

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.

IPR2024-00278
Patent 11,033,318 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, 9, 10, 12, 13, and 15–17 of U.S. Patent No. 11,033,318 B2 (Ex. 1001, “the ’318 patent”). We instituted review. Paper 9, 29 (“Dec.”).

Aerin Medical Inc. (“Patent Owner”) filed a Response to the Petition (Paper 21, “Resp.”), Petitioner filed a Reply (Paper 24, “Reply”) and Patent Owner filed a Sur-reply (Paper 29, “Sur-reply.”). We heard argument on April 23, 2025, and a transcript is of record. Paper 36 (“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 ’318 patent. Pet. 3; Paper 6, 2.

The parties also identify the following IPR proceedings involving patents related to the ’318 patent: IPR2024-00275, IPR2024-00276,

IPR2024-00277, and IPR2024-00282. Pet. 3–4; 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. 3–4 (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 '318 Patent

The '318 patent issued on June 15, 2021, 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 '318 patent discloses methods and devices for treating nasal airways. Ex. 1001, code (57). In one embodiment, the '318 patent describes “a device for treating a patient’s nasal airway” comprising a shaft with a handle at the proximal end and a treatment element “sized to be inserted into the nasal airway” at the distal end. *Id.* at 4:34–41. The treatment element “is configured to reshape a region of the nose” and “comprises an electrode configured to deliver radiofrequency (RF) energy to the nasal tissue.” *Id.* at 4:41–44. The device may also include a control system “to control the characteristics of energy applied to tissue” and “[a] thermocouple or other sensor . . . to measure a temperature near tissue or other tissue or device parameter.” *Id.* at 5:20–24

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 '318 patent, reproduced below, is “a schematic illustration of a nasal valve re-shaping treatment device.” Ex. 1001, 8:66–67.

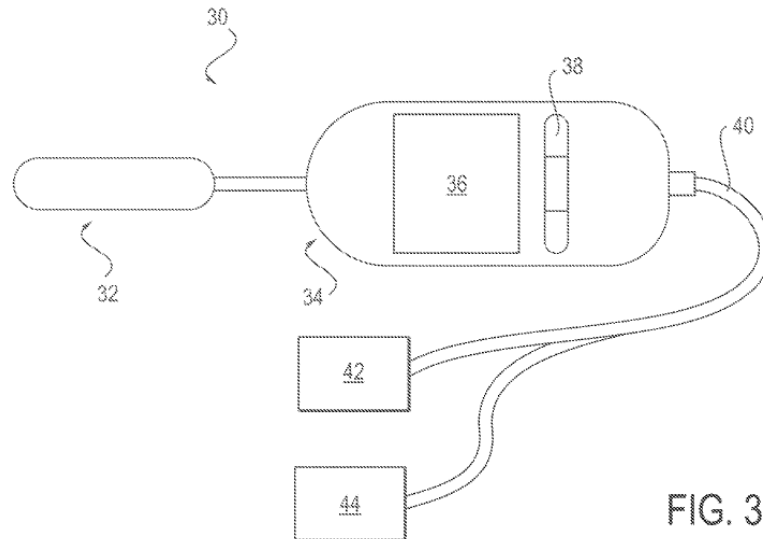


FIG. 3

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 15:65–16:1. The device in Figure 3 further comprises handle section 34 “for easy handheld operation by a clinician.” *Id.* at 16:1–4. 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 16:4–20.

Figure 18 of the '318 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, 9:50–52.

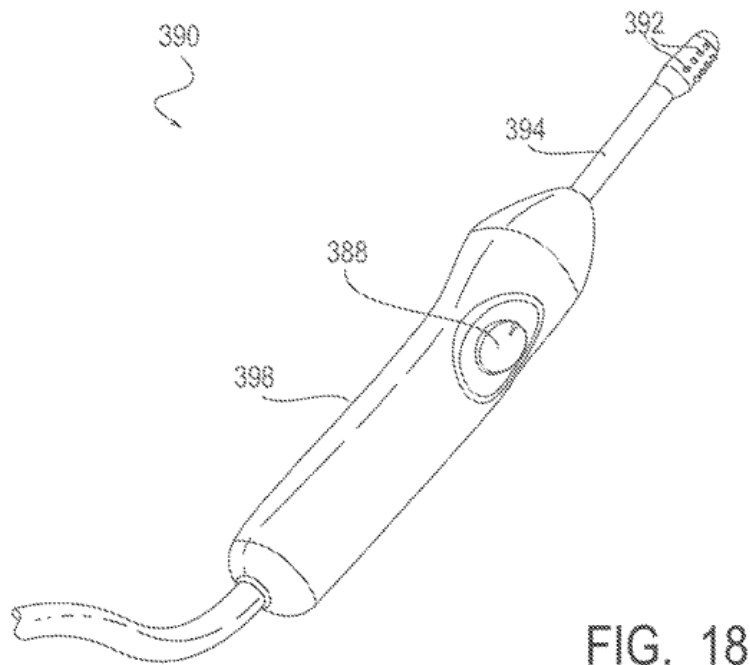


FIG. 18

Figure 18 above shows “device 390 comprising pairs of bipolar electrodes 392 located at the distal end of a shaft 394.” *Id.* at 27:45–46. In the embodiment of Figure 18, the electrodes are arranged in rows. This is consistent with other portions of the specification, which describe an “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 8:6–19; *see also id.* at Fig. 8F, 24:21–24 (depicting an electrode arrangement comprising pairs of bipolar needles “located on a treatment element configured to be placed into contact with the cartilage”). The ’318 patent further explains that “each pair of electrodes may have a separate, controlled electrical channel to allow for different regions of the treatment element to be activated separately.” Ex. 1001, 48:63–65.

D. Challenged Claims

The Petition challenges claims 1, 4–6, 9, 10, 12, 13, and 15–17. Claim 1 is illustrative and reproduced below with the same bracketed annotations the Petition includes to identify particular limitations.

1[pre] A device for delivering energy to a nasal airway to improve nasal airflow, the device comprising:

[1a] a handle;

[1b] a shaft extending from one end of the handle;

[1c] a treatment element coupled with a distal end of the shaft, sized to be inserted into a nostril, and configured to change from a first configuration to a second configuration, wherein the treatment element comprises a tissue treatment surface;

[1d] an array of multiple pairs of bipolar radiofrequency electrodes disposed along the treatment surface of the treatment element;

[1e] multiple radiofrequency output channels connected with the multiple pairs of bipolar radiofrequency electrodes, wherein each pair of the multiple pairs of bipolar radiofrequency electrodes is connected with a respective one of the multiple radiofrequency output channels; and

[1f] multiple sensors on the tissue treatment surface, wherein the multiple sensors are selected from the group consisting of impedance sensors, electrodes and thermocouples.

Ex. 1001, 52:15–36. All of the other challenged claims depend directly or indirectly from claim 1 and recite further limitations relating to the treatment element comprising multiple segments (claims 4–6), a radiofrequency generator (claims 9 and 10), and the type/configuration of the electrodes (claims 12, 13, and 15–17). *See id.* at 52:45–54:16.

E. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability:

Claim(s) Challenged	35 U.S.C. §²	Reference(s)/Basis
1, 4, 5, 9, 10, 12, 13, 15–17	103	Edwards-535, ³ Stern ⁴
6	103	Edwards-535, Stern, Patel ⁵
9, 10	103	Edwards-535, Stern, Edwards-886 ⁶
1, 4–6, 12, 13, 15–17	103	Makower, ⁷ Stern
9, 10	103	Makower, Stern, Edwards-886

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

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 ’318 patent was examined under the provisions of the AIA” and cites to the AIA version of these statutes in the Petition. Pet. 6 n. 3. 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 US 5,562,720, issued Oct. 8, 1996 (Ex. 1033) (“Stern”).

⁵ US 2007/0287994 A1, published Dec. 13, 2007 (Ex. 1034) (“Patel”).

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

⁷ US 2005/0240147 A1, published Oct. 27, 2005 (Ex. 1021) (“Makower”).

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; (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. 19–20 (citing Ex. 1002 ¶¶ 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 33–34 (identifying evidence that clinical experience is relevant). The devices and methods in the challenged patent and asserted prior art are designed to be used by clinicians. Accordingly, clinical experience using and testing them would inform their design and therefore 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’s 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 declarant, Dr. Martin, is qualified to offer the opinions in his declarations under either definition. Moreover, Patent Owner does not identify any testimony it contends would be different under its POSITA definition. *See* Ex. 1083 ¶ 103 (Dr. Martin testifying that his opinions “remain the same regardless of which definition applies”). Accordingly, all of the findings and conclusions herein would be the same under either side’s definition of the level of ordinary skill in the art.

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).

Neither side proposes any terms for express construction. Petitioner contends “the Board need not construe any terms because the Challenged Claims are invalid under any reasonable interpretation.” Pet. 20. “Patent Owner believes that no claim constructions are required to resolve the issues raised” in this IPR. Resp. 13.

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 3–10 (urging that Patent Owner’s arguments read requirements into elements 1[d] and 1[e]); Sur-Reply 9–15 (arguing Petitioner applies an incorrect definition of “radio frequency output channel”). To the extent the

parties' arguments raise any implicit issues of claim construction, we address those issues within the context they are raised in our analysis below. No further express claim construction is necessary for this decision.

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 Edwards-535 qualifies as prior art under 35 U.S.C. § 102(a)(1) and (2). *See* Pet. 5.

Edwards-535 discloses methods 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, 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.

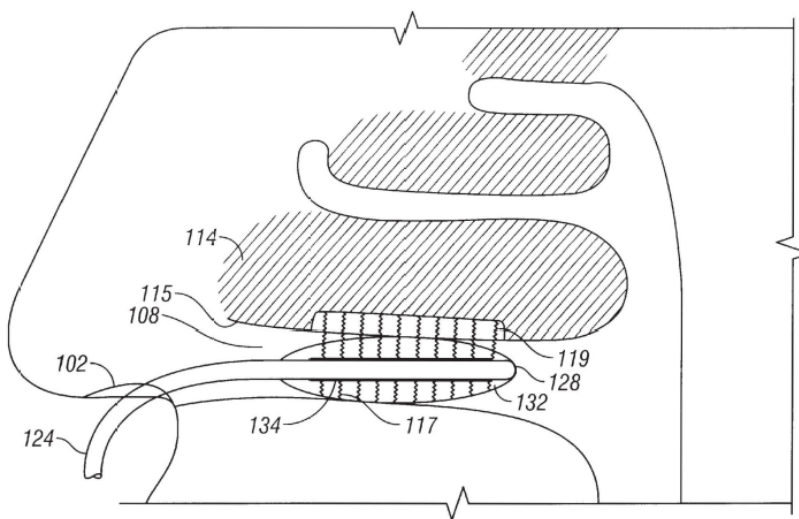


FIG. 3B

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.

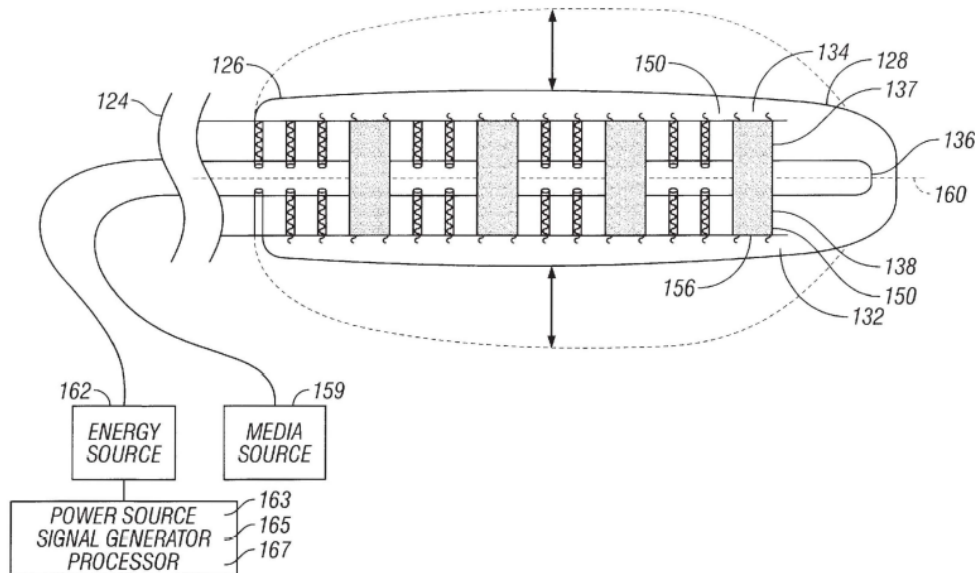


Figure 6 above depicts an embodiment comprising multiple ring electrodes 156 “disposed on the surface of the expandable member 132” in a row such that their “axes [are] aligned with a long axis 160 of the catheter body 126.” *Id.* at 8:18–23.

