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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 IPR2024-00277
Patent No. 11,241,271

PATENT OWNER'S PRELIMINARY RESPONSE

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I. Introduction

U.S. Patent No. 11,241,271 (“the ’271 patent”) is directed to novel methods for treating a nasal airway to reduce mucus production. Petitioner challenges claims 1-4, 6-12, and 16 of the ’271 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.

All four Grounds 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. Petitioner’s failure to establish a motivation to combine Edwards-535 and Stern is sufficient to deny institution because Petitioner relies on the combination of Edwards-535 and Stern in all Grounds of the Petition.

But there are additional reasons to deny institution. Petitioner also relies on the combination of Edwards-535 and Kong (in Grounds 1 and 2) and Edwards-535 and Liang (in Grounds 3 and 4), and Petitioner fails to establish a motivation to combine Edwards-535 and Kong and Edwards-535 and Liang. Edwards-535 and Kong have fundamental differences, including that Kong involves cutting the turbinates, another name for the nasal concha, and forming a wound on the surface of the turbinates, which is exactly what Edwards-535 is trying to avoid. Edwards-535 actively disparages the technique of Kong, defeating any motivation to combine them. Similarly, 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.

Moreover, even if one of ordinary skill in the art would have been motivated to make the proposed combinations, they still do not result in the claimed inventions because they do not teach “contacting a treatment element of a nasal airway treatment device directly with nasal mucosa of the nasal airway, wherein the treatment element comprises two rows of bipolar electrode pairs.”

II. The '271 Patent

The '271 patent claims methods “for treating a nasal airway to reduce mucus production.” *See, e.g.*, Ex. 1001-'271 patent, claim 1. The '271 patent describes

“treating a nasal airway by modifying a property of a nasal tissue of or near a nasal valve of the airway, *without using a surgical incision* or an implant” *Id.*, Abstract (emphasis added). The '271 patent provides a system and a noninvasive method for decreasing nasal congestion, including reducing mucus production, and increasing nasal air flow. *Id.*, 10:56-67, 48:1-7. It includes treating a patient's nasal airway by using a treatment device to deliver energy to tissues within the nose to modify a property of that tissue without using a surgical incision. *Id.*, 8:1-13.

The '271 patent discloses treatment probes having bipolar electrodes on the outside surface to contact directly with the nasal mucosa, which apply radiofrequency energy to target tissue underlying the nasal mucosa. *See, e.g., id.*, 7:51-67, 20:18-38, 23:40-24:1, 26:63-27:4, 33:27-62, 42:60-66, 39:52-56. The '271 patent further teaches 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.*, 6:28-36, 7:43-50, 8:26-34, 15:56-60, 30:24-30, 33:27-48, 43:45-57, 44:50-45:5. The '271 patent describes that “[o]ne mechanism of action that may be involved” in its method “may be to reduce mucus production and/or accumulation in and/or around any treated areas.” *Id.*, 48:1-7.

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. Kong

Kong is a clinical study that discusses “[s]urgical methods” using “radiofrequency ablation treatment [for] perennial allergic rhinitis.” Ex. 1040-Kong, 214. The study’s authors describe a surgical technique involving delivering RF energy via an electrode inserted into “1-2 holes made in each part” of the inferior turbinate, which was divided into two or three parts. *Id.* The holes were “approximately 1.5-2.0 cm” deep “under the mucosa.” *Id.* The authors described that “blood loss” from the surgery was “approximately 5-10 ml” and that in 5 out of the 35 patients, “scabs were formed at the hole site.” *Id.*

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, Kong, 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. Edwards-535 and Kong also describe fundamentally different methods, and a person of ordinary skill in the art would not have been motivated to combine them either. And, even if one were to make Petitioner's proposed combination, it would still not result in the claimed invention.

A. The Petition Fails to Establish a Motivation to Combine

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, Kong, and Stern used in Ground 1.

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

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).

