

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEURENT MEDICAL INC. & NEURENT MEDICAL LTD.

Petitioners,

v.

AERIN MEDICAL, INC.

Patent Owner.

Case No. IPR2024-00278

U.S. Patent No. 11,033,318

**PETITION FOR *INTER PARTES* REVIEW
OF CLAIMS 1, 4-6, 9-10, 12-13, AND 15-17 OF
U.S. PATENT NO. 11,033,318
UNDER 35 U.S.C. Section 312 AND 37 C.F.R. Section 42.104**

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I. INTRODUCTION

The claims of U.S. Patent No. 11,033,318 (the “’318 patent”), titled “Methods and Devices to Treat Nasal Airways,” are directed to a radiofrequency (“RF”) ablation device that can be inserted into the nose and that has multiple pairs of bipolar electrodes. *See* Ex.1001-USP318, Abstract, Clm.1. The claims recite only standard well-known components present in many RF ablation devices: a handle, a shaft, a treatment element, bipolar electrodes to deliver treatment, sensors to monitor treatment, and individual output channels. *See id.*, Clm.1.

Two prior art references—one to Edwards (“Edwards-’535”), a prolific inventor cited 25 times on the face of the ’318 patent and another to Makower, which was used by the examiner as a basis of rejection—each disclose many of the standard ablation features that appeared in the as-filed claims: bipolar RF electrodes, sensors, and a treatment element that has different configurations all for use in the nose to improve airflow—the same use touted by the ’318 patent. To obtain issuance, PO narrowed its claims to require that the electrodes be arranged (1) in an array, (2) in

pairs, and (3) with each pair connected to its own RF output channel.¹ *See* Ex.1001-USP318, Clm.1. But none of those added features were new.

The features added by amendment were taught by Stern, which was not before the Patent Office. Stern discloses pairing bipolar RF electrodes and wiring them such that each pair has a respective output channel. Stern's teachings, in combination with Edwards-'535 or Makower, renders the claims obvious. Stern relates to the same type of ablation technology as Edwards-'535 and Makower—devices that use an expandable component with surface electrodes to apply RF energy to hollow cavities in a person's body—and the teachings of Stern would have been obvious to combine with the teachings in Edwards-'535 and Makower. Such combination is nothing more than using a known technique (pairing bipolar electrodes and wiring them to individual output channels) to improve similar devices (Edwards-'535's and Makower's bipolar RF ablation devices) in the same way (to pair bipolar electrodes coupled to individual output channels).

¹ PO also added the requirement of multiple sensors during prosecution. *See* Ex.1003-USP318FH, 574.

Accordingly, Petitioners request that the Board grant this Petition and institute an *inter partes* review of the '318 patent and cancel these claims which do not meet the standards of patentability.

II. MANDATORY NOTICES

A. Real Parties in Interest

Pursuant to 37 C.F.R. Section 42.8(b)(1), Petitioners certify that Neurent Medical Inc. and Neurent Medical Ltd. are the real parties-in-interest.

B. Related Matter

Pursuant to 37 C.F.R. Section 42.8(b)(2), Petitioners submit that Patent Owner ("PO") has asserted five patents, including the '318 patent in *Aerin Medical Inc. and The Foundry LLC v. Neurent Medical Inc. and Neurent Medical Ltd.*, Case No. 1:23-cv-00756-JLH (D. Del) (Exs.1006-1007). Three other patents allegedly owned by The Foundry LLC and alleged to be exclusively licensed by PO are also asserted against Petitioners in this litigation. Petitioners are concurrently filing *inter partes* review petitions challenging certain claims of the following patents asserted against Petitioners by PO and The Foundry LLC:

Challenged Patent	PO	Case No.
9,072,597	Aerin Medical Inc.	IPR2024-00275
9,415,194	Aerin Medical Inc.	IPR2024-00276
11,241,271	Aerin Medical Inc.	IPR2024-00277
10,610,675	The Foundry LLC	IPR2024-00279
10,894,011	The Foundry LLC	IPR2024-00280
11,679,077	The Foundry LLC	IPR2024-00281
11,766,286	Aerin Medical Inc.	IPR2024-00282

C. Counsel

Lead Counsel: David Cavanaugh (Reg. No. 36,476)

Back-up Counsel: Gregory Lantier (*pro hac vice* to be filed)

Alexis Cohen (Reg. No. 76,998)

Joshua Stern (*pro hac vice* to be filed)

Alexander Nemtzow (Reg. No. 82,130)

Sarah Murphy (Reg. No. 80,104)

D. Service Information

Email: David.Cavanaugh@wilmerhale.com;
Gregory.Lantier@wilmerhale.com;
Alexis.Cohen@wilmerhale.com;
Joshua.Stern@wilmerhale.com;
Alex.Nemtsov@wilmerhale.com;
Sarah.J.Murphy@wilmerhale.com;
WHNeurentIPRService@wilmerhale.com

Post & Hand Delivery: Wilmer Cutler Pickering Hale and Dorr LLP

2100 Pennsylvania Avenue NW

Washington, DC 20037

Tel: (202) 663-6000, Facsimile: (202) 663-6363

Petitioners agree to accept service by email.

III. CERTIFICATION OF GROUNDS FOR STANDING

Petitioners certify under 37 C.F.R. Section 42.104(a) that the '318 patent is available for IPR and that Petitioners are not barred or estopped from requesting IPR on the Grounds identified herein.

IV. OVERVIEW OF CHALLENGE AND RELIEF REQUESTED

Petitioners request cancellation of claims 1, 4-6, 9-10, 12-13, and 15-17 (“challenged claims”) of the ’318 patent.

A. Prior Art

The ’318 patent was filed on May 15, 2019, and claims priority through multiple parent applications to U.S. Provisional Application No. 61/496,930 filed on June 14, 2011.² Ex.1001-USP318, Cover.³

1. **USP 6,517,535** (“Edwards-’535”), Ex.1010-Edwards-’535, published February 11, 2003 and filed November 9, 1999, is prior art under §§102(a)(1) and 102(a)(2).
2. **USP 5,562,720** (“Stern”), Ex.1033-Stern, published October 8, 1996 and filed October 6, 1994, is prior art under §§102(a)(1) and 102(a)(2).

² Petitioners assume for purposes of this Petition that the ’318 patent is entitled to the claimed priority date but reserve the right to argue in the parallel litigation that it is not.

³ The ’318 patent was examined under the provisions of the AIA, but the relied-upon references each qualify as prior art regardless of whether the AIA or pre-AIA provisions apply.

3. **U.S. Publication No. 2005/0240147** (“Makower”), Ex.1021-Makower, published October 27, 2005 and filed April 21, 2004, is prior art under §§102(a)(1) and 102(a)(2).
4. **U.S. Publication No. 2007/0287994** (“Patel”), Ex.1034-Patel, published December 13, 2007 and filed June 12, 2006, is prior art under §§102(a)(1) and 102(a)(2).
5. **USP 6,273,886** (“Edwards-’886”), Ex.1016-Edwards-’886, published August 14, 2001 and filed May 4, 1999, is prior art under §§102(a)(1) and 102(a)(2).

B. Discretionary Denial Is Not Warranted

Discretionary denial is inappropriate under 35 U.S.C. §314(a) and §325(d). *First*, no Fintiv factor favors denial. *See Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 15 (P.T.A.B. May 13, 2020). The parallel litigation has not progressed past the pleadings, and there is no current case schedule or trial date. The Final Written Decision would be expected well before the approximately 3-year median time to trial in District of Delaware. *See* Ex.1008. And this Petition presents compelling merits underlying five Grounds.

Second, as detailed below, Makower was applied to the claims during the prosecution of the ’318 patent. However, because this Petition contains arguments

not previously considered by the Patent Office, discretionary denial is not warranted.

No other references relied on in this Petition are of record.

1. Makower

Although Makower was used as a basis of rejection during prosecution of the '318 patent, the examiner did not have the benefit of Stern, and therefore discretionary denial is not warranted because the same arguments were not previously presented to the PTO. *See Advanced Bionics, LLC v. MED-EL Elektromedizinische Gerate GmbH*, IPR2019-01469, 2020 WL 740292, at *4 (Feb. 13, 2020). Additionally, the other references applied in Grounds I-IV demonstrate ample basis to merit institution.

2. Edwards-'535

Edwards-'535 is not of record in the '318 patent, nor was any other reference containing the relied upon teachings of Edwards-'535 applied to the challenged claims during prosecution.

a. USP 5,746,224 and USP 5,800,429

Edwards-'535 is a continuation of USP 5,746,224 ("continuation parent") and continuation-in-part of USP 5,800,429 ("CIP parent"). Both of these references were cited in an IDS during prosecution but were among at least 100 other references, and neither were discussed in any meaningful regard on the record. The

Board has made clear that “[i]f the record of the Office’s previous consideration of the art is not well-developed or silent, then a petitioner may show the Office erred by overlooking something persuasive....,” *Advanced Bionics* at *4 (emphasis added); *see also Amazon.com, Inc., v. M2M Solutions LLC*, IPR2019-01205, 2020 WL 44835, at *7 (P.T.A.B. Jan. 27, 2020).

As presented herein, Edwards-’535 discloses the limitations of each of the challenged claims. *See* §§X.A-D. To the extent the same teachings exist in USP 5,746,224 and USP 5,800,429, the examiner committed a material error by overlooking those teachings even if it could be argued that USP 5,746,224 and USP 5,800,429 were considered. 35 U.S.C. §325(d); *Advanced Bionics* at *3.

The Board has previously instituted review under these circumstances, and Petitioners respectfully request that it do so again here. *See, e.g., Mylan Pharm. Inc., v. Merck Sharp & Dohme Corp.*, No. IPR2020-00040, 2020 WL 2478503, at *7 (P.T.A.B. May 12, 2020) (instituting review even though “WO ’498 was presented to the Examiner” because the “Examiner never discussed WO ’498 or made a rejection based on it” and “gave no reasons for allowance” even though the “disclosure meets the claimed invention” and “[t]he likeliest explanation...is that the Examiner simply overlooked [its] teachings”); *see also Advanced Bionics*, 2020 WL 740292, at *3 n.9.

b. Other Cited References

Edwards-'535 shares a named inventor with many other references that were cited (but not discussed) during prosecution. Ex.1003-USP318FH, 1-21, (IDS citing 26 references with first inventor named Edwards-'535). These other references are in different patent families from Edwards-'535 and contain distinct teachings; moreover, they were not discussed during prosecution, so even if PO argues that they contain the same or similar teachings, the record's silence as to these references confirms that the record is not clear as to why the claims are patentable over the cited but not distinguished art. *See, infra*, §§IV.B.2(a)-(b).

C. Grounds for Challenge

Petitioners request cancellation of the Challenged Claims as unpatentable under 35 U.S.C. Section 103. The Grounds for challenge are:

Ground	35 U.S.C. Section	Claims	References
I	103	1, 4, 5, 9, 10, 12, 13, 15-17	Edwards-'535 + Stern
II	103	6	Edwards-'535 + Stern + Patel
III	103	9, 10	Edwards-'535 + Stern + Edwards-'886
IV	103	1, 4-6, 12, 13, 15-17	Makower + Stern
V	103	9, 10	Makower + Stern + Edwards-'886

This Petition, supported by the declaration of Dr. Gregory T. Martin, Ex.1002-Decl., demonstrates that there is a reasonable likelihood that Petitioners will prevail with respect to at least one challenged claim. 35 U.S.C. §314(a). Petitioners respectfully request institution. *SAS Institute Inc. v. Iancu*, 138 S. Ct. 1348 (2018).

V. TECHNOLOGY BACKGROUND

A. RF Ablation

RF ablation uses high frequency alternating electric current, typically in the range of 300kHz-700kHz, to modify tissue. The current flows through tissue and causes tissue temperature to rise. The temperature increase creates lesions, damaging or killing portions of tissue. Ex.1002-Decl., ¶29.

Long before the '318 patent, RF ablation was well understood and being used successfully, for example, to remove a blockage or shrink enlarged tissue. Ex.1010-Edwards-'535, Abstract; Ex.1012-Goble, 3:35-48; Ex.1023-Coste, 894; Ex.1024-Hovda, 11:13-31; Ex.1031-Hytönen, Abstract. Ex.1002-Decl., ¶30.

B. Applying RF Energy to the Nose

The use of RF ablation within the nasal cavity was also well-known. For example, RF tissue reduction was “successfully used in neurosurgery, urology, and cardiology for many years” and was safely and effectively used to treat nasal turbinates at least ten years before the '318 patent. Ex.1023-Coste, 894; *see also*

Ex.1021-Makower, Abstract, [0187]. RF ablation had been used for treating a wide variety of nasal conditions by 2011, including nasal polyps (Ex.1024-Hovda, 11:13-12:4), snoring, nasal obstruction secondary to non-allergic or allergic rhinitis (Ex.1031-Hytönen, Abstract), and rhinitis, Ex.1056-Liang, Abstract, 341-42. RF ablation had also been used to improve nasal airflow. Ex.1010-Edwards-'535, 4:53-67. Ex.1002-Decl., ¶35.

C. RF Ablation Devices

RF ablation devices for the treatment of chronic pain have been known for decades. Ex.1054-Koyyalagunta, 6. By 2011, many types of RF ablation devices had been disclosed for a wide range of uses. For example, RF ablation devices had been designed to include bipolar and monopolar configurations (Ex.1011-Baker, 5:47-58; Ex.1012-Goble, 6:33-68, 11:23-49), handles (*id.*, 5:27-47), steerable shafts (Ex.1021-Makower, [0186]), visualization capabilities (Ex.1010-Edwards-'535, 10:39-45), expandable cages made out of shape memory alloys (Ex.1015-Laufer, 9:5-14; Ex.1012-Goble, 10:61-12:30), ablating forceps (Ex.1022-Odom, [0002]), sensor-based feedback to physicians (Ex.1010-Edwards-'535, 9:14-11:44), penetrating or non-penetrating electrodes (Ex.1016-Edwards-'886, 26:54-28:8 (penetrating); Ex.1010-Edwards-'535, 4:55-60 (non-penetrating)), cooling systems

(Ex.1010-Edwards-'535, 4:60-65, 6:10-40, 11:23-44), and techniques for targeting subsurface tissue (*id.*, 4:60-65). Ex.1002-Decl., ¶31-34.

D. Monopolar and Bipolar RF Electrode Configurations

RF ablation devices had been designed in both monopolar and bipolar configurations prior to 2011. Both configurations involve electrical current flowing from a generator to an active (+) electrode and back to a return (-) electrode. In a monopolar device, current passes from the active electrode, through target tissue in a patient's body, and out of the patient via a return electrode (usually a grounding pad) placed on the patient's body.

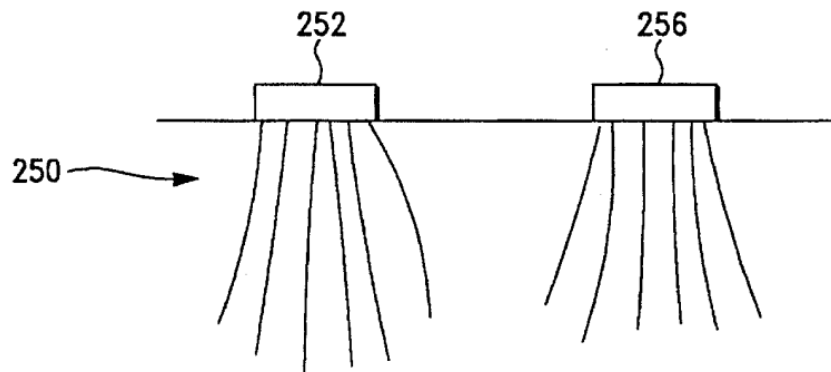


FIG. – 16

Ex.1033-Stern, FIG.16 (showing electrical field lines for a monopolar configuration, having two active electrodes 252 and 256, where the field lines travel from the active electrodes to a return electrode (not shown)). Ex.1002-Decl., ¶36-37.

In a bipolar device, the return electrode is placed inside the body, normally near the active electrode, and current only passes through the tissue between the active and return electrodes to heat the tissue.

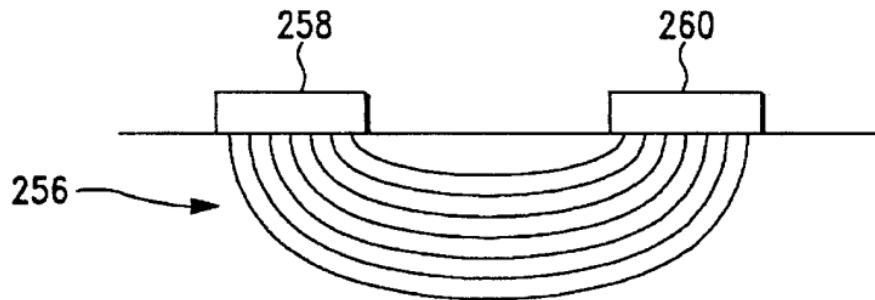


FIG.-17

Ex.1033-Stern, FIG.17 (showing electrical field lines for a bipolar configuration, having, *e.g.*, active electrode 258 and return electrode 260). Ex.1002-Decl., ¶38.

Bipolar RF electrodes have particular benefit when ablating tissue located in a patient's head. Due to the proximity between the active and return electrodes, the electric field lines in a bipolar configuration are more controllable than in a monopolar arrangement, allowing for precise direction of energy and current to specific locations. It is well known that this can be safer than a monopolar arrangement where current flows more broadly through a patient's body and could interfere with the electrical signals in a patient's head. Ex.1002-Decl., ¶38-40.

Other known techniques can be used with bipolar RF ablation to ablate subsurface tissue while leaving the surface intact, such as cooling systems that cool surface tissue while allowing underlying uncooled tissue to heat and become ablated. *See, e.g.*, Ex.1010-Edwards-'535, 4:53-67, 6:10-51, 6:66-7:24 (using a balloon with a cooled fluid during ablation); Ex.1015-Laufer, 7:45-54, 12:56-14:50 (same). Ex.1002-Decl., ¶39.

VI. The '318 Patent

A. Brief Description

The '318 patent relates generally to “systems and methods for improving breathing” by “reshaping, remodeling, strengthening, or changing the properties of the tissues of the nose.” Ex.1001-USP318, 11:16-22. Although the '318 patent discloses delivering various forms of energy to the targeted tissue, the claims of the '318 patent are focused on a device that delivers RF energy and is sized to be inserted into a nostril. Ex.1001-USP318, 6:49-51, Clm.1. Ex.1002-Decl., ¶41.

Figure 18 shows “a device for applying energy to the nasal valve area comprising an array of non-penetrating electrodes.” Ex.1001-USP318, 9:50-54. The device 390 has a shaft 394 connected to a handle 398. “[P]airs of bipolar electrodes 392 located at the distal end of [the] shaft 394.” Ex.1001-USP318, 27:45-51.

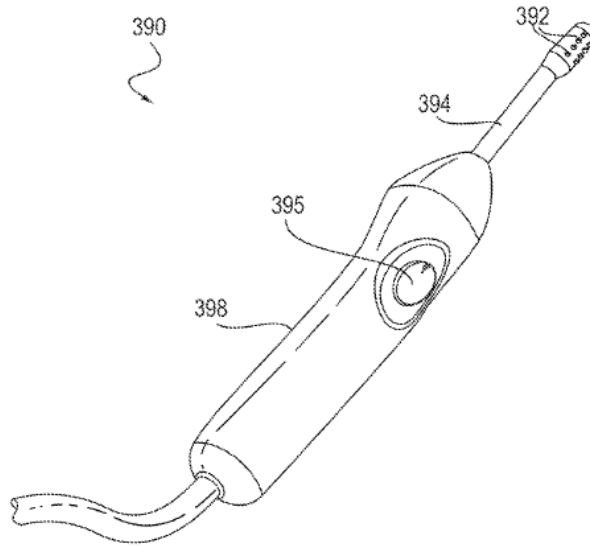


FIG. 18

Id., FIG.18. Ex.1002-Decl., ¶42.

To overcome prior art in the parent patent application, PO added limitations requiring electrodes that are (1) in an array, (2) in pairs, and (3) provided with RF energy to by connecting each pair to its own RF output channel.⁴ Figure 8F, for example, shows “an array of [penetrating] electrodes comprising one, two, or many

⁴ PO also added the requirement of multiple sensors during prosecution. *See* Ex.1003-USP318FH, 574.

pairs of bipolar needles 252...located on a treatment element.” Ex.1001-USP318, 24:21-23.

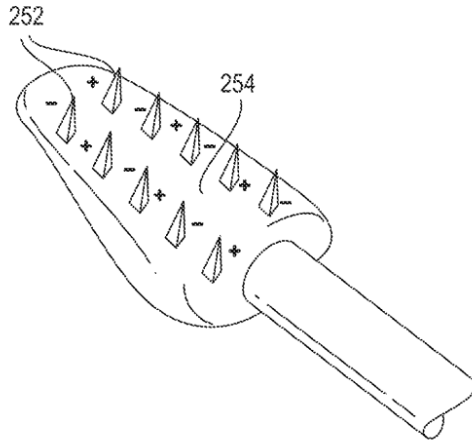


FIG. 8F

Id., FIG.8F. Ex.1002-Decl., ¶43-44.

According to the '318 patent, “each electrode pair...may have its own individual subsystem 970” with “a positive electrode 973 and a negative electrode 974,” “controlled RF channels 971, a first thermocouple 972*a*, and a second thermocouple 972*b* to allow for independent temperature readings.” Ex.1001-USP318, 49:33-40; *see also id.*, 49:18-21 (describing a “multiplexed configuration”), FIG.40.

