

Filed: April 25, 2024

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEURENT MEDICAL INC. & NEURENT MEDICAL LTD.,
Petitioner,

v.

AERIN MEDICAL INC.,
Patent Owner.

Case IPR2024-00282
Patent No. 11,766,286

PATENT OWNER'S PRELIMINARY RESPONSE

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I. Introduction

U.S. Patent No. 11,766,286 (“the ’286 patent”) is directed to novel devices for delivering energy to a nasal airway to improve nasal airflow. Petitioner challenges claims 1-4 and 7-9 of the ’286 patent. The references in Petitioner’s Grounds are fundamentally different and have contradictory purposes to one another. Petitioner fails to provide a reason that, despite these fundamental differences, a person of ordinary skill in the art would have been motivated to combine these references.

Grounds 1-2 and 5-6 of the Petition are based on the combination of Edwards-535 and Stern, which are diametrically opposed and have the exact opposite objective and effect on the areas they treat. Edwards-535 seeks to treat sleep apnea by ablating underlying tissue of the nasal concha while preventing ablation of surface tissue. Stern, on the other hand, seeks to ablate the surface of the uterus, called the endometrium, while preventing ablation of underlying tissue. Edwards-535 and Stern are so fundamentally different that a person of ordinary skill in the art would not have been motivated to combine them, and, in fact, would have been discouraged from combining them.

Grounds 3-4 and 7-8 of the Petition are based on the combination of Makower and Stern. In addition to this being a hindsight-driven combination, Petitioner has also failed to establish a motivation to combine those references.

Makower and Stern have vastly different objectives and effects on the areas they treat, namely that Makower shrinks tissue, removing only as much tissue as necessary, while causing minimal damage, and that Stern destroys large areas of surface tissue. Applying Stern's teachings to Makower would have devastating effects on the function of the turbinates and the nose, and a person of ordinary skill in the art would not have made such a deleterious combination.

Petitioner's failure to establish a motivation to combine both Edwards-535 and Stern, and Makower and Stern, is sufficient to deny institution because Petitioner relies on either the combination of Edwards-535 and Stern or Makower and Stern in all Grounds of the Petition. But there are additional reasons to deny institution. Petitioner relies on the combination of Edwards-535 and Liang (in Grounds 5 and 6) and Makower and Liang (in Grounds 7 and 8), and Petitioner failed to establish a motivation to combine Edwards-535 and Liang, and Makower and Liang. The techniques of Edwards-535 and Liang are fundamentally different, such that a person of ordinary skill in the art would not have been motivated to combine them, especially when Edwards-535 is trying to avoid the very problems of bleeding and nasal adhesions that Liang suffers from. Petitioner's motivation to combine Makower and Liang is also woefully deficient because it relies almost entirely on a motivation for a different combination and merely identifies alleged

similarities between Makower and Liang without establishing a reason to combine those references.

All told, Petitioner presents eight Grounds, some of which balloon to a total of four, and even five, references, and none of which present an adequate motivation to combine. The Board should deny institution of this deficient, scattershot Petition.

II. The '286 Patent

The '286 patent claims devices “delivering energy to a nasal airway to treat rhinitis.” *See, e.g.*, Ex. 1001-'286 patent, claim 1. The '286 patent describes “reshap[ing] tissue without a surgical incision or implant.” *Id.*, 5:62-64. The '286 patent describes a device with a handle, shaft, and a treatment element that can be inserted into a nostril. *Id.*, 4:30-47, 9:5-6, Fig. 3. The '286 patent discloses an inflatable or expandable treatment element that is configured to expand from a collapsed configuration for insertion into the nasal passageway to an expanded configuration for contacting a surface of the nasal passageway. *Id.*, 9:7-15, 18:12-26, 18:30-41, Figs. 4A-4C. The '286 patent further teaches bipolar electrodes on the treatment element with radiofrequency energy applied to the electrodes via radiofrequency output channels to target tissue underlying the nasal mucosa. *Id.*, 5:4-16, 6:38-46, 23:38-40, 24:46-48, 24:56-60, Figs. 8B, 8G. The '286 patent discloses sensors on the treatment element for measuring a temperature or

impedance near the tissue to be treated and adjusting the level of energy to be delivered with a control system. *Id.*, 5:21-33, 8:26-31, 16:36-49. The '286 patent describes that “[r]emodeling or changing the structure of the nasal valve can improve nasal airflow in people with inadequate nasal airflow resulting from causes other than nasal valve dysfunction, such as deviated septum, enlarged turbinates, mucosal swelling, and/or mucous production.” *Id.*, 11:37-42.

III. The Asserted Art

A. Edwards-535

Edwards-535 discloses “a method and apparatus for treating airway obstructions,” like those caused by “[s]leep apnea syndrome,” by “reducing the volume of the turbinates in order [to] reduce nasal airway obstructions.” Ex. 1010-Edwards-535, 1:22-26, 1:30-33. In all embodiments of Edwards-535, the “invention provides a method for reducing the size of a nasal concha without the formation of a wound on the surface of the nasal concha.” *Id.*, 4:63-66.

Edwards-535 describes providing cooling to the surface of the nasal concha to deliver energy to ablate the internal portion of the nasal concha while preventing ablation of the surface of the nasal concha. *See id.*, 4:60-63 (“By cooling the surface of the nasal concha being ablated, ablation can be performed to remove an internal section of a nasal concha without damaging the surface of the nasal concha.”); *see also id.*, 6:12-16 (“The extent of cooling provided is preferably

sufficient to prevent the nasal concha surface from being ablated. As a result, an interior portion of a nasal concha is ablated without ablating the surface of the nasal concha.”), 6:26-27 (“[A]n exposed wound site is not generated during the method.”); *see also id.*, 6:23-25, 7:2-4. Edwards-535 describes how its “procedure can be performed bloodlessly and without the need to penetrate tissue” and “eliminates the need for surgical cutting.” *Id.*, 4:58-60, 4:55-57.

B. Stern

Stern discloses “a method and an apparatus for in situ destruction of the inner lining of body organs, and more particularly the providing of a selective destruction of the endometrium,” the thin layer of tissue lining the uterus. Ex. 1033-Stern, 1:17-22, 6:56-59. Stern explains that its “goal” is “destruction of the endometrial cells.” *Id.*, 6:60-62. Stern describes destroying the endometrium by using radiofrequency (“RF”) energy to heat it to an ablative temperature while maintaining the average temperature of the myometrium, which is the tissue beneath the endometrium surrounding the uterine cavity. *See id.*, 2:11-18 (describing “heat[ing] the endometrium” and “destroy[ing] the cells of the lining while maintaining the average temperature of the myometrium”), 7:29-33 (explaining that “the temperature of the endometrium 22 can be heated to a destructive temperature faster than the myometrium 14 and the rest of the uterus”), 6:66-7:6 (“Radio frequency electric current passes through the dilated endometrial

surface for a time sufficient to destroy the endometrial cells by elevating the temperature of the endometrium The temperature is maintained until the endometrial tissue is destroyed”), Figs. 1, 3, 6:51-59, 7:62-67 (showing and describing the myometrial tissue beneath the endometrial lining).

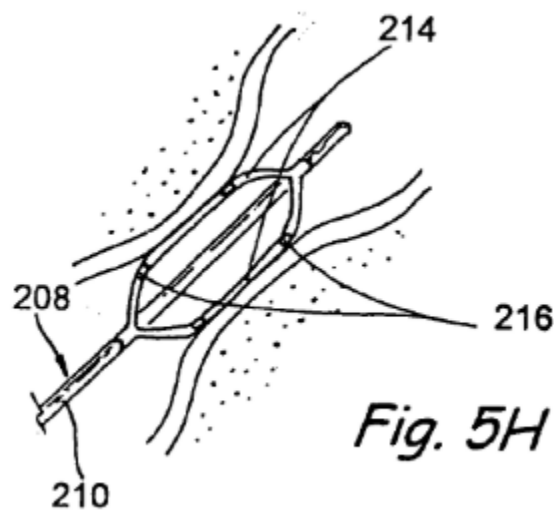
C. Makower

Makower discloses a smattering of embodiments of devices used to perform diagnostic or therapeutic procedures for ear, nose, and throat disorders.

Ex. 1021-Makower, [0001], [0042], [0161]. For example, Makower discloses various occluder, suction, and access devices (Figs. 2A-2R, Figs. 3A-3M’), an occluder/endotracheal tube device (Fig. 4), a cutting or ablation device (Fig. 5A), devices with laterally deployable projections (Figs. 5B, 5D), a drill (Fig. 5C), a catheter (Fig. 5D), various balloon catheters (Figs. 5E-5G’’), a tissue shrinking electrode (Fig. 5H), a cryogenic device (Fig. 5I), a tissue expanding device (Fig. 5J), various forward cutting/suction catheter/endoscope devices (Figs. 5K-5O), various balloon catheter/stent/endoscope devices (Figs. 5P-5R’’), a snare catheter (Fig. 5S), forceps (Fig. 5T), a guide catheter and guidewire and endoscope (Fig. 5U-5U’), a microbrider catheter (Fig. 5V), various bone remodeling devices (Figs. 5W-5X’’’’), a substance delivering implant device (Figs. 5Y-5Y’’’’), various guide catheters (Figs. 6A-6D), a plugging guide catheter (Fig. 6E), and

various other catheters (Figs. 7A-7G), and a cochlear implant procedure (Figs. 9A-9C). *Id.*, [0049]-[0128].