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,⁸ 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

⁸ More precisely, Edwards-535 cites the patent application that issued as US 5,575,788 (Ex. 1011) (“Baker”).

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. 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). *See* 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, 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.

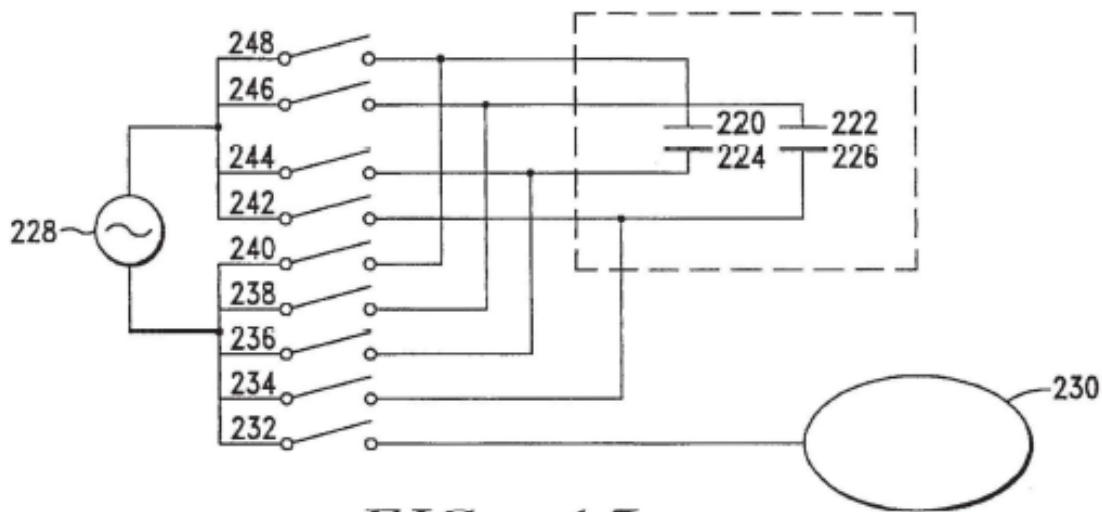


FIG. - 15

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 the 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.

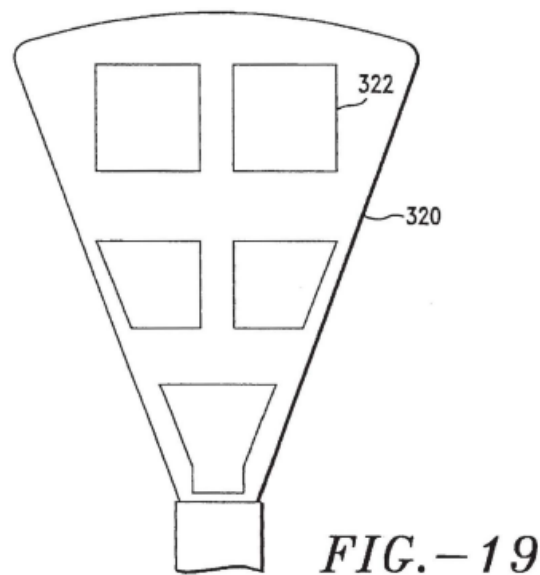


Figure 19 above show a plurality of electrodes 322 arranged on the surface of bladder 320.⁹

iii. Patel

Patel is a United States patent application published December 13, 2007. Ex. 1034, code (43). It is undisputed that Patel qualifies as prior art under 35 U.S.C. § 102(a)(1) and (2). Pet. 7.

Patel discloses “an endoscopically introducible, bipolar cautery probe for engagement and treatment of body tissue on the basis of tissue conduction of RF energy and subsequent thermal effect.” Ex. 1034 ¶ 36. In relevant part, Patel describes a probe with electrodes positioned on the surface of an expandable balloon. *Id.* at Fig. 5, ¶ 90. Patel teaches that the electrodes “are made of thin flexible metallic strips to allow folding or furling of the balloon” and that nitinol is suitable metal for such electrodes. *Id.* ¶ 90.

⁹ 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.

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). Pet. 6.

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, Abstr. 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 radio frequency energy with a sinusoidal waveform at 460 kHz.” Ex. 1016, 36:66–37:2.

v. Makower

Makower is a United States patent application published October 27, 2005. Ex. 1021, code (43). It is undisputed that Makower qualifies as prior art under 35 U.S.C. § 102(a)(1) and (2). Pet. 7.

Makower discloses devices for diagnosing and treating sinusitis and other disorders of the ears, nose, and throat. Ex. 1021 ¶ 42. One such device, described as a “tissue shrinking electrode device,” is depicted in Figure 5H, which is reproduced below. *Id.* ¶ 92.

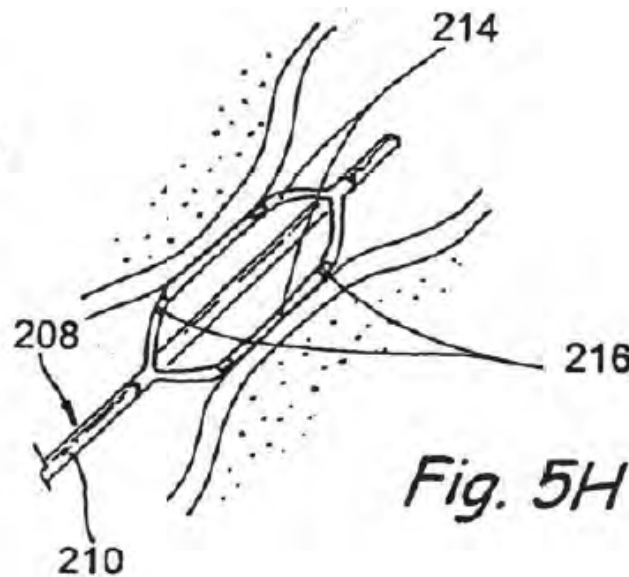


Figure 5H above “shows an electrosurgical device 208 comprising a flexible shaft 210 (e.g., a catheter or solid shaft) having arched strut member 214” and electrodes 216 located on the strut members. *Id.* ¶ 187. Makower teaches that device 208 is “advanced into a passageway such as a nostril” and “current is applied to electrodes 216 causing tissue adjacent to the struts 214 to be cauterized or heated.” *Id.* Makower further teaches that “electrodes 216 may be bipolar” and that “sensing elements” may be included on the catheter or strut members “to monitor various parameters of the catheter and/or surrounding tissue (e.g., temperature, etc.).” *Id.*

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

Petitioner contends claims 1, 4, 5, 9, 10, 12, 13, and 15–17 would have been obvious over Edwards-535 and Stern. *See* Pet. 24–71. Patent Owner disputes Petitioner’s contentions, raising global arguments for certain elements of claim 1 that also apply to the dependent claims. Resp. 14–28. Patent Owner also raises separate arguments for the additional limitations recited in claims 5, 9, 15 and 17. *Id.* at 28–38. 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. 24–51. To illustrate its position, Petitioner offers annotated versions of Edwards-535’s figures, including the annotated version of Figure 3C reproduced below. *Id.* at 28.

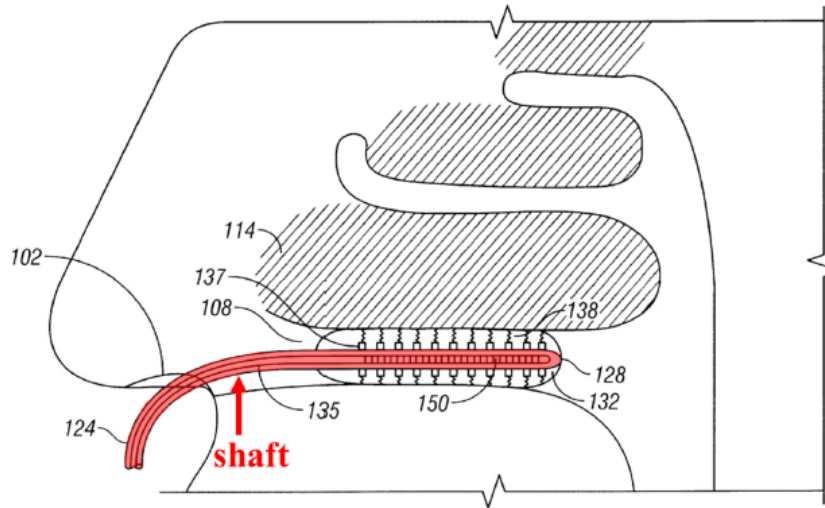
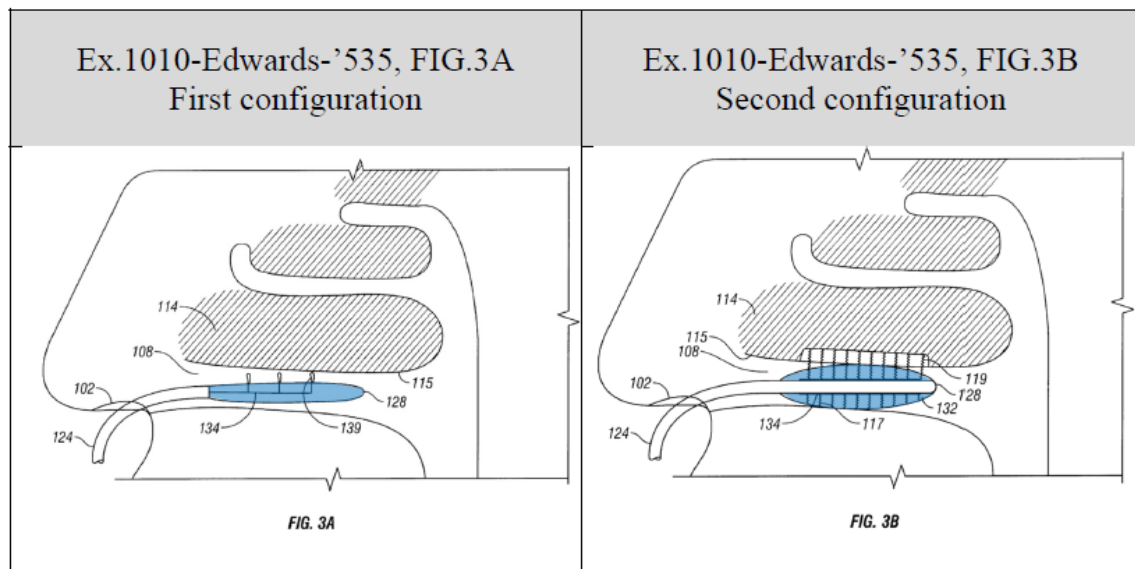


FIG. 3C

In the annotated figure above, Petitioner identifies in red the portion of Edwards-535’s device 124 that it maps to the “shaft” of claim 1 (element 1[b]).¹⁰ Petitioner also provides a side-by-side comparison of Figures 3A and 3B, which is reproduced below. *Id.* at 31.

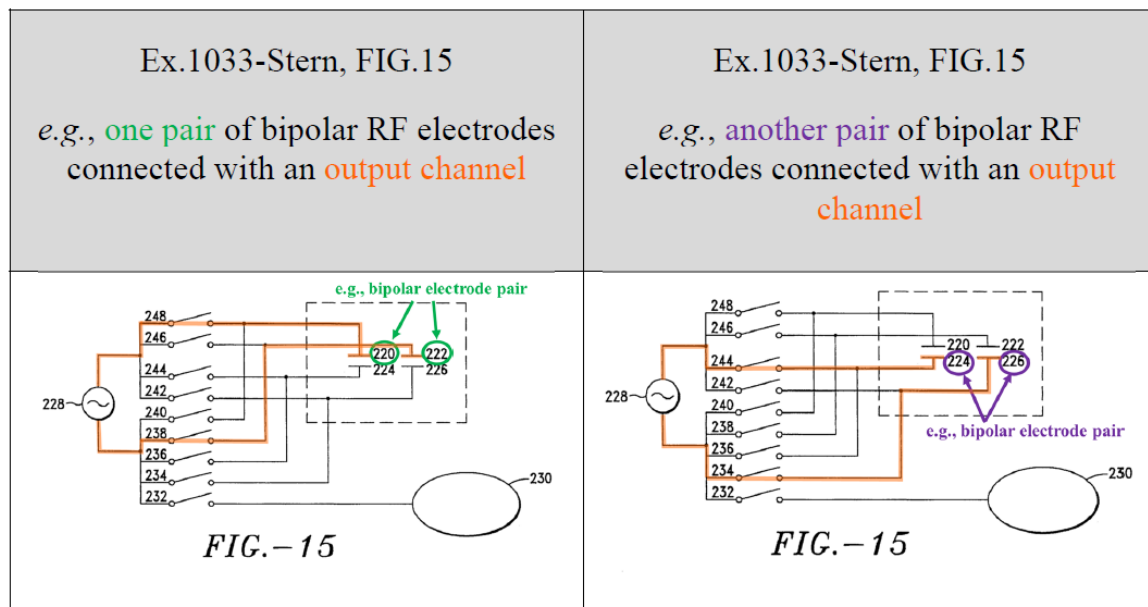
¹⁰ Petitioner observes Edwards-535 “omits whether its device includes a handle” for this shaft, but asserts it would have been obvious include a handle in view of Stern and Edwards-535’s other teachings. *See* Pet. 25–27 (addressing element 1[a]).



