

Filed on behalf of: Serendia, LLC

Entered: April 25, 2024

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

SERENDIA, LLC,
Patent Owner.

Case IPR2024-00386
Patent 9,480,836

**PATENT OWNER'S
PRELIMINARY RESPONSE**

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2001	[Proposed] Stipulated Protective Order
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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	Rebuttal Expert Report of Daniel W. van der Weide, dated August 28, 2023 (PROTECTIVE ORDER MATERIAL)
2006	Rebuttal Expert Report of David Goldberg, M.D., J.D., dated August 28, 2023 (PROTECTIVE ORDER MATERIAL)
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2010	Deposition transcript of Daniel W. van der Weide, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C.), taken September 1, 2023 (excerpt)

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2017	Parties’ Proposed Procedural Schedule and Notice of USPTO/PTO Proceedings and State and Federal Litigation Pursuant to Order No. 3, <i>In re Certain Dermatological Treatment Devices & Components Thereof</i> , No. 337-TA-1356 (U.S.I.T.C. Apr. 24, 2023)
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2020	Response of Ilooda 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)
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2037	Brochure: Sylfirm X Dual Wave RF Microneedling System (2022) (“Brochure”)
2038	ViOL Patent List (Dec. 1, 2023), https://violmedical.com/about/patent
2039	Sylfirm X Video
2040	Transcript of Exhibit 2039 – Sylfirm X Video
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2071	[REDACTED] Profit & Loss, January–December 2021 (Accrual Basis) (July 6, 2023, 2:31 PM) (PROTECTIVE ORDER MATERIAL)
2072	<i>Curriculum Vitae</i> of Daniel W. van der Weide
2073	Christopher L. Brace et al., <i>Microwave Ablation with a Triaxial Antenna: Results in Ex Vivo Bovine Liver</i> ," 53 IEEE TRANSACTIONS MICROWAVE THEORY TECHS. 215 (2005)
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2075	Luca Zilberti, <i>Charge Relaxation in Biological Tissues with Extremely High Permittivity</i> , 7 IEEE MAGNETICS LETTERS 1 (2016)
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2086	Sylfirm X Product Photographs
2087	Presentation: D. van der Weide, RF Microneedle Arrays: Thermal Results, dated July 26, 2023
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2089	Cirtec Medical System Drawings, Project: AW000083_A GTW RF PCB, including Certificate of Translation (PROTECTIVE ORDER MATERIAL)

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2098	Transcript of Exhibit 2097 - Sylfirm X Introduction Video 1
2099	Sylfirm X Introduction Video 2
2100	Transcript of Exhibit 2099 - Sylfirm X Introduction Video 2
2101	Press Release, BENEV Co., Inc., <i>BENEV Launches Sylfirm X Ultimate Edition, a Novel Radiofrequency Micro-needling Device, in the U.S. as the Exclusive Distributor</i> (Apr. 26, 2021, 14:51 ET), https://www.prnewswire.com/news-releases/benev-launches-sylfirm-x-ultimate-edition-a-novel-radiofrequency-micro-needling-device-in-the-us-as-the-exclusive-distributor-301277036.html
2102	Presentation: Jiehoon Kim, ViOL / Sylfirm, <i>Pigmentary and Vascular Treatment with Pulsed RF “Sylfirm,”</i> including Certificate of Translation (PROTECTIVE ORDER MATERIAL)
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2139	Declaration of Vincent A. Thomas, dated April 23, 2024 ("Thomas Decl.") (PROTECTIVE ORDER MATERIAL AND REDACTED VERSIONS)

I. INTRODUCTION

Petitioners Ilooda Co., Ltd.'s ("Ilooda") and Jeisys Medical Inc.'s ("Jeisys") petition for *inter partes* review ("IPR") of U.S. Patent ("USP") No. 9,480,836 (the "'836 Patent") should be denied for two reasons. First, this is the second IPR petition filed against the '836 Patent, and the Board should exercise its discretion to reject this serial attack, which was filed long after the Board denied the first IPR petition. Second, even if the Board were to reach the merits, this second IPR petition—*like the first*—fails to show a reasonable likelihood of establishing any claim of the '836 Patent is unpatentable.

First, the Board should exercise its discretion to deny institution because Petitioners not only filed the second IPR petition long after the Board denied the first petition, but also after Petitioners tactically waited *more than seven months* after being aware of the prior art they present here. With this tactical delay, Petitioners gained an unfair advantage by fully litigating that prior art at the U.S. International Trade Commission ("ITC"). Petitioners were aware of their alleged infringement of the '836 Patent before the first IPR petition was filed and were co-respondents with the prior petitioners at the ITC. The current and former Petitioners also filed a joint notice of prior art in May 2023, identifying each prior art reference in the second petition.

Rather than promptly pursuing an 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. Specifically, Petitioners Illooda and Jeisys chose to wait to file this IPR until after they had the benefit of 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 Serendia presented in response to Petitioners' invalidity case in the ITC. This is the exact type of gamesmanship the Board's discretionary denial authority exists to prevent. Patent Owner respectfully requests that the Board exercise that authority to deny institution.

Second, even if the Board were to reach the merits, the second IPR petition is at least as deficient as the first. Petitioners' primary reference in the second petition, Ganz, is directed to an entirely different approach than the '836 Patent, and both Ganz and the '836 Patent expressly distinguish their respective operation. Specifically, the '836 Patent is directed to a milder, safer approach to treating tissue by inducing coagulation around treatment electrodes, while minimizing overheating and leaving the treated tissue intact. By contrast, Ganz is directed to aggressively removing tissue to create "ablation holes" and cauterizing the edges of those holes

to stop bleeding. None of Petitioners' secondary references address this fundamental difference, and Petitioners do not contend otherwise.

Furthermore, despite waiting until after they received full exposition of Patent Owner's objective indicia evidence of non-obviousness in the ITC, Petitioners fail to controvert them again here—just as they did in the ITC. That is because they have no valid response. 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. PROCEDURAL HISTORY AND BACKGROUND OF THE IPR PETITIONS

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

On August 6, 2021, Patent Owner sued Sung Hwan E&B Co., Ltd (“SHEnB”) and Cartessa Aesthetics, LLC (“Cartessa”) in District Court for infringing Patent Owner's patents, including the '836 Patent. *SynKloud Techs., LLC v. SHEnB*, No. 6:21-cv-00811 (W.D. Tex. Aug. 6, 2021), ECF No. 1; *SynKloud Techs., LLC v. Cartessa*, No. 2:21-cv-04423 (E.D.N.Y. Aug. 6, 2021), ECF No. 1. On January 4, 2022, Patent Owner also sued Aesthetics Biomedical Incorporated (“ABM”) in District Court for infringing the '836 Patent and other patents. *SynKloud Techs., LLC v. ABM*, No. 2:22-cv-00015 (D. Ariz. Jan. 4, 2022), ECF No. 1.

On February 10, 2022, Cartessa and ABM filed the first IPR petition challenging all claims of the '836 Patent. *See Cartessa v. Serendia, LLC*, IPR2022-00594, Paper 1 (P.T.A.B. Feb. 10, 2022) (“*Cartessa IV*”). On May 16, 2022, Patent Owner filed its Patent Owner Preliminary Response (“POPR”). *Id.*, Paper 8. On August 12, 2022, the Board denied institution because petitioners failed to show a reasonable likelihood of prevailing with respect to any of the challenged claims. *Id.*, Paper 9 at 2.

B. The Current And Former Petitioners Fully Litigate The '836 Patent's Validity In The ITC

About six months after the Board denied the first IPR petition, on March 1, 2023, Patent Owner filed additional complaints alleging infringement of the '836 Patent (and others), against Lutronic Aesthetics, Inc. (“Lutronic”), Rohrer Aesthetics, Inc. (“Rohrer”), EndyMed Medical, Inc. (“EndyMed”), Cynosure, LLC (“Cynosure”), and Cutera, Inc. (“Cutera”). On the same day, Patent Owner filed an ITC complaint alleging infringement of the '836 Patent (and others), against the District Court defendants identified above, as well as Cynosure's and Cutera's Korean suppliers: Jeisys Medical Inc. and Illooda Co., Ltd., the current Petitioners. *Certain Dermatological Treatment Devices and Components Thereof*, Inv. No. 337-TA-1356 (the “1356 Investigation”).

On May 24, 2023, the ITC respondents, including the current and former Petitioners, filed a Notice of Prior Art in the 1356 Investigation. Ex. 2053 (1356

Investigation NOPA). In that notice, they identified each prior art reference raised in this second IPR petition against the '836 Patent. *See id.*, 3, 5. On June 16, 2023, Patent Owner served its Initial Validity Contentions, responding to Respondents' contentions that the '836 Patent claims were invalid in view of this prior art. Ex. 2054 (Serendia's June 16, 2023 Initial Validity Contentions). Patent Owner specifically addressed Petitioners' allegations that the '836 Patent claims were invalid in view of Ganz, Hantash, and Lee—three of the four references that Petitioners assert again in the second petition at issue here. *Id.* On July 24, 2023, Patent Owner provided its Supplemental Validity Contentions, again addressing Respondents' contentions that the '836 Patent claims were invalid in view of Ganz, Hantash, and Lee. Ex. 2003 (Serendia's July 24, 2023 Supplemental Validity Contentions).

On August 14, 2023, the ITC respondents, including the current and former Petitioners, jointly served the Expert Report of Dr. Jean Woloszko on the purported invalidity of the patents in the 1356 Investigation, including the '836 Patent, which he opined was invalid in view of at least Ganz, Hantash, and Lee. Ex. 2004 (Aug. 14, 2023 Woloszko Expert Report). Patent Owner served rebuttal reports from Dr. Daniel van der Weide and Dr. David Goldberg on the validity of the '836 Patent (among others). Ex. 2005 (Aug. 28, 2023 Daniel van der Weide ("VDW") Rebuttal Expert Report); Ex. 2006 (Aug. 28, 2023 Goldberg Rebuttal Expert Report). They

explained why Petitioners and the other ITC respondents failed to show that any claim of the '836 Patent was invalid. *Id.* All these experts were deposed about their opinions. Exs. 2007-2011 (Deposition transcripts excerpts).

On November 1-2, November 6-7, and December 11-12, 2023, evidentiary hearings were held in the ITC. The ITC respondents, including Petitioners Jeisys and Ilooda, presented testimony from Dr. Woloszko, once again alleging that claims of the '836 Patent were invalid in view of Ganz and Hantash. Ex. 2012 (Woloszko Hr'g Tr.), 867:24-902:19. Patent Owner presented rebuttal testimony from by Dr. van der Weide and Dr. Goldberg, explaining why the asserted claims of the '836 Patent were valid over Ganz and Hantash. Ex. 2013 (VDW Hr'g Tr.), 1441:6-1455:13; Ex. 2014 (Goldberg Hr'g Tr.), 1299:1-1335:8. All the experts were cross-examined about their opinions. Ex. 2012 (Woloszko Hr'g Tr.), 1002:13-1016:9, 1033:7-1040:24; Ex. 2013 (VDW Hr'g Tr.), 1474:23-1480:16; Ex. 2014 (Goldberg Hr'g Tr.), 1335:15-1343:16.

