

**UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD**

NEURENT MEDICAL INC. & NEURENT MEDICAL LTD.,
Petitioners,

v.

AERIN MEDICAL, INC.,
Patent Owner.

Case IPR2024-00277
U.S. Patent No. 11,241,271

PATENT OWNER'S RESPONSE

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TABLE OF EXHIBITS

Exhibit No.	Description
2001	Declaration of Dr. Marom Bikson
2002	Curriculum Vitae of Dr. Marom Bikson
2003	Transcript of the September 24, 2024, Deposition of Dr. Gregory T. Martin
2004	Transcript of the September 25, 2024, Deposition of Dr. Gregory T. Martin
2005	Exhibit 2 to the Deposition of Dr. Gregory T. Martin
2006	Exhibit 3 to the Deposition of Dr. Gregory T. Martin
2007	Transcript of the October 10, 2024, Deposition of Dr. John M. DelGaudio
2008	U.S. Patent No. 8,986,301 to Wolf et al.
2009	U.S. Patent No. 11,033,318 to Wolf et al.

I. INTRODUCTION

Petitioners Neurent Medical Inc. and Neurent Medical Ltd. (collectively, “Petitioners”) petitioned for *Inter Partes* Review of Claims 1-4, 6-12, and 16 (collectively, the “Challenged Claims”) of U.S. Patent No. 11,241,271 (“the ’271 patent”), which is owned by Patent Owner Aerin Medical, Inc. (“Patent Owner”). Petitioners have failed to meet their burden of proving that the Challenged Claims are invalid as obvious because Petitioners have failed to show that their asserted obviousness combinations disclose, teach, or suggest every limitation of the Challenged Claims.

For instance, every Challenged Claim requires the step of “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.” Petitioners rely upon a single reference (Stern) as allegedly teaching the claimed “two rows of bipolar electrode pairs” for all grounds. However, Stern fails to do so.

As shown herein, Stern teaches a device comprising at most a *single pair* of bipolar electrodes. Petitioners’ expert’s admissions on cross examination further confirm that Stern’s device is limited to a *single pair* of bipolar electrodes. Even if Stern taught bipolar electrode pairs (it does not), Stern teaches at most two rows of a *single pair* each—not two rows of *pairs*. Moreover, regardless of Stern’s alleged

teachings, Petitioners failed to show that a POSITA would have been motivated to combine Stern with their primary reference, Edwards-535. Accordingly, Petitioners' proposed combinations of Edwards-535, Kong, and Stern (Ground I) and Edwards-535, Liang, and Stern (Ground III) fail to render obvious Challenged Claim 1, the sole independent claim of the '271 patent.

For at least these reasons, Petitioners have failed to carry their burden of showing that any Challenged Claim is unpatentable, and Patent Owner respectfully requests that the Board confirm the patentability of the Challenged Claims.

II. BACKGROUND

A. The '271 Patent and the Challenged Claims.

The '271 patent, entitled "Methods and Devices to Treat Nasal Airways," issued on February 8, 2022, from U.S. Patent Application No. 16/514,316 (filed on July 17, 2019). (Ex-1001 at [21], [22], [45], [54].) The '271 patent claims priority to a provisional patent application (Application No. 61/496,930) which was filed on June 14, 2011. (*Id.* at [60].)¹

The '271 patent and the Challenged Claims are generally directed toward methods "for treating a nasal airway to reduce mucus production." (*Id.* at claim 1.) The '271 patent describes "treating a nasal airway by modifying a property of a nasal

¹ Petitioners have applied a priority date of June 14, 2011. (Petition at 5.)

tissue of or near a nasal valve of the airway, without using a surgical incision or an implant...” (*Id.* at Abstract.) The ’271 patent discloses a method for decreasing nasal congestion, including reducing mucus production, and increasing nasal air flow. (*Id.* at 10:56-67, 48:1-7.) The method of the ’271 patent includes treating a patient’s nasal airway 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.* at 8:1-13.)

The method of the ’271 patent uses a treatment probe having multiple pairs of bipolar electrodes on the outside surface that directly contact the nasal mucosa and apply radiofrequency (“RF”) energy to target tissue underlying the nasal mucosa. (*See, e.g., id.* at 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 describes a pair of bipolar electrodes as comprising electrodes of opposite polarities. (*Id.* at 22:28-30; *see also id.* at FIGS. 8F-G.) As shown below, the ’271 patent discloses a claimed embodiment where the bipolar electrodes are arranged in two rows, with each row having multiple bipolar electrode pairs:

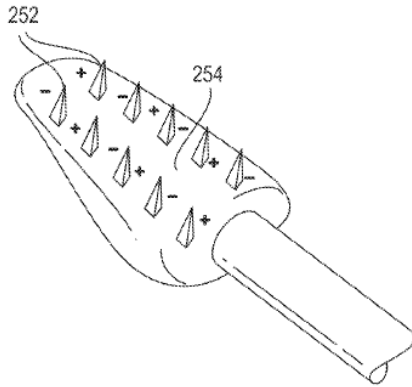


FIG. 8F

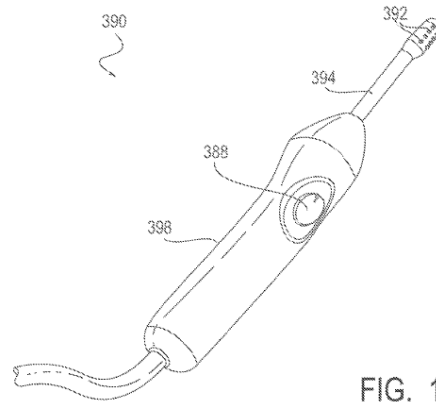


FIG. 18

(*Id.* at FIGS. 8F and 18; *see also id.* at Abstract, 8:21-25.)

The '271 patent also discloses an embodiment where the bipolar electrode pairs are arranged in a single row:

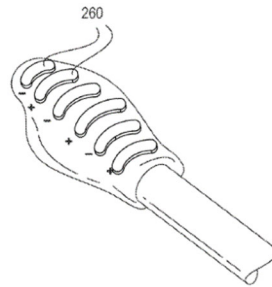


FIG. 8G

(*Id.* at FIG. 8G; *see also id.* at 23:54-59.)

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.* at 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.* at 48:1-7.)

Independent Challenged Claim 1, the only independent claim of the '271 patent, is reproduced below:

1. A method for treating a nasal airway to reduce mucus production, the method comprising:

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;

1[b] applying radiofrequency energy with the bipolar electrode pairs through the nasal mucosa to a target tissue underlying the nasal mucosa for an amount of time to heat the target tissue; and

1[c] removing the treatment element from the nasal airway,

1[d] wherein heating the target tissue with the applied radiofrequency energy modifies at least one property of the target tissue, and

1[e] wherein the modified at least one property of the target tissue causes a reduction in mucus production in the nasal airway.

(*Id.* at claim 1.)

B. The Level Of Ordinary Skill In The Art.

Petitioners' definition of a POSITA is: "(1) a Doctor of Medicine (M.D.) or at least a bachelor of science degree in engineering or a related discipline and (2) at least three years of experience in the clinical use, design, development, **and/or** testing of medical devices, including medical devices that deliver energy to tissue."

(Petition at 20-21.)² Patent Owner agrees with part (1) of Petitioners' definition. However, Patent Owner disputes part (2) of Petitioners' definition because the "and/or" encompasses within the definition of a POSITA persons who **only** have experience with the clinical use or testing of medical devices. A POSITA in the field of the '271 patent would have had more experience than just clinically using medical devices or simply conducting tests with medical devices. (Ex-2001-Bikson, ¶ 38.)

As noted previously, the claims of the '271 patent require a "nasal airway treatment device" having a "treatment element" comprising "two rows of bipolar electrode pairs." (Ex-1001 at claim 1.) Challenged Claims 4 and 8-10 additionally recite: (i) applying radiofrequency energy "in the form of a 460 kHz sinusoid wave"; (ii) "wherein the radiofrequency energy is produced by a radiofrequency energy source configured to run between 1 Watt and 100 Watts"; (iii) "wherein applying the radiofrequency energy comprises heating the target tissue to a temperature between 50 degrees Celsius to 70 degrees Celsius"; and (iv) "wherein the amount of

² Emphasis added herein unless otherwise noted.

time the radiofrequency energy is applied to the target tissue is between fifteen seconds and one minute.” (*Id.* at claims 4, 8-10.)³

As Petitioners’ expert, Dr. DelGaudio, admitted at his deposition, each of the above limitations presents a “technical issue” associated with the features of the Challenged Claims. (Ex-2007 at 45:1-10, 231:6-12, 231:15-18, 234:5-8, 234:18-235:3; Ex-2001-Bikson, ¶ 40.) A person who merely tests or uses a medical device is not qualified to speak to these technical issues. (Ex-2001-Bikson, ¶ 40.) For instance, an M.D. who has merely used or tested medical devices is not qualified to speak to the technical issues associated with implementing a “nasal airway treatment devices” having a “treatment element” comprising “two rows of bipolar electrode pairs.” (*Id.*) Someone who has never designed or developed such a medical device would lack the requisite background to implement such a device. (*Id.*)

Dr. DelGaudio’s deposition testimony confirms that Petitioners’ and Dr. DelGaudio’s definition of a POSITA is incorrect. According to Dr. DelGaudio, Petitioners and Dr. DelGaudio based their definition of a POSITA around Dr. DelGaudio’s own qualifications. (Ex-2007 at 125:12-21, 126:6-9, 127:13-16.) This

³ Claim 5 of the ’271 patent, which was not challenged, recites “a thermocouple positioned between the two rows of bipolar electrode pairs on the treatment element.” (*Id.* at claim 5.)

is completely backwards. Factors that may be considered in determining the level of ordinary skill in the art include, for example, the educational level of the inventor and the types of problems encountered in the art. *See Daiichi Sankyo Co., Ltd. v. Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007) (listing factors). Unsurprisingly, reverse engineering a POSITA definition around an expert's qualifications is not one of the factors that may be considered. *Id.*

Further, when asked whether various individuals (*e.g.*, someone that has only a Bachelor of Science in engineering) would qualify as a POSITA under Dr. DelGaudio's definition, Dr. DelGaudio repeatedly refused to apply his own definition and did not know what would be needed to qualify these individuals as a POSITA. (Ex-2007 at 125:12-21, 125:22-126:12, 126:18-22, 128:10-15, 131:14-22; *see also id.* at 133:19-22, 141:16-142:22.) If Dr. DelGaudio does not know what his own definition means, or how to apply it, then Dr. DelGaudio's definition is unreliable and improper.