In one of these embodiments, Figure 5H shown below, Makower depicts a non-invasive device that can be inserted into the nasal cavity and cauterize or heat adjacent tissue, which it describes in one paragraph. *Id.*, [0092], [0187], Fig. 5H.



Id., Fig. 5H.

Makower alleges that a benefit of the “present invention” is that its devices are “delivered and positioned to perform the desired diagnostic or therapeutic procedures with *minimal trauma* to other tissues, as can result from the insertion of rigid scopes and rigid instruments in accordance with the methodology of the prior art.” *Id.*, [0161] (emphasis added). In fact, causing “minimal damage to the surrounding tissues” is one of the objectives of Makower’s devices. *Id.*, [0016].

Makower further explains that removing too much tissue from the turbinates can impair the function of the turbinates:

It is typically desirable to remove only as much tissue as necessary to restore normal breathing and drainage, as removal of too much tissue from the turbinates can impair the ability of the turbinates to perform their physiological functions of warming and humidifying inspired air and conserving warmth and moisture from expired air.

Id., [0030].

D. Liang

Liang is a clinical study describing using a radiofrequency device “to perform thermal coagulation treatment on the bilateral nasal ridge and the corresponding nasal septum mucosa.” Ex. 1056-Liang, 341. The study’s authors state that an “SHP-I radiofrequency treatment device for facial organs (manufactured by Guangzhou Medical Device Factory)” was used to “perform thermal coagulation treatment” in its study but provide no details on the device or settings used in the study. *Id.* The authors explain that radiofrequency treatment can cause “degeneration and atrophy of the sensitive mucosa on the nasal ridge and corresponding nasal septum.” *Id.*, 341-42. And the authors describe that “the patients might experience symptoms such as . . . a small amount of bloody secretions” following treatment and that some “developed nasal adhesion.” *Id.*,

341. As a result, the authors of Liang recognize and warn that their procedure can damage the sensitive mucosa surface. *See id.*, 341-42.

IV. Petitioner Has Not Demonstrated a Reasonable Likelihood of Prevailing on Any Claim Challenged in Ground 1

In Ground 1, Petitioner seeks to combine Edwards-535 and Stern. But Edwards-535 and Stern are diametrically opposed and do the exact opposite of one another, and the Petition fails to adequately explain why a person of ordinary skill in the art would have been motivated to combine such contradictory references.

It is Petitioner's burden to demonstrate "that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so." *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367-68 (Fed. Cir. 2016) (citations omitted). Petitioner has not met that burden for its combination of Edwards-535 and Stern used in Ground 1.

A person of ordinary skill in the art would not have combined Edwards-535 and Stern because those references are diametrically opposed and have the exact opposite objective and effect on the areas they treat. Edwards-535 delivers energy to *ablate an internal portion* of the nasal concha while *preventing ablation of the*

surface of the nasal concha, and Stern delivers energy to *destroy the surface* of the endometrium while *not ablating the myometrium* below the endometrium.

As discussed in Section III.A above, Edwards-535 discloses “a method and apparatus for treating airway obstructions” by “reducing the volume of the turbinates in order [to] reduce nasal airway obstructions.” Ex. 1010-Edwards-535, 1:22-26. Edwards-535 “reduc[es] the size of a nasal concha *without the formation of a wound on the surface* of the nasal concha.” *Id.*, 4:63-66 (emphasis added); *see also id.*, 6:26-27 (“[A]n exposed wound site is not generated during the method.”).

Edwards-535 describes methods of ablating a portion of the nasal concha. For example, Edwards-535 describes an embodiment shown in Figures 3A-3D where “[s]ufficient energy 117 is delivered *through the surface 115* of the nasal concha 114 to *ablate at least a portion 119 of the nasal concha 114*.” *Id.*, 5:32-34 (emphases added).

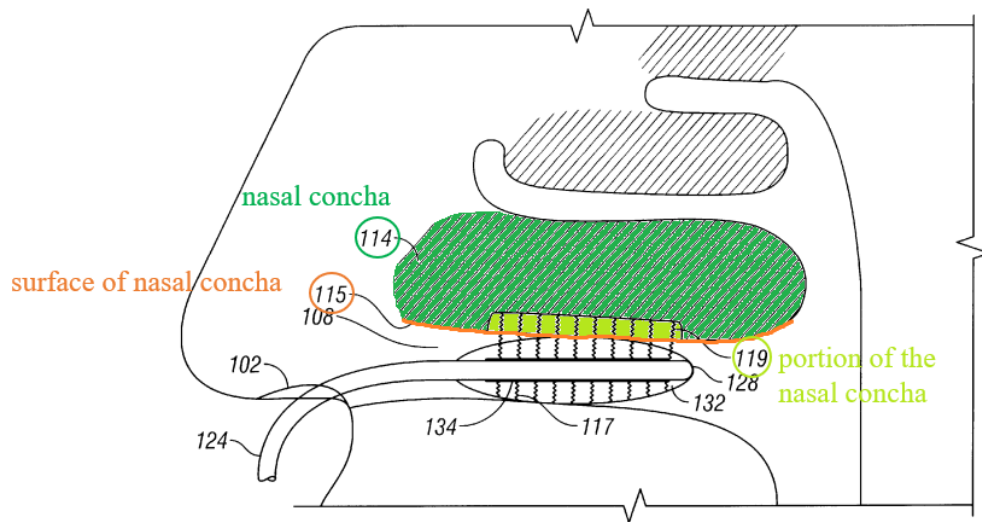


FIG. 3B

Id., Fig. 3B (annotated). As noted above, Edwards-535 explains that “the present invention provides a method for reducing the size of a nasal concha *without the formation of a wound on the surface of the nasal concha.*” *Id.*, 4:63-66 (emphasis added). Thus, in Edwards-535, a portion of the nasal concha 119 is ablated without ablating the surface of the nasal concha 115. *See id.*, 5:32-34, 4:63-66.

One way Edwards-535 prevents ablating the surface of the nasal concha is by providing cooling to the surface of the nasal concha. *Id.*, 7:2-4 (“Cooling of the surface of the nasal concha may be performed in order to prevent the ablation of the surface of the nasal concha.”), 6:10-14 (“[T]he surface of the nasal concha to be ablated is cooled during the delivery of energy The extent of cooling provided is preferably sufficient to prevent the nasal concha surface from being ablated.”); *see also id.*, 6:23-25.

Edwards-535 explains that by cooling the surface of the nasal concha, the internal section of the nasal concha can be ablated without ablating the surface of the nasal concha. *Id.*, 4:60-63 (“By cooling the surface of the nasal concha being ablated, ablation can be performed to remove an internal section of a nasal concha without damaging the surface of the nasal concha.”), 6:14-16 (“As a result, an interior portion of a nasal concha is ablated without ablating the surface of the nasal concha.”). As illustrated below, “the ablated tissue region 146 is an interior region, i.e., the surface 115 of the nasal concha has not been ablated. This may be achieved by cooling the surface 115 of the nasal concha during the delivery of ablative energy to the nasal concha.” *Id.*, 7:6-11.

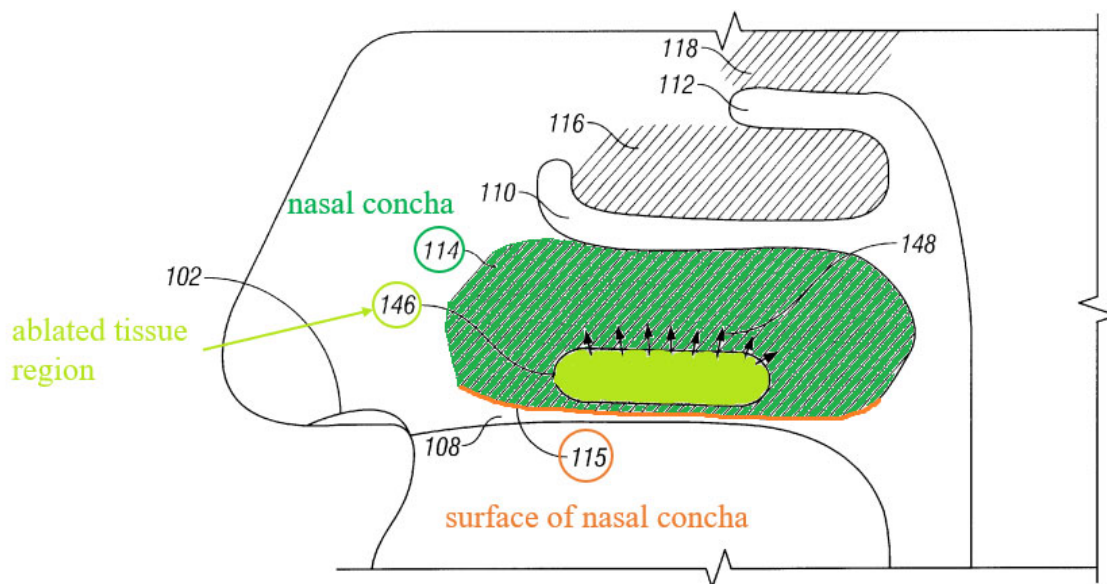


FIG. 4B

Id., Fig. 4B (annotated). Edwards-535, therefore, prevents ablation of the surface of the nasal concha while ablating an internal section of the nasal concha.

