

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEURENT MEDICAL INC. & NEURENT MEDICAL LTD.

Petitioners,

v.

AERIN MEDICAL, INC.

Patent Owner.

Case No. IPR2024-00278

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

**DECLARATION OF DR. GREGORY T. MARTIN
REGARDING CLAIMS 1, 4-6, 9-10, 12-13, AND 15-17 OF
U.S. PATENT NO. 11,033,318**

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I, Gregory T. Martin, Ph.D., declare as follows:

I. INTRODUCTION

1. My name is Gregory T. Martin.

2. I am making this declaration at the request of Neurent Medical Inc. and Neurent Medical Ltd. (“Neurent” or “Petitioners”) as an independent expert consultant in this proceeding before the United States Patent and Trademark Office and to provide testimony pertinent to Petitioners’ Petition for *Inter Partes* Review of U.S. Patent No. 11,033,318 (the “’318 patent”). I understand that Petitioners are challenging claims 1, 4-6, 9-10, 12-13, and 15-17 of the ’318 patent (“Challenged Claims”).

II. QUALIFICATIONS AND EXPERIENCE

3. My qualifications for setting forth the opinions in this declaration are summarized below. My curriculum vitae, which describes *inter alia* my education, experience, professional activities, my publications, and patents, is attached as **Appendix A**.

4. I received my Bachelor of Science (in 1988), Master of Science (in 1991), and PhD (in 1995), all in mechanical engineering, from the Massachusetts Institute of Technology (MIT).

5. I have over two decades of experience designing and developing medical devices, with a focus on energy-based medical devices. From 1998-2000, I was the Vice President of Research and Development, and Corporate Director, for Thermal Technologies, Inc., a medical device incubator and contract research company that developed technologies for the measurement of tissue blood flow, cardiac output, tissue oxygen concentration, radiotherapy dosage and tumor temperature for use in hyperthermia therapy. From 2000-2007, I was the co-founder, Chief Technology Officer, and Corporate Director for Hemedex, Inc., a medical device start-up that developed and commercialized a device—a minimally invasive catheter with monitor and software—to monitor cerebral blood flow at the bedside in neurosurgery patients with traumatic brain injury, cerebro-vascular disease and stroke. In 2007, I served as the Vice President of R&D for Cytoc Corporation, a company that developed and commercialized medical devices including for treatment of menorrhagia, breast cancer with radiotherapy, and brain cancer with radiotherapy. From 2007-2011, I served as the Vice President of R&D for Hologic, Inc., a leading women's health company, where I was responsible for developing devices in the Surgical Products Division—including tissue ablation medical devices. From 2017-2018, I served as Vice President of R&D for Opsonix, Inc., where I developed a device-biologic combination product and companion diagnostic

to remove pathogens and endotoxins from blood via an extracorporeal circuit. Between 2012-2013 and since 2018, I have been a Principal at Tremont Consulting, LLC, where I provide consulting services in the medical device and diagnostics industries.

6. In addition to my work in industry, I have also served as Senior Lecturer in Boston University's Department of Biomedical Engineering from 2013-2017 and from 2019-2020. In that capacity, I taught classes on medical device product design in biomedical engineering (to undergraduates, and to graduate students), and on healthcare entrepreneurship. I have published more than 20 peer-reviewed scientific articles and have 9 issued U.S. patents, including Martin, et al., *Theoretical analysis of localized heating in human skin subjected to high voltage pulses*, 57 BIOELECTROCHEMISTRY 55-64 (July 1, 2002) and U.S. Patent No. 8,814,796 to Martin et al. (Aug. 26, 2014), titled "System and method for tissue ablation in a body cavity."

7. Throughout my career designing medical devices and diagnostics, I have routinely consulted with medical practitioners. This includes, but is not limited to consulting medical journals and discussing design, performance, and treatment criteria with medical practitioners.

8. I am being compensated for my work in this matter at my standard consulting rate of \$400 per hour. However, my opinions are based on my own understanding of the prior art, the knowledge of a person of ordinary skill in the art, and the patent at issue. My compensation is not dependent on and in no way affects the content of my statements, opinions, or conclusions in this Declaration nor does it affect any testimony I give or on the outcome of this proceeding.

9. I have no financial interest in Petitioners. I similarly have no financial interest in the '318 patent and have had no contact with the named inventors of the '318 patent.

III. LEGAL PRINCIPLES

10. I am not an attorney. For the purposes of this declaration, I have been informed about certain aspects of the law that are relevant to my opinions. My understanding of the law was provided to me by Petitioners' attorneys.

A. Scope of Opinion

11. I have been informed and understand that the petitioner in an *inter partes* review may request cancellation of claims as unpatentable only on grounds that such claims are anticipated or would have been obvious to a person of ordinary skill in the art at the time of the purported invention, and only on the basis of prior

art consisting of patents or printed publications. My opinions in this matter address only such grounds.

B. Anticipation

12. I have been informed by counsel that a patent claim is anticipated and therefore unpatentable if each element of that claim is present in a single prior art reference.

C. Obviousness

13. I understand that a claim is unpatentable if it would have been obvious to a person of ordinary skill in the art at the time the alleged invention was made. I understand that a claim could have been obvious based on the teachings or suggestions of a single prior art reference or from a combination of two or more prior art references. I understand that an obviousness analysis requires an understanding of the scope and content of the prior art, any differences between the alleged invention and the prior art, and the level of ordinary skill in evaluating the pertinent art.

14. I further understand that a claim would have been obvious if it unites old elements with no change to their respective functions, or alters prior art by mere substitution of one element for another known in the field, and that combination yields predictable results. Also, I understand that obviousness does not require

physical combination/bodily incorporation, but rather consideration of what the combined teachings would have suggested to persons of ordinary skill in the art at the time of the alleged invention.

15. In connection with obviousness, I have been informed that there must have been some reason or motivation that would have led a person of ordinary skill in the art to combine or modify the relevant teachings in the prior art to obtain the claimed invention, and one of ordinary skill in the art must have had a reasonable expectation of success in doing so.

16. While it may be helpful to identify a reason for this combination, I understand that there is no rigid requirement of finding an express teaching, suggestion, or motivation to combine within the references. If a person of ordinary skill in the art can implement a predictable variation, obviousness likely bars its patentability. For the same reason, if a technique has been used to improve one device and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique would have been obvious. I understand that a claim would have been obvious if a person of ordinary skill in the art would have had reason to combine multiple prior art references or add missing features to reproduce the alleged invention recited in the claims.

17. In sum, I understand that a determination of whether a claim would have been obvious is based upon a variety of considerations, including, among others:

- whether the teachings of the prior art references disclose known concepts combined in familiar ways, which, when combined, would yield predictable results;
- whether a person having ordinary skill in the art could implement a predictable variation, and would see the benefit of doing so;
- whether the claimed elements represent one of a limited number of known design choices, and would have a reasonable expectation of success by those skilled in the art;
- whether a person having ordinary skill would have recognized a reason to combine known elements in the manner described in the claim;
- whether there is some teaching or suggestion in the prior art to make the modification or combination of elements claimed in the patent; and
- whether the alleged invention applies a known technique that had been used to improve a similar device or method in a similar way.

18. I also understand that in considering obviousness, it is important not to determine obviousness using the benefit of hindsight derived from the patent being

considered. I also understand that one of ordinary skill in the art has ordinary creativity, and is not an automaton.

19. I further understand that certain factors, commonly referred to as secondary considerations, may support or rebut the obviousness of a claim. I also understand that secondary considerations cannot be used to overcome anticipation. I understand that such secondary considerations include, among other things, commercial success of the patented invention, skepticism of those having ordinary skill in the art at the time of invention, unexpected results of the invention, any long-felt but unsolved need in the art that was satisfied by the alleged invention, the failure of others to make the alleged invention, praise of the alleged invention by those having ordinary skill in the art, and copying of the alleged invention by others in the field. I understand that there must be a nexus, that is, a connection, between any such secondary considerations and the alleged invention. I also understand that contemporaneous and independent invention by others is a secondary consideration tending to show obviousness.

20. I reserve the right to respond to any allegations that may be put forth by Patent Owner in this proceeding that any secondary considerations tend to rebut the obviousness of any claim of the '318 patent discussed in this declaration.

D. Claim Dependency

21. I understand that a patent may include two types of claims, independent claims and dependent claims. An independent claim stands alone and includes only the limitations it recites. A dependent claim can depend from an independent claim or another dependent claim. I understand that a dependent claim includes all the limitations that it recites in addition to all of the limitations recited in the claim or claims from which it depends.

* * *

22. The analysis in this declaration is in accordance with the above-stated legal principles.

IV. MATERIALS CONSIDERED

23. In preparing this declaration, I reviewed and considered the materials cited in this declaration and in **Appendix B** as well as any document cited in this declaration.

V. LEVEL OF ORDINARY SKILL IN THE ART

24. It is my understanding that when considering the claims of the '318 patent and the prior art, I must do so based on the perspective of one of ordinary skill in the art at the relevant effective priority date.

25. As detailed in Section VII.A (Relevant Prosecution History), the '318 patent was filed on May 15, 2019, and claims priority to a series of patent applications, starting with provisional application 61/496,930 filed on June 14, 2011. *See* Ex.1001-USP318, Cover. Therefore, I understand the claimed priority date is June 14, 2011. I do not offer any opinion as to whether the '318 patent is entitled to that priority date. In any event, my opinion regarding the level of ordinary skill in the art is the same for all relevant times from June 14, 2011, to May 15, 2019.

26. I understand from Petitioners' counsel that several factors are to be considered in determining who would be a person of ordinary skill in the art. These factors include: (1) the types of problems encountered in the art; (2) the prior art solutions to those problems; (3) the rapidity with which innovations are made; (4) the sophistication of the technology; and (5) the educational level of active workers in the field.

27. Based on these factors as well as my experience and expertise, a person of ordinary skill in the art at relevant times (2011-2019) would have had (1) a Doctor of Medicine (M.D.) or at least a bachelor of science degree in engineering or a related discipline and (2) at least three years of experience in the clinical use, design, development, and/or testing of medical devices, including medical devices that deliver energy to tissue. A higher level of education may compensate for less work

experience, and vice versa. Before June 14, 2011, which is the claimed priority date of the '318 patent, I would have qualified at least as a person of ordinary skill in the art under this standard.

28. Although my qualifications and experience exceed those of a person of ordinary skill in the art as defined above, my analysis and opinions herein regarding the '318 patent have been based on the knowledge and perspective a person of ordinary skill in the art would have had as of the relevant times of the '318 patent.

VI. OVERVIEW OF THE TECHNOLOGY

A. An Overview of Radiofrequency (“RF”) Ablation

29. RF ablation utilizes high frequency alternating electrical voltage or current—generally between 300 kHz-700 kHz—to modify tissue. Specifically, as an alternating voltage is applied to tissue, small ions in the tissue start to move, which induces current flow and creates friction that generates heat in the tissue. *See* Ex.1051-Haemmerich, 54 (describing the thermodynamics of RF tissue heating). The increase in temperature damages portions of tissue and/or kills tissue cells, creating lesions. These lesions are formed at therapeutically advantageous locations, such as to tissue containing a nerve to prevent the nerve from sending signals.

30. RF ablation devices for the treatment of chronic pain have been known for decades. *See* Ex.1054-Koyyalagunta, 6. For example, in 1931, Koyyalagunta

taught using RF ablation to target the gasserion ganglion, a nerve in the head to treat Trigeminal neuralgia. Since their introduction decades ago, and long before the '318 patent's claimed priority date, many RF ablation devices have been used as medical devices, for example, to destroy a blockage, treat tissue, or shrink tissue. *See, e.g.*, Ex.1010-Edwards-'535, Abstract (“[b]y reducing the size of a nasal concha, obstruction of a nasal meatus is reduced or eliminated”); Ex.1011-Baker, 5:59-65 (delivering RF energy to the endometrial lining of a patient's uterus); Ex.1012-Goble, 3:35-48 (using RF energy to treat “the bladder, the gall bladder, portions of the gastrointestinal tract, the heart, ... hemorrhoids, intestinal walls, the lining of the rectum, the lining of the blader...”); Ex.1023-Coste, 894 (using RF energy “for reduction of inferior turbinate volume”); Ex.1024-Hovda, 11:13-12:4 (providing “ablation and hemostasis of swollen or enlarged tissue structures in the nose, such as turbinates”); Ex.1031-Hytönen, Abstract (reducing “inferior turbinate submucosal tissue volume in patients having chronic nasal obstruction”).

31. By the early 2000s, many devices incorporated RF ablation technology and different components needed to deliver RF energy. Most had similar features, like handles and shafts that were flexible and steerable. Ex.1011-Baker, 5:27-47; Ex.1021-Makower, [0186].

32. Electrically, these devices were capable of either bipolar or monopolar configurations, or both. Ex.1011-Baker, 5:47-58. These devices involved the use of multiple electrodes, either bipolar or monopolar depending on the configuration. Ex.1012-Goble, 6:33-68; 11:23-49. These electrodes could penetrate target tissue, for example, if they were needle electrodes (sometimes referred to as “penetrating electrodes”), Ex.1016-Edwards-’886, 26:54-28:8, or the electrodes could be surface electrodes and only contact the surface of tissue without puncturing it (sometimes referred to as “non-penetrating electrodes”), Ex.1010-Edwards-’535, 4:55-60; Ex.1011-Baker, 5:47-58.

33. Sometimes, bipolar electrodes were used in combination with forceps such that electrodes having opposite polarities were used on either side of the forceps to ablate target tissue in between the electrodes. Ex.1022-Odom, [0002]. Other devices had expandable cages or balloons, including some cages that were made from shape memory materials. Ex.1015-Laufer, 9:5-14; Ex.1021-Makower, [0187], [0194] (using “shape memory alloys such as nitinol” to “predictably deflect various sections of the catheter.”), [0149] (using nickel titanium alloy for frame).

34. To avoid overheating tissue, some devices had cooling systems. Ex.1010-Edwards-’535, 20:60-31:14. Additionally, some devices were designed to target tissue below the surface of where the electrodes were placed. *Id.*, 4:60-65.

Moreover, many devices included systems that would help the clinician monitor the treatment, like visualization capabilities and guidance, *id.*, 10:39-45; Ex.1012-Goble, 10:61-12:30, and temperature and impedance sensor feedback, Ex.1010-Edwards-'535, 9:14-11:44.

B. Pre-2011 Application of RF Energy to the Nasal Cavity

35. Before 2011, it was well-known that tissue could be modified or reconfigured by RF energy. One way this was done was by directly applying electrodes to tissue. The electrodes would be capable of applying RF energy to the tissue such that it would heat and destroy it. For example, Edwards-'535 discloses an expandable member 132 that “is brought into contact with the surface 115 of the nasal concha 114 to be treated” and “[a]blative energy 117 is then delivered through the apparatus and the energy delivery device 134 to the nasal concha 114.” Ex.1010-Edwards-'535, 5:27-32, 8:12-14, 8:26-39; *see also* Ex.1033-Stern, 3:12-15, 3:29-37. RF energy was applied to the nasal cavity to ablate nasal tissue well before the '318 patent. A clinical review paper authored by Coste reports that at least ten years before the '318 patent, RF tissue reduction was “successfully used in neurosurgery, urology, and cardiology for many years,” and that it was safely and effectively used to treat nasal turbinates. Ex.1023-Coste, 894. The reduction in nasal turbinate size helped improve chronic nasal obstruction. A patent publication to Makower, which

published in 2005, discloses applying RF energy to a broad range of locations in the ear, nose, and throat region to treat a variety of ailments, like sinusitis, enlarged nasal turbinates, tumors, infections, allergic conditions, and other disorders of the ear, nose, and throat. Ex.1021-Makower, Abstract, [0182], [0187]. Other references that published prior to 2011 reported using RF ablation to treat numerous nasal conditions, including nasal polyps (Ex.1024-Hovda, 11:13-12:4), snoring, nasal obstruction secondary to non-allergic or allergic rhinitis (Ex.1031-Hytönen, Abstract), or rhinitis (Ex.1056-Liang, Abstract, 341-42). RF ablation had also been used to improve nasal airflow. Ex.1010-Edwards-'535, 4:53-67.

C. Monopolar and Bipolar RF Electrode Configurations

36. By the early 2000s, RF ablation devices could be configured in monopolar and/or bipolar configurations. Both use electrical current flowing from a generator to an active electrode (+), and then the current flowing back to a return electrode (-).

37. In a monopolar configuration, current passes from an active electrode (+), through the tissue contacting the active electrode, and then out of the patient to a return electrode (-), typically a grounding pad placed on the patient's body. A depiction of a monopolar scheme from Stern, Figure 16 is copied below. In that

figure, current (shown by electrical field lines) passes from the active electrodes 252 and 256 to the return electrodes (not shown).

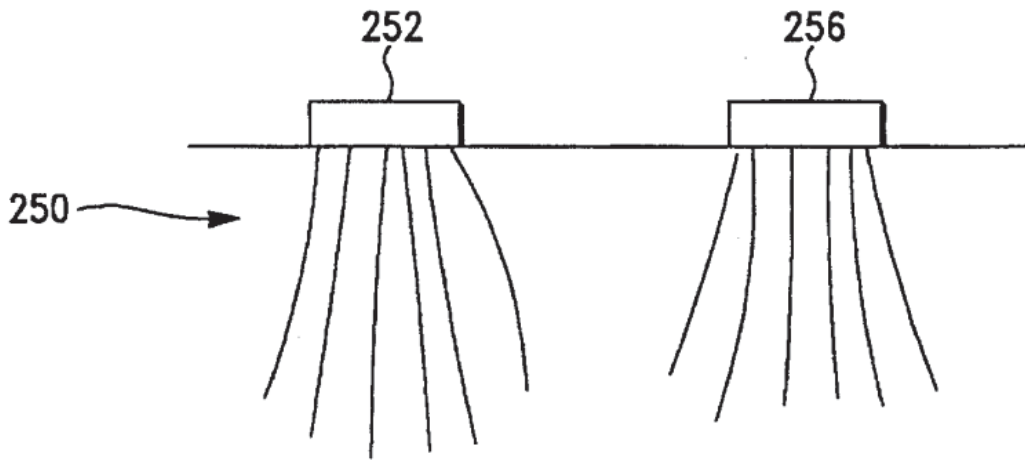


FIG. - 16

38. In a bipolar configuration, as depicted in Ex.1033-Stern's Figure 17 copied below, current flows from an active electrode (258 in Stern's Figure 17), through the tissue contacted by the active electrode, to a return electrode (260 in Stern's Figure 17) located near the active electrode. Because the active and return electrodes are close in proximity, the electrical field lines are more controllable and only travel through a small portion of tissue. This arrangement allows precise direction of energy and current to specific locations and may be of particular use when ablating tissue in a patient's head to avoid the current from interfering with the patient's own electrical signals his or her brain. Ex.1024-Hovda, 5:4-18. By the

early 2000s, it was well known that this can be safer than a monopolar arrangement, where current flows more broadly through a patient's body to a more distant return electrode. Such uncontrolled and dispersed current could interfere with the electrical signals (e.g., brain signals) in a patient's head.

