

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
Patent 11,241,271 B2

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

VALEK, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

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”). Aerin Medical Inc. (“Patent Owner”) filed a Preliminary Response. Paper 7 (“Prelim. Resp.”).

Considering the arguments and evidence of record, we determine that the Petition demonstrates “a reasonable likelihood that [P]etitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a). Accordingly, we institute an *inter partes* review.

II. BACKGROUND

A. Real Parties in Interest

The parties identify only themselves as real parties-in-interest. Pet. 2; 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.), referred to herein as “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 and asserted in the Delaware litigation: IPR2024-00275, IPR2024-00276, IPR2024-00278, and IPR2024-00282. Pet. 3; Paper 6, 2. In addition, Petitioner identifies three 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, Abstr.; *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.

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.

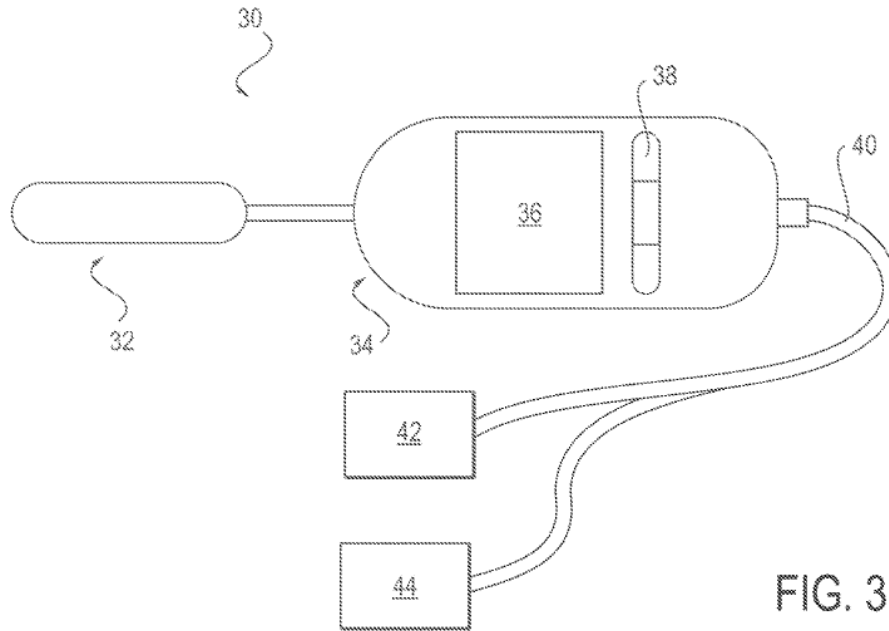


FIG. 3

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.

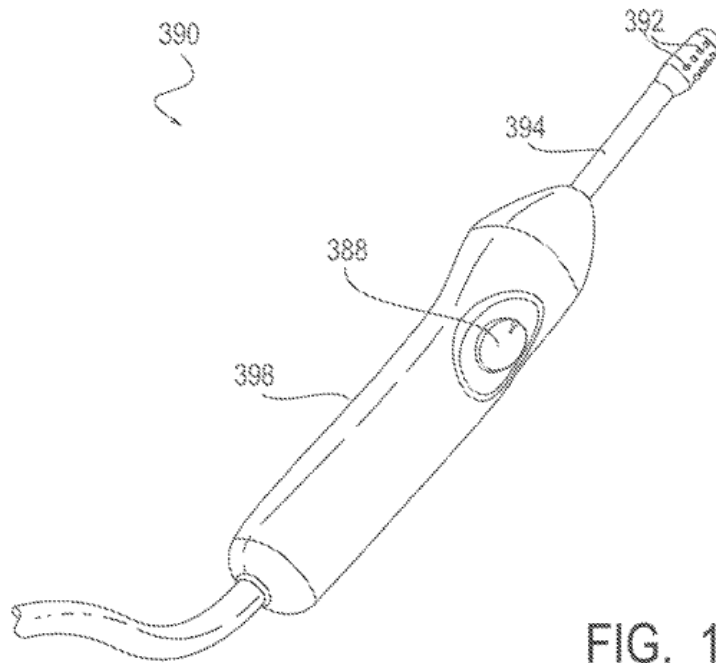


FIG. 18

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 with electrodes in “two rows . . . where radio frequency energy travels from one row of electrodes to the other row of electrodes.” *Id.* at Abstr., 8:21–25; *see also id.* at Fig. 8F, 23:40–43 (depicting an electrode arrangement comprising pairs of bipolar needles “located on a treatment element configured to be placed into contact with the cartilage”).

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. §¹	Reference(s)/Basis
1–3, 6–12, 16	103	Edwards-535, ² Kong, ³ Stern ⁴
4	103	Edwards-535, Kong, Stern, Edwards-886 ⁵
1–3, 6–12, 16	103	Edwards-535, Liang, ⁶ Stern
4	103	Edwards-535, Liang, Stern, Edwards-886

In addition to these and other references, Petitioner relies on the declarations of Dr. John Delgaudio (Ex. 1002) and Dr. Gregory T. Martin (Ex. 1004).

