

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. IPR2024-00282

U.S. Patent No. 11,766,286

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 have merit.

PO improperly contends claim 1 requires unrecited limitations and then incorrectly asserts the prior art fails to teach the unrecited features. POR, 14-278. 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 '286 patent and as PO's expert drew at his deposition.

PO arguments regarding dependent claims 3, 4, and 7, also fail. For claim 3, PO does not address any substantive issue and instead relies on a mischaracterization of the Petition to contend Petitioners have failed to meet their burden. For claim 4, PO relies on an unsupported narrow reading of the prior art to argue the prior art does not disclose the required claim limitations. For claim 7, PO relies yet again on

unrecited claim requirements to contend the claims are patentable. 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. I.D., 17. 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, 14-27. 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 In View of Stern and Makower In View of Stern and Edwards-'535 Teaches “multiple pairs of bipolar radiofrequency electrodes”

Petitioners showed that Edwards-'535 in view of Stern (Ground I) and Makower in view of Stern and Edwards-'535 (Ground III) render obvious “multiple pairs of bipolar radiofrequency electrodes.” Pet., 33-40, 67-71; Ex.1002, ¶¶103-133, 238-254. PO argues that Stern does not disclose this limitation because its pairs are not active “at the same time.” POR, 14-19. 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.1082-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, 18, 24. The Board should reject PO’s arguments. Ex.1083-Reply-Decl., ¶17.

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. June 22, 2023). The '286 patent explicitly discloses activating each electrode pair separately. Ex.1001-USP286, 49:10-49:12 ("each pair of electrodes may have a ***separate, controlled electrical channel*** to allow for different regions of the treatment element to be ***activated separately***"), 24:56-62 (explaining that electrode pairs "may be ***individually controlled*** to produce an optimal treatment effect."); 49:32-38 (describing "multiplexed configuration" allowing any electrodes to be paired); 49:60-50:1 (same); 20:39-42 (controlling electrodes "individually or in selected groups."). Ex.1083-Reply-Decl., ¶¶19-21.

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 and 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 ’286 patent’s description. Ex.1001-USP286, 24:56-66. 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, which results in a single electrode pair. POR, 14, 19. The Petition identifies multiple activation examples in Stern, including both one-at-a-time *and* activating all pairs simultaneously. Pet., 35-41, 82-87. Ex.1002, ¶111. Stern must be considered as a whole, including this example. *Sony Interactive Entertainment LLC v. Intellectual*

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

Pixals Ltd., 2023 WL 6773879, *4 (Fed. Cir. Oct. 13, 2023) (holding that “[t]he Board erred when it narrowed the disclosure” in a reference to exclude an expressly-disclosed example “and only focused on the more detailed examples”). Ex.1083-Reply-Decl., ¶¶23-28.

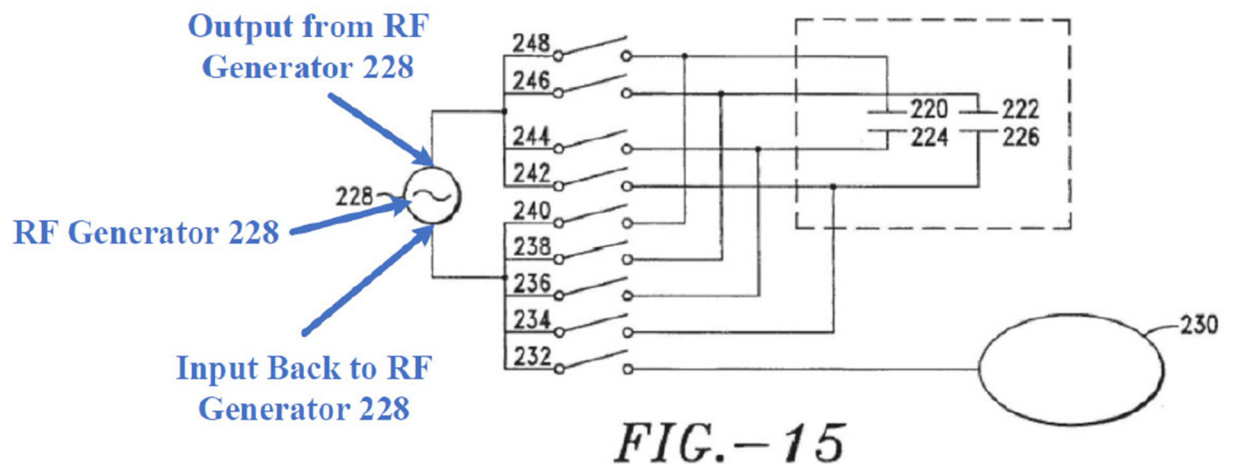
2. Edwards-535 In View of Stern and Makower In View of Stern and Edwards-’535 Teaches “multiple radiofrequency output channels”

