

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. IPR2024-00282

U.S. Patent No. 11,766,286

**PETITION FOR *INTER PARTES* REVIEW
OF CLAIMS 1-4, 7-9 OF
U.S. PATENT NO. 11,766,286
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. 11,766,286 (the “’286 patent”), titled “Methods and Devices to Treat Nasal Airways,” are directed to a radiofrequency (“RF”) device that has multiple pairs of bipolar electrodes and an impedance sensor. *See* Ex.1001-USP286, Abstract, Clm.1. The claims recite only standard well-known components present in many RF ablation devices: a handle, a shaft, a treatment element, pairs of bipolar electrodes to deliver treatment, an impedance sensor, and individual output channels by which to operate the electrodes. *See id.*, Clm.1.

The challenged claims were never rejected on the basis of prior art during examination, and no reasons for allowance were provided. *See* Ex.1003-USP286FH, 218-23, 277-83. However, by 2011 there was nothing new or nonobvious about using a RF device having these features. For example, both Edwards-’535 and Makower teach RF devices having handles, shafts, treatment elements, bipolar electrodes, and impedance sensors. Stern provides additional detail regarding how to pair electrodes and operate them via individual output channels, rendering 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. The teachings of Stern would have been obvious to combine with the teachings in Edwards-’535

and Makower. This 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).

The preamble of the '286 patent also contemplates using the claimed device “to treat rhinitis.” Ex.1001-USP286, Clm.1. Treating rhinitis—which is neither described in the specification nor imparts any essential structure on the device—is presumptively nonlimiting and, at most, a bare statement of intended use. However, even if treating rhinitis is required (it is not), Liang explains that RF ablation devices used in the nasal cavity, like those in Edwards-'535 and Makower, were known to be effective for treating rhinitis.

Accordingly, Petitioners request that the Board grant this petition and institute an *inter partes* review of the '286 patent and cancel claims 1-4 and 7-9.

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 submits that Patent Owner (“PO”) has asserted five patents, including the ’286 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 owned by The Foundry LLC and 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	Patent Owner	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
11,033,318	Aerin Medical Inc.	IPR2024-00278
10,610,675	The Foundry LLC	IPR2024-00279
10,894,011	The Foundry LLC	IPR2024-00280
11,679,077	The Foundry LLC	IPR2024-00281

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III. CERTIFICATION OF GROUNDS FOR STANDING

Petitioners certify under 37 C.F.R. Section 42.104(a) that the '286 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

Under Rules 42.22(a)(1) and 42.104(b)(1)-(2), Petitioners request cancellation of claims 1-4, 7-9 ("Challenged Claims") of the '286 patent.

A. Prior Art

The '286 patent was filed on May 21, 2021 and claims priority through multiple parent applications to U.S. Provisional No. 61/496,930 filed on June 14, 2011.¹ Ex.1001-USP286, Cover.²

¹ Petitioners assume for purposes of this Petition that the '286 patent is entitled to the claimed priority date but reserve the right to argue in the parallel litigation that it is not.

² The '286 patent was examined under the provisions of the AIA, but each of the relied-upon references qualifies as prior art regardless of whether the AIA or pre-AIA provisions apply.

1. **USP 6,517,535** to Edwards (“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** to Stern (“Stern”), Ex.1033-Stern, published October 8, 1996 and filed October 6, 1994, is prior art under §§102(a)(1) and 102(a)(2).
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. **Liang et al.**, “Radiofrequency treatment of ethmoidal nerve with allergic rhinitis under nasal endoscopy,” 13:8 J. Clin Otorhinolaryngology (China) 341 (August 1999) (“Liang”), Ex.1056-Liang, published August 1999, is §102(a)(1) prior art. *See* Ex.1070-Munford-Decl.; Ex.1072-Liang-Decl.; Ex.1076-Liang-Appx.; *Telefonaktiebolaget LM Ericsson v. TCL Corp.*, 941 F.3d 1341, 1346-47 (Fed. Cir. 2019).
5. **U.S. Patent No. 6,273,886** to Edwards (“Edwards-’886”), Ex.1016-Edwards-’886, published May 7, 2000 and filed September 26, 1996, 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 here would be expected well before the approximately 3-year median time to trial in the District of Delaware. *See* Ex.1008. And this Petition presents compelling merits underlying eight Grounds.

Second, as detailed below, none of references in the Grounds presented in this Petition were previously applied to the claims during the prosecution of the '286 patent. Neither Edwards-'535, Stern, Liang, nor Edwards-'886 were before the patent office. Although Makower was cited by PO during prosecution, it was buried among nearly 200 other references and was not discussed materially during prosecution. Accordingly, discretionary denial is not warranted.

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	1-3,7-9	Edwards-'535 + Stern
II	103	8	Ground I + Edwards-'886
III	103	1-4, 7-9	Makower + Stern + Edwards-'535
IV	103	8	Ground III + Edwards-'886
V	103	1-3,7-9	Ground I + Liang
VI	103	8	Ground I + Liang + Edwards-'886
VII	103	1-4,7-9	Ground III + Liang
VIII	103	8	Ground III + Liang + 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

The below sections detail (1) known concepts for RF ablation and RF ablation devices, including bipolar devices with electrode pairs, impedance sensors, and multiple output channels, (2) known aspects of nasal anatomy, and (3) known methods for treating rhinitis.

A. RF Ablation

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

B. 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 with bipolar and monopolar configurations (Ex.1011-Baker, 5:47-58; Ex.1012-Goble, 6:33-68, 11:23-49), handles (Ex.1011-Baker, 5:27-47), multiple bipolar electrodes (Ex.1012-Goble, 6:33-68, 11:23-49), steerable shafts (Ex.1021-Makower, [0186]), expandable cages made out of shape memory alloys (Ex.1015-Laufer, 9:5-14; Ex.1012-Goble, 10:61-12:30), 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., ¶30.

It was well known that RF energy could be delivered to (and modify) tissue in various ways. For example, electrodes could directly contact and apply RF energy to tissue to heat and destroy the tissue. Ex.1010-Edwards-'535, 5:27-32, 8:12-14, 8:26-39; Ex.1017-Chen, 240; Ex.1033-Stern, 3:12-15, 3:29-37. Other systems used RF energy to heat a liquid, where the liquid either transfers heat to the tissue or produces ionization that destroys tissue. Ex.1038-Thapliyal, 26:12-40, 4:38-58; Ex.1040-Kong, 215. Some devices could do both. *See, e.g.*, Ex.1038-Thapliyal, 26:12-44. Ex.1002-Decl., ¶¶31-34.

C. Monopolar and Bipolar RF Electrode Configurations

As noted above, RF ablation devices included both monopolar and/or 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 (252 and 256 shown in Stern Figure 16), 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.

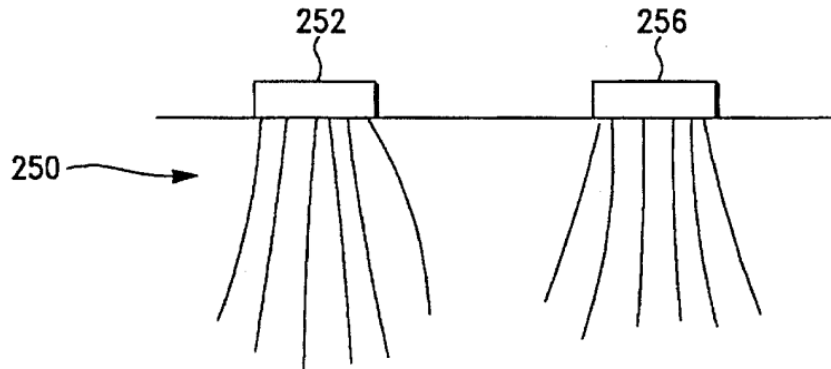


FIG. – 16

Ex.1033-Stern, FIG.16. Ex.1002-Decl., ¶¶39-40.

In a bipolar device, the return electrode (260 in Stern Figure 17) is placed inside the body, normally near the active electrode (258 in Stern Figure 17), and current only passes through the tissue between the active and return electrodes.

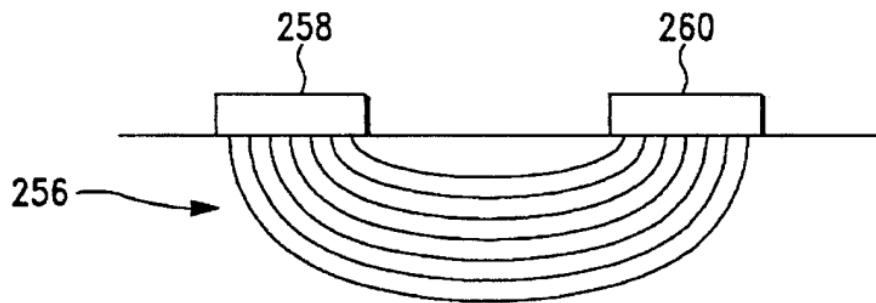


FIG. – 17

Ex.1033-Stern, FIG.17. Ex.1002-Decl., ¶41.

Bipolar RF electrodes present particular benefits 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 brain. Ex.1002-Decl., ¶¶42,44.

Known techniques can be used with bipolar RF ablation to ablate subsurface tissue while leaving the surface tissue 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 filled with a cooled fluid during ablation); Ex.1015-Laufer, 7:45-54 (same). Ex.1002-Decl., ¶43.

D. RF Energy in the Nasal Cavity

Prior to 2011, RF ablation was used in the nasal cavity to treat a variety of different conditions. For example, RF ablation was used to treat snoring, nasal obstruction secondary to non-allergic or allergic rhinitis, (Ex.1031-Hytönen, Abstract), rhinitis, (Ex.1056-Liang, Abstract, 341-42), or to remove a blockage or

shrink enlarged tissue (Ex.1010-Edwards-'535, Abstract; Ex.1023-Coste, 894; Ex.1031-Hytönen, Abstract). Ex.1002-Decl., ¶¶35-36.

By the 2000s, different commercial RF devices were used in the nose. Ex.1021-Makower, [0020]-[0021], [0038]-[0040]; *see also* Ex.1042-Bäck, Abstract, 1808; Ex.1044-Lee, Abstract, 108-09. Ex.1002-Decl., ¶37.

Also prior to 2011, clinicians were using RF ablation to treat rhinitis and reduce mucus production by targeting the nerves in the nasal cavity. Ex.1040-Kong, 215; Ex.1017-Chen, Abstract, 243; Ex.1055-Fang, 877; Ex.1056-Liang, 341. *See generally* Ex.1031-Hytönen, (surveying RF ablation for both nasal obstruction and rhinitis); *see also* Ex.1029-Arora (targeting nerve branches in the nose with cryotherapy in 1980). Ex.1002-Decl., ¶¶37-38.

VI. The '286 Patent

A. Brief Description

The '286 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-USP286, 11:24-30. Although the '286 patent discloses delivering various forms of energy to the targeted tissue, the claims of the '286 patent are focused on a device that delivers RF energy and is sized to be inserted into a nostril. *Id.*, 5:49-51, Clm.1. Ex.1002-Decl., ¶45.

The challenged claims require that the claimed treatment device comprise a handle, a shaft, and pairs of bipolar electrodes. *See, e.g.*, Ex.1001-USP286, FIG.18 (showing device 390 having shaft 394 connected to handle 398 with “pairs of bipolar electrodes 392 located at the distal end of [the] shaft 394,” *id.*, 27:34-57):

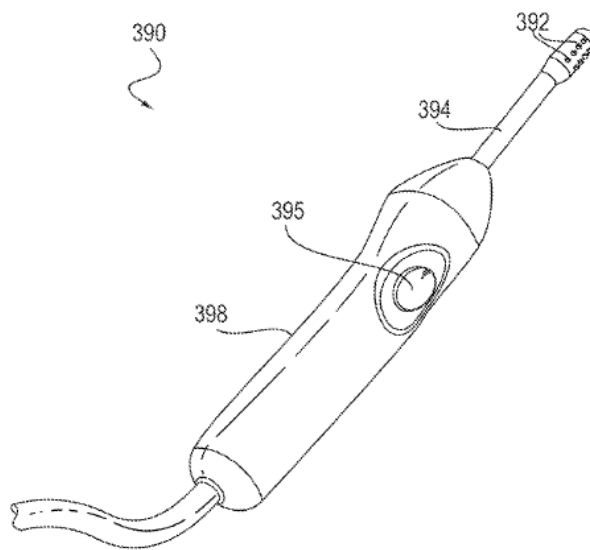


FIG. 18

Id., FIG.18. Ex.1002-Decl., ¶46.

To overcome prior art in the parent patent application, PO added limitations requiring (1) electrode pairs, and (2) providing RF energy to these pairs by

connecting each pair to its own RF output channel.³ See Ex.1063-USP318FH, 574. Those limitations are also in the presently challenged claims. Figure 8F, for example, shows “electrodes comprising one, two, or many pairs of bipolar needles 252...located on a treatment element.” Ex.1001-USP286, 24:32-34.

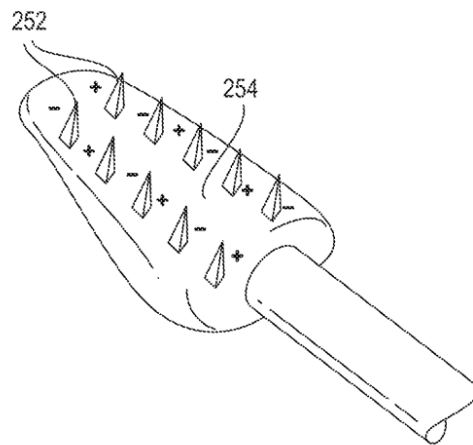


FIG. 8F

Id., FIG.8F. Ex.1002-Decl., ¶¶47-48.

According to the '286 patent, “each electrode pair...may have its own individual subsystem 970” with “a positive electrode 973 and a negative electrode 974,” and a “controlled RF channels 971.” Ex.1001-USP286, 49:46-52, FIG.41.

³ PO also added the requirement of multiple sensors during prosecution of the '318 patent. Ex.1063-USP318FH, 574.

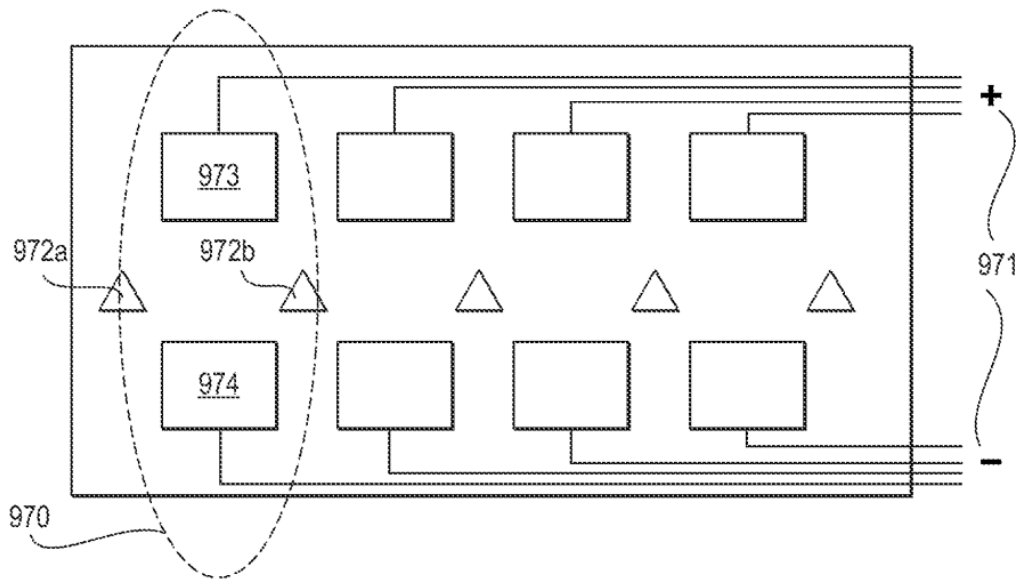


FIG. 41

Id., FIG.41. Ex.1002-Decl., ¶49.