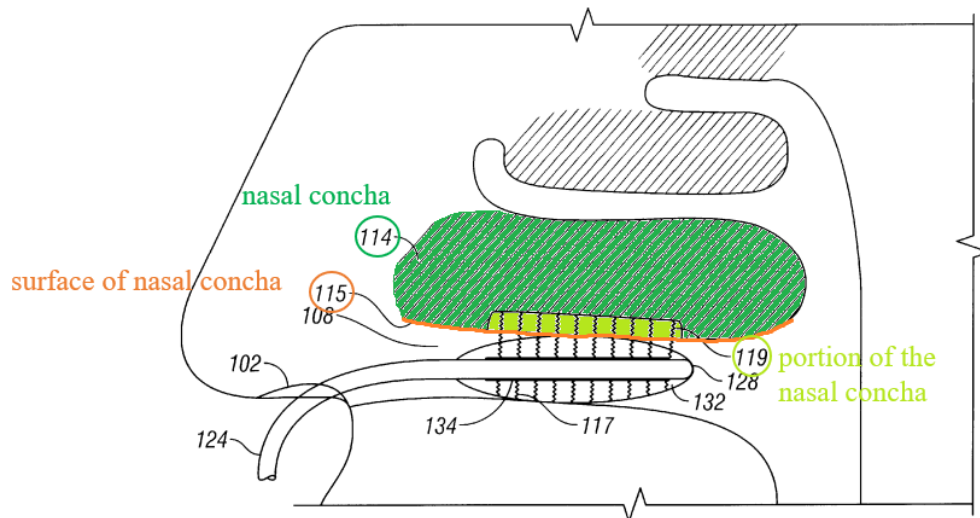


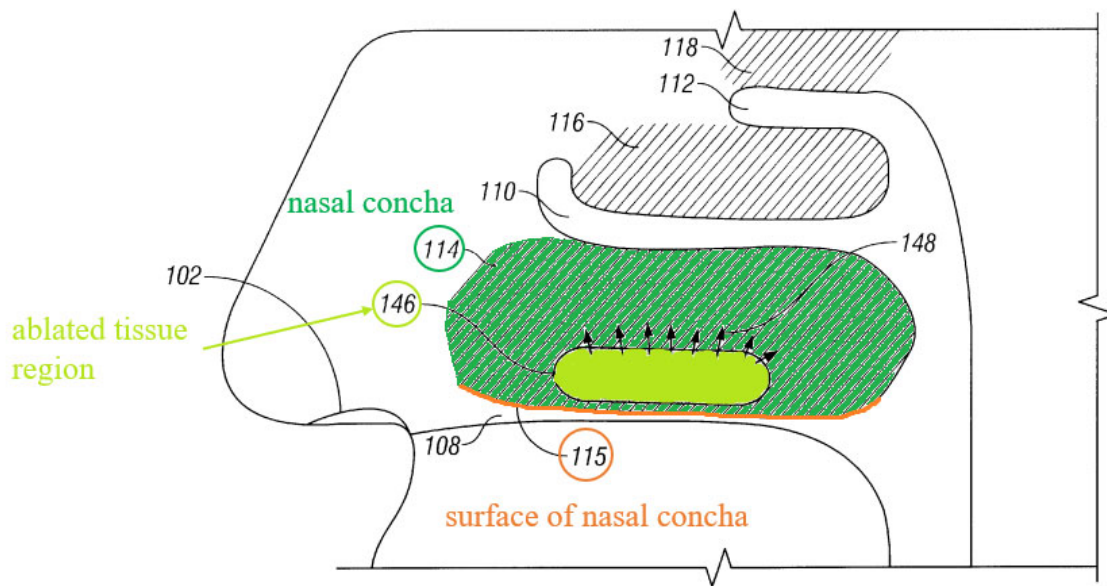
FIG. 3B

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.



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.

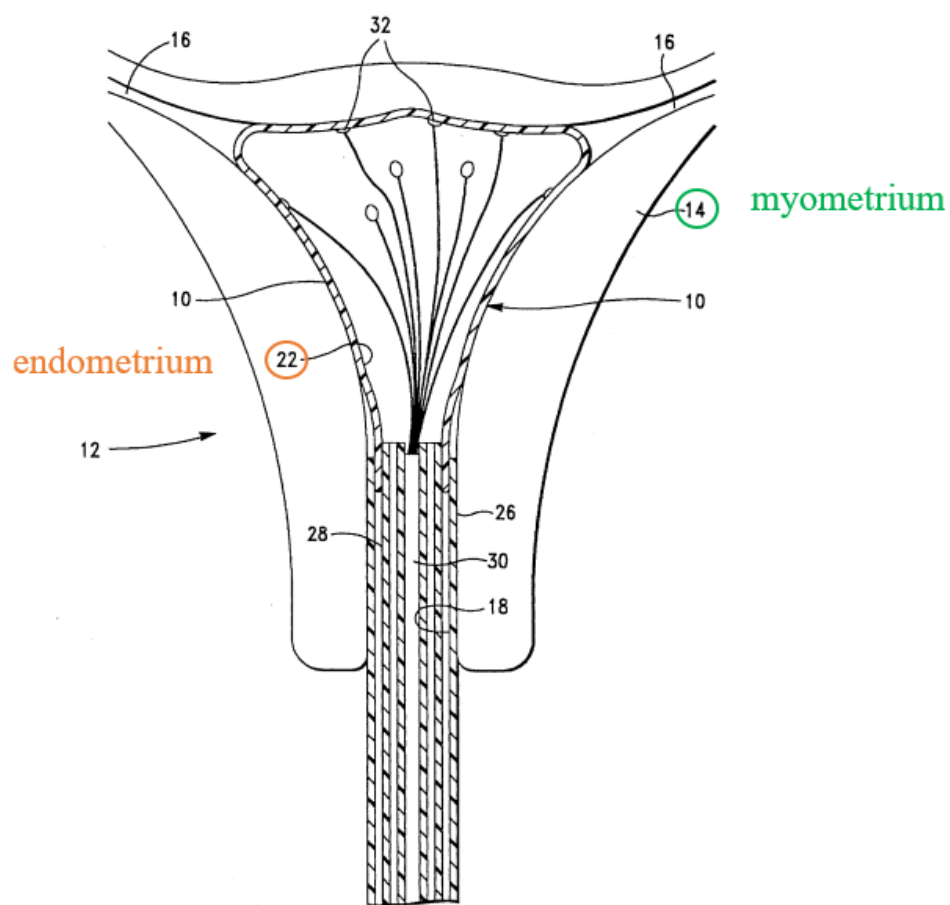
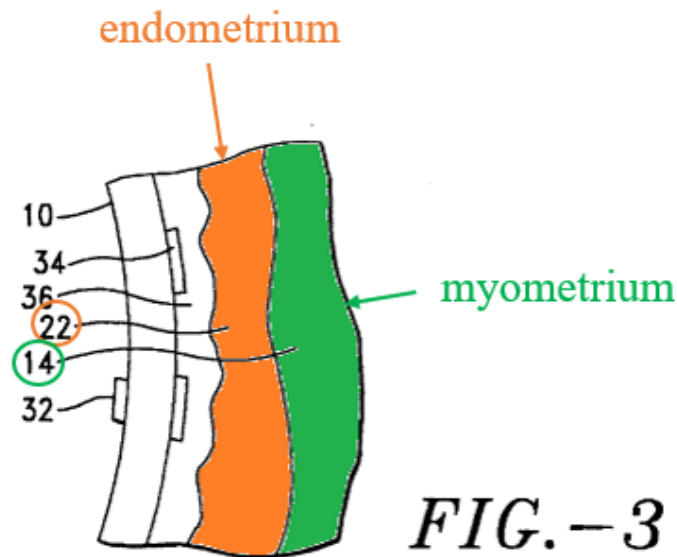


FIG.-1

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., 41-49, 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.*, 41-42. 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 “omits details on how to implement” its energy delivery and was “therefore ready for improvement, and a

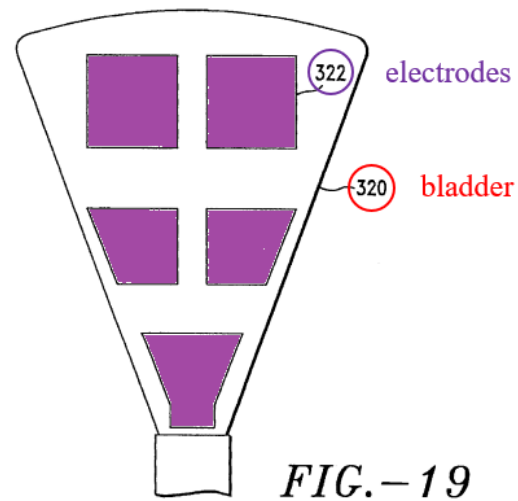
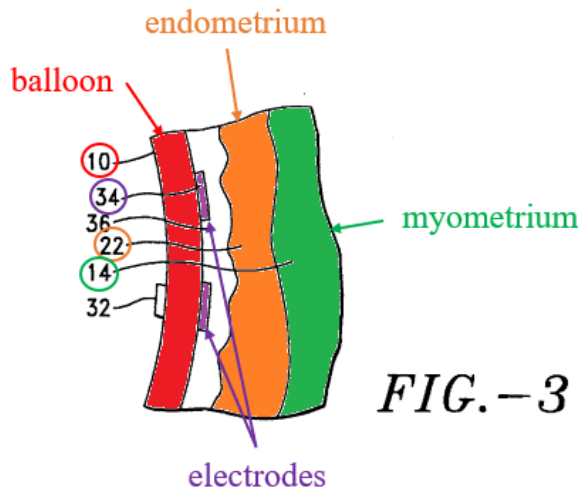
POSITA would have been motivated to turn to other sources for information.”

