

**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 SUR-REPLY

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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.
2010	Transcript of the February 7, 2025, Deposition of Dr. John M. DelGaudio
2011	Transcript of the February 20, 2025, Deposition of Dr. Gregory T. Martin

I. INTRODUCTION

Petitioners Neurent Medical Inc. and Neurent Medical Ltd. (collectively, “Petitioners”) bear the burden to establish that Claims 1-4, 6-12, and 16 (collectively, the “Challenged Claims”) of U.S. Patent No. 11,241,271 (“the ’271 patent”) are unpatentable. Patent Owner Aerin Medical, Inc. (“Patent Owner”) identified multiple deficiencies in the Petition, and Petitioners attempt to remedy those deficiencies with untimely and improper new arguments, as identified below.

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.

II. CLAIM CONSTRUCTION

Claim 1 of the ’271 patent recites a method comprising three steps: (1) “contacting a treatment element,” (2) “applying radiofrequency energy with the bipolar electrode pairs,” and (3) “removing the treatment element.” (Ex-1001 at 48:24-33.) As set forth in the Patent Owner Response (“POR”), the Board should construe Claim 1 to require the that the claimed method steps be performed in their specific sequential order. (POR at 15 (citing *E-Pass Techs., Inc. v. 3COM Corp.*, 473 F.3d 1213, 1222 (Fed. Cir. 2007) (when steps of a method claim refer to the completed results of a prior step, the steps must be performed in order)).)

Petitioners argue that the Board need not adopt this construction because Patent Owner does not advance arguments that the prior art does not meet the sequence. (Reply at 3.) However, Patent Owner argued in the Patent Owner Response that Edwards-535 in view of Kong and Stern fails to teach that “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.” (POR at 30.) Specifically, Petitioners failed to explain “how the proposed combination of Edwards-535 in view of Kong and Stern teaches the claimed ‘applying radiofrequency energy with the bipolar electrode pairs’ as Petitioners’ analysis only identifies a single pair of electrodes. (*Id.* at 31 (citing Petition at 39-40, 49-51).) Accordingly, the sequence of the steps in claim 1 is important, as each step is dependent upon the completion of the previous step. Furthermore, Petitioners have failed to sufficiently establish that the proposed combination of prior art renders obvious the sequence of steps in Claim 1.

Accordingly, the Board should construe Claim 1 to require the that the claimed method steps be performed in their specific sequential order.

III. 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 the Challenged Claims Obvious.

1. Petitioners Failed To Show Edwards-535 In View Of Kong And Stern Teaches the Claimed “Bipolar Electrode Pairs.”

As demonstrated in the POR, Petitioners failed to show Edwards-535 in view of Kong and Stern teaches a treatment element comprising the claimed “bipolar electrode *pairs*” because Stern teaches a device configured to have at most a *single pair* of bipolar electrodes. (POR at 19-23.) Nothing in Petitioners’ Reply demonstrates otherwise.

(a) Petitioners’ Reply Is Premised On A Mischaracterization of Patent Owner’s Argument.

Petitioners assert in their Reply that “[Patent Owner] argues that Stern does not disclose this limitation because its pairs are not active, i.e., delivering energy, ‘**at the same time.**’” (Reply at 4.) Petitioners mischaracterize Patent Owner’s argument as requiring the pairs to be activate at the same time.

As Patent Owner explained in the POR, there is no dispute that a “pair” of bipolar electrodes comprises two electrodes located near each other that have opposite polarities. (POR at 21; Ex-2003 at 254:20-22, 256:4-6, 263:19-264:16; Ex-2001-Bikson, ¶65; Ex-2011 at 200:7-15.) There is also no dispute a bipolar electrode “pair” is formed in Stern’s Figure 15 only when certain switches are closed. (POR

at 21; Ex-2003 at 254:11-255:3, 265:20-266:18; Ex-2001-Bikson, ¶68; Ex-2011 at 202:14-203:4, 204:4-6.) Thus, for Stern's Figure 15 device to comprise multiple pairs of bipolar electrodes, as claimed, three or more of Stern's switches must be closed. (POR at 21-22; Ex-2001-Bikson, ¶69.) Stern does not teach this. (*Id.*) Rather, Stern teaches a device that, at any given time, comprises at most one pair of electrodes. (*Id.*)

