

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.

IPR2024-00277
U.S. Patent No. 11,241,271 B2

PATENT OWNER'S NOTICE OF APPEAL

Pursuant to 35 U.S.C. §§ 141, 142, and 319, and in accordance with 37 C.F.R. §§ 90.2-90.3, Patent Owner Aerin Medical Inc. (“Aerin”) hereby appeals to the United States Court of Appeals for the Federal Circuit from the Final Written Decision of the Patent Trial and Appeal Board (“Board”) entered on July 11, 2025 in IPR2024-00277 (Paper No. 41) (“Final Written Decision”), and from all underlying findings, determinations, rulings, opinions, orders, and decisions regarding the above-captioned *inter partes* review (Case IPR2024-00277) of U.S. Patent No. 11,241,271 (the “’271 Patent”).

In accordance with 37 C.F.R. § 90.2(a)(3)(ii), Aerin states that the issues on appeal may include, but are not limited to: the Board’s determination that claims 1–4, 6–12, and 16 of the ’271 Patent have been shown to be unpatentable under 35 U.S.C. § 103; the Board’s construction of those claims; the Board’s consideration of the expert testimony, prior art, and other evidence in the record; and the Board’s factual findings, conclusions of law, or other determinations supporting or related to those issues, as well as all other issues decided adversely to Aerin in any orders, decisions, rulings, and opinions.

This Notice of Appeal is timely under 37 C.F.R. § 90.3(a)(1).

In accordance with Fed. Cir. R. 15 and its Practice Note, Patent Owner attaches to this Notice of Appeal a copy of the Final Written Decision referenced above from which review is sought. (Attachment A.)

This Notice of Appeal is being e-filed with the Clerk of the United States Court of Appeals for the Federal Circuit, along with payment of the required docketing fees. In addition, a copy of this Notice of Appeal is being filed simultaneously with the Patent Trial and Appeal Board and with the Director of the United States Patent and Trademark Office.

GREENBERG TRAURIG, LLP

Date: September 11, 2025

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that on this 11th day of September 2025, a copy of this **PATENT OWNER'S NOTICE OF APPEAL** was served by electronic mail on Petitioners' lead and backup counsel at the following email addresses:

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Attachment A

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEURENT MEDICAL INC. & NEURENT MEDICAL LTD.,
Petitioner,

v.

AERIN MEDICAL INC.,
Patent Owner.

IPR2024-00277
Patent 11,241,271 B2

Before MICHAEL J. FITZPATRICK, ZHENYU YANG, and
MICHAEL A. VALEK, *Administrative Patent Judges*.

VALEK, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

Neurent Medical Inc. and Neurent Medical Ltd. (collectively “Petitioner”) filed a Petition (Paper 3, “Pet.”), seeking *inter partes* review of claims 1–4, 6–12, and 16 of U.S. Patent No. 11,241,271 B2 (Ex. 1001, “the ’271 patent”). We instituted review. Paper 9, 31 (“Dec.”).

Aerin Medical Inc. (“Patent Owner”) filed a Response to the Petition (Paper 24, “Resp.”), Petitioner filed a Reply (Paper 27, “Reply”) and Patent Owner filed a Sur-reply (Paper 33, “Sur-reply.”). We heard argument on April 23, 2025, and a transcript is of record. Paper 40 (“Tr.”).

After considering the parties’ arguments and evidence, we find that Petitioner has shown by a preponderance of the evidence that all of the challenged claims are unpatentable. Our reasoning is explained below.

II. BACKGROUND

A. Real Parties in Interest

The parties identify themselves as the only real parties-in-interest. Pet. 3; Paper 6, 2.

B. Related Matters

The parties identify *Aerin Medical Inc. and The Foundry LLC v. Neurent Medical Inc. and Neurent Medical Ltd.*, Case No. 1:23-cv-00756-JLH (D. Del.) (“the Delaware litigation”) as a related matter involving the ’271 patent. Pet. 2; Paper 6, 2.

The parties also identify the following IPR proceedings involving patents related to the '271 patent: IPR2024-00275, IPR2024-00276, IPR2024-00278, and IPR2024-00282. Pet. 3; Paper 6, 2.¹

Petitioner additionally identifies other IPR proceedings involving “patents owned by The Foundry LLC and allegedly exclusively licensed by [Patent Owner]” that are asserted in the Delaware litigation. *See* Pet. 2–3 (identifying IPR2024-00279, IPR2024-00280, and IPR2024-00281); Paper 8, 2–3 (updated disclosures identifying termination of IPR2024-00281 and filing of IPR2024-00669 challenging same patent).

C. The '271 Patent

The '271 patent issued on February 8, 2022, and claims priority to a series of applications, the earliest of which was filed on June 14, 2011. Ex. 1001, codes (45), (60), (63).

The '271 patent describes methods of treating nasal airways using a device comprising a “radiofrequency delivery member . . . sized to be inserted into a nose and configured to at least temporarily deform the nasal tissue and deliver radiofrequency [RF] energy.” Ex. 1001, code (57); *see also id.* at 4:38–47 (“methods described herein may be utilized to reshape, remodel, strengthen, or change the properties of the tissues of the nose, including but not limited to the skin, muscle, mucosa, submucosa and cartilage in the area of the nasal valves”). According to the Specification, such treatment can provide a variety of benefits to the patient, including mucus reduction. *Id.* at 10:35–53; 48:1–7.

¹ The 275 and 276 IPRs were terminated by joint motion following Patent Owner’s disclaimer of all challenged claims. *See* IPR2024-00275, Paper 22; IPR2024-00276, Paper 22.

Figure 3 of the '271 patent, reproduced below, is “a schematic illustration” of a device for use in this treatment. Ex. 1001, 8:53–54.

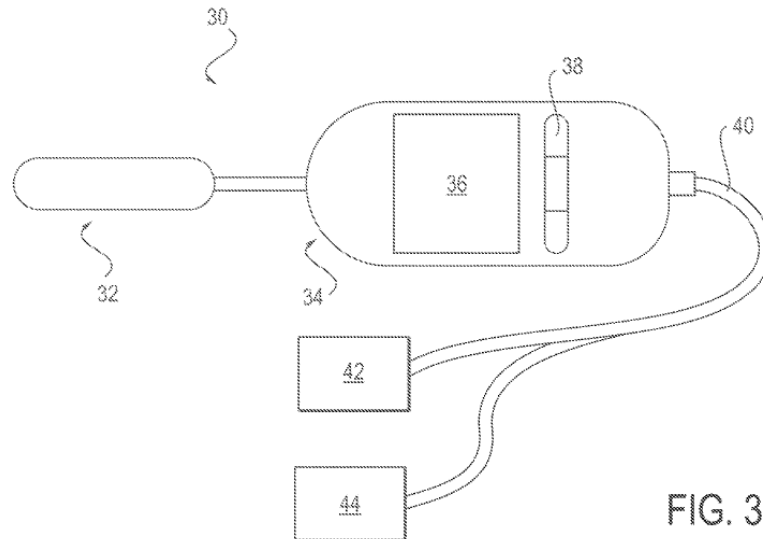


FIG. 3

Figure 3 above shows device 30 comprising “a treatment element 32 which may be configured to be placed inside the nasal cavity, nasal passage, and/or nasal airway to deliver the desired treatment.” *Id.* at 15:18–21. The device in Figure 3 further comprises handle section 34 “for easy handheld operation by a clinician.” *Id.* at 15:21–23. To this end, handle section 34 includes input controls 38 and display 36 for displaying information, e.g., “quantitative information describing the energy being delivered” and “feedback information from sensors within the device and/or within the treatment element,” to the clinician during treatment. *Id.* at 15:23–38.

Figure 18 of the '271 patent, reproduced below, depicts “an embodiment of a device for applying energy to the nasal valve area comprising an array of non-penetrating electrodes.” Ex. 1001, 9:37–39.

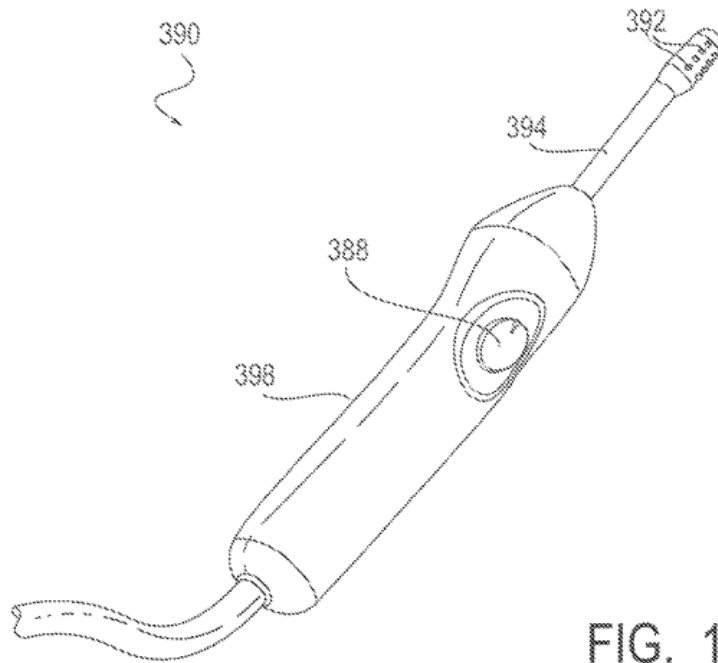


FIG. 18

Figure 18 above shows “device 390 comprising pairs of bipolar electrodes 392 located at the distal end of a shaft 394.” *Id.* at 26:63–64. In the embodiment of Figure 18, the electrodes are arranged in rows. This is consistent with other portions of the specification, which describe a “radiofrequency” or “energy delivery” member that “includes two rows of protruding electrodes disposed on a tissue contact surface” and which “deliver radiofrequency energy from one row of electrodes to the other row of electrodes.” *Id.* at Abstr., 8:21–25.

For example, Figure 8F of the '271 patent is reproduced below.

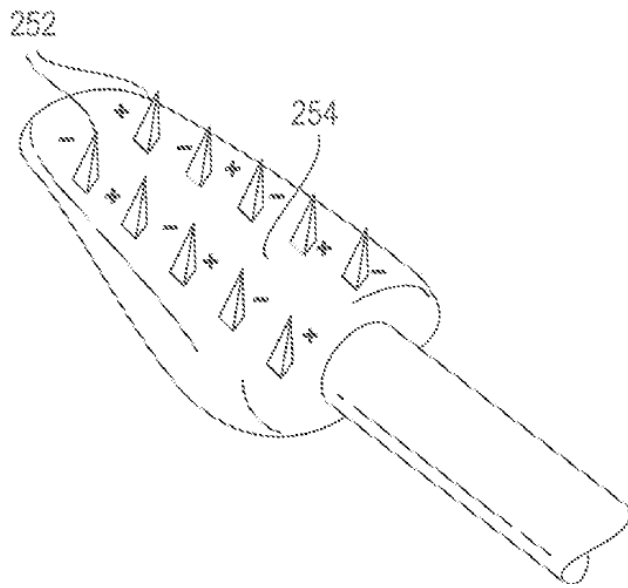


FIG. 8F

Figure 8F above depicts an array of electrodes “comprising one, two, or many pairs of bipolar needles 252” that are “arranged side-by-side” and “located on a treatment element configured to be placed into contact with the cartilage.” *Id.* at 23:40–43, 23:56–59.

D. Challenged Claims

The Petition challenges claims 1–4, 6–12, and 16. Claim 1 is illustrative and reproduced below with the same bracketed annotations the Petition includes to identify particular limitations.

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

[1a] contacting a treatment element of a nasal airway treatment device directly with nasal mucosa of the nasal airway, wherein the treatment element comprises two rows of bipolar electrode pairs;

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

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

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

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

Ex. 1001, 48:22–39. All of the other challenged claims depend directly from claim 1 and recite further limitations relating to the target tissue or property of target tissue modified (claims 2 and 12), the radiofrequency energy applied (claims 3, 4, and 8–10), or add steps related to operation of the device or method (claims 6, 7, 11, and 16). *See id.* at 48:40–50:18.

E. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability:

Claim(s) Challenged	35 U.S.C. §²	Reference(s)/Basis
1–3, 6–12, 16	103	Edwards-535, ³ Kong, ⁴ Stern ⁵

² The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (“AIA”), included revisions to 35 U.S.C. § 102 and § 103 that became effective March 16, 2013. Petitioner notes that “[t]he ’271 patent was examined under the provisions of the AIA” and cites to the AIA version of these statutes in the Petition. Pet. 5 n. 2. Patent Owner does not address whether the AIA or pre-AIA version applies, nor do we discern a reason why the differences between those versions would affect our analysis. Accordingly, we cite the AIA version herein.

³ US 6,517,535 B2, issued Feb. 11, 2003 (Ex. 1010) (“Edwards-535”).

⁴ Kong Yonggang et al., “Low-temperature Plasma Ablation of Inferior Turbinate for the Treatment of Perennial Allergic Rhinitis,” 19 J. Clin. Otorhinolaryngol (China) 214–215, Mar. 2005 (Ex. 1040). Exhibit 1040, referred to as “Kong” herein, is a translation of the original Chinese language reference on which Petitioner relies. Exhibit 1074 is a declaration from Petitioner’s translator that attests to the accuracy of that translation and attaches the original reference.

⁵ US 5,562,720, issued Oct. 8, 1996 (Ex. 1033) (“Stern”).

Claim(s) Challenged	35 U.S.C. §²	Reference(s)/Basis
4	103	Edwards-535, Kong, Stern, Edwards-886 ⁶
1–3, 6–12, 16	103(a)	Edwards-535, Liang, ⁷ Stern
4	103(a)	Edwards-535, Liang, Stern, Edwards-886

In addition to these and other references, Petitioner relies on the declarations of Dr. John Delgaudio submitted with the Petition (Ex. 1002) and Reply (Ex. 1083), and Dr. Gregory T. Martin submitted with the Petition (Ex. 1004) and Reply (Ex. 1097). Patent Owner relies on the declaration of Dr. Marom Bikson (Ex. 2001).