Patent Owner proposes the following modifications to Petitioners' proposed definition for POSITA: (1) a Doctor of Medicine (M.D.) or at least a bachelor of science degree in engineering or a related discipline and (2) at least three years of experience in the ~~clinical use~~, design and[[,]] development, ~~and/or testing~~ of medical devices, including medical devices that deliver energy to tissue." This definition eliminates the "and/or" from Petitioners' definition while requiring design

and development experience irrespective of any clinical use or testing experience.

Patent Owner's definition properly aligns with the technical issues presented in this proceeding and should be adopted by the Board. *See, e.g., Nespresso USA, Inc. v. K-fee System GmbH*, IPR2022-01574, Paper 29 at 19-23 (PTAB April 10, 2024) (holding that a POSITA would have had five years of design experience and declining to credit the testimony of an expert who lacked such design experience).

Regardless of which definition the Board adopts, the prior art fails to render obvious any of the Challenged Claims.

C. Petitioner's Asserted Prior Art References.

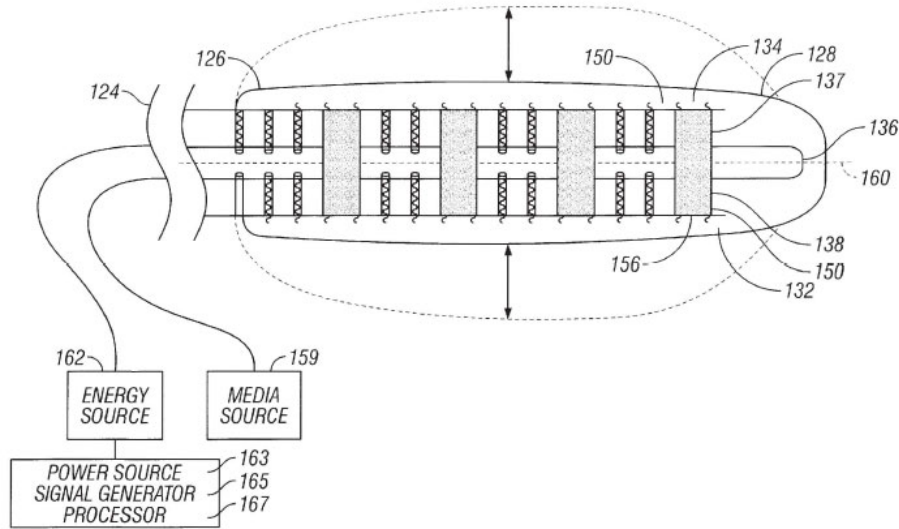
1. U.S. Patent No. 6,517,535 ("Edwards-535").

Edwards-535 is generally directed towards "a method and apparatus for treating airway obstructions," such as 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 at 1:22-26, 1:30-33.) Edwards-535's "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.* at 4:63-66, 6:26-27.) To that end, Edwards-535 teaches cooling the surface of the nasal concha being ablated such that ablation can be performed to remove an internal section of a nasal concha without damaging the surface of the nasal concha. (*Id.* at 4:60-63, 6:12-16.)

Thus, Edwards-535's method can be performed bloodlessly and eliminates the need for surgical cutting. (*Id.* at 4:58-60, 4:55-57.)

Edwards-535 further teaches an apparatus 124 comprising an expandable member 132 that conforms to the surface of the nasal concha and an energy delivery device 134 for delivering ablative energy. (*Id.* at 7:28-39.) To expand the expandable member 132, a medium 138 is delivered through apertures 137 from a lumen 136 coupled with a catheter body 126. (*Id.* at 7:40-47.) The expandable member 132 is preferably formed of a material that is permeable to the medium used to expand the member, thus allowing the medium to pass through the expandable member 132 to the surface of the nasal concha being ablated. (*Id.* at 7:66-8:5.) In one embodiment, the expandable member 132 is an expandable porous membrane. (*Id.* at 8:5-7.)

Edwards-535 teaches that the energy delivery device 134 may include one or more ring electrodes 156 disposed on the surface of the expandable member 132. (*Id.* at 8:18-20.) The plurality of ring electrodes 156 are disposed in parallel with their axes aligned with a long axis 160 of the catheter body 126. (*Id.* at 8:21-23.)



(*Id.* at FIG. 6.)

2. U.S. Patent No. 5,562,720 (“Stern”).

Stern is generally directed to “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 at 1:17-22, 6:56-59.) Stern explains that its “goal” is “destruction of the endometrial cells.” (*Id.* at 6:60-62.) Stern describes destroying the endometrium using ablative radiofrequency energy while maintaining the average temperature of the myometrium, the tissue beneath the endometrium surrounding the uterine cavity. (*Id.* at 2:11-18, 6:66-7:6, 7:29-33.)

As illustrated below, Stern’s apparatus includes a “conventional” RF generator 158, a separate power source controller 156, a portable computer 164, an application device 124 with an electrode balloon 150, and an electrode belt 154 that

provides a reference electrode for connection to the power source controller 156. (*Id.* at FIG. 12, 10:36-55.) An example schematic representation of the power source controller 156 is shown in FIG. 5. (*Id.* at 8:66-9:2.)

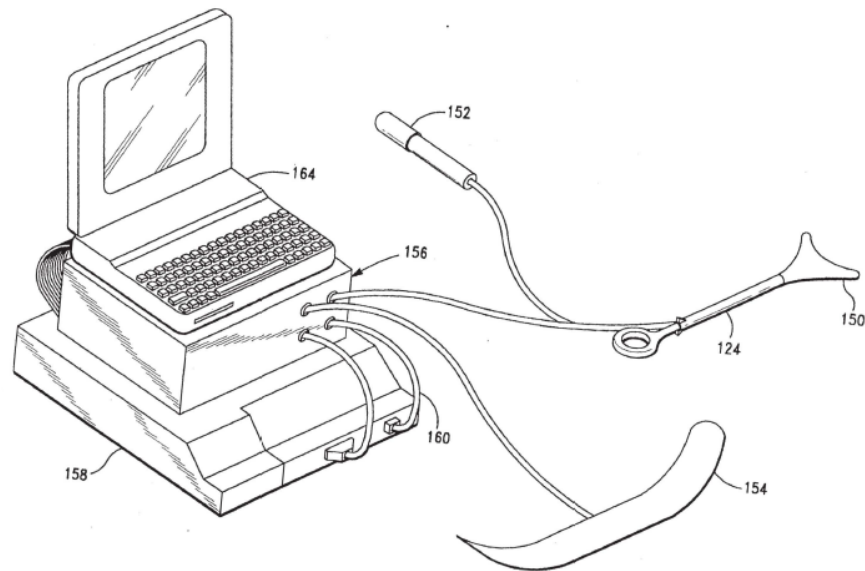


FIG. - 12

(*Id.* at FIG. 12.)

3. Kong.

Kong is a clinical study that discusses “[s]urgical methods” using “radiofrequency ablation treatment [for] perennial allergic rhinitis.” (Ex-1040-Kong at 214.) The study describes 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.*) Kong states 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.*)

4. 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 at 341.) The study states that an “SHP-I radiofrequency treatment device for facial organs (manufactured by Guangzhou Medical Device Factory)” was used to “perform thermal coagulation treatment,” but provides no details on the device or the settings used in the study. (*Id.*) The study explains that radiofrequency treatment can cause “degeneration and atrophy of the sensitive mucosa on the nasal ridge and corresponding nasal septum.” (*Id.* at 341-42.) The study also states that “the patients might experience symptoms such as ... a small amount of bloody secretions” following treatment and that some patients “developed nasal adhesion.” (*Id.* at 341.) Liang recognizes that the described procedure can damage the sensitive mucosa surface. (*Id.* at 341-42.)

III. LEGAL STANDARDS

In an *Inter Partes* Review, the Petitioner bears the burden of persuasion to prove unpatentability by a preponderance of the evidence. *See Dynamic Drinkware, LLC v. Natl. Graphics, Inc.*, 800 F.3d 1375, 1379 (Fed. Cir. 2015). The Board “will not consider arguments and information that are not presented and developed in the

Petition...” See *DIRECTV, LLC v. Qurio Holdings, Inc.*, Case IPR2015-02007, Paper No. 6 at 14 (PTAB April 4, 2016); see also *Valeo North America, Inc. v. Magna Electronics, Inc.*, IPR2014-01206, Paper No. 13 at 17 (PTAB Dec. 23, 2014) (“we will not consider an argument not made in the petition.”). “[T]he Board is not bound by any findings made in its Institution Decision.” *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1376 (Fed. Cir. 2016). “The Board is free to change its view of the merits after further development of the record.” *Id.*

To establish obviousness, the Petitioner must show “how the prior art references, either alone or in combination, teach or suggest the claimed invention.” See *In re Bell*, 991 F.2d 781, 783 (Fed. Cir. 1993); see also *Metalcraft of Mayville, Inc. v. The Toro Co.*, 848 F.3d 1358, 1367 (Fed. Cir. 2017). The Petitioner must also demonstrate “that a skilled artisan would have had reason 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 from doing so.” *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Pat. Litig.*, 676 F.3d 1063, 1068-69 (Fed. Cir. 2012); see also *Orexo AB v. Actavis Elizabeth LLC*, 903 F.3d 1265, 1271 (Fed. Cir. 2018) (holding that a finding of obviousness requires a showing “that a person of ordinary skill would have selected and combined and modified the subject matter of the references in the manner of the claimed invention, with a reasonable expectation of success.”).

IV. CLAIM CONSTRUCTION

Petitioners set forth no claim constructions in their Petition and do not state which claim construction standard was applied. Patent Owner applies the plain meaning to the claims. While the Board need not construe any claim terms to determine that Petitioners have failed to carry their burden in this proceeding, *see Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017), the Board should construe Challenged Claim 1 to require that the claimed method steps be performed in their specified, sequential order.⁴

The Federal Circuit has explained that a claim “requires an ordering of steps when the claim language, as a matter of logic or grammar, requires that the steps be performed in the order written, or the specification directly or implicitly requires” an order of steps. *TALtech Ltd. v. Esquel Apparel, Inc.*, 279 Fed. Appx. 974, 978 (Fed. Cir. 2008). For example, when steps of a method claim refer to the completed results of a prior step, the steps must be performed in order. *E-Pass Techs., Inc. v. 3COM Corp.*, 473 F.3d 1213, 1222 (Fed. Cir. 2007).