In direct contrast to Edwards-535, and as discussed above in Section III.B, Stern discloses “a method and an apparatus for in situ destruction of the inner lining of body organs, and more particularly the providing of a selective destruction of the endometrium.” Ex. 1033-Stern, 1:17-22. As shown below, the endometrium 22 is the thin layer of tissue lining the uterus, and the myometrium 14 is tissue beneath the endometrium. *Id.*, 6:51-59, 7:62-67.

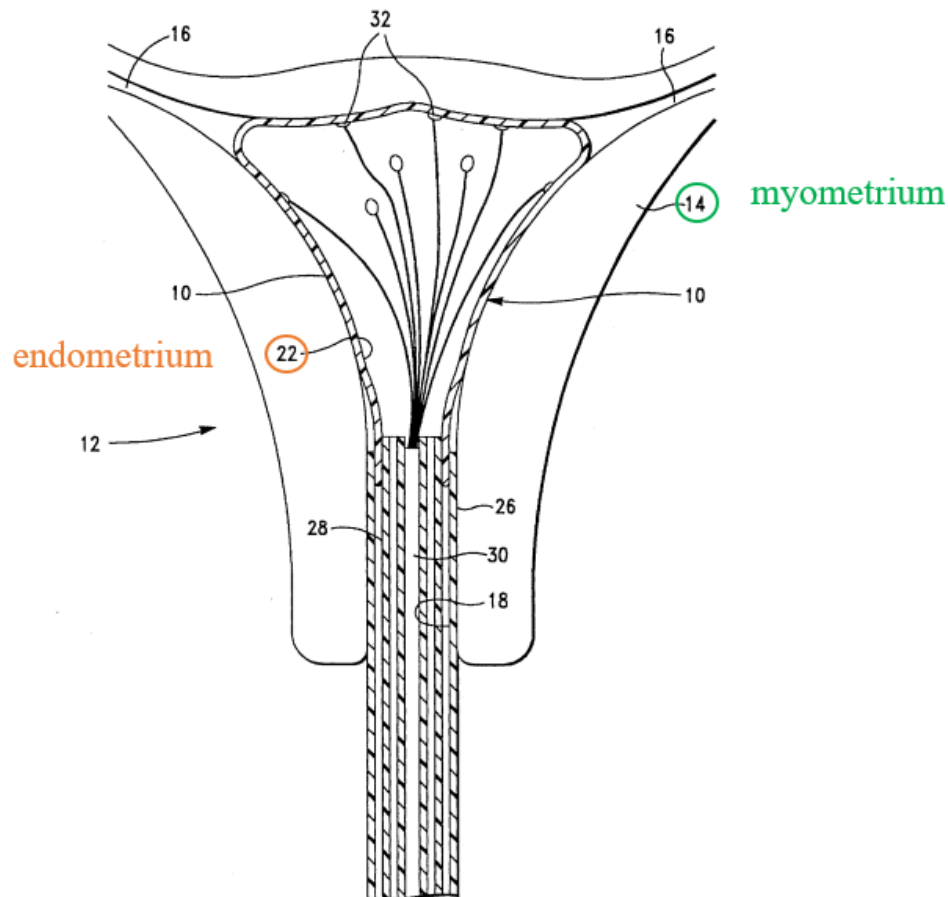
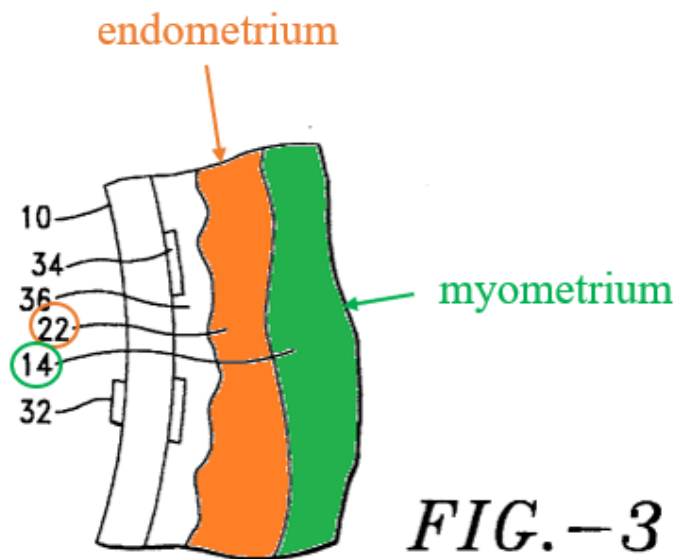


FIG.-1

Id., Fig. 1 (annotated).



Id., Fig. 3 (annotated).

The express “goal” of Stern is “destruction of the endometrial cells.” *Id.*, 1:17-22, 6:60-62. Stern describes using RF energy to heat the endometrium to an ablative temperature and destroy it. *See id.*, 2:11-18 (describing “heat[ing] the endometrium” and “destroy[ing] the cells of the lining”), 6:66-7:6 (“Radio frequency electric current passes through the dilated endometrial surface for a time sufficient to destroy the endometrial cells by elevating the temperature of the endometrium The temperature is maintained until the endometrial tissue is destroyed”).

In Stern, while the endometrium is destroyed, the tissue beneath the endometrium, the myometrium, is maintained at a nonablative temperature. *See id.*,

7:29-33 (explaining that “the temperature of the endometrium 22 can be heated to a destructive temperature faster than the myometrium 14 and the rest of the uterus”), 2:13-18 (describing “destroy[ing] the cells of the lining while maintaining the average temperature of the myometrium”), Figs. 1, 3, 1:17-22, 6:51-59, 7:62-67 (showing and describing the endometrium lining the uterus and the myometrium beneath the endometrium). Stern ablates the inner lining of the surface of the uterus (the endometrium) while not destroying the tissue underlying the endometrium (the myometrium).

Even though Edwards-535 and Stern both deliver energy, albeit to very different areas of the body, they do the exact opposite to the tissue in the areas they treat. Edwards-535 delivers energy to *ablate the internal portion* of the nasal concha while *preventing ablation of the surface* of the nasal concha, and Stern delivers energy to *destroy the surface* of the endometrium while *not ablating the myometrium* below the endometrium. Put simply, Edwards-535 ablates underlying tissue while preventing ablation of surface tissue, and Stern ablates surface tissue while preventing ablation of underlying tissue. In this important way, Edwards-535 and Stern are essentially opposites.

The Petition fails to acknowledge this fundamental difference between Edwards-535 and Stern and fails to explain why a person of ordinary skill in the art would have been motivated to combine Edwards-535 and Stern when they have

diametrically opposed objectives and outcomes—Edwards-535 ablating underlying tissue while preventing ablation of surface tissue, and Stern ablating surface tissue while preventing ablation of underlying tissue. “The obviousness inquiry does not merely ask whether a skilled artisan could combine the references, but instead asks whether ‘they would have been motivated to do so.’ . . . *Fundamental differences* between the references are *central* to this motivation to combine inquiry.” *Adidas AG v. Nike, Inc.*, 963 F.3d 1355, 1359 (Fed. Cir. 2020) (emphases added) (quoting *InTouch Techs., Inc. v. VGO Commc’ns, Inc.*, 751 F.3d 1327, 1352 (Fed. Cir. 2014)) (affirming the Board’s finding of no motivation to combine where there were “fundamental differences” in the references, which the “Board properly considered” in its motivation-to-combine inquiry). If anything, these differences would have discouraged those skilled in the art from making the proposed combination.

The Board has denied institution in similar cases where the references were so fundamentally different that there was insufficient motivation to combine. *See, e.g., Johns Manville Corp. v. Knauf Insulation, Inc.*, IPR2018-00827, Paper 9 at 11-12, 21 (P.T.A.B. Oct. 16, 2018) (informative) (denying institution for insufficient reasons to combine references where petitioner failed “to show that one of ordinary skill in the art would have had a reason to substitute [one

reference's] binder for the binder disclosed in [the other reference]" when the two references taught "considerably different binding systems" (citation omitted)).

Petitioner advances several purported reasons that a person of ordinary skill in the art would have been motivated to combine Edwards-535 and Stern, Pet., 36-40, but none are sufficient, especially considering the fundamental differences between Edwards-535 and Stern discussed above.