III. ANALYSIS OF THE ASSERTED GROUNDS

A. Legal Standards

A claim is unpatentable for obviousness if, to one of ordinary skill in the pertinent art, “the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains.” 35 U.S.C. § 103; *see also KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art;

⁶ US 6,273,886 B1, issued Aug. 14, 2001 (Ex. 1016) (“Edwards-886”).

⁷ Liang Jianping et al., “Radiofrequency Treatment of Ethmoidal Nerve with Allergic Rhinitis Under Nasal Endoscopy,” 13 J. Clin. Otorhinolaryngol (China) 341–342, Aug. 1999 (Ex. 1056). Exhibit 1056, referred to as “Liang” herein, is a translation of the original Chinese language reference on which Petitioner relies. Exhibit 1072 is a declaration from Petitioner’s translator that attests to the accuracy of that translation and attaches the original reference.

(2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) when in evidence, objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

Additionally, the obviousness inquiry typically requires an analysis of “whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.” *KSR*, 550 U.S. at 418 (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2016) (requiring “articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”)). Petitioner cannot satisfy its burden of proving obviousness by employing “mere conclusory statements,” but “must instead articulate specific reasoning, based on evidence of record, to support the legal conclusion of obviousness.” *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016).

B. Level of Ordinary Skill in the Art

Petitioner contends a person of ordinary skill in the art (“POSITA”) would have had (1) a Doctor of Medicine (M.D.) or at least a bachelor of science degree in engineering or a related discipline and (2) at least three years of experience in the clinical use, design, development, and/or testing of medical devices, including medical devices that deliver energy to tissue.

Pet. 20–21 (citing Ex. 1002 ¶¶ 27–29; Ex. 1004 ¶¶ 24–28).

Patent Owner disputes the second part of Petitioner’s definition “because the ‘and/or’ encompasses within the definition . . . persons who **only** have experience with the clinical use or testing of medical devices.”

Resp. 6. According to Patent Owner, one of ordinary skill “would have had

more experience than just clinically using medical devices or simply conducting tests with medical devices.” *Id.* at 6–7.

To the extent Petitioner’s definition could be interpreted to encompass someone who only has experience using or testing *unrelated* medical devices, we tend to agree with Patent Owner. But it does not follow that experience with the clinical use and testing of medical devices, including those that deliver energy to tissue, would not be relevant background for one of ordinary skill. *See* Reply 29–31 (identifying evidence that clinical use and testing experience is relevant). The devices and methods in the challenged patent and asserted prior art are designed to be used by clinicians. Ex. 1083 ¶¶ 5, 14–15 (explaining that clinicians who use such devices gain extensive experience regarding how they work); *see also* Ex. 1084, 82:13–83:20 (Dr. Bikson testifying that a physician would perform the claimed method steps). Accordingly, clinical experience using and testing them would inform their design and be relevant experience for one of ordinary skill in the art. For these reasons, we do not adopt Patent Owner’s proposed modification of Petitioner definition, which would remove clinical use and testing from the list of activities in Petitioner’s POSITA definition. *See* Resp. 7 (proposing redlines).

Instead, we apply Petitioner’s definition. Regardless, Petitioner’s expert, Dr. Martin, is qualified to offer the opinions in his declarations under either definition and Patent Owner does not identify any testimony it contends would be different under its POSITA definition. *See* Ex. 1097 ¶ 49 (Dr. Martin testifying that his opinions “remain the same regardless of which definition applies”). Moreover, as explained below, we are not persuaded by Patent Owner’s challenge to Dr. DelGaudio’s qualifications and give his

testimony appropriate weight in our analysis. For these reasons, our findings and conclusions would be the same under either side’s definition of the level of ordinary skill in the art.

i. Patent Owner’s challenge to Dr. DelGaudio’s qualifications

Patent Owner argues that one of Petitioner’s experts, Dr. DelGaudio, is not qualified to offer testimony from the perspective of one of ordinary skill in the art. *See* Resp. 53–54 (citing *Kyocera Senco Indus. Tools Inc. v. Int’l Trade Comm’n*, 22 F.4th 1369, 1376–77 (Fed. Cir. 2022)). Dr. DelGaudio is a medical researcher and clinician with “almost three decades of experience in clinical practices as an otolaryngologist.” Ex. 1002 ¶¶ 6–9. Since 1995, he has “frequently used radiofrequency (RF) energy for the treatment of nasal conditions” in his practice. *Id.* ¶ 10. Nevertheless, Patent Owner asserts that “Dr. DelGaudio does not qualify as a POSITA” under its POSITA definition and thus his testimony “should be disregarded or given no weight.” *Id.*

We disagree with Patent Owner for a number of reasons. First, as explained above, we do not adopt Patent Owner’s definition of one of ordinary skill. It is undisputed that Dr. DelGaudio meets the qualifications of one of ordinary skill in the art under Petitioner’s definition.

Second, given the subject matter of this case it was logical for Petitioner to offer testimony from an experienced clinician such as Dr. DelGaudio. Unlike the related IPRs, which involve claims to a treatment device, the claims challenged in this proceeding recite a method of treating a nasal airway in a patient and include steps performed by a clinician, e.g., elements 1[a] and 1[c], to achieve a clinical result, i.e., the “reduction in mucus production” in elements 1[d] and 1[e]. *Compare* Ex. 1001, 48:21–39

(claim 1) *with* IPR2024-00278, Ex. 1001, 52:15–36 (claim 1). Indeed, as Petitioner points out, Kong, Liang, and other references cited for their teachings regarding these aspects of the challenged claims are publications from medical journals detailing clinical procedures. Reply 29–30. This suggests that clinical expertise would be of particular relevance here. Because the subject matter at issue involves multiple disciplines, Petitioner offers testimony from two experts—a clinician (Dr. DelGaudio) and an engineer (Dr. Martin).

Third, nothing suggests that Dr. DelGaudio is not qualified to offer opinions regarding the knowledge and skill of one of ordinary skill in the art. In addition, to his relevant clinical experience, Dr. DelGaudio has experience designing different types of medical devices and consulting with device manufacturers to provide feedback and improve devices used in nasal surgery. Ex. 1083 ¶¶ 9–11. Thus, even if we had adopted a POSITA definition requiring design and development experience, Dr. DelGaudio would qualify as one of ordinary skill in the art because he has such experience in addition to his extensive clinical background. *Id.*

Nevertheless, Patent Owner argues he is “not an individual *capable* of designing and developing the medical device used in the claimed method” because “Dr. DelGaudio has no experience in designing medical devices that deliver energy to tissue.” *Sur-reply* 22–24 (emphasis added). That argument is unavailing because such devices and methods of using them such as those recited in the claims of the ’271 patent are often developed by a team of individuals with different backgrounds and expertise. That Dr. DelGaudio working alone may not be capable of designing and developing such a device does not disqualify him from offering testimony from the perspective

of one of ordinary skill in the art, particularly as it relates to those claim elements that recite the use of the device as opposed to its technical details.⁸ Moreover, Dr. DelGaudio was careful not to overstep the bounds of his expertise, relying on testimony from Dr. Martin to confirm his understanding concerning some of the engineering details of the devices themselves. *See* Ex. 1002 ¶¶ 94, 124, 127, 130, 151; *see also* Ex. 1083 ¶ 12 (explaining he relied on Dr. Martin to confirm his understanding of teachings in Stern that disclose “implementation details about circuitry used to operate the bipolar electrodes, the physics of delivering energy to tissue, among other things”); Ex. 1004 ¶¶ 66–131 (Dr. Martin testifying regarding a POSITA’s understanding of the prior art as it relates to such elements).

Fourth, even if Dr. DelGaudio did not himself qualify as one of ordinary skill, we could still consider his testimony on those matters on which he was qualified. *See* Consolidated Trial Practice Guide (Nov. 2019), 52, available at <https://www.uspto.gov/sites/default/files/documents/tpgnov.pdf> (“CTPG”) (“A person may not need to be a person of ordinary skill in the art in order to testify as an expert under Rule 702, but rather must be ‘qualified in the pertinent art.’”) (citing cases). We agree with Petitioner that this would include matters such as the use of the devices described in the cited references in a clinical setting. *See* Reply 28.

⁸ Indeed, by its logic, Patent Owner’s own expert would not be one of ordinary skill in the art because he is not himself capable of practicing the claimed method. *See* Ex. 1084, 24:13–22, 82:19–83:8 (testifying he has never used an RF device to treat a patient and would not himself perform the recited method).

Fifth, Patent Owner has not moved to strike or exclude any of Dr. DelGaudio's testimony. Thus, that testimony is of record and we give it appropriate weight in our analysis.⁹

C. Claim Construction

In an *inter partes* review, claim terms "shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. [§] 282(b), including construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." 37 C.F.R. § 42.100(b).

Petitioner contends "the Board need not construe any terms because the Challenged Claims are invalid under any reasonable interpretation." Pet. 20. Patent Owner similarly asserts "the Board need not construe any claim terms." Resp.15.

Nevertheless, in their arguments over whether the prior art teaches certain claim elements, each side accuses the other of misinterpreting or reading requirements beyond their ordinary meaning into those terms. *See* Reply 4–5, 7–12 (urging that Patent Owner's "bipolar pairs" and "two rows" arguments read requirements into the claims); Resp. 28–29 (asserting that the "doctrine of claim differentiation" supports its position); Sur-reply 8–10 (urging that the claim language "two rows of bipolar electrode pairs" requires at least two pairs per row). To the extent the parties' arguments

⁹ This is not to suggest that Dr. DelGaudio cannot be impeached for what Patent Owner contends is a deficiency in his credentials. We have considered Dr. DelGaudio's experience, or alleged lack thereof, in assessing the credibility of his testimony and weighing it against the other evidence in our analysis below.

raise any implicit issues of claim construction, we address those issues within the context they are raised in our analysis below.

Patent Owner also asserts that claim 1 should be construed “to require that the claimed method steps be performed in their specified, sequential order.” Resp. 15. We need not reach this argument because the combinations of art in Petitioner’s grounds carry out the steps of claim 1 in the recited order. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Matal*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (“[W]e need only construe terms that are in controversy, and only to the extent necessary to resolve the controversy.”) (internal quotation omitted).

D. References Relied Upon

i. Edwards-535

Edwards-535 is a United States patent issued February 11, 2003. Ex. 1010, code (45). It is undisputed that Edwards-535 qualifies as prior art under 35 U.S.C. § 102(a)(1) and (2).

Edwards-535 discloses methods and apparatus “for ablating at least a portion of a nasal concha”¹⁰ to reduce its size and improve “air flow through the nasal meatus.” Ex. 1010, code (57). According to Edwards-535’s method, an apparatus comprising an energy delivery device and expandable member is inserted into the patient’s nostril to deliver ablative energy, e.g., RF radiation. *See id.* at 5:16–50.

Figure 3B of Edwards-535, reproduced below, depicts an embodiment of Edwards-535’s apparatus inserted into a nostril.

¹⁰ The concha, also referred to as turbinates, are anatomical features that protrude from the lateral wall of the nasal cavity and are located posterior to the internal nasal valve. Ex. 1002 ¶ 30 (describing anatomical features).

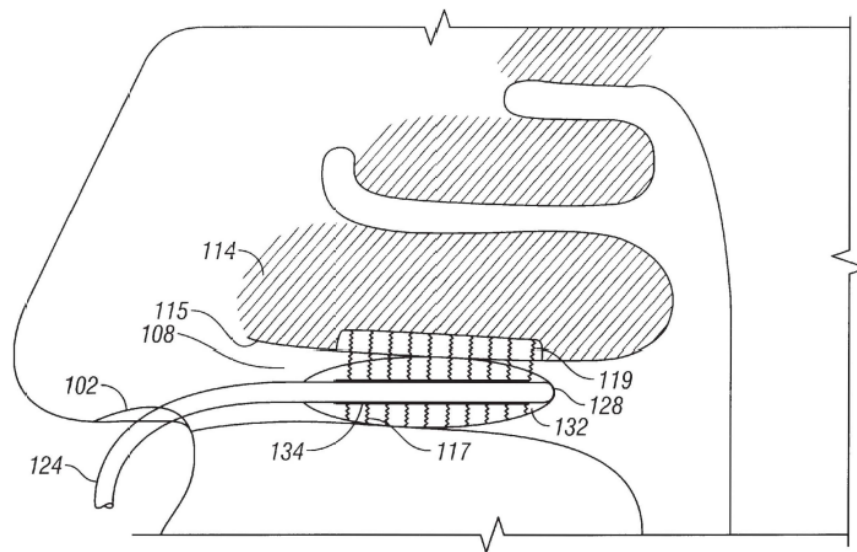


FIG. 3B

Figure 3B above shows “apparatus 124 having a distal portion 128 with an expandable member 132 and an energy delivery device 134 for delivering ablative energy” that has been “introduced through a nostril 102” into the nasal meatus 108 adjacent a surface of the nasal concha 114. *Id.* at 5:20–26. In Figure 3B, expandable member 132 has been “expanded within the nasal meatus 108 so that the expandable member 132 is brought into contact with the surface 115 of the nasal concha 114 to be treated.” *Id.* at 5:27–30. “Ablative energy 117 is then delivered through the apparatus and the energy delivery device 134 to the nasal concha 114” in order “to ablate at least a portion 119 of the nasal concha 114.” *Id.* at 5:30–34.