The Petition showed that Edwards-’535 in view of Stern (Ground I) and Makower in view of Stern and Edwards-’535 (Ground III) render obvious “multiple radiofrequency output channels.” Pet., 40-43, 71-72; Ex.1002-Decl., ¶¶134-158, 255-267. PO argues this limitation requires multiple radiofrequency output channels to be connected directly to the voltage source or generator. POR, 19-24. 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”

To distinguish Stern’s disclosure of a switching arrangement that provides multiple output channels to respective electrodes (Pet., 40-43, 71-72), 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,

19-25; Ex. 1082-Bikson-Tr., 185:16-19. PO contends that Stern does not disclose the “multiple radiofrequency output channels” because Stern shows only two wires connected to its voltage source 228, which PO contends is equivalent to the system’s RF generator:



POR, 23 (PO’s annotation of Stern’s Figure 15); *see also* Ex.2001-Bikson-Decl., ¶79 (providing a similar annotation of Figure 15 that points to “two wires” connected to the voltage source). The Board should reject PO’s arguments for three reasons. Ex.1083-Reply-Decl., ¶30.

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 particular 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 7 and 8. Claim 7 makes clear that even when the generator is included it 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., ¶¶31-32.

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-USP286, 49:19-24. Every discussion of “electrical channel” or “output channel” in the ’286 patent refers to connections to *electrodes*—not wires within a generator. Ex.1001-USP286, 24:56-65, 49:10-12, 49:19-25, 49:26-28, 49:24-26, 49:38-40, 49:51-54, 50:12-16, 50:20-27; *see also* FIGs. 39, 40, 42A-42B, 43, 44. The ’286 patent’s discussions of multiplexing further confirms that output channels are electrical connections between chosen pairs of electrodes. *Id.*, 10:54-57 (“an electrode array arranged in a multiplexed configuration allow[s] pairing of any of the positive electrodes to any of the negative electrodes to form a complete circuit”); 49:32-46 (similar); 49:60-50:7 (similar); FIG.40, 42A-42B.