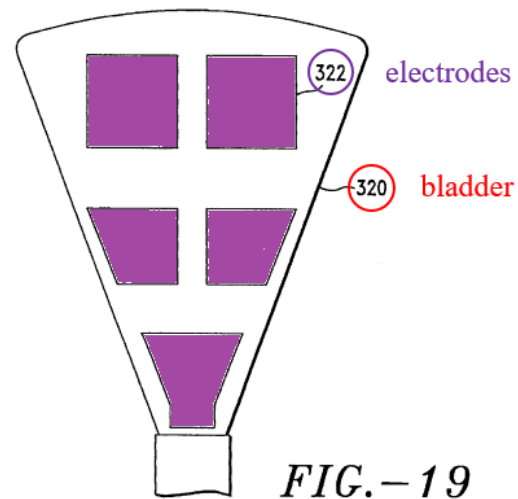
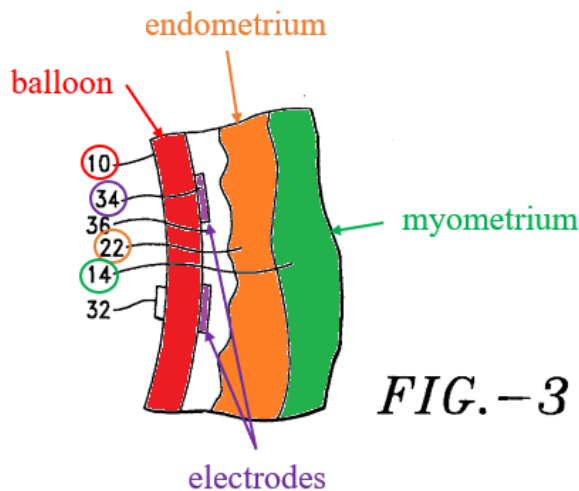
First, Petitioner argues that "Edwards-'535 and Stern are analogous art to the Challenged Claims." *Id.*, 36-37. However, even assuming for purposes of argument that Edwards-535 and Stern are analogous art (which Patent Owner does not concede), "[a]nalogous art is merely a threshold inquiry as to whether a reference can be considered in an obviousness analysis." *Johns Manville*, IPR2018-00827, Paper 9 at 10. "Demonstrating that a reference is analogous art or relevant to the field of endeavor of the challenged patent *is not sufficient* to establish that one of ordinary skill would have had reason to combine its teachings with other prior art in the manner set forth in the claim." *Id.* (emphasis added) (citing *Securus Techs., Inc. v. Glob. Tel*Link Corp.*, 701 F. App'x 971, 977 (Fed. Cir. 2017) ("[A] broad characterization of [prior art references] as both falling within the same alleged field . . . , without more, is not enough for [petitioner] to meet its burden of presenting a sufficient rationale to support an obviousness conclusion.'")).

Second, Petitioner argues that Edwards-535 “leaves details on how to implement” its energy delivery “up to a POSITA” and was therefore “ready for improvement, and a POSITA would have been motivated to turn to other sources for information.” Pet., 37-38. Petitioner argues that a person of ordinary skill in the art “would have found Stern to be a good source for this information given its detailed disclosure and schematic Figures.” *Id.*

Specifically, Petitioner argues that a person of ordinary skill in the art would have been motivated to “improve Edwards-’535’s device to include Stern’s technique for pairing bipolar RF surface electrodes . . . and wiring them to allow for independent delivery of RF energy to each bipolar pair.” *Id.*, 38. But Petitioner fails to acknowledge the major problem with this purported combination—that Edwards-535 “reduc[es] the size of a nasal concha *without the formation of a wound on the surface* of the nasal concha,” Ex. 1010-Edwards-535, 4:63-66 (emphasis added), and that if Stern’s “surface electrodes” were added to Edwards-535 as the Petition suggests, Pet., 38, that would ablate the surface of the nasal concha in direct opposition to the objective of Edwards-535.

As shown in Figures 3 and 19 of Stern below, Stern’s electrodes are located on the outside of the expandable balloon or bladder. Ex. 1033-Stern, 2:8-11 (“The outer surface of the expandable member contains one or more electrodes . . .”), 7:62-8:5 (referring to Figure 3 and describing the “[e]lectrical contact between the

conductive surface of the electrodes 34 and the endometrium 22”), 14:26-28 (“In the embodiment illustrated in FIG. 19, a plurality of electrodes 322 are formed on the surface of the bladder 320.”).



Id., Figs. 3, 19 (annotated). When the electrodes are activated, and RF energy is applied, the cells of the lining of the uterus (the endometrium) are destroyed. *Id.*, 1:17-22, 2:6-19, 6:60-62, 6:63-7:6 (monopolar arrangement), 13:27-31 (bipolar arrangement).

Adding Stern's "surface electrodes" to Edwards-535 as Petitioner proposes would cause ablation of the surface of the nasal concha. Ablating the surface of the nasal concha is directly contrary to Edwards-535's express objectives of not "form[ing] . . . a wound on the surface of the nasal concha" and "prevent[ing] the ablation of the surface of the nasal concha." *See* Ex. 1010-Edwards-535, 4:63-66, 6:10-14, 7:2-4. The Petition fails to acknowledge that its proposed combination

would result in surface ablation of the nasal concha, which is the exact opposite of the objective of Edwards-535. And the Petition fails to explain why, despite the fundamental differences and diametrically opposed objectives of Edwards-535 and Stern, a person of ordinary skill in the art would combine the references. In reality, adding Stern's "surface electrodes" to Edwards-535 would have been contrary to the objective of Edwards-535, which is fatal to Petitioner's alleged motivation to combine.

Third, Petitioner argues that Stern identifies "benefits" that would have led a person of ordinary skill in the art to modify Edwards-535 in view of Stern. Pet., 38-39. One alleged benefit that Petitioner identifies is that Stern's "bipolar electrode pairs allow a physician to precisely control the location of electrical current delivered by the device." *Id.*, 38. But the very portions of Stern that Petitioner relies on for this alleged advantage make it clear that the purpose of using a bipolar arrangement to allegedly achieve "precise control" is to "insure [sic] complete heating of an area" to achieve "tissue destruction." *See* Ex. 1033-Stern, 12:26-34, 13:21-35. Stern even criticizes prior procedures as lacking "control" to "ensure complete ablation" of a large treatment area, again making it clear that any alleged "control" taught by Stern is for the complete destruction of large areas of surface tissue. *Id.*, 1:51-55. Stern's objective to destroy the surface tissue is contrary to Edwards-535's objective of not ablating the surface tissue.

And Petitioner provides no reason one of ordinary skill in the art would have sought to combine Stern's alleged "control" to completely destroy a large area of surface tissue with Edwards-535, which has the goal of not destroying any surface tissue, let alone a large area of surface tissue.

Another alleged benefit that Petitioner identifies is that Stern "allows heating of targeted tissue while ensuring that surrounding tissue is unaffected." Pet., 38 (citing Ex. 1033-Stern, 13:21-39, Fig. 15). But the disclosure of Stern on which Petitioner relies does not disclose this alleged advantage. *See* Ex. 1033-Stern, 13:21-38. To the contrary, Stern seeks to destroy a large area of tissue, and even the portion of Stern cited by Petitioner merely states that Stern seeks "complete heating of an area." *Id.*, 1:51-55, 13:21-31. And, even if Stern did disclose this alleged advantage, the targeted tissue and surrounding tissue in Stern and Edwards-535 are the exact opposite of one another. In Stern, the targeted tissue for ablation is the surface tissue, called the endometrium, and the surrounding tissue that is unaffected is the underlying tissue, called the myometrium. In Edwards-535, the targeted tissue for ablation is the tissue of the nasal concha underneath the surface tissue, and the surrounding tissue that is unaffected is the surface tissue of the nasal concha. And Stern nowhere discloses or teaches how to use its electrode arrangement to ablate internal tissue while preserving surface tissue, further undermining Petitioner's alleged reason to combine.

The other alleged benefits Petitioner identifies are that pairs of bipolar electrodes can “ensure even heating” and allow “selective tissue destruction over an entire area of tissue” Pet., 38. But, again, the electrodes of Stern, even when allegedly ensuring “uniform heating,” are designed to provide “complete heating of an area” of the surface of the uterus, the endometrium, to destroy it, and Edwards-535 has the opposite objective of protecting the surface of the nasal concha. *Compare, e.g.,* Ex. 1033-Stern, 13:21-40, *with, e.g.,* Ex. 1010-Edwards-535, 4:63-66. Thus, none of these alleged benefits of Stern support a motivation to combine Stern with Edwards-535.

Fourth, Petitioner argues that Edwards-535 and Stern “describe similar techniques of delivering bipolar RF ablation energy . . . such that their combination would have been straightforward and yielded predictable results.” Pet., 39. But as discussed above, Edwards-535 and Stern describe radically different techniques. Edwards-535 ablates underlying tissue while preventing ablation of surface tissue. And in sharp contrast, Stern ablates surface tissue while preventing ablation of underlying tissue. In making this argument in the Petition, Petitioner overlooks that these are fundamentally different techniques.

And even if Edwards-535 and Stern had some similarities, mere similarities between the references do not constitute the required *reason* to combine them.

William Wesley Carnes, Sr., Inc. v. Seaboard Int’l Inc., IPR2019-00133, Paper 10,

at 17-18 (P.T.A.B. May 8, 2019) (denying institution and rejecting argument that “alleged similarities would have provided a POSITA with a reason to modify” the references and determining that the “statement of similarity . . . does not constitute an articulated reasoning with rational underpinning as to why a POSITA would combine elements of one reference with another, and why a POSITA would modify the teachings of the references to arrive at the claimed invention”); *In re Van Os*, 844 F.3d 1359, 1361 (Fed. Cir. 2017) (requiring an “actual *reason* why a skilled artisan would have combined the elements in the manner claimed”).

Petitioner has, therefore, failed to carry its burden of demonstrating why a person of ordinary skill in the art would have been motivated to combine Edwards-535 and Stern, which is sufficient to defeat Ground 1.

The teachings of Edwards-535 and Stern are so in conflict with one another that they rise to the level of teaching away, which prevents Edwards-535 and Stern from being combined and provides another, independent reason to reject Ground 1. “There is no suggestion to combine . . . if a reference teaches away from its combination with another source.” *Tec Air, Inc. v. Denso Mfg. Mich. Inc.*, 192 F.3d 1353, 1360 (Fed. Cir. 1999). The disclosures of Edwards-535 and Stern teach away from the combination of Edwards-535 and Stern because Edwards-535 teaches delivering energy to *ablate an internal portion* of the nasal concha while *preventing ablation of the surface* of the nasal concha, and Stern teaches delivering

energy to *destroy the surface* of the endometrium while *not ablating the myometrium* below the endometrium. *See, e.g., In re Sponnoble*, 405 F.2d 578, 587 (C.C.P.A. 1969) (reversing multi-reference obviousness rejection “for reasons existing within the disclosures of the references themselves, namely, that the references themselves teach away from the combination”); *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1550, 1559 (Fed. Cir. 1983) (reversing obviousness determinations for “disregarding disclosures in the references that diverge from and teach away from the invention at hand”). For this additional reason, Petitioner has not carried its burden of proving a reasonable likelihood of prevailing on any challenged claim in Ground 1.