Edwards-535 further teaches that the surface of the nasal concha may be cooled, e.g., by “introducing cooled medium into the expandable member,” during the delivery of the ablative energy. *See* Ex. 1010, 6:9–37. According to Edwards-535:

Cooling serves at least two purposes. Cooling may be used to prevent ablation of the surface of the nasal concha by preventing the ablation of the surface of the nasal concha. As a

result, an exposed wound site is not generated during the method. Cooling may also be used to control the location of the ablation site. For example, cooling the nasal concha surface enables the formation of an entirely internal ablation site. The extent of cooling can be used to control the thickness of the non-ablated tissue at the surface of the nasal concha adjacent the internal ablation site.

Id. at 6:23–32.

Regarding configuration of its apparatus, Edwards-535 teaches that “the energy delivery device 134 may be positioned within the expandable member.” Ex. 1010, 8:8–9. For example, Figure 6 of Edwards-535, reproduced below, shows an embodiment of an energy delivery device comprising a plurality of “ring electrodes.” *See id.* at 4:1–2, 8:18–23.

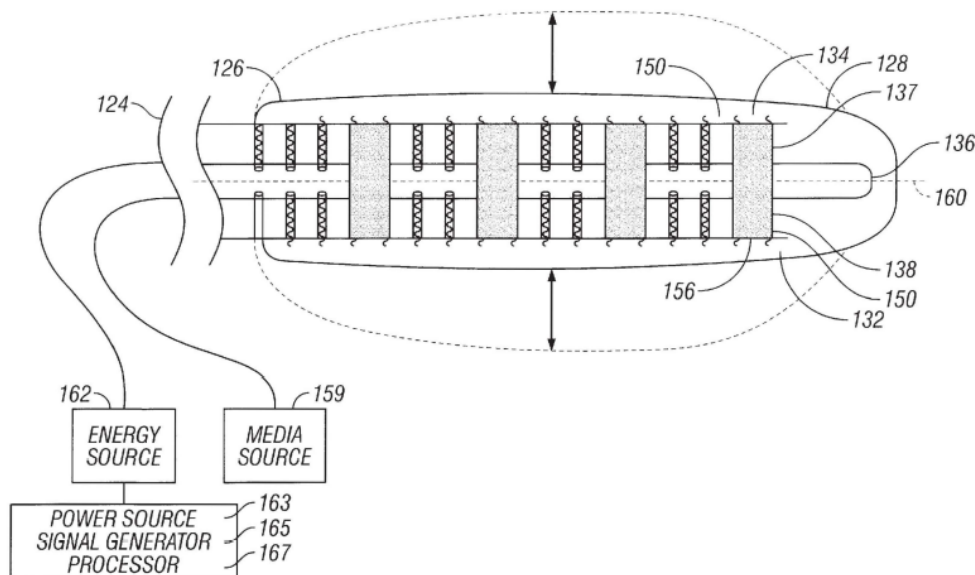


Figure 6 above depicts an embodiment comprising multiple ring electrodes 156 “disposed on the surface of the expandable member 132” in a row such that their “axes [are] aligned with a long axis 160 of the catheter body 126.” *Id.* at 8:18–23.

Edwards-535 teaches that, “[i]n another embodiment, a plurality of energy delivery devices are positioned on a surface of the expandable

member.” Ex. 1010, 8:25–27; *see also id.* at 8:12–14 (“Alternatively, the energy delivery device may be positioned on a surface 147 of the expandable member.”). Edwards-535 cites another reference, Baker,¹¹ as describing “[a]n example of a suitable surface for disposition on the membrane.” *Id.* at 8:27–31.

Edwards-535 explains that energy to each of the plurality of electrodes or individual energy delivery devices may be independently delivered. *See* Ex. 1010, 8:14–17, 8:23–25. Edwards-535 further teaches that the energy can be delivered in “monopolar or bipolar fashion” and monitored/controlled by various sensors, including voltage and current sensors to calculate energy and impedance and temperature sensors. *See id.* at 10:4–11:44 (describing block diagrams in Figures 8–10 of Edwards-535).

ii. Kong

Petitioner offers evidence that the original Chinese language version of Kong was publicly accessible as of March 2005. Ex. 1070 ¶¶ 58–65. It is undisputed that Kong qualifies as prior art under 35 U.S.C. § 102(a)(1).

Kong describes a study involving the use of a “low-temperature ablation plasma surgery system” to treat perennial allergic rhinitis. Ex. 1040, 214 (Abstr.). Kong explains that all of the 35 patients in its study exhibited symptoms, including “clear nasal discharge, and nasal congestion” that did not respond to systemic treatment with medication. *Id.* at 214 (1.1 Clinical data).

The patients in Kong’s study were treated with “endoscopic ablation of the inferior turbinate.” Ex. 1040, 214 (Abstr.). Surface and infiltration

¹¹ More precisely, Edwards-535 cites the patent application that issued as US 5,575,788 (Ex. 1011) (“Baker”).

anesthesia was administered and a surgical hole was made “at the lower or medial edge of the inferior turbinate” so that the RF electrode could be inserted to ablate the surrounding tissue. *Id.* at 214 (1.2 Surgical methods). Kong reports that its procedure resulted in decreased secretion and was effective to reduce symptoms such as watery discharge with a total effective rate of 94.3%. *Id.* at 214 (2 Results). According to Kong, these results show that “low-temperature plasma ablation of the inferior turbinate . . . is simple in operation, and safe and reliable, and has high clinical application values” in the treatment of perennially allergic rhinitis. *Id.* at 214 (Abstr.).

iii. Stern

Stern is a United States patent issued October 8, 1996. Ex. 1033, code (45). It is undisputed that Stern qualifies as prior art under 35 U.S.C. § 102(a)(1) and (2).

Stern describes an “endometrial ablation device” that passes RF energy to body organ tissue, such as the endometrium, to heat it. Ex. 1033, code (57); *see also id.* at 3:12–40 (describing an apparatus and “method of heating body organ tissue by the selective application of RF energy to said tissue”). “An electroconductive expandable member such as a balloon is used as the medium for passing the current and causing the heating” *Id.* at code (57). Power is “selectively provided to a plurality of electrode area segments on the balloon” and can provide either monopolar or bipolar power. *Id.*

Figure 15 of Stern, reproduced below, is an electrical “schematic of a selectable bipolar/monopolar RF energy delivery system for a plurality of electrodes or electrode segments.” Ex. 1033, 5:48–50.

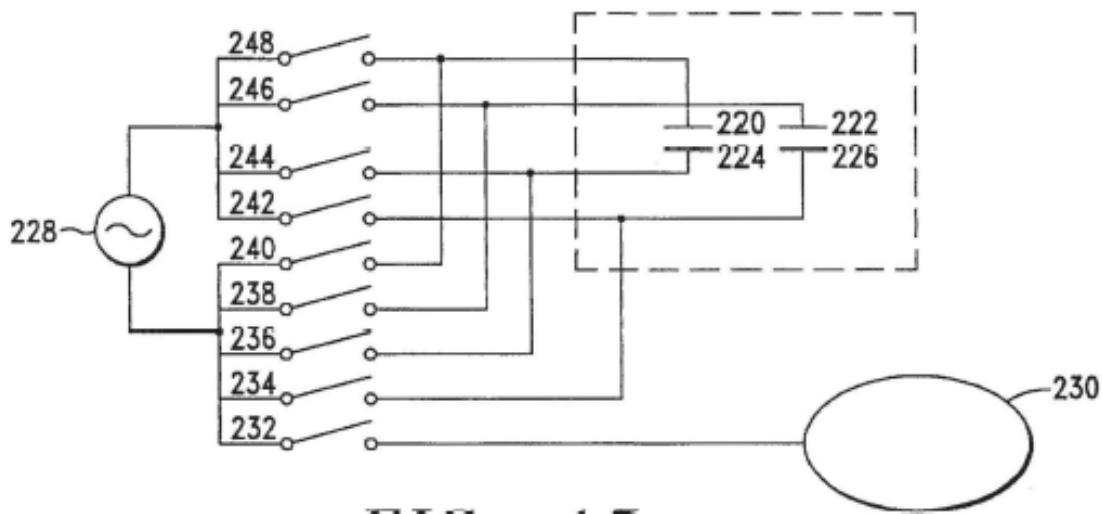


FIG. - 15

Figure 15 above shows four electrodes 220, 222, 224, and 226 connected to a voltage source 228 by a series of switches. *Id.* at 12:46–49. Stern explains that the switches allow the operator to select between monopolar and bipolar operation of electrode pairs with the latter involving current flowing between different “pair couplings.” *See id.* at 12:50–13:2; *see also id.* at Fig. 17, 13:11–35 (describing bipolar operation of an electrode pair). According to Stern, this type of “bipolar arrangement allows various pairs of electrodes to be picked in order to heat uneven or rather asymmetrical areas within individual patients in which the balloons are inserted or within specialized needs for certain tissue destruction.” *Id.* at 13:27–31. Stern also teaches that the embodiment of Figure 15 “provides flexibility within bipolar operation so that any pair or any combination of pairs of electrodes may be utilized together.” *Id.* at 13:39–43.

Figure 19 of Stern, reproduced below, is a side view of an embodiment of Stern’s ablation balloon. Ex. 1033, 5:58–59.

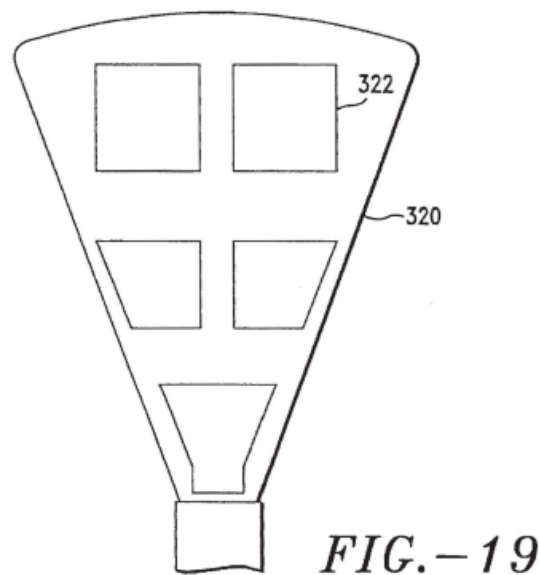


Figure 19 above shows a plurality of electrodes 322 arranged on the surface of bladder 320.¹²

iv. Edwards-886

Edwards-886 is a United States patent issued August 14, 2001. Ex. 1016, code (45). It is undisputed that Edwards-886 qualifies as prior art under 35 U.S.C. § 102(a)(1) and (2).

Edwards-886 relates to “[s]ystems and methods [that] integrate the control of an energy generator, to supply energy to an electrode structure to heat a tissue region.” Ex. 1016, code (57). In relevant part, Edwards-886 teaches that its generator “has four independent radio frequency channels” and each channel “is capable of supplying up to 15 watts of radiofrequency energy with a sinusoidal waveform at 460 kHz.” Ex. 1016, 36:66–37:2.

¹² Stern also refers to “balloon 320.” See Ex. 1033, 14:25–38 (describing Figure 19). We do not discern a difference between Stern’s use of the terms balloon and bladder.

v. *Liang*

Petitioner offers evidence that the original Chinese language version of Liang was publicly accessible as of August 1999. Ex. 1070 ¶¶ 30–38. It is undisputed that Liang qualifies as prior art under 35 U.S.C. § 102(a)(1).

Liang describes a study of “the effect of radiofrequency treatment of ethmoidal nerve on allergic rhinitis.” Ex. 1056, 341 (Abstr.). Liang explains that RF treatment “can cause varying degrees of damage to the deep ethmoidal nerve, reducing its sensitivity to adverse external physical and chemical stimuli . . . reducing runny nose, and improving nasal ventilation, thus achieving the goal of treating allergic rhinitis.” *Id.* at 342.

In Liang’s study, the “emitter” of a radiofrequency device “[u]nder direct nasal endoscopy . . . was used to perform thermal coagulation treatment on the bilateral nasal ridge and the corresponding nasal septum mucosa.” *Id.* at 341 (1.2 Treatment methods). Liang reports a 95.5% “overall effective rate” and that “the symptoms of allergic rhinitis were significantly relieved” for the 88 patients in its study. *Id.* at 341 (2 Results), 342.

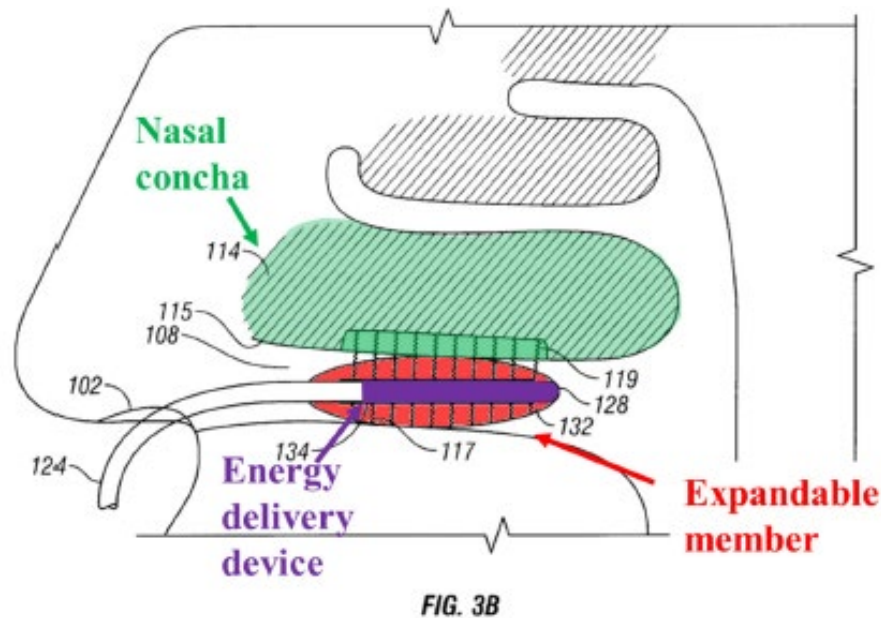
E. Ground I: Obviousness over Edwards-535, Kong, and Stern

Petitioner contends claims 1–3, 6–12, and 16 would have been obvious over Edwards-535, Kong, and Stern. *See* Pet. 17–51. Patent Owner disputes Petitioner’s contentions, raising global arguments for some aspects of claim 1 that also apply to the dependent claims. Resp. 18–39. Patent Owner also raises separate arguments for the additional limitations recited in claims 11 and 16. *Id.* at 39–46. We begin with claim 1.

i. *Claim 1*

Petitioner asserts that Edwards-535 teaches or suggests most of the elements of claim 1. *See generally* Pet. 26–56. To illustrate its position,

Petitioner offers annotated versions of several of Edwards-535's figures, including the annotated version of Figure 3B reproduced below.