Petitioner’s annotated comparison shows Figure 3A on the left and Figure 3B on the right with expandable member 132 highlighted in blue in both figures. According to Petitioner, these figures depict “a treatment element (e.g., expandable member 132 [highlighted in blue] and energy delivery device 134)” coupled to the distal end (i.e., distal portion 128) of the shaft and configured to change from a first configuration (i.e., one where the expandable member is deflated as shown in Figure 3A) to a second configuration (i.e., one where the expandable member 132 is inflated as shown in Figure 3B) as recited in element 1[c]. *See id.* at 29–32. Petitioner also contends that Edwards-535 discloses the use of multiple sensors, including temperature and impedance sensors, on the treatment surface as recited in element 1[f]. *See id.* at 45–48.

Regarding the “multiple pairs of bipolar radiofrequency electrodes” and “multiple radiofrequency output channels” recited in elements 1[d] and 1[e], Petitioner contends that Edwards-535 teaches a device comprising an array of multiple bipolar electrodes, but “leaves the details of how to deliver bipolar RF energy to the discretion and skill of a POSITA.” *See Pet.* 32–34.

Petitioner relies on Stern for its teaching of “implementation details” for Edwards-535’s device and specifically the selective delivery of RF energy to chosen multiple pairs of bipolar electrodes in an array where each bipolar pair is connected with its own radiofrequency output channel. *See* Pet. 34–45. Petitioner illustrates its position with a figure, reproduced below, showing two annotated versions of Figure 15 of Stern side-by-side. *Id.* at 43.



In the annotated figure above, Petitioner identifies two different pairs of bipolar RF electrodes, i.e., electrodes 220 and 222 (marked in green on the left) and electrodes 224 and 226 (marked in purple on the right). Petitioner highlights the output channel for each pair in orange to show they are connected to voltage source 228 “via separate output channels” and therefore can be independently activated and separately controlled. *See id.* at 43–44.

Petitioner contends it would have been obvious to combine Stern’s teachings with Edwards-535 because one of ordinary skill “would have found Stern to be a good source” for details on how to implement Edwards-

535’s teachings of a device capable of delivering bipolar energy independently to different electrodes. Pet. 37. In particular, Petitioner asserts:

a POSITA would have been faced with a finite choice between implementations with switches/relays and a single voltage source (like Stern) or with multiple individual voltage sources for each electrode/electrode pair, and would have been motivated to select the former because it is safer, more practical, more reliable, smaller, simpler, and cheaper.

Id. (citing Ex. 1002 ¶¶ 103–105). Petitioner further asserts that Stern teaches that “its bipolar RF surface electrodes pairing technique . . . and wiring for independent delivery of RF energy to each bipolar pair . . . provides numerous benefits.” *See id.* at 38–40 (alleging specific benefits the combination would provide). Moreover, Petitioner argues “Stern’s teaching would have been applied to Edwards-535 in the same way those teachings are used in Stern itself” and “a POSITA would have had a reasonable expectation of success because Edwards-535 points a POSITA” to Baker, which has “similar attributes as Stern.” *Id.* at 40–41 (comparing Ex. 1011, code (57), 5:67, 9:13–23, Figs. 8–9 with Ex. 1033, 2:26–35).

Patent Owner does not dispute Petitioner’s allegations for claim elements 1[a]-[c] and [f] above, nor does Patent Owner challenge Petitioner’s reasoning for combining Edwards-535 with Stern.¹¹ *See*

¹¹ Patent Owner does not continue its arguments from the Preliminary Response disputing Petitioner’s reasoning for combining the references in its Response. *Compare* Prelim. Resp. 7–22 *with* Resp. 14–28. Accordingly, those arguments have been waived and we do not consider them further. *See In re Nurvasis, 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*

Resp. 14. Instead, Patent Owner focuses its arguments on elements 1[d] and 1[e], urging that Petitioner has failed to show that Stern teaches these elements “because Stern teaches a device comprising only a *single pair* of bipolar radiofrequency electrodes and a *single* radiofrequency output channel.” *Id.*

We find that one of ordinary skill in the art would have been motivated to combine Edwards-535 and Stern, and had a reasonable expectation of success in doing so for the reasons set forth in the Petition. We also find that the articulated combination of Edwards-535 and Stern teaches all of the limitations of claim 1. We adopt Petitioner’s undisputed analysis of claim elements 1[a]-[c] and [f] and reasoning for combining the references, and credit its supporting evidence. *See* Pet. 7–14, 17–20; Ex. 1002 ¶¶ 79–103, 113–21. Below we address the parties’ arguments regarding the disputed elements 1[d] and 1[e].

1. Element 1[d]: “multiple pairs of bipolar radiofrequency electrodes”

Patent Owner argues that “Stern teaches a device configured to have at most a *single pair* of bipolar radiofrequency electrodes.” Resp. 15. 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 16–18. Referring to Petitioner’s annotated, side-by-side version of Figure 15 depicting switches 248 and 238 closed to form a first bipolar pair on the left and switches 244 and 234 closed to form a second bipolar pair on the right,

Consolidated Trial Practice Guide (Nov. 2019), 52, available at <https://www.uspto.gov/sites/default/files/documents/tpgnov.pdf>.

Patent Owner argues that “[e]ither configuration has only a single ‘pair’ of electrodes” and that 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 18–19. 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 19–20 (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 treatment element’s pairs of bipolar electrodes must be delivering energy ‘*at the same time,*’” nor is there any basis in the intrinsic record for reading such a requirement into the claims. Reply 4. All element 1[d] recites is an array with “multiple pairs.” Ex. 1001, 52:24. 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, 24:45–49, 48:63–49:4; *see also* Ex. 1083 ¶¶ 19–20 (discussing embodiment in the ’318 patent with “only one pair being active at any given 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

3), such disclosure would still teach or suggest the “multiple pairs of bipolar radiofrequency electrodes” recited in element 1[d].

Indeed, on page 2 of its Sur-reply, Patent Owner concedes that “[c]laim 1 does not require simultaneous activation of multiple pairs.” Notwithstanding, Patent Owner continues to argue that Stern does not teach element 1[d] because its device is not “configured to have multiple pairs.” Sur-reply 2.

Again, we disagree. 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 that “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 radiofrequency electrodes,’ as claimed.” Resp. 19. 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. 1002 ¶¶ 98–101, 124–128. Indeed, Stern consistently uses the word “pairs,” i.e., the plural not the singular, to describe the bipolar operation of its device. *See, e.g.*, 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 ¶¶ 59–65), 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 may be utilized together *sequentially*.” Sur-Reply 4. According to Patent Owner, its interpretation is informed by other disclosures in Stern teaching that its electrodes are independently and sequentially energized. *Id.* at 4–5 (citing Ex. 1033, 2:31–33, 2:49–53, 10:48–52, 17:54–55; Ex. 2001 ¶ 64; Ex. 1002 ¶¶ 177, 206). Thus, Patent Owner urges that “when Stern is properly read in its entirety, any potential ambiguity is resolved *in Patent Owner’s favor*.” *Id.* at 4.

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 ¶ 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. 1083 ¶¶ 22–28.

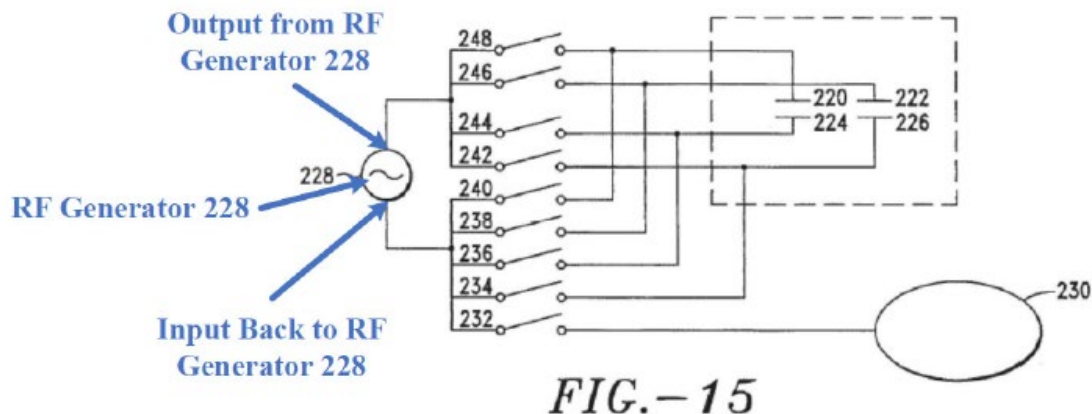
Finally, Patent Owner’s argument that activating multiple pairs at the same time could result in uneven heating does not compel a different interpretation. *See* Sur-Reply 5. Even assuming that the sequential activation of just one pair of bipolar electrodes at a time would provide better control over 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.*

For these reasons, Petitioner has sufficiently demonstrated that the combination of Edwards-535 and Stern teaches or suggests element 1[d].

2. Element 1[e]: “multiple radiofrequency output channels . . . wherein each pair of the multiple pairs of bipolar radiofrequency electrodes is connected with a respective one of the multiple radiofrequency output channels”

Similar to its argument that Stern teaches only a single bipolar pair, Patent Owner argues that “Stern teaches at most a *single* radiofrequency output channel.” *See* Resp. 20–25. According to Patent Owner, both sides’ experts “agree that the term ‘radio frequency output channel’ means ‘an

output from a radiofrequency generator” and that “the number of radiofrequency output channels depends on the number of outputs from the radiofrequency generator.” *Id.* at 21–24 (citing testimony). Patent Owner therefore contends that Stern discloses only a single channel, using the annotated version of Stern’s Figure 15 below to illustrate its position. *Id.* at 24.

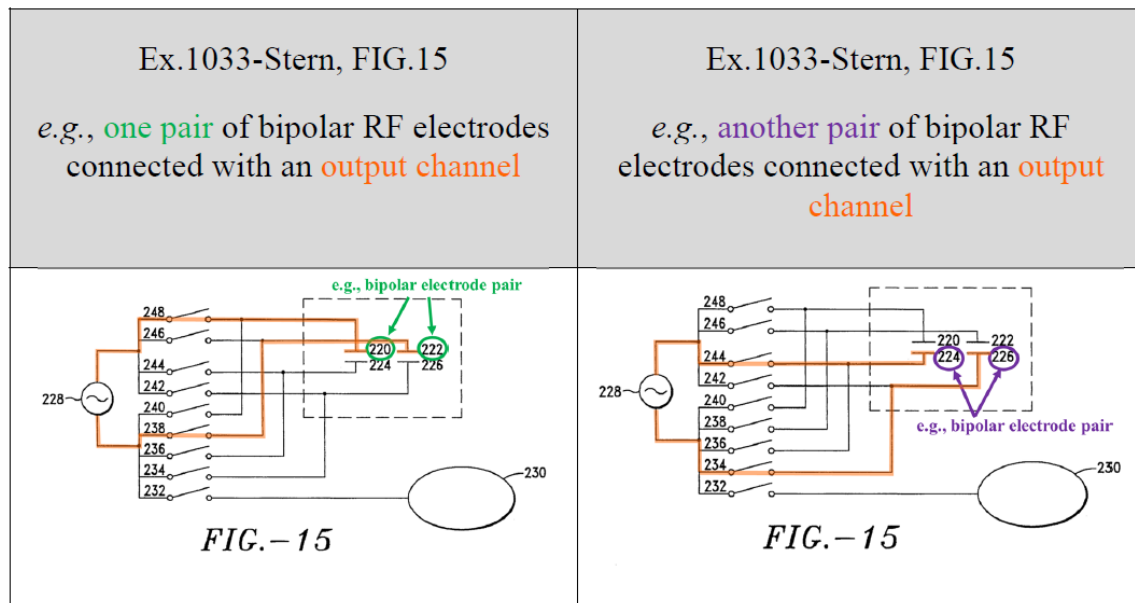


In this version of Figure 15, Patent Owner annotates voltage source 228 as the “RF Generator” and the two lines leading to the switches as the “output from” and “input back to RF Generator.” *Id.*

For the same reasons, Patent Owner argues that Petitioner has also failed to show that Stern teaches the second part of element 1[e], i.e., “wherein each pair of the multiple pairs of bipolar radiofrequency electrodes is connected with a respective one of the multiple radiofrequency output channels.” Resp. 26–28 (urging that Petitioner’s annotated version of Figure 15 depicting different output channels shows the electrodes connected “to the same output of Stern’s radiofrequency generator 228” and that Petitioner cannot show any pair “connected to a different output . . . as Stern’s radiofrequency generator 228 has only a single output.”).