¹ 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. At this stage, 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.

² US 6,517,535 B2, issued Feb. 11, 2003 (Ex. 1010) (“Edwards-535”).

³ 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 (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.

⁴ US 5,562,720, issued Oct. 8, 1996 (Ex. 1033) (“Stern”).

⁵ US 6,273,886 B1, issued Aug. 14, 2001 (Ex. 1016) (“Edwards-886”).

⁶ Liang Jianping et al., “Radiofrequency Treatment of Ethmoidal Nerve with Allergic Rhinitis Under Nasal Endoscopy,” 13 J. Clin. Otorhinolaryngol (China) 341–342 (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.

III. ANALYSIS OF THE ASSERTED GROUNDS

A. Legal Standards

A claim is unpatentable as obvious under 35 U.S.C. § 103 if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *See also KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007); 35 U.S.C. § 103. The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art; (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 does not respond to Petitioner’s description of a POSITA in its Preliminary Response.

At this stage, we find Petitioner’s description of the level of ordinary skill in the art to be sufficiently supported by the record and apply it for purposes of this decision.

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. 21. At this stage, Patent Owner does not respond to this contention, nor propose any express claim construction of its own.

For this decision, and given that neither party seeks any express claim construction, we determine that no express claim construction is necessary. To the extent our consideration of Petitioner’s grounds touches on any implicit issues of claim construction, those are addressed in our analysis below.

D. References Relied Upon

i. Edwards-535

Edwards-535 is a United States patent issued February 11, 2003. Ex. 1005, code (45). Petitioner asserts that Edwards-535 qualifies as prior art under 35 U.S.C. § 102(a)(1) and (2). Pet. 5.

Edwards-535 discloses a method and apparatus “for ablating at least a portion of a nasal concha” to reduce its size and improve “air flow through the nasal meatus.” Ex. 1010, Abstr. 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.

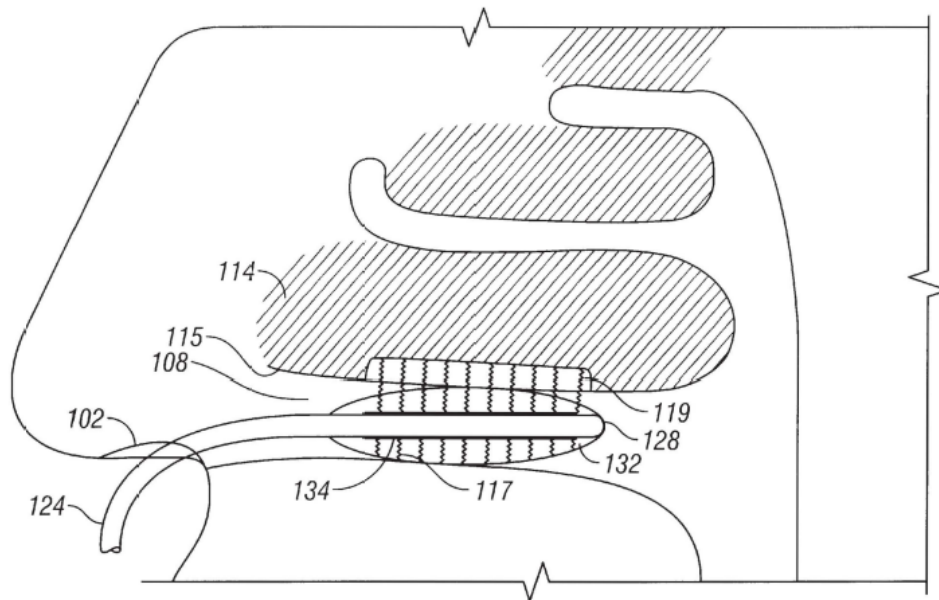


FIG. 3B

Figure 3B 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.