The preamble to claim 1 in the '286 patent contemplates treatment of rhinitis. However, the '286 patent provides no detail regarding how RF energy can be applied to treat rhinitis. The '286 patent instead discloses methods and devices “to improve nasal airflow” “[w]hatever the cause.” Ex.1001-USP286, 4:4-16. Allergic rhinitis and non-allergic rhinitis are just two of at least six possible causes of poor nasal airflow. *Id.* Ex.1002-Decl., ¶50.

B. Prosecution History

The '286 patent was filed as application 17/327,254 on May 21, 2021, and claims priority to provisional application 61/496,930 filed on June 14, 2011. Ex.1003-USP286FH, 30, 34-35. After filing, PO filed a preliminary amendment to

replace claims 1-13 with 14-23. *Id.*, 215. The examiner rejected claims 14-23 on the basis of nonstatutory double patenting as being unpatentable over claims 1-17 of USP 11,033,318—the parent patent application. *Id.*, 219-22. Ex.1002-Decl., ¶¶51-53.

During prosecution of the **parent** patent application, PO amended the claims to require “pairs” of bipolar RF electrodes, “multiple radiofrequency output channels connected with the multiple pairs of bipolar radiofrequency electrodes,” and multiple sensors, such as “impedance sensors,”—the same limitations that appear in the challenged claims—to distinguish Makower. Ex.1063-USP318FH, 571-88, 590-613. But as shown below, none of these features were new or non-obvious. Ex.1002-Decl., ¶54.

VII. PERSON OF ORDINARY SKILL IN THE ART

A person of ordinary skill in the art (“POSITA”) at relevant times (2011-2021) 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 only determine the effect of claim 1's preamble, which is presumptively non-limiting: "*A device for delivering energy to a nasal airway to treat rhinitis, the device comprising....*" When read in the context of the entire claim, the preamble's recitation of a device "to treat rhinitis" is not limiting because (1) the preamble does not limit the structure of the claimed invention, or, at most, (2) it recites a mere statement of purpose or intended use. *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002); *Shoes by Firebug LLC v. Stride Rite Children's Grp., LLC*, 962 F.3d 1362, 1367 (Fed. Cir. 2020); *Howmedica Osteonics Corp. v. Zimmer, Inc.*, 640 F. App'x 951, 956 (Fed. Cir. 2016) ("medical implant" in preamble was not limiting where the claim body defined a structurally complete invention).

The preamble of challenged claim 1 envisions using the claimed device to "treat rhinitis." This aspect of the preamble is not limiting because it does not recite an essential structure, and is not necessary to give life, meaning, and vitality to the claim. *Catalina Mktg. Int'l, Inc.*, 289 F.3d at 808, 809 ("[P]reambles describing the use of an invention generally do not limit the claims because the patentability of apparatus or composition claims depends on the claimed structure, not on the use or purpose of that structure."). Indeed, the challenged claims here are very similar to

the allowed claims in the parent '318 patent that were found patentable based on the claimed structure. Ex.1063-USP318FH, 571-88, 590-613. Here, like in *Howmedica*, the body of the claims recites a structurally complete apparatus that was purportedly patentable based on its structure, not its use.

The preamble only states an intended use for the device—to treat rhinitis. Indeed, the '286 patent is directed to improving nasal airflow, Ex.1001-USP286, 4:4-16, and only mentions rhinitis in passing as a **cause** of poor nasal airflow, *id.*; *see also supra*, §VI.A, without describing how to **treat** the underlying rhinitis itself, much less the device structure required to do so. *Catalina Mktg. Int'l, Inc*, 289 F.3d at 809; *Shoes by Firebug LLC*, 962 F.3d at 1367. The intended use is therefore not limiting.

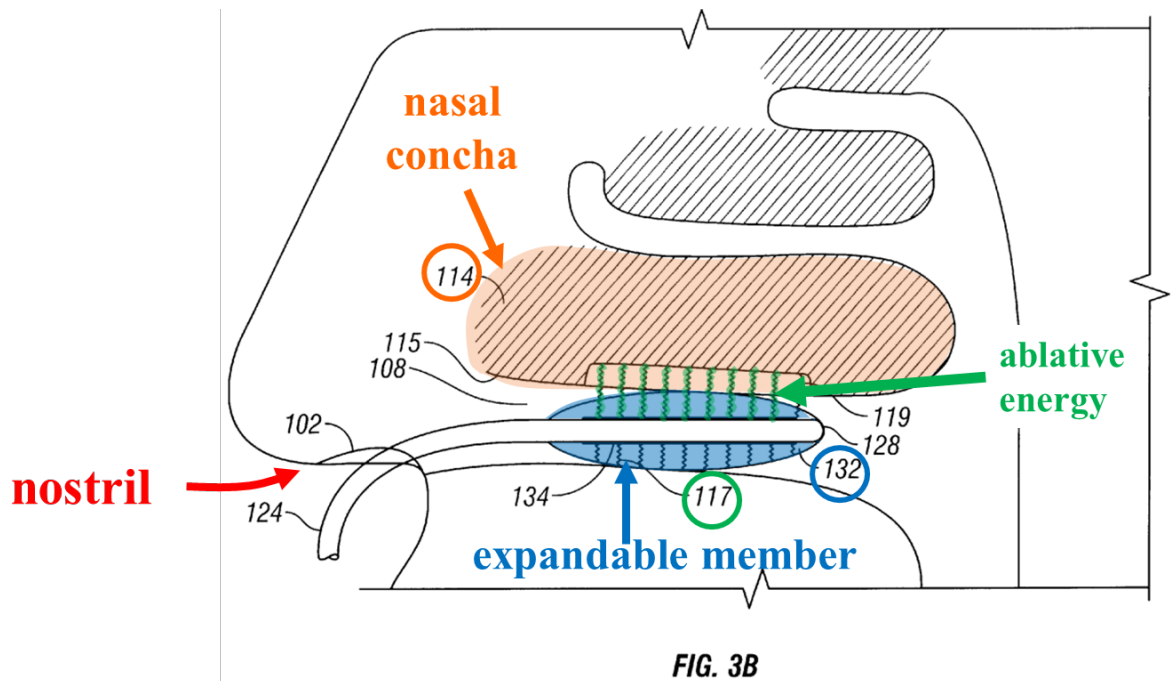
Other than the preamble, the Board need not construe any terms because the Challenged Claims are invalid under any reasonable interpretation. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017). Ex.1002-Decl., ¶¶55-60.⁴

⁴ 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.

IX. OVERVIEW OF THE ASSERTED PRIOR ART

A. Edwards-'535

Edwards-'535 discloses an RF device “introduced through a nostril” and used “for ablating an internal section of a nasal concha” to “improv[e] airflow.” Ex.1010-Edwards-'535, 5:23, 3:19, 4:31. 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 **nasal concha 114** without ablating the surface. *Id.*, 4:53-67, 5:27-30, 6:10-51, 6:66-7:24, FIGs.3A-4C.



Ex.1010-Edwards-'535, FIG.3B.⁵ Ex.1002-Decl., ¶¶64-67.

B. Stern

Stern discloses an 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 tissue surface. *Id.*, 7:49-61. An exemplary arrangement 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**.

⁵ All annotations added unless otherwise stated.

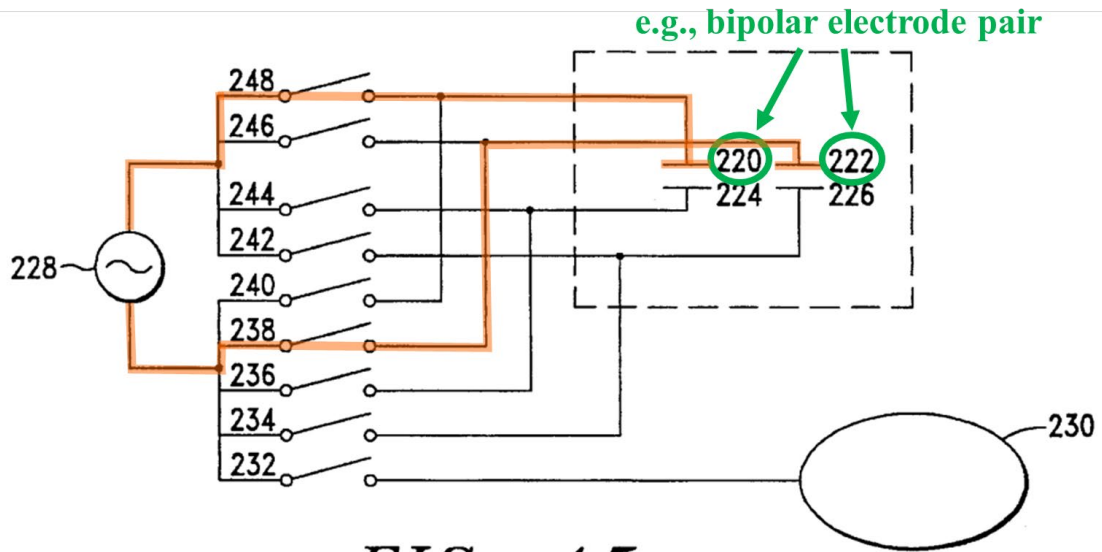
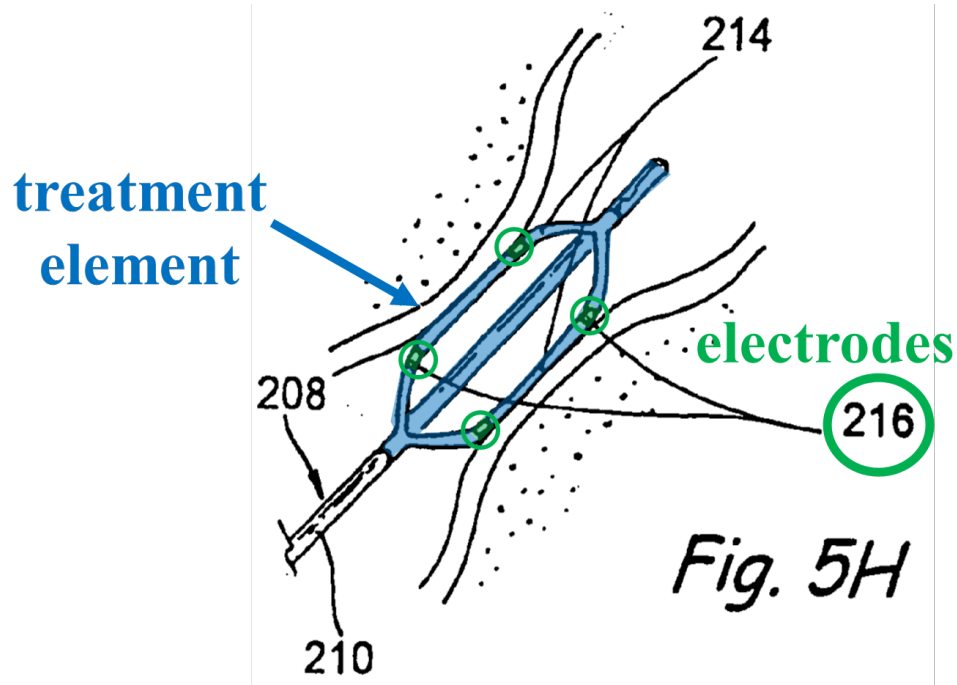


FIG. – 15

Id., FIG.15. Ex.1002-Decl., ¶¶68-71.

C. Makower

Makower discloses “medical devices and methods ... for treating sinusitis and other ear, nose & throat disorders.” Ex.1021-Makower, [0001]. In particular, Makower discloses a variety of electrosurgical devices that can be inserted into nasal passageways “to perform...therapeutic procedures.” *Id.*, [0161]. For example, Figure 5H of Makower depicts an 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., ¶¶72-73.

D. Liang

Liang discloses the results of a clinical study showing that applying RF energy to the nasal airway is a promising technique for treating rhinitis. Ex.1056-Liang, Abstract, 342. Liang states that RF energy delivery can generate high tissue temperatures and cause thermal coagulation to treat disease. *Id.*, 341. Liang discloses that such RF energy to the nose “can cause varying degrees of damage to the deep ethmoidal nerve,” which can reduce a patient’s runny nose and improve other rhinitis symptoms. Ex.1002-Decl., ¶¶74-76.

E. Edwards-'886

As detailed in the grounds below, Edwards-'886 discloses the features in dependent claim 8 and thereby renders that claim obvious in combination with other prior art. Ex.1002-Decl., ¶¶77-78.

X. SPECIFIC GROUNDS FOR UNPATENTABILITY

Grounds I-II demonstrate unpatentability should the Board find that the preamble's statement that the claimed device "treat rhinitis" is not limiting. Grounds III-VIII demonstrate unpatentability should the Board find that the preamble's recitation to "treat rhinitis" is limiting.

A. Ground I: Claims 1-3, 7-9 Are Invalid as Obvious over Edwards-’535 and Stern

1. Claim 1

a. 1[pre]

If the portion of the preamble other than “treat rhinitis” is limiting,⁶ 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).*⁷ Ex.1002-Decl., ¶¶80-81.

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.*, 1:21-25, 1:60-2:6, 3:18-36, FIGs.3A-4C. The nasal concha “form at least a portion of the[] nasal passageways.” Ex.1010-Edwards-’535, 1:60-2:6. Ex.1002-Decl., ¶82.

Edwards-’535 further teaches that the disclosed apparatus ablates “at least a portion of a nasal concha” to reduce its size, which, “improv[es] airflow through a

⁶ To the extent that the preamble recites an intended use, the device of Edwards-’535 (as modified by Stern) could have been used to treat rhinitis for the reasons such use would have been obvious. *See* §X.E.

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

nasal meatus of the body.” Ex.1010-Edwards-’535, 4:18-32, 8:50-54, FIGs.4A-4C.
Ex.1002-Decl., ¶83.

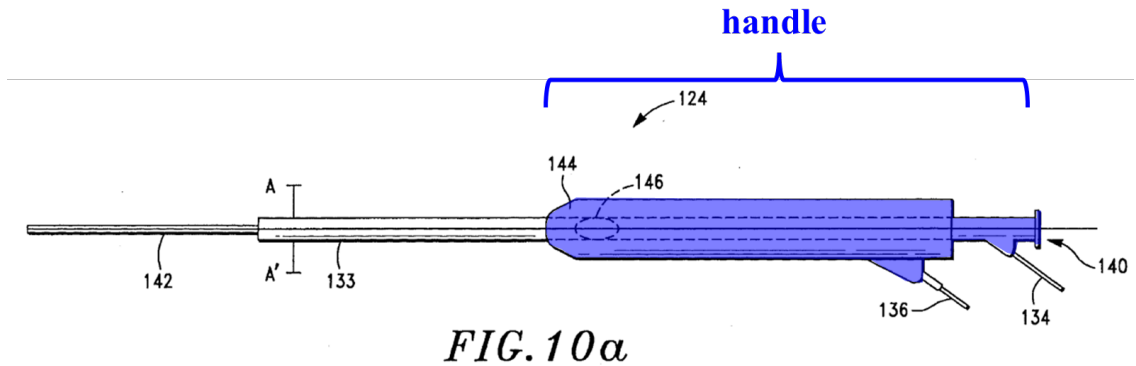
b. 1[a]

Edwards-’535 in view of Stern renders obvious a *handle*. Ex.1002-Decl., ¶84.

Edwards-’535 is silent as to whether its device includes a handle, but it would have been obvious to include a handle in Edwards-’535’s device 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-4C. 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 an expandable member were ubiquitous in the art at that time. Ex.1002-Decl., ¶85.