Claim 1 does not require simultaneous activation of multiple bipolar electrode pairs, but it does require a device configured to have multiple bipolar electrode pairs. In other words, Patent Owner's argument is based on how Stern's particular device is configured, irrespective of whether Stern's electrodes are simultaneously turned on. (POR at 19-23.) Indeed, Patent Owner's expert, Dr. Bikson, confirmed this several times during his deposition—despite Petitioners' counsel's repeated efforts to get him to say otherwise. (Ex-1084 at 100:17-102:2, 104:20-105:9, 105:21-106:13; *id.* at 95:11-96:1, 125:9-126:1, 237:10-238:18; Ex-2011 at 17:2-18:13.) Petitioners fail to identify how their proposed combination teaches a device configured to have multiple bipolar electrode pairs, as Stern only teaches the configuration of a single bipolar electrode pair. Accordingly, the Board should dismiss Petitioners' "at the same time" argument.

(b) Stern Does Not Teach a Device Comprising Multiple Bipolar Electrode Pairs

Patent Owner demonstrated in the POR that Stern teaches a device that, at any given time, comprises at most one pair of electrodes. (POR at 22-23.) Petitioners disagree, based on a single sentence in Stern stating that “any combination of pairs of electrodes may be utilized together.” (Reply at 5-6 (quoting Ex-1033-Stern at 13:39-43).) Petitioners point to Dr. DelGaudio's and Dr. Martin's interpretation of this sentence where they conclude, based solely on their *ipse dixit*, that a POSITA would have understood a “combination” of pairs that is “utilized together” as disclosing pairs that are active at the same time. (*Id.* (citing Ex-1083-DelGaudio, ¶25; Ex-1097-Martin, ¶22).)

Petitioners' attempt to remedy the deficiencies in the Petition is without merit. The Petition relies on a single example where Stern is configured to have one pair of electrodes. (Petition at 39-40.) Nothing in the Petition shows that Stern's device comprises more than a single pair of electrodes. (*Id.*)

Petitioners' Reply likewise fails to show that Stern's device comprises more than a single pair of electrodes. When read in isolation, Stern's statement that “any combination of pairs of electrodes may be utilized together” is at best ambiguous. A POSITA could have (and would have) read the sentence as teaching that any combination of pairs of electrodes may be utilized together **sequentially** (i.e., one pair at a time). (Ex-1084 at 110:7-112:12, 113:21-114:9, 115:17-116:20; *id.* at

131:13-21.) The problem for Petitioners is that it is improper to read portions of the prior art in isolation. According to the Federal Circuit, “[a] reference must be considered for everything it teaches.” *EWP Corp. v. Reliance Universal Inc.*, 755 F.2d 898, 907 (Fed. Cir. 1985); *see also Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F. 2d 443 (Fed. Cir. 1986) (“It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position”). Here, when Stern is properly read in its entirety, any potential ambiguity is resolved **in Patent Owner’s favor**.

First, Stern expressly teaches that its electrodes are “**independently and sequentially energized**.” (Ex-1033-Stern at 2:31-33, 2:49-53, 10:48-52, 17:54-55; Ex-2001-Bikson, ¶69; Ex-1004-Martin, ¶81.) As Dr. Bikson explained, 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.)

Second, Stern expressly teaches closing **one** of switches 242, 244, 246, and 248 and **one** of switches 234, 236, 238, and 240 to form **one pair** of bipolar electrodes at a time. (Ex-1033-Stern at 12:55-13:2; Ex-2001-Bikson, ¶69.) Stern does not teach closing three or more switches at the same time. (*Id.*)

Third, as Dr. Martin testified, Stern’s goal is to avoid uneven heating. (Ex-1097-Martin, ¶26; Ex-1033-Stern at 12:25-33; Ex-2011 at 170:12-171:13.) However, both parties’ experts agree that utilizing multiple pairs at the same time in

Stern's Figure 15 would **exacerbate** the problem of uneven heating—not help it. (Ex-2011 at 50:2-15; *id.* at 28:7-19, 29:3-11, 33:9-19; Ex-1084 at 253:6-254:4.)¹

Further, both parties' experts agree that utilizing multiple pairs at the same time in Stern's Figure 15 would result in a loss of control because “you don't know exactly where the current's going to flow.” (Ex-2011 at 24:21-25:21; *id.* at 23:7-21; Ex-1084 at 250:20-251:7 (“if you did that you would lose control.”).) Thus, a POSITA reading Stern would have known **not** to form multiple pairs. (*Id.*)

Accordingly, Petitioners failed to show Edwards-535 in view of Kong and Stern teaches a treatment element comprising “bipolar electrode pairs.”

