

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 No. IPR2024-00278

U.S. Patent No. 11,033,318

PETITIONERS' REPLY TO PATENT OWNER'S RESPONSE

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I. INTRODUCTION

The Petition demonstrates the Challenged Claims are unpatentable. None of the Patent Owner Response's ("POR") attempts to save the claims has merit.

PO improperly contends claim 1 requires unrecited limitations and then incorrectly asserts the prior art fails to teach the unrecited features. POR, 14-28. Contrary to PO's arguments, claim 1 does not require that the "multiple pairs of bipolar radiofrequency electrodes" deliver bipolar energy at the same time. Even if it did, however, Stern satisfies this incorrect interpretation by disclosing that its pairs can be "utilized together." Ex.1033-Stern, 13:39-43. Claim 1 also does not require "multiple radiofrequency output channels" constituting multiple channels/wires connected directly to the voltage source in the radiofrequency generator. Even if it did, though, Stern again satisfies this incorrect interpretation because it shows the same configuration of electrodes and wires as is shown in the '318 patent and as PO's expert drew at his deposition.

PO arguments regarding dependent claims 5, 6, 9, 15, and 17 also fail. For claims 5, 6, 9, and 17, PO relies yet again on unrecited claim requirements and mischaracterizations of the prior art to contend the claims are patentable. For claim 15, PO makes a legally unsupportable argument that Petitioners were required to explain why arranging bipolar electrodes in two rows was better than any other

arrangement. Regardless of whether *other* arrangements were obvious, however, a two-row arrangement would have been obvious. The Board should cancel all Challenged Claims.

II. THE CHALLENGED CLAIMS ARE UNPATENTABLE

The Petition, supported by the testimony of Dr. Martin, demonstrated the challenged claims are obvious based on “multiple, specific reasons for the combination” “supported with numerous citations to other evidence of record.” I.D., 22. PO does not dispute that a POSITA would have been motivated to combine the references as set forth in Grounds I-V. Instead, PO argues that the combinations do not teach particular limitations in the challenged claims.

A. Claim 1 Is Obvious

PO argues the prior art does not disclose (1) “multiple pairs of bipolar radiofrequency electrodes,” (2) “multiple radiofrequency output channels,” or (3) “wherein each pair of the multiple pairs of bipolar radiofrequency electrodes is connected with a respective one of the multiple radiofrequency output channels.” POR, 14-28, 42. PO’s arguments fail, not only because they do not address the actual language of the claims, but also because Stern discloses the disputed limitations even under PO’s incorrect interpretation. Under any reasonable

interpretation, certainly one based on *Phillips*, the claims are unpatentable. Ex.1083-Reply-Decl., ¶¶14-16.

**1. Edwards-535 or Makower In View of Stern Teaches
“multiple pairs of bipolar radiofrequency electrodes”**

Petitioners showed that Edwards-'535 in view of Stern (Ground I) and Makower in view of Stern (Ground IV) render obvious “multiple pairs of bipolar radiofrequency electrodes.” Pet., 32-41, 82-87; Ex.1002, ¶¶93-122. PO argues that Stern does not disclose this limitation because its pairs are not active “at the same time.” POR, 14-20. However, the challenged claims do not require multiple pairs to be active at the same (*see infra* Section II.A.1.a) and, even if they did, Stern discloses this limitation (*see infra* Section II.A.1.b). Ex.1083-Reply-Decl., ¶17.

**a. “Multiple pairs of bipolar radiofrequency electrodes”
need not be delivering energy “at the same time”**

Stern discloses “pairs” of bipolar electrodes nine separate times, and there is no dispute that Stern discloses at least two different pairs of bipolar electrodes. Ex.1033-Stern, 2:36-40, 3:38-40, 12:20-22, 12:22-24, 12:29-33, 13:27-31, 13:31-38, 13:39-42, 20:6-9; Ex.1084-Bikson-Tr., 107:16-108:9, 109:4-12, 112:4-12, 113:3-116:20. PO nevertheless argues, incorrectly, that it can avoid Stern’s teachings if the claims are interpreted to require bipolar pairs that are delivering energy “at the same time.” POR, 19, 25. The Board should reject PO’s arguments.

First, the claims do not recite that the treatment element's pairs of bipolar electrodes must be delivering energy "*at the same time*," nor does anything else in the claims suggest this unrecited feature. The claims simply require "multiple pairs of bipolar electrodes," i.e., more than one bipolar electrode pair, which Stern undisputedly discloses. Ex.1083-Reply-Decl., ¶18.

Second, PO's arguments are inconsistent with the specification and exclude a preferred embodiment, which is "rarely, if ever, correct." *Broadcom Corp. v. Netflix, Inc.*, 2023 WL 4115909, at *1 (Fed. Cir. 2023). The '318 patent explicitly discloses activating each electrode pair separately. Ex.1001-USP318, 48:63-49:4 ("each pair of electrodes may have a *separate, controlled electrical channel* to allow for different regions of the treatment element to be *activated separately*"), 24:45-55 (electrode pairs "may be *individually controlled*"); 49:18-24 (describing "multiplexed configuration" allowing any electrodes to be paired); 49:46-54 (same); 20:30-33 (controlling electrodes "individually or in selected groups."). Ex.1083-Reply-Decl., ¶¶19-20.

Accordingly, the term should be given its plain and ordinary meaning—multiple bipolar electrode pairs that are not necessarily active “at the same time,”¹ which PO does not dispute is disclosed by Stern.

b. Stern teaches “bipolar electrode pairs” that are active “at the same time”

Even under PO’s incorrect interpretation, Stern teaches activating multiple bipolar electrode pairs “at the same time.” For example, Stern states that “*any combination of pairs* of electrodes [shown in Figure 15] may be *utilized together*” and therefore expressly contemplates activating all electrodes at one time. Ex.1033-Stern, 13:39-43. This is similar to the ’318 patent’s description. Ex.1001-USP318, 24:45-55. Ex.1083-Reply-Decl., ¶22.

PO wrongly asserts that Petitioners’ analysis “identifies only a single pair of electrodes” and that Stern’s teachings are limited to closing two switches at a time. POR, 14, 19. The Petition identifies multiple activation examples in Stern, including activating one pair at a time *and* activating pairs simultaneously. Pet., 34-41, 82-87. Ex.1002, ¶101. Stern must be considered as a whole, including this example. *Sony Interactive Entertainment LLC v. Intellectual Pixals Ltd.*, 2023 WL 6773879, *4

¹ The term “bipolar electrode pairs” was not addressed during prosecution. *See* Pet., 18-19.

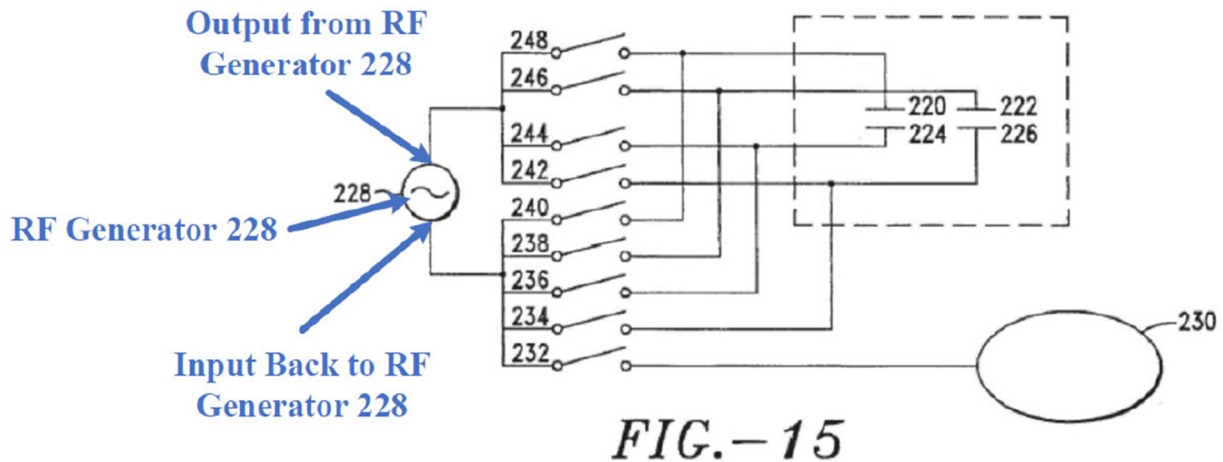
(Fed. Cir. 2023) (“The Board erred when it narrowed [a reference’s] disclosure” to exclude an expressly-disclosed example “and only focused on the more detailed examples.”). Ex.1083-Reply-Decl., ¶¶23-28.