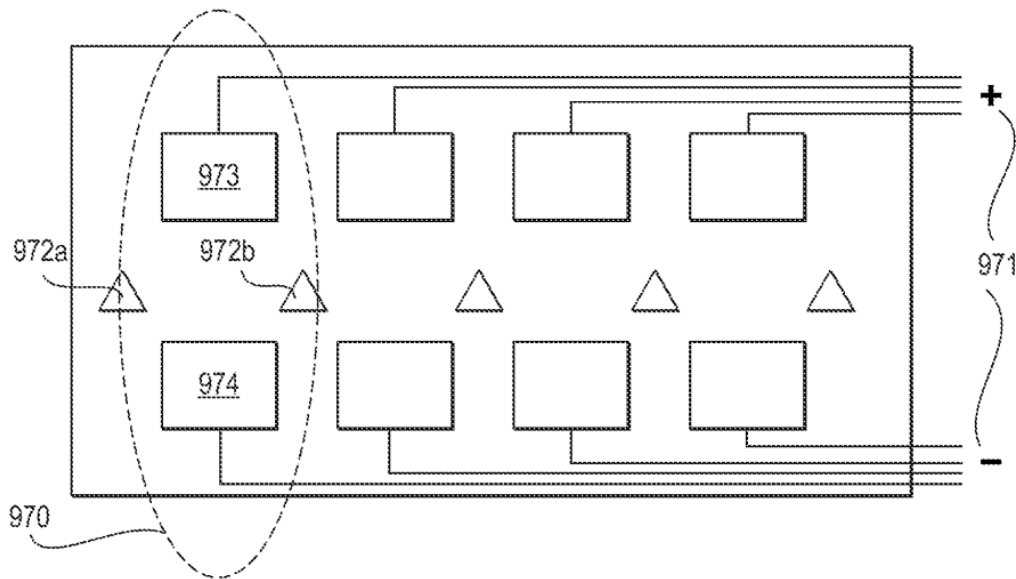


FIG. 41

Ex.1001-USP318, FIG.41. Ex.1002-Decl., ¶45.

B. Prosecution History

The '318 patent was filed on May 15, 2019. Ex.1003-USP318FH, 25. After filing, PO filed a preliminary amendment to replace claims 1-12 with 13-28. *Id.*, 186-195. The examiner rejected independent claim 13 (now claim 1), among others, as being anticipated Makower. *Id.*, 508-09. Ex.1002-Decl., ¶46-47.

In response, PO amended the claims substantially, including by adding multiple pairs of bipolar RF electrodes, multiple RF output channels, and multiple sensors:

13. (Currently amended) A device for delivering energy to a nasal airway to improve nasal airflow, the device comprising:

...

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

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

Ex.1003-USP318FH, 572-88 (amendments underlined). Ex.1002-Decl., ¶48.

PO argued that these features were missing from Makower, and the application was allowed with no Reasons for Allowance. Ex.1003-USP318FH, 577-78, 590-613. But as explained herein, these added features were well known in the art. The examiner did not have the benefit of the combinations in Grounds I-V, discussed below, during prosecution. Ex.1002-Decl., ¶49.

VII. PERSON OF ORDINARY SKILL IN THE ART

A person of ordinary skill in the art (“POSITA”) at relevant times (2011-2019) 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. Less work experience may be compensated by a higher level of education, and vice versa. Ex.1002-Decl., ¶24-28.

VIII. CLAIM CONSTRUCTION

For the purposes of this IPR, the Board need not construe any terms because the Challenged Claims are invalid under any reasonable interpretation. Ex.1002-Decl., ¶50-53.⁵

IX. OVERVIEW OF THE PRIOR ART USED IN THE GROUNDS

A. Edwards-'535

Edwards-'535 discloses an RF device introduced “through a nostril” and used “for ablating an internal section of a nasal concha,” Ex.1010-Edwards-'535, 3:7-19, to “improv[e] airflow,” *id.* 7:18-25. *Cf.* Ex.1001-USP318, Clm.1 (reciting a “device for delivering energy to a nasal airway to improve nasal airflow”). The RF device has an expandable member 132 through which ablative energy is delivered to nasal concha 114. In certain embodiments, the delivered energy targets the subsurface of

⁵ Petitioners reserve the right to propose constructions for claim terms in the parallel litigation and respond to any claim construction arguments advanced by PO or any real party in interest in this proceeding and the parallel litigation.

nasal concha 114 without ablating the surface. Ex.1010-Edwards-'535, 4:53-67, 5:18-26, 6:10-51, 6:66-7:24, FIGs.3A-4C.

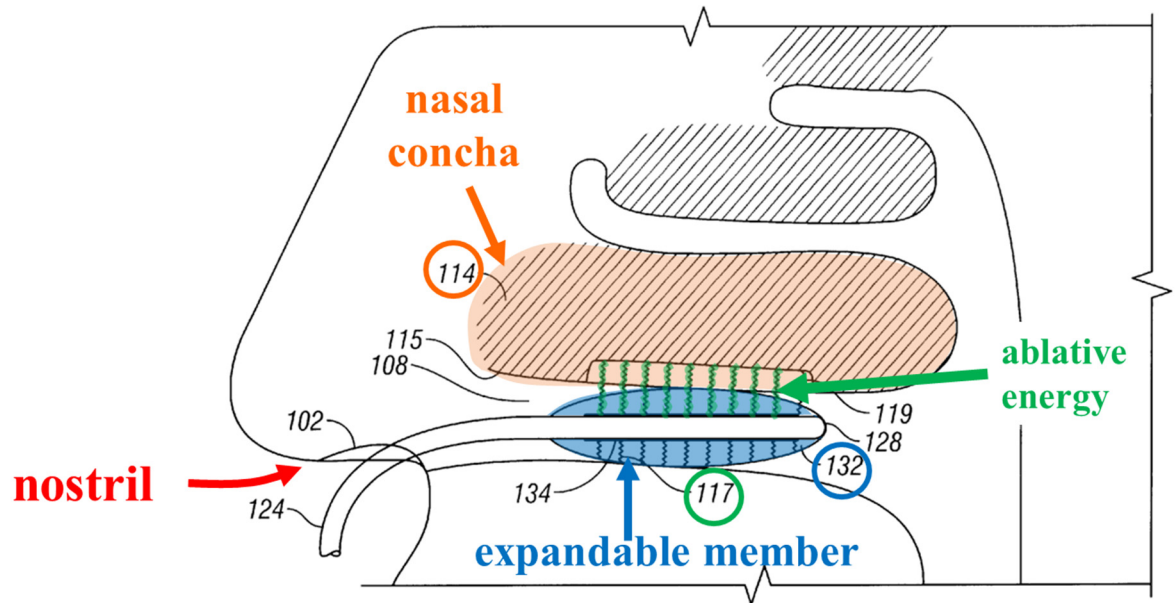


FIG. 3B

Id., FIG.3C.⁶ Ex.1002-Decl., ¶57-60.

B. Stern

Stern discloses an endometrial ablation device designed to ablate “the inner lining of body organs” and body tissue. Ex.1033-Stern, 1:16-18, Abstract, 2:6-18, 18:27-40. The device has an expandable member with RF electrodes on its surface. *Id.*, 2:26-35. Stern also teaches that temperature sensors are positioned on the expandable member to contact the surface. *Id.*, 7:49-61. An exemplary arrangement

⁶ All annotations added unless otherwise stated.

of the device uses an array of multiple pairs of bipolar RF electrodes and a mechanism for delivering RF energy to each electrode pair. *Id.*, 2:36-40, 3:29-40, 12:7-13:55. For example, Stern discloses selectively energizing certain **electrode pairs** based on a switching arrangement. *Id.*, Abstract. As shown below, Stern teaches that each **pair** is connected to its own **output channel**.

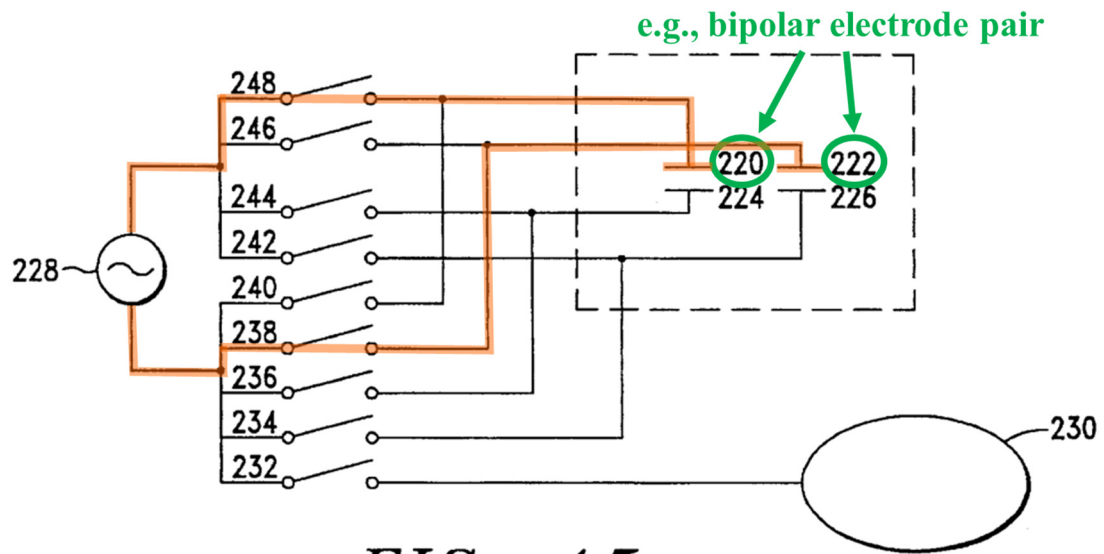


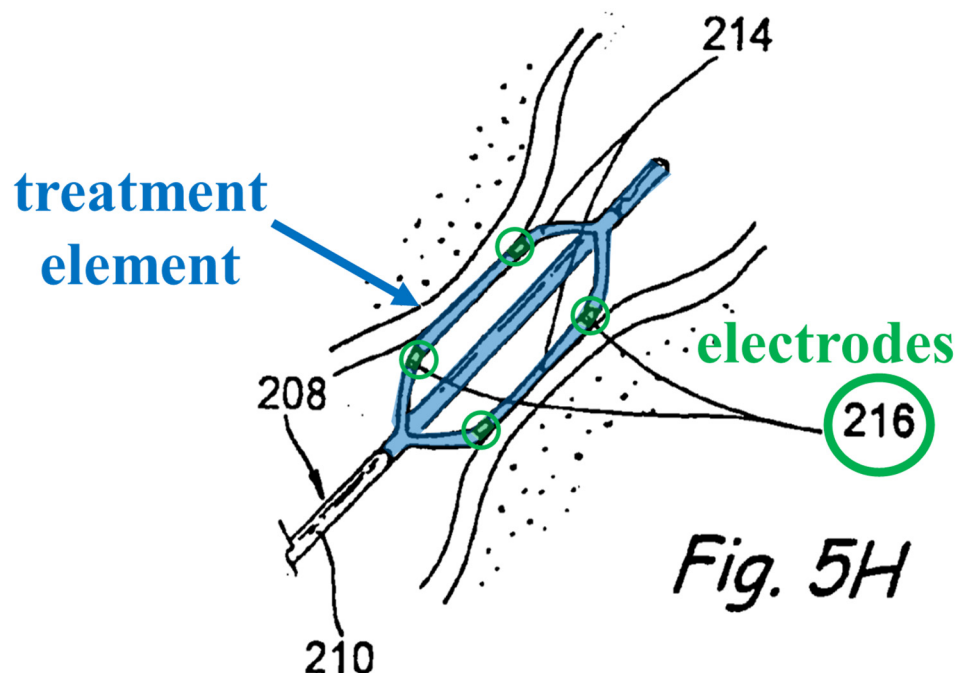
FIG. – 15

Ex.1033-Stern, FIG.15. Ex.1002-Decl., ¶¶61-64.

C. Makower

Makower discloses “medical devices and methods...for treating sinusitis and other ear, nose & throat disorders.” Ex.1021-Makower, [0001]. For example, Makower discloses electrosurgical devices that can be inserted into nasal passageways “to perform diagnostic or therapeutic procedures.” *Id.*, [0016], [0043],

[0161]. Figure 5H of Makower depicts one such electrosurgical device that is inserted into the nasal cavity and includes **strut members 214** with multiple monopolar or bipolar **electrodes 216**. *Id.*, [0043], [0161], [0187], FIG.5H. The strut members 214 are expanded to contact the surrounding tissue, and “current is applied to the electrodes 216 causing tissue adjacent to the struts 214 to be cauterized or heated.” *Id.*, [0187].



Id., FIG.5H. Ex.1002-Decl., ¶65.

D. Patel and Edwards-'886

As detailed in the Grounds below, Patel and Edwards-'886 each disclose features recited by certain challenged dependent claims and thereby render those claims obvious in combination with other prior art. Ex.1002-Decl., ¶66-69.

X. SPECIFIC GROUNDS FOR UNPATENTABILITY

A. Ground I: Claims 1, 4, 5, 9, 10, 12, 13, 15-17 Are Invalid as Obvious Over Edwards-'535 in View of Stern.

1. Claim 1

a. 1[pre]

If the preamble is limiting, Edwards-'535 discloses it; Edwards-'535 discloses *a device (e.g., apparatus 124) for delivering energy (e.g., ablative energy) to a nasal airway (e.g., nasal concha 114) to improve nasal airflow (e.g., through nasal meatus 108).*⁷ Ex.1002-Decl., ¶71-72.

Edwards-'535 discloses “an apparatus 124...for delivering ablative energy...introduced through a nostril 102 into a nasal meatus adjacent a surface of a nasal concha.” Ex.1010-Edwards-'535, 5:20-26; *see also id.*, 3:18-36, FIGs.3A-4C. The nasal concha “form at least a portion of the[] nasal passageways,” and are therefore part of the nasal airway. *Id.*, 1:60-2:6. Ex.1002-Decl., ¶73.

Edwards-'535 further teaches that the “apparatus [is used] for reducing the volume of the turbinates in order [to] reduce nasal airway obstructions.” Ex.1010-Edwards-'535, 1:21-25, 1:60-2:6, FIGs.4A-4C. “By ablating at least a portion of a nasal concha, the size of the nasal concha can be reduced,” which, in turn,

⁷ *Italicized text* indicates claim language unless otherwise noted.

“improv[es] *airflow* through a *nasal* meatus of the body.” *Id.*, 4:18-32, 8:50-54; FIGs.4A-4C. Ex.1002-Decl., ¶74.

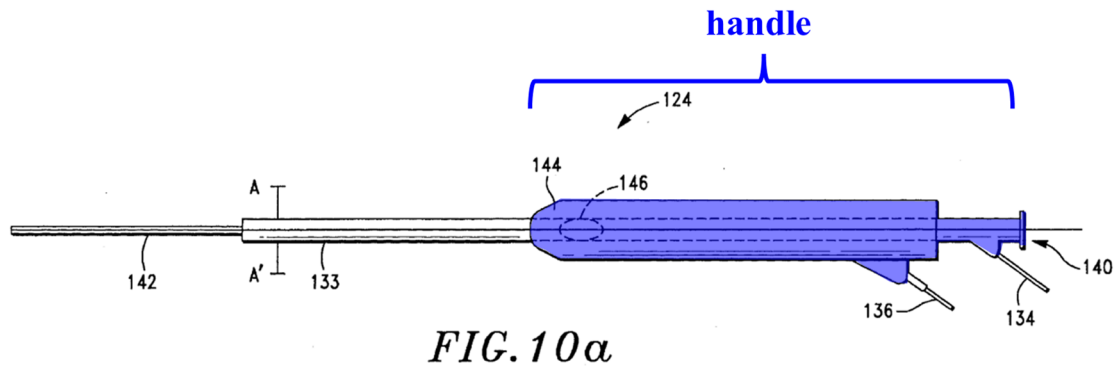
b. 1[a]

Edwards-’535 or Edwards-’535 in view of Stern renders obvious a *handle*. Ex.1002-Decl., ¶75.

Edwards-’535 omits whether its device includes a handle, but it would have been obvious to include a handle to control the device and/or deploy the expandable member. Edwards-’535 discloses introducing a catheter-based energy delivery device “through a nostril,” and “positioning the distal portion of the catheter” “adjacent a surface of the nasal concha [114]” once inside the nostril. Ex.1010-Edwards-’535, 5:20-26, Clm.1, FIGs.3A-3D. Further, as above for limitation 1[pre], Edwards-’535 discloses delivering energy to nasal concha 114 with an expandable member 132 and an energy delivery device 134. *Id.*, 2:9-14, 2:44-46, 5:20-26, Clm.1. Surgical catheter-based energy delivery devices with *handles* to control positioning and expansion of expandable members were ubiquitous in the art at that time. Ex.1002-Decl., ¶76.

Stern discloses one example of a *handle* (e.g., *application device 124*) that allows a physician to control the apparatus and deploy an expandable member. Ex.1033-Stern, 10:11-29, 10:37-49, 13:56-65, 14:5-8, 18:13-28, FIGs.10a, 11a, 12.

Stern's *handle* has retraction knob 144 allowing a physician to deploy and collapse bladder 142. *Id.*, 10:11-29, 10:37-49, 18:18-26, FIGs.10a, 11a, 12.



Id., FIG.10a. Ex.1002-Decl., ¶77-78.

A POSITA would have been motivated to use a *handle* in a device like Edwards-'535's to be able to have control over the position of the device and inflation of Edwards-'535's expandable member as taught by Stern. A *handle* would have facilitated introduction of Edwards-'535's apparatus 124 through a patient's nostril, into position adjacent nasal concha 114, and would have allowed a physician to deploy and later collapse the expandable member. Ex.1010-Edwards-'535, 5:20-34, 5:52-61, 6:66-7:17, Clm.1, FIGs.3A-3D. Thus, the design and application of handles to different devices would have been obvious and predictable, and a POSITA would have had a reasonable expectation of success given the numerous examples known in the art. Indeed, including a *handle* for control of Edwards-'535's apparatus 124 would have involved the addition of simple, straightforward

components with self-evident results (*e.g.*, providing a location to hold and manipulate the device for a procedure and controls for the various components of the device). Ex.1002-Decl., ¶79-80.

c. 1[b]

Edwards-’535 in view of Stern renders obvious *a shaft* (*e.g.*, the portion of catheter body 126 extending through nostril 102/lumen 135 in Edwards-’535) *extending from one end of the handle* (*e.g.*, in Stern, the catheter sleeve 133 is shown extending from one end of the applicator device 124). Ex.1002-Decl., ¶81-82.

As shown in Figures 3A-3D Edwards-’535 discloses that the apparatus 124 has a *shaft* extending through the nostril 102 to the “distal portion 128.” Ex.1010-Edwards-’535, 5:20-26, 5:52-61. The use of the phrase “distal portion 128” connotes that the distal portion 128 is placed at the end of an elongated member (*i.e.*, *a shaft*).

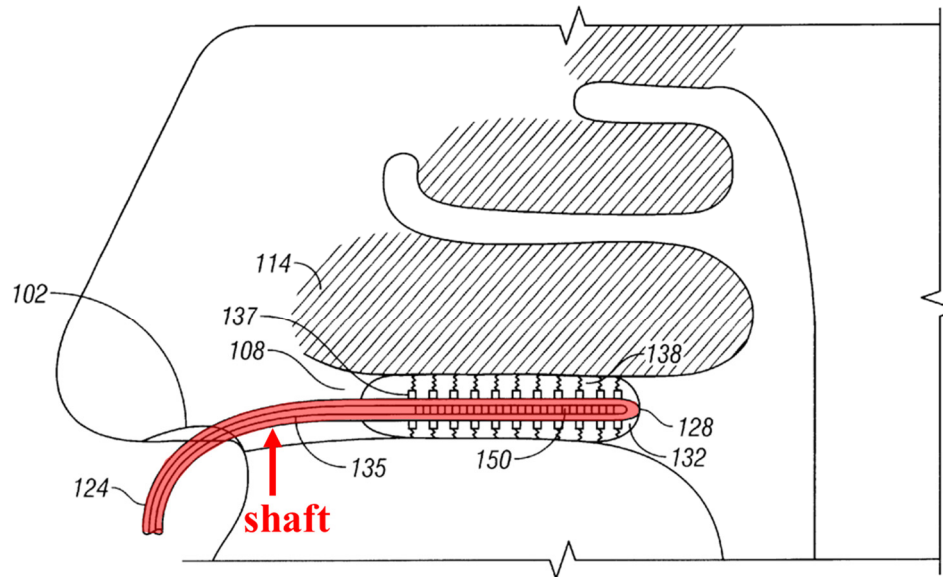
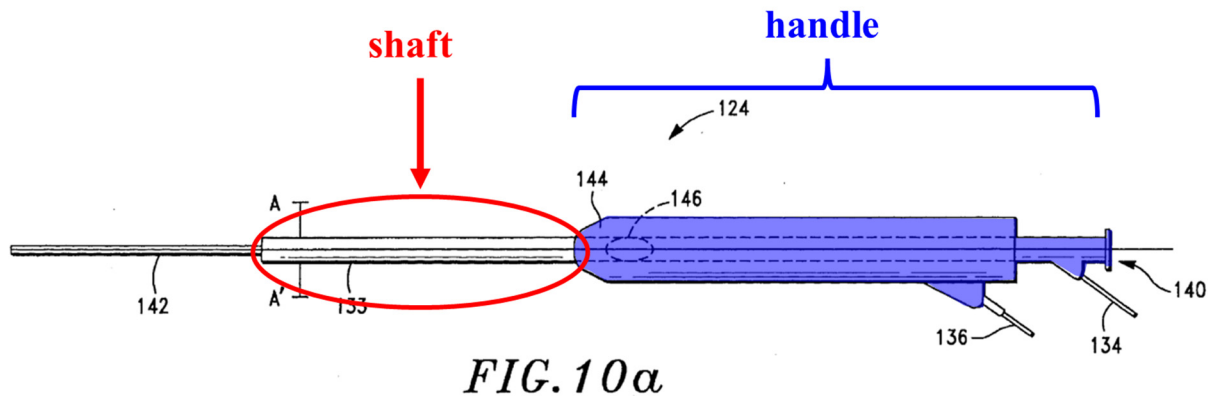


FIG. 3C

Ex.1010-Edwards-'535, FIG.3C. Ex.1002-Decl., ¶83.

Given that Edwards-'535 does not explicitly teach a handle (*see* limitation 1[a]), it also does not explicitly teach that its *shaft extend[s] from one end of the handle*. But a shaft extending from one end of the handle is an obvious implementation of Edwards-'535 in view of Stern. *See supra*, §X.A.1.b. For example, Stern teaches a *shaft* (e.g., *element connecting distal end to the handle extending from one end of the handle*) (e.g., *applicator device 124*).