Petitioner replies, arguing that we should reject Patent Owner’s attempt to limit element 1[e] to require “output channels” that directly connect to the voltage source in the radiofrequency generator for three reasons. *See* Reply 6–10. First, Petitioner contends that “the plain language of the claim does not require the ‘multiple radiofrequency output channels’ to be channels connected directly to the voltage source in the radiofrequency generator.” *Id.* at 7. Second, Petitioner contends that Patent Owner’s arguments are inconsistent with the specification of the ’318 patent, which consistently uses the terms “electrical channel” and “output channel” to “refer[] to connections to *electrodes*—not wires within a generator.” *Id.* at 8 (citing Ex. 1001, Fig. 39, 24:45–52, 48:63–65, 49:5–10, 49:12–15, 49:24–46, 49:65–50:2, 50:9–15). Third, Petitioner contends that the only support for Patent Owner’s interpretation is Dr. Bikson’s “say-so” and mischaracterized testimony from Dr. Martin. *Id.* at 9–10.

We find that Petitioner has the more persuasive position and has demonstrated that Stern teaches element 1[e]. Petitioner demonstrates Stern’s multiple RF output channels with the annotated version of Figure 15 shown below. Pet. 42–43.



As shown by Petitioner’s annotations above, the channel (highlighted in orange) connecting the output received from voltage source 228 to the first bipolar pair (circled in green on the left) is distinct from the channel connecting the output to the second bipolar electrode pair (circled in purple on the right) because depending on which switches are closed, energy travels through a separate connection between those switches and the corresponding electrodes. We agree with Petitioner, and credit Dr. Martin’s testimony, that each of the output channels highlighted in orange in Stern’s Figure 15 above “are *output channels* as required by the claims because the channels are separately/individually connected to the electrodes” and “control individual pairs of bipolar RF electrodes.” *Id.* at 43–44; Ex. 1002 ¶¶ 124–128; *see also* Ex. 1083 ¶ 45 (“an ‘output channel’ connects electrodes and provides the ability to independently control pairs of electrodes”).

This understanding of the term “output channel” is consistent with the claim language. Claim 1 recites “multiple radiofrequency output channels” wherein “each pair” of bipolar RF electrodes “is connected with a respective

one of the multiple radio frequency output channels.” Ex. 1001, 52:27–33. The RF generator itself and its connection to the output channels is not recited in claim 1. Instead, the claim language focuses on the connection between the electrode pair and its respective output channel.

The description in the specification also focuses on the connection to the electrodes and further explains that having a “separate, controlled electrical channel” for “each pair of electrodes” allows for “different regions of the treatment element to be activated separately.” Ex. 1001, 24:45–52, 48:63–65; *see also* Ex. 1083 ¶ 33 (“[e]very time the patent mentions ‘electrical channel’ or ‘output channel,’ it is referring to connections to electrodes”). This aligns with the depiction of the output channels in the ’318 patent’s figures. *See* Ex. 1001, Figs. 39–44 (showing RF output channel 961 connected to electrodes). Petitioner demonstrates this in the annotated version of Figure 39 shown below. Reply 8.

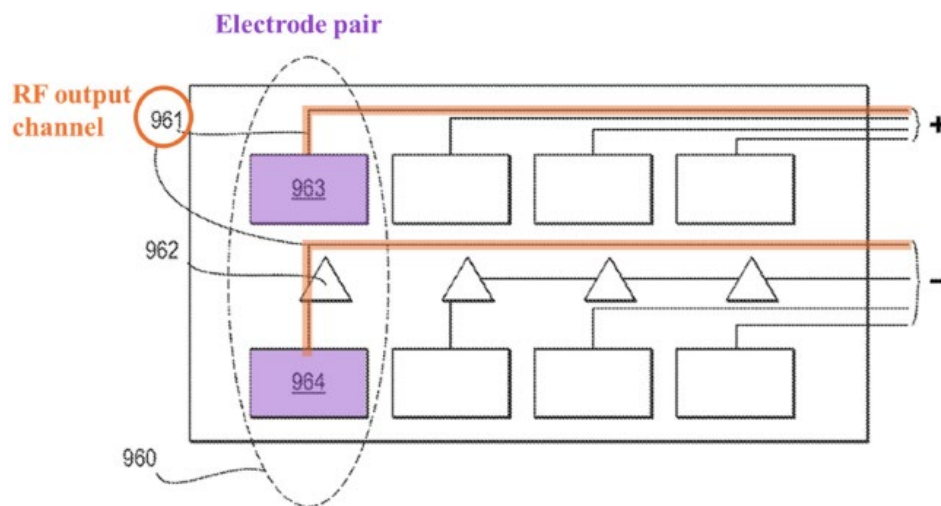


FIG. 39

Petitioner’s annotations highlight the “RF output channel 961” in orange, which the figure shows as a line connecting positive electrode 963 and negative electrode 964 in an electrode pair. Figure 39 shows separate lines

connecting the electrodes in other pairs, but how those lines connect to the generator is not shown or otherwise specified. Ex. 1083 ¶ 35 (explaining that the channel 961 is “clearly pointing to wires lines carrying both an active signal shown by a ‘+’ sign and a return signal shown by a ‘-’ sign,” but the ’318 patent “never explains, shows, or limits the *beginning* of that output channel, i.e., how the channel connects to the voltage source in the RF generator”).¹² Instead, the description in the ’318 patent again focuses only on how the channel provides for separate control over the pair to which it is connected. Ex. 1001, 49:5–17 (explaining that in Figure 39 “an RF output channel 961” is “assigned to each electrode pair for feedback” and “independent adjustments”); *see also id.* at 49:24–46 (similar for Fig. 40); Ex. 1083 ¶¶ 36–40 (providing similar annotations and testimony regarding a POSITA’s understanding of Figures 40–44).

The output channels Petitioner identifies in Stern’s Figure 15 provide the same separate control over different bipolar pairs that is described in the ’318 patent. For example, Stern teaches:

The bipolar arrangement allows various pairs of electrodes to be picked in order to heat uneven or rather asymmetrical areas

¹² In the Sur-reply, Patent Owner asserts that the channels in Figures 39–44 are “depicted as a separate output from the radiofrequency generator (denoted with a ‘+’ sign).” Sur-reply 7–8 (citing Ex. 1001, Figs. 39–44; Ex. 1084, 177:2–14; Ex. 2008, 61:13–62:18). But the testimony it cites does not support that the “+” sign depicts a separate output from the generator. *See* Ex. 1084, 177:2–14 (Dr. Bikson referring to figures in Stern not the challenged patent); Ex. 2008, 61:13–62:18 (Dr. Martin testifying that the active signal “*could be* one of the outputs from the generator”) (emphasis added); *cf* Ex. 2008, 136:19–138:1 (reiterating that none of Figures 39–44 show a generator or how the depicted channels connect to it). Indeed, at the hearing, Patent Owner’s counsel acknowledged that Figure 39 does not show the actual connection to the generator. Tr. 74:13–18.

within individual patients . . . That is, any unusual features within an area to be heated may be taken into account in a bipolar operation by selection of different pairs of electrodes for energization utilizing the circuitry of FIG. 15.

Ex. 1033, 13:27–35; *see also id.* at 12:25–33 (“if particular pairs of electrodes were chosen in a bipolar arrangement to receive RF energy, the return path could be controlled selectively by a physician”), 12:43–45 (“the switches [in Figure 15] allow for the selective application of RF energy to various combinations of electrodes”). This is the same type of control the ’318 patent teaches its output channels provide. *See, e.g.*, Ex. 1001, 24:45–49, 48:63–65; Ex. 1083 ¶ 44. Patent Owner argues that if multiple pairs in Stern’s Figure 15 were activated “at the same time,” this control would be lost because “current would be diverted to whichever electrodes experience less impedance.” Resp. 25; Sur-reply 5–6 (same). But that argument only applies to embodiments in which multiple pairs are activated at the same time, which is not required by claim 1. *See supra* § II.E.i.1. As explained above, Stern teaches embodiments in which the pairs in Figure 15 are individually and sequentially activated as well as embodiments where combinations of pairs are utilized together. *Id.* Even for the latter, Stern teaches that different combinations of pairs can be separately controlled, which is consistent with the description of control in the ’318 patent.

Patent Owner interprets element 1[e] to have an additional requirement. That is, in addition to connecting the electrodes and providing separate control, Patent Owner and Dr. Bikson assert that element 1[e] requires that there be multiple outputs, i.e., direct connections, from the generator. *See* Resp. 21–24; Sur-reply 6–7 (asserting the “number of radiofrequency output channels depends on the number of outputs from the

radiofrequency generator”); Tr. 58:14–61:25 (explaining Patent Owner’s position that “at a minimum” the claims require “multiple outputs and a connection between each pair and the multiple outputs from the generator”); Ex. 2001 ¶¶ 68–71. According to that view, a switching arrangement that provides separate channels for the output from the generator to independently control different bipolar pairs does not disclose element 1[e] unless there are also multiple output lines extending from the generator or voltage source. *See* Ex. 2001 ¶ 79 (testifying that voltage source 228 in Stern’s Figure 15 has only one output channel because that figure shows only a single output and input line from that voltage source).

But as explained above, there is no basis in the intrinsic record for Patent Owner’s additional requirement. That is, nothing in the claim language, written description, or patent figures describes, much less requires, separate direct connections to the voltage source or generator.¹³

Accordingly, the fact that Stern’s Figure 15 shows a single line connecting voltage source 228 to its switches does not undermine Petitioner’s showing that those switches operate to provide the recited “multiple radiofrequency output channels” wherein “each pair of the multiple pairs of bipolar radiofrequency electrodes is connected with a respective one of the multiple radiofrequency output channels.” *See* Pet. 41–45 (citing evidence).

Patent Owner’s argument that Petitioner’s expert, Dr. Martin, agrees with its position is unavailing. *See* Resp. 21–24. Patent Owner points to Dr. Martin’s testimony that he interpreted “output channel” to mean “output from a radiofrequency generator.” Ex. 2004, 318:12–14. But Dr. Martin also

¹³ Neither party directs us to anything in the prosecution history that bears on their arguments concerning this limitation.

made clear his view that according to that interpretation Stern's Figure 15 discloses multiple output channels:

A. So the '318 patent I think doesn't fully teach what the output channel is. But if you look at Stern, Stern figure 15 has a number of output channels from their device. That's how I interpret "output channel" to mean: output from a radiofrequency generator.

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

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

Id. at 318:9–19 (objection omitted), 319:17–320:12 (similar). Patent Owner ignores the fuller context of this testimony, suggesting that Dr. Martin agreed the ordinary meaning of element 1[e] requires multiple outputs directly from the generator. However, as Dr. Martin persuasively explained on redirect, Patent Owner and Dr. Bikson have taken his testimony out of context. Ex. 1083 ¶¶ 42–46 (explaining he meant "the 'output channel' must be carrying energy, and that energy is what is output from the radiofrequency generator" and this does not mean that channel "is required to be directly connected to the generator, or voltage source within a generator, for it to be an 'output channel'").