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.



Ex.1033-Stern, FIG.10a. Ex.1002-Decl., ¶86.

A POSITA would have been motivated to use a *handle* in the Edwards-'535 device 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-4C. 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., ¶¶87-89.

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 shaft is shown extending from one end of the applicator device 124). Ex.1002-Decl., ¶¶90-91.

As shown in Figures 3A-4A, 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*).

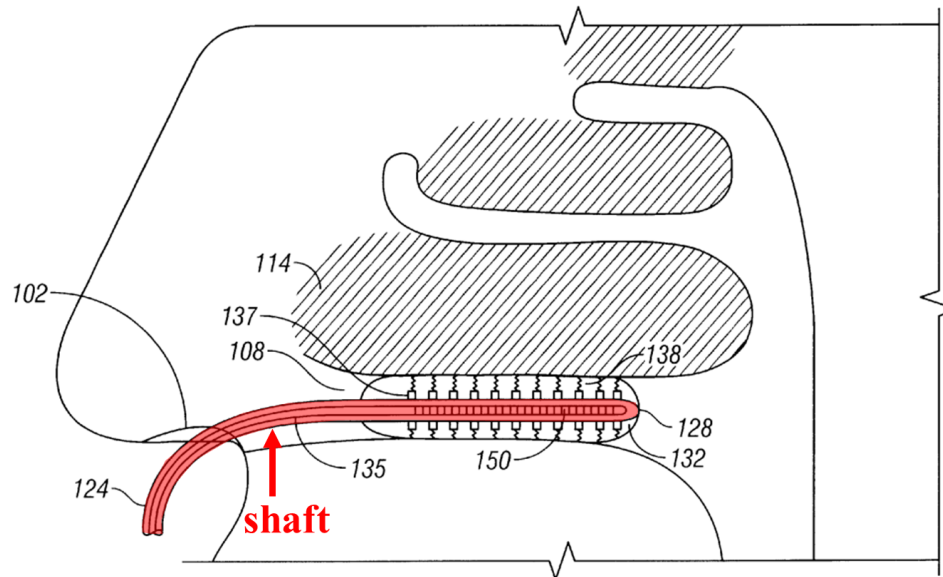
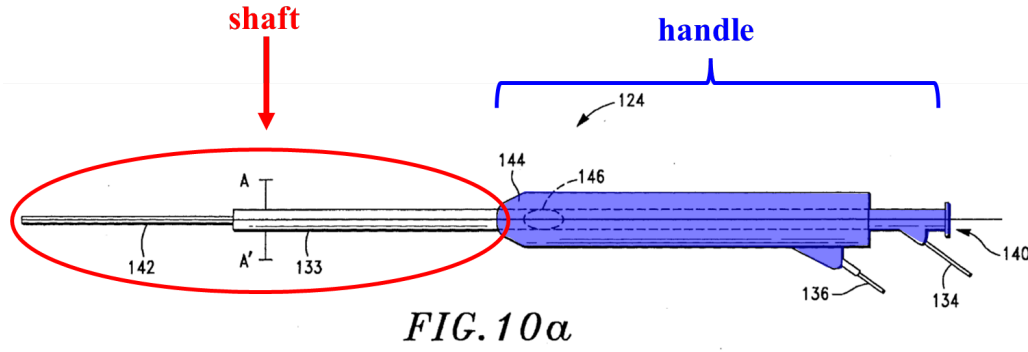


FIG. 3C

Ex.1010-Edwards-'535, FIG.3C. Ex.1002-Decl., ¶92.

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*).



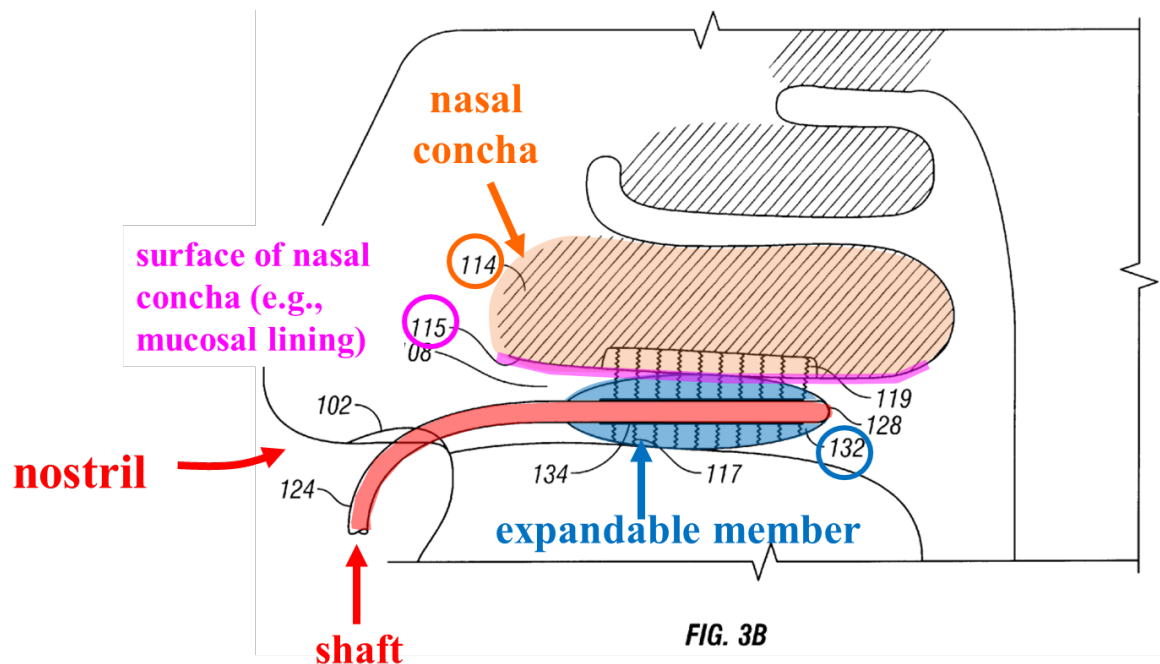
Ex.1033-Stern, FIG.10a. Ex.1002-Decl., ¶¶93-94.

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 for limitation 1[a], 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., ¶95.

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) to contact **nasal mucosa lining the nasal airway** (e.g., the **surface 115** of the nasal concha 114).

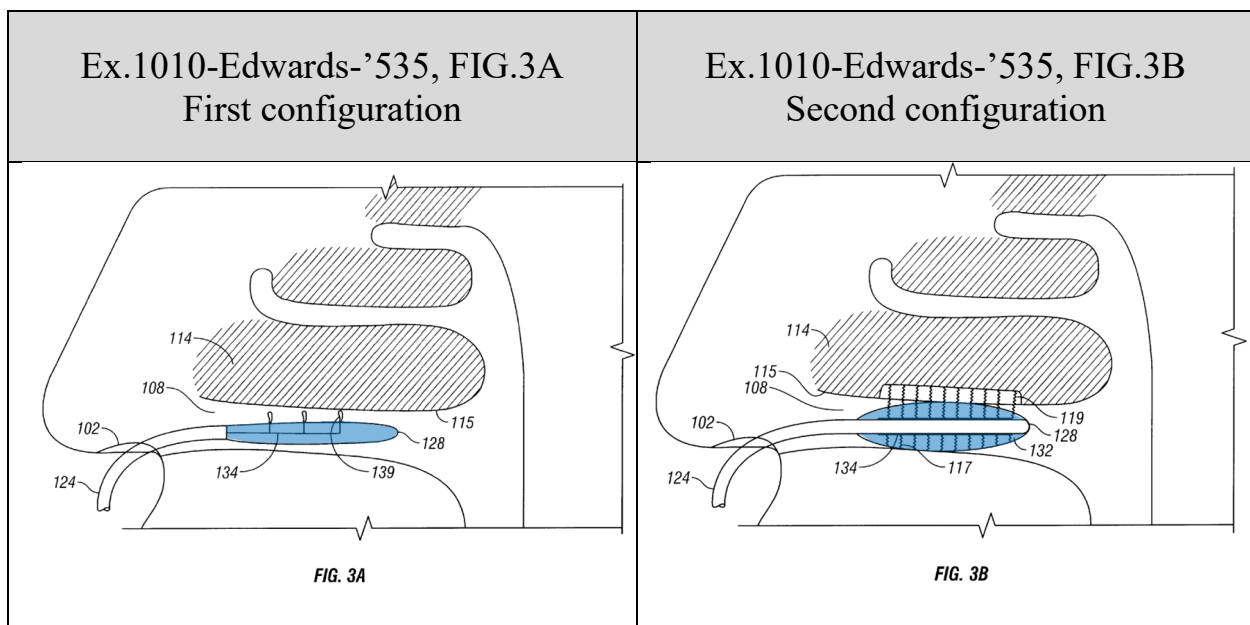


Ex.1010-Edwards-'535, FIG.3C. Ex.1002-Decl., ¶¶96-98.

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].” *Id.*, 5:21-23, FIGs.3A-3D; see also *id.*, 6:10-22. As shown in FIGs.3A-3D and 5, the apparatus has a catheter body

126 to which the [expandable member 132](#) is coupled. *Id.*, 7:33-35, 7:43-45.
Ex.1002-Decl., ¶99.

As shown in Figures 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, 4:53-67, 5:22-30, 5:52-60, 6:33-36, 7:33-46, 7:61-8:46.



Ex.1002-Decl., ¶100.

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 “preferably conforms to the surface of the nasal concha [114] to be ablated.” Ex.1010-Edwards-'535, 5:18-26, 7:37-40. Ex.1002-Decl., ¶101.

An “energy delivery device [134] may be positioned on a surface 147 of the expandable member.” Ex.1010-Edwards-’535, 8:12-16, FIG.6, 8:17-32. “[T]he expandable member 132 is brought into contact with the **surface 115** of the nasal concha 114 to be treated.” *Id.*, 5:28-30. RF energy is then applied to treat the nasal concha 114. *Id.*, 8:50-54. The **surface of the nasal concha** is lined with a mucus membrane. Therefore, by contacting the nasal concha 114, Edwards-’535 teaches that its treatment element is configured to *contact nasal mucosa lining the nasal airway*. Ex.1002-Decl., ¶102.

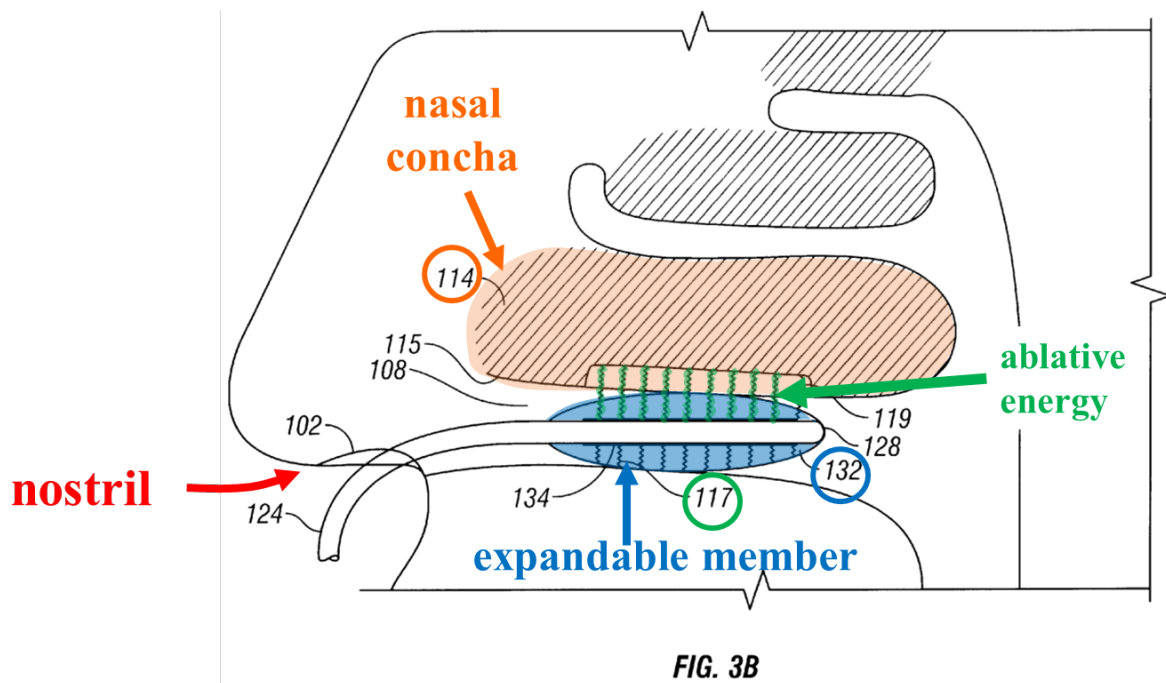
e. 1[d]

Edwards-’535 in view of Stern renders obvious *multiple pairs of bipolar radiofrequency electrodes* (e.g., plurality of **bipolar energy delivery devices**) *disposed on the treatment element* (e.g., on the surface of **expandable member 132**). Ex.1002-Decl., ¶¶103-104.

- i. Edwards-’535 teaches *multiple...bipolar radiofrequency electrodes disposed on the treatment element*.

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.3. For example, Edwards-’535 teaches that the energy delivery member can include ring electrodes 156, *id.*, 8:19-33, and a POSITA

further would have been aware of a number of other surface energy delivery device configurations. *See, e.g.*, Ex.1011-Baker, Abstract, 5:66-67, 9:13-23; Ex.1033-Stern, 2:26-35. These energy delivery devices/electrodes deliver RF energy in a bipolar mode. Ex.1010-Edwards-'535, 8:17-32, 8:50-54, 10:30-32, 10:52-61.

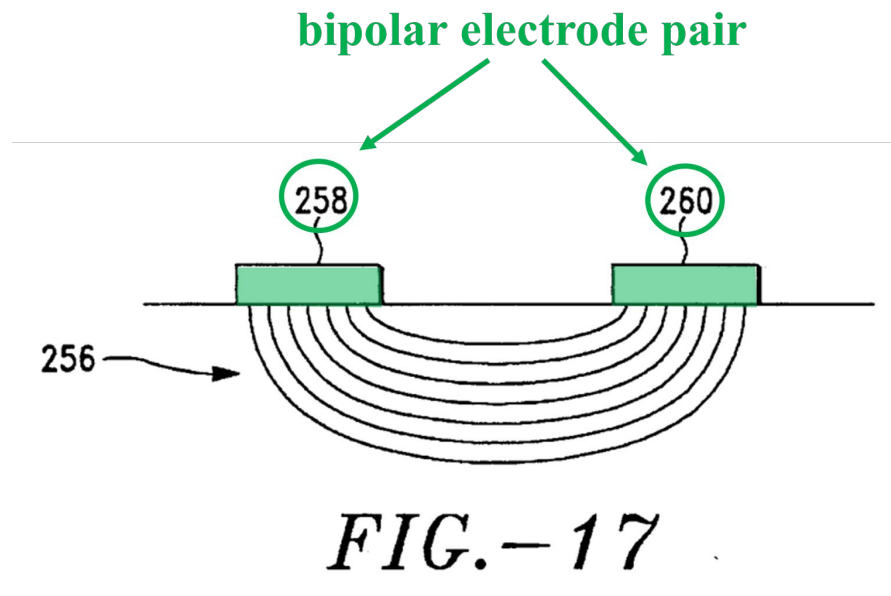


Ex.1010-Edwards-'535, FIG.3B. Ex.1002-Decl., ¶¶105-106.

Edwards-'535 leaves the details of how to deliver bipolar RF energy to the discretion and skill of a POSITA. *See* Ex.1010-Edwards-535, 10:52-61. Ex.1002-Decl., ¶107.