Ex.1033-Stern, FIG.10a. Ex.1002-Decl., ¶84-85.

A POSITA would have understood Edwards-'535's description of the catheter to refer to a shaft extending between the handle and the device's distal end, as taught by Stern. Ex.1010-Edwards-'535, 5:20-26, 5:52-61. As discussed above, it would have been obvious to use a handle, similar the one taught by Stern, to control the apparatus 124 of Edwards-'535. Moreover, given that Stern's *handle* directly controls the *shaft* (e.g., for deployment of the expandable energy delivery component), it would be obvious for the shaft to *extend[] from one end of the handle* and is an implementation commonly known in the art. Ex.1002-Decl., ¶86.

d. 1[c]

Edwards-'535 discloses *a treatment element (e.g., expandable member 132 and energy delivery device 134) coupled with a distal end of the shaft (e.g., distal portion 128), sized to be inserted into a nostril (e.g., nostril 102), and configured to change from a first configuration to a second configuration (e.g., the expandable*

member 132 is expanded), wherein the treatment element comprises a tissue treatment surface (e.g., energy delivery device 134/electrodes are placed on the surface of the expandable member 132, which is brought into contact with the surface 115 of the nasal concha 114).

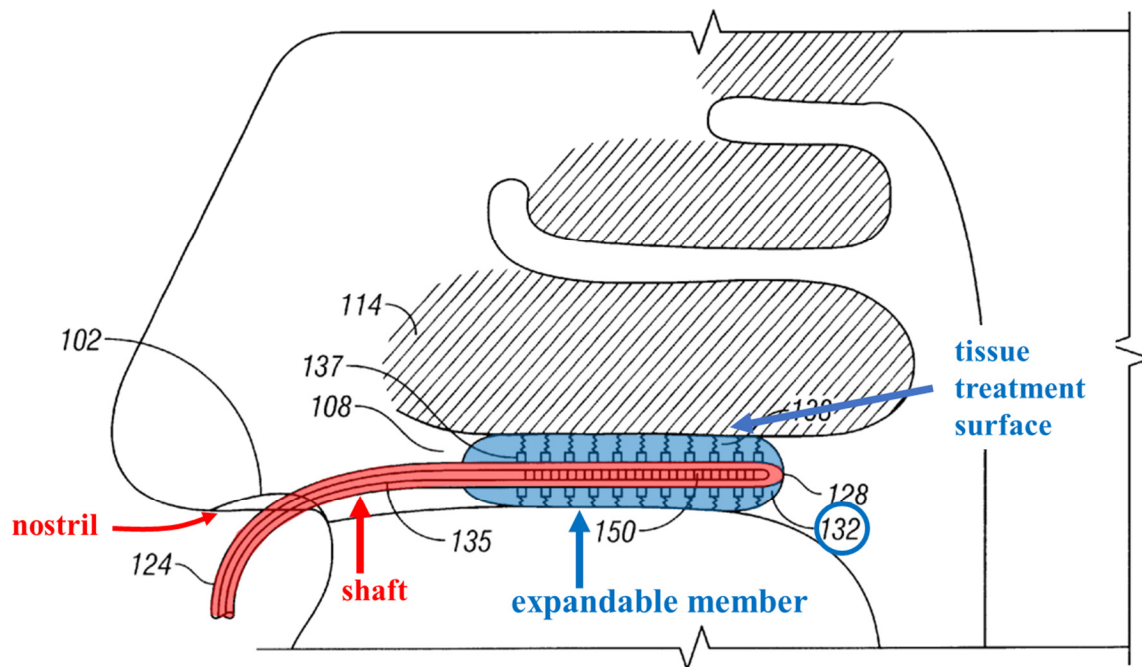


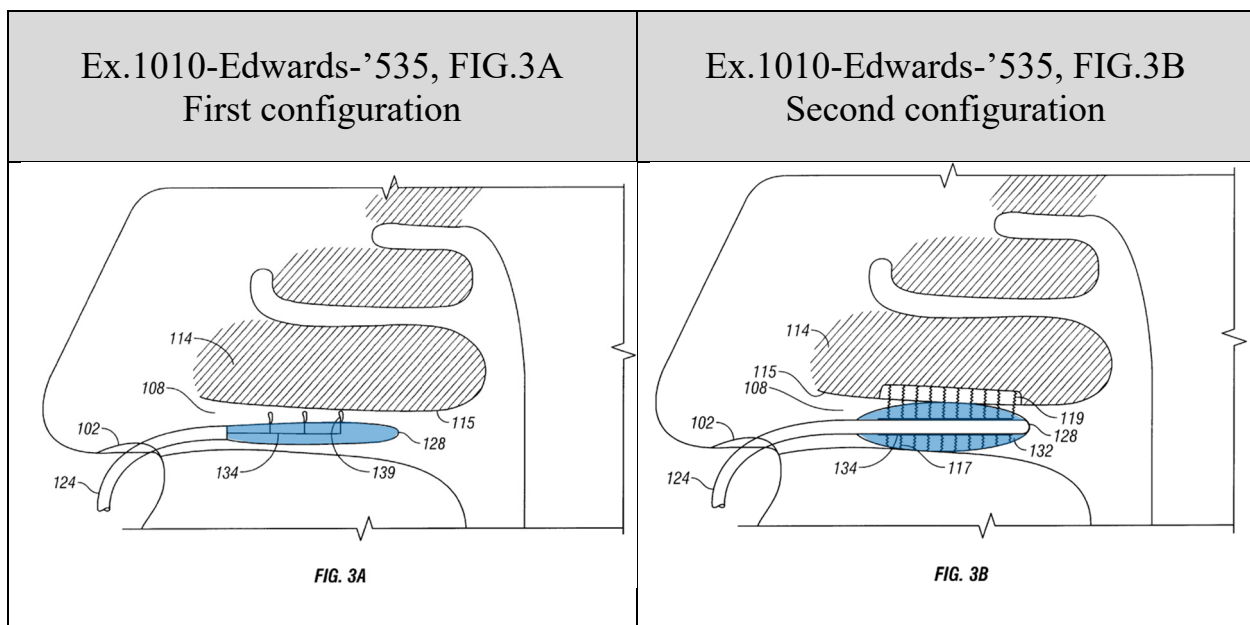
FIG. 3C

Ex.1010-Edwards-'535, FIG.3C. Ex.1002-Decl., ¶87-89.

For example, Edwards-'535 discloses “an apparatus 124 having a distal portion 128 with an expandable member 132 and an energy delivery device 134 for delivering ablative energy is introduced through a nostril 102 into a nasal meatus [108] adjacent a surface of a nasal concha [114].” Ex.1010-Edwards-'535, 5:21-23, FIGs.3A-3D. As shown in FIGs.3A-3D and 5, the apparatus has a catheter body 126

to which the **expandable member 132** is coupled. Ex.1010-Edwards-'535, 7:33-35, 7:43-45. Ex.1002-Decl., ¶90.

As shown in FIGs.3A-3B, delivery of a medium causes the **expandable member 132** to expand from a *first configuration* to a *second configuration*. Ex.1010-Edwards-'535, 5:22-30, 5:52-60, 6:33-36, 7:33-46, 7:61-8:46.



Ex.1002-Decl., ¶91.

Once **expandable member 132** and energy delivery member 134 are “introduced through a nostril 102 into a nasal meatus adjacent a surface of a nasal concha [114]” (*i.e., sized to be inserted into a nostril*), “the **expandable member [132]**” is inflated and “conforms to the surface of the nasal concha [114] to be ablated.” Ex.1010-Edwards-'535, 5:18-26, 7:37-40. An “energy delivery device [134] may be positioned on a surface 147 of the expandable member.” *Id.*, 8:12-16,

FIG.6, 8:17-32. RF energy is applied to treat tissue (*e.g.*, nasal concha 114), as discussed above for limitation 1[pre]. *Id.*, 8:50-53. Accordingly, the surface of the [expandable member \[132\]](#), in combination with surface-mounted energy delivery devices, constitutes a *tissue treatment surface*. Ex.1002-Decl., ¶92.

e. 1[d]

Edwards-'535 in view of Stern renders obvious *an array of multiple pairs of bipolar radiofrequency electrodes* (*e.g.*, plurality of [bipolar energy delivery devices](#)) *disposed along the treatment surface of the treatment element* (*e.g.*, on the surface of [expandable member 132](#)). Ex.1002-Decl., ¶93-94.

- i. Edwards-'535 teaches an array of multiple...[bipolar radiofrequency electrodes](#) disposed along the treatment surface of the [treatment element](#).

As discussed in limitation 1[c], Edwards-'535 discloses “[a plurality of energy delivery](#) devices...positioned on the surface of the [expandable member \[132\]](#).” Ex.1010-Edwards-'535, 8:17-32; *see also id.* 5:27-31, 7:33-40.

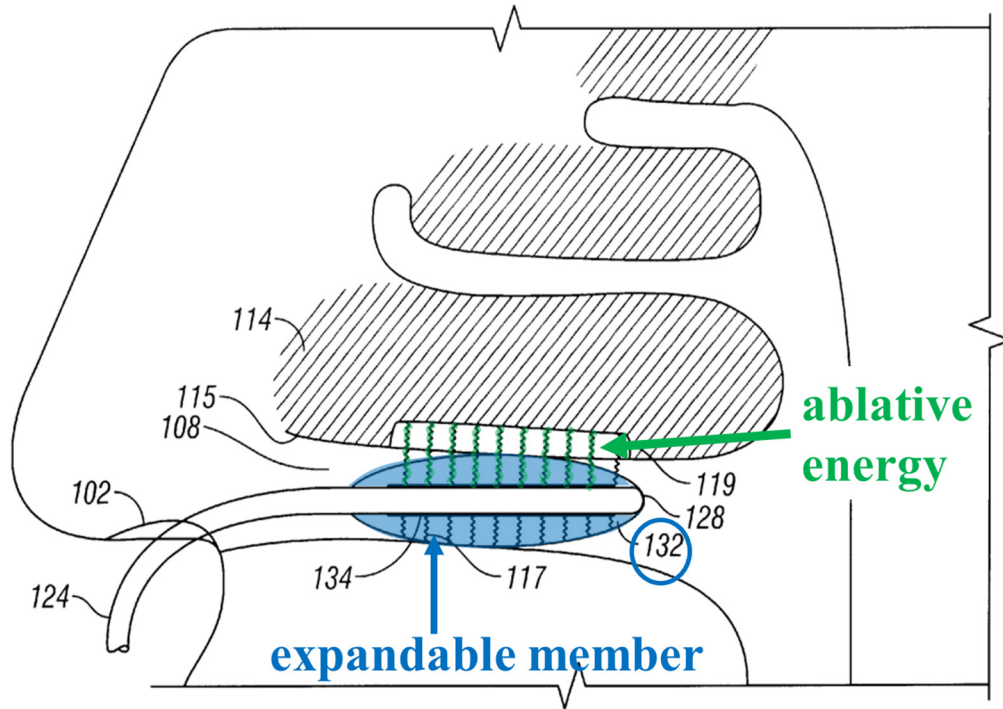


FIG. 3B

Id., FIG.3B. Ex.1002-Decl., ¶95.

For example, Edwards-'535 teaches that the energy delivery member can include multiple “ring electrodes 156,” *id.*, 8:19-33, and a POSITA would have been aware of a number of other surface energy delivery configurations. *See, e.g.*, Ex.1011-Baker, Abstract, 5:66-67, 9:13-23; Ex.1033-Stern, 2:26-35. These energy delivery device(s)/electrode(s) deliver RF energy in a bipolar mode. *Id.*, 8:17-32, 8:50-54, 10:30-32, 10:52-61. As shown in Figure 6, these energy delivery device(s)/electrode(s) are “disposed in parallel with their axes aligned with a long

axis 160 of the catheter body 126,” and are therefore placed in an *array*. *Id.*, 8:19-33.

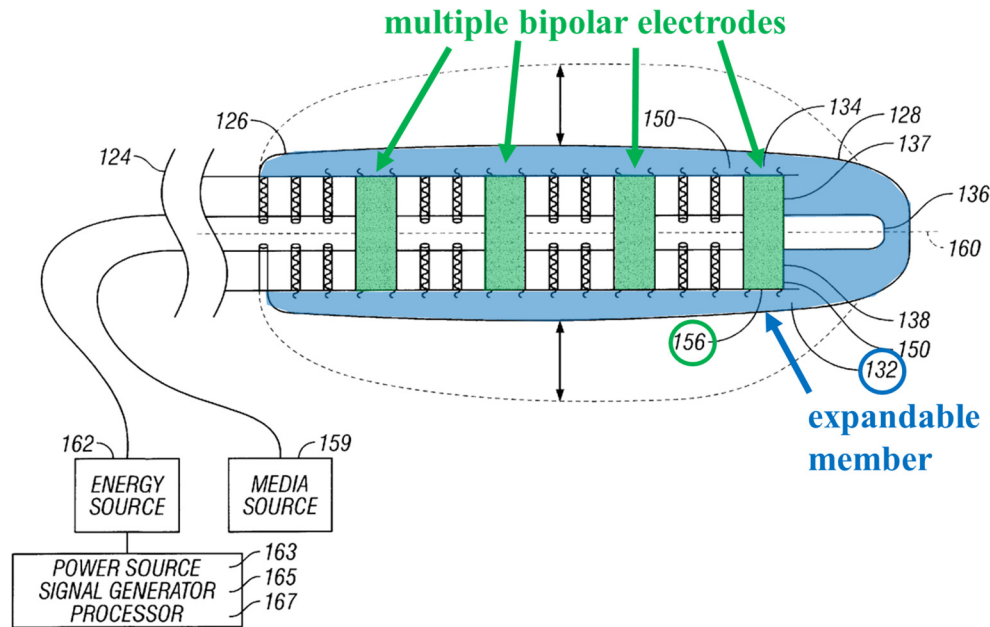


FIG. 6

Ex.1010-Edwards-’535, FIG.6. Ex.1002-Decl., ¶96.

Edwards-’535 leaves the details of how to deliver bipolar RF energy to the discretion and skill of a POSITA. *See id.*, 10:52-61. Ex.1002-Decl., ¶97.

- ii. Stern teaches an array of multiple *pairs of bipolar radiofrequency electrodes* disposed along the treatment surface of the treatment element.

Stern teaches “a system of selective delivery of...bipolar RF energy to chosen **pairs** of an array of separate [bipolar] electrodes.” Ex.1033-Stern, 2:36-40; *see also id.*, 3:29-40, 12:7-13:55, Clm.4, FIGs.13, 15, 17, 18. For example, Stern discloses placing an array of RF electrodes on the surface of its expandable member. *Id.*, 2:26-

35. Stern further teaches a mechanism for “selective delivery of...bipolar RF energy to chosen pairs [within the] array.” *Id.*, 2:36-40. Stern shows an example of a bipolar pair below:

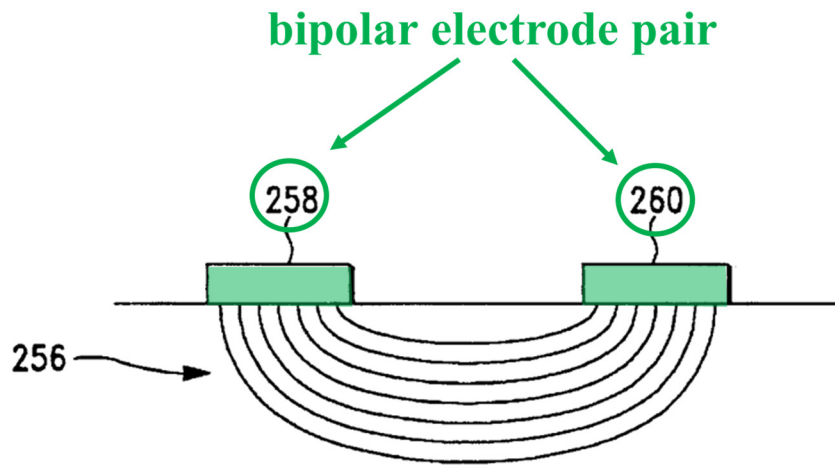


FIG. – 17

Id., FIG.17. Ex.1002-Decl., ¶98-100.

Stern’s Figure 15 shows that the circuitry to operate bipolar pairs includes four electrodes 220, 222, 224 and 226 and various switches that determine the type of bipolar configuration depending on which switch(es) are closed. Ex.1033-Stern, 12:41-45. As an example, “[i]f switch 248 and switch 238 are closed there will be bipolar operation between the electrodes 220 and 222.” *Id.*, 12:65-13:2.

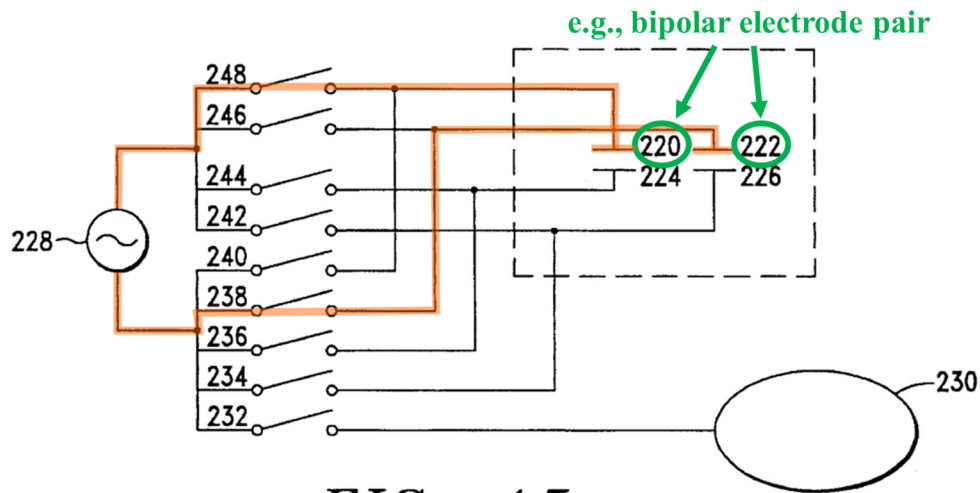


FIG. – 15

Id., FIG.15. Ex.1002-Decl., ¶101.

iii. Motivation to combine

Obviousness requires the references in a combination “are analogous to the claims being challenged,” and that a POSITA would have been motivated to combine the references with a reasonable expectation of success. *See Corephotonics, Ltd. v. Apple Inc.*, 84 F.4th 990, 1004 (Fed. Cir. 2023). Each is met here.

First, Edwards-’535 and Stern are analogous art to the Challenged Claims. All are in the same field as the ’318 patent and are reasonably pertinent to solving the problems addressed in the ’318 patent—treating tissue in a body cavity—with the same types of solutions—applying bipolar RF energy to tissue via an expandable device having surface electrodes. *See, e.g.*, Ex.1010-Edwards-’535, Abstract, 5:43-

51, 8:47-53, 10:25-31, 10:51-57; Ex.1033-Stern, Abstract, 1:15-23, 10:4-10, 10:40-65, 12:38-45. Ex.1002-Decl., ¶102, 114.

Second, a POSITA would have been motivated to combine Edwards-'535 and Stern with a reasonable expectation of success. Edwards-'535 demonstrates that RF ablation devices with multiple bipolar surface electrodes for use in body cavities were well-known. *See also, e.g.*, Ex.1021-Makower, [0187], [0001], [0131], [0164], FIG.5H. Although Edwards-'535 teaches that “energy...may be independently delivered to each [electrode],” Ex.1010-Edwards-'535, 8:18-25, and that its system can deliver “bipolar or monopolar energy,” *id.*, 10:52-57, Edwards-'535 omits details on how to implement such energy delivery. Thus, a POSITA would have been motivated to turn to other sources for information regarding how to implement independent energy delivery through each bipolar electrode. A POSITA would have found Stern to be a good source for this information given its detailed disclosure and schematic figures. Further, 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. Ex.1002-Decl., ¶103-105.

Edwards-'535 is ready for improvement as it leaves the specific implementation of pairing and wiring electrodes to the discretion and skill of a POSITA. *See id.*, 10:52-61. A POSITA would have been motivated to improve Edwards-'535's device with Stern's multiple pairs of bipolar electrodes because of the benefits Stern discloses. Ex.1002-Decl., ¶105-107.

Stern teaches that its bipolar RF surface electrodes pairing technique (described above) and wiring for independent delivery of RF energy to each bipolar pair (described above and in limitation 1[e]) provides numerous benefits. **First**, bipolar electrode pairs allow a physician to precisely control the location of electrical current delivered by the device. Ex.1033-Stern, 13:21-27, 12:26-37, FIGs.15, 18. **Second**, energizing electrodes in bipolar pairs directs heat to targeted tissue while ensuring that surrounding tissue is unaffected, especially where there is uneven (or heterogeneous) tissue morphology. *See id.*, 13:21-39, FIG.15. **Third**, pairs of bipolar electrodes facilitate uniform heating. *See id.*, 12:25-27 (“[I]t would be more precise to provide a more even heating of a uterus or other body organ if the electrode could have a controlled return path for the current.”). **Finally**, in view of the above, Stern teaches it would have been desirable to have more than one pair of bipolar electrodes to allow for selective tissue destruction over an entire area of tissue, as

opposed to a single discrete portion. *Id.* 2:6-19 (discussing “entire surface” of tissue), 6:44-62, 10:49-65. Ex.1002-Decl., ¶106-110.

These benefits are teachings, suggestions, and motivations that would have led a POSITA to modify Edwards-’535 in view of Stern to realize these same results in Edwards-’535’s device. Doing so would have simply involved using Stern’s known bipolar pairing technique to implement the missing details of Edwards-’535 in the way that Stern teaches, which would have been particularly desirable in the nose for increased safety, control, and even heating. Moreover, using Stern’s known bipolar pairing technique would have improved Edwards-’535’s similar device in the same way as Stern’s. Further, a POSITA would have been motivated to combine Edwards-’535 and Stern because it would have involved applying Stern’s known bipolar pairing technique to Edwards-’535’s known device that was ready for improvement (because Edwards-’535 omits details as to how to pair and wire the bipolar electrodes) to yield predictable results (detailed further below). Ex.1002-Decl., ¶111-113, 116.