**2. Edwards-535 or Makower in View of Stern Teaches
“multiple radiofrequency output channels”**

Petitioners showed that Edwards-’535 in view of Stern (Ground I) and Makower in view of Stern (Ground IV) render obvious “multiple radiofrequency output channels.” Pet., 41-45, 87-88; Ex.1002-Decl., ¶¶123-148, 289-302. PO argues this limitation requires multiple output channels to be connected directly to the voltage source or generator. POR, 20-25. This is incorrect. Even if it did, PO’s expert confirmed Stern discloses this limitation. Ex.1083-Reply-Decl., ¶29.

**a. Each “radiofrequency output channel” need not be a
separate channel “connected directly to the voltage
source”**

PO improperly seeks to add the requirement that each “output channel” must be connected directly to the voltage source in the radiofrequency generator. *See* POR, 20-25; Ex.1084-Bikson-Tr., 185:16-19. PO contends that Stern does not disclose the “multiple radiofrequency output channels” because Stern shows two wires connected to its voltage source 228, which PO contends is equivalent to the system’s RF generator:



POR, 24 (PO's annotation of Stern's Figure 15); *see also* Ex.2001-Bikson-Decl.,

¶77. The Board should reject PO's arguments for three reasons.

First, the plain language of the claim does not require the “multiple radiofrequency output channels” to be channels connected directly to the voltage source in the radiofrequency generator. In fact, the claim does not require any specific connection between the output channels and the generator. Claim 1 is about a “device for delivering energy to a nasal airway”—the generator is not included until claims 9 and 10. Claim 9 states the generator simply needs to be “configured to...deliver radiofrequency energy separately to each of the multiple radiofrequency output channels.” This does not require separate wires or channels connected directly to the voltage source or to the generator, as PO contends (*see infra* Section II.D.1). Ex.1083-Reply-Decl., ¶¶30-31.

Second, PO's arguments are inconsistent with the specification, which shows “an RF output channel 961” in Figure 39 as the connection to an electrode in the nasal treatment device. Ex.1001-USP318, 49:5-10. Every discussion of “electrical channel” or “output channel” in the '318 patent refers to connections to *electrodes* —not wires within a generator. Ex.1001-USP318, 24:45-52, 48:63-65, 49:5-10, 49:12-15, 49:24-46, 49:65-50:2, 50:9-15; *see also* FIGs. 39, 40, 42A-42B, 43, 44. The '318 patent's discussions of multiplexing further confirms that output channels are electrical connections between chosen pairs of electrodes. *Id.*, 10:46-50; 49:18-32; 49:46-60; FIG.40, 42A-42B.

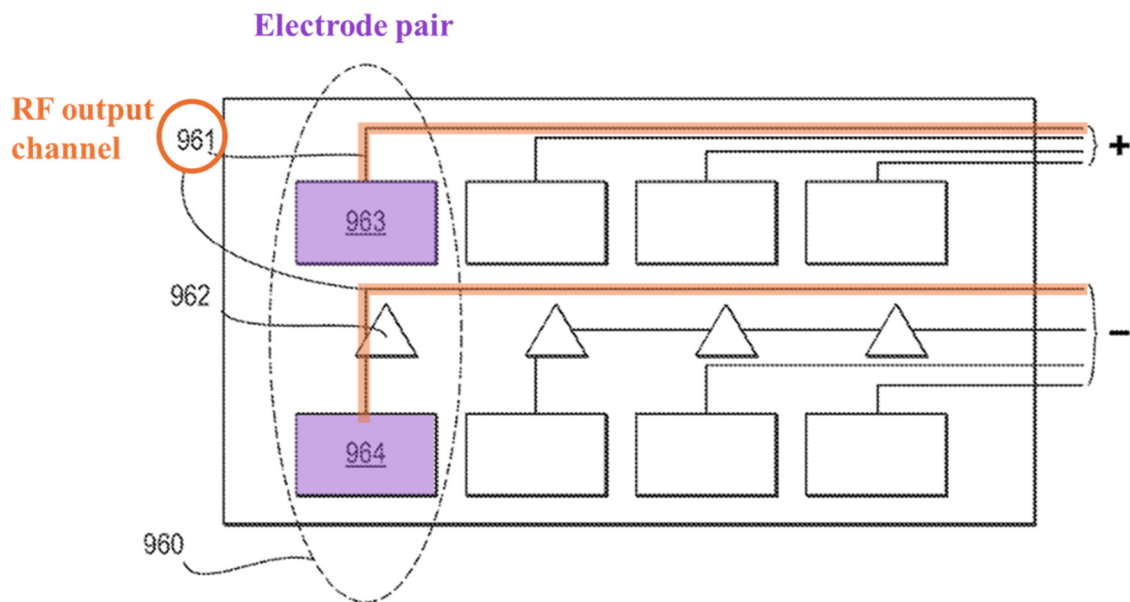


FIG. 39

Ex.1001-USP318, FIG.39; 49:5-9 (“As shown in FIG. 39, the nasal treatment device may include one or more thermocouples 962 and an *RF output channel 961* assigned to each electrode pair for feedback. An electrode pair may include a positive electrode 963 and a negative electrode 964.”); *see also id.*, 50:5-13, FIG. 44 (showing multiple output channels to different electrodes paired with a single return electrode). Ex.1083-Reply-Decl., ¶¶32-40.

The '318 patent never explains or limits how the output channel ultimately connects to the voltage source or to the RF generator. Requiring a direct connection between the generator's voltage source and output channels is improper. *See, e.g., Zenith Elecs Corp. v. PDI Commc'n Sys., Inc.*, 522 F.3d 1348, 1355-56 (Fed. Cir. 2008) (rejecting argument that a television did not provide “operating power” to a speaker even though there was a capacitor serving as an intermediary between the television and speaker). Ex.1083-Reply-Decl., ¶¶34-41.

Third, PO's only support for its interpretation is Dr. Martin's testimony, taken out of context, and its expert's say-so (Ex.2001-Bikson, ¶¶66-83), which was refuted at his deposition (*see* Section II.A.2.b. *infra*). PO's mischaracterizations of Dr. Martin's testimony (POR, 21-22) do not outweigh the intrinsic record of the patent. Ex.1002, ¶¶123-156, 289-302. The full context of Dr. Martin's testimony is

included below and makes clear that PO ignores Dr. Martin's repeated opinion that Stern has multiple radiofrequency output channels:

A. If you look at Stern, Stern figure 15 has a number of output channels from their device. That's how I interpret 'output channel' to mean: output from a radiofrequency generator.

Q. Okay. So you understand a radiofrequency output channel to be an output from a radiofrequency generator; is that correct?