Here, as a matter of grammar, the plain language of Challenged Claim 1 requires that the claimed method steps be performed in their specified, sequential

⁴ Patent Owner reserves the right to propose additional claim constructions in the underlying litigation.

order. The first method step of Challenged Claim 1 recites “***contacting a treatment element*** of a nasal airway treatment device directly ***with nasal mucosa of the nasal airway...***” (Ex-1001 at claim 1 (emphases added).) The second method step of Challenged Claim 1 recites “applying radiofrequency energy with the bipolar electrode pairs through ***the nasal mucosa*** to a target tissue underlying ***the nasal mucosa*** for an amount of time to heat the target tissue...” (*Id.*) The third method step of Challenged Claim 1 recites “removing ***the treatment element*** from the nasal airway.” (*Id.*) Thus, in step two, the “nasal mucosa” to which RF energy is applied is the same “nasal mucosa” that was contacted with the treatment element in step one. (*Id.*) Similarly, in step three, the “treatment” element that is removed from the nasal airway is the same “treatment element” that was inserted into the nasal airway in step one. (*Id.*)

Additionally, as a matter of logic, the plain language of Challenged Claim 1 requires that the claimed method steps be performed in their specified, sequential order, as each step is dependent upon the completion of the previous step. As noted above, Challenged Claim 1 recites the steps of “contacting a treatment element of a nasal airway treatment device directly with nasal mucosa of the nasal airway,” “applying radiofrequency energy ... through the nasal mucosa to a target tissue underlying the nasal mucosa,” and “removing the treatment element from the nasal airway.” (Ex-1001 at claim 1.) Because RF energy cannot be applied to the target

tissue until the treatment element contacts the nasal mucosa, the “contacting ... nasal mucosa” step must be complete before the “applying radiofrequency energy” step. (Ex-2001-Bikson, ¶ 60.) Similarly, the “applying radiofrequency energy” step must be complete before the “removing the treatment element from the nasal airway” step, as RF energy cannot be applied to the target tissue if the treatment element is not inside the nasal airway. (*Id.*)

Indeed, Petitioners’ expert, Dr. Martin, agreed that “it makes logical sense to perform [the three method steps of Challenged Claim 1 of the ’271 patent] in order.” (Ex-2004 at 316:15-17; *see also id.* at 316:5-10.)

Because the sequential nature of the claimed method steps is readily apparent from the claims themselves, the Board should construe Challenged Claim 1 to require that the claimed method steps be performed in their specified sequential order. *Mantech Env'tl. Corp. v. Hudson Env'tl. Servs., Inc.*, 152 F.3d 1368, 1376 (Fed. Cir. 1998); *Mformation Techs., Inc. v. Research in Motion Ltd.*, 764 F.3d 1392, 1399 (Fed. Cir. 2014).

As discussed further below, Petitioners’ asserted prior art combinations fail to render the Challenged Claims obvious because, among other reasons, the asserted combinations do not teach the performance of the claimed method steps in their specified, sequential order.

V. PETITIONERS HAVE FAILED TO SHOW THAT THE CHALLENGED CLAIMS OF THE '271 PATENT ARE UNPATENTABLE AS OBVIOUS.

A. Ground 1: Petitioners Have Failed To Show That Edwards-535 In View Of Kong And Stern Renders Challenged Claims 1-3, 6-12, And 16 Obvious.

1. Petitioners Have Failed To Show That Edwards-535 In View Of Kong And Stern Renders Challenged Claim 1 Obvious.

As discussed in detail below, Challenged Claim 1 requires, among other things, the steps of “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” and “applying radiofrequency energy with the bipolar electrode pairs.” Petitioners have failed to show that Stern teaches these limitations because Stern teaches a device comprising only a *single pair* of bipolar electrodes. Further, even if Stern did teach the claimed bipolar electrode pairs (it does not), Stern teaches at most two rows of a *single pair* each—not two rows of *pairs*. Regardless of whether Stern teaches what is claimed, Petitioners have failed to show that a POSITA would have been motivated to combine Stern with Edwards-535. Accordingly, Petitioners have failed to show that Edwards-535 in view of Kong and Stern renders Challenged Claim 1 obvious.

(a) Petitioners Have Failed To Show That Edwards-535 In View Of Kong And Stern Teaches “bipolar electrode pairs.”

Petitioners have failed to show that Edwards-535 in view of Kong and Stern teaches a treatment element comprising “bipolar electrode *pairs*” because Stern teaches a device comprising at most a *single pair* of bipolar electrodes.

Challenged Claim 1 of the '271 patent recites “contacting a treatment element of a nasal airway treatment device directly with nasal mucosa of the nasal airway, wherein the treatment element comprises ... *bipolar electrode pairs*” and “applying radiofrequency energy with the *bipolar electrode pairs*.” (Ex-1001 at claim 1.) Petitioners assert that Stern’s Figure 15 teaches “bipolar electrode pairs” and that a POSITA would have been motivated to implement Stern’s Figure 15 in Edwards-535’s device. (Petition at 39-40; Ex-1004-Martin, ¶¶ 70-72; Ex-2003 at 232:13-18.) Petitioners argue that “Stern’s teachings would have been applied to Edwards-’535 in the same way they are used in Stern.” (Ex-1004-Martin, ¶ 88; Petition at 45.)

As shown below, Petitioners’ analysis provides a single example where Stern’s Figure 15 device is configured to have a *single pair* of electrodes (*i.e.*, electrodes 220 and 220) by closing switches 248 and 238. (Petition at 39-40 (citing Ex-1033-Stern at 12:65-13:2); Ex-1004-Martin, ¶ 71 (same).)

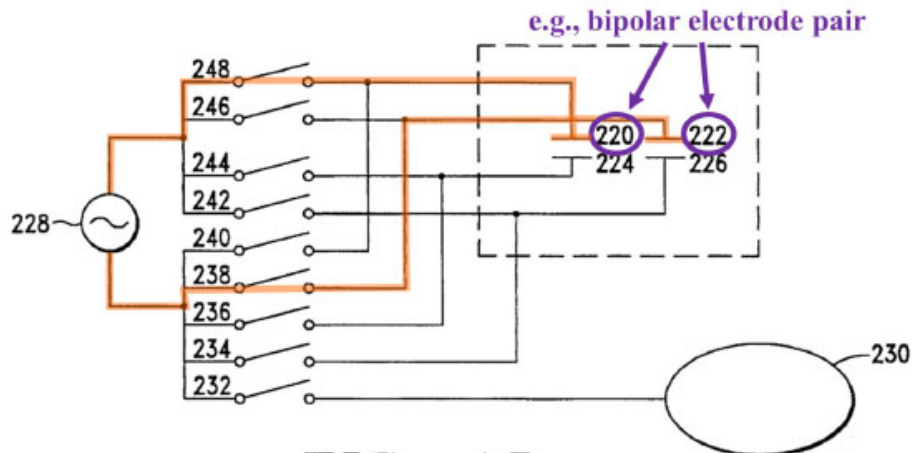


FIG.-15

(Petition at 40 (annotations in original).

At most, this example demonstrates that Stern's Figure 15 device can be configured to have a *single pair* of electrodes. (Ex-2001-Bikson, ¶ 70.) However, Challenged Claimed 1 expressly requires a treatment element comprising *multiple pairs* of bipolar electrodes. (Ex-1001 at claim 1; Ex-2003 at 285:2-9.) Thus, Petitioners have failed to show that Stern teaches what is claimed, and the Board should confirm the patentability of Challenged Claim 1 for this reason alone.

Irrespective of Petitioners' failure to address what is claimed, Stern does not teach a treatment element comprising "bipolar electrode pairs."

As shown above, Stern's Figure 15 discloses a voltage source 228, four electrodes 220, 222, 224, and 226, a grounding pad 230, and nine switches 232, 234, 236, 238, 240, 242, 244, 246, and 248. (Ex-1033-Stern at FIG. 15; *id.* at 12:46-13:2; Ex-2001-Bikson, ¶ 66.) Stern describes its electrodes as "an array of separate

electrodes.” (Ex-1004-Martin, ¶ 70; Ex-1033-Stern at 2:26-29, 2:39-40, 2:59-60; Ex-2001-Bikson, ¶ 67.) Depending on which switches are closed, any of electrodes 220, 222, 224, and 226 can be a monopolar electrode. (Ex-2003 at 261:2-16, 264:18-265:1; Ex-2001-Bikson, ¶ 67.) Similarly, depending on which switches are closed, any of electrodes 220, 222, 224, and 226 can be a positive electrode or a negative electrode. (Ex-2003 at 265:2-13, 265:14-19; Ex-2001-Bikson, ¶ 67.)

Both parties' experts agree that a “pair” of bipolar electrodes comprises two electrodes located near each other that have opposite polarities. (Ex-1004-Martin, ¶ 40; Ex-2003 at 254:20-22, 256:4-6, 263:19-264:16; *id.* at 253:15-21; Ex-2001-Bikson, ¶ 65; Ex-1001 at 22:28-30, FIGS. 8F-G.) When all the switches in Stern's Figure 15 are open, none of the electrodes in Figure 15 have opposite polarities. (Ex-2001-Bikson, ¶ 68; Ex-1033-Stern at FIG. 15, 12:37-13:2.) Thus, when all the switches in Figure 15 are open there are no electrode “pairs.” (*Id.*) As Petitioners' expert, Dr. Martin, conceded on cross examination, a bipolar electrode “pair” is formed in Stern's Figure 15 ***only when certain switches are closed.*** (Ex-2003 at 254:11-255:3, 265:20-266:18; Ex-1004-Martin, ¶ 71 (“Stern teaches examples in which electrodes can be paired by closing particular subsets of switches.”); Ex-1033-Stern at 12:37-13:2; Ex-2001-Bikson, ¶ 68.)

