

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. IPR2024-00277

U.S. Patent No. 11,241,271

PETITIONERS' REPLY TO PATENT OWNER'S RESPONSE

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I. INTRODUCTION

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

First, PO seeks to advance improper interpretations of claim 1 that require unrecited features and incorrectly asserts that Stern is missing those features. POR, 19-32. But contrary to PO's arguments, claim 1 does not require the bipolar electrode pairs to be active "at the same time"; even if it did, Stern satisfies this incorrect interpretation by disclosing that its pairs can be "utilized together." Ex.1033-Stern, 13:39-43. Claim 1 likewise does not require multiple pairs per row of bipolar electrode pairs, and even if it did, Stern satisfies this incorrect interpretation by disclosing, in Figure 4a, an embodiment with two rows of electrodes and multiple bipolar pairs in each row.

Second, PO disputes two reasons that Petitioners identify as supplying a motivation to combine Edwards-'535 and Stern. POR, 32-39. However, PO ignores many other reasons that Petitioners identify. These un rebutted reasons alone are sufficient to establish motivation. Moreover, the narrow disputes that PO does raise are irrelevant. Even if Edwards-'535 does not incorporate Baker by reference "in its entirety," as PO contends, Edwards-'535 directs a POSITA to Baker, and Baker has similar embodiments to Stern. And regardless of PO's argument that alternative

electrode configurations could have produced similar benefits to Stern's configuration, Stern's electrode configuration had known benefits that would have motivated a POSITA to apply these teachings to Edwards-'535.

PO's only additional disputes relate to dependent claims 11 and 16. PO's arguments for these claims are based on an incorrect reading of the references and supported only by the testimony of an expert who lacks the relevant clinical experience to inform his opinions on those claims.

Facing preponderant obviousness, PO resorts to disparaging Petitioners' eminently qualified expert, Dr. John DelGaudio, despite raising *no issue* on which he is unqualified to opine. Most issues are undisputed and where the parties' declarants disagree, the weight of evidence supports Petitioners. The Board should cancel all Challenged Claims.

II. PO'S EXPRESS CONSTRUCTION OF CLAIM 1 IS UNNECESSARY BECAUSE THERE IS NO DISPUTE THAT THE PETITION'S COMBINATIONS CARRY OUT THE CLAIM STEPS IN THEIR RECITED ORDER

PO seeks a construction requiring that the method steps of claim 1 "be performed in their specified, sequential order." POR, 15. The Board need not adopt

this construction, as PO advances no arguments that the prior art does not meet it.¹ *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (claim terms need only be construed to the extent necessary to resolve the controversy). Petitioners' combinations carry out the steps of claim 1 in the order recited. Pet., 34, 49-51, 79-82; Ex.1002-DelGaudio-Decl., ¶¶83, 95, 100. Ex.1083-DelGaudio-Reply-Decl., ¶¶18-19.

III. PO'S ARGUMENTS DO NOT ESTABLISH THAT THE CHALLENGED CLAIMS ARE PATENTABLE

A. Claim 1 Is Obvious

PO argues the prior art does not disclose “two rows of bipolar electrode pairs” or “applying radiofrequency energy with the bipolar electrode pairs” as required by claim 1. POR, 19-32. These 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.

¹ To the extent PO raises any specific argument in its Sur-reply, that argument is waived. Paper 10 (Scheduling Order), 10.

1. Edwards-'535 In View of Stern Renders Obvious "bipolar electrode pairs"

Petitioners showed that Edwards-'535 in view of Stern renders obvious "bipolar electrode pairs." Pet., 38-47; Ex.1002-DelGaudio-Decl., ¶¶92-94. PO argues that Stern does not disclose this limitation because its pairs are not active, i.e., delivering energy, "at the same time." POR, 19-22. However, the challenged claims do not require multiple pairs to be active at the same time and, even if they did, Stern discloses this limitation. Ex.1097-Martin-Reply-Decl., ¶¶14-16.

a. "Bipolar electrode pairs" need not be active "at the same time"

Stern discloses "pairs" of bipolar electrodes nine separate times, Ex.1033-Stern, 2:36-40, 3:37-39, 12:19-22, 12:22-24, 12:29-33, 13:27-31, 13:31-38, 13:39-42, 20:6-9, and there is no dispute that Stern discloses at least two different bipolar electrode pairs, Ex.1084-Bikson-Tr., 107:16-108:9, 109:4-12, 112:4-12, 113:3-116:20. Stern also expressly discloses activating those pairs at the same time, *see* Section III.A.1.b below. PO nevertheless argues, incorrectly, that it can avoid Stern's teachings if the claims are interpreted to require bipolar pairs that are active "at the same time." POR, 21-22. The Board should reject PO's arguments, starting with PO's improper attempt to add unrecited features to the claim language. Ex.1083-DelGaudio-Reply-Decl., ¶20; Ex.1097-Martin-Reply-Decl., ¶17.

First, the claims do not recite that the “pairs” must be active “*at the same time*,” nor does anything else in the claims suggest this unrecited feature. The claims simply require “bipolar electrode pairs,” i.e., more than one pair, which Stern undisputedly discloses. Ex.1083-DelGaudio-Reply-Decl., ¶¶21-22; Ex.1097-Martin-Reply-Decl., ¶18.

Second, PO’s arguments would exclude a preferred embodiment, which is “rarely, if ever, correct.” *Broadcom Corp. v. Netflix, Inc.*, 2023 WL 4115909, at *1 (Fed. Cir. 2023). The ’271 patent describes activating electrode pairs separately and individually. Ex.1001-USP271, 23:64-24:1 (“each pair of electrodes (bipolar) ... may have a *separate, controlled electrical channel* to allow for different regions of the treatment element to be *activated separately*”), 24:1-3 (electrode pairs “may be *individually controlled*”). Ex.1083-DelGaudio-Reply-Decl., ¶23; Ex.1097-Martin-Reply-Decl., ¶¶19-21.