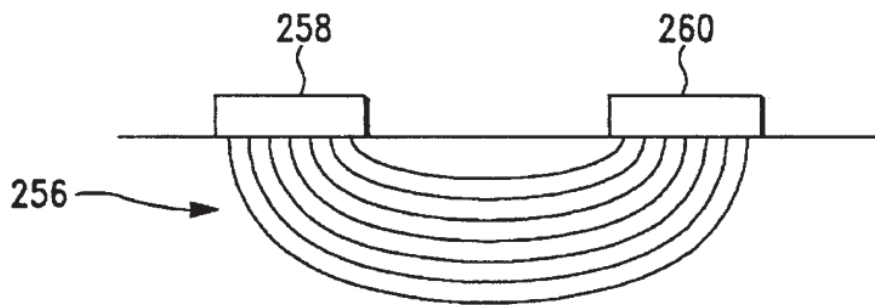


FIG. - 17

39. Bipolar RF ablation electrodes and arrangements can also be combined with other components to target tissue underneath the tissue's surface while leaving the surface tissue intact. For example, both Edwards-'535 and Laufer teach placing bipolar electrodes on the outside of a balloon filled with fluid: the fluid inside the balloon cools the surface tissue while allowing underlying uncooled tissue to heat and become ablated. *See, e.g.,* Ex.1010-Edwards-'535, 4:53-67, 6:10-51, 6:66-7:24 (using a balloon with a cooled fluid during ablation); Ex.1015-Laufer, 7:45-54 (same)

40. The Stern reference discussed in this Declaration also describes how field lines can be more controllable in bipolar configurations. “The ability to control field lines, and therefore the heated area, utilizing bipolar operation is exemplified in Figure 18 wherein there is a balloon 262 having electrodes 264 and 266 with the field lines passing through the patient in such a way that effectively the bipolar energy may be directed to flow around the edges of the balloon 262 in order to insure [*sic*] complete heating of an area...” Ex.1033-Stern, 13:21-27. This was a known benefit of using bipolar RF electrodes before 2011. For example, Goble teaches that using bipolar electrodes allows for more granular control over a specific location to heat: “[f]or example, if the system desired...the distal portion of the bladder to have greater heat, just the most distal active electrode 24a and return electrode 26a might be activated.” Ex.1012-Goble, 8:46-57. Likewise, Goble teaches activating the bipolar electrodes in “sets,” for example by using “three active electrodes 24a-c” and “three return electrodes 26a-c” and only activating select pairs of electrodes. *Id.*

VII. OVERVIEW OF THE '318 PATENT

A. Overview of the Patent

41. The '318 patent states that it “relates generally to the field of medical devices and treatments, and in particular to systems, devices and methods for treating structures within the nose and upper airway to reduce resistance to airflow and/or

change the pressure level in the nose, nasal cavities, and/or and nasal passages and improve airflow and/or the feeling and effects of nasal obstruction during breathing,” Ex.1001-USP318, 1:30-37, and more specifically by “reshaping, remodeling, strengthening, or changing the properties of the tissues of the nose.” *Id.*, 11:16-22. The specification describes various forms of energy, but the claims are directed to a device that delivers RF energy. *See, e.g., id.*, Clm.1.

42. The challenged claims require that the claimed device for treatment include various mechanical components, like a handle, a shaft, and pairs of bipolar electrodes. *See, e.g., id.* FIG.18, Clm.1. I have copied Figure 18 below, which depicts “a device for applying energy to the nasal valve area comprising an array of non-penetrating electrodes.” *Id.*, 9:50-54. The specification describes device 390 having a shaft 394 connected to a handle 398, and “pairs of bipolar electrodes 392 located at the distal end of [the] shaft 394.” *Id.*, 27:45-51.

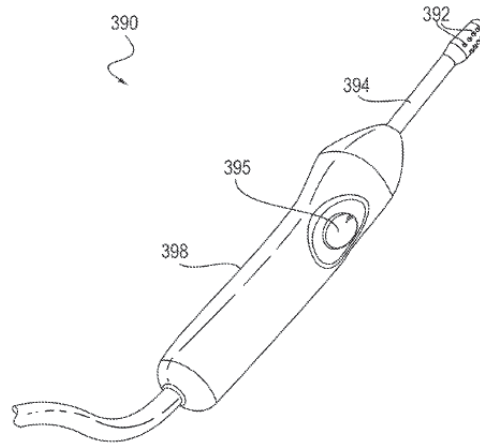


FIG. 18

43. The challenged claims in the '318 patent require a device having electrodes that are configured in a particular way. The electrodes must be in an array and in pairs, and the claimed device must provide RF energy to these pairs by connecting each pair to its own RF output channel. The challenged claims also require that the device have multiple sensors.

44. The '318 patent includes Figure 8F, copied below, which depicts: “an array of [penetrating] electrodes comprising one, two, or many pairs of bipolar needles 252...located on a treatment element.” *Id.*, 24:21-23.

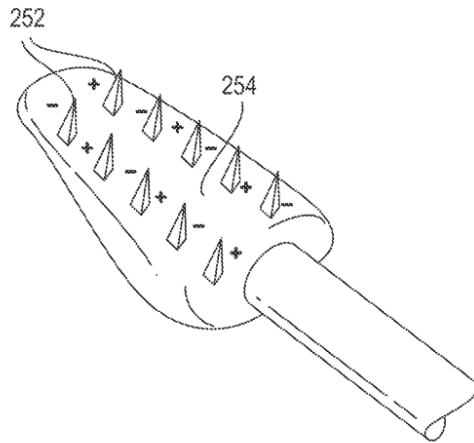


FIG. 8F

45. As shown below in Figure 41, “[e]ach electrode pair...may have its own individual subsystem 970” with “a positive electrode 973 and a negative electrode 974,” “controlled RF channels 971, a first thermocouple 972a, and a second thermocouple 972b to allow for independent temperature readings.” *Id.*, 49:33-40; *see also id.*, 49:18-21 (a “multiplexed configuration”), FIG.40, FIG.41 (copied below).

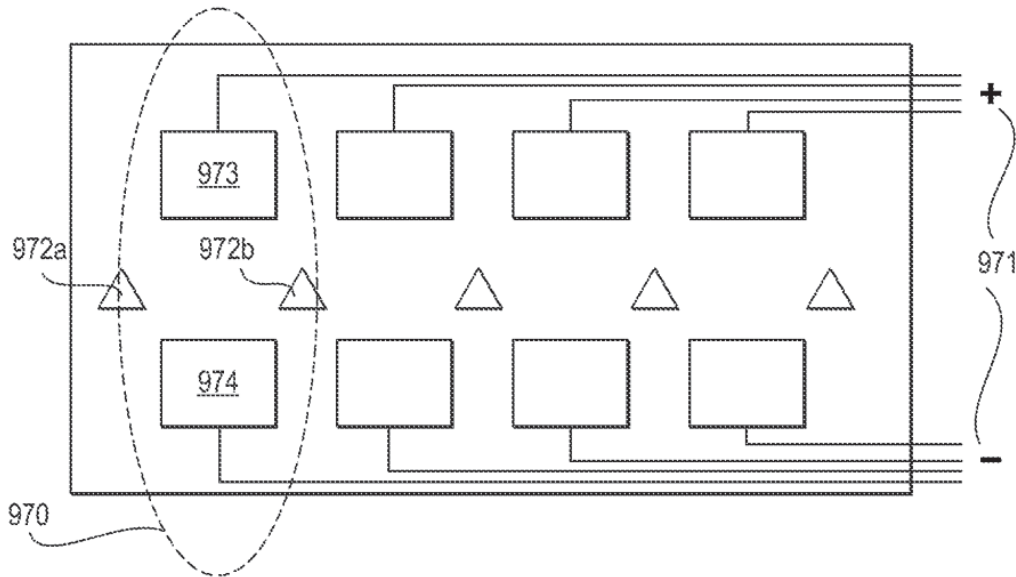


FIG. 41

B. An Overview of the Prosecution History for the '318 Patent

46. The Patent Owner filed the application that issued as the '318 patent on May 15, 2019. Ex.1003-USP318FH, 25. The application claimed priority to a series of patent applications, starting with provisional application 61/496,930 filed on June 14, 2011. *See* Ex.1001-USP318, Cover. I have assumed that priority date is correct for my analysis in this Declaration and have not analyzed whether the '318 patent is entitled to that priority date under the law.

47. When the application was filed, Patent Owner filed a preliminary amendment to replace the originally filed claims 1-12 with new claims 13-28. Ex.1003-USP318FH, 186-95. Independent claim 13 (now claim 1) initially

required: a handle, a shaft, a treatment element having a tissue treatment surface, and multiple bipolar electrodes. *Id.* On December 30, 2020, the examiner rejected independent claim 13 (now claim 1), among others, as being anticipated by the Makower reference discussed in this Declaration, which I understand to mean that the examiner found each of the limitations of the then-pending claims could be found in Makower. *Id.*, 508-09, 613.

48. In response to the examiner's rejection, Patent Owner amended the claims to include additional limitations, or requirements. The amendments added multiple pairs of bipolar RF electrodes, multiple RF output channels, and multiple sensors (amendments shown below in underlining):

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

...

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

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

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

Id., 572-88 (amendments underlined).

49. When making these amendments, Patent Owner argued that these underlined features were missing from Makower. *Id.*, 577-78, 590-613. The examiner, not having had the benefit of the references I describe below in Grounds I-V, allowed the application with no explanation as to why the claims were allowable.

VIII. CLAIM CONSTRUCTION

50. I was informed and I understand that, in my analysis, I should give claim terms their ordinary and customary meaning, as understood by a person of skill in the art at the time of the invention. I was informed and I understand that the words of the patent's claims and the context in which the term is used in the claims are highly instructive in ascertaining the term's meaning. I further understand that the terms of a claim are to be interpreted in the context of the entire patent, including the patent's claims, its specification, and its figures.

51. I have been further instructed that a patent's prosecution history may often provide helpful evidence about how the U.S. Patent and Trademark Office and the applicant understood the patent and its claims. Therefore, I have been instructed

that claim terms should also be interpreted in light of the patent's prosecution history.

52. In addition to the claims, the specification, the figures, and the prosecution history, I have been instructed that certain "extrinsic evidence," such as scientific or technical references, may also help inform the way in which a person of ordinary skill in the art understands the claim term. I have been instructed that extrinsic evidence must always be considered in the context of the intrinsic evidence.

53. For the purposes of this declaration, I will give the claim terms their plain and ordinary meaning, including as understood in the field of the '318 patent, and as understood by a person of ordinary skill in the art. To the extent an express claim construction is proposed in this proceeding or in another proceeding involving the '318 patent, I reserve the right to respond to such a construction and/or propose an express construction consistent with the term's plain and ordinary meaning.

IX. GROUNDS FOR FINDING THE CHALLENGED CLAIMS INVALID

54. It is my opinion that the Challenged Claims are invalid on the following grounds.

- **Ground I:** Claims 1, 4, 5, 9, 10, 12, 13, and 15-17 are rendered obvious by the combination of Edwards-'535 and Stern under 35 U.S.C. §103.
- **Ground II:** Claim 6 is rendered obvious by the combination of Edwards-'535, Stern, and Patel under 35 U.S.C. §103.

- **Ground III:** Claims 9 and 10 are rendered obvious by the combination of the combination of Edwards-'535, and Stern, and Edwards-'886 under 35 U.S.C. §103.
- **Ground IV:** Claims 1, 4-6, 12, 13, 15-17 are rendered obvious by the combination of Makower in view of Stern under 35 U.S.C. §103.
- **Ground V:** Claims 9 and 10 are rendered obvious by the combination of the combination of Makower, and Stern, and Edwards-'886 under 35 U.S.C. §103.

55. These grounds demonstrate in detail that claims 1, 4-6, 9-10, 12-13, and 15-17 are unpatentable as being obvious in view of the prior art. A copy of the Challenged Claims are attached as **Appendix C**.

56. Before discussing the specific grounds, I provide below a brief overview of the references in the grounds:

1. Edwards-'535

57. U.S. Patent No. 6,517,535, entitled “Apparatus for Ablating Turbinates,” issued on February 11, 2003 to Edwards (“Edwards-'535”). It is directed to “[a]n apparatus ... for ablating at least a portion of a nasal concha,” by which “the size of the nasal concha is reduced.” Ex.1010-Edwards-'535, Abstract. Edwards-'535 explains that the nasal concha may also be called “turbinates.” *Id.*, 1:63-66.

58. Edwards-'535 describes an RF ablation device to “improv[e] airflow” that is inserted “through a nostril” and used “for ablating an internal section of a nasal concha.” *Id.*, 3:7-19.¹ Edwards-'535's RF device includes an expandable member 132 through which ablative energy was delivered to nasal concha 114, as annotated below in Edwards-'535 Figure 3C. “[T]o expand the expandable member 132,” fluid such as an electrolytic medium (e.g., saline) is delivered through a lumen 135 “within the distal portion of the apparatus into the expandable member 132.” *Id.*, 5:52-67.

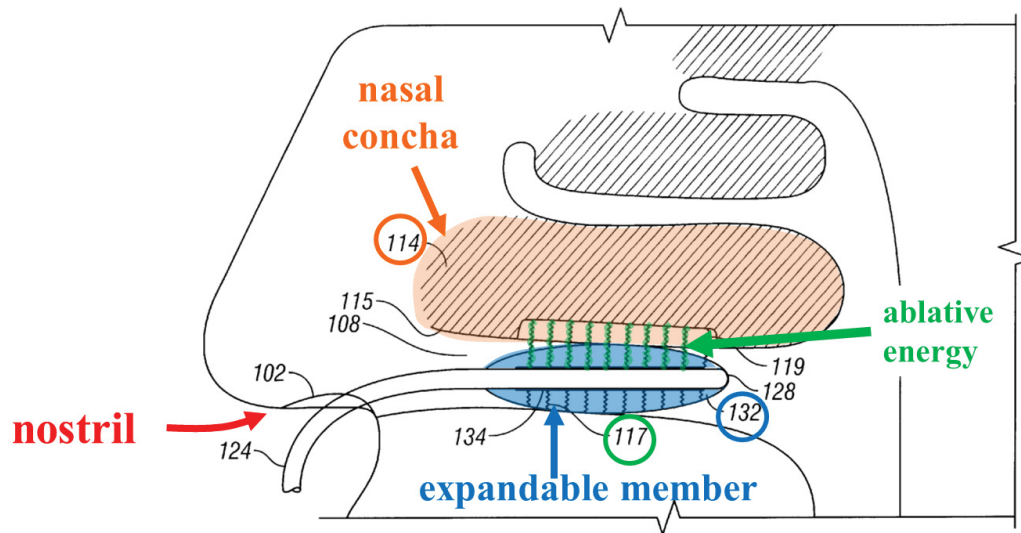


FIG. 3B

¹ Claim 1 of the '318 patent claims a “device for delivering energy to a nasal airway to improve nasal airflow...” Ex.1001-USP318, Clm.1.

Id., FIG.3B.²

59. In certain embodiments, cooling fluid is used inside the expandable member 132 to cool the surface of the nasal concha 114; this allows the delivered RF energy to target the subsurface of nasal concha 114 without ablating the surface of the nasal concha. *See id.*, 4:53-67, 5:18-26, 6:10-51, 6:66-7:24, FIGs.3A-4C.

60. Edwards-'535 discloses using different sensors as part of a control system used to monitor and control ablative energy. *See, e.g., id.*, 9:14-23, 9:46-56 (explaining that “sensors can be used to detect a variety of operating parameters including the amount of energy delivered, the impedance generated, and the temperature of a region adjacent the apparatus” and can be used in a feedback system “so that the output energy of the energy source is adjusted in relation to the property sensed by the sensor.”); Ex.1001-USP318, 16:17-40 (describing a “control system 42 configured to control the timing, location, intensity and/or other properties and characteristics of energy” including “any number of sensors...configured to detect treatment variables or other control parameters.”). Edwards-'535 describes how

² All annotations added unless otherwise stated.

these sensors could measure different parameters, including impedance and tissue temperature. Ex.1010-Edwards-'535, 9:14-23, 9:46-56.

2. Stern

61. U.S. Patent No. 5,562,720, entitled “Bipolar/Monopolar Endometrial Ablation Device and Method,” issued on October 8, 1996 to Stern et al. (“Stern”). Stern discloses an endometrial, RF ablation device and a method of making and using the device, where power can be provided on “either monopolar or [a] bipolar” basis. Ex.1033-Stern, Abstract.

62. Stern describes an RF ablation device that has an expandable member with RF electrodes on the member’s surface. *Id.*, 2:26-35. Stern also teaches “temperature sensors...are positioned on zones of the balloon which will contact areas of the [tissue] surface.” *Id.*, 7:49-61. Stern explains that the temperature can be monitored and used to enable “temperature feedback control to bring the endometrial temperature to a desired level.” *Id.*, 10:49-52.

63. One embodiment of Stern’s RF ablation device includes an array of pairs of bipolar RF electrodes where RF energy can be delivered independently to each electrode pair via distinct connections. *Id.*, 2:36-40, 3:29-40, 12:7-13:55, FIG.15 (copied and annotated below). Stern teaches selectively energizing certain

electrode pairs using a switching arrangement. *Id.*, Abstract. Stern also teaches that each pair may be connected to its own output channel. *Id.*, FIG.15.

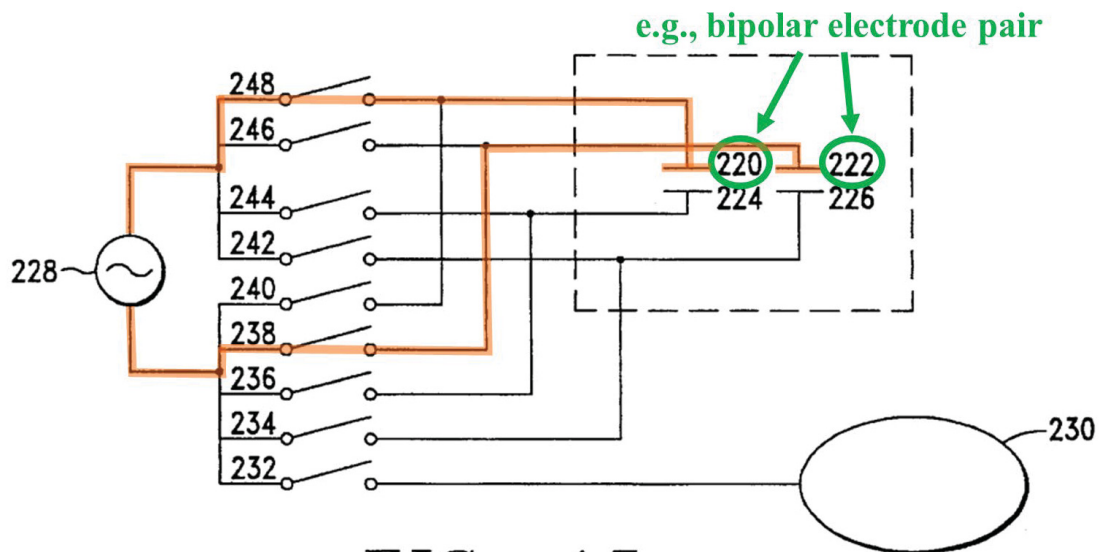
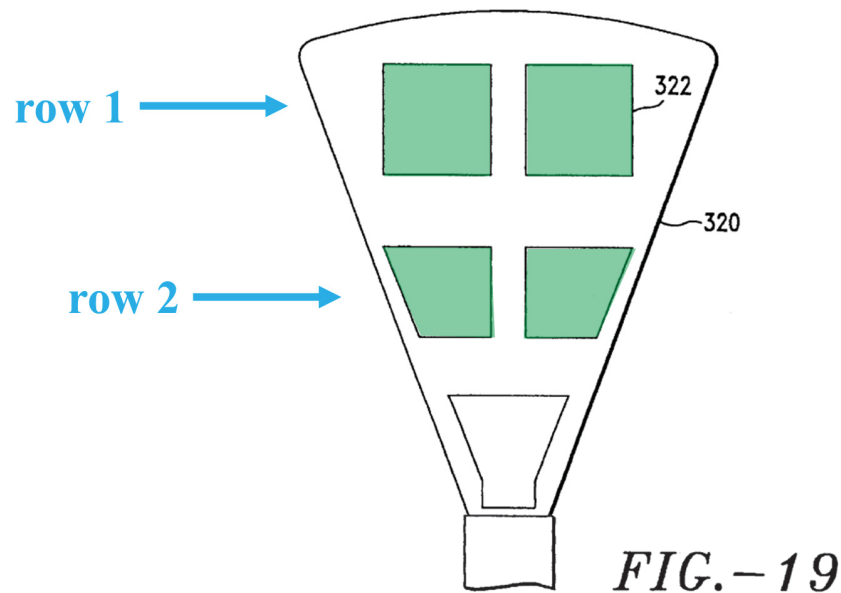


FIG. - 15

64. Stern discloses various arrangements for the disclosed bipolar pairs of electrodes, including the arrangement shown in Figure 19 below, which depicts an arrangement of electrodes in two rows of multiple pairs of bipolar RF electrodes. *Id.*, FIG.19, 2:36-40, 3:29-40, 12:7-13:55.