Pet., 42-43. Petitioner argues that “[a] POSITA would have found Stern to be a good source for this information given its detailed disclosure and schematic Figures,” and further contends that “Stern discloses implementation details for how an RF device like Edwards-’535’s can be implemented.” *Id.*

Specifically, Petitioner argues that a person of ordinary skill in the art would have been motivated to “implement[] Edwards-’535’s energy delivery device 134 with Stern’s two rows of bipolar RF electrode pairs on the surface of the expandable member 132.” *Id.*, 42 (emphases omitted). 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 electrodes were added to the “surface of the expandable member 132” of Edwards-535 as the Petition suggests, 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 electrodes to the outer surface of the expandable member 132 of 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 electrodes to the outer surface of the expandable member 132 of 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's "bipolar electrode pairs provide a number of advantages and benefits" that would have led a person of ordinary skill in the art to modify Edwards-535 in view of Stern. Pet., 43-47 (emphasis omitted). 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.*, 43 (emphasis omitted). 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., 44 (citing Ex. 1033-Stern, 13:21-39). 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., 44. But, again, 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 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., 45-46. 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 deny institution.

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 deny institution. “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”).

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

Edwards-535 and Kong also 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 Kong intentionally *cuts holes into* the turbinates, *causing blood loss and forming scabs*. Put simply, Kong does exactly what Edwards-535 is trying to avoid—cutting the turbinates and forming a wound on the surface of the turbinates.

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 explains that its use of ablative energy “*eliminates the need for surgical cutting* to remove a portion of a nasal concha and the risks associated therewith.” *Id.*, 4:55-57 (emphasis added). Edwards-535 further describes how its “procedure can be performed *bloodlessly* and *without the need to penetrate tissue.*” *Id.*, 4:58-60 (emphases added). Edwards-535 contends that its method “should be significantly less painful for the patient than traditional surgical methods.” *Id.*, 4:66-67. Edwards-535 emphasizes that it “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, therefore, 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.

As discussed above in Section III.C, Kong discusses “[s]urgical methods” using “radiofrequency ablation” for “perennial allergic rhinitis.” Ex. 1040-Kong, 214. In direct contrast to Edwards-535, Kong’s surgical method involves making “1-2 *holes* . . . in each part” of the inferior turbinate, which was divided into two or three parts. *See id.* (emphasis added). The holes made by the surgical method of

Kong are “approximately 1.5-2.0 cm” deep “under the mucosa.” *Id.* Kong describes that “blood loss” from the surgery is “approximately 5-10 ml.” *Id.* And Kong explained that in 5 out of the 35 patients in the study, “scabs were formed at the hole site.” *Id.* Kong, therefore, ablates the turbinates by making holes that penetrate the turbinates, causing blood loss, and causing scabbing in some patients.

Edwards-535 and Kong both deliver radiofrequency energy to the nasal concha (turbinates) but do so in fundamentally different ways. Edwards-535 delivers energy *without cutting or penetrating* the turbinates, and Kong *cuts 2 to 6 holes* approximately 1.5-2.0 cm deep into the turbinates. Edwards-535 describes a *bloodless* procedure that *does not form a wound on the surface* of the turbinates, and Kong describes a surgical procedure with *blood loss* of approximately 5-10 ml that resulted in *scabs* at the hole site in 5 out of 35 patients. In these important ways, Edwards-535 and Kong are fundamentally different. Even Petitioner is forced to acknowledge these differences and recognize the “contrast” between Edwards-535 and Kong. *See* Pet., 30 (describing Kong’s technique as “requir[ing] inserting a device through the nasal mucosa, which Kong recognizes can be damaging,” and describing Edwards-535 in “contrast” as “us[ing] a non-puncturing balloon” and being “less damaging to the surface mucosa”).

The Petition fails to overcome these fundamental differences between Edwards-535 and Kong and fails to explain why a person of ordinary skill in the

art would have been motivated to combine Edwards-535 and Kong when they are vastly different methods—Edwards-535 not cutting or penetrating the turbinates in a bloodless procedure that does not form wounds on the surface, and Kong cutting the turbinate and penetrating it with holes in a bloody procedure that sometimes forms scabs at the hole site. These “[f]undamental differences between the references are *central* to this motivation to combine inquiry.” *Adidas*, 963 F.3d at 1359 (emphases added) (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 analysis); *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)).

Importantly, “[t]he 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.’” *Adidas*, 963 F.3d at 1359 (emphases added) (quoting *InTouch Techs.*, 751 F.3d at 1352). There are many teachings of Edwards-535 that would have actively discouraged a person of ordinary skill in the art from combining Edwards-535 with Kong.

For example, Edwards-535 describes “surgical cutting” of the nasal concha as having “risks associated therewith.” Ex. 1010-Edwards-535, 4:55-57. 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 Kong, which is a surgical method that expressly teaches cutting 2-6 holes in the nasal concha. Ex. 1040-Kong, 214. Edwards-535 also touts that its method “should be significantly less painful for the patient than traditional surgical methods.” Ex. 1010-Edwards-535, 4:66-67. And Petitioner fails to explain why a person of ordinary skill in the art would have turned to Kong’s “[s]urgical methods,” Ex. 1040-Kong, 214, when Edwards-535 wanted to avoid pain caused by traditional surgical methods, *see* Ex. 1010-Edwards-535, 4:66-67. As these disclosures of Edwards-535 show, Edwards-535 does more than just discourage a person of ordinary skill in the art from combining Edwards-535 and Kong—Edwards-535 actively disparages the surgical cutting method of Kong and its attendant risks and pain. *See id.*, 4:55-57, 4:66-67.

These disclosures of Edwards-535 and Kong teach away and further prevent Petitioner from establishing a motivation to combine Edwards-535 and Kong. “There is no suggestion to combine . . . if a reference teaches away from its combination with another source.” *Tec Air*, 192 F.3d at 1360; *see also, e.g., In re Sponnoble*, 405 F.2d at 587 (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*, 721 F.2d at 1550, 1559 (reversing obviousness determinations for “disregarding disclosures in the references that diverge from and teach away from the invention at hand”).

