

**UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD**

NEURENT MEDICAL INC. & NEURENT MEDICAL LTD.,
Petitioners,

v.

AERIN MEDICAL, INC.,
Patent Owner.

Case IPR2024-00278
U.S. Patent No. 11,033,318

PATENT OWNER'S RESPONSE

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TABLE OF EXHIBITS

Exhibit No.	Description
2001	Declaration of Dr. Marom Bikson
2002	Curriculum Vitae of Dr. Marom Bikson
2003	Transcript of the September 24, 2024, Deposition of Dr. Gregory T. Martin
2004	Transcript of the September 25, 2024, Deposition of Dr. Gregory T. Martin
2005	Exhibit 6 to the Deposition of Dr. Gregory T. Martin
2006	Exhibit 7 to the Deposition of Dr. Gregory T. Martin
2007	Exhibit 8 to the Deposition of Dr. Gregory T. Martin

I. INTRODUCTION

Petitioners Neurent Medical Inc. and Neurent Medical Ltd. (collectively, “Petitioners”) petitioned for *Inter Partes* Review of Claims 1, 4-6, 9-10, 12-13, and 15-17 (collectively, the “Challenged Claims”) of U.S. Patent No. 11,033,318 (“the ‘318 patent”), which is owned by Patent Owner Aerin Medical, Inc. (“Patent Owner”). Petitioners have failed to meet their burden of proving that the Challenged Claims are invalid as obvious because Petitioners have failed to show that their asserted obviousness combinations disclose, teach, or suggest every limitation of the Challenged Claims.

For instance, every Challenged Claim requires, among other things, (i) “multiple pairs of bipolar radiofrequency electrodes” and (ii) “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.”

Petitioners rely upon only a single reference (Stern) as allegedly teaching these claim limitations for all grounds. However, Stern fails to do so. As shown herein, Stern teaches a device comprising only a *single pair* of bipolar radiofrequency electrodes and a *single* radiofrequency output channel. Petitioners’ expert’s admissions on cross examination further confirm that Stern’s teachings are

limited to a device comprising a *single pair* of bipolar radiofrequency electrodes and a *single* radiofrequency output channel. Accordingly, Petitioners' proposed combinations of Edwards-535 and Stern (Ground I) and Makower and Stern (Ground IV) fail to render obvious Challenged Claim 1, the sole independent claim of the '318 patent.

For at least these reasons, Petitioners have failed to carry their burden of showing that any Challenged Claim is unpatentable, and Patent Owner respectfully requests that the Board confirm the patentability of the Challenged Claims.

II. BACKGROUND

A. The '318 Patent And The Challenged Claims.

The '318 patent, entitled "Methods and Devices to Treat Nasal Airways," issued on June 15, 2021, from U.S. Patent Application No. 16/412,982 (filed on May 15, 2019). (Ex-1001 at [21], [22], [45], [54].) The '318 patent claims priority to a provisional patent application (Application No. 61/496,930) which was filed on June 14, 2011. (*Id.* at [60].)¹

The '318 patent and the Challenged Claims are generally directed toward a medical device "for delivering energy to a nasal airway to improve nasal airflow." (*Id.* at claim 1; *see also id.* at 1:31-37.) Figure 3, reproduced below, provides an exemplary illustration of the medical device:

¹ Petitioners have applied a priority date of June 14, 2011. (Petition at 5.)

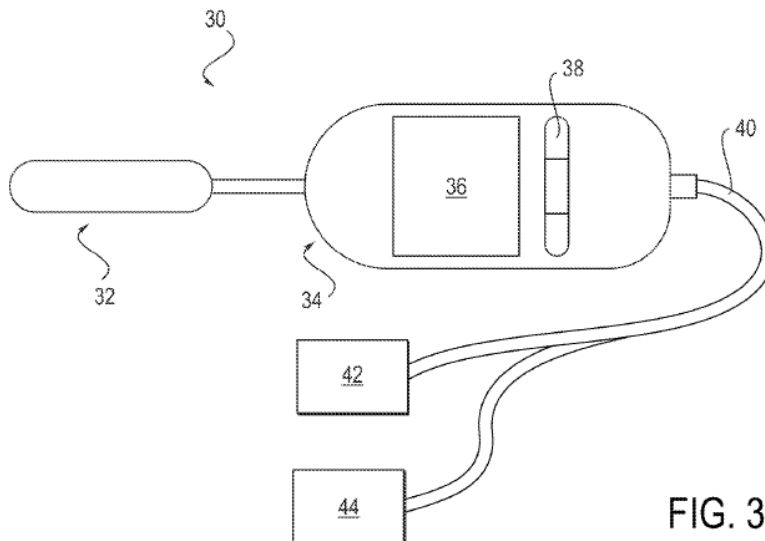


FIG. 3

(*Id.* at FIG. 3.)

As shown above, the medical device 30 of the '318 patent includes a handle 34, a shaft, and a treatment element 32 that can be inserted into a nostril. (*Id.* at FIG. 3, 4:34-44, 8:66-67, 15:64-16:5.) The '318 patent discloses that the treatment element is configured to expand from a collapsed configuration for insertion into the nasal passageway to an expanded configuration for contacting a surface of the nasal passageway. (*Id.* at FIGS. 4A-4C, 9:1-6, 18:3-17, 18:21-32.)

The device of the '318 patent also comprises an array of multiple pairs of bipolar electrodes disposed on a treatment surface of the treatment element. (*Id.* at FIG. 8F, FIG. 8G, FIG. 18, 5:1-13, 24:21-49.) The '318 patent describes a pair of bipolar electrodes as comprising electrodes of opposite polarities. (*Id.* at 23:7-11, 49:7-9, 49:18-24, 49:35-37, 49:46-54.) Two exemplary arrays of bipolar electrode pairs described in the '318 patent are shown below:

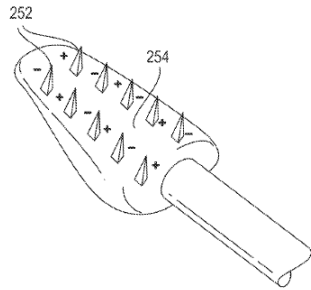


FIG. 8F

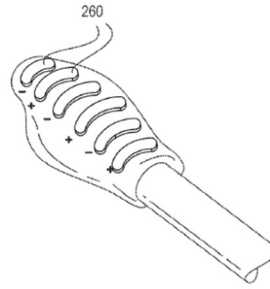


FIG. 8G

(*Id.* at FIGS. 8F-G.)

Further, the '318 patent discloses that a radiofrequency ("RF") output channel may be assigned to each electrode pair. (*Id.* at 49:5-14, 49:18-26, 49:33-38, 49:61-66; *see also id.* at 24:45-49, 48:63-65.) The '318 patent discloses that the RF output channels can be separately controllable, allowing different regions of the treatment element to be activated separately and avoiding the situation where, due to varying degrees of contact with the target tissue, treatment energy is "diverted to pairs of electrodes that experience a relatively lower magnitude of impedance due to a relatively lower degree of tissue contact." (*Id.* at 24:45-64, 48:42-49:4; *see also id.* at 49:65-50:2, 50:9-15.)

The device of the '318 patent may also have sensors on the treatment element for measuring a temperature or impedance near the tissue to be treated and adjusting the level of energy to be delivered with a control system. (*Id.* at 5:18-30, 8:20-25, 16:27-40.) According to the '318 patent, "[r]emodeling or changing the structure of the nasal valve can improve nasal airflow in people with inadequate nasal airflow resulting from causes other than nasal valve dysfunction, such as

deviated septum, enlarged turbinates, mucosal swelling, and/or mucous production.” (*Id.* at 11:29-34.)

Independent Challenged Claim 1, the only independent claim of the '318 patent, is reproduced below:

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

1[a] a handle;

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

1[c] 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;

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

1[e] 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

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

(*Id.* at claim 1.)

B. The Level Of Ordinary Skill In The Art.

Petitioners' definition of a POSITA is: "(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." (Petition at 20-21.)² Patent Owner agrees with part (1) of Petitioners' definition. However, Patent Owner disputes part (2) of Petitioners' definition because the "and/or" encompasses within the definition of a POSITA persons who *only* have experience with the clinical use or testing of medical devices. A POSITA in the field of the '318 patent would have had more experience than just clinically using medical devices or simply conducting tests with medical devices. (Ex-2001-Bikson, ¶ 37.)

As noted previously, the claims of the '318 patent require a "device for delivering energy to a nasal airway to improve nasal airflow" having:

"an array of multiple pairs of bipolar radiofrequency electrodes disposed along the treatment surface of the treatment element;

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

² Emphasis added herein unless otherwise noted.

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 at claim 1.)

A person who merely tests or uses such devices is not qualified to speak to the technical requirements associated with the features of the claimed device. (Ex-2001-Bikson, ¶ 39.) For instance, an M.D. who has merely used or tested medical devices is unqualified to speak to the technical issues associated with implementing an “an array of multiple pairs of bipolar radiofrequency electrodes disposed along the treatment surface of the treatment element” in combination with “multiple radiofrequency output channels” and “multiple sensors on the tissue treatment surface.” (*Id.*) Having never designed or developed such a medical device, an M.D. has no background on how to implement “an array of multiple pairs of bipolar radiofrequency electrodes disposed along the treatment surface of the treatment element” in combination with “multiple radiofrequency output channels” and “multiple sensors on the tissue treatment surface.” (*Id.*)

Patent Owner proposes the following modifications to Petitioners’ proposed definition for POSITA: (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~~ and ~~development, and/or testing~~ of medical devices, including medical devices that deliver energy to tissue.” This

definition eliminates the “and/or” from Petitioners’ definition while requiring design and development experience irrespective of any clinical use or testing experience.

Regardless of how a POSITA is defined, the prior art fails to render obvious any of the Challenged Claims.