¹ The amount of current that flows between the electrodes, which correlates to the amount of heating of the tissue between the electrodes, depends primarily on the impedance of the tissue between the electrodes. (Ex-2011 at 24:12-20, 26:8-27:3, 29:12-30:7, 31:1-32:14, 39:3-9, 41:15-42:5; Ex-1084 at 252:19-253:5, 255:10-19, 256:8-17.) Differences in impedance lead to different amounts of heating. (Ex-2011 at 42:10-43:3, 43:18-22, 44:14-20, 46:10-47:11.) Differences in impedance cannot be controlled—and are, in fact, expected—and thus the tissue between Stern's four electrodes will inevitably be heated **unevenly** if activated at the same time. (Ex-1084 at 248:5-11, 253:6-254:4, 257:10-14; Ex-2011 at 30:16-22.)

2. Petitioners Failed To Show Edwards-535 In View Of Kong And Stern Teaches “Two Rows of Bipolar Electrode Pairs.”

(a) The Claimed “Two Rows of Bipolar Electrode Pairs” Requires At Least Two Rows With At Least Two Pairs of Bipolar Electrodes Per Row.

As demonstrated in the POR, Edwards-535 in view of Kong and Stern fails to teach a treatment element comprising “two rows of bipolar electrode pairs” because Stern, at best, teaches two rows of a single pair each—not two rows of pairs. (POR at 23-30.)²

Petitioners respond that the '271 patent specification teaches an embodiment with multiple rows having a single pair each. (Reply at 7-9.) Even if the '271 patent specification is deemed to disclose an embodiment with multiple rows having a single pair each, this embodiment is not recited in the Challenged Claims. The Challenged Claims expressly require “two rows of bipolar electrode pairs.” Yet, Stern at best teaches two rows of a single pair each.

Contrary to Petitioners' allegations, the '271 patent does not just use the term “row” to describe an arrangement where “radio frequency energy travels from one row of electrodes to the other row of electrodes.” (Reply at 8.) The '271 patent describes embodiments in which multiple rows, each comprising multiple bipolar

² Patent Owner assumes, *arguendo*, that Stern teaches multiple “pairs.” As discussed above and in the POR, Stern does not teach multiple “pairs.”

electrode pairs, are used to apply radiofrequency energy. (Ex-1001 at Figs. 8F and 23G.) For example, Dr. DelGaudio testified that Figure 23G of the '271 patent discloses multiple rows of multiple bipolar electrode pairs in each row. (Ex-2010 at 119:7-13 (“So you would agree that 23G discloses multiple rows of multiple bipolar electrodes. A Correct.”).) Additionally, as Patent Owner's expert, Dr. Bikson, explained, Figure 8F of the '271 patent, reproduced with Dr. Bikson's annotations below, “depicts a treatment element with two rows of five electrodes each.” (Ex-2001-Bikson, ¶77.)

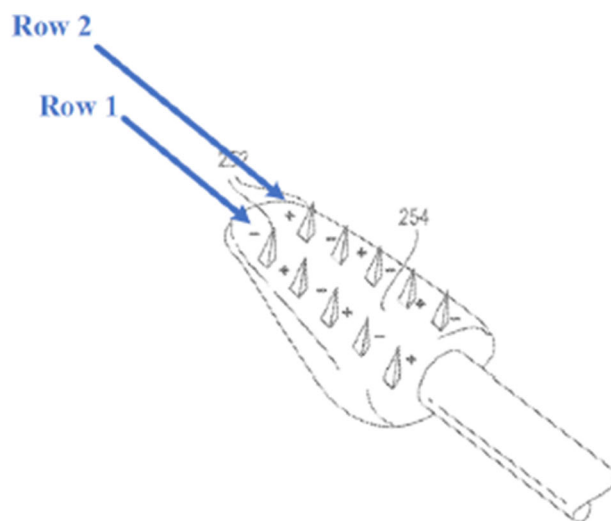


FIG. 8F

(Ex-1001 at FIG. 8F (annotated).)

