

Filed on behalf of: Serendia, LLC

Entered: April 23, 2024

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

JEISYS MEDICAL INC. and ILOODA CO., LTD.,
Petitioner,

v.

SERENDIA, LLC,
Patent Owner.

Case IPR2024-00383
Patent 9,775,774

**PATENT OWNER'S
PRELIMINARY RESPONSE**

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Exhibit List

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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)

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2016	Complainant's Public Interest Statement & Complaint of Serendia, LLC, Under Section 337 of the Tariff Action of 1930, as Amended, <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	Ilooda'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)
2021	Jeisys Medical Inc.'s and Cynosure, LLC's Response to the Complaint and Notice of Investigation, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C. May 1, 2023)
2022	Letter from Merle W. Richman, CKR Law, to Justin S. Cohen, Thompson & Knight LLP, Cutera, dated March 20, 2018
2023	Letter from Keith K. Im, SynKloud Technologies, LLC, to Todd Tillemans, Cynosure, LLC, dated Nov. 29, 2021
2024	Order No. 33: Granting Parties' Joint Motion to Amend the Amended Procedural Schedule [Motion Docket No. 1356-027], <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C. Oct. 19, 2023)

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2025–2036	RESERVED
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, Sylfirm X Revolutionises [sic] the Clinical Applications of RF Microneedling, 12 PRIME INT'L J. AESTHETIC ANTI-AGEING [sic] MED. 50 (2022)

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2067	World-Class Product of Korea 2020, Certificate to ViOL Co., Ltd., dated December 9, 2020 ("Sylfirm X Award")
2068–2069	RESERVED
2070	<i>Curriculum Vitae</i> 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
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2097	Sylfirm X Introduction Video 1
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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)

Exhibit	Description
2105	Statement Under 37 C.F.R. § 3.73(c) and Disclaimer in a Patent Under 37 C.F.R. § 1.321(a) of U.S. Patent 9,775,774 ('774 Patent) ("Disclaimer")
2106–2107	RESERVED
2108	U.S. Patent Application Publication No. 2002/0120260 A1 ("Morris")
2109	U.S. Patent Application Publication No. 2003/0130711 A1 ("Pearson")
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	Appendix 6 to Respondents' Final Invalidity Contentions, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C. July 10, 2023)
2114	File History for U.S. Patent No. 9,320,536
2115	U.S. Patent No. 6,890,319 B1 ("Crocker")
2116	U.S. Patent No. 10,869,812 B2 ("812 Patent")
2117	U.S. Patent No. 8,540,705 B2 ("Mehta '705")
2118	File History for U.S. Patent No. 10,869,812
2119	U.S. Patent. No. 6,277,116 B1 ("Utely")

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2120	U.S. Patent Application Publication No. 2002/0120261 A1 (“Morris ’261”)
2121	RESERVED
2122	Cartessa Aesthetics, <i>Innovations in RF Microneedling: A Closer Look at VirtueRF</i> , Observations Aesthetics, Issue No. 1 (June 2021)
2123	Declaration of Peter Crosby, dated April 22, 2024 (“Crosby Decl.”) (PROTECTIVE ORDER MATERIAL AND REDACTED VERSIONS)
2124	Declaration of Vincent A. Thomas, dated April 22, 2024 (“Thomas Decl.”) (PROTECTIVE ORDER MATERIAL AND REDACTED VERSIONS)
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.”)
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)
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I. Introduction

Petitioners Ilooda Co., Ltd.'s ("Ilooda's") and Jeisys Medical Inc.'s ("Jeisys's") petition for *inter partes* review ("IPR") of U.S. Patent No. 9,775,774 (the "'774 Patent") should be denied for two reasons. First, this is the second petition filed against the '774 Patent, and the Board should exercise its discretion to reject this serial attack, long after the Board denied a first petition. Second, even if the Board were to reach the merits, this second petition—like the first—fails to show a reasonable likelihood of establishing that any claim of the '774 Patent is unpatentable.

First, the Board should exercise its discretion to deny institution under *General Plastic*. Petitioners not only filed this second petition long after the Board denied institution of the first petition, but also after Petitioners fully litigated the prior art presented here. Specifically, Petitioners were aware of their alleged infringement of the '774 Patent before filing of the first petition and were co-respondents with the prior Petitioners in a parallel litigation in the U.S. International Trade Commission ("ITC"). The current and former Petitioners filed a joint notice of prior art in May 2023—***more than seven months*** before the Petition—identifying each prior art reference in the second petition.

Rather than promptly pursuing IPR, the current Petitioners tactically delayed, waiting until they fully litigated their invalidity arguments through the evidentiary

hearing in the ITC and post-hearing briefing. Petitioners Ilooda and Jeisys chose to wait to file this IPR until after seeing Patent Owner's validity experts testify, cross examining them, and seeing Patent Owner's validity arguments in post-hearing briefing. Petitioners thus not only used Patent Owner's prior Preliminary Response and the Board's prior Institution Decision as a roadmap for their petition, but also delayed filing their petition until they had the *full benefit* of seeing *all* the evidence and arguments Patent Owner presented in response to Petitioners' invalidity case in the ITC. Indeed, the Board's discretionary denial authority exists to prevent such gamesmanship. Patent Owner respectfully requests that the Board exercise that authority to deny institution under § 314(a).

Second, even if the Board were to reach the merits, the second petition is at least as deficient as the previously-denied petition. Patent Owner has disclaimed claims 1-12 and 15-20 (Ex. 2105 (Disclaimer)), leaving only claims 13 and 14 at issue. Petitioners' primary reference in the second petition, U.S. Patent No. 8,608,737 ("Mehta"), is directed to an entirely different approach than claims 13-14 of the '774 Patent. Specifically, those claims relate to a dermatological treatment device with a microneedle cartridge, where the needles are deployed a desired distance based on selection by a user. This approach provides precise control over the depth of needle insertion into dermatological tissue so that energy can be delivered to those needles to treat that target tissue. Conversely, Mehta's system does

not permit the user to select the distance that the needles extend. Mehta discloses a treatment device that requires using different cartridge configurations (e.g., different needle lengths or angles), to reach different target depths. Rather than precise depth control, Mehta discloses a verification approach to check whether the already extended needles are in the correct region of tissue before applying energy. In Mehta, if the needles are not at the right depth, then the needles are repositioned manually or a new cartridge with a different needle configuration is selected.

Furthermore, despite waiting until after receiving full exposition of Patent Owner's objective indicia evidence of non-obviousness in the ITC, Petitioners fail to rebut that evidence. Nor can they. Petitioners' 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 The *General Plastic* Factors

A. Background Of The Denial Of Institution Of The First IPR Petition

On August 6, 2021, Patent Owner sued Cartessa Aesthetics, LLC ("Cartessa") in District Court for infringing multiple patents, including the '774 Patent. *See SynKloud Techs., LLC v. Cartessa Aesthetics, LLC*, No. 2:21-cv-04423 (E.D.N.Y. Aug. 6, 2021), ECF No. 1. Patent Owner also asserted U.S. Patent Nos. 9,320,536

(the “536 Patent”) and 10,869,812 (the “812 Patent”) (both related to the ’774 Patent), as well as U.S. Patent No. 9,480,836 (the “836 Patent”).

On December 28, 2021, Cartessa petitioned for IPR challenging claims 1-7 and 9-19 of the ’774 Patent. *Cartessa v. Serendia, LLC*, IPR2022-00376, Paper 1 (P.T.A.B. Dec. 28, 2021) (“*Cartessa I*”). The single invalidity ground presented relied on U.S. Patent Application Publication Nos. 2002/0120260 to Morris, et al. and 2003/0130711 to Pearson, et al. Ex. 2108 (Morris); Ex. 2109 (Pearson). Patent Owner filed its Patent Owner Preliminary Response (“POPR”) on April 18, 2022. *Cartessa I*, IPR2022-00376, Paper 8. On June 27, 2022, the Board denied institution. *Id.*, Paper 9.

On February 10, 2022, Cartessa also petitioned for IPR challenging all the claims of the ’836 Patent, including based on the same Mehta reference Petitioners now rely on in this second Petition against the ’774 Patent. *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 as well. *Id.*, Paper 9.

Cartessa petitioned for IPR of the ’536 and ’812 Patents (which are related to the ’774 Patent), and the Board also denied institution of IPR as to those patents. *Cartessa v. Serendia, LLC*, IPR2022-00378, Paper 9 (P.T.A.B. June 30, 2022) (“*Cartessa III*”); *Cartessa v. Serendia, LLC*, IPR2022-00377, Paper 9 (P.T.A.B. June 28, 2022) (“*Cartessa II*”).

B. The Current And Former Petitioners Fully Litigated the Issues Raised in the Petition In The ITC

About nine months after the Board denied the first petition, on March 1, 2023, Patent Owner filed additional District Court complaints alleging infringement of the '774 Patent (and others), against various parties, including Cynosure, LLC ("Cynosure") and Cutera, Inc. ("Cutera"). The same day, Patent Owner also filed an ITC complaint alleging infringement of the '774 Patent (and others), against the named District Court defendants, as well as Cynosure's and Cutera's Korean suppliers: Jeisys and Ilooda, the current Petitioners. *Certain Dermatological Treatment Devices and Components Thereof*, No. 337-TA-1356 (the "1356 Investigation").