- ii. Stern teaches *multiple pairs of bipolar radiofrequency electrodes disposed on the treatment element.*

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



Id., FIG.17. Ex.1002-Decl., ¶¶108-110.

Stern’s Figure 15, reproduced below, shows that the circuitry used to operate bipolar pairs includes four electrodes 220, 222, 224 and 226 and various switches that determine the type of bipolar configuration. 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.

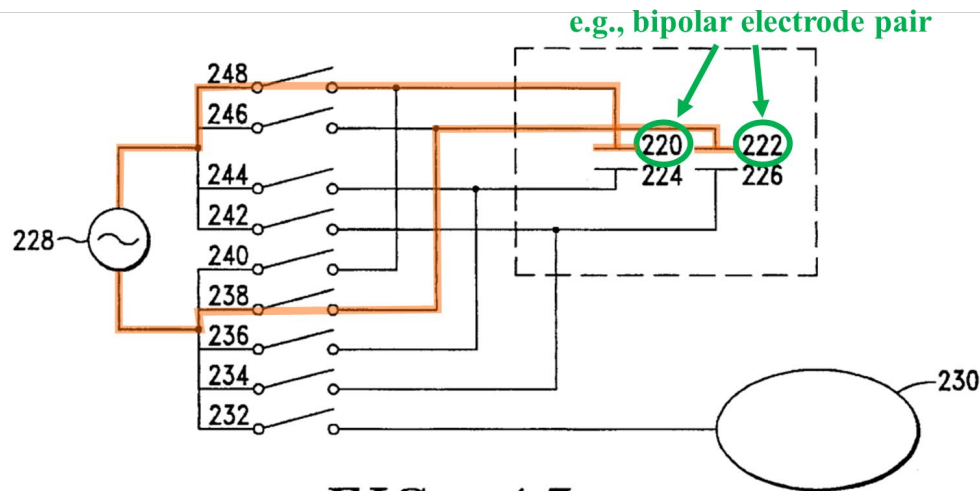


FIG. – 15

Ex.1033-Stern, FIG.15. Ex.1002-Decl., ¶111.

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. Ex.1002-Decl., ¶112.

First, Edwards-’535 and Stern are analogous art to the Challenged Claims. All are in the same field as the ’286 patent and are reasonably pertinent to solving the problems addressed in the ’286 patent—treating tissue in a body cavity—with

the same types of solutions—applying RF energy to tissue via an expandable device having multiple surface electrodes. Ex.1010-Edwards-'535, 8:18-25; Ex.1033-Stern, 12:25-27, 3:21-25. Ex.1002-Decl., ¶113.

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 and used 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 teaches delivering “bipolar or monopolar energy,” *id.*, 10:52-61, Edwards-'535 leaves details on how to implement such energy delivery up to a POSITA. Thus, Edwards-'535 is ready for improvement, and a POSITA would have been motivated to turn to other sources for information 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 implementing a system with switches/relays and a single voltage source (like Stern) or 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., ¶¶113-115.

A POSITA would have also been motivated to improve Edwards-'535's device to include Stern's technique for pairing bipolar RF surface electrodes (described above) and wiring them to allow for independent delivery of RF energy to each bipolar pair (described above and in limitation 1[e]) because of the benefits Stern identifies. **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**, configuring electrodes in bipolar pairs allows heating of targeted tissue while ensuring that surrounding tissue is unaffected, especially where there is uneven (e.g., non-heterogeneous) tissue morphology. *See id.*, 13:21-39, FIG.15. **Third**, pairs of bipolar electrodes can ensure even heating. *See id.*, 12:25-33. **Finally**, in view of the above, 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., ¶¶116-121.

These benefits are a teaching, suggestion, or motivation that would have led a one of ordinary skill to modify Edwards-'535 in view of Stern to accomplish these

same results in Edwards-'535's device with a reasonable expectation of success. Doing so is simply 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 improves the similar device of Edwards-'535 in the same way as the technique is used in Stern. Further, combining Edwards-'535 and Stern involves applying Stern's known bipolar pairing technique to Edwards-'535's known device that was ready for improvement (because Edwards-'535 omits electrode wiring details) to yield predictable results. Ex.1002-Decl., ¶122.

Edwards-'535 and Stern each describe similar techniques of delivering bipolar RF ablation energy through expandable devices to the mucosal tissue of different body cavities, such that their combination would have been straightforward and 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 electrodes 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. Ex.1002-Decl., ¶123.

Edwards-'535's silence regarding the circuitry to independently control bipolar electrodes demonstrates that implementing Stern's bipolar electrode pairing technique would have been within a POSITA's skill and that a POSITA would have expected doing so to be successful. 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, 5:66-67, 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., ¶¶124-132.

Accordingly, applying Stern's teachings to Edwards-'535 would have been a matter of routine implementation within a POSITA's skill 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., ¶133.

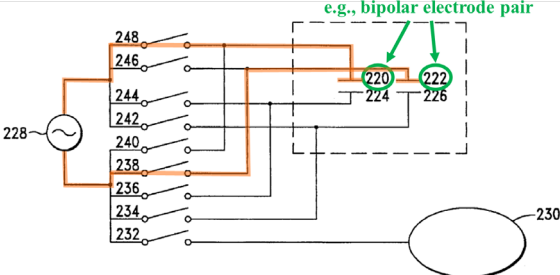
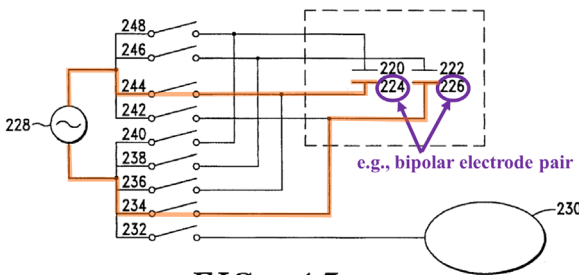
f. 1[e]

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., ¶¶134-135.

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., ¶136.

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.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

Ex.1002-Decl., ¶137.

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 particular **bipolar pairs** are activated. *Id.*, 12:46-13:2. 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. For example, Stern 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 FIG.5). Ex.1002-Decl, ¶138.

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 bipolar electrodes taught by Stern), to a known device (Edwards-'535 inflatable RF ablation device) that was ready for improvement (because Edwards-'535 is silent 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 local temperature and ablation depth 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., ¶¶139-149.

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., ¶¶150-158.

g. 1[f]

Edwards-'535 discloses *at least one impedance sensor* (e.g., *impedance sensors, impedance calculation device 194, and/or monitor 210*) *configured to*

measure impedance in the multiple pairs of bipolar radiofrequency electrodes (e.g., measurement is based on the current and voltage delivered to the multiple bipolar electrodes, configured in pairs as taught by Stern). Ex.1002-Decl., ¶¶159-160.

Edwards-'535 explains that sensors can be used to “detect a variety of operating parameters including...**the impedance generated.**” Ex.1010-Edwards-'535, 9:14-23. Edwards-'535 teaches impedance sensing based on the current and voltage delivered to the electrodes. *Id.*, 10:4-8, FIG.8. Edward-'535 does not limit impedance measurements to its monopolar embodiments, *id.*, 9:14-23, 10:4-11, 10:62-11:45, and Edwards-'535's disclosure of impedance sensing is equally applicable when arranging such electrodes in one or more bipolar pairs, as Stern teaches. With reference to Figure 8, annotated below, 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.” Ex.1010-Edwards-'535, 10:4-11.

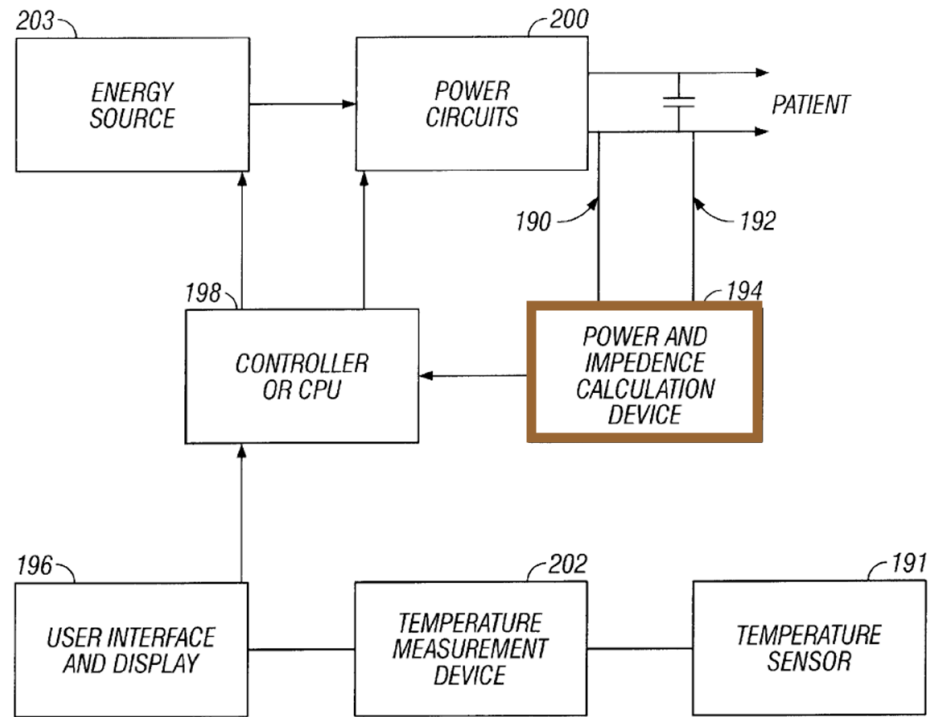


FIG. 8

Ex.1010-Edwards-'535, FIG.8. Ex.1002-Decl., ¶¶161, 163.

Edwards-'535 further explains that its system can use an impedance feedback loop “so that the output energy of the energy source is adjusted in relation to the [impedance] sensed by the sensor.” Ex.1010-Edwards-'535, 9:45-55. For example, Edwards-'535 explains that “[a] monitor 210 ascertains tissue impedance,” and if the measured impedance exceeds a set value, energy delivery is stopped, otherwise energy is delivered. *Id.*, 11:23-44.

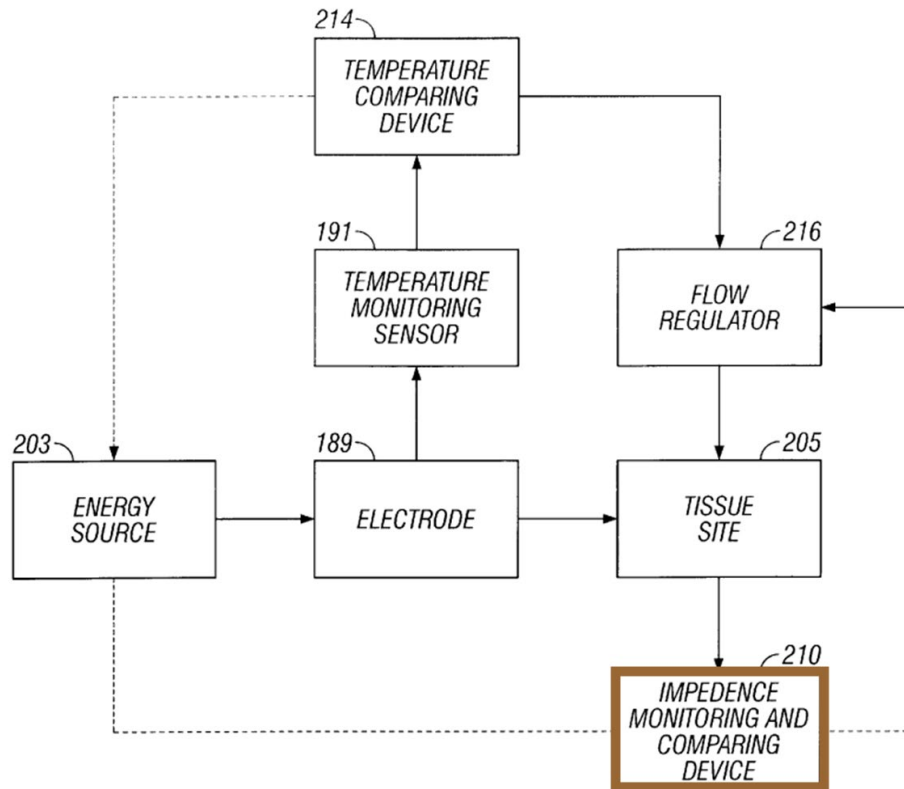


FIG. 10

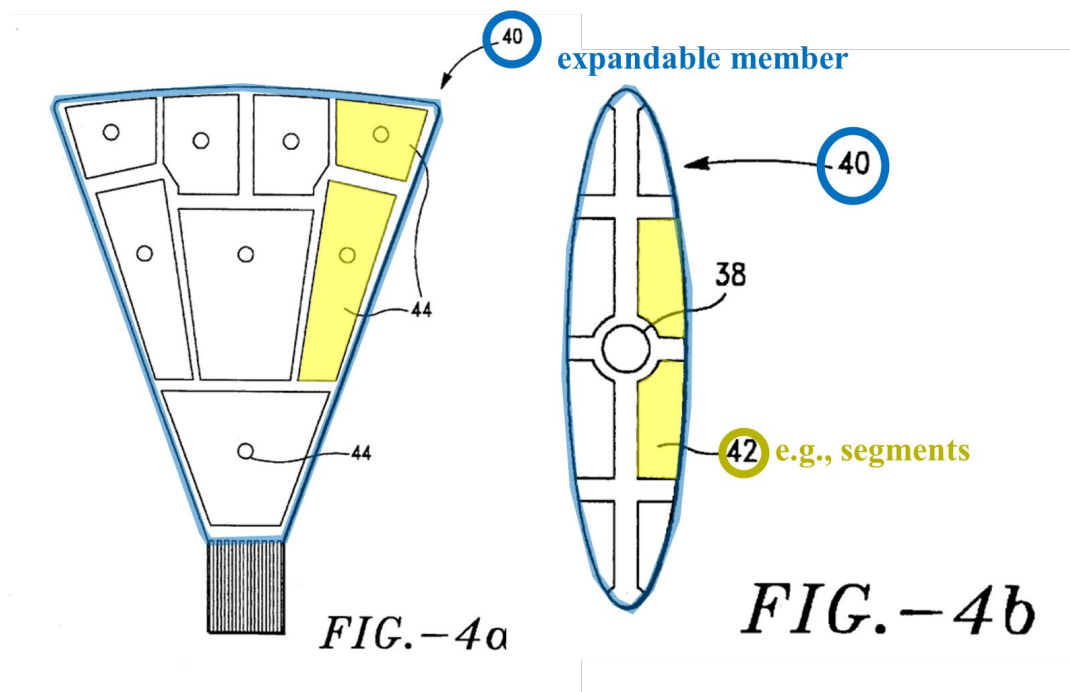
Ex.1010-Edwards-'535, FIG.10; *see also id.* 10:4-11, 11:1-44 (describing the impedance feedback loop system). Ex.1002-Decl., ¶¶162, 164-165.

2. Claim 2

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., ¶¶166-168.

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.



Ex.1033-Stern, FIGs.4a, 4b. Ex.1002-Decl., ¶¶169-170.