Thereafter, the parties submitted post-hearing briefing on validity. Patent Owner filed its rebuttal brief on validity on January 5, 2024. Ex. 2015 (Rebuttal Post-Hearing Brief). ***Three days later***, on January 8, 2024, Petitioners Ilooda and Jeisys filed the second IPR petition at issue here.

III. THIS BOARD SHOULD EXERCISE ITS DISCRETION TO DENY INSTITUTION OF THIS SECOND IPR PETITION, WHICH PETITIONERS TACTICALLY DELAYED FILING FOR MANY MONTHS TO BENEFIT FROM FULLY LITIGATING VALIDITY AT THE ITC

A. Legal Standard

The Director has discretion to decide whether to institute IPR (35 U.S.C. § 314(a)), and that discretion has been delegated to the Board. 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, addressed in turn below. *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 14-15 (P.T.A.B. Sept. 5, 2018) (“*Shenzhen I*”). Instead, as the Board has explained, the central issue is balancing the equities between a petitioner and a patent owner. *Gen. Plastic*, IPR2016-01357, Paper 19 at 15-19. Here, each *General Plastic* factor weighs in favor of discretionary denial.

B. 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 the petitioners, such coordination paired with “**other relevant or extenuating facts or circumstances**” may evidence said “significant relationship.” *Ford Motor Co. v. Neo Wireless LLC*, IPR2023-00763, Paper 28 at 10-11 (P.T.A.B. Mar. 22, 2024). For example, even in instances where the petitioners were not 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 discretionary denial where “there is sufficient evidence

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

indicating that Mitek was aware of USAA's infringement allegations at the time Wells Fargo filed its two prior petitions").

Here, the current petition challenges the same claims of the '836 Patent as the prior petition. *Compare Cartessa IV*, IPR2022-00594, Paper 1, *with* Pet. Further, Petitioners Ilooda and Jeisys, and prior Petitioners ABM and 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 ("ALJ") 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 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-defendants in the ITC, Petitioners Ilooda and Jeisys, and prior Petitioners ABM and Cartessa, submitted a single joint validity expert report and presented a joint validity defense at the evidentiary hearing through their *shared* expert Dr. Jean Woloszko—the same expert the current Petitioners rely on here. Ex. 2004; Ex. 2012, 867:24-902:19. Petitioners then submitted a joint invalidity defense in their post-hearing briefing, relying on the positions presented at the hearing. Ex. 2019 (Respondents' Post-hearing Brief).

Furthermore, additional relevant and extenuating facts and circumstances exist that 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 Ilooda and Jeisys, and prior Petitioners ABM and Cartessa, are part of the same RF microneedling manufacturing and distribution community. Ex. 2020 (Ilooda 1356 Investigation Complaint Response), ¶3.13; Ex. 2021 (Jeisys 1356 Investigation Complaint Response (Public)), ¶3.17. And, as in *Mitek Systems*, Petitioners Ilooda and Jeisys were aware of their potential infringement of the ’836 Patent before the first IPR petition was filed on February 10, 2022. Specifically, Patent Owner sent the U.S. distributors of Petitioners Ilooda and Jeisys letters providing notice of infringement on March 20, 2018, and November 29, 2021, respectively (Exs. 2022 (Notice Letter to Cutera), 2023 (Notice Letter to Cynosure)), [REDACTED]

[REDACTED]

[REDACTED]

Further, as discussed in further detail below, since at least May 24, 2023, when they filed their Notice of Prior Art in the 1356 Investigation, Petitioners were aware of each prior art reference they now rely on. Ex. 2053 (1356 Investigation NOPA). This Notice of Prior Art, filed jointly by Petitioners Ilooda and Jeisys and prior Petitioners ABM and Cartessa, confirms that Petitioners Ilooda and Jeisys were

indisputably 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 Petitioners ABM and Cartessa throughout the ITC proceedings. 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 potential infringement of the '836 Patent before the prior petition's filing; (ii) were aware of litigation filed against other RF microneedling manufacturers and distributors before the initial petition's filing; (iii) were co-defendants with the prior petitioners in parallel litigation; (iv) worked closely with the prior petitioners 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 petitioners were complete in the parallel litigation.

Thus, the first *General Plastic* factor weighs in favor of denying institution.

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 relied on 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 a 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, Petitioners Ilooda and Jeisys were indisputably on notice of potential infringement of the '836 Patent since at least March 20, 2018 and November 29, 2021, and thus would have had a reason to begin searching for relevant prior art long before the first petition was filed on February 10, 2022. Ex. 2022; Ex. 2023; Ex. 2052. Thus, as in *American Honda*, 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) (each of 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*, IPR2018-00348, Paper 10 at 16 (a reasonably diligent search would have likely identified at least some of the patent documents given that the references used term in common with the challenged patent).

Here, Petitioners Ilooda and Jeisys rely on U.S. Patent Application Publication No. 2007/0208340 (“Ganz”) as their primary reference. Both Ganz and the ’836 Patent are classified as surgical patents (USPC classifications 606 and 607, respectively). *Compare* Ex. 1005 (Ganz), *with* Ex. 1001 (’836 Patent). Moreover, as Petitioners admit, Ganz uses similar terminology as the ’836 Patent, including claim terms such as “bipolar” electrodes, and “coagulation.” *E.g.*, Pet. at 11, 15-16

(quoting Ex. 1005, [0006], [0028], [0056]). Because Ganz is a U.S. patent document in the same classification and field as the '836 Patent, and further uses similar terminology as the '836 Patent claims, Ganz “presumably could have been uncovered with a reasonably diligent search.” *Shanghai Lunion*, IPR2018-00995, Paper 12 at 17.

Similarly, each of WO 2008/005477 (“Livneh”), WO 2007/064718 (“Hantash”), and Korean Patent No. KR20-0441552 (“Lee”), relate to electrosurgical devices used to generate a thermal injury in tissue. Ex. 1006 (Livneh); Ex. 1007 (Hantash); Ex. 1008 (Lee) (translation). These references also use similar terminology as the '836 Patent. For example, Livneh discusses “bipolar” operation, along with the application of “RF energy” to the surface of the skin via an RF generator and using the system to coagulate “collagen.” Ex. 1006 (Livneh), [0003], [0010], [0027], [0039].²

Further, since Petitioners cited each reference in their Petition in the May 24, 2023 Notice of Prior Art in the 1356 Investigation, Petitioners were indisputably aware of these references *more than seven months* before filing this second IPR petition. Ex. 2053.

² While Lee is a Korean patent, Petitioners are Korean entities.

In short, at the time of the filing of the prior petition, Petitioners Ilooda and Jeisys (co-defendants of the original Petitioners ABM and Cartessa), either knew of the prior art being 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. And where the prior petition was denied *on the merits*, Factor 3 weighs against institution even without a showing of “road-mapping.” *See Code200, UAB v. Bright Data Ltd.*, IPR2022-00861, Paper 18 at 4-5 (P.T.A.B. Aug. 23, 2022) (precedential).

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 Response and the Board’s Decision 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*, 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 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 from 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 Patent Owner Preliminary Response and the

Board's conclusions of law and findings of fact in the prior petition. For example, in the original petition, Petitioners ABM and Cartessa argued that the claim term "cause coagulation around each electrode rather than coagulating between the electrodes[]" should be construed as "concentrate heat around the needle(s) to cause coagulation while minimally affecting the area between the needles." *Cartessa IV*, IPR2022-00594, Paper 1 at 16-18. In the POPR, Patent Owner explained that Petitioners' construction impermissibly allowed for this limitation to be satisfied "even where coagulation is continuous between electrodes." *Id.*, Paper 8 at 5. Patent Owner pointed out that Petitioners' primary reference failed to disclose the coagulation limitation under the proper construction. *Id.* at 16-21. The Board agreed, rejecting Petitioner's proposed claim construction, and denied institution. *Id.*, Paper 9 at 13-26.

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. For example, the new petition now argues that the asserted prior art discloses the coagulation limitation under the construction Patent Owner supported in its prior Preliminary Response, which is *the same construction that the Board applied in denying institution on the merits*. See, e.g., Pet. at 25-30. This strongly indicates that the current 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” and the Board’s acceptance of those positions. *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 ITC evidentiary hearing*. See, e.g., Ex. 2024 (1356 ITC 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 the references Petitioners raise here do not invalidate the claims, taking into account all the expert testimony on validity. Ex. 2015.

When, as here, a party has waited to file a subsequent petition until after validity positions have been disclosed in 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 (finding

Factor 3 favors denial of institution where “Petitioner also had the Patent Owner’s Responses *and Patent Owner’s expert testimony in the other related proceedings* when the Petition was filed”).

Here, Petitioners Ilooda and Jeisys not only waited to file this second petition until *after* they had the benefit of receiving Patent Owner’s full evidentiary presentation and exposition of its validity positions in post-hearing briefing, but *also* used this information to inform their arguments in their Petition. Indeed, their Petition is replete with examples of leveraging what Petitioners learned about Patent Owner’s positions from fully litigating the ’836 Patent’s validity at the ITC.

For example, in the ITC, Patent Owner’s experts explained that Petitioners’ primary reference, Ganz, does not disclose causing coagulation around each needle electrode, but rather discloses creating perforations in the tissue by removing the tissue around each needle electrode. Ex. 2013 (VDW Hr’g Tr.), 1451:4-8 (“Ganz is actually overheating and burning epidermis in order to create its perforations. So these are completely distinct teachings.”); Ex. 2014 (Goldberg Hr’g Tr.), 1308:21-1309:2 (explaining that Ganz creates perforations, which are “vertical areas of thermal damage or ablation”). Now, in an attempt to pre-but this argument, Petitioners argue that “[i]t was well known that inserting small needles into skin creates small holes[]” and that “Ganz does *not* teach creating perforations to the exclusion of zones of coagulation.” Pet. 26 (original emphasis). Putting aside the

infirmities in Petitioners' arguments, their attempts to pre-empt Patent Owner's positions that they learned through fully litigating validity at the ITC shows how Petitioners are abusing the IPR process through their tactical delay in filing their petition.

As another example, in their preliminary invalidity contentions in the ITC, Petitioners asserted that Ganz disclosed an RF energy source "configured to provide an Alternating Current (AC) RF signal to the plurality of electrodes," as claim 1 of the '836 Patent requires. Ex. 2025 (Exhibit A2 (Ganz Chart) to Respondents' May 24, 2023 Invalidity Contentions), 5-6, 41-42. Because Ganz lacks any disclosure of Alternating Current (AC), Respondents further asserted that "it was well-known in the art that a radio frequency signal is generated from alternating current (AC)." *Id.* at 42. In response, Patent Owner served validity contentions in the ITC pointing out that RF energy can be delivered as *either* Alternating Current (AC) or Direct Current (DC) pulses. Ex. 2054, 44-45. Patent Owner further pointed out that Respondents' own cited prior art disclosed that RF energy can be delivered "***in a series of voltage pulses or alternating current***" *Id.* (citing Ex. 2026 (USP 6,766,202)).³

³ Indeed, as Patent Owner's expert Dr. van der Weide opined at the ITC Evidentiary Hearing, even Dr. Woloszko's *own* patents distinguished between AC and DC RF energy sources. *See, e.g.*, Ex. 2013 (VDW Hr'g Tr.), 1446:13-1448:7 (citing Ex.