On May 24, 2023, the respondents in the ITC, including the former and current Petitioners, filed a Notice of Prior Art. There they identified each of the prior art references raised in this second IPR petition. Ex. 2053 (1356 Investigation NOPA). In addition to identifying each of the prior art references in this second IPR petition, the Notice of Prior Art identified a second Lee reference, KR 10-0852500 to Lee ("Lee '500"), which has similar disclosures to the Lee reference Petitioners now rely on. *Compare* Ex. 2110 (Lee '500), *with* Ex. 1011 (Lee). On June 2, 2023, the ITC respondents served an Amended Notice of Prior Art that removed the Lee reference Petitioners now rely on in their second petition, but kept Lee '500. Ex. 2111 (1356 Investigation Amended NOPA).

On June 16, 2023, Patent Owner served its Initial Validity Contentions, responding to the contentions that the '774 Patent claims were invalid in view of this prior art. Notably, Patent Owner addressed Petitioners' allegations that the '774 Patent claims were invalid in view of Mehta and Lee '500. Ex. 2054 (Patent Owner's June 16, 2023 Initial Validity Contentions). One month later, Patent Owner provided its Supplemental Validity Contentions, again addressing Respondents' contentions that the '774 Patent claims were invalid in view of Mehta and Lee '500. *See* Ex. 2003 (Patent Owner's July 24, 2023 Supplemental Validity Contentions).

On August 14, 2023, the respondents in the ITC, including the current and former Petitioners, jointly served the Expert Report of Dr. Woloszko on the purported invalidity of the patents asserted in the 1356 Investigation, in which he opined that '774 Patent claims 13 and 14 were invalid. *See* Ex. 2004 (August 14, 2023 Woloszko Expert Report). Dr. Woloszko presented alleged invalidity grounds based on Mehta and other references. *Id.* Patent Owner served the Rebuttal Expert Report of Mr. Crosby on validity explaining why Dr. Woloszko failed to show that claims 13 and 14 of the '774 Patent were invalid. Ex. 2112 (August 28, 2023 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 in the ITC, including Petitioners Jeisys and Ilooda, presented

testimony from Dr. Woloszko, again alleging that the asserted claims of the '774 Patent were invalid in view of Mehta. *See* Ex. 2125 (Woloszko Hr'g Tr.). The Patent Owner presented rebuttal testimony from Mr. Crosby, explaining why the asserted claims of the '774 Patent were valid. *See* Ex. 2126 (Crosby Hr'g Tr.). All the experts were cross-examined about their opinions. Exs. 2125, 2126.

On January 5, 2024, the parties submitted post-hearing briefing on validity. *See* Ex. 2015 (Serendia's Rebuttal Post-Hearing Brief); Ex. 2019 (Respondents' Post-Hearing Brief). Patent Owner filed its rebuttal brief on validity on January 5, 2024. Ex. 2015 (Serendia's Rebuttal Post-Hearing Brief). On January 8, 2024, Petitioners Ilooda and Jeisys 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 Elec. 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 16-17 (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 Heavily 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. 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

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). Even in instances where the petitioners were not

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

involved in the same litigation, the Board has considered other factors, such as awareness of the infringement allegations, sharing of information, and coordination among the petitioners in the separate litigations, to find a significant and meaningful relationship between them. *Mitek Sys., Inc. v. United Servs. Auto. Assoc.*, IPR2020-00882, Paper 29 at 17 (P.T.A.B. Nov. 6, 2020) (finding Factor 1 favored denial because “there [was] 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 indisputably challenges claims 13 and 14, just as the prior petition. *Compare Cartessa I*, IPR2022-00376, Paper 1, *with* Pet. Further, Petitioners Ilooda and Jeisys, and prior Petitioner Cartessa, were “co-defendants” in parallel infringement 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 procedural schedule in the ITC, which the Administrative Law Judge adopted. Ex. 2017 (April 24, 2023 Joint Submission of Schedule); Ex. 2018 (April 27, 2023 Procedural Schedule). Moreover, the level of coordination between the prior and current Petitioners case goes significantly beyond merely presenting initial invalidity contentions and a claim construction statement (as was the case in *Ford Motor Co. v. Neo Wireless*). As co-respondents in the ITC, Petitioners Ilooda and Jeisys, and prior Petitioner Cartessa, 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 Petitioners rely on here. Ex. 2004; Ex. 2125. Petitioners then submitted a joint invalidity defense in their post-hearing briefing, relying on the positions presented at the hearing. Ex. 2019.

Additional relevant and extenuating facts and circumstances further warrant 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. Petitioners Illooda and Jeisys, and prior Petitioner Cartessa, are part of the same RF microneedling manufacturing and distribution community. Ex. 2020 (Illooda 1356 Investigation Complaint Response), ¶3.13; Ex. 2021 (Jeisys 1356 Investigation Complaint Response (Public)), ¶3.17. And, as in *Mitek Systems*, Petitioner Jeisys was indisputably on notice of its potential infringement of the ’774 Patent before the first IPR petition was filed on December 28, 2021. Specifically, Patent Owner sent Cynosure, the U.S. distributor for Petitioner Jeisys, a notice letter on November 29, 2021 (Ex. 2023 (Notice Letter to Cynosure), [REDACTED]).

Petitioner Illooda was also aware of its infringement since Patent Owner sent its U.S. distributor Cutera a notice letter on the patent to the ’774 Patent on March 20, 2018. Ex. 2022 (Notice Letter to Cutera).

Further, as discussed below, *infra* Section II.B, since at least May 24, 2023, when they filed their Notice of Prior Art in the 1356 Investigation, Petitioners were aware of each reference they now rely on. Ex. 2053. This Notice of Prior Art, filed jointly by Petitioners Ilooda and Jeisys and prior Petitioner Cartessa, confirms that Petitioners Ilooda and Jeisys were aware of the prior art asserted in this second Petition *more than seven months* prior filing of this Petition. Thus, Petitioners Ilooda and Jeisys tactically waited to file the present petition until *after* they had fully presented their joint invalidity case, working hand-in-hand with prior Petitioner Cartessa throughout the ITC proceedings. *See infra* Section II.B. This tactical delay, paired with the significant coordination between the prior and current Petitioners throughout the entirety of 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 Petitioners who: (i) were on notice of their potential infringement before the prior petition's filing; (ii) were aware of litigation filed against other RF microneedling manufacturers and distributors before the prior petition's filing; (iii) were co-defendants with the prior petitioners 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 their 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 has considered whether the petitioner would have some reason to begin searching for relevant 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,

[REDACTED]

[REDACTED]. And Petitioner Ilooda was also on notice of its potential infringement of the '774 Patent since at least March 20, 2018. Ex. 2022. Therefore, they both would have had a reason to begin

searching for relevant prior art long before the first petition was filed on December 28, 2021. 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 since the references used terms in common with the challenged patent).

Here, Petitioners Ilooda and Jeisys rely on Mehta as their primary reference. Both Mehta and the '774 Patent include classifications as surgical patents (USPC

classifications 606 and 607, respectively). *Compare* Ex. 1004 (Mehta), *with* Ex. 1001 ('774 Patent). As Petitioners admit, Mehta uses similar terminology as the '774 Patent, including claim terms such as 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 '774 Patent, and further uses similar terminology as the '774 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 (a continuation of the '774 Patent), the Examiner considered Mehta as U.S. Patent No. 8,540,705 (“Mehta '705”) (Ex. 2117), which has the substantially same disclosures as Mehta. Ex. 2123 (Crosby Decl.), ¶¶70-71. Similarly, Lee relates to a skin regeneration apparatus where microneedles are inserted into tissue and uses similar terminology as the '774 Patent. *See* Ex. 1011, Abstract.

Further, since Petitioners cited each of the references they now assert in the May 24, 2023 Notice of Prior Art in the ITC, Petitioners indisputably were aware of these references ***more than seven months*** before filing this second Petition. *See* Ex. 2053.

In short, at the time of the filing of the prior petition, Petitioners Ilooda and Jeisys (co-defendants of the original Petitioner Cartessa), either explicitly knew of the prior art asserted in their second petition or “presumably could have been

uncovered with a reasonably diligent search.” *Shanghai Lunion*, IPR2018-00995, Paper 12 at 17. Thus, Factor 2 weighs in favor of 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. As the Board has explained, “factor 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 on Institution. *See, e.g., Shanghai Lunion*, IPR2018-00995, Paper 12 at 18 (denying institution where the petitioner had ample opportunity to study the arguments raised by Patent Owner, as well as 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, the Board has found that this factor weighs “*strongly*” against institution where there is evidence that the petitioner adjusted its arguments in the subsequent petition to account for those made in the prior Patent Owner Preliminary Response and for the Board’s Institution Decision. For example, in *Shenzhen I*, the Board noted that in the second petition the petitioner preempted a claim construction argument based on the Patent Owner’s Preliminary Response to the first petition. IPR2018-00761, Paper 15 at 12. The petitioner 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 Petitioners adjusted their 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 I*, IPR2022-00376, Paper 1 at 11 (describing Morris). In the POPR, Patent Owner explained that Petitioner’s proposed combination would not have taught a number of limitations, including “a method or apparatus for ‘treating

dermatological tissue” as recited in the claims, 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 6-9. Informed by Patent Owner’s argument and the Board’s agreement with it, the current Petitioners rely on Mehta and Lee, which are directed toward treatment of dermatological tissue.

