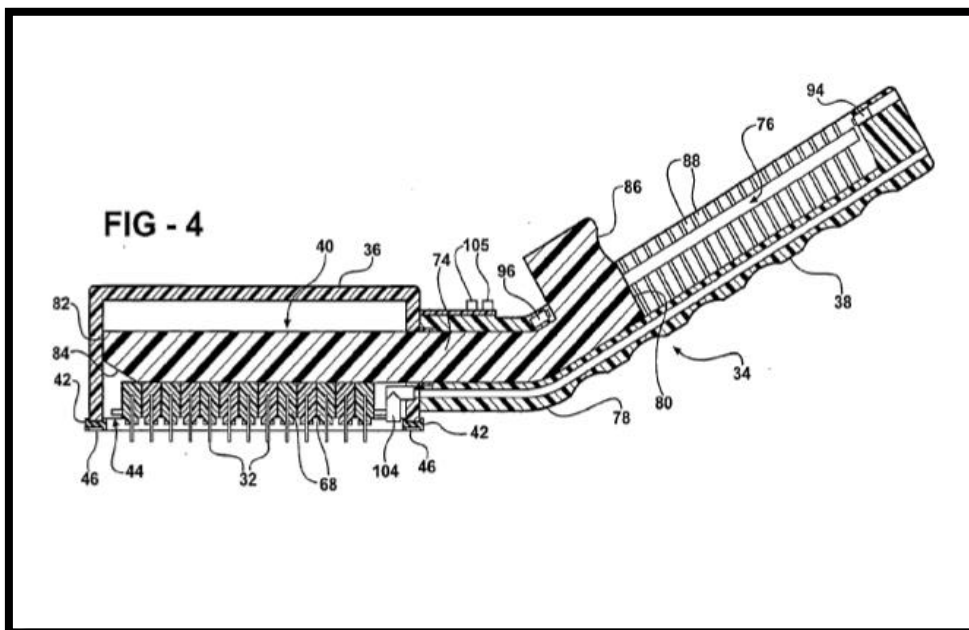
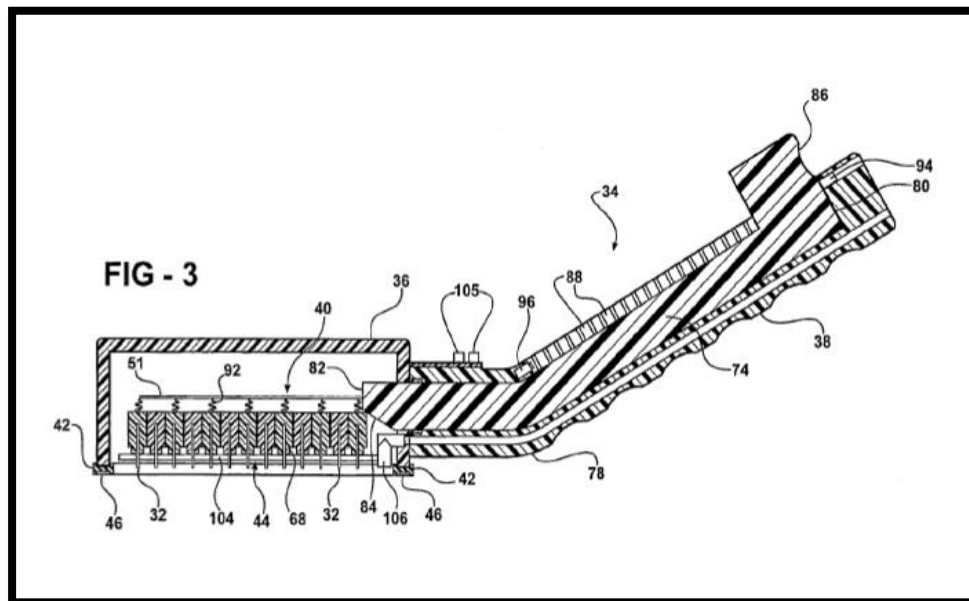
2. Lee

Lee is a Korean patent publication that published on August 25, 2008. Ex. 1009. It “relates to a skin regeneration apparatus used for performing multi-hole

procedures to remove or treat stretch marks, calluses, wrinkles, hair loss, scars, etc.” *Id.*, Abstract. Lee’s device is a “gun equipped with a plurality of microneedles[.]” *Id.* The invention of Lee seeks to create “hundreds to tens of thousands of tiny holes ... to regenerate tissue” “without removing or damaging the epidermis of the skin[.]” and explains that medication applied to the area where the holes are created allows “the drugs to quickly permeate the skin through the tiny holes, thereby maximizing the efficacy of treatment.” *Id.* ¶¶15-16. Lee’s device “provides an actuator means that can control the insertion depth of the microneedles.” *Id.* ¶44. “[T]he process of reciprocating operation of the microneedles is repeated multiple times by repetitively driving the motor back and forth, allowing creation of hundreds to tens of thousands of holes on the human skin” using Lee’s gun-shaped device. *Id.* ¶63. Lee’s gun performs this process “at a speed of about 66-420 times per minute.” *Id.* ¶58.