C. Petitioner’s Asserted Prior Art References.

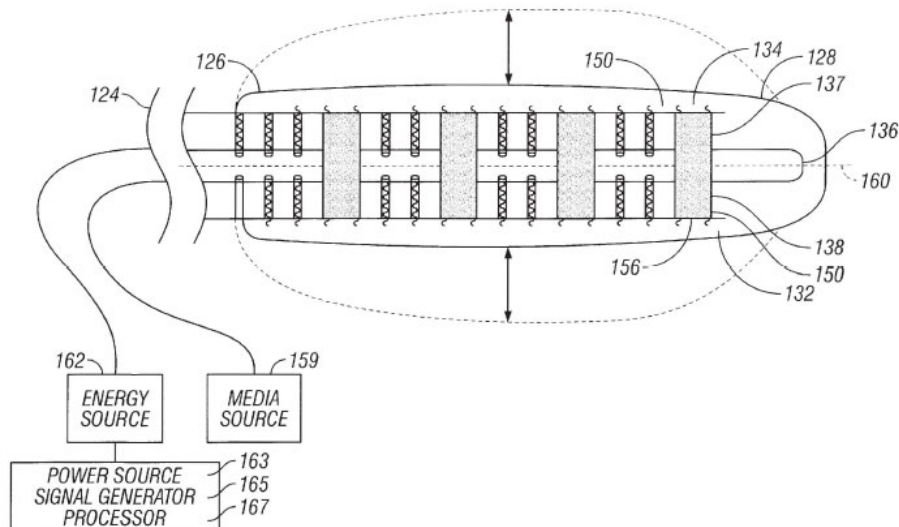
1. U.S. Patent No. 6,517,535 (“Edwards-535”).

Edwards-535 is generally directed towards “a method and apparatus for treating airway obstructions,” such as those caused by “[s]leep apnea syndrome,” by “reducing the volume of the turbinates in order [to] reduce nasal airway obstructions.” (Ex-1010-Edwards-535 at 1:22-26, 1:30-33.) Edwards-535’s “invention provides a method for reducing the size of a nasal concha without the formation of a wound on the surface of the nasal concha.” (*Id.* at 4:63-66, 6:26-27.) To that end, Edwards-535 teaches cooling the surface of the nasal concha being ablated such that ablation can be performed to remove an internal section of a nasal concha without damaging the surface of the nasal concha. (*Id.* at 4:60-63, 6:12-16.) Thus, Edwards-535’s method can be performed bloodlessly and eliminates the need for surgical cutting. (*Id.* at 4:58-60, 4:55-57.)

Edwards-535 further teaches an apparatus 124 comprising an expandable member 132 that conforms to the surface of the nasal concha and an energy

delivery device 134 for delivering ablative energy. (*Id.* at 7:28-39.) To expand the expandable member 132, a medium 138 is delivered through apertures 137 from a lumen 136 coupled with a catheter body 126. (*Id.* at 7:40-47.) The expandable member 132 is preferably formed of a material that is permeable to the medium used to expand the member, thus allowing the medium to pass through the expandable member 132 to the surface of the nasal concha being ablated. (*Id.* at 7:66-8:5.) In one embodiment, the expandable member 132 is an expandable porous membrane. (*Id.* at 8:5-7.)

Edwards-535 teaches that the energy delivery device 134 may include one or more ring electrodes 156 disposed on the surface of the expandable member 132. (*Id.* at 8:18-20.) The plurality of ring electrodes 156 are disposed in parallel with their axes aligned with a long axis 160 of the catheter body 126. (*Id.* at 8:21-23.)



(*Id.* at FIG. 6.)

2. U.S. Patent No. 5,562,720 (“Stern”).

Stern is generally directed to a device for the “selective destruction of the endometrium,” the thin layer of tissue lining the uterus. (Ex-1033-Stern at 1:17-22, 6:56-59.) Stern explains that its “goal” is “destruction of the endometrial cells.” (*Id.* at 6:60-62.) Stern describes destroying the endometrium using ablative radiofrequency energy while maintaining the average temperature of the myometrium, the tissue beneath the endometrium surrounding the uterine cavity. (*Id.* at 2:11-18, 6:66-7:6, 7:29-33.)

As illustrated below, Stern’s apparatus includes a “conventional” RF generator 158, a separate power source controller 156, a portable computer 164, an application device 124 with an electrode balloon 150, and an electrode belt 154 that provides a reference electrode for connection to the power source controller 156. (*Id.* at FIG. 12, 10:36-55.) An example schematic representation of the power source controller 156 is shown in FIG. 5. (*Id.* at 8:66-9:2.)

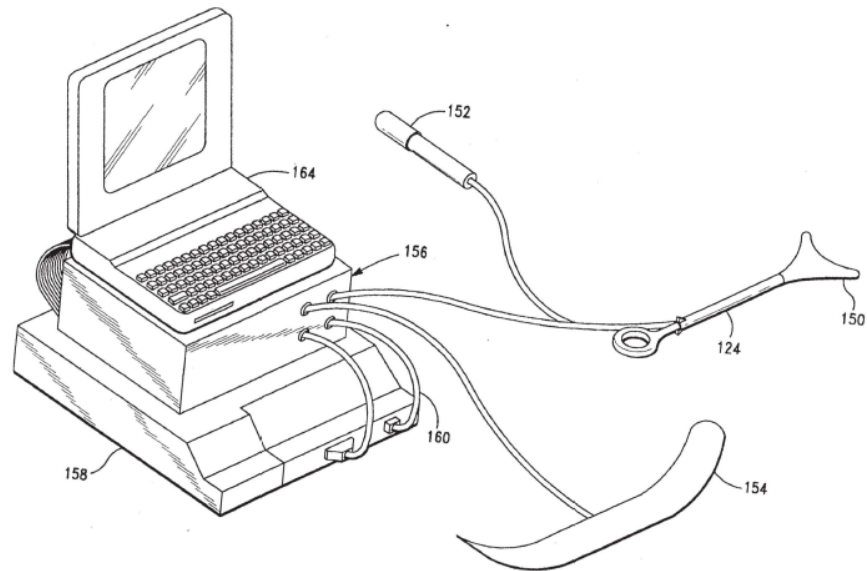


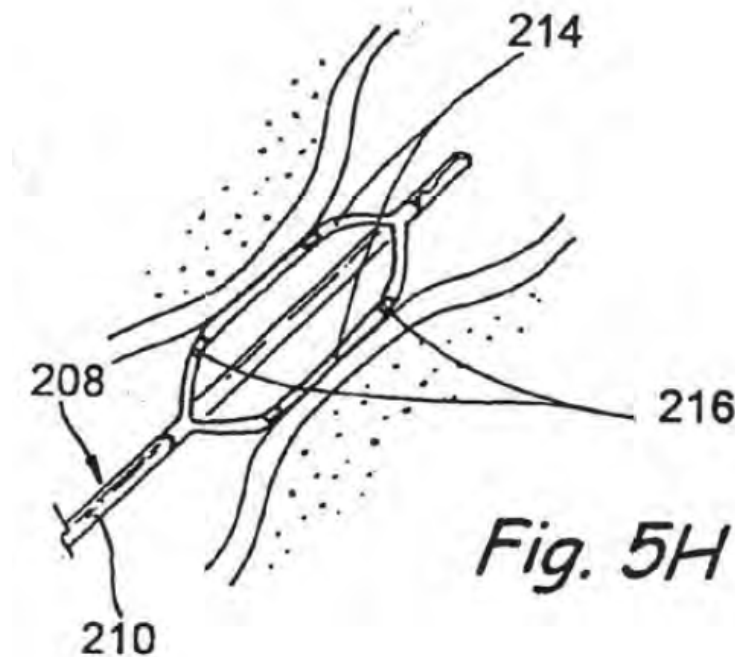
FIG. - 12

(*Id.* at FIG. 12.)

3. U.S. Patent App. Pub. No. 2005/0240147 (“Makower”).

Makower is generally directed to “minimally invasive, catheter based devices, systems and methods for treating sinusitis and other ear, nose & throat disorders.” (Ex-1021-Makower at [0001], [0042].) Makower discloses numerous device embodiments. (*Id.* at [0161]; *see also id.* at [0049]-[0128].)

Makower’s Figure 5H embodiment (reproduced below) comprises an electrosurgical device 208 comprising a catheter 210 with arched strut members 214 attached thereto. (*Id.* at [0187].) Electrodes 216 are located on the strut members 214. (*Id.*) In operation, the device 208 is advanced into the nostril and then current is applied to the electrodes 216 causing tissue adjacent to the struts 214 to be cauterized or heated. (*Id.*)



(*Id.* at FIG. 5H.)

III. LEGAL STANDARDS

In an *Inter Partes* Review, the Petitioner bears the burden of persuasion to prove unpatentability by a preponderance of the evidence. See *Dynamic Drinkware, LLC v. Natl. Graphics, Inc.*, 800 F.3d 1375, 1379 (Fed. Cir. 2015). The Board “will not consider arguments and information that are not presented and developed in the Petition...” See *DIRECTV, LLC v. Qurio Holdings, Inc.*, Case IPR2015-02007, Paper No. 6 at 14 (PTAB April 4, 2016); see also *Valeo North America, Inc. v. Magna Electronics, Inc.*, IPR2014-01206, Paper No. 13 at 17 (PTAB Dec. 23, 2014) (“we will not consider an argument not made in the petition.”). “[T]he Board is not bound by any findings made in its Institution Decision.” *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1376 (Fed. Cir.

2016). “The Board is free to change its view of the merits after further development of the record.” *Id.*

To establish obviousness, the Petitioner must show “how the prior art references, either alone or in combination, teach or suggest the claimed invention.” *See In re Bell*, 991 F.2d 781, 783 (Fed. Cir. 1993); *see also Metalcraft of Mayville, Inc. v. The Toro Co.*, 848 F.3d 1358, 1367 (Fed. Cir. 2017). The Petitioner must also demonstrate “that a skilled artisan would have had reason to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success from doing so.” *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Pat. Litig.*, 676 F.3d 1063, 1068-69 (Fed. Cir. 2012); *see also Orexo AB v. Actavis Elizabeth LLC*, 903 F.3d 1265, 1271 (Fed. Cir. 2018) (holding that a finding of obviousness requires a showing “that a person of ordinary skill would have selected and combined and modified the subject matter of the references in the manner of the claimed invention, with a reasonable expectation of success.”).

IV. CLAIM CONSTRUCTION

For the purposes of this IPR, Patent Owner believes that no claim constructions are required to resolve the issues raised herein. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999). Patent Owner reserves the right to propose claim construction(s) in the underlying litigation.