As in *Shenzhen I*, Petitioners Ilooda and Jeisys adjusted their arguments in this second petition in view of Patent Owner’s prior Preliminary Response and the Board’s Institution Decision. This strongly indicates that Petitioners 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 Petitioners Ilooda and Jeisys use Patent Owner’s Preliminary Response and the Board’s prior Institution Decision to inform the positions in their second petition, they *also* tactically delayed filing their second petition to benefit from studying Patent Owner’s validity positions ***all the way through the evidentiary hearing***. See, e.g., Ex. 2024 (1356 Investigation, Order No. 33) (setting the final date of the evidentiary hearing for December 12, 2023). Indeed, Petitioners waited to file their Petitions until ***after*** receiving Patent Owner’s post-

hearing brief explaining why Mehta does not invalidate the claims, taking into account all the expert testimony on validity. Ex. 2015.

When, as here, a party waits to file a subsequent petition until after validity positions have been disclosed in related proceeding, the Board has held that 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.”).

Petitioners Illooda and Jeisys not only waited to file this second petition until ***after*** they had the benefit of receiving the Patent Owner’s full evidentiary presentation on validity and exposition of its validity positions in post-hearing briefing in the ITC, but also used this information to inform the arguments in their 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). Petitioners now expressly seek to preempt the plain meaning interpretation that Patent Owner's expert applied in the ITC in explaining why Metha's "fixed" needles do not meet this limitation. Petitioners argue that "Patent Owner's interpretation should be rejected" and that it is "inconsistent" with the '774 Patent's claims. Pet. 16-17. Thus, Petitioners are making direct use of Patent Owner's expert testimony in framing the arguments in their Petition.

As another example, in their invalidity contentions in the ITC, Petitioners presented **23 different invalidity grounds** for each of claims 13 and 14 of the '774 Patent alone. Ex. 2113 (Appendix 6 to Respondents' Final Invalidity Contentions). After having the benefit of Patent Owner's responses, Petitioners dropped all but one of those grounds (anticipation based on Mehta), and now assert a new ground based on the combination of Mehta and Lee, having had the benefit of the Patent Owner's responses to the combination of Mehta and Lee '500 that Petitioners proposed (and then dropped) during the 1356 Investigation. Petitioners evidently changed their minds about relying on Mehta-Lee combination after reviewing Patent Owner's post-hearing briefing explaining why Mehta alone does not render claims 13 and 14 invalid.

In short, in crafting the arguments in their petition, Petitioners Ilooda and Jeisys have 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**” weighs in favor of 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).

Petitioners Ilooda and Jeisys indisputably were aware of the asserted prior art no later than May 24, 2023, when they filed their Notice of Prior Art in the ITC identifying the same references on which they now rely. *See* Ex. 2053. Petitioners thus were aware of these references ***at least seven months*** before filing their Petition against the '774 Patent. This lengthy delay alone “***strongly***” weighs in favor of denial of institution—it is substantially longer than other delays have supported 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).

Petitioners provide *no explanation whatsoever* for their lengthy delay. Petitioners’ failure to offer *any* explanation for their delay, let alone an “adequate” explanation, 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 Petitioners' long delay and lack of any explanation for it, and powerfully favor 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*, PR2016-01357, 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 that the Board addressed in deciding whether to institute the first Petition.

Petitioners argue that reviewing this petition would further “the Board's mission to improve patent quality” (Pet. 72), but the Board already has served this mission by considering the first petition on the merits. Petitioners' second Petition,

which is a “sequential attack[] against the same claims” challenged in the first Petition, where Petitioners 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).

Petitioners also rely on *Western Digital* to assert that a petition filed “by a different petitioner ..., applying substantially different prior art, based on substantially different arguments,” “cannot be said to be wasteful of resources of the Board.” Pet. 75 (original alteration) (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, there is substantial evidence that Petitioners Ilooda and Jeisys 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 Decision on Institution but also Patent Owner's full evidentiary presentation and briefing on validity in related litigation. This behavior is "of particular concern" and weighs heavily against institution. *Gen. Plastic*, IPR2016-01357, Paper 19 at 11.

In short, Petitioners' second attack against the '774 Patent claims—purposely staggered to benefit from earlier IPR filings and full litigation on 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 IP*") (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 petitioner were co-respondents in the ITC and filed their invalidity contentions at the same time; thus, the Board found that 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, Petitioners Ilooda and Jeisys were on notice of the ’774 Patent before the prior Petition was filed, were co-respondents 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 they assert here. Thus, Petitioners tactically delayed to have the benefit of Patent Owner’s fully developed record at the ITC. *See supra* Sections II.B, D.1, and D.5. Therefore, for the same reasons as in *Shenzhen II*, proposed Factor 8 favors denial of institution.

III. None of the Grounds Petitioners Present Show a Reasonable Likelihood of Prevailing as to Any of the Challenged Claims

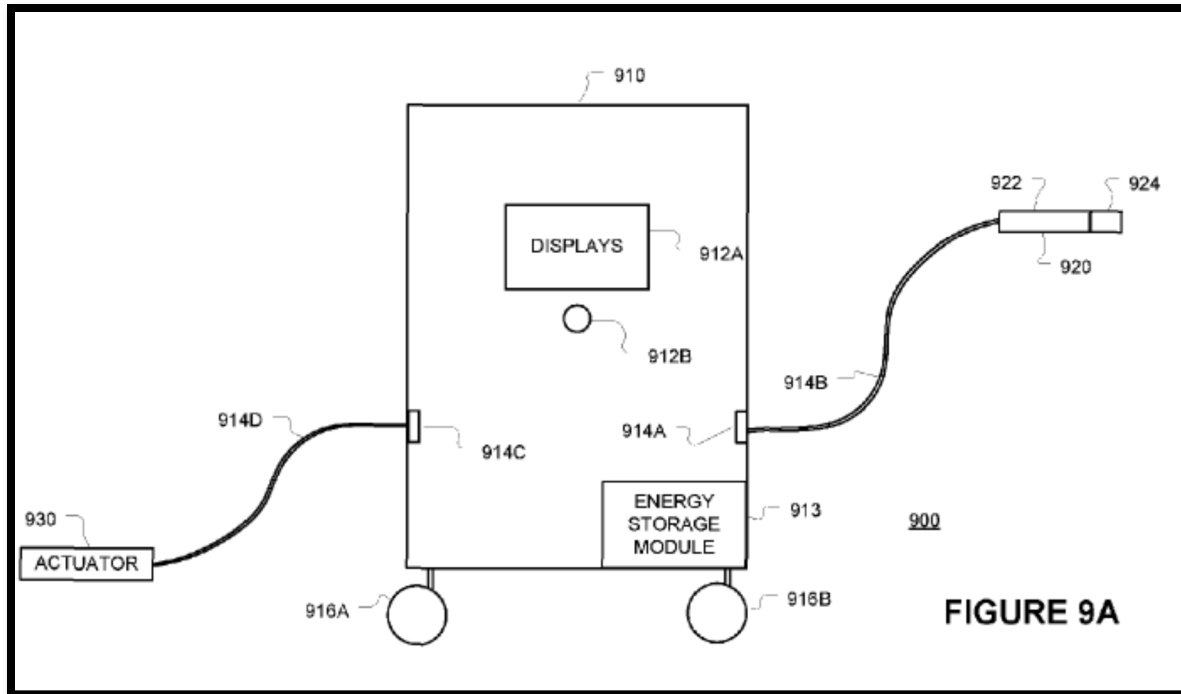
IPR shall only be instituted if the Petition “demonstrates that there is a reasonable likelihood that at least one of the claims challenged in the petition is unpatentable.” 37 C.F.R. § 42.108(c). And as the Federal Circuit has emphasized, “the petitioner has the burden from the onset to show with particularity why the

patent it challenges is unpatentable.” *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016); 37 C.F.R. § 42.20(c); *see also* Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,763 (2012). Here, Petitioners have failed to do so.