Edwards-’535 and Stern each describe similar techniques of delivering bipolar RF ablation energy through expandable devices to mucosal tissue of different body cavities, such that their combination would have yielded predictable results. Ex.1010-Edwards-’535, 4:53-66, 5:21-23, 7:33-46, 7:61-8:46; Ex.1033-Stern, 1:16-

43, 7:38-8:38. In fact, Edwards-'535 and Stern each disclose delivering treatment in the same way, *e.g.*, by independently delivering RF energy to the different bipolar electrode pairs to adequately heat and ablate tissue. Ex.1010-Edwards-'535, 5:36-44, 6:9-22, 8:17-25; 9:1-44, 10:18-32; Ex.1033-Stern, 10:48-65. Thus, their combination would have been straightforward and yielded predictable results. Ex.1002-Decl., ¶113-115.

A POSITA would have had a reasonable expectation of success in implementing Stern's bipolar RF electrode *pairs* and individual output channels in Edwards-'535's device given that, as explained above, Edwards-'535 omits details as to particular circuitry and therefore recognizes it was within a POSITA's skill to design a system to independently deliver RF energy to different electrodes. Ex.1002-Decl., ¶113-116.

Moreover, in the combination, the known techniques of Stern would have been used to improve Edwards-'535's similar device in the same way because Stern discloses a way to pair surface bipolar surface RF electrodes, like those in Edwards-'535, and wire such electrodes for independent energy delivery. Ex.1033-Stern, 2:49-53, 12:25-27, 13:21-39; Ex.1010-Edwards-'535, 8:19-33. Thus, Stern's teachings would have been applied to Edwards-'535 in the same way those teachings are used in Stern itself. Additionally, a POSITA would have had reasonable

expectation of success because Edwards-'535 points a POSITA to references that have similar attributes as Stern. *See* Ex.1010-Edwards-'535, 8:25-33 (incorporating USP 5,575,788 to Baker). *Compare* Ex.1011-Baker, Abstract, 5:67, 9:13-23, FIGs.8-9, *with* Ex.1033-Stern, 2:26-35. A POSITA would have known that technology from ablation devices for one part of the body would be applicable to devices used in other areas of the body. *See, e.g.,* Ex.1033-Stern, 18:27-40. Ex.1002-Decl., ¶117-121.

Accordingly, applying Stern's teachings to Edwards-'535 would have been a matter of routine implementation well within the skill of a POSITA and would have yielded predictable results—*e.g.,* Edwards-'535's device having bipolar RF electrode pairs, as taught by Stern—with a reasonable expectation of success. Ex.1002-Decl., ¶121-122.

f. 1[e]

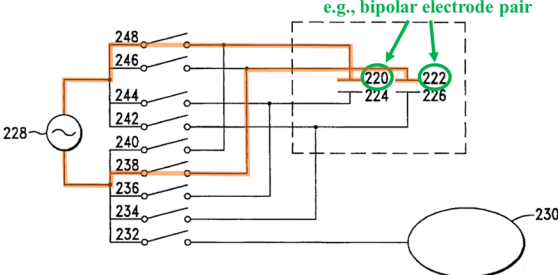
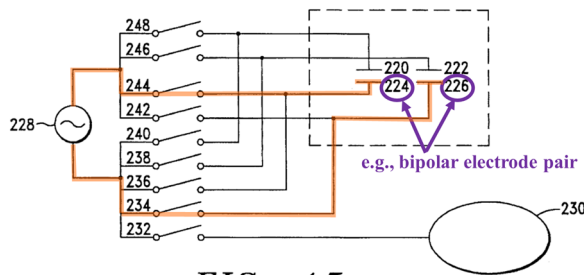
Edwards-'535 in view of Stern renders obvious *multiple radiofrequency output channels* (*e.g.,* energy output shown in orange in Figure 15 in Stern) *connected with the multiple pairs of bipolar radiofrequency electrodes* (*e.g.,* one pair shown in green and another pair shown in purple), *wherein each pair of the multiple pairs of bipolar radiofrequency electrodes is connected with a respective one of the*

multiple radiofrequency output channels (e.g., shown in Figure 15 in Stern).

Ex.1033-Stern, FIG.15. Ex.1002-Decl., ¶123-124, 126.

As explained above for limitation 1[d], Edwards-'535 omits details on how to pair and wire bipolar electrodes to deliver RF energy. *See* Ex.1010-Edwards-'535, 8:17-32, 10:52-61. A POSITA would have been motivated to look to Stern, which describes implementation details regarding how to pair bipolar electrodes and independently deliver energy to such pairs to carry out Edwards-'535's stated goal of independent bipolar energy delivery. Ex.1033-Stern, Abstract, 1:16-23, 2:36-40, 3:12-40, 11:29-46, 12:38-45, Clm.4. Ex.1002-Decl., ¶125.

Figure 15 of Stern shows circuitry capable of supplying energy to selected bipolar pairs via a “switching means” where each bipolar pair is wired to its own output channel. Ex.1033-Stern, 2:49-53, 3:12-29, Clm.1, FIG.15. Ex.1002-Decl., ¶124, 127.

Ex.1033-Stern, FIG.15 e.g., one pair of bipolar RF electrodes connected with an output channel	Ex.1033-Stern, FIG.15 e.g., another pair of bipolar RF electrodes connected with an output channel
 FIG. - 15	 FIG. - 15

To accomplish independent activation of each electrode pair, Stern's switching scheme connects each bipolar pair to voltage source 228 via separate output channels. Ex.1033-Stern, 12:46-13:2. When particular switches are closed, only the connected bipolar pair(s) are activated. *Id.* Stern's teaching of various **output channels** are *output channels* as required by the claim because the channels are separately/individually connected to the electrodes.⁸ For example, Stern

⁸ In addition to disclosing output channels within the device itself, Edwards-'535 and Stern disclose RF generators that would include two ports for active and return signals, as is necessary to operate a device in bipolar mode. Ex.1010-Edwards-'535, 8:18-33, 9:11-22, 11:24-44; Ex.1033-Stern, 10:43-48. Ex.1002-Decl., ¶128, n.4.

discloses “electrical leads” “by way of connectors 50” that connect the output of electrode switch bank 54 to the electrodes on the device. *Id.*, 8:66-9:6, FIG.5. Such connectors would have also been included in the bipolar embodiment of Figure 15. *Id.*, FIG.15, 12:38-13:2 (describing operation of switches similar to those in bank 54 of Figure 5). Ex.1002-Decl., ¶128.

A POSITA would have been motivated to combine Edwards-’535 and Stern for the same reasons provided in limitation 1[d]—because it involves applying a known technique (pairing and wiring electrodes taught by Stern), to a known device (Edwards-’535’s inflatable RF ablation device) that was ready for improvement (because Edwards-’535 omits details as to how to pair and wire the bipolar electrodes) to yield predictable results. A POSITA would have been motivated to incorporate Stern’s teachings of output channels to control individual pairs of bipolar RF electrodes for the same reasons provided for limitation 1[d]—for example, to provide for local and even temperature control when ablating tissue and because Stern discloses a simple option for bipolar energy delivery and control out of a finite number of options. Ex.1002-Decl., ¶129-148.

Further, a POSITA would have had a reasonable expectation of success as the combination results in predictable results discussed in limitation 1[d], including the ability to finely control where heat is being applied. Ex.1002-Decl., ¶129-148.

g. 1[f]

Edwards-'535 discloses *multiple sensors* (e.g., *impedance sensors* and/or *temperature sensors*, among others) *on the tissue treatment surface* (e.g., on the surface of expandable member 132), *the multiple sensors are selected from the group consisting of impedance sensors* (e.g., impedance sensors), *electrodes, and thermocouples* (e.g., thermocouples). Ex.1002-Decl., ¶149-150.

First, Edwards-'535 discloses *multiple sensors* (e.g., *impedance sensors* and/or *temperature sensors, among others*). Edwards-'535 explains that *sensors* can be used “to monitor the amount of energy delivered and the amount of heat generated,” Ex.1010-Edwards-'535, 9:14-18, and can “detect a variety of operating parameters including the amount of energy delivered, the impedance generated, and the temperature of a region adjacent the apparatus.... In addition, chemical or biochemical *sensors* can be used to detect ablation.” *Id.*, 9:14-23, FIG. 8. Edwards-'535 does not condition impedance measurements on monopolar embodiments, *id.*, 9:14-23, 10:4-11, 10:26-11:45, and Edwards-'535's disclosure of impedance sensing

is equally applicable when arranging such electrodes in one or more bipolar pairs, as Stern teaches. Ex.1002-Decl., ¶151.

Second, Edwards-'535 discloses that the *multiple sensors* are *on the tissue treatment surface* (e.g., on the surface of expandable member 132). Edwards-'535 explains that “[a] variety of positionings for the sensors are possible” and can be “coupled to the expandable member.” Ex.1010-Edwards-'535, 9:43-45. Because the expandable member has a tissue treatment surface, *see supra* §X.A.1.d, Edwards-'535 therefore teaches that sensors are *on the tissue treatment surface*. *See also* Ex.1010-Edwards-'535, 9:14-23 (discussing measuring “temperature of a region adjacent the apparatus,” which would require measurement from the tissue treatment surface). Ex.1002-Decl., ¶152.

Furthermore, a POSITA would have been motivated to place such sensors on the tissue treatment surface (*i.e.*, on *expandable member 132*) to obtain an accurate local temperature reading. Edwards-'535 explains that the sensors can be “used to[] maintain[] tissue adjacent to an energy delivery device at a desired temperature for a selected period of time without impeding out.” Ex.1010-Edwards-'535 9:64-10:1. That is, placing the temperature sensors anywhere else other than where the *expandable member 132* contacts tissue could result in an inaccurate temperature reading, which would result in less reliable fine-scale control of ablation. Further,

temperature sensors placed on the tissue treatment surface of an ablation device were well-known as of the priority date of the '318 patent. *See, e.g.*, Ex.1033-Stern, 7:49-61 (teaching that “temperature sensors 32 are conventional thermistors or **thermocouples** and are positioned on the zones of the balloon which will contact areas of the [tissue] surface.”). Ex.1002-Decl., ¶153.

Third, Edwards-'535 teaches that *the multiple sensors are selected from the group consisting of impedance sensors, electrodes, and thermocouples*. As described above, Edwards-'535 teaches that “sensors can...detect a variety of operating parameters including...the impedance generated,” and therefore teaches using *impedance sensors*. Edwards-'535 teaches **impedance sensing** based on the current delivered to the electrodes on the surface of the device. Ex.1010-Edwards-'535, 9:14-18, FIG.8. With reference to Figure 8, Edwards-'535 explains that “current...delivered through energy delivery device 189 is measured by current sensor 190. Voltage is measured by voltage sensor 192. **Impedance** and energy are then calculated at energy and **impedance** calculation device 194.” *Id.*, 10:4-11.

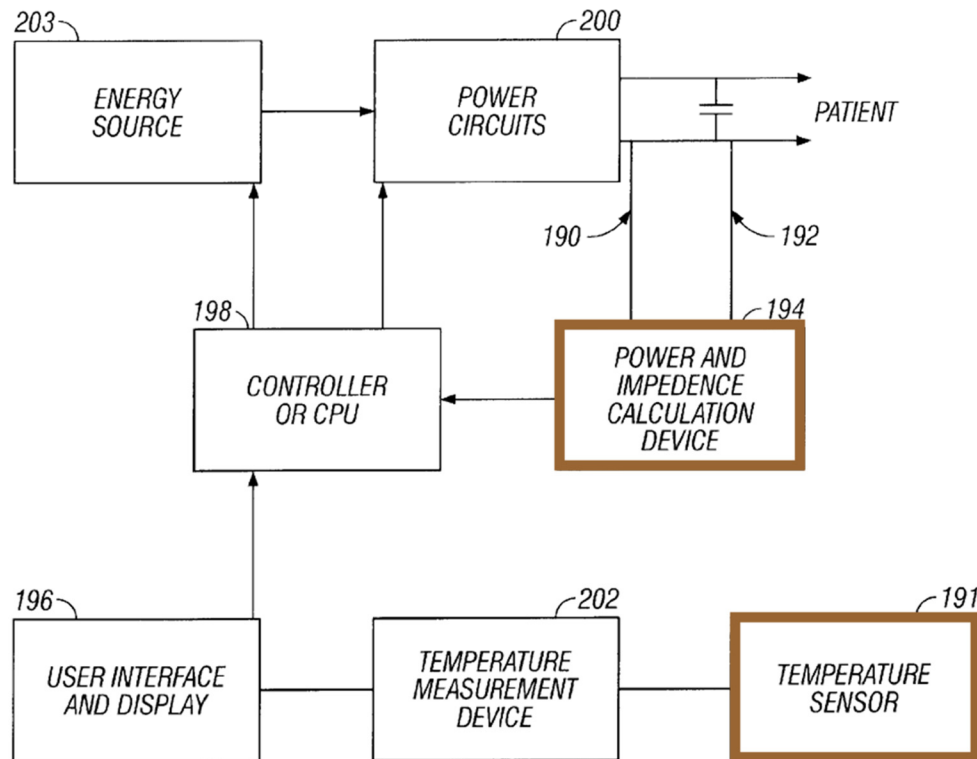


FIG. 8

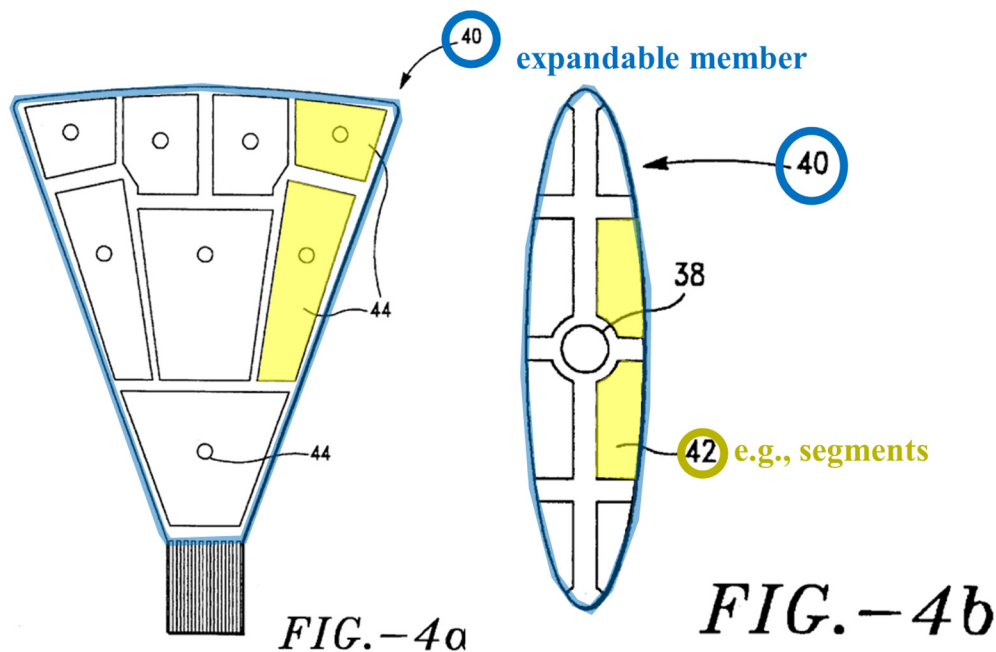
Ex.1010-Edwards-'535, FIG.8. Edwards-'535 also teaches using “at least one temperature sensor, such as a *thermocouple*.” *Id.*, 9:24-25. Ex.1002-Decl., ¶154.

Edwards-'535 explains that its sensors, including its temperature sensors are part of a feedback control system where the processor uses the sensed values to “control the delivery of RF energy to achieve delivery of a selected amount of energy, to achieve a selected temperature, or to achieve a selected amount of ablation of a section of a nasal concha.” *Id.*, 9:34-44. Ex.1002-Decl., ¶155-156.

2. Claim 4

Edwards-'535 in view of Stern discloses that the *treatment element* (e.g., expandable member 132 in Edwards-'535) comprises multiple segments (e.g., a plurality of surface segments 42 in Stern) that are expandable from the first configuration (e.g., the surface segments are compressed along with the expandable member when inserted into the body) to the second configuration (e.g., the surface segments are expanded along with the expandable member when deployed). Ex.1002-Decl., ¶157-159.

Stern discloses “using a balloon 40 with a plurality of surface segments 42 as the expandable bladder member” and that “[e]ach of the surface segments has a conductive surface and a temperature sensor.” Ex.1033-Stern, 8:48-66.



Id., FIGs.4a, 4b. Ex.1002-Decl., ¶160-161.

Stern explains that “[e]ach segment 42 is electrically connected through conventional leads to a power source” “to permit controlled delivery of power to each segment.” Ex.1033-Stern, 8:53-59. As shown below, Edwards-’535’s expandable member 132 is segmented in the same way as Stern:

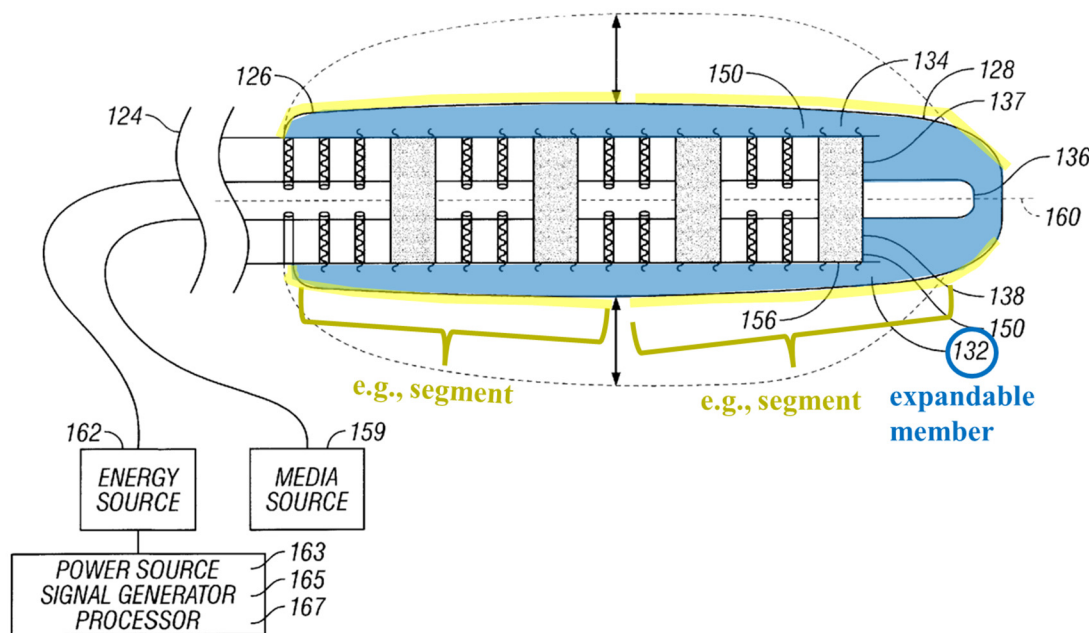


FIG. 6

Ex.1010-Edwards-’535, FIG.6. Ex.1002-Decl., ¶163.

As explained with reference to limitation 1[d], Edwards-’535 instructs a POSITA that its device can independently delivery energy to electrodes but omits detail regarding how to accomplish independent energy delivery. *Id.*, 8:17-32, 10:30-32, 10:52-61. A POSITA would have been motivated to segment Edwards-’535’s

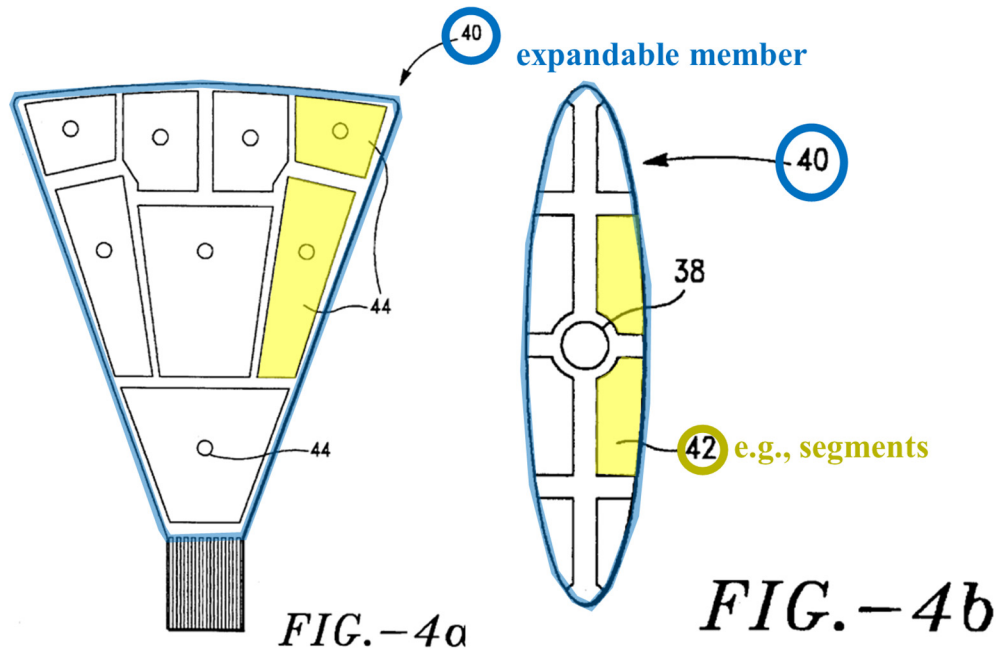
expandable member “to permit controlled delivery of power to each segment” as taught by Stern, for the same reasons as discussed in limitation 1[d]-1[f]. Ex.1033-Stern, 8:53-59. Indeed, such segmented devices were well known. *See, e.g.*, Ex.1021-Makower [0187], FIG.5H. A POSITA would have had a reasonable expectation of success to segment Edwards-’535’s expandable member 132 as taught by Stern to allow controlled delivery of power to each segment because doing so would have improved Edwards-’535’s expandable member 132 in the same way, to connect each segment to a power source for independent RF energy delivery and providing local temperature control. *See supra* §X.A.1.f; Ex.1010-Edwards-’535, 4:53-66. Ex.1002-Decl., ¶164-165.