Petitioner advances several purported reasons that a person of ordinary skill in the art would have been motivated to combine Edwards-535 and Kong, Pet., 28-34, but none are sufficient, especially considering the fundamental differences between Edwards-535 and Kong discussed above.

First, Petitioner argues that “Edwards-’535 and Kong are analogous art to the Challenged Claims.” *Id.*, 28. However, even if so, 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 “Kong discloses the benefits of using RF energy to treat the same location (interior of the inferior turbinate) as Edwards.” Pet., 29. But Petitioner fails to acknowledge the major problem with this purported combination—that 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 that Kong makes several 1.5-2.0 cm deep holes in the surface of the nasal concha, Ex. 1040-Kong, 214. So while Edwards-535 and Kong treat a similar location, they do so in fundamentally different ways—Edwards-535 in a bloodless procedure that does not penetrate the surface of the turbinates, and Kong in a bloody surgical procedure that cuts holes into the turbinates. The alleged “benefits” of Kong are achieved in a method that punctures the nasal concha with several holes, Ex. 1040-Kong, 214, which is precisely the “surgical cutting” that Edwards-535 is trying to avoid, *see* Ex. 1010-Edwards-535, 4:55-57.

Third, Petitioner argues that “Kong discusses shortcomings of its approach to delivering treatment that Edwards-’535 expressly overcomes.” Pet., 30. But this argument makes no legal or factual sense. Indeed, this is precisely the reason one of ordinary skill in the art would *not* have turned to Kong to modify Edwards-535. Legally, the argument reverses the purported combination. The Petition purports to rely on *Edwards-535 in view of Kong, id.*, 26, not the other way around. Yet with its argument, Petitioner appears to be modifying *Kong in view of Edwards-535*. Petitioner’s shifting articulation of its combination is further shown where Petitioner contends that “Kong’s teachings . . . would be applied to the use of Edwards-’535’s apparatus,” *id.*, 32-33, and then contends that “Edwards-’535’s RF energy device . . . would have likewise been applied [to] Kong[],” *id.*, 33.

In a similar situation where a party 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, the Federal Circuit determined that it “cannot fault the Board for being at a loss in trying to decipher” the party’s “kitchen-sink of unclear and confusing motivation-to-combine arguments,” and affirmed the Board’s finding of no motivation to combine. *Sisvel Int’l S.A. v. Sierra Wireless, Inc.*, 82 F.4th 1355, 1364 (Fed. Cir. 2023). 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 Kong and at other times on allegedly improving Kong 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 Kong when Edwards-535 itself recognizes Kong as disadvantageous. And if Edwards-535 had already “expressly overcome[]” the “shortcomings” of Kong, like the Petition contends, Pet., 30, there would have been no reason for a person of ordinary skill in the art to look to Kong, which has the very shortcomings 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" (citation omitted)). Here, the fact that Edwards-535 allegedly already provides a solution to the problem of Kong defeats any argument that seeking the solution would provide a motivating reason to combine the references.

Fourth, Petitioner argues that Edwards-535 and Kong "describe similar techniques such that their combination would have yielded predictable results." Pet., 30-31. But as discussed above, Edwards-535 and Kong describe radically different techniques. Edwards-535 delivers energy without cutting or penetrating the turbinates, in a bloodless procedure that does not form wounds on the surface. And in sharp contrast, Kong delivers energy after cutting the turbinate and penetrating it with holes in a bloody procedure that sometimes forms scabs at the hole site. In making this argument in the Petition, Petitioner overlooks that these are fundamentally different techniques.

And even if Edwards-535 and Kong 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”).

Fifth, Petitioner argues that because Kong’s equipment is “off-the-shelf” and “well-known,” “a POSITA would have found it obvious to substitute Kong’s target tissue . . . for Edwards-’535’s target tissue” Pet., 31-32. But the Petition fails to explain how Kong’s *equipment* allegedly being “off-the-shelf” or “well-known” would provide any motivation to “substitute Kong’s *target tissue* . . . for Edwards-’535’s *target tissue*.” *Id.* (emphases added). To the extent Petitioner is suggesting that Kong’s equipment could be used, that would be another confusing reversal of the combination, further undermining any motivation to combine.

Petitioner further argues that it “would have been obvious to combine Edwards-’535 with Kong.” *Id.*, 38; *see also id.*, 53, 54, 55. But, as the Federal

Circuit has explained, merely stating that “the combination ‘would have been obvious’” is legally inadequate to support a motivation to combine:

Absent some articulated rationale, a finding that a combination of prior art would have been “common sense” or “intuitive” is no different than merely stating the combination “would have been obvious.” Such a conclusory assertion with no explanation is inadequate to support a finding that there would have been a motivation to combine. This type of finding, without more, tracks the *ex post* reasoning *KSR* warned of and fails to identify any actual *reason* why a skilled artisan would have combined the elements in the manner claimed.

In re Van Os, 844 F.3d at 1361 (citing *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007)). The correct question is whether “a skilled artisan *would have had reason to combine* the teachings of the prior art references to achieve the claimed invention.” *Purdue Pharma L.P. v. Depomed, Inc.*, 643 F. App’x 960, 965 (Fed. Cir. 2016) (emphasis added); *see also 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”). As explained above, Petitioner has failed to identify a reason or motivation why a person of ordinary skill in the art 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 Kong.

* * * * *

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 Kong. Petitioner has, therefore, not carried its burden of proving a reasonable likelihood of prevailing on any challenged claim in Ground 1.

B. Even if the References Could Be Combined, the Combination of Edwards-535, Kong, and Stern Does Not Teach “Contacting a Treatment Element of a Nasal Airway Treatment Device Directly with Nasal Mucosa of the Nasal Airway”