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.” *Id.*, 8:53-59. As shown below, Edwards-’535’s expandable member 132 is segmented in the same way as Stern:

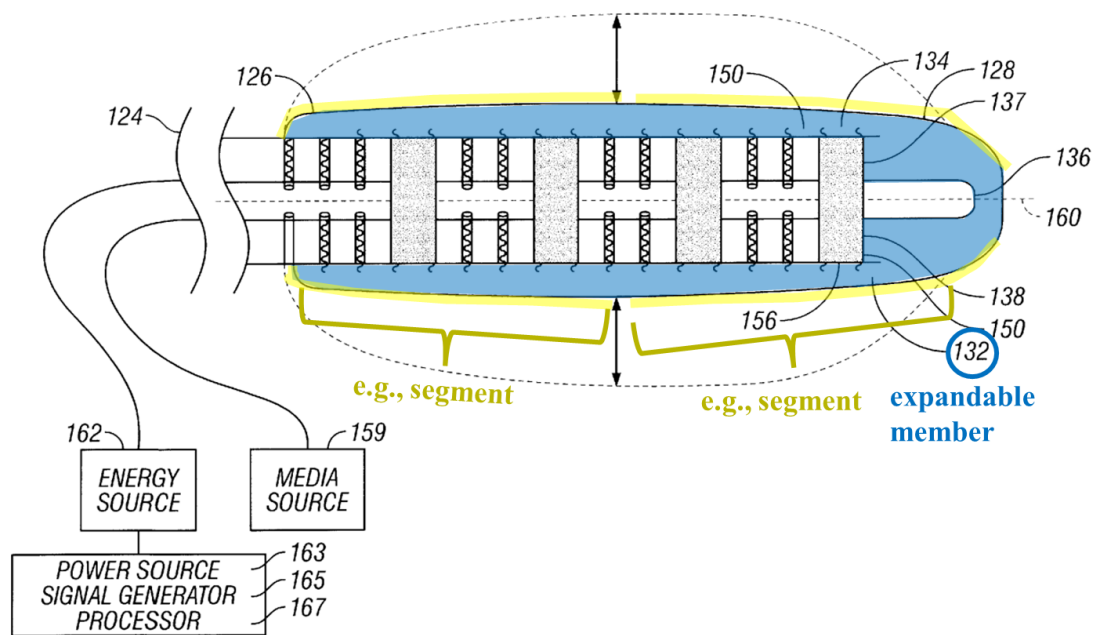


FIG. 6

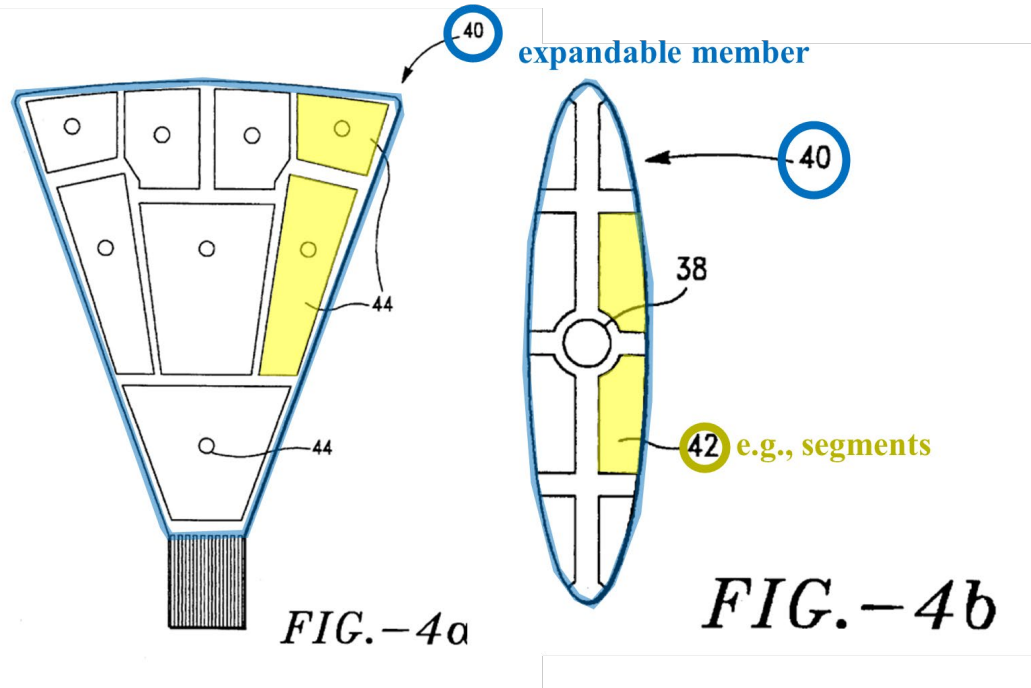
Ex.1010-Edwards-'535, FIG.6. As explained with reference to limitations 1[d] and 1[e], Edwards-'535 instructs a POSITA that its device can independently deliver energy to electrodes but omits detail regarding how to accomplish independent energy delivery. *Id.*, 8:17-32, 10:30-32, 10:52-61. A POSITA 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 limitations 1[d] and 1[e]. 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. *See supra*, §X.A.1; Ex.1010-Edwards-'535, 4:53-66. Ex.1002-Decl., ¶¶171-173.

3. Claim 3

Edwards-'535 in view of Stern discloses that *at least one electrode* (e.g., an energy delivery device in Edwards-'535) *of the multiple pairs of bipolar radiofrequency electrodes* (e.g., a plurality of energy delivery device 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., ¶¶174-175.

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.



Ex.1033-Stern, FIGs.4a, 4b. Ex.1002-Decl., ¶176.

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 electrode of the multiple pairs of bipolar RF electrodes. Ex.1002-Decl., ¶¶177-178.

As explained above for claims 1 and 2, a POSITA would have been motivated to use the electrode configuration as taught by Stern in combination 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., ¶179.

4. Claim 7

a. 7[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 at least one impedance sensor* (e.g., Edwards-'535's impedance sensor) *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). Ex.1002-Decl., ¶¶180-182.

As discussed above for limitation 1[f], Edwards-'535 teaches an impedance feedback control system where a “the output energy of the energy source is adjusted in relation to the property sensed by the sensor.” Ex.1010-Edwards-'535, 9:45-56. Specifically, Edwards-'535 discloses that a controller 198 receives the impedance value calculated by the impedance calculation device, and then generates a “control signal” that is “used by energy circuits 200 to adjust the energy output in an appropriate amount in order to maintain the desired energy delivered at each energy delivery device 189.” *Id.*, 10:3-18. Using impedance in a feedback loop like the one described in Edwards-'535 is advantageous because it indicates when little current

is flowing to the tissue and energy delivery can be reduced or stopped. Ex.1002-Decl., ¶183.

Thus, Edwards-'535 teaches *a radiofrequency generator* (i.e., signal generator) that *receives sensed signals from the from the at least one impedance sensor* (e.g., impedance sensor) *and delivers radiofrequency energy*. Ex.1002-Decl., ¶184.

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. Ex.1010-Edwards-'535, 8:22-24. Stern provides those details, using *multiple radiofrequency output channels* and teaching a similar feedback control loop to Edwards-'535, only Stern's feedback control loop uses temperature control 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. Ex.1002-Decl., ¶185.

Edwards-'535 also explains that both temperature and impedance can be used together in one feedback system, shown in Figure 10:

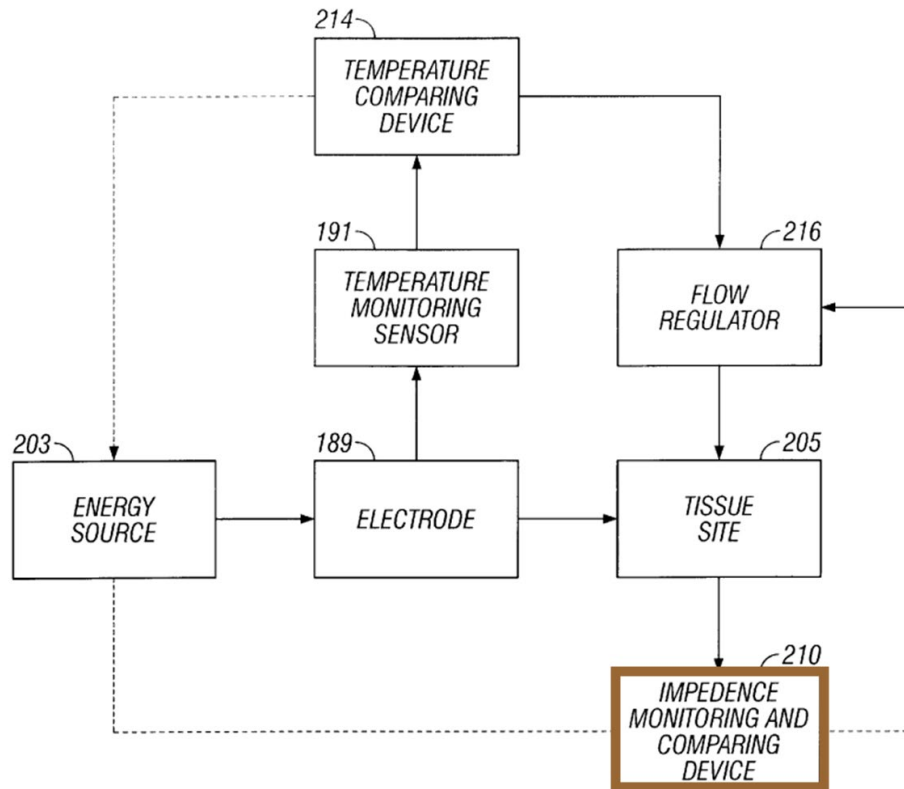


FIG. 10

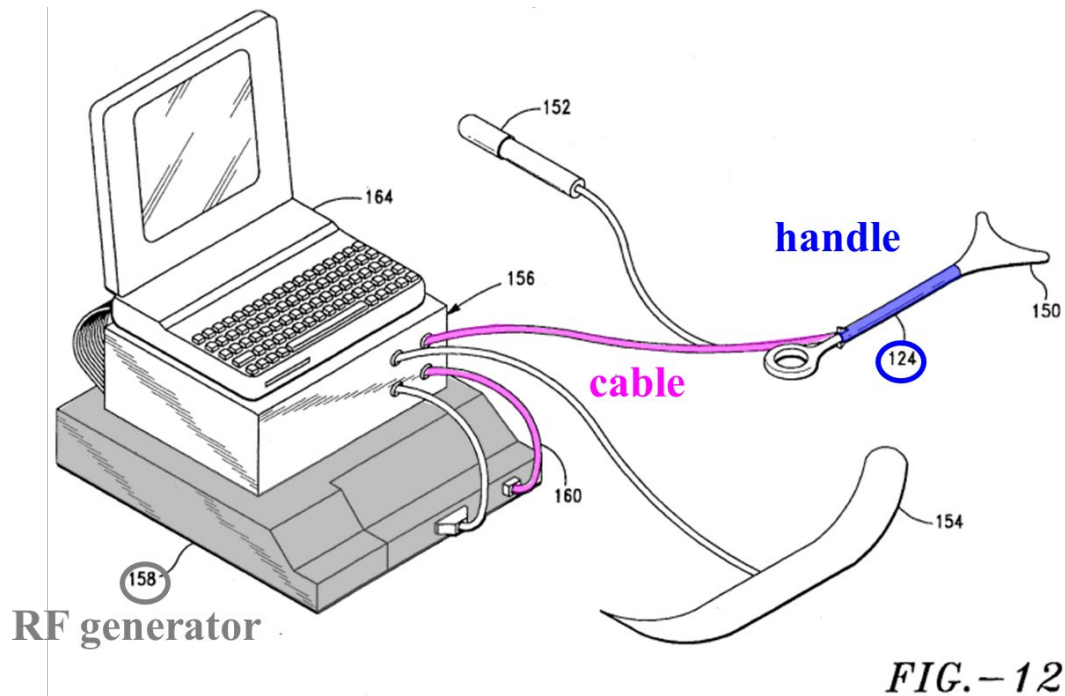
Ex.1010-Edwards-'535, FIG.10. Ex.1002-Decl., ¶186.

For this reason and the reasons in limitation 1[d]-[e], a POSITA would have been motivated to combine these aspects of Edwards-'535 and Stern, and would have had a reasonable expectation of success in doing so. Ex.1002-Decl., ¶187.

b. 7[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., ¶¶188-190.

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 7[a]. Ex.1002-Decl., ¶191.

5. Claim 8

Edwards-'535 in view of Stern discloses that the *radiofrequency generator* (e.g., signal generator 165 in Edwards-'535 and/or RF generator 158 in Stern) is configured to deliver the radiofrequency energy in a 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.1033-Stern, 2:18-20), *and 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). Ex.1002-Decl., ¶¶192-194.

First, 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 250kHz and less than 100 MHz,” which includes *460 kHz*. Ex.1033-Stern, 2:18-20, 3:15-20, Clm.1. Ex.1002-Decl., ¶195.

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.1010-Edwards-’535, 2:18-20, 3:15-20, Clm.1. Indeed, most RF ablation devices used in the body operate at a frequency of 460 kHz—including another reference to the same Edwards-’535 that teaches a generator that supplies RF energy “with a sinusoidal waveform at 460kHz.” Ex.1016-Edwards-’886, 36:66-37:3; *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., ¶196.

A POSITA would have been motivated to use a frequency of 460 kHz as taught by Stern to deliver RF energy using the Edwards-'535 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). 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.* 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 energy is lost over the length of a cable needed to connect the generator to the energy delivery device. Based on these considerations, a POSITA would have been aware 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. Ex.1002-Decl., ¶197.

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., ¶¶198-199.

The '286 patent does not disclose anything critical about ablation at 460 kHz sine wave—it is described as one “example” from the entire RF range. Ex.1001-USP286, 34:49-51. Thus, selecting an appropriate frequency for ablation would have involved mere routine optimization from a range disclosed by Stern. *See E.I. du Pont de Nemours & Co. v. Synvina C.V.*, 904 F.3d 996 (Fed. Cir. 2018). Ex.1002-Decl., ¶200.

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 and obvious output of a RF generator. Furthermore, all waveforms 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 just 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., ¶¶201-202.

Third, Edwards-'535 discloses that “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., ¶203.

6. Claim 9

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) and the *multiple radiofrequency output channels* (e.g., shown in orange in FIG.15 in Stern) are organized into multiple subsystems, and wherein each of the multiple subsystems comprises one of the multiple pairs of bipolar radiofrequency electrodes and one of the multiple radiofrequency output channels. Ex.1002-Decl., ¶¶205-206.

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

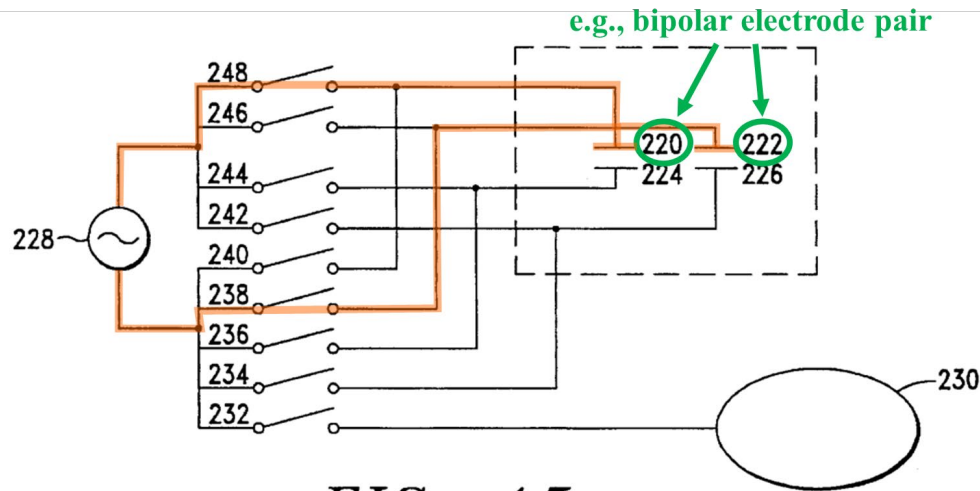


FIG. – 15

Ex.1033-Stern, FIG.15. Ex.1002-Decl., ¶207.