Accordingly, the term should be given its plain and ordinary meaning, which encompasses multiple pairs that are not necessarily active “at the same time,” 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 pairs “at the same time.” For example, Stern states that “*any combination of pairs*

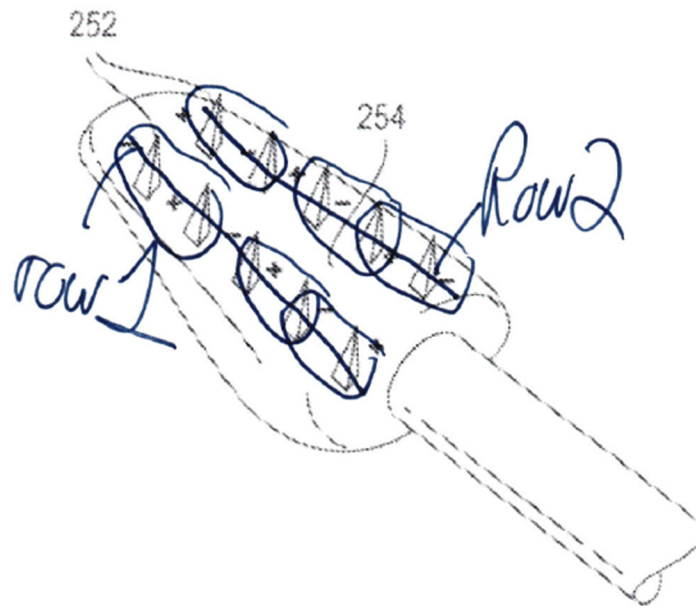
of electrodes [in Figure 15] may be *utilized together*” and therefore expressly contemplates activating pairs at the same time. Ex.1033-Stern, 13:39-43 (cited at Pet., 39). This is similar to the '271 patent's description. Ex.1001-USP271, 23:64-24:4. Ex.1083-DelGaudio-Reply-Decl., ¶¶24-26; Ex.1097-Martin-Reply-Decl., ¶¶22-24.

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, 31. The Petition identifies multiple activation examples in Stern, including both one-at-a-time *and* activating all pairs in the array simultaneously. Pet., 38-41, 51; Ex.1002-DelGaudio-Decl., ¶¶92-94. The Petition also identifies two different pairs of electrodes distributed across two different rows. Pet., 41; Ex.1002-DelGaudio-Decl., ¶92. Stern must be considered as a whole, including these examples. *Sony Interactive Entertainment LLC v. Intellectual Pixals Ltd.*, 2023 WL 6773879, *4 (Fed. Cir. 2023) (focus on “more detailed example” to exclusion of additional example erroneous). Ex.1083-DelGaudio-Reply-Decl., ¶25; Ex.1097-Martin-Reply-Decl., ¶¶25-28.

2. Edwards-'535 In View of Stern Renders Obvious “two rows of bipolar electrode pairs”

Stern clearly discloses “two rows of bipolar electrode pairs,” as required by claim 1. Pet., 47-49; POR, 23. In an attempt to avoid this disclosure, PO seeks to

add yet another unclaimed requirement—that the rows of bipolar pairs must have *multiple pairs in each row*. POR, 23-30; Ex.1084-Bikson-Tr., 136:15-22. Dr. Bikson provided the following annotations to Figure 8F of the patent at his deposition to explain PO's position:



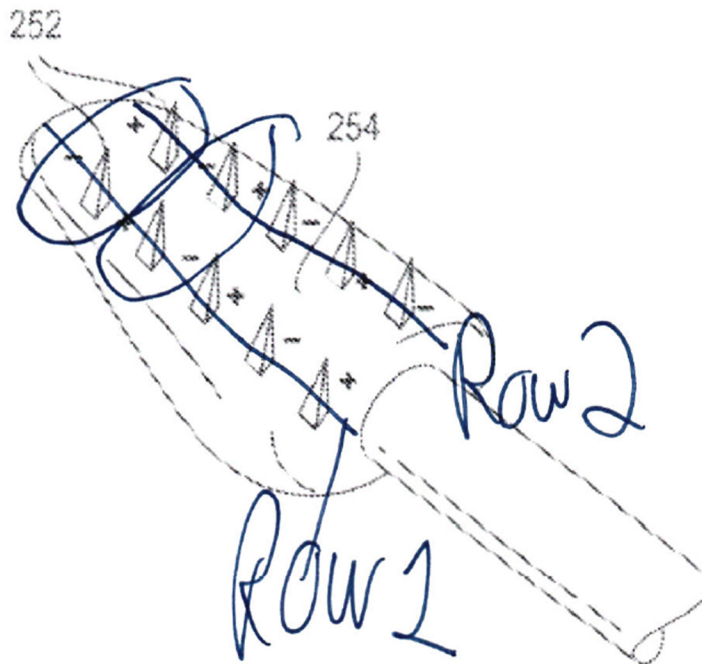
Ex.1086-Bikson-Tr.-Ex.-B. As above, this interpretation is not only wrong but also inconsequential. Ex.1083-DelGaudio-Reply-Decl., ¶¶27-28; Ex.1097-Martin-Reply-Decl., ¶29.

a. “Two rows of bipolar electrode pairs” need not have *multiple pairs within each row*

First, the use of “pairs” (plural) in the phrase “two rows of bipolar electrode pairs” does not necessitate *multiple pairs within each row*. PO's argument incorrectly assumes that the “s” in “pairs” modifies pairs within a single row.

Ex.1084-Bikson-Tr., 136:15-22. This unsupported assumption would improperly exclude preferred embodiments. The specification confirms the pluralization simply requires multiple pairs in the two rows, i.e., it reflects the presence of multiple pairs *either* in a single row *or* in the two rows, which Stern undisputedly discloses. POR, 23-25. Ex.1083-DelGaudio-Reply-Decl., ¶¶29-31; Ex.1097-Martin-Reply-Decl., ¶30.