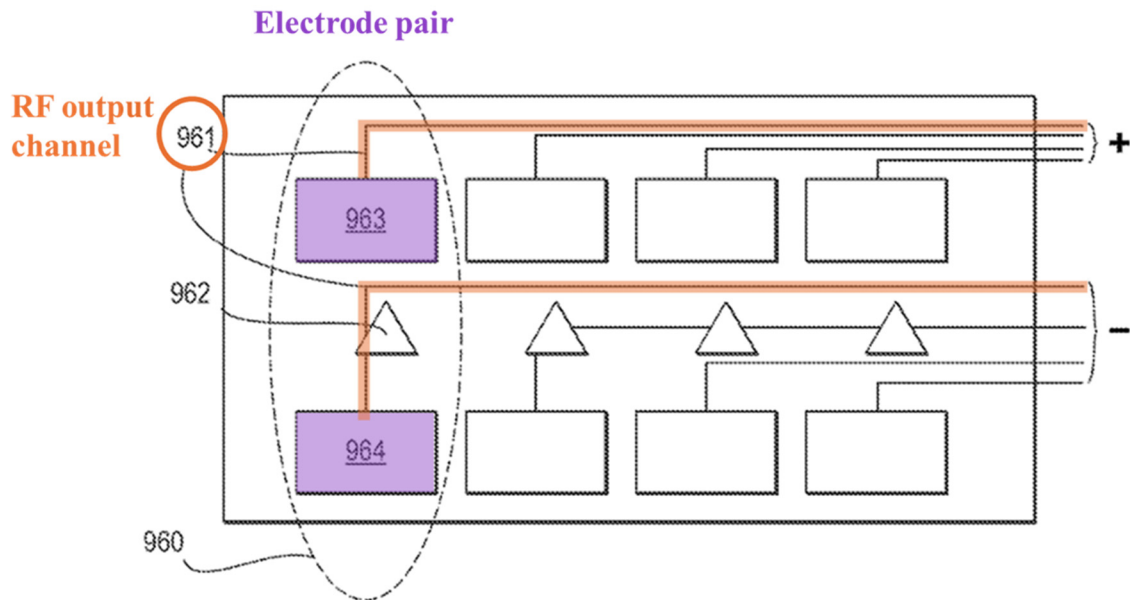


FIG. 39

Ex.1001-USP286, FIG.39; 49:19-23 (“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.*, 50:19-16, FIG. 44 (showing multiple output channels to different electrodes paired with a single return electrode). Ex.1083-Reply-Decl., ¶¶33-40.

The '286 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., ¶¶34-40.

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, ¶¶66-80), which was refuted at his deposition (*see* Section II.A.2.b. *infra*). PO’s mischaracterizations of Dr. Martin’s testimony (POR, 20-23) do not outweigh the intrinsic record of the patent. Ex.1002, ¶¶134-158, 255-267. 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.-Vol.2, 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.

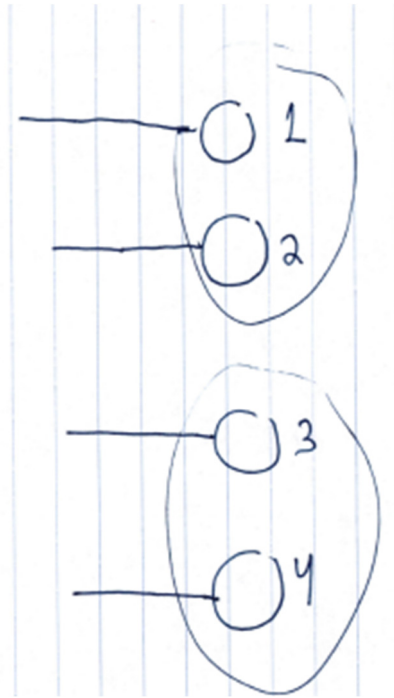
b. The prior art discloses “multiple radiofrequency output channels” under either construction

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., 40-43, 71-72; Ex.1002, ¶¶134-158, 255-267. 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 U.S. Patent No. 11,033,318 patent].”³ Ex. 1082-Bikson-Tr.,194:13-15. Dr. Bikson drew the following:

² The term “multiple radiofrequency output channels” was not addressed during prosecution. *See* Pet., 16-17.

³ Dr. Bikson’s drawing applies with equal force to the ’286 patent claims because the ’286 patent is the direct continuation of the ’318 patent and includes the same claim limitation.



Ex.1087. He explained:

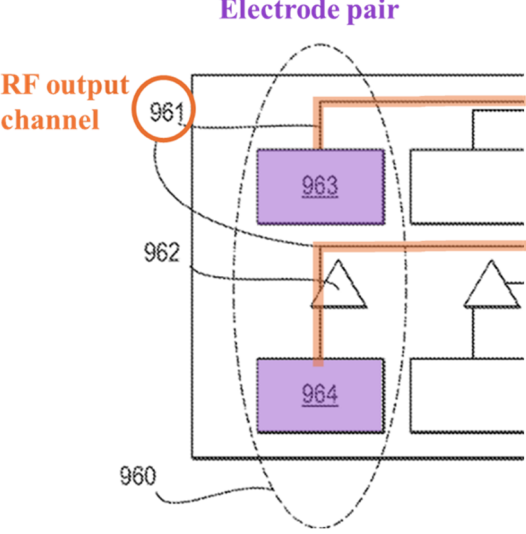
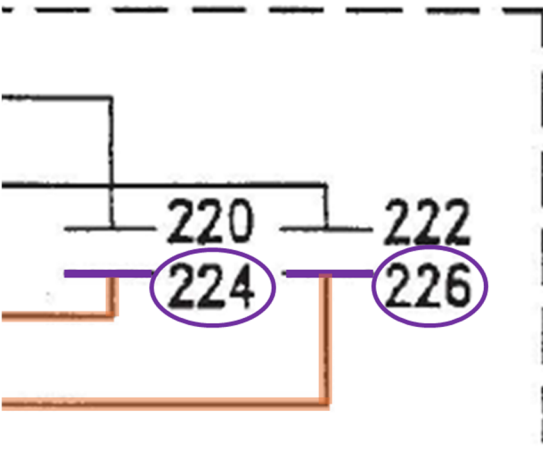
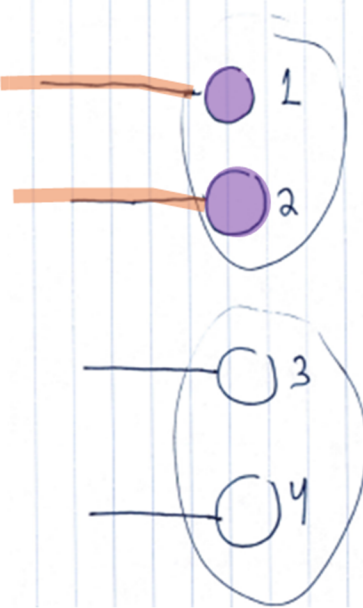
And I'm drawing wires going to electrodes one and two. And I'm drawing wires going to electrode three and four. And I guess I'll put a circle around one and two and around three and four, so each -- this is one bipole and this is another bipole. And the wires coming to them would represent one channel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