Petitioners argue that “[t]he above arrangement has no pairs within a single row—pairs are formed across rows, not within them.” (Reply at 9.) Petitioners are incorrect. As Dr. Bikson explained, both row 1 and row 2 in Fig. 8F have multiple pairs of electrodes as enabled by the five electrodes in each row. (Ex-2001-Bikson,

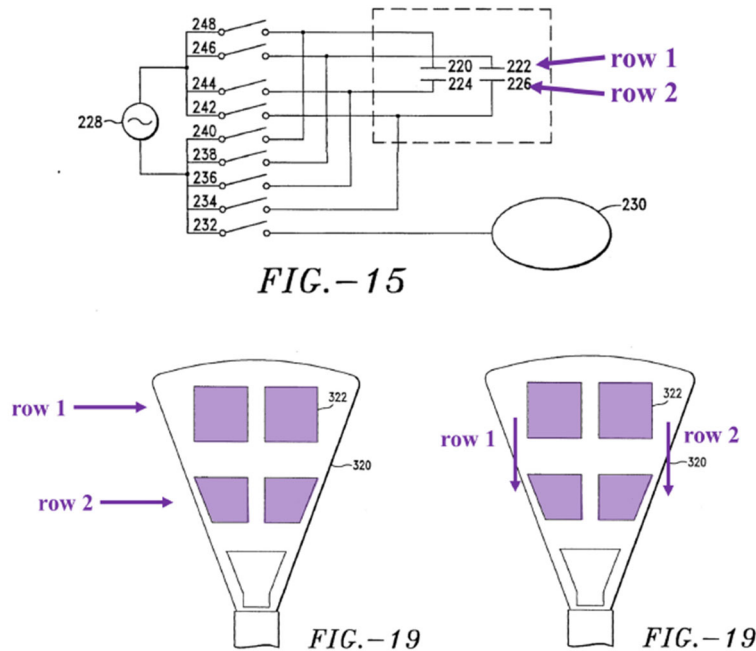
¶79.) The Challenged Claims—which require each row to have multiple pairs of electrodes—are directed to this embodiment, not alternative embodiments where each row has only one pair of electrodes. (*Id.*)

Petitioners cite to certain Federal Circuit cases for the proposition that “a plural term can be interpreted to require only one item.” (Reply at 9 (citing *Dayco Prod., Inc. v. Total Containment, Inc.*, 258 F.3d 1317, 1328 (Fed. Cir. 2001) and *Versa Corp. v. Ag-Bag Intern. Ltd.*, 392 F.3d 1325, 1330 (Fed. Cir. 2004)). Although these cases establish that there can be certain special circumstances in which a plural term can require only one item, this does not remove the presumption instructed by the Federal Circuit that a plural term requires more than one item. In *Apple Inc. v. MPH Techs. Oy*, the Federal Circuit held that “[i]n accordance with common English usage, we presume a plural term refers to two or more items.” 28 F.4th 254, 261 (Fed. Cir. 2022) (affirming a finding by the Board that “fields” referred to more than one field.). Here, Petitioners fail to establish that the presumption should not apply; thus, the claim phrase “two rows of bipolar electrode pairs” requires two rows with multiple bipolar electrode pairs in each row.

(b) Stern Does Not Teach Two Rows That Have Multiple Pairs Within Each Row.

In the Petition, Petitioners relied only upon Stern's Figures 15 and 19 for the claimed “two rows of bipolar electrode pairs” and argued that “Stern's Figures 15

and 19 illustrate electrodes arranged in two rows.” (Petition at 40.) Reproduced below are the annotated figures from the Petition:



As established in the POR, “there is no dispute that a row of only two electrodes is not a row of “bipolar electrode pairs [plural]” and, as shown in Figures 15 and 19 above, Stern at most teaches two rows of a single pair each—not two rows of multiple pairs. (POR at 25.)