3. Livneh

Livneh is an international patent application filed on July 5, 2007. It relates to “[a]n electro surgical apparatus” to “appl[y] electrical current to skin[.]” Ex. 1010, Abstract. Livneh discloses an apparatus 30 with handheld unit 34 that includes a “housing 36 [that] is connected to handle portion 38.” *Id.*, [0033]. Mechanism 74 fully extends (as shown in Figure 4) and fully retracts to move the electrodes between a first and a second position. *Id.*, [0042], [0046].



D. Ground I: Petitioner fails to demonstrate that Mehta anticipates claims 2-5, 8, and 13-16

Claims 2-5, 8, and 13-16 recite a motor that causes the plurality of the extendable needles to extend a “desired distance” from an end surface, whether of

the needle module or assembly. Ex. 1001, cls. 2, 8, 13.⁴ Petitioner fails to meet its burden to show that Mehta anticipates the challenged claims at least because Mehta does not disclose a device including needles that extend a “desired distance,” as claimed.

In Mehta, the user does not select how far the needles extend to penetrate dermatological tissue. Ex. 2140 ¶76. Mehta instead discloses selecting cartridges having different probe *lengths* or *angles*, not selecting *how far* the probes in a given cartridge extend. *Id.* Mehta discloses “[s]electing probes having sufficient length to reach” different layers of the dermis (Ex. 1006, 2:47-49, 8:16-18), and explains that “the length of the probes 104 is generally selected so that the energy delivery occurs in the dermis layer of the skin 10” (*id.*, 10:21-23). But Mehta does not disclose any selection by a user of how far the needles extend from the device’s end surface to penetrate the skin. Ex. 2140 ¶76.

Mehta’s system is designed for full insertion of the needles by their entire lengths—i.e., they extend a *fixed distance*. Ex. 1006, 10:2-7, 10:19-25, 12:31-34, 16:1-8; Ex. 2140 ¶77. In fact, Mehta cautions against electrodes not extending their full length to ensure energy is not delivered to an intended location. Ex. 1006, 16:1-

⁴ Because Patent Owner disclaimed claims 1, 6, and 12 (Ex. 2144), this preliminary response does not address those claims.

11; Ex. 2140 ¶¶60, 100. Thus, in Mehta, the distance the needles extend when using a particular cartridge is not selected by the user, but rather is determined by the needles' "fixed length." Ex. 2140 ¶77. Petitioner's expert admits as much, equating the distance the needles extend to "a *distance corresponding to a length* of the needles of a removable cartridge selected by a user for a particular application." Ex. 1003 ¶95.

Petitioner fails to identify any disclosure in Mehta of any selection by a user of how far the needles extend from an end surface to penetrate skin—there is none. Ex. 2140 ¶79. Petitioner relies on actuator 250 as the motor and contends that "Mehta teaches that the motor drives the shaft 256 to advance and retract the needles 104" (Pet. 27), and that "[w]hen the needles 104 are advanced by the motor, they extend by a desired distance to carry out a treatment." *Id.* But Petitioner identifies no disclosure of a user selecting a distance that the needles extend. *Id.* (citing Ex. 1006, 18:26-37); Ex. 2140 ¶80. As Petitioner and its expert recognize, the only "selecting" disclosed in Mehta that relates to the distance the needles extend is based on "*choosing a particular removable cartridge having needles of a particular length.*" Ex. 1003 ¶95. They also rely on "choosing" a cartridge having a particular insertion "angle." Pet. 28-29; *see also* Ex. 1003 ¶95. But neither of those are a selection by a user of how far the needles extend from the device's end surface to penetrate skin.

Ex. 2140 ¶80. Nothing in the passages of Mehta that Petitioner and its expert cite discloses a distance that the needles extend based on user selection. *Id.*

The only disclosure that Petitioner and its expert identify of “desired depth” in Mehta is not a “desired depth” that a user selects for the needles to extend; instead, it is a displayed depth for comparison to where the needles were extended. *Id.*, ¶81. Specifically, Mehta’s “virtual depth/location depiction” “show[s] ‘the desired depth of placement’” “for providing treatment” to compare it to the “location of the probe array,” so that a user can determine whether the probes are in the desired region or “an undesired region.” Ex. 1006, 32:63-33:43 (cited in Pet. 27). The fact that Mehta discloses a virtual display for **comparing** “actual depth” to the “desired depth” (and other ways of tracking insertion depth, e.g., “depth markings”), as Petitioner concedes (*see* Pet. 28), only reinforces that Mehta does not disclose extending the needles “a desired distance.” Ex. 2140 ¶81.