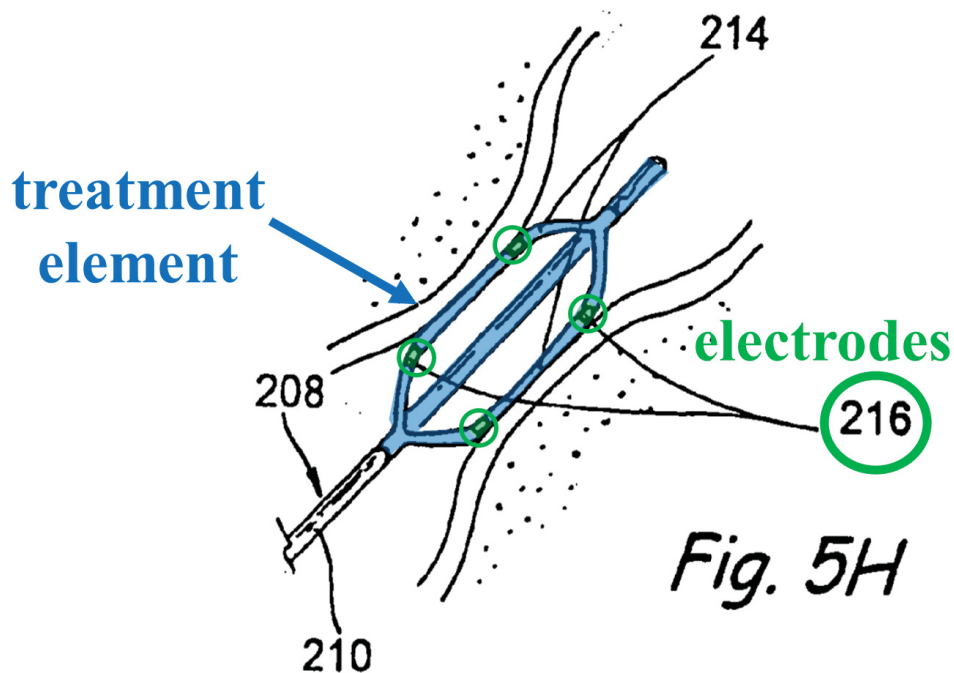


Id., FIGs.15, 19.

3. Makower

65. U.S. Patent Application Publication No. 2005/0240147, entitled “Devices, Systems and Methods for Diagnosing and Treating Sinusitis and Other Disorders of the Ears, Nose and/or Throat,” was filed on April 21, 2004 by Makower et al. and published on October 27, 2005 (“Makower”). The publication discloses medical devices and methods and more particularly to minimally invasive, catheter-based devices, systems, and methods for treating sinusitis and other ear, nose & throat disorders. Ex.1021-Makower, [0001]. Makower teaches, for example, inserting electrosurgical devices into nasal passageways “to perform diagnostic or therapeutic procedures.” *Id.*, [0016], [0043], [0161]. An embodiment of such a

device is shown in Figure 5H, wherein the device is inserted into the nasal cavity and the device comprises strut members 214 with multiple monopolar or bipolar electrodes 216. *Id.*, [0043], [0161], [0187], FIG.5H. Makower teaches that the strut members 214 may be expanded to contact the nasal cavity tissue, and then “current is applied to the electrodes 216 causing tissue adjacent to the struts 214 to be cauterized or heated.” *Id.*, [0187].



Id., FIG.5H. Makower discloses that the strut members 214 can be made from nitinol. For example, Makower explains that “any...elongate flexible devices of this invention”—which includes the struts members 214 in FIG. 5H—“may include design elements that impact performance features.” *Id.*, [0194]. One example of a

design element is the use of a “shape memory alloys such as nitinol” to “predictably deflect various sections of the catheter.” *Id.*; *see also id.*, [0149] (discussing nickel titanium alloy frame).

4. Patel

66. U.S. Patent Application Publication No. 2007/0287994 entitled “Endoscopically Introdudible Expandable Bipolar Probe” was filed on June 12, 2006 by Patel and published on December 13, 2007 (“Patel”). It is generally directed to “endoscopic medical devices” including “devices used for ablation of lesions and control of bleeding using bipolar or multipolar cautery technique” using the technique of “RF cauterization of tissue ... such as monopolar or bipolar coagulation.” Ex.1034-Patel, [0002]-[0004]. Patel teaches its devices can be configured to apply RF energy to cavities within the body, specifically in small passageways like the nasal cavities. *Id.*, [0008]-[0009].

67. Patel discloses an endoscopic bipolar probe for applying RF energy. *Id.*, Abstract. Specifically, Patel describes an expandable balloon 106 having electrodes 302 and 304, where the electrodes “are made of thin flexible metallic strips to allow folding or furling of the balloon during insertion.” *Id.*, [0090]. Patel teaches that the electrodes can be made of “nitinol,” a shape-memory alloy. *Id.*

5. Edwards-'886

68. U.S. Patent No. 6,273,886 entitled “Integrated Tissue Heating and Cooling Apparatus” issued on August 14, 2001 to Edwards et al. (“Edwards-'886”). Edwards-'886 is generally directed to “[s]ystems and methods integrate the control of an energy generator, to supply energy to an electrode structure to heat a tissue region, and the control of a pumping mechanism, to supply cooling fluid to control tissue temperature in the region.” Ex.1016-Edwards-'886, Abstract.

69. Edwards-'886 teaches “an energy generator, to supply energy to an electrode structure to heat a tissue region.” *Id.* Edwards-'886 teaches configuring and using such devices to apply RF energy to cavities within the body including—but not limited to—the alimentary canal including the mouth, pharynx, esophagus, stomach, intestines, and rectum. *Id.*, 1:10-25.

A. GROUND I: Claims 1, 4, 5, 9, 10, 12, 13, 15-17 In View of the Combination of Edwards-'535 and Stern

70. As detailed below, the combination of Edwards-'535 and Stern teaches each limitation of the Challenged Claims.

1. **Claim 1**

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

71. Should the preamble be found to be limiting (which I understand is a legal determination), Edwards-'535 teaches Element 1[preamble].

72. Edwards-'535 teaches apparatus 124 (i.e., a *device*) for delivering ablation energy (i.e., *delivering energy*) into a nasal meatus adjacent to nasal concha (i.e., *a nasal airway*) to reduce airway obstructions (i.e., *improve airflow*).³

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

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

³ I have included the relevant claim language in italics to help explain and demonstrate how the prior art discloses the claim limitations.

of the nasal concha can be reduced,” which “improv[es] airflow through a nasal meatus of the body.” *Id.*, 4:18-32, 8:50-54, FIGs.4A-4C.

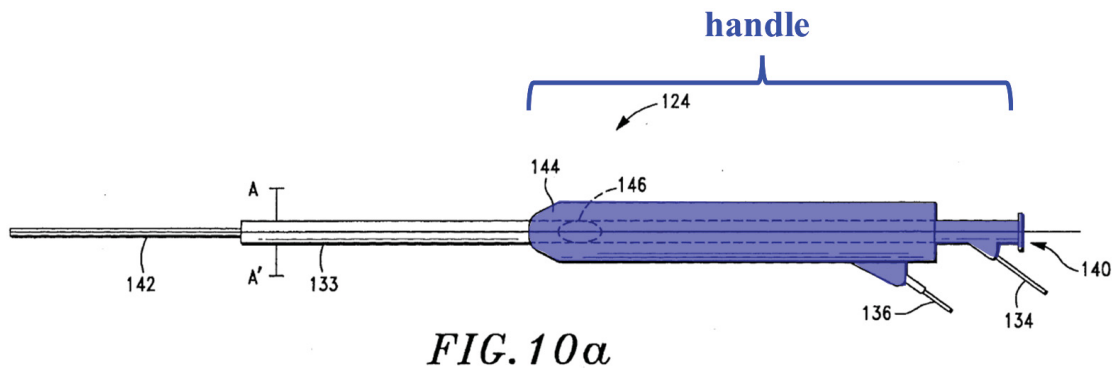
b. Element 1[a]: a handle;

75. Edwards-’535, or Edwards-’535 in view of Stern, renders obvious Element 1[a].

76. Although Edwards-’535 does not expressly state that its apparatus includes a handle, it would have been obvious to a person of ordinary skill in the art to use a handle with Edwards-’535’s device so that the user could manipulate and control the device and/or assist in deploying the expandable member. For example, Edwards-’535 teaches *introducing* an energy delivering catheter “through a nostril,” and “*positioning* the distal portion of the catheter” “adjacent a surface of the nasal concha [114]” once inside the nostril. *Id.*, 5:20-26 Clm.1, FIGs.3A-3D. Edwards-’535 also recognizes that “[a] variety of mechanisms known in the art may be used to expand the expandable member.” *Id.*, 7:39-41. Additionally, Edwards-’535 describes 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. It would have been obvious for a person of ordinary skill in the art to use a *handle* so that the user could introduce, position, and/or expand the treatment element of the device. And including such a handle would have had self-evident

results for a clinician to manipulate the device for a procedure and use various controls for the various portions of the device. Indeed, by 2011 it was ubiquitous to find *handles* in surgical devices and catheter-based energy delivery devices including to help control positioning and expansion of an expandable member. Ex.1045-Savage, 4:49-5:20; Ex.1030-Kunis, 11:18-48, FIGs.4A, 15A; Ex.1024-Hovda, 31:21-29, 33:3-14, FIG.2; Ex.1022-Odom, [0040]; Ex.1067-Edwards-'730, 4:16-41, 6:65-68, FIGs.1D, 7; Ex.1012-Goble, 4:1-6; Ex.1011-Baker, 5:28-46, 10:32-34, FIG.2; Ex.1013-Baker-'980, 11:7-12:6, 13:5-15, FIG.1.

77. Further, Figure 10a from Stern, shown below, shows a handle.



78. Using a handle would have been obvious based on Stern's disclosure. Stern discloses a region of application device 124 (*a handle*) that allows a physician to manually handle/control the device 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 (shown above and

annotated), 11a, 12. Stern's teaching of a handle includes a retraction knob 144 permitting the user to deploy and collapse the bladder 142. *Id.*, 10:11-29, 10:37-49, 18:18-26, FIGs.10a, 11a, 12. Stern teaches that once the treatment has been completed, the physician can use the handle to push the sheath back over the bladder, 142, collapsing the bladder. *Id.*, 18:18-26.

i. Motivation to Combine and Reasonable Expectation of Success

79. As I explained in Section III.C, I have been informed by Petitioners' counsel and understand that for a claim to be obvious, a person of ordinary skill in the art must have had a reason or motivated to combine or modify the relevant teachings in the prior art to obtain the claimed invention, and one of ordinary skill in the art must have had a reasonable expectation of success in doing so. It is my opinion that a person of ordinary skill in the art would have been motivated to incorporate a *handle* in Edwards-'535's device to gain control over the device positioning and the inflation and collapse of Edwards-'535's expandable member as Stern teaches. A *handle* mechanism would have facilitated the user's guidance of Edwards-'535's apparatus 124 into a patient's nostril, to a position adjacent to nasal concha 114, and would have allowed a user to inflate and later collapse the expandable member. Ex.1010-Edwards-'535, 5:20-34, 5:52-61, 6:66-7:17, Clm.1, FIGs.3A-3D, 4A-4C. Edwards-'535 does not expressly state how to position the

device within the nostril or control the expansion of the expandable member 132, but recognizes that “[a] variety of mechanisms known in the art may be used to expand the expandable member.” *Id.*, 7:39-41. Edwards-’535 therefore underscores that identifying and designing techniques for positioning, controlling, expanding, and collapsing these types of RF ablation devices were well within the level of ordinary skill in the art. For example, Edwards-’535 describes that “[o]ne mechanism, illustrated in FIG. 5, involves the use of a lumen 136 coupled with the catheter body 126 for delivering a medium 138 to expand the expandable member 132.” *Id.*, 7:42-53. A person of skill in the art would have been motivated to use a handle as a mechanism to help control the expandable member’s expansion.

80. Surgical catheter-based energy delivery devices with *handles* were ubiquitous in the art at that time. Ex.1045-Savage, 4:49-5:20; Ex.1030-Kunis, 11:18-48, FIGs.4A, 15A; Ex.1024-Hovda, 31:21-29, 33:3-14, FIG.2; Ex.1022-Odom, [0040]; Ex.1067-Edwards-’730, 4:16-41, 6:65-68, FIGs.1D, 7; Ex.1012-Goble, 4:1-6; Ex.1011-Baker, 5:28-46, 10:32-34, FIG.2; Ex.1013-Baker-’980, 11:7-12:6, 13:5-15, FIG.1. The result of the design and application of handles to different devices was predictable, and a person of ordinary skill in the art would have expected success given the numerous examples known in the art including in Stern. Including a *handle* in Edwards-’535’s apparatus 124 would have merely required

straightforward components like a handle with buttons, switches, thumb-indents, etc. with self-evident results (*e.g.*, creating a location to hold the device and control various components of the device).

c. Element 1[b]: a shaft extending from one end of the handle;

81. Edwards-'535 in view of Stern renders obvious Element 1[b].

82. Edwards-'535 in view of Stern together teach a portion of catheter body 126 extending through nostril 102 in Edwards-'535 (*a shaft*). In Stern, the shaft is shown extending from one end of the applicator device 124 (*i.e.*, *extending from one end of the handle*).

83. Here, I focus in particular on the Edwards-'535's embodiments depicted in Figures 3A-3D and 4A-4C. These figures show 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. Further, Edwards-'535's "distal portion 128" indicates to a person of ordinary skill in the art that the distal portion 128 is at the end of the elongated member (*i.e.*, *a shaft*). *See id.*, FIG.3C (copied and annotated below).

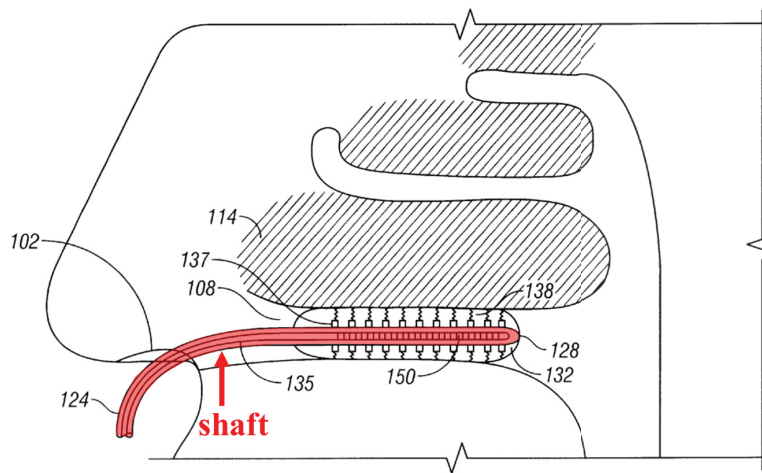
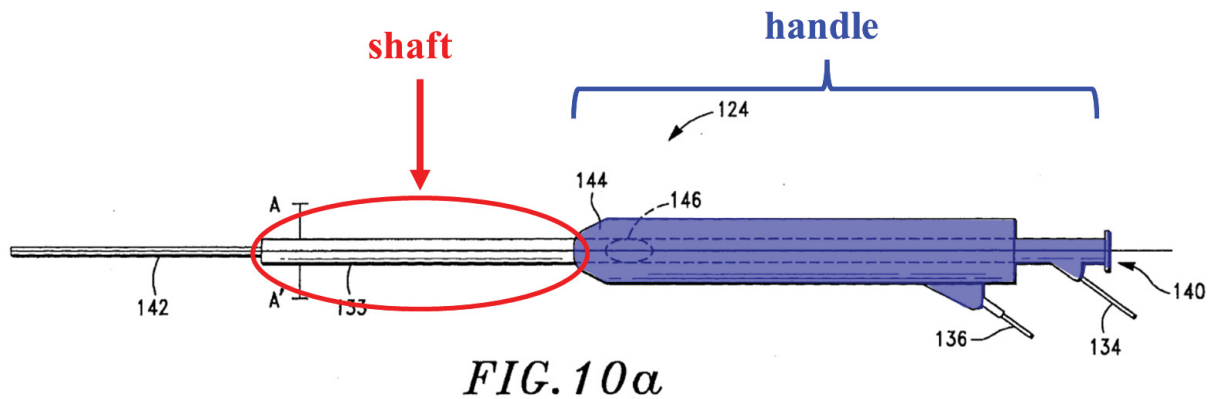


FIG. 3C

84. Because Edwards-’535 does not expressly disclose a handle (*see* Element 1[a] analysis), Edwards-’535 also does not expressly teach that a *shaft extends from one end of the handle*. However, a shaft extending from one end of the handle is an obvious further implementation of Stern’s teachings in Edwards-’535, because example, Stern teaches an element (*a shaft*) connected to the distal end (*extending from one end*) of the applicator device 124 (*of the handle*).

85. I have reproduced Figure 10a below, which shows a *shaft* (in red) and *handle* (in blue):



86. Accordingly, once Stern's teaching of a handle is implemented, a person of ordinary skill in the art would have understood Edwards-'535's description of the catheter to be a shaft extending between the handle and the device's distal end, just as Stern discloses. *Id.*, 5:20-26, 5:52-61. As discussed in Element 1[a], it would have been obvious for a person of ordinary skill in the art to use a handle, similar the one Stern teaches, to control the apparatus 124 of Edwards-'535 and deploy/collapse the expandable member. Furthermore, because Stern's teaching of a *handle* controls the *shaft* (e.g., for deployment of the expandable energy delivery component), it would have been obvious for the shaft to *extend[] from one end of the handle*. In fact, a shaft extending from a handle is the natural and predicable orientation of a shaft and handle, and it is commonly known in the art. Ex.1045-Savage, 4:49-5:20; Ex.1030-Kunis, 11:18-48, FIGs.4A, 15A; Ex.1024-Hovda, 31:21-29, 33:3-14, FIG.2; Ex.1022-Odom, [0040]; Ex.1067-Edwards-'730, 4:16-41, 6:65-68, FIGs.1D,

7; Ex.1012-Goble, 4:1-6; Ex.1011-Baker, 5:28-46, 10:32-34, FIG.2; Ex.1013-Baker-'980, 11:7-12:6, 13:5-15, FIG.1. In other words, the addition of a handle in Edwards-'535, for the motivations and reasons stated above for Element 1[a], naturally creates in Edwards-'535's device a shaft extending from the handle.