In response, Petitioners' expert Dr. Woloszko (incorrectly) opined at the evidentiary hearing in the ITC that: (i) international standard IEC 60601-2-2 precluded the use of DC RF energy sources with electrosurgical devices; and (ii) that the '836 Patent's inventor, Dr. Na, equated high frequency waves with alternating current in another patent application. Ex. 2012 (Woloszko Hr'g Tr.), 882:6-884:5. Now, in their petition, Petitioners present this *same* response that they developed in the ITC in an attempt to pre-but Patent Owner's arguments that Ganz fails to disclose AC RF. See, e.g., Pet. 24 (arguing that "IEC 60601-2-2, prohibits use of DC signals"); *id.* 23-24 (arguing that "[a] patent application filed by Jongju Na, the inventor of the '836 Patent, confirms that RF energy is basically AC[]").

Moreover, Petitioners have exploited fully litigating validity in the ITC by crafting their proposed grounds in view of Patent Owner's validity positions. Recognizing the vulnerability of their position that Ganz alone discloses or renders the AC RF limitation obvious in view of Patent Owner's explanations in the ITC, Petitioners now propose combining Ganz with Livneh to meet the AC RF limitation. *Id.* 24-25. This is the paradigm of road-mapping. *Shenzhen I*, IPR2018-00761,

2026; Ex. 2027 (USP 9,095,358 (Woloszko '358)); Ex. 2028 (USP 8,012,153 (Woloszko '153)).

Paper 15 at 12-13 (finding evidence of road-mapping “**strongly**” weighed in favor of denying institution).

As another example, during the 1356 ITC Investigation, the ALJ construed the term “a plurality of electrodes, the electrodes being bipolar” to exclude configurations where the electrodes are arranged as alternating rows of commonly-polarized electrodes (i.e., the “Intracel” configuration, addressed in the Board’s prior decision to deny institution of IPR proceedings against the ’836 Patent). Ex. 1028 (Markman Order), 53. In response, at the Evidentiary Hearing, Patent Owner’s expert Dr. van der Weide opined that Ganz did not disclose “a plurality of electrodes, the electrodes being bipolar” in part because Ganz only discloses electrodes which are arranged as alternating rows of commonly-polarized electrodes. Ex. 2013 (VDW Hr’g Tr.), 1444:21-1445:4. Now, in an effort to pre-but this argument, Petitioners argue that “Ganz’s disclosure of bipolar electrodes are **not** limited to the Intracel configuration (alternating rows of commonly-polarized electrodes).” Pet. 17 (original emphasis).

As another example, in the ITC, Patent Owner’s expert explained that a person of ordinary skill in the art (“POSITA”) would not have been motivated to combine Ganz and Hantash to achieve the inventions claimed in the ’836 Patent because Hantash disclosed coagulation “between” electrodes—the opposite of what the ’836 Patent claims require. Ex. 2013 (VWD Hr’g Tr.), 1454:1-1455:15. Now, in an effort

to pre-but this argument, Petitioners argue that Hantash merely discloses “denatured zones, not coagulation zones.” Pet. 55-56.

In short, in crafting the arguments in their petition, Petitioners Ilooda and Jeisys have not only leveraged the Preliminary Response and the 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 first learning of the prior art and filing the petition. *See, e.g., Valve Corp. v. Elec. Scripting Prods., Inc.*, IPR2019-00064, Paper 10 at 13-14 (P.T.A.B. May 1, 2019) (precedential) (“*Valve II*”) (delay of five months favored denial of institution); *Shenzhen I*, IPR2018-00761, Paper 15 at 13 (Factor 4 “**strongly**” favored denying institution where “Petitioner knew of the majority of the asserted art for at least five and a half months before filing this Petition.”); *Guangdong Boltpower Energy Co. v. Noco Co.*, IPR2021-00309, Paper

11 at 9-12 (P.T.A.B. May 10, 2021) (seven-month delay favored denying institution); *Mitek Sys.*, IPR2020-00882, Paper 29 at 31 (“waiting five months to file its own petition still, by itself, is unreasonable and weighs in favor of discretionary denial”); *Intel Corp. v. Inst. of Microelectronics Chinese Acad. of Scis.*, IPR2019-00834, Paper 14 at 10-12 (P.T.A.B. June 19, 2020) (six-month delay favored denying institution); *Abiomed, Inc. v. Maquet Cardiovascular, LLC*, IPR2017-02134, Paper 7 at 11-13 (P.T.A.B. Apr. 16, 2018) (“nearly six months” delay favored denying institution).

Here, 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 that they rely on in their Petition. *See* Ex. 2053. Petitioners thus were aware of these references ***at least seven months*** before filing their Petition against the '836 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. The Board has ***repeatedly*** held that Factor 5 weighs in favor of denying institution where the Petitioner fails to provide an adequate explanation for the delay. *See, e.g., Videndum Prod. Sols., Inc. v. Rolight Ltd.*, IPR2023-01220, 2024 WL 266434, at *7 (P.T.A.B. Jan. 24, 2024) (“Although Petitioner is correct that it was not obligated under 35 U.S.C. § 315(b) to file this Petition sooner, that does not constitute an adequate explanation” for delaying filing its petition.”). Indeed, when such a delay exists, it is incumbent on the petitioner to provide an explanation for it. *See, e.g., Apple Inc. v. Corephotonics Ltd.*, IPR2018-01356, 2019 WL 462483, at *3 (P.T.A.B. Feb. 5, 2019) (“To the extent a reasonable explanation exists for Petitioner’s delay, it was incumbent upon Petitioner to identify those circumstances in its Petition.”); *Shenzhen I*, IPR2018-00761, Paper 15 at 13 (same).

Here, Petitioners provide ***no explanation whatsoever*** for their lengthy delay. Petitioners’ failure to offer ***any*** explanation, let alone an “adequate” explanation, weighs heavily in favor of 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.

In considering these factors, 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. 69), 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, and 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. 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 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. 72 (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. *See 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 Institution Decision 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 '836 Patent claims, purposely staggered to game the system and benefit from both earlier IPR filings and fully litigating the invalidity challenges raised here, abuses the IPR process and imposes inequities on Patent Owner. *Id.* at 11, 17. This factor favors denying institution.

7. Factor 8

In certain circumstances the Board has considered an additional factor 8, which takes into account "the extent to which the petitioner and any prior petitioner(s) were similarly situated defendants or otherwise realized a similar-in-time hazard regarding the challenged patent." *Shenzhen Silver Star Intelligent Tech. Co. v. iRobot Corp.*, IPR2018-00897, Paper 9 at 12 (P.T.A.B. Oct. 1, 2018) ("*Shenzhen 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." *Id.*

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. The same is true here as Petitioners Ilooda and Jeisys were on notice of the '836 Patent before the first 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 first petition, but also months after being aware of the prior art they assert here. As discussed above, Petitioners tactically delayed to have the benefit of Patent Owner's fully developed record at the ITC addressing that prior art. Therefore, for the same reasons as in *Shenzhen II*, proposed Factor 8 favors denial of institution.

IV. TECHNICAL BACKGROUND

A. Person of Ordinary Skill in the Art

As Petitioners note, in the ITC, the ALJ specified the level of skill of a POSITA for the '836 patent. Pet. 9. For the purposes of this preliminary response, Patent Owner does not dispute the POSITA definition adopted in the ITC.

B. Claim Construction

As Petitioners note, in the ITC Investigation, Petitioners and Patent Owner agreed to certain constructions (Ex. 1028, 39-40), and the ALJ adopted certain constructions (*id.*, 41-62). Petitioner advocates that the Board should apply those constructions, and Patent Owner likewise applies them for purposes of this preliminary response.

C. The '836 Patent

A brief description of the '836 Patent's claimed technology is included below, *infra* Section V.A.1.a.

D. The '836 Patent's Prosecution History

During prosecution, the '836 Patent claims were initially rejected in view of U.S. Patent Application Publication No. 2005/0222565 ("Manstein" (Ex. 1014)). *See, e.g.*, Ex. 1002 ('836 File History), 290-298 (August 4, 2015 Non-Final Rejection at 4-5), 321-328 (January 22, 2016 Final Rejection at 2-3). However, as the Applicant pointed out, Manstein did not disclose at least: (i) bipolar electrodes configured to cause coagulation around electrodes (rather than between them); and (ii) an RF generator configured to provide AC RF energy.

Specifically, as Applicant noted, while Manstein disclosed bipolar configurations, "Manstein, actually teaches and notes that its bipolar configuration generates *intersecting damage*" *Id.*, 378 (May 5, 2016 Supplemental Response at 11). Applicant also noted that "the Manstein reference does not teach applying a

high frequency Alternating Current signal to bipolar electrodes.” *Id.*, 316 (October 18, 2015 Response to Office Action at 9). For example, as Applicant pointed out, “the RF and AC stimulation are used in different embodiments in the Manstein reference.” *Id.*, 366 (March 15, 2016 Applicant-Initiated Interview Summary). The Examiner subsequently agreed, explaining in the Notice of Allowance that:

The examiner agrees that with the applicant’s argument that the AC signal and RF signal are applied in different embodiments in the prior art (e.g. see [0032] of Manstein) and that there would be no motivation to combine the embodiments. [0052] of the applicant’s specification is where the applicant discloses the RF AC signal being implemented in one embodiment.

Id., 390 (Notice of Allowance at 2).

V. PETITIONERS’ GROUNDS FOR REQUESTING *INTER PARTES* REVIEW ARE DEFICIENT

A. Grounds I & II: Petitioner Fails To Show That Claims 1-2, 11-15, 23-24, And 26 Would Have Been Obvious Based On Ganz Alone Or In View Of Livneh

Petitioners’ contention that Ganz in view of a POSITA’s knowledge, or in view of Livneh, renders obvious claims 1-2, 11-15, 23-24, and 26 fails because Ganz is directed to a completely different treatment method than the ’836 Patent, and Ganz alone or in view of Livneh fails to disclose or suggest multiple claim limitations.