Consistent with Dr. Martin's admission that a bipolar electrode “pair” is formed only when certain switches are closed, three or more of Figure 15's switches

must be closed at the same time to form **multiple pairs** of bipolar electrodes, as claimed. (Ex-2001-Bikson, ¶ 69.) However, Petitioners and Dr. Martin do not identify where Stern teaches closing three or more switches at the same time. (Petition at 38-41; Ex-1004-Martin, ¶¶ 70-74.) Again, in Petitioners' cited disclosure from Stern only two switches are closed to form a single pair of electrodes. (*Id.*)

To be sure, Stern teaches closing **one** of switches 242, 244, 246, and 248 and **one** of switches 234, 236, 238, and 240 to form a **single pair** of bipolar electrodes. (Ex-1033-Stern at 12:55-13:2; Ex-2001-Bikson, ¶ 69.) Stern's disclosure of having only a single pair of electrodes at a time is consistent with Stern's express teaching that the RF electrodes are "***independently and sequentially energized.***" (Ex-1004-Martin, ¶ 81 (quoting Ex-1033-Stern at 2:31-35); Ex-2001-Bikson, ¶ 69; Ex-1033-Stern at 2:31-33, 2:49-53, 10:48-52, 17:54-55.) To energize Stern's electrodes "independently and sequentially," at most two of Stern's switches would be closed at a time. (Ex-2001-Bikson, ¶ 69.) Thus, Stern itself confirms that its device is configured to have at most a single pair of bipolar electrodes. (*Id.*)

Petitioners also cite to Stern's Figure 19 (Petition at 41), but Figure 19 likewise fails to teach multiple pairs of bipolar electrodes. (Ex-2001-Bikson, ¶ 71.) Stern's description of Figure 19 merely states that "a plurality of electrodes 322 are formed on the surface of the bladder 320." (Ex-2001-Bikson, ¶ 71; Ex-1033-Stern

at FIG. 19, 14:8-42.) Stern's Figure 19 does not illustrate, and the related description of Figure 19 does not mention anything about, "bipolar" electrodes or electrode "pairs." (*Id.*) As Petitioners concede, Figure 19 discloses a "physical arrangement[] of electrodes on the surface of a bladder that can be used to implement the [circuit of Figure 15]." (Petition at 40; Ex-1004-Martin, ¶ 72; Ex-2001-Bikson, ¶ 71.) Thus, Stern's Figure 19 and the associated description also fail to teach the claimed "bipolar electrode pairs." (Ex-2001-Bikson, ¶ 71.)

Accordingly, Petitioners have failed to show that Edwards-535 in view of Kong and Stern teaches a treatment element comprising "bipolar electrode pairs," as claimed.

(b) Petitioners Have Failed To Show That Edwards-535 In View Of Kong And Stern Teaches "wherein the treatment element comprises two rows of bipolar electrode pairs."

Regardless of whether Stern teaches a treatment element comprising "bipolar electrode pairs" (it does not), Petitioners have failed to show that Edwards-535 in view of Kong and Stern teaches "wherein the treatment element comprises two rows of bipolar electrode pairs" because Stern, at best, teaches two rows of a *single pair* each—not two rows of *pairs*.

Challenged Claim 1 of the '271 patent recites, *inter alia*, "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 at claim 1.) Petitioners assert that Stern’s Figures 15 and 19 teach the claimed “two rows of bipolar electrode pairs” and that a POSITA would have been motivated to implement Stern’s electrode arrangement on Edwards-535’s expandable member 132. (Petition at 38-41, 47-49; Ex-1002-DelGaudio, ¶¶ 92-94; Ex-1004-Martin, ¶¶ 70-74, 94-97.)

Both parties’ experts agree that the term “bipolar electrode pairs” requires “multiple pairs.” (Ex-2003 at 285:2-9; Ex-2001-Bikson, ¶ 75.) According to Dr. Martin, a row of only two electrodes is not a “row of bipolar electrode pairs.” (Ex-2003 at 287:13-17 (discussing Ex-2006); Ex-2001-Bikson, ¶ 75.) Rather, a row of only two electrodes comprises “just one pair,” not “electrode pairs plural.” (Ex-2003 at 286:6-11; Ex-2001-Bikson, ¶ 75.) Both parties’ experts agree that a “row of bipolar electrode pairs” requires at least three electrodes in the row. (Ex-2003 at 286:6-287:17; *see also id.* at 244:1-245:4; Ex-2001-Bikson, ¶ 75.)

As shown in Petitioners’ own annotations to Stern’s Figures 15 and 19, reproduced below, each of Petitioners’ alleged “rows” comprises ***only two electrodes***:

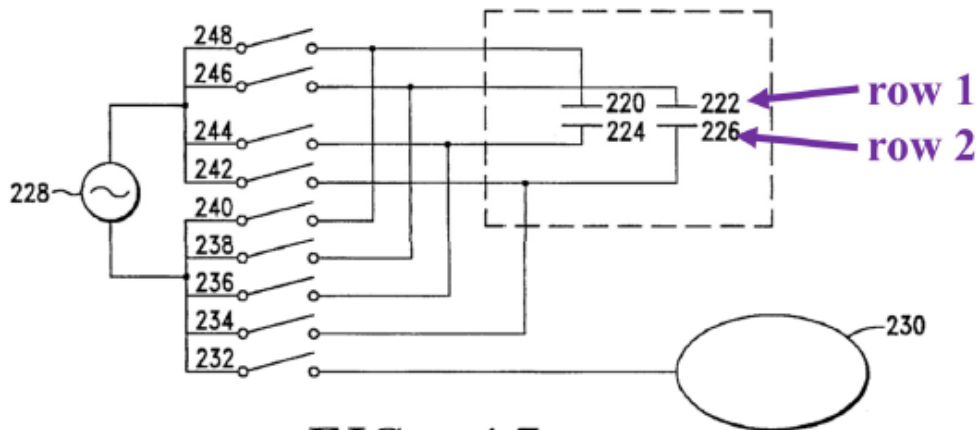


FIG. -15

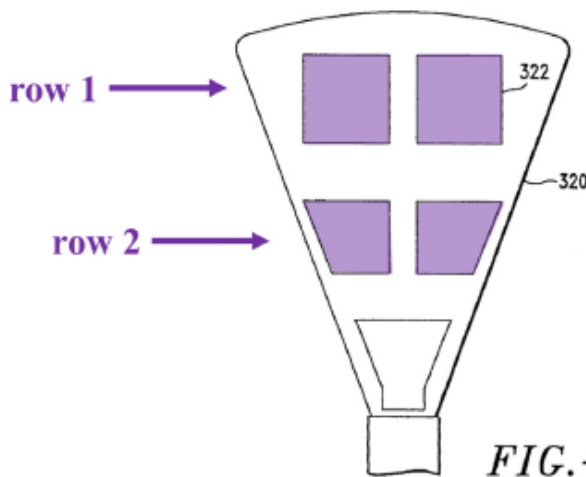


FIG. -19

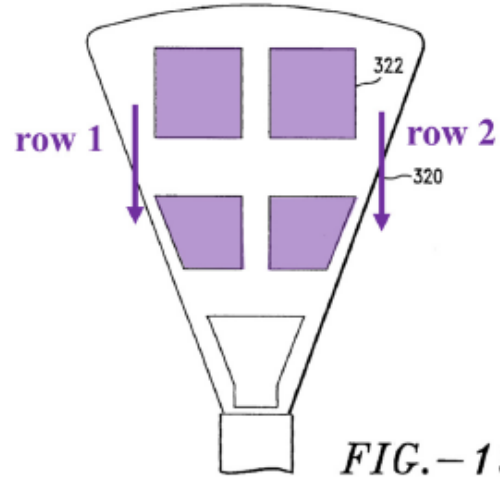


FIG. -19

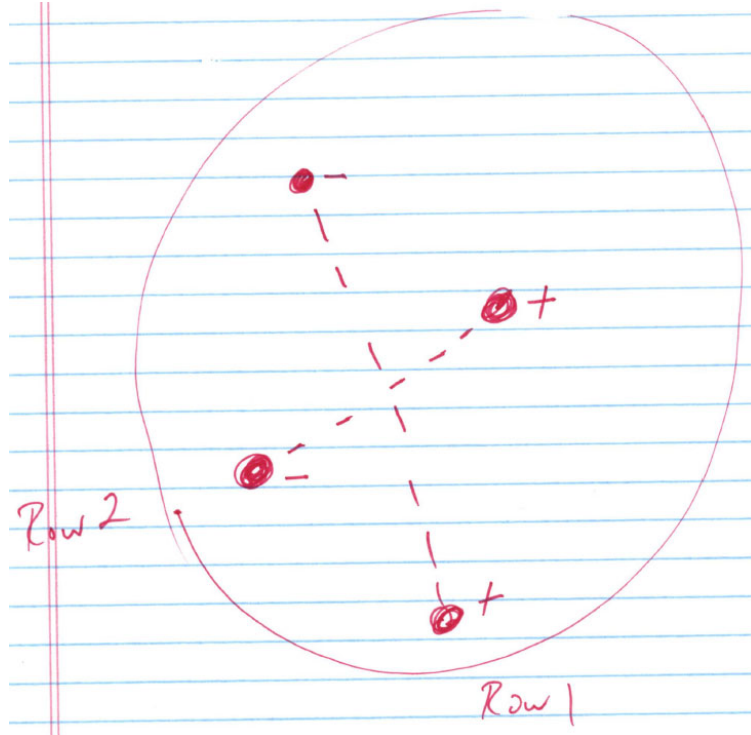
(Petition at 41 (annotations in original); Ex-1004-Martin, ¶ 73 (same); *see also* Ex-2007 at 240:17-241:22, 242:4-20; Ex-2001-Bikson, ¶ 76.)

Again, there is no dispute that a row of only two electrodes is not a row of “bipolar electrode *pairs* [plural].” (Ex-2001-Bikson, ¶ 76; Ex-2003 at 244:1-245:4, 285:2-9, 286:6-287:17.) As shown above, Stern at most teaches two rows of a *single pair* each—not two rows of *pairs*. (Ex-2001-Bikson, ¶ 76; *see also id.*, ¶ 77; Ex-1001 at FIG. 8F (depicting a treatment element with two rows of five electrodes

each); *id.* at FIG. 18 (depicting a treatment element with two rows of four electrodes each).) Thus, Petitioners have failed to show that Stern teaches “two rows of bipolar electrode pairs,” as claimed. (*Id.*)

Dr. Martin’s deposition testimony confirms that Petitioners’ interpretation of Challenged Claim 1 is overbroad, improperly reads terms out the claims, and is incorrect. Dr. Martin agreed that “placing electrode pairs at random” does not meet the claimed “two rows of bipolar electrode pairs.” (Ex-2003 at 270:15-19; *see also* Ex-2001-Bikson, ¶ 78.) According to Dr. Martin, a “row” “requires some measure of order” in the placement of the electrodes. (Ex-2003 at 270:21-271:1; *see also id.* at 270:21-271:15 (Dr. Martin testifying that a “row” requires “some kind of repeating dimensional aspect”).)

However, when Dr. Martin created a drawing with electrode pairs arranged at random (reproduced below), Dr. Martin still identified what he considered to be two rows of bipolar electrode pairs. (Ex-2003 at 279:8-283:1 (discussing Ex-2005).)



(Ex-2005.)