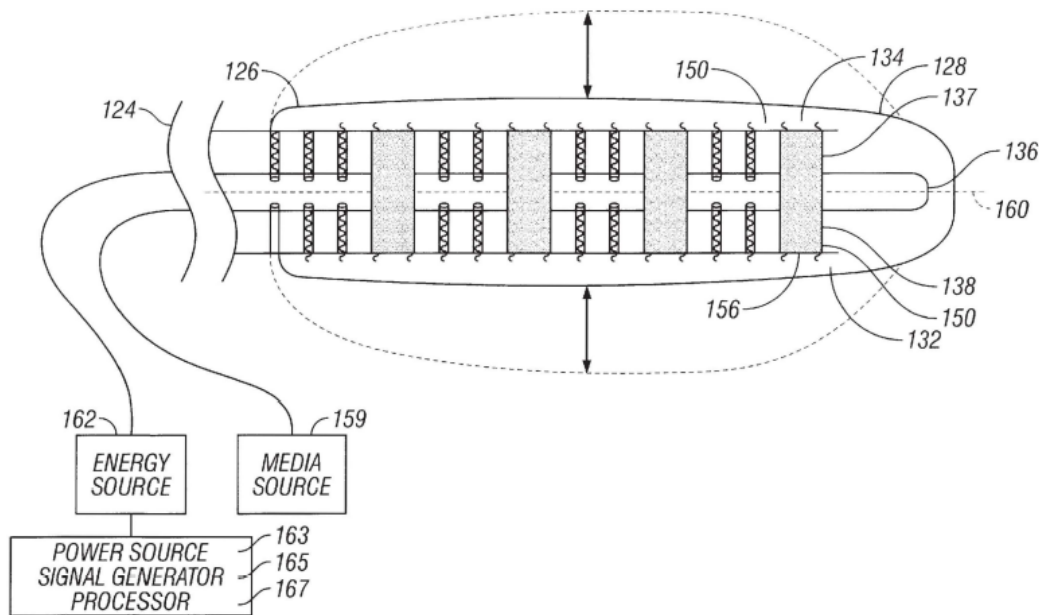


Figure 6 above depicts an embodiment comprising multiple ring electrodes 156 “disposed on the surface of the expandable member 132” in a row such that their “axes [are] aligned with a long axis 160 of the catheter body 126.” *Id.* at 8:18–23.

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 8:12–13 (“Alternatively, the energy delivery device may be positioned on a surface 147 of the expandable member.”). Edwards-535 cites another reference, Baker,⁷ 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

⁷ More precisely, Edwards-535 cites the patent application that issued as US 5,575,788 (Ex. 1011) (“Baker”).

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. Petitioner contends Kong qualifies as prior art under 35 U.S.C. § 102(a)(1). Pet. 5–6. Patent Owner does not presently dispute that contention.

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 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. 1005, code (45). Petitioner asserts that Stern qualifies as prior art under 35 U.S.C. § 102(a)(1) and (2). Pet. 6.

Stern describes an “endometrial ablation device” that passes RF energy to body organ tissue, such as the endometrium, to heat it. Ex. 1033, Abstr.; *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.* 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 an embodiment comprising a plurality of electrodes or electrode segments. Ex. 1033, 5:48–50.

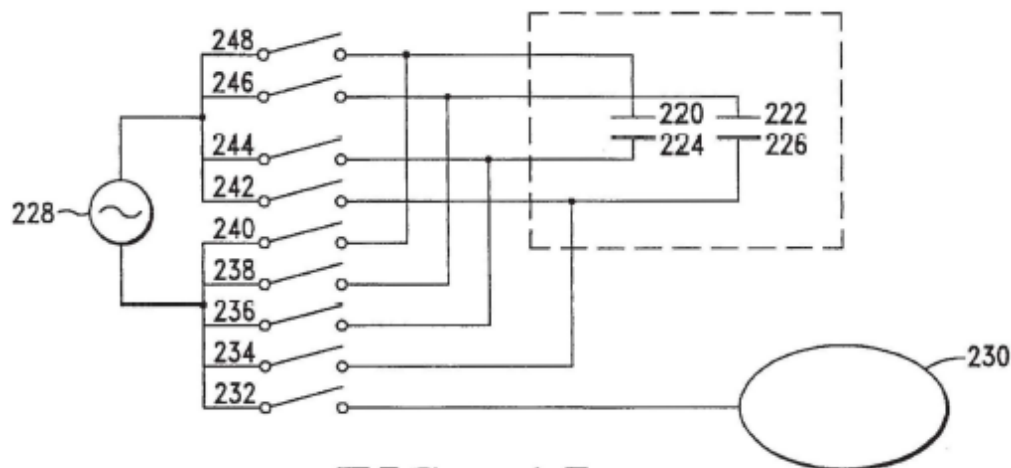


FIG. – 15

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 “biopolar 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.

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

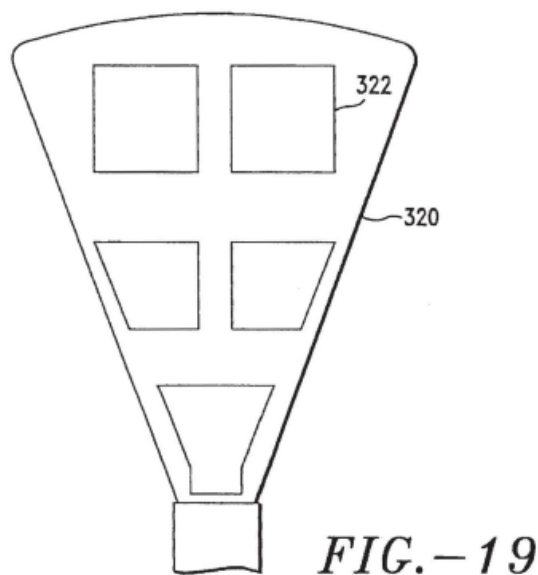


Figure 19 above show a plurality of electrodes 322 arranged on the surface of bladder 320.⁸

⁸ Stern also refers to “balloon 320.” *See* Ex. 1033, 14:25–38 (describing Figure 19). On the current record, we do not discern a difference between Stern’s use of the terms balloon and bladder.

iv. Edwards-886

Edwards-886 is a United States patent issued August 14, 2001. Ex. 1016, code (45). Petitioner asserts that Edwards-886 qualifies as prior art under 35 U.S.C. § 102(a)(1) and (2). Pet. 6.