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

87. Edwards-'535 teaches Element 1[c].

88. Figure 3C from Edwards-'535 is shown below.

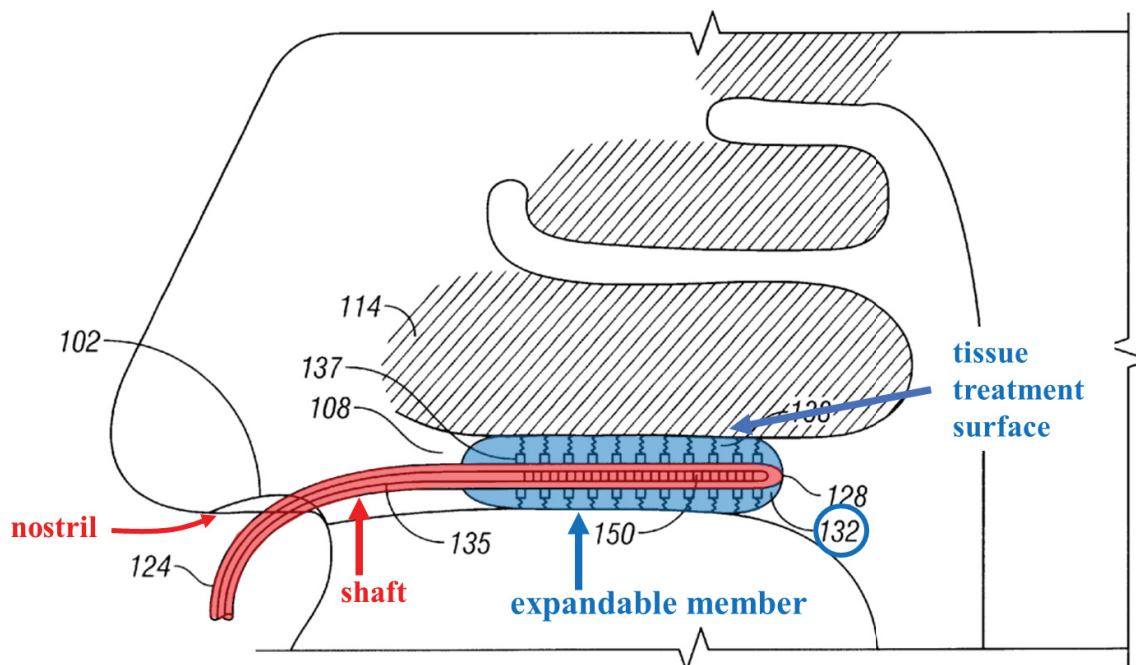
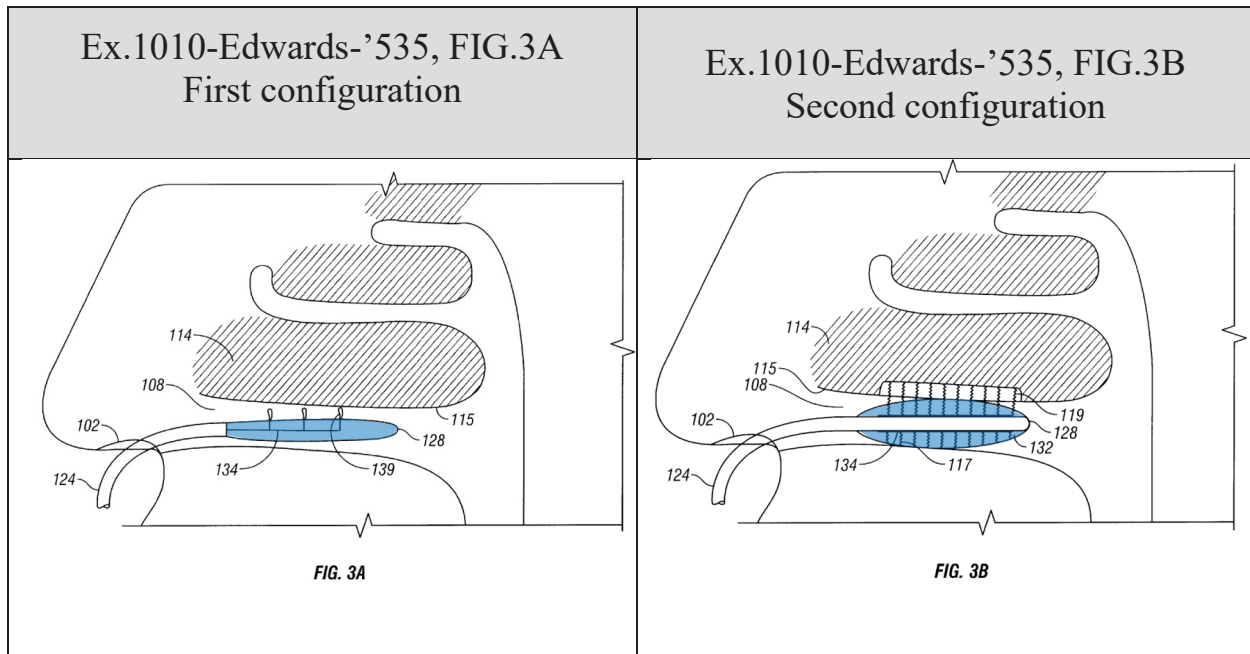


FIG. 3C

89. As shown in Figure 3C, Edwards-'535 shows an expandable member 132 and energy delivery device 134 (i.e., *treatment element*) that is located at the distal portion 128 of the device (i.e., *coupled with a distal end of the shaft*) inserted into nostril 102 (i.e., *sized to be inserted into a nostril*), where expandable member 132 is expanded (i.e., *configured to change from a first configuration to a second configuration*), and wherein energy delivery device 134, for example electrodes, are placed on the surface of expandable member 132. The surface of the expandable member 132 is brought in contact with surface 115 of nasal concha 114 (i.e., *wherein the treatment element comprises a tissue treatment surface*).

90. For instance, Edwards-'535 describes “an apparatus 124 having a distal portion 128 with an expandable member 132 and an energy delivery device 134 for delivering ablative energy is introduced through a nostril 102 into a nasal meatus [108] adjacent a surface of a nasal concha [114].” Ex.1010-Edwards-'535, 5:21-23, FIGs.3A-3D. As I have shown and annotated in Figures 3A and 3B below (and further shown in Figures 3C, 3B, 3D, and 5), the apparatus has a catheter body 126 to which the expandable member 132 is coupled. *Id.*, 7:33-35 (“An expandable member 132 is attached to the catheter body 126 at the catheter distal portion 128....”), 7:43-45.

91. Figures 3A and 3B show how medium 138 is delivered through lumen 135 and therefore causes the expandable member 132 to change from a *first configuration* (collapsed, Figure 3A) to a *second configuration* (expanded, Figure 3B). *Id.*, 5:22-30, 5:52-60, 6:33-36, 7:33-46, 7:61-8:46. Edwards-’535 also explains that this medium can help cool the surface of the nasal concha so that energy can “penetrate into an internal section of tissue.” *Id.*, 6:10-32, 4:60-67.



92. In normal use, the 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.*, they must be *sized to be inserted into a nostril*), “the expandable member [132]” is expanded or inflated and “preferably conforms to

the surface of the nasal concha [114] to be ablated.” *Id.*, 5:18-26, 7:37-40. The “energy delivery device [134] may be positioned on a surface 147 of the expandable member.” *Id.*, 8:12-16, FIG.6, 8:17-32. Then, RF energy is used to treat nasal tissue (*e.g.*, nasal concha 114), as discussed above for Element 1[pre]. *Id.*, 8:50-53. Accordingly, the surface of the expandable member [132], with energy delivery devices mounted on the surface, is a *tissue treatment surface*.

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

93. Edwards-’535 in view of Stern renders obvious Element 1[d].

94. Edwards-’535 in combination with Stern discloses having a plurality of bipolar energy delivery devices (*i.e.*, *an array of multiple pairs of bipolar radiofrequency electrodes*), on the surface of expandable member 132 (*disposed along the treatment surface of the treatment element*).

95. Edwards-’535 teaches a device where there are “a plurality of energy delivery devices...positioned on the surface of the expandable member [132].” *Id.*, 8:17-32. I have shown this below in Figure 3B.

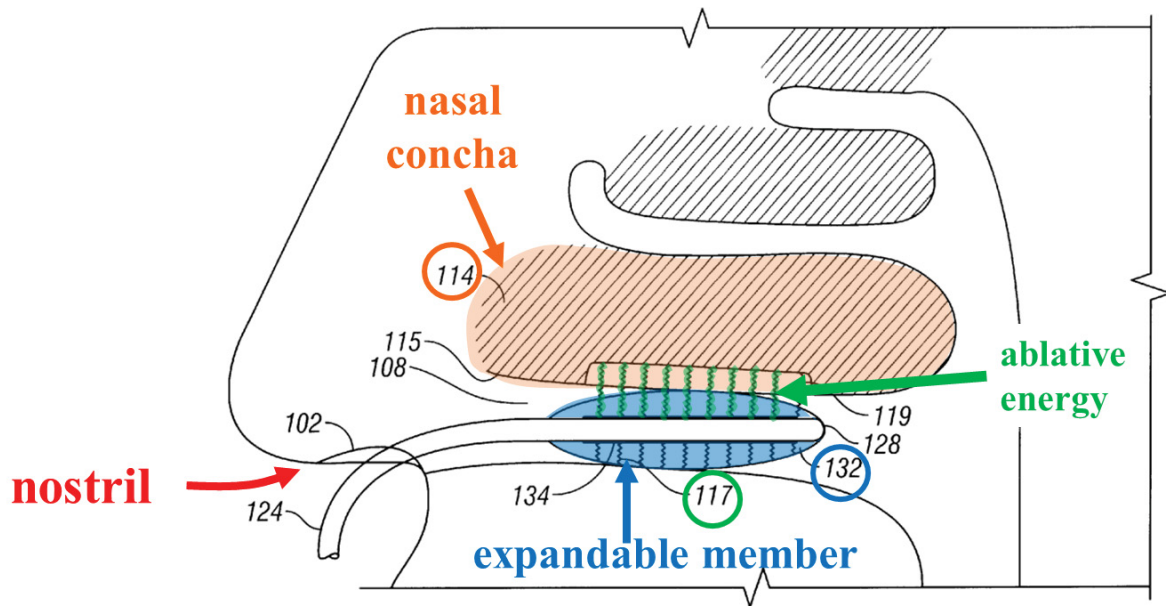


FIG. 3B

96. Edwards-’535 also describes that in one embodiment, there are “ring electrodes 156” are “disposed on the surface of the expandable member 132.” *Id.*, 8:19-33. A person of ordinary skill in the art would have also been aware of other configurations for a surface energy delivery device. *See, e.g.*, Ex.1011-Baker, Abstract, 5:60-67, 9:13-23; Ex.1033-Stern, 2:26-35. These surface-mounted electrodes or energy delivery devices can deliver RF energy in a bipolar mode. *Id.*, 8:17-32, 8:50-54, 10:30-32, 10:52-61. As I have shown in Figure 6 (annotated below), these electrodes/energy delivery devices are shown placed in an array—i.e., “disposed in parallel with their axes aligned with a long axis 160 of the catheter body 126.” *Id.*, 8:19-33.

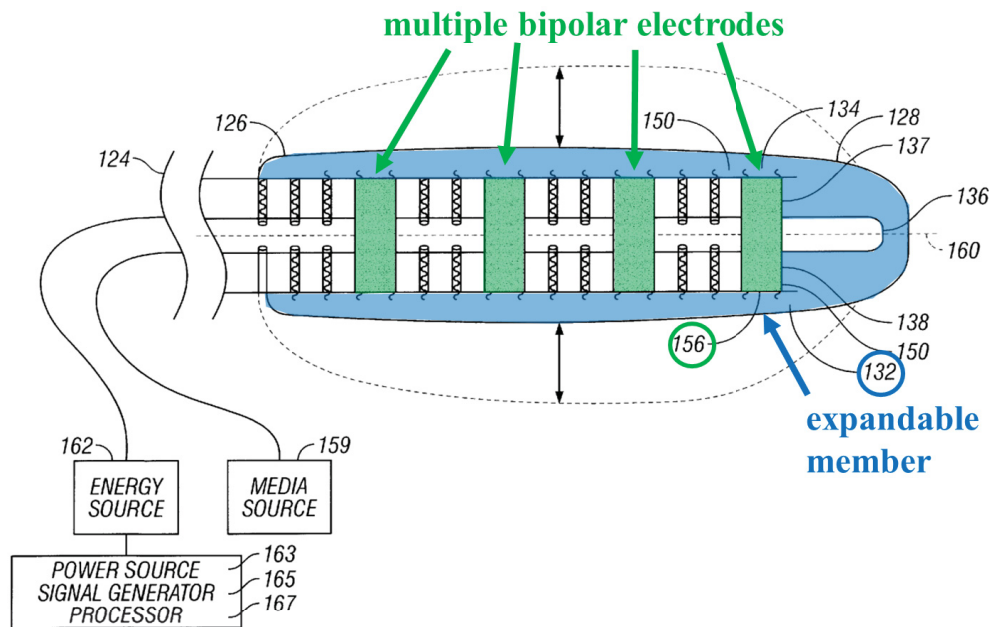


FIG. 6

Id., FIG.6.

97. Edwards-’535 leaves the implementation of the bipolar electrodes to the person of ordinary skill in the art, as it was well within the person of ordinary skill in the art’s knowledge and skill. *See id.*, 10:52-61.

98. Stern further teaches that the electrodes are part of an RF ablation device that can be arranged as bipolar pairs. *See* Ex.1033-Stern, 2:36-40 (“[i]t is a further object of the present invention to provide a system of selective delivery of...bipolar RF energy to chosen pairs of an array of separate electrodes”), 13:1-44.

99. Stern discloses “a system of selective delivery of...bipolar RF energy to chosen pairs of an array of separate [bipolar] electrodes.” *Id.*, 2:36-40; *see also*

id., 3:29-40, 12:7-13:55, Clm.4, FIGs.13, 15, 17, 18. I show an example of a bipolar electrode pair below:

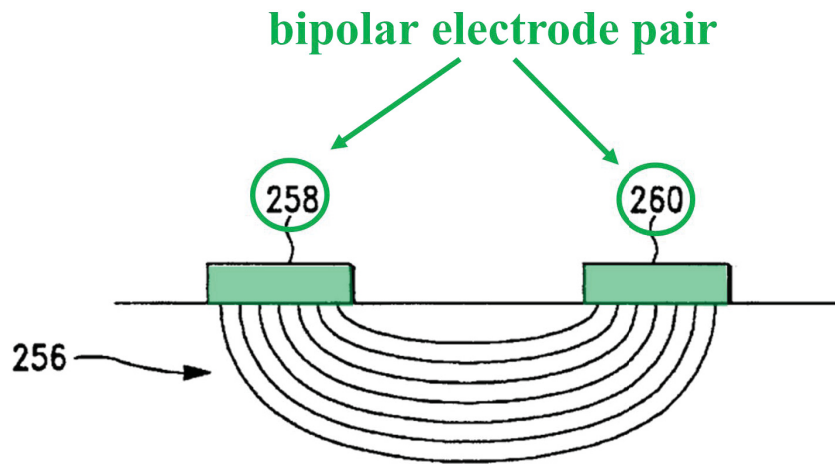


FIG.-17

Stern's Figure 17, above, also shows the field lines for the current that travels between the bipolar electrodes. *Id.* 13:13-14. As shown above, current travels from one electrode to another. *Id.*

100. Stern teaches that its RF ablation device may have an expandable member, like Edwards-'535's device, and that an array of RF electrodes may be placed on the surface of its expandable member. *Id.*, 2:26-35. Stern further teaches "selective delivery of...bipolar RF energy to chosen pairs [within the] array." *Id.*, 2:36-40.

101. Stern's Figure 15, which I have reproduced below, depicts that the circuitry that controls the bipolar pairs and includes four electrodes 220, 222, 224 and 226. The figure includes switches that determine the type of bipolar configuration depending on which switches are open and which are closed. *Id.*, 12:41-45 ("within the bipolar mode...the switches allow for the selective application of RF energy to various combinations of electrodes."). Stern teaches examples in which electrodes can be *paired* by closing particular subsets of switches. *Id.*, 12:7-24, 12:37-13:2. For instance, "[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.

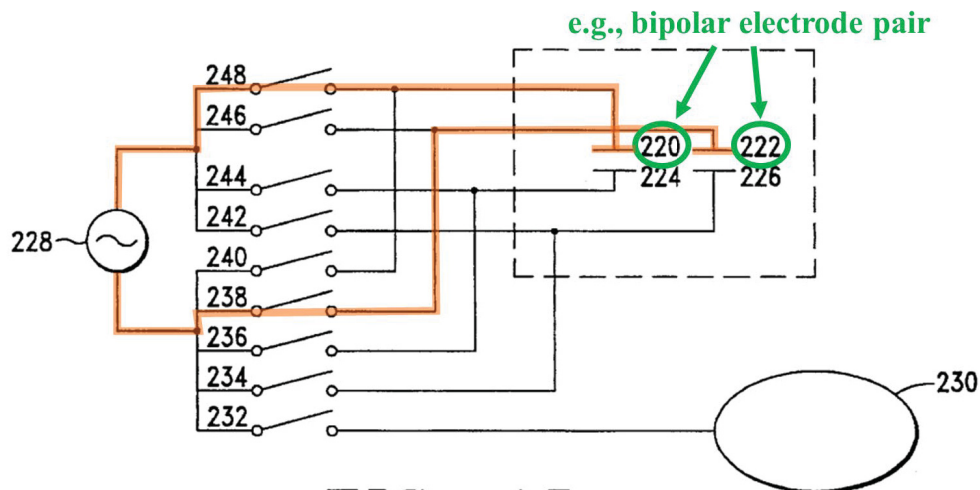


FIG. - 15

i. Motivation to Combine and Reasonable Expectation of Success

102. I note that a person of ordinary skill in the art would have considered Edwards-'535 and Stern to be in the same field as the '318 patent and reasonably pertinent to solving the problems addressed in the '318 patent (e.g., treating human tissue) using the same type of solution (expandable devices for applying energy to the tissue). Ex.1010-Edwards-'535, 8:18-25; Ex.1033-Stern, 12:25-27, 3:21-25.

103. As I explained in Section III.C, I have been informed by Petitioners' counsel and understand that for a claim to be obvious, a person of ordinary skill in the art must have had a reason or motivated to combine or modify the relevant teachings in the prior art to obtain the claimed invention, and one of ordinary skill in the art must have had a reasonable expectation of success in doing so. It is my opinion that a person of ordinary skill in the art would have been motivated to incorporate Stern's teaching regarding at least two rows of bipolar electrode pairs into the device in Edwards-'535 for several reasons. First, delivering bipolar RF energy and delivering energy to each electrode independently are two device design goals Edwards-'535 articulates, but Edwards-'535 does not provide detailed information on how to accomplish these goals. A person of ordinary skill in the art would have been motivated to incorporate the teachings from Stern because it provides detailed information and schematics regarding how to design an RF ablation device with surface electrodes so the electrodes deliver bipolar RF energy

and can deliver energy independently through the different electrodes. Second, Stern teaches that its bipolar electrode configuration provides a number of benefits, including providing even heating and precise energy delivery control that are particularly beneficial when trying to ablate an entire heterogeneous surface.

104. Edwards-'535 exemplifies that using RF ablation devices with an array of multiple bipolar surface electrodes in body cavities was well-known. *See, e.g.*, Ex.1021-Makower, [0187] (disclosing device with “electrodes 216 [that] may be bipolar”), [0001] (describing treatment in nasal cavities), [0131] (same), [0164] (describing devices), FIG.5H (showing device with electrodes on the surface of a frame for ablating in the nasal cavity). Edwards-'535 teaches that “energy...may be independently delivered to each [electrode],” Ex.1010-Edwards-'535, 8:18-25, and that its system can deliver “bipolar or monopolar energy,” *id.*, 10:52-57. However, Edwards-'535 does not provide details on how to implement such energy delivery, demonstrating that arranging electrodes in an array having multiple bipolar pairs and how to energize such pairs was well within the skill of a person of ordinary skill in the art. *See id.*, 10:52-61. A person of ordinary skill in the art would have used Stern's scheme to implement Edwards-'535's feature that “energy may be delivered to all of the energy devices or may be independently delivered to each energy

delivery device,” *id.*, 8:18-25, because Stern provides detailed schematics and information about how to design a device that can accomplish this goal.

105. In view of Edwards-’535’s silence on how to specifically configure its bipolar electrodes or independent energy delivery, a person having ordinary skill in the art would already know how to implement such energy delivery or would have been motivated to turn to other sources for that information, including regarding how to implement independent energy delivery through each electrode for bipolar energy delivery. When faced with how to independently deliver energy to each electrode or electrode pair, a person having ordinary skill in the art would have had only a limited number of choices. Specifically, a person of skill in the art would have had to choose whether to use multiple RF generators or just a single RF generator. If using multiple RF generators, electrodes would be individually wired to each generator. If using a single RF generator, circuitry would have been required to control the route of energy (taught by Stern), which would have been obvious to implement by switches or relays. A person having skill of the art would have been motivated to use only one RF generator, as was common at the time. Further, a system incorporating only one voltage source is safer (e.g., there are fewer components and more consistency in output for each bipolar pair), more practical (e.g., it would impractical to use multiple generators when one would suffice, and

multiple generators would take up more space in the device), and more reliable (e.g., there would be fewer complex generators that could fail and cause the entire device to be inoperative by virtue of one pair not being usable) than one with numerous power sources. Switches or relays take up less space than multiple generators, and would have been simpler and cheaper than multiple complex voltage sources.

106. A person of ordinary skill in the art would have been motivated to refer to Stern because it provides detailed information regarding how to design and wire a device that provides RF energy to electrodes independently with a single voltage source. Stern's Figures 5 and 15 each provide detailed electrical schematics showing how to wire and control various sensors and electrodes independently in a bipolar arrangement. For example, Figure 5 of Stern shows multiple electrodes 50 connected to a switch bank for independent energy delivery, as well as a temperature measurement circuitry including switch bank 52 for each respective electrode. Ex.1033-Stern, 9:2-24, FIG.5. Likewise, cir shows a flexible circuit that can be used to provide power from a voltage source 228 to any pair of electrodes in the array 220, 222, 224, and 226 for bipolar RF energy application. *Id.*, 12:38-13:2, FIG.15.

107. Furthermore, a person of ordinary skill in the art would have also been motivated to improve or implement Edwards-'535's device by including Stern's teachings of multiple pairs of bipolar electrodes based on the advantages and benefits

of Stern's design, as Stern explains. Stern teaches that pairing bipolar RF surface electrodes and wiring them with switches (i.e., to multiple output channels) to permit independent delivery of RF energy to each bipolar pair (which I described above and in Element 1[e]), and that doing so provides multiple advantages. One advantage of bipolar electrode pairs is that a user can precisely control the electrical current delivered to the tissue. Ex.1033-Stern, 13:21-27 (bipolar pairs provide a user with "[t]he ability to control field lines, and therefore the heated area...to insure [*sic*] complete heating of an area"), 12:20-37 (bipolar pairs provide a user with "precise control" by selecting "particular pairs" of bipolar electrodes), FIGs.15, 18. This was an advantage of using bipolar electrode pairs in RF ablation devices that was well known before 2011. *See generally* Ex.1050-Hong, S183 (describing the benefits of using bipolar electrodes versus electrodes designed for monopolar configurations).