A. Background

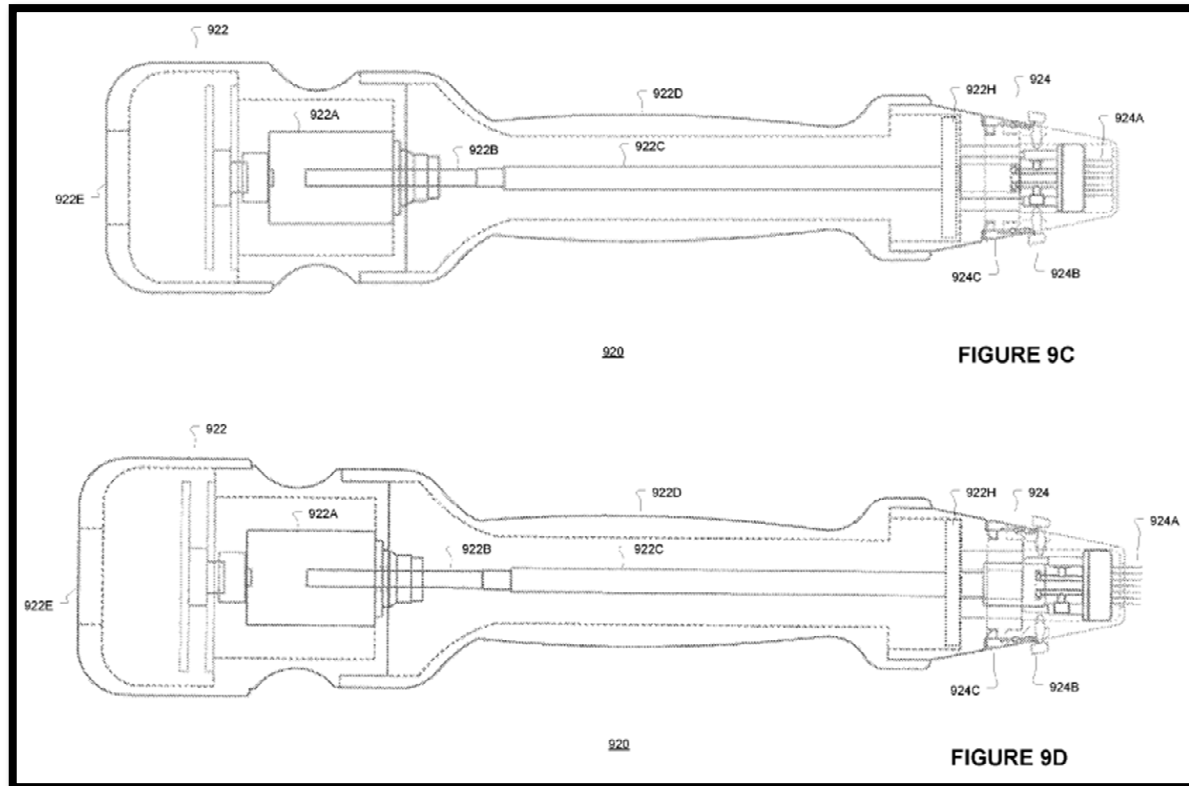
1. The '774 Patent (Ex. 1001)

The '774 Patent claims at issue 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, 9:39-43.



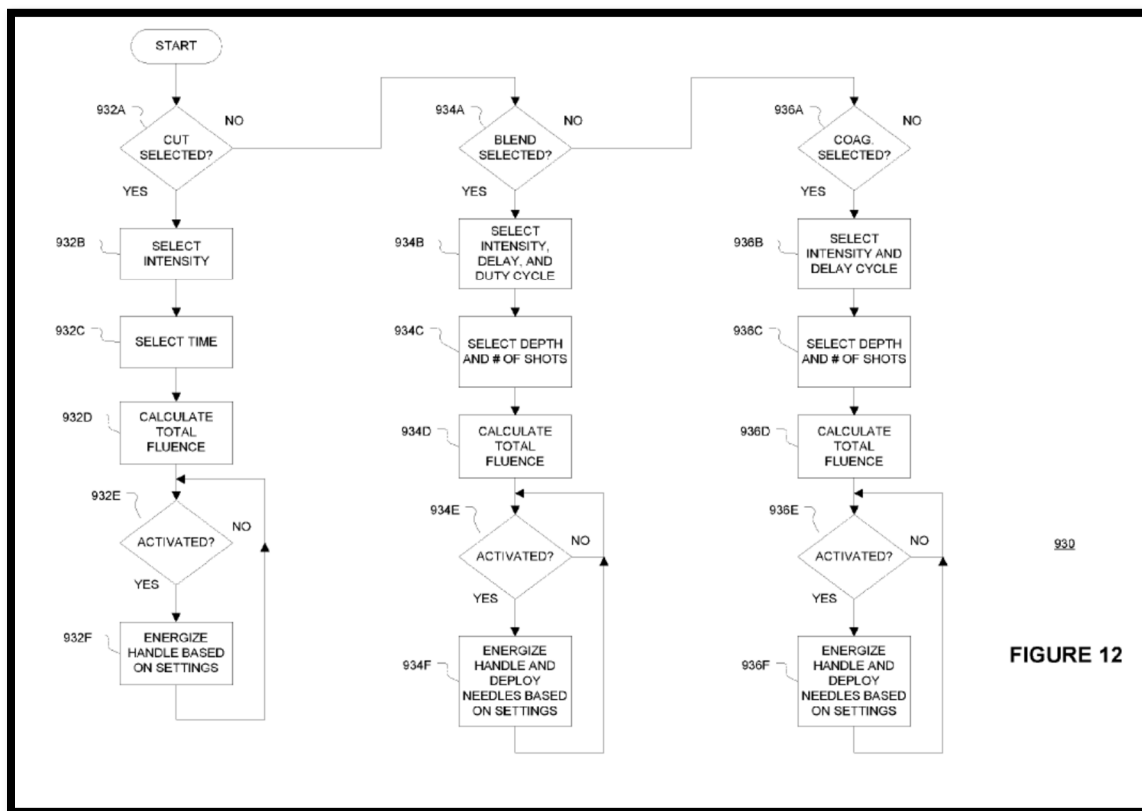
As shown above and in Figures 9C and 9D (copied below), the “handle module 920” may include (1) “a deployable needle module (DNM) 924” (which “may be a detachable cartridge module (DCM)”), and (2) “a motor and LED module (MLM) 922.” *Id.*, 9:43-45, 11:5-11. “[A] needle deployment motor controller (NDMC) module 911B” (shown above), “may control the deployment of one or more needles 924A” (shown below), of the deployable needle module 924 “based one or more user selected operational parameters,” which include “the depth” of needle insertion. *Id.*, 10:20-23, 10:31-36; *see also id.*, 9:64-10:4 (“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.*, 10:51-59. Figure 9C shows the “needles

924A retracted,” and Figure 9D shows the “needles 924A deployed.” *Id.*, 10:65-11:4.