V. PETITIONERS HAVE FAILED TO SHOW THAT THE CHALLENGED CLAIMS OF THE '318 PATENT ARE UNPATENTABLE AS OBVIOUS.

A. Ground 1: Petitioners Have Failed To Show That Edwards-535 In View Of Stern Renders Challenged Claims 1, 4-5, 9-10, 12-13, And 15-17 Obvious.

1. Petitioners Have Failed To Show That Edwards-535 In View Of Stern Renders Challenged Claim 1 Obvious.

As discussed in detail below, Challenged Claim 1 requires, among other things, (i) “multiple pairs of bipolar radiofrequency electrodes” and (ii) “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.”

Petitioners rely only upon Stern as allegedly teaching these claim limitations. However, Petitioners have failed to show that Stern teaches these limitations because Stern teaches a device comprising only a *single pair* of bipolar radiofrequency electrodes and a *single* radiofrequency output channel. Accordingly, Petitioners have failed to show that Edwards-535 in view of Stern renders Challenged Claim 1 obvious.

(a) Petitioners Have Failed To Show That Edwards-535 In View Of Stern Teaches “multiple pairs of bipolar radiofrequency electrodes.”

Petitioners have failed to show that Edwards-535 in view of Stern teaches “multiple pairs of bipolar radiofrequency electrodes” because Stern teaches a device configured to have at most a *single pair* of bipolar radiofrequency electrodes. (Ex-2001-Bikson, ¶ 59.)

Challenged Claim 1 of the '318 patent recites, *inter alia*, a device comprising “multiple pairs of bipolar radiofrequency electrodes.” (Ex-1001 at claim 1.)³ Petitioners assert that Stern’s Figure 15 teaches “multiple pairs of bipolar radiofrequency electrodes” and that a POSITA would have been motivated to implement Stern’s Figure 15 in Edwards-535’s device. (Petition at 34-41; Ex-1002-Martin, ¶¶ 101, 124; Ex-2003 at 228:20-229:3.) Petitioners also assert that “Stern’s teachings would have been applied to Edwards-‘535 in the same way they are used in Stern.” (Petition at 40; Ex-1002-Martin, ¶¶ 116, 143.)

³ Challenged Claims 5, 13, 15, and 17 also recite “multiple pairs of bipolar radiofrequency electrodes.” (Ex-1001 at claims 5, 13, 15, 17.)

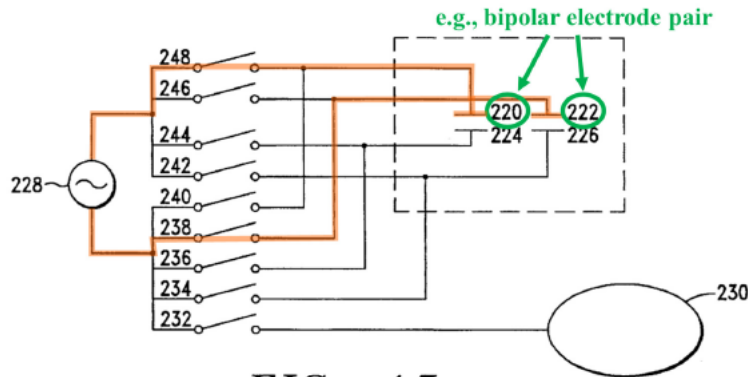


FIG. - 15

(Petition at 36 (annotations in original).)

As shown above, Stern's Figure 15 discloses a voltage source 228, four electrodes 220, 222, 224, and 226, a grounding pad 230, and nine switches 232, 234, 236, 238, 240, 242, 244, 246, and 248. (Ex-1033-Stern at FIG. 15; *id.* at 12:46-13:2; Ex-2001-Bikson, ¶ 61.) Petitioners agree that Stern's Figure 15 teaches "an array of separate electrodes." (Ex-1033-Stern at 2:26-29, 2:39-40, 2:59-60; Ex-2001-Bikson, ¶ 62; Petition at 34, 61.) Depending on which switches are closed, any of electrodes 220, 222, 224, and 226 can be a monopolar electrode. (Ex-2003 at 261:2-16, 264:18-265:1; Ex-2001-Bikson, ¶ 62.) Similarly, depending on which switches are closed, any of electrodes 220, 222, 224, and 226 can be a positive electrode or a negative electrode. (Ex-2003 at 265:2-13, 265:14-19; Ex-2001-Bikson, ¶ 62.)

Both parties' experts agree that a "pair" of bipolar radiofrequency electrodes comprises two electrodes located near each other that have opposite polarities. (Ex-1002-Martin, ¶ 38; Ex-2003 at 254:20-22, 256:4-6, 263:19-264:16; Ex-2001-

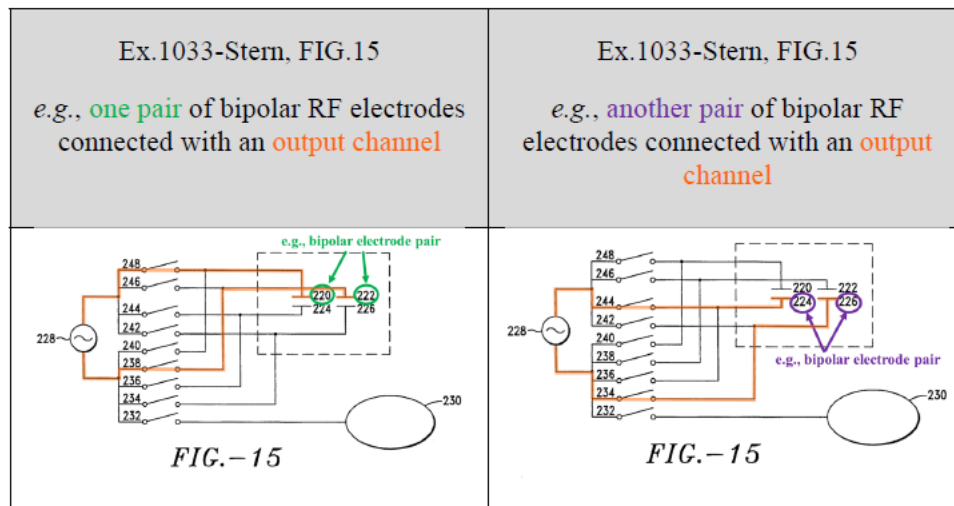
Bikson, ¶ 60; Ex-1001 at 23:7-11, 49:7-9, 49:18-24, 49:35-37, 49:46-54.) None of the electrodes in Stern's Figure 15 have opposite polarities when all the switches are open, and thus there are no bipolar electrode "pairs" when all the switches are open. (Ex-2001-Bikson, ¶ 63; Ex-1033-Stern at FIG. 15, 12:37-13:2.) As Petitioners' expert, Dr. Martin, conceded on cross examination, a bipolar electrode "pair" is formed in Stern's Figure 15 ***only when certain switches are closed***. (Ex-2003 at 254:11-255:3, 265:20-266:18; Ex-1002-Martin, ¶ 101 ("Stern teaches examples in which electrodes can be paired by closing particular subsets of switches."); Ex-1033-Stern at FIG. 15, 12:37-13:2; Ex-2001-Bikson, ¶ 63.)

As noted above, Challenged Claim 1 recites a device comprising "***multiple pairs*** of bipolar radiofrequency electrodes." (Ex-1001 at claim 1 (emphasis added).) However, Stern teaches a device configured to have at most a ***single pair*** of electrodes. (Ex-1033-Stern at 12:65-13:2; Ex-2001-Bikson, ¶ 59.)

For limitation 1[d], Petitioners and Dr. Martin identify one example where Stern's Figure 15 device is configured to have a ***single pair*** of electrodes (*i.e.*, electrodes 220 and 220) by closing switches 248 and 238. (Petition at 35-36 (citing Ex-1033-Stern at 12:65-13:2); Ex-1002-Martin, ¶ 101 (same).) For limitation 1[e], Petitioners and Dr. Martin identify a second example where Stern's Figure 15 device is again configured to have a ***single pair*** of electrodes (*i.e.*,

electrodes 224 and 226) by instead closing switches 244 and 234. (Petition at 42; Ex-1002-Martin, ¶ 124.)

At most, Petitioners' examples demonstrate that Stern's Figure 15 device can be configured in different ways to have a *single pair* of electrodes. (Ex-2001-Bikson, ¶ 65.) This deficiency is illustrated in Petitioners' own annotations to Stern's Figure 15, reproduced below, which show two different ways to configure Stern's device to have a *single pair* of electrodes:



(Petition at 43 (annotations in original); Ex-2001-Bikson, ¶ 65.)

As shown above, Stern teaches “one pair” of electrodes (*i.e.*, electrodes 220 and 222) in a first configuration (*i.e.*, switches 248 and 238 closed), and “another pair” of electrodes (*i.e.*, electrodes 224 and 226) in a second configuration (*i.e.*, switches 244 and 234 closed). (Petition at 43 (citing Ex-1033-Stern at FIG. 15); Ex-2001-Bikson, ¶ 65.) Either configuration has only a single “pair” of electrodes. (*Id.*)

Consistent with Dr. Martin's admission that a bipolar electrode "pair" is formed only when certain switches are closed, three or more of Figure 15's switches must be closed at the same time to form "***multiple pairs*** of bipolar radiofrequency electrodes," as claimed. (Ex-2001-Bikson, ¶ 64.) However, Petitioners and Dr. Martin do not identify where Stern teaches closing three or more switches at the same time. (Petition at 34-36, 42-43; Ex-1002-Martin, ¶¶ 98-101, 124.) Again, in both of Petitioners' examples reproduced above only two switches are closed to form a single pair of electrodes. (*Id.*)

To be sure, Stern teaches closing ***one*** of switches 242, 244, 246, and 248 and ***one*** of switches 234, 236, 238, and 240 to form a ***single pair*** of bipolar electrodes. (Ex-1033-Stern at 12:55-13:2; Ex-2001-Bikson, ¶ 64.) Stern's disclosure of having only a single pair of electrodes at a time is consistent with Stern's express teaching that the RF electrodes are "***independently and sequentially energized***." (Petition at 54, 61-62; Ex-1002-Martin, ¶¶ 177, 206; Ex-1033-Stern at 2:31-33, 2:49-53, 10:48-52, 17:54-55; Ex-2001-Bikson, ¶ 64.) To energize Stern's electrodes "independently and sequentially," at most two of Stern's switches would be closed at a time. (Ex-2001-Bikson, ¶ 64.) Thus, Stern itself confirms that its Figure 15 device is configured to have at most a single pair of bipolar electrodes. (*Id.*)