108. Another advantage of energizing electrodes in bipolar pairs is that heat can be directed to targeted tissue while minimizing the chance that tissue that is not being targeted is affected (e.g., not heated and remaining unchanged). This feature—the ability to direct heat to one particular area and not others—is particularly advantageous where the target tissue areas have different properties and characteristics (i.e., uneven tissue morphology). Stern expressly teaches this advantage of its electrode arrangement. *See* Ex.1033-Stern, 13:21-39 ("The bipolar

arrangement allows various pairs of electrodes to be picked in order to heat uneven or rather asymmetrical areas.... That is, any unusual features within an area to be heated may be taken into account in a bipolar operation by selection of different pairs of electrodes for energization utilizing the circuitry of FIG.15.”), FIG.15. For example, if the targeted tissue has uniform electrical and thermal properties, a clinician would apply the same current and voltage to the tissue and expect the same result across the treated tissue. However, the clinician likely would not know whether the electrical or thermal properties of the target tissue are uniform prior to the ablation procedure. If the targeted tissue has uneven morphology, the clinician would be able to apply different currents and voltages at different bipolar pairs for different lengths of time to obtain the same intended result across the uneven tissue. This benefit would be further improved with circuitry that incorporates localized feedback control to allow the clinician to understand the tissue’s real-time response to the energy. *See* Ex.1033-Stern, 2:31-35 (“The plurality of separate electrodes are independently and sequentially energized and controlled with thermistor temperature feedback control to bring the [tissue] temperature to a desired level.”). Overall, using bipolar pairs, like those taught by Stern, to direct such energy means that the clinician (or an automated system) can target small, specific areas of tissue and adjust the treatment as necessary.

109. Similarly, another advantage of bipolar electrode pairs is that they lead to more precise and even heating. For example, Stern explains that “it would be more precise to provide a more even heating of a uterus or other body organ if the electrode could have a controlled return path for the current.” Ex.1033-Stern, 12:25-27. As I explained in Section VI.C in relation to the differences between monopolar and bipolar electrodes, using bipolar RF energy allows a user to control the return path because the electrical current flows only between the active and return electrodes, which are placed inside of the body. As I explained, this can be a safer option for the patient, especially when performing ablation in the head. This precision and even heating is also exactly what Edwards-’535’s technique calls for—i.e., Edwards-’535 seeks to “maintain[] tissue...at a desired temperature,” which requires precision and control of heating on a local level to account for variations. Ex.1010-Edwards-’535, 9:65-10:1.

110. Stern also teaches that more than one pair of bipolar electrodes provides the additional benefit of selective tissue destruction across an “entire surface” of tissue, which a person of skill in the art would consider a benefit over only providing for ablation of one small portion between two discrete electrodes. Ex.1033-Stern, 2:6-19, 6:44-62, 10:49-65.

111. A person of ordinary skill in the art would have recognized these advantages and would have been motivated by these advantages to modify Edwards-'535 in view of Stern. Doing so would have involved using Stern's known bipolar pairing technique to fill in the missing details of Edwards-'535, which would have been desirable for increased safety and control. Increased safety would have been a predictable result from this combination, as increased control and even tissue heating would avoid unwanted ablation of adjacent tissue and over-heating of target tissue.

112. Stern's teaching of a bipolar pairing technique would have also improved Edwards-'535's similar device in the same way as it improved or led to advantages in Stern's similar device. A person of ordinary skill in the art also would have been motivated to combine Edwards-'535 and Stern because Edwards-'535's known device was ready for improvement (given that Edwards-'535 is silent as to how to pair and wire the electrodes). As I noted above, it would have been apparent to a person of ordinary skill in the art that Stern's advantages of pairing and controlling electrodes would have readily achieved Edwards-'535's stated goal of temperature-based control by allowing a user to control how much RF energy is applied to each respective electrode pair, and to evenly heat the tissue. *See* Ex.1010-Edwards-'535, FIGs.4A-4C, 6:66-7:17.

113. A person of ordinary skill in the art would have had a reasonable expectation of success in implementing Stern's bipolar RF electrode pairs and individual output channels in Edwards-'535's device given that, as explained above, Edwards-'535 does not teach a particular circuitry design and therefore implicitly recognized that it was within a person of ordinary skill in the art's skill to design a circuitry system for bipolar electrode pairs that would selectively control each pair. Indeed, configuring and wiring bipolar electrode pairs with individual output channels is a well understood and predictable aspect of designing electrosurgical devices. For example, I recently worked on designing Adiana and NovaSure, two RF ablation devices that use pairs of bipolar electrodes.

114. The Edwards-'535 and Stern references describe very similar objectives, devices, and techniques for delivering bipolar RF ablation energy. For example, both disclose independently controllable electrodes, both describe the use of expandable devices with surface bipolar RF electrodes, and both discuss delivering energy to the mucosal tissue of different body cavities. Ex.1010-Edwards-'535, 4:53-66, 5:21-23, 7:33-46, 7:61-8:46, 5:36-44, 6:9-22, 8:17-25, 9:1-44, 10:18-32; Ex.1033-Stern, 1:16-43, 7:38-8:38, 10:48-65.

115. These similarities would have led a person of ordinary skill in the art to expect that applying the teachings from Stern to the device of Edwards-'535 would

have been straightforward and have yielded predictable results. Based on my experience developing ablation devices during the relevant time period, my knowledge of the level of skill in the art at that time, and the disclosure of the references themselves, I believe a person of ordinary skill in the art would have would have had a reasonable expectation of success in implementing Edwards-'535's device to include Stern's bipolar RF electrode pairs. As I noted above, Edwards-'535 is silent as to particular surface electrode arrangement and control technique. Ex.1010-Edwards-'535, 8:19-33. Consistent with my recollection from the relevant time period, Edwards-'535 recognized that it was well within a person of ordinary skill in the art's skill to implement a system that independently delivers RF energy to different bipolar electrodes using, for example, the wiring of Stern. Ex.1033-Stern, 2:49-53, 12:25-27, 13:21-39, FIGs.5, 15. Doing so would have merely involved the use of a standard switching apparatus as well as routine implementation of software that selectively controls such switches.

116. Moreover, in the combination, Stern's known techniques would have been used to improve Edwards-'535's similar device in the same way. For example, Edwards-'535 describes an expandable device that has bipolar surface RF electrodes for delivering RF energy to a body cavity, Ex.1010-Edwards-'535, Abstract, 5:18-34, 8:19-33, 10:25-31, 10:51-61, FIGs.3A-3B, and Stern discloses a way to pair such

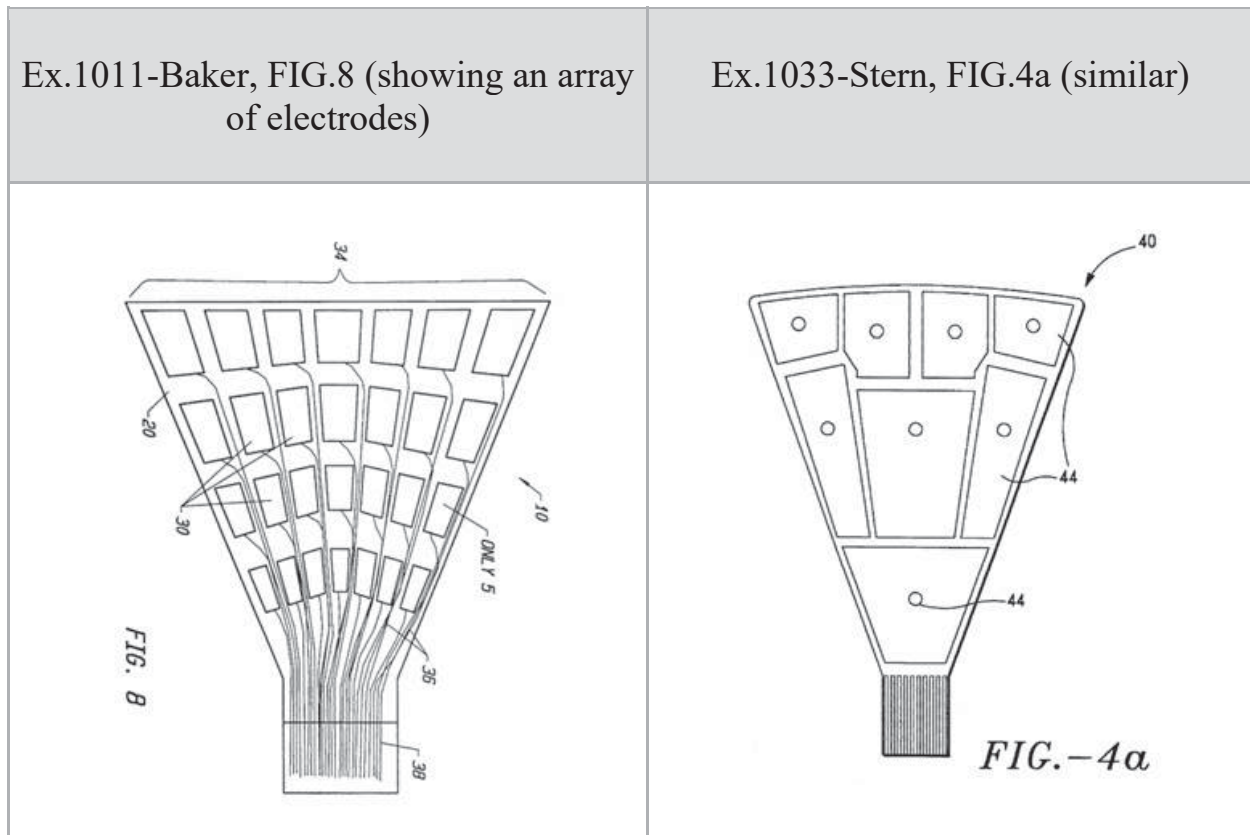
bipolar surface RF electrodes on an expandable device and wire such electrodes for independent energy delivery, Ex.1033-Stern, FIGs.15, 19, 2:49-53, 12:38-13:55. Stern's teachings would have been applied to Edwards-'535 in the same way they are used in Stern.

117. Further, a person of ordinary skill in the art would have reasonably expected success in incorporating teachings from Stern for the additional reason that Edwards-'535 instructs a person of ordinary skill in the art that references having similar attributes as Stern may be incorporated into the Edwards-'535 device. *See* Ex.1010-Edwards-'535, 8:25-33 (incorporating the reference of U.S. Patent No. 5,575,788 to Baker). Specifically, Edwards-'535 incorporates the disclosure of U.S. Patent No. 5,575,788 to Baker ("Baker") for teaching how energy delivery devices can be positioned on a surface of an expandable member. *Id.* Edwards-'535 states, "[a]n example of a suitable surface for disposition on the membrane is described in application Ser. No. 08/319,373, "Thin Layer Ablation Apparatus", filed Oct. 6, 1994, which is incorporated by reference." *Id.* This patent application ultimately issued as U.S. Patent No. 5,575,788 to Baker and other named inventors, including Stuart Edwards, the sole named inventor on Edwards-'535. Ex.1011-Baker, Cover.

118. Baker, like Stern, discloses an "ablation apparatus for ablating an inner layer in an organ or lumen of a body" using an expandable member with bipolar

surface electrodes. *Compare* Ex.1011-Baker, Abstract, 5:60-67, 9:13-23, FIGs.8-9 (disclosing a RF ablation device used for endometrial ablation, which includes an expandable member with bipolar electrodes on its surface), *with* Ex.1033-Stern, 2:26-35. Like Stern, one of the specific tissues that Baker treats is the lining of the uterus. Ex.1011-Baker, Abstract, 5:60-67, 9:13-23; Ex.1033-Stern, 2:26-35.

119. Baker and Stern both depict very similar devices:



120. Thus, a person having ordinary skill in the art would have recognized that the teachings of Stern could be incorporated into Edwards-'535's device given

Edwards-'535 incorporation of Baker and the similarity between Stern and Baker, as I explained above.

121. This is consistent with my experience in the field of ablation devices. Persons of ordinary skill in the art routinely considered techniques and technology from ablation devices suitable for treating one area of the body applicable to devices in another area of the body. When developing an ablation device, persons of skill in the art would not have reinvented the wheel—instead they would have looked to existing ablation technology to identify relevant and useful teachings, and expected success in doing so. Stern expressly notes the applicability of its disclosure to other parts of the body:

One of the more obvious variations based upon the above disclosure is the utilization of such an electrode partitioning structure and the accompanying heating for treatment of other body organs or tissues either externally or internally. The principles embodied herein and the methods utilizing those principles with respect to the delivery of controlled RF energy in a controlled environment have application in many areas, not only for controlled destruction of tissue but also for controlled heat treatment of tissue. It is therefore to be understood that,

within the scope of the appended claims, the invention may be practiced
otherwise than as specifically described herein.

Ex.1033-Stern, 18:27-40.

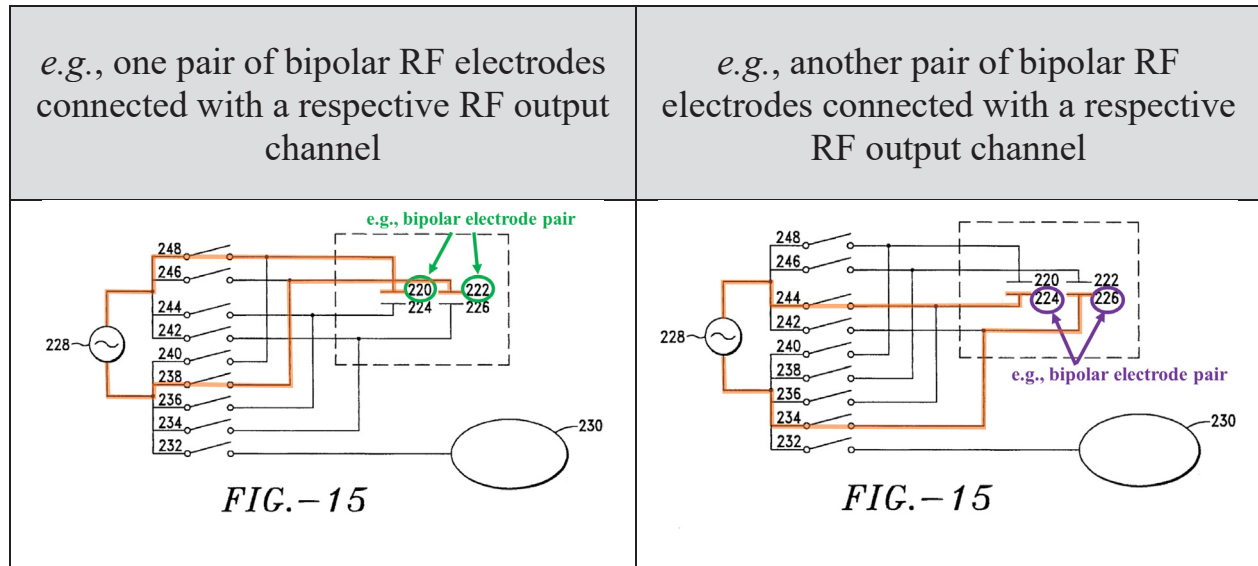
122. Accordingly, applying Stern's teachings to Edwards-'535 would have been a matter of routine implementation within the skill of a person of ordinary skill in the art that would have yielded predictable successful results. For example, by using Edwards-'535's device having bipolar RF electrode pairs and energizing them via independent energy delivery as Stern teaches, with a reasonable expectation of success.

- f. 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**

123. Edwards-'535 and Stern teach Element 1[e].

124. Edwards-'535 in view of Stern teach energy outputs shown in orange in Stern's Figure 15 (*multiple radiofrequency output channels*) connected to pairs of bipolar electrodes, for example, one pair is shown in green in Figure 15 and another pair is shown in purple (i.e., *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 (e.g., shown in Figure 15). Ex.1033-Stern, FIG.15.



125. As I explained above for Element 1[d], Edwards-'535 does not provide details on how to pair and wire bipolar electrodes. *See* Ex.1010-Edwards-'535, 8:17-32, 10:52-61. As I explained, a person of ordinary skill in the art would have been motivated to incorporate the teachings of Stern, which describes implementation details on how to pair bipolar electrodes and to supply power independently to bipolar pairs. Doing so would allow a person of ordinary skill in the art to implement Edwards-'535's stated result of independent energy delivery. Ex.1033-Stern, Abstract, 1:16-23, 2:36-40, 3:12-40, 11:29-46, 12:38-45, Clm.4.

126. The '318 patent teaches that "[i]n some embodiments of treatment devices comprising an array or multiple pairs of electrodes, each pair of electrodes

(bipolar) or each electrode (monopolar) may have a separate, controlled electrical channel to allow for different regions of the treatment element to be activated separately.” Ex.1001-USP318, 24:45-49.

127. As shown above, Stern’s Figure 15 depicts the circuitry that supplies energy to selected bipolar pairs via separate, controlled electrical channels to allow each bipolar pair to be activated separately. For example, Stern teaches a “switching means” that receives an output from an RF power source, and then energize bipolar electrodes by selectively providing RF energy to particular electrodes depending on which switches are open or closed. Ex.1033-Stern, 2:49-53, 3:12-29, Clm.1.

128. Stern’s switching mechanism accomplishes independent activation of each electrode pair by connecting each bipolar pair to voltage source 228 via separate output channels. *Id.*, 12:46-13:2. When particular switches are closed, only the associated bipolar pair(s) is/are activated. *Id.* Stern’s teaching of output channels are the *output channels* required by Element 1[e], as the channels are separately/individually connected to the electrodes.⁴ In the hybrid schematic/device

⁴Edwards-’535 and Stern disclose output channels within the device itself, but also teach RF generators that a person of ordinary skill would understand to have two

diagram of Figure 15, Stern shows that the device includes “electrical leads” “by way of connectors 50” that are used to connect the device electrodes to switch bank 54, which is used to provide signals to the electrodes. *Id.*, 8:66-9:6, FIG.5. A person of ordinary skill in the art would have recognized the term “connector” to refer to the output of a channel, such as an output port or connection from a generator, used to carry electrical signals. Furthermore, a person of ordinary skill in the art would have recognized that similar connectors 50 would have also been included in Figure 15, which as I discussed above discloses switches that can be used to implement a bipolar device. *Id.*, FIG.15, 12:38-13:2 (describing operation of switches similar to those in bank 54 of Figure 5).

i. Motivation to Combine and Reasonable Expectation of Success

129. As I explained in Section III.C, I have been informed by Petitioners’ counsel and understand that for a claim to be obvious, a person of ordinary skill in

ports or connection points for connecting an energy delivery device and providing the device with active and return signals, which is necessary to operate a device in bipolar mode. Ex.1010-Edwards-’535, 8:18-33, 9:11-22, 11:24-44; Ex.1033-Stern, 10:43-48. Such generator channels were ubiquitous prior to 2011.

the art must have had a reason or motivated to combine or modify the relevant teachings in the prior art to obtain the claimed invention, and one of ordinary skill in the art must have had a reasonable expectation of success in doing so. It is my opinion that a person of ordinary skill in the art would have been motivated to combine Edwards-'535 and Stern for the same reasons I explained in Element 1[d], which I incorporate by reference here. The combination would have involved applying a known technique (Stern's pairing and wiring of bipolar electrodes) to a known device (Edwards-'535's expandable RF ablation device with surface bipolar RF electrodes) that was ready for improvement (because Edwards-'535 did not describe how to pair and wire the electrodes, leaving it to the person of ordinary skill in the art's knowledge and skill) to yield predictable results and a reasonable expectation of success. A person of ordinary skill in the art would have been motivated to incorporate Stern's teachings of output channels to control individual pairs of bipolar RF electrodes for the same reasons as I explained with respect to Element 1[d], for example to provide for localized energy application, precise temperature control, and ablation depth control. The combination results in the predictable results discussed in Element 1[d], including the result of precisely controlling where and how much heat is being applied.

130. A person of ordinary skill in the art would have been motivated to incorporate Stern's teaching regarding output channels into the device in Edwards-'535 for the same reasons I explained in Element 1[d], which I incorporate by reference, and for the following reasons: (1) delivering bipolar RF energy and delivering energy to each electrode independently are two device design goals Edwards-'535 articulates, but Edwards-'535 does not provide detailed information on how to accomplish these goals. A person of ordinary skill in the art would have been motivated to incorporate the teachings from Stern because Stern provides detailed information and schematics regarding how to design an RF ablation device with surface electrodes so the electrodes deliver bipolar RF energy and can deliver energy independently through the different electrodes (e.g., using separate output channels); (2) Stern teaches that its bipolar electrode configuration and signaling circuitry provides a number of benefits, including providing even heating and precise energy delivery control that are particularly beneficial when trying to ablate an entire heterogenous surface.