V. Petitioner Has Not Demonstrated a Reasonable Likelihood of Prevailing on Any Claim Challenged in Ground 2

In Ground 2, Petitioner seeks to add teachings from Edwards-886 to the Edwards-535 and Stern combination from Ground 1 to reach claim 8. Pet., 60-62. But claim 8 depends from claim 7, which depends from claim 1, and at no point does Petitioner allege that Edwards-886 makes up for the deficiencies regarding claim 1 noted above, including the lack of a motivation to combine Edwards-535 and Stern and that Edwards-535 and Stern teach away, as discussed in Section IV. *See id.* For these reasons, Petitioner has not carried its burden of proving a reasonable likelihood of prevailing on the single challenged claim in Ground 2.

VI. Petitioner Has Not Demonstrated a Reasonable Likelihood of Prevailing on Any Claim Challenged in Ground 3

In Ground 3, Petitioner seeks to combine Makower, Stern, and Edwards-535. But Petitioner's combination of Makower and Stern suffers from impermissible hindsight. Moreover, Makower and Stern are fundamentally different, and the Petition fails to adequately explain why a person of ordinary skill in the art would have been motivated to combine such divergent references.

A. The Petition's Proposed Combination of Makower and Stern is Infected with Impermissible Hindsight

Petitioner's combination of Makower and Stern is grounded in impermissible hindsight because it uses the claims of the '286 patent itself and the prosecution history of its parent patent application, which became U.S. Patent No. 11,033,318 ("the '318 patent"), as a roadmap. *See Grain Processing Corp. v. Am. Maize-Prods. Co.*, 840 F.2d 902, 907 (Fed. Cir. 1988) ("Care must be taken to avoid hindsight reconstruction by using 'the patent in suit as a guide through the maze of prior art references, combining the right references in the right way so as to achieve the result of the claims in suit.'" (*quoting Orthopedic Equip. Co. v. United States*, 702 F.2d 1005, 1012 (Fed. Cir. 1983))); *Cf. Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1275 (Fed. Cir. 2004) ("This form of hindsight reasoning, using the invention as a roadmap to find its prior art components, would discount the value of combining various existing features or principles in a new way to achieve a new

result—often the very definition of invention.”); *see also KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007) (“A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning.”).

As Petitioner admits, during prosecution of the parent patent application that became the ’318 patent, the Examiner used Makower in a rejection but, according to Petitioner, allowed the claims after Patent Owner “amended the claims to require ‘pairs’ of bipolar RF electrodes, ‘multiple radiofrequency output channels connected with the multiple pairs of bipolar radiofrequency electrodes,’ and multiple sensors, such as ‘impedance sensors,’—the same limitations that appear in the challenged claims” of the ’286 patent. Pet., 16-17; *see also id.*, 14-15. Armed with this information, the Petition is nothing more than an allegation that this very same prior art reference (Makower) can be combined with a reference (Stern) that, as explained in Section VI.B below, is diametrically opposed to satisfy the missing limitations. This uses the patent and prosecution history as a blueprint for the petitioned ground and is the epitome of impermissible hindsight.

Aside from the hindsight reason that the Examiner applied Makower during prosecution of the parent application, the Petition presents no reason at all that a person of ordinary skill in the art would have looked to Makower. As discussed in Section III.C, Makower discloses a smattering of embodiments of devices used to

perform diagnostic or therapeutic procedures for ear, nose, and throat disorders.

Ex. 1021-Makower, [0001], [0042], [0161]. It discloses devices and procedures as far ranging as various occluder, suction, and access devices (Figs. 2A-2R, Figs. 3A-3M''), an occluder/endotracheal tube device (Fig. 4), a cutting or ablation device (Fig. 5A), devices with laterally deployable projections (Figs. 5B, 5D), a drill (Fig. 5C), a catheter (Fig. 5D), various balloon catheters (Figs. 5E-5G'''), a tissue shrinking electrode (Fig. 5H), a cryogenic device (Fig. 5I), a tissue expanding device (Fig. 5J), various forward cutting/suction catheter/endoscope devices (Figs. 5K-5O), various balloon catheter/stent/endoscope devices (Figs. 5P-5R''), a snare catheter (Fig. 5S), forceps (Fig. 5T), a guide catheter and guidewire and endoscope (Fig. 5U-5U'), a microbrider catheter (Fig. 5V), various bone remodeling devices (Figs. 5W-5X'''''), a substance delivering implant device (Figs. 5Y-5Y'''''), various guide catheters (Figs. 6A-6D), a plugging guide catheter (Fig. 6E), and various other catheters (Figs. 7A-7G), and a cochlear implant procedure (Figs. 9A-9C). *Id.*, [0049]-[0128].

Other than the hindsight reason that the Examiner applied Makower during prosecution of the parent application, there is no reason that a person of ordinary skill in the art would have looked to Makower, much less plucked the single Figure 5H embodiment, for which Makower provides incredibly little detail, to use in the combination presented in the Petition. *Personal Web Techs., LLC v. Apple, Inc.*,

848 F.3d 987, 993-94 (Fed. Cir. 2017) (requiring “a motivation to pick out [the] two references and combine them”); *Metalcraft of Mayville, Inc. v. The Toro Co.*, 848 F.3d 1358, 1367 (Fed. Cir. 2017) (“[W]e cannot allow hindsight bias to be the thread that stitches together prior art patches into something that is the claimed invention.”).

Makower provides no detail about the procedure using the embodiment shown in Figure 5H other than stating that the Figure 5H device can be “advanced into a passageway” and that “current is applied to the electrodes 216, causing tissue adjacent to the struts 214 to be cauterized or heated.” Ex. 1021-Makower, [0187]. And as Petitioner admits, Makower “leaves details on how to deliver energy up to a POSITA.” Pet., 69.

Considering the sheer number of embodiments in Makower and the lack of detail about this Figure 5H embodiment, the Petition fails to make any argument, other than hindsight, as to why a person of ordinary skill in the art would have been looking to Makower in the first place, much less the Figure 5H embodiment, and much less combining it with Stern, as discussed in the next section. *See Shire LLC v. Amneal Pharms., LLC*, 802 F.3d 1301, 1307-09 (Fed. Cir. 2015) (affirming summary judgment that claims directed to methods of using amphetamine derivatives having a mesylate salt of LDX to treat ADHD were not obvious, where the primary prior art reference, which had been considered by the PTO, did not

disclose the LDX ingredient, but broadly disclosed a series of compounds that could include the claimed LDX ingredient; however, only with hindsight knowledge of the claimed invention would one of skill in the art know to apply the LDX ingredient, as the prior art did not teach a “finite and limited class including LDX”).

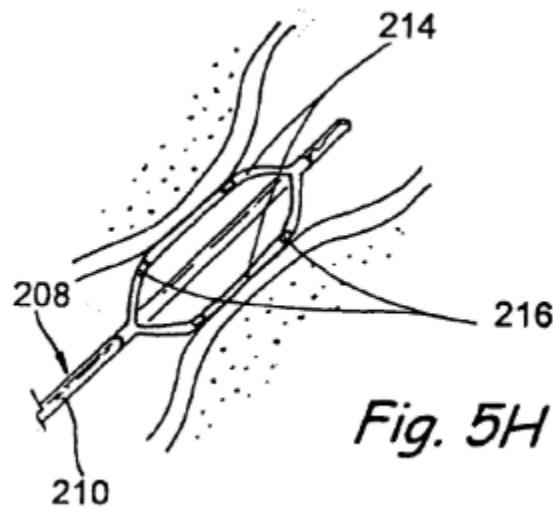
B. The Petition Fails to Establish That a Person of Ordinary Skill in the Art Would Have Combined Makower and Stern

It is Petitioner's burden to demonstrate “that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.” *Intelligent Bio-Sys.*, 821 F.3d at 1367-68 (citations omitted). Petitioner has not met that burden for the combination of Makower and Stern used in Ground 3.

A person of ordinary skill in the art would not have combined Makower and Stern because those references are diametrically opposed and have vastly different objectives and effects on the areas they treat. Makower is concerned about shrinking tissue while causing *minimal damage* and removing only as much tissue as necessary. Stern's objective is the *destruction* of a large area of surface tissue.

As discussed in Section III.C above, Makower describes “a variety of apparatus that may be inserted into the nasal cavity” to perform diagnostic or

therapeutic procedures. Ex. 1021-Makower, [0161]. Makower alleges that a benefit of its devices is that they are “delivered and positioned to perform the desired diagnostic or therapeutic procedures with *minimal trauma* to other tissues” *Id.* (emphasis added). In fact, Makower identifies causing “*minimal damage* to the surrounding tissues” as one of the objectives of its devices. *Id.*, [0016] (emphasis added). The Petition relies on a single embodiment of Makower depicted in Figure 5H, that shows a tissue-shrinking electrode device that cauterizes or heats adjacent tissue. *See id.*, [0092], [0187], Fig. 5H.



Id., Fig. 5H.