Patent Owner's related arguments that Dr. Martin's testimony regarding the hand-drawn circuit diagrams (Ex. 2005–2007) he was asked about in his deposition supports its position are also unavailing. *See* Resp. 21–24; Sur-reply 7 (citing testimony). Unlike the prior art, these drawings do not depict any switches, much less a switching arrangement similar to that in Stern's Figure 15. *See* Ex. 2005–2007; Ex. 1083 ¶ 45 n.4. Thus, we do not find Dr. Martin's testimony concerning them to be particularly relevant. Even if it were, the testimony Patent Owner cites is consistent with

Dr. Martin’s other opinions. *See* Ex. 1083 ¶¶ 45–46 (explaining and persuasively rebutting Patent Owner and Dr. Bikson’s interpretation of this testimony). Thus, none of the cross-examination testimony Patent Owner cites impeaches Dr. Martin’s opinion that Stern describes “a multi-channel circuit” in Figure 15 “and clearly shows that the energy is broken down into multiple channels after it is output from the radiofrequency generator—no direct connection to the voltage source is required to form multiple output channels.” Ex. 1083 ¶ 44. We credit that opinion and Dr. Martin’s related testimony (Ex. 1002 ¶¶ 123–128, 133; Ex. 1083 ¶¶ 33–46, 50–53) over Dr. Bikson’s competing opinions (*see* Ex. 2001 ¶¶ 68–83) because they are consistent with the description in the intrinsic record of the ’318 patent and supported by the teachings in Stern.

We also disagree with Patent Owner’s suggestion that Petitioner and Dr. Martin have changed position in the Reply or have offered inconsistent definitions of “radiofrequency output channel.” Sur-reply 9–14. The alleged “smorgasbord of new definitions” that Patent Owner pulls from Dr. Martin’s reply declaration (*see id.* at 10–11) are not inconsistent with each other. They are just phrases from Dr. Martin’s testimony that Patent Owner parses, but taken together say the same thing,¹⁴ i.e., “output channels” are the connections to the electrodes that deliver output from a voltage source and as recited in element 1[e] allow for independent/separate control of different bipolar pairs. As explained above, that interpretation is consistent with the

¹⁴ What Patent Owner suggests is “inconsistent” in these phrases is the result of its parsing Dr. Martin’s testimony, rather than considering that testimony as a whole. *See* Sur-reply 11.

intrinsic record of the challenged patent. It is also the same understanding of element 1[e] articulated and applied in the Petition. *See* Pet. 43–44.

Finally, we disagree with Patent Owner’s argument that Petitioner and Dr. Martin’s interpretation is “completely subjective” and therefore untenable. Sur-reply 13 (citing *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1350 (Fed. Cir. 2005)). In *Datamize*, the claim at issue recited an “aesthetically pleasing” interface screen and the patentee urged a construction that depended only on subjective intent, i.e., that the person practicing the invention “simply must intend to create an ‘aesthetically pleasing’ interface screen; whether that person actually succeeds is irrelevant.” 417 F.3d at 1349. The Federal Circuit found that construction unreasonable and affirmed the district court’s finding that the claim was indefinite. *Id.* at 1350, 1356. Here, however, there is no argument that element 1[e] is indefinite and the interpretation Petitioner advances, requiring multiple connections to the electrodes that provide separate control over different bipolar pairs, is an objective standard. Indeed, it is no less objective than Patent Owner’s competing interpretation that the term requires multiple outputs directly from the generator. The difference is that Petitioner’s understanding is reflected in the language of claim 1 and described in the intrinsic record, whereas the additional requirement that Patent Owner seeks to put on element 1[e] is not so specified.

For these reasons, Petitioner has sufficiently demonstrated that the asserted combination of Edwards-535 and Stern teaches or suggests element 1[e].

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

ii. Claims 4 and 5

Claim 4 depends from claim 1 and additionally recites that “the treatment element comprises multiple segments that are expandable from the first configuration to the second configuration.” Ex. 1001, 52:45–47.

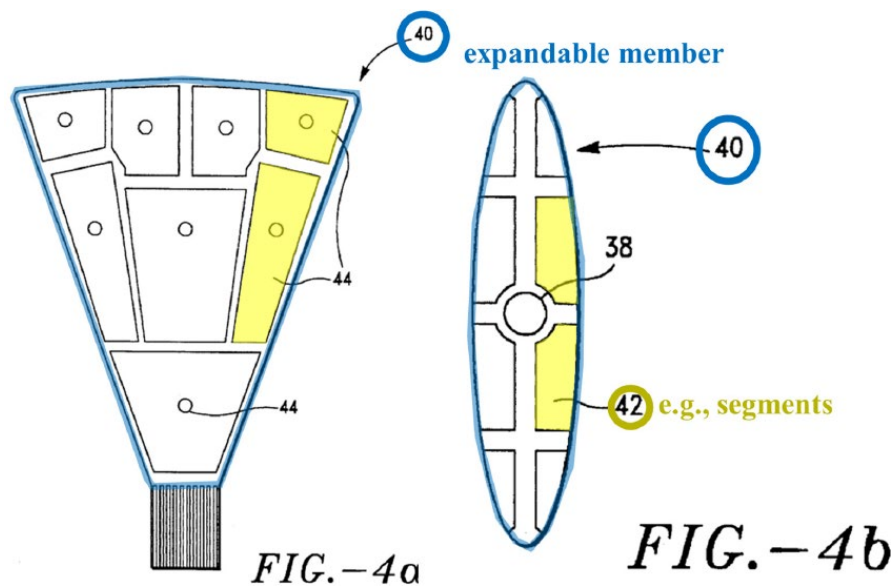
Claim 5 depends from claim 4 and further recites that “at least one pair of the multiple pairs of bipolar radiofrequency electrodes is coupled with each of the multiple segments.” *Id.* at 52:48–50.

Petitioner provides argument supported by evidence explaining how the combination of Edwards-535 and Stern teaches these additional limitations. *See* Pet. 49–53. Patent Owner does not dispute that this combination teaches multiple segments as recited in claim 4, but raises a separate argument for claim 5. *See* Resp. 28–30.¹⁵

We adopt Petitioner’s undisputed analysis of the additional limitations of claim 4 and credit its supporting evidence. *See* Pet. 49–51; Ex. 1002 ¶¶ 157–165. We address Petitioner’s showing and Patent Owner’s separate argument for claim 5 below.

Petitioner argues that both Edwards-535 and Stern disclose segmented expandable members. Pet. 49–52. Petitioner offers annotated figures from the references to illustrate its position, including the annotated version of Stern’s Figures 4a and 4b below. *Id.*

¹⁵ To the extent Patent Owner’s arguments for claim 1 also apply to the dependent claims challenged in this or other grounds, those arguments are unavailing for the same reasons explained above. *See supra* § III.E.i.



The figures above show Stern’s balloon 40, Petitioner maps the balloon to the recited “expandable member” and highlights the plurality of surface segments 42 in yellow. According to Petitioner, “Stern describes these segments as ‘electrode area segments’” and teaches “that power can be selectively provided to these segments via the circuitry of Figures 15” resulting in an at least one pair of bipolar electrodes coupled to the segments. *Id.* at 52 (citing Ex. 1033, code (57), 5:48–51; Ex. 1002 ¶¶ 169–172).

Patent Owner argues there is no evidence that each of Stern’s surface segments 42 include a pair of electrodes. Resp. 29. According to Patent Owner, Stern “teaches that each of its surface segments 42 has one electrode and one thermistor—not two electrodes.” *Id.* (citing Ex. 1033, 8:49–59; Ex. 2001 ¶ 88).

Petitioner replies that what Patent Owner is referring to “is just one configuration that Stern contemplates.” Reply 17. According to Petitioner, Stern also teaches that the “electrode area segments” in Figures 4a and 4b

can be “powered by Figure 15’s bipolar embodiment,” resulting in segments with at least two electrodes. *Id.*

We agree with Petitioner for several reasons. First, Stern describes its Figure 15 as “a selectable bipolar/monopolar RF energy delivery system for a plurality of electrodes *or electrode segments*.” Ex. 1033, 5:48–50 (emphasis added). Thus, Stern reasonably suggests that the circuitry in Figure 15 can be used to power electrode area segments such as those depicted in Figures 4a and 4b. One of ordinary skill would have understood that in bipolar operation the segments would have at least two electrodes with separate leads to connect to the power source as shown in Stern’s Figure 15. Ex. 1083 ¶¶ 58–59. Indeed, this understanding is confirmed by Stern’s teaching that “[e]ach segment 42” in Figure 4 “is electrically connected through conventional leads” plural “to a power source (not shown in FIG. 4).”¹⁶ Ex. 1033, 8:56–57; Ex. 1083 ¶ 59.

Second, Petitioner’s showing is not limited to the teachings in Stern and further relies on Edwards-535 for its disclosure of a segmented expandable member comprising various electrodes. *See* Pet. 50–53. Petitioner asserts that one of ordinary skill “would have been motivated to use the electrode configuration of Stern,” which would include that taught in Stern’s Figure 15, “with Edwards-535’s expandable member to

¹⁶ Patent Owner argues we should interpret this teaching to mean “that each segment has two leads: one for an electrode and one for a thermistor.” Sur-reply 16. We disagree because Stern separately describes the thermistor being connected by “leads to a switch matrix.” Ex. 1033, 8:58–59. But even if Patent Owner’s interpretation were correct, it does not overcome Stern’s other teaching that the circuitry in Figure 15 can be used to power “electrode segments” in a bipolar embodiment. *Id.* at 5:48–50.

independently deliver energy to electrodes.” *Id.* at 52–53. Thus, even if Stern did not itself disclose an expandable member with multiple segments and a bipolar electrode pair coupled to those segments, the combination of Edwards-535 and Stern does. *See* Ex. 1002 ¶¶ 164, 171; Ex. 1083 ¶ 60 (articulating credible rationale for the combination and explaining how that combination teaches the limitations of claim 5).

For these reasons, Petitioner has shown by a preponderance of the evidence that claims 4 and 5 would have been obvious over the asserted combination of Edwards-535 and Stern.

iii. Claim 9

Claim 9 recites:

9[a]. The device of claim 1, further comprising:
a radiofrequency generator configured to receive sensed signals from the multiple sensors and deliver radiofrequency energy separately to each of the multiple radiofrequency output channels in the form of a 460 KHz sinusoid wave; and
[9b] a cable coupled to the handle for plugging the handle into the radiofrequency generator.

Ex. 1001, 52:65–53:5 (including Petitioner’s bracketing).

Petitioner asserts that Edwards-535 teaches a RF generator that receives sensed signals from multiple sensors and delivers RF energy. Pet. 53–54. Relying on its contentions for elements 1[d] and 1[e], Petitioner argues that it would have been obvious to combine Stern’s teachings with Edwards-535 to deliver the RF energy separately to each of the multiple radiofrequency output channels. *Id.* at 54. In addition, Petitioner provides detailed contentions showing that Stern discloses applying energy in a 460 KHz wave and explaining why one of ordinary skill would have been motivated to combine those teachings with Edwards-535. *Id.* at 54–57.

Petitioner also argues that Stern teaches the cable in element 9[b], illustrating its position with the annotated version of Stern's Figure 12 below. Pet. 58.

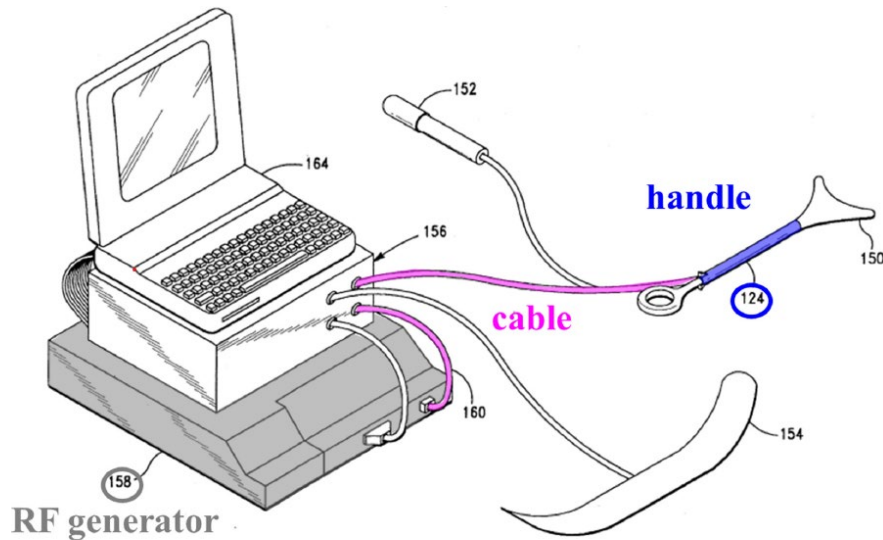


FIG. - 12

In the annotated figure above, Petitioner highlights cables 160 in pink. Those cables are connected to RF generator 158 (highlighted in gray) and the handle of application device 124 (highlighted in blue).

Patent Owner separately disputes Petitioner's contentions for both element 9[a] and 9[b]. *See* Resp. 30–36. Regarding element 9[a], Patent Owner argues that the asserted combination does not teach “a radiofrequency generator configured to . . . deliver radiofrequency energy separately.”¹⁷ *Id.* at 30–34. Referring to Stern's Figure 12, Patent Owner argues that Stern “teaches an ‘RF generator 158’ in the form of ‘a conventional electrosurgical power supply’” that “has a single ‘output,’ which is provided to a separate power source controller 156” via cables 160.