A. Yes. *Similar to what Stern has in figure 15.*

Ex.2004-Martin-Tr.II, 318:3-320:3, 326:14-327:10, 328:7-329:5, 329:20-330:3; 331:1-9. As Dr. Martin explains, "output from a radiofrequency generator" does not mean that multiple channels need to be connected directly to the generator's voltage source. Ex.1083-Reply-Decl., ¶¶41-46.

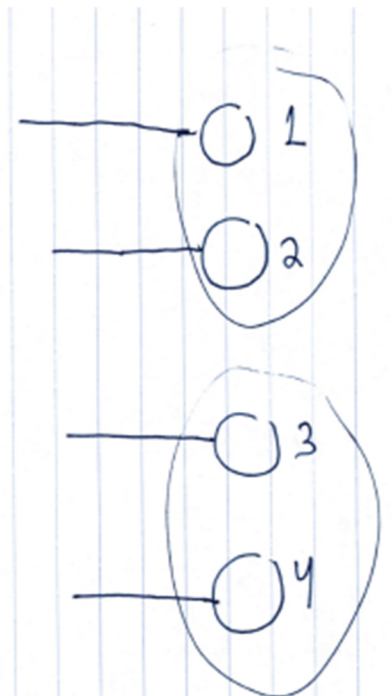
Accordingly, the term should be given its plain and ordinary meaning—multiple channels² that are not necessarily connected *directly* to the voltage source or generator, and which PO does not dispute is disclosed by Stern.

² The term "multiple radiofrequency output channels" was not addressed during prosecution. *See* Pet., 18-19.

b. The prior art discloses “multiple radiofrequency output channels” under either construction

Petitioners demonstrated how Stern discloses the claimed “multiple radiofrequency output channels” under its plain and ordinary meaning, and why it would have been obvious to a POSITA to modify Edwards-’535 to include such channels. *See* Pet., 41-45, 87-88; Ex.1002, ¶¶123-156, 289-306. Even under PO’s incorrect interpretation, PO’s expert confirms that Stern discloses “multiple radiofrequency output channels.” Ex.1083-Reply-Decl., ¶47.

Dr. Bikson was asked to “draw a device that has multiple radiofrequency output channels as required by [claim 1 of the ’318 patent].” Ex. 1084-Bikson-Tr.,194:13-15. Dr. Bikson drew the following:



Ex.1087-Bikson-Dep-Ex.E. He explained:

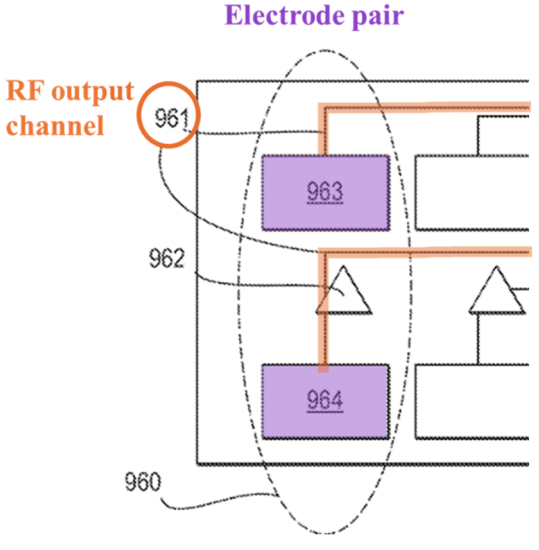
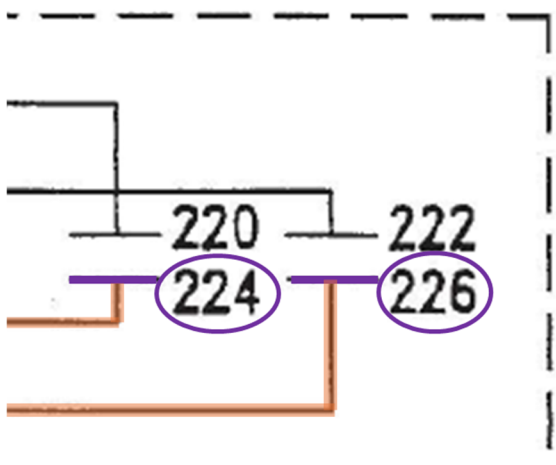
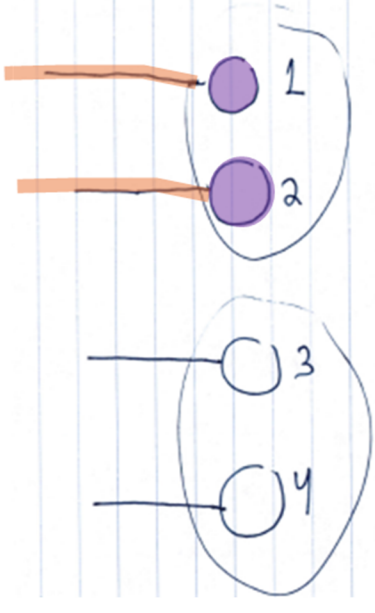
And I'm drawing wires going to electrodes one and two. And I'm drawing wires going to electrode three and four. And I guess I'll put a circle around one and two and around three and four, so each -- this is one bipole and this is another bipole. And the wires coming to them would represent one channel and this would represent another channel.

Ex. 1084-Bikson-Tr.,194:19-195:4. He explained the "voltage source is not shown here." *Id.*, 195:6. Dr. Bikson agreed that "in the dashed box in Stern Figure 15, it also shows four electrodes and each electrode is connected to its own wire":

It's correct that in Figure 15 from Stern you have four electrodes and each electrode is associated with a wire.

Id., 96:6-11.³ Dr. Bikson's drawing is consistent with the '318 patent's figures and Stern Figure 15 because it similarly shows an electrode pair (annotated in purple) connected to an individual output channel (annotated in orange):

³ Dr. Bikson noted that all of the electrodes are “energized” in his depiction, consistent with his opinion discussed in Section II.A.1. For the reasons explained above, the claims do not require the electrodes to be active at the same time. Further, it makes little sense why, in Dr. Bikson's view, the claims both require “separate control” of the bipolar electrode pairs (POR, 24-25), but multiple bipolar pairs must be active at the same time (POR, 19). Petitioners have explained in detail how Stern provides “separate control” of the bipolar electrode pairs. *See, e.g.*, Pet., 38-45, 53-54, 61-62.

Ex.1001-USP318, FIG.39.	Ex.1033-Stern, FIG.15.
 Electrode pair RF output channel 961 962 963 964 960	 220 222 224 226
Ex.1087-Bikson-Dep-Ex.E	
 1 2 3 4	

Ex.1083-Reply-Decl., ¶¶48-49.