Makower explains that removing too much tissue from the turbinates can impair the function of the turbinates:

[i]t is typically desirable to remove only as much tissue as necessary to restore normal breathing and drainage, as removal of too much tissue from the turbinates can

impair the ability of the turbinates to perform their physiological functions of warming and humidifying inspired air and conserving warmth and moisture from expired air.

Id., [0030]. Makower further explains that the “human nose is responsible for warming, humidifying and filtering inspired air and for conserving heat and moisture from expired air,” so, according to Makower, the proper functioning of the turbinates is key to the proper functioning of the nose. *See id.*, [0002], [0030]. Makower describes shrinking, but not removing too much tissue from the turbinates, while causing minimal damage to other tissue.

In direct contrast to Makower, and as discussed above in Sections III.B and IV, Stern discloses “a method and an apparatus for in situ *destruction* of the inner lining of body organs, and more particularly the providing of a selective destruction of the endometrium.” Ex. 1033-Stern, 1:17-22 (emphasis added). The express “goal” of Stern is “*destruction* of the endometrial cells.” *Id.*, 1:17-22, 6:60-62 (emphasis added). Stern describes using RF energy to heat the endometrium to an ablative temperature and destroy it. *See id.*, 2:13-18 (describing “heat[ing] the endometrium” and “*destroy[ing]* the cells of the lining” (emphasis added)), 6:66-7:6 (“Radio frequency electric current passes through the dilated endometrial surface for a time sufficient to *destroy* the endometrial cells by elevating the temperature of the endometrium The temperature is maintained until the

endometrial tissue is *destroyed*. . . .” (emphases added)). Stern, therefore, destroys a large area of the surface tissue of the uterus (the endometrium).

Even though Makower and Stern both deliver energy, albeit to very different areas of the body, they have drastically different effects on the tissue in the areas they treat. Makower describes delivering energy to shrink tissue, without removing too much tissue and while causing minimal damage to other tissue. Stern describes delivering energy to destroy the surface of the endometrium. Put simply, Makower shrinks tissue with minimal damage, and Stern destroys tissue. In this important way, Makower and Stern are fundamentally different.

The Petition fails to acknowledge this fundamental difference between Makower and Stern—Makower shrinking tissue without removing too much tissue and while causing minimal damage to other tissue, and Stern destroying large areas of surface tissue—and fails to explain why a person of ordinary skill in the art would have been motivated to combine Makower and Stern when they have drastically different objectives and outcomes. “The obviousness inquiry does not merely ask whether a skilled artisan could combine the references, but instead asks whether ‘they would have been motivated to do so.’ . . . *Fundamental differences* between the references are *central* to this motivation to combine inquiry.” *Adidas AG*, 963 F.3d at 1359 (emphases added) (quoting *InTouch Techs.*, 751 F.3d at 1352); *see also Johns Manville*, IPR2018-00827, Paper 9 at 11-12, 21 (denying

institution for insufficient reasons to combine references where petitioner failed “to show that one of ordinary skill in the art would have had a reason to substitute [one reference’s] binder for the binder disclosed in [the other reference]” when the two references taught “considerably different binding systems” (citation omitted)).

If anything, these differences between Makower and Stern would have discouraged those skilled in the art from making the proposed combination. Stern’s destruction of large areas of surface tissue would be devastating if applied in the nose, as Makower itself acknowledges when it explains that “removal of too much tissue from the turbinates can impair the ability of the turbinates to perform their physiological functions of warming and humidifying inspired air and conserving warmth and moisture from expired air,” which Makower identifies as the key function of the nose. Ex. 1021-Makower, [0002], [0030].

Petitioner advances several purported reasons that a person of ordinary skill in the art would have been motivated to combine Makower and Stern, Pet., 68-71, but none are sufficient, especially considering the fundamental differences between Makower and Stern discussed above.

First, Petitioner argues that Makower and Stern are “analogous art to the Challenged Claims.” *Id.*, 68-69. Even if so, however, as noted above, “[a]nalogous art is merely a threshold inquiry as to whether a reference can be considered in an obviousness analysis” and “*is not sufficient* to establish that one of ordinary skill

would have had reason to combine its teachings with other prior art in the manner set forth in the claim.” *Johns Manville*, IPR2018-00827, Paper 9 at 10 (emphasis added) (citing *Securus Techs.*, 701 F. App’x at 977).

Second, Petitioner argues that Makower explains that “[r]adiofrequency energy is . . . delivered to heat . . . submucosal tissue’ using electrodes.” Pet., 69 (quoting Ex. 1021-Makower, [0040]). But this portion of Makower is not describing the Figure 5H embodiment Petitioner relies on for its purported combination. Ex. 1021-Makower, [0040]. Instead, this portion of Makower is describing a specific prior device called the “Somnoplasty® system” made by “Somnus Medical Technologies.” *Id.*, [0040].

Petitioner then argues that Makower “leaves details on how to deliver energy up to a POSITA”—referring to the energy delivery of the “Somnoplasty® system”—and was therefore “ready for improvement” and that “a POSITA would have been motivated to turn to other sources for information” for implementation details. Pet., 69. Petitioner never explains why a person of ordinary skill in the art would have been motivated to turn to *any* other information for “details on how to implement” the Somnoplasty® system’s energy delivery when it was presumably *already implemented* in the Somnoplasty® system itself, much less why a person of ordinary skill in the art would have turned to *Stern* for that information.

Also, the full description of the “energy delivery” of the Somnoplasty® system that Petitioner relies on for its purported motivation to combine further undermines its motivation to combine. The full description of the Somnoplasty® system is that “[t]he probe is inserted through the mucosa into the underlying soft tissue of the turbinate, usually under direct visualization[, and] [r]adiofrequency energy is then delivered to heat the submucosal tissue around the probe, thereby creating a submucosal coagulative lesion *while allowing the mucosa to remain intact*.” Ex. 1021-Makower, [0040] (emphasis added). This Somnoplasty® device described in Makower creates a lesion in the submucosal tissue while allowing the surface of the nasal mucosa to remain intact. *See id.* This only serves to highlight why a person of ordinary skill in the art would not have turned to Stern, which does the exact opposite and ablates and destroys the surface tissue (the endometrium). Ex. 1033-Stern, 1:17-22, 2:6-19, 6:60-7:6, 7:29-33.

Petitioner fails to acknowledge what would be a major problem with its purported combination—that Makower teaches shrinking but not removing too much tissue from the turbinates while causing minimal damage to the surrounding tissue, and that if Stern’s electrodes were added to Makower as the Petition suggests, they would ablate a large area of the surface of the turbinates in direct opposition to what Makower teaches. Petitioner argues that applying Stern’s teachings to Makower “would have been particularly desirable in the nose for

increased safety and control.” Pet., 70. But nothing could be further from the truth. Stern’s complete destruction of large areas of surface tissue would be devastating if applied in the nose, which Makower recognizes. Ex. 1021-Makower, [0030] (explaining that “removal of too much tissue from the turbinates can impair the ability of the turbinates to perform their physiological functions of warming and humidifying inspired air and conserving warmth and moisture from expired air”).

Third, Petitioner argues that Stern identifies “benefits” that would have led a person of ordinary skill in the art to modify Makower in view of Stern and refers to the “benefits” it identified in Ground 1. Pet., 69. But as discussed in Section IV, the very portions of Stern that Petitioner relies on for its alleged advantages make it clear that the purpose of Stern to allegedly achieve “precise control” is to “insure [sic] complete heating of an area” to achieve “tissue destruction.” See Ex. 1033-Stern, 12:26-34, 13:21-35. Stern even criticizes prior procedures as lacking “control” to “ensure complete ablation” of a large treatment area, again making it clear that any alleged “control” taught by Stern is for the complete destruction of a large area of surface tissue. *Id.*, 1:51-55.

Stern’s objective to destroy the surface tissue is contrary to Makower’s stated desires of not removing too much tissue and of causing minimal damage. And Petitioner provides no reason why one of ordinary skill in the art would have sought to combine Stern’s alleged “control” to completely destroy a large area of

surface tissue with Makower, which has the goals of not removing too much tissue and causing minimal damage. Similarly, the electrodes of Stern, even when allegedly ensuring “even heating,” are designed to provide “complete heating of an area” of the surface of the uterus (the endometrium) to destroy it, and Makower has the opposite objective of shrinking but not removing too much tissue and causing “minimal damage.” *Compare, e.g.*, Ex. 1033-Stern, 13:21-40, *with, e.g.*, Ex. 1021-Makower, [0030], [0092], [0161], [0187]. Thus, none of these alleged benefits of Stern support a motivation to combine Makower with Stern.

Fourth, Petitioner argues that Makower and Stern “each describe similar techniques of delivering bipolar RF ablation energy . . . such that their combination would have been straightforward and yielded predictable results.” Pet., 70-71. As an initial matter, this argument that Makower allegedly describes a technique of delivering energy is contrary to Petitioner’s previous argument that Makower “leaves details on how to deliver energy up to a POSITA.” *Compare id.*, 69, *with id.*, 70. Moreover, as discussed above, the limited information Makower includes about its technique reveals that it is radically different from Stern’s technique. Makower delivers energy to shrink tissue while causing “minimal damage” and not removing too much tissue. Ex. 1021-Makower, [0016], [0030], [0092], [0161], [0187]. In sharp contrast, Stern delivers energy to destroy surface tissue. Ex. 1033-

Stern, 1:17-22, 6:60-62, 2:15-18, 6:66-7:6. In making this argument in the Petition, Petitioner overlooks that these are fundamentally different techniques.