¹⁷ Patent Owner does not dispute Petitioner's showing for the “sensed signals” or “460 KHz” aspects of element 9[a]. *See* Resp. 30–34. We adopt Petitioner's undisputed analysis for these aspects as our own.

Id. at 32 (quoting Ex. 1033, 10:53–55). Patent Owner asserts that “[s]witches in the power source controller 156 control which electrodes in the application device 124 receive radiofrequency energy.” *Id.*; *see also id.* at 33–34 (arguing this is also consistent with the disclosure in Stern’s Figures 5 and 15).

Regarding element 9[b], Patent Owner argues that Stern’s Figure 12 shows that “the cable coupled to the handle of Stern’s application device 124 is plugged into Stern’s ***power source controller 156***—not into Stern’s RF generator 158 (*i.e.*, the alleged radiofrequency generator), as claimed.” *Id.* at 35–36.

Petitioner counters that Patent Owner’s argument “miscomprehends the proposed combination” and that one of ordinary skill “would have been motivated to modify Edwards-[]535’s generator to include the functionality of Stern’s controller.” Reply 26, 28. Petitioner also argues that Patent Owner is taking an “improperly narrow view of the claim limitation” and that, under the correct view, Stern itself discloses these limitations. *See id.* at 24–25, 27–28.

We agree with Petitioner. The Petition asserts that Edwards-535 discloses a RF generator and “teaches that energy may be independently delivered to each electrode pair . . . but omits details regarding how to implement the circuitry for independent energy delivery.” Pet. 53–54 (citing Ex. 1005, 8:22–25; Ex. 1002 ¶¶ 173–175) (internal quotations omitted). Referring to its showing for elements 1[d] and 1[e] regarding the circuitry in Stern’s Figure 15, Petitioner contends it would have been obvious to combine these teachings with Edwards-535. *Id.* at 54. Accordingly, the asserted combination is Edwards-535’s generator configured to deliver

energy separately as taught by Stern, e.g., by modifying that generator to include the switching circuitry shown in Stern’s Figure 15. We find that one of ordinary skill in the art would have been motivated to make that combination with a reasonable expectation of success. Ex. 1002 ¶¶ 129–148, 173–175.

Patent Owner’s arguments are unavailing because they are premised on reading Stern too narrowly. It is true that Stern depicts RF generator 158 and controller 156 in two boxes connected by cables in Figure 12. But the switching circuitry shown in Stern’s Figure 15 need not be implemented in a separate controller. *See* Ex. 1083 ¶ 78 (“A person of ordinary skill would have understood Stern’s disclosure to encompass both a configuration where switches directing energy are inside a generator, and a configuration where switches directing energy are inside a power source controller that is connected to the generator.”). Accordingly, it does not follow that one of ordinary skill seeking to modify Edwards-535’s generator with Stern’s circuitry for the independent delivery of energy would be limited to bodily incorporating it in a separate box, e.g., controller 156, as opposed to housing that circuitry with the generator in the same box. *See AliveCor, Inc. v. Apple Inc.*, 130 F.4th 1006, 1015 (Fed. Cir. 2025) (explaining that “[t]o restrict each reference’s teaching to the particular way it implements [a technique], would improperly fail to read these references for all they disclose”).

Moreover, even if Stern’s teachings or Petitioner’s contentions regarding those teachings were as limited as Patent Owner contends,¹⁸ the

¹⁸ Patent Owner urges that Petitioner limited itself to applying Stern’s teachings exactly as depicted in Stern’s two-box embodiment. *See* Sur-reply 18–19, 20 (quoting Pet. 40). As noted above, we disagree. *See* Pet. 53–54.

language of claim 9 is broad enough to read on the two-box implementation shown in Stern's Figure 12. That is, by connecting it to power source controller 156, Stern's RF generator 158 is "configured to . . . deliver radiofrequency energy separately to each of the multiple radiofrequency output channels" as recited in claim 9. Ex. 1001, 52:66–53:2; Ex. 1083 ¶ 80. This interpretation is consistent with the specification of the '318 patent, which describes embodiments with a generator and separately housed controller. Ex. 1001, Fig. 3, 16:27–57 (depicting control system 42 and power system 44 in separate boxes), 34:31–35 (stating that the generator may be integrated with the "electrode handpiece or part of a separate assembly that delivers energy or controls signals"); Ex. 1083 ¶ 79.

Patent Owner's arguments regarding element 9[b] are similarly unavailing. First, Stern's Figure 12 shows the handle of the device plugged into RF generator 158 by a first cable between the device and controller 156 and a second cable between that controller and the generator. The fact that element 9[b] recites "a" cable for this purpose does not distinguish Stern's teachings because it is well-settled that "'a' . . . can mean 'one or more'" *Baldwin Graphic Sys., Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1342 (Fed. Cir. 2008) (describing this "as a rule, rather than merely a presumption or even a convention" for open-ended comprising claims). This rule of interpretation is consistent with the specification of the '318 patent, which describes embodiments with separately housed components that would require more than one cable to connect the handle to the generator. *See* Ex. 1083 ¶¶ 86–87 (discussing disclosures). Accordingly, element 9[b] encompasses the use of multiple cables, at least one of which is "coupled to the handle for plugging the handle into the radio frequency generator." Ex. 1001, 53:4–5. Contrary

to Patent Owner’s assertions, this does not require that the same cable be directly coupled to *both* the handle and generator. *See* Sur-reply 19–20.

Second, when the controller circuitry is incorporated into Edwards-535’s generator as in Petitioner’s asserted combination, there is no need for a second cable connecting the controller to the generator as shown in Stern’s Figure 12. Thus, in the asserted combination it would have been obvious to use a single cable to directly connect the handle of the treatment device to the generator. Ex. 1083 ¶ 88; *see also AliveCor*, 130 F.4th at 1015 (rejecting argument that “conflicts with the reality that the skilled artisan is not an automaton, so we must ‘take account of the inferences and creative steps that a person of ordinary skill in the art would employ’”) (quoting *KSR*, 550 U.S. at 418).

For these reasons, Petitioner has shown by a preponderance of the evidence that claim 9 would have been obvious over the asserted combination of Edwards-535 and Stern.

iv. Claims 10, 12, 13, and 16

Claim 10 depends from claim 9 and further recites that the generator “is configured to run at a power of between 5 and 75 watts.” Ex. 1001, 53:6–8. Claims 12, 13, and 16 each depend from claim 1 and further recite limitations relating to the electrodes, subsystems, and sensors of the device. *See id.* at 53:11–17, 54:10–12.

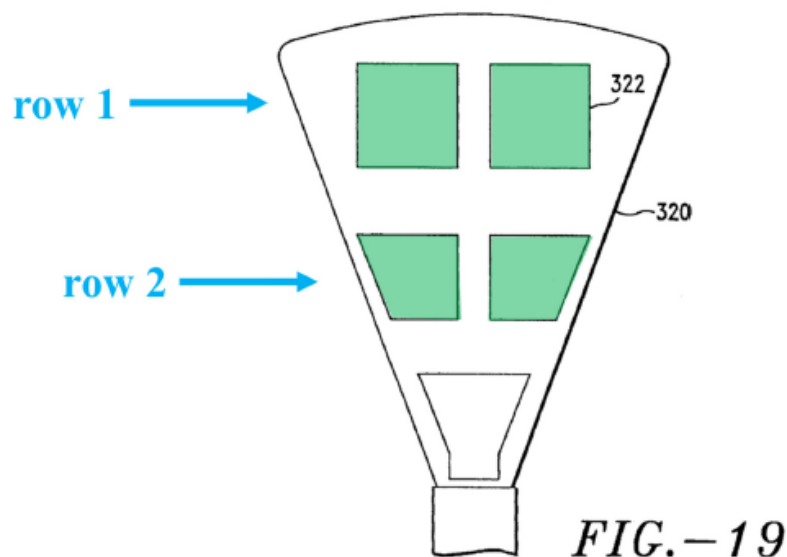
Petitioner provides argument supported by evidence explaining how the combination of Edwards-535 and Stern teach these additional limitations. *See* Pet. 59–69. Patent Owner does not dispute Petitioner’s showing for claims 10, 12, 13, and 16 separately from the arguments already addressed above for the base claims.

We adopt Petitioner’s undisputed analysis of the additional limitations of claims 10, 12, 13, and 16, and credit its supporting evidence. *See* Pet. 59–69; Ex. 1002 ¶¶ 191–211, 218–224. Petitioner has shown by a preponderance of the evidence that these claims would have been obvious over the asserted combination of Edwards-535 and Stern.

v. *Claim 15*

Claim 15 depends from claim 1 and additionally recites “wherein the multiple pairs of bipolar radiofrequency electrodes comprise two rows of electrodes.” Ex. 1001, 54:7–9.

Petitioner contends that Stern discloses arrays of electrodes having two rows of electrodes. Pet. 66 (citing Ex. 1033, Figs. 4a, 19). Petitioner illustrates its position with the annotated version of Stern’s Figure 19 below. *Id.*



Petitioner’s annotations to Figure 19 show electrodes 322 (highlighted in green) and arranged in rows (annotated in blue) on the surface of bladder 320. According to Petitioner, such an arrangement would have been obvious to incorporate in Edwards-535 for the same reasons it would have been

obvious to incorporate Stern’s multiple bipolar pairs and RF output channels. *Id.* at 67 (referring to showing for elements 1[d]-[e]). Petitioner further contends there are “only a finite number of ways to configure an array of bipolar electrodes” as recited in claim 1 and “a POSITA would have considered more ordered arrangements of electrodes, such as two or more rows of active and return electrodes, respectively, or alternating active and return electrodes.” *Id.* (citing Ex. 1002 ¶¶ 216–217).

Patent Owner separately disputes Petitioner’s showing for claim 15, arguing that Petitioner’s reliance on the reasoning for combining Stern’s teachings in elements 1[d] and 1[e] is insufficient because there it “propose[d] combining Edwards-535 and Stern’s Figure 15 schematic” not Figure 19. Resp. 36–37; *see also* Sur-reply 22 (same). Patent Owner also disputes “Petitioner’s assertion that ‘there are only a finite number of ways to configure an array of bipolar electrodes,’” urging instead that “[t]her are a significant (if not infinite) number of ways.” *Id.* at 37 (quoting Pet. 67). According to Patent Owner, Petitioner has failed “to explain why, out of the multitude of possible electrode arrangements, a POSITA would have specifically picked out Stern’s Figure 19 electrode arrangement for use in Edwards-535’s device.” *Id.*

Petitioner counters that the Petition’s reasoning for combining Stern’s teachings regarding element 1[d], e.g., that doing so “would allow for location control and ‘even heating,’” is equally applicable to Stern’s Figure 19. Reply 29–30. Petitioner also notes that Patent Owner’s arguments ignore the additional motivations Petitioner provides for combining Stern’s two-row arrangements. *Id.* at 30.

We agree with Petitioner. Stern's figures repeatedly depict arrangements of electrodes comprising two rows. *See* Ex. 1033, Figures 4a, 15, 19. Stern further teaches that implementing those electrodes as bipolar pairs (i.e., "bipolar operation") allows for better control and more even heating of tissue. *See, e.g., id.* at 13:27–39. We agree with Petitioner that this provides sufficient reasoning for combining Stern's teachings and circuitry for bipolar operation, including the arrangement of electrodes in two rows, with Edwards-535. Ex. 1002 ¶¶ 107–122; Ex. 1083 ¶ 91.

Patent Owner's argument that Petitioner's showing is insufficient because the showing for elements 1[d] and 1[e] proposes combining the teaching in Stern's Figure 15, rather than Figure 19, is unavailing. *See* Resp. 36–37. First, Figure 15 itself depicts electrodes 220, 222, 224 and 226 arranged in two rows. Ex. 1033, Fig. 15. Second, Stern's teachings regarding the better control that bipolar operation provides is not limited to a particular figure or embodiment. We consider Stern for all it teaches to one of ordinary skill, rather than parsing its disclosure to ignore these teachings as Patent Owner's arguments invite us to do. *See AliveCor*, 130 F.4th at 1015.