Recognizing the Petition failed to establish a *prima facie* case of obviousness, Petitioners abandoned their original argument that Stern’s Figures 15 and 19 teach “two rows of bipolar electrode pairs” and assert for the first time that Stern’s Figure 4a teaches two rows that have multiple pairs within each row. (Reply at 13.) Specifically, Petitioners argue that Stern’s Figure 4a discloses “an ordered arrangement of electrodes that can be configured as a first row with four electrodes

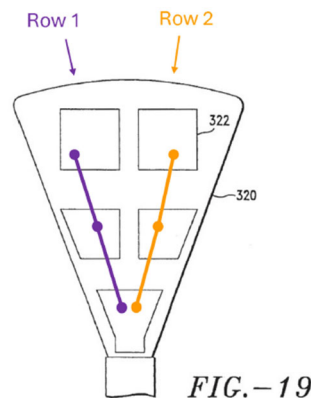
and a second row with three electrodes.” (*Id.*) Significantly, Petitioners provide no citation to Stern for this proposition. (*Id.*)

At the outset, Petitioners’ entire line of argument based upon Stern Figure 4a is improper as it was untimely added for the first time in Petitioners’ Reply. Figure 4a of Stern was not relied upon in the Petition as allegedly disclosing the claimed “two rows of bipolar electrode pairs.” (Petition at 41.) In fact, the Petition only cited to Figure 4a of Stern as an example of a “device[] for ablating tissue.” (*Id.* at 46.) Petitioners’ attempt to extend their arguments regarding Figure 15 to Figure 4a is improper and untimely. (Reply at 14 (“a POSITA would have readily applied these teachings to the array in Figure 4a.”).)

Further, irrespective of whether Petitioners’ new argument is proper (it is not), Stern does not disclose that Figure 4a illustrates bipolar electrode pairs. Rather, Stern teaches that Figure 4a is a *unipolar* arrangement, not a bipolar arrangement. (Ex-1033-Stern at 8:66-9:4, 12:8-11, 12:47-49.) Accordingly, Petitioners cannot show that Stern’s Figure 4a teaches “two rows of bipolar electrode pairs.” Petitioners offer no explanation as to how Stern purportedly teaches combining the embodiment of Figure 4a with the embodiment for Figure 15. To be sure, no such teaching exists in Stern.

Petitioners’ Reply also proffers a new theory regarding Stern’s Figure 19 in a footnote and attempts to incorporate by reference Petitioners’ experts’ reply

testimony on this new theory. (Reply at 14 n.3.) Specifically, Dr. DelGaudio and Dr. Martin provide new annotations to Figure 19, reproduced below, in which they allege that there is a fifth electrode at the bottom of Figure 19 and there are three electrodes per row if this fifth electrode is considered. (Ex-1083-DelGaudio, ¶39; Ex-1097-Martin, ¶39.)



There are numerous problems with Petitioners' new and untimely Reply argument. First, Petitioners' new argument was not raised in the Petition, and it may not be raised for the first time in Petitioners' Reply. (Petition at 40.) Indeed, Dr. Martin confirmed at his deposition that he had not even considered that Stern's Figure 19 has a fifth electrode. (Ex-2003 at 276:14-277:22.) Second, arguments raised in footnotes (and particularly *new* arguments raised in footnotes) are improper. See *In re Zte Corp.*, 2022 U.S.P.Q.2D (BNA) 438 at *6 (Fed. Cir. May 5, 2022) ("requiring arguments to ordinarily be fully developed in the briefs and not in footnotes."). Third, Petitioners' attempt to incorporate by reference their experts' reply testimony on this untimely new theory is an improper attempt to circumvent

the word limit for their Reply. *See* 37 C.F.R. 42.6(a)(3) (“Arguments must not be incorporated by reference from one document into another document.”). Fourth, Petitioners fail to identify where Stern allegedly discloses configuring a bipolar electrode pair with the fifth electrode in Figure 19. Fifth, the fifth electrode in Figure 19 is not in a “row” with the other electrodes in what Drs. DelGaudio and Martin have labeled “row 1” and “row 2.” Only the electrodes above the fifth electrode are in “rows.” Accordingly, Petitioners’ untimely attempts to modify its reliance upon Stern’s Figure 19 should be disregarded as improper and unsupported.