As annotated above, switches 248 and 238 are closed to make bipolar pairs 220 and 222. But the circuit has numerous switches, and therefore the possibility of numerous subsystems having different bipolar pairs and output channels. Ex.1002-Decl., ¶208.

A POSITA would have found it obvious to modify Edwards-'535 in view of Stern's teachings regarding the circuitry required to energize bipolar RF electrodes, which includes subsystems, where each subsystem has a bipolar electrode pair and an output channel for the reasons discussed above for limitations 1[d] and 1[e]. Such a combination involves applying a known technique (Stern's subsystems connecting a pair of bipolar electrodes with an output channel) 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 ’286 patent does not provide any detail beyond what someone skilled in the art would know. Ex.1002-Decl., ¶209.

B. Ground II: Claim 8 Is Invalid as Obvious Over Edwards-’535 in view of Stern in further view of Edwards-’886

As discussed in Sections X.A.1 and X.A.4, claims 1 and 7 are obvious over Edwards-’535 in view of Stern. Claim 8 is obvious in further view of Edwards-’886. Ex.1002-Decl., ¶210.

1. Claim 8

As explained in claim 8 in Ground I, Edwards-’535 in view of Stern discloses this limitation. Ex.1002-Decl., ¶211.

Edwards-’886 likewise discloses applying a *460 KHz sinusoid wave and to run at a power of between 5 and 75 watts* 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, 39:35-55, 39:56-40:3 (describing usage of sensor signals), FIGs.2, 73, 77. 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.* Ex.1002-Decl., ¶¶212-213.

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 using an expandable device, Ex.1016-Edwards-’886, Abstract, 10:58-11:15, 11:42-48, 36:66-37:10, and is therefore analogous art to the ’286 patent. Furthermore, although Edwards-’535 in view of Stern renders obvious a frequency range encompassing 460 kHz, it also would have been obvious to apply RF energy with a sinusoidal waveform at 460 kHz as taught by Edwards-’886. *See, supra*, §X.A.4. 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 in doing so. Indeed, most RF ablation generators sold prior to 2011 operated at a frequency of

460 kHz at a power of between 5 and 75 watts, making this frequency and power selection an almost necessary choice. A POSITA therefore would have been motivated to ablate using Edwards-'886's parameters and had a reasonable expectation of success in doing so. Ex.1002-Decl., ¶¶214-217.

C. Ground III: Claims 1-4, 7-9 Are Invalid as Obvious over Makower in view of Stern and Edwards-'535

Claims 1-3 and 7-9 are obvious over Makower in view of Stern and Edwards-'535. Ex.1002-Decl., ¶218.

1. Claim 1

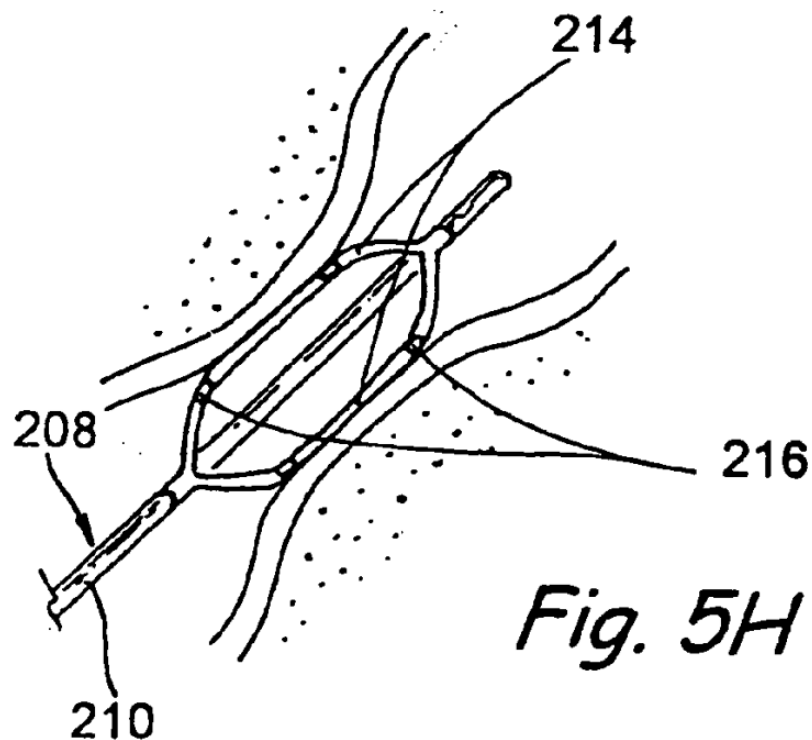
a. 1[pre]

If the portion of the preamble other than “treat rhinitis” is limiting, 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)*. Ex.1021-Makower, [0001], [0131]. Ex.1002-Decl., ¶¶219-221.

In the alternative, if the entire preamble is limiting, Makower teaches that its device can *treat rhinitis*. For example, Makower teaches that its device, a “working device,” can be used “for treating sinusitis and other ear, nose & throat disorders,” which a POSITA would understand to include rhinitis. Ex.1021-Makower, [0001], [0131], [0164]. Indeed, Makower notes that some of its working devices may deliver “substances that are used to treat rhinitis, nasal polyps, nasal inflammation, and other

disorders of the ear, nose and throat...” Ex.1021-Makower, [0161], [0164], [0169]-[0176]. Moreover, Makower indicates that its device can treat “nasal polyps, which may result from chronic allergic rhinitis.” *Id.* [0006], [0176]. Ex.1002-Decl., ¶222.

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., ¶223.

b. 1[a]

Makower or Makower in view of Stern render obvious a *handle*. Ex.1002-Decl., ¶224.

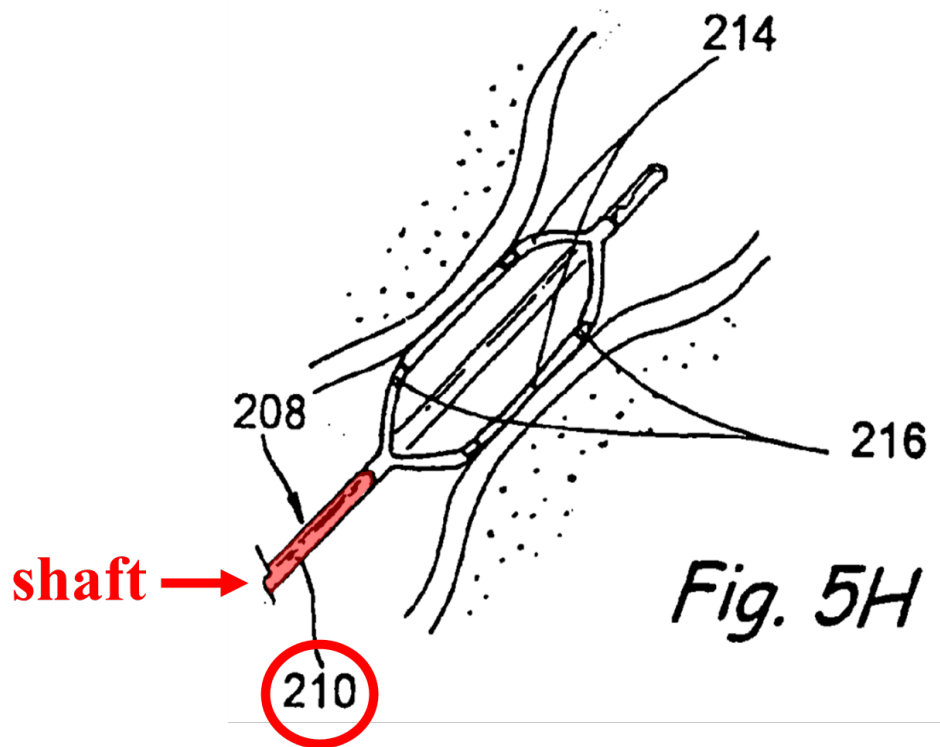
Although Makower does not specify that a *handle* is attached to electrosurgical device 208, Makower teaches that device 208 may be steerable and that “[s]teerable catheters and scopes are well known in the art.” Ex.1021-Makower, [0195], [0187]. Makower cites and incorporates several references that 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., ¶¶224-226.

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* §X.A.1.b-c, for example, to control and deploy the ablation device. Ex.1021-Makower, [0137], [1053]. Ex.1002-Decl., ¶¶227-228.

c. 1[b]

Makower discloses a *shaft* (e.g., *shaft 210*) *extending from one end of the handle*. Ex.1002-Decl., ¶229.

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



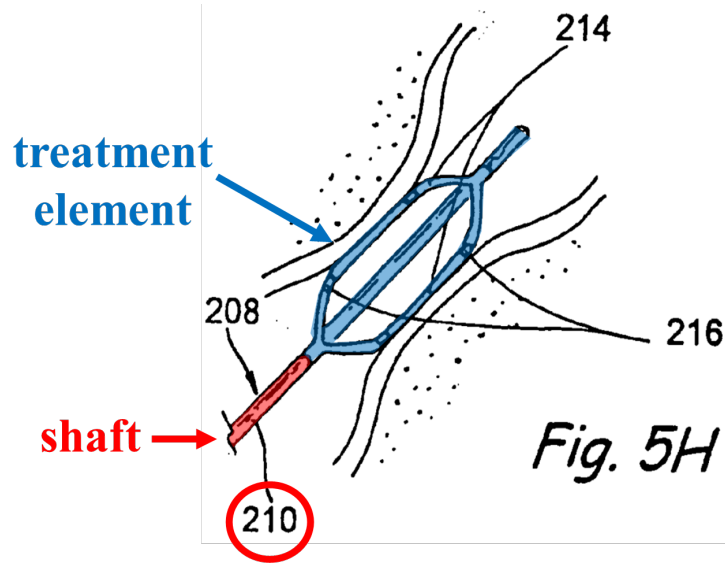
Ex.1021-Makower, FIG.5H, [0187]. Ex.1002-Decl., ¶230.

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., ¶¶231-232.

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) *to contact nasal mucosa lining the nasal airway* (e.g., the device may be placed to contact mucosal tissue in the nose such as the nasal turbinates). Ex.1002-Decl., ¶233.

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.



Ex.1021-Makower, FIG.5H. Ex.1002-Decl., ¶¶234-235.

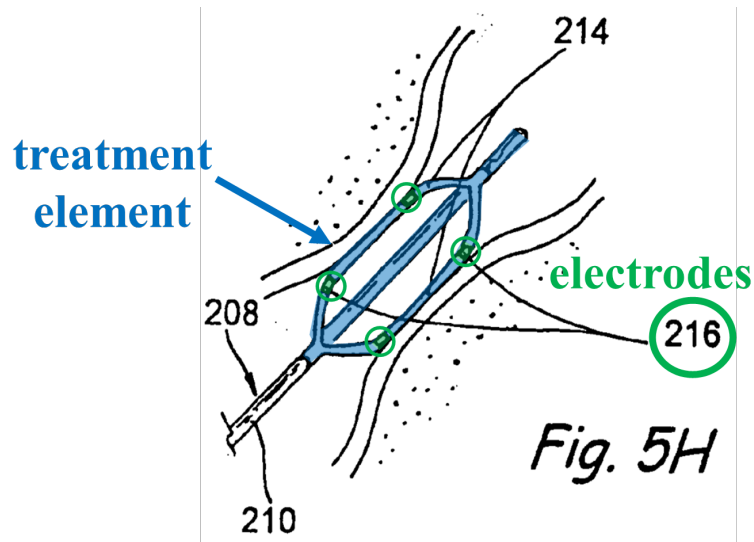
Makower describes that its device can be used in a variety of places in the nose where it would contact mucosal tissue. *Id.*, [0043]. For example, Makower describes using its device to contact the nasal turbinates, which are covered with mucosal tissue. *Id.*, [0004], [0018], [0020]-[0021], [0030], [0040], [0132], [0140], [0182], [0188]. Ex.1002-Decl., ¶¶236-237.

e. 1[d]

- i. Makower teaches multiple...*bipolar radiofrequency electrodes* disposed on the *treatment element*.

Makower discloses *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., ¶¶238-239.

- ii. Stern teaches multiple *pairs* of *bipolar radiofrequency electrodes* disposed on 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. Ex.1002-Decl., ¶¶240-244.

- iii. Motivation to combine

First, Makower and Stern (and Edwards-'535) are analogous art to the Challenged Claims. All are in the same field as the '286 patent and are reasonably pertinent to solving the problems addressed in the '286 patent—treating tissue in a body cavity—with the same types of solutions—applying RF energy to tissue via an

expandable device having surface electrodes. Ex.1021-Makower, [0032], [0187], [0191], [0207]; Ex.1010-Edwards-'535, 8:18-25; Ex.1033-Stern, 12:25-27, 3:21-25. Ex.1002-Decl., ¶245.

Second, a POSITA would have been motivated to combine Makower and Stern with a reasonable expectation of success. 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], [0032], [0187], [0191], [0207], but leaves details on how to deliver energy up to a POSITA. Thus, Makower is ready for improvement, and a POSITA would have been motivated to turn to other sources for information regarding how to specifically deliver energy to heat the tissue. *See id*, [0039]-[0040]. Ex.1002-Decl., ¶¶246-248.

A POSITA would therefore have also been motivated to improve Makower’s device to include Stern’s 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 Grounds I) because of the benefits identified by Stern. *See supra*, §X.A.1.e-f. Ex.1002-Decl., ¶¶249-250.

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 with a reasonable expectation of success in doing so. 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, combining Makower and Stern would have involved applying Stern's known bipolar pairing technique to Makower's known device that was ready for improvement (because Makower omits control and wiring details) to yield predictable results. Ex.1002-Decl., ¶¶251-252.

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 been straightforward and yielded predictable results. Ex.1021-Makower, [0040], [0043], [0161], [0167], [0185]-[0188]; Ex.1033-Stern, 1:16-43, 7:38-8:38, 10:48-65. Makower's silence regarding the circuitry to independently control bipolar electrodes demonstrates that implementing Stern's bipolar electrode pairing technique would have been within a POSITA's skill and that a POSITA would have expected doing so to be successful. Accordingly,

applying Stern’s teachings to Makower would have been a matter of routine implementation within a POSITA’s skill 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 in doing so. Ex.1002-Decl., ¶253-254.

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., ¶255.

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., ¶256.

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 Grounds I and III 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 is silent as to how to pair and wire the bipolar electrodes) to yield predictable results. Ex.1002-Decl., ¶¶257-264.

A POSITA would have had a reasonable expectation of success in implementing multiple RF output channels as taught by Stern 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., ¶¶265-267.

g. 1[f]

Makower in view of Stern and Edwards-’535 disclose *at least one impedance sensor* (e.g., *impedance sensors, impedance calculation device 194, and/or monitor 210* in Edwards-’535) *configured to measure impedance in the multiple pairs of*

bipolar radiofrequency electrodes (e.g., measurement is based on the current and voltage delivered to the multiple bipolar electrodes in Makower, configured in pairs as taught by Stern). Ex.1002-Decl., ¶268.

Both Makower and Stern teach the use of temperature sensors. Ex.1021-Makower, [0192]; Ex.1033-Stern, 15:11-31. In fact, Stern teaches using a feedback system where the system monitors tissue temperature and controls RF energy “to bring the [tissue] temperature up to a desired level.” Ex.1033-Stern, 10:48-52. But Makower and Stern are silent as to sensing impedance. Edwards-’535 teaches the use of impedance sensors and explains that *both* temperature and impedance can be used as helpful metrics in a feedback system to monitor the status of RF treatment. Ex.1010-Edwards-’535, 10:3-18, 10:48-52, 11:24-45. Ex.1002-Decl., ¶269.