And even if Makower and Stern had some similarities, mere similarities between the references do not constitute the required *reason* to combine them. *William Wesley Carnes, Sr.*, IPR2019-00133, Paper 10 at 17-18 (denying institution and rejecting argument that “alleged similarities would have provided a POSITA with a reason to modify” the references and determining that the “statement of similarity . . . does not constitute an articulated reasoning with rational underpinning as to why a POSITA would combine elements of one reference with another, and why a POSITA would modify the teachings of the references to arrive at the claimed invention”); *In re Van Os*, 844 F.3d at 1361 (requiring an “actual *reason* why a skilled artisan would have combined the elements in the manner claimed”).

Petitioner has failed to carry its burden of demonstrating why a person of ordinary skill in the art would have been motivated to combine Makower and Stern.

VII. Petitioner Has Not Demonstrated a Reasonable Likelihood of Prevailing on Any Claim Challenged in Ground 4

In Ground 4, Petitioner seeks to add teachings from Edwards-886 to the Makower, Stern, and Edwards-535 combination from Ground 3 to reach claim 8.

Pet., 82. But claim 8 depends from claim 7, which depends from claim 1, and at no point does Petitioner allege that Edwards-886 makes up for the deficiencies regarding claim 1 noted above in Ground 3, including the lack of a motivation to combine Makower and Stern discussed in Section VI.B. *See id.*, 82. For these reasons, Petitioner has not carried its burden of proving a reasonable likelihood of prevailing on the single challenged claim in Ground 4.

VIII. Petitioner Has Not Demonstrated a Reasonable Likelihood of Prevailing on Any Claim Challenged in Ground 5

In Ground 5, Petitioner seeks to combine Edwards-535, Liang, and Stern. But as discussed in Ground 1, Edwards-535 and Stern are diametrically opposed and do the exact opposite of one another, and the Petition again fails in Ground 5 to adequately explain why a person of ordinary skill in the art would have been motivated to combine such contradictory references. Edwards-535 and Liang are also in direct contrast to one another, and a person of ordinary skill in the art would not have been motivated to combine them either.

Petitioner has failed to meet its burden to demonstrate “that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention” for its combination of Edwards-535, Liang, and Stern used in Ground 5. *See Intelligent Bio-Sys.*, 821 F.3d at 1367-68 (citations omitted).

A. The Petition Fails to Establish That a Person of Ordinary Skill in the Art Would Have Combined Edwards-535 and Stern

The Petition relies on the combination of Edwards-535 and Stern for Ground 5, just like in Ground 1. *See* Pet., 83, 85-88. Petitioner does not present any additional motivation to combine arguments for Edwards-535 and Stern in Ground 5. *See id.*, 83-88. Petitioner failed to establish a motivation to combine Edwards-535 and Stern for the reasons discussed in above with respect to Ground 1 and for the additional reason that Edwards-535 and Stern teach away. *See* Section IV.

B. The Petition Fails to Establish that a Person of Ordinary Skill in the Art Would Have Combined Edwards-535 and Liang

The Petition's motivation to combine Edwards-535 and Liang in Ground 5 is also deficient. Edwards-535 and Liang have fundamental differences such that a person of ordinary skill in the art would not have been motivated to combine them. Edwards-535 emphasizes that its method does *not involve cutting or penetrating* and is done *bloodlessly, without forming a wound on the surface* of the turbinates, and Liang describes a method that in at least some patients results in *bloody secretions* and *nasal adhesion*.

As previously discussed, Edwards-535 reduces the size of the nasal turbinates without cutting or penetrating the turbinates in a bloodless procedure that does not form a wound on the surface of the turbinates. *See* Sections III.A, IV. Edwards-535 criticizes prior art methods that cause complications, including

“hemorrhage” and “scarring or adhesion,” and refers to adhesions as a “particular problem” to be avoided. Ex. 1010-Edwards-535, 2:25-43. As discussed in Section III.D, Liang describes using radiofrequency “to perform thermal coagulation treatment on the bilateral nasal ridge and the corresponding nasal septum mucosa.” Ex. 1056-Liang, 341. In direct contrast to Edwards-535, Liang explains that “the patients might experience symptoms such as . . . a small amount of bloody secretions” following treatment and that, in some cases, “patients developed nasal adhesion.” *Id.* Liang, therefore, causes blood loss and adhesion in some patients.

Even though Edwards-535 and Liang both deliver radiofrequency energy to the nasal concha, they have very different effects on the nasal concha. Edwards-535 describes a *bloodless* procedure that *does not form a wound on the surface* of the turbinates, and Liang describes a procedure that results in *bloody secretions* and *nasal adhesion* in some patients. In this important way, Edwards-535 and Liang are very different. Even Petitioner is forced to acknowledge these differences and acknowledge that Edwards-535's procedure is “unlike” Liang's procedure. *See* Pet., 85.

The teachings of Edwards-535 would have actively discouraged a person of ordinary skill in the art from combining Edwards-535 with Liang. For example, Edwards-535 criticizes prior art methods that cause complications, including “hemorrhage” and “scarring or adhesion,” and refers to adhesions as a “particular

problem” to be avoided. Ex. 1010-Edwards-535, 2:25-43. Based on this teaching of Edwards-535, Petitioner has failed to explain why a person of ordinary skill in the art would have been motivated to turn to Liang, which is a method that results in “bloody secretions” and “nasal adhesion” in some patients. Ex. 1056-Liang, 341.

Petitioner advances several purported reasons that a person of ordinary skill in the art would have been motivated to combine Edwards-535 and Liang, Pet., 83-87, but none are sufficient to overcome the contrast between Edwards-535 and Liang and explain why a person of ordinary skill in the art would have been motivated to combine Edwards-535 and Liang. *Adidas*, 963 F.3d at 1359; *see also Johns Manville*, IPR2018-00827, Paper 9 at 11-12, 21. Petitioner argues that Edwards-535 and Liang are analogous art. Pet., 84. However, even if so, “[a]nalogous art is merely a threshold inquiry as to whether a reference can be considered in an obviousness analysis” and “*is not sufficient* to establish that one of ordinary skill would have had reason to combine its teachings with other prior art in the manner set forth in the claim.” *Johns Manville*, IPR2018-00827, Paper 9 at 10 (emphasis added) (citing *Securus Techs.*, 701 F. App’x at 977).

Petitioner also argues that “Liang discloses the benefits of using RF energy to treat the same location as Edwards-’535 (middle turbinate)” and that Edwards-535 and Liang “describe similar techniques.” Pet., 84-86. Contrary to Petitioner’s assertion, Edwards-535 and Liang are not similar techniques. They are quite

different—Edwards-535 treats the interior of the nasal concha “without the formation of a wound on the surface of the nasal concha,” Ex. 1010-Edwards-535, 4:63-66, and Liang’s treatment is not described in any meaningful detail but may result in “bloody secretions” and “nasal adhesion,” Ex. 1056-Liang, 341. So while Edwards-535 and Liang treat a similar location, they do so in very different ways—Edwards-535 in a bloodless procedure that does not form wounds on the surface, and Liang in a procedure that can result in blood loss and adhesion. Petitioner overlooks and fails to overcome the fact that Edwards-535 and Liang use fundamentally different techniques. And Petitioner never explains why one of ordinary skill in the art would have looked to modify Edwards-535 based on a reference that has the very problem it was seeking to avoid. And, as discussed above, even if Edwards-535 and Liang had some similarities, mere similarities between the references do not constitute the required *reason* to combine them. *William Wesley Carnes, Sr.*, IPR2019-00133, Paper 10 at 17-18 (denying institution and rejecting argument that “alleged similarities would have provided a POSITA with a reason to modify” the references); *In re Van Os*, 844 F.3d at 1361 (requiring an “actual *reason* why a skilled artisan would have combined the elements in the manner claimed”).

Petitioner’s most prominent motivation-to-combine argument is that “Liang . . . recognizes certain drawbacks with Liang’s device” and that “Edwards-

'535 teaches how to solve the problems presented by the device used in Liang.”

Pet., 84-85. But this is an argument *against* the combination and makes no legal or factual sense. Legally, the argument reverses the purported combination. The Petition purports to rely on *Edwards-535 in view of Liang* (and Stern), *id.*, 83, not Liang in view of Edwards-535. Yet with its arguments, Petitioner appears to be modifying *Liang in view of Edwards-535*. Petitioner's reversal of the combination is further shown where Petitioner argues that a person of ordinary skill in the art would have been motivated to “use a device like that taught in Edwards-'535 . . . (which does not damage surrounding tissue) for the same purpose as Liang's RF device.” *Id.*, 85. This “kitchen-sink of unclear and confusing motivation-to-combine arguments” is insufficient. *See Sisvel Int'l S.A. v. Sierra Wireless, Inc.*, 82 F.4th 1355, 1364 (Fed. Cir. 2023) (affirming the Board's finding of no motivation to combine where the patent challenger was “inconsistent as to how . . . [the] references should be combined” and “[i]n some instances . . . allege[d] that a skilled artisan would improve” Reference A with Reference B and “[i]n other instances . . . allege[d] the converse—that a skilled artisan would improve” Reference B with Reference A). Petitioner in this case has done the exact same thing—shifting between confusing motivation-to-combine arguments based at times on allegedly improving Edwards-535 with Liang and at other times on allegedly improving Liang with Edwards-535.