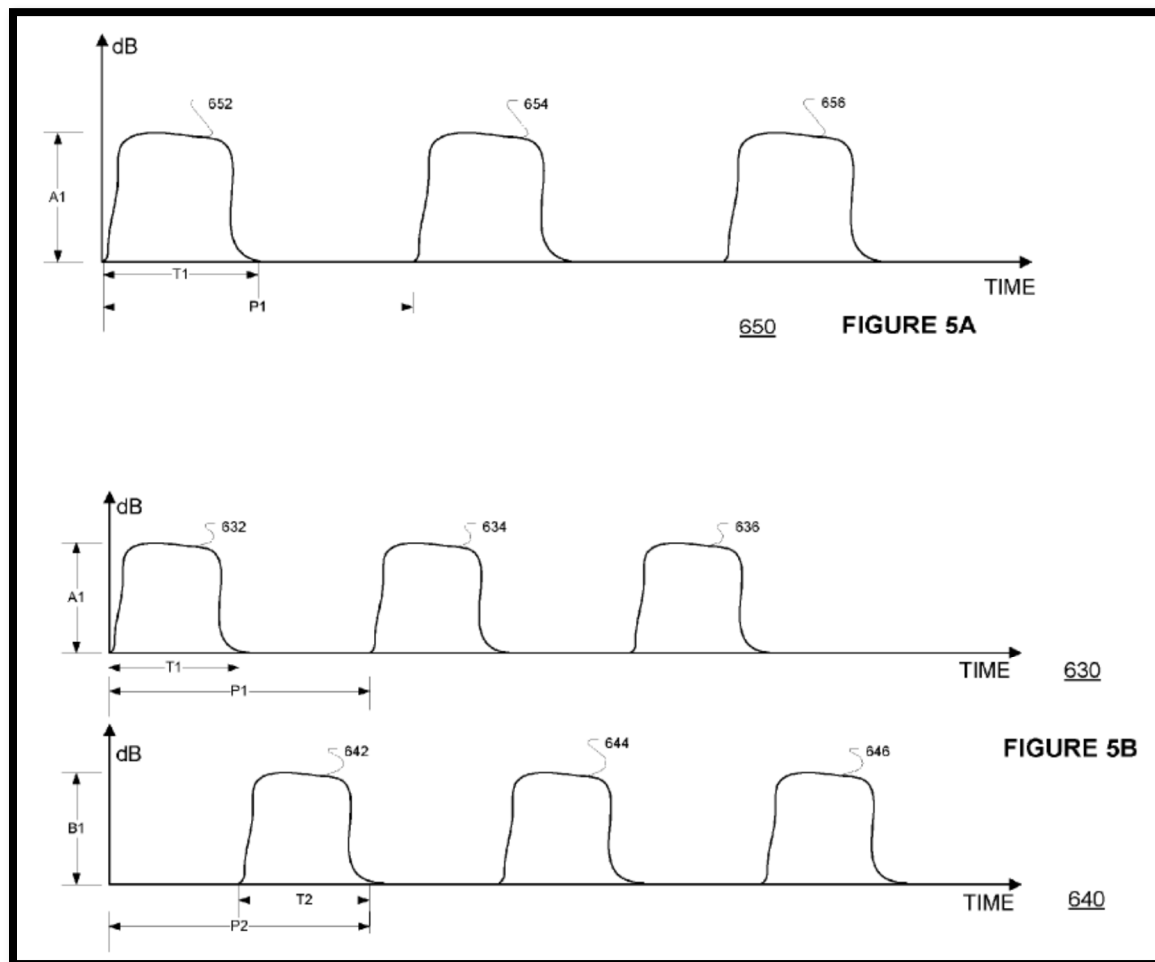


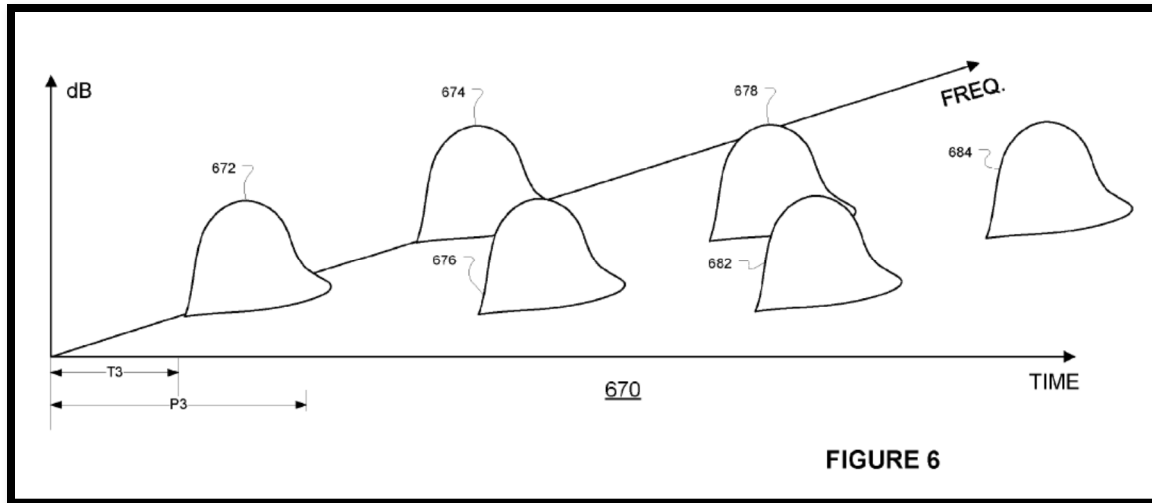
Extension of the needles to a particular depth based on the user's selection is performed by the MLM 922, which “may include one or more motors 922A, longitudinally extendable drive arms 922B, drive shaft 922C, outer casing 922D, [and] signal interface 922E” that receive “control signals and energy to operate [the] one or more motors 922A.” *Id.*, 11:14-23. 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.*, 11:23-26, 14:3-4, 14:24-26.

Accordingly, “a desired depth of needle 924A penetration within tissue” can be achieved “based on the operational parameters” selected by the user. *Id.*, 14:14-20, 14:28-34. Figure 12 (copied 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, 13:63-66, 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.*, 9:64-10:4, 10:20-24, 10:31-36, 11:23-27, 14:3-4, 14:24-26; Ex. 2123 ¶46.



The '774 Patent describes providing pulsed RF signals to the needles when they are extended to affect the dermatological tissue near the needles. In addition to the “needle deployment motor controller (NDMC) module 911B,” “CPU module 911” also “may include a radio frequency (RF) signal generator module (RFSG) 911A.” Ex. 1001, 10:20-24. “[T]he RFSG 911A may apply signals 650, 630, 640, 670 shown in FIGS. 5A, 5B, and 6” (copied below). *Id.*, 10:48-50. As shown below, the signal waveforms 650, 630, 640, and 670 include pulses. *Id.*, 6:13-7:10.





2. Priority and Prosecution History

The application for the '774 Patent was filed on April 12, 2016, as a continuation of the application for the '536 Patent, which Petitioners also have challenged, and claims priority to U.S. Provisional Application No. 61/449,080, filed on March 3, 2011. Ex. 1001, 1, 32. For purposes of this preliminary response, Patent Owner accepts a priority date of March 3, 2011, for the '774 Patent. The '812 Patent, which Petitioners have also challenged, is a continuation of the '774 Patent.

All of the original claims of the '774 patent were cancelled and new claims were added with the transmittal of the application. Ex. 1002, 72-75. The Examiner rejected the claims based on double patenting in view of the '536 Patent. *Id.*, 191-192. The applicant filed a terminal disclaimer (*id.*, 207), and after compliance with the disclaimer requirements (*id.*, 218, 233-235), the Examiner allowed the claims with no further comments (*id.*, 253).

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. 14-15.

B. Claim Construction

The prior art relied on by Petitioners fails to disclose the subject matter of the claims at issue—claims 13 and 14—under any reasonable construction, including their plain and ordinary meaning. Patent Owner addresses claim constructions relevant to those claims below.

1. Causing / To Cause “the plurality of the extendable needles to extend a desired distance from the end surface”

The proper construction of “desired distance,” which appears in the claim limitation “the plurality of the extendable needles to extend a desired distance from the end surface” in claims 13 and 14, is its plain meaning in the context of the claims. The particular distance is “desired” 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 the device's end surface to penetrate dermatological tissue. Accordingly, the “desired distance” is how far the needles extend from the device's end surface, based on a user's selection, to penetrate the dermatological issue. Ex. 2123 ¶¶58-59. This construction is supported by the claims themselves, the specification's description of the claimed invention, the prosecution history of this patent family relating to the “desired distance.”

Here “the claims themselves provide substantial guidance as to the meaning of” the claim term “desired distance” in claims 13 and 14. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc). Dependent claims 13 and 14, respectively, recite a mechanism or motor that causes “the plurality of the extendable needles to extend a desired distance from the end surface.” Ex. 1001, cl. 13 (“a mechanism for causing the plurality of the extendable needles to extend a desired distance from the end surface”), cl. 14 (“a motor coupled to the plurality of extendable needles that may be directed to cause the plurality of the extendable needles to extend a desired distance from the end surface”). Dependent claims 13 and 14 depend from independent claim 11 and dependent claim 12, which specify that this “desired distance” is “selected to enable the plurality of needles to penetrate the dermatological tissue” (*id.*, cl. 11) and is “a desired distance from the end surface” of the device (*id.*, cl. 12). Taking all the claims into account, the “desired distance” that the extendable needles extend is selected by a user to enable the needles to penetrate dermatological tissue (using a mechanism or motor).

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 the device’s end surface, based on a user’s selection, to penetrate dermatological issue. *Phillips*, 415 F.3d at 1315 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). The ’774 Patent explains

that the user may configure several operational parameters, including needle deployment depth. Ex. 1001, 9:64-10:4. The step of selecting the needle deployment depth 934C, 936C is shown in Figure 12 (copied above), for two operational modes (blend and coagulation). *Id.*, 13:45-46, 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.*, 10:31-36; *see also id.*, 10:62-65, 13:63-66, 14:3-6; 14:12-34. This is how “needle deployment” “via one or more motors 922A” is controlled by the user. *Id.*, 10:51-59.

Specifically, the '774 Patent explains that,

upon activation (activity 934E, 934F) the DTA [dermatological treatment architecture] 900 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. In this manner, the motors “enable precise needle deployment depth or extension beyond the DNM 924 shell.” *Id.*, 11:57-60; *see also id.*, 14:3-6, 14:24-26.

Thus, the specification confirms that the “desired distance” in claims 13 and 14 is how far the needles extend from the device’s end surface, based on a user’s selection, to penetrate dermatological issue. Ex. 2123 ¶60.

The prosecution history of the parent of the ’536 Patent, the parent of the ’774 Patent, reinforces this construction by “provid[ing] evidence” that this is “how the PTO ... understood the patent.” *Phillips*, 415 F.3d 1303, 1317. During the prosecution of the ’536 Patent, the Examiner relied on column 10, lines 11-20, in asserting that U.S. Patent No. 6,890,319 to Crocker (“Crocker”) disclosed that “[a] motor is energized to extend the needles a desired distance.” Ex. 2114 (’536 Patent File History), 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 to assert that Crocker disclosed energizing a motor to extend needles “a desired distance” shows that the Examiner 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). *Alloc, Inc. v. ITC*, 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).

Petitioners fail 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. 16 (original emphasis). Petitioners’ construction, which merely states that a claim term is different than its opposite, is meaningless. Petitioners’ proposed construction sheds no light on the meaning of the term “desired distance.”

Petitioners’ proposed construction also has no support in the intrinsic record. The ’774 patent specification explains in connection with Figure 12 (shown above), that a user “select[s] depth” in steps 934C, 936C and that “based on the operational parameters” (including the selected depth) the system “deploy[s] the needle assembly to a *desired* extension beyond the DNM 924 shell 924E to enable a *desired* depth of needle 924A penetration within tissue.” Ex. 1001, 14:14-20, 14:28-34. The term “undesired,” however, appears nowhere in the ’774 Patent. To the extent it would have any meaning based on this intrinsic evidence, “undesired” would be a different distance than the distance that the needles extend based on the depth that the user selected. *Id.*; Ex. 2123 ¶62.

Furthermore, Petitioners’ contention the claims must embrace an “embodiment having fixed, non-extendable needles” is inapplicable to claims 13 and 14 at issue here. Pet. 17. Claims 13 and 14 depend on claim 12, which requires “a plurality of needles *extendable* a desired distance from the end surface,” which expressly excludes “fixed, non-extendable needles.” *Id.*, 17, 32; Ex. 1001, cl. 12.

Claims 13 and 14 further require a mechanism or motor for causing “the plurality of extendable needles to extend a desired distance from the end surface,” which also by their plain language exclude “fixed, non-extendable needles.”² Ex. 1001, cls. 13-14; Pet. 17, 32. Instead, these claims are directed to an apparatus with a mechanism or motor for extending extendable needles a distance from the device's end surface, based on a user's selection, to penetrate dermatological issue. Ex. 2123 ¶¶59, 75.