Dr. Martin's testimony confirms that Petitioners' and Dr. Martin's interpretation of Challenged Claim 1 is broad enough to encompass random arrangements, even though Dr. Martin agreed that random arrangements do not fall within the scope of the claims. (Ex-2001-Bikson, ¶ 78; Ex-2003 at 270:15-19, 279:8-283:1; *see also id.* at 275:14-18, 278:5-279:6.) Petitioners' and Dr. Martin's interpretation requires nothing more than drawing an imaginary line between two electrodes. (*Id.*) However, it is always possible to draw an imaginary line between two objects, even if the objects are arranged at random. (Ex-2001-Bikson, ¶ 78.) Petitioners' and Dr. Martin's overbroad interpretation of the claims reads out and

renders meaningless “rows of ... pairs,” which cannot be correct. *See Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 951 (Fed. Cir. 2006).

Further, Petitioners’ and Dr. Martin’s interpretation of the claims is inconsistent with the doctrine of claim differentiation. “Under the doctrine of claim differentiation, it is presumed that different words used in different claims result in a difference in meaning and scope for each of the claims.” *Clearstream Wastewater Sys., Inc. v. Hydro-Action, Inc.*, 206 F.3d 1440, 1446 (Fed. Cir. 2000).⁵ “[C]laim differentiation takes on relevance in the context of a claim construction that would render additional, or different, language in another independent claim superfluous.” *Curtiss-Wright Flow Control Corp. v. Velan, Inc.*, 438 F.3d 1374, 1381 (Fed. Cir. 2006). The doctrine of claim differentiation applies across related patents. *Clare v. Chrysler Group LLC*, 819 F.3d 1323, 1330 (Fed. Cir. 2016).

Here, the ’271 patent family distinguishes between “two rows of electrode pairs” and “two rows of electrodes.” For example, U.S. Patent No. 8,986,301—which is related to the ’271 patent (*see* Ex-1001 at [63])—recites the step of “applying energy to the at least one tissue by transmitting radio frequency energy from *a first row of electrodes* to *a second row of electrodes*.” (Ex-2008 at claim 1.)

⁵ *See also Karlin Tech., Inc. v. Surgical Dynamics, Inc.*, 177 F.3d 968, 971-72 (Fed. Cir. 1999); *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005).

Similarly, U.S. Patent No. 11,033,318—which, like the '271 patent, claims priority to U.S. Patent No. 8,936,594, U.S. Provisional App. No. 61/603,864, and U.S. Provisional App. No. 61/496,930 (*see* Ex-1001 at [60], [63]; Ex-2009 at [60], [63])—recites a device comprising “multiple pairs of bipolar radiofrequency electrodes” wherein “the multiple pairs of bipolar radiofrequency electrodes comprise ***two rows of electrodes.***” (Ex-2009 at claims 1, 15.)

Despite the presumption that “two rows of electrode pairs” is different than “two rows of electrodes,” Petitioners and their experts treat them as the same thing. (*See, e.g.*, Petition at 40 (“Stern’s Figures 15 and 19 illustrate electrodes arranged in two rows”); *id.* at 47 (“A POSITA also would have been motivated to implement Edwards-’535’s electrodes as two rows of bipolar electrodes as disclosed by Stern.”); *id.* (“Baker, like Stern, also discloses electrodes in rows.”); Ex-1004-Martin, ¶¶ 94-95 (“two rows of electrodes would have been obvious”).)

Contrary to this oversimplification by Petitioners, “two rows of electrodes” has different requirements than “two rows of electrode pairs.” (Ex-2001-Bikson, ¶ 79.) “Two rows of electrodes” requires each row to have multiple “electrodes” (*i.e.*, at least two electrodes per row). (*Id.*) “Two rows of electrode pairs,” on the other hand, requires each row to have multiple “pairs” of electrodes (*i.e.*, at least three electrodes per row). (*Id.*) The patentee clearly knew how to claim “two rows of electrodes” if it wanted to. (Ex-2008 at claim 1; Ex-2009 at claims 1, 15.) However,

the patentee instead elected to claim “two rows of bipolar electrode pairs.” (Ex-1001 at claim 1.)

For all these reasons, Petitioners have failed to show that Edwards-535 in view of Kong and Stern teaches “wherein the treatment element comprises two rows of bipolar electrode pairs.”

(c) Petitioners Have Failed To Show That Edwards-535 In View Of Kong And Stern Teaches “applying radiofrequency energy with the bipolar electrode pairs.”

Regardless of whether Stern teaches “bipolar electrode pairs” (it does not), Petitioners have failed to show that Edwards-535 in view of Kong and Stern teaches the step of “applying radiofrequency energy with the bipolar electrode pairs.”

Challenged Claim 1 recites the step of “applying radiofrequency energy with the bipolar electrode pairs.” (Ex-1001 at claim 1.) The plain language of the claim requires applying radiofrequency energy with “*pairs*” of bipolar electrodes, not just a single pair. (*Id.*; *see also* Ex-2003 at 285:2-9.)

Further, as discussed in Section IV, *supra*, the method steps of Challenged Claim 1 must be performed in their specified sequential order. Thus, the step of “applying radiofrequency energy with the bipolar electrode pairs” must be performed after the step of contacting the treatment element directly with nasal mucosa and before the step of removing the treatment element from the nasal airway. (Ex-1001 at claim 1.)

In Petitioners' limitation 1[b] "analysis," Petitioners simply state, without explanation, that "Edwards-'535 in view of Kong and Stern discloses applying RF energy with the bipolar electrode pairs." (Petition at 49-51; Ex-1002-DelGaudio, ¶¶ 95-96.) This statement—which simply repeats the claim language *verbatim*—is conclusory, factually unsupported, and legally insufficient to establish obviousness. *See ActiveVideo Networks, Inc. v. Verizon Communications, Inc.*, 694 F.3d 1312, 1327 (Fed. Cir. 2012); *see also Xerox Corp. v. Bytemark, Inc.*, IPR2022-00624, Paper 9, at 15-16 (PTAB Aug. 24, 2022) (precedential) (holding that the Board may not credit declaration testimony that "merely repeats, verbatim, the conclusory assertion for which it is offered to support"). Neither Petitioners nor Dr. DelGaudio explains how the proposed combination of Edwards-535 in view of Kong and Stern teaches the claimed "applying radiofrequency energy with the bipolar electrode pairs." (Petition at 49-51; Ex-1002-DelGaudio, ¶¶ 95-99.) Notably, Petitioners' limitation 1[a] analysis identifies only a ***single pair*** of electrodes (*i.e.*, electrodes 220 and 222). (Petition at 39-40.)

To be sure, Stern does not teach the step of "applying radiofrequency energy with the bipolar electrode pairs." (Ex-2001-Bikson, ¶¶ 82-83.) As noted above, Stern teaches closing ***one*** of switches 242, 244, 246, and 248 and ***one*** of switches 234, 236, 238, and 240 to form a ***single pair*** of bipolar electrodes. (Ex-1033-Stern at 12:55-13:2; Ex-2001-Bikson, ¶ 83.) Nothing in Stern teaches applying energy

with multiple electrode pairs before removing the treatment device from the nasal airway, as Challenged Claim 1 requires. (*Id.*) Furthermore, “applying radiofrequency energy with the bipolar electrode pairs” (*i.e.*, applying energy with multiple bipolar electrode pairs) would be contrary to Stern’s teaching that its electrodes “are independently and sequentially energized.” (Ex-2001-Bikson, ¶ 83; Ex-1033-Stern at 2:31-33, 2:49-53, 10:48-52, 17:54-55.)

Thus, Petitioners have failed to show that Edwards-535 in view of Kong and Stern teaches “applying radiofrequency energy with the bipolar electrode pairs.”

(d) Petitioners Have Failed To Show That A POSITA Would Have Been Motivated To Combine Edwards-535 With Stern.

Petitioners have failed to show that a POSITA would have been motivated to combine Edwards-535 with Stern’s electrode arrangement, as Petitioners have proposed. (Petition at 38-41, 47-49; Ex-1002-DelGaudio, ¶¶ 92-94; Ex-1004-Martin, ¶¶ 70-74, 94-97.)

Petitioners identify two reasons why a POSITA purportedly would have been motivated to combine Edwards-535 with Stern’s electrode arrangement, namely: (i) Edwards-535 “instructs a POSITA to look to Baker for how to dispose electrodes on the surface of a membrane” and “Baker, like Stern, also discloses electrodes in rows”; and (ii) arranging electrodes in rows “facilitates simple spatial resolution of the applied energy” for targeting particular portions of tissue. (Petition at 47-48; Ex-

1004-Martin, ¶¶ 94-95; *see also* Institution Decision (“ID”) at 20.) Petitioners also argue that the proposed combination “would have involved an obvious duplication of parts.” (Petition at 48; Ex-1004-Martin, ¶ 95.) As discussed in detail below, Petitioners’ alleged reasons for combining Edwards-535 with Stern’s electrode arrangement, and Petitioners’ “duplication of parts” argument, are not persuasive.

First, Edwards-535 does not “instruct[] a POSITA to look to Baker for how to dispose electrodes on the surface of a membrane,” as Petitioners assert. (Petition at 47 (citing Ex-1010-Edwards-535 at 8:26-33); Ex-2001-Bikson, ¶ 85.)

Edwards-535 states only the following with respect to U.S. Patent App. Ser. No. 08/319,373 (“Baker Application”):

An example of a suitable surface for disposition on the membrane is described in application Ser. No. 08/319,373, “Thin Layer Ablation Apparatus”, filed Oct. 6, 1994, which is incorporated by reference.

(Ex-1010-Edwards-535 at 8:28-31; Ex-2001-Bikson, ¶ 85.)

Contrary to Petitioners’ assertion, the above passage does not disclose anything about electrodes or electrode arrangements. (*Id.*; *see also* Ex-2003 at 165:1-166:3.) Rather, the passage refers only to an unspecified example of a “suitable surface” for disposition on Edwards-535’s unidentified “membrane.” (*Id.*) Dr. Martin testified that he did not know what the terms “a suitable surface” and “membrane” are referring to in the quote from Edwards-535 above, and he did not know what Edwards-535 was incorporating from the Baker Application. (Ex-2003

at 170:16-173:22, 174:14-19.) In fact, Dr. Martin did not even know whether he had reviewed the Baker Application. (*Id.* at 166:4-6, 166:16-168:1.)