Petitioner cites Mehta’s disclosure of a “step-motor” as one of the possible “mode[s] of movement of the actuator.” Ex. 1006, 15:36-40 (cited in Ex. 1003 ¶94). How the actuator can be implemented is not a disclosure of selecting how far the needles extend. Ex. 2140 ¶82. As Petitioner’s expert admits, a motor that extends a plurality of needles a predetermined distance only meets the claims “[a]s long as **you can program this distance[]**” and otherwise “does not” meet the claims. Ex.

2125, 1151:8-12, 1151:23-1152:3. There is no disclosure in Mehta of programming the distance that the needles extend. Petitioner does not contend otherwise.

In his declaration here, Petitioner's expert merely contends that a step-motor is "suitable" for controlling needle deployment and posits that a "rotation-to-translation mechanical conversion unit ***can be constructed*** in such a manner to provide a desired rotation-to-translation ratio[.]" Ex. 1003 ¶98. But anticipation requires more. It requires that Mehta describe each claim element—not merely disclose a motor that is suitable to be used by some undisclosed "rotation-to-translation conversion unit" that "can be constructed" to (allegedly) satisfy the claim. *Id.*; *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.").

Petitioner also relies on Mehta's disclosure of "[o]ver-inserting and then partially retracting" the needles. Pet. 28 (original alteration). But Mehta discloses this as an automated process to "compensate[] for the movement and laxity of the skin resulting in a more reliable insertion." Ex. 1006, 16:34-41; Ex. 2140 ¶83. Mehta does not disclose a user selection that determines how far the needles extend, over-insert, or retract. Ex. 2140 ¶83. Mehta's display includes no such option. *Id.*

Petitioner's failure to show that Mehta discloses needles extending a "desired distance" from the needle module or assembly end surface supports denial of

institution. 37 C.F.R. §§ 42.22(a)(2), 42.104(b)(4)-(5); *Cuozzo Speed Techs., LLC v. Lee*, 579 U.S. 261, 296-97 (2016).

E. Ground II: Petitioner fails to demonstrate that Mehta in view of the knowledge of a POSITA renders obvious claims 2-6, 8 and 13-16

Claims 2-6, 8, and 13-16 recite needles that extend a “desired distance.” Ex. 1001, cls. 2-6, 8, 13-16.⁵ Petitioner fails to meet their burden to show that Mehta in view of the knowledge of a POSITA renders the claims obvious least because Mehta does not disclose a device including needles that extend a “desired distance” (*see supra* Section IV.D), and a POSITA would not have been motivated to modify Mehta to include that feature.

Petitioner relies on Mehta’s disclosure of a “step-motor” to argue that a POSITA “would have understood that a step-motor would move the needles 104 from a fully retracted position, through a plurality of discrete, intermediate steps ..., to a fully extended position.” Pet. 40. But this description of the operation of a step-motor does not disclose or suggest that a user selects a distance to extend the needles. Ex. 2140 ¶86. And even assuming, as Petitioner’s expert contends, that a POSITA “would ... have known how to program a controller to cause the step-motor of Mehta

⁵ Because Patent Owner disclaimed claims 1, 10, 12, and 17 (Ex. 2144), this preliminary response does not address those claims.

to move the needles 104 to any specific intermediate step between a fully retracted position and a fully extended position[]” (Ex. 1003 ¶148), Petitioner and its expert fail to explain **why** a POSITA would have been motivated to modify Mehta’s step-motor to include such a feature. *See e.g., Dropworks Inc. v. Bio Rad Laboratories Inc.*, IPR2021-00212, Paper 7 at 14 (P.T.A.B. June 1, 2021).

To the extent Petitioner proposes **other** modifications to Mehta to “provide input to select a distance of needle extension[]” to Mehta’s user interface (Pet. 40), they are wrong. A POSITA would not have been motivated to modify Mehta to add a “distance setting” because that would only increase the variation in “actual depth” and thus the likelihood that the probes would not be at the “desired depth” that the physician intended to achieve based on the physician’s choice of cartridge. Ex. 2140 ¶87.

Mehta is directed to minimizing the variance associated with different needle insertions, recognizing that this variation affects the actual insertion depth, and providing information to the physician to compare the actual to the desired depth so that the physician can make adjustments. *Id.* ¶88. Specifically, Mehta discloses a “tissue engagement surface” that provides a “consistent starting point” to try to minimize “undesirable outcomes” where probes 104 “may be advanced too far or may not be advanced far enough.” Ex. 1006, 21:10-16. Recognizing that variation in probe depth will still occur, Mehta discloses ways for a physician to compare

“actual depth” to the “desired depth” and other ways of tracking insertion depth, as Petitioner acknowledges. Pet. 28. Modifying Mehta to add a “distance setting” would increase not only the complexity of the system, but also the variation in the depth of the probes. *Id.* 41-42; Ex. 2140 ¶88.