In Petitioner's annotated version of Figure 3B, expandable member 132 is marked in red, energy delivery device 134 is marked in purple, and nasal concha 114 is marked in green. Petitioner explains that the expandable member and energy delivery device are part of "distal portion 128 (i.e., *treatment element*)" and that the expandable member portion of that element is brought into contact with the surface 115 of nasal concha 114 to deliver ablative energy to the nasal airway. *See* Pet. 36 (internal quotation omitted). Petitioner also relies on Edwards-535's disclosure of alternative embodiments where the electrodes "are disposed on the surface of, rather than inside expandable member 132" such that those "electrodes would also contact the nasal concha 114." *Id.* at 37–38 (internal quotations omitted). Petitioner contends that in both configurations, Edwards-535 teaches "contacting a treatment element . . . directly with nasal mucosa" as recited in element 1[a]. *Id.* at 35. Petitioner also contends that Edwards-535 and Kong

teach the removal of the treatment element after application of RF energy.
Id. at 51–53.

Regarding the claim language relating to reduced mucus production (e.g., elements 1[pre] and 1[e]), Petitioner contends that one of ordinary skill would have been motivated to “us[e] the method taught by Edwards-535[] to target specified nerve tissue as taught by Kong—to reduce mucus production by applying RF energy to parasympathetic nerves underneath the lower surface of the in[f]erior turbinate . . . with a reasonable expectation of success.” Pet. 29. Petitioner offers several reasons for this combination, including that “Kong discloses the benefits of using RF energy to treat the same location . . . as Edwards[-535],” but that unlike Kong’s approach, Edwards-535 “uses a non-puncturing balloon that provides cooling to the contacted tissue and is less damaging to the surface mucosa.” *Id.* at 29–30. In addition to such reasoning, Petitioner argues that “Edwards-’535 and Kong describe similar techniques such that their combination would have yielded predictable results,” i.e., “reducing mucus production without damaging mucosal tissue.” *Id.* at 30–32. Petitioner asserts that one of ordinary skill would have had a reasonable expectation of success for similar reasons. *See id.* at 32–34.

Petitioner relies on Stern for its teaching of “implementation details” for “an RF device like Edwards-’535’s” and specifically an “exemplary arrangement of *two rows of bipolar RF electrodes*.” *See* Pet. 38–49. That is, Petitioner asserts that Stern’s Figure 15 “shows circuitry to operate bipolar pairs that includes four electrodes 220, 222, 224 and 226 and various switches 232-248 to *pair* electrodes in a bipolar configuration.” *Id.* at 39.

Petitioner illustrates its position with the annotated version of Stern's Figure 15 below. *Id.* at 39.

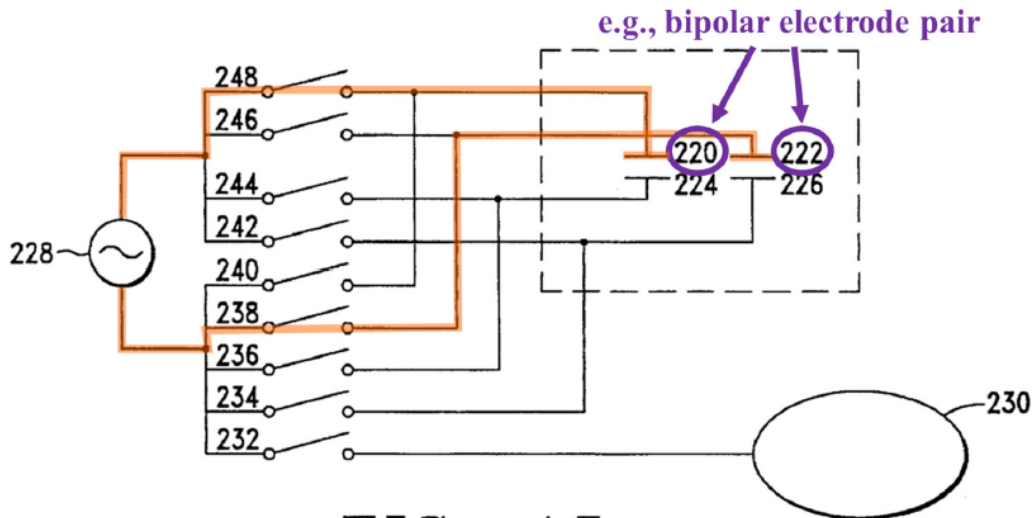


FIG.-15

In the figure above, Petitioner uses purple annotations to identify an exemplary bipolar electrode pair between electrodes 220 and 222.

Petitioner further contends that Stern teaches these pairs arranged in two rows, offering the annotated versions of Stern's Figures 15 and 19 below to illustrate its position.

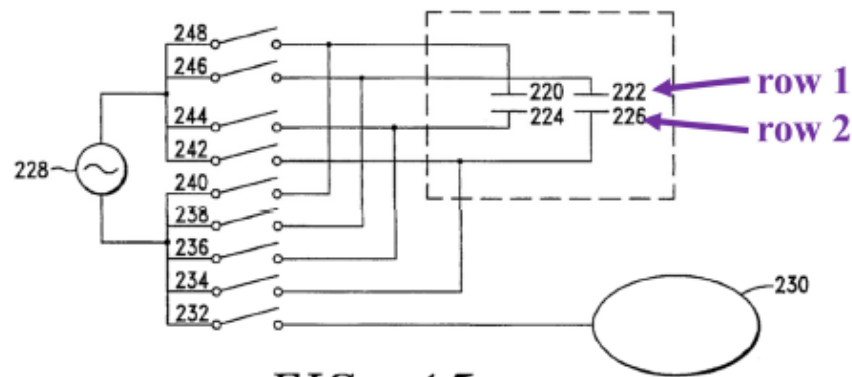
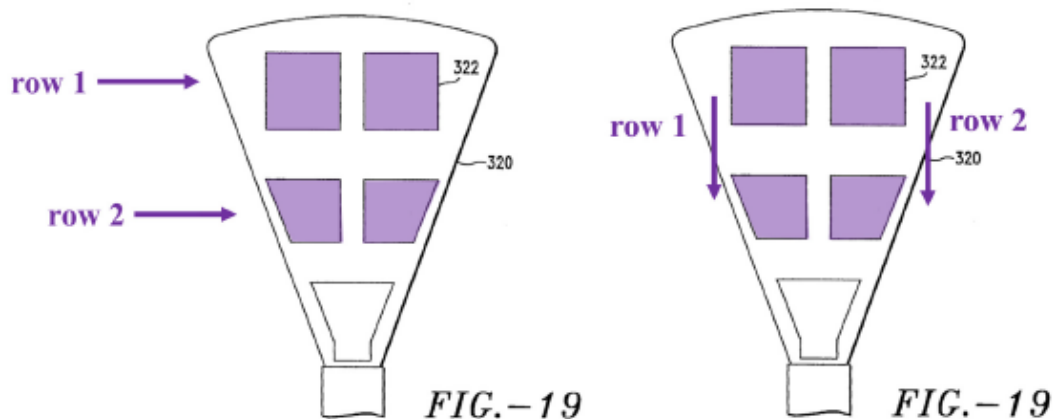


FIG. -15



In the figures above, Petitioner uses purple annotations to identify a “row 1” and “row 2” of electrodes pairs. *Id.*; see also Ex. 1002 ¶ 92; Ex. 1004 ¶¶ 72–74. For example, in Figure 15 of Stern, Petitioner identifies electrodes 220 and 222 as a bipolar electrode pair arranged in a first row and electrodes 224 and 226 as a bipolar electrode pair in a second row. *Id.* Petitioner identifies a similar arrangement for the electrodes 322 shown in Figure 19 of Stern. See *id.*

Petitioner contends it would have been obvious to “implement[] Edwards-’535’s energy delivery device 134 with Stern’s *two rows of bipolar RF electrode pairs* on the surface of the expandable member 132.” See Pet. 42–49. According to Petitioner, “Edwards-’535 demonstrates that it was well

known to provide RF ablation devices with multiple bipolar surface electrodes for ablation of various locations in the body,” but “omits details on how to implement such energy delivery.” *Id.* at 42. Petitioner contends a POSITA would have looked to Stern for such details because Stern teaches that bipolar electrode pairs “provide a number of advantages and benefits” (*id.* at 43–47), and “arranging electrodes in rows” as taught in Stern “as opposed to a more disorganized pattern or a single row, facilitates simple spatial resolution of the applied energy” that “enables targeting particular portions of tissue” (*id.* at 47–48). Regarding the latter point, Petitioner further explains that “Edwards-’535 instructs a POSITA to look to Baker for how to dispose electrodes on the surface of a membrane” and “Baker, like Stern, . . . discloses electrodes in rows.” *See id.* at 46–47 (comparing figures from Baker and Stern). Petitioner further asserts that a two-row arrangement “would have involved an obvious duplication of parts” because Edwards-535 “already discloses one row of electrodes.” *Id.* at 48. Petitioner supports these and its other contentions above with testimony from its declarants. *See id.* at 26–56 (citing Ex. 1002 ¶¶ 68–108; Ex. 1004 ¶¶ 66–97).

Patent Owner does not dispute Petitioner’s allegations for claim elements 1[c]-[e] or Petitioner’s reasoning for combining Edwards-535 with Kong. *See Resp.* 18. Patent Owner also does not dispute Petitioner’s showing that the asserted combination of references teaches some aspects of elements 1[a] and 1[b], i.e., a method for treating a nasal airway involving the steps of contacting a treatment element of a nasal airway treatment device directly with the nasal mucosa and applying RF energy to heat an underlying target tissue. Instead, Patent Owner focuses its arguments on Petitioner’s allegation that Stern teaches “two rows of bipolar electrode

pairs” and applying RF energy with those “bipolar electrode pairs” in elements 1[a] and 1[b]. *Id.* More specifically, Patent Owner asserts that Petitioner’s showing fails because (1) “Stern teaches a device comprising only a *single pair* of bipolar electrodes” and (2) “Stern teaches at most two rows of a *single pair* each—not two rows of *pairs*.” *Id.* Patent Owner also disputes Petitioner’s showing regarding the motivation “to combine Edwards-535 with Stern’s electrode arrangement.”¹³ *Id.* at 32–39.

We find that one of ordinary skill in the art would have been motivated to combine Edwards-535, Kong, and Stern with a reasonable expectation of success for the reasons set forth in the Petition. *See* Pet. 26–56. We also find that the articulated combination of Edwards-535, Kong, and Stern teaches all of the steps of claim 1 in the recited order. We adopt the undisputed portions of Petitioner’s element-by-element analysis and its reasoning for combining the references. *See id.* at 26–38, 51–56; Ex. 1002 ¶¶ 68–91, 100–107. Below we address the parties’ arguments regarding the disputed aspects of elements 1[a] and 1[b] and the motivation for combining Stern’s electrode arrangement with the other references.

¹³ Patent Owner previously argued that there was no motivation to combine any of the teachings in Stern with Edwards-535 because the references were “diametrically opposed.” *See* Paper 7 (Preliminary Resp.) 8–23. The Response, however, focuses only on the motivation to combine a two-row electrode arrangement. *See* Resp. 32–39. Patent Owner’s arguments disputing Petitioner’s showing regarding the motivation to combine these references more generally have been waived, and we do not consider them further. *See In re Nuvasive, Inc.*, 842 F.3d 1376, 1381 (Fed. Cir. 2016) (explaining that a patent owner waives an issue presented in its preliminary response if it fails to renew the issue in its response after trial is instituted); *see also* CTPG 52.

1. Elements 1[a] and 1[b]: “bipolar electrode pairs”

Patent Owner argues that Petitioner has failed to show that the asserted combination “teaches a treatment element comprising ‘bipolar electrode *pairs*,’” i.e., more than one pair, because “Stern teaches a device comprising at most a *single pair* of bipolar electrodes.” Resp. 19. According to Patent Owner, a bipolar pair is formed only when two electrodes near each other have opposite polarities, which requires operation (i.e., closing) of various switches shown in Stern’s Figure 15. *Id.* at 20–21. Patent Owner argues that Petitioner’s annotated version of Figure 15 shows only a single bipolar pair and it is only by closing “three or more of Figure 15’s switches . . . at the same time” that multiple pairs of bipolar radiofrequency electrodes will be formed. *Id.* at 18, 21–22. According to Patent Owner, Stern contains no such disclosure because its device’s electrodes are “*independently and sequentially energized*” and thus configured to have no more than a single pair of bipolar electrodes at any given time. *Id.* at 22 (quoting Ex. 1033, 2:31–33, 10:48–52).

We disagree with Patent Owner for several reasons. First, as Petitioner correctly points out, “the claims do not recite that the ‘pairs’ must be active ‘*at the same time*,’” nor is there any basis in the intrinsic record for reading such a requirement into the claims. Reply 4–5. Claim 1 recites the use of a treatment element comprising “bipolar electrode pairs” to apply RF energy through those pairs. Ex. 1001, 48:27–29. Nothing in the claim language suggests those pairs must be active or energized at the same time.