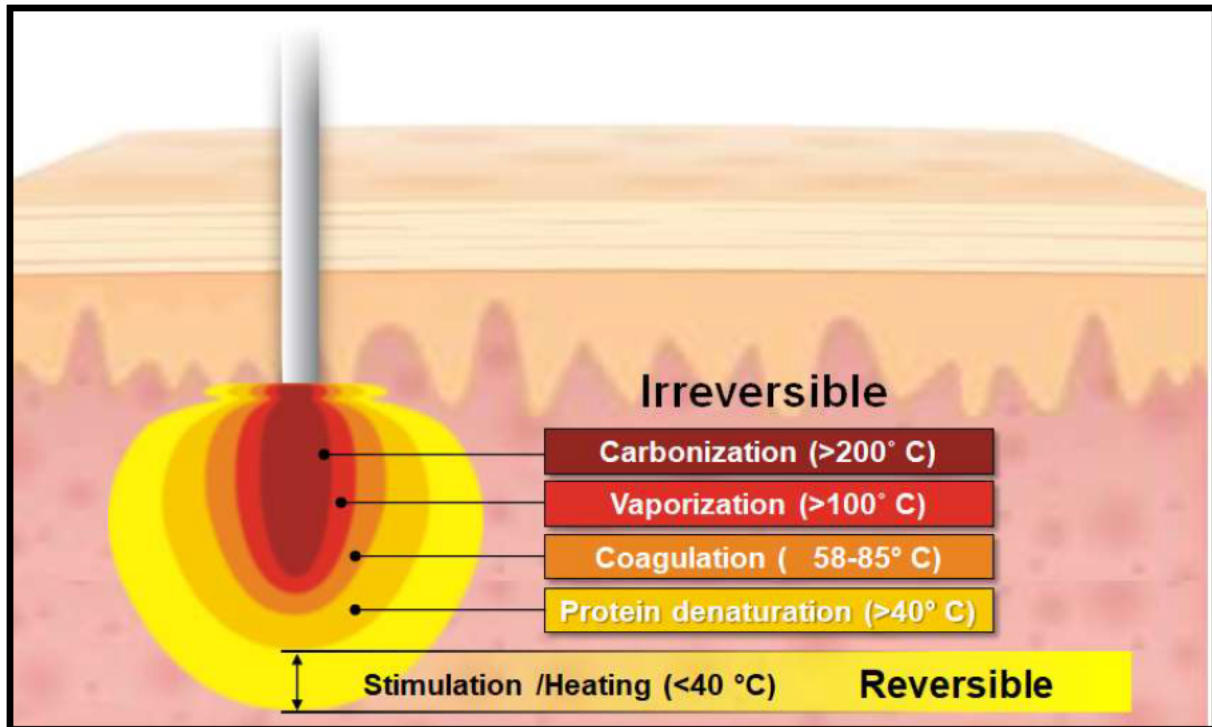
Petitioner also fails to show that a POSITA would have been motivated to combine Ganz and Livneh as Petitioner proposes.

1. Ganz Is Directed To A Completely Different Approach Than The '836 Patent

a. The '836 Patent Is Directed To Coagulation Around Electrodes, Rather Than Aggressively Burning Away Tissue Around The Electrodes

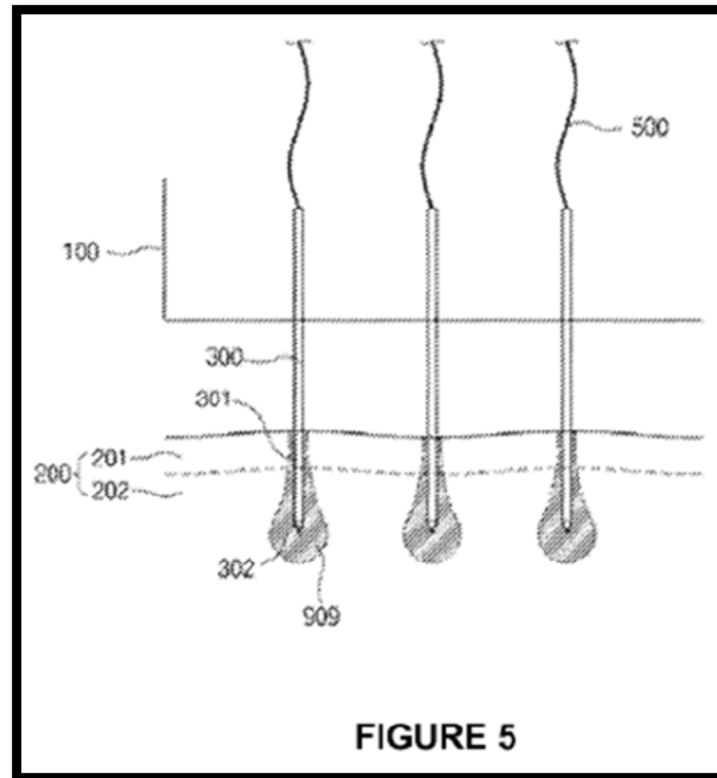
The '836 Patent generally relates to improved delivery of RF energy to the skin, which reduces side effects such as burning that may cause scarring. Ex. 2030 (VWD Decl.) ¶35.

The '836 Patent differentiates between different types of tissue effects that can occur based on the amount of energy supplied, explaining that “[w]hen energy is applied to dermis, the effect on the dermis may differ based on the amount of energy applied and the effect is generally divided into three phenomena: carbonization, vaporization, and coagulation.” Ex. 1001, 2:62-65. As discussed in the affidavit of Dr. David Goldberg (a nationally renowned dermatologist who has worked with RF Microneedling devices for decades), as more energy is applied, the tissue temperature increases, leading to protein denaturation (above 40 degrees C), then coagulation (between 58 and 85 degrees C), then vaporization (above 100 degrees C), then carbonization (above 200 degrees C). Ex. 2031 (Goldberg Decl.) ¶15. This is further illustrated below:



The '836 Patent explains that the invention treats tissue through coagulation (i.e., not carbonization or vaporization). *Id.* ¶29; *see also* Ex. 1001, 2:65-3:4 (“The present invention improves skin condition by primarily using coagulation.”). More specifically, in the claimed inventions, the skin treatment is “configured to cause coagulation around each electrode rather than coagulating between the electrodes.” Ex. 1001, cls. 1, 14. The '836 Patent explains that “[i]n the present invention the temperature may be raised and the heat may be concentrated at an area in dermis by the needle(s) to cause coagulation[]”—and “not be concentrated between needles[]”—as claimed. *Id.*, 3:20-29. As shown in Figure 5 (copied below), in this treatment method each “the heated area[s]” 909 are “around the needle end tips” 302

of the needles 300 in the dermis 202, and accordingly this heat “minimally affect[s] the adjacent epidermis area.” *Id.*; see also *id.*, 5:1-20.

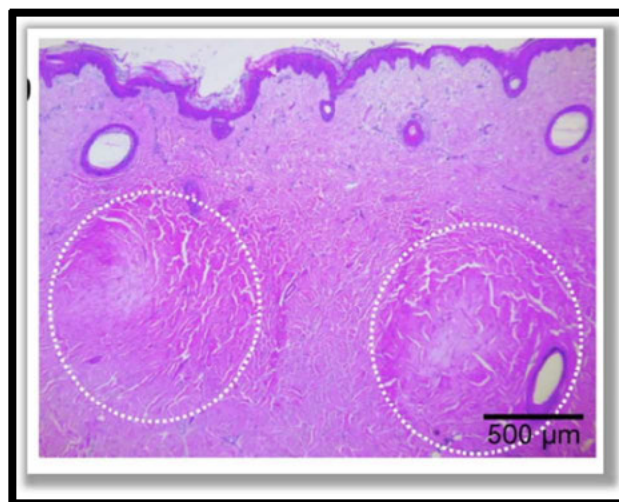


Id., Fig. 5. The treatment claimed in the '836 Patent thus concentrates energy around each electrode, while limiting the energy applied to ensure that the tissue surrounding each electrode is not carbonized or vaporized. Ex. 2030 (VWD Decl.) ¶91; Ex. 2031 (Goldberg Decl.) ¶29.

As the '836 Patent explains, this inventive approach “shown in FIG .5” can “resolve problems of existing technologies[,]” including the “*serious side effect*” of “overheating or burning of both dermis and epidermis ..., which may cause permanent skin damage[,]” e.g., “scars created in overheated or burned epidermis.”

Ex. 1001, 4:4-22. Accordingly, the '836 Patent disparages prior technologies that overheat the skin and explains that the claimed treatment overcame this problem. *Id.*; Ex. 2030 (VWD Decl.) ¶47; Ex. 2031 (Goldberg Decl.) ¶30. A POSITA is thus informed that the prior art approaches for tissue cutting, cauterization, or ablation (involving carbonization and vaporization), is distinct from the '836 Patent's claimed approach that "improves skin condition by primarily using coagulation." Ex. 1001, 2:65-66; Ex. 2030 (VWD Decl.) ¶¶37, 47.

As shown above, the '836 Patent uses drawings to illustrate how heat is concentrated around electrodes using the claimed invention, but does not show the coagulation around each needle electrode (rather than between them), in an actual tissue sample. However, the named inventor of the '836 Patent, Dr. Jongju Na, published about his invention in *Nature's Scientific Reports*. In that article, Dr. Na showed cross sections of micropig skin with "coagulation columns (broken lines) ... separately around each microneedle electrode," including Figure 1(b), copied below:



Ex. 2032 (Na Nature Paper), 3. This “novel finding of independent tissue coagulation around each electrode” was termed the “Na effect” “to distinguish it from other RF tissue reactions.” *Id.*, 7.

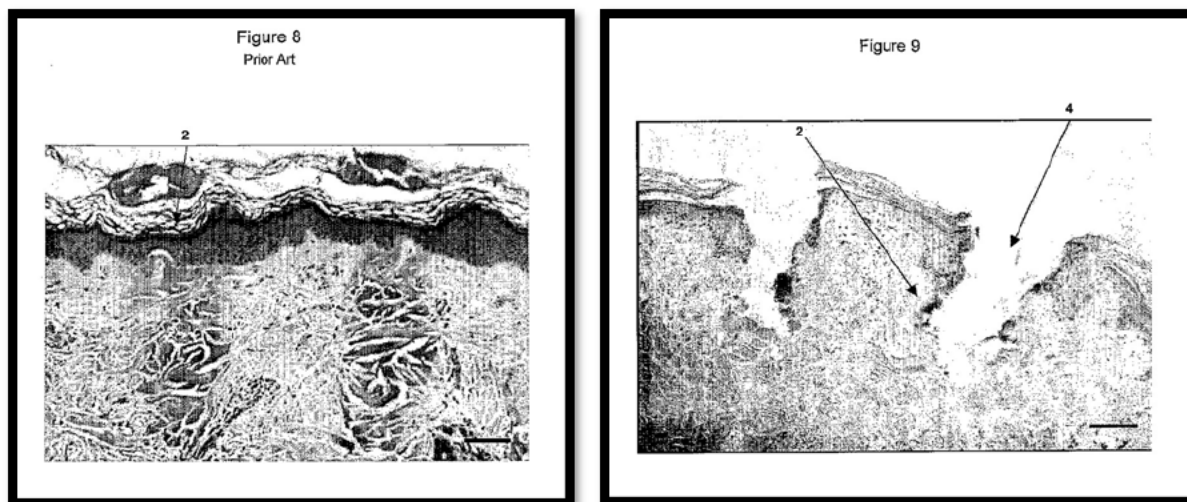
b. Ganz Is Directed To Burning Away Tissue Around Electrodes

Ganz is a published patent application, U.S. Patent Application Publication No. 2007/0208340, that was published in 2007 and never issued as a patent. Ex. 1005. In contrast to the '836 Patent's claimed skin treatment, Ganz is directed to burning away tissue around needles inserted into the skin “to create vertical perforations or ablation holes in tissue[]” to “prompt[] an even more aggressive wound healing response.” *Id.*, [0006]; *see also* Ex. 2030 (VWD Decl.) ¶75; Ex. 2031 (Goldberg Decl.) ¶22. Indeed, Ganz expressly distinguishes systems which “*only cause[] zones of coagulation[,]*” like the '836 Patent's claimed approach, which Ganz views as a “*drawback.*” Ex. 1005 (Ganz), [0006]. Ganz explains that “rather than merely imparting coagulations into the skin[,]” Ganz's approach provides for the “creation of actual perforations leads to more aggressive healing responses.” *Id.*, [0032]. Ganz also explains that “the term ‘perforation’” means “vertical areas of thermal damage or ablation to the tissue causing tissue necrosis.” *Id.*, [0027].