131. Edwards-'535 exemplifies that using RF ablation devices with an array of multiple bipolar surface electrodes in body cavities was well-known. *See, e.g.*, Ex.1021-Makower, [0187] (disclosing device with "electrodes 216 [that] may be bipolar"), [0001] (describing treatment in nasal cavities), [0131] (same), [0164]

(describing devices), FIG.5H (showing device with electrodes on the surface of a frame for ablating in the nasal cavity). Edwards-'535 teaches that "energy...may be independently delivered to each [electrode]," Ex.1010-Edwards-'535, 8:18-25, and that its system can deliver "bipolar or monopolar energy," *id.*, 10:52-57. However, Edwards-'535 does not provide details on how to implement such energy delivery, demonstrating that developing the control architecture for how to energize such pairs was well within the skill of a person of ordinary skill in the art. *See id.*, 10:52-61. A person of ordinary skill in the art would have used Stern's scheme to implement Edwards-'535's feature that "energy may be delivered to all of the energy devices or may be independently delivered to each energy delivery device," *id.*, 8:18-25, because Stern provides detailed schematics and information about how to design a device that can accomplish this goal using separate output channels to different pairs of electrodes.

132. In view of Edwards-'535's silence on how to specifically configure its bipolar electrodes or independent energy delivery, a person having ordinary skill in the art would already know how to implement such energy delivery or would have been motivated to turn to other sources for that information, including regarding how to implement independent energy delivery through each electrode for bipolar energy delivery. When faced with how to independently deliver energy to each electrode

or electrode pair, a person having ordinary skill in the art would have had only a limited number of choices. Specifically, a person of skill in the art would have had to choose whether to use multiple RF generators or just a single RF generator. If using multiple RF generators, electrodes would be individually wired to each generator. If using a single RF generator, circuitry would have been required to control the route of energy (taught by Stern), which would have been obvious to implement by switches or relays. Both examples would require individual output channels for each pair of bipolar electrodes—the former with multiple output channels from each respective RF generator, the latter with multiple output channels from the same RF generator. As I explained above, a person having skill of the art would have been motivated to use only one RF generator, as was common at the time. Further, a system incorporating only one voltage source is safer (e.g., there are fewer components and more consistency in output for each bipolar pair), more practical (e.g., it would be impractical to use multiple generators when one would suffice, and multiple generators would take up more space in the device), and more reliable (e.g., there would be fewer complex generators that could fail and cause the entire device to be inoperative by virtue of one pair not being usable) than a one with system having numerous power sources. Switches or relays take up less space than

multiple generators, and would have been simpler and cheaper than multiple complex voltage sources.

133. A person of ordinary skill in the art would have been motivated to refer to Stern because it provides detailed information regarding how to design and wire a device that provides RF energy to electrodes independently with a single voltage source. Stern's Figures 5 and 15 each provide detailed electrical schematics showing how to wire and control various sensors and electrodes in a bipolar arrangement. For example, Figure 5 of Stern shows multiple electrodes 50 connected to a switch bank for independent energy delivery, as well as a temperature measurement circuitry including switch bank 52 for each respective electrode. Ex.1033-Stern, 9:2-24, FIG.5. Likewise, Figure 15 shows a flexible circuit that can be used to provide power from a voltage source 228 to any pair of electrodes in the array 220, 222, 224, and 226 for bipolar RF energy application, thereby forming multiple output channels. *Id.*, 12:38-13:2, FIG.15.

134. Furthermore, a person of ordinary skill in the art would have also been motivated to improve or implement Edwards-'535's device by including Stern's multiple pairs of bipolar electrodes based on the advantages and benefits of Stern's design, as Stern teaches. Stern teaches that pairing bipolar RF surface electrodes and wiring them with switches (i.e., to multiple output channels) to permit

independent delivery of RF energy to each bipolar pair (which I described above), and that doing so provides multiple advantages. One advantage of bipolar electrode pairs is that a user can precisely control the electrical current delivered to the tissue. Ex.1033-Stern, 13:21-27 (bipolar pairs provide a user with “[t]he ability to control field lines, and therefore the heated area...to insure [*sic*] complete heating of an area”), 12:26-37 (bipolar pairs provide a user with “precise control” by selecting “particular pairs” of bipolar electrodes), FIGs.15, 18. This was an advantage of using bipolar electrode pairs in RF ablation devices that was well known before 2011. *See generally* Ex.1050-Hong, S183 (describing the benefits of using bipolar electrodes versus electrodes designed for monopolar configurations).

135. Another advantage of energizing electrodes in bipolar pairs is that heat can be directed to targeted tissue while minimizing the chance that tissue that is not being targeted is affected (e.g., not heated and remaining unchanged). This feature—the ability to direct heat to one particular area and not others—is particularly advantageous where the target tissue areas have different properties and characteristics (i.e., uneven tissue morphology). Stern expressly teaches this advantage of its electrode arrangement. *See* Ex.1033-Stern, 13:21-39 (“The bipolar arrangement allows various pairs of electrodes to be picked in order to heat uneven or rather asymmetrical areas.... That is, any unusual features within an area to be

heated may be taken into account in a bipolar operation by selection of different pairs of electrodes for energization utilizing the circuitry of FIG.15.”), FIG.15. For example, if the targeted tissue has uniform electrical and thermal properties, a clinician would apply the same current and voltage to the tissue and expect the same result across the treated tissue. However, the clinician likely would not know whether the electrical or thermal properties of the target tissue are uniform prior to the ablation procedure. If the targeted tissue has uneven morphology, the clinician would be able to apply different currents and voltages at different bipolar pairs for different lengths of time to obtain the same intended result across the uneven tissue. This benefit would be further improved with circuitry that incorporates localized feedback control to allow the clinician to understand the tissue’s real-time response to the energy. *See* Ex.1033-Stern, 2:31-35 (“The plurality of separate electrodes are independently and sequentially energized and controlled with thermistor temperature feedback control to bring the [tissue] temperature to a desired level.”). Overall, using bipolar pairs to direct such energy means that the clinician (or an automated system) can target small, specific areas of tissue and adjust the treatment as necessary.

136. Similarly, another advantage of bipolar electrode pairs is that they lead to more precise and even heating. For example, Stern explains that “it would be

more precise to provide a more even heating of a uterus or other body organ if the electrode could have a controlled return path for the current.” Ex.1033-Stern, 12:25-27. As I explained in Section VI.C in relation to the differences between monopolar and bipolar electrodes, using bipolar RF energy allows a user to control the return path because the electrical current flows only between the active and return electrodes, which are placed inside of the body. As I explained, this can be a safer option for the patient, especially when performing ablation in the head. This precision and even heating is also exactly what Edwards-’535’s technique calls for—i.e., Edwards-’535 seeks to “maintain[] tissue...at a desired temperature,” which requires precision and control of heating on a local level to account for variations. Ex.1010-Edwards-’535, 9:65-10:1.

137. Stern also teaches that more than one pair of bipolar electrodes provides the additional benefit of selective tissue destruction across an “entire surface” of tissue, which a person of skill in the art would consider a benefit over only providing for ablation of one small portion between two discrete electrodes. Ex.1033-Stern, 2:6-19, 6:44-62, 10:49-65.

138. A person of ordinary skill in the art would have recognized these advantages and would have been motivated by these advantages to modify Edwards-’535 in view of Stern to include separate output channels to each bipolar

pair of electrodes. Doing so would have involved using Stern's known multiple output channels to fill in the missing details of Edwards-'535, which would have been desirable for increased safety and control. Increased safety would have been a predictable result from this combination, as increased control and even tissue heating would avoid unwanted ablation of adjacent tissue and over-heating of target tissue.

139. Stern's multiple output channels would have also improved Edwards-'535's similar device in the same way as it improved or led to advantages in Stern's similar device. A person of ordinary skill in the art also would have been motivated to combine Edwards-'535 and Stern because Edwards-'535's known device was ready for improvement (given that Edwards-'535 is silent as to how to pair and wire the electrodes). As I noted above, it would have been apparent to a person of ordinary skill in the art that Stern's advantages of pairing and controlling electrodes would have readily achieved Edwards-'535's stated goal of temperature-based control by allowing a user to control how much RF energy is applied to each respective electrode pair, and to evenly heat the tissue by providing energy to such electrode pairs over separate output channels. *See* Ex.1010-Edwards-'535, FIGs.4A-4C, 6:66-7:17.

140. A person of ordinary skill in the art would have would have had a reasonable expectation of success in implementing Stern's individual output

channels in a device like Edwards-'535's given that, as explained above, Edwards-'535 does not teach a particular circuitry design and therefore implicitly recognized that it was within a person of ordinary skill in the art's skill to design a circuitry system for bipolar electrode pairs that would selectively control each pair. Indeed, configuring and wiring bipolar electrode pairs with individual output channels is a well understood and predictable aspect of designing electrosurgical devices. For example, I recently worked on designing Adiana and NovaSure, two RF ablation devices that use multiple pairs of bipolar electrodes.

141. The Edwards-'535 and Stern references describe very similar objectives, devices, and techniques for delivering bipolar RF ablation energy. For example, both disclose independently controllable electrodes, both describe the use of expandable devices with surface bipolar RF electrodes, and both discuss delivering energy to the mucosal tissue of different body cavities. Ex.1010-Edwards-'535, 4:53-66, 5:21-23, 7:33-46, 7:61-8:46, 5:36-44, 6:9-22, 8:17-25, 9:1-44, 10:18-32; Ex.1033-Stern, 1:16-43, 7:38-8:38, 10:48-65.

142. These similarities would have led a person of ordinary skill in the art to expect that applying the teachings from Stern to the device of Edwards-'535 would have been straightforward and would have yielded predictable results. Based on my experience developing ablation devices during the relevant time period, my

knowledge of the level of skill in the art at that time, and the disclosure of the references themselves, I believe a person of ordinary skill in the art would have would have had a reasonable expectation of success in implementing Edwards-'535's device to include Stern's teaching of individual output channels. As I noted above, Edwards-'535 is silent as to particular electrode control circuitry to effectuate individual bipolar electrode control. Ex.1010-Edwards-'535, 8:19-33. Consistent with my recollection from the relevant time period, Edwards-'535 recognized that it was well within a person of ordinary skill in the art's skill to implement a system that independently delivers RF energy to different bipolar electrodes using, for example, the circuitry of Stern. Ex.1033-Stern, 2:49-53, 12:25-27, 13:21-39, FIGs.5, 15. Doing so would have merely involved the use of a standard switching apparatus and output channels as well as routine implementation of software that selectively controls such switches to energize particular channels.

143. Moreover, in the combination, Stern's known techniques would have been used to improve Edwards-'535's similar device in the same way. For example, Edwards-'535 describes an expandable device that has bipolar surface RF electrodes for delivering RF energy to a body cavity, Ex.1010-Edwards-'535, Abstract, 5:18-34, 8:19-33, 10:25-31, 10:52-61, FIGs.3A-3B, and Stern discloses a way to pair such bipolar surface RF electrodes on an expandable device and wire such electrodes for

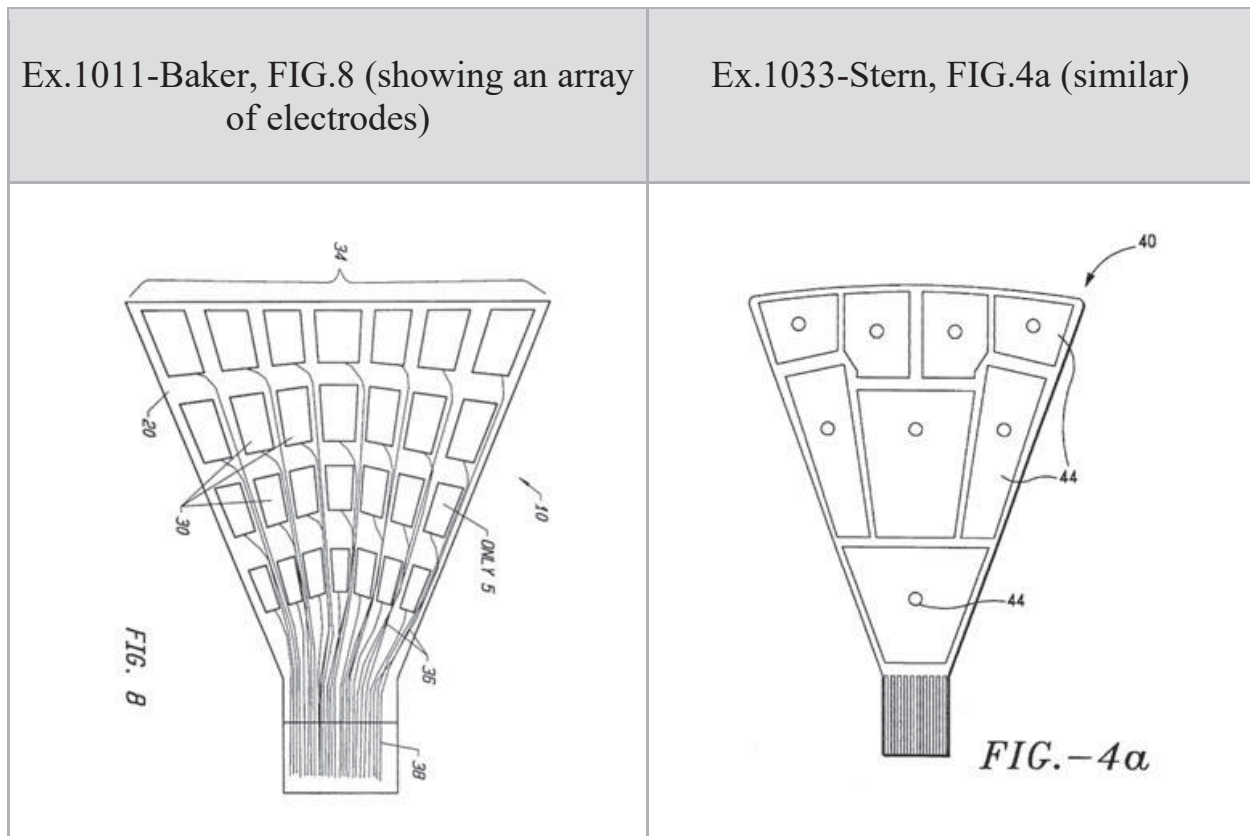
independent energy delivery, Ex.1033-Stern, FIGs.15, 19, 2:49-53, 12:38-13:55. Stern's teachings would have been applied to Edwards-'535 in the same way they are used in Stern.

144. Further, a person of ordinary skill in the art would have reasonably expected success in incorporating teachings from Stern for the additional reason that Edwards-'535 instructs a person of ordinary skill in the art that references having similar attributes as Stern may be incorporated into the Edwards-'535 device. *See* Ex.1010-Edwards-'535, 8:25-33 (incorporating the reference of U.S. Patent No. 5,575,788 to Baker). Specifically, Edwards-'535 incorporates the disclosure of U.S. Patent No. 5,575,788 to Baker ("Baker") for teaching how energy delivery devices can be positioned on a surface of an expandable member. *Id.* Edwards-'535 states, "[a]n example of a suitable surface for disposition on the membrane is described in application Ser. No. 08/319,373, "Thin Layer Ablation Apparatus", filed Oct. 6, 1994, which is incorporated by reference." *Id.* This patent application ultimately issued as U.S. Patent No. 5,575,788 to Baker and other named inventors, including Stuart Edwards, the sole named inventor on Edwards-'535. Ex.1011-Baker, Cover.

145. Baker, like Stern, discloses an "ablation apparatus for ablating an inner layer in an organ or lumen of a body" using an expandable member with bipolar surface electrodes. *Compare* Ex.1011-Baker, Abstract, 5:60-67, 9:13-23, FIGs.8-9

(disclosing a RF ablation device used for endometrial ablation, which includes an expandable member with bipolar electrodes on its surface), *with* Ex.1033-Stern, 2:26-35. Like Stern, one of the specific tissues that Baker treats is the lining of the uterus. Ex.1011-Baker, Abstract, 5:60-67, 9:13-23; Ex.1033-Stern, 2:26-35.

146. Baker and Stern both depict very similar devices:



147. Thus, a person having ordinary skill in the art would have recognized that the teachings of Stern could be incorporated into Edwards-'535's device given Edwards-'535 incorporation of Baker and the similarity between Stern and Baker, as I explained above.

148. Accordingly, applying Stern's teachings to Edwards-'535 would have been a matter of routine implementation within the skill of a person of ordinary skill in the art that would have yielded predictable successful results. For example, by using Edwards-'535's device having bipolar RF electrode pairs and energizing them via independent output channels as Stern teaches, with a reasonable expectation of success.

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

149. Edwards-'535 teaches Element 1[f].

150. Edwards-'535 discloses multiple sensors (i.e., *multiple sensors*) on the surface of expandable member 132 (i.e., *on the tissue treatment surface*) including *impedance sensors, electrodes, and thermocouples*.

151. For example, Edwards-'535 teaches that multiple sensors may be used "to monitor the amount of energy delivered and the amount of heat generated," Ex.1010-Edwards-'535, 9:14-18, and "detect a variety of operating parameters including the amount of energy delivered, the impedance generated, and the temperature of a region adjacent the apparatus.... In addition, chemical or biochemical sensors can be used to detect ablation." *Id.*, 9:14-23. Thus, the sensors

that Edwards-'535 teaches include impedance sensors, temperature sensors, electrodes, as well as other sensors, like chemical and biological sensors. By 2011, most RF ablation devices incorporated multiple sensors of various types to provide the clinician feedback about the treatment. *See, e.g.*, Ex.1052-Sackenheim, 90 (thermosensors); Ex.1051-Haemmerich, 5 (thermal sensors, impedance control); Ex.1034-Patel, [0015] (thermal sensor), [0083] (imaging sensor); Ex.1030-Kunis, 7:1-52 (temperature sensors), 14:20-24 (physiological sensors); Ex.1024-Hovda, 10:13-21 (temperature sensors); Ex.1022-Odom, [0057] (smart sensors that communicate with the electrosurgical generator and measure tissue temperature, tissue impedance, or tissue property changes); Ex.1021-Makower, [0033] (sensors that help with visualization), [0192], [0218]; Ex.1067-Edwards-'730, 6:13-20, 7:17-20, (temperature sensors and sensors used to measure voltage and current, used to control the delivery of RF power); Ex.1033-Stern, 7:50-60 (thermistors and thermocouples). Clinicians need this feedback to know if the treatment has been successfully started, *see, e.g.*, Ex.1011-Baker, 11:50-68 ("Voltage and current are then measured to confirm electrical contact."), whether ongoing treatment is successful, and/or if there is an issue that needs to be addressed. *See id.* 3:5-10, 6:25-30, 8:58-63, 9:47-56, 11:34-12:55, FIGs.2-3, 10 (discussing impedance feedback control).

152. Edwards-'535 also teaches that the *multiple sensors* are *on the tissue treatment surface* (e.g., on the surface of expandable member 132). Edwards-'535 states, “[a] variety of positionings for the sensors are possible” and that they can be “coupled to the expandable member.” Ex.1010-Edwards-'535, 9:43-45. The expandable member has a tissue treatment surface as I explained in Element 1[c] and therefore Edwards-'535 teaches that sensors are *on the tissue treatment surface*. See also *id.*, 9:14-23 (discussing measuring “temperature of a region adjacent the apparatus,” which a person of ordinary skill in the art would understand to include measurement of an adjacent tissue region of interest by a temperature sensor accordingly placed on the tissue treatment surface). Edwards-'535 teaches that the sensors can be “used to[] maintain[] tissue adjacent to an energy delivery device at a desired temperature for a selected period of time without impeding.” *Id.*, 9:64-10:1.