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

Petitioner’s rationale for its obviousness combination is insufficient. Specifically, Petitioners’ rationale for its proposed combination is that a POSITA would have consulted the Baker reference, which is incorporated by reference in part in Edward-535 for a topic unrelated to the relevant claim limitation, for teachings regarding how to arrange electrodes, and then a POSITA would have separately consulted Stern for the alleged disclosure regarding the claimed arrangement of electrodes. Yet, Petitioners fail to establish why Baker is relevant to the inquiry or why a POSITA would have been directed to Stern. Petitioners merely argue that both Baker and Stern “depict similar devices for ablating tissue.” (Petition at 46.) The mere depiction of allegedly similar devices does not provide a sufficient tie between the references, much less a sufficient motivation to combine Stern with

another reference (*i.e.*, Edwards-535). Even assuming a POSITA would have been led to consult Stern, Petitioners fail to sufficient establish why and how a POSITA would have modified Edwards-535 in view of Stern.

Petitioners argue that their proposed “combination involves ‘simply substituting’ Edwards-’535’s energy delivery device 134 with Stern’s two rows of bipolar electrodes,” that “combination uses Stern’s two rows of bipolar electrodes to improve Edwards-’535’s ‘similar device’ in the ‘same way,’” and “Edwards-’535’s apparatus 124 is ‘ready for improvement’ using Stern’s two rows of bipolar electrodes.” (Reply at 17.) Each of these arguments fails because Stern does not disclose “two rows of bipolar electrode pairs”; thus, no substitution is possible to bring about this alleged improvement to Edwards-’535.

First, Petitioners’ only explanation as to why Edwards-’535 was “ready for improvement” was that it “omits details on how to implement [] energy delivery.” (Petition at 42.) A lack of disclosure does not provide a motivation to make a very specific modification provided in an unidentified secondary reference (in this case, Stern).

Second, the only rationale provided by Petitioners for consulting Stern is that Edwards-535 points a POSITA to Baker, which teaches non-nasal ablation devices, and Baker’s devices are purportedly similar to the devices disclosed in Stern. (Petition at 46.) The cited disclosure in Baker, however, simply states that “[i]n

another embodiment, a plurality of energy delivery devices are positioned on a surface of the expandable member. An example of a suitable surface for disposition on the membrane is described in [Baker].” (Ex-1010-Edwards-535 at 8:25-33.) Baker’s cited disclosures are not relevant to the claim limitations supposedly addressed by Baker. More particularly, the cited disclosure in Baker about positioning energy delivery devices on a balloon (expandable member) does not provide a motivation to configure the “two rows of bipolar electrode pairs” recited in claim 1. Further, as discussed in the POR, Edwards-535 only points a POSITA to Baker for a topic that is completely unrelated to the relevant claim limitation.

Third, even assuming that the disclosures of Baker are relevant, which they are not, Petitioners’ proposed combination is deficient because it does not rely upon Baker. Instead, Petitioners’ proposed combination relies upon Stern, which Petitioners do not allege is referenced in any of the cited prior art but merely argue that “Baker and Stern depict similar devices for ablating tissue.” (Petition at 46.) Even if Baker and Stern depict similar devices for ablating tissue, which they do not, Petitioners fail to explain why a citation to an embodiment from Baker about positioning energy delivery devices on a balloon (expandable member) would have led a POSITA to consult Stern for disclosure concerning the configuration the claimed “two rows of bipolar electrode pairs.”

Accordingly, Petitioners fail to sufficiently establish a connection between the disclosures in Baker and the cited disclosures in Stern. Thus, Petitioners alleged motivation is non-existent. Petitioners also argue that the fact that other arrangements of electrodes were known “does not weigh against a motivation to use a given arrangement taught in the prior art.” (Reply at 19-20.) Yet the arrangement taught in the prior art is not the claimed arrangement of electrodes. Furthermore, it is Petitioners’ burden to establish obviousness; thus, Petitioners bear the burden of establishing that their specific proposed combination would have been obvious and the availability of numerous alternatives makes it more difficult to establish a POSITA would have been motivated to choose the particular claimed embodiment over numerous alternatives.