Thus, rather than teaching coagulation of tissue around treatment electrodes (as in the '836 Patent's claimed approach), Ganz teaches removing the tissue around

electrodes to form “ablation holes,” i.e., perforations, formed by vaporizing and/or carbonizing the tissue around the electrodes. *Id.*, [0006]; Ex. 2030 (VWD Decl.) ¶¶75, 92; Ex. 2031 (Goldberg Decl.) ¶¶22, 29. Ganz therefore discloses creating the perforations by burning away tissue using energy, rather than forming the perforation mechanically because, “when perforations are made mechanically rather than with the use of energy, excess bleeding takes place.” Ex. 1005, [0008-0009]. In other words, Ganz discloses using energy to cauterize the holes created via Ganz’s treatment approach. Ex. 2031 (Goldberg Decl.) ¶24.

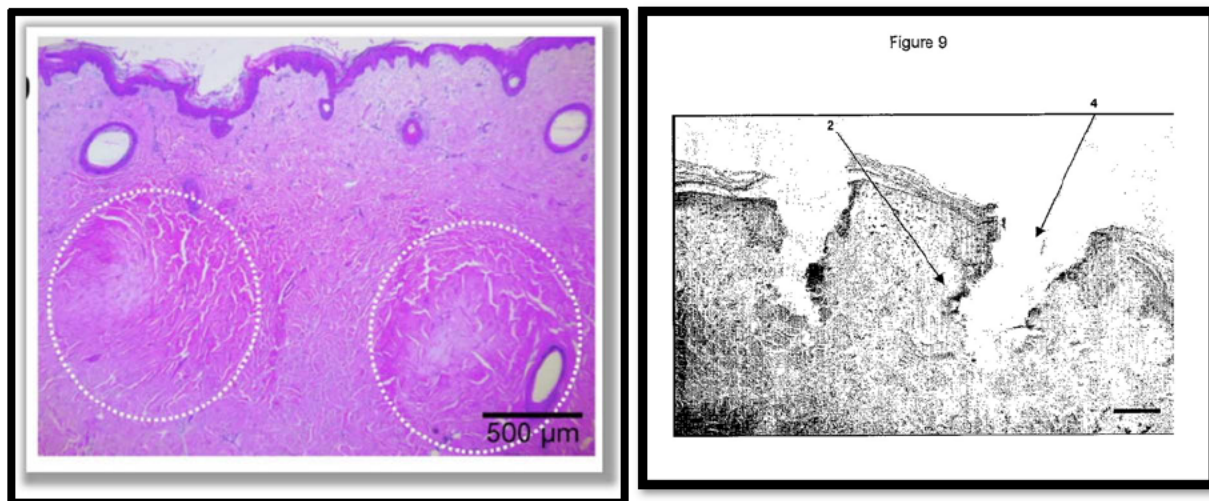
Ganz also illustrates the distinction between treatment approaches that “merely impart[] coagulations into the skin[]” and the Ganz approach, which burns holes in the skin, using Figures 8 and 9, shown below:



Ex. 1005, [0032], Figs. 8-9; Ex. 2031 (Goldberg Decl.) ¶¶26-29. As shown in Figure 8, merely imparting coagulations 2 into the skin (as shown using the prior art FRAXEL laser treatment), leaves the tissue intact. Ex. 1005, [0028]. By contrast,

as shown in Figure 9, in the Ganz approach, the tissue around each electrode is gone because it has been removed using energy that burned away the tissue, leaving holes (i.e., perforation 4), in the skin. *Id.*; Ex. 2031 (Goldberg Decl.) ¶¶26-27.

The distinction between the '836 Patent's claimed treatment approach and Ganz's approach is similarly illustrated by comparing histological images of tissue treated using the '836 Patent's claimed approach (on the left below), to create coagulation around each electrode (dotted lines) with Ganz approach (on the right below), of burning away tissue to create holes 4:



Compare Ex. 2032 (Na Nature Paper) *with* Ex. 1005 (Ganz), Fig. 9.

Thus, just as Ganz's approach is distinct from the prior art FRAXEL approach shown in Ganz's Figure 8 above, Ganz's approach is similarly distinct from the '836 Patent's claimed skin treatment. Ex. 2030 (VWD Decl.) ¶¶88, 91; Ex. 2031 (Goldberg Decl.) ¶¶29-31. While Ganz intentionally ablates and removes the tissue to create the desired "ablation holes," the claimed treatment in the '836 Patent "does

not involve ablation,” as Petitioner’s original (and now withdrawn) expert, Dr. Dany Bérubé, conceded. Ex. 1005 (Ganz), [0006]; Ex. 2033 (Bérubé Hr’g Tr.), 1268:24-1269:1. As Dr. Goldberg explains, while he frequently uses systems applying the ’836 Patent’s treatment technique in his clinical practice, he would ***never*** use a system like Ganz that burns away tissue to create holes in the skin because it is dangerous. Ex. 2031 (Goldberg Decl.) ¶32.

2. Ganz Alone, Or In View of Livneh, Fails To Disclose Or Render Obvious “provid[ing] an Alternating Current (AC) RF signal to the plurality of electrodes”

Ganz alone or in combination with Livneh does not disclose or render obvious “provid[ing] an Alternating Current (AC) RF signal to the plurality of electrodes.” Ex. 2030 (VWD Decl.) ¶¶61-63.

a. Ganz Does Not Disclose Or Suggest Using AC RF

Focusing first on Ganz alone, there is no mention anywhere in Ganz of alternating (or oscillating) current. Ex. 2030 (VWD Decl.) ¶61. Faced with this lack of disclosure, Petitioners argue that “a POSITA would understand that Ganz’s energy source provides with alternating current (AC) having a radio frequency (RF)” because “[a] POSITA would know that in the field of skin treatment using RF energy to heat the tissue, the energy is delivered by an alternating current (AC) that oscillates at the RF frequency.” Pet. 22. But as discussed below: (i) ***non-AC*** RF

energy was used for skin treatment; and (ii) when POSITAs meant to RF that is AC, they specified that the RF was AC – *and Ganz does not specify using RF that is AC.*

First, patents naming Petitioners' own expert, Dr. Woloszko, as an inventor show that ***non-AC*** RF energy was used for skin treatment. For example, Dr. Woloszko is a named inventor of several patents relating to skin treatment. *See, e.g.,* Ex. 2026 (US Pat No. 6,766,202), 1:43-47 ("The present invention relates ... more particularly to surgical devices and methods which employ high frequency electrical energy to treat a patient's skin"); Ex. 2028 (USP 8,012,153), 7:38-43 ("the present invention may be employed for ... surgical procedures on the skin, such as tissue rejuvenation, wrinkle removal, etc."); Ex. 2027 (USP 9,095,358), 6:44-49 ("The power source allows the user to select the voltage level according to the specific requirements of a ... dermatological procedure"). These patents also disclose application of RF energy for this skin treatment. *See* Ex. 2026 (USP 6,766,202), 5:30-34 ("The present invention applies high frequency (RF) electrical energy to ... the outer surface of the skin, to modify the structure of tissue structures within the skin."); Ex. 2028 (USP 8,012,153), 7:44-46 ("radio frequency (RF) electrical energy is applied"); Ex. 2027 (USP 9,095,358), 4:8-11 ("high frequency (RF) electrical energy is applied").

Moreover, Dr. Woloszko's patents (and other patents) for skin treatment using RF energy disclose that this RF can be provided as ***non-AC*** RF. For example, Dr.

Woloszko's U.S. Patent No. 6,766,202, confirms that RF energy for skin treatment "is usually delivered in a series of *voltage pulses or alternating current.*" Ex. 2026 (USP 6,766,202), 6:42-52; *see also* Ex. 2030 (VWD Decl.) ¶64. His U.S. Patent No. 9,095,358 states the same, and Dr. Woloszko's patents are not the only skin treatment patents that refer to use of non-AC RF. Ex. 2027 (USP 9,095,358), 6:28-34. For example, U.S. Patent Application Publication No. 2011/0288543 ("Chang"), which relates to "cosmetic applications including treatment of wrinkles," discloses a "hand-held radio frequency generator" that can emit "*direct current pulses.*" Ex. 2034 (Chang), [0005], [0017], [0035], [0036]; *see also* Ex. 2030 (VWD Decl.) ¶65.

Second, POSITAs specify AC RF when they mean to refer to AC RF specifically. For example, Dr. Woloszko specifically claimed "radiofrequency *alternating-current*" when he meant AC RF—just as the '836 Patent does—and in contrast to Ganz's disclosure. Ex. 2028 (USP 8,012,153), cl. 37. As Dr. van der Weide explains, the fact that Dr. Woloszko expressly claimed RF energy being delivered as "alternating-current" confirms that a generic reference to RF energy is not synonymous with AC RF because, if that were true, then claiming "radiofrequency alternating-current" would then be redundant. Ex. 2030 (VWD Decl.) ¶67. POSITAs specify that the RF is AC when they mean to refer to AC RF because, as Dr. Na, the named inventor of the '836 patent testified, "for RF there [is] DC RF and also AC RF." Ex. 2035 (Na Dep. Tr.), 44:5-8.

Because RF in the skin treatment context can refer to *non-AC* RF and POSITAs specify when they mean to refer to AC RF, Petitioners' contention that a POSITA would understand Ganz's generic reference to RF as AC RF is wrong. None of Petitioner's evidence indicates otherwise. Petitioners' evidence merely shows that an RF generator that provides AC RF *can* be used for skin treatment, but they do not show a POSITA would have understood Ganz to be using such an RF generator.

Moreover, Petitioners' arguments as to why a POSITA would have understood the RF in Ganz to be AC RF are without merit. First, Petitioners cite a statement in a book that a "RF generator produces an alternating current." Pet. 23 (quoting Ex. 1015, 4). But Petitioners do not contend that RF generators *only* produce AC, and the above-cited evidence shows that they can produce non-AC RF too. Petitioner offers no explanation why Ganz would have used an RF generator of the type referenced in the book as opposed to a non-AC RF generator.⁴

⁴ It is also surprising that Petitioners rely on this book because it undermines Petitioners' obviousness argument, confirming the drawbacks with ablative approaches, as used in Ganz, and the trend away from them as of 2009—years before the '836 Patent was filed. Ex. 1015, 3, 5-6 (identifying "adverse effects" associated with an existing ablative approach, which resulted in the device being "no longer in

Second, Petitioners rely on a statement made in one of Dr. Na's unrelated Korean patent application that "radio waves are basically alternating current." Pet. 23-24 (quoting Ex. 1025, [0016]). But Na's characterization of RF energy in the context of *that specific patent application* says nothing about whether Ganz means to refer to AC or non-AC RF. Ex. 2030 (VWD Decl.) ¶73.