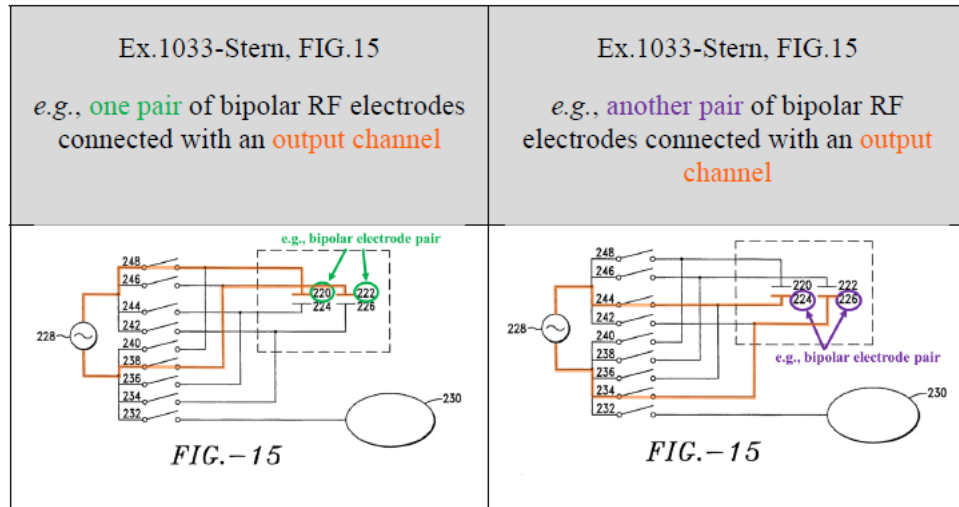
Accordingly, Petitioners have failed to show that Edwards-535 in view of Stern teaches a device comprising “multiple pairs of bipolar radiofrequency electrodes.”

(b) Petitioners Have Failed To Show That Edwards-535 In View Of Stern Teaches “multiple radiofrequency output channels.”

Petitioners have failed to show that Edwards-535 in view of Stern teaches “multiple radiofrequency output channels” because Stern teaches at most a *single* radiofrequency output channel. (Ex-2001-Bikson, ¶ 68.)

Challenged Claim 1 of the '318 patent recites, *inter alia*, a device comprising “multiple radiofrequency output channels.” (Ex-1001 at claim 1.)⁴ Petitioners assert that Stern's Figure 15 teaches “multiple radiofrequency output channels” and that a POSITA would have been motivated to implement Stern's Figure 15 in Edwards-535's device. (Petition at 41-44; Ex-1002-Martin, ¶¶ 124-148; Ex-2003 at 228:20-229:3.) Petitioners also assert that “Stern's teachings would have been applied to Edwards-535 in the same way they are used in Stern.” (Petition at 40; Ex-1002-Martin, ¶¶ 116, 143.)

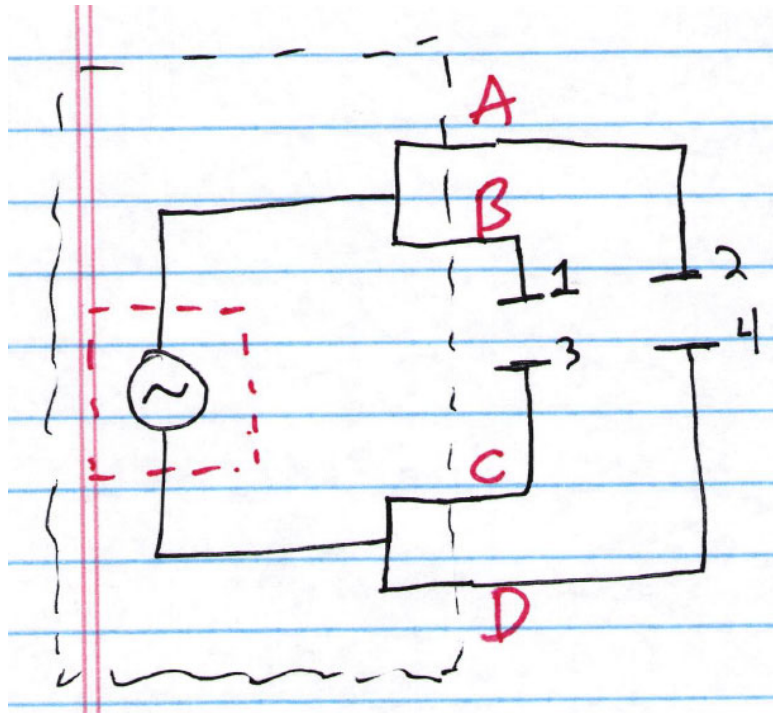
⁴ Challenged Claims 9, 13, 16, and 17 also recite “multiple radiofrequency output channels.” (Ex-1001 at claims 9, 13, 16, 17.)



(Petition at 43 (annotations in original).)

Both parties' experts agree that the term "radiofrequency output channel" means "an output from a radiofrequency generator." (Ex-2004 at 318:12-19; *id.* at 318:20-319:9, 319:17-320:2, 327:3-4, 329:21-22; Ex-2001-Bikson, ¶ 69; *see also* Petition at 41 (referring to a "radiofrequency output channel" as an "energy output").)

Further, Dr. Martin confirmed at his deposition that the number of radiofrequency output channels depends on the number of outputs from the radiofrequency generator. (Ex-2001-Bikson, ¶ 70.) The demonstrative circuit reproduced below was introduced as an exhibit at Dr. Martin's deposition:



(Ex-2007.)

Dr. Martin testified that if the red dashed box in the circuit above designates the radiofrequency generator, then the circuit above has only one radiofrequency output channel. (Ex-2004 at 430:2-431:5 (discussing Ex-2007); *id.* at 432:16-433:4 (testifying that “the RF generator as defined by the red dotted line constitutes a one-channel RF generator.”); Ex-2001-Bikson, ¶ 70.)⁵

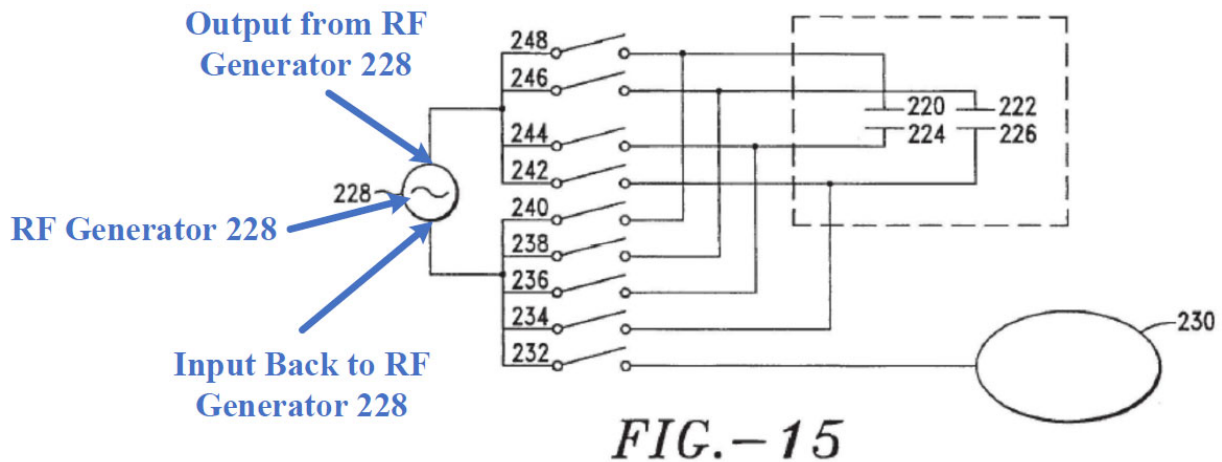
⁵ Both parties' experts agree that a radiofrequency generator with a single radiofrequency output channel will have two connection points—one for the output from the generator (*i.e.*, the active signal) and one for the input back to the generator (*i.e.*, the return signal). (Ex-2001-Bikson, ¶ 71; Petition at 43 n. 8; Ex-1002-Martin, ¶ 128 n. 4; Ex-2003 at 156:6-157:13; Ex-2004 at 323:16-324:1,

In Stern's Figure 15, voltage source 228 represents the radiofrequency generator. (Ex-2001-Bikson, ¶¶ 73-78; Ex-2003 at 226:16-227:2 (Dr. Martin testifying that, in Stern's Figure 15, voltage source 228 is "a placeholder for the rest of the RF generator.")) Indeed, Petitioners and Dr. Martin use the terms "voltage source" and "RF generator" synonymously/interchangeably. (Petition at 96; Ex-1002-Martin, ¶¶ 105, 132, 336.) Petitioners and Dr. Martin also clearly rely upon Stern's voltage source 228 as the radiofrequency generator, as the orange lines in their annotated diagrams originate at the voltage source 228. (Petition at 43; Ex-1002-Martin, ¶ 124.)⁶

Like the radiofrequency generator in the red dashed box of the circuit drawing reproduced above (Ex-2007), Stern's radiofrequency generator 228 has ***only one radiofrequency output channel***. (Ex-2001-Bikson, ¶ 79.) As shown in annotated Figure 15 below, radiofrequency generator 228 has only a single output and a single input. (*Id.*; Ex-1033-Stern at FIG. 15; *id.* at 2:49-53, 3:12-21, 10:53-324:14-325:9; *id.* at 335:10-336:16 (testifying regarding Ex-2005), 343:10-344:21 (testifying regarding Ex-2006).)

⁶ In any case, Dr. Martin confirmed that he did not opine in his declaration that Figure 15's switches are in the radiofrequency generator. (Ex-2004 at 331:15-332:11.) Dr. Martin also agreed that Stern does not expressly teach that Figure 15's switches are in the radiofrequency generator. (*Id.* at 332:12-333:3.)