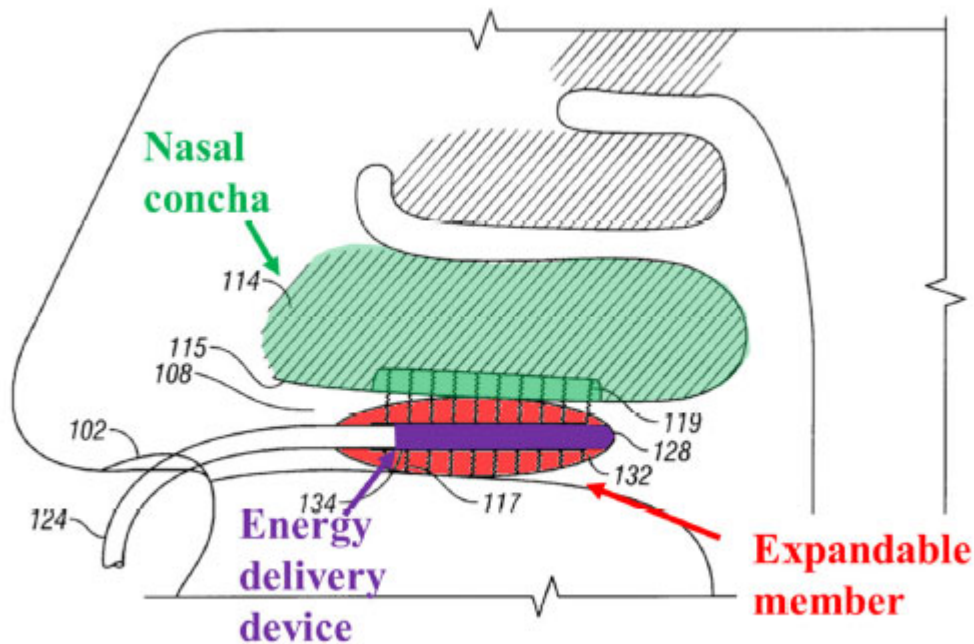
The combination of Edwards-535, Kong, and Stern—even if one were motivated to make the combination—does not disclose or suggest each and every limitation of the challenged claims. Specifically, the combination fails to satisfy at least limitation [1.a], “contacting a treatment element of a nasal airway treatment device directly with nasal mucosa of the nasal airway, wherein the treatment element comprises two rows of bipolar electrode pairs.” Ex. 1001-’271 patent, claim 1.

The Petition relies on the combination of Edwards-535, Stern, and Kong for limitation [1.a]. Pet., 34-41. And the Petition relies on Edwards-535 in an attempt to satisfy the “contacting a treatment element of a nasal airway treatment device directly with nasal mucosa of the nasal airway” portion of the limitation. *Id.*, 34-

38. Edwards-535, however, does not teach “contacting a treatment element of a nasal airway treatment device *directly* with nasal mucosa of the nasal airway” as required by the claims.

Petitioner contends that “multiple configurations” of Edwards-535’s “energy delivery device 134” each satisfy the “contacting a treatment element . . . directly with nasal mucosa of the nasal airway” limitation. *Id.*, 35 (emphasis omitted). But neither “configuration” of Edwards-535 addressed in the Petition describes “contacting a treatment element of a nasal airway treatment device *directly* with nasal mucosa of the nasal airway.”

First, Petitioner points to a configuration of Edwards-535 with “energy delivery device 134 positioned within expandable member 132.” *Id.*, 36. That configuration is shown in Petitioner’s annotated version of Figure 3B below.



Id., 36-37 (Petitioner's annotations of Fig. 3B of Edwards-535). Petitioner concedes that the "energy delivery device 134 [is] *positioned within* expandable member 132." *Id.*, 36 (emphasis added). As is clear from the annotated figure above, energy delivery device 134 does *not* directly contact the nasal mucosa. *See* Ex. 1010-Edwards-535, Fig. 3B. Instead, as the Petition also concedes, in this configuration, the "expandable member 132 is . . . brought into *contact* with the surface 115 of the nasal concha 114 to be treated." Pet., 36 (quoting Ex. 1010-Edwards-535, 5:27-30). The expandable member 132 contacts the nasal mucosa, and the energy delivery device 134 does not contact the nasal mucosa. *See* Ex. 1010-Edwards-535, Fig. 3B, 5:27-30. Therefore, this configuration of Edwards-

535 does not satisfy the “contacting a treatment element of a nasal airway treatment device *directly* with nasal mucosa of the nasal airway” limitation.

Second, Petitioner identifies a second alleged “configuration” of Edwards-535 that it contends “discloses that energy delivery device 134 can include RF electrodes (such as ring electrodes 156) that are ‘disposed on the surface’ of, rather than inside expandable member 132.” Pet., 37 (quoting Ex. 1010-Edwards-535, 8:18-20). In support of this argument, Petitioner cites Figures 5-6 and column 8, lines 8-25, of Edwards-535. *Id.* But none of these disclosures of Edwards-535 teach “contacting a treatment element of a nasal airway treatment device *directly* with nasal mucosa of the nasal airway.”

Beginning with Figures 5 and 6, as shown below, both of those figures show the energy delivery device 134 *inside* the expandable member 132.

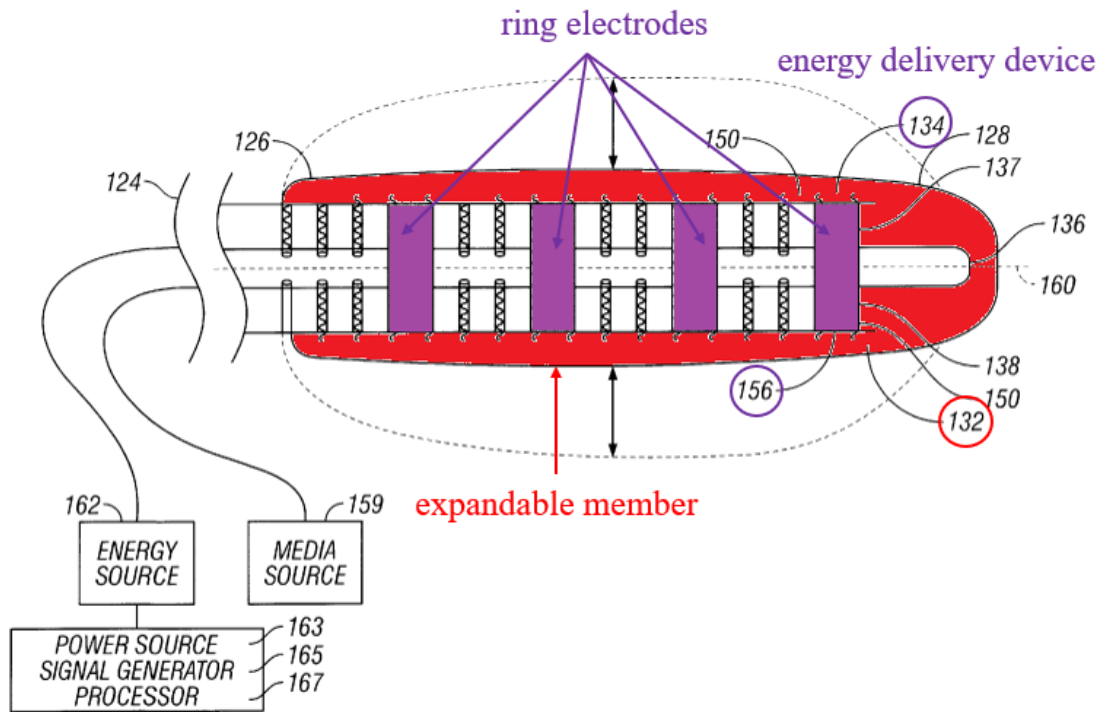


FIG. 6

Ex. 1010-Edwards-535, Fig. 6 (annotated).