This is consistent with the specification of the challenged patent, which describes embodiments in which each electrode pair is separately controlled and therefore may be “activated separately,” i.e., at different

times. Ex. 1001, 23:64–24:1; *see also* Ex. 1083 ¶¶ 19–20 (explaining that the ’271 patent’s description of activating pairs “‘separately’ is the opposite of activating pairs ‘at the same time’” and concluding that the disclosure Dr. Bikson cites “is consistent with pairs of electrodes being activated either at different times (i.e., ‘separately’) *or* at the same time”). Accordingly, even if Stern’s disclosure were limited to switching on only a single pair of the bipolar electrodes in Figure 15 at a time, as Patent Owner contends (*see* Sur-reply 4), it would still teach or suggest the “bipolar electrode pairs” as recited in elements 1[a] and 1[b].

Indeed, on page 4 of its Sur-reply, Patent Owner concedes that “[c]laim 1 does not require simultaneous activation of multiple bipolar electrode pairs.” Notwithstanding that concession, Patent Owner continues to argue that Stern does not teach “bipolar electrode pairs” because its device is not “configured to have multiple bipolar electrode pairs.” Sur-reply 4.

We disagree with Patent Owner. The distinction, if any, that Patent Owner draws between what it acknowledges is *not* required by claim 1 (i.e., “simultaneous activation” of the multiple pairs) and what it says *is* required for Stern to teach this limitation (i.e., a device “configured” to form multiple bipolar pairs) is not well-explained. Patent Owner argues that a bipolar electrode pair is formed only when two electrodes are energized and therefore, “three or more of [Stern’s] Figure 15’s switches must be closed at the same time,” i.e., simultaneously activated, “to form ‘*multiple pairs* of bipolar electrodes,’ as claimed.” Resp. 21–22. Accordingly, it is not clear what—short of simultaneous activation of more than one pair of the

electrodes in Figure 15—Patent Owner contends is missing from Stern’s disclosure.

In our view, nothing is missing. Stern teaches that the circuitry in Figure 15 is configured to form multiple pairs of bipolar RF electrodes. Ex. 1033, 12:61–13:2 (explaining “[a]s an example” the closing of certain switches in Figure 15 to activate a bipolar pair between electrodes 220 and 224 and a second bipolar pair between electrodes 222 and 226 and further noting that “[c]learly bipolar operation is not limited to these . . . pair couplings” because other switches could be operated to activate a bipolar pair between electrodes 220 and 222); Ex. 1004 ¶¶ 70–71; Ex. 1097 ¶¶ 24, 27–28. Indeed, Stern consistently uses the word “pairs,” i.e., the plural not the singular, to describe the bipolar operation of its device. *See* Ex. 1033, 2:36–40, 3:38–40, 12:20–25, 12:29–30, 13:27–44, 20:9–10 (describing the bipolar operation of “pairs” nine times). In view of these disclosures, Patent Owner’s argument that Stern teaches a device configured to have at most only a single pair of bipolar RF electrodes, and Dr. Bikson’s testimony in support of the same (Ex. 2001 ¶¶ 64–71), are not credible.

Second, even if claim 1 did require simultaneous activation of multiple bipolar pairs, we agree with Petitioner that such functionality is also taught by Stern. *See* Reply 5–6. That is, Stern teaches that the “embodiment of FIG. 15 . . . provides flexibility within the bipolar operation so that any pair *or any combination of pairs* may be utilized together.” Ex. 1033, 13:39–43 (emphasis added).

Patent Owner argues this passage should be read to mean that “any combination of pairs of electrodes may be utilized together **sequentially** (i.e., one pair at a time).” Sur-reply 5. According to Patent Owner, its

interpretation is informed by other disclosures in Stern teaching that its electrodes are independently and sequentially energized. *Id.* at 5–6 (citing Ex. 1033, 2:31–33, 2:49–53, 10:48–52, 17:54–55; Ex. 2001 ¶ 69; Ex. 1004 ¶ 81). Patent Owner urges that “when Stern is properly read in its entirety, any potential ambiguity is resolved **in Patent Owner’s favor.**” *Id.* at 6.

We disagree. First, there is nothing ambiguous about Stern’s teaching that “any pair or any combination of pairs may be utilized together.” Ex. 1033, 13:39–43. Utilized together means at the same time. Ex. 1083 ¶ 25; Ex. 1097 ¶ 22. Second, there is no reason to modify this clear teaching, as Patent Owner attempts to do, because it is entirely consistent with Stern’s other disclosures. Read in context of the full reference, one of ordinary skill would have understood that the circuitry of Figure 15 allows for independent and sequential energization of any pair or any combination of pairs (i.e., multiple pairs at once) of bipolar RF electrodes. Ex. 1097 ¶¶ 22–28.

Patent Owner’s argument that activating multiple pairs at the same time could result in uneven heating does not compel a different interpretation. *See* Sur-reply 6–7. Even assuming that the sequential activation of just one pair of bipolar electrodes at a time would provide better control over heating, Stern must be considered for all it teaches. *See In re Inland Steel Co.*, 265 F.3d 1354, 1361 (Fed. Cir. 2001); *Merck & Co., Inc. v. Biocraft Labs., Inc.*, 874 F.2d 804, 807 (Fed. Cir. 1989) (“all disclosures of the prior art, including unpreferred embodiments, must be considered”). Accordingly, one of ordinary skill in the art would have understood that Stern discloses embodiments in which each pair is activated sequentially as well as those in which “combinations of pairs are utilized

together,” even if there are technical reasons why one might be preferable over the other. *Id.*

Finally, Patent Owner’s argument that “[r]egardless of whether Stern teaches ‘bipolar electrode pairs,’” the cited references do not teach “the step of ‘applying radiofrequency energy with the bipolar electrode pairs’” in element 1[b] is likewise unavailing. Resp. 30–32. Petitioner demonstrates that it would have been obvious to apply RF energy through the multiple bipolar pairs taught in Stern *before* removing the treatment device from the nasal airway. Ex. 1002 ¶¶ 100–102 (explaining that both Edwards-535 and Kong teach that the treatment element is removed after applying RF energy and that it would be “impractical” to leave the treatment element inserted in the patient’s nasal passages indefinitely); *see also* Ex. 1083 ¶¶ 50–52 (explaining that one of ordinary skill would want to minimize the number of times the treatment element is inserted and removed). While Patent Owner frames this as a separate argument over the order of the claim steps, it does not offer a substantive response to Petitioner’s showing that the recited ordering would have been obvious. *See* Resp. 31–32. Instead, Patent Owner rehashes the same arguments that Stern does not teach more than one bipolar pair. *Id.*; *see also* Sur-reply 2 (urging the “sequence of steps in claim 1 is important” because “Petitioner[’s] analysis only identifies a single pair of electrodes”). As explained above, those arguments are not persuasive because Stern teaches applying RF energy through multiple bipolar pairs both activated in sequence and combinations of pairs activated simultaneously. *See also* Ex. 1087 ¶¶ 42–43.

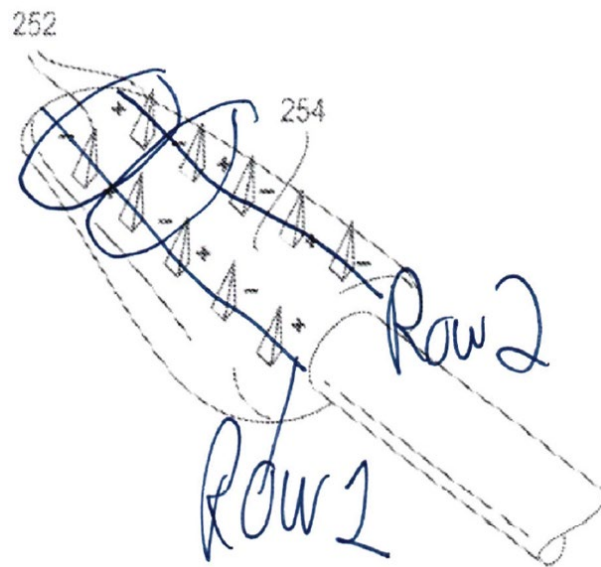
For these reasons, Petitioner has sufficiently demonstrated that the combination of Edwards-535, Kong, and Stern teaches or suggests “bipolar electrode pairs” as recited in elements 1[a] and 1[b].

2. Element 1[a]: “two rows of bipolar electrode pairs”

According to Patent Owner, the phrase “two rows of bipolar electrode pairs” in element 1[a] requires “at least two rows with at least two pairs of bipolar electrodes per row.” Sur-reply 8. Patent Owner argues that Stern does not teach this limitation because “Stern, at best, teaches two rows of a *single pair* each—not two rows of *pairs*.” See Resp. 23–25 (referring to Petitioner’s annotated versions of Stern’s Figures 15 and 19 showing a “row 1” and “row 2” each having two electrodes).

Petitioner counters that Patent Owner’s interpretation of the claim language “incorrectly assumes that the ‘s’ in ‘pairs’ modifies pairs within a single row.” Reply 7. According to Petitioner, this “unsupported assumption would improperly exclude preferred embodiments” and “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.” *Id.* at 8. In particular, Petitioner points to Figure 8F of the ’271 patent, using the annotated version of Figure 8F below to illustrate its position. *Id.* (citing Ex. 1087).¹⁴

¹⁴ Dr. Bikson apparently made these annotations during his deposition. See Ex. 1084, 159:1–161:20. Exhibit 1087 is the annotated version of Figure 8F of the ’271 patent marked as Exhibit C in that deposition.



The figure above includes handwritten annotations identifying two rows containing five electrodes. According to Petitioner, Figure 8F shows pairs of electrodes “arranged ‘side-by-side’” (and circled in the annotated figure) such that “energy travels from one row of electrodes to the other row of electrodes.” *Id.* at 8–9 (quoting Ex. 1001, 8:24–25, 23:56–59). Petitioner argues that Patent Owner’s interpretation of the claim language would exclude that embodiment because “each row contains one electrode—half—of a given pair and no complete pairs.” *Id.* at 9. Petitioner also identifies cases, where “in analogous circumstances, a plural term [was] interpreted to require only one item” and argues that the ’271 patent applies such a usage by referring to “*one*, two, or many *pairs* of bipolar needles 252.” *Id.* at 9–10 (quoting Ex. 1001, 23:40–43) (citing *Dayco Prod., Inc. v. Total Containment, Inc.*, 258 F.3d 1317, 1328 (Fed. Cir. 2001); *Versa Corp. v. Ag-Bag Intern. Ltd.*, 392 F.3d 1325, 1330 (Fed. Cir. 2004)).

Petitioner’s position is persuasive. Stern’s Figure 15 shows bipolar electrodes 220 and 224 in a first horizontal row and electrodes 222 and 226 in a second horizontal row. Stern teaches that bipolar pairs can be formed

between various combination of these electrodes resulting in both pairs within a row and pairs formed across two rows. *See* Ex. 1033, 12:61–13:2 (explaining that “bipolar operation is not limited to [electrode] 220-224 and 222-226 pair couplings” because pairs could also be formed across rows, e.g., between electrodes 220 and 222). Stern’s Figure 19 likewise depicts a plurality of electrodes arranged in two rows. *See* Ex. 1004 ¶¶ 71–74 (Dr. Martin explaining that the physical arrangement in Figure 19 is complementary to the control structure in Figure 15 and that there are two rows regardless of which electrodes are paired). In bipolar operation, each of these figures depicts “two rows of bipolar electrode pairs” as recited in element 1[a] because there are two rows comprising multiple pairs.¹⁵

Patent Owner’s narrower interpretation of the phrase “two rows of bipolar electrode pairs” is not consistent with the intrinsic record. According to Patent Owner and Dr. Bikson, it is not enough that there are two rows of electrodes comprising multiple pairs—rather each row must itself contain multiple pairs. *See* Resp. 23; Ex. 2001 ¶ 75 (“A row of only two electrodes is not a row of bipolar electrode pairs because a row of only two electrodes has at most a single pair (not multiple pairs).”). As Petitioner points out, Patent Owner’s interpretation assumes that the “s” in “pairs” modifies each row individually, rather than the recited “rows” collectively. But the claim

¹⁵ In reply to Patent Owner’s argument that there must be at least three electrodes in a row for that row to contain multiple pairs, Petitioner shows that Stern also discloses rows with three or more electrodes. Ex. 1083 ¶¶ 36–40; Ex. 1097 ¶¶ 39–41 (identifying rows with three or more electrodes in Stern’s Figures 4a and 19). We need not address that showing in detail because, as explained below, element 1[a] does not require that there be more than one pair in each row.

language does not specify that *each* row has pairs (plural). Rather, given its plain meaning, “two rows of bipolar electrode pairs” encompasses an arrangement like that shown in Stern’s Figure 15. Ex. 1097 ¶ 30 (Dr. Martin explaining that “what is required is (1) more than one bipolar electrode pair that are (2) spread across rows”).

This broader understanding is confirmed by the specification of the ’271 patent. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2004) (en banc) (explaining that the specification “is the single best guide” for discerning the meaning of a claim term). The specification repeatedly describes embodiments comprising two rows of electrodes where bipolar pairs are formed between an electrode in one row and an electrode in the second row such that “the device is configured to deliver radiofrequency energy from one row of electrodes to the other row of electrodes.” Ex. 1001, Abstr., 8:21–25. In such embodiments, neither row considered individually would have a bipolar electrode pair, much less multiple pairs as Patent Owner contends. But considering the rows collectively, those embodiments have “two rows of bipolar electrode pairs” as recited in claim 1.

This arrangement is depicted in Figure 8F of the ’271 patent. As shown in Petitioner’s annotated figure above, Figure 8F has two rows with five electrodes each and the pairs are arranged “side-by-side” between electrodes in different rows. Ex. 1001, 23:40–59 (contrasting Fig. 8F with Fig. 8G); *see also* Ex. 1097 ¶ 31 (explaining Fig. 8F in light of this description).