The '271 patent only uses the term “row” to describe an arrangement where “radio frequency energy travels from one row of electrodes to the other row of electrodes.” Ex.1001-USP271, 8:21-25, Abstract. Thus, using Dr. Bikson’s annotations of Figure 8F, the pairs are arranged as follows:



Ex.1087-Bikson-Tr.-Ex.-C. Figure 8F's description makes this clear, explaining that its pairs are arranged "side-by-side" whereas, in contrast, the pairs in Figure 8G are arranged "along the length of the treatment element." Ex.1001-USP271, 23:56-59.² Ex.1083-DelGaudio-Reply-Decl., ¶30; Ex.1097-Martin-Reply-Decl., ¶¶31-32.

The above arrangement has no pairs within a single row—pairs are formed across rows, not within them. That is, each row contains one electrode—half—of a given pair and no complete pairs. The preferred embodiment is therefore excluded under PO's interpretation that requires multiple pairs within a single row. The preferred embodiment does, however, satisfy an interpretation that simply requires multiple pairs in the two rows. Ex.1083-DelGaudio-Reply-Decl., ¶31; Ex.1097-Martin-Reply-Decl., ¶¶31-32.

Second, even if the claim requires "pairs" in a single row, as PO argues, the Federal Circuit has repeatedly held that, in analogous circumstances, a plural term can be interpreted to require only one item. *Dayco Prod., Inc. v. Total Containment*,

² PO's expert agreed that the device shown in Figure 8F could be configured as annotated above (Ex.1084-Bikson-Tr., 158:11-160:9; Ex.1087-Bikson-Tr.-Ex.-C); however, without support, he contends this does not constitute "two rows of bipolar pairs." Ex.1084-Bikson-Tr., 241:13-19.

Inc., 258 F.3d 1317, 1328 (Fed. Cir. 2001) (phrase “plurality of ... projections with recesses therebetween” does not require “three or more projections” because “the use of ‘recesses’ can be understood to mean a single recess where there are only two projections and more than one recess where there are three or more projections”); *Versa Corp. v. Ag-Bag Intern. Ltd.*, 392 F.3d 1325, 1330 (Fed. Cir. 2004) (phrase “means for creating air channels,” plural, “does not imply that multiple channels are required”). Like the plural terms in *Dayco* and *Versa*, “pairs” in claim 1 can encompass one pair given that, as Dr. DelGaudio explained, “it’s grammatically incorrect to say two rows of bipolar pair ... [s]o it’s two rows of bipolar pairs.” Ex.2007-DelGaudio-Tr., 243:16-244:8. The patent itself adopts this usage. Ex.1001-USP271, 23:40-43 (“**one**, two, or many **pairs** of bipolar needles 252”).

Third, PO misrepresents Dr. Martin’s testimony, arguing that he agrees with its interpretation. POR, 24-25. However, in the cited testimony, Dr. Martin was asked only about a “**single row** of bipolar electrode pairs,” which is not claimed. POR, 24; Ex.2003-Martin-Tr., 285:10-11 (“So please draw for me a **single row** of bipolar electrode pairs”), 285:18-19, 285:21-22, 287:3-5 (“So you agree that row 1 of what you drew depicts a **single row** of bipolar electrode pairs; correct?”), 287:8-10, 287:13-15. Thus, far from supporting PO’s arguments, Dr. Martin’s testimony is consistent with his declaration—whereas “a single row of pairs” requires pairs

within a row, “two rows of pairs” does not. *Roku Inc. v. Universal Electronics Inc.*, IPR2022-01289, Paper 28 (Final Written Decision), 18 (PTAB, Mar. 20, 2024) (declining to rely on alleged expert admissions to construe claim term, reasoning that the testimony was off point and “extrinsic evidence”). Ex.1083-DelGaudio-Reply-Decl., ¶32; Ex.1097-Martin-Reply-Decl., ¶¶35-36.

Fourth, PO argues that its interpretation is necessary so “random arrangements do not fall within the scope of the claims.” POR, 27. PO does not dispute that Stern discloses *ordered* rows, so this argument is hypothetical and moot. Moreover, PO does not identify any authority that avoiding “random arrangements” is a proper reason to interpret a claim, and, even if it were, it still would not support the interpretation that PO advances. A construction can exclude random arrangements without further requiring *multiple pairs within each row*. Ex.1083-DelGaudio-Reply-Decl., ¶33; Ex.1097-Martin-Reply-Decl., ¶33.

Fifth, PO’s claim differentiation arguments lack merit. POR, 28. PO relies on the ’271 patent’s great-great-great-great grandparent patent and a separate patent (challenged in IPR2024-00278) that claims priority to applications in the ’271 patent’s priority chain to argue “two rows of bipolar electrode pairs” is different than “the multiple pairs of bipolar radiofrequency electrodes comprise two rows of electrodes.” POR, 28-29. Ex.1097-Martin-Reply-Decl., ¶34.

Contrary to PO's representations, the doctrine of claim differentiation is "not as strong across related patents as it would be if the different claim limitations appeared in the same patent." *Clare v. Chrysler Group LLC*, 819 F.3d 1323, 1330 (Fed. Cir. 2016). Claim differentiation also does not apply where, as here, PO's construction is contradicted by the plain language in the claim and the specification. *Mycogen Plant Sci. v. Monsanto Co.*, 243 F.3d 1316, 1329 (Fed. Cir. 2001). Finally, claim differentiation does not apply where differences exist among other claim limitations. *Apple, Inc. v. Ameranth, Inc.*, 842 F.3d 1229, 1238 (Fed. Cir. 2016). Here, the '301 patent requires applying "sufficient force to at least temporarily deform the at least one tissue," Ex.2008-USP301, 47:29-32, and the '318 patent requires several additional limitations, including "multiple radiofrequency output channels," Ex.2009-USP318, 52:27-32. Ex.1083-DelGaudio-Reply-Decl., ¶34.