The additional rationale Petitioner provides for implementing a two-row arrangement is also persuasive. *See* Pet. 67. In particular, we credit Dr. Martin's testimony that "[a] person of ordinary skill would have considered ordered arrangements of electrodes (such as two or more rows of active and return electrodes, respectively, or alternating active and return electrodes) to be appropriate arrangements." Ex. 1002 ¶ 216; *see also* Ex. 1083 ¶ 92 ("[A] person of ordinary skill in the art would have considered ordered arrangements of electrodes and would have had finite choices regarding the arrangement of electrodes in rows and columns."). Indeed,

Stern’s Figure 15 discloses this type of simple, ordered arrangement for a bipolar embodiment with four electrodes. The testimony Patent Owner cites from its cross-examination of Dr. Martin does not impeach this opinion. *See* Resp. 37 (citing Ex. 2003, 207:22–208:20, 209:3–6). And we do not find Dr. Bikson’s competing opinion (Ex. 2001 ¶ 102) credible in view of the disclosure in Stern and the breadth of claim 15.¹⁹

For these reasons, Petitioner has shown by a preponderance of the evidence that claim 15 would have been obvious over the asserted combination of Edwards-535 and Stern.

vi. Claim 17

Claim 17 depends from claim 1 and additionally recites “wherein the multiple pairs of bipolar radiofrequency electrodes are connected to one another and to the multiple radiofrequency output channels in a multiplexed configuration.” Ex. 1001, 54:13–16.

Petitioner provides argument supported by evidence explaining how the combination of Edwards-535 and Stern teaches these additional limitations. *See* Pet. 69–71.

Patent Owner separately disputes Petitioner’s showing for claim 17, arguing that Petitioner has not shown that Stern’s bipolar electrode pairs “are connected to one another.” Resp. 38; *see also* Sur-reply 23 (arguing “it is not

¹⁹ Patent Owner’s suggestion that claim 15 is limited to a particular arrangement out of “substantial (if not infinite) number” of possibilities is inaccurate. Resp. 37. Claim 15 merely recites that the bipolar pairs “comprise two rows of electrodes.” Ex. 1001, 54:7–9. It does not limit the number of electrodes in those rows, would encompass arrangements with more than two rows, and does not exclude embodiments with additional electrodes beyond those in the recited two rows.

enough “that two electrodes can be paired”” because claim 17 requires that “the **multiple pairs** of bipolar radiofrequency electrodes **are connected to one another**”).

We find Petitioner’s showing sufficient to meet its burden. Claim 17 recites that the pairs are “connected to one another . . . *in a multiplexed configuration*.” Ex. 1001, 54:13–16 (emphasis added). The ’318 patent describes that multiplexed configuration as follows: “an electrode array arranged in a multiplexed configuration allowing pairing of any of the positive electrodes to any of the negative electrodes to form a complete circuit.” Ex. 1001, 10:47–50, 49:18–21 (referring to Fig. 40), 49:47–51 (similar for Figs. 42A-B); Ex. 1002 ¶ 227. As Petitioner points out, the showing in the Petition demonstrates that Stern “teaches the same kind of multiplexing contemplated by the ’318 patent in which **any** two electrodes can be paired” and that one of ordinary skill in the art would have been motivated to combine that teaching with Edwards-535. Reply 31 (citing Pet. 70–71 (citing Ex. 1033, 12:19–24, 41–45; Ex. 1002 ¶¶ 225–232)). We credit that showing because it is supported by the disclosure in Stern. *See, e.g.*, Ex. 1033, 12:55–13:2 (describing operation of switches to form pairs between different electrodes in Fig. 15).

Patent Owner’s suggestion that, notwithstanding its multiplexed configuration, the pairs in Stern are not connected to each other conflicts with the disclosure in the ’318 patent. For example, Figure 40 of the ’318 patent is reproduced below.

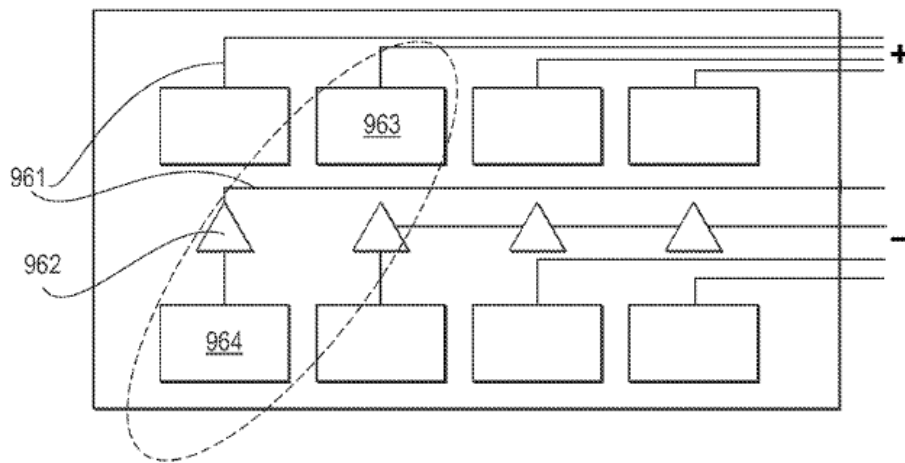


FIG. 40

As shown above, the individual positive electrodes (top row) and negative electrodes (bottom row) are not depicted as connected to each other. Yet, the '318 patent teaches they are connected in a multiplexed configuration because pairs *can be* formed between any of them, e.g., the pairing shown by the dashed oval in Figure 40 connecting positive electrode 963 and negative electrode 964. Ex. 1001, 49:18–24. Stern teaches the same type of connection, *i.e.*, the bipolar pairs in Stern's Figure 15 are "connected to each other . . . in a multiplexed configuration," as recited in claim 17, because various switches can be operated to form pairs between any of electrodes 220, 222, 224, and 226. Ex. 1083 ¶¶ 96–97.

For these reasons, Petitioner has shown by a preponderance of the evidence that claim 17 would have been obvious over the asserted combination of Edwards-535 and Stern.

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

Ground II challenges claim 6. Pet. 72–74. Claim 6 depends from claim 4 and additionally recites that the "multiple segments comprise a shape-memory alloy material configured to expand to a desired size and shape." Ex. 1001, 52:51–53.

Petitioner relies on the same combination of Edwards-535 and Stern for base claims 1 and 4, and adds Patel for its disclosure of flexible electrodes made of nitinol that are wrapped around a balloon and “allow folding or furling” of that balloon during insertion. Pet. 72–74 (quoting Ex. 1034 ¶ 90; *see also* Ex. 1002 ¶ 237 (testifying and citing evidence that “nitinol, a nickel titanium alloy, is a commonly used shape memory alloy”).

Petitioner contends one of ordinary skill “would have been motivated to implement the electrodes on Edwards-[]535’s expandable member 132 as modified by Stern using nitinol as taught by Patel.” Pet. 73. According to Petitioner, “[t]here are a finite number of conductive materials to make electrodes from . . . for use inside the body” and nitinol would have been an obvious choice “because it is flexible while still being highly conductive” and “would therefore have been particularly desirable in ablation devices, as it is used in many devices.” *Id.* at 73 (citing Ex. 1002 ¶¶ 238–239). Moreover, Petitioner asserts that one of ordinary skill would have understood that “nitinol would be especially advantageous in devices like Edwards-[]535’s that are collapsed for insertion into the body, expanded to deliver treatment, and re-collapsed for removal.” *Id.* at 73–74 (citing Ex. 1002 ¶¶ 239–240).

Separately from its arguments for claim 1, Patent Owner argues that “Petitioner[’s] proposed combination at most shows that the electrodes disposed on the surface of Edwards-535’s expandable member 132 comprise a shape-memory alloy material—not that the ‘multiple segments’ of Edwards-535’s expandable member 132 comprise a shape-memory allow material, as claimed.” Resp. 39–40. Patent Owner further contends that Petitioner has “failed to show that Patel’s electrodes are ‘configured to

expand to a desired size and shape,’ as claimed.” *Id.* at 40. According to Patent Owner, “folding and furling,” as taught in Patel, “are the opposite of expanding.” *Id.* at 40–41.

Petitioner counters that claim 6 does not require the recited “segments” to be different than the “electrodes” and that the ’318 patent “makes clear that the ‘segments’ can include electrodes.” Reply 20–21. Petitioner further contends that Patel’s electrodes “necessarily expand as they fold or furl for insertion into the body and ***unfold*** after insertion.” *Id.* at 21 (citing Ex. 1083 ¶ 67). According to Petitioner, this means they are configured to “expand to a desired size and shape,” as claimed. *Id.*

We find Petitioner’s showing sufficient to meet its burden. We agree with Patent Owner that the fact that the claims recite different terms, i.e., “segments” and “electrodes,” suggests the two are different. *See* Sur-reply 24. However, that does not mean that the electrodes cannot be part of the segments themselves. Patent Owner relies on the fact that claim 5 recites an embodiment wherein at least one pair of electrodes is “‘coupled’ with the ‘multiple segments’” to suggest otherwise. *Id.* (quoting Ex. 1001, 52:48–50 (claim 5)). But as Petitioner points out, claim 6 does not depend from claim 5 and presumably is not limited to the embodiment recited therein. Reply 20. Thus, we agree that the segments recited in claims 4 and 6 may comprise the electrodes themselves.²⁰

²⁰ Notably, claim 6 recites that the segments “*comprise* a shape-memory alloy material.” Ex. 1001, 52:51–53 (emphasis added). It does not exclude other materials from those segments and thus would encompass segments comprising both electrodes made from a shape-memory alloy material (e.g., nitinol) and other parts made of other types of materials.

Petitioner's showing for claim 4 identifies segments in Stern and Edwards-535's treatment elements that include multiple segments comprising, *inter alia*, electrodes. *See* Pet. 49–50. Petitioner also shows that Edwards-535's treatment element is collapsed for insertion and expanded during treatment. *Id.* at 30–31. As Dr. Martin credibly explains, the need to accommodate such expansion and contraction would have made nitinol an obvious choice for the electrodes in Edwards-535's segments. Ex. 1002 ¶ 239. This is especially true given that Patel teaches the use of nitinol to make electrodes covering a balloon that is folded for insertion and then expanded upon insertion. *See* Ex. 1034 ¶ 90 (referring to Patel's Figs. 5–6).

Patent Owner's argument that Patel's teaching regarding folding or furling is inapposite because that is the opposite of expanding to a desired size and shape is unavailing. First, Patel teaches that its balloon expands. Ex. 1034 ¶ 90. Thus, one of ordinary skill would understand that the electrodes covering that balloon, which Patel teaches are configured to allow the balloon to fold for insertion, are also configured to facilitate its expansion to a desired shape and size after insertion. *Id.*; Ex. 1083 ¶ 67 (“whenever a balloon is folded or furled during insertion, it necessarily expands from its folded to unfolded state during deployment”). Second, we credit Dr. Martin's testimony that nitinol was a well-known and commonly used “shape memory alloy.” Ex. 1002 ¶ 237 (citing Ex. 1061, 1493–96). This means it will return to its memorized shape after deformation. Ex. 1061, 1493. Accordingly, a skilled artisan would have understood and reasonably expected that segments comprising nitinol could be configured to expand to a desired size and shape.

For these reasons, Petitioner has shown by a preponderance of the evidence that claim 6 would have been obvious over the asserted combination of Edwards-535, Stern, and Patel.

G. Ground III: Obviousness over Edwards-535, Stern, and Edwards-886

Ground III challenges claims 9 and 10. Pet. 74–76. In addition to its showing for these claims in Ground I, Petitioner relies on teachings in a second Edwards reference, Edwards-886. *Id.* at 74. More specifically, Petitioner relies on Edwards-886’s teaching of a RF generator and controller that provides “four independent radio frequency channels” operating eight electrodes in “a bipolar mode.” Pet. 74 (quoting Ex. 1016, 36:66–37:10). Petitioner also relies on Edwards-886’s teaching that “[e]ach channel is capable of supplying up to 15 watts of radio frequency energy with a sinusoidal waveform at 460 kHz.” *Id.* Petitioner articulates reasoning, supported by evidence, explaining why one of ordinary skill would have been motivated to “ablate using Edwards-[]886’s parameters and would have had a reasonable expectation of success” in combining them with the other cited references. *Id.* at 75–76.

Patent Owner does not dispute Petitioner’s showing in Ground III separately from its arguments for claims 1 and 9 in Ground I. *See* Resp. 41.