Specifically, as described in Ground I, limitation 1[f], incorporated herein, Edwards-’535 discloses impedance sensors, Ex.1010-Edwards-’535, 9:14-23, an impedance calculation device 194 that uses current and voltage inputs to calculate impedance, *id.*, 10:4-11, FIG.8, and a monitor 210 that ascertains tissue impedance and adjusts energy delivery according to an impedance feedback loop, *id.*, 11:23-44, FIG.10. Ex.1002-Decl., ¶270.

As described in Sections X.C.1.e and f, it would have been obvious to combine the teachings of Makower and Stern. It would have also been obvious to

supplement Makower and Stern's teachings with Edwards-'535's teachings of impedance sensors due to the numerous advantages of measuring impedance in an RF ablation system, for example, for detecting initial contact with tissue and for determining whether the target tissue has been desiccated, or dried out, as a result of the heating. Ex.1002-Decl., ¶271.

As explained in Ground I, limitation 1[f], impedance is simply the ratio of voltage divided by current. Edwards-'535 describes using impedance measurement in a feedback loop, such that when the impedance exceeds a certain value, the delivery of RF energy can be reduced or stopped. Ex.1010-Edwards-'535, 11:24-45. When the impedance is above a certain threshold, it indicates that very little current is flowing to the tissue. This means that the tissue has already been heated up enough and dried out, so there is no need to apply more energy. If the impedance is within acceptable limits, energy continues to be applied. *Id.* Thus, Edwards-'535 provides a teaching, suggestion, or motivation to use impedance sensors—to monitor the progression of RF treatment—that would have led a POSITA to combine Edwards-'535's teaching of impedance sensors with the combination of Makower and Stern. Even beyond the reasons disclosed in Edwards-'535, impedance can serve as a proxy for other information about what is happening in the body. For example, a POSITA would have known to use impedance monitoring to ensure that

the device has made good contact with the tissue prior to ablating, to monitor how much tissue has been ablated during the procedure, and to determine when to stop treatment. Ex.1002-Decl., ¶272.

Further, a POSITA would have been motivated to use both temperature sensing and impedance sensing as each measurement provides different information about the tissue being treated. It was known that using *both* temperature and impedance measurements in RF ablation feedback systems is desirable to take advantages of their unique benefits—for example, if tissue temperature has not yet reached the target temperature, the clinician may still desire to shut off the device if impedance is above a predetermined threshold. Ex.1002-Decl., ¶¶273-274.

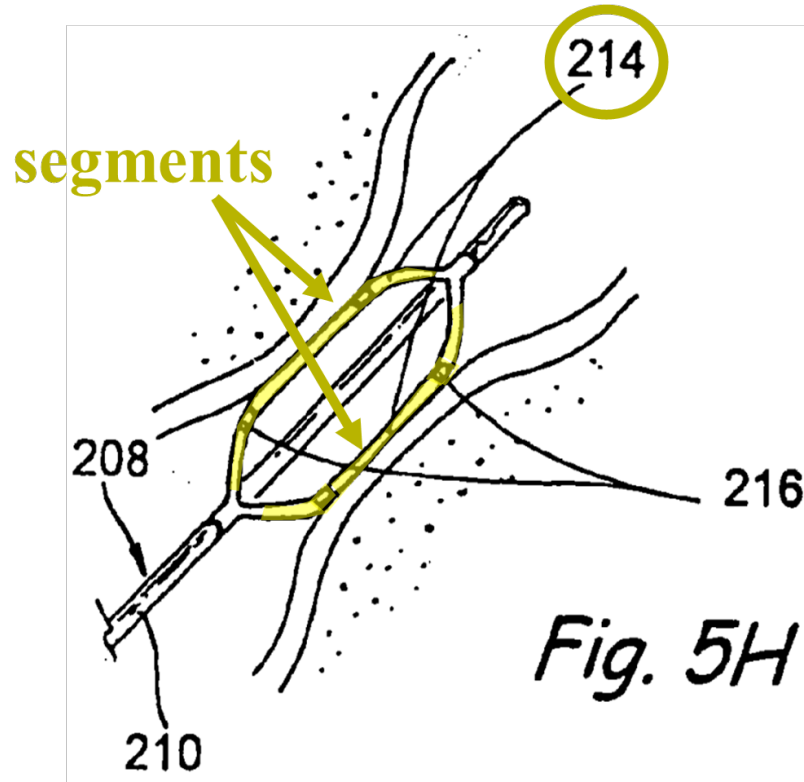
A POSITA would have reasonable expectation of success in implementing the combination. The combination would have been a simple application of a known technique (impedance feedback control) to a known device (Makower's device incorporating Stern's teaching of the circuitry required to operate bipolar pairs) which was ready for improvement (Makower and Stern are silent as to impedance monitoring) in the same way (using a sensed property—i.e., temperature or impedance—to adjust RF energy delivery). Ex.1002-Decl., ¶275.

Even if a POSITA opted to use *either* temperature or impedance feedback, the use of impedance amounts to simple substitution of one known element (temperature

sensors for feedback control) for another (impedance sensors for feedback control) to obtain predictable results (adjusting RF energy delivery based on a property of the tissue—i.e., temperature or impedance). For the reasons described above, each offers unique benefits. Further, a POSITA would have found using impedance sensing and feedback as taught by Edwards-'535 an obvious technique to try given that there are only a finite number of identified, predictable solutions (i.e., monitoring temperature or monitoring impedance) with a reasonable expectation of success. Ex.1002-Decl., ¶275.

2. Claim 2

Makower discloses that the *treatment element* (e.g., electrosurgical 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], FIG.5H.

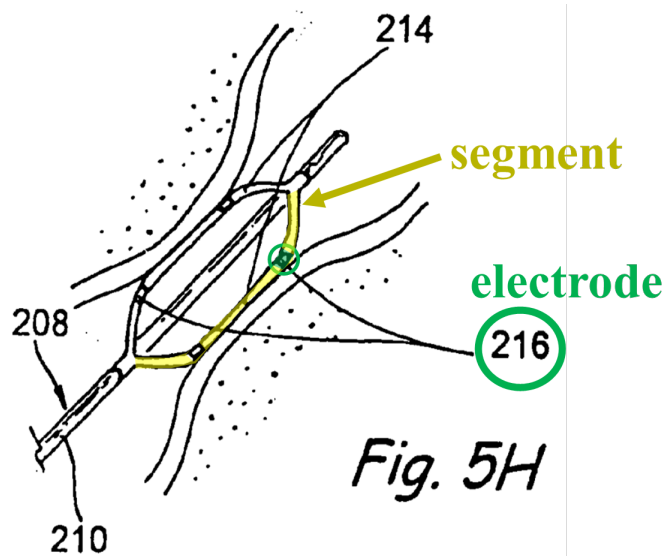


Ex.1021-Makower, FIG.5H. Ex.1002-Decl., ¶¶276-280.

3. Claim 3

Makower in view of Stern discloses that *at least one electrode 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., ¶¶281-282.

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. As shown in Figure 5H below, at least one electrode 216 is coupled with each strut 214.



Ex.1021-Makower, FIG.5H. Ex.1002-Decl., ¶¶283-284.

4. Claim 4

Makower teaches *the multiple segments (e.g., struts 214) are pre-shaped (e.g., a POSITA would understand the elongate members to be mechanically shaped) and 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., ¶¶285-286.

As discussed above for claim 2, 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., ¶287.

Because the strut members 214 deflect when expanded, a POSITA would have understood that Makower suggests that strut members 214 are mechanically shaped, or *pre-shaped*, and made out of a *shape memory alloy* to facilitate collapse and expansion. Ex.1002-Decl., ¶288.

5. Claim 7

a. 7[a]

The combination of Makower, Stern, and Edwards-’535 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 at least one impedance sensor* (e.g., Edwards-’535’s impedance sensor) *and deliver radiofrequency energy separately to each of the multiple radiofrequency output channels* (e.g., selective control of electrodes in Makower implemented by multiple RF output channels as taught by Stern). Ex.1002-Decl., ¶¶289-291.

Edwards-’535, Stern, and Makower each disclose *a radiofrequency generator* (e.g., signal generator 165 in Edwards-’535, RF generator 158 in Stern, RF generator in Makower) that serves as RF input power. Ex.1010-Edwards-’535, 9:2-11; Ex.1033-Stern, 10:43-50; Ex.1021-Makower, [0040]. Ex.1002-Decl., ¶292.

As discussed in Grounds I and V for limitation 1[f], Edwards-’535 teaches an impedance feedback control system that uses impedance values “to adjust the energy output in an appropriate amount in order to maintain the desired energy delivered at each energy delivery device 189.” Ex.1010-Edwards-’535, 10:3-18; *see also id.* 9:45-56. Ex.1002-Decl., ¶¶293-294.

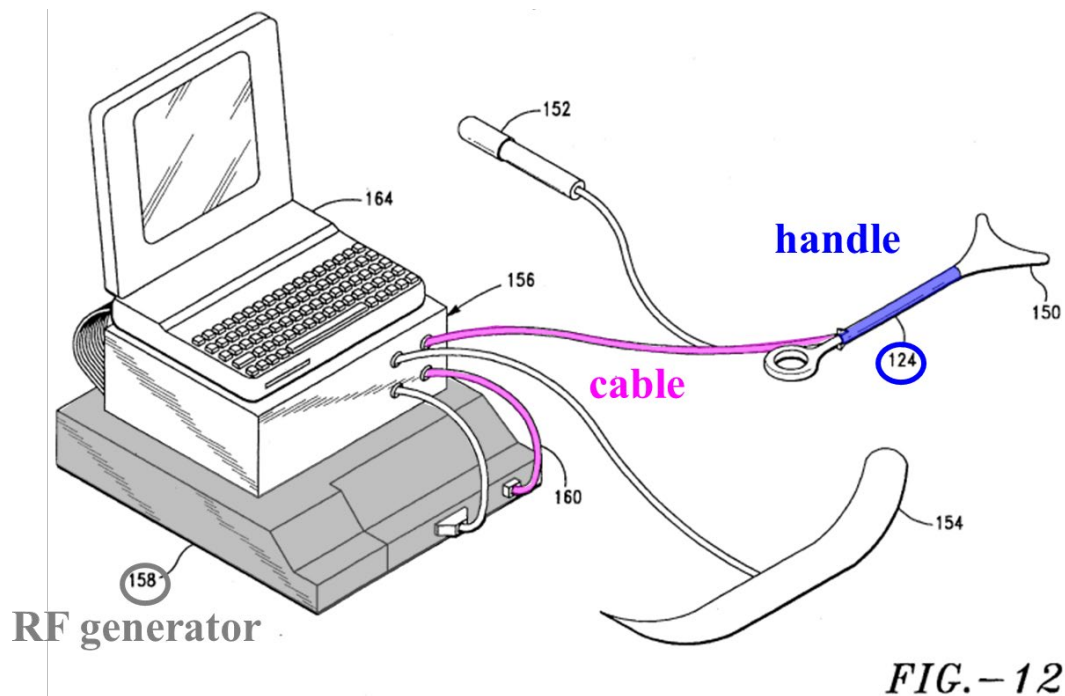
As described in limitation 1[d]-[e], Makower in view of Stern teaches the delivery of *radiofrequency energy separately to each of the multiple radiofrequency output channels*. Makower omits details regarding to how implement the circuitry for energy delivery. Stern provides those details, using *multiple radiofrequency output channels*. Ex.1002-Decl., ¶295-296.

And as described in Grounds I and III limitations 1[d]-1[f], a POSITA would have been motivated to use Edwards-’535’s impedance control system in combination with Makower’s device using the circuitry taught by Stern and had a reasonable expectation of success in doing so, especially given that Stern’s feedback control loop uses temperature control and Edwards-’535’s impedance control is compatible with a temperature control feedback system. Ex.1002-Decl., ¶¶293-297.

a. 7[b]

The combination of Makower and Stern discloses *a cable* (e.g., *interference cables 160* in Stern) *coupled to the handle* (e.g., *application device 124* in Stern) *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 in Stern).



Ex.1033-Stern, FIG.12. Ex.1002-Decl., ¶298-300.

Providing a handle with a cable to couple to the RF generator in Makower as taught by Stern would have been obvious and predictable for the same reasons discussed above for limitations 1[a], 1[e], and 7[a]. Ex.1002-Decl., ¶301.

6. Claim 8

As discussed in Ground I, claim 8, Edwards-'535 in view of Stern teaches or renders obvious this limitation. Makower discloses using RF energy and a power source to ablate tissue in the nose, Ex.1021-Makower, [0156], [0182], [0187],

Clm.81, but omits implementation details on the particular frequency, waveform, and wattage. It would have been obvious to modify the combination in Ground III, claim 7 to include a RF generator configured to deliver RF energy in a form of a 460 kHz sinusoid wave and to run at a power of between 5 and 75 watts for the same reasons discussed for claim 8 in Ground I. Ex.1002-Decl., ¶¶302-304.

7. Claim 9

As discussed in Ground I, claim 9, 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. Ex.1002-Decl., ¶¶305-306.

D. Ground IV: Claim 8 Is Invalid as Obvious Over Makower in view of Stern and Edwards-'535 in further view of Edwards-'886

1. Claim 8

As discussed in Ground III, claim 8 is obvious over Makower, Stern, and Edwards-'535. It would have also been obvious to modify the combination in Ground III, claim 8 to include a RF generator configured to deliver RF energy in a form of a 460 kHz sinusoid wave and to run at a power of between 5 and 75 watts in further view of Edwards-'886 for the same reasons discussed in Ground II. Ex.1002-Decl., ¶¶307-311.

E. Ground V: Claims 1-3, 7-9 Are Invalid as Obvious over Edwards-’535 in view of Stern and Liang.

Claims 1-3 and 7-9 are obvious over Edwards-’535 in view of Stern and Liang. Ex.1002-Decl., ¶312.

1. Claim 1

a. 1[pre]

If the portion of the preamble other than “treat rhinitis” is limiting, 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). *See supra* §X.A.1.

In the alternative, if the entire preamble is limiting, Edwards-’535 in view of Liang render obvious a device that can *treat rhinitis* (e.g., RF treatment has been used with success to treat rhinitis as taught by Liang). Ex.1002-Decl., ¶313.

Liang discloses using an RF ablation device to treat the “middle turbinate,” which Liang also refers to as the “nasal ridge,” to *treat rhinitis*. Ex.1056-Liang, 341; *see also id.* Abstract, 342. Ex.1002-Decl., ¶¶314-315.

i. Motivation to Combine

As explained herein, Edwards-’535 teaches a method of using RF energy to ablate the turbinates, including the middle turbinate. *See, e.g.,* §X.A.1.a. Edwards-’535 further teaches ablating an interior portion of tissue on any of the turbinates, including a middle turbinate. Ex.1010-Edwards-’535, 1:60-2:29, 4:19-52, 4:53-67,

6:66-7:4, 6:39-42, 7:5-17, 11:23-44. Liang discloses techniques for using RF energy to treat nasal airway conditions, including ablating and damaging the “deep ethmoidal nerve” in the middle turbinate. Ex.1056-Liang, 341-42. Like Edwards-’535 and Stern, Liang is directed to the problem of treating tissue in a body cavity and solves that problem by applying RF energy to the tissue, *id.*, 341-42, and is therefore analogous art to the ’286 patent. Furthermore, a POSITA would have been motivated to combine these teachings—namely, by using Edwards-’535’s device in Liang’s technique—to reduce mucus production by applying RF energy to the ethmoidal nerve within the middle turbinate, *id.*, 341-42, with a reasonable expectation of success for the following reasons. Ex.1002-Decl., ¶314.