Ex. 1082-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., 96:6-11.⁴ Dr. Bikson's drawing is consistent with the '286 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):

⁴ 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., 35-43, 58-60, 68-72.

Ex.1001-USP286, FIG.39.	Ex.1033-Stern, FIG.15.
	
Ex.1087-Bikson-Dep-Ex.E	
	

Ex.1083-Reply-Decl., ¶¶48-49.

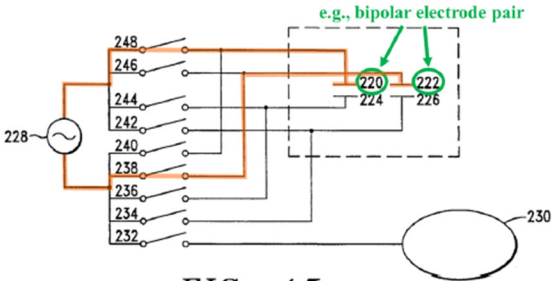
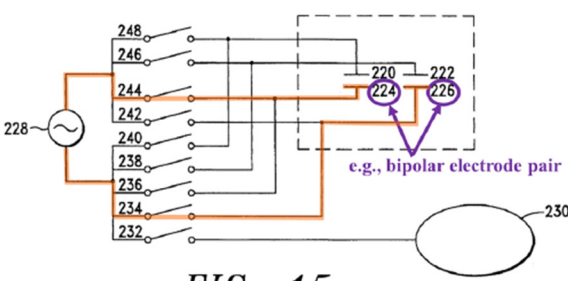
3. **Edwards-535 In View of Stern and Makower In View of Stern and Edwards-’535 Teaches “wherein each pair of the**

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., 41-43 (citing Ex.1033-Stern, 2:49-53, 3:12-29, Clm.1, FIG.15. Ex.1002-Decl., ¶¶135-138); *see also* Pet., 40-43, 71-72. *See* Ex.1002-Decl., ¶137 (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**:

Ex.1033-Stern, FIG.15 e.g., one pair of bipolar RF electrodes connected with an output channel	Ex.1033-Stern, FIG.15 e.g., another pair of bipolar RF electrodes connected with an output channel
 FIG. - 15	 FIG. - 15

Pet., 41-42; Ex.1002-Decl., ¶135. 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 3 Is Obvious

1. **Edwards-’535 In View of Stern and Makower In View of Stern and Edwards-’535 Teaches “wherein at least one electrode of the multiple pairs of bipolar radiofrequency electrodes is coupled with each of the multiple segments”**

The Petition demonstrated how claim 3 is obvious. Pet., 49-51, 77-78, 88. PO does not raise any specific dispute for claim 3 as to the combination of Makower and Stern and Edwards-’535 (Ground III). POR, 36. As to Edwards-’535 and Stern (Ground I), PO argues that Petitioners failed to establish that a “POSITA would have

been motivated to use Stern's electrode configuration in Edwards-'535's device." POR, 28. This argument is based on PO's position that the sole basis for Petitioners' motivation to combine for claim 3 is based on an incorporation of the positions for claims 1 and 2. *Id.* According to PO, the only motivations set forth in claims 1 and 2 of the Petition relate to the motivation for a POSITA to use Stern's handle and Figure 15 schematic in Edwards-'535's device, and the motivation to segment Edwards-'535's expandable member. *Id.*, 28-29. Ex.1083-Reply-Decl., ¶¶54-55.