B. Dependent Claim 11: Petitioners’ Allegations Fail To Establish Repositioning the Treatment Element to Contact a Different Portion of Nasal Mucosa and Applying Radiofrequency Energy With Bipolar Electrode Pairs.

With respect to dependent claim 11, Petitioners argue that “PO relies on a very narrow and incorrect interpretation of the cited references to contend this step is not taught by the prior art.” (Reply at 21.) Claim 11 recites “repositioning the treatment element to contact a different portion of nasal mucosa.” Petitioners argue that a “POSITA would have understood that, in practice, the repositioning would occur before removing the treatment element from the nostril,” and Petitioners rely upon

Dr. DelGaudio for this assertion. (Reply at 22 (citing Ex-1002-DelGaudio, ¶133. Ex-1083-DelGaudio, ¶¶49-56).)

First, if Petitioners intended to rely upon the knowledge of one of skill in the art, they failed to present such a proposed combination in their Petition. Petitioners' Ground 1 contends that "Claims 1-3, 6-12, 16 Are Invalid as Obvious Over Edwards-'535 in View of Kong and Stern." (Petition at 26.)³ Notably, Ground 1 does not allege that the knowledge of one of skill in the art is to be relied upon in the combination.

Second, Petitioners fail to identify any disclosures in the cited prior art regarding repositioning much less applying energy to multiple portions or sections of the nasal concha before removing the device from the nasal airway. Petitioners do not rely upon Stern for this teaching and 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. In fact, the prior art teaches the application of energy to a "single portion of nasal mucosa." (Ex-2001-Bikson, ¶ 98.)

³ Patent Owner notes that Petitioners' Grounds 2-4 similarly do not rely upon the knowledge of one of skill in the art.

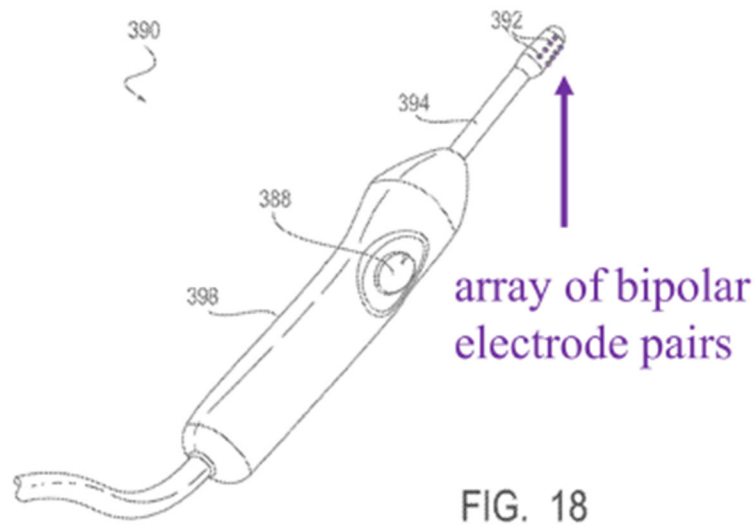
Dr. DelGaudio offered testimony about repositioning for certain procedures in his own practice but failed to offer any support for his assertion that a POSITA would have known about the repositioning set forth in claim 11. (Ex-1083-DelGaudio, ¶¶50-52.) Furthermore, Dr. DelGaudio fails to offer any rationale for why a POSITA would have motivated to conduct the claimed repositioning for the combination of prior art proposed by Petitioners. More particularly, even if the prior art was found to teach repositioning, Petitioner fails to establish that the prior art teaches applying radiofrequency energy to a different portion of nasal mucosa with “bipolar electrode pairs [plural],” as required by claim 11.

C. Dependent Claim 16: Petitioners’ Attempt to Rely on Inherency for a Bend in the Shaft Is Unpersuasive.

Claim 16 recites “bending a shaft of the nasal airway treatment device before contacting the treatment element with the nasal mucosa.” Petitioners argue that “POSITA would have understood that the **shaft is necessarily bent** before the treatment element reaches its target location in order to properly transport the treatment element to that location.” (Reply at 23.)