Edwards-886 relates to “[s]ystems and methods [that] intergrate the control of an energy generator, to supply energy to an electrode structure to heat a tissue region.” Ex. 1016, Abstr. In relevant part, Edwards-886 teaches that the generator supplies RF energy “with a sinusoidal waveform at 460 kHz.” Ex. 1016, 36:66–37:2.

v. Liang

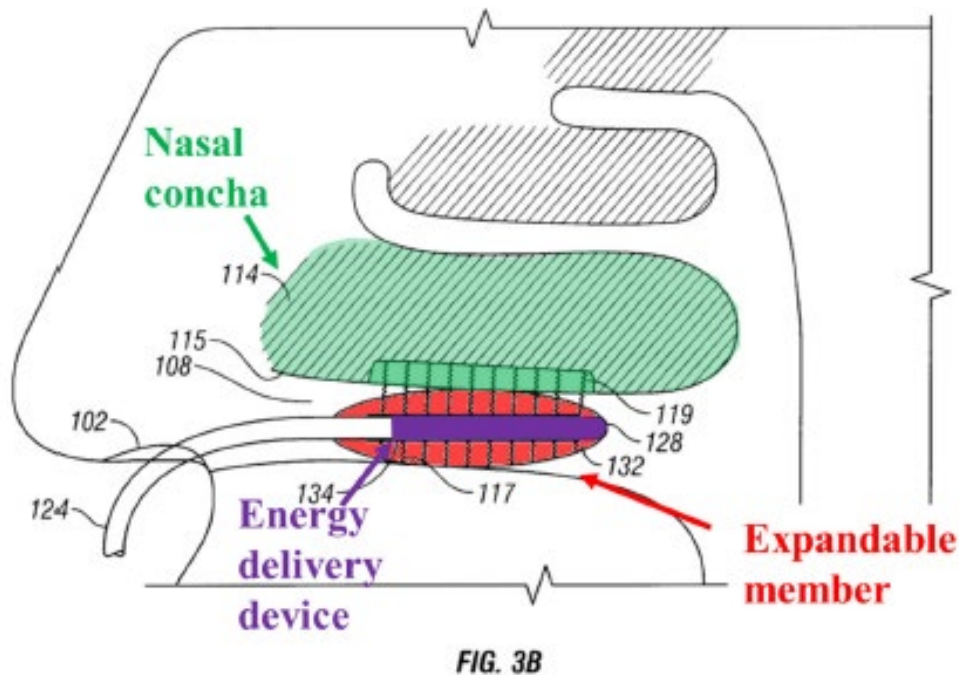
Petitioner offers evidence that the original Chinese language version of Liang was publicly accessible as of August 1999. Ex. 1070 ¶¶ 30–38. Petitioner contends Liang qualifies as prior art under 35 U.S.C. § 102(a)(1). Pet. 6. Patent Owner does not presently dispute that contention.

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 1: 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. Beginning with claim 1, Petitioner asserts that Edwards-535 teaches or suggests most of the elements of claim 1. *See generally id.* at 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 these components 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 separately 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.

Regarding the claim language relating to reduced mucus production (e.g., elements 1[pre] and 1[e]), Petitioner contends that a POSITA 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 a POSITA 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. Petitioner illustrates its position with annotated versions of Figures 15 and 19 of Stern, reproduced below. *Id.* at 41.