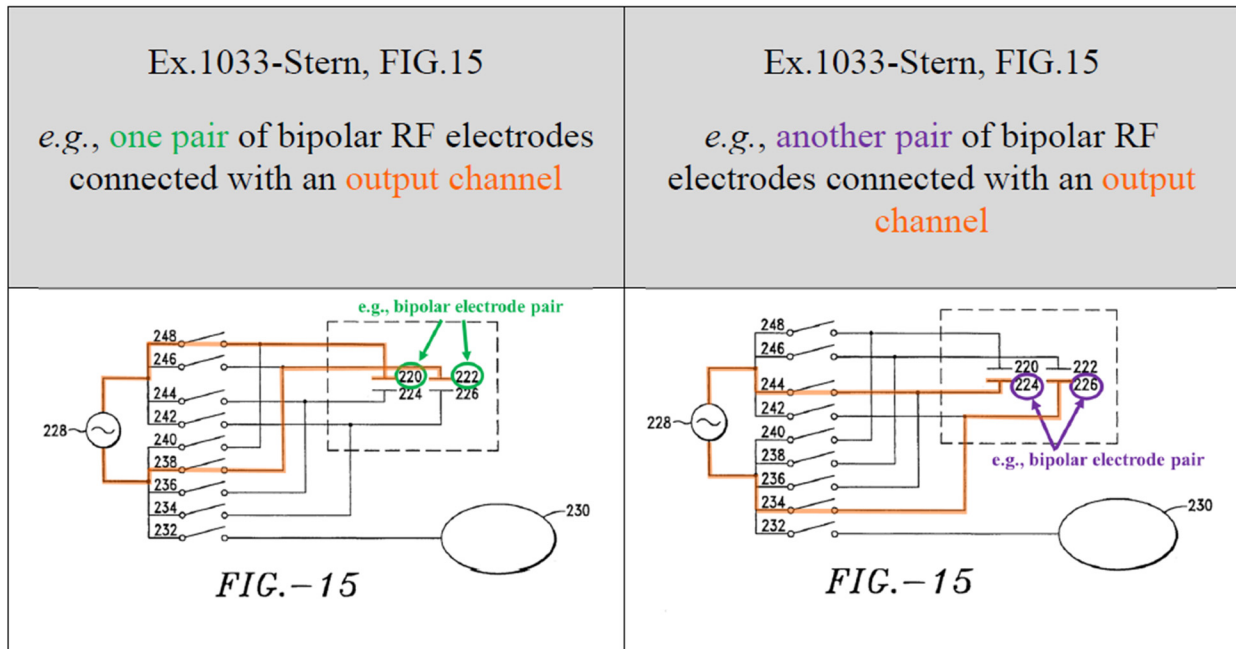
**3. Edwards-535 or Makower In View of Stern Teaches
“wherein each pair of the multiple pairs of bipolar**

radiofrequency electrodes is connected with a respective one of the multiple radiofrequency output channels”

PO argues Petitioners failed to show that Stern teaches this limitation, largely restating its arguments addressed in Section II.A.1 and A.2. As above, these arguments fail.

PO mischaracterizes the Petition as conclusory, asserting that the Petition repeats the claim language and states this limitation is “shown in Figure 15.” POR, 26. This is incorrect. The Petition, supported by the Dr. Martin’s declaration, explains how Stern’s Figure 15 “shows circuitry capable of supplying energy to selected bipolar pairs via a ‘switching means’ *where each bipolar pair is wired to its own output channel.*” Pet., 42 (citing Ex.1033-Stern, 2:49-53, 3:12-29, Clm.1, FIG.15. Ex.1002-Decl., ¶¶124-128); *see also* Pet., 41-45, 87-88. *See* Ex.1002-Decl., ¶127 (explaining that Stern’s Figure 15 “depicts the circuitry that supplies energy to selected bipolar pairs *via separate, controlled electrical channels to allow each bipolar pair to be activated separately.*”). Ex.1083-Reply-Decl., ¶¶50-52.

Moreover, the Petition and Dr. Martin provide an example of **one pair** of bipolar RF electrodes connected with a respective **one RF output channel**, and **another pair** of bipolar RF electrodes connected with **another output channel**:



Pet., 43; Ex.1002-Decl., ¶124. This is not conclusory analysis. *Vivint, Inc. v. SB IP Holdings LLC*, IPR2022-01449, Paper 24, 65 (P.T.A.B. June 5, 2024) (finding, in the context of the petition, Petitioner's rationale was supported by the prior art and was therefore not conclusory). Ex.1083-Reply-Decl., ¶53.

B. Claim 5 Is Obvious

Petitioners demonstrated that Claim 5 is obvious. Pet., 51-53, 90-92. PO does not raise any specific dispute for claim 5 regarding the combination of Makower and Stern (Ground IV). PO argues Edwards-'535 and Stern (Ground I) do not disclose "wherein at least one pair of the multiple pairs of bipolar radiofrequency electrodes is coupled with each of the multiple segments." POR, 28-30; *see* Pet, 51-53. Ex.1083-Reply-Decl., ¶¶54-56.

This is incorrect. PO views Stern's "electrode area segment" as having only one electrode. POR, 29. But that is just one configuration that Stern contemplates. Stern discloses Figures 4a and 4b have "electrode area segments," and teaches power can be selectively supplied to these segments for bipolar energy delivery Ex.1033-Stern, 8:49-51, 5:48-50, 8:55-56; *see* Pet., 50-52; Ex.1002-Decl., ¶¶167-172. When powered by Figure 15's bipolar embodiment, a segment would have at least two electrodes. This is supported by Stern explaining "each conductive *segment*" (singular) is electrically connected through "conventional leads" (plural) to a power source. Ex.1033, 8:56-57. A segment would need multiple leads for bipolar operation to connect multiple electrodes to the power source. Stern therefore teaches that each segment includes a pair of electrodes. Ex.1083-Reply-Decl., ¶¶57-58.

Even if PO's interpretation of Stern is correct (it is not), it would have been obvious to a POSITA to combine two segments, each having one electrode, in light of Stern's teaching that Figure 15's bipolar embodiment can power the electrode area segments. Ex.1083-Reply-Decl., ¶59.

The adequacy of Stern's teaching is confirmed by the paucity of disclosure in the '318 patent. "Segment" appears just once in this context: "[i]n alternative embodiments, an expandable treatment element may comprise one or more *segments* comprising a shape-memory alloy material which may be configured to

expand to a desired size and shape in response to a change of temperature past a transition temperature.” Ex.1001-USP318, 18:13-20. This explanation appears in a paragraph discussing Figures 4A-4C. *See* Ex.1001-USP318, 18:3-17. Though there may be “segments” in Figures 4A and 4B, there are no reference numerals pointing to any. Figure 4C points to bifurcated “elements 72, 74,” that “may include substantially self-expandable sections” and further indicates that these “halves 72, 75” “may also carry energy delivery structures.” *See* Ex.1001-USP318, 17:28-49; FIG.4C. It is unclear whether these “halves” are “segments.” Therefore, Stern’s disclosure that the bipolar Figure 15 schematic can power electrode area segments is sufficient. The specification’s sparse disclosure does not support a more specific disclosure in the prior art. *In re Epstein*, 32 F.3d 1559, 1568 (Fed. Cir. 1994) (“The Board’s observation that appellant did not provide the type of detail in his specification that he now argues is necessary in prior art references supports the Board’s finding that one skilled in the art would have known how to implement the features of the references.”). Ex.1083-Reply-Decl., ¶59.

Moreover, the Petition did not rely exclusively on Stern for claims 5 and 4 (from which claim 5 depends). Pet., 49-52. Rather, the Petition explained the Ground I combination as “a *plurality of bipolar energy delivery devices in Edwards-*

'535 controlled as pairs as taught by Stern.” Pet., 51. PO does not dispute Edwards-
'535 discloses segments that include two electrodes 156:

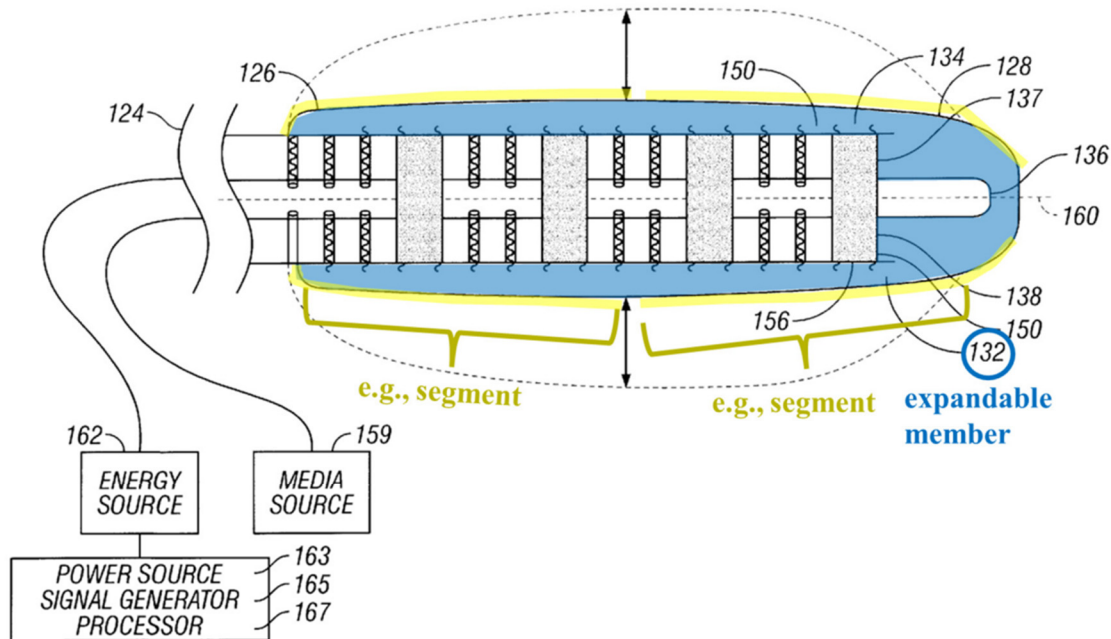


FIG. 6

Pet., 50. Thus, when controlling Edwards-'535's electrodes in pairs as taught by Stern, the prior art shows each pair of electrodes *on* a respective segment. Pet., 549-52. Ex.1083-Reply-Decl., ¶60.

C. Claim 6 Is Obvious

Petitioners demonstrated that Claim 6 is obvious. Pet., 72-74, 92. PO argues that the prior art does not disclose “multiple segments comprise a shape-memory alloy material configured to expand to a desired size and shape.” Ex.1001-USP318,

cl.6; POR, 43-45, 47-49. PO's arguments lack merit. Ex.1083-Reply-Decl., ¶¶61-63.

1. Edwards-535 In View Of Stern And Patel Teaches Claim 6

The Petition showed how Edwards-'535 in view of Stern and Patel (Ground II) renders obvious claim 6. Pet., 72-74. PO argues Patel does not disclose (1) segments comprising a shape-memory alloy and (2) segments configured to expand. POR, 38-41. The Board should reject PO's arguments. Ex.1083-Reply-Decl., ¶¶64.

First, PO argues that “segments” are different than “electrodes,” because the claims recite both “bipolar radiofrequency electrodes” and “multiple segments” separately, and therefore the two must be distinct elements. POR, 40-44. This position again improperly narrows the claim.

Nothing in the claims requires the “segments” to be different than “electrodes.” Claim 5, not claim 6, is the only claim requiring a specific relationship between the segments and electrodes (i.e., that they must be “coupled”). Ex.1001-USP318, cl.5. Therefore, claim 4 is broader and encompasses segments that comprise electrodes. Claim 6 limits the “segments” of claim 4 to “comprise a shape-memory alloy material” but does not otherwise limit the scope of claim 4. Ex.1083-Reply-Decl., ¶¶65-66.

Further, the '318 patent's description of "segments" provides little guidance to a POSITA other than they are "configured to expand." *See* Section II.B (discussing the '318 patent's disclosure of "segments.>"). Nothing in the specification requires "segments" to be physical components, much less separate from electrodes. Ex.1001-USP318, 17:41-42. Moreover, the patent's discussion of segments comprising a "shape memory alloy material" does not preclude electrodes. Ex.1001-USP318, 18:13-32. Thus, the specification makes clear that the "segments" can include electrodes. Ex.1083-Reply-Decl., ¶66.

Second, PO argues that Patel's segments are configured to "fold[]" and "furl[]" which is "the opposite of expanding." POR, 41. Patel's segments necessarily expand as they fold or furl for insertion into the body and ***unfold*** after insertion. This constitutes "expand[ing] to a desired size and shape." Ex.1083-Reply-Decl., ¶67.

2. Makower In View of Stern Teaches Claim 6

The Petition showed how Makower in view of Stern (Ground IV) renders obvious claim 6. Pet., 92. PO argues Makower does not teach that its strut members 214 are made of a shape-memory alloy, and that Petitioners do not propose

modifying Makower's struts to include nitinol.⁴ POR, 43-46. PO is incorrect. Ex.1083-Reply-Decl., ¶68.

Petitioners explained how a "POSITA would have understood that Makower suggests making strut members 214 of a shape memory alloy to facilitate collapse and expansion." Pet., 92. Petitioners further explained that Makower teaches that "strut members 214 may be collapsible and expandable." Pet., 92 (citing Ex.1021-Makower, [0187]). PO selectively ignores Makower's disclosure that "any catheters *or elongate flexible devices* of this invention may include design elements that impact performance features." Ex.1021-Makower, [0194]. This includes using "*shape memory alloys such as nitinol*" to "predictably deflect various sections of the catheter." Pet., 92 (citing Ex.1021-Makower, [0194]). This is the exact same mapping that the Examiner applied when it found that Makower anticipated this claim.⁵ Ex.1003-USP318FH, 509. Ex.1083-Reply-Decl., ¶¶69-70, 72.

Makower's disclosure that components other than the elongate flexible device shown in Figure 5H can be made from nitinol does not negate Makower's clear

⁴ To be clear, claim 6 requires that the segments be made of a "shape-memory alloy material."

⁵ PO overcame Makower by amending the independent claims. Pet., 18-19.

teaching to use the same material for the elongate flexible device, including its strut members 214. *Nextremity Solutions, Inc. et al v. Extremity Medical, LLC*, IPR2022-00802, Paper 35 (P.T.A.B July 26, 2023) (“Simply because one embodiment of [the prior art] teaches the limitation and one does not ‘is not controlling, since all disclosures of the prior art, including unpreferred embodiments, must be considered.’” (citations omitted)). Ex.1083-Reply-Decl., ¶71.