Finally, Petitioners assert that using DC RF "is undesirable" and "IEC 60601-2-2, prohibits use of DC signals." Pet. 24. But Ganz is just a published patent application—it never issued as a patent—and is not commercial device that would need to meet any safety standard. Regardless, micro-coagulation surgical devices are exempt from the IEC 60601-2-2 standard, and the IEC standard does not "prohibit" DC RF systems, it just requires an appropriate control circuitry. Ex. 1030, 10 (§ 201.1.1), 22 (§ 201.8.4) ("[i]n order to minimize the possibility of neuromuscular stimulation, a capacitance shall be incorporated into the patient circuit...."). Indeed, there were "direct current" electrosurgical devices on the market, which were cleared for commercial use by the FDA. *See, e.g.*, Ex. 2036 (K212871 FDA Letter). And as discussed above, there are many patents referring to non-AC RF for use in skin treatment.

popular use" and explaining that "trends in the use of RF energy for skin rejuvenation have since focused on *non-ablative* technologies").

b. A POSITA Would Not Be Motivated To Combine Ganz And Livneh

Petitioners contend that, “[t]o the extent Ganz does not disclose” AC RF (and as discussed above Ganz does not), “Ganz in combination with Livneh renders this limitation obvious[.]” arguing a “POSITA implementing Ganz’s device would have been motivated to use Livneh’s power supply that provides an alternating current having a radio frequency.” Pet. 24-25, 30-31. But Petitioners offer no evidence that Livneh’s power supply would be suitable for Ganz’s purpose. As discussed, Ganz is directed to applying sufficient energy to create “ablation holes” to prompt “an even more aggressive wound healing response.” Ex. 1005, [0006]. To achieve these ablation holes, Ganz discloses RF electrodes with substantial “power in the range of about 50 to about 200 watts per square centimeter and also configured to provide an energy of at least about 1 joule per square centimeter.” *Id.*, [0011]; *see also id.* [0065] (“A power of 50 watts and an energy of 1 joule were delivered to the electrode array.”). Livneh, however, discloses nothing about the wattage or energy level its power supply provides to electrodes. Petitioners do not address this issue either.

Moreover, a POSITA would not have been motivated to use Livneh’s power supply in Ganz’s device, as Petitioners propose. Ex. 2030 (VWD Decl.) ¶76. There is no evidence that Livneh’s power supply would work in Ganz’s device, let alone any suggestion that it would work as well or better than Ganz’s power supply. Livneh merely states that its power supply “preferably converts commercial AC

electrical power” to “an AC signal operating at a radio frequency[,]” but discloses no details about this power supply or any advantages compared to other power supplies, such as those that provide non-AC RF. Ex. 1006, [0037]; Ex. 2030 (VWD Decl.) ¶76.

At bottom, Petitioners’ argument is that because both Ganz and Livneh are directed to skin treatment and there would not have been technical hurdles to using Livneh’s power supply in Ganz’s device, a POSITA could have done so. But “obviousness concerns whether a skilled artisan not only *could have made* but *would have been motivated to make* the combinations or modifications of prior art to arrive at the claimed invention.” *Pers. Web Techs., LLC v. Apple, Inc.*, 848 F.3d 987, 994 (Fed. Cir. 2017) (original emphasis). Petitioners offer only conclusory and unsupported expert testimony that AC RF is generally “suitable for skin treatment” (Pet. 31 (citing Ex. 1003 ¶117)), but fail to address whether Livneh’s power supply is suitable for the specific skin treatment of creating ablation holes that Ganz describes.⁵ *TQ Delta, LLC v. CISCO Sys., Inc.*, 942 F.3d 1352, 1359 (Fed. Cir. 2019) (obviousness findings “cannot be sustained by mere conclusory statements”).

⁵ As discussed above, Petitioners’ arguments that RF energy is inherently AC, or that a POSITA would find DC RF energy sources “undesirable,” are factually and legally erroneous. *See supra* Section V(A)(2)(a).

3. Ganz Fails To Disclose Or Render Obvious “a plurality of electrodes, the electrodes being bipolar” that are “configured to cause coagulation around each electrode rather than coagulating between the electrodes”

Ganz further does not disclose or render obvious “a plurality of electrodes, the electrodes being bipolar,” that are “configured to cause coagulation around each electrode rather than coagulating between the electrodes.” Ex. 2030 (VWD Decl.) ¶¶78-85.

First, Ganz fails to disclose “electrodes being bipolar” under the parties’ agreed construction adopted in the ITC, which is the same construction Petitioners rely on here. Pet. 9; Ex. 1028 (Markman Order), 40 (adopting the parties’ agreed construction of “electrodes being bipolar” as meaning “an electrodes change or alternate between being positive or negative as the current alternates between them (as opposed to a monopolar configuration where current flows from one or more electrodes that deliver current to one or more ground electrodes).”).

While Petitioners point to disclosure in Ganz that “[i]n bipolar electrode arrangements, both the positive and negative electrodes serve as treating electrodes” (Pet. 15 (citing Ex. 1005, [0056])), Petitioners fail to identify any disclosure in Ganz regarding any electrode “chang[ing] or alternat[ing] between being positive or negative as the current alternates between them (as opposed to a monopolar configuration where current flows from one or more electrodes that deliver current to one or more ground electrodes.” *Id.* Instead, Petitioners argue that Ganz’s

electrodes satisfy the claim construction because: (1) “a POSITA would understand that alternating current (AC) having a radio frequency is delivered to the bipolar electrodes[;]” and (2) because “[a]lternating current is current that reverses directions (or changes polarity).” *Id.* 16. But as discussed above, Ganz does not disclose use of AC RF. *Supra* Section V(A)(2)(a). Thus, because Petitioners rely on disclosure of AC RF that does not exist in Ganz, Ganz fails to disclose “electrodes being bipolar” under the parties’ agreed construction.⁶

Second, Ganz fails to disclose a plurality of “bipolar” electrodes “configured to cause coagulation around each electrode rather than coagulating between the electrodes,” as claimed. Ex. 2030 (VWD Decl.) ¶81. Petitioners simply point to disclosure of “bipolar electrodes” in Ganz, but claim 1 requires more than the mere presence of bipolar electrodes—it requires them to be configured to cause the claimed coagulation. *Id.* While Petitioners point to disclosure of coagulation in Ganz (*see, e.g.*, Pet. 26-27 (citing Ex. 1005, [0048])), Petitioners fail to show that any embodiment discussing coagulation utilizes bipolar electrodes, rather than monopolar electrodes that Ganz also discloses. Ex. 1005, [0011], [0013], [0055];

⁶ Petitioners only argue that “Ganz discloses” this limitation. Pet. 16. Petitioner does not contend that this limitation would have been obvious in view of Ganz and Livneh.

Ex. 2030 (VWD Decl.) ¶81. The only example in Ganz used a “monopolar electrode array.” Ex. 1005, [0065]. Indeed, Dr. Woloszko *admitted* that he cannot tell whether *any* of the “outcome[s] or results” in Ganz were obtained using bipolar electrodes because it is impossible to do so. Ex. 2012 (Woloszko Hr’g. Tr.), 1038:13-15 (“Q. *So you don’t know whether Ganz shows any outcome or results using bipolar electrodes, right? A. That’s correct.*”); *see also* Ex. 2030 (VWD Decl.) ¶82 (“*No one can identify how Ganz got the results that it produces.*”).

Third, Ganz does not disclose “a plurality of electrodes, the electrodes being bipolar,” under the “adopted construction,” which “excludes the Intracel configuration (alternating rows of commonly-polarized electrodes).” Pet. 17; Ex. 2030 (VWD Decl.) ¶¶83-84. Petitioners appear to concede that Ganz only discloses this excluded configuration, but argue that “Ganz does not limit its bipolar electrodes to such arrangements.” Pet. 17. But it is undisputed that Ganz discloses no other arrangements, and Petitioners do not contend that it would have been obvious to implement another configuration that is not excluded. Instead, Petitioners repeatedly argue that “Ganz discloses” this limitation when it undisputedly discloses only a configuration expressly excluded by the claim construction Petitioners apply.⁷ Pet.

⁷ Petitioners argue “that other configurations may include ... a checkerboard pattern[,]” (Ex. 1003 ¶82), but this is neither an argument for express nor inherent

17-18. Petitioner's reliance on *Upsher-Smith Laboratories, Inc. v. PamLab, L.L.C.*, is misplaced because, as Petitioners concede, that case involved disclosure of two alternatives, one of which was claimed, while here Ganz **only** discloses an configuration excluded from the claims. 412 F.3d 1319, 1322 (Fed. Cir. 2005); Pet. 18.

Further, Petitioners have failed to show that Ganz discloses a bipolar configuration that is **not** the Intracel configuration that produces the results in Ganz on which they rely (e.g., Ganz's Figures 9-10). Ex. 2030 (VWD Decl.) ¶¶83-84.

4. Ganz Fails To Disclose Or Render Obvious “configured to cause coagulation around each electrode rather than coagulating between the electrodes”

Ganz does not disclose or render obvious the limitation “configured to cause coagulation around each electrode rather than coagulating between the electrodes.” Ex. 2030 (VWD Decl.) ¶¶78, 81, 86-87, 92. As an initial matter, Ganz fails to disclose “coagulation around each electrode” because Ganz instead discloses **removal** of tissue around each electrode, i.e., the creation of “ablation holes.” *Id.*

disclosure. Petitioners do not argue obviousness and, even if they did, the conclusory expert testimony on which they rely (*id.*), is infected by hindsight. While the '836 Patent discloses a checkerboard pattern (Ex. 1001, 3:63-4:3, Fig. 6), Petitioners identify no evidence that prior art used such a pattern.

¶¶75, 92; Ex. 2031 (Goldberg Decl.) ¶¶32-33. As Dr. Goldberg explains, “there’s no coagulation around the microneedles because the tissue is gone.” Ex. 2031 (Goldberg Decl.) ¶32.