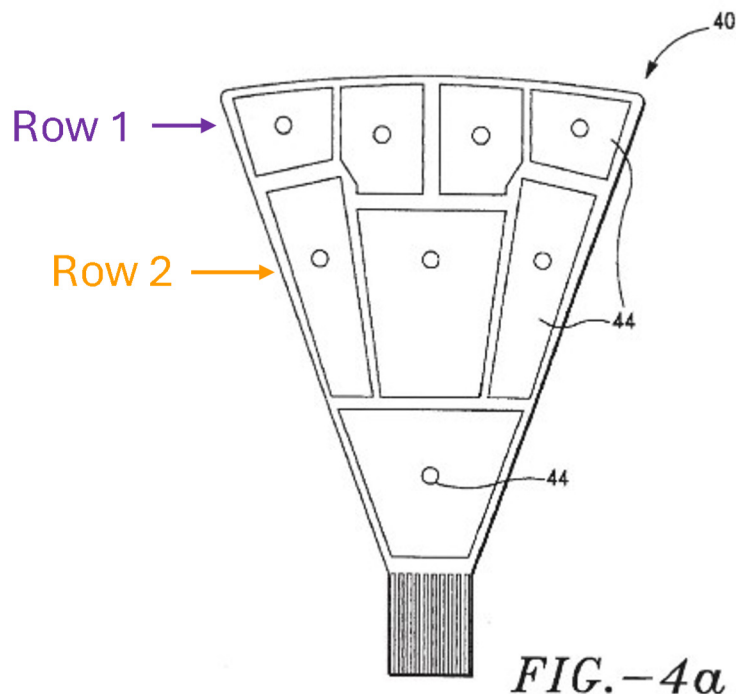
Accordingly, this term should be given its plain and ordinary meaning, which encompasses pairs arranged in two rows where there are not necessarily *multiple pairs within each row*, and which PO does not dispute is disclosed by Stern.

b. Stern teaches "two rows of bipolar electrode pairs" that have "*multiple pairs within each row*"

Even under PO's incorrect interpretation, Stern discloses arrangements of two rows with *multiple pairs within each row*. PO attempts to artificially restrict Petitioner's mapping for this limitation to the 2x2 array of electrodes described in

Stern's Figures 15 and 19. POR, 24-25. Neither Stern nor the Petition are so limited. Ex.1083-DelGaudio-Reply-Decl., ¶35; Ex.1097-Martin-Reply-Decl., ¶37.

As explained in the Petition, Stern discloses “various physical arrangements of electrodes on the surface of a bladder” along with “circuitry for selective delivery of bipolar RF energy to chosen pairs within the array.” Pet., 39-40 (citing Ex.1033-Stern, 2:36-40). The Petition thus also relied on the arrangement in Figure 4a (Pet., 46), which shows an ordered arrangement of electrodes that can be configured as a first row with four electrodes and a second row with three electrodes. Each row can thus have multiple pairs within the row.



Ex.1033-Stern, Figure 4a (annotated). Ex.1083-DelGaudio-Reply-Decl., ¶¶36;
Ex.1097-Martin-Reply-Decl., ¶¶38-41.

Stern further teaches how to configure these rows to have multiple bipolar pairs in each row. The circuitry to do so is described using Figure 15 (Pet., 39-41), which illustrates how to configure a “plurality of electrodes” for “either monopolar or bipolar operation.” Ex.1033-Stern, 5:48-50, 12:49-52, 13:39-43, Fig. 15. Although Figure 15 illustrates circuitry for a 2x2 array of electrodes, a POSITA would have readily applied these teachings to the array in Figure 4a—the simplicity evidenced by the fact that the '271 patent does not describe *any* circuitry to implement bipolar energy delivery. Petitioners' motivation to combine analysis applies equally to Stern's various electrode arrangements, including Figure 4a specifically. Pet., 46 (citing Figure 4a).³ Ex.1083-DelGaudio-Reply-Decl., ¶¶37-38; Ex.1097-Martin-Reply-Decl., ¶¶38-41.

³ Stern discloses various other arrangements of electrodes that satisfy PO's interpretation. For example, the fifth electrode at the bottom of Figure 19 could be activated, providing a third electrode for each of the rows. Ex.1033-Stern, Figure 19; Ex.2003-Martin-Tr., 278:5-279:6. Ex.1081-Reply-Decl., ¶¶39-40; Ex.1097-Martin-Reply-Decl., ¶39.

3. Edwards-535 In View of Stern Renders Obvious “applying radiofrequency energy with the bipolar electrode pairs”

Like the argument addressed in Section III.A.1 above, PO argues that “applying radiofrequency energy with the bipolar electrode pairs” requires applying energy through multiple bipolar pairs at the same time. POR, 30-32. PO’s attempt to add unrecited features is yet again wrong and irrelevant. Ex.1083-DelGaudio-Reply-Decl., ¶41.

a. “Bipolar electrode pairs” need not apply radiofrequency energy at the same time

First, contrary to PO’s interpretation, limitation 1[b] does not specify whether one, two, or more pairs are *active* when applying energy. POR, 30. The claim simply requires that the pairs collectively apply energy, which only requires one or more of the pairs to be active. *See Arlington Indus., Inc. v. Bridgeport Fittings, Inc.*, 632 F.3d 1246, 1254 (Fed. Cir. 2011) (“claims will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words of expressions of manifest exclusion or restriction”). Ex.1083-DelGaudio-Reply-Decl., ¶42.

Second, PO’s interpretation is also inconsistent with the specification, which, as explained above, discloses separate and independent pairs that need not be active

at the same time. *See, supra*, Section III.A.1; Ex.1001-USP271, 23:40-43, 23:64-24:4. Ex.1083-DelGaudio-Reply-Decl., ¶42.

Accordingly, the term should be given its plain and ordinary meaning, which encompasses applying energy with any one or more of the pairs, and which PO does not dispute is disclosed by Stern.

b. Stern teaches bipolar pairs that apply radiofrequency energy at the same time

Even under PO's incorrect interpretation, Stern teaches applying radiofrequency energy with the bipolar electrode pairs *at the same time* for the same reasons that Stern teaches activating multiple pairs "*at the same time.*" *See, supra* Section III.A.1.b. Ex.1083-DelGaudio-Reply-Decl., ¶43.