55, claim 1 (disclosing that the RF generator has “an output [singular]”); Petition at 43 n. 8; Ex-1002-Martin, ¶ 128 n. 4; *id.*, ¶¶ 127, 291 (Dr. Martin opining that Stern’s switches receive “an output [singular] from an RF power source.”).)



(Ex-1033-Stern at FIG. 15 (annotated); Ex-2001-Bikson, ¶ 79.)

Dr. Martin confirmed at his deposition that a radiofrequency generator such as Stern’s radiofrequency generator 228 has only a single radiofrequency output channel. (Ex-2004 at 335:10-336:16 (testifying regarding Ex-2005); *id.* at 343:10-344:21 (testifying regarding Ex-2006); *id.* at 429:22-431:5, 433:1-4 (testifying regarding Ex-2007).)

Accordingly, Stern teaches at most a single radiofrequency output channel, and thus Edwards-535 in view of Stern fails to teach a device comprising “multiple radiofrequency output channels,” as claimed. (Ex-2001-Bikson, ¶ 79.)

Further, as noted above, the ’318 patent teaches that one of the benefits of the claimed multiple radiofrequency output channels is that they are separately

controllable, which prevents the situation where, due to varying degrees of contact with the target tissue, treatment energy is “diverted to pairs of electrodes that experience a relatively lower magnitude of impedance due to a relatively lower degree of tissue contact.” (Ex-1001 at 24:45-64, 48:42-49:4; *see also id.* at 49:65-50:2, 50:9-15; Ex-2001-Bikson, ¶ 80.) However, Dr. Martin confirmed at his deposition that Stern’s Figure 15 does not offer the same “separate control” described in the ’318 patent. (Ex-2001-Bikson, ¶ 80.)

For example, Dr. Martin testified that if switches 248, 246, 236, and 234 were closed at the same time,⁷ then “you would not be able to separately control how much current’s going through the electrode pairs.” (Ex-2004 at 442:11-21; *see also id.* at 434:15-435:15, 439:22-440:6, 442:6-10 (discussing Ex-2007).) Rather, current would be diverted to whichever electrodes experience less impedance, which the ’318 patent states is a problem with *single channel* designs. (Ex-2001-Bikson, ¶ 80; Ex-1001 at 48:50-59.)

Thus, for this additional reason, Edwards-535 in view of Stern fails to teach a device comprising “multiple radiofrequency output channels.” (Ex-2001-Bikson, ¶ 80.)

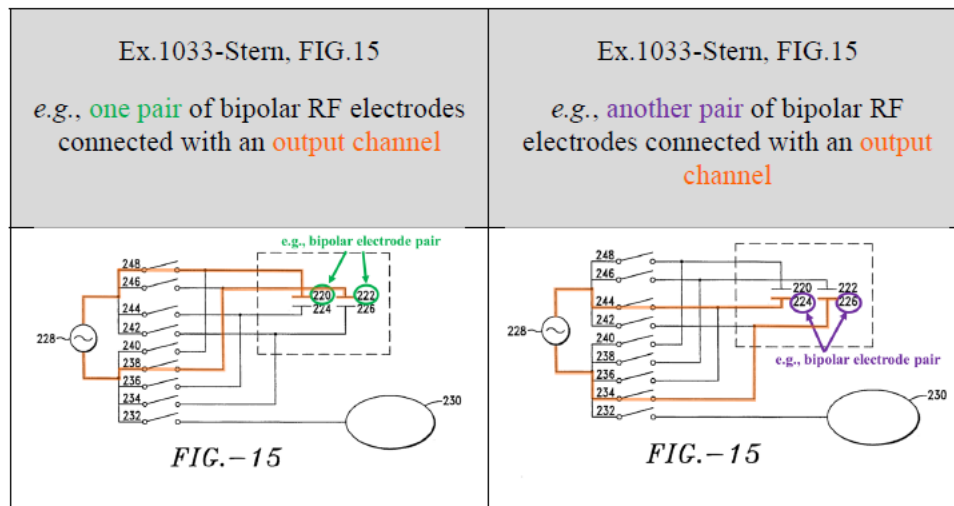
⁷ To be clear, as explained earlier, Stern does not teach closing switches 248, 246, 236, and 234 at the same time. (Ex-2001-Bikson, ¶ 80.)

(c) Petitioners Have Failed To Show That Edwards-535 In View Of Stern Teaches “wherein each pair of the multiple pairs of bipolar radiofrequency electrodes is connected with a respective one of the multiple radiofrequency output channels.”

Regardless of whether Edwards-535 in view of Stern teaches “multiple pairs of bipolar radiofrequency electrodes” and “multiple radiofrequency output channels” (it does not), Petitioners have failed to show that Edwards-535 in view of Stern teaches “wherein each pair of the multiple pairs of bipolar radiofrequency electrodes is connected with a respective one of the multiple radiofrequency output channels,” as recited in Challenged Claim 1. (Ex-1001 at claim 1; Ex-2001-Bikson, ¶ 81.)

Petitioners and Dr. Martin simply repeat the above claim language *verbatim* and then conclude that this limitation is “shown in Figure 15” in Stern. (Petition at 41-42 (citing Ex-1033-Stern at FIG. 15); Ex-1002-Martin, ¶ 124 (same).) Such conclusory, factually unsupported statements are legally insufficient to establish obviousness. *See ActiveVideo Networks, Inc. v. Verizon Communications, Inc.*, 694 F.3d 1312, 1327 (Fed. Cir. 2012); *see also Xerox Corp. v. Bytemark, Inc.*, IPR2022-00624, Paper 9, at 15-16 (PTAB Aug. 24, 2022) (precedential) (holding that the Board may not credit declaration testimony that “merely repeats, verbatim, the conclusory assertion for which it is offered to support”).

Moreover, as noted above, Dr. Martin agreed that the term “radiofrequency output channel” means “an output from a radiofrequency generator.” (Ex-2004 at 318:12-19; *id.* at 318:20-319:9, 319:17-320:2, 327:3-4, 329:21-22; Ex-2001-Bikson, ¶ 69.) However, in Petitioners’ and Dr. Martin’s annotated versions of Stern’s Figure 15, reproduced below, the “one pair” of electrodes and the “another pair” of electrodes are connected by wires to the same output of Stern’s radiofrequency generator 228:



(Petition at 43 (annotations in original); Ex-1002-Martin, ¶ 124 (same); Ex-2001-Bikson, ¶ 82.)

Petitioners and Dr. Martin do not show any alleged electrode pair connected to a different output of Stern’s radiofrequency generator 228—nor could they, as Stern’s radiofrequency generator 228 has only a single output. (*Id.*; Ex-2001-Bikson, ¶ 83.) Thus, Petitioners have failed to show that Edwards-535 in view of Stern teaches “wherein *each pair of the multiple pairs* of bipolar radiofrequency

electrodes *is connected with a respective one of the multiple radiofrequency output channels*,” as claimed. (Ex-2001-Bikson, ¶ 81.)

2. Petitioners Have Failed To Show That Edwards-535 In View Of Stern Renders Dependent Challenged Claims 4-5, 9-10, 12-13, And 15-17 Obvious.

Petitioners have failed to show that Edwards-535 in view of Stern renders dependent Challenged Claims 4-5, 9-10, 12-13, and 15-17 obvious in view of their dependency on Challenged Claim 1. Challenged Claims 4-5, 9-10, 12-13, and 15-17 depend from Challenged Claim 1, and thus incorporate each and every limitation of Challenged Claim 1. *See* 35 U.S.C. § 112(d). Because Petitioners have failed to show that Edwards-535 in view of Stern renders Challenged Claim 1 obvious, Petitioners have likewise failed to show that Edwards-535 in view of Stern renders dependent Challenged Claims 4-5, 9-10, 12-13, and 15-17 obvious.

Additionally, Petitioners have failed to show that Edwards-535 in view of Stern renders dependent Challenged Claims 5, 9, 15, and 17 obvious for the reasons discussed below.

(a) Challenged Claim 5.

Challenged Claim 5 recites, *inter alia*, “wherein at least one pair of the multiple pairs of bipolar radiofrequency electrodes is coupled with each of the multiple segments.” (Ex-1001 at claim 5.) According to the plain language of

Challenged Claim 5, each of the claimed “multiple segments” must have “at least one pair” of electrodes (*i.e.*, more than one electrode) coupled thereto. (*Id.*)

Petitioners assert that Stern teaches a plurality of surface segments 42 (*i.e.*, the alleged “multiple segments”). (Petition at 51-52; Ex-1002-Martin, ¶ 167.) Petitioners also assert that “Stern teaches that the segments include at least one pair of the multiple pairs of bipolar RF electrodes...” (Petition at 52; Ex-1002-Martin, ¶ 170).)

At the outset, Petitioners and Dr. Martin fail to identify *any evidence* that Stern teaches that each of its surface segments 42 includes a pair of electrodes. (Petition at 52 (failing to cite any teachings in Stern for the position that each segment includes a pair of electrodes); Ex-1002-Martin, ¶ 170 (same).) Thus, the Board should find that Challenged Claim 5 is patentable over Edwards-535 in view of Stern for this reason alone. *See ActiveVideo*, 694 F.3d at 1327.

Additionally, Petitioners’ unsupported argument that Stern teaches that each of its surface segments 42 includes a *pair* of electrodes is simply wrong. Stern expressly teaches that each of its surface segments 42 has one electrode and one thermistor—not two electrodes. (Ex-2001-Bikson, ¶ 88; Ex-1033-Stern at 8:49-59; *see also id.* at 11:8-12 (“In the embodiments of FIGS. 6-9, ... one power lead provides the power for an individual electrode as well as its associated thermistor”); *id.* at FIGS. 4a-4b, 5-7, 8a, 8:66-9:6, 11:14-16, 11:21-24, 11:30-32.)

Thus, Stern does not teach “wherein at least one pair of the multiple pairs of bipolar radiofrequency electrodes is coupled with each of the multiple segments,” as Petitioners assert. (*Id.*)

(b) Challenged Claim 9 – Element 9[a].