3. Claim 5

Edwards-’535 in view of Stern discloses that *at least one pair of multiple pairs of bipolar radiofrequency electrodes (e.g., a plurality of bipolar energy delivery devices in Edwards-’535 controlled as pairs as taught by Stern) is coupled with each of the multiple segments (e.g., a plurality of surface segments 42 in Stern)*. Ex.1002-Decl., ¶166-167.

As discussed with respect to limitation 1[d], Stern teaches pairing multiple bipolar RF electrodes, where the pairs can be selectively powered via the circuitry

of Figure 15. Likewise, Stern discloses a plurality of surface segments on the expandable member. Ex.1033-Stern, 8:53-59.



Id., FIGs.4a, 4b. Ex.1002-Decl., ¶168.

Stern describes these segments as “electrode area segments,” Ex.1033-Stern, Abstract, and that power can be selectively provided to these segments via the circuitry of Figure 15. *Id.*, 5:48-51. Therefore, Stern teaches that the segments include at least one pair of the multiple pairs of bipolar RF electrodes, and therefore at least one pair of the multiple pairs of electrodes are coupled to at least one segment. Ex.1002-Decl., ¶169-170.

As explained above for claim 4, a POSITA would have been motivated to use the electrode configuration of Stern with Edwards-’535’s expandable member to

independently deliver energy to electrodes and would have had a reasonable expectation of success in doing so. Ex.1002-Decl., ¶171-172.

4. Claim 9

a. 9[a]

The combination of Edwards-'535 with Stern discloses *a radiofrequency generator (e.g., signal generator 165 in Edwards-'535 and/or RF generator 158 in Stern) configured to receive sensed signals from the multiple sensors (e.g., Edwards-'535's impedance sensors and/or thermocouples) and deliver radiofrequency energy separately to each of the multiple radiofrequency output channels (e.g., selective control of electrodes in Edwards-'535 implemented by multiple RF output channels as taught by Stern) in the form of a 460 KHz sinusoid wave (e.g., Stern's "radio frequency power means for selectively providing current to said electrode means at a frequency greater than 250 kHz.")*. Ex.1002-Decl., ¶173-175.

As discussed above for limitation 1[f], Edwards-'535 teaches a feedback control system where a "processor reads [a] sensor value from the sensor and, responsive thereto, controls the signal generator so as to achieve delivery of an effective amount of RF energy to a desired section of tissue to be ablated. The processor thus uses the signal generator...energy delivery device, and temperature sensor, as a feedback loop for controlled delivery of RF energy to a section of a nasal

concha.” Ex.1010-Edwards-’535, 9:1-44. Thus, Edwards-’535 teaches *a radiofrequency generator (i.e., signal generator) that receives sensed signals from the multiple sensors and delivers radiofrequency energy.* Ex.1002-Decl., ¶176.

As 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.* Edwards-’535 teaches that “energy may be independently delivered to each [electrode pair]” and but omits details regarding to how implement the circuitry for independent energy delivery. *Id.*, 8:22-25. Stern provides those details, using *multiple radiofrequency output channels* and teaching a similar feedback control loop to Edwards-’535 where “RF electrodes are separately, independently and sequentially energized with thermistor temperature feedback to bring the [tissue] temperature up to a desired level.” Ex.1033-Stern, 10:48-52. That is, Stern explains that these are further details of the disclosed technique for precisely and evenly heating target tissue. Thus, a POSITA would have been motivated to combine these aspects of Edwards-’535 and Stern to achieve the same benefits and would have had a reasonable expectation of doing so as discussed in limitation 1[d]-[f]. Ex.1002-Decl., ¶177.

Lastly, Stern discloses applying RF energy in a range of frequencies including a *460 KHz wave* across multiple channels. For example, Stern discloses that “[t]he

RF current has a frequency of at least 250 kHz and less than 100 MHz,” which includes 460 kHz. Ex.1033-Stern, 2:18-20, 3:15-20, Clm.1. Ex.1002-Decl., ¶178.

Although Edwards-’535 teaches that RF energy is “preferably” in the MHz range, it would have been obvious to apply RF energy with the device of Edwards-’535 at 460 kHz as taught by Stern, as such a frequency was known to deliver RF energy to adequately ablate tissue. Ex.1033-Stern, 2:18-20; 3:15-20, Clm.1. Indeed, most RF ablation devices used in the body operate at a frequency of about 460 kHz—including another reference to the same Edwards that teaches a generator that supplies RF energy “with a sinusoidal waveform at 460 kHz.” Ex.1016-Edwards-’886, 36:66-37:2; *see also* Ex.1050-Hong, S181; Ex.1052-Sackenheim, 90; Ex.1053-Bronzino, 63-4, Table.63-4, Tbl.63.3; Ex.1054-Koyyalagunta, 4; Ex.1051-Haemmerich, 53. Ex.1002-Decl., ¶179-180, 182.

A POSITA would have been motivated to use a frequency of 460 kHz as taught by Stern to deliver RF energy using Edwards-’535’s device because such a frequency balances the ability to deliver RF energy with energy loss in the circuit. The higher the frequency, the easier it is for the RF energy to travel through the tissue (*i.e.*, the lower the impedance). *See, e.g.*, Ex.1035-Philippson, 3, FIG.2. But the relationship between frequency and impedance is logarithmic, meaning that the benefits of reduced impedance are marginal as the frequency approaches the MHz

range. *Id.* Conversely, as the frequency range approaches MHz levels, it becomes increasingly difficult for the transmitted energy to travel from the generator to the electrodes, and then to the tissue. This is because high frequency cables act like an antenna at high frequency, dissipating energy from the generator elsewhere before it reaches the delivery device. Likewise, due to skin effects, high frequency currents travel closer to the cable surface, using less space and therefore creating more resistance. Based on these considerations, a POSITA would have known that a frequency in the kHz range would be the most desirable to ensure reduced impedance of tissue while avoiding the challenges associated with delivering energy at higher frequencies. Selecting a number from this range would have been a matter of routine experimentation and optimization. Stern discloses using bipolar RF energy for the same purposes as Edwards-'535—to ablate tissue. Because Edwards-'535 and Stern both relate to similar devices (inflatable energy delivery devices) which apply RF energy to a body cavity to ablate tissue, a POSITA would have been motivated to perform ablation in the same way and would have a reasonable expectation of success because such a modification simply involves applying a known RF energy waveform using known equipment. Additionally, a POSITA would have understood that mucosal tissue lining different body cavities would have similar properties and

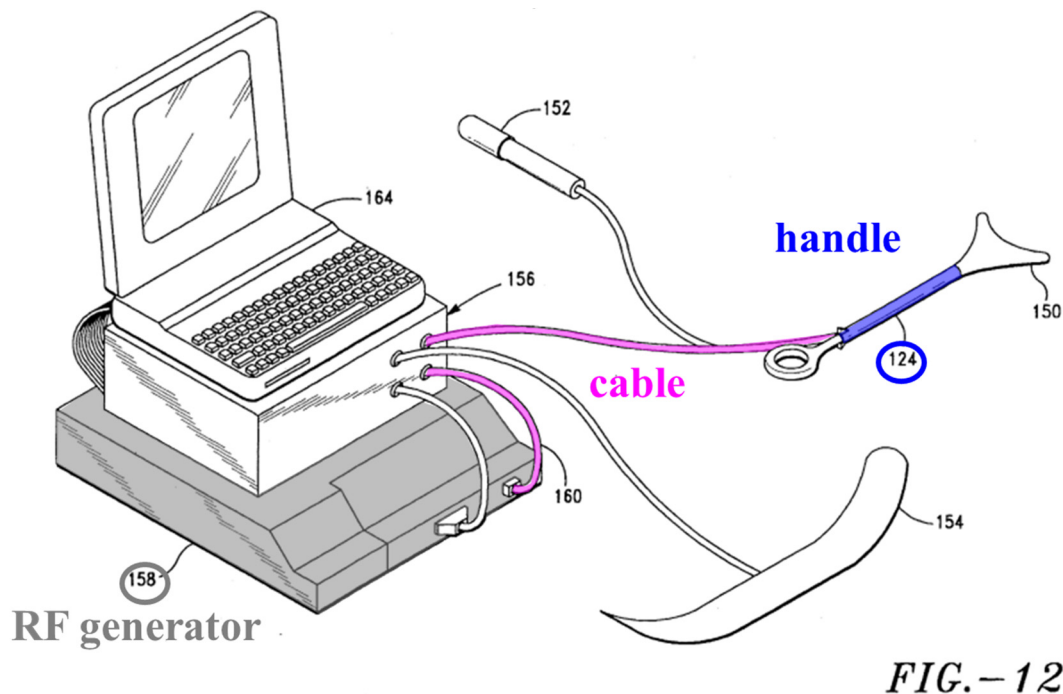
would therefore behave similarly when ablated at a frequency in the kHz range. Ex.1002-Decl., ¶181-182.

Second, A POSITA would have also understood Stern’s disclosure of a 460 kHz wave to be a *sinusoid* wave, or found it obvious to implement the signal as such. A pure sine wave is the most common output of a RF generator. Furthermore, all wave forms output by RF generators include a component in the form of a sine wave, and are therefore considered *sinusoid* waves. See Ex.1062-Sedra, 1-3. Indeed, Edwards-’535 recognizes that sine waves are one of a few suitable options for use with its device. Ex.1010-Edwards-’535, 8:54-60; see also Ex.1016-Edwards-’886, 36:66-37:3. Faced with such limited options, a POSITA would have found it obvious to choose a sine wave, which is the most simple and well-known alternating signal. Ex.1002-Decl., ¶184-185.

The ’318 patent does not disclose anything critical about ablation at 460 kHz sinewave—it is described as just one “example” from the entire RF range. Ex.1001-USP318, 34:35-39. Thus, selecting an appropriate frequency for ablation would have involved mere routine optimization from a range disclosed by Stern. *E.I. duPont de Nemours & Co. v. Synvina C.V.*, 904 F.3d 996 (Fed. Cir. 2018). Ex.1002-Decl., ¶183.

b. 9[b]

Edwards-'535 in view of Stern renders obvious *a cable* (e.g., *interference cables 160*) *coupled to the handle* (e.g., *application device 124*) *for plugging the handle into the radiofrequency generator* (e.g., cables 160 connect the RF generator 158 to controller 156, which is connected to application device 124).



Ex.1033-Stern, FIG.12. Ex.1002-Decl., ¶186-188.

Providing a handle with a cable to couple to the RF generator in Edwards-'535 as taught by Stern would have been obvious and predictable for the same reasons discussed above for limitations 1[a], 1[e], and 9[a]. Ex.1002-Decl., ¶189-190.

5. Claim 10

Edwards-'535 discloses that the *radiofrequency generator* (e.g., signal generator 165) *is configured to run at a power of between 5 and 75 watts* (e.g., “RF energy delivered to the nasal concha is [preferably] sufficient to deliver **between about 5 and about 30 watts** of RF energy to at least a portion of the nasal concha being treated,” Ex.1010-Edwards-'535, 5:48-51. Because Edwards-'535 discloses a range of power within the claimed range, Edwards-'535 in view of Stern discloses this limitation. *See Titanium Metals Corp. v. Banner*, 778 F.2d 775,782 (Fed. Cir. 1985). Ex.1002-Decl., ¶191-194.

6. Claim 12

Edwards-'535 in view of Stern renders obvious that the *radiofrequency electrodes comprise non-penetrating electrodes*. For example, Edwards-'535 describes electrodes that contact the nasal concha, but do not penetrate the tissue. Ex.1010-Edwards-'535, 4:53-66. Edwards-'535 emphasizes that the disclosed treatment is performed “without damaging the surface of the nasal concha.” *Id.*, 4:53-66; 6:67-7:2. This is shown in Figure 3C of Edwards-'535:

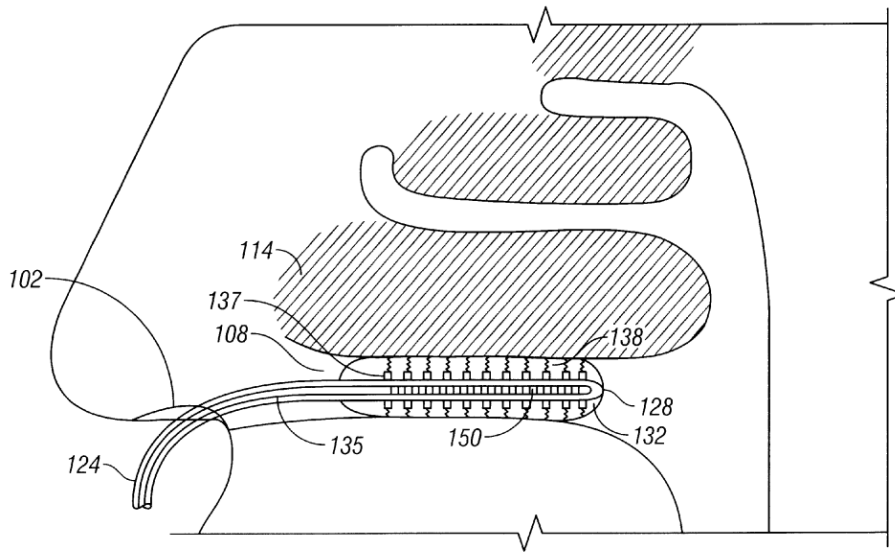


FIG. 3C

Id., FIG.3C. Ex.1002-Decl., ¶195-197.

Further, the ring electrodes of Edwards-’535 and the surface-mounted electrodes of Stern both appear flat and incapable of penetrating tissue. Ex.1010-Edwards-’535, 8:19-33; Ex.1033-Stern, 2:36-40, 3:29-40, 12:7-13:55, FIGs.13, 15, 17, 18. Ex.1002-Decl., ¶198-199.

Like Edwards-’535, Stern describes “[e]lectrical contact between the conductive surface of the electrodes 34 and the [tissue to be ablated].” Ex.1033-Stern, 7:67-8:3; *see also id.*, 1:30-35, 17:10-15, Clms.1, 3. Further, Stern teaches that when the expandable member 12 is expanded, it will contact the lining to be destroyed. *Id.*, 8:32-36. Accordingly, a POSITA would have understood the

electrodes of Edwards-'535, along with the electrodes of Stern, to be *non-penetrating electrodes*. Ex.1002-Decl., ¶200-202.

7. Claim 13

Edwards-'535 in view of Stern renders obvious that *the multiple pairs of bipolar radiofrequency electrodes* (e.g., bipolar electrode pairs 220 and 222 and/or bipolar electrode pairs within each segment of the multi-segment balloon in Stern), *the multiple radiofrequency output channels* (e.g., shown in orange in FIGs.5 and 15 in Stern) and *the multiple sensors* (e.g., thermocouples in Edwards-'535 and/or Stern) are organized into multiple subsystems, and wherein each of the multiple subsystems comprises one of the multiple pairs of bipolar radiofrequency electrodes, one of the multiple radiofrequency output channels and one of the multiple sensors. Ex.1002-Decl., ¶203-205.

As explained in limitation 1[f], Edwards-'535 teaches temperature feedback control systems, and discloses advantages of providing temperature feedback and control for individual electrodes. See Ex.1010-Edwards-'535, 9:11-12:5. Stern teaches similar temperature feedback control, explaining that the “expandable member includes a thin bladder having an array of separate electrodes on one surface and further having...a thermistor associated with each separate electrode in order to provide a feedback temperature for each electrode. The plurality of separate

electrodes are [each] independently and sequentially energized and controlled with thermistor temperature feedback control to bring the [tissue] temperature to a desired level.” Ex.1033-Stern, 2:26-40, 10:48-65. Ex.1002-Decl., ¶206.

Stern discloses *multiple subsystems, and wherein each of the multiple subsystems comprises one of the multiple pairs of bipolar radiofrequency electrodes (e.g., bipolar electrode pairs 220 and 222), one of the multiple radiofrequency output channels (shown in orange in Figures 5 and 15) and one of the multiple sensors (e.g., thermocouples in Edwards-’535 and/or Stern).* As shown below, Figure 5 of Stern discloses a monopolar configuration having one *electrode (ELECTR1), one output channel, and one thermistor.* Ex.1033-Stern, 2:26-35, 2:59-65, 3:12-28, 4:45-55, 5:15-20, 7:39-60, 8:48-60, 9:1-10, 10:49-65, 11:25-30, 15:11-31, 18:1-13.

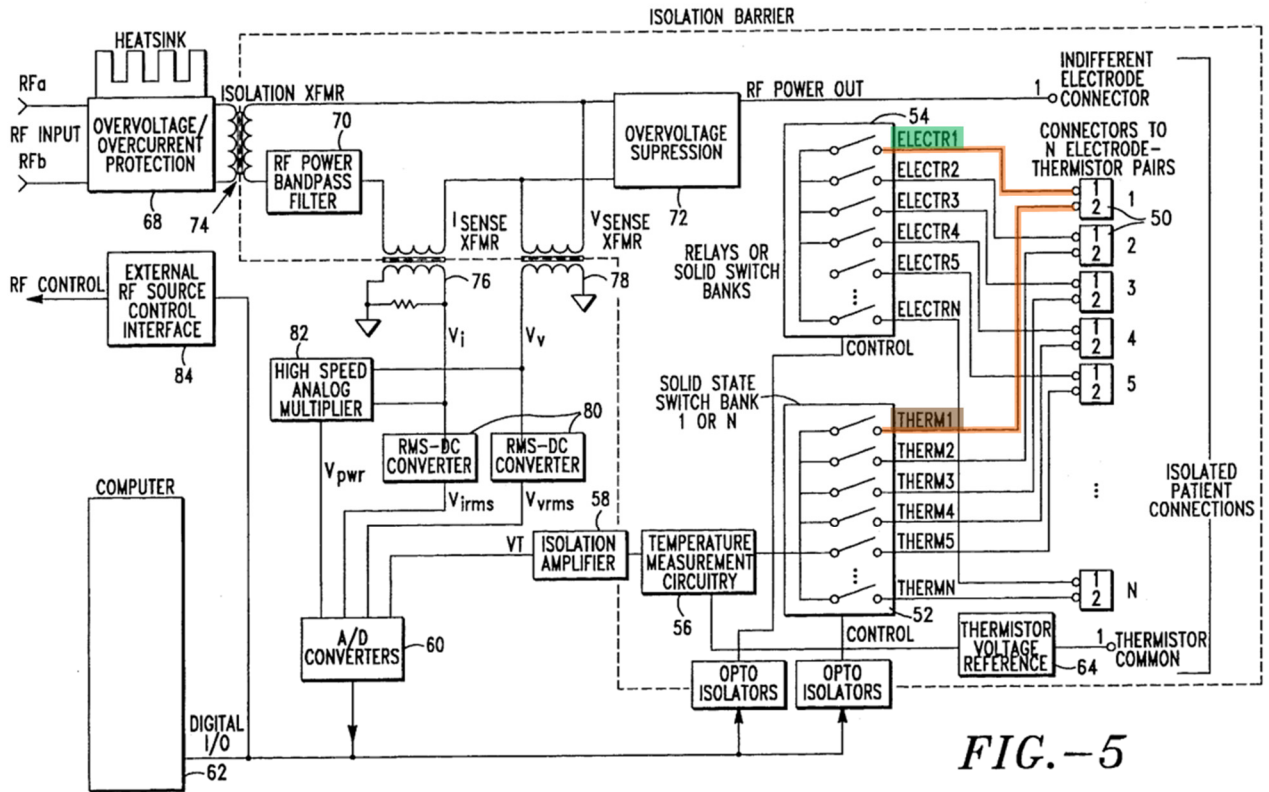


FIG.-5

Id., FIG.5. Ex.1002-Decl., ¶207.

As shown below, Figure 15 of Stern discloses a bipolar configuration having bipolar **electrode pairs** (e.g., electrodes 220 and 222), and one **output channel**.

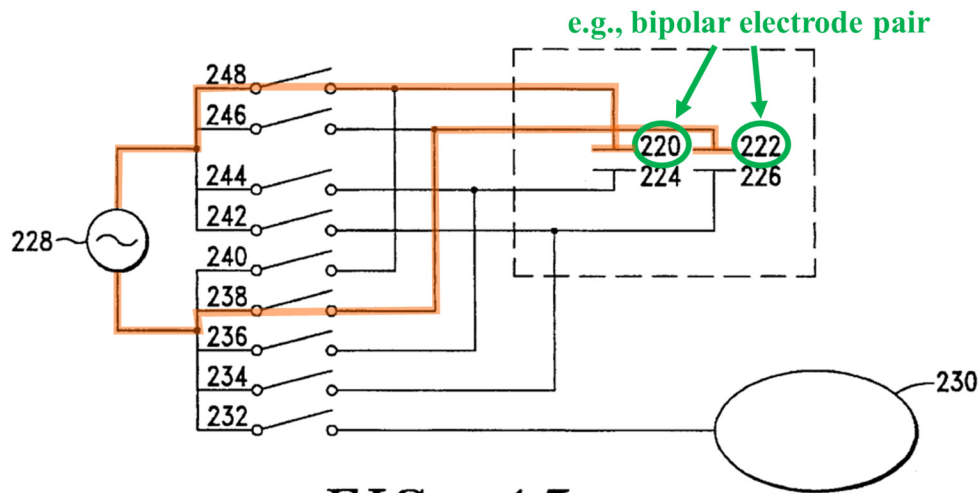


FIG. – 15

Id., FIG.15. Ex.1002-Decl., ¶208.

Stern teaches that the monopolar embodiment of Figure 5 can be combined with the bipolar configuration of Figure 15. While describing the monopolar configuration of Figure 5, Stern explains that heating depends on the return path of the current, which is dictated by the placement of the return patch. Stern explains that “improved control can be achieved...if a bipolar operation is utilized,” where the current flows between “selected pairs of the electrodes.” Ex.1033-Stern, 11:20-27; 12:8-24. That bipolar mode is discussed with reference to Figure 15. Stern therefore provides a teaching, suggestion, or motivation that would have led one of ordinary skill to modify the circuitry of Figure 5 to include bipolar pairs having respective output channels, and explains the benefit of doing so. Such a modification would require nothing more than adding switches and wires to selectively connect

the electrodes in pairs with a generator as in Figure 15 so they can be controlled in a bipolar mode, as contemplated by Stern for Figure 5. Indeed, Stern teaches that each thermistor and electrode can have its own power lead and that such circuitry is “well known.” *Id.*, 11:20-27. Ex.1002-Decl., ¶209.