4. A POSITA Would Have Been Motivated To Combine Edwards '535 and Stern to Configure Edwards-'535's Bipolar Electrodes in Two Rows

PO disputes that Petitioners established a motivation to combine Edwards-'535 and Stern. POR, 32-39. But PO's arguments are so narrow that, even if they were correct (they are not), a POSITA would still have been motivated to combine Edwards-'535 and Stern for the reasons established in the Petition that PO has not even attempted to rebut.

First, PO does not challenge whether a POSITA would have been motivated to use Stern's bipolar electrode pairs in Edwards-'535's device, instead disputing

only whether a POSITA would have been motivated to implement Edwards-'535's bipolar electrodes in two rows as opposed to a single row. *See* POR, 32 (citing Petition at 47-49, but not Petition at 43-47). Generally, increasing the quantity of a component in a device that functions in the same, predictable way is not patentable. *Tyco Healthcare Group LP v. Ethicon Endo-Surgery, Inc.*, 774 F.3d 968, 978 (Fed. Cir. 2014).

Second, PO's narrow dispute is incomplete and leaves uncontested many motivations established in the Petition, including the following:

- Edwards-'535 “acknowledg[es] the need for selective delivery of energy to tissue...and giv[es] a POSITA discretion on how to implement that scheme.” Pet., 48.
- Edwards-'535's device and Stern's two rows of bipolar electrodes were “known prior art elements” that could be combined using “known methods.” *Id.*, 48-49.
- The combination involves “simply substituting” Edwards-'535's energy delivery device 134 with Stern's two rows of bipolar electrodes and control scheme *Id.*, 49.
- The combination uses Stern's two rows of bipolar electrodes to improve Edwards-'535's “similar device” in the “same way.” *Id.*, 49.

- Edwards-'535's apparatus 124 is "ready for improvement" using Stern's two rows of bipolar electrodes. *Id.*, 49.

Thus, PO has not contested the overwhelming majority of reasons in the Petition regarding why a POSITA would have been motivated to arrange Edwards-'535's electrodes into two rows in view of Stern. Ex.1083-DelGaudio-Reply-Decl., ¶44; Ex.1097-Martin-Reply-Decl., ¶42.

Moreover, for the few reasons that it does dispute, PO's arguments are wrong.

First, PO disputes that Edwards-'535's incorporation by reference of Baker would have motivated a POSITA to turn to Stern. POR, 33-36. This is a narrow dispute. The Petition explains, and PO does not contest, that Edwards-'535 points a POSITA to Baker, and Baker's teaches non-nasal ablation devices similar to Stern. Pet. 47; POR, 33. Instead, PO raises an irrelevant dispute over whether Edwards-'535 incorporates Baker by reference "in its entirety" and contends that, if it does not, Baker's "other teachings...are not part of this case." POR, 34. Contrary to PO's assertions—which cite no authority despite raising a legal issue—Edwards-'535

uses language sufficient to incorporate Baker in its entirety.⁴ *Paice LLC v. Ford Motor Co.*, 881 F.3d 894, 907 (Fed. Cir. 2018) (finding “U.S. Pat. No. 5,343,970 (the “’970 patent”), which is incorporated herein by this reference” incorporated the patent in its entirety). Regardless, even incorporating only a portion of Baker would demonstrate motivation to look to similar non-nasal ablation devices like Stern. *Nat’l Steel Car, Ltd. v. Canadian P. Ry., Ltd.*, 357 F.3d 1319, 1337 (Fed. Cir. 2004) (motivation to combine “can be found ‘in the knowledge generally available to [a POSITA].’”). Ex.1083-DelGaudio-Reply-Decl., ¶45; Ex.1097-Martin-Reply-Decl., ¶43.

Second, PO argues that a POSITA would not have used Stern’s two-row electrode arrangement because there are other known “ordered arrangements.” POR, 36-38; *see also id.*, 47-48 (arguing that Stern’s electrode arrangement is not, “in and of itself, superior to any other electrode arrangement”). This position is contrary to law. It is well-established that the presence of alternatives does not weigh

⁴ Confirming this incorporation, Edwards-’535 also undisputedly incorporates U.S. Patent No. 5,505,730 (Ex.1010-Edwards-’535, 1:1-19), which includes a figure (Figure 3) that is very similar to the cited Figure 8 in Baker. *Compare* Ex.1067-Edwards-’730, Fig.3 *with* Ex.1011-Baker, Fig. 8.

against a motivation to use a given arrangement taught in the prior art. *Honeywell Intl. Inc. v. 3G Licensing, S.A.*, No. 2023-1354, 2025 WL 16397, at *5 (Fed. Cir. 2025); *Neurent Medical Inc. et al v. Aerin Medical Inc.*, IPR2024-00278, Paper 9 (Institution Decision), 28-29 (PTAB, July 22, 2024) (summarizing cases). The Petition includes numerous reasons why a POSITA would have selected Stern's arrangement. Pet., 47-49. Ex.1083-DelGaudio-Reply-Decl., ¶¶46-47; Ex.1097-Martin-Reply-Decl., ¶44.

Third, PO disagrees that the combination would have required a mere “duplication of parts.” POR, 38-39. PO's argument focuses only on Edwards-'535's ring electrode embodiment and ignores Edwards-'535's surface electrodes embodiment, which could be duplicated as described in the Petition. Pet., 35 (citing Ex.1033-Edwards-'535, 8:19-33 (covering surface electrode embodiments)). Regardless, duplication of parts is just one of many reasons that a POSITA would have had a reasonable expectation of success. Pet., 44-49. Ex.1083-DelGaudio-Reply-Decl., ¶48; Ex.1097-Martin-Reply-Decl., ¶45.

5. A POSITA Would Have Been Motivated to Combine Liang with Edwards-'535 and Stern

PO's only additional argument for claim 1 relates to Ground 3 and addresses Petitioners' point that Stern's electrode arrangement can help accomplish Liang's goal of avoiding perforation of the nasal septum. POR, 47-48. PO again erroneously

argues that the presence of alternative solutions weighs against motivation to combine. *Id.* As explained above, PO's position is contrary to law.