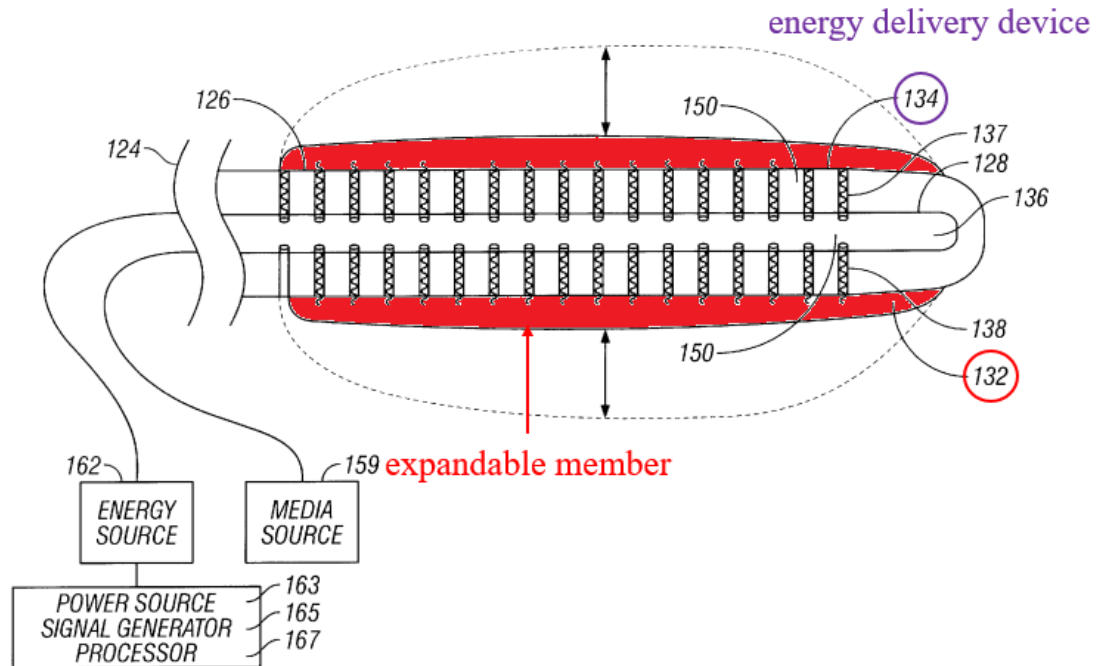


FIG. 5

Id., Fig. 5 (annotated). In Figures 5 and 6, the energy delivery device 134 is *inside* the expandable member 132 and does not directly contact the nasal mucosa. *Id.*, Figs. 5, 6. Therefore, neither Figure 5 nor Figure 6 of Edwards-535 satisfies the “contacting a treatment element of a nasal airway treatment device *directly* with nasal mucosa of the nasal airway” limitation.

Column 8, lines 8-17—the next portion of Edwards-535 that Petitioner cites in support of this second “configuration” argument—also does not teach an energy delivery device that directly contacts the nasal mucosa. Pet., 37. Column 8, lines 8-17 of Edwards-535 refers to Figure 5 and explains that “the energy delivery device 134 may be positioned *within* the expandable member.” Ex. 1010-Edwards-535, 8:8-9 (emphasis added). As discussed above and shown again below, Figure 5 shows the energy delivery device 134 *inside* the expandable member 132, so this energy delivery device does not *directly* contact the nasal mucosa. *Id.*, 8:8-17, Fig. 5.



expandable member

Id., Fig. 5. This portion of Edwards-535 further states that the energy delivery device positioned “within the expandable member” may be a “needle electrode” or “a conductive film lining the outside of the lumen,” and that “[t]he sheath may also serve as the energy delivery device.” *Id.*, 8:8-12. As shown in annotated Figure 5 above, the lumen 136 and the sheath 150 are both inside the expandable member 132, so an energy delivery device at these locations would not *directly* contact the nasal mucosa. *Id.*, Fig. 5.

Edwards-535 then states that, “[a]lternatively, the energy delivery device may be positioned on a surface 147 of the expandable member.” *Id.*, 8:12-14.

“[S]urface 147” is not annotated on Figure 5 of Edwards-535. *Id.*, 8:12-14, Fig. 5.

The Petition seems to assume, though does not expressly contend, that “surface

147” is referring to the *outside* surface of the expandable member. But there is no indication in Edwards-535 that “surface 147” in this single sentence is the *outside* surface of the expandable member. To the contrary, and as explained in greater detail below, how Edwards-535 describes what it means to have an electrode on the surface of the expandable member demonstrates that Edwards-535 is referring to the *inside* surface of the expandable member.

Column 8, lines 18-25—the last portion of Edwards-535 that Petitioner cites—also does not teach an energy delivery device that directly contacts the nasal mucosa. Pet., 37. This portion of Edwards-535 refers to Figure 6, which, as discussed above, also shows the energy delivery device 134 *inside* the expandable member 132. Ex. 1010-Edwards-535, 8:18-25, Fig. 6. As shown in annotated Figure 6 below, the ring electrodes 156 are *inside* the expandable member 132, so these energy delivery devices do not *directly* contact the nasal mucosa.