First, Liang discloses the benefits of using RF energy to treat the same location as Edwards-’535 (middle turbinate) but recognizes certain drawbacks with Liang’s device. As for benefits, Liang teaches an “effective rate of 95.5%” in treating allergic rhinitis, including by “reducing its sensitivity to adverse external physical and chemical stimuli, reducing the secretion of vasoactive peptides, inhibiting sneezing reflex, reducing runny nose, and improving nasal ventilation.” Ex.1056-Liang, 341-42. The clinical results from treatment using Liang’s method indicated that of 88 patients, 83% “showed marked effectiveness.” *Id.*, 341. However, Liang also discloses that its technique resulted in “bloody secretions due

to nasal reactions” after treatment and that some patients “developed nasal adhesion” (where two surfaces damaged during the procedure heal together). *Id.*, 341-42. Liang is thus ready for improvement with a device that is less damaging to the surface tissue, and therefore would be less likely to result in adhesion. Ex.1002-Decl., ¶315.

Second, Edwards-’535 teaches how to solve the problems presented by the device used in Liang. Edwards-’535’s device, which provides cooling to the contacted tissue, is less damaging to the surface mucosa. For example, Edwards-’535 discloses that its method can “remove an internal section of a nasal concha **without damaging the surface of the nasal concha.**” Ex.1010-Edwards-’535, 4:53-67. Furthermore, unlike Liang’s procedure, Edwards-’535’s “procedure can be performed **bloodlessly..., thereby significantly reducing the risk of infection.**” *Id.*, 4:53-67, 6:10-22. These teachings would have motivated a POSITA to use a device like that taught in Edwards-’535, as modified by Stern, (which does not damage surrounding tissue) for the same purpose as Liang’s RF device. Ex.1002-Decl., ¶316.

Third, as discussed above, Edwards-’535 and Liang describe similar techniques such that their combination would have yielded predictable results. Both Edwards-’535’s and Liang teach delivering RF energy to tissue within the middle

turbinate, which destroys tissue. *See, e.g.*, Ex.1010-Edwards-'535, 5:30-34, 6:66-7:17, 6:9-65, 4:53-5:15, FIGs.3A-4C; Ex.1056-Liang, 341-42. Thus, using Edwards-'535's device as augmented by Stern's teachings is simply improving Liang's technique in the same way as the device is used in Edwards-'535. Ex.1002-Decl., ¶317.

Indeed, many other references disclose using turbinate reduction devices or using RF ablation devices (as disclosed by Edwards-'535) to treat rhinitis. *See generally* Ex.1031-Hytönen. Because using off-the-shelf turbinate reduction devices for treating rhinitis was well-known, a POSITA would have found it obvious to use a turbinate reduction device like that taught by Edwards-'535, as augmented by Stern, with Liang's technique to obtain predictable results of treating rhinitis without damaging mucosal tissue. Ex.1002-Decl., ¶318.

Fourth, a POSITA would have had a reasonable expectation of success in using Edwards-'535's apparatus 124 for Liang's method to treat rhinitis and reduce mucus production given that, as explained above, Edwards-'535 expressly discloses that its methods can be used to ablate the same portions of tissue as ablated in Liang, and that both Edwards-'535's and Liang's methods result in destroying turbinate tissue. Indeed, prior to 2011, other researchers had recognized reduction in mucus production resulting from ablation of the nasal turbinates. Ex.1042-Bäck, 1808,

FIG.2. Accordingly, combining the teachings of Edwards-'535 and Liang 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 apparatus 124 being used to deliver RF energy to treat allergic rhinitis and reduce mucus production, as taught by Liang—with a reasonable expectation of success.⁸ Liang's reported 95.5% effectiveness rate using a standard RF energy, Ex.1056-Liang, 341, would have further led a POSITA to expect success using other RF energy devices like that disclosed by Edwards-'535. Ex.1002-Decl., ¶319.

Thus, a POSITA would have been motivated to combine the teachings of Edwards-'535, Stern, and Liang. Ex.1002-Decl., ¶320.

b. Limitations 1[a] and 1[b].

As discussed in Ground I, Edwards-'535 in view of Stern render obvious these limitations. *See supra*, §§X.A.1.b-c. Ex.1002-Decl., ¶321.

c. 1[c]

As discussed in Ground I, Edwards-'535 in view of Stern teach this limitation. *See supra*, §X.A.1.d. Liang further teaches that the device is configured *to contact*

⁸ This is consistent with the '286 patent itself, which does not specify any technical prerequisites for reducing mucus production. *See supra*, §VI.A.

nasal mucosa lining the nasal airway. Specifically, Liang notes that the RF device contacts the “bilateral nasal ridge and the corresponding nasal septum mucosa” and that the treatment should result in “white spots of local mucosa.” Ex.1056-Liang, 341. Ex.1002-Decl., ¶322.

d. Limitations 1[d]-1[f].

As discussed in Ground I, Edwards-’535 in view of Stern teaches these limitations. *See supra*, §§X.A.1.e-g. Ex.1002-Decl., ¶323.

2. Claims 2, 3, and 7-9

As discussed in Ground I, these claims would have been obvious in view of Edwards-’535 and Stern, and for the additional reasons discussed in Ground V for claim 1, above. *See supra*, §X.A.2-6. Ex.1002-Decl., ¶324.

F. Ground VI: Claim 8 Is Invalid as Obvious over Edwards-’535 in view of Stern, Liang, and Edwards-’886.

1. Claim 8

As discussed in Ground V, claim 8 is obvious over Edwards-’535, Stern, and Liang. *See supra*, §X.E.1. It also would have been obvious to modify the combination in Ground V, claim 8 to include a RF generator configured to deliver radiofrequency energy in a form of a 460 kHz sinusoid wave and to run at a power

of between 5 and 75 watts for the same reasons discussed in Ground II.⁹ Ex.1002-Decl., ¶325.

G. Ground VII: Claims 1-4, 7-9 Are Invalid as Obvious over Makower in view of Stern, Edwards-'535, and Liang.

Claims 1-4 and 7-9 are obvious over Makower in view of Stern, Edwards-'535, and Liang. Ex.1002-Decl., ¶326.

1. Claim 1

a. 1[pre]

If the portion of the preamble other than “treat rhinitis” is limiting, 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). *See supra* §X.C.1.

In the alternative, if the entire preamble is limiting, Makower in view of Liang render obvious a device that can *treat rhinitis* (e.g., RF treatment has been used with success to treat rhinitis as taught by Liang). Ex.1002-Decl., ¶327.

⁹ *Intel Corp. v. Xmtt, Inc.*, IPR2020-00145, Paper 37, 20 (P.T.A.B. May 11, 2021) (number of references in an obviousness combination, “without more, does not demonstrate nonobviousness”) (citations omitted); *In re Gorman*, 933 F.2d 982, 986 (Fed. Cir. 1991).

As discussed in Ground V, Liang discloses using an RF ablation device to *treat rhinitis*. *See supra*, §X.E.1.a. Ex.1002-Decl., ¶328.

i. Motivation to Combine

As explained above, Makower teaches a method of using RF energy to ablate tissue, including the turbinates. *See, e.g.*, §X.C.1.a, d; Ex.1021-Makower, [0004], [0018], [0020]-[0021], [0030]-[0031], [0039]-[0041], [0130], [0132], [0140], [0179] (describing meatus), [0182], [0186], [0188], Abstract. Makower further teaches that the disclosed device can ablate submucosal tissue in the turbinates. *Id.*, [0039]-[0041]. Liang discloses techniques for using RF energy to treat nasal airway conditions, including ablating and damaging the “deep ethmoidal nerve” in the middle turbinate. Ex.1056-Liang, 341-42. A POSITA would have been motivated to combine these teachings—namely, by using a device like that taught by Makower device in a technique like that taught by Liang—to reduce mucus production by applying RF energy to the ethmoidal nerve within the middle turbinate, *id.*, 341-42, with a reasonable expectation of success for at least the reasons discussed in Ground V. *See supra*, §X.E.1.a; *see also supra*, n.9. For example, Liang uses a similar RF ablation device to Makower, Ex.1056-Liang, 341; Ex.1059-Liang-’271, 1-2 (describing SHP-I device in Liang with electrodes, energy source for use in nasal treatments), and teaches numerous benefits to using RF energy to treat the turbinates

that would have been equally applicable when using Makower's device (*see supra*, §X.E.1.a.i). Ex.1002-Decl., ¶329.

A POSITA would have had a reasonable expectation of success in using Makower's device for Liang's method to treat rhinitis and reduce mucus production for the reasons discussed in Ground V, including that both Makower and Liang treat the same tissue (middle turbinate). *See supra*, §X.E.1.a.i. Ex.1002-Decl., ¶330.

Thus, a POSITA would have been motivated to combine the teachings of Makower, Stern, Edwards-'535, and Liang. Ex.1002-Decl., ¶331.

b. Limitations 1[a]-1[b] and 1[d]-1[e].

As discussed in Ground III, Makower or Makower in view of Stern teach these limitations. *See supra*, §§X.C.1.b-c, e-f. Ex.1002-Decl., ¶332.

c. 1[c]

As discussed in Ground III, Makower discloses this limitation. *See supra*, §X.C.1.d. As discussed in Ground V, Liang further teaches that the device is configured *to contact nasal mucosa lining the nasal airway*. *See supra*, §X.E.1.d. Ex.1002-Decl., ¶333.

d. 1[f]

As discussed in Ground III, Makower in view of Stern and Edwards-'535 discloses this limitation. *See supra*, §X.C.1.g. Ex.1002-Decl., ¶334.

2. Claims 2-4, 7-9

As discussed in Ground III, these claims would have been obvious in view of Makower, Stern, and Edwards-'535, and for the additional reasons discussed in Ground VII for claim 1, above. *See supra*, §X.C.2-6. Ex.1002-Decl., ¶335.

H. Ground VIII: Claim 8 Is Invalid as Obvious over Makower in view of Stern, Edwards-'535, Liang, and Edwards-'886.

1. Claim 8

As discussed in Ground VII, claim 8 is obvious over Edwards-'535, Stern, and Liang. *See supra*, §X.G.1. It also would have been obvious to modify the combination in Ground VII, claim 8 to include a RF generator configured to deliver radiofrequency energy in a form of a 460 kHz sinusoid wave and to run at a power of between 5 and 75 watts for the same reasons discussed in Ground IV. Ex.1002-Decl., ¶336.

XI. CONCLUSION

The Challenged Claims of the '286 patent are rendered obvious by the prior art grounds set forth herein. Accordingly, Petitioners request institution of an *inter partes* review to cancel these claims.

Respectfully submitted,

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Registration No. 36,476

Counsel for Petitioners

CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing, Petition for *Inter Partes* Review, contains 13,998 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. 11,766,286
- Appendix of Claims
- Petitioners' Table of Exhibits
- Exhibits 1001-1003, 1006-1008, 1010-1013, 1015-1017, 1021-1024, 1029-1031, 1033-1035, 1038, 1040, 1042, 1044-1045, 1050-1056, 1059, 1061-1063, 1067, 1070-1080
- 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) via electronic mail to:

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Petitioners’ Table of Exhibits

Exhibit	Description
1001	U.S. Patent No. 11,766,286 (“’286 patent”)
1002	Declaration of Dr. Gregory Martin (“Decl.”)
1003	File History of U.S. Patent No. 11,766,286
1004-1005	RESERVED
1006	District Court Amended Complaint
1007	District Court Amended Complaint Exhibit BB
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	Chen et al., Radiofrequency Treatment of Nasal Posterior-Under Nerve, Ethmoidal Nerve and Infratubinal for Perennial Allergic Rhinitis Under Nasal Endoscope, CHINA J. ENDOSCOPY 11:3 (2005) (English translation) (“Chen”)
1018-1020	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”)

Exhibit	Description
1025-1028	RESERVED
1029	Arora et al., Cryodestruction of Vidian Nerve Branches, INDIA J. OTOLARYNGOLOGY 32:3 (1980) (“Arora”)
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”)
1035	M. Philippson, Principles of Electrical Resistance of Living Tissue, BULL. CL. SCI. ACAD. R. BELG. ser. 5, vol. 7 (1921) (English Translation) (“Philippson”)
1036-1037	RESERVED
1038	U.S. Patent No. 6,109,268 (“Thapliyal”)
1039	RESERVED
1040	Kong et al., Clinical Observation on Radiofrequency Ablation Treatment in Perennial Allergic Rhinitis, J. CLIN OTORHINOLARYNGOL (China) Vol.19, No.5 (2005) (English translation) (“Kong”)
1041	RESERVED
1042	Bäck et al., Submucosal Bipolar Radiofrequency Thermal Ablation of Inferior Turbinates: A Long-Term Follow-up With Subjective and Objective Assessment, 112 LARYNGOSCOPE 1806 (October 2002) (“Bäck”)
1043	RESERVED
1044	Lee et al., Surgical Management of Turbinate Hypertrophy in the Office: Three Mucosal Sparing Techniques, 12:2 OPERATIVE

Exhibit	Description
	TECHNIQUES IN OTOLARYNGOLOGY—HEAD AND NECK SURGERY 107 (June 2001) (“Lee”)
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	Fang et al., Nasal Endoscopy Combined with Multiple Radiofrequency for Perennial Allergic Rhinitis, J. FIRST MIL MED UNIV 25:7 (2005) (“Fang”)
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”)
1057-1058	RESERVED
1059	CN Patent No. 2225227Y (“Liang-’271”)
1060	RESERVED
1061	Szold, Nitinol: Shape-Memory and Super-Elastic Materials in Surgery, 20 SURGICAL ENDOSCOPY & OTHER INTERVENTIONAL TECHNIQUES 1493 (2006) (“Szold”)

Exhibit	Description
1062	Sedra et al., MICROELECTRONIC CIRCUITS (3d Ed. 1991) (Excerpts) (“Sedra”)
1063	File History of U.S. Patent No. 11,033,318
1064-1066	RESERVED
1067	U.S. Patent No. 5,505,730 (“Edwards-’730”)
1068-1069	RESERVED
1070	Declaration of June Munford
1071	Translator Declaration for Chen
1072	Translator Declaration for Liang
1073	Translator Declaration for Fang
1074	Translator Declaration for Kong
1075	Munford Appendices for Chen
1076	Munford Appendices for Liang
1077	Munford Appendices for Fang
1078	Munford Appendices for Kong
1079	Additional Appendices to Munford Declaration
1080	Translator Declaration for Liang ’227

Appendix of Claims

Claim 1	
Limitation	Claim Language
1[pre]	A device for delivering energy to a nasal airway to treat rhinitis, 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 to contact nasal mucosa lining the nasal airway;
1[d]	multiple pairs of bipolar radiofrequency electrodes disposed on 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]	at least one impedance sensor configured to measure impedance in the multiple pairs of bipolar radiofrequency electrodes.

Claim 2	
2	The device of claim 1, wherein the treatment element comprises multiple segments that are expandable from the first configuration to the second configuration.

Claim 3	
3	The device of claim 2, wherein at least one electrode of the multiple pairs of bipolar radiofrequency electrodes is coupled with each of the multiple segments.

Claim 4	
4	The device of claim 2, wherein the multiple segments are pre-shaped and comprise a shape-memory alloy material configured to expand to a desired size and shape.

Claim 7	
Limitation	Claim Language
7[a]	7. The device of claim 1, further comprising: a radiofrequency generator configured to receive sensed signals from the at least one impedance sensor and deliver radiofrequency energy separately to each of the multiple radiofrequency output channels; and
7[b]	a cable coupled to the handle for plugging the handle into the radiofrequency generator.

Claim 8	
8	The device of claim 7, wherein the radiofrequency generator is configured to deliver the radiofrequency energy in a form of a 460 kHz sinusoid wave and to run at a power of between 5 and 75 watts.

Claim 9	
9	The device of claim 1, wherein the multiple pairs of bipolar radiofrequency electrodes and the multiple radiofrequency output channels are organized into multiple subsystems, and wherein each of the multiple subsystems comprises one of the multiple pairs of bipolar radiofrequency electrodes and one of the multiple radiofrequency output channels.