PO's argument relies on a mischaracterization of the Petition. The Petition incorporates the explanation for claims 1 and 2 regarding how a POSITA would have been motivated to use the electrode configuration in Edwards-'535 as taught by Stern. Pet., 50; Ex.1002-Decl., ¶179. Regarding claim 1, the Petition expressly describes improving Edwards-'535's device by "hav[ing] more than one pair of bipolar electrodes to allow for selective tissue destruction over an entire area of tissue, as opposed to a single discrete portion." Pet., 38. That discussion cites portions of Stern that discuss electrode configurations (Ex.1033-Stern, 10:55-65) and Dr. Martin's extensive explanation about such configurations (Ex.1002-Decl., ¶¶116-121). Regarding claim 2, the Petition describes how a POSITA would have been motivated to segment Edwards-'535's expandable member "to permit controlled delivery of power to each segment" as taught by Stern. Pet., 48. The

Petition also *shows* “at least one electrode of the multiple pairs of bipolar radiofrequency electrodes is coupled with each of the multiple segments” as required by claim 3. Pet., 48 (citing Ex.1033-Stern, 8:53-59 and Ex.1002-Decl. ¶¶171-173). Ex.1083-Reply-Decl., ¶¶56-58.

These motivations clearly set forth why a POSITA would have been motivated to use Stern’s particular arrangement of electrodes in the Edwards-’535 device to achieve independent control over bipolar electrode pairs on different segments. As explained in the Petition, amongst other reasons, this arrangement and control scheme provide even heating and precise control over an entire area. *See, e.g.,* Pet., 38, 48-49. PO does not dispute that these motivations would apply to claim 3. Ex.1083-Reply-Decl., ¶¶56-58.

C. Claim 4 Is Obvious

Petitioners showed how Makower in view of Stern and Edwards-’535 renders obvious claim 4 (Pet., 78-79), which requires “the multiple segments are preshaped and comprise a shape-memory alloy material configured to expand to a desired size and shape.” Ex.1001-USP286, cl.4. PO argues Makower does not teach that its strut members 214 are made of any particular material, including nitinol, and that

Petitioners do not propose modifying Makower's struts to include nitinol.⁵ POR, 37-40. PO is incorrect. Ex.1083-Reply-Decl., ¶59.

The Petition clearly explained how a "POSITA would have understood that Makower suggests that strut members 214 are mechanically shaped, or pre-shaped, and made out of a shape memory alloy to facilitate collapse and expansion." Pet., 79. The Petition further explained that Makower teaches that "strut members 214 may be collapsible and expandable." Pet., 78 (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., 78 (citing Ex.1021-Makower, [0194]). This is the exact same mapping that the Examiner applied when it found that Makower anticipated a similar claim during prosecution of the patent application.⁶ Ex.1063-USP318FH, 509; Pet. 17. Ex.1083-Reply-Decl., ¶¶60-62.

⁵ To be clear, claim 4 requires that the segments be made of a "shape-memory alloy material."

⁶ PO overcame Makower by amending the independent claims. Pet., 18-19.

Makower's disclosure that components other than the elongate flexible device shown in Figure 5H can be made from nitinol (or a nickel titanium alloy) does not negate Makower's clear 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., ¶¶63-66.