153. A person of ordinary skill in the art would have been motivated to place the sensors on the tissue treatment surface (*i.e.*, on expandable member 132) to obtain an accurate localized temperature reading, especially with a device that is not piercing the mucosal tissue. Placement elsewhere would defeat the purpose of taking a localized temperature reading of the targeted tissue. In other words, placing the temperature sensors anywhere other than where the expandable member 132

contacts tissue (where the device is designed to not pierce tissue, like Edwards-'535's device) could result in an inaccurate temperature reading which would result in less reliable ablation control. Further, temperature sensors placed on the tissue treatment surface of the ablation device were well-known before the '318 patent. *See, e.g.*, Ex.1033-Stern, 7:49-61 (teaching that “temperature sensors 32 are conventional thermistors or thermocouples and are positioned on the zones of the balloon which will contact areas of the [tissue] surface.”); *see also* Ex.1052-Sackenheim, 90; Ex.1051-Haemmerich, 5; Ex.1034-Patel, [0015]; Ex.1030-Kunis, 7:1-52; Ex.1024-Hovda, 10:13-21; Ex.1067-Edwards-'730, 6:13-20, 7:17-20.

154. Moreover, Edwards-'535 teaches that the multiple sensors can be *impedance sensors, electrodes, or thermocouples*. As described above, Edwards-'535 teaches using “at least one temperature sensor, such as a thermocouple.” Ex.1010-Edwards-'535, 9:24-25. Edwards-'535 also teaches that “sensors can...detect a variety of operating parameters including...the impedance generated”—Edwards-'535 therefore teaches using impedance sensors. *Id.* A conventional manner of measuring impedance is measuring the voltage drop between two electrodes on a surface, given a known current. Edwards-'535 describes impedance sensing based on the current delivered to the electrodes on the surface of the device. *Id.*, 9:14-18, FIG.8. As I show in Figure 8, which I have

annotated below, Edwards-'535 teaches 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. These values can then be displayed at a user interface and display 196. Signals representative of energy and impedance values are received by a controller 198.” *Id.*, 10:4-11.

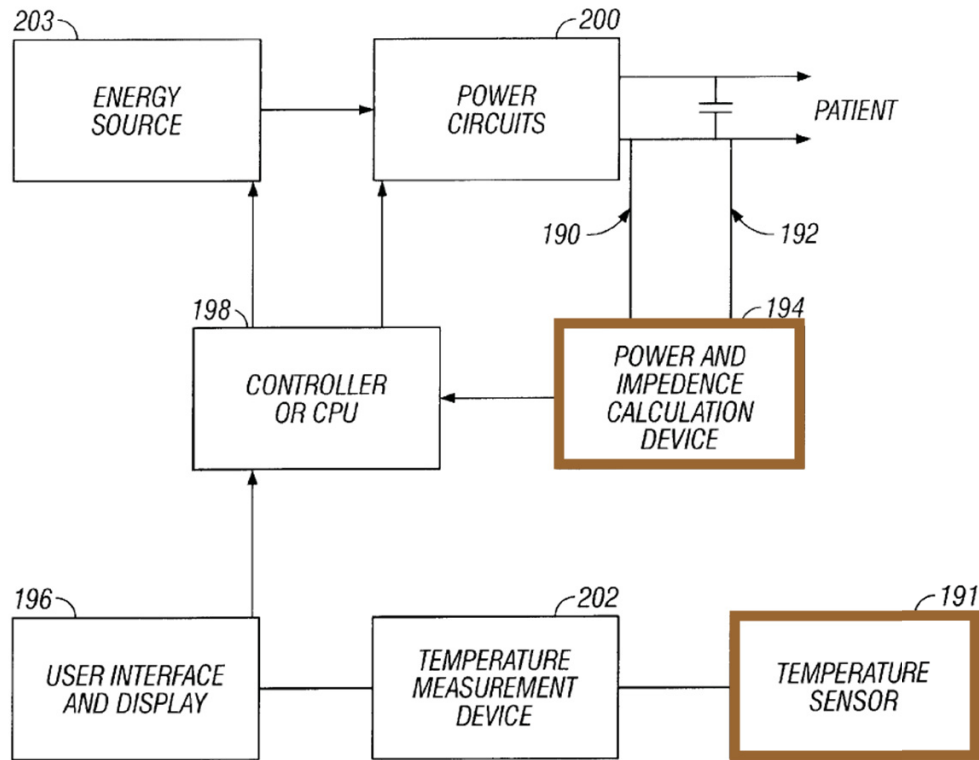


FIG. 8

Id., FIG.8.

155. Edwards-'535 teaches that its sensors, including the temperature sensors are part of a feedback system wherein the processor uses sensed values to “control the delivery of RF energy to achieve delivery of a selected amount of energy, to achieve a selected temperature, or to achieve a selected amount of ablation of a section of a nasal concha.” *Id.*, 9:34-44. These types of feedback systems were also ubiquitous in the art at the time. *See, e.g.*, Ex.1067-Edwards-'730, 7:33-45; Ex.1022-Odom, [0057]-[0059].

156. For these reasons, it is my opinion that claim 1 is obvious in view of Edwards-'535 and Stern.

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

157. Claim 4 depends from claim 1. Therefore, I incorporate by reference my discussion of claim 1.

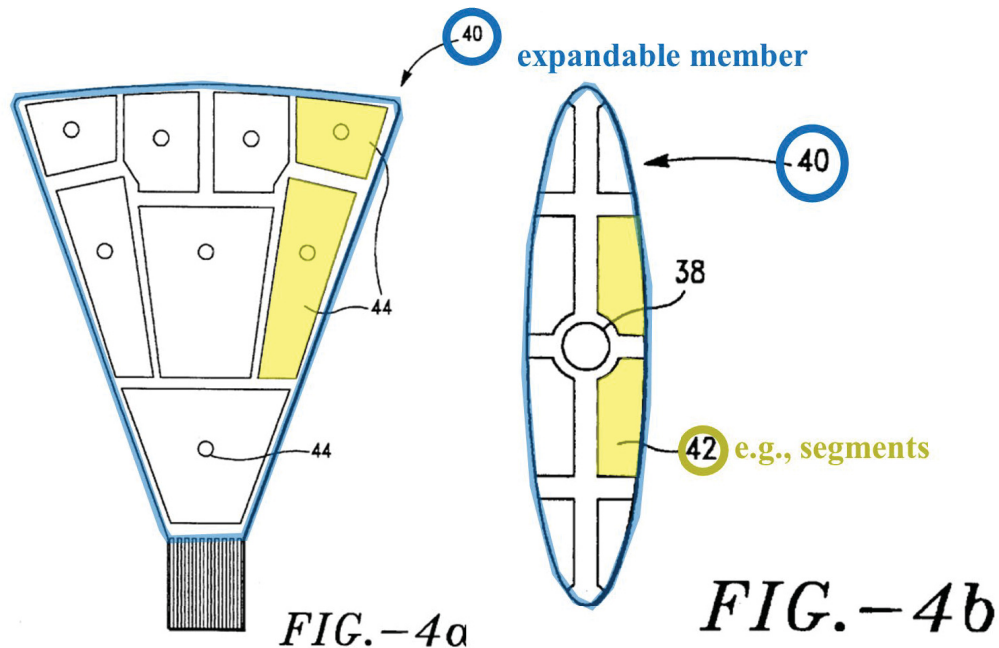
158. Edwards-'535 in view of Stern teaches the additional requirement of claim 4.

159. Edwards-'535 in view of Stern discloses an expandable member 132 in Edwards-'535 (*treatment element*) that includes a plurality of surface segments 42 in Edwards-'535 and/or Stern (*comprises multiple segments*) where the surface segments are compressed along with the expandable member when inserted into the

body (*that are expandable from the first configuration*) and the surface segments are expanded along with the expandable member when deployed (*the second configuration*).

160. Stern teaches “using a balloon 40” that has “a plurality of surface segments 42” and that “[e]ach of the surface segments has a conductive surface and a temperature sensor.” Ex.1033-Stern, 8:48-66, FIGs.4A, 4B.

161. I have reproduced Figures 4A and 4B below, showing the expandable member in blue and the surface segments in yellow.



162. Stern teaches that “[e]ach segment 42 is electrically connected through conventional leads to a power source” and that the leads “permit controlled delivery of power to each segment.” *Id.*, 8:53-59.

163. As I have shown below in Figure 6, Edwards-’535’s expandable member 132 can be subdivided or segmented like Stern:

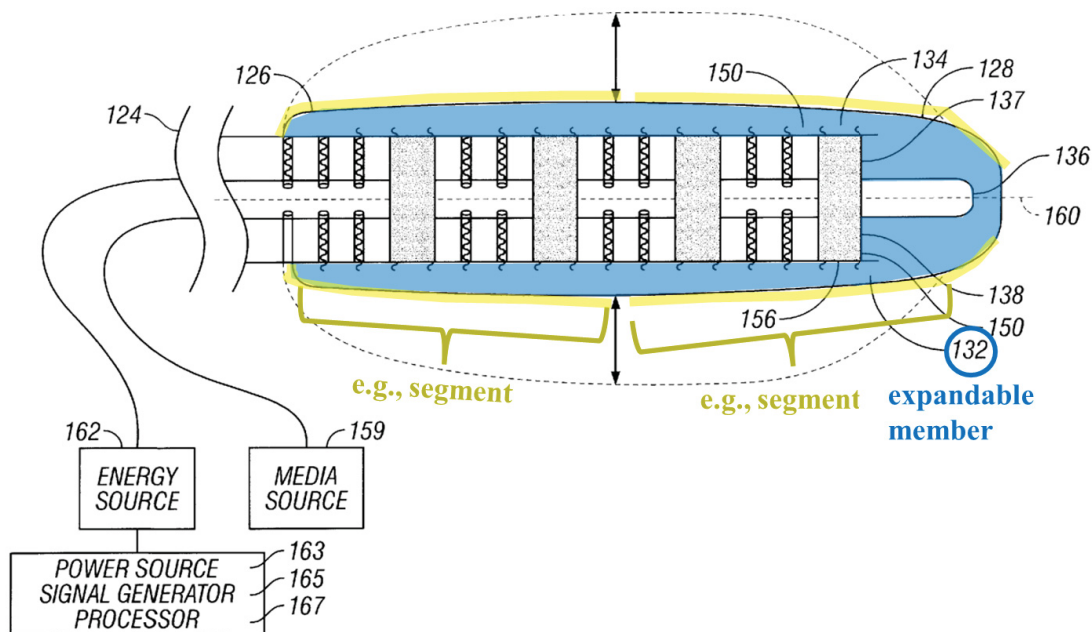


FIG. 6

164. As I explained with reference to Element 1[d], Edwards-’535 instructs a person of ordinary skill in the art that the device can independently deliver energy to electrodes but does not provide detail regarding how to accomplish that. Ex.1010-Edwards-’535, 8:17-32, 10:30-32, 10:52-61. A person of ordinary skill in the art would have been motivated to subdivide Edwards-’535’s expandable member

in segments “to permit controlled delivery of power to each segment” as Stern teaches, for the same reasons as I discussed in Elements 1[d]-1[f]. Ex.1033-Stern, 8:53-59. Segmented devices for delivering bipolar energy were well-known before 2011. *See, e.g.*, Ex.1021-Makower [0187] (noting that “electrodes 216 may be bipolar”), FIG.5H (showing device with multiple segments on struts 214). A person of ordinary skill in the art would have had a reasonable expectation of success in segmenting Edwards-’535’s expandable member 132 as Stern teaches, because doing so would have improved Edwards-’535’s expandable member 132 in the same way as Stern. That is, the segmented areas could be connected to a power source for independent RF energy delivery and provide precise temperature control in the same way and for the same benefits that Stern describes, and I explained with respect to Elements 1[d]-1[f]. Ex.1010-Edwards-’535, 4:53-66.

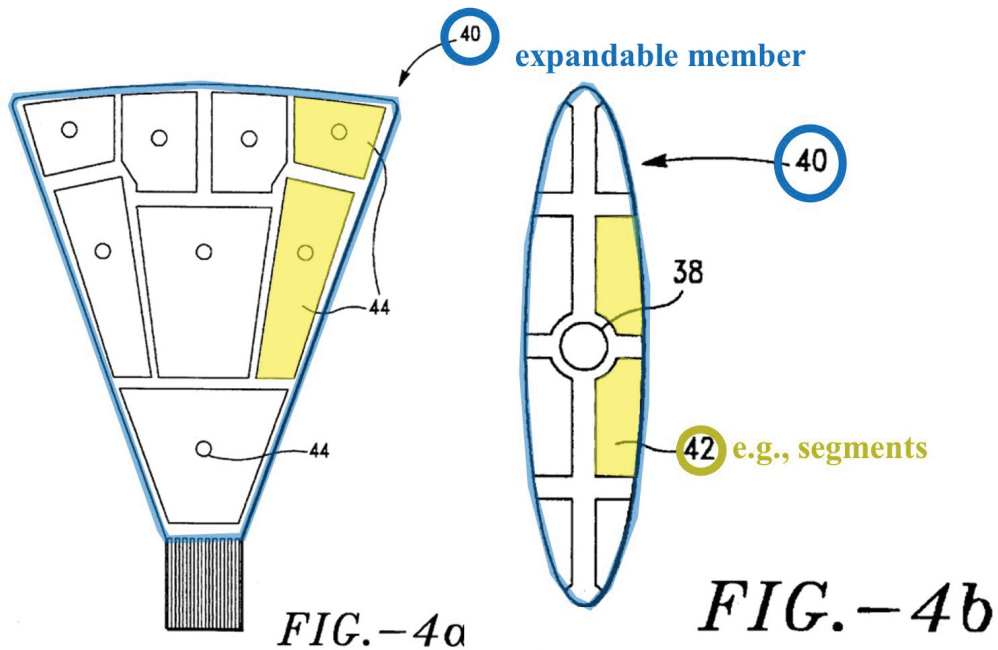
165. For these reasons, it is my opinion that claim 4 is obvious in view of Edwards-’535 and Stern.

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

166. Claim 5 depends from claim 4. Therefore, I incorporate by reference my discussion of claim 4 .

167. Edwards-'535 in view of Stern teaches the additional limitation of claim 5. Edwards-'535 in view of Stern discloses a plurality of bipolar energy delivery devices in Edwards-'535 controlled as pairs as Stern teaches (*at least one pair of multiple pairs of bipolar radiofrequency electrodes*) is coupled with a plurality of surface segments 42 in Stern (*coupled with each of the multiple segments*).

168. As I discussed above with respect to Element 1[d], Stern teaches pairing multiple bipolar RF electrodes, where the pairs can be selectively powered by circuitry that includes multiple output channels (shown in Stern Figure 15). Likewise, as I discussed with respect to claim 4, Stern's Figures 4A and 4B show a plurality of surface segments on the expandable member. Ex.1033-Stern, 8:53-59.



169. As I explained with respect to claim 4, Stern teaches that these segments are “electrode area segments,” *Id.*, Abstract, and that power can be selectively provided to these segments via the circuitry of Figure 15, which I have reproduced below. *Id.*, 5:48-51.

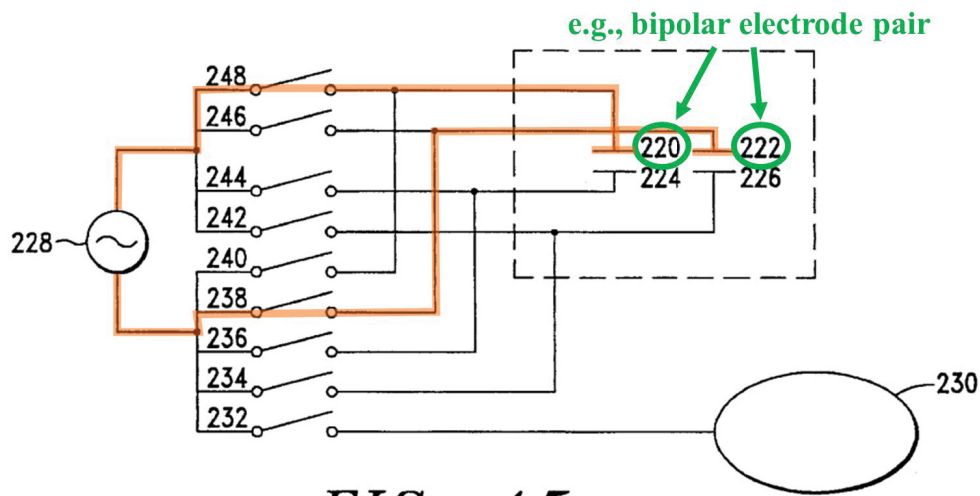


FIG. - 15

170. Stern teaches that each segment includes at least one pair of the plurality of pairs of bipolar RF electrodes; thus, at least one pair of the multiple pairs of electrodes are coupled to at least one segment.

171. As I explained above for claim 4, a person of ordinary skill in the art would have been motivated to use the electrode configuration of Stern with Edwards-'535's expandable member to independently energize pairs of bipolar RF electrodes, and a person of ordinary skill in the art would have had a reasonable expectation of success in doing so. The same rationale applies to claim 5, which would be implemented in the same way I discussed in claim 4.

172. For these reasons, it is my opinion that claim 5 is obvious in view of Edwards-'535 and Stern.

4. Claim 9:

- a. Element 9[a]: The device of claim 1, further comprising: a radiofrequency generator configured to receive sensed signals from the multiple sensors and deliver radiofrequency energy separately to each of the multiple radiofrequency output channels in the form of a 460 KHz sinusoid wave; and**

173. The combination of Edwards-'535 and Stern teach Element 9[a].

174. Claim 9 depends from claim 1. Therefore, I incorporate by reference my discussion of Claim 1.

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

176. As I discussed above for Element 1[f], Edwards-'535 teaches a feedback control system where a "processor reads [a] sensor value from the sensor

and, responsive thereto, controls the signal generator” to deliver an effective amount of RF energy to the target tissue. Ex.1010-Edwards-’535, 9:1-44. “The processor thus uses the signal generator...energy delivery device, and temperature sensor, as a feedback loop for controlled delivery of RF energy to a section of a nasal concha.” *Id.* Thus, Edwards-’535 teaches *a radiofrequency generator (i.e., signal generator) that receives sensed signals from the multiple sensors and delivers radiofrequency energy.*

177. As I discussed above for Elements 1[d]-[e], Edwards-’535 in combination with 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 does not provide details regarding to how implement the circuitry, leaving it to the person of ordinary skill in the art’s knowledge. Stern fills in the gap, using *multiple radiofrequency output channels* and teaching a feedback control loop similar to Edwards-’535’s, 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. Stern therefore complements Edwards-’535’s disclosure by providing further details regarding how to precisely and evenly heat target tissue using a feedback system with multiple RF

output channels. Thus, a person of ordinary skill in the art would have been motivated to combine these aspects of Edwards-'535 and Stern to achieve the same benefits with a reasonable expectation of success in doing so as I discussed in Elements 1[d], 1[e], and 1[f]. Likewise, a person of ordinary skill in the art would have reasonably expected success in doing so for the same reasons.

178. Stern teaches applying RF energy in a range of frequencies including a *460 KHz wave* across multiple channels. For instance, Stern teaches the “RF current has a frequency of at least 250 kHz and less than 100 MHz,” which includes the claimed 460 kHz. *Id.*, 2:18-20, 3:15-20, Clm.1. This is because 100 MHz is equal to 100000 kHz.

179. Edwards-'535 teaching that RF energy is “preferably” in the MHz range, would not have deterred a person of ordinary skill in the art from applying energy at other frequencies. For example, it would have been obvious for a person of ordinary skill in the art to apply RF energy in Edwards-'535's device at 460 kHz as Stern teaches, because that frequency was also known by a person of ordinary skill in the art to deliver RF energy to adequately ablate tissue. *See Id.*, 2:18-20; 3:15-20, Clm.1 Indeed, most RF ablation devices operate at a frequency of about 460 kHz—including another reference to the same inventor that teaches a generator that supplies RF energy “with a sinusoidal waveform at 460 kHz.” Ex.1016-

Edwards-'886, 36:66-37:2; *see also* Ex.1050-Hong, S181 (explaining that “generators manufactured in the United States are capable of...delivering high frequency (460-500 kHz) alternating current via RF electrodes”); Ex.1052-Sackenheim, 90 (explaining that one of three companies that manufactured RF ablation generators in the United States used a 460 kHz generator); Ex.1053-Bronzino, 63-4, Tbl.63-4 (teaching that a typical bipolar mode frequency range is between 300 kHz and 1050 kHz); Ex.1054-Koyyalagunta, 4 (explaining that modern RF ablation probes use frequencies of 100-500 kHz); Ex.1051-Haemmerich, 53 (noting that RF ablation devices operate in the 450-500 kHz frequency range).