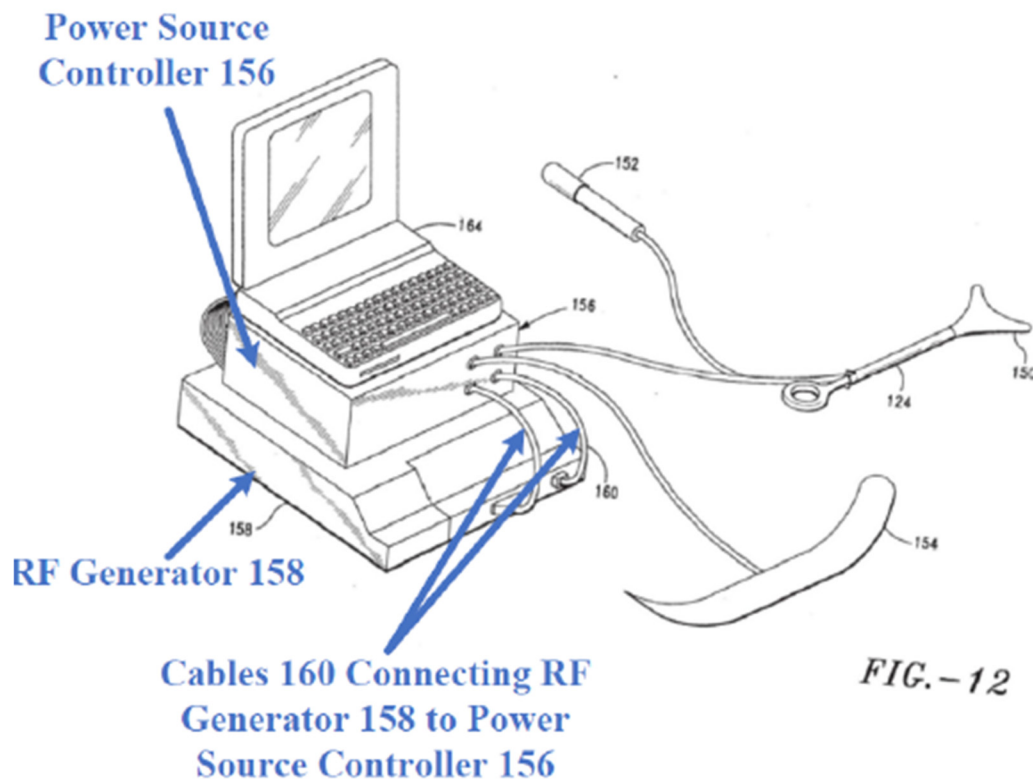
D. Claim 9 Is Obvious

Petitioners demonstrated that Claim 9 is obvious. Pet., 53-59, 74-76, 93-102, 125-130, 164-167. PO argues that the prior art fails to disclose limitation 9[a]: “a radiofrequency generator configured to...deliver radiofrequency energy separately to each of the multiple radiofrequency output channels” and limitation 9[b]: “a cable coupled to the handle for plugging the handle into the radiofrequency generator.” POR, 30-36, 41, 47. PO’s arguments fail. Ex.1083-Reply-Decl., ¶¶73-75.

1. Edwards-535 In View of Stern (and Edwards-’886) and Makower in view of Stern and Edwards-’886 Teach Limitation 9[a]

PO does not dispute that the prior art teaches delivering energy to a single pair of electrodes at a time. Pet., 53-57, 74-75. Instead, PO argues that Stern fails to disclose a *radiofrequency generator* configured to “deliver radiofrequency energy separately to each of the alleged multiple radiofrequency output channels.” POR,

30. PO alleges that it is the switches in Stern's "power source controller 156,"—not the "RF generator 158,"—that deliver energy to each of the RF output channels. PO further argues that generator 158 does not deliver energy "separately" because it has a single output to power source controller 156, and power source controller 156 further divides the output to deliver energy "separately." POR, 31-32.



POR, 34. This argument fails for at least two reasons. Ex.1083-Reply-Decl., ¶¶76-77.

First, PO again takes an improperly narrow view of the claim limitation that is contradicted by the '318 patent. The patent includes embodiments having a "control system 42 configured to control the timing, location, intensity and/or other

properties and characteristics of energy or other treatment applied to targeted regions of a nasal passageway.” Ex.1001-USP318, 16:27-31, FIG.3. This control system is separate from power supply 44 that “may be configured to deliver a radio frequency alternating current signal to an RF energy delivery element.” Ex.1001-USP318, 16:55-57. The patent notes that the generator may be “part of a *separate assembly* that delivers energy or control signals.” Ex.1001-USP318, 34:33-34. Ex.1083-Reply-Decl., ¶¶77-79.

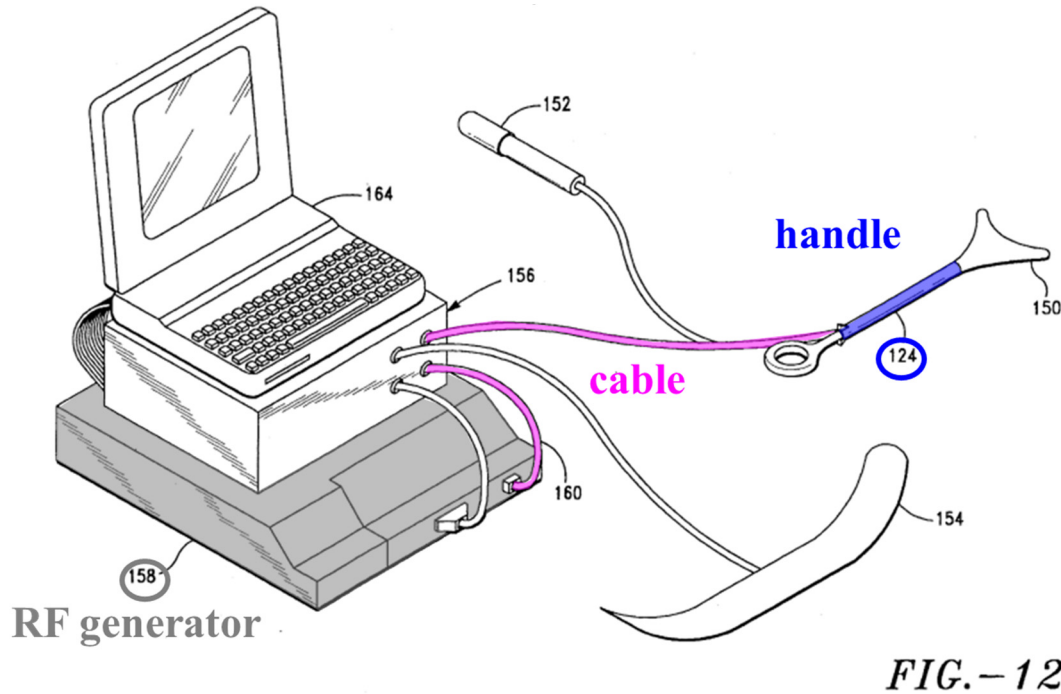
Nowhere in the '318 patent does it describe what PO claims—that to “deliver radiofrequency energy separately,” the generator must have multiple output ports.⁶ Therefore, even though Stern discloses an “RF generator 158 [that] serves as the RF input power for the controller 156,” “[o]nce the device 124 and the controller 156 are connected, the RF electrodes are separately, independently and sequentially energized....” Ex.1033-Stern, 10:33-53. This discloses the claim limitation. *See* Ex.1001-USP318, FIG.22A. Ex.1083-Reply-Decl., ¶¶80-81.

⁶ As explained above (*see* note 3), Stern’s design provides separate, independent control of energy delivered through the different electrode pairs. Pet., 41-45; Ex.1002-Decl., ¶¶123-148.

Second, PO's argument miscomprehends the proposed combination in Ground I and III and improperly focuses on the physical combinability of Stern into Edwards-'535. *Allied Erecting & Dismantling Co. v. Genesis Attachments, LLC*, 825 F.3d 1373, 1381 (Fed. Cir. 2016). The Petition expressly relied on Edwards-'535's signal generator—which PO does not dispute is a generator—that delivers energy independently to electrodes, as modified by Stern's teaching regarding how to do so. Pet., 53-54. A POSITA would have been motivated to modify Edwards-'535's generator to include the functionality of Stern's controller. *Id.* Whether Stern discloses a separate RF generator and controller is irrelevant to the proposed combination. Ex.1083-Reply-Decl., ¶82.

2. Edwards-535 In View of Stern and Edwards-'535 or Makower in view of Stern and Edwards-'886 Teach Limitation 9[b]

PO argues that Stern does not teach “a cable coupled to the handle for plugging the handle into the radiofrequency generator.” PO instead argues there are *two cables* leading to the generator, as shown below in Stern's Figure 12. For at least three reasons, PO's position is baseless.



Pet., 58. Ex.1083-Reply-Decl., ¶¶83-84.

First, “a” does not require one and only one. *Baldwin Graphic Sys., Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1342 (Fed. Cir. 2008) (“a” means “one or more” in open-ended “comprising” claims). The fact that Stern’s Figure 12 depicts a cable connecting the handle to power source controller 156, and an allegedly different cable connecting power source controller 156 to RF generator 158, is immaterial. Indeed, PO’s own specification includes embodiments where other elements, like adapter 544, are intermediaries between the RF generator and electrodes. See Ex.1001-USP318, FIG.22A. Ex.1083-Reply-Decl., ¶85.