Petitioner ignores that Mehta was aware of distance control. For example, U.S. Patent No. 6,277,116 to Utely (“Utely”), cited in the Background of Mehta, discloses a controller that can “establish and maintain a control depth” that can be “set by the physician.” Ex. 2119 (Utely), 11:26-30. As another example, U.S. Patent Application Publication No. 2002/0120261 to Morris (“Morris ’261”), which Mehta cites and is a continuation of the Morris reference that formed the basis for the first IPR petition on the ’812 Patent, discloses electrodes that can be “advanced to a selected deployment depth.” Ex. 2120 (Morris ’261), Abstract.

Mehta understood that selection of probe depth was known but teaches a different approach to ensure that energy would be delivered to “a predetermined target area while minimizing delivery of energy to undesired region of tissue.” Ex. 1006, 2:10-12. Specifically, Mehta teaches how to consistently insert probes and how to measure and validate probe placement before delivering energy. *E.g., id.*, 12:1-4 (ultrasound “to assess the penetration depth of the electrodes”), 21:10-12 (“a consistent starting point for the probes”), 32:46-57 (“virtual depiction ... of the depth”), 39:33-36 (“impedance measurements to precisely determine depth of

placement of the active electrode portion”); Ex. 2140 ¶90. Mehta thus addressed the problem of needle insertion depth in a different way than the prior art methods of selecting among variable insertion depths for a particular set of needles.

Modifying Mehta as Petitioner proposes would not lead to “superior treatment outcomes” or “decrease[d] treatment costs” because doing so would only add variance to the treatment and complexity to the system, and would increase costs by adding additional components. Petitioner thus fails to support why a POSITA would have modified Mehta to achieve the inventions of the '812 Patent claims. Petitioner instead improperly uses those claims as a roadmap for reconstructing the claimed invention without showing that a POSITA would have been motivated to modify Mehta to achieve the claimed inventions. *Samsung Elecs. Co. v. Netlist, Inc.*, IPR2022-00063, 2023 WL 5065223, at *18 (P.T.A.B. May 3, 2023); *Vivint, Inc. v. Alarm.com Inc.*, 754 F. App'x 999, 1006-07 (Fed. Cir. 2018), *aff'd*, 856 F. App'x 300 (Fed. Cir. 2021).

F. Ground III: Petitioner fails to demonstrate that Mehta in view of Na '848 and the knowledge of a POSITA renders obvious claims 4-5

Petitioner's Ground III fail for the same reasons set forth above. *See supra* Sections IV.D and E. Petitioner does not argue Na '848 discloses or suggests the “desired distance” limitation that Mehta fails to disclose or render obvious.

Accordingly, Petitioner fails to show that claims 4-5 would have been obvious in view of Metha and Na '848. This is sufficient to deny institution as to Ground III.

G. Ground IV: Petitioner fails to demonstrate that Mehta in view of Lee renders obvious claims 2-3, 6, 8, or 13-16

Petitioner fails to show that a POSITA would have combined Mehta with Lee to achieve a motor coupled to the plurality of needles to extend the needles a “desired distance” from the needle module or assembly end surface, as required by the claims. Ex. 1001, cls. 2, 8, 13.

Again, a determination of obviousness cannot be based on hindsight, but that is precisely what Petitioner employs here by selectively culling from the prior art to try to reconstruct the claimed invention without identifying a teaching or suggestion to combine them. *Dropworks*, IPR2021-00212, Paper 7 at 13.

Petitioner superficially asserts, “A POSA would have been motivated to combine Mehta and Lee because they are directed to similar technologies and a [skilled artisan] would have understood the benefits of combining these two references.” Pet. 54 (citing Ex. 1003 ¶194). The cited paragraph of Petitioner's expert declaration simply parrots the statement in the Petition. Ex. 1003 ¶194. But even assuming Mehta and Lee relate to “similar technologies,” that merely supports that they **could** be combined; it is not a **reason** to do so. *Adidas AG v. Nike, Inc.*, 963 F.3d 1355, 1359 (Fed. Cir. 2020) (“The obviousness inquiry does not merely ask

whether a skilled artisan could combine the references, but instead asks whether they would have been motivated to do so.”), *cert. denied*, 141 S. Ct. 1376 (2021).

Petitioner otherwise argues that a POSITA would have been motivated to use Lee's motor in Mehta's system because that motor is capable of precisely controlling needle extension. Pet. 55 (A “POSA would have been motivated to modify Mehta in view of Lee to precisely control a needle extension distance along the axis of extension and thereby gain benefits taught by both Mehta and Lee....”). Petitioners' argument fails for two reasons.