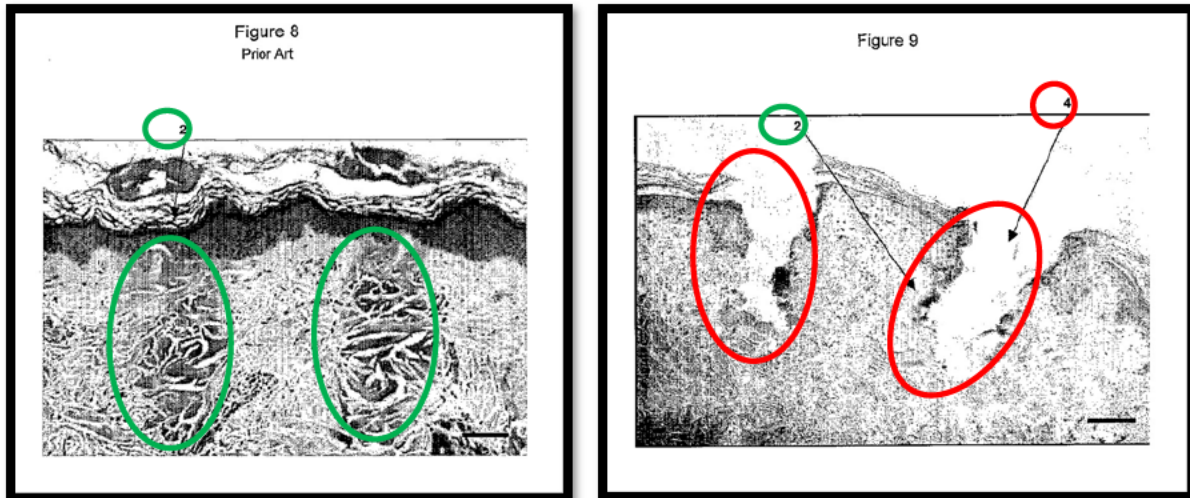
While Petitioners assert that any needle electrodes will cause perforations in the skin, Ganz expressly discloses doing more to create “ablation holes” by using “energy,” rather than “a simple knife, needle, or other device” that can cause “excess bleeding” to create “perforations without causing undue bleeding.” Ex. 1005, [0006], [0008]. “Ganz thus discloses cauterizing and removing tissue, which is very different than the types of treatments claimed in the ’836 Patent, which cause coagulation localized around each needle electrode.” Ex. 2031 (Goldberg Decl.) ¶32.

As discussed above, ’836 Patent and Ganz expressly distinguish each other’s approaches. *Supra* Section V(A)(1). While Ganz discloses burning away the epidermis and dermis around the electrode to form “ablation holes,” the ’836 Patent discloses and claims achieving coagulation around each electrode to “resolve problems of existing technologies[,]” including the “*serious side effect*” of “overheating or burning of both dermis and epidermis ..., which may cause permanent skin damage[,]” e.g., “scars created in overheated or burned epidermis.” Ex. 1001, 4:4-22. Indeed, the ’836 Patent distinguishes the claimed effect of “coagulation” from the other tissue effects—“carbonization” and “vaporization”—used by Ganz to remove the tissue around the electrodes. *Id.*, 2:62-3:10; Ex. 2030

(VDW Decl.) ¶87 (“Ganz is actually overheating and burning the epidermis in order to create its perforations.”); Ex. 2031 (Goldberg Decl.) ¶33 (“Ganz is directed to ablating and removal tissue, i.e., cauterizing the tissue surrounding the puncture sites.”).

Conversely, Ganz distinguishes systems which “*only cause[] zones of coagulation[,]*” like the ’836 Patent’s claimed approach, which Ganz views as a “*drawback.*” Ex. 1005, [0006]. Ganz explains that “rather than merely imparting coagulations into the skin” around electrodes as claimed in the ’836 Patent, Ganz’s approach provides for the “creation of actual perforations” around the electrodes to achieve a “more aggressive healing responses.” *Id.*, [0032]. In short, Ganz’s approach of creating “ablation holes” (*id.*, [0006]), stands in contrast to the ’836 Patent which, as Petitioner Ilooda’s original expert here, Dr. Bérubé admitted, “does not involve ablation.” Ex. 2033 (Bérubé Hr’g. Tr.), 1268:24-1269:1.

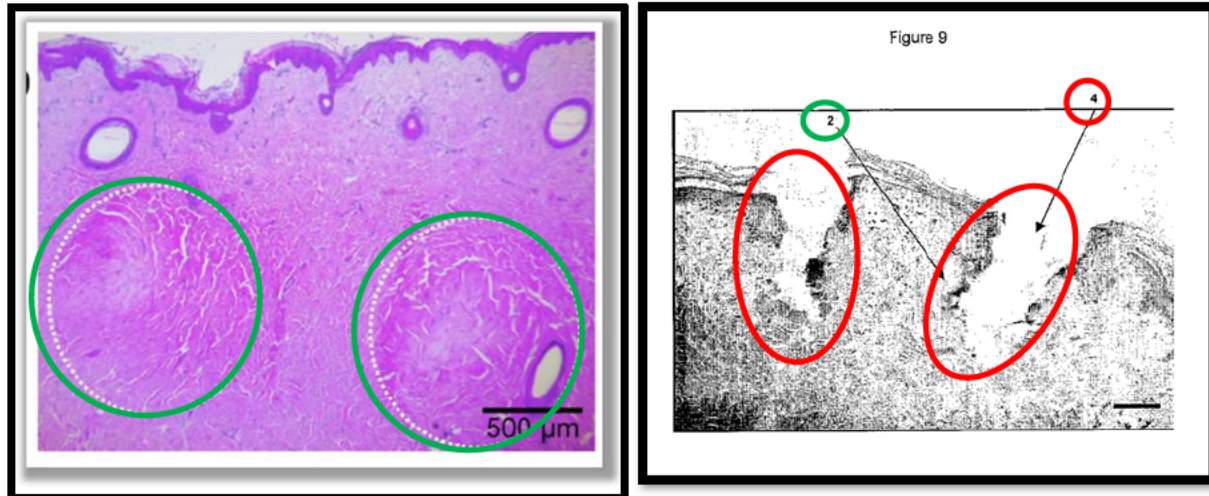
The fact that Ganz fails to disclose “coagulation around each electrode” is further demonstrated by examining Figures 8 and 9 of Ganz, copied below.



Compare Ex. 1005, Fig. 8 (annotated), with Fig. 9 (annotated).

As shown above on the left in Figure 8, the FRAXEL laser imparts zones of coagulation in the tissue being treated (labeled as No. 2, and annotated in green); conversely, the Ganz approach ablates and removes tissue, leaving only small residual zones of coagulation around the edges of the perforated holes (labeled as No. 4, and annotated in red).

Likewise, comparing histological images of coagulation around needle insertion sites produced using the '836 Patent's claimed approach (shown below on the left), with Ganz's approach (shown below on the right), similarly confirms that Ganz teaches an entirely different approach than claimed in the '836 Patent:



Compare Ex. 2032 (Na Nature Paper) (showing zones of coagulation around needle injection sites, annotated in green), with Ex. 1005, Fig. 9 (showing only residual coagulation around the “ablation holes,” annotated in red). While the ’836 Patent’s claimed approach leaves the tissue around the electrodes intact with “coagulation around each electrode” that was inserted, the Ganz approach results in removal of the tissue that was around each electrode. Ex. 2031 (Goldberg Decl.) ¶¶32-33; Ex. 2030 (VWD Decl.) ¶¶88, 92.

Petitioners’ arguments as to why Ganz discloses this limitation lack merit. For example, Petitioners argue that Ganz discloses the claimed “coagulation around each electrode” because Ganz discloses “[z]ones of coagulation” in “tissue surrounding each perforation,” i.e., coagulation at the edges of the perforations. Pet. 25-27. But this is not “coagulation *around each electrode*” as claimed—it is coagulation around the edge of the “ablation holes” that Ganz created by removing tissue around each electrode. Ex. 2030 (VWD Decl.) ¶¶75, 94. Once again, “there’s

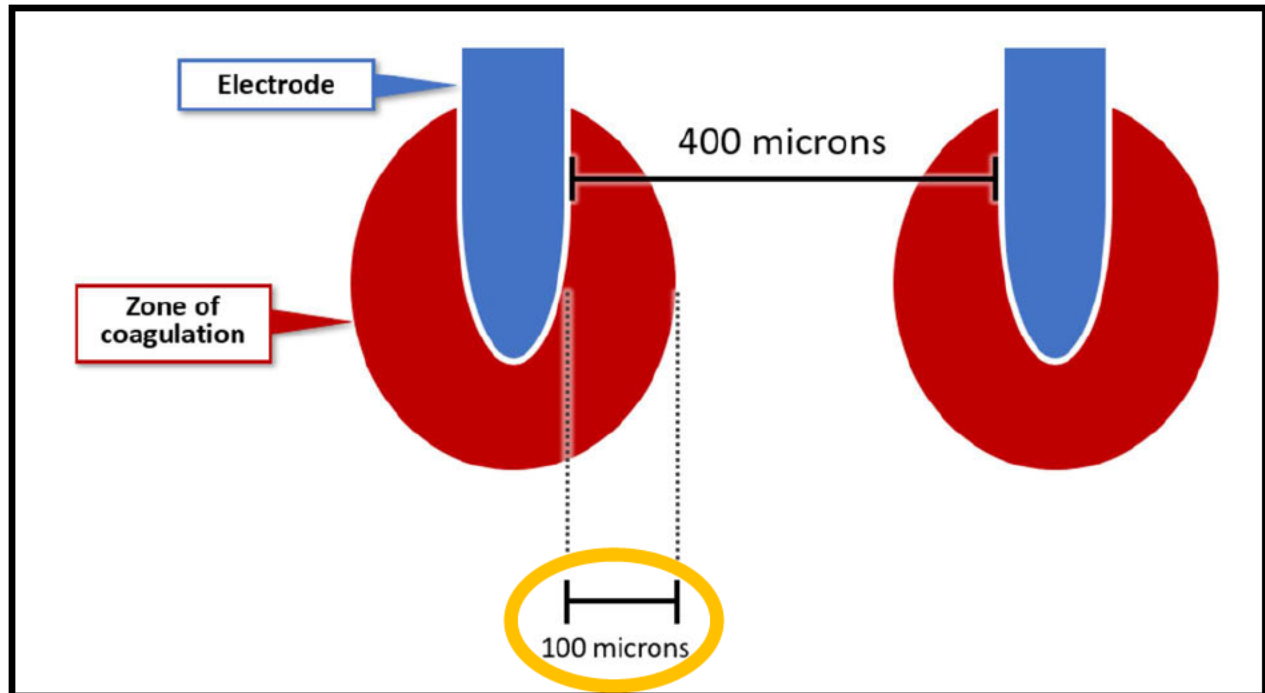
no coagulation around the microneedles because the tissue is gone.” Ex. 2031 (Goldberg Decl.) ¶32.

To try to pre-but this argument, Petitioners assert that “the claim limitation merely requires that coagulation be formed ‘around each electrode,’ not ‘immediately around each electrode.’” Pet. 29 (emphasis omitted). But by its plain language the claim requires “coagulation *around each electrode*”—not coagulation at the edges of ablation holes created near where electrodes were inserted. As shown above, cauterizing the edges of a hole created by inserting an electrode that applies energy to remove tissue, as in Ganz, is entirely different from inserting an electrode to cause coagulation around it in tissue that remains intact. Ex. 2031 (Goldberg Decl.) ¶¶9, 32-34; Ex. 2030 (VWD Decl.) ¶94.