Importantly, Edwards-535's incorporation by reference passage does not incorporate the Baker Application in its entirety. (Ex-1010-Edwards-535 at 8:28-31; Ex-2003 at 174:9-13; Ex-2001-Bikson, ¶ 87.) Edwards-535 merely cites to the Baker Application for one limited example (*i.e.*, "An example of a suitable surface for disposition on the membrane"). (Ex-1010-Edwards-535 at 8:28-31; Ex-2001-Bikson, ¶ 87.) The Baker Application's other teachings (*e.g.*, the Baker Application's electrode arrangement) are not incorporated by reference in Edwards-535 and are not part of this case. (Ex-2001-Bikson, ¶ 87; Petition at 8 (Petitioners failing to include Baker in their Grounds); Ex-2003 at 155:4-12 (Dr. Martin confirming that he did not apply Baker in any of the Grounds); *see also id.* at 174:20-175:1.) Dr. Martin's admission during cross-examination that he did not know what Edwards-535 was incorporating from the Baker Application is further evidence that Petitioners have not shown (and cannot show) that Edwards-535 incorporates by reference the Baker Application's electrode arrangement. (Ex-2003 at 174:14-19;

see generally Petition (Petitioners failing to include the Baker Application as an exhibit to the Petition).)⁶

To be sure, Edwards-535's incorporation by reference passage has nothing to do with the Baker Application's electrodes or electrode arrangement. (Ex-2001-Bikson, ¶ 86.) Edwards-535 discloses that the expandable member may be "an expandable porous membrane" that is "permeable to [an] electrolytic medium used to expand the member." (Ex-1010-Edwards-535 at 7:66-8:7; Ex-2001-Bikson, ¶ 86.)⁷ Similarly, the Baker Patent describes "an expandable member made of a material with a porous exterior surface," wherein an electrolytic solution is released through the porous exterior surface. (Ex-1011-Baker at Abstract; *see also id.* at 3:11-17, 3:33-37, claim 1, claim 17; Ex-2001-Bikson, ¶ 86.) As is evident from the above, Edwards-535's incorporation by reference passage incorporates the Baker Application's description of a "porous exterior surface" for releasing an electrolytic

⁶ U.S. Patent No. 5,575,788 ("Baker Patent"), which issued from the Baker Application, was included as an exhibit to the Petition. (Ex-1011-Baker.) However, it is unclear whether, and to what extent, the Baker Patent differs from the Baker Application. (Ex-2003 at 168:16-20.)

⁷ Other than the incorporation by reference passage reproduced above, this is the only mention of a "membrane" in Edwards-535. (Ex-2001-Bikson, ¶ 86.)

solution, not the Baker Application's electrode arrangement. (Ex-2001-Bikson, ¶ 86.)

Second, Petitioners' assertion that arranging electrodes in rows "facilitates simple spatial resolution of the applied energy" does not provide a motivation to combine Edwards-535 with Stern's electrode arrangement. (Petition at 47-48; Ex-1004-Martin, ¶ 95; Ex-2001-Bikson, ¶ 88.) To prove obviousness, the patent challenger must demonstrate "a motivation to pick out [the] references and combine them to arrive at the claimed invention." *See, e.g., Personal Web Techs., LLC v. Apple, Inc.*, 848 F.3d 987, 993-94 (Fed. Cir. 2017).

Here, Dr. Martin testified that he used the phrase "simplified spatial resolution of the applied energy" to mean that "if the electrodes have some regularity to their spacing, the power deposition, therefore the temperature rise and the ablation field, is more predictable." (Ex-2003 at 288:8-13.) According to Dr. Martin, when he used the phrase "simplified spatial resolution of the applied energy" in his declaration he was comparing "some sort of ordered arrangement" to "a random arrangement." (*Id.* at 291:7-16.) Dr. Martin agreed that any kind of "ordered arrangement," such as a single row or a circle, would "allow for simplified spatial

resolution of the applied energy.” (*Id.* at 288:20-290:3, 290:19-291:2.)⁸ Because Dr. Martin used the phrase “simplified spatial resolution of the applied energy” merely to distinguish “ordered arrangements” from “random arrangements,” Dr. Martin’s testimony provides no insight into why a POSITA would have picked out Stern’s electrode arrangement for use in Edwards-535.

Indeed, there are numerous (if not infinite) “ordered arrangements” for bipolar electrodes, of which Stern’s electrode arrangement is merely one possibility. (Ex-2001-Bikson, ¶ 88.) Petitioners fail to explain why, out of a multitude of possible electrode arrangements, a POSITA would have specifically picked out Stern’s electrode arrangement for use in Edwards-535’s device. (Petition at 47-48; Ex-1004-Martin, ¶ 95.) This is especially true in view of Stern’s teachings regarding activating a single electrode pair, not multiple electrode pairs, as recited in the Challenged Claims.

⁸ The Petition and Dr. Martin’s declaration are inconsistent. The Petition says that “arranging electrodes in rows, as opposed to a more disorganized pattern or a single row, facilitates simple spatial resolution of the applied energy.” (Petition at 47-48.) Dr. Martin’s declaration, on the other hand, does not compare multiple rows to a single row. (Ex-1004-Martin, ¶ 95.)

As Patent Owner's expert, Dr. Bikson, explained, in bipolar operation energy flows from a positive electrode to a negative electrode. (Ex-2001-Bikson, ¶ 88.) The application of this energy can be controlled in many ways, such as varying the position or orientation of the device, varying which electrodes are activated (*e.g.*, electrodes that are closer together or further away, electrodes that have different orientations with respect to each other, etc.), varying the power, placing an insulating material near the electrodes, and the like. (*Id.*) Using only two electrodes, or arranging the electrodes in a single row, provides the "simplest" way to control the applied energy. (*Id.*) Dr. Bikson testified that other electrode arrangements do not simplify anything—they add complexity. (*Id.*)

Third, Petitioners' assertion that the proposed combination would have been a mere "duplication of parts" is incorrect because Edwards-535 and Stern have completely different "parts." (Ex-2001-Bikson, ¶ 89.) Edwards-535 discloses a single row of four ring electrodes, each of which wraps around the circumference of the device. (Ex-1010-Edwards-535 at FIG. 6, 8:18-24; Ex-2001-Bikson, ¶ 89.) Stern, however, discloses five surface electrodes positioned on just one side of the device. (Ex-1033-Stern at FIG. 19, 14:14-42; Ex-2001-Bikson, ¶ 89.) Duplicating Edwards-535's electrodes would have resulted in a single row of eight ring electrodes—not two rows of electrodes, or anything remotely resembling Stern's electrode arrangement. (Ex-2001-Bikson, ¶ 89.) Rather than merely "duplicating

parts,” Petitioners have, in fact, proposed a complete redesign of Edwards-535’s electrode arrangement. (*Id.*)

Accordingly, Petitioners have failed to show that a POSITA would have been motivated to combine Edwards-535 with Stern’s electrode arrangement.

2. Petitioners Have Failed To Show That Edwards-535 In View Of Kong And Stern Renders Dependent Challenged Claims 2-3, 6-12, And 16 Obvious.

Petitioners have failed to show that Edwards-535 in view of Kong and Stern renders dependent Challenged Claims 2-3, 6-12, and 16 obvious in view of their dependency on Challenged Claim 1. Challenged Claims 2-3, 6-12, and 16 depend from Challenged Claim 1, and thus incorporate each and every limitation of Challenged Claim 1. *See* 35 U.S.C. § 112(d). Because Petitioners have failed to show that Edwards-535 in view of Kong and Stern renders Challenged Claim 1 obvious, Petitioners have likewise failed to show that Edwards-535 in view of Kong and Stern renders dependent Challenged Claims 2-3, 6-12, and 16 obvious.

Additionally, Petitioners have failed to show that Edwards-535 in view of Kong and Stern renders dependent Challenged Claims 11 and 16 obvious for the reasons discussed below.

(a) Challenged Claim 11.

Challenged Claim 11 recites, *inter alia*, “before removing the treatment element from the nasal airway: repositioning the treatment element to contact a

different portion of nasal mucosa; and applying radiofrequency energy with the bipolar electrode pairs through the different portion of nasal mucosa to a different portion of target tissue.” (Ex-1001 at claim 11.)

Petitioners assert that Edwards-535 in view of Kong discloses repositioning the treatment element to contact a different portion of nasal mucosa before removing the treatment element from the nasal airway and applying radiofrequency energy with the bipolar electrode pairs through the different portion of nasal mucosa. (Petition at 65-68; Ex-1002-DelGaudio, ¶¶ 132-139.) Petitioners do not cite to or discuss Stern in their analysis of Challenged Claim 11. (*Id.*)

Petitioners have failed to show that Edwards-535 in view of Kong discloses Challenged Claim 11 because neither Edwards-535 nor Kong, alone or in combination, discloses before removing the treatment element from the nasal airway repositioning the treatment element to contact a different portion of nasal mucosa and applying radiofrequency energy with bipolar electrode pairs through the different portion of nasal mucosa. (Ex-2001-Bikson, ¶ 94.)

Neither Edwards-535 nor Kong discloses “bipolar electrode pairs.” (Ex-2001-Bikson, ¶ 95; *see also* Petition at 34-38 (Petitioners failing to assert that Edwards-535 in view of Kong teaches “bipolar electrode pairs”).) Thus, Edwards-535 in view of Kong cannot disclose “applying radiofrequency energy with [] bipolar electrode pairs,” as claimed. (*Id.*)

Further, neither Edwards-535 nor Kong discloses applying radiofrequency energy to a different portion of nasal mucosa before removing the treatment element from the nasal airway. (Ex-2001-Bikson, ¶ 96.)

As Dr. DelGaudio admits, Edwards-535 discloses that “energy is delivered to *a selected section* [singular] of one of the nasal concha.” (Ex-1002-DelGaudio, ¶ 134 (emphasis added); Ex-2001-Bikson, ¶ 97.) “For example, energy may be selectively delivered to the anterior *or* posterior sections of the inferior nasal concha.” (*Id.*; *see also* Ex-1010-Edwards-535 at FIGS 3B, 3D, 3:7-17, 6:38-55.).) Petitioners fail to cite any disclosure in Edwards-535 teaching applying energy to multiple portions or sections of the nasal concha before removing the device from the nasal airway. (Petition at 64-68.) Dr. Bikson confirmed that nothing in Edwards-535 discloses applying energy to multiple portions or sections of the nasal concha before removing the device from the nasal airway. (Ex-2001-Bikson, ¶ 97.)