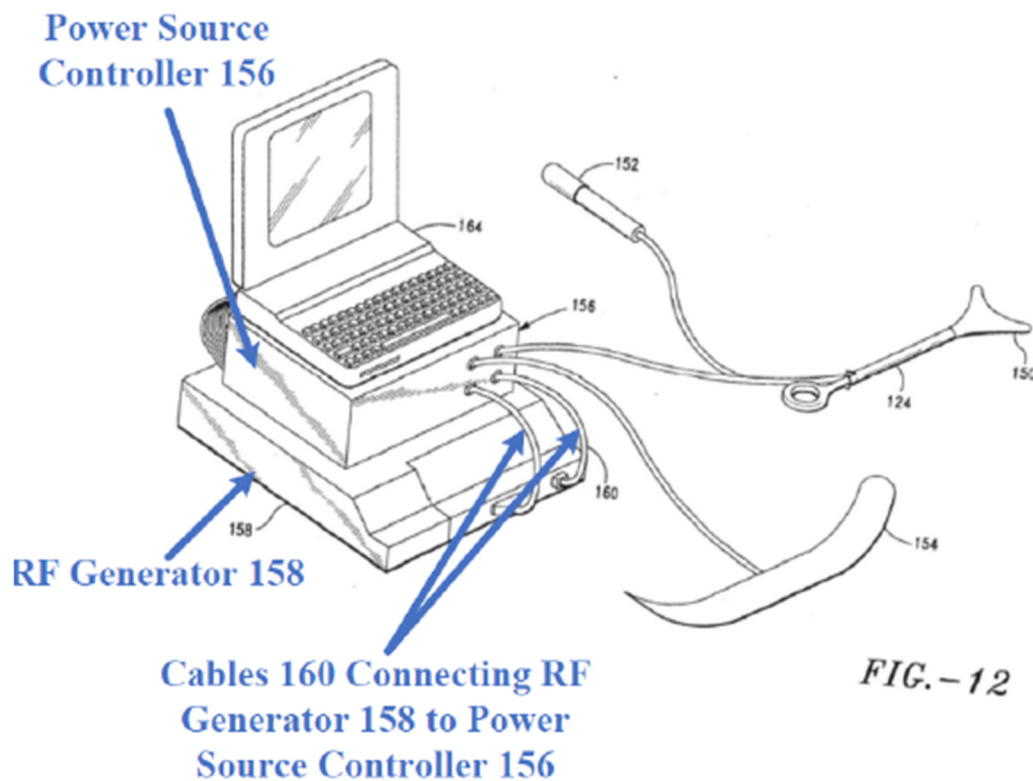
D. Claim 7 Is Obvious

Petitioners demonstrated that Claim 7 is obvious. Pet., 51-54, 79-81, 88, 92. PO argues that the prior art fails to disclose limitation 7[a]: "a radiofrequency generator configured to...deliver radiofrequency energy separately to each of the multiple radiofrequency output channels" and limitation 7[b]: "a cable coupled to the handle for plugging the handle into the radiofrequency generator." POR, 29-35, 40-41. PO's arguments fail. Ex.1083-Reply-Decl., ¶¶67-69.

1. Edwards-535 In View of Stern, and Makower In View of Stern and Edwards-'535 Teaches Limitation 7[a]

PO does not dispute that the prior art teaches delivering energy to a single pair of electrodes at a time. Pet., 51-53, 79-80. 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 alleges that RF generator 158 does not deliver radiofrequency 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, 31-33.



POR, 32. This argument fails for at least two reasons. Ex.1083-Reply-Decl., ¶70.

First, PO again takes an improperly narrow view of the claim limitation that is contradicted by the disclosure in the '286 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-USP286, 16:36-40, 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-USP286, 16:50-66. The patent notes that the generator may be “part of a *separate assembly* that delivers energy or control signals.” Ex.1001-USP286, 34:43-45. Ex.1083-Reply-Decl., ¶¶71-72.

Nowhere in the '286 patent does it describe what PO claims—that to “deliver radiofrequency energy separately,” the generator must have multiple output ports.⁷ 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 with thermistor temperature feedback to bring the endometrial