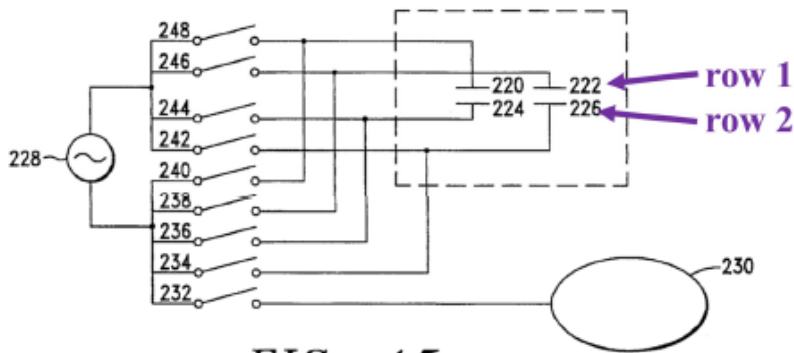


FIG. - 15

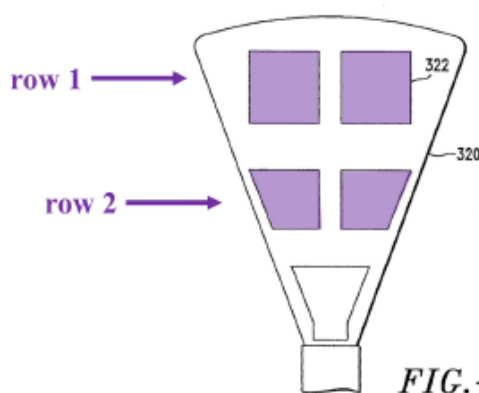


FIG. - 19

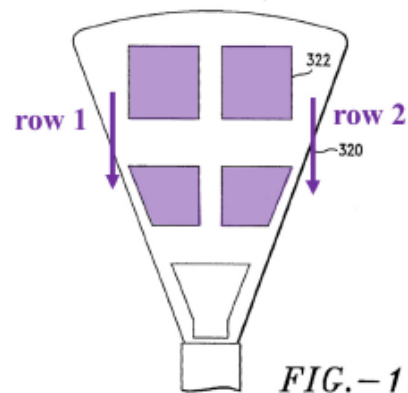


FIG. - 19

In the figures above, Petitioner and its declarants use purple annotations to identify what they contend are a “row 1” and a “row 2” of electrodes. *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” (*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 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).

Petitioner’s showing above is sufficient to establish a reasonable likelihood that it will prevail in demonstrating that claim 1 is unpatentable over Edwards-535, Kong, and Stern. Patent Owner’s arguments in the Preliminary Response are unavailing on the current record. We address those arguments below.

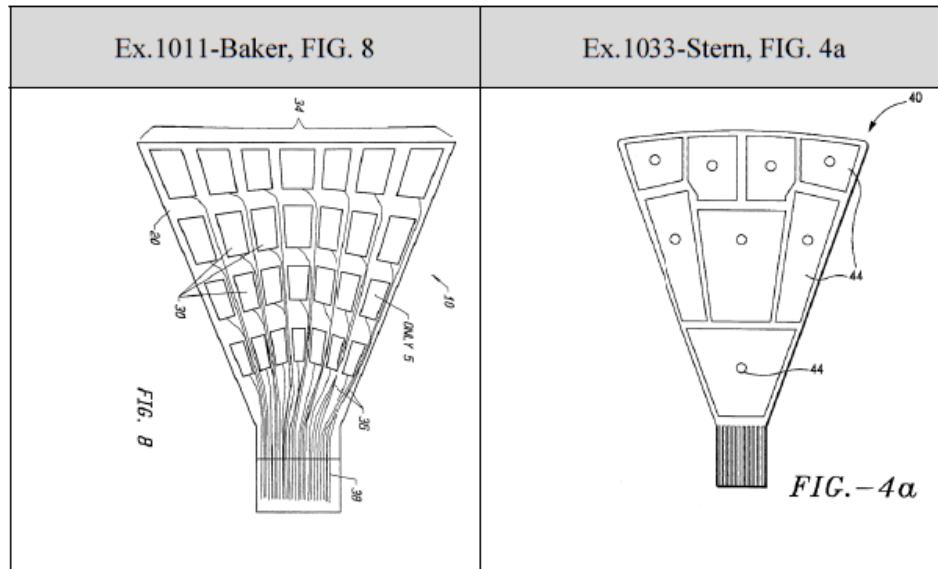
Patent Owner argues that a POSITA “would not have combined Edwards-535 and Stern because those references are diametrically opposed and have the exact opposite objective and effect on the areas they treat.” *See* Prelim. Resp. 8–23. According to Patent Owner, “Edwards-535 delivers energy to *ablate an internal portion* of the nasal concha while *preventing ablation of the surface* of the nasal concha,” whereas Stern delivers energy to *destroy the surface* of the endometrium while *not ablating the myometrium* below the endometrium.” *Id.* at 8. Patent Owner argues that

Petitioner “fails to explain why a [POSITA] would have been motivated to combine Edwards-535 and Stern when they have diametrically opposed objectives and outcomes—Edwards-535 ablating underlying tissue while preventing ablation of surface tissue, and Stern ablating surface tissue while preventing ablation of underlying tissue.” *Id.* at 14–15. Patent Owner urges that given these “fundamental differences” between Edwards-535 and Stern, the reasoning Petitioner articulates for their combination is not sufficient to carry its burden. *See id.* at 16–22.

On the current record, Patent Owner’s arguments are unavailing for several reasons. First, Petitioner’s reasoning for combining Edwards-535 and Stern is supported by testimony from its declarants who identify multiple, specific reasons for the combination. Ex. 1002 ¶¶ 93–94; Ex. 1004 ¶¶ 75–97. This testimony is not conclusory and is supported with numerous citations to other evidence of record. *Id.* Patent Owner does not offer any countervailing testimony with its Preliminary Response, electing instead to rely on attorney argument at this stage.

Second, Patent Owner’s assertions that Petitioner’s reasoning is insufficient because Stern describes treating the endometrium and ablating a different tissue, i.e., surface versus underlying tissue, are undermined by Edwards-535’s citation to Baker. As Petitioner points out, “Edwards-’535 instructs a POSITA to look to Baker for how to dispose electrodes on the surface of a membrane.” Pet. 47. This is true even though Baker, like Stern, is largely focused on treating the uterus and describes preferred embodiments for delivering RF energy to the endometrium. *See, e.g.,* Ex. 1011, Abstr., 3:5–9, 5:50–65. Moreover, Petitioner offers evidence,

including the figure reproduced below, to show that “Baker and Stern depict similar devices for ablating tissue.” Pet. 46.