Petitioners’ argument requires that all shafts provide a bend. However, Petitioners’ argument is contradicted by the multiple shafts disclosed in the ’271 patent and the cited prior art that do not provided a bend. For example, Figure 18 of the ’271 patent, reproduced below, illustrates “a device 390 comprising

pairs of bipolar electrodes 392 located at the distal end of a shaft 394.” (Ex-1001 at 26:63-64, Fig. 18.)



As shown above in Figure 18 of the '271 patent, shaft 394 is not bent. Accordingly, Petitioners' arguments that the “**shaft is necessarily bent**” (Reply at 23) is unpersuasive.

D. 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 do not address Patent Owner's arguments against Ground 2. Accordingly, Ground 2 is deficient for the reasons raised in the Patent Owner Response. (POR at 46.)

E. 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.

Similar to Ground 1, Petitioners argue that Patent Owners argument regarding the presence of alternative solutions does not detract from Petitioners' proposed motivation to combine Liang provided in Ground 3. (Reply at 21.) 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.*)

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, Petitioners' arguments regarding Ground 3 are unpersuasive.

F. 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 do not separately argue Ground 4 in the Reply. Accordingly, the deficiencies in Ground 4 identified in the Patent Owner Response are unrebutted. (POR at 53.)

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

Petitioners argue that is undisputed that a “clinician would perform the claimed method of the ’271 patent.” (Reply at 25.) “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).

Regardless of who performs the claimed method, the pertinent question to determine the person of ordinary skill in the art is to determine whether the individual is capable of designing and developing the medical devices disclosed and associated methods of use. It is clear from Dr. DelGaudio’s declaration and his testimony on cross-examination that he is not an individual capable of designing and developing the medical device used in the claimed method. On cross-examination Dr. DelGaudio testified as follows: “I don't consider myself developing. I consider myself **involved in the development** of the system, right, because I helped to direct some of the software updates.” (Ex-2010 at 38:11-19.) Dr. DelGaudio conceded that “**I'm not the one who developed or designed the system**, who came up with the idea of the system who then worked with others to -- to put the system together.” (*Id.* at 40:1-4.) Dr. DelGaudio’s experience providing feedback after the use of

certain medical devices is not a sufficient basis to qualify him as person of ordinary skill in the art for this proceeding.

Dr. DelGaudio testifies that he offered feedback to “improve an image-guided computer navigation system used for tracking the tip of an instrument inside a patient during sinus surgery.” (Ex-1083-DelGaudio, ¶9.) Offering “feedback” on testing is hardly experience in the design and development of medical device, especially given that is was in an unrelated filed of “image-guided computer navigation.” In fact, on cross examination, Dr. DelGaudio himself testified that an individual giving feedback on a medical device is **not** involved in developing the device if their feedback is not being implemented. (Ex-2010 at 43:13-21.) Dr. DelGaudio offers no testimony that his feedback regarding any devices was followed or otherwise implemented.

Dr. DelGaudio also testified that he was on a team that designed a “microdebrider,” which “is a medical device with a powered blade and suction, which delivers mechanical energy using a blade to a patient to cut and remove tissue.” (Ex-1083-DelGaudio, ¶10.) As with the “image-guided computer navigation” device, this “microdebrider” has no relevance to the instant matter.

Petitioners argue that Patent Owner seeks to “disqualify Dr. DelGaudio as a procedural matter.” (Reply at 25.) However, Patent Owner established that Dr. DelGaudio’s testimony is unreliable due to his lack of relevant experience. 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.

Petitioners do not contest that Dr. DelGaudio has no experience in designing medical devices that delivery energy to tissue, the types of medical devices at issue in this proceeding. (Reply at 26.)

Petitioners cite to case law for the premise that the "Board has repeatedly found in medical device matters that POSITA-clinicians would have access to engineers." (Reply at 27.) Yet, in none of the cited cases was the testimony of the clinician relied upon for matters of medical device design. Accordingly, Dr. DelGaudio's testimony should be given little to no weight.

IV. CONCLUSION

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

Dated: March 4, 2025

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This paper complies with the requirements of 37 C.F.R. § 42.24 and contains 4,883 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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The undersigned hereby certifies that on the below date, I caused the forgoing to be served by electronic mail to the following:

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