Patent Owner, however, offers a different view of Figure 8F. Sur-reply 8–10. It urges that Figure 8F has multiple pairs in each row because pairs could be formed between electrodes in the same row along the length

of the treatment element. *Id.* (citing Ex. 2001 ¶ 79). The problem with Patent Owner’s view is that it conflicts with the description in the specification indicating that in contrast to the embodiment in Figure 8G, which “arranges the pairs of electrodes along the length of the treatment element,” the pairs in Figure 8F “are arranged side-by-side.” Ex. 1001, 23:56–59.¹⁶

Accordingly, Dr. Martin’s testimony on this point (Ex. 1097 ¶¶ 30–36) is more consistent with the intrinsic record of the ’271 patent than Dr. Bikson’s (Ex. 2001 ¶¶ 74–79), and we credit it over the latter. The fact that it may be possible to form multiple pairs within each of the rows depicted in Figure 8F or elsewhere in the ’271 patent, does not suggest that claim 1 is limited to such. This is especially true given that all of the express description of two-row embodiments in the specification refers to pairs being formed between electrodes in *different* rows, rather than electrodes in the same row. Ex. 1001, Abstr., 8:21–25, 23:40–59. Neither Patent Owner, nor Dr. Bikson, identify any persuasive reason why we should construe claim language that does not specify that there are multiple pairs *in each row* to require such when doing so would exclude these embodiments.

¹⁶ Patent Owner also argues that Figure 23G of the ’271 patent discloses “multiple rows with multiple bipolar electrode pairs in each row.” Sur-reply 9 (citing Ex. 2010, 119:7–13). We disagree. Figure 23G shows multiple rows of electrodes, but it does not show the pairing between those electrodes. Thus, it is consistent with the other description in the ’271 patent describing RF energy passing between electrodes in two different rows such that the rows collectively comprise multiple pairs. The testimony Patent Owner cites from Dr. DelGaudio does not say otherwise. *See* Ex. 2010, 119:7-13 (“Q: So you would agree that [Fig.] 23G discloses multiple rows of multiple bipolar electrodes. A: Correct”).

Patent Owner’s claim differentiation argument is also unavailing. *See* Resp. 28–29. According to Patent Owner, the claims of two related patents show that “the ’271 patent family distinguishes between ‘two rows of electrode pairs’ and ‘two rows of electrodes.’” *Id.* (referring to claim 1 of U.S. Patent 8,986,301 (Ex. 2008) and claims 1 and 15 of U.S. Patent 11,033,318 (Ex. 2009)). However, the claims of those related patents differ in multiple respects from claim 1 of the ’271 patent.¹⁷ Because the claims “are not otherwise identical in scope,” the doctrine of claim differentiation does not apply to distinguish the claim language Patent Owner identifies. *See Apple, Inc. v. Ameranth, Inc.*, 842 F.3d 1229, 1238 (Fed. Cir. 2016) (quoting *Indacon, Inc. v. Facebook, Inc.*, 824 F.3d 1352, 1358 (Fed. Cir. 2016)). Even if it did, “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,” and, in our view, would not provide sufficient

¹⁷ In addition to reciting a substantially different preamble, claim 1 of the ’301 patent recites contacting the treatment element “with sufficient force to at least temporarily deform” the nasal tissue. Ex. 2008, 47:24-37. It also limits the applying energy step to require “transmitting radio frequency energy from a first row of electrodes to a second row of electrodes.” *Id.* In some respects, this is narrower than element 1[b] of the ’271 patent, which would encompass both pairs between electrodes in a single row as well as pairs formed by transmitting RF energy between electrodes in different rows. In other respects, it is broader because element 1[b] further requires that the energy be applied “through the nasal mucosa to a target tissue underlying the nasal mucosa for an amount of time to heat the target tissue.” Ex. 1001, 48:29–31. Claims 1 and 15 of the ’318 patent are even more different because they are apparatus claims and recite numerous element (e.g., “handle,” “shaft,” “output channels,” “sensors,” etc.) that do not appear in claim 1 of the ’271 patent. Ex. 2009, 52:15–36 (claim 1), 54:7–9 (claim 15, which depends from claim 1).

basis to supplant the broader plain meaning of the claim language in view of the specification of the '271 patent itself. *See Clare v. Chrysler Group LLC*, 819 F.3d 1323, 1330 (Fed. Cir. 2016).

For these reasons, Petitioner has sufficiently demonstrated that the combination of Edwards-535, Kong, and Stern teaches or suggests “two rows of bipolar electrode pairs” as recited in element 1[a].

3. Motivation to combine Stern’s electrode arrangement

Patent Owner argues that Petitioner’s reasoning for combining Stern’s two-row arrangement of bipolar electrode pairs with the other references is unpersuasive. *See* Resp. 32–39. First, regarding the reasoning based on Baker, Patent Owner urges that the passage in Edwards-535 incorporating Baker “does not disclose anything about electrodes or electrode arrangements” and “[i]mportantly . . . does not incorporate the Baker Application in its entirety.” *Id.* at 33–34. According to Patent Owner, Dr. Martin was unable to identify what was incorporated from Baker on cross-examination and, in fact, the teachings Edwards-535 incorporates have “nothing to do with the Baker Applications’ electrodes or electrode arrangement.” *Id.* at 34–35.

Second, Patent Owner argues that Petitioner’s reasoning that “arranging electrodes in rows facilitates simple spatial resolution of the applied energy” is unpersuasive because “there are numerous (if not infinite) ordered arrangements for bipolar electrodes, of which Stern’s electrode arrangement is merely one possibility.” Resp. 36–37 (internal quotations omitted). According to Patent Owner and Dr. Bikson, there are many ways to control the application of energy and “[u]sing only two electrodes, or arranging the electrodes in a single row, provides the ‘simplest’ way to

control the applied energy”—thus incorporating Stern’s two-row arrangement would “not simplify anything.” *Id.* at 38 (quoting Ex. 2001 ¶ 88).

Third, Patent Owner challenges Petitioner’s argument that a two-row arrangement would have been a mere duplication of Edwards-535’s existing one row of ring electrodes. Resp. 38–39. According to Patent Owner, “[d]uplicating Edwards-535’s electrodes would have resulted in a single row of eight ring electrodes—not two rows of electrodes, or anything remotely resembling Stern’s electrode arrangement.” *Id.* at 38.

Petitioner counters that Patent Owner’s arguments are “incomplete and leave[] uncontested many [of Petitioner’s] motivations” for combining a two-row electrode arrangement. Reply 17–18. In particular, Petitioner reiterates that the asserted combination is a “simple substitut[ion]” of “known prior art elements,” i.e., the use of Stern’s two rows of bipolar electrodes and control scheme to improve Edwards-535’s “similar device” in the same way. *Id.* (quoting Pet. 48–49). According to Petitioner, the fact that there are alternative ways to order the electrodes “does not weigh against a motivation to use a given arrangement taught in the prior art” and it need not show that a two-row arrangement is superior to other known arrangements in the art. *Id.* at 19–20 (citing *Honeywell Int’l Inc. v. 3G Licensing, S.A.*, 124 F.4th 1345, 1353 (Fed. Cir. 2025)). Petitioner also disputes Patent Owner’s arguments concerning Baker and the duplication of parts in Edwards-535. *See id.* at 18–20.

Petitioner’s position is persuasive. Even without taking into account the reasoning based on Baker (which we address separately below), Petitioner has demonstrated a sufficient rationale for incorporating Stern’s

arrangement of two rows of bipolar electrode pairs into Edwards-535's device. Edwards-535 teaches that a plurality of electrodes may be positioned on the surface of its treatment element, but does not specify how those electrodes are arranged or controlled. Ex. 1010, 8:25–27; Ex. 1004 ¶¶ 68–69. Stern teaches a control system for selectively delivering power to bipolar electrode pairs arranged in two rows on the surface of its device that provides even heating and precise control. Ex. 1004 ¶¶ 80–85. As Dr. DelGaudio explains, one of ordinary skill in the art would have regarded these attributes to be particularly beneficial when delivering treatment to the “nasal passages . . . given the uneven morphology of nasal cavity tissue and the proximity of the RF energy delivery to a patient's brain and other critical tissues within the head.” Ex. 1002 ¶ 94. We credit the testimony of Petitioner's experts that one of ordinary skill would have been motivated to incorporate Stern's teachings, including the complementary two-row surface electrode arrangement shown in Figure 19, for these reasons. *See* Ex. 1002 ¶¶ 93–94; Ex. 1004 ¶¶ 72–73, 75–88, 96–97 (explaining that Stern's techniques would have been used to improve Edwards-535's device in a similar way).

Petitioner's reasoning that “arranging electrodes in rows . . . facilitates simple spatial resolution of the applied energy” is also persuasive. *See* Pet. 47–48. As Dr. Martin explains, one of ordinary skill in the art would have understood that arranging bipolar electrodes in two or more rows was a “common way to arrange such electrodes” (Ex. 1004 ¶ 34) and a “simple way to direct energy to specific locations for treatment would have been to place pairs of electrodes in rows . . . along the device at the locations being treated.” *Id.* ¶ 95.

Patent Owner and Dr. Bikson do not dispute these points, but assert that Petitioner’s reasoning is deficient because there are numerous other ways to provide ordered arrangements of electrodes, including using only two electrodes or arranging electrodes in a single row, which would be even simpler. *See* Resp. 36–38 (citing Ex. 2001 ¶ 88). We disagree for several reasons.

First, Patent Owner’s suggestion that claim 1 is limited to a particular arrangement amongst a “substantial (if not infinite) number” of possibilities is inaccurate. *See* Resp. 37; Sur-reply 17. Claim 1 recites that “the treatment element comprises two rows of bipolar electrode pairs.” Ex. 1001, 48:26–27. Beyond requiring “pairs” spread across the two rows, it does not limit the number of electrodes in those rows. It also captures arrangements with more than two rows, and does not exclude embodiments with additional electrodes beyond those in the recited two rows. Thus, while there are undoubtably many ways bipolar electrode pairs could be ordered, claim 1 broadly encompasses the choice of putting them into two or more rows, which, as Dr. Martin credibly testifies, is one simple way of targeting the energy delivery that was known in the art and used in other ablation devices. Ex. 1004 ¶ 95; *see also* Ex. 1010, Fig. 8; Ex 1012, Fig. 4; Ex. 1033, Figs. 4a, 15, 19 (depicting devices with two or more rows of electrodes). “The combination of familiar elements” such as these “according to known methods is likely to be obvious when,” as here, it yields “predictable results.” *See KSR*, 550 U.S. at 416.

Second, “obviousness ‘does not require that a particular combination be the preferred or the most desirable, combination described in the prior art in order to provide motivation for the current invention.’” *Honeywell*, 124

F.4th at 1355 (quoting *Novartis Pharms. Corp. v. West-Ward Pharms. Int'l Ltd.*, 923 F.3d 1051, 1059 (Fed. Cir. 2019)). Accordingly, the fact that are other simple ways of arranging bipolar electrodes, e.g., two electrode and single row arrangements, does not diminish Petitioner's showing that a two-row arrangement like that taught in Stern was another simple way to direct energy to a specific area of treatment.

Third, Petitioner provides specific reasoning why Stern's two-row arrangement would be preferable to the allegedly simpler arrangements suggested by Patent Owner and Dr. Bikson. That is, consistent with his opening testimony that Stern's benefits would have been particularly important in nasal applications given the relevant anatomy (*see* Ex. 1002 ¶ 94), Dr. DelGuadio explains that depending on the anatomy, "two or more rows may be preferred" over a single row of electrodes for some patients. Ex. 1083 ¶ 47. Dr. Martin further explains that "[t]wo rows provides even more tissue that can be ablated in a controlled fashion" and that "[u]sing two electrodes or a single row as Dr. Bikson suggests . . . would not achieve that goal, as the operator would have to move the device if a desired target location was not adjacent to the electrodes." Ex. 1097 ¶ 44.

We also agree with Petitioner that a two-row arrangement of bipolar surface electrodes would have involved an obvious duplication of parts already taught in Edwards-535. *See* Pet. 48. Figure 6 of Edwards-535 discloses an embodiment with multiple ring electrodes arranged in a row along the length of expandable member 132. Ex. 1010, Fig. 6; Ex. 1004 ¶ 95; Ex. 2001 ¶ 89. Patent Owner argues that these ring electrodes are completely different parts than the electrodes in Stern, which would require "a complete redesign of Edward-535's electrode arrangement" to

incorporate into two rows. Resp. 38–39 (citing Ex. 2001 ¶ 89). But that argument ignores the fact that Edwards-535 is not limited to ring electrodes. Edwards-535 teaches “another embodiment” in which “a plurality of energy delivery devices are positioned on a surface of the expandable member.” Ex. 1010, 8:25–33 (also noting that “a combination of ring electrodes and surface energy delivery devices may be used”). We credit Dr. Martin’s testimony that incorporation of Stern’s two-row arrangement would be an obvious duplication of parts from Stern’s surface electrode embodiment. Ex. 1004 ¶ 95; Ex. 1097 ¶ 45.

Finally, for completeness, we address the parties’ arguments regarding Baker.¹⁸ Petitioner initially argued that Edwards-535 “instructs a POSITA to look to Baker for how to dispose electrodes on the surface of a membrane.” Pet. 47 (citing Ex. 1010, 8:26–33) (emphasis added). In replying to Patent Owner’s argument that Edwards-535 does not specifically refer to Baker’s electrode arrangement (*see* Resp. 33–36), Petitioner backs away from its argument that Edwards-535’s instructs one to look to Baker specifically for its electrode arrangement. *See* Reply 18–19 (urging that Edwards-535 incorporates the entirety of Baker and even incorporating only a portion would still “demonstrate motivation to look to similar non-nasal ablation devices like Stern”).