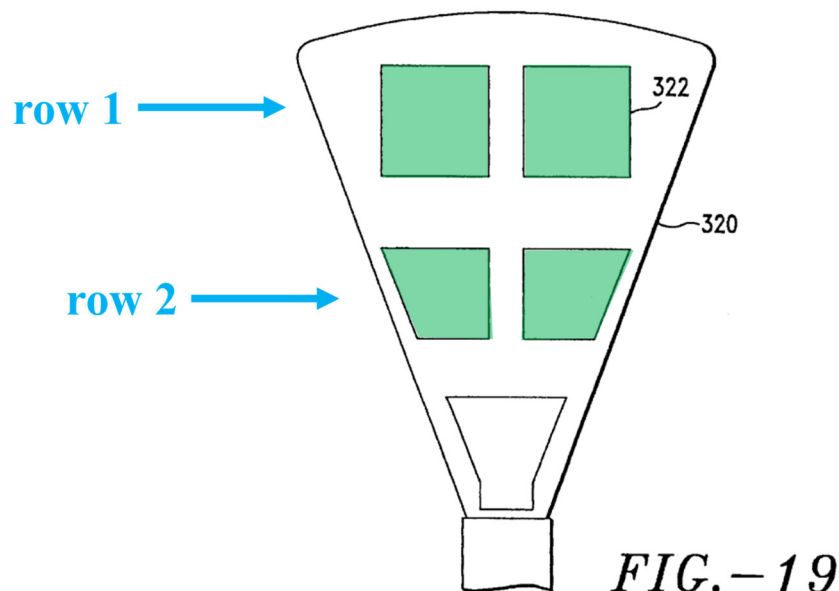
A POSITA would have found it obvious to modify the Edwards-’535 and Stern combination set forth above for claim 1, *see supra* §§X.A.1.a-g, to organize the bipolar RF electrodes, output channels, and sensors into multiple subsystems and reasonably expected success for the same reasons provided above for limitations 1[d]-1[f]. Such a combination involves applying a known technique (Stern’s subsystems connecting a pair of bipolar electrodes with an output channel and a sensor) to a known device (Edwards-’535’s energy delivery device) ready for improvement (Edwards-’535’s silence regarding independent energy delivery) to yield predictable results (independent feedback and control systems for each bipolar pair). Indeed, configuring the circuitry of an RF ablation device to include multiple subsystems was well known long before 2011. *See, e.g.*, Ex.1011-Baker Abstract (dividing electrodes into individually controlled “zones”), 9:13-56, 11:6-27, 11:33-39, 12:7-53, FIGs.8-10, 13-14; Ex.1012-Goble, 2:11-22 (describing “multiplexer for independently controlling the delivery of power to individual electrodes”), 8:46-57,

FIG. 8. The '318 patent does not provide any detail beyond what someone skilled in the art would know. Ex.1002-Decl., ¶210-211.

8. Claim 15

Edwards-'535 in view of Stern discloses or renders obvious that the *multiple pairs of bipolar radiofrequency electrodes comprise two rows of electrodes*. Ex.1002-Decl., ¶212-214.

Stern teaches that “a plurality of **electrodes 322** are formed on the surface of the bladder 320.” Ex.1033-Stern, 14:26-38. For example, as shown in Figure 19 below, the **electrodes 322** are arranged in *two rows*:



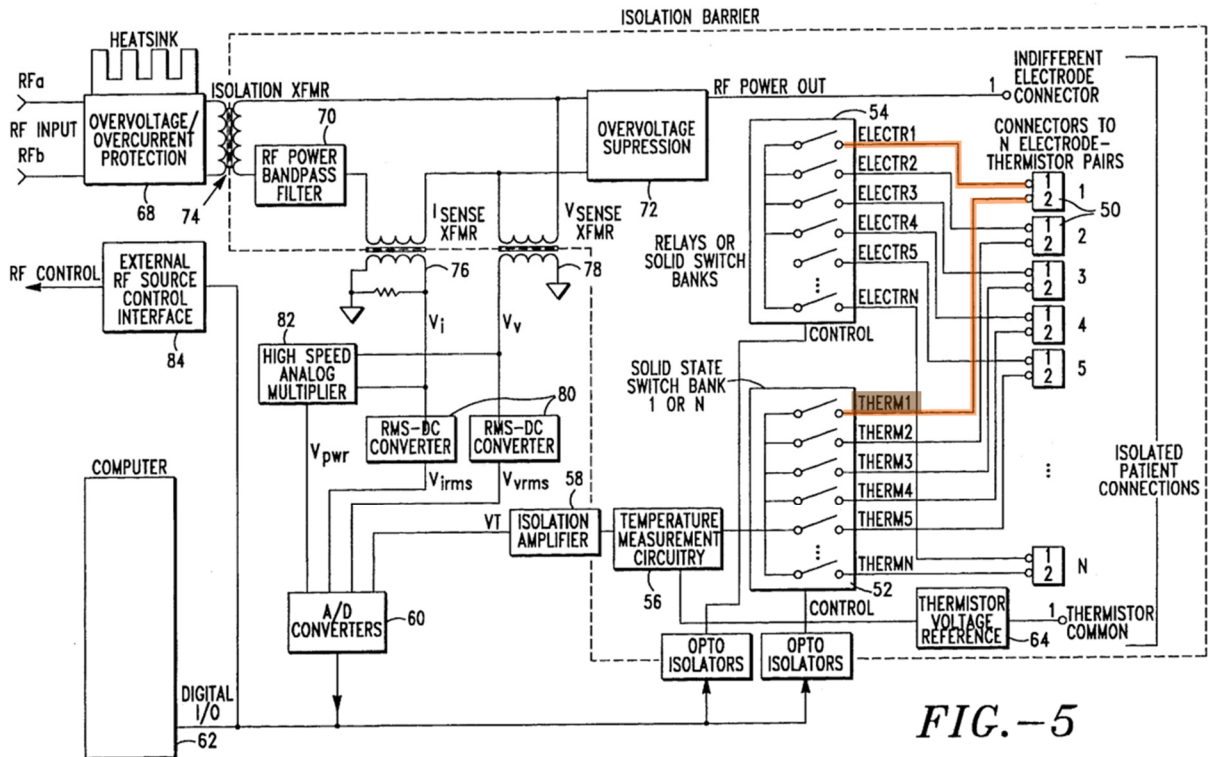
Id., FIG.19; *see also* FIG.4a (showing an array of electrodes having two rows of electrodes). Stern discloses that the electrodes can be bipolar pairs. *Id.*, 2:36-40, 13:1-44. Ex.1002-Decl., ¶214-215.

Moreover, as discussed above for limitations 1[d] and 1[e], such an electrode arrangement would have been obvious to incorporate in Edwards-'535, and a POSITA would have reasonably expected success in doing so. Furthermore, there are only a finite number of ways to configure an array of bipolar electrodes, especially when the array contains bipolar pairs, *see* Ex.1033-Stern, 2:26-40, and thus 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. Deciding among such arrangement amounts to a mere rearrangement of parts that would have been obvious and well within the level of ordinary skill. For the same reason, a POSITA would have found it obvious and had a reasonable expectation of success in implementing two rows of electrodes as taught by Stern. *See supra*, §§X.A.1.e-f. Ex.1002-Decl., ¶216-217.

9. Claim 16

Edwards-'535 in view of Stern renders obvious that *each of the multiple sensors (e.g., impedance sensors and/or thermocouples in Edwards-'535, or thermistors in Stern) is coupled with a respective one of the multiple radiofrequency output channels (e.g., output channels in Stern).* Ex.1002-Decl., ¶218-220.

For example, Figure 5 shows that thermistors are coupled with output channels.



Ex.1033-Stern, FIG.5. Ex.1002-Decl., ¶221.

Additionally, Figure 15, reproduced below, shows electrodes that are connected to **output channels**. Stern further teaches that “a **temperature sensor** [can be] mounted on at least one of the electrodes.” Ex.1033-Stern, 4:56-68. A POSITA would have understood that like the electrodes, these temperature sensors would also be connected with the output channels.

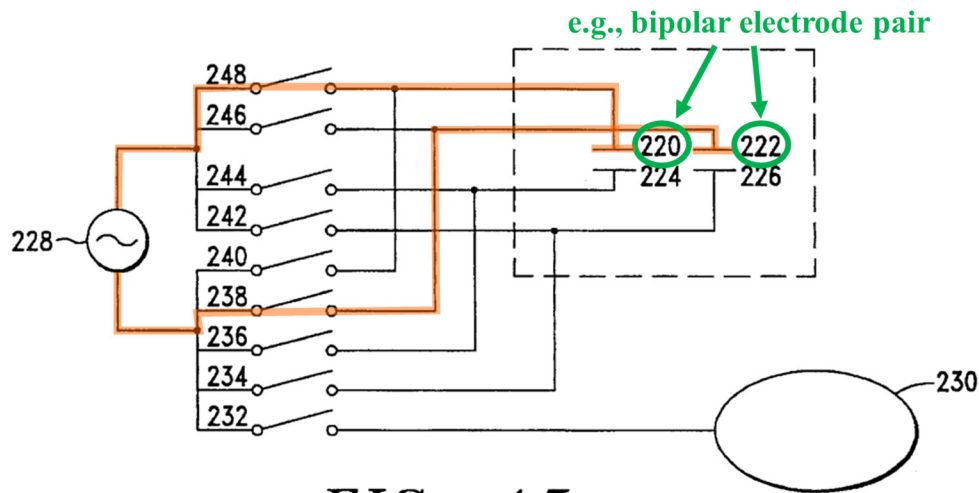


FIG. – 15

Ex.1033-Stern, FIG.15. Ex.1002-Decl., ¶222.

Organizing electrodes, sensors, and output channels in this manner in the apparatus 124 of Edwards-'535 would have been obvious and a POSITA would have reasonably expected success for the reasons provided above for limitations 1[d]-1[f] and claim 13. Ex.1002-Decl., ¶223-224.

10. Claim 17

Edwards-'535 in view of Stern discloses that *the multiple pairs of bipolar radiofrequency electrodes* (e.g., one bipolar **electrode pair 220 and 222**) *are connected to one another and to the multiple radiofrequency output channels* (e.g., **channels** in Figure 15) *in a multiplexed configuration* (e.g., switching arrangement).

Ex.1033-Stern, 12:46-13:2. Ex.1002-Decl., ¶225-227.

The '318 patent describes a “multiplexed configuration” as “allowing pairing of any of the positive electrodes to any of the negative electrodes to form a complete circuit.” Ex.1001-USP318, 10:47-50; *see also id.*, 49:19-32, 49:46-60. Ex.1002-Decl., ¶227.

Edwards-'535 teaches that “[a] multiplexer can be included to measure current, voltage and temperature, at numerous sensors, and energy can be delivered to the energy delivery device 189 in monopolar or bipolar fashion.” Ex.1010-Edwards-'535, 8:15-35, 10:28-32. Because the “numerous sensors” can include the electrodes themselves (*see supra*, §X.A.1.g; Ex.1010-Edwards-'535, FIGs.8-9, 10:26-11:7), the multiplexer 206 is connected to the output channels from power circuits 200 of Edwards-'535, thereby forming a *multiplexed configuration*. Ex.1002-Decl., ¶228.

Additionally, Stern teaches that “[w]hen a bipolar operation occurs, the flow of the current return is a path between selected pairs of the electrodes” and that “[a] switching arrangement to be described determines such pairs of electrodes or combinations of electrodes between which the current flows in the return path.” Ex.1033-Stern, 12:19-24. Stern further explains that “within the bipolar mode...the switches allow for the selective application of RF energy to various combinations of electrodes.” *Id.*, 12:41-45.

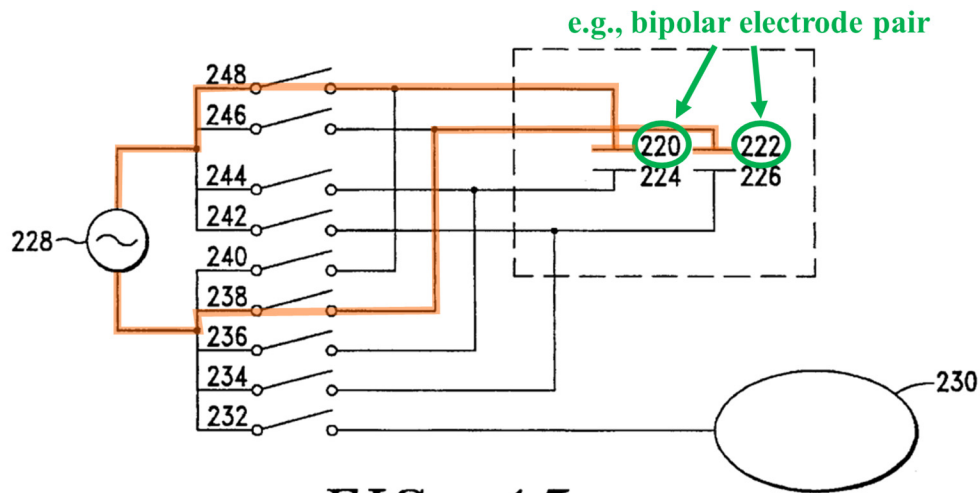


FIG. – 15

Id., FIG.15. Accordingly, the electrodes can be selectively controlled in pairs (*i.e.*, connected to one another) through the **output channels** in a multiplexed configuration. Ex.1002-Decl., ¶229.

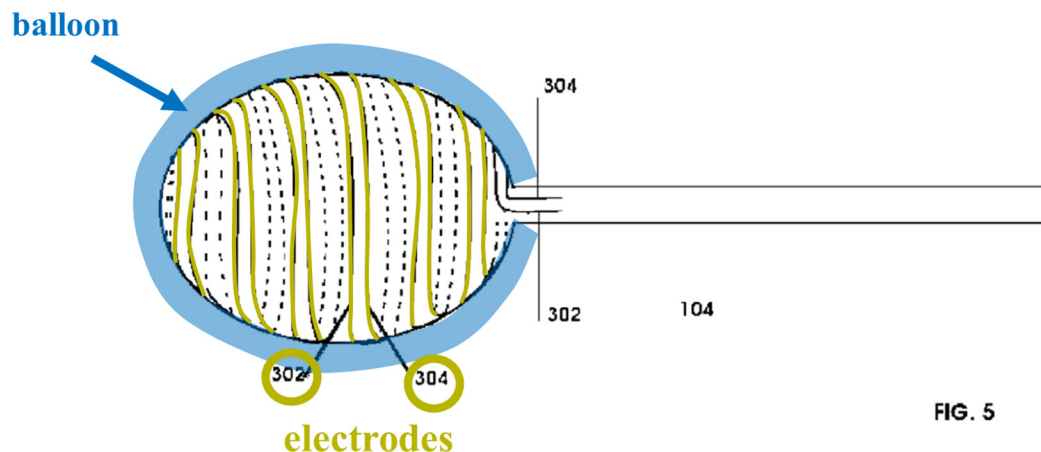
Organizing electrodes and output channels in the manner taught by Stern in a device like Edwards-'535's would have been obvious and a POSITA would have reasonably expected success for the same reasons discussed above for limitations 1[d]-1[f]. Similarly, for the reasons explained in Section X.A.1.e, *supra*, a POSITA would have been motivated to include the circuitry, and therefore multiplexed configuration, of Stern. Ex.1002-Decl., ¶230-232.

B. Ground II: Claim 6 Is Invalid as Obvious Over Edwards-'535 in view of Stern in further view of Patel.

1. Claim 6

As discussed in Ground I, claims 1 and 4 are obvious over Edwards-'535 in view of Stern. Edwards-'535 in view of Stern and Patel teaches that *the multiple segments (e.g., a plurality of surface segments 42 in Stern) comprise a shape-memory alloy material (e.g., the nitinol electrodes as taught by Patel) configured to expand to a desired size and shape (e.g., “allow folding or furling of the balloon during insertion.”)*. Ex.1002-Decl., ¶233-236.

Patel discloses a bipolar probe to treat tissue using RF energy. Ex.1034-Patel, [0036]. The probe includes a balloon with two bipolar electrodes disposed on its surface. *Id.*, [0090], FIG.5.



Ex.1034-Patel, FIG.5. Patel explains that “[t]he electrodes 302 and 304 on the balloon are made of thin flexible metallic strips to allow folding or furling of the

balloon during insertion. Suitable metals for the electrodes on the balloon include nitinol....” *Id.*, [0090]. Nitinol is a known shape memory alloy. Ex.1002-Decl., ¶237.

Like Edwards-’535 and Stern, Patel is directed to treating tissue in a body cavity and does so by applying RF energy to the tissue using an expandable device, Ex.1034-Patel, Abstract, [0002], [0036]-[0038], [0090], FIG.5, and is therefore analogous art to the ’318 patent. Furthermore, a POSITA 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. There are a finite number of conductive materials to make electrodes from, especially for use inside the body. When determining what material to make electrodes from, it would have been obvious for a POSITA to choose nitinol because it is flexible while still being highly conductive, and a POSITA would have had reasonable expectation of success in doing so. Ex.1002-Decl., ¶238-239.

A POSITA would have understood that nitinol has excellent thermal conductivity and biocompatibility and would therefore have been particularly desirable in ablation devices, as it is used in many devices. And because nitinol is a shape-memory alloy, a POSITA would have understood that electrodes made of 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, as nitinol is flexible and provides easy shape transformation. Ex.1002-Decl., ¶239-240.

C. Ground III: Claims 9-10 Are Invalid as Obvious Over Edwards-'535 in view of Stern in further view of Edwards-'886

1. Claim 9

a. 9[a]

As explained in claim 9 in Ground I, Edwards-'535 in view of Stern discloses this limitation. Ex.1002-Decl., ¶241-42.

Edwards-'886 likewise discloses applying a *460 KHz sinusoid wave* across multiple channels. For example, Edwards-'886 discloses “controller 52 [that] commands the generator 38 to apply bursts of low level radio frequency energy through each electrode selected for operation” to “derive[] a local impedance value for each electrode” (*i.e.*, sensor signal) and then apply energy from electrodes. Ex.1016-Edwards-'886, FIGs.77, 2, 39:35-55, 39:56-40:3 (describing usage of sensor signals). Edwards-'886 further teaches that “four independent radio frequency channels” can be “configured to operate eight electrodes...in...a bipolar mode.” *Id.*, 36:66-37:10. “Each channel is capable of supplying up to 15 watts of radio frequency energy with a sinusoidal waveform at 460 kHz.” *Id.*, 36:66-37:10. Ex.1002-Decl., ¶244.

Like Edwards-'535 and Stern, Edwards-'886 is directed to treating tissue in a body cavity and does so by applying RF energy to the tissue, Ex.1016-Edwards-'886, Abstract, 10:58-11:15, 11:42-48, 36:66-37:10, and is therefore analogous art to the '318 patent. Furthermore, although Edwards-'535 in view of Stern renders obvious a frequency range encompassing 460 kHz, *see, supra*, §X.A.4, it also would have been obvious to apply RF energy with a sinusoidal waveform at 460 kHz as taught by Edwards-'886. Stern discloses applying a frequency of “at least 250 kHz and less than 100 MHz.” Ex.1033-Stern, 2:18-20; 3:15-20, Clm.1. Because Edwards-'535 and Edwards-'886 have a common inventor and relate to similar devices used for similar purposes, a POSITA would have been motivated to ablate using Edwards-'886's parameters and would have had a reasonable expectation of success. Indeed, most RF ablation generators sold prior to 2011 operated at a frequency of 460 kHz, making this frequency selection an almost necessary choice. Ex.1002-Decl., ¶245-246.

b. 9[b]

The analysis in Ground I for limitations 1[a] and 9[b] are incorporated by reference. Ex.1002-Decl., ¶247-248.

2. Claim 10

As explained in claim 10 in Ground I, Edwards-'535 discloses this limitation.
Ex.1002-Decl., ¶249.

Edwards-'886 likewise discloses that the *radiofrequency generator* (e.g., generator 38) *is configured to run at a power of between 5 and 75 watts* (e.g., “the integrated generator 38 has four independent radio frequency channels. Each channel is capable of supplying **up to 15 watts** of radio frequency energy.”). A POSITA would have been motivated to ablate using Edwards-'886's parameters and would have had a reasonable expectation of success at doing so for the same reasons discussed above for Claim 9. Ex.1002-Decl., ¶250-251.

D. Ground IV: Claims 1, 4-6, 12, 13, 15-17 Are Invalid as Obvious over Makower in view of Stern

Claims 1, 4-6, 12, 13, 15-17 are obvious over Makower in view of Stern.
Ex.1002-Decl., ¶252.