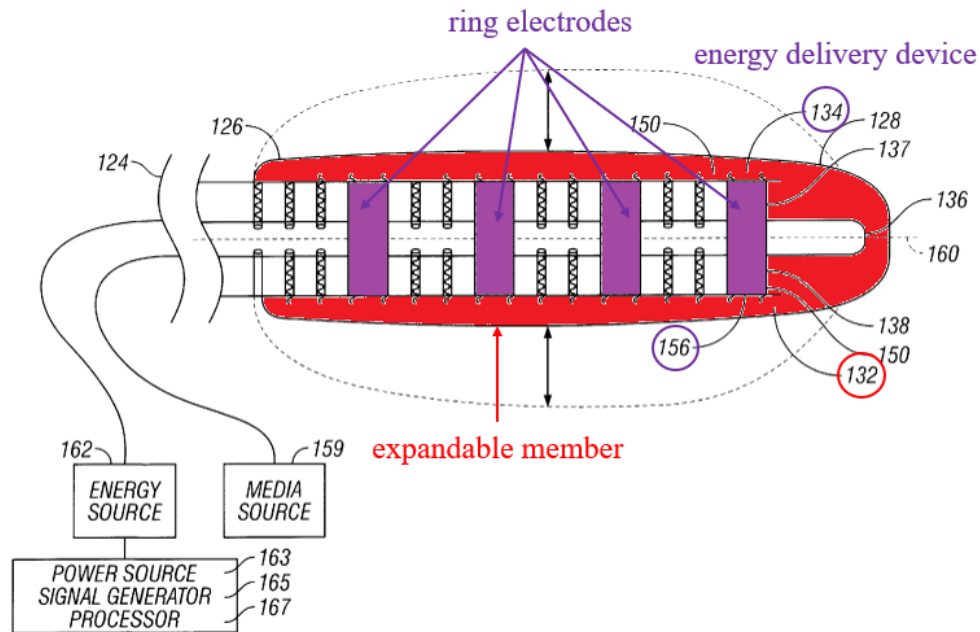


FIG. 6

Id., Fig. 6. This portion of Edwards-535 explains that Figure 6 illustrates an “embodiment” where “the energy delivery device includes one or more ring electrodes 156 disposed on the surface of the expandable member 132.” *Id.*, 8:18-20. The Petition again seems to assume that “the surface” is referring to the *outside* surface of the expandable member 132. But, yet again, this assumption is not supported by Edwards-535. Figure 6, shown above, shows electrodes 156 *inside* the expandable member 132. *Id.*, Fig. 6. It plainly does not show “one or more ring electrodes 156 disposed on” the *outside* surface of the expandable member 132, and Edwards-535 nowhere states that the ring electrodes are disposed on the outside surface. *Id.*, Fig. 6, 8:18-20. Indeed, Figure 6 shows that when Edwards-535 discusses an electrode being disposed on the “surface” of an expandable

member, it is referring to the *inside* surface of that member. Thus, the unlabeled “surface” of the expandable member 132 that Edwards-535 describes the ring electrodes as being “disposed on” must be the *inside* surface of the expandable member 132, which does not directly contact the nasal mucosa. Therefore, none of the disclosures of Edwards-535 that Petitioner relies on for this second alleged “configuration” of Edwards-535 teach an energy delivery device that directly contacts the nasal mucosa.

Edwards-535 then explains how “a plurality of energy delivery devices are positioned on a surface of the expandable member” by pointing to Application Serial No. 08/319,373, which issued as U.S. Patent No. 5,575,788 to Baker (Ex. 1011-Baker). Ex. 1010-Edwards-535, 8:26-31. Baker describes sealing electrodes 28 between layers 20(a) and 20(b) of conformable member 20. Ex. 1011-Baker, 7:66-8:8. And Figure 4 of Baker, which is a cross-section of the ablative end of the device, shows that electrode 28 is *inside* of conforming member 20, not on the outside of it. *Id.*, Fig. 4. Likewise, Figure 8 of Baker, which also illustrates a cross-section, shows zones 30 for electrodes that are not on the outer surface of conforming member 20. *Id.*, Fig. 8.

Thus, every time Edwards-535 describes what it means to have an electrode disposed on the surface of the expandable member, Edwards-535 is referring to it being either on the *inside* surface of the expandable member or *within* the

expandable member. Edwards-535 *never* shows an electrode disposed on the *outer* surface of the expandable member whether through the specification itself or by reference to Baker. And, notably, Edwards-535 *never* shows or discloses that the energy delivery device is *outside* of the expandable member. The single sentence cited by Petitioner is insufficient to teach an energy delivery device that directly contacts the nasal mucosa, particularly in view of the full description in Edwards-535.

Edwards-535, therefore, fails to teach the “contacting a treatment element of a nasal airway treatment device directly with nasal mucosa of the nasal airway” limitation. Petitioner does not rely on any other references to teach this portion of limitation [1.a]. *See* Pet., 34-38. And Petitioner has not carried its burden of proving a reasonable likelihood of prevailing on any challenged claim in Ground 1 for this additional reason.

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 its Edwards-535, Kong, and Stern combination from Ground 1 to reach claim 4. *Id.*, 72-74. But claim 4 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 1, 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.A.1, the lack of a motivation to combine Edwards-535 and Kong discussed in Section IV.A.2, and the lack of a teaching of limitation [1.a] discussed in Section IV.B. *See* Pet., 72-74. 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 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 3 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. And, even if one were to make Petitioner's proposed combination, it would still not result in the claimed invention.

A. The Petition Fails to Establish a Motivation to Combine

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 3. *See Intelligent Bio-Sys.*, 821 F.3d at 1367-68 (citations omitted).

1. 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 3, just like it did for Ground 1. *See Pet.*, 74, 79-80. For its motivation to combine Edwards-535 and Stern in Ground 3, Petitioner primarily refers to its arguments for combining Edwards-535 and Stern in Ground 1. *Id.*, 79-80. Petitioner has failed to establish a motivation to combine Edwards-535 and Stern for the reasons discussed above with respect to Ground 1 and for the additional reason that Edwards-535 and Stern teach away. *See Section IV.A.1.*

Petitioner makes a single unique motivation-to-combine argument for Edwards-535 and Stern in Ground 3:

The precise control afforded by Stern's electrode pairing and arrangement would have been particularly useful for the combination of Edwards-'535 and Liang. Liang emphasizes the need to avoid perforating the nasal septum. Using two rows of bipolar electrode pairs to direct and control energy, a practitioner could specifically target the middle turbinate without perforating the nasal septum.

Pet., 80 (citations omitted). But, as discussed in Section IV.A.1, the portions of Stern that describe "precise control" make it clear that Stern refers to "precise control" as ensuring "complete heating of an area" to achieve "tissue destruction."

See Ex. 1033-Stern, 12:26-34, 13:21-35. Stern's objective to destroy the surface tissue is contrary to Edwards-535's objective of not ablating the surface tissue. Moreover, the alleged objective of precisely controlling energy delivery specifically to avoid perforating the nasal septum does not overcome the fatal flaw of the attempted combination of Edwards-535 and Stern, namely, that 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.

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

Much like the Petition's motivation to combine Edwards-535 and Kong in Ground 1, the Petition's motivation to combine Edwards-535 and Liang in Ground 3 is 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.A.2. 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 the “contrast” between Edwards-535 and Liang. *See* Pet., 76 (describing Liang and Edwards-535 in “contrast” to one another).