First, even if a POSITA modified Mehta to use Lee's stepper motor, that would not meet the claims. As Petitioner recognizes, Mehta already discloses a stepper motor. *Id.* 54 (“Mehta discloses ... a ‘step-motor.’”). As discussed regarding Ground I (*see supra* Section IV.D), Mehta is missing any teaching of a user selecting how far the needles extend. Modifying Mehta to replace its stepper motor with Lee's, as Petitioner proposes, equally fails to meet the claims because this combination still lacks any teaching of a user selecting how far the needles extend.

Second, to the extent Petitioner argues for **other** modifications to Mehta to “configure Mehta's control system/energy supply unit 90 in the conventional manner taught by Lee—i.e., controlling a motor, via routine programming, to extend needles a desired distance corresponding to a user selection[]” Pet. 56, Petitioner fails to explain why a POSITA would have been motivated to make those modifications. A

POSITA would not have been motivated to implement a distance setting in Mehta's interface or reconfigure Mehta's control system to implement a distance control signal based on Lee.

Lee is about creating mechanical holes using a “gun” that can “vertically insert the microneedles” at a very high “speed of about 66-420 times per minute” at a particular insertion depth. Ex. 1009 ¶¶56-58. Lee's only disclosure of a user selection is a “mode switch” that can be pressed to select the mode, which “controls the speed of reciprocating insertions (number of repetitive insertions) and the insertion depth of the needles.” *Id.* ¶33. Lee does not have any “distance setting,” which Petitioner proposes to include in Mehta, and to the extent Petitioner relies on Lee's disclosure of a “mode switch,” Petitioner fails to explain why that disclosure would have motivated a POSITA to implement a distance setting in Mehta. A POSITA would not have been motivated to implement a “distance setting” in Mehta based on Lee's disclosure of a “mode switch.” Ex. 2140 ¶96.

Petitioner contends that “via routine programming” a POSITA could have “configure[d] Mehta's control[ler] ... to extend needles a desired distance corresponding to a user selection.” Pet. 56. Again, Petitioner is simply arguing changes that a POSITA conceivably could make to Mehta based on hindsight reconstruction of the claimed invention, without articulating a motivation to do so. *See, e.g., Dropworks*, IPR2021-00212, Paper 7 at 14.

Further, as discussed above, Mehta was aware of distance control (Ex. 2119, 11:26-30; Ex. 2120, Abstract; *supra* Section IV.D and E) and disclosed a different approach. A POSITA would not have been motivated to modify Mehta to add a “distance setting” in view of Lee because that would only increase the variation in “actual depth” and thus the likelihood that the probes would not be at the “desired depth” that the physician intended to achieve based on the physician’s choice of cartridge. *Supra* Section IV.D and E; Ex. 2140 ¶101.

Petitioner thus fails to explain why a POSITA would have modified Mehta in view of Lee to achieve the inventions of the '812 Patent claims. *Netlist*, 2023 WL 5065223, at *18; *Vivint*, 754 F. App'x at 1006-07.

H. Ground V: Petitioner fails to demonstrate that Mehta, Lee, Na '848 and the knowledge of a POSITA render obvious claims 4-5

For Ground V, Petitioner merely incorporates by reference its arguments for the Mehta-Lee combination as well as the Mehta-Na '848 combination in a single paragraph to conclusorily argue that “the combination of these [three] references would have been a matter of routine engineering and would have yielded predictable results.” Pet. 57-58. Petitioner’s arguments fail for the same reasons discussed above. *See supra* Sections IV.D-G.

I. Ground VI: Petitioner fails to demonstrate that Mehta, Livneh and the knowledge of a POSITA render obvious claims 9 and 18

The combination of Livneh, Mehta, and the knowledge of a POSITA does not render claims 9 and 18 obvious for at least two reasons.

First, claims 9 and 18 (by their dependency on claims 1 and 12) require a “releasably couplable deployable needle module” that is “mechanically separabl[e] from the user holdable device.” Ex. 1001, cls. 1, 12. Nothing in Livneh teaches those limitations. In fact, Livneh teaches that “housing 36” (which Petitioners map to the needle module of the '812 Patent) is “**connected**” to a “handle portion 38” (which Petitioner maps to the user holdable device). Ex. 1010, [0033]; Pet. 60. Livneh neither teaches nor suggests that housing 36 is releasably couplable or mechanically separable from handle portion 38. Knowing as much, Petitioner proposes a “Modified Livneh Device” and “Modified Livneh Method” arguing a “A POSA would have been motivated to make the connection between the housing and the handle portion in Livneh releasably couplable, as taught by Mehta.” Pet. 61. They are wrong. Ex. 2140 ¶104.