Likewise, Petitioners fail to cite any disclosure in Kong teaching applying energy to multiple portions or sections of the nasal concha before removing the device from the nasal airway. (Petition at 64-68.) Dr. Bikson confirmed that nothing in Kong discloses applying energy to multiple portions of nasal mucosa before removing the device from the nasal airway. (Ex-2001-Bikson, ¶ 98.) Rather, Kong discloses applying energy to a *single portion* of nasal mucosa before removing the device from the nasal airway. (*Id.*) Specifically, Kong discloses inserting an RF

electrode into the inferior turbinate, pressing and holding a “cutting pedal” for ten seconds while “the RF electrode remained stationary,” deactivating the RF electrode, and then slowly removing the RF electrode. (*Id.*; Ex-1040-Kong at 214.) While Kong discloses making holes in various parts of the inferior turbinate, making holes in the nasal mucosa is not what is claimed. (*Id.*)

Further, even if Edwards-535 in view of Kong disclosed “bipolar electrode pairs” and applying radiofrequency energy to a different portion of nasal mucosa before removing the treatment element from the nasal airway (it does not), Petitioners have failed to show that Edwards-535 in view of Kong discloses applying radiofrequency energy to a different portion of nasal mucosa with “bipolar electrode pairs [plural].” (Petition at 67-68; Ex-1002-DelGaudio, ¶¶ 137-138; Ex-2001-Bikson, ¶ 99.) Challenged Claim 11 expressly requires applying RF energy to a different portion of nasal mucosa with “bipolar electrode pairs [plural].” (Ex-1001 at claim 11.) However, Petitioners merely assert (incorrectly) that Edwards-535 in view of Kong discloses “apply[ing] RF energy” to different locations of the turbinate. (Petition at 67-68; Ex-1002-DelGaudio, ¶¶ 137-138.) Petitioners make no attempt to show that Edwards-535 in view of Kong discloses what is claimed. (*Id.*)

Lastly, Petitioners’ assertion that it would have been obvious to move Edwards-535’s to different locations before removing the device and to apply RF

energy at each of these locations is conclusory, unsupported, and legally insufficient. *See ActiveVideo*, 694 F.3d at 1327. Petitioners fail to identify any reason why it allegedly would have been obvious to move Edwards-535's to different locations before removing the device and to apply RF energy at each of these locations. (Petition at 67-68; Ex-1002-DelGaudio, ¶ 136.) As discussed above, nothing in Edwards-535 or Kong supports Petitioners' conclusory argument. (Ex-2001-Bikson, ¶ 100.)

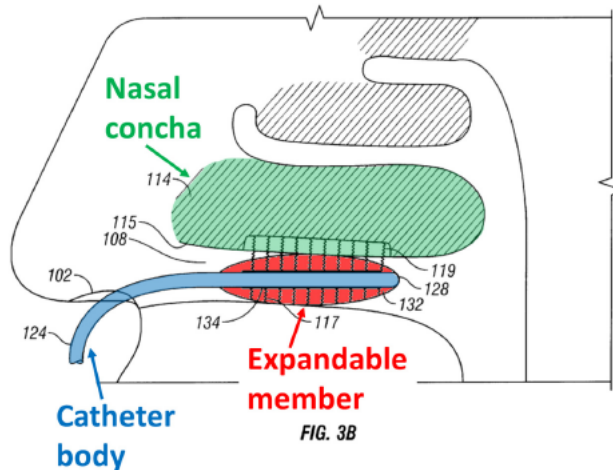
Thus, Petitioners have failed to show that Edwards-535 in view of Kong and Stern renders Challenged Claim 11 obvious.

(b) Challenged Claim 16.

Challenged Claim 16 recites, *inter alia*, “bending a shaft of the nasal airway treatment device before contacting the treatment element with the nasal mucosa.” (Ex-1001 at claim 16.)

Petitioners assert that Edwards-535 discloses or renders obvious this limitation. (Petition at 69-71; Ex-1002-DelGaudio, ¶¶ 143-148.) Specifically, Petitioners assert that Edwards-535's Figure 3B “depicts an apparatus 124 (i.e., treatment device) with a bent catheter body (i.e., shaft) inserted into a patient's nostril.” (Petition at 69; Ex-1002-DelGaudio, ¶ 144.) Petitioners also assert that, “to the extent PO argues that claim 16 requires ... a particular mechanism for forming the bend shown in Figure 3B, a POSITA would have found it obvious to

implement Edwards-'535 teachings using any number of well-known mechanisms for forming bends in catheter shafts.” (Petition at 70; Ex-1002-DelGaudio, ¶¶ 145-146.)



(Petition at 70 (annotations in original).)

Petitioners are wrong that Figure 3B of Edwards-535 discloses Challenged Claim 16. (Ex-2001-Bikson, ¶ 103.) As shown above, Figure 3B depicts the treatment element (*i.e.*, the expandable member) already in contact with the nasal mucosa (*i.e.*, the nasal concha). (*Id.*; Ex-1010-Edwards-535 at FIG. 3B.) However, Challenged Claim 16 expressly requires bending the shaft of the nasal airway treatment device “*before* contacting the treatment element with the nasal mucosa.” (Ex-1001 at claim 16.) Notably, Dr. DelGaudio admitted on cross examination that “[Edwards-535] doesn’t describe putting a bend in the shaft.” (Ex-2007 at 247:11-12.) Thus, Edwards-535 fails to disclose what is claimed. (Ex-2001-Bikson, ¶ 103.)

Additionally, Petitioners have failed to show that Edwards-535, alone, renders Challenged Claim 16 obvious. (Ex-2001-Bikson, ¶ 104.) Challenged Claim 16 does not recite **how** the shaft of the nasal airway treatment device is bent. (Ex-1001 at claim 16; Ex-2001-Bikson, ¶ 104.)⁹ Rather, Challenged Claim 16 recites **when** the shaft is bent (*i.e.*, “before contacting the treatment element with the nasal mucosa”). (*Id.*) While Petitioners assert that there were a “number of well-known mechanisms for forming bends in catheter shafts,” Petitioners do not explain what these unidentified techniques were or whether any of them involved bending a catheter shaft before contacting a nasal mucosa. (Petition at 70-71.)¹⁰

As Dr. DelGaudio confirmed at his deposition, Dr. DelGaudio did not rely upon any of these unidentified techniques. (Ex-2007 at 248:1-6.) Rather, these unidentified techniques “are just additional examples ... that show that it’s very common to put a bend in the shaft, as we see in figure 3B of [Edwards-535].” (*Id.* at 247:2-10.) As noted above, however, Figure 3B of Edwards-535 does not disclose bending the shaft “before contacting the treatment element with the nasal mucosa.”

⁹ Despite Petitioners’ concern, Patent Owner does not assert that Challenged Claim 16 requires “a particular mechanism for forming the bend.” (Petition at 70.)

¹⁰ Petitioners also do not explain why a POSITA would have been motivated to use any of these unidentified techniques with Edwards-535’s device. (*Id.*)

(Ex-2001-Bikson, ¶ 103.) Thus, Petitioners' unidentified techniques are of no help to Petitioners.

Accordingly, Petitioners have failed to show that Edwards-535 in view of Kong and Stern renders Challenged Claim 16 obvious.

B. Ground 2: Petitioners Have Failed To Show That Edwards-535 In View Of Kong, Stern, And Edwards-886 Renders Dependent Challenged Claim 4 Obvious.

Petitioners have failed to show that Edwards-535 in view of Kong, Stern, and Edwards-886 renders dependent Challenged Claim 4 obvious in view of its dependency on Challenged Claim 1. Challenged Claim 4 depends from Challenged Claim 1, and thus incorporates each and every limitation of Challenged Claim 1. *See* 35 U.S.C. § 112(d). Because Petitioners have failed to show that Edwards-535 in view of Kong and Stern renders Challenged Claim 1 obvious, Petitioners have likewise failed to show that Edwards-535 in view of Kong, Stern, and Edwards-886 renders Challenged Claim 4 obvious.

C. Ground 3: Petitioners Have Failed To Show That Edwards-535 In View Of Liang And Stern Renders Challenged Claims 1-3, 6-12, And 16 Obvious.

1. Petitioners Have Failed To Show That Edwards-535 In View Of Liang And Stern Renders Challenged Claim 1 Obvious.

Petitioners' Ground III analysis of the limitations "wherein the treatment element comprises two rows of bipolar electrode pairs" and "applying radiofrequency energy with the bipolar electrode pairs" relies on Petitioners' Ground

I analysis thereof. (Petition at 79-81; Ex-1002-DelGaudio, ¶¶ 164-169.) For the same reasons discussed above in Ground I, Petitioners have failed to show that Edwards-535 in view of Liang and Stern teaches the following requirements of Challenged Claim 1:

- “wherein the treatment element comprises two rows of bipolar electrode pairs”; and
- “applying radiofrequency energy with the bipolar electrode pairs.”

(Ex-2001-Bikson, ¶ 106.)

Likewise, Petitioners’ Ground III analysis for the motivation to combine Edwards-535 with Stern’s electrode arrangement relies on Petitioners’ Ground I analysis. (Petition at 79-80; Ex-1002-DelGaudio, ¶ 166.) To the extent Petitioners’ Ground III analysis adds anything to Petitioners’ Ground I analysis, Petitioners merely assert, without explanation, that using two rows of bipolar electrode pairs would have been “useful” to avoid perforating the nasal septum. (*Id.*) However, Petitioners fail to explain why a POSITA would have been motivated to implement Stern’s electrode arrangement for this purpose. (*Id.*)

To be sure, as it relates to avoiding nasal septum perforation, there is no evidence in the record that Stern’s electrode arrangement is, in and of itself, superior to any other electrode arrangement, including the single row arrangement already disclosed in Edwards-535. (*Id.*; *see also* Ex-2001-Bikson, ¶ 108.) Regardless of the electrode arrangement, perforating the nasal septum can be avoided by, for example,

placing a piece of insulative material over the nasal septum, controlling the intensity of the applied energy, and/or controlling the amount of time the energy is applied. (Ex-2001-Bikson, ¶ 108.)

Indeed, Edwards-535 expressly discloses “an insulator” designed to ensure that ablative energy is delivered only to the selected portion of the nasal concha while insulating other nasal tissues from the ablative energy. (Ex-2001-Bikson, ¶ 109; Ex-1010-Edwards-535 at FIG. 3D, 3:7-17, 3:56-57, 4:3-5, 6:46-58, 8:34-46.) A POSITA would have had no reason to look beyond Edwards-535’s teachings to address any potential issue of nasal septum perforation, and Petitioners fail to identify any such reason. (Ex-2001-Bikson, ¶ 109; Petition at 79-80.)

Accordingly, and for the same reasons discussed above in Ground I, Petitioners have failed to show in Ground III that a POSITA would have been motivated to combine Edwards-535 with Stern’s electrode arrangement. (Ex-2001-Bikson, ¶ 110.)

2. Petitioners Have Failed To Show That Edwards-535 In View Of Liang And Stern Renders Dependent Challenged Claims 2-3, 6-12, And 16 Obvious.