B. The Challenged Dependent Claims Are Obvious

PO raises additional arguments for just two dependent claims, claims 11 and 16. POR, 39-46. These arguments fail, as explained below.

1. Claim 11

Claim 11 recites, in part, “before removing the treatment element from the nasal airway: repositioning the treatment element to contact a different portion of nasal mucosa.” PO relies on a very narrow and incorrect interpretation of the cited references to contend this step is not taught by the prior art. POR, 39-43.

Each of Edwards-'535, Kong, and Liang discloses repositioning a treatment element to contact different portions of the mucosa. Pet., 65-66 (citing Ex.1010-Edwards-'535, FIGs. 3D, 3B; Ex.1040-Kong, 214), 87 (citing Ex.1056-Liang, 341). For example, Liang discloses delivering treatment for a “treatment duration of 5 seconds for the nasal ridge [(first portion)] and 3 seconds for the septal side of the nose [(second portion)].” Ex.1056-Liang, 341. A POSITA would have understood that, in practice, the repositioning would occur before removing the treatment element from the nostril. Pet., 64, 67-68. This is confirmed by Dr. DelGaudio—the only practicing otolaryngologist to testify in this proceeding—who explained that

clinicians like himself “will often reposition an RF treatment element six or more times to deliver treatment to different areas of the turbinate.” Ex.1002-DelGaudio-Decl., ¶133. Ex.1083-DelGaudio-Reply-Decl., ¶¶49-56.

PO and Dr. Bikson incorrectly assert, without supporting evidence or analysis, that these disclosures are insufficient. POR, 41, 51.⁵ PO’s unsupported assertions are undermined by the ’271 specification, which never describes repositioning a treatment element before removing it from the nasal airway. The specification’s lack of detail confirms that a POSITA would have known to implement the references’ teachings by repositioning the treatment element before removing it from the nasal airway. *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.”).

⁵ Dr. Bikson has never treated a patient for any nasal condition and would not perform claim 11. Ex.1084-Bikson-Tr., 24:13-22, 46:2-16, 163:11-164:8. The Board should therefore credit Dr. DelGaudio’s well-reasoned analysis based on actual clinical practice.

PO also contends that Petitioners have failed to show the art discloses applying radiofrequency energy with “bipolar electrode pairs [plural],” as recited by claim 11, because Petitioners purportedly “do not cite to or discuss Stern.” POR, 40, 42. PO is incorrect. The Petition cross-references the analysis of limitation 1[b], Pet., 66-67, 88-89, which clearly shows that the Edwards-’535/Stern combination discloses applying energy with bipolar pairs, as does Dr. DelGaudio’s declaration (Ex.1002-DelGaudio-Decl., ¶¶138, 167). PO’s arguments that the combination does not satisfy this limitation are wrong as explained in Section III.A.3.

2. Claim 16

Claim 16 recites “bending a shaft of the nasal airway treatment device before contacting the treatment element with the nasal mucosa.” As the Petition explains, Edwards-’535’s disclosure that the treatment element is at the end of a bent shaft renders claim 16 obvious. Pet., 69-71. PO’s argument is based on the unsubstantiated assertion of Dr. Bikson that the bend may have been formed *after* contacting the treatment element with the mucosa. ’271 POR, 44 (citing Ex.2001-Bikson-Decl., ¶103).

Dr. Bikson’s assertion ignores clinical practice and basic physiology. As Dr. DelGaudio explains, a clinician must be able to see around his hand when inserting

the treatment element. Further, the nasal passages do not form a straight line from the nostrils. Thus, a 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. Ex1002-DelGaudio-Decl., ¶¶143-148. Dr. DelGaudio cited several prior art references to show this limitation is “common sense” to practicing physicians. *Id.*, ¶145⁶; *see B/E Aerospace, Inc. v. C&D Zodiac, Inc.*, 962 F.3d 1373, 1380 (Fed. Cir. 2020) (“[c]ommon sense has long been recognized to inform the analysis of obviousness if explained with sufficient reasoning”). Again, given that Dr. Bikson has not carried out clinical procedures within the nose, his unsupported opinion should be given less weight. Ex.1083-DelGaudio-Reply-Decl., ¶¶57-63.

⁶ PO argues that Petitioners’ cited techniques are “unidentified” and that Dr. DelGaudio “did not rely” on them. POR, 45. Dr. DelGaudio’s fulsome discussion shows otherwise. Ex1002-DelGaudio-Decl., ¶145. Thus, contrary to PO’s assertions, the techniques are both “identified” and “relied upon” for the purposes set forth by Dr. DelGaudio.

IV. DR. DELGAUDIO IS A POSITA

It is undisputed that a clinician would perform the claimed method of the '271 patent. Ex.1084-Bikson-Tr., 82:13-84:5, 46:2-16, 164:9-164:12, 165:3-21. Petitioners therefore supported their Petition with testimony from Dr. DelGaudio—a renowned otolaryngologist who has treated nasal tissue with energy-based devices for decades.

PO disputes Petitioners' POSITA definition—which the Board adopted at institution—but not because of any disputed issue that turns on that definition or on Dr. DelGaudio's qualifications.⁷ Instead, PO aims solely to disqualify Dr. DelGaudio as a procedural matter. POR, 53-56. This should be rejected. PO's restrictive proposal—which seeks to exclude doctors that have used/tested medical devices but have not designed/developed them—is divorced from the facts and governing standard. Moreover, Dr. DelGaudio—whose experience is far more relevant to the issues in this IPR—qualifies as a POSITA under either definition. Ex.1083-DelGaudio-Reply-Decl., ¶¶4-7; Ex.1097-Martin-Reply-Decl., ¶¶46-69.

⁷ Dr. Bikson states his opinions “are the same regardless of which definition the Board applies.” Ex.2001, ¶42; Ex.1084-Bikson-Tr., 244:22-245:3.