Indeed, Petitioners' argument here conflicts with their expert's testimony in the ITC about what is required to meet the claims. Specifically, 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. His testimony thus undermines Petitioners' contention that inserting “fixed, non-extendable” needles meets the claims, and supports Patent Owner's position that the “desired distance” is based on a user's selection.

2. Other Claim Terms

Petitioners address two other claim terms that are relevant to claims 13 and 14: “pulsed radio frequency signals” (claims 13 and 14) and “mechanism” (claim

² Petitioners' reliance on the agreed construction of “extending” needles (Pet. 17), is similarly inapt because claims 13 and 14, as well as claims 12 from which they depend, are restricted to “extendable needles.” Ex. 1001, cls. 11-14.

13). As Petitioners note, “pulsed radio frequency signals” was construed in the ITC to have “its plain and ordinary meaning” (Pet. 18), specifically “radio frequency signals that are normally off and suddenly on for a period of time (i.e., a rapid, transient change from a baseline to a different amplitude, followed by rapid return to baseline).” Ex. 1007, 36.

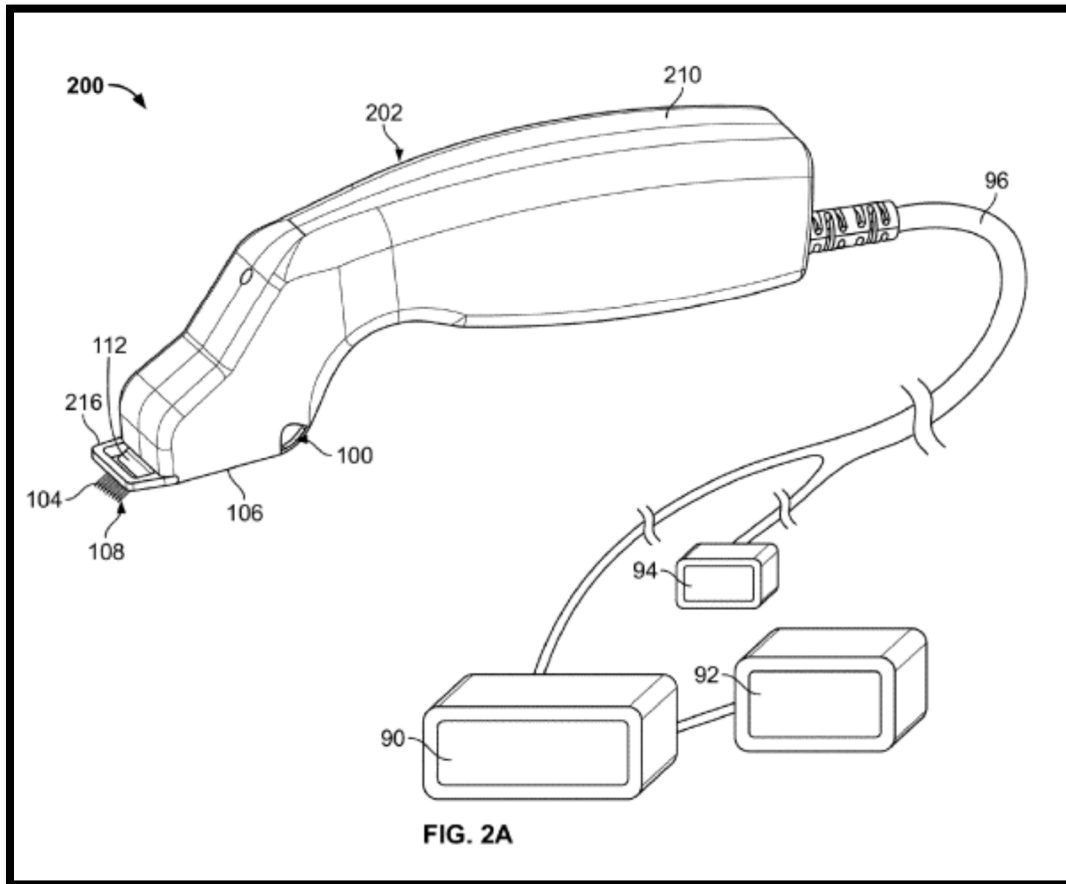
While “Petitioners note that different interpretations of the ‘mechanism’ of claim 13” were offered in the ITC, they assert that construction of this term “is not relevant.” Pet. 18. However, in the ITC, all parties agreed that the recited function of the “mechanism for causing the plurality of the extendable needles to extend a desired distance from the end surface” is “causing the plurality of extendable needles to extend a desired distance from the end surface,” as expressly recited in the claim. Ex. 1007, 4-5. As discussed above, Petitioners’ proposed interpretation of the term “desired distance” in this recited function is incorrect.

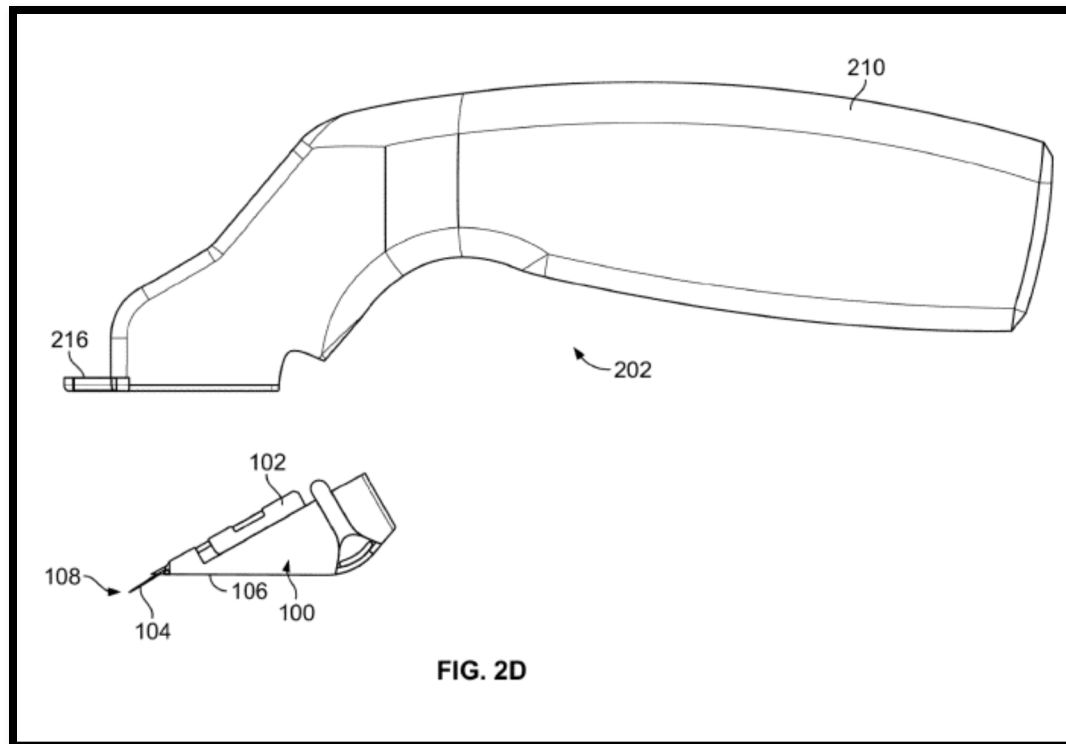
C. Summary Of The Prior Art Upon Which Petitioners Rely

1. Mehta

Mehta is a U.S. patent that was filed in 2009 and issued in 2013. Ex. 1004. 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.” Ex. 1004, 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. 2123 ¶64. *See also id.* ¶¶80, 92, 97.