Petitioner’s figure above is a side-by-side comparison of Figure 8 of Baker and Figure 4a of Stern, depicting devices that, at least on their face, appear to share a similar shape and configuration. Petitioner offers a similar figure showing that both Baker and Stern teach the arrangement of “electrodes in rows.” *See id.* at 47 (showing side-by-side comparison of Figure 8 of Baker to Figure 19 of Stern). At this stage, Patent Owner does not dispute that Petitioner’s comparisons are apt, nor otherwise address Petitioner’s reliance on Baker as evidence of a motivation to combine Stern. Thus, on the current record, we agree with Petitioner that Edwards-535’s express citation to Baker suggests that a POSITA would have been motivated to combine the similar teachings Petitioner identifies in Stern.

Third, Stern also contradicts Patent Owner’s assertion that a POSITA would have considered its teachings to be inapplicable to treating the nasal concha as taught in Edwards-535 and Kong. While Stern is primarily

concerned with endometrial ablation applications, that does not mean its teachings are limited to such. Indeed, Stern explains that its “electrode partitioning structure” may be used to treat “other body organs or tissues either externally or internally” and that its “principles with respect to the delivery of controlled RF energy” can be applied “not only for controlled destruction of tissue but also for controlled heat treatment of tissue.” *Id.* Such teachings further support the testimony of Petitioner’s declarants that “[a] POSITA would have . . . know that technology from ablation devices for one part of the body would be applicable to others.” Pet. 47 (citing Ex. 1002 ¶ 94; Ex. 1004 ¶¶ 89–93; Ex. 1033, 18:27–40).

We also disagree with Patent Owner’s argument that “Edwards-535 and Stern are so in conflict with one another that they rise to the level of teaching away.” Prelim. Resp. 22. A teaching away requires that the reference “criticize, discredit, or otherwise discourage the solution claimed.” *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004). But Patent Owner has not shown that any of the references cited here discourage the articulated combination of Stern’s electrode configuration, i.e., two rows of bipolar electrode pairs, with Edwards-535’s device and method. To the contrary, Stern expressly states that its “electrode partitioning structure” can be used for other applications (*see* Ex. 1033, 18:27–40), which on the current record would seem to include the targeted ablation of particular nasal tissue taught by Petitioner’s combination of Edwards-535 and Kong.

Patent Owner also challenges Petitioner’s combination of Edwards-535 with Kong, urging there are “fundamental differences” in these references’ methods such that a POSITA would not have been motivated to combine them. Prelim. Resp. 23. The differences Patent Owner identifies

relate to its observation that Edwards-535's method "does *not involve cutting or penetrating* and is done *bloodlessly, without forming a wound on the surface* of the turbinates," whereas "Kong intentionally *cuts holes into* the turbinates, *causing blood loss and forming scabs*." *See id.* at 23–26. According to Patent Owner, a POSITA would not have been motivated to combine Kong's surgical approach because Edwards'535 describes "“surgical cutting’ of the nasal concha as having ‘risks associated therewith’” and therefore the references “teach away” from their combination. *See id.* at 27 (quoting Ex. 1010, 4:55–57).

Again, on the current record, we disagree with Patent Owner. As an initial matter, Patent Owner's argument misapprehends the combination of Edwards-535 and Kong in the Petition, which does not purport to combine Kong's surgical cutting of the turbinate with the teachings in Edwards-535. *See* Pet. 28–34. Instead, Petitioner contends that a POSITA would have been motivated to use “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 interior turbinate.” *Id.* at 29 (citing Ex. 1040, 214). Indeed, Petitioner specifically explains that this combination would *not* include Kong's surgical approach because Edwards-535's method ““can be performed bloodlessly without the need to penetrate tissue.”” *Id.* at 30 (quoting Ex. 1010).

Moreover, the current record sufficiently supports Petitioner's position that a POSITA would have been motivated to make this combination because Edwards-535's method could accomplish the same result as Kong with less damage to the surrounding nasal tissue. *See* Pet. 30;

Ex. 1002 ¶ 76 (testifying that “Kong’s teachings regarding the limitations of piercing RF energy delivery devices would have motivated a [POSITA] to use Edwards-’535’s method of using a non-piercing RF energy delivery device” and applying “cooling to the tissue surface to avoid damaging the mucosa when targeting the underlying tissue”); Ex. 1010, 4:58–60 (Edwards-535 explaining that because its method can be performed bloodlessly and without penetrating tissues, the risk of infection is reduced). Thus, at least on the preliminary record, what Patent Owner identifies as fundamental differences between Edwards-535 and Kong do not teach away from their combination in the Petition, but rather supports the reasoning Petitioner articulates to show why that combination would have been obvious.