A. Dr. DelGaudio Is a POSITA Under Either Definition

PO seeks to exclude Dr. DelGaudio solely because he purportedly lacks sufficient development/design experience under PO's definition. POR, 53-56. But PO misrepresents the record, relying on deposition testimony (Ex.2007-DelGaudio-Tr., 94:12-16, 95:1-16, 99:5-15) that only discusses *designing* medical devices *that deliver energy to tissue*—Dr. DelGaudio plainly testified that he has experience developing medical devices more generally. *Id.*, 95:6-13, 99:5-15. PO's expert agrees this experience is sufficient. Ex.1084-Bikson-Tr., 88:3-18.

Dr. DelGaudio also has experience developing devices that deliver energy to tissue by providing feedback to vendors, including PO. Ex.2007-DelGaudio-Tr., 100:13-101:22. His experience thus covers the very “technical issues” PO suggests are out of Dr. Delgaudio's wheelhouse. *Compare* POR, 7-9 *with* Ex.1083-DelGaudio-Reply-Decl., ¶¶8-11. Clearly, device vendors like PO value Dr. DelGaudio's depth of knowledge of how the devices he uses work. *Apple Inc. v. Corephotonics Ltd.*, IPR2019-00030, Paper 32 at 18 (April 6, 2020); *Godbersen-Smith Construction Co. v. Guntert & Zimmerman Const. Div., Inc.*, IPR2021-00136, Paper 61 at 23-27 (May 18, 2022) (machine operators can gain relevant technical knowledge by using machines).

PO also faults Dr. DelGaudio for his discussion with Dr. Martin—who is also and indisputably a POSITA—to “confirm” his opinions and for declining to offer opinions on certain aspects of the case (POR at 54-55).⁸ That logic is flawed—Dr. DelGaudio’s decision not to offer certain opinions does not mean that he was not qualified, and PO cites no contrary authority. In fact, PO’s litigation partner, The Foundry, does the same thing with Drs. Levine and Bikson in copending IPRs 2024-00279, -00280, and -00281. The Board has repeatedly found in medical device matters that POSITA-clinicians would have access to engineers. *Edwards Lifesciences Corp. et al v. Cardiovalve Ltd.*, IPR2021-01051, Paper 36 at 11 (December 6, 2022); *Medtronic, Inc. et al v. Teleflex Life Sciences Limited et al.*, IPR2020-01343, Paper 85 at 17-18 (February 23, 2022); *Abbott Vascular, Inc. et al*

⁸ PO is wrong that Dr. DelGaudio fails to offer an opinion on Stern’s Figure 15 (POR at 55)—Figure 15 and its corresponding disclosure are repeatedly cited in his declaration. Ex.1002-DelGaudio-Decl., ¶¶61, 92, 93. PO also cherry-picks from Dr. DelGaudio’s declaration to allege he relied entirely on Dr. Martin for one limitation. POR, 55. Dr. DelGaudio’s two pages of independent analysis for that limitation show otherwise. Ex.1002-Decl., ¶¶92-94.

v. FlexStent, LLC, IPR2019-00882, Paper 48 at 6 (October 2, 2020). Ex.1083-DelGaudio-Reply-Decl., ¶12.

Dr. DelGaudio is the **only** witness in this proceeding with clinical experience using RF energy to ablate tissue. His perspective is therefore far more relevant than Dr. Bikson's to issues in this IPR, including which features a POSITA would be motivated to include in a nasal ablation device (*supra*, §III.A) and how such devices would be used in a clinical setting (*supra*, §III.B). Ex.1081- Reply-Decl., ¶¶8-11. Dr. Bikson, in contrast, has little to offer. He has no experience using RF devices (Ex.1084-Bikson-Tr., 24:16-22) or designing devices intended to ablate tissue (*id.*, 41:12-42:11, 65:5-9).

B. PO's Restrictive Definition Should Be Rejected

PO's narrow POSITA definition is not supported by the evidence.⁹ *Godbersen-Smith Construction Co.*, IPR2021-00136, Paper 61 at 23-27 (refusing to limit level of ordinary skill to only design/development experience).

⁹ Contrary to PO's allegation, Petitioners did not "base [their] definition of a POSITA around Dr. DelGaudio's own qualifications." POR at 7-8. His declaration was merely "referring to whether [he met] the criteria for a person of ordinary skill in the art." Ex-2007 at 126:6-9.

- The patent's purported solution relates to a "'treatment element' comprising 'two rows of bipolar electrode pairs.'" POR, 6. The claims recite only user-facing, functional features of the treatment element, not its internal implementation. Ex.1001-USP271, claim 1. Ex.1083-DelGaudio-Reply-Decl., ¶13.
- RF devices were known and used safely and effectively by clinicians, including in the nose. *Id.*, 19:6-26; Pet. 16-18; Ex.1040-Kong, 214-215; Ex.1056-Liang, 341-342. Indeed, Dr. DelGaudio performed nasal RF ablation in the 1990s. Ex.1083-DelGaudio-Reply-Decl., ¶51.
- Clinicians learn to safely and effectively operate RF electrode devices through use and testing, instructions for use, education, and data review. Ex.1084-Bikson-Tr., 89:2-94:8; Ex.1083-DelGaudio-Reply-Decl., ¶14.
- Physicians "***must*** be familiar" with devices they use to understand, e.g., "safety, energy dosage...and instrumentation." Ex.1093-Levine, 451. Moreover, physicians routinely perform "off-label" uses of medical devices, which requires knowledge and intuition of a device's capabilities. Ex.1083-DelGaudio-Reply-Decl., ¶15.
- The Kong, Liang, Fang, and Chen references in this proceeding appear in *medical* journals and address the problem of treating rhinitis using RF ablation

devices. Ex.1040-Kong, 214 (selecting “grade 6” and treatment time); Ex.1056-Liang, 341 (selecting “Level 3” and treatment time); Ex.1055-Fang, 876 (similar); Ex.1017-Chen, 240 (similar).¹⁰ PO represented to the patent office that Kong, Fang, and Chen were material to the patentability of the '271 patent (Ex.1003-USP271FH, 573-574) and does not dispute that Kong and Liang are analogous art to the claimed invention.