Challenged Claim 9 recites, *inter alia*, “a radiofrequency generator configured to ... deliver radiofrequency energy separately to each of the multiple radiofrequency output channels.” (Ex-1001 at claim 9.) Petitioners assert that Edwards-535 in combination with Stern “discloses a radiofrequency generator (*e.g.*, signal generator 165 in Edwards-’535 and/or RF generator 158 in Stern).” (Petition at 53; Ex-1002-Martin, ¶ 175.) Petitioners also assert that, “[a]s described in limitation 1[d]-[e], Edwards-’535 in view of Stern teaches the delivery of radiofrequency energy separately to each of the multiple radiofrequency output channels.” (Petition at 54; Ex-1002-Martin, ¶ 177.)

Regardless of whether Edwards-535 in view of Stern teaches “multiple radiofrequency output channels” (it does not), Petitioners’ analysis of Challenged Claim 9 fails to address what is claimed. (Ex-2001-Bikson, ¶ 91.)

Challenged Claim 9 expressly recites that the *radiofrequency generator* is configured to deliver radiofrequency energy separately to each of the multiple radiofrequency output channels. (Ex-1001 at claim 9; Ex-2001-Bikson, ¶ 91.) However, Petitioners and Dr. Martin fail to explain in their Challenged Claim 9

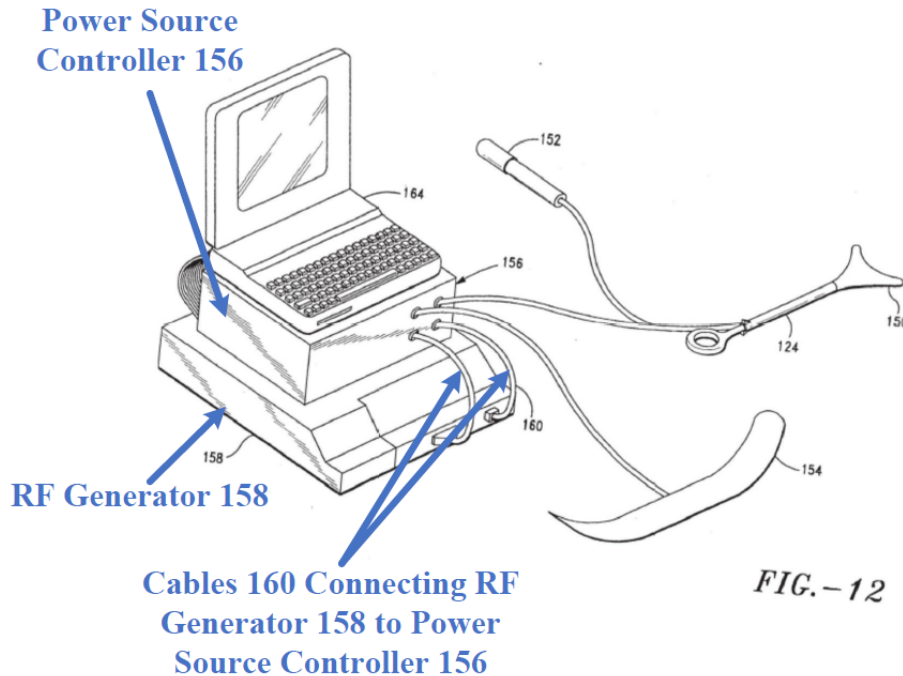
analysis how Edwards-535 in view of Stern purportedly teaches a **radiofrequency generator** configured to deliver radiofrequency energy separately to each of the alleged multiple radiofrequency output channels, as claimed. (Petition at 54; Ex-1002-Martin, ¶ 177; Ex-2001-Bikson, ¶ 91.) Similarly, at no point in their analysis of limitations 1[d] and 1[e] do Petitioners or Dr. Martin assert or demonstrate that Edwards-535 in view of Stern teaches a **radiofrequency generator** configured to deliver radiofrequency energy separately to each of the alleged multiple radiofrequency output channels. (See generally Petition at 32-45; Ex-1002-Martin, ¶¶ 93-148; Ex-2001-Bikson, ¶ 91.) Thus, Petitioners have failed to show that Edwards-535 in view of Stern renders dependent Challenged Claim 9 obvious for this reason alone.

Additionally, Petitioners fail to show that Edwards-535 in view of Stern renders dependent Challenged Claim 9 obvious because Stern fails to teach that its RF generator 158 is configured to “deliver radiofrequency energy separately.” (Ex-2001-Bikson, ¶ 92.)⁸

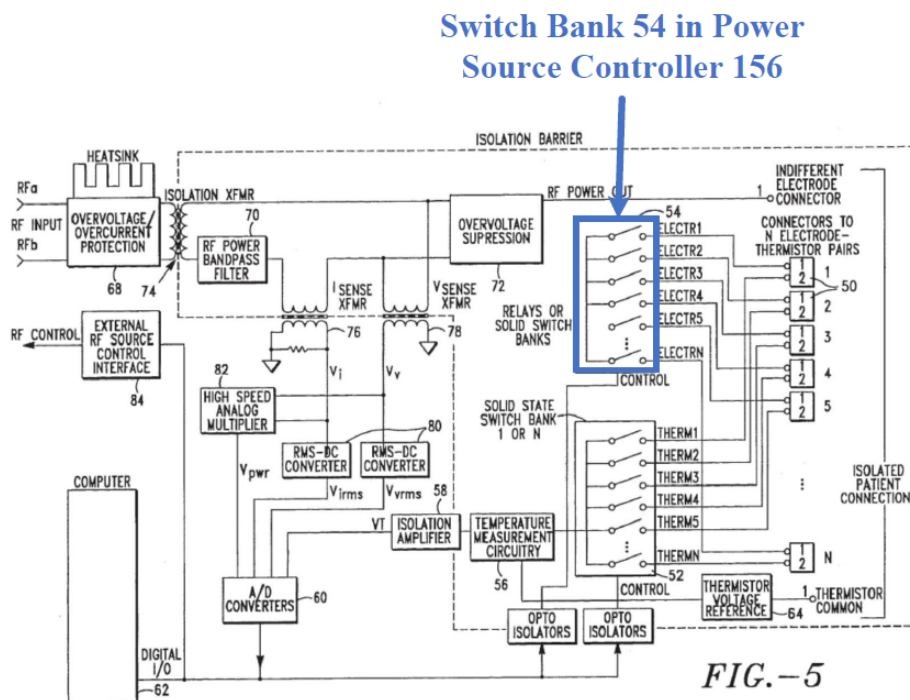
⁸ Edwards-535 discloses a signal generator 165 but provides no details regarding how signal generator 165 is configured other than it can generate pulses, sine waves, and square waves. (Ex-1010-Edwards-535 at 8:54-60; Ex-2001-Bikson, ¶ 96.) Further, Petitioners do not assert that Edwards-535 teaches “multiple radiofrequency output channels,” and thus Edwards-535 indisputably fails to teach

Stern teaches an “RF generator 158” in the form of “a conventional electrosurgical power supply.” (Ex-2001-Bikson, ¶ 92; Ex-1033-Stern at FIG. 12, 10:44, 10:54-55; *id.* at 2:50-51.) The RF generator 158 has a single “output,” which is provided to a separate power source controller 156 via electrosurgical interface cables 160. (Ex-2001-Bikson, ¶ 92; Ex-1033-Stern at FIG. 12, 10:42-46; *id.* at 2:49-53, 3:12-21, 9:14-17, 10:53-55, claim 1; Petition at 87-88.) Switches in the power source controller 156 control which electrodes in the application device 124 receive radiofrequency energy. (Ex-2001-Bikson, ¶ 92; Ex-1033-Stern at 3:12-21, 8:66-67, 11:49-51, 12:21-24, 12:38-61, claim 1, FIG. 5, FIG. 12, FIG. 15.)

the claimed “radiofrequency generator.” (Petition at 41-45; Ex-2001-Bikson, ¶ 96.) Petitioners argue that “Stern’s teachings would have been applied to Edwards-’535 in the same way those teachings are used in Stern itself.” (Petition at 40.)



(Ex-1033-Stern at FIG. 12 (annotated); Ex-2001-Bikson, ¶ 92.)



(Ex-1033-Stern at FIG. 5 (annotated); *see also id.* at 8:66-67 (“FIG. 5 is a schematic representation of the power source controller”); Ex-2001-Bikson, ¶ 92.)

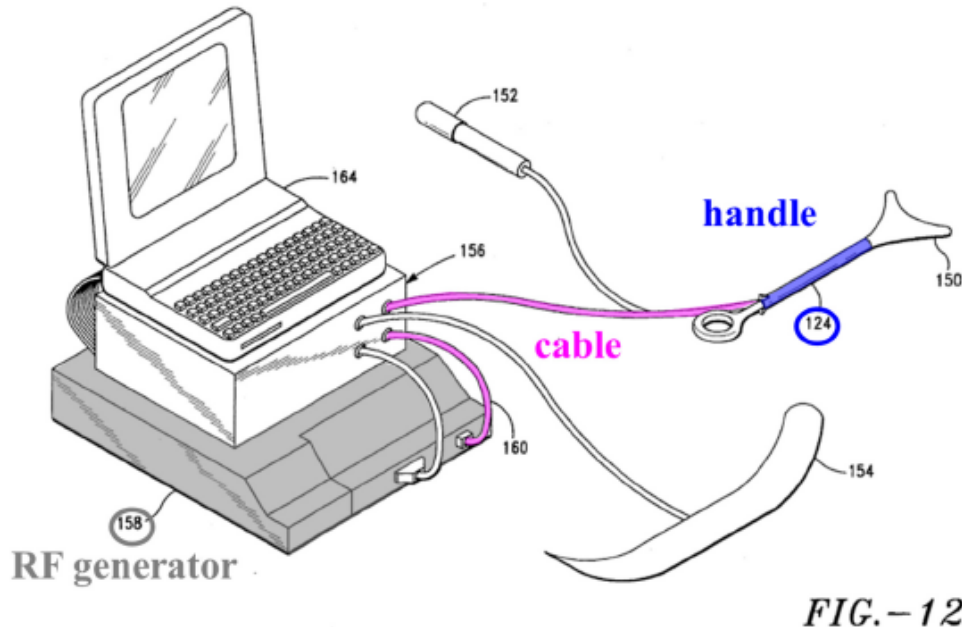
Stern's Figures 5 and 12 are consistent with Stern's Figure 15. (Ex-2001-Bikson, ¶ 95; Ex-1033-Stern at FIGS. 5, 12, 15.) Figure 15 depicts a radiofrequency generator 228 with two wires connected to it. (*Id.*) Figure 12 similarly depicts a radiofrequency generator 158 with two cables 160 connected to it. (*Id.*) Likewise, Figure 5 shows that the power source controller is connected to the radiofrequency generator with two wires. (*Id.*)

Because Stern's RF generator 158 is configured to deliver only a single radiofrequency "output" to the power source controller 156, Stern's RF generator 158 is not configured to "deliver radiofrequency energy separately." (Ex-2001-Bikson, ¶ 93; *see also id.*, ¶ 94.) Thus, for this additional reason, Petitioners fail to show that Edwards-535 in view of Stern teaches "a radiofrequency generator configured to ... deliver radiofrequency energy separately to each of the multiple radiofrequency output channels."