Petitioner relies on “retention fasteners 114” in Mehta’s cartridge to argue that a POSITA would modify Livneh to “make the connection between the needle module and the handle portion releasably couplable in light of Mehta’s teaching of a removable needle module.” Pet. 60-61. But the opposite is true. The “retention

fasteners” would have to be included where housing 36 connects to handle portion 38 (noted in red below). Ex. 2140 ¶105.

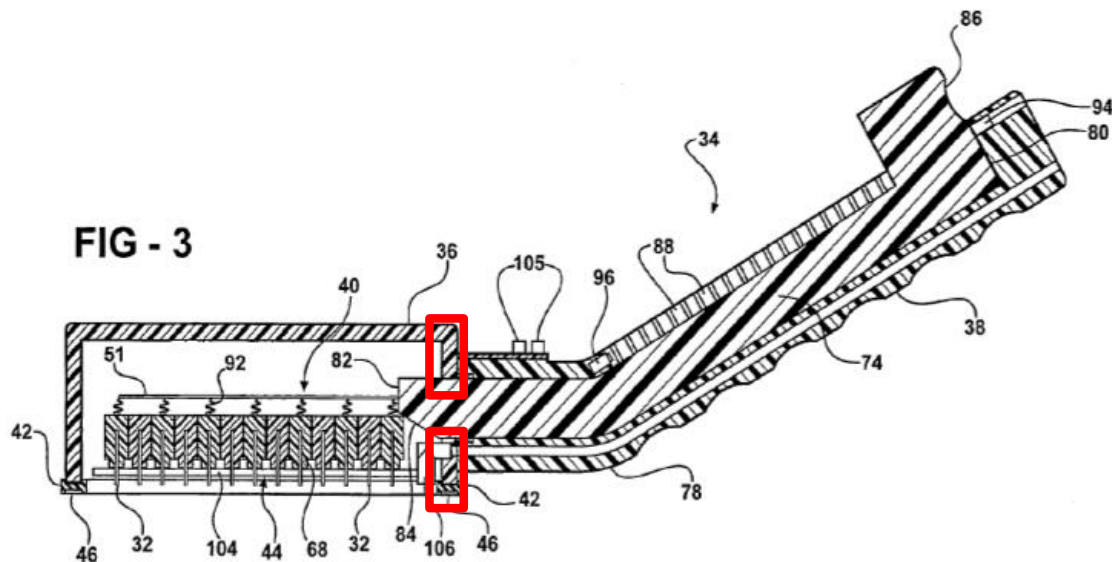


Figure 1 - Figure 3 of Ex. 1010 (Livneh) (annotated)

Making housing 36 releasably couplable as Petitioner contends would leave mechanism 74 exposed, risking potential damage to mechanism 74 and therefore lack of engagement with the electrodes to move them from a first to a second position as Livneh teaches. Ex. 2140 ¶106; Ex. 1010, [0044], [0045]. Therefore, a POSITA would not be motivated to modify Livneh as Petitioner contends. Ex. 2140 ¶106.

Even if “retention fasteners” were included, housing 36 and handle portion 38 would still be electrically connected. Petitioner admits as much, acknowledging the electrical connections between the needle module and the handle portion of Livneh. Pet. 61; Ex. 1010, [0049], Figs. 10 & 11. Other than summarily contending that

“[m]aking the needle module in Livneh releasably couplable to the handle portion would have been a matter of routine engineering” (Pet. 63), Petitioner fails to explain how a POSITA would modify the wires and electrical connections in Livneh to arrive at the claimed invention.

Specifically, Petitioner does not explain what modifications would need to be made not just to housing 36 and handle portion 38, but to the electrode carrier and its components, including wires 51, coils 92, combs 62, holder 68, and others. Ex. 1010, [0048]-[0049]. That is particularly relevant to the portion of the '812 Patent claims requiring that “at least one electrical contact of the needle assembly remains electrically coupled to at least one electrical contact of the user holdable device proximal end” while the needle assembly moves within the needle module. Ex. 1001, cls. 1, 12. Petitioner brushes past that limitation, merely arguing that “there must be at least one electrical contact disposed on the proximal end of the handle portion such that, when the device is coupled thereto, said at least one electrical contact contacts a corresponding at least one electrical contact disposed on the needle module or a component thereof[.]” Pet. 71-72. Petitioner fails to explain why the electrical contact would be located in the proximal end of the user holdable device versus elsewhere.

Petitioner also argues that “[a] POSA would also have been motivated to use detachable needle cartridges to easily replace damaged or contaminated needles”

(Pet. 61), but even Petitioner acknowledges that Livneh already discloses replaceable needles in a non-releasably couplable needle module. *Id.* Replacing a single needle if damaged would be more cost effective than replacing an entire needle module with the full array of needles. Ex. 2140 ¶108.