Petitioners have failed to show that Edwards-535 in view of Liang and Stern renders dependent Challenged Claims 2-3, 6-12, and 16 obvious in view of their dependency on Challenged Claim 1. Challenged Claims 2-3, 6-12, and 16 depend from Challenged Claim 1, and thus incorporate each and every limitation of

Challenged Claim 1. *See* 35 U.S.C. § 112(d). Because Petitioners have failed to show that Edwards-535 in view of Liang and Stern renders Challenged Claim 1 obvious, Petitioners have likewise failed to show that Edwards-535 in view of Liang and Stern renders dependent Challenged Claims 2-3, 6-12, and 16 obvious.

Additionally, Petitioners have failed to show that Edwards-535 in view of Liang and Stern renders dependent Challenged Claims 11 and 16 obvious for the reasons discussed below.

(a) Challenged Claim 11.

Challenged Claim 11 recites, *inter alia*, “before removing the treatment element from the nasal airway: repositioning the treatment element to contact a different portion of nasal mucosa; and applying radiofrequency energy with the bipolar electrode pairs through the different portion of nasal mucosa to a different portion of target tissue.” (Ex-1001 at claim 11.)

Petitioners assert that Edwards-535 in view of Liang discloses repositioning the treatment element to contact a different portion of nasal mucosa before removing the treatment element from the nasal airway and applying radiofrequency energy with the bipolar electrode pairs through the different portion of nasal mucosa. (Petition at 87-89; Ex-1002-DelGaudio, ¶¶ 186-187.) Petitioners do not cite to or discuss Stern in their Ground III analysis of Challenged Claim 11. (*Id.*)

Petitioners have failed to show that Edwards-535 in view of Liang discloses Challenged Claim 11 because neither Edwards-535 nor Liang, alone or in combination, discloses before removing the treatment element from the nasal airway repositioning the treatment element to contact a different portion of nasal mucosa and applying radiofrequency energy with bipolar electrode pairs through the different portion of nasal mucosa. (Ex-2001-Bikson, ¶ 115.)

Neither Edwards-535 nor Liang discloses “bipolar electrode pairs.” (Ex-2001-Bikson, ¶ 116; *see also* Petition at 78-79 (Petitioners failing to assert that Edwards-535 in view of Liang teaches “bipolar electrode pairs”).) Indeed, Liang discloses a monopolar device. (Ex-2001-Bikson, ¶ 116; Ex-1056-Liang at 341 (disclosing that a reference electrode, which is used in monopolar devices, is “connected to the lower part of the patient’s chin”).) Thus, Edwards-535 in view of Liang cannot disclose “applying radiofrequency energy with [] bipolar electrode pairs,” as claimed. (*Id.*)

Further, neither Edwards-535 nor Liang discloses applying radiofrequency energy to a different portion of nasal mucosa before removing the treatment element from the nasal airway. (Ex-2001-Bikson, ¶ 117.)

As discussed above in Ground I, Edwards-535 does not disclose applying energy to multiple portions or sections of the nasal concha before removing the device from the nasal airway. (Ex-2001-Bikson, ¶ 118.)

Likewise, Liang does not disclose applying energy to multiple portions of nasal mucosa before removing the device from the nasal airway. (Ex-2001-Bikson, ¶ 119.) At best, Liang discloses that “the emitter was used to perform thermal coagulation treatment on the bilateral nasal ridge and the corresponding nasal septum mucosa.” (*Id.*; Ex-1056-Liang at 341.) However, Liang does not specify whether the treatment device was removed from the nasal airway between treatments. (*Id.*) In view of this ambiguity, Liang does not disclose applying energy to multiple portions of nasal mucosa before removing the device from the nasal airway. *See, e.g., Wasica Fin. GmbH v. Cont'l Auto. Sys., Inc.*, 853 F.3d 1272, 1284 (Fed. Cir. 2017).

Further, even if Edwards-535 in view of Liang disclosed “bipolar electrode pairs” and applying radiofrequency energy to a different portion of nasal mucosa before removing the treatment element from the nasal airway (it does not), Petitioners have failed to show that Edwards-535 in view of Liang discloses applying radiofrequency energy to a different portion of nasal mucosa with “bipolar electrode pairs [plural].” (Petition at 87-89; Ex-1002-DelGaudio, ¶¶ 186-187; Ex-2001-Bikson, ¶ 120.) Challenged Claim 11 expressly requires applying RF energy to a different portion of nasal mucosa with “bipolar electrode pairs [plural].” (Ex-1001 at claim 11.) However, Petitioners merely assert that Edwards-535 in view of Liang discloses “apply[ing] RF energy” to different locations of the turbinate. (Petition at

87-88; Ex-1002-DelGaudio, ¶¶ 186-187.) Petitioners make no attempt to show that Edwards-535 in view of Liang discloses what is claimed. (*Id.*)¹¹

Lastly, Petitioners' assertion that it would have been obvious to move Edwards-535's to different locations before removing the device and to apply RF energy at each of these locations is conclusory, unsupported, and legally insufficient. *See ActiveVideo*, 694 F.3d at 1327. Petitioners fail to identify any reason why it allegedly would have been obvious to move Edwards-535's to different locations before removing the device and to apply RF energy at each of these locations. (Petition at 87-89; Ex-1002-DelGaudio, ¶¶ 186-187.) As discussed above, nothing in Edwards-535 or Liang supports Petitioners' conclusory position. (Ex-2001-Bikson, ¶ 121.)

Thus, Petitioners have failed to show that Edwards-535 in view of Liang and Stern renders Challenged Claim 11 obvious.

¹¹ Curiously, Petitioners point to their Ground I analysis of limitation 11[c], even though Liang is not a Ground I reference. (Petition at 88.) In any case, as discussed above, Petitioners' Ground I analysis also fails to demonstrate that the prior art discloses what is claimed.

(b) Challenged Claim 16.

Petitioners' Ground III analysis of Challenged Claims 16 relies entirely on Petitioners' Ground I analysis of Challenged Claim 16. (Petition at 90.) For the same reasons discussed above in Ground I, Petitioners have failed to show that Edwards-535 in view of Liang and Stern renders Challenged Claim 16 obvious in Ground III. (Ex-2001-Bikson, ¶ 122.)

D. Ground 4: Petitioners Have Failed To Show That Edwards-535 In View Of Liang, Stern, And Edwards-886 Renders Dependent Challenged Claim 4 Obvious.

Petitioners have failed to show that Edwards-535 in view of Liang, Stern, and Edwards-886 renders dependent Challenged Claim 4 obvious in view of its dependency on Challenged Claim 1. Challenged Claim 4 depends from Challenged Claim 1, and thus incorporates each and every limitation of Challenged Claim 1. *See* 35 U.S.C. § 112(d). Because Petitioners have failed to show that Edwards-535 in view of Liang and Stern renders Challenged Claim 1 obvious, Petitioners have likewise failed to show that Edwards-535 in view of Liang, Stern, and Edwards-886 renders Challenged Claim 4 obvious.

E. Dr. DelGaudio Does Not Qualify as a POSITA Under the Correct Definition.

Petitioners' invalidity analysis relies primarily on the declaration of Dr. DelGaudio. (*See generally* Petition.) However, Dr. DelGaudio does not qualify as

a POSITA under the correct definition, and thus Dr. DelGaudio's testimony should be disregarded or given no weight.

“To offer expert testimony from the perspective of a skilled artisan in a patent case—like for claim construction, validity, or infringement—a witness must at least have ordinary skill in the art.” *See Kyocera Senco Indus. Tools Inc. v. Int'l Trade Comm'n*, 22 F.4th 1369, 1376–77 (Fed. Cir. 2022).

Here, Dr. DelGaudio admitted that he has no experience in the design or development of medical devices. (Ex-2007 at 94:12-16, 95:1-16, 99:5-15.) Rather, Dr. DelGaudio has only clinically used medical devices. (*Id.* at 125:14-18, 131:18-22.)¹² Because he has no design or development experience, Dr. DelGaudio is not qualified to opine on the technology of the '271 patent from the perspective of a POSITA.

Tellingly, Dr. DelGaudio—who, again, has never designed or developed a medical device (Ex-2007 at 94:12-16, 95:1-16, 99:5-15)—relied on the testimony of Dr. Martin—who has designed medical devices—*for each of the '271 patent's "technical issues."* (Ex-1002-DelGaudio, ¶¶ 94, 124, 127, 130, 151, 166, 183-185, 193.)

¹² Dr. DelGaudio considers his clinical use experience to be the same thing as testing. (*Id.* at 99:16-100:12.)

While Dr. DelGaudio insisted at his deposition that he relied on Dr. Martin merely to “confirm” his interpretations of the prior art with someone “much more involved in the technical side of devices like this” (Ex-2007 at 45:10; *see also id.* at 227:9-14, 228:20-229:3, 231:6-12, 231:15-18, 234:18-235:3), Dr. DelGaudio’s declaration tells a very different story.

For example, as discussed above, Petitioners propose combining Edwards-535’s device with Stern’s Figure 15 schematic for the limitation “two rows of bipolar electrode pairs.” (Ex-2003 at 232:13-18; Petition at 39-40, 43, 46.) However, Dr. DelGaudio does not discuss (or even cite to) Stern’s Figure 15 *anywhere in his analysis of the grounds*. (See generally Ex-1002-DelGaudio, ¶¶ 67-193; *id.*, ¶¶ 83-94 (Dr. DelGaudio failing to discuss Stern’s Figure 15 in his analysis of limitation 1[a]).)

Further, in Dr. DelGaudio’s Ground III “analysis” of the claimed “two rows of bipolar electrode pairs,” Dr. DelGaudio conceded that he relied entirely on Dr. Martin for this limitation. (Ex-1002-DelGaudio, ¶ 166 (“As I explained above in my analysis of limitation 1[a] in Ground I, based on my discussion with Dr. Martin and my review of his declaration, I understand that Stern discloses two rows of bipolar RF electrodes and that the combination of Edwards-’535 and Stern would have been obvious.”).)

Thus, Dr. DelGaudio's own opinions (or lack thereof) confirm that he is not qualified as a POSITA in the field of the '271 patent. Accordingly, Dr. DelGaudio's testimony should be given little to no weight.

VI. CONCLUSION

Accordingly, for at least the foregoing reasons, Patent Owner respectfully requests that the Board confirm the patentability of Challenged Claims 1-4, 6-12, and 16 of the '271 patent.

Dated: October 25, 2024

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CERTIFICATE OF COMPLIANCE

This paper complies with the requirements of 37 C.F.R. § 42.24 and contains 11,100 words (exclusive of the table of contents, the table of exhibits, the certificate of service, and this certification).

This paper complies with the typeface requirements of 37 C.F.R. § 42.6 and has been prepared in 14 point Times New Roman proportionally spaced typeface with normal spacing.

Respectfully submitted,

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