Second, the ’318 patent does not indicate that the cable must **directly connect** the generator to the handle. As discussed in Section II.D.1., the patent explains that

the generator may be separate from a control system “that delivers energy or control signals.” Ex.1001-USP318, 16:27-31, 34:33-34, 5:25-30, 16:27-35, FIG.3. Therefore, the patent contemplates a control system between the generator and handle. Stern therefore teaches this limitation. Ex.1083-Reply-Decl., ¶¶86-87.

Third, as explained in Section II.D.1, in Grounds I and III, the Petition expressly relied on Edwards-’535’s signal generator—which PO does not dispute is a generator—that delivers energy independently to electrodes, as modified by Stern’s disclosure of a cable. Pet., 53-54. That is, Edwards-’535’s generator would have been modified to include a cable to plug Edwards-’535’s device into the generator. *Id.* Thus, whether Stern discloses a separate RF generator and cable is irrelevant to the proposed combination. *See Allied Erecting & Dismantling*, 825 F.3d at 1381. Ex.1083-Reply-Decl., ¶88.

E. Claim 15 Is Obvious

Petitioners demonstrated that claim 15, which requires “two rows of electrodes” is obvious. Pet., 66-67, 93-94. PO’s sole argument as to claim 15 in Ground I is that the Petition did not address why “it would have been obvious to incorporate Stern’s electrode arrangement of Figure 19 in Edwards-535’s device” because, according to PO, Petitioners “fail to explain why, out of the multitude of possible electrode arrangements, a POSITA would have specifically picked out

Stern's Figure 19 electrode arrangement for use in Edwards-535's device." POR, 36-37. That argument fails for at least three reasons. Ex.1083-Reply-Decl., ¶¶89-91.

First, PO's argument is contrary to law. It is well settled that the presence of alternatives does not defeat obviousness. *Intel Corp. v. Qualcomm Inc.*, 21 F.4th 784, 800 (Fed. Cir. 2021) ("It's not necessary to show that a combination is 'the best option, only that it be a suitable option.'" (citations omitted)); *Par Pharm., Inc. v. Twi Pharms., Inc.*, 773 F.3d 1186, 1197-98 (Fed. Cir. 2014) ("Our precedent...does not require that the motivation be the best option, only that it be a suitable option from which the prior art did not teach away."). As the Board has already recognized, "[i]t is well-settled that a reference must be considered for everything it teaches." I.D., 28 (citing *CRFD Research, Inc. v. Matal*, 876 F.3d 1330, 1349 (Fed. Cir. 2017)). Petitioners were therefore not required to show why Stern Figure 19 may have been a better option compared to alternative electrode arrangements.

Second, contrary to PO's assertion (POR, 36) the Petition did explain why Stern's teaching of "two rows" was "an electrode arrangement [that] would have been obvious to incorporate in Edwards-'535" and proceeds to conclude that "a POSITA would have found it obvious and had a reasonable expectation of success in implementing two rows of electrodes as taught by Stern." Pet., 67. The Petition

further cited to the analysis of Stern's teachings for limitation 1[d], which are equally applicable to Stern's Figure 19. Pet., 34-36. For example, the analysis in limitation 1[d] included a discussion of how Stern's disclosure would allow for location control and "even heating," which would have been the natural result of including Stern's ordered arrangement in Figure 19 in combination with Stern's bipolar pairing technique. Pet., 38-39. Ex.1083-Reply-Decl., ¶91.

Third, PO ignores the Petition's *additional* motivations as to why Stern's Figure 19 in particular would have been obvious—it is a "more ordered arrangement[]" and would have merely been a "rearrangement of parts." Pet., 67. These un rebutted motivations alone are sufficient grounds to find claim 15 obvious. Ex.1083-Reply-Decl., ¶91.

F. Claim 17 Is Obvious

Petitioners demonstrated that Edwards-'535 or Makower with Stern (Grounds I and IV) render claim 17 obvious. *See* Pet., 69-71, 95. PO argues that Stern fails to teach "wherein the multiple pairs of bipolar radiofrequency electrodes are connected to one another." POR, 38, 46. This argument lacks merit. Ex.1083-Reply-Decl., ¶¶93-94.

The '318 patent discloses "an electrode array arranged in a multiplexed configuration allowing pairing of *any* of the positive electrodes 963 to any of the

negative electrodes 964 to form a complete circuit.” Ex.1001-USP318, 10:47-50. Consistent with this disclosure, Petitioners showed that Edwards-’535 and Stern contemplate “multiplexed” configurations where multiple pairs of bipolar RF electrodes are connected to one another. Pet., 70-71 (citing Ex.1002-Decl., ¶¶225-232). Ex.1083-Reply-Decl., ¶¶94-98.

PO nonetheless argues that the Petition does not show how “the *multiple pairs* of bipolar radiofrequency electrodes are connected to one another,” focusing on only one portion of the Petition that discussed the exemplary connection of Stern’s electrodes 220 and 222. POR, 38. But PO ignores two additional pages of the Petition—and Dr. Martin’s uncontroverted testimony—explaining that, in addition to this exemplary pairing, Edwards-535 and Stern teach the same kind of multiplexing contemplated by the ’318 patent in which *any* two electrodes can be paired. Pet., 70-71 (citing Ex.1003-Stern, 12:19-24, 41-45; Ex.1002-Decl., ¶¶225-232); *see also Networks, Inc. v. Centripetal Networks, LLC*, No. 2023-1636, 2024 WL 5114204, at *6 (Fed. Cir. 2024) (“Where, as here, the grounds for obviousness are based on a specific combination of references, arguments that attack the disclosures of the two references individually lack merit.” (citations omitted)). Indeed, Petitioner’s analysis for claim 1 (from which claim 17 depends) plainly showed two different pairings of electrodes with reference to Stern’s Figure 15. Pet.

42-44. PO does not (and cannot) explain how this multiplexing arrangement is different from the claimed “multiplexed configuration.” Ex.1083-Reply-Decl., ¶¶94-98.

G. Claims 4, 10, 12, 13, and 16 Are Obvious.

PO’s arguments regarding claims 4, 12, 13, and 16 (Grounds I, IV) and claim 10 (Grounds I, III, and V) are based solely on their dependency on claim 1. POR, 28, 41, 42, 46. These claims are therefore also obvious for the reasons discussed above. *See* Pet., 49-51, 59-65, 67-68, 76, 90, 92-95, 97-98. Ex.1083-Reply-Decl., ¶99.

III. THE LEVEL OF ORDINARY SKILL IN THE ART

Although PO disputes the POSITA definition proposed by Petitioners and adopted by the Institution Decision, POR, 6-8, PO does not dispute that Dr. Martin qualifies as a POSITA or that any issue in this IPR depends on which definition governs. Accordingly, the Board need not decide this issue.⁷

⁷ PO contends that the definition of a POSITA is material to the outcome of IPR2024-00277 involving USP 11,241,271 (Paper 24). Petitioners present additional reasons why PO’s proposal is incorrect in their Reply filed in IPR2024-00277.

Regardless, PO's purported reasons to winnow Neurent's POSITA definition are not supported by the evidence. *Godbersen-Smith Construction Co.*, IPR2021-00136, Paper 61 at 23-27 (refusing to limit level of ordinary skill to only design/development experience).