- One of the named inventors, 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, 3-4. His apparent work with liposuction alternatives and tissue fastening/repair devices¹¹ is certainly less relevant to understanding the

¹⁰ PO and Dr. Bikson point to purported “technical issue[s],” such as particular treatment parameters (POR at 6-8 (citing Ex.2001-Bikson-Decl., ¶¶38, 40), but aside from the external arrangement of electrodes do not contend these limitations were non-obvious.

¹¹ PO did not submit any evidence that Dr. Scott Wolf actually participated in designing/developing these devices.

claimed RF-based treatment method than Dr. DelGaudio's decades of experience using such devices in the nose.

Thus, the POSITA factors all support that an M.D. or engineer with three years' experience with medical device use/testing had ordinary skill. PO's litigation-driven attempt to *exclude* clinical use and testing from treatment claims is illogical. Ex.1083-DelGaudio-Reply-Decl., ¶16-17.

V. 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 5,521 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).

/Brian J. Lambson/
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Registration No. 72,570

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 1067, 1083-1091, 1093-1097
- 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.11,241,271 (“’271 patent”)
1002	Declaration of Dr. John DelGaudio (“Decl.”)
1003	File History of U.S. Patent No.11,241,271
1004	Declaration of Dr. Gregory Martin (“Decl.”)
1005	RESERVED
1006	District Court Amended Complaint
1007	District Court Amended Complaint Exhibit Y
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	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	RESERVED
1019	U.S. Patent App. No. 2007/0219600 (“Gertner”)
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	U.S. Patent No. 874,178 (“De Forest”)
1026	U.S. Patent No. 3,538,919 (“Meyer”)
1027	U.S. Patent No. 3,117,571 (“Fry”)
1028	RESERVED
1029	Arora et al., Cryodestruction of Vidian Nerve Branches, INDIA J. OTOLARYNGOLOGY 32:3 (1980) (“Arora”)

Exhibit	Description
1030	RESERVED
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	RESERVED
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	RESERVED
1037	Chung, Cough: Causes, Mechanisms and Therapy, Blackwell Publ’g Ltd (2003) (“Chung”))
1038	U.S. Patent No. 6,109,268 (“Thapliyal”)
1039	Banhiran, Quality of life in patients with chronic rhinitis after radiofrequency inferior turbinate reduction, J. MED ASSOC THAI, Vol. 93 No.8 (2010) (“Banhiran”)
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	Snow, Blessed Days of Anesthesia (Oxford U. Press, 2008) (available at: http://ndl.ethernet.edu.et/bitstream/123456789/3165/1/360.pdf) (“Snow”)
1042	Bäck et al., Submucosal Bipolar Radiofrequency Thermal Ablation of Inferior Turbinates: A Long-Term Follow-up With Subjective and Objective Assessment, 112 LARYNGOSCOPE 1806 (October 2002) (“Bäck”)
1043	Ilgner et al., Feasibility of coblation versus laser resection in recurrent nasal polyps, 5686 PROC. OF SPIE 322 (April 25, 2005)
1044	Lee et al., Surgical Management of Turbinate Hypertrophy in the Office: Three Mucosal Sparing Techniques, 12:2 OPERATIVE TECHNIQUES IN OTOLARYNGOLOGY—HEAD AND NECK SURGERY 107 (June 2001) (“Lee”)
1045	RESERVED
1046	U.S. Patent No. 3,941,121 (“Olinger”)
1047	U.S. Patent No. 4,271,848 (“Turner”)

Exhibit	Description
1048	Nomura et al., Distribution and Clinical Significance of Autonomic Nervous System in the Human Nasal Mucosa, 73 ACTA OTOLARYNG 493 (1972) (“Nomura”)
1049	Akiyoshi Konno, Historical, Pathophysiological, and Therapeutic Aspects of Vidian Neurectomy, 10 CURR ALLERGY ASTHMA REP 105 (2010) (“Konno”)
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 63, 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	Excerpts from File History of U.S. Patent No. 10,398,489
1058	U.S. Patent App. No. 2002/0016588 (“Wong”)
1059	CN Patent No. 2225227Y (“Liang-’227”)
1060	Andrew P. Lane, Nasal Anatomy and Physiology 12 FACIAL PLAST SURG CLIN N AM 387 (2004) (“Lane”)
1061	RESERVED
1062	Sedra et al., MICROELECTRONIC CIRCUITS (3d Ed. 1991) (Excerpts) (“Sedra”)
1063	RESERVED
1064	G.A.G. Mitchel, The Automatic Nerve Supply of the Throat, Nose, and Ear, 68(8) J. OF LARYNGOLOGY & OTOTOLOGY 495 (August 1954) (“Mitchel”)

Exhibit	Description
1065	RESERVED
1066	U.S. Patent App. No. 2004/0230188 (“Cioanta”)
1067	U.S. Patent No. 5,505,730 (“Edwards-’730”)
1068- 1069	RESERVED
1070	Declaration of June Munford
1071	Translator Declaration for Chen
1072	Translator Declaration for Liang
1073	Translator Declaration for Fang
1074	Translator Declaration for Kong
1075	Munford Appendices for Chen
1076	Munford Appendices for Liang
1077	Munford Appendices for Fang
1078	Munford Appendices for Kong
1079	Additional Appendices to Munford Declaration
1080	Translator Declaration for Liang ’227
1081	Declaration of Gregory H. Lantier
1082	Declaration of Joshua L. Stern
1083	Reply Declaration of Dr. John DelGaudio (“DelGaudio-Reply-Decl.”)
1084	Transcript of the January 7, 2025, 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”).
1094	Errata Sheet for the Transcript of the September 24, 2024 Deposition of Dr. Gregory Martin (“Martin-Tr.I-Errata”)

Exhibit	Description
1095	Errata Sheet for the Transcript of the September 25, 2024 Deposition of Dr. Gregory Martin (“Martin-Tr.I-Errata”)
1096	Errata Sheet for the Transcript of the October 10, 2024 Deposition of Dr. John DelGaudio (“DelGaudio-Tr.-Errata”)
1097	Reply Declaration of Dr. Gregory Martin (“Martin-Reply-Decl.”)