Moreover, as a factual matter, it would not make sense for a person of ordinary skill in the art to modify Edwards-535 with Liang if Edwards-535 itself recognizes Liang as disadvantageous. And if Edwards-535 had already “solve[d] the problems” of Liang, like the Petition contends, Pet., 85, there would have been no reason for a person of ordinary skill in the art to look to Liang, which has the very problems that Edwards-535 has already allegedly overcome. *See, e.g., Taiwan Semiconductor Mfg. Co. v. Godo Kaisha IP Bridge 1*, IPR2016-01442, Paper 7 at 19-20, 22 (P.T.A.B. Jan. 27, 2017) (denying institution and rejecting petitioner’s argument that a person of ordinary skill in the art “would have looked to [a secondary reference] as a possible solution to the problem disclosed in [the primary reference]” when “[the primary reference] already purports to solve the problem,” reasoning that “[the primary reference] already addresses the problem that Petitioner asserts would provide a motivating reason to seek a solution”). Here, the fact that Edwards-535 allegedly already solves the problem of Liang defeats any argument that seeking the solution would provide a motivating reason to combine the references.

* * * * *

For these reasons, Petitioner has failed to carry its burden of demonstrating why a person of ordinary skill in the art would have been motivated to combine Edwards-535 and Stern and Edwards-535 and Liang. Petitioner has, therefore, not

carried its burden of proving a reasonable likelihood of prevailing on any challenged claim in Ground 5.

IX. Petitioner Has Not Demonstrated a Reasonable Likelihood of Prevailing on Any Claim Challenged in Ground 6

In Ground 6, Petitioner seeks to add teachings from Edwards-886 to the Edwards-535, Stern, and Liang combination from Ground 5 to reach claim 8. Pet., 88-89. But claim 8 depends from claim 7, which depends from claim 1, and at no point does Petitioner allege that Edwards-886 makes up for the deficiencies regarding claim 1 noted above in Ground 5, including the lack of a motivation to combine Edwards-535 and Stern and that Edwards-535 and Stern teach away, discussed in Section VIII.A, and the lack of a motivation to combine Edwards-535 and Liang, discussed in Section VIII.B. *See id.* For these reasons, Petitioner has not carried its burden of proving a reasonable likelihood of prevailing on the single challenged claim in Ground 6.

X. Petitioner Has Not Demonstrated a Reasonable Likelihood of Prevailing on Any Claim Challenged in Ground 7

In Ground 7, Petitioner seeks to combine Makower, Stern, Edwards-535, and Liang. But as discussed above in Ground 3, Petitioner's combination of Makower and Stern suffers from impermissible hindsight, and the Petition fails to adequately explain why a person of ordinary skill in the art would have been motivated to combine Makower and Stern, which are fundamentally different and

divergent references. Petitioner's motivation to combine Makower and Liang is also woefully deficient because it relies almost entirely on a motivation to combine another reference, Edwards-535, and Liang. And the Petition's identification of alleged similarities between Makower and Liang is insufficient alone to establish a reason to combine those references, much less all four references used in Ground 7.

A. The Petition Fails to Establish That a Person of Ordinary Skill in the Art Would Have Combined Makower and Stern

The Petition relies on the combination of Makower and Stern for Ground 7, just like it did for Ground 3. *See* Pet., 89, 91-92. Petitioner does not present any additional motivation to combine arguments for Makower and Stern in Ground 7. *See id.*, 89-92. Petitioner has failed to establish a motivation to combine Makower and Stern for the reasons discussed above with respect to Ground 3. *See* Section VI.B.

B. The Petition Fails to Establish that a Person of Ordinary Skill in the Art Would Have Combined Makower and Liang

The Petition's short and conclusory motivation to combine argument for Makower and Liang in Ground 7 is woefully deficient. Petitioner falls well short of its burden to show "that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that

the skilled artisan would have had a reasonable expectation of success in doing so.” *Intelligent Bio-Sys.*, 821 F.3d at 1367-68 (citations omitted).

Petitioner's primary argument is that a person of ordinary skill in the art would have been motivated to combine *Makower and Liang* for the same reasons they would have been motivated to combine *Edwards-535 and Liang*:

A POSITA would have been motivated to combine these teachings—namely, by using a device like that taught by Makower device in a technique like that taught by Liang—to reduce mucus production by applying RF energy to the ethmoidal nerve within the middle turbinate . . . with a reasonable expectation of success for at least the *reasons discussed in Ground V*.

Pet., 90 (citation omitted). But Edwards-535 is not the same as Makower, and any alleged motivations to combine Edwards-535 and Liang would necessarily differ from any alleged motivations to combine Makower and Liang. Petitioner cannot establish a motivation to combine Makower and Liang by simply referring to an alleged motivation to combine Edwards-535 and Liang. *See Intelligent Bio-Sys.*, 821 F.3d at 1367-68 (requiring showing “that a skilled artisan would have been motivated to combine *the teachings of the prior art references* to achieve the claimed invention” (emphasis added)). By relying almost entirely on its argument regarding an alleged motivation to combine Edwards-535 and Liang, Petitioner has failed to establish an alleged motivation to combine Makower and Liang.

The only motivation to combine that Petitioner presents for the specific combination of Makower and Liang is that “Liang uses a similar RF ablation device to Makower . . . and teaches numerous benefits to using RF energy to treat the turbinates” Pet., 90-91. As an initial matter, the Petition does not identify what Makower device it is referring to for these alleged “similar[ities].” *Id.* Petitioner refers vaguely to “the disclosed device” of Makower, “a device like that taught by Makower,” and “Makower’s device.” *Id.* But as noted in Section III.C, Makower discloses a smattering of devices. Ex. 1021-Makower, [0001], [0042], [0161]. The Petition does not identify which of the several dozen different Makower devices it is referring to for its alleged “similar[ities]” with Liang for its motivation to combine. Pet., 90-91.

Moreover, to establish the alleged “similar[ity]” between the unspecified Makower device and Liang, Petitioner improperly relies on Exhibit 1059, which is a Chinese utility model patent. *See id.*, 90. Exhibit 1059 is not part of the alleged combination of Ground 7. Petitioner asserts, without any support, that Exhibit 1059 describes the device used in Liang. *Id.* But Liang does not incorporate the Chinese utility model patent at Exhibit 1059 by reference or otherwise describe any details of the device used in its procedure. *See* Ex. 1056-Liang, 341 (stating only that the “SHP-I radiofrequency treatment device for facial organs (manufactured by Guangzhou Medical Device Factory) was used”). Petitioner likewise does not

allege, let alone establish, that the description of Exhibit 1059 is inherent in the short Liang reference.¹ Indeed, Exhibit 1059 itself acknowledges that there are different versions of the SHP-I device with different treatment heads. Ex. 1059, 1-2, Fig. 4.

Even with its improper reliance on Exhibit 1059, the only thing Petitioner identifies as allegedly “similar” about the unspecified Makower device and the Liang device is that they both have “electrodes,” an “energy source for use in nasal treatments,” and “treat the same tissue (middle turbinate).” Pet., 90-91. But mere similarities between the references do not constitute the required *reason* to combine them. *William Wesley Carnes, Sr.*, IPR2019-00133, Paper 10 at 17-18 (denying institution and rejecting argument that “alleged similarities would have provided a POSITA with a reason to modify” the references and determining that the “statement of similarity . . . does not constitute an articulated reasoning with rational underpinning as to why a POSITA would combine elements of one

¹ Petitioner refers to Exhibit 1059 as “Liang-’271,” but the two “Designers” listed on Exhibit 1059, while having the name Liang, are not any of the authors listed on Ex. 1056-Liang. *Compare* Ex. 1059-Liang-227, cover page (listing Liang Xiao-ming and Liang Zhi-jian as designers), *with* Ex. 1056-Liang, 341 (listing Liang Jianping as an author).

reference with another, and why a POSITA would modify the teachings of the references to arrive at the claimed invention”); *In re Van Os*, 844 F.3d at 1361 (requiring an “actual *reason* why a skilled artisan would have combined the elements in the manner claimed”).

XI. Petitioner Has Not Demonstrated a Reasonable Likelihood of Prevailing on Any Claim Challenged in Ground 8

In Ground 8 Petitioner seeks to add teachings from Edwards-886 to the Makower, Stern, Edwards-535, and Liang combination from Ground 7 to reach claim 8 with a *total of five references*. Pet., 92. But claim 8 depends from claim 7, which depends from claim 1, and at no point does Petitioner allege that Edwards-886 makes up for the deficiencies regarding claim 1 noted above in Ground 7, including the lack of a motivation to combine Makower and Stern discussed in Section X.A and the lack of a motivation to combine Makower and Liang discussed in Section X.B. *See id.* For these reasons, Petitioner has not carried its burden of proving a reasonable likelihood of prevailing on the single challenged claim in Ground 8.

XII. Conclusion

For at least the reasons provided above, the Petition should be denied, and trial should not be instituted.

Respectfully submitted,

Dated: April 25, 2024

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CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), I, Sonja W. Sahlsten, certify that
PATENT OWNER'S PRELIMINARY RESPONSE contains 11,037 words,
excluding those portions identified in 37 C.F.R. § 42.24(a), as measured by the
word-processing system used to prepare this paper.

Dated: April 25, 2024

By: /Sonja W. Sahlsten/
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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that on April 25, 2024, a copy of
PATENT OWNER'S PRELIMINARY RESPONSE was served upon the
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