Finally, Patent Owner argues that Petitioner’s combination of references does not teach or suggest “contacting a treatment element of a nasal airway treatment device directly with nasal mucosa of the nasal airway” as recited in element 1[a]. *See* Prelim. Resp. 34–44. According to Patent Owner, the Petition relies solely on Edwards-535 for this limitation, but Edwards-535 does not teach that its treatment element is contacted “directly” with the nasal mucosa. *See id.* at 34–35. In support of this argument, Patent Owner refers to Petitioner’s annotated version of Figure 3B of Edwards-535 above, urging that it is expandable member 132 (shown in red) and not energy delivery device 134 (shown in purple) that contacts the nasal mucosa (shown in green). *Id.* at 36. Patent Owner also refers to Figures 5 and 6 of Edwards-535, arguing that they too “show the energy delivery device 134 *inside* the expandable member 132” such that it does not directly contact the nasal mucosa. *Id.* at 37–38.

This argument too is unavailing on the current record. The Petition maps Edwards-535's distal portion 128, which includes both energy delivery device 134 and expandable member 132, to the "treatment element" recited in claim 1. Pet. 36. According to Petitioner's mapping, Edwards-535 teaches the directly contacting limitation because the expandable member portion of the treatment element is brought into direct contact with the nasal mucosa. *See* Ex. 1010, Fig. 3B, 5:27–35 (showing and explaining that "expandable member 132 is brought into contact with the surface 115 of the nasal concha 114 to be treated").

At this stage, Patent Owner offers no reason why Petitioner's mapping is incorrect. Rather, the Preliminary Response assumes without explanation that Edwards-535's "treatment element" is limited to only the energy delivery device 134 and/or electrodes on the interior of the expandable member as shown in Figures 5 and 6. *See* Prelim. Resp. 36–39. But, as explained above, this is not Petitioner's position. To the extent Patent Owner believes Petitioner's mapping is incorrect because, e.g., Patent Owner believes Petitioner is relying on an overly-broad interpretation of the term "treatment element," Patent Owner will have an opportunity to present that argument in its Response at trial. On the present record, however, we do not discern any reason why Petitioner's mapping is incorrect.

In addition, Petitioner's reliance on Edwards-'535's alternative configuration, i.e., where the energy delivery device is "disposed on a surface of the expandable member," is also sufficient to meet its burden at this stage of the proceeding. *See* Pet. 37–38 (quoting Ex. 1010, 8:8–25). According to Petitioner's interpretation, in this alternative configuration, the electrodes are arranged on the outer surface of expandable member 132 such

that the electrodes directly contact the nasal concha. *Id.* Petitioner supports this interpretation with testimony from Dr. DelGaudio. Ex. 1002 ¶¶ 88–89.

Patent Owner disputes Petitioner’s interpretation, urging that Edwards-535 states that, “[a]lternatively, the energy delivery device may be positioned on a surface 147 of the expandable member” (Ex. 1010, 8:12–14), but surface 147 “is not annotated on Figure 5 of Edwards-535.” Prelim. Resp. 40–41. According to Patent Owner, “there is no indication” in Edwards-535 that surface 147 “is the *outside* surface of the expandable member” and Edwards-535’s other disclosures suggest that it is, in fact, “referring to the *inside* surface of the expandable member” such that electrodes positioned on that inside surface would not directly contact the nasal mucosa. *Id.* at 41–44 (referring to Figure 6 of Edwards-’535).

On the current record, we disagree with Patent Owner for several reasons. First, while Patent Owner is correct that surface 147 is not annotated in Figure 5, that surface is annotated in Figure 7 of Edwards-535, which is reproduced below.

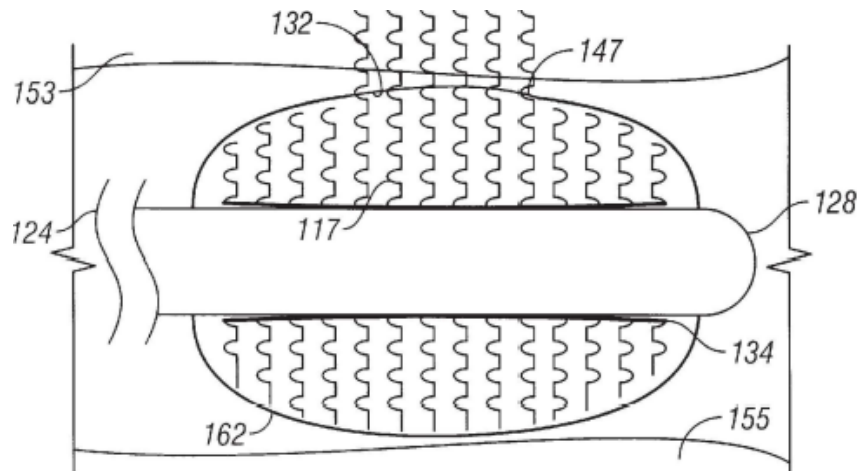


FIG. 7

Figure 7 above depicts a “further embodiment of the invention” that includes an insulator 162 “positioned over the surface 147 of the expandable member 132. Ex. 1010, 8:34–39. As shown in Figure 7, the line for surface 147 points to the outside surface of expandable member 132. Thus, on the current record, Figure 7 appears to contradict Patent Owner’s position that, when Edwards-535 teaches that the energy delivery device may be positioned “on a surface 147 of the expandable member,” it is referring only to the inside surface of the expandable member.