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., 75-78, 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., 75. 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 (middle turbinate)” as Edwards-535 and that Edwards-535 and Liang “describe similar techniques.” Pet., 75-77. 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 discusses shortcomings of its approach to delivering treatment that Edwards-'535 overcomes.” Pet., 76. But, just like its nearly identical argument for Edwards-535 and Kong, 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, id.*, 74, not the other way around. 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 method like that of Edwards-'535 (which does not damage surrounding tissue) to deliver treatment to the specific tissue identified by Liang to avoid the shortcomings of Liang's technique while obtaining its benefits.” *Id.*, 76. This “kitchen-sink of unclear and confusing motivation-to-combine arguments” is insufficient. *See Sisvel*, 82 F.4th at 1364 (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 “overcome[]” the “shortcomings” of Liang, like the Petition contends, Pet., 76, there would have been no reason for a person of ordinary skill in the art to look to Liang, which has the very shortcomings that Edwards-535 has already allegedly overcome. *See, e.g., Taiwan Semiconductor*, IPR2016-01442, Paper 7 at 19-20, 22 (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

provides a solution to the problem of Liang defeats any argument that seeking the solution would provide a motivating reason to combine the references.

Petitioner further argues that it “would have been obvious to combine Edwards-’535 with Liang.” Pet., 79; *see also id.*, 81, 82, 83, 84, 89. But, as the Federal Circuit has explained, merely stating that “the combination ‘would have been obvious’” is legally inadequate to support a motivation to combine:

Absent some articulated rationale, a finding that a combination of prior art would have been “common sense” or “intuitive” is no different than merely stating the combination “would have been obvious.” Such a conclusory assertion with no explanation is inadequate to support a finding that there would have been a motivation to combine. This type of finding, without more, tracks the *ex post* reasoning *KSR* warned of and fails to identify any actual *reason* why a skilled artisan would have combined the elements in the manner claimed.

In re Van Os, 844 F.3d at 1361 (citing *KSR*, 550 U.S. at 418). The correct question is whether “a skilled artisan *would have had reason to combine* the teachings of the prior art references to achieve the claimed invention.” *Purdue Pharma*, 643 F. App’x at 965 (emphasis added); *see also 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 identify a reason or motivation why a person of ordinary skill in the art would have combined the elements in the manner claimed.

Throughout its obviousness arguments in Ground 3, Petitioner also improperly relies on Exhibit 1059, which is a Chinese utility model patent. *See* Pet., 79, 81, 83, 86. Exhibit 1059 is not part of the alleged combination of Ground 3. Petitioner asserts, without any support, that Exhibit 1059 describes the device used in Liang. *Id.*, 79. 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.

¹ Petitioner refers to Exhibit 1059 as “Liang-’227,” 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).

Petitioner also never provides a reason to combine Exhibit 1059 with any of the references in the proposed combination. *RPX Corp. v. Parity Networks, LLC*, IPR2018-00097, Paper 7 at 14 (P.T.A.B. Apr. 24, 2018) (denying institution where petitioner “cite[d] to several other references that implement hardware queues but [did] not assert these references are part of the combination,” and explaining that “[r]elying on knowledge in the art does not obviate the need to prove a reference is prior art as of the critical date and show a motivation to combine existing components in the manner claimed free of hindsight motivation”). As a result, Petitioner’s reliance on Exhibit 1059 for elements of the claims without providing any reason to combine the references further undermines Petitioner’s Ground 3.

* * * * *

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 3.

B. Even if the References Could Be Combined, the Combination of Edwards-535, Liang, and Stern Does Not Teach “Contacting a Treatment Element of a Nasal Airway Treatment Device Directly with Nasal Mucosa of the Nasal Airway”

The combination of Edwards-535, Liang, and Stern—even if one were motivated to make the combination—does not disclose or suggest each and every limitation of the challenged claims. Specifically, the combination of Edwards-535, Liang, and Stern fails to satisfy at least limitation [1.a], “contacting a treatment element of a nasal airway treatment device directly with nasal mucosa of the nasal airway, wherein the treatment element comprises two rows of bipolar electrode pairs.” Ex. 1001-’271 patent, claim 1.

Just like it did for Ground 1, the Petition relies on Edwards-535 in an effort to satisfy the “contacting a treatment element of a nasal airway treatment device directly with nasal mucosa of the nasal airway” portion of limitation [1.a] and refers to its arguments in Ground 1. Pet., 78-79. However, Edwards-535 does not teach “contacting a treatment element of a nasal airway treatment device *directly* with nasal mucosa of the nasal airway” for the reasons discussed above with respect to Ground 1. *See* Section IV.B.

In a single sentence, Petitioner seems to suggest that Liang cures this deficiency. *See* Pet., 79. Specifically, Petitioner contends that “the SHP-I device used in Liang is specifically designed so as to ‘*contact . . . patient’s tissue to*

produce an internal thermal effect . . . , which causes protein tissues to heat . . . and gradually subside or disappear” *Id.* (quoting Ex. 1059, 1). But this disclosure is *found nowhere* in the two-page Liang reference Petitioner uses in the combination for Ground 3. *See* Ex. 1056-Liang, 341-42. Rather, as discussed above, Petitioner is citing an entirely different reference (Ex. 1059)—a Chinese utility model patent—for this disclosure.² The Chinese utility model patent is not incorporated by reference into the Liang reference used in the combination. *See* Ex. 1056-Liang, 341-42. And Petitioner has not even attempted to establish that the Chinese utility model is actually prior art or articulate a motivation to combine the Chinese utility model patent with any of Edwards-535, Stern, or Liang as would be required to actually rely on its disclosure in the combination for satisfying the limitation. *RPX*, IPR2018-00097, Paper 7 at 14 (denying institution where petitioner “cite[d] to several other references that implement hardware queues but

² Coincidentally, Exhibit 1059 lists the “[d]esigners” as including two individuals with the name Liang, but the full names of those individuals are not the same as the full name of the author of the Liang reference used in Ground 3 and 4 of the Petition. *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 the author).

[did] not assert these references are part of the combination,” and explaining that “[r]elying on knowledge in the art does not obviate the need to prove a reference is prior art as of the critical date and show a motivation to combine existing components in the manner claimed free of hindsight motivation”). The Board should disregard this disclosure from the Chinese utility model patent because it is an improper attempt by Petitioner to rely on a disclosure outside of the combination presented in Ground 3 to satisfy a limitation without establishing that it has been incorporated by reference into Liang or articulating a motivation to combine it with the other references in the combination.

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 its Edwards-535, Liang, and Stern combination from Ground 3 to reach claim 4. Pet., 90. But claim 4 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 Edwards-535 and Stern and that Edwards-535 and Stern teach away, as discussed in Section VI.A.1, the lack of a motivation to combine Edwards-535 and Liang discussed in Section VI.A.2, and the lack of a teaching of limitation [1.a] discussed in Section VI.B. *See*

Pet., 90. 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. 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 11,812 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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