The Examiner initially rejected issued claim 1 (originally claim 13) over Makower but found that Makower did not disclose (1) *pairs of bipolar radiofrequency electrodes*, (2) *multiple radiofrequency output channels connected with the multiple pairs of bipolar radiofrequency electrodes...*, or (3) *multiple sensors on the tissue treatment surface...*. Ex.1003-USP318FH, 572-588

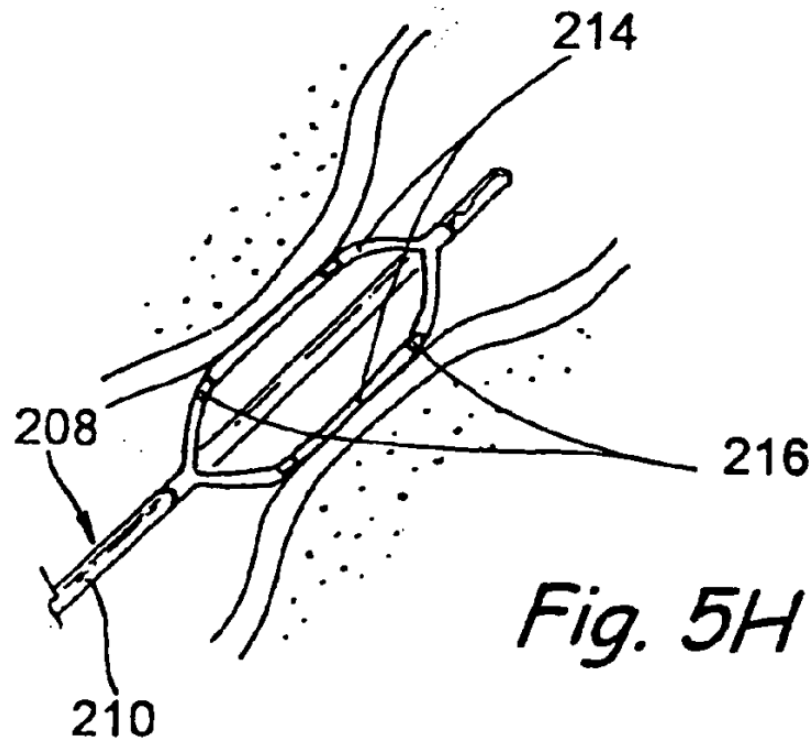
(amendments underlined). Stern, which was not considered by the Examiner, discloses each of these limitations. Ex.1002-Decl., ¶253.

1. Claim 1

a. 1[pre]

If the preamble is limiting, Makower discloses it; Makower discloses *a device* (e.g., electrosurgical device 208) *for delivering energy* (e.g., laser, RF, thermal or other energy) *to a nasal airway* (e.g., nasal cavity) *to improve nasal airflow* (e.g., “for treating sinusitis and other ear, nose & throat disorders”). Ex.1021-Makower, [0001], [0131]. Ex.1002-Decl., ¶254-255.

Figure 5H shows an electrosurgical device 208 that includes electrodes 216 that deliver energy, such that device 208 is used *for delivering energy*. Ex.1021-Makower, [0187]. Additionally, “device 208 is advanced into a passageway such as a nostril, nasal cavity...” and is therefore used to deliver energy *to a nasal airway*. *Id.*, [0043], [0161], [0187].



Ex.1021-Makower, FIG.5H. Ex.1002-Decl., ¶256.

Makower discloses treatment of “sinusitis,” *id.*, [0001], one symptom of which is “difficulty breathing through one or both nostrils,” *id.*, [0007]-[0014]. Thus, Makower teaches a device to *improve nasal airflow*. Ex.1002-Decl., ¶257.

b. 1[a]

Makower or Makower in view of Stern renders obvious a *handle*. Ex.1002-Decl., ¶258.

Although Makower does not specify that a *handle* is attached to electrosurgical device 208, Makower teaches that device 208 may be steerable and that “[s]teerable catheters and scopes are well known in the art.” Ex.1021-Makower,

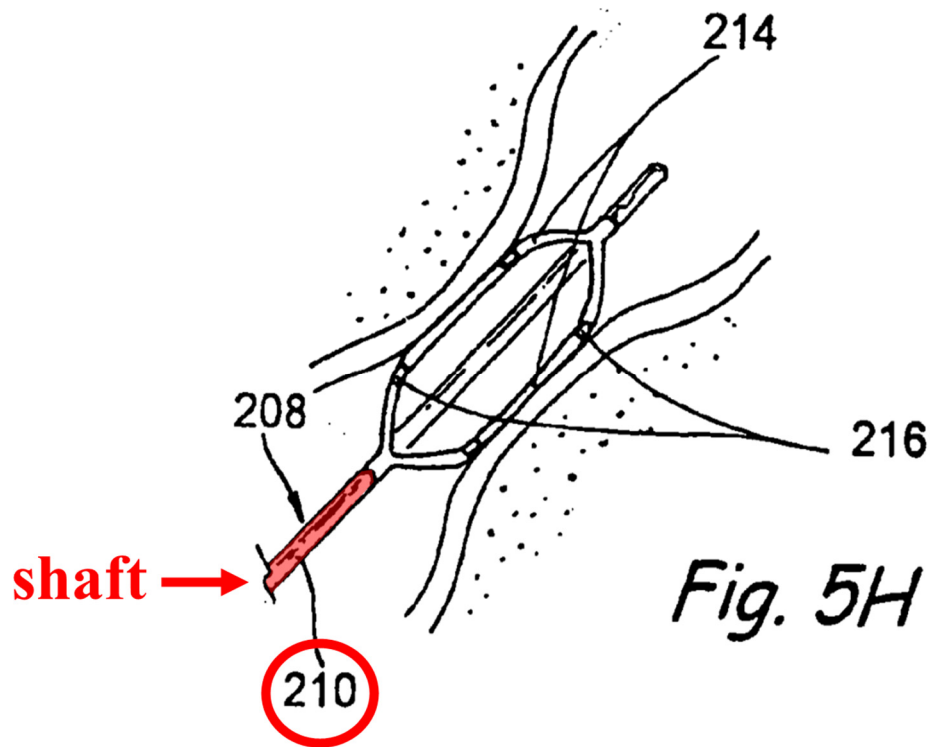
[0195], [0187]. Makower cites and incorporates several references that disclose handles as mechanisms for how to control steerable devices, including USP 5,507,725 which teaches a handle having a pulley mechanism that controls the movement of a catheter through the body. *Id.*; Ex.1045-Savage, 4:49-60. Ex.1002-Decl., ¶259-260.

Alternatively, including a *handle* in Makower would have been obvious in view of Stern for the same reasons it would have been obvious to include a handle in Edwards-'535, *see supra* §§X.A.1.b-c, for example, to control and deploy the ablation device. Ex.1021-Makower, [0138], [0161]. Ex.1002-Decl., ¶261-262.

c. 1[b]

Makower discloses a *shaft* (e.g., *shaft 210*) *extending from one end of the handle*. Ex.1002-Decl., ¶263.

As shown in Figure 5H, Makower discloses *a shaft* (e.g., *shaft 210*) extending from the working device.



Ex.1021-Makower, FIG.5H, [0187]. Ex.1002-Decl., ¶264.

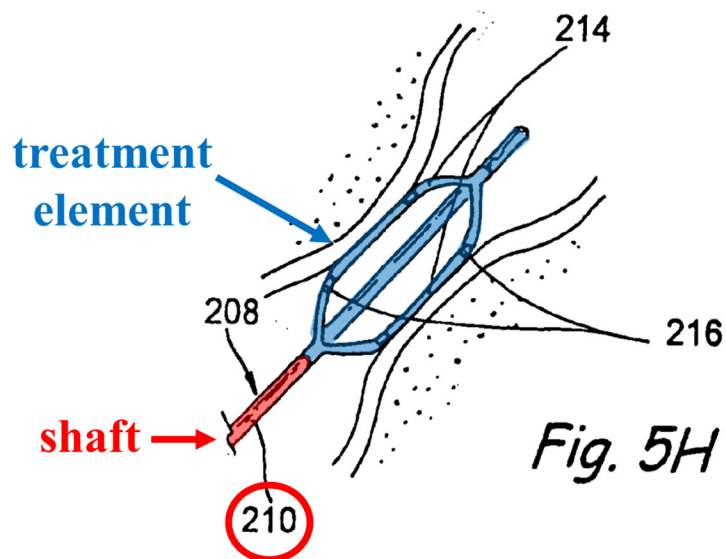
Although Makower does not specify that a *handle* is attached to shaft 210, it would have been obvious for the same reason in explained above in limitations 1[a]. Alternatively, including a *shaft* extending from one end of the *handle* in Makower in view of Stern would have been obvious for the same reasons provided for limitations 1[a] and 1[b] in Ground I—for example, to control the ablation device. *See also* Ex.1021-Makower, Abstract, [0153], [0159], [0187]. Ex.1002-Decl., ¶265-266.

d. 1[c]

Makower discloses a *treatment element* (e.g., shown in Figure 5H) *coupled* with a distal end of the *shaft* (e.g., *shaft 210*), sized to be inserted into a nostril (e.g.,

“device 208 is advanced into...a nostril”), and configured to change from a first configuration to a second configuration (e.g., strut members 214 are collapsible and expandable), wherein the treatment element comprises a tissue treatment surface (e.g., electrodes 216 on the surface of strut members 214 are brought into contact with tissue). Ex.1002-Decl., ¶267.

For example, Makower teaches “an electrosurgical device 208...having arched strut members 214.... Electrodes 216 are located on the strut members 214.... [T]he strut members 214 may be collapsible and expandable. In operation, the device 208 is advanced into a [nasal] passageway.... Thereafter, current is applied to the electrodes 216 causing tissue adjacent to the struts 214 to be cauterized or heated.” Ex.1021-Makower, [0187], [0164], FIG.5H.

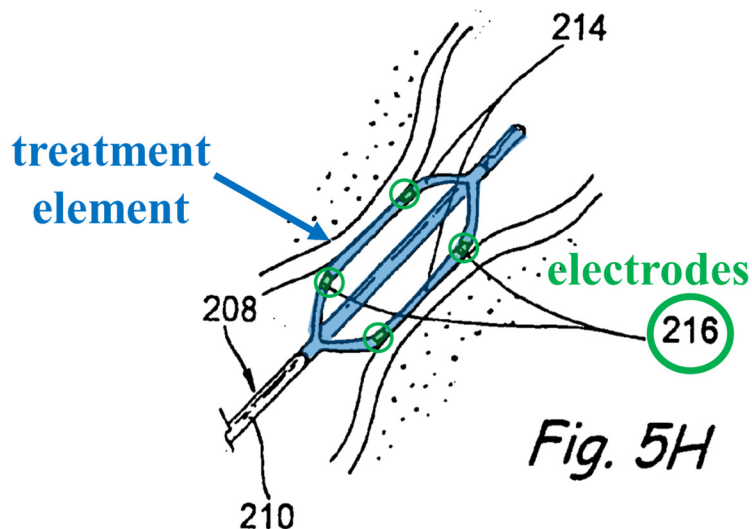


Id., FIG.5H. Ex.1002-Decl., ¶268-269.

e. 1[d]

- i. Makower teaches *an array of multiple...bipolar radiofrequency electrodes disposed along the treatment surface of the treatment element.*

Makower discloses an *array of multiple...bipolar radiofrequency electrodes* (e.g., electrodes 216) *disposed along the treatment surface of the treatment element* (e.g., electrodes 216 are placed on the surface of the strut members 214). Ex.1021-Makower, [0187] (noting that “electrodes 216 may be bipolar”), [0164], FIG.5H.



Ex.1021-Makower, FIG.5H. Ex.1002-Decl., ¶270-272.

- ii. Stern teaches *an array of multiple pairs of bipolar radiofrequency electrodes disposed along the treatment surface of the treatment element.*

As discussed in limitation 1[d] in Ground I, Stern teaches controlling bipolar RF electrodes in *multiple pairs* (e.g., between electrodes 220 and 222). Ex.1033-Stern, 12:41-45, 12:65-13:2, FIGs.15, 17.

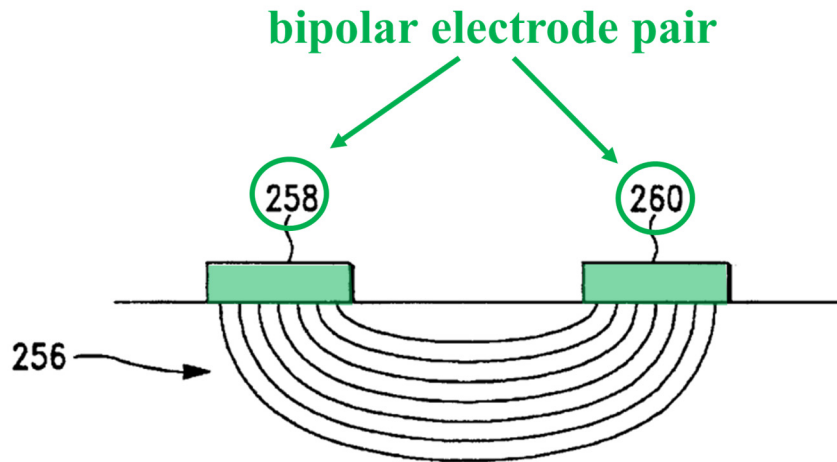


FIG. - 17

Id., FIG.17. Stern's Figure 15, annotated below, shows circuitry that operates the bipolar pairs. *See id.*, FIG.15. Stern provides that "[i]f switch 248 and switch 238 are closed there will be bipolar operation between the electrodes 220 and 222." *Id.*, 12:65-13:2.

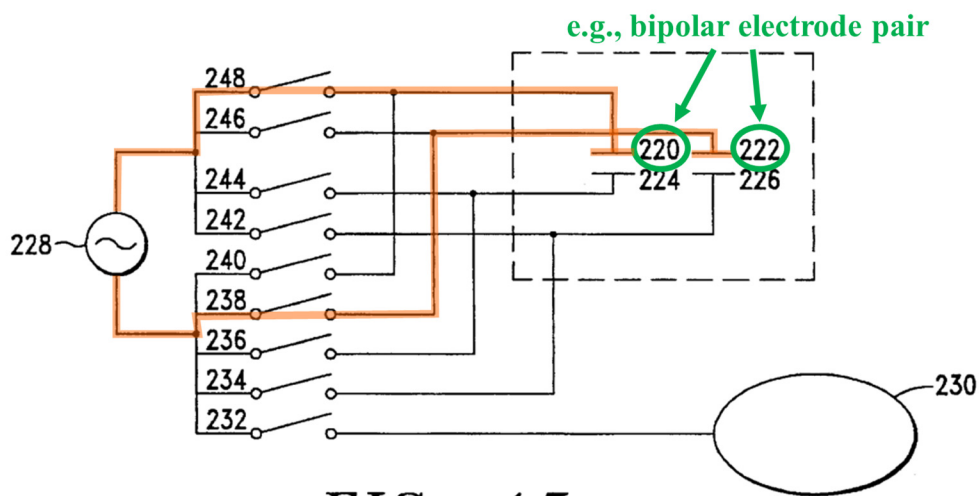


FIG. - 15

Ex.1033-Stern, FIG.15. Ex.1002-Decl., ¶273-276.

iii. Motivation to Combine

Like Stern, Makower is directed to treating tissue in a body cavity and does so by applying RF energy to the tissue using an expandable device, Ex.1021-Makower, [0001], [0043], [0132], [0164], [0187], and is therefore analogous art to the '318 patent. Ex.1002-Decl., ¶277.

Furthermore, Makower demonstrates that bipolar RF ablation devices with multiple surface electrodes were well-known. Makower explains that “[r]adiofrequency energy is...delivered to heat...submucosal tissue” using electrodes, Ex.1021-Makower, [0040], but omits details on how to implement such energy delivery. Thus, a POSITA would have been motivated to turn to other sources for information regarding how to specifically deliver energy to heat the tissue. Makower is ready for improvement as it leaves specific implementation of pairing and wiring electrodes up to the discretion and skill of a POSITA. *See id.*, [0043]-[0046], [0187], [0191], [0232]. A POSITA would therefore have been motivated to improve Makower’s device to include Stern’s teachings of multiple pairs of bipolar electrodes because of the advantages and benefits Stern discloses. Ex.1002-Decl., ¶278-281.

Stern teaches that its technique for pairing bipolar RF surface electrodes (described above and in limitation 1[d] in Ground I) and wiring them to allow for independent delivery of RF energy to each bipolar pair (described above and in limitation 1[e] in Ground I) provides numerous benefits, including the ability to control electrical field lines and heating targeted tissue, and to ensure that tissue is heated evenly. Ex.1033-Stern, 12:25-37, 13:21-29, FIGs.15, 18. Ex.1002-Decl., ¶282.

These benefits are teachings, suggestions, and motivations that would have led a POSITA to modify Makower in view of Stern to realize these same results in Makower's device. Doing so would have simply involved using Stern's known bipolar pairing technique to implement the missing details of Makower in the way that Stern teaches, which would have been particularly desirable in the nose for increased safety and control. Moreover, using Stern's known bipolar pairing technique would have improved Makower's similar device in the same way as Stern's. Further, a POSITA would have been motivated to combine Makower and Stern because it would have involved applying Stern's known bipolar pairing technique to Makower's known device that was ready for improvement (because Makower omits details as to how to pair and wire the bipolar electrodes) to yield predictable results (detailed further below). Ex.1002-Decl., ¶283-284.

Makower and Stern each describe similar techniques of delivering bipolar RF ablation energy through expandable devices to tissue of different body cavities, such that their combination would have yielded predictable results. Ex.1021-Makower, [0040], [0043]; Ex.1033-Stern, 1:16-43, 7:38-8:38. Makower leaves detail regarding how to deliver bipolar RF energy to a POSITA, and Stern explains the benefits of independently delivering RF energy to the different bipolar electrode pairs to adequately heat and ablate tissue. Ex.1021-Makower, [0040], [0161], [0167], [0185]-[0188]; Ex.1033-Stern, 10:48-65. Ex.1002-Decl., ¶285.

As discussed above for limitations 1[d]-1[e] in Ground I, A POSITA would have had a reasonable expectation of success in implementing Stern's bipolar RF electrode *pairs* and individual output channels in Makower's device given that, as explained above, Makower omits details as to the circuitry required and therefore recognizes it was within a POSITA's skill to design a system to deliver RF energy to various electrodes. *See supra*, §§X.A.1.e-f. Ex.1002-Decl., ¶286.

Moreover, in the combination, the known techniques of Stern would have been used to improve Makower's similar device in the same way. For example, Makower discloses an expandable device with surface RF electrodes to deliver energy, Ex.1021-Makower, [0187], and Stern discloses a way to pair surface bipolar RF electrodes and wire such electrodes for independent energy delivery, Ex.1033-

Stern, 2:49-53, 12:25-27, 13:21-39. Thus, Stern’s teachings would have been applied to Makower in the same way those teachings are used in Stern itself. Ex.1002-Decl., ¶287.

Accordingly, applying Stern’s teachings to Makower would have been a matter of routine implementation well within the skill of a POSITA and would have yielded predictable results—*e.g.*, Makower’s device having bipolar RF electrode pairs, as taught by Stern—with a reasonable expectation of success. Ex.1002-Decl., ¶288.

f. 1[e]

Makower in view of Stern renders obvious *multiple radiofrequency output channels* (*e.g.*, **energy output** in Stern’s Figure 15) *connected with the multiple pairs of bipolar radiofrequency electrodes* (*e.g.*, electrodes 216 in Makower, controlled in pairs as taught by Stern), *wherein each pair of the multiple pairs of bipolar radiofrequency electrodes is connected with a respective one of the multiple radiofrequency output channels* (*e.g.*, shown in Figure 15 in Stern). Ex.1002-Decl., ¶289-290.

As discussed above in Ground I limitation 1[e], Stern teaches a “switching means” that receives an output from an RF power source and provides bipolar energy

to electrodes by controlling the current to the electrodes. Ex.1033-Stern, 2:49-53, 3:12-29, Clm.1. Ex.1002-Decl., ¶291.

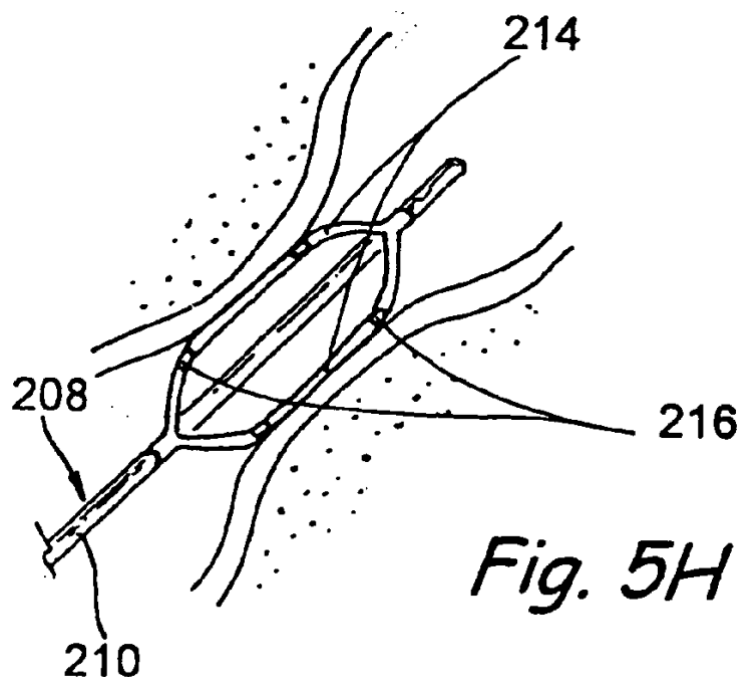
As explained above for limitation 1[d], Makower omits details on how to pair and wire bipolar electrodes to deliver RF energy. A POSITA would have therefore been motivated to look to Stern, which discloses how to do so. Connecting each bipolar pair to a respective output channel as taught by Stern would have been obvious in order to selectively energize each pair of electrodes to obtain the benefits of bipolar pairs discussed in Ground I for limitation 1[d]—for example, because it provides for local and even temperature control when ablating tissue. Combining Makower and Stern would have involved applying a known technique (pairing and wiring bipolar electrodes taught by Stern), to a known device (Makower’s expandable RF ablation device) that was ready for improvement (because Makower omits details as to how to pair and wire the bipolar electrodes) to yield predictable results. Ex.1002-Decl., ¶292-301.

A POSITA would have had a reasonable expectation of success in implementing Stern’s multiple RF output channels in Makower for the same reasons as provided in Ground I limitation 1[e], to obtain the benefits of bipolar pairs of electrodes, including the ability to finely control where heat is being applied. Ex.1002-Decl., ¶300-302.

g. 1[f]

Makower teaches *multiple sensors (e.g., sensing elements) on the tissue treatment surface (e.g., attached to strut members 214), wherein the multiple sensors are selected from the claimed group (e.g., thermocouples)*. Ex.1002-Decl., ¶303.