Second, the passages Petitioner relies upon in column 8 of Edwards-535 refer to an alternative or different embodiment from the ones shown in Figures 5 and 6. *See* Ex. 1010, 8:8–13 (discussing Figure 5 before stating that, “[a]lternatively, the energy delivery device may be positioned on a surface 147 of the expandable member), 8:25–27 (after a paragraph describing Figure 6, stating that, “[i]n another embodiment, a plurality of energy delivery devices are positioned on a surface of the expandable member”) (emphases added). This suggests a different placement of the energy delivery device than that depicted in those figures. For that reason, we are skeptical of Patent Owner’s argument that Edwards-535 must be referring to the inside surface of the expandable member because, e.g., Figure 6 “shows electrodes 156 *inside* the expandable member 132.” Prelim. Resp. 42. In any event, these issues would benefit from further development at trial.

For these reasons, and based on the current record, Petitioner has shown a reasonable likelihood it will prevail in demonstrating that claim 1 is unpatentable over Edwards-535, Kong, and Stern.

Petitioner’s showing for dependent claims 2, 3, 6–12, and 16 also demonstrates a reasonable likelihood of prevailing as to those claims. The Petition presents evidence and argument to support Petitioner’s assertion that the cited references teach or suggest the additional limitations recited in each of these claims. Pet. 56–71 (addressing additional limitations in claims 2, 3, 6–12, and 16). At this stage, Patent Owner does not make any arguments against Petitioner’s showing for these claims beyond its arguments for the independent claim, which are unavailing for the reasons explained above.

F. Ground 2: obviousness over Edwards-535, Kong, Stern, and Edwards-886

Ground 2 challenges claim 4, which depends from claim 1 and additionally recites that the “radiofrequency energy is applied in the form of a 460 kHz sinusoid wave.” Ex. 1001, 48:48–49. Ground 2 relies on the same combination of Edwards-535, Kong, and Stern for the base claim and includes Edwards-886 to address the additional limitation recited in claim 4. Pet. 72.

According to Petitioner, “[i]t would have been obvious to apply RF energy with the modified device of Edwards-’535 using a sinusoidal waveform at 460 kHz as taught by Edwards-’886.” Pet. 72. Petitioner supports this assertion by articulating why, in its view, a POSITA would have been motivated to combine these teachings with a reasonable expectation of success. *Id.* at 73–74. Petitioner cites evidence, including the testimony of its declarants, to support that reasoning. *Id.* (citing Ex. 1002 ¶¶ 149–152; Ex. 1004 ¶¶ 120–131)

Patent Owner does not raise any separate argument regarding the merits of Ground 2 in its Preliminary Response, but urges that Edwards-866

does not “make[] up for the deficiencies regarding claim 1” in Ground 1. Prelim. Resp. 44–45.

On the current record, we are persuaded that Petitioner’s showing for Ground 2 is sufficient to meet the burden for institution of *inter partes* review. To the extent Patent Owner asserts the same arguments for Ground 2 as it does for Ground 1, those arguments are unavailing on the current record for the reasons explained above. *See supra* § IV.E.

G. Grounds 3 and 4: obviousness over Edwards-535, Liang, Stern, and Edwards-886

Grounds 3 and 4 respectively challenge the same claims as Grounds 1 and 2, but substitute the teachings in Liang for those in Kong. *See* Pet. 74–79 (asserting, as Petitioner did with Kong, that a POSITA would have found it obvious to use “Edwards-’535’s method to target specified nerve tissues as taught by Liang”). As for the other references, Petitioner relies on largely the same combinations, arguments, and evidence discussed above for Grounds 1 and 2. *See id.* at 79–90.

At this stage, Patent Owner’s arguments against Grounds 3 and 4 are similar to those discussed above for Ground 1. To the extent they overlap, we have already explained why those arguments are unavailing on the current record.

Because Petitioner demonstrates a reasonable likelihood of prevailing with respect to its challenges in Grounds 1 and 2, we do not see the need to further address Grounds 3 and 4 at this time.

IV. CONCLUSION

Based on the current record, we determine Petitioner has shown a reasonable likelihood that it will prevail in establishing that at least one

claim of the '271 patent is unpatentable. Accordingly, we institute review of all claims challenged on all of the grounds in the Petition. *SAS Institute, Inc. v. Iancu*, 138 S.Ct. 1348, 1356 (2018); *see also* 37 C.F.R. § 42.108(a) (“When instituting *inter partes* review, the Board will authorize the review to proceed on all of the challenged claims and on all grounds of unpatentability asserted for each claim.”); Consolidated Trial Practice Guide (Nov. 2019), 64, available at <https://www.uspto.gov/sites/default/files/documents/tpgnov.pdf>.

V. ORDER

Accordingly, it is:

ORDERED that pursuant to 35 U.S.C. § 314, an *inter partes* review is hereby instituted as to claims 1–4, 6–12, and 16 of the '271 patent based on the unpatentability challenges presented in the Petition; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial commencing on the entry date of this decision.

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