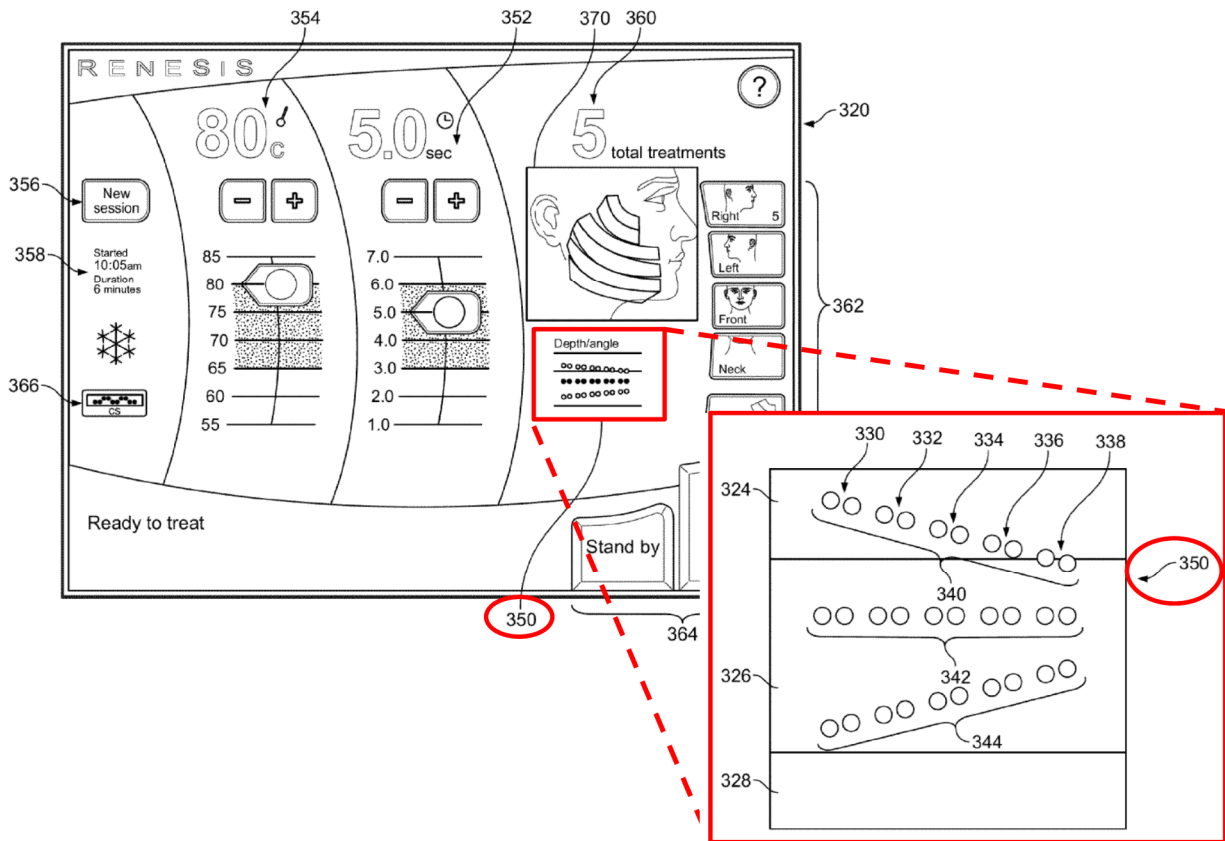
Other than manually adjusting placement of the device on the patient’s skin by the physician, the only mechanisms Mehta discloses for adjusting probe placement is selecting a different cartridge with a different needle array configuration, e.g., a different length or angle for needle insertion. Mehta 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. 1004, 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. 2123 ¶67. “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. 2123 ¶67 (quoting Ex. 1004, 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. 1004, 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. 1011. 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.

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

This preliminary response addresses claims 13 and 14; Patent Owner has disclaimed the other claims to focus on those two claims, which includes claim 14 at issue in the ITC. Regarding Ground I, Petitioners fail to meet their burden that Mehta anticipates those claims at least because Mehta does not disclose “a mechanism for causing the plurality of the extendable needles to extend a desired distance from the end surface” (claim 13), or a “motor coupled to the plurality of

extendable needles that may be directed to cause the plurality of the extendable needles to extend a desired distance from the end surface” (claim 14). As discussed in the claim construction section (*see supra* Section III.B.1), the claimed “desired distance” is how far the needles extend from the device’s end surface, based on a user’s selection, to penetrate dermatological issue. Ex. 2123 ¶75. Mehta fails to disclose this limitation. *Id.*

In Mehta, the user does not select how far the needles extend to penetrate dermatological tissue. *Id.* ¶76. Mehta instead discloses selecting cartridges having different probe *lengths* or *angles*, not selecting *how far* the probes in a given cartridge extend when used in Mehta’s system. *Id.* Mehta discloses “[s]electing probes having sufficient length to reach” different layers of the dermis (Ex. 1004, 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. 2123 ¶76.

Mehta’s system is designed for full insertion of the needles by their entire lengths—i.e., they extend a *fixed distance*. Ex. 1004, 10:2-7, 10:19-25, 12:31-34, 16:1-8; Ex. 2123 ¶77. Petitioners also admit as much, stating, “Mehta discloses needles 104 extending a *fixed length* from an inner surface of the cartridge 100.” Pet. 37. Thus, in Mehta, the distance that the needles extend when using a particular

cartridge is not selected by the user but rather is determined by the “fixed length” of the needles. Ex. 2123 ¶¶77. In fact, Mehta cautions against electrodes not extending their full length to ensure energy is not delivered to an unintended location. Ex. 1004, 16:1-11; Ex. 2123 ¶¶64, 95.

The prosecution of the '812 Patent, which is a continuation of the '774 Patent, reinforces that Mehta does not disclose needles that extend the claimed “desired distance.” Claims of the '812 Patent, like those of the '774 Patent, recite needles that extend “a desired distance.” Ex. 2116 ('812 Patent), cls. 2, 8, 13. During prosecution of the '812 Patent, the Examiner considered U.S. Patent No. 8,540,705 (Mehta '705), which contains the same disclosures that Petitioners rely on here. *Id.* at 2 (56) (References Cited); Ex. 2117, 10:20-11:27, 15:63-17:19, 19:1-25; Ex. 2123 ¶¶78. But the Examiner did not reject any of those claims based on Mehta '705. Ex. 2118 ('812 Patent File History), 577-582, 645-651. In other words, although the Examiner of the application for the '812 Patent had before him the same disclosures in Mehta that Petitioners rely on here, the Examiner did **not** contend that they disclose the claimed “desired distance.”

Petitioners rely on their arguments for claims 3-4 for claims 13-14, respectively. Pet. 43. Claims 13-14 depend on claims 11-12. Petitioners rely on their arguments for claim 2 as to claim 12 and have a single paragraph addressing the “desired distance” limitation in claim 11, mainly relying on their arguments for

claim 1. In addressing claim 11, Petitioners add an assertion that “Mehta also discloses the desired distance is selected to enable the plurality of needles to penetrate dermatological tissue,” but Petitioners merely refer to choice of sufficient needle length to penetrate the tissue. Pet. 42. They do not cite any disclosure of user selection of the distance that the needles extend. Ex. 2123 ¶79.

In addressing claims 1-4, Petitioners fail to identify any disclosure in Mehta of any selection by a user of how far the needles extend from the device's end surface to penetrate the skin—there is none. *Id.* ¶79. In their arguments for claim 1, Petitioners assert, “Control of the actuator 250 [in Mehta] confers the ability of the needles 104 to be extendable a desired distance from the surface[.]” and “the needles are extendable to a distance selected by a user.” Pet. 26-27. Petitioners cite Mehta's disclosure of using an actuator to extend the needles but identify no disclosure of a user selecting a distance that the needles extend. *Id.* (citing Ex. 1004, 18:26-37); Ex. 2123 ¶80. Petitioners cite paragraph 86 of Petitioners' expert declaration, which merely parrots the statements in the Petition and reference using the tissue engaging surface to ensure that actuator 250 extends the needles from a consistent starting point. Ex. 1003 ¶86.

The only disclosure that Petitioners and their 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.

Ex. 2123 ¶81. Specifically, Mehta's "virtual depth/location depiction" "show[s] 'the desired depth of placement for providing a 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. 1004, 32:63-33:43 (cited in Pet. 26-27 & Ex. 1003 ¶¶86-87). 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 Petitioners concede (*see* Pet. 27-28), only reinforces that Mehta does not disclose extending the needles "a desired distance." Ex. 2123 ¶81.

Petitioners cite Mehta's disclosure of a "step-motor" as one of the possible "mode[s] of movement of the actuator." Ex. 1004, 15:36-40 (cited in Pet. 27). This disclosure of how the actuator can be implemented, however, is not a disclosure of selecting how far the needles extend. Ex. 2123 ¶82. As the Petitioner's own 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. Petitioners do not contend otherwise.

In his declaration, Petitioners' 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 ¶88. 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.”).

As Petitioners recognize, the only “selecting” disclosed in Mehta that relates to the distance that the needles extend is “*selecting a cartridge* having needles of a particular length and coupling that cartridge to the proximal end of the handpiece” or “choosing” one having a particular insertion “angle.” Pet. 27-28; *see also* Ex. 1003 ¶89 (“a user may select the distance by which the needles extend from the tissue engaging surface 106 by choosing a particular removable cartridge having needles of a particular length”). Neither of those selections are a selection by a user of how far the needles extend from the device’s end surface to penetrate the skin. Ex. 2123 ¶83. Nothing in those passages in Mehta discloses how far needles extend based on user selection. *Id.*

Petitioners also rely on Mehta’s disclosure of “[o]ver-inserting and then partially retracting” the needles. Pet. 27-28 (original alteration). But Mehta discloses this as an automated process that simply “compensates for the movement and laxity

of the skin resulting in a more reliable insertion.” Ex. 1004, 16:34-41; Ex. 2123 ¶84. Mehta does not disclose a user making a selection that determines how far the needles extend, over-insert, or retract. Ex. 2123 ¶84. Mehta’s display includes no such option. *Id.*

When addressing claims 3 and 4, Petitioners do not even argue that the distance the actuator or motor extend the needles is based on user selection. Pet. 34-35. Petitioners instead merely reiterate that Mehta discloses that a motor can be used to drive the probes into the tissue. *Id.* (citing *e.g.*, Ex. 1004, 10:33-39, 13:63-65). Again, there is no dispute that Mehta discloses a motor to drive the needles into the tissue, but what is entirely missing from Mehta is any disclosure that a user can select how far the needles extend into such tissue, as the claims require.

Petitioners’ failure to show that Mehta discloses claim 13’s limitation “a mechanism for causing the plurality of the extendable needles to extend a desired distance from the end surface” and claim 14’s limitation “motor coupled to the plurality of extendable needles that may be directed to cause the plurality of the extendable needles to extend a desired distance from the 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: Patent Owner Disclaimed Claims 8, 19, And 20, The Only Claims Pertinent To This Ground

Because Patent Owner disclaimed claims 8, 19, and 20, Ground II is moot.