Second, modifying Livneh as Petitioner proposes would not lead to claims 9 and 18, which require that at least one of the electrical contacts include a “pin that is extendable in the same direction as the plurality of needles.” Ex. 1001, cls. 9, 18. Nowhere does Petitioner argue that Mehta satisfies that limitation. *See, e.g.*, Grounds I & II. Instead, Petitioner relies on Livneh’s coil 92 (Pet. 72-75), but a coil is different from a pin. Petitioner admits as much, arguing simply that coil 92 of Livneh “operates in the same manner and performs the same function” as the pin illustrated in the Figures of the ’812 Patent. *Id.* 75. But that too is incorrect, and relevant to an obviousness analysis, a POSITA would not be motivated to replace Livneh’s coils with a pin because this would risk damaging the pins as mechanism 74 moves from a retracted to an extended position since a pin does not have the same degrees of freedom as a coil. Ex. 2140 ¶109; Ex. 1010, [0046] & Figs. 3-4.

Petitioner thus fails to explain why a POSITA would have modified Livneh in view of Mehta to achieve the inventions of the ’812 Patent claims. *Netlist*, 2023 WL 5065223, at *18; *Vivint*, 754 F. App’x at 1006-07.

J. Objective Indicia Of Nonobviousness Supports That Grounds II-VI Fail To Raise A Substantial Question Of Patentability

Whether patent claims would have been obvious to a POSITA is a legal question assessed based on underlying factual findings, known as the *Graham* factors. *See generally KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The Federal Circuit has “repeatedly emphasized that an obviousness inquiry requires examination of ***all four*** *Graham* factors and that an obviousness determination can be made only after consideration of each factor.” *Nike, Inc. v. Adidas AG*, 812 F.3d 1326, 1335 (Fed. Cir. 2016), *aff'd*, No. 2021-1903, 2022 WL 4002668 (Fed. Cir. Sept. 1, 2022). And “when secondary considerations are present ... it is error not to consider them.” *Id.* at 1339 (emphasis omitted).

Here, evidence of secondary considerations is present, and Petitioner has been on notice of that evidence since at least June 16, 2023, through Patent Owner's validity contentions in the 1356 Investigation. Ex. 2054. Indeed, because Petitioner waited until after the evidentiary hearing in the ITC and post-hearing briefing to file its Petition, Petitioner filed its Petition with knowledge of the full evidentiary record on secondary considerations developed in the ITC. Respondents failed to address Patent Owner's evidence of secondary considerations at all in the ITC and Petitioner also fails to do so here. This alone is sufficient to deny institution on the merits.

The Board has repeatedly admonished petitioners that they cannot ignore known evidence of secondary considerations. *Semiconductor Component Indus.*,

LLC v. Power Integrations, Inc., IPR2016-01588, Paper 15 at 29 (P.T.A.B. Feb. 17, 2017) (denying institution and presuming the commercial success was due to the patented invention when the “Petitioner was well aware of evidence of objective considerations from the prior litigations, and elected not to address them in the Petition”); *Coal. for Affordable Drugs V LLC v. Hoffman-LaRoche, Inc.*, IPR2015-01792, Paper 14 at 17-18 (P.T.A.B. Mar. 11, 2016) (denying institution where petitioner failed to address objective indicia presented during prosecution); *Merial Ltd. v. Virbac*, IPR2014-01279, Paper 13 at 27 (P.T.A.B. Jan. 22, 2015) (denying institution for failure to address objective indicia, noting “Merial was aware of the unexpected results showing which the Examiner found persuasive.... Merial should have addressed unexpected results in the first instance”); *Omron Oilfield & Marine Inc. v. MD/TOTCO*, IPR2013-00265, Paper 11 (P.T.A.B. Oct. 31, 2013) (denying institution for failure to address objective indicia successfully argued in a reexamination).

When, as here, an expert “fail[s] to account for objective evidence of nonobviousness, [his or her] analysis [i]s incomplete, and ultimately insufficient to establish obviousness,” and thus the expert cannot offer an “ultimate question of obviousness” because the “expert must consider all factors relevant to that ultimate question” to render an opinion on it. *InTouch Techs., Inc. v. VGO Commc’ns, Inc.*, 751 F.3d 1327, 1352 & n.8 (Fed. Cir. 2014). Because Petitioner’s expert failed to

consider all four *Graham* factors, his analysis is incomplete and his opinion on the ultimate issue of obviousness is not competent. *Id.*; see also *Inline Plastics Corp. v. Lacerta Grp., LLC*, 97 F.4th 889 (Fed. Cir. 2024).