On this record, Petitioner has not shown that Edwards-535 provides a specific instruction to look to Baker’s electrode arrangement. Edwards-535 refers to Baker as providing “[a]n example of a suitable surface for

¹⁸ These arguments are largely beside the point because Petitioner’s other reasoning is sufficient to demonstrate a motivation to combine Stern’s two-row arrangement of bipolar electrode pairs.

disposition on the membrane.” Ex. 1010, 8:28–31. Patent Owner credibly explains that this refers to teachings in Baker other than its electrode arrangement. *See* Resp. 35–36 (citing Ex. 2001 ¶ 86). Even so, we agree with Petitioner that the fact that Edwards-535 refers to and incorporates Baker in at least some respect provides further support for combining Stern generally because the devices in Baker and Stern are similar.¹⁹ *See* Ex. 1004 ¶¶ 90–92 (explaining similarities and noting that persons of ordinary skill in the art “routinely consider techniques and technology from ablation devices suitable for treating one area of the body applicable to devices in another area of the body”). Moreover, the fact that Baker discloses devices with surface electrodes arranged in two or more rows (Ex. 1011, Fig. 8; Ex. 1004 ¶ 94) provides additional underpinning for Petitioner’s position that arrangements comprising two or more rows of electrodes were well-known in the art.

For these reasons, Petitioner has demonstrated that one of ordinary skill would have been motivated to incorporate Stern’s two-row arrangement of bipolar electrode pairs into the asserted combination of Edwards-535 and Kong. Petitioner has also shown that this combination teaches or suggests all the limitations of claim 1. In sum, Petitioner has shown by a preponderance

¹⁹ This is true whether Edwards-535 incorporates Baker in its entirety or only in part as Patent Owner contends. Because none of Petitioner’s grounds is premised on the teachings in Baker, we need not resolve the parties’ dispute regarding the extent to which Edwards-535 incorporates Baker by reference. *See* Reply 18 (urging this is “an irrelevant dispute”); Sur-reply 16 (observing that Petitioner’s proposed combination relies on Stern, not Baker).

of the evidence that claim 1 would have been obvious over the asserted combination of Edwards-535, Kong, and Stern.

ii. Claims 2, 3, 6–10, and 12

Each of these claims depends directly from claim 1. Claims 2 and 12 recite additional limitations for the target tissue (claim 2) and the modified property of the targeted tissue (claim 12). Ex. 1001, 48:40–42, 50:1–4. Claim 3 recites the use of a control system to control a characteristic of the applied RF energy. *Id.* at 48:43–46. Claim 6 recites the display of various parameters on a consol while the RF energy is applied. *Id.* at 48:58–64. Claim 7 recites applying local anesthesia before applying the RF energy. *Id.* at 48:65–67. Claims 8–10 recite further limitations relating to wattage, the temperature of heating, and the amount of time the energy is applied. *See id.* at 49:1–11.

Petitioner provides argument, supported by evidence, explaining how the combination of Edwards-535 and Stern teach these additional limitations. *See* Pet. 56–64, 68–69. Patent Owner does not dispute Petitioner’s showing for claims 2, 3, 6–10, and 12 separately from the arguments already addressed above for claim 1.

We adopt Petitioner’s undisputed analysis of the additional limitations of claims 2, 3, 6–10, and 12, and credit its supporting evidence. *See* Pet. 56–64, 68–69; Ex. 1002 ¶¶ 109–131, 140–142; Ex. 1004 ¶¶ 98–119. Petitioner has shown by a preponderance of the evidence that these claims would have been obvious over the asserted combination of Edwards-535, Kong, and Stern.

iii. Claim 11

Claim 11 depends from claim 1 and additionally recites the steps of “repositioning the treatment element to contact a different portion of nasal mucosa” and “applying radiofrequency energy with the bipolar electrode pairs” to heat a different portion of target tissue. Ex. 1001, 49:12–19. Claim 11 further specifies that these steps occur before removing the treatment element from the nasal airway. *Id.*

According to Petitioner, both Edwards-535 and Kong teach contacting a treatment element with and applying RF energy to various locations along the lower surface of the nasal concha. Pet. 65–66. Petitioner therefore contends “when using the apparatus of Edwards-[]535 to ablate nerve tissue in the turbinates as taught by Kong, a POSITA would have found it obvious to move the expandable member 132 [of Edwards-535] to different locations (e.g., the anterior, middle, and posterior part of the turbinate)” and apply RF energy to each of these portions to heat them before removing the device. *Id.* at 67–68.

Petitioner’s showing is persuasive. In particular, we credit Dr. DelGaudio’s testimony that Kong teaches the application of RF energy to multiple locations in the turbinates to ablate different portions of nerve tissue. Ex. 1002 ¶¶ 133–135; Ex. 1083 ¶ 54. As Dr. DelGaudio explains, this would have made it obvious to reposition expandable member 132 (i.e., the treatment element) of Edwards-535’s device, as modified with Stern’s bipolar electrode pairs, to contact different portions of the nasal mucosa and apply energy through those pairs to heat different portions of tissue. *Id.* ¶¶ 136–138. Moreover, it would have been obvious to do this *before* removing the treatment element from the nasal airway to minimize insertion

and removal of the treatment element. Ex. 1083 ¶¶ 49–52 (explaining that “[d]oing so minimizes patient discomfort and trauma to tissue,” “maximizes efficiency” and is “a well-understood sequence for a clinical procedure . . . consistent with how similar procedures in the nose have been carried out since long before the ’271 patent was filed”).

Patent Owner offers various arguments against Petitioner’s showing for claim 11—all of which are unavailing. *See* Resp. 39–43. First, Patent Owner asserts that “neither Edwards-535 nor Kong” discloses “bipolar electrode pairs.” *Id.* at 40. Patent Owner also urges that “even if Edwards-535 in view of Kong disclosed ‘bipolar electrode pairs,’” Petitioner has not shown that “Edwards-535 in view of Kong discloses applying radiofrequency energy to a different portion of nasal mucosa with ‘bipolar electrode pairs [plural].’” *Id.* at 42 (alternation in original).

These arguments are unavailing because they attack the teachings in Edwards-535 and Kong individually without addressing their combination with Stern. As explained above, Stern teaches the “two rows of bipolar electrode pairs” in element 1[a] and the application of RF energy thorough those pairs in element 1[b]. *Supra* § III.E.i.1–2. Petitioner’s showing for claim 11 is premised on the incorporation of those elements into Edwards-535’s device. *See* Pet. 67–68 (cross-referencing showing for claim 1); Ex. 1002 ¶ 138 (referring to showing for element 1[b] to explain that the “combined method would have delivered treatment at each of the different locations by applying RF energy with the bipolar electrode pairs”). Patent Owner’s “focused attack” on only the teachings in Edwards-535 and Kong does not distinguish Petitioner’s showing “based on a [broader] combination

of references.” *See Soft Gel Techs., Inc. v. Jarrow Formulas, Inc.*, 864 F.3d 1334, 1341 (Fed. Cir. 2017).

Patent Owner’s assertions that Edwards-535 and Kong disclose applying energy to only a single portion of nasal mucosa are also unavailing. *See* Resp. 41. Edwards-535 teaches that its apparatus may be delivered into “the inferior, middle *and/or* superior nasal meatus” and that “[t]he nasal concha ablated may be the inferior, middle *and/or* superior nasal concha.” Ex. 1010, 6:38–42 (emphases added); Ex. 1083 ¶ 53 (explaining that the use of “and/or” teaches the device may deliver energy to multiple locations). While Edwards-535 describes embodiments in which only a single location is treated (*see* Ex. 1010, 6:42–51), those embodiments do not limit its teaching that the apparatus may also be used to treat multiple locations in the nasal concha. *See Inland Steel*, 265 F.3d at 1361; *Merck*, 874 F.2d at 807 (“all disclosures of the prior art, including unpreferred embodiments, must be considered”).

Kong also teaches repositioning the treatment element, i.e., Kong’s RF electrode, to apply energy to multiple locations in the turbinate. Kong teaches that its RF electrode was inserted into the inferior turbinate and used to make multiple “holes” in different parts of that turbinate through which RF energy is applied before slowly removing the electrode. Ex. 1040, 214; *see also* Ex. 1002 ¶¶ 56, 135; Ex. 1083 ¶ 54 (explaining Kong’s teachings).

Patent Owner and Dr. Bikson acknowledge that “Kong discloses making holes in various parts of the inferior turbinate,” but argue that “making holes in the nasal mucosa is not what is claimed.” Resp. 41–42 (quoting Ex. 2001 ¶ 98). That argument is unavailing because it does not explain why those holes would be made. We credit Dr. DelGaudio’s

testimony that based on his clinical experience one of ordinary skill in the art would have understood these holes to be a location where RF energy is delivered because they are made by Kong's RF electrode and there is no other clinical purpose for making them. Ex. 1083 ¶ 54.²⁰

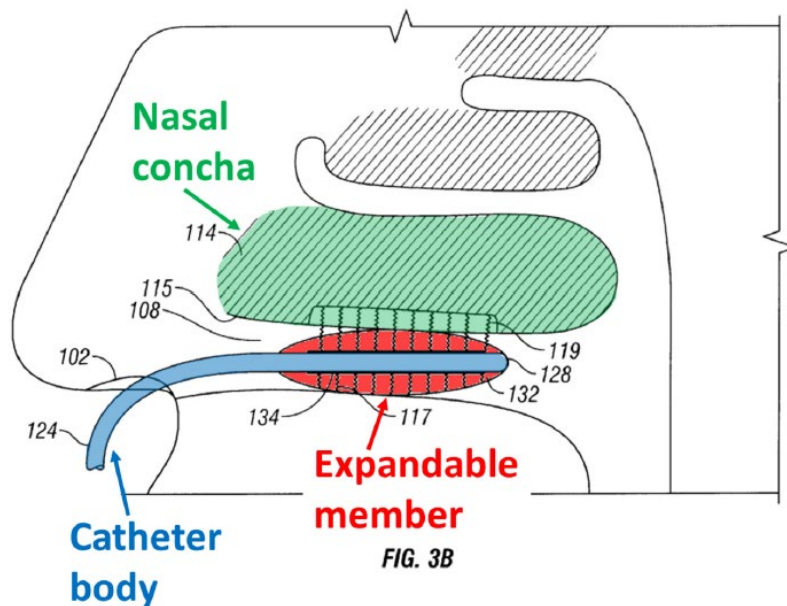
For these reasons, Petitioner has shown by a preponderance of the evidence that claim 11 would have been obvious over the asserted combination of Edwards-535, Kong, and Stern.

iv. Claim 16

Claim 16 depends from claim 1 and additionally recites the step of “bending a shaft of the nasal airway treatment device before contacting the treatment element with the nasal mucosa.” Ex. 1001, 50:16–18.

Petitioner argues that Edwards-535 teaches or suggests this limitation, using the annotated version of Edwards-535's Figure 3B below to illustrate its position. Pet. 69–70.

²⁰ Patent Owner suggests Petitioner's ground is improper because it relies on Dr. DelGaudio's knowledge as one of skill in the art, rather than Kong itself. *See* Sur-reply 17–19. We disagree. Dr. DelGaudio testified regarding what one of ordinary skill in the art would have understood Kong to teach and his testimony on this point is more credible than Dr. Bikson's.



According to Petitioner, the figure above “depicts apparatus 124 (i.e., *treatment device*) with a bent catheter body (i.e., *shaft*) [annotated in blue] inserted into a patient’s nostril.” *Id.* Petitioner argues it would have been obvious to implement Edwards-535’s teaching of a bent catheter shaft “using any number of well-known mechanisms for forming bends in catheter shafts” as it was commonplace to do so to achieve goals “such as more accurate placement of the distal end of Edwards-[]535’s catheter shaft and/or the ability to contact surfaces (e.g., portions of the inferior turbinate) that would otherwise be obstructed.” *Id.* at 70–71 (citing Ex. 1002 ¶¶ 145–148).

Patent Owner separately disputes Petitioner’s showing for claim 16. According to Patent Owner, Petitioner has not shown that it would have been obvious to bend the shaft of the device “before” contacting the treatment element with the nasal mucosa. *See* Resp. 44–46. Patent Owner observes that Edwards-535’s Figure 3B depicts the treatment element “already in contact with the nasal mucosa” and does not describe when the shaft was bent. *Id.* at 44. Patent Owner also takes issue with Petitioner’s

reference to “well-known mechanisms for forming bends in catheter shafts,” urging that Petitioner does “not explain what these unidentified techniques were or whether any of them involved bending a catheter shaft before contacting nasal mucosa.” *Id.* at 45.

Petitioner counters that Patent Owner’s suggestion that the bend shown in Edwards-535’s Figure 3B “may have been formed *after* contacting the treatment element with the mucosa . . . ignores clinical practice and basic physiology.” Reply 23. Petitioner supports this argument with citations to Dr. DelGaudio’s testimony. *See Id.* at 24 (citing Ex. 1002 ¶¶ 143–148; Ex. 1083 ¶¶ 57–63).

We find Petitioner’s showing sufficient to meet its burden. It is undisputed that Edwards-535 teaches the step bending the shaft of its nasal treatment device. *See* Ex 1010, Fig. 3B (depicting bent catheter). While Figure 3B does not show when that bending occurred, we credit Dr. DelGaudio’s testimony that such bending often occurs “during the medical procedure itself for the purpose of reaching arounds contours and bends in the patient’s nasal passages” in order to allow “the distal end to reach otherwise hard-to-reach locations of the nose, e.g., posterior surfaces of a nasal turbinate.” Ex. 1002 ¶¶ 144–145 (citing examples from various references), 147. Since “many portions of the inferior turbinate (like the target location shown in Figure 3B, and portions distal to that target location) are accessible from the opening of the nostril only by bending the shaft,” one of ordinary skill would have understood that the bending occurs before the treatment element contacts the mucosa where the RF energy will be delivered. Ex. 1083 ¶ 60. In addition, Dr. DelGaudio provides other credible reasons why one of ordinary skill would have understood or at least

found obvious that the shaft of Edwards-535's device was bent prior to contacting the nasal mucosa, including that bending the shaft avoids blocking the clinician's line of sight when inserting the device (*id.* ¶ 59) and that bending the after it was already in contact with the mucosa would be deleterious (*id.* ¶ 61).