As explained above, Petitioner’s showing in Ground I is sufficient for claims 9 and 10, and Patent Owner’s arguments to the contrary are unavailing. *Supra* § III.E. 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 and Stern. *See* Pet. 74–76; Ex. 1002 ¶¶ 244–251. For these reasons, Petitioner has shown by a preponderance of the evidence that claims 9 and 10 would have

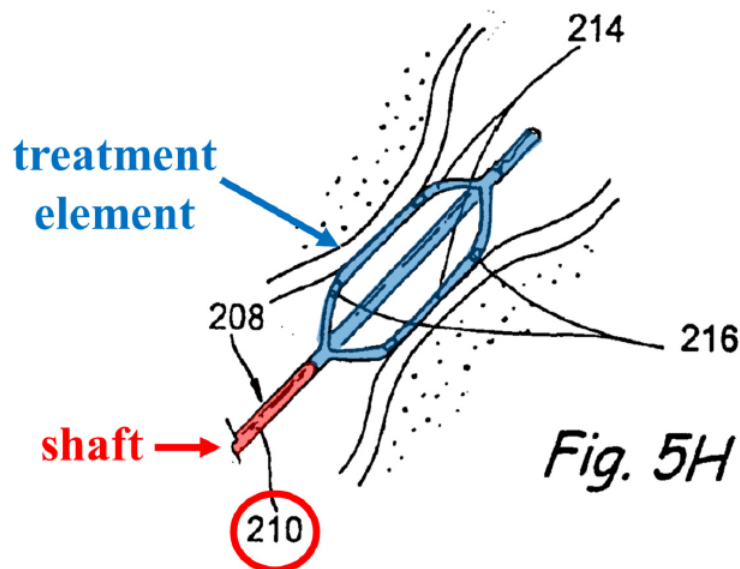
been obvious over the asserted combination of Edwards-535, Stern, and Edwards-886.

H. Ground IV: Obviousness over Makower and Stern

Petitioner contends claims 1, 4–6, 12, 13, and 15–17 would have been obvious over Makower and Stern. *See* Pet. 76–95. Patent Owner disputes Petitioner’s contentions, raising the same global arguments regarding Stern’s teachings and elements 1[d]–[e] that it did in Ground I. Resp. 42–43. Patent Owner also raises separate arguments regarding the additional limitations recited in claims 6 and 17. *Id.* at 43–46. As before, we begin with claim 1.

i. Claim 1

Petitioner’s contentions are similar to those in Ground I, but substitute the teachings in Makower for Edwards-535. *See* Pet. 77–89 (relying on the electrosurgical device in Figure 5H of Makower with further teachings/modifications from Stern for elements 1[d] and 1[e]). Petitioner offers several annotated versions of Makower’s Figure 5H, including the one reproduced below, to illustrate its position. *Id.* at 81.



Petitioner's annotations above identify shaft 210 (highlighted in red) and treatment element (highlighted in blue) in device 208. According to Petitioner, Makower teaches that electrodes 216 disposed on strut members 214 of the treatment element may be bipolar, but "leaves specific implementation of pairing and wiring electrodes up to the discretion and skill of a POSITA." *Id.* at 82, 84.

Similar to its contentions for Ground I, Petitioner argues that one of ordinary skill in the art would turn to Stern for its teachings regarding the multiple bipolar pairs and output channels in elements 1[d] and 1[e]. Pet. 82–88. Petitioner articulates reasoning, supported by evidence, explaining why one of ordinary skill in the art would have been motivated to combine these teachings with a reasonable expectation of success. *Id.*

Patent Owner does not dispute Petitioner's allegations for claim elements 1[a]-[c] and [f], nor does Patent Owner challenge Petitioner's reasoning for combining Makower with Stern. *See* Resp. 42. Instead, Patent Owner observes that Petitioner's Ground IV analysis of elements 1[d] and 1[e] relies on the same disclosure in Stern and analysis for those elements as in Ground I. *Id.* For this reason, Patent Owner asserts the combination of Makower and Stern fails to disclose elements 1[d] and 1[e] "[f]or the same reasons discussed above in Ground I." *Id.*

We find that one of ordinary skill in the art would have been motivated to combine Makower and Stern, and would have had a reasonable expectation of success in doing so, for the reasons set forth in the Petition. We also find that the articulated combination of Makower and Stern teaches all of the limitations of claim 1. We adopt Petitioner's undisputed analysis of claim elements 1[a]-[c] and [f] and reasoning for combining the references,

and credit its supporting evidence. *See* Pet. 77–81, 89–90; Ex. 1002 ¶¶ 254–269, 303–306. Regarding elements 1[d] and 1[e], we credit Petitioner’s showing (*see* Pet. 82–88; Ex. 1002 ¶¶ 253, 270–302) and find Patent Owner’s arguments to the contrary unavailing for the same reasons discussed above for Ground I. *See supra* §§ III.E.i.1–2. For these reasons, Petitioner has shown by a preponderance of the evidence that claim 1 would have been obvious over the asserted combination of Makower and Stern.

ii. Claims 4, 5, 12, 13, 15, and 16

Petitioner provides argument supported by evidence explaining how the combination of Makower and Stern teaches the additional limitations recited in claims 4, 5, 12, 13, 15, and 16. *See* Pet. 90–94. Patent Owner does not dispute Petitioner’s showing for these claims separately from the arguments already addressed above for the base claims. *See* Resp. 42–43.

We adopt Petitioner’s undisputed analysis of the additional limitations of claims 4, 5, 12, 13, 15, and 16, and credit its supporting evidence. *See* Pet. 90–94; Ex. 1002 ¶¶ 307–315, 320–329. Accordingly, Petitioner has shown by a preponderance of the evidence that these claims would have been obvious over the asserted combination of Makower and Stern.

iii. Claim 6

For claim 6, Petitioner maps the strut members 214 in Makower’s Figure 5H to the “multiple segments” recited in claim 4. Pet. 90. According to Petitioner, Makower teaches these strut members “may be collapsible and expandable” and teaches the use of shape memory alloys such as nitinol “to predictably deflect various sections of the catheter.” *Id.* at 92 (quoting Ex. 1021 ¶¶ 187, 194). “Because the strut members 214 deflect when expanded,” Petitioner contends one of ordinary skill “would have understood that

Makower suggests making strut members 214 of a shape memory alloy to facilitate collapse and expansion” as recited in claim 6. *Id.*

Patent Owner separately disputes Petitioner’s showing for claim 6, urging that Makower does not teach or suggest that strut members 214 are made of nitinol. Resp. 43. According to Patent Owner, “[w]hile Makower teaches that ‘nitinol’ can be used to ‘predictably deflect various sections of the catheter,’ the “strut members 214 are different than Makower’s catheter 210.” *Id.* at 44. Patent Owner further asserts that “Makower does not teach that its strut members 214 deflect the catheter” and, as shown in Figure 5H, “Makower’s catheter 210 is ***straight*** (not deflected) when the strut members 214 are expanded.” *Id.* at 45. For these reasons, Patent Owner argues that Petitioner’s assertion that the strut members 214 deflect when expanded “is irrelevant to Makower’s teaching that nitinol can be used to deflect various sections of the ***catheter***.” *Id.*

Petitioner replies, reiterating its position from the Petition. Reply 22. Petitioner further explains that Patent Owner’s argument “ignores Makower’s disclosure that ‘any catheters ***or elongate flexible devices*** of the invention may include design elements that impact performance features” and this would include using shape memory alloys. *Id.* (quoting Ex. 1021 ¶ 194).

We find Petitioner’s showing sufficient to meet its burden. Petitioner contends Makower reasonably “suggests making strut members 214 of a shape memory alloy to facilitate collapse and expansion.”²¹ Pet. 92. That

²¹ Patent Owner attempts to narrowly frame the Petition as limited to an argument that the strut members 214 *are* made of nitinol. *See* Resp. 41. Petitioner’s actual contention is broader.

contention is supported by Makower's teachings: (1) that strut members 214 in Figure 5H may be designed to collapse and expand during operation (Ex. 1021 ¶ 187); and (2) "any catheters or elongate flexible devices of this invention may include design elements that impact performance features" such as the "use of elements to predicably deflect various sections of the catheter (e.g., tension straps or wires, shape memory alloys such as nitinol, etc.)" (*Id.* ¶ 194).

Patent Owner's argument that the teachings regarding nitinol in Makower's paragraph 194 are limited to just the catheter is unavailing for several reasons. First, the text of that paragraph makes clear that it applies to "any catheters *or elongate flexible devices*," and the latter would encompass the strut members in Figure 5H, particularly for those embodiments where the strut members are designed to collapse and expand and thus be understood to be flexible. Ex. 1021 ¶ 194 (emphasis added).

Second, while it is true that the example describing the use of nitinol in paragraph 194 refers to predictably deflecting "the catheter," that is just one of the non-limiting examples Makower provides of a "design element." Ex. 1021 ¶ 194. There is nothing in the record that suggests that one of ordinary skill in the art would consider the use of nitinol to be limited to the catheter. To the contrary, Makower elsewhere teaches that "any of the catheters, scopes, elongate working devices or other devices disclosed [therein] may be rendered steerable or volitionally bendable" through the use of "shape memory materials (e.g., nickel titanium alloys, shape memory polymers, etc.) to induce the device to undergo the desired bending or curvature after it has been inserted into the body." *Id.* ¶ 195; *see also* Ex. 1083 ¶ 71 (identifying other structures that Makower teaches may be made

of nitinol). Thus, it would be error to interpret these teachings as applying only to the catheter without also considering what they suggest for other structures (e.g., strut members 214) in view of the reference as a whole. *See AliveCor*, 130 F.4th at 1015.

Third, we agree with Petitioner, and credit Dr. Martin’s supporting testimony, that the example describing the use of nitinol to predictably deflect sections of the catheter would reasonably suggest to one of ordinary skill in the art that the same design element could be applied to other structures that are also intended to predictably deflect, e.g., the collapsible and expandable strut members of Figure 5H. Ex. 1002 ¶¶ 318–319; Ex. 1083 ¶¶ 69–71. We credit Dr. Martin’s testimony over Dr. Bikson’s (Ex. 2001 ¶¶ 120–123) because the latter focuses only on the distinction between the catheter and the strut members without addressing what Makower read as a whole would have suggested regarding the use of shape memory alloys such as nitinol.

For these reasons, Petitioner has shown by a preponderance of the evidence that claim 6 would have been obvious over the asserted combination of Makower and Stern.

iv. Claim 17

Relying on its analysis for Ground I, Petitioner asserts that Stern teaches the additional limitations recited in claim 17. Pet. 95. Petitioner further contends that one of ordinary skill “would have found it obvious to incorporate Stern’s teaching of the paired electrode control architecture, i.e., the electrical connections between the electrodes, channels, and sensors into a device like Makower’s, and would have reasonably expected success in doing so.” *Id.*

Patent Owner separately disputes Petitioner’s showing for claim 17, asserting that Petitioner’s showing is deficient for “[f]or the same reasons” it argued for claim 17 in Ground I. Resp. 46.

We find Petitioner’s showing to be sufficient for the same reasons explained above. That is, Stern teaches that its multiple bipolar pairs “are connected to one another . . . in a multiplexed configuration” as recited in claim 17. *Supra* § III.E.vi. 1. We adopt Petitioner’s undisputed analysis and reasoning for combining Stern’s teachings with Makower, and credit its supporting evidence. *See* Pet. 84–88; Ex. 1002 ¶¶ 254–269, 303–306, 331. For these reasons, Petitioner has shown by a preponderance of the evidence that claim 17 would have been obvious over the asserted combination of Makower and Stern.

v. *Ground V: Obviousness over Makower, Stern and Edwards-886*

Ground V challenges claims 9 and 10. *See* Pet. 95–97. Having determined these claims are unpatentable as obvious over the references in Grounds I and III, we need not reach Petitioner’s argument that those same claims are also unpatentable as obvious over the references in Ground V.

IV. CONCLUSION²²

Petitioner has shown, by a preponderance of the evidence, that claims 1, 4–6, 9, 10, 12, 13, and 15–17 of the ’318 patent are unpatentable.

²² Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this 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

Claims	35 U.S.C. §	Reference(s)/ Basis	Claims Shown Unpatentable	Claims Not shown Unpatentable
1, 4, 5, 9, 10, 12, 13, 15–17	103	Edwards-535, Stern	1, 4, 5, 9, 10, 12, 13, 15–17	
6	103	Edwards-535, Stern, Patel	6	
9, 10	103	Edwards-535, Stern, Edwards-886	9, 10	
1, 4–6, 12, 13, 15–17	103	Makower, Stern	1, 4–6, 12, 13, 15–17	
9, 10 ²³	103	Makower, Stern, Edwards-886		
Overall Outcome			1, 4–6, 9, 10, 12, 13, 15–17	

V. ORDER

Accordingly, it is:

ORDERED that Petitioner has shown that claims 1, 4–6, 9, 10, 12, 13, and 15–17 of U.S. Patent 11,033,318 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.

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).

²³ As explained above, we do not reach this ground. *See supra* § III.I.

IPR2024-00278
Patent 11,033,318 B2

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