Ex. 2105 (Disclaimer).

F. Ground III: Patent Owner Disclaimed Claims 1, 5-11, And 15-20, The Only Claims Pertinent To This Ground

Because Patent Owner disclaimed claims 1, 5-11, and 15-20, Ground III is moot. Ex. 2105 (Disclaimer).

G. Ground IV: Petitioners Failed To Demonstrate That Mehta And Lee Render Obvious Any Claim Of The '774 Patent

Patent Owner again focuses on claims 13-14, which are the only claims at issue. Petitioners fail to show that Mehta in combination with Lee renders those claims obvious. Petitioners fail to show that a POSITA would have combined Mehta with Lee to achieve “a mechanism for causing the plurality of the extendable needles to extend a desired distance from the end surface” (claim 13) or “motor coupled to the plurality of extendable needles that may be directed to cause the plurality of the extendable needles to extend a desired distance from the end surface” (claim 14).

As Federal Circuit precedent makes clear

A “[d]etermination of obviousness can not [sic] be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention. Instead, ‘[t]here must be a teaching or suggestion within the prior art, or within the field of invention, to look for particular sources of

information to select particular elements, and to combine them in the way they are combined by the inventor.’”

Dropworks, Inc. v. Bio-Rad Laboratories Inc., IPR2021-00212, Paper 7 at 13 (June 1, 2021) (quoting *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 546 (Fed. Cir. 1998)). But selectively culling from the prior art to try to reconstruct the claimed invention is precisely what Petitioners do here, without identifying a teaching or suggestion to combine them as Petitioners propose.

Petitioners superficially assert, “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. 65 (citing Ex. 1003 ¶223). The cited paragraph of Petitioners’ expert declaration simply parrots the statement in the Petition. *Compare* Ex. 1003 ¶223, *with* Pet. 65-66. 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).

Petitioners otherwise argue 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. 66 (“A POSA would have been motivated to use and configure the Mehta system in view of Lee to include the stepper motor taught by Lee to precisely control a needle extension distance”); *id.* 67-68 (“A POSA would have been motivated to modify Mehta with the Lee motor to gain the benefits of being able to control needle insertion”); *id.* (“Modifying Mehta to use the motor in the manner taught by Lee would have yielded predictable results”). Petitioners’ argument fails to support their obviousness challenge to claims 13-14 for two reasons.

First, even if a POSITA modified Mehta to use Lee’s stepper motor, that would not meet the claim requirements. As Petitioners recognize, Mehta itself already discloses a stepper motor. *Id.* 27 (“Mehta ... provides a stepper motor”); *id.* 67-68 (“a stepper motor as disclosed in Mehta and as also disclosed in Lee”); Ex. 1004, 15:34-40 (“[t]he mode of movement of the actuator can include ... stepping (via an step-motor)”). As discussed in addressing 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 Mehta’s stepper motor with Lee’s stepper motor, as Petitioners propose, 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 that Petitioners argue for *other* modifications to Mehta to “provide a distance setting on Mehta’s I/O interface” and to “configure Mehta’s

control system/energy supply unit 90 ... to convert the user-selected needle extension distance to a control signal,” Petitioners failed to explain why a POSITA would have been motivated to make those modifications. Pet. 68. Petitioners merely assert that “a POSA would have readily been able to perform routine programming” to implement these modifications (*id.*), but do not explain why a POSITA would have done so. 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.

As an initial matter, 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. 1011 ¶¶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 Petitioners’ propose to include in Mehta, and to the extent Petitioners rely on Lee’s disclosure of a “mode switch” (which they do not even mention in the Petition), Petitioners fail 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. 2123 ¶91.

Petitioners contend that “through routine programming” a POSA could have “configure[d] Mehta’s controller ... to extend needles a desired distance corresponding to a user selection.” Pet. 68. Again, Petitioners are 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 Inc.*, IPR2021-00212, Paper 7 at 14 (denying institution and finding that the petitioner’s analysis failed to explain what would have led a POSITA, absent disclosures in the patent at issue, to combine the prior art as argued).

Moreover, 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 desired depth so that the physician can make adjustments accordingly. Ex. 2123 ¶¶92. 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. 1004, 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, e.g., “depth markings,” as Petitioners acknowledge. Pet. 27-28. 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. Ex. 2123 ¶92.

Mehta was undoubtedly aware of distance control but teaches a different approach to minimize depth variation in the first instance and allows the physician to address undesired insertion depth. As one 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 which is a continuation of the Morris reference that formed the basis for the first petition on the ’774 Patent for which the PTAB denied institution, discloses electrodes that can be “advanced to a selected deployment depth.” Ex. 2120 (Morris ’261), Abstract. And these references (like Mehta), relate to application of energy to the electrodes, unlike Lee which relates to rapidly creating a large number of holes. *Compare* Ex. 2119, 4:38-41, and Ex. 2120, [0084], *with* Ex. 1011 ¶58.³

³ Even most charitably viewed, Lee is a less relevant example of distance control. While Lee’s modes include the number and depth of insertions, Lee does not disclose

Thus, 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. 1004, 2:10-12. Specifically, Mehta teaches how to insert probes consistently and how to measure and validate probe placement before delivering energy, to ensure it is delivered at the intended location in the tissue. *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. 2123 ¶97. 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. Pet. 67.

Petitioners thus fail to explain why a POSITA would have modified Mehta in view of Lee to achieve the inventions of claims 13 and 14. They instead improperly use 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

user selection of distance or teach how to configure a controller to provide a distance control signal. Ex. 2123 ¶91.

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).

H. Objective Indicia Of Nonobviousness Further Supports That Ground IV Fails To Raise A Substantial Question Of Patentability

Whether patent claims would have been obvious to a POSITA is a legal question that is assessed based on underlying factual findings, known as the *Graham* factors: (1) the level of ordinary skill in the pertinent art; (2) the scope and content of the prior art; (3) the differences between the prior art and the claims at issue; and (4) secondary considerations of non-obviousness such as commercial success, long-felt but unsolved needs, failure of others, etc. *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 (original emphasis).

Here, evidence of secondary considerations is present, and Petitioners have been on notice of that evidence since at least June 16, 2023, when Patent Owner served its initial validity contentions in the 1356 Investigation. Ex. 2054. Indeed, because Petitioners waited until after the evidentiary hearing in the ITC and post-hearing briefing to file their Petition, Petitioners filed their Petition with knowledge

of the *full* evidentiary record on secondary considerations that was developed in the ITC. Respondents failed to address Patent Owner's evidence of secondary considerations at all in the ITC. Their obviousness arguments suffer from the same glaring omission here.

Specifically, despite being aware of the substantial evidence of secondary considerations, Petitioners and their expert completely ignore it. 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). Petitioners’ expert was properly informed that he needed to consider evidence of secondary considerations (Ex. 1003 ¶21), but he failed to do so. Because Petitioners’ expert failed to consider all four *Graham* factors, his analysis is incomplete and his opinion on the ultimate issue of obviousness is not competent. *InTouch Techs.*, 751 F.3d at 1352 & n.8; *see also Inline Plastics Corp. v. Lacerta Grp., LLC*, No. 2022-1954, 2024 WL 1292741 (Fed. Cir. Mar. 27, 2024).

1. The ’774 Patent has achieved commercial success

The Sylfirm X [REDACTED] is one of the many products that practices the ’774 Patent. Ex. 2123 ¶¶99-129. As explained above, the ’774 Patent claims extending a plurality of needles into skin a desired distance based on user selection and discloses how the motors enable such precise needle extension depth control based on the distance the user selects. *See supra*

Section III.A.1. This is one of the main features of the '774 Patent.

The brochure for the Sylfirm X highlights that 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. 2123 ¶130. If the needles are inserted too deeply, the treatment could have an adverse consequence. Thus, “the desired distance” as claimed 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 '774 Patent. *Id.* ¶¶129-131. As Patent Owner's economic expert, Mr. Thomas explains, the Sylfirm X has been commercially

successful. Ex. 2124 (Thomas Decl.), ¶¶14-15. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Thus, the Sylfirm X has been commercially successful, and there is a nexus between the '774 Patent and Sylfirm X's commercial success.

2. The '774 Patent has obtained industry praise

Extending needles a desired distance and a mechanism for precise needle depth control as claimed by the '774 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. 2123 ¶¶132-133. For example, medical providers have praised products that use this technology for their ability to “accurately target and treat[]” at the desired skin depth. Ex. 2066 (Sylfirm X Revolutionises [sic] the Clinical Applications of RF Microneedling), 3; Ex. 2122 (Cartessa Aesthetics, Innovations in RF Microneedling), 2. That former respondents 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 also received a world-class product award for the Sylfirm X in Korea. Ex. 2067 (Sylfirm

X Award).

Thus, the technology claimed in the '774 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”).

I. Ground V: The Patent Owner Disclaimed Claims 8, 19, And 20, The Only Claims Pertinent To This Ground

Because the Patent Owner disclaimed claims 8, 19, and 20, Ground V is moot. Ex. 2105 (Disclaimer).

IV. Conclusion

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

Respectfully submitted,

Dated: April 23, 2024

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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 13,873 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).

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that on this 23rd day of April, 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:

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