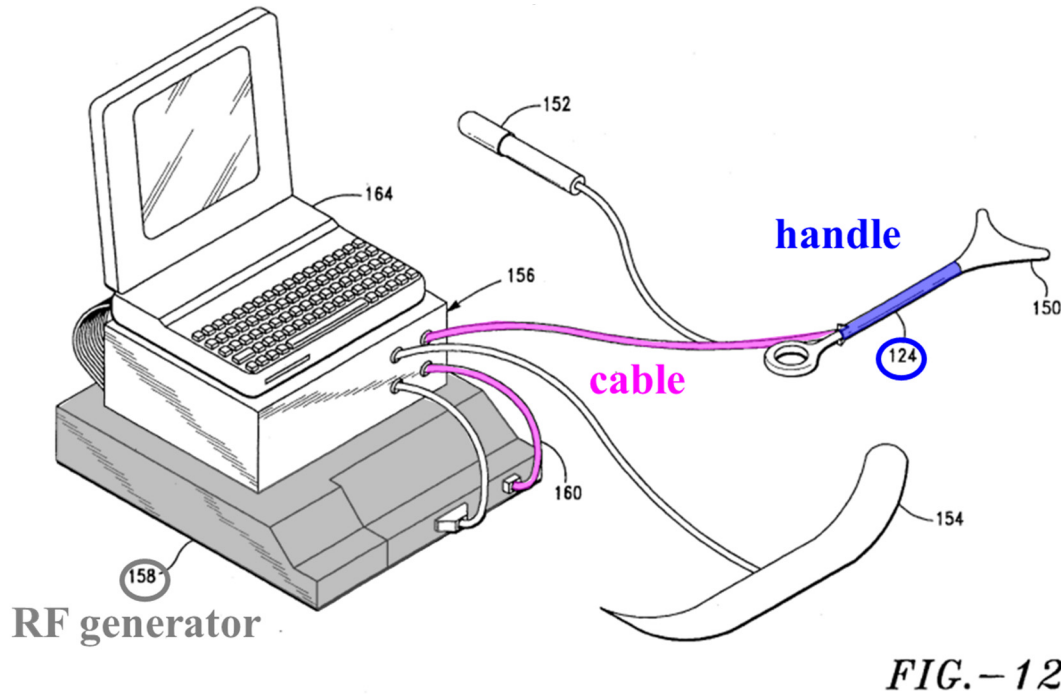
⁷ As explained above (*see* note 4), Stern’s design provides separate, independent control of energy delivered through the different electrode pairs. Pet., 41-45; Ex.1002-Decl., ¶¶255-267.

temperature up to a desired level.” Ex.1033-Stern, 10:33-53. This discloses the claim limitation. *See* Ex.1001-USP286, FIG.22A. Ex.1083-Reply-Decl., ¶¶73-75.

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—which delivers energy independently to electrodes, as modified by Stern’s teaching regarding how to do so. Pet., 53. That is, a POSITA would have been motivated to modify Edwards-’535’s generator to include the functionality of Stern’s controller. *Id.*, 54-57. Thus, whether Stern discloses a separate RF generator and controller is irrelevant to the proposed combination. Ex.1083-Reply-Decl., ¶76.

2. Edwards-535 In View of Stern, and Makower In View of Stern and Edwards-’535 Teaches Limitation 7[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. POR, 34-35. For at least three reasons, PO’s position is baseless.



Pet., 53-54. Ex.1083-Reply-Decl., ¶¶61-66.

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-USP286, FIG.22A. Ex.1083-Reply-Decl., ¶80.

Second, the ’286 patent does not indicate that the cable must *directly connect* the generator to the handle. As discussed in Section II.A.2., the patent explains that

the generator may be separate from a control system “that delivers energy or control signals.” Ex.1001-USP286, 5:28-33, 16:36-44, 16:50-66, 34:43-47, FIG.3. Therefore, the patent contemplates a control system between the generator and handle. Stern therefore teaches this limitation. Ex.1083-Reply-Decl., ¶¶70-76.

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. That is, Edwards-’535’s generator would have been modified to include a cable to plug Edwards-’535’s device into the generator. *Id.*, 54-57. 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., ¶76.

E. Claims 2, 8, and 9 Are Obvious

PO’s arguments regarding claims 2 and 9 (Grounds I, III) and claim 8 (Grounds I, III, and IV) are based solely on their dependency on claim 1. POR, 27, 36; POR, 27, 36, 41. These claims are therefore also obvious for the reasons discussed above. *See* Pet., 46-49, 54-60, 76-77, 81-82. Ex.1083-Reply-Decl., ¶83.

F. Grounds V-VII Further Demonstrate Unpatentability of the Challenged Claims

Neither Petitioners nor PO contend the preamble is limiting. Pet. 18-19. The Petition nonetheless showed that, if limiting, the preamble would have been obvious in further view of Liang (Pet., 83-92), which PO does not dispute. Therefore, should the Board find that preamble's statement that the claimed device "treat rhinitis" is limiting, Grounds V-VIII demonstrate unpatentability of the challenged claims. *See* Pet., 83-92. Ex.1083-Reply-Decl., ¶84.