Petitioners also posit a hypothetical example “where the width of the perforation is the same as the width of the electrode.” Pet. 28. Specifically, Petitioners rely on Ganz’s disclosure that “[t]he width of the perforation created will be at least the width of the electrode, and in many cases larger[.]” to argue that Ganz at least contemplates an embodiment where the width of the perforation is the same width as the electrodes. *Id.* (citing Ex. 1005, [0053]). But Ganz’s technique would still apply energy to remove the tissue that existed where the electrode was inserted, and Petitioners identify *no* example in Ganz of generating perforations the same size as electrodes. Ex. 2031 (Goldberg Decl.) ¶33. Nor have Petitioners identified any

disclosure in Ganz regarding whether (or how) such an example would have been achieved with bipolar electrodes, or any disclosure in of where coagulation (if any), would be located. As discussed above, Ganz only discloses coagulation around the edges of holes, i.e., “*surrounding each perforation.*” Ex. 1005, [0010].

Petitioners also create an illustration based on Ganz's disclosure of “*perforations*” that are “spaced apart by about 50 to about 400 microns” and “[z]ones of coagulation” that “can extend from the perforation site into the tissue for a *length* ranging from about 5 microns to about 100 microns.” Pet. 29 (quoting Ex. 1005, [0047]-[0048]). Putting aside the fact that coagulation extends from the “*perforation site*,” not the electrodes as Petitioners show, Petitioners erroneously illustrate the 100-micron “*length*” of coagulation vertically along the edge of the “perforation site” as the *width* of the coagulation extending horizontally away from the electrode. Ex. 2030 (VWD Decl.) ¶96. As shown in Petitioners' figure, copied below, they have assigned a width of 100 microns to the coagulation (circled in orange):



Pet. 29. But length is not width, and Ganz discloses a 100-micron **length**—not a **width**. Ex. 1005, [0048]. Moreover, Ganz (like any POSITA), understood the difference. *Id.*, [0015] (“a different electrode **width**, a different electrode **length**”), [0051] (“the electrodes are provided having a **length** and **width**”). Petitioners’ treatment of Ganz’s disclosure of “length” as a “width” “is plainly inconsistent with the record[]” and thus must be “disregard[ed].” *Homeland Housewares, LLC v. Whirlpool Corp.*, 865 F.3d 1372, 1378 (Fed. Cir. 2017).

In sum, Petitioners have failed to show that Ganz discloses “caus[ing] coagulation around each electrode rather than coagulating between the electrodes,” as Ganz is directed to removing tissue around the electrodes to create “ablation

holes”—so the tissue around each electrode is gone—and cauterizing the edges of those holes to prevent excess bleeding. Ex. 2031 (Goldberg Decl.) ¶¶24, 32.

5. Ganz Alone, Or In View of Livneh, Fails To Disclose Or Render Obvious Claims 2, 11-15, 23-24, And 26

Petitioners have further failed to show that Ganz in view of a POSITA's knowledge, and/or in further view of Livneh, discloses or renders obvious the limitations of claims 2, 11-15, 23-24, and 26. Ex. 2030 (VWD Decl.) ¶99. Claims 2 and 11-13 depend on claim 1, and thus Petitioners have failed to demonstrate that Ganz in view of a POSITA's knowledge, and/or in further view of Livneh, discloses or renders obvious these claims for the same reasons discussed with respect to claim 1 of the '836 Patent. *Id.* Independent claim 14 of the '816 Patent is the method version of claim 1's system claim, and as Petitioners point to the same evidence for claim 14 as they do for claim 1 (Pet. 36), Petitioners similarly have failed to demonstrate that independent claim 14 is invalid under these grounds. Likewise, because claims 15 and 23-24 depend upon claim 14 of the '836 Patent, Petitioners have failed to demonstrate the prior art discloses or renders obvious these claims for the same reasons discussed with respect to claim 1 of the '836 Patent. Ex. 2030 (VDW Decl.) ¶100.

B. Ground III And IV: Petitioner Failed To Demonstrate That Claims 2-10, 15-22, And 25 Would Have Been Obvious Based On Ganz In View Of Hantash, Or Ganz In View Of Livneh And Hantash

Petitioners have failed to show that Ganz in view of a POSITA's knowledge, and/or in further view of Livneh and Hantash, discloses or renders obvious the limitations of claims 2-10, 15-22, and 25. Ex. 2030 (VWD Decl.) ¶101. As discussed above, independent claim 14 of the '816 Patent is the method version of claim 1's system claim, and each of the other claims depend upon these two independent claims. Thus, Petitioners have failed to demonstrate that Ganz in view of a POSITA's knowledge, and/or in further view of Livneh and Hantash, discloses or renders obvious these claims for the same reasons discussed with respect to claim 1 of the '836 Patent. *Id.*

C. Ground V And VI: Petitioner Failed To Demonstrate That That Claims 27-29 Would Have Been Obvious Based On Ganz In View Of Lee, Or Ganz In View Of Livneh And Lee

Petitioners have further failed to show that Ganz in view of a POSITA's knowledge, and/or in further view of Lee and Livneh, discloses or renders obvious the limitations of claims 27-29. Ex. 2030 (VWD Decl.) ¶102. As discussed above, independent claim 14 of the '836 Patent is the method version of claim 1's system claim, and each of the other claims depend upon these two independent claims. Thus, Petitioners have failed to demonstrate that Ganz in view of a POSITA's knowledge,

and/or in further view of Lee and Livneh, discloses or renders obvious these claims for the same reasons discussed with respect to claim 1 of the '836 Patent. *Id.*

D. Objective Indicia Support Non-Obviousness

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 alteration).

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 ITC Investigation. Ex. 2054 (Serendia's June 16, 2023 Initial Validity Contentions). 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. Yet Respondents failed to address Patent Owner's evidence of secondary considerations at all in the ITC, and Petitioners' 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 the evidence of objective considerations from 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) (Paper 13) (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. Commercial Success

The introduction of the technology claimed in the ’836 Patent “radically revolutionized the way practitioners use RF microneedling devices and made treatments more effective, reduced patient pain and downtime, and increased the patient compliance.” Ex. 2031 (Goldberg Decl.) ¶36. Thus, products utilizing the

inventions have achieved commercial success, at least partially, from incorporating the '836 Patent's technology. *Id.* ¶37 ("The benefits of the '836 Patent make us all busier every day.").

As the '836 Patent explains, concentrating heat in the dermis while minimally affecting the epidermis is an advantage of the invention that avoids the scarring that had been associated with existing technology that (like Ganz) burned the epidermis. Ex. 1001, 3:21-25 ("In the present invention ... the heat may be concentrated at an area in dermis by the needle(s) to cause coagulation. The heat generated by the present invention may minimally affect the adjacent epidermis area."), 3:37-39 ("In an embodiment, higher temperatures may be concentrated in dermis, not epidermis"), 4:6-9 ("A serious side effect of some existing ... treatments is overheating or burning of both dermis and epidermis ..., which may cause permanent skin damage."), 4:18-23 ("Existing technology may create scars created in overheated or burned epidermis.... Embodiment of the present invention attempt to prevent overheating or burning of epidermis.").

With respect to commercialization of the '836 Patent's technology, the Sylfirm X RF Microneedling Device practices the claimed invention. *See, e.g.*, Ex. 2037 (Sylfirm X Brochure), 2-3 (identifying the '836 Patent); Ex. 2038 (ViOL Patent Marking), 1 (same); Ex. 2030 (VDW Decl.) ¶¶35-47. The Sylfirm X was designed by the inventor of the '836 Patent, Dr. Jung Ju Na, who, as discussed above,

discovered how to utilize bipolar AC RF energy to generate coagulation around microneedle electrodes, a phenomenon he called the “Na Effect.” Ex. 2037 (Sylfirm X Brochure), 4.

Advertisements for the Sylfirm X tout this benefit of the '836 Patent technology (and directly cite the '836 Patent). *Id.*, 2-3; Ex. 2038 (Patent Marking), 1. Sylfirm X's marketing materials explain that its treatments provide significant benefits over previous treatments and link these benefits to the ability to “maximize[] the thermal effect on the target with little to no epidermal damag[e].” Ex. 2037, 2-4; Ex. 2039 (Video) at 0:52; Ex. 2031 (Goldberg Decl.) ¶37. Other marketing and training materials likewise focus on the treatment benefits associated with implementing the technology claimed in the '836 Patent. Ex. 2031 (Goldberg Decl.) ¶39; Ex. 2101 (press release), 2 (“Undoubtedly the most profound advantage seen with the Sylfirm X Ultimate Edition is the ‘Na Effect[.]’”). “Th[is] prominence of the patented technology in ... advertising creates an inference that links the ... invention to this success.” *Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573, 1579 (Fed. Cir. 1997).

Moreover, as Patent Owner's economic expert, Mr. Thomas explains, the Sylfirm X has been commercially successful. Ex. 2139 (Thomas Decl.) ¶¶13-14. For example, [REDACTED] [REDACTED]

[REDACTED]

██
██

Thus, the Sylfirm X has been commercially successful, and there is a nexus between the '836 Patent and Sylfirm X's commercial success.

2. Industry Praise

The localized and targeted coagulation claimed by the '836 Patent has also received industry praise and recognition, and thus supports a finding of non-obviousness. Ex. 2031 (Goldberg Decl.) ¶¶48-55; *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1334 (Fed. Cir. 2016). For example, numerous medical providers have praised the “Na Effect,” and its implementation sets products “apart from the pack.” Ex. 2031 (Goldberg Decl.) ¶45; Ex. 2042 (Aesthetic Guide), 1, 3, 6; Ex. 2043 (Testimonials). Many industry studies also recognize the advancements claimed in the '836 Patent. Ex. 2031 (Goldberg Decl.) ¶¶51-54; Ex. 2044 (Paper Summary); Ex. 2045 (Cho Study); Ex. 2046 (Jung Study); Ex. 2047 (Wootten Study), 1-3; Ex. 2048 (Harth Study), 5-6.

Thus, the technology claimed in the '836 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*, 110 F.3d at 1579; *WBIP*, 829 F.3d at 1334 (Fed. Cir. 2016) (“competitors, are not likely to praise an obvious advance over the known art”).

3. Long-Felt Need

The '836 Patent's approach also overcame drawbacks associated with the prior art systems, addressing a long-felt but unsolved need in the industry. *Millennium Pharms., Inc. v. Sandoz Inc.*, 862 F.3d 1356, 1369 (Fed. Cir. 2017). As Dr. Goldberg explains, prior art treatments were known to cause burns, blisters, scarring, longer downtime, and pain. Ex. 2031 (Goldberg Decl.) ¶¶57-58; *see also* Ex. 2049 (Manstein '899), 3:31-59; Ex. 2050 (Woloszko '071), 2:35-50; Ex. 2051 (Manstein 090), [0040]. The technology claimed in the '836 Patent addressed these long-felt issues and “radically revolutionized the way we use these devices for skin tightening, acne scarring, aging skin, a whole different variety of entities and all different skin types and colors.” Ex. 2031 (Goldberg Decl.) ¶62; *see also* Ex. 1001, 4:4-19.

VI. CONCLUSION

For the reasons set forth above, the Board should deny institution of *Inter Partes* Review.

Respectfully submitted,

Dated: April 25, 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 13,918 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 25th 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 Petitioners' lead and backup counsel at the following email addresses:

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