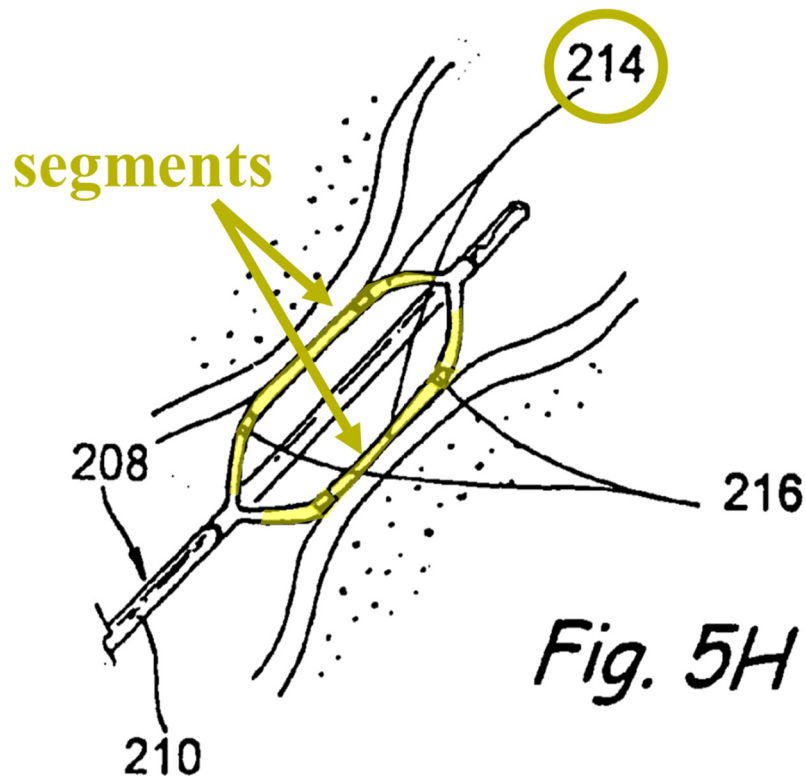
For example, referring to Figure 5H, Makower teaches that “sensing elements may...be attached to the catheter and/or strut members to monitor...temperature.” Ex.1021-Makower, [0187]. Thermocouples were a well-known type of temperature sensor, and thus a POSITA would have been motivated to implement the sensors of Makower using common, readily available thermocouples. *Id.* Makower further explains that “any of the devices described...may be further modified to include...sensor[s],” such as an “RF sensor,” or “thermal sensor.” *Id.*, [0192].



Id., FIG.5H. Ex.1002-Decl., ¶304-306.

2. Claim 4

Makower discloses that the *treatment element* (e.g., electro-surgical device 208) comprises *multiple segments* (e.g., *strut members 214*) that are expandable from the first configuration to the second configuration (e.g., collapsible/expandable). Ex.1021-Makower [0187], [0194], FIG.5H.



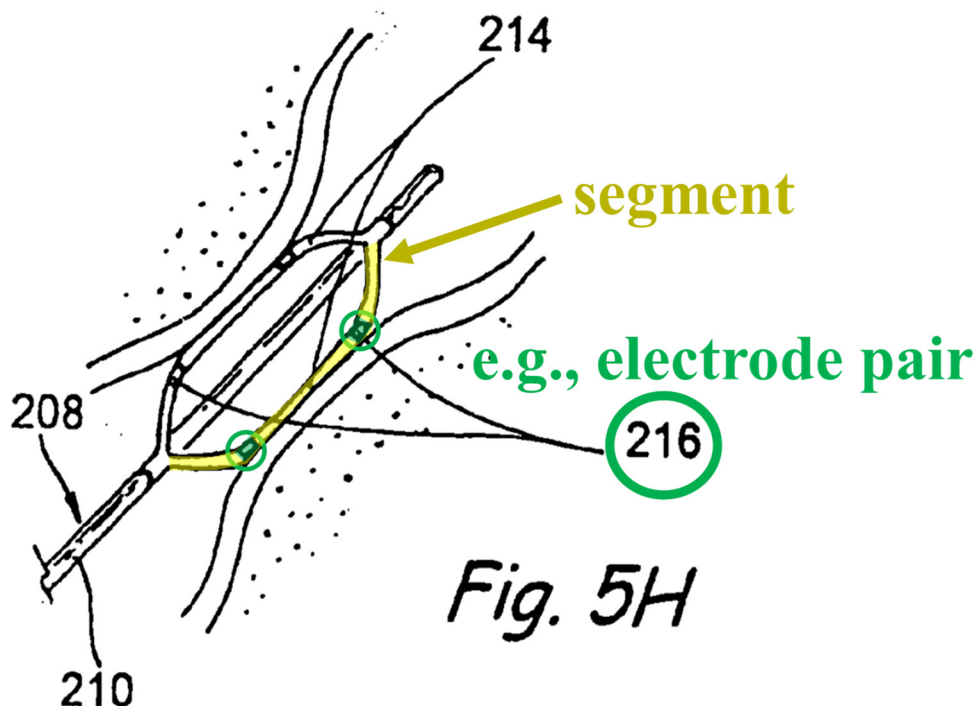
Ex.1021-Makower, FIG.5H. Ex.1002-Decl., ¶307-311.

3. Claim 5

Makower in view of Stern discloses that *at least one pair of multiple pairs of bipolar radiofrequency electrodes* (e.g., electrodes 216 in Stern controlled as pairs

as taught by Stern) *is coupled with each of the multiple segments (e.g., a plurality of surface segments 42 in Stern).* Ex.1021-Makower, FIG.5H, [0187], [0194]; Ex.1033-Stern, 8:53-59, 5:48-51, FIGs.4a, 4b. Ex.1002-Decl., ¶312-313.

As discussed above for limitations 1[d]-[e], it would have been obvious to control Makower's bipolar RF electrodes in pairs, as taught by Stern and a POSITA would have reasonably expected success. Based on Stern's teachings, a POSITA would have been motivated to pair two adjacent electrodes 216 on each strut 214 to provide localized control of tissue temperature in that region. Such a configuration is shown below in Figure 5H of Makower.



Ex.1021-Makower, FIG.5H, [0187], [0194]. Ex.1002-Decl., ¶314-315.

4. Claim 6

Makower teaches *the multiple segments (e.g., elongate members 42) comprise a shape-memory alloy material (e.g., nitinol) configured to expand to a desired size and shape (e.g., “strut members 214 may be collapsible and expandable.”)*. Ex.1002-Decl., ¶316-317.

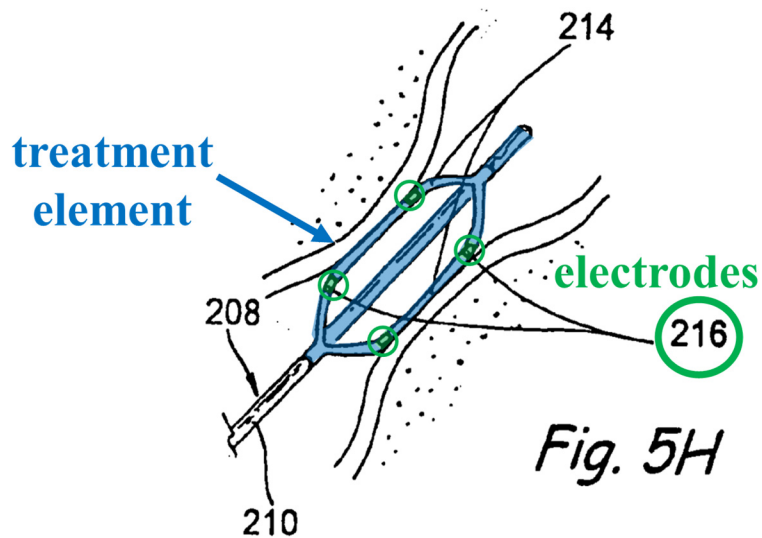
As discussed above for claim 4, Makower teaches that “strut members 214 may be collapsible and expandable.” Ex.1021-Makower, [0187]. Makower further explains that “any...elongate flexible devices of this invention may include design elements that impact performance features.” *Id.*, [0194]. This includes using “**shape memory alloys such as nitinol**” to “predictably deflect various sections of the catheter.” *Id.*; *see also id.*, [0149] (discussing nickel titanium alloy frame). Ex.1002-Decl., ¶318.

Because the strut members 214 deflect when expanded, a POSITA would have understood that Makower suggests making strut members 214 of a shape memory alloy to facilitate collapse and expansion. Ex.1002-Decl., ¶319.

5. Claim 12

Makower discloses that the *radiofrequency electrodes (e.g., electrodes 216) comprise non-penetrating electrodes*. For example, Figure 5H shows that the

electrodes sit on the surface of, and do not penetrate the tissue. Ex.1021-Makower, [0187].



Id., FIG.5H. Ex.1002-Decl., ¶320-322.

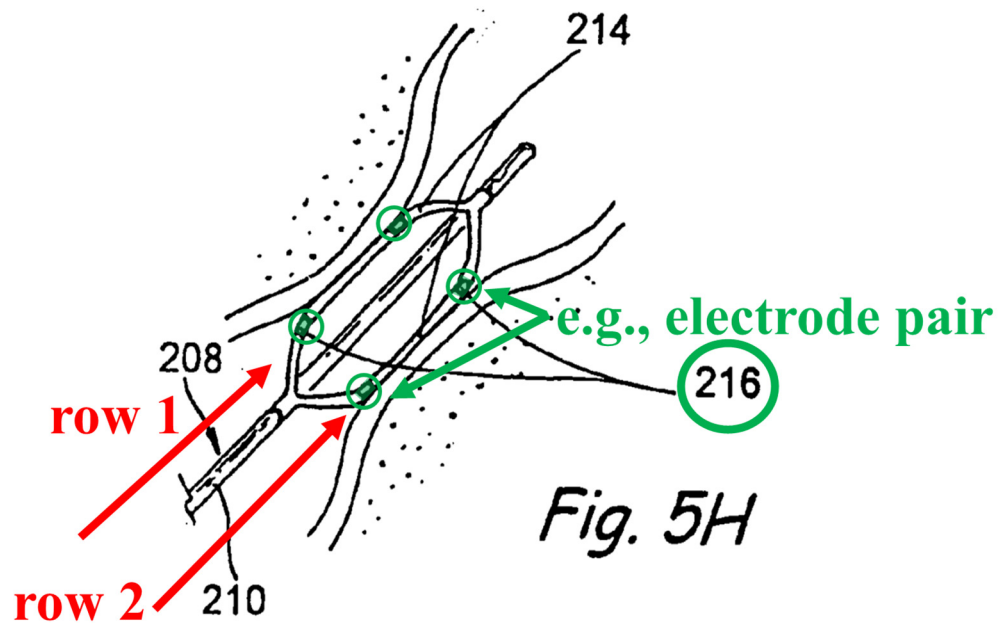
6. Claim 13

As discussed in Ground I, claim 13, Stern teaches this limitation. And as explained in limitations 1[d] and 1[e], a POSITA would have found it obvious to incorporate Stern's paired-electrode control architecture, *i.e.*, the electrical connections between the electrodes, channels, and sensors, into Makower's device, and would have reasonably expected success in doing so. Ex.1002-Decl., ¶323-324.

7. Claim 15

Makower discloses that the *multiple...radiofrequency electrodes* (e.g., *electrodes 216*) *comprise two rows of electrodes* (e.g., as shown in Figure 5H). Ex.1021-Makower, [0187]. And as discussed in limitation 1[d] and claim 5, a

POSITA would have been motivated to incorporate Stern's teachings of using *pairs* of bipolar electrodes on the struts 214.



Ex.1021-Makower, FIG.5H. Ex.1002-Decl., ¶325-327.

8. Claim 16

As discussed in Ground I limitation 1[f], Stern teaches this limitation. And as explained in limitations 1[d] and 1[e], a POSITA 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 Makower's device, would have reasonably expected success in doing so. Ex.1002-Decl., ¶328-329.

9. Claim 17

As discussed in Ground I, claim 17, Stern teaches this limitation. And as explained in limitations 1[d] and 1[e], a POSITA 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. Ex.1002-Decl., ¶330-331.

E. Ground V: Claims 9-10 Are Invalid as Obvious Over Makower in view of Stern in further view of Edwards-'886

1. Claim 9

a. 9[a]

As discussed in Ground IV, claim 1 is obvious over Makower in view of Stern. The combination of Makower with Stern and Edwards-'886 discloses *a radiofrequency generator (e.g., RF generator 158 in Stern) configured to receive sensed signals from the multiple sensors (e.g., Makower's thermocouples) and deliver radiofrequency energy separately to each of the multiple radiofrequency output channels (e.g., multiple RF output channels as taught by Stern) in the form of a 460 KHz sinusoid wave (e.g., Edwards-'886's sinusoidal waveform at 460 kHz).* Ex.1002-Decl., ¶332-334.

As discussed above for claim 1, Makower in view of Stern renders obvious thermocouples on Makower's strut members 214 and multiple RF output channels to control electrodes on the strut members. Makower omits implementation details on how to generate the disclosed RF energy. Stern discloses an RF generator (or voltage source) that is controlled based on received temperature measurements ("feedback arrangement") to produce "an RF current [that] has a frequency of at least 250 kHz and less than 100 MHz." Ex.1033-Stern, Abstract, 2:6-18, 2:25-64, 3:12-28, 8:66-9:24, 10:36-48, 10:49-65, 12:46-13:2, Clm.1, FIGs. 5, 12, 15. This feedback arrangement facilitates the benefits discussed for limitations 1[d]-1[f]. It would have therefore been obvious to provide RF energy to Makower's electrodes using an RF generator controlled based on feedback from Makower's temperature sensing elements (i.e., thermocouples) for the reasons discussed above for limitations 1[e]-1[f]. Ex.1002-Decl., ¶335-337.

As discussed above for claim 9 in Ground III, Edwards-'886 discloses applying a *460 KHz sinusoid wave* across multiple channels. This frequency falls within the range disclosed by Stern, and as discussed for claim 9 in Grounds I and III, a 460 kHz sine wave is a common and obvious form in which to deliver RF energy. It therefore would have been obvious to configure Stern's generator to generate a *460 KHz* to be delivered via Makower's modified device, and a POSITA

would have reasonably expected success for the reasons discussed for claim 9 in Grounds I and III. Ex.1002-Decl., ¶338.

b. 9[b]

As discussed in Ground I limitation 9[b], Stern discloses this limitation. It would have been obvious to incorporate *a cable coupled to the handle for plugging the handle into the radiofrequency generator* and a POSITA would have reasonably expected success for the reasons disclosed in Ground I limitation 9[b], and Ground V limitation 9[a]. Ex.1002-Decl., ¶339-340.

2. Claim 10

Edwards-'886 discloses that the *radiofrequency generator (e.g., generator 38) is configured to run at a power of between 5 and 75 watts (e.g., “the integrated generator 38 has four independent radio frequency channels. Each channel is capable of supplying **up to 15 watts** of radio frequency energy.”)*. It would have been obvious to run the generator of Makower in view of Stern at a power of up to 15 watts and a POSITA would have reasonably expected success for the reasons discussed above for Ground V claim 9 and Ground III claim 10. Ex.1002-Decl., ¶341-343.

XI. CONCLUSION

The Challenged Claims of the '318 patent are obvious in view of the prior art Grounds set forth herein. Accordingly, Petitioners request institution of an *inter partes* review to cancel these claims.

Respectfully submitted,

By: /David L. Cavanaugh/
David L. Cavanaugh
Registration No. 36,476

Counsel for Petitioners

CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing, Petition for *Inter Partes* Review, contains 13,970 words as measured by the word processing software used to prepare the document, in compliance with 37 C.F.R. Section 42.24(d), excluding the parts of the Petition exempted from the word count by 37 C.F.R. Section 42.24(a)(1).

/Sarah J. Murphy/
Sarah J. Murphy
Registration No. 80,104

CERTIFICATE OF SERVICE

Pursuant to an agreement between Petitioners and Patent Owner, I hereby certify that, on January 18, 2024, I caused a true and correct copy of the following materials:

- Petition for *Inter Partes* Review of U.S. Patent No. 11,033,318
- Appendix of Claims
- Petitioners' Table of Exhibits
- Exhibits 1001-1003, 1006-1008, 1010-1013, 1015-1016, 1021-1024, 1030-1031, 1033-1035, 1045, 1050-1054, 1056, 1061-1062, 1067, 1072
- Certificate of Compliance Regarding Word Count
- Fee Authorization
- Power of Attorney

to be served on Patent Owner (Merchant & Gould P.C., P.O. Box 2903, Minneapolis, MN 55402-0903, United States) by electronic mail to:

Kathleen.Daley@finnegan.com
Sonja.Sahlsten@finnegan.com
Mike.Jakes@finnegan.com

/Sarah J. Murphy/
Sarah J. Murphy
Registration No. 80,104

Petitioners’ Table of Exhibits

Exhibit	Description
1001	U.S. Patent No. 11,033,318 (“’318 patent”)
1002	Declaration of Dr. Gregory Martin (Excerpts)
1003	File History of U.S. Patent No. 11,033,318
1004-1005	RESERVED
1006	District Court Amended Complaint
1007	District Court Amended Complaint Exhibit X
1008	Docket Navigator District of Delaware Statistics as of January 18, 2024
1009	RESERVED
1010	U.S. Patent No. 6,517,535 (“Edwards-’535”)
1011	U.S. Patent No. 5,575,788 (“Baker”)
1012	U.S. Patent No. 5,891,134 (“Goble”)
1013	WO 2010/077980 (“Baker-’980”)
1014	RESERVED
1015	U.S. Patent No. 6,033,397 (“Laufer”)
1016	U.S. Patent No. 6,273,886 (“Edwards-’886”)
1017-1020	RESERVED
1021	U.S. Patent App. No. 2005/0240147 (“Makower”)
1022	U.S. Patent App. No. 2006/0064086 (“Odom”)
1023	Coste et al., Radiofrequency Is a Safe and Effective Treatment of Turbinate Hypertrophy, LARYNGOSCOPE, 111(5) (2001) (“Coste”)
1024	WO1999030655A1 (“Hovda”)
1025-1029	RESERVED
1030	U.S. Patent No. 8,979,841 (“Kunis”)
1031	Hytönen et al., Radiofrequency Thermal Ablation for Patients with Nasal Symptoms: A Systematic Review of Effectiveness and Complications, 266 EUR. ARCH. OTORHINOLARYNGOL. (2009) (“Hytönen”)
1032	RESERVED
1033	U.S. Patent No. 5,562,720 (“Stern”)
1034	U.S. Patent Application No. 2007/0287994 (“Patel”)

Exhibit	Description
1035	M. Philippon, Principles of Electrical Resistance of Living Tissue, BULL. CL. SCI. ACAD. R. BELG. ser. 5, vol. 7 (1921) (English Translation) (“Philippon”)
1036-1044	RESERVED
1045	U.S. Patent No. 5,507,725 (“Savage”)
1046-1049	RESERVED
1050	Hong, Radiofrequency Ablation: Mechanism of Action and Devices, J. VASC. INTERV. RADIOL. 21 (2010) (“Hong”)
1051	Haemmerich, Biophysics of Radiofrequency Ablation, CRITICAL REVIEWS IN BIOMEDICAL ENGINEERING, 38(1) (2010) (“Haemmerich”)
1052	Sackenheim, Radio Frequency Ablation the Key to Cancer Treatment, J. DIAGNOSTIC MEDICAL SONOGRAPHY Vol.19, No. 2 (2003) (“Sackenheim”)
1053	Bronzino, Medical Devices and Systems, Chapter 63, THE BIOMEDICAL ENGINEERING HANDBOOK 3E (2006) (“Bronzino”)
1054	Koyyalagunta et al., Radiofrequency and Cryoablation for Cancer Pain, TECHNIQUES IN REGIONAL ANESTHESIA & PAIN MANAGEMENT Vol.14 (2010) (“Koyyalagunta”)
1055	RESERVED
1056	Liang et al., Radiofrequency Treatment of Ethmoidal Nerve with Allergic Rhinitis Under Nasal Endoscopy, 13:8 J. CLIN OTORHINOLARYNGOL. (China) 341 (August 1999) (English Translation) (“Liang”)
1057-1060	RESERVED
1061	Szold, Nitinol: Shape-Memory and Super-Elastic Materials in Surgery, 20 SURGICAL ENDOSCOPY & OTHER INTERVENTIONAL TECHNIQUES (2006) (“Szold”)
1062	Sedra et al., MICROELECTRONIC CIRCUITS (3d Ed. 1991) (Excerpts) (“Sedra”)
1063-1066	RESERVED
1067	U.S. Patent No. 5,505,730 (“Edwards-’730”)
1068-1071	RESERVED
1072	Translator Declaration for Liang

Appendix of Claims

Claim 1	
Limitation	Claim Language
1[pre]	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

Claim 1	
Limitation	Claim Language
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.

Claim 4
The device of claim 1, wherein the treatment element comprises multiple segments that are expandable from the first configuration to the second configuration.

Claim 5
The device of claim 4, wherein at least one pair of the multiple pairs of bipolar radiofrequency electrodes is coupled with each of the multiple segments.

Claim 6
The device of claim 4, wherein the multiple segments comprise a shape-memory alloy material configured to expand to a desired size and shape.

Claim 9	
Limitation	Claim Language
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
9[b]	a cable coupled to the handle for plugging the handle into the radiofrequency generator.

Claim 10
The device of claim 9, wherein the radiofrequency generator is configured to run at a power of between 5 and 75 watts.

Claim 12
The device of claim 1, wherein the radiofrequency electrodes comprise non-penetrating electrodes.

Claim 13

The device of claim 1, wherein the multiple pairs of bipolar radiofrequency electrodes, the multiple radiofrequency output channels and the multiple sensors are organized into multiple subsystems, and wherein each of the multiple subsystems comprises one of the multiple pairs of bipolar radiofrequency electrodes, one of the multiple radiofrequency output channels and one of the multiple sensors.

Claim 15

The device of claim 1, wherein the multiple pairs of bipolar radiofrequency electrodes comprise two rows of electrodes.

Claim 16

The device of claim 1, wherein each of the multiple sensors is coupled with a respective one of the multiple radiofrequency output channels.

Claim 17

The device of claim 1, wherein the multiple pairs of bipolar radiofrequency electrodes are connected to one another and to the multiple radiofrequency output channels in a multiplexed configuration.