(c) Challenged Claim 9 – Element 9[b].

Challenged Claim 9 also recites, *inter alia*, "a cable coupled to the handle for plugging the handle into the radiofrequency generator." (Ex-1001 at claim 9.) Petitioners assert that Stern's RF generator 158 is the claimed "radiofrequency generator." (Petition at 53; Ex-1002-Martin, ¶ 175.) Petitioners also assert that Stern teaches a cable 160 coupled to the handle of application device 124 for

plugging the handle into RF generator 158. (Petition at 58; Ex-1002-Martin, ¶¶ 187-188.)



(Petition at 58 (annotations in original).)

Petitioners have failed to show that Edwards-535 in view of Stern teaches “a cable coupled to the handle for plugging the handle into the radiofrequency generator” because the cable coupled to Stern’s handle 124 is not plugged into RF generator 158 (*i.e.*, the alleged radiofrequency generator). (Ex-2001-Bikson, ¶ 99.)

As depicted in Petitioners’ annotated diagram above, RF generator 158 is connected to a separate power source controller 156 via electrosurgical interface cables 160. (Ex-2001-Bikson, ¶ 99; Ex-1033-Stern at FIG. 12, 10:36-49.) The handle of application device 124 is plugged into power source controller 156 via a different cable. (*Id.*) Thus, as Petitioners’ annotations above show, 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.*)

Accordingly, Petitioners have failed to show that Edwards-535 in view of Stern teaches “a cable coupled to the handle for plugging the handle into the radiofrequency generator.”

(d) Challenged Claim 15.

Challenged Claim 15 recites, *inter alia*, “wherein the multiple pairs of bipolar radiofrequency electrodes comprise two rows of electrodes.” (Ex-1001 at claim 15.) Petitioners assert that Stern's Figure 19 discloses electrodes 322 arranged in two rows, and that, “as discussed above for limitations 1[d] and 1[e], such an electrode arrangement would have been obvious to incorporate in Edwards-'535.” (Petition at 66-67; Ex-1002-Martin, ¶¶ 214-216.)

Petitioners have failed to show that Edwards-535 in view of Stern renders obvious “wherein the multiple pairs of bipolar radiofrequency electrodes comprise two rows of electrodes” because Petitioners and Dr. Martin do not assert or demonstrate in their limitation 1[d] or 1[e] analyses that it would have been obvious to incorporate Stern's electrode arrangement of Figure 19 in Edwards-535's device. (*See generally* Petition at 32-45; Ex-1002-Martin, ¶¶ 93-148; Ex-2001-Bikson, ¶ 101.)

Rather, in their limitation 1[d] and 1[e] analyses, Petitioners and Dr. Martin propose combining Edwards-535 with Stern's Figure 15 schematic. (*Id.*; *see also* Ex-2003 at 228:20-229:3.) Tellingly, Petitioners and Dr. Martin do not discuss Stern's Figure 19 until their Challenged Claim 15 "analysis." (Petition at 66-67; Ex-1002-Martin, ¶ 214.)

Additionally, Petitioners' assertion that "there are only a finite number of ways to configure an array of bipolar electrodes" is simply wrong. (Petition at 67; Ex-1002-Martin, ¶ 216.) There are a significant (if not infinite) number of ways to configure an array of bipolar electrodes. (Ex-2001-Bikson, ¶ 102.) As Dr. Martin testified, an "array" of bipolar electrodes simply requires some sort of ordering—no particular ordering is required. (Ex-2003 at 207:22-208:20, 209:3-6; Ex-2001-Bikson, ¶ 102.) Petitioners fail 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. (Petition at 67; Ex-1002-Martin, ¶ 216; Ex-2001-Bikson, ¶ 102.) Accordingly, Petitioners have not met their burden of proving obviousness. *See, e.g., Personal Web Techs., LLC v. Apple, Inc.*, 848 F.3d 987, 993-94 (Fed. Cir. 2017) (holding that the patent challenger must demonstrate "a motivation to pick out [the] references and combine them to arrive at the claimed invention.").

(e) Challenged Claim 17.

Challenged Claim 17 recites, *inter alia*, “wherein the multiple pairs of bipolar radiofrequency electrodes are connected to one another.” (Ex-1001 at claim 17.) According to Petitioners, Stern teaches that electrodes 220 and 222 can be connected to one another as a bipolar electrode pair. (Petition at 69-71; Ex-1002-Martin, ¶¶ 227, 229.) However, Challenged Claim 17 expressly recites that “the *multiple pairs* of bipolar radiofrequency electrodes are *connected to one another*.” (Ex-1001 at claim 17 (emphases added).) Petitioners and Dr. Martin make no attempt to show that Edwards-535 in view of Stern teaches what is claimed. (Petition at 69-71; Ex-1002-Martin, ¶¶ 227, 229; Ex-2001-Bikson, ¶ 104.)

B. Ground 2: Petitioners Have Failed To Show That Edwards-535 In View Of Stern And Patel Renders Dependent Challenged Claim 6 Obvious.

Petitioners have failed to show that Edwards-535 in view of Stern and Patel renders dependent Challenged Claim 6 obvious in view of its dependency on Challenged Claim 1. Challenged Claim 6 depends from Challenged Claim 1, and thus incorporates each and every limitation of Challenged Claim 1. *See* 35 U.S.C. § 112(d). Because Petitioners have failed to show that Edwards-535 in view of Stern renders Challenged Claim 1 obvious, Petitioners have likewise failed to show that Edwards-535 in view of Stern and Patel renders Challenged Claim 6 obvious.

Additionally, Petitioners have failed to show that Edwards-535 in view of Stern and Patel renders Challenged Claim 6 obvious because Petitioners have failed to show that the proposed combination teaches the additional limitations of Challenged Claim 6.

Challenged Claim 6 recites: “The device of claim 4, wherein the multiple segments comprise a shape-memory alloy material configured to expand to a desired size and shape.” (Ex-1001 at claim 6.)⁹

Petitioners assert that Patel discloses electrodes made of nitinol, “a known shape memory alloy,” and that Patel’s electrodes “allow folding or furling of the balloon during insertion.” (Petition at 72-73; Ex-1002-Martin, ¶¶ 236-237.) Petitioners propose implementing Patel’s nitinol electrodes on Edwards-535’s expandable member 132. (Petition at 73; Ex-1002-Martin, ¶ 239.)

Importantly, the claims of the ’318 patent are clear that electrodes are *different* than the claimed “multiple segments.” (Ex-1001 at claims 1 and 4-5; *see also id.* at 18:3-20; Ex-2001-Bikson, ¶ 110.) Specifically, the claims recite a device with a “treatment element” comprising “multiple segments that are expandable from [a] first configuration to [a] second configuration.” (Ex-1001 at

⁹ Challenged Claim 4 recites: “The device of claim 1, wherein the treatment element comprises multiple segments that are expandable from the first configuration to the second configuration.” (*Id.* at claim 4.)

claims 1 and 4; Ex-2001-Bikson, ¶ 110.)¹⁰ “Bipolar radiofrequency electrodes,” which are separately claimed, are “disposed along [a] treatment surface of the treatment element.” (Ex-1001 at claim 1; *see also id.* at claim 5 (“at least one pair ... of bipolar radiofrequency electrodes is coupled with each of the multiple segments.”); Ex-2003 at 204:10-12 (Dr. Martin confirming that electrodes are different than the treatment element); Ex-2001-Bikson, ¶ 110.) Thus, Petitioners’ 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 alloy material, as claimed. (Ex-2001-Bikson, ¶ 111.)

Additionally, even if Patel’s electrodes could be considered the claimed “multiple segments” (they cannot), Petitioners have failed to show that Patel’s electrodes are “configured to expand to a desired size and shape,” as claimed. (Ex-1001 at claim 6; Ex-2001-Bikson, ¶ 112.) Petitioners do not assert that Patel’s electrodes are configured to expand to a desired size and shape. (Petition at 72-74; Ex-1002-Martin, ¶¶ 236-237.) At best, Petitioners assert that Patel’s electrodes

¹⁰ Petitioners assert that Edwards-535’s expandable member 132 is the claimed “treatment element” and that a POSITA would have been motivated to “segment” Edwards-535’s expandable member 132. (Petition at 49-51.)

“allow folding or furling of the balloon during insertion.” (*Id.*) But folding and furling are the opposite of expanding. (Ex-2001-Bikson, ¶ 112.) Moreover, whether Patel’s *balloon* can fold, furl, or expand has no bearing on whether Patel’s *electrodes* are configured to expand. (*Id.*)

C. Ground 3: Petitioners Have Failed To Show That Edwards-535 In View Of Stern And Edwards-886 Renders Dependent Challenged Claims 9-10 Obvious.

Petitioners have failed to show that Edwards-535 in view of Stern and Edwards-886 renders dependent Challenged Claims 9-10 obvious in view of their dependency on Challenged Claim 1. Challenged Claims 9-10 depend from Challenged Claim 1, and thus incorporate each and every limitation of Challenged Claim 1. *See* 35 U.S.C. § 112(d). Because Petitioners have failed to show that Edwards-535 in view of Stern renders Challenged Claim 1 obvious, Petitioners have likewise failed to show that Edwards-535 in view of Stern and Edwards-886 renders Challenged Claims 9-10 obvious.