- The Challenged Claims recite a generic, not specialized, device for “delivering energy to a nasal airway.” Ex.1001-USP318, cl.1.
- RF devices were known and used safely and effectively by clinicians, including in the nose. Ex.1001-USP318, 19:53-20:4; Pet., 11-15; Ex.1056-Liang, 341-342.
- Clinicians learn to safely and effectively use RF electrode devices through use and testing, instructions for use, education, and data review. Ex.1084-Bikson-Tr, 89:2-94:8.
- Physicians “*must* be familiar” with devices they use to understand, e.g., “safety, energy dosage...and instrumentation.” Ex.1093-Levine-Article, 451.
- The Liang, Hytönen, and Coste references in this proceeding appear in *medical* journals and treat rhinitis by selecting settings for off-the-shelf RF ablation devices in a clinical setting. Ex.1056-Liang, 341 (selecting “Level 3” and treatment time); Ex.1031-Hytönen, Abstract (compiling

a literature review of nasal radiofrequency ablation procedures);
Ex.1023-Coste, 894 (specifying the mean energy per puncture, mean
duration time, and plateau tissue temperature).

- One named inventor, Scott Wolf, is an MD with no apparent clinical
experience (much less in ablation) who nonetheless began developing
medical devices immediately after graduating medical school.
Ex.1091-Wolf-Podcast-Ep., 3-4.

Thus, the POSITA factors all support that an M.D. or engineer with three
years' medical device *use*, design, development, *and/or testing* had ordinary skill.
Ex.1083-Reply-Decl., ¶¶100-103.

IV. CONCLUSION

For the reasons above and in the Petition, the challenged claims should be
found unpatentable.

Respectfully submitted,

By: /David L. Cavanaugh/
David L. Cavanaugh
Registration No. 36,476

Counsel for Petitioners

CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing, Petitioners' Reply, contains 5,574 words as measured by the word processing software used to prepare the document, in compliance with 37 C.F.R. Section 42.24(d), excluding the parts of the Petition exempted from the word count by 37 C.F.R. Section 42.24(a)(1).

/Sarah J. Murphy/
Sarah J. Murphy
Registration No. 80,104

CERTIFICATE OF SERVICE

Pursuant to an agreement between Petitioners and Patent Owner, I hereby certify that, on January 17, 2025, I caused a true and correct copy of the following materials:

- Petitioners' Reply to Patent Owner Response
- Exhibits 1083-1091, 1093-1095
- Petitioners' Updated Table of Exhibits
- Certificate of Compliance Regarding Word Count

to be served on Patent Owner via electronic mail to:

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Petitioners' Updated Table of Exhibits

Exhibit	Description
1001	U.S. Patent No. 11,033,318 (“’318 patent”)
1002	Declaration of Dr. Gregory Martin
1003	File History of U.S. Patent No. 11,033,318
1004-1005	RESERVED
1006	District Court Amended Complaint
1007	District Court Amended Complaint Exhibit X
1008	Docket Navigator District of Delaware Statistics as of January 18, 2024
1009	RESERVED
1010	U.S. Patent No. 6,517,535 (“Edwards-’535”)
1011	U.S. Patent No. 5,575,788 (“Baker”)
1012	U.S. Patent No. 5,891,134 (“Goble”)
1013	WO 2010/077980 (“Baker-’980”)
1014	RESERVED
1015	U.S. Patent No. 6,033,397 (“Laufer”)
1016	U.S. Patent No. 6,273,886 (“Edwards-’886”)
1017-1020	RESERVED
1021	U.S. Patent App. No. 2005/0240147 (“Makower”)
1022	U.S. Patent App. No. 2006/0064086 (“Odom”)
1023	Coste et al., Radiofrequency Is a Safe and Effective Treatment of Turbinate Hypertrophy, LARYNGOSCOPE, 111(5) (2001) (“Coste”)
1024	WO1999030655A1 (“Hovda”)
1025-1029	RESERVED
1030	U.S. Patent No. 8,979,841 (“Kunis”)
1031	Hytönen et al., Radiofrequency Thermal Ablation for Patients with Nasal Symptoms: A Systematic Review of Effectiveness and Complications, 266 EUR. ARCH. OTORHINOLARYNGOL. (2009) (“Hytönen”)
1032	RESERVED
1033	U.S. Patent No. 5,562,720 (“Stern”)
1034	U.S. Patent Application No. 2007/0287994 (“Patel”)

Exhibit	Description
1035	M. Philippson, Principles of Electrical Resistance of Living Tissue, BULL. CL. SCI. ACAD. R. BELG. ser. 5, vol. 7 (1921) (English Translation) (“Philippson”)
1036-1044	RESERVED
1045	U.S. Patent No. 5,507,725 (“Savage”)
1046-1049	RESERVED
1050	Hong, Radiofrequency Ablation: Mechanism of Action and Devices, J. VASC. INTERV. RADIOL. 21 (2010) (“Hong”)
1051	Haemmerich, Biophysics of Radiofrequency Ablation, CRITICAL REVIEWS IN BIOMEDICAL ENGINEERING, 38(1) (2010) (“Haemmerich”)
1052	Sackenheim, Radio Frequency Ablation the Key to Cancer Treatment, J. DIAGNOSTIC MEDICAL SONOGRAPHY Vol.19, No. 2 (2003) (“Sackenheim”)
1053	Bronzino, Medical Devices and Systems, Chapter 13, THE BIOMEDICAL ENGINEERING HANDBOOK 3E (2006) (“Bronzino”)
1054	Koyyalagunta et al., Radiofrequency and Cryoablation for Cancer Pain, TECHNIQUES IN REGIONAL ANESTHESIA & PAIN MANAGEMENT Vol.14 (2010) (“Koyyalagunta”)
1055	RESERVED
1056	Liang et al., Radiofrequency Treatment of Ethmoidal Nerve with Allergic Rhinitis Under Nasal Endoscopy, 13:8 J. CLIN OTORHINOLARYNGOL. (China) 341 (August 1999) (English Translation) (“Liang”)
1057-1060	RESERVED
1061	Szold, Nitinol: Shape-Memory and Super-Elastic Materials in Surgery, 20 SURGICAL ENDOSCOPY & OTHER INTERVENTIONAL TECHNIQUES (2006) (“Szold”)
1062	Sedra et al., MICROELECTRONIC CIRCUITS (3d Ed. 1991) (Excerpts) (“Sedra”)
1063-1066	RESERVED
1067	U.S. Patent No. 5,505,730 (“Edwards-’730”)
1068-1071	RESERVED
1072	Translator Declarations for Liang
1073-1080	RESERVED

Exhibit	Description
1081	Declaration of Gregory H. Lantier
1082	Declaration of Joshua L. Stern
1083	Reply Declaration of Dr. Gregory Martin ("Reply-Decl.")
1084	Transcript of the January 7, 2024, Deposition of Dr. Marom Bikson
1085	Exhibit A to the Deposition of Dr. Marom Bikson
1086	Exhibit B to the Deposition of Dr. Marom Bikson
1087	Exhibit C to the Deposition of Dr. Marom Bikson
1088	Exhibit D to the Deposition of Dr. Marom Bikson
1089	Exhibit E to the Deposition of Dr. Marom Bikson
1090	Exhibit F to the Deposition of Dr. Marom Bikson
1091	<i>How a Serial Entrepreneur Identifies and Evaluates Product Ideas and Brings Them to Market</i> , Mastering Medical Device, https://www.masteringmedicaldevice.com/episodes/wolf ("Wolf-Podcast-Ep.")
1092	RESERVED
1093	Howard L. Levine, Lasers in Endonasal Surgery, 30:3 OTOLARYNGOLOG. CLINICS OF N. AM. (June 1997) ("Levine-Article").
1094	Errata Sheet for the Transcript of the September 24, 2024 Deposition of Dr. Gregory Martin ("Martin-Tr.I-Errata")
1095	Errata Sheet for the Transcript of the September 25, 2024 Deposition of Dr. Gregory Martin ("Martin-Tr.I-Errata")