Indeed, Patent Owner does not dispute the substance of any of Dr. DelGaudio's testimony on these points. *See* Resp. 43–46; Sur-reply 19–20. Instead, Patent Owner asserts that Petitioner's argument "requires that all shafts provide a bend." Sur-reply 19. This is a strawman that Patent Owner knocks down by pointing to an embodiment in the '271 patent depicting a device with a straight shaft. *Id.* at 20 (citing Ex. 1002, Fig. 18). However, Petitioner's position is not that all shafts in all devices are necessarily bent, but rather that it would have been obvious that the bend shown in Edwards-535's device was formed before its treatment element was contacted with the nasal mucosa through which RF energy was applied. As explained above, that position is supported by the record here.

For these reasons, Petitioner has shown by a preponderance of the evidence that claim 16 would have been obvious over the asserted combination of Edwards-535, Kong, and Stern.

F. Ground II: Obviousness over Edwards-535, Kong, Stern, and Edwards-886

This ground challenges claim 4, which depends from claim 1 and additionally recites that the RF energy "is applied in the form of a 460 kHz sinusoid wave." Ex. 1001, 48:48–49. In addition to the combination in Ground I, Petitioner relies on a second Edwards' reference, Edwards-886, that teaches applying a 460 kHz sinusoid wave with a RF device. *Id.* at 72.

Petitioner also cites evidence that “most RF ablation generators sold prior to 2011 operated at a frequency of 460 kHz” and that “using a sinusoid—the most common and widely known RF waveform and one waveform used in Edwards-[]535—would have . . . been obvious.” *Id.* at 73 (citing Ex. 1002 ¶¶ 149–152; Ex. 1004 ¶¶ 124–130).

Patent Owner does not dispute Petitioner’s showing in Ground II separately from its arguments for claim 1 in Ground I. *See* Resp. 46.

As explained above, Petitioner’s showing for claim 1 is sufficient, and Patent Owner’s arguments to the contrary are unavailing. *Supra* § III.E.i. We adopt Petitioner’s undisputed analysis of the additional teachings in Edwards-886 and credit its showing that it would have been obvious to combine these teachings with Edwards-535, Kong, and Stern. *See* Pet. 72–74; 1002 ¶¶ 149–152; Ex. 1004 ¶¶ 120–131. For these reasons, Petitioner has shown by a preponderance of the evidence that claim 4 would have been obvious over the asserted combination of Edwards-535, Kong, Stern, and Edwards-886.

G. Ground III: Obviousness over Edwards-535, Liang, and Stern

Petitioner contends claims 1–3, 6–12, and 16 would have been obvious over Edwards-535, Liang, and Stern. *See* Pet. 74–90. Patent Owner disputes Petitioner’s contentions, raising largely the same arguments it did for Ground I. Resp. 46–53. As before, we begin with claim 1.

i. Claim 1

Petitioner’s contentions essentially are the same as those in Ground I, but substitute the teachings in Liang for those in Kong. *See* Pet. 74–79. That is, Petitioner contends that Liang teaches directly contacting nasal mucosa with an RF device to deliver RF energy to locations within the middle

turbinate (i.e., target tissue underlying the nasal mucosa) to reduce mucus production. *See id.* at 74–75, 78–84.

Petitioner articulates essentially the same reasoning for combining Liang with the other references that it does for Kong. *Compare* Pet. 75–78 (motivation for combining Liang) *with id.* at 28–34 (motivation for combining Kong). Petitioner also articulates the same reasoning for combining Stern’s two rows of bipolar electrode pairs that it does in Ground I. *Id.* at 79–80. In addition, Petitioner asserts that “[t]he precise control afforded by Stern’s electrode pairing and arrangement would have been particularly useful for the combination of Edwards-535 and Liang” because “Liang emphasizes the need to avoid perforating the nasal septum” and by using Stern’s teaching “a practitioner could specifically target the middle turbinate without perforating the nasal septum.” *Id.* at 80.

Patent Owner challenges the same three aspects of Petitioner’s showing that it did in Ground I. That is, Patent Owner contends that the asserted combination does not teach a treatment element comprising “two rows of bipolar electrode pairs” (recited in element 1[a]) and “applying radiofrequency energy with the bipolar electrode pairs” (recited in element 1[b]) for the “same reasons” it does in Ground I. Resp. 47.

Patent Owner also repeats its arguments contesting Petitioner’s reasoning for combining Stern’s two-row arrangement of bipolar electrode pairs. Resp. 47–48. Regarding Petitioner’s additional reasoning based on Liang, Patent Owner asserts that, “as it relates to avoiding nasal septum perforation, there is no evidence in the record that Stern’s electrode arrangement is, in and of itself, superior to any other electrode arrangement, including the single row arrangement already disclosed in Edwards-535.” *Id.*

at 47. Patent Owner further asserts that one of ordinary skill “would have no reason to look beyond Edwards-535’s teachings to address any potential issue of nasal septum perforation” because there were other ways to avoid this problem, including through the use of “an insulator” as disclosed in Edwards-535 itself. *Id.* at 47–48 (internal quotations omitted).

We find that one of ordinary skill in the art would have been motivated to combine Edwards-535, Liang, and Stern with a reasonable expectation of success for the reasons set forth in the Petition. *See* Pet. 74–84. We also find that the articulated combination of Edwards-535, Liang, and Stern teaches all of the steps of claim 1 in the recited order. We adopt Petitioner’s element-by-element analysis and reasoning for combining the references and credit the related testimony of Petitioner’s experts. *See id.* at 74–84; Ex. 1002 ¶¶ 153–176; Ex. 1004 ¶¶ 66–97. Patent Owner’s arguments challenging that showing are unavailing for the same reasons explained in Ground I. *Supra* § III.E.i.1–3.

Moreover, regarding Liang specifically, we agree with Petitioner that it provides additional motivation for combining Stern’s two-row arrangement of bipolar electrode pairs. Liang teaches that “nasal septum perforation” is a potential complication of treating the nasal airway with RF energy to reduce mucus production and suggests techniques to try to “avoid perforation of the nasal septum.” Ex. 1056, 341–342; *see* Ex. 1002 ¶ 166 (“Liang teaches that one outcome to avoid is perforated nasal septum.”). We credit Dr. DelGaudio’s testimony that “Stern’s teachings to use two rows of bipolar electrode pairs that can individually control and direct energy would have been useful tools to help a clinician avoid perforating the nasal septum.” Ex. 1002 ¶ 166.

Dr. Bikson does not dispute that incorporating these teachings into Edward-535's device would help avoid nasal septum perforation. *See* Ex. 2001 ¶¶ 108–109. Instead, he testifies that Stern's electrode arrangement is not “superior” to other electrode arrangements for this purpose. *Id.* ¶ 108. But as explained above, Petitioner need not show that its combination incorporating Stern's two-row arrangement is the “preferred or the most desirable, combination described in the prior art.” *See Honeywell*, 124 F.4th at 1355. It is enough that Stern's two-row arrangement was one simple, known way to order bipolar electrode pairs such that they precisely deliver energy to a target tissue. Ex. 1004 ¶ 95. The fact that one of ordinary skill in the art would have understood that doing so could help avoid the known complication of septum perforation provides an additional motivation for doing so. This is true even accepting Patent Owner's position that there were other known ways to mitigate this risk. *See* Resp. 47–48 (citing Ex. 2001 ¶¶ 108–109).

For these reasons, Petitioner has shown by a preponderance of the evidence that claim 1 would have been obvious over the asserted combination of Edwards-535, Liang, and Stern.

ii. Claims 2, 3, 6–10, 12, and 16

Petitioner provides argument supported by evidence explaining how the combination of Edwards-535, Liang, and Stern teaches the additional limitations recited in these claims. *See* Pet. 84–86, 89–90.

Patent Owner does not dispute Petitioner's showing for claims 2, 3, 6–10, and 12 separately from the arguments already addressed above for claim 1. *See* Resp. 48–49. Patent Owner raises the same separate argument for

claim 16 that it did in Ground I. *Id.* at 53. These arguments are unavailing for the reasons explained above.

We adopt Petitioner’s undisputed analysis of the additional limitations of claims 2, 3, 6–10, 12, and 16, and credit its supporting evidence. *See* Pet. 84–86, 89–90; Ex. 1002 ¶¶ 177–185, 189–192; Ex. 1004 ¶¶ 98–119.

Accordingly, Petitioner has shown by a preponderance of the evidence that these claims would have been obvious over the asserted combination of Edwards-535, Liang, and Stern.

iii. Claim 11

Similar to its showing for this claim in Ground I, Petitioner contends that both Edwards-535 and Liang teach contacting a treatment element with and applying RF energy at multiple locations, including the nasal septum mucosa before removing the treatment element from the nasal airway. Pet. 87–89. Petitioner also cross-references its showing for claim 1, including that regarding element 1[b] involving the combination of Stern’s two-row arrangement of bipolar electrode pairs to deliver energy. *Id.* at 88; Ex. 1002 ¶ 187 (referring to the combination of Edwards-535 and Liang “as modified according to the teachings of Stern”).

We find Petitioner’s showing for the additional elements of claim 11 sufficient and credit its supporting evidence. Pet. 87–89; Ex. 1002 ¶¶ 187–188. Many of Patent Owner’s separate arguments for claim 11 in Ground III are the same as those in Ground I. *Compare* Resp. 49–52 (Ground III claim 11 argument) *with* 39–43 (Ground I claim 11 argument). To the extent those arguments overlap, they are unavailing for reasons explained above. *Supra* § III.E.iii. We address the arguments relating to Liang specifically below.

As it did with Kong, Patent Owner argues that “Liang does not disclose applying energy to multiple portions of nasal mucosa before removing the device from the nasal airway.” Resp. 51. Patent Owner acknowledges that “Liang discloses that ‘the emitter was used to perform thermal coagulation treatment on the bilateral nasal ridge and the corresponding nasal septum mucosa,’” i.e., repositioning Liang’s treatment element at different portions of the nasal mucosa and applying energy to target different portions of tissue. *Id.* (quoting Ex. 1056, 341). But according to Patent Owner, “Liang does not specify whether the treatment device was removed from the nasal airway between treatments” and given this “ambiguity” cannot be said to teach or suggest this aspect of claim 11. *Id.*

We disagree with Patent Owner. Petitioner offers evidence showing that it would have been obvious to one of ordinary skill in the art to perform the steps of repositioning and applying energy to treat a different portion of tissue in claim 11 before removing the treatment element from the nasal airway. Ex. 1002 ¶¶ 133, 135, 136, 138, 187–189; Ex. 1083 ¶¶ 49–56. Dr. Bikson’s testimony to the contrary (*see* Ex. 2001 ¶¶ 115–121) is premised on his observation that Liang does not specify whether the treatment element was removed between treatments, which fails to consider the “ordinary creativity” of one of skill in this art. *See KSR*, 550 U.S. at 421 (“A person of ordinary skill in also a person of ordinary creativity, not an automaton.”). As Dr. DelGaudio credibly testifies, there are several practical reasons why a skilled artisan would perform these steps in the recited order to avoid having to remove and reinsert the treatment elements multiple times. *See* Ex. 1083 ¶¶ 49–56. Thus, the record supports that one of ordinary skill in the art would have understood that the repositioning to apply energy to different

tissue taught by the asserted combination should occur before removing the treatment element from the nasal airway.

For these reasons, Petitioner has shown by a preponderance of the evidence that claim 11 would have been obvious over the asserted combination of Edwards-535, Liang, and Stern.

H. Ground IV: Obviousness over Edwards-535, Liang, Stern, and Edwards-886

Like Ground II, this ground challenges claim 4 based on the same teachings in Edwards-886. *See* Pet. 90.

Patent Owner does not dispute Petitioner's showing in Ground IV separately from its arguments for claim 1 in Ground III. *See* Resp. 53.

As explained above, Petitioner's showing for claim 1 is sufficient and Patent Owner's arguments to the contrary are unavailing. *Supra* § III.G.i. We adopt Petitioner's undisputed analysis of the additional teachings in Edwards-886 and credit its showing that it would have been obvious to combine these teachings with Edwards-535, Liang, and Stern. *See* Pet. 72–74; 1002 ¶¶ 149–152; Ex. 1004 ¶¶ 120–131. For these reasons, Petitioner has shown by a preponderance of the evidence that claim 4 would have been obvious over the asserted combination of Edwards-535, Liang, Stern, and Edwards-886.

IV. CONCLUSION²¹

Petitioner has shown, by a preponderance of the evidence, that claims 1, 2–4, 6–12, and 16 of the '271 patent are unpatentable.

²¹ Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this

Claims	35 U.S.C. §	Reference(s)/ Basis	Claims Shown Unpatentable	Claims Not shown Unpatentable
1, 2, 3, 6–12, 16	103	Edwards-535, Kong, Stern	1, 2, 3, 6–12, 16	
4	103	Edwards-535, Kong, Stern, Edwards-886	4	
1, 2, 3, 6–12, 16	103	Edwards-535, Liang, Stern	1, 2, 3, 6–12, 16	
4	103	Edwards-535, Liang, Stern, Edwards-886	4	
Overall Outcome			1, 2–4, 6–12, 16	

V. ORDER

Accordingly, it is:

ORDERED that Petitioner has shown that claims 1, 2–4, 6–12, and 16 of U.S. Patent 11,241,271 B2 are unpatentable; and

FURTHER ORDERED that, because this is a Final Written Decision, parties to this proceeding seeking judicial review of our Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

Decision, we draw Patent Owner’s attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. See 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. See 37 C.F.R. §§ 42.8(a)(3), 42.8(b)(2).

IPR2024-00277
Patent 11,241,271 B2

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