Additionally, Petitioners’ Ground III analysis of Challenged Claim 9 relies on Petitioners’ Ground I analysis of Challenged Claim 9, except as to the claimed “460 KHz sinusoid wave.” (Petition at 74-75; Ex-1002-Martin, ¶¶ 242-243, 247-248.) For the same reasons discussed above in Ground I, Petitioners have failed to show that Edwards-535 in view of Stern and Edwards-886 renders Challenged Claim 9 obvious in Ground III. (Ex-2001-Bikson, ¶ 114.)

D. Ground 4: Petitioners Have Failed To Show That Makower In View Of Stern Renders Challenged Claims 1, 4-6, 12-13, And 15-17 Obvious.

1. Petitioners Have Failed To Show That Makower In View Of Stern Renders Challenged Claim 1 Obvious.

Petitioners' Ground IV analysis of the claimed "multiple pairs of bipolar radiofrequency electrodes" and the claimed "multiple radiofrequency output channels" relies on Stern's Figure 15 and Petitioners' Ground I analysis thereof. (Petition at 82-88; Ex-1002-Martin, ¶¶ 272-276, 289; Ex-2003 at 229:10-16.) For the same reasons discussed above in Ground I, Petitioners have failed to show that Makower in view of Stern teaches at least the following requirements of Challenged Claim 1:

- "an array of multiple pairs of bipolar radiofrequency electrodes disposed along the treatment surface of the treatment element"; and
- "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."

(Ex-2001-Bikson, ¶ 115.)

2. Petitioners Have Failed To Show That Makower In View Of Stern Renders Dependent Challenged Claims 4-6, 12-13, And 15-17 Obvious.

Petitioners have failed to show that Makower in view of Stern renders dependent Challenged Claims 4-6, 12-13, and 15-17 obvious in view of their dependency on Challenged Claim 1. Challenged Claims 4-6, 12-13, and 15-17

depend from Challenged Claim 1, and thus incorporate each and every limitation of Challenged Claim 1. *See* 35 U.S.C. § 112(d). Because Petitioners have failed to show that Makower in view of Stern renders Challenged Claim 1 obvious, Petitioners have likewise failed to show that Makower in view of Stern renders dependent Challenged Claims 4-6, 12-13, and 15-17 obvious.

Additionally, Petitioners have failed to show that Makower in view of Stern renders dependent Challenged Claims 6 and 17 obvious for the reasons discussed below.

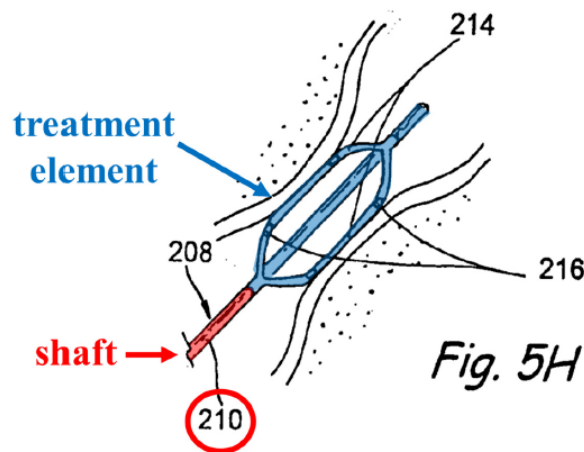
(a) Challenged Claim 6.

Challenged Claim 6 recites, *inter alia*, “wherein the multiple segments comprise a shape-memory alloy material configured to expand to a desired size and shape.” (Ex-1001 at claim 6.) Petitioners assert that Makower’s strut members 214 are the claimed “multiple segments,” and that Makower teaches or suggests that strut members 214 are made of a shape-memory alloy material (*i.e.*, nitinol). (Petition at 90, 92; Ex-1002-Martin, ¶¶ 317-319.) Petitioners do not propose modifying Makower’s strut members 214 to be made of nitinol. (*Id.*)

Petitioners have failed to show that Makower in view of Stern renders Challenged Claim 6 obvious because Makower does not teach or suggest that its strut members 214 are made of nitinol. (Ex-2001-Bikson, ¶ 120.)

First, Makower does not teach that its strut members 214 are made of nitinol. (Ex-2001-Bikson, ¶ 121; Ex-1021-Makower at FIG. 5H, [0187], [0194].) Makower simply has no teachings regarding what strut members 214 are made of. (*Id.*)

While Makower teaches that “nitinol” can be used “to predictably deflect various sections of the catheter” (Ex-1021-Makower at [0194]), Makower teaches that its strut members 214 are different than the catheter. (Ex-2001-Bikson, ¶ 123; Ex-1021-Makower at [0187], FIG. 5H.) Specifically, Makower teaches that strut members 214 are attached to the flexible catheter 210 and that “sensing elements may also be attached to the catheter and/or strut members to monitor various parameters of the catheter and/or surrounding tissue (e.g., temperature, etc.).” (*Id.*) Indeed, as shown in Petitioners’ own annotated figure, reproduced below, the Petition itself confirms that Makower’s strut members 214 are different than Makower’s catheter 210:



(Petition at 81 (annotations in original).)

Second, Makower does not suggest that its strut members 214 are made of nitinol. (Ex-2001-Bikson, ¶ 122.) With respect to nitinol, Makower teaches at most the “use of elements to predictably deflect various sections of the *catheter* (e.g., tension straps or wires, shape memory alloys such as nitinol, etc.).” (Ex-2001-Bikson, ¶ 122; Ex-1021-Makower at [0194] (emphasis added).)¹¹ However, Makower does not teach that its strut members 214 deflect the catheter, and Petitioners do not make any such claim. (Ex-2001-Bikson, ¶ 122; Ex-1021-Makower at FIG. 5H, [0187]; Petition at 92.) Indeed, as shown in Petitioners’ own annotated figure reproduced above, Makower’s catheter 210 is *straight* (not deflected) when the strut members 214 are expanded. (Petition at 81 (citing Ex-1021-Makower at FIG. 5H).)

While Petitioners assert that Makower’s “*strut members 214* deflect when expanded” (Petition at 92 (emphasis added); Ex-1002-Martin, ¶ 319), this is irrelevant to Makower’s teaching that nitinol can be used to deflect various sections of the *catheter*. (Ex-2001-Bikson, ¶ 123.) As noted above, there is no evidence in the record that Makower’s strut members 214 deflect the catheter. (Ex-2001-Bikson, ¶ 123; Ex-1021-Makower at FIG. 5H, [0187].)

¹¹ This is the only time the word “nitinol” appears in Makower. (*Id.*)

Accordingly, Petitioners have failed to show that Makower teaches or suggests that its strut members 214 are made of nitinol. (Ex-2001-Bikson, ¶ 120.)

(b) Challenged Claim 17.

Petitioners' Ground IV analysis of Challenged Claim 17 relies on Petitioners' Ground I analysis of Challenged Claim 17. (Petition at 95; Ex-1002-Martin, ¶ 331.) For the same reasons discussed above in Ground I, Petitioners have failed to show that Makower in view of Stern renders Challenged Claim 17 obvious in Ground IV. (Ex-2001-Bikson, ¶ 124.)

E. Ground 5: Petitioners Have Failed To Show That Makower In View Of Stern And Edwards-886 Renders Dependent Challenged Claims 9-10 Obvious.

Petitioners have failed to show that Makower in view of Stern and Edwards-886 renders dependent Challenged Claims 9-10 obvious in view of their dependency on Challenged Claim 1. Challenged Claims 9-10 depend from Challenged Claim 1, and thus incorporate each and every limitation of Challenged Claim 1. *See* 35 U.S.C. § 112(d). Because Petitioners have failed to show that Makower in view of Stern renders Challenged Claim 1 obvious, Petitioners have likewise failed to show that Makower in view of Stern and Edwards-886 renders Challenged Claims 9-10 obvious.

Petitioners have also failed to show that Makower in view of Stern and Edwards-886 renders Challenged Claim 9 obvious for the additional reasons discussed below.

1. Challenged Claim 9.

Challenged Claim 9 recites, *inter alia*, “a radiofrequency generator configured to ... deliver radiofrequency energy separately to each of the multiple radiofrequency output channels.” (Ex-1001 at claim 9.) Petitioners’ Ground V analysis merely repeats the language of the claim and provides no explanation or analysis as to how Makower in view of Stern and Edwards-886 purportedly teaches “a radiofrequency generator configured to ... deliver radiofrequency energy separately to each of the multiple radiofrequency output channels.” (Petition at 95-97; Ex-1002-Martin, ¶ 334.) Thus, the Board should find that Petitioners have failed to prove that Makower in view of Stern and Edwards-886 renders Challenged Claim 9 obvious for this reason alone.

To the extent the Board allows Petitioners to incorporate their Ground I arguments into Ground V (it should not), for the same reasons discussed above in Ground I Petitioners still fail to show that Makower in view of Stern and Edwards-886 teaches the claimed “radiofrequency generator configured to ... deliver

radiofrequency energy separately to each of the multiple radiofrequency output channels.” (Ex-2001-Bikson, ¶ 128.)¹²

Additionally, Challenged Claim 9 recites “a cable coupled to the handle for plugging the handle into the radiofrequency generator.” (Ex-1001 at claim 9.) Petitioners, relying entirely on their Ground I analysis of Challenged Claim 9, assert that Stern discloses this limitation. (Petition at 97; Ex-1002-Martin, ¶ 339.) However, as discussed above in Ground I, Stern fails to disclose “a cable coupled to the handle for plugging the handle into the radiofrequency generator.” (Ex-2001-Bikson, ¶ 131.)

VI. CONCLUSION

Accordingly, for at least the foregoing reasons, Patent Owner respectfully requests that the Board confirm the patentability of Challenged Claims 1, 4-6, 9-10, 12-13, and 15-17 of the '318 patent.

¹² Makower adds nothing to Petitioners' Challenged Claim 9 “analysis” as Makower mentions “a radio frequency generator” a single time without providing any details. (Ex-1021-Makower at [0040]; Ex-2001-Bikson, ¶ 129.)

Dated: October 25, 2024

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CERTIFICATE OF COMPLIANCE

This paper complies with the requirements of 37 C.F.R. § 42.24 and contains 8,703 words (exclusive of the table of contents, the table of exhibits, the certificate of service, and this certification).

This paper complies with the typeface requirements of 37 C.F.R. § 42.6 and has been prepared in 14 point Times New Roman proportionally spaced typeface with normal spacing.

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