1. The '812 Patent has achieved commercial success

The Sylfirm X [REDACTED], is one of the many products that practices the '812 Patent. Ex. 2140 ¶¶110-135. As explained above, the '812 Patent claims extending a plurality of needles into the skin a desired distance based on user selection. See *supra* Section IV.A.1. This is one of the main features of the '812 Patent. The brochure for the Sylfirm X highlights that very feature, noting that “[t]reatment depth ... [is] adjustable by the user[.]” to deliver the “most direct and accurate energy into the skin without any thermal damage to the skin surface[.]” and to treat different medical indications such as rosacea, melasma, and others. Ex. 2037 (Sylfirm X Brochure), 10, 13. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Treatment success depends on precise placement of the coagulation in the tissue, which is achieved by the RF energy delivered through the needles. Ex. 2140

¶137. If the needles are inserted too deeply, the treatment could have an adverse consequence. Thus, the “desired distance” as claimed in the ’812 Patent allows more indications for these products to treat more types of patients, which is a deciding factor in purchasing decisions. *Id.*

The Sylfirm X has achieved commercial success due in part to implementation of the inventions claimed in the ’812 Patent. Ex. 2140 ¶¶136-138. As Patent Owner’s economic expert, Mr. Thomas explains, the Sylfirm X has been commercially successful. Ex. 2141 (Thomas Decl.), ¶¶14-15. [REDACTED]

[REDACTED] Thus, the Sylfirm X has been commercially successful, and there is a nexus between the ’812 Patent and Sylfirm X’s commercial success.

2. The ’812 Patent has obtained industry praise

Extending needles a desired distance and a mechanism for precise needle depth control as claimed by the ’812 Patent and the products implementing the inventions have received industry praise and recognition. *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1334 (Fed. Cir. 2016); Ex. 2140 ¶139. For example, medical providers have praised the products that use this technology for their ability to “accurately target and treat[]” at the desired skin depth. Ex. 2066, 3; Ex. 2122, 2. That former respondents in the ITC, including former petitioner, Cartessa have praised the patented technology in their brochures and magazine placements is

indicative of non-obviousness. *WBIP*, 829 F.3d at 1334 (“competitors, are not likely to praise an obvious advance over the known art”). Further, in 2020, ViOL [REDACTED], also received a world-class product award for the Sylfirm X in Korea. Ex. 2067 (Sylfirm X Award).

Thus, the technology claimed in the '812 Patent has become widely recognized and praised, and “[r]ecognition of the importance of this advance is relevant to a determination of nonobviousness.” *Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573, 1579 (Fed. Cir. 1997); *WBIP*, 829 F.3d at 1334 (“competitors, are not likely to praise an obvious advance over the known art”).

V. CONCLUSION

For the reasons set forth above, the Board should deny the Petition for Inter Partes Review.

Respectfully submitted,

Dated: May 22, 2024

By: / Charles H. Sanders /

Charles H. Sanders (Reg. No. 47,053)
charles.sanders@lw.com
Latham & Watkins LLP
200 Clarendon Street
Boston, MA 02116
Telephone: 617.948.6000
Fax: 617.948.6001

*Counsel for Patent Owner
Serendia, LLC*

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

I hereby certify that this Patent Owner's Preliminary Response complies with the word count limitation of 37 C.F.R. § 42.24(b)(1) because the Patent Owner's Preliminary Response contains 13,988 words using Microsoft Word's counting feature, excluding the cover page, signature block, and the parts of the Patent Owner's Preliminary Response exempted by 37 C.F.R. § 42.24(b)(1).

By: / Charles H. Sanders /

Charles H. Sanders (Reg. No. 47,053)
charles.sanders@lw.com
Latham & Watkins LLP
200 Clarendon Street
Boston, MA 02116
Telephone: 617.948.6000
Fax: 617.948.6001

*Counsel for Patent Owner
Serendia, LLC*

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that on this 22nd day of May, 2024, a true and correct copy of the foregoing **Patent Owner's Preliminary Response and all Exhibits** were served by electronic mail on Petitioner's lead and backup counsel at the following email addresses:

Wesley O. Mueller
Leonard Z. Hua
Paul J. Filbin
Brent A. Chatham (Reg. No. 73,954)
LEYDIG, VOIT & MAYER, LTD.
Two Prudential Plaza, Suite 4900
180 North Stetson Avenue
Chicago, Illinois 60601-6731
Tel.: 312.616.5600
Fax: 312.616.5700
wmueller@leydig.com
lhua@leydig.com
pfilbin@leydig.com
bchatham@leydig.com
Jeisys-IPR@leydig.com

By: / Charles H. Sanders /

Charles H. Sanders (Reg. No. 47,053)
charles.sanders@lw.com
Latham & Watkins LLP
200 Clarendon Street
Boston, MA 02116
Telephone: 617.948.6000
Fax: 617.948.6001

*Counsel for Patent Owner
Serendia, LLC*