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.⁸

Regardless, PO's purported reasons to winnow Neurent's POSITA definition are not supported by the evidence. *Godbersen-Smith Construction Co.*, IPR2021-

⁸ 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 its Reply filed in IPR2024-00277.

00136, Paper 61 at 23-27 (refusing to limit level of ordinary skill to only design/development experience).

- The Challenged Claims recite only a generic, not specialized, device for “delivering energy to a nasal airway.” Ex.1001-USP286, cl.1.
- RF devices were known and used safely and effectively by clinicians, including in the nose. Ex.1001-USP286, 19:62-20:13; Pet., 9-13; 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.1082-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 already of record in this proceeding appear in *medical* journals and address the problem of treating rhinitis by selecting settings for various 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

appearing in the MEDLINE and Cochrane Controlled Trials Register databases); 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., ¶¶85-88.

IV. CONCLUSION

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

Respectfully submitted,

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Counsel for Petitioners

CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing, Petitioners' Reply, contains 4,657 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/
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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. 11,766,286 (“’286 patent”)
1002	Declaration of Dr. Gregory Martin (“Decl.”)
1003	File History of U.S. Patent No. 11,766,286
1004-1005	RESERVED
1006	District Court Amended Complaint
1007	District Court Amended Complaint Exhibit BB
1008	DocketNavigator Statistics for Delaware District Court 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	Chen et al., Radiofrequency Treatment of Nasal Posterior-Under Nerve, Ethmoidal Nerve and Infratubinal for Perennial Allergic Rhinitis Under Nasal Endoscope, CHINA J. ENDOSCOPY 11:3 (2005) (English translation) (“Chen”)
1018-1020	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”)
1025-1028	RESERVED
1029	Arora et al., Cryodestruction of Vidian Nerve Branches, INDIA J. OTOLARYNGOLOGY 32:3 (1980) (“Arora”)
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

Exhibit	Description
	Complications, 266 EUR. ARCH. OTORHINOLARYNGOL. (2009) ("Hytonen")
1032	RESERVED
1033	U.S. Patent No. 5,562,720 ("Stern")
1034	U.S. Patent Application No. 2007/0287994 ("Patel")
1035	M. Philippson, Principles of Electrical Resistance of Living Tissue, BULL. CL. SCI. ACAD. R. BELG. ser. 5, vol. 7 (1921) (English Translation) ("Philippson")
1036-1037	RESERVED
1038	U.S. Patent No. 6,109,268 ("Thapliyal")
1039	RESERVED
1040	Kong et al., Clinical Observation on Radiofrequency Ablation Treatment in Perennial Allergic Rhinitis, J. CLIN OTORHINOLARYNGOL (China) Vol.19, No.5 (2005) (English translation) ("Kong")
1041	RESERVED
1042	Bäck et al., Submucosal Bipolar Radiofrequency Thermal Ablation of Inferior Turbinates: A Long-Term Follow-up with Subjective and Objective Assessment, LARYNGOSCOPE 112 (2002) ("Back")
1043	RESERVED
1044	Lee et al., Surgical Management of Turbinate Hypertrophy in the Office: Three Mucosal Sparing Techniques, OPERATIVE TECHNIQUES IN OTTOLARYNGOLOGY--HEAD AND NECK SURGERY 12:2 (2001) ("Lee")
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")

Exhibit	Description
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	Fang et al., Nasal Endoscopy Combined with Multiple Radiofrequency for Perennial Allergic Rhinitis, J. FIRST MIL MED UNIV 25:7 (2005) (“Fang”)
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”)
1057-1058	RESERVED
1059	CN Patent No. 2225227Y (“Liang-’271”)
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) (“Sedra”)
1063	File History of U.S. Patent No. 11,033,318
1064-1066	RESERVED
1067	U.S. Patent No. 5,505,730 (“Edwards-’730”)
1068-1068	RESERVED
1070	Declaration of June Munford
1071	Translator Declarations for Chen
1072	Translator Declarations for Liang
1073	Translator Declarations for Fang
1074	Translator Declarations for Kong
1075	Munford Appendices for Chen
1076	Munford Appendices for Liang
1077	Munford Appendices for Fang
1078	Munford Appendices for Kong
1079	Appendices to Munford Declaration
1080	Translator Declaration for Liang ’227

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.II-Errata”)