180. Edwards-'535's teaching that RF energy is “preferably” in the MHz range, would not have deterred a person of ordinary skill in the art from applying energy at other frequencies. For example, it would have been obvious for a person of ordinary skill in the art to apply RF energy in Edwards-'535's device at 460 kHz as Stern teaches, because that frequency was also known by a person of ordinary skill in the art to deliver RF energy to adequately ablate tissue. *See* Ex.1033-Stern, 2:18-20; 3:15-20, Clm.1. Indeed, most RF ablation devices for various body tissues operate at a frequency of about 460 kHz. *See, e.g.*, Ex.1016-Edwards-'886, 36:66-37:2; *see also* Ex.1050-Hong, S181 (explaining that “generators manufactured in the United States are capable of...delivering high frequency (460-500 kHz) alternating

current via RF electrodes”); *id.*, S179 (“Radiofrequency waves as applied in medicine cause thermal ablation of a defined volume of tissue.”); Ex.1052-Sackenheim, 90 (explaining that one of three companies that manufactured RF ablation generators in the United States used a 460 kHz generator); Ex.1053-Bronzino, 63-4 (teaching that a typical bipolar mode frequency range for an electrosurgical device is between 300 kHz and 1050 kHz); Ex.1054-Koyyalagunta, 4 (explaining that modern RF ablation probes use frequencies of 100-500 kHz); Ex.1051-Haemmerich, 53 (noting that RF ablation devices for different tissues, including cancer tissue, cardiac tissue, and uterine tissue, operate in the 450-500 kHz frequency range). In light of the overwhelming evidence that the kHz range is more commonly used, and given the fact that it would be more challenging to apply MHz range energy to tissue as compared to kHz energy, I believe Edwards-’535 disclosure of MHz range energy may be a typo. To the extent Edwards-’535’s range is not a typographical error, the disclosed range would have been unusual and a person of ordinary skill in the art would have found it more common to use the frequency range disclosed in Stern or the known 460 kHz disclosed in Edwards-’886 and widely used in the field.

181. A person of ordinary skill in the art also would have been motivated to use a frequency of 460 kHz as taught by Stern to deliver RF energy using an

apparatus like Edwards-'35's device because such a frequency adequately balances the ability to deliver RF energy with the amount of energy lost in the circuit. The higher the frequency of delivery, the easier it is for RF energy to travel through the tissue (i.e., the lower the impedance). Ex.1035-Philippson, 3, FIG.2. But there is a logarithmic relationship between frequency and impedance, which means the advantages of reduced impedance are marginal as the frequency approaches the MHz range. *Id.* Ex. 1035-Philippson, 3, FIG.2. As the delivery frequency range approaches MHz levels, it becomes more 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 cable length that connects the generator to the energy delivery device. This is analogous to cables acting like antennas at high frequencies, dissipating energy from the generator before it reaches the delivery device. Due to skin effects, high frequency currents travel closer to the cable surface, using less space and therefore creating more resistance. Furthermore, the physical mechanism by which MHz energy is converted into heat differs from the mechanism at play in the kHz range. Based on these considerations, a person of ordinary skill in the art would have understood that a frequency in the kHz range would have been the most desirable to ensure reduced impedance of tissue while avoiding the challenges associated with the delivery of RF energy at high frequencies. Further, choosing a

number in the kHz range would have been a matter of routine experimentation and optimization for a person of ordinary skill in the art, and Stern suggests such a range.

182. Stern teaches 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) that apply RF energy to a body cavity to ablate tissue, a person of ordinary skill in the art would have been motivated to perform ablation in the same way (e.g., picking up Stern's frequency range) and would have had a reasonable expectation of success because such a modification simply involves applying a known RF energy waveform using known equipment. Additionally, a person of ordinary skill in the art would have understood that mucosal tissue lining different body cavities, like the fallopian tube, the duodenum, and the nasal cavity, would have similar electric and thermal properties, based on their moisture content, and would therefore behave similarly when ablated at a frequency in the kHz range. This is consistent with my experience in the field of ablation devices. Persons of ordinary skill in the art routinely considered techniques and technology from ablation devices suitable for treating one area of the body applicable to devices in another area of the body. When developing an ablation device, persons of skill in the art would not have reinvented the wheel—instead they would have looked to existing ablation technology to identify relevant and useful

teachings, and expected success in doing so. Stern expressly notes the applicability of the disclosure to other parts of the body:

One of the more obvious variations based upon the above disclosure is the utilization of such an electrode partitioning structure and the accompanying heating for treatment of other body organs or tissues either externally or internally. The principles embodied herein and the methods utilizing those principles with respect to the delivery of controlled RF energy in a controlled environment have application in many areas, not only for controlled destruction of tissue but also for controlled heat treatment of tissue. It is therefore to be understood that, within the scope of the appended claims, the invention may be practiced otherwise than as specifically described herein.

Ex.1033-Stern, 18:27-40.

183. The '318 patent does not describe anything critical or significant about ablation at 460 kHz in particular—it is just one “example” from the entire RF range. Ex.1001-USP318, 34:35-39. Thus, selecting an appropriate frequency for ablation would have simply involved routine optimization from a range of frequencies Stern already discloses.

184. A person of ordinary skill in the art 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. For example, Edwards-'535 teaches that its generator can generate "pulses, [s]ine waves, [s]quare waves, or [s]ome combination of these wave forms with each other or with some other wave form," demonstrating that sine waves were a common way to implement an RF energy generator. Ex.1010-Edwards-'535, 8:54-60 (using "a generator for pulses, sine waves, square waves, or some combination of these wave forms with each other or with some other wave form"); *see also* Ex.1016-Edwards-'886, 36:66-37:3 (using 460 kHz sine wave). A person of ordinary skill would have known that a *sinusoid* wave is the most common and simple output of a RF generator. As an engineer in the field of ablation devices, when encountering disclosure of a specific RF frequency, I would expect the wave form to be a sine wave unless deviation from that norm is specifically noted. Indeed, the first wave any physics or engineering student would have been introduced to would have been a sine wave—likely in middle or high school. Furthermore, when faced with the limited set of standard wave forms to select from (or to select a combination of waveforms), a person of skill in the art would have chosen the simplest and most well-known and understood waveform unless there was a

significant reason to deviate from that norm. Neither the '318 patent nor the cited prior art provide such reason.

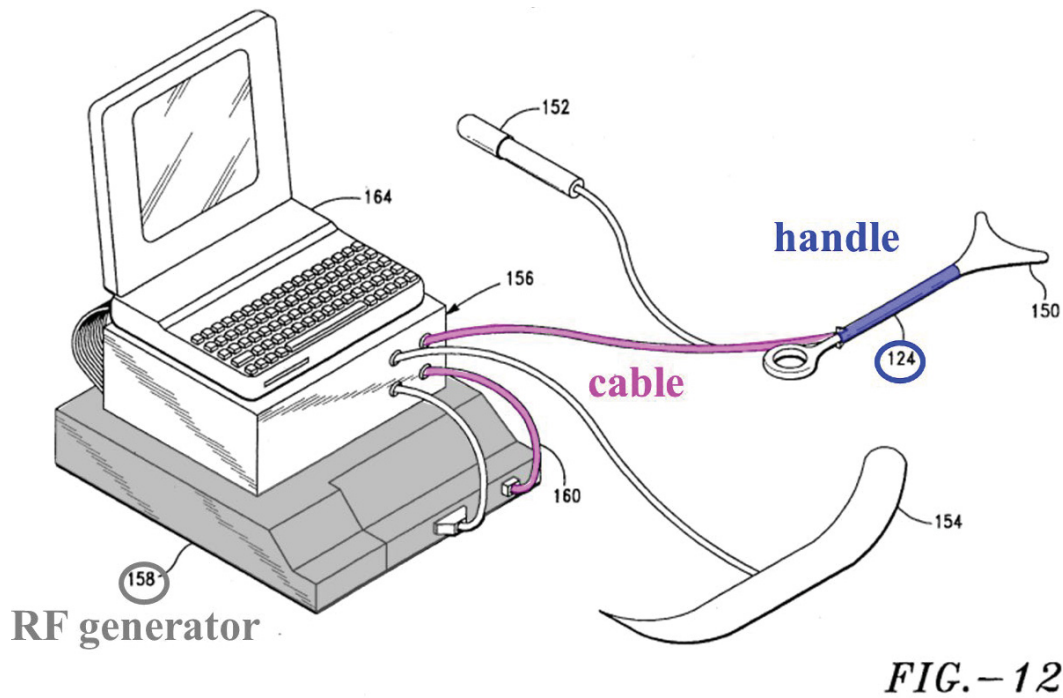
185. Furthermore, all other wave forms output by a RF generator would at least include a component in the form of a sine wave. Indeed, a universal and basic mathematical principle is that any periodic function can be represented by the sum of sinusoidal waves. Ex.1062-Sedra, 1-3; *see also* Ex.1016-Edwards-'886, 37:1-2 (describing an RF generator “with a sinusoidal waveform at 460 kHz); Ex.1010-Edwards-'535, 8:54-60 (explaining that signal generator 165 can produce sine waves and other waveforms).

b. Element 9[b]: a cable coupled to the handle for plugging the handle into the radiofrequency generator.

186. Edwards-'535 in view of Stern teaches Element 9[b].

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

188. I have reproduced Figure 12 of Stern below, which shows a cable in pink and handle.



189. Providing a handle with a cable to attach to the RF generator in Edwards-'535 as Stern teaches would have been obvious and predictable for the same reasons I discussed above for Elements 1[a], 1[e], and 9[a]. Likewise, a person of ordinary skill in the art would have reasonably expected success in doing so for the same reasons.

190. For these reasons, it is my opinion that claim 9 is obvious in view of Edwards-'535 and Stern.

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

191. Claim 10 depends from claim 9. Therefore, I incorporate by reference my discussion of claim 9.

192. Edwards-'535 teaches the additional limitation of claim 10.

193. Edwards-'535 teaches that signal generator 165 (*radiofrequency generator*) delivers “RF energy [] to the nasal concha [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,” (*is configured to run at a power of between 5 and 75 watts*). Ex.1010-Edwards-'535, 5:48-51. I have been instructed that, under the law, Edwards-'535 teaches this additional limitation because Edwards-'535 discloses a range (5 to 30 watts) within the claimed range (5 to 75 watts). Indeed, this wattage range was commonly used by RF generators. *See, e.g.*, Ex.1053-Bronzino, 63-4, Tbl.63.3 (teaching that typical power for bipolar mode is between 1 and 70 watts); Ex.1034-Patel, [0087] (noting that “radiofrequency electrosu[r]gical generators are generally used to provide a wattage of typically 15-40 watts”).

194. For these reasons, it is my opinion that claim 10 is obvious in view of Edwards-'535 and Stern.

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

195. Claim 12 depends from claim 1. Therefore, I incorporate by reference my discussion of claim 1.

196. The combination of Edwards-'535 and Stern teach claim 12.

197. Edwards-'535 in view of Stern teaches that the *radiofrequency electrodes comprise non-penetrating electrodes*. For example, Edwards-'535 describes electrodes that contact the nasal concha, but do not penetrate the tissue. Ex.1010-Edwards-'535, 4:53-66. Edwards-'535 emphasizes that the treatment is performed “without damaging the surface of the nasal concha.” *Id.*, 4:53-66; 6:67-7:2. This lack of penetration is shown in Figure 3C of Edwards-'535 (below) where the electrodes are at the surface of the nasal concha but do not pierce the surface:

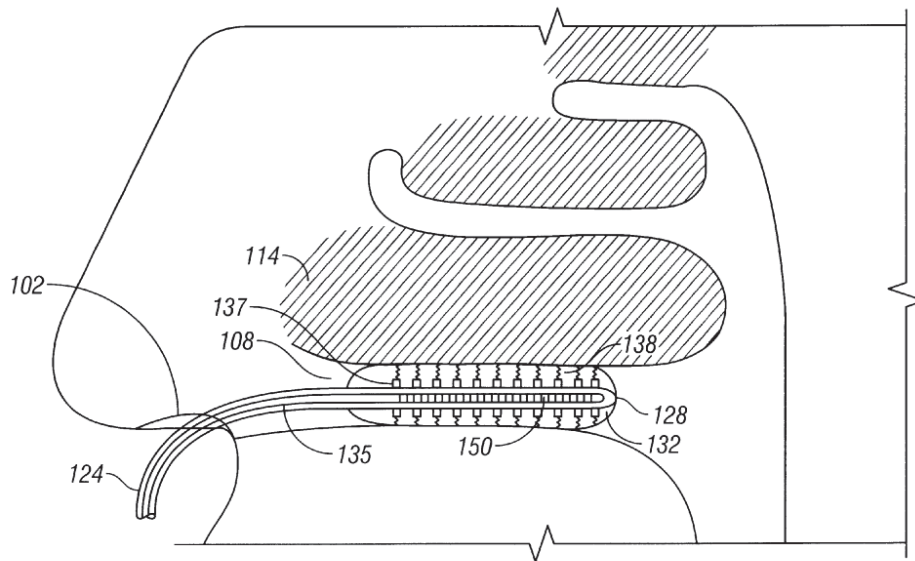


FIG. 3C

198. Figure 4A similarly illustrates “introducing ablative energy 144 into an interior section of a nasal concha through the surface of the nasal concha.” Ex.1010-Edwards-35, 6:66-7:4. In other words, the ablative energy goes through the surface of the tissue, but the electrodes do not pierce the surface. *Id.*, 3:59-61; 6:67-7:4, FIG.4A. Additionally, the ring electrodes shown in Figure 6 of Edwards-’535 appear flat. *Id.*, FIG.6.

199. Similarly, the surface-mounted electrodes of Stern are flat. Therefore, a person of ordinary skill in the art would understand that these types of electrodes are incapable of penetrating tissue. Ex.1033-Stern, 2:36-40, 3:29-40, 12:7-13:55, FIGs.13, 15, 17, 18. This is true especially when comparing these types of electrodes

to needle electrodes, which are commonly used to penetrate tissue. *See* Ex.1010-Edwards-'535, 26:54-28:8; Ex.1001-USP318, 24:21-23.

200. Further, like Edwards-'535, Stern teaches “[e]lectrical contact between the conductive surface of the electrodes 34 and the [tissue to be ablated].” Ex.1033-Stern, 7:67-8:3, 1:30-35, 17:10-15, Clms.1, 3. Stern teaches that when the expandable member 12 is expanded, it will contact the lining to be destroyed. *Id.*, 8:32-36. Stern does not mention that the electrodes penetrate tissue, only that they contact tissue.

201. Accordingly, a person of ordinary skill in the art would have understood the electrodes of Edwards-'535, along with the electrodes of Stern, to be *non-penetrating electrodes*.

202. For these reasons, it is my opinion that claim 12 is obvious in view of Edwards-'535 and Stern.

7. **Claim 13: The device of claim 1, wherein the multiple pairs of bipolar radiofrequency electrodes, the multiple radiofrequency output channels and the multiple sensors are organized into multiple subsystems, and wherein each of the multiple subsystems comprises one of the multiple pairs of bipolar radiofrequency electrodes, one of the multiple**

radiofrequency output channels and one of the multiple sensors.

203. Claim 13 depends from claim 1. Therefore, I incorporate by reference my discussion of claim 1.

204. Edwards-'535 and Stern teach the additional requirement of claim 13. For the purposes of this claim, I focus on Edwards-'535's disclosure regarding temperature sensors.

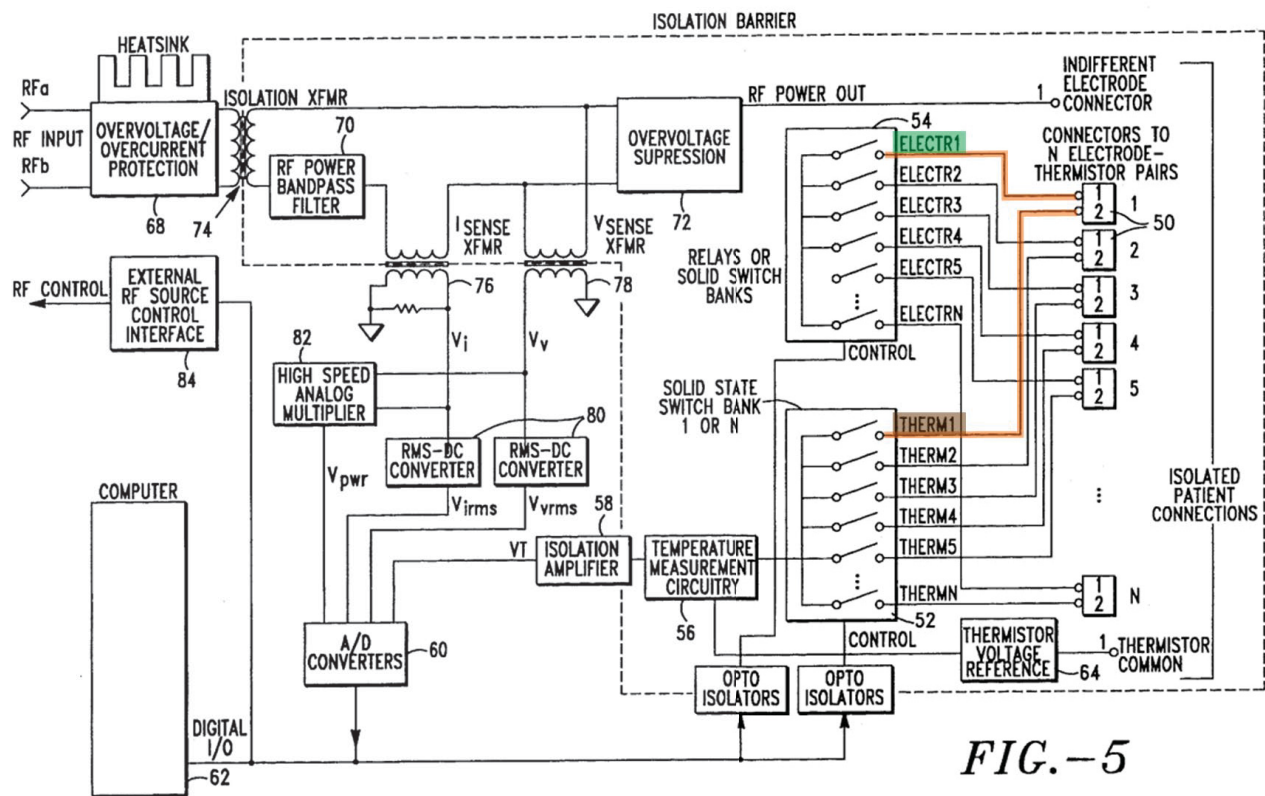
205. Edwards-'535 in combination with Stern disclose bipolar electrode pairs 220 and 222 and/or bipolar electrode pairs within each segment of the multi-segment balloon in Stern (*the multiple pairs of bipolar radiofrequency electrodes*), the output channels shown in orange in Figures 5 and 15 in Stern (*multiple radiofrequency output channels*), or thermocouples in Edwards-'535 and/or Stern (*multiple sensors*), and that they are *organized into multiple subsystems, and wherein each of the multiple subsystems comprises one of the multiple pairs of bipolar radiofrequency electrodes, one of the multiple radiofrequency output channels and one of the multiple sensors.*

206. As I discussed with respect to Element 1[f], which I incorporate by reference, Edwards-'535 teaches temperature feedback control systems, and advantages to providing temperature feedback and control for individual electrodes.

See Ex.1010-Edwards-'535, 9:11-12:5. Stern teaches similar temperature-based feedback control, including that the “expandable member includes a thin bladder having an array of separate electrodes on one surface and further having ... a thermistor associated with each separate electrode in order to provide a feedback temperature for each electrode. The plurality of separate electrodes are [each] independently and sequentially energized and controlled with thermistor temperature feedback control to bring the [tissue] temperature to a desired level.” Ex.1033-Stern, 2:26-40, 10:48-65. Stern teaches that each thermistor and electrode in Figure 5 can have its own separate power lead and that such circuitry is “well known.” “[T]he temperature measurement circuitry 56 of FIG. 5 has additional requirements beyond the construction with a separate power lead for each thermistor and for each individual electrode. The construction with separate power leads for the electrodes and the thermistor are well known and any one of a variety of temperature measurements schemes for individual electrodes could be utilized.” *Id.*, 11:20-27.

207. Stern also discloses *multiple subsystems* as I show below in Stern’s Figure 5 and 15. Each of the multiple subsystems comprises one of the multiple pairs of bipolar RF electrodes (bipolar electrode pairs 220 and 222), one of the multiple RF output channels (annotated in orange in Figures 5 and 15) and one of

the multiple sensors (thermistors in Stern and/or Edwards-'535). As I have shown below, Stern's Figure 5 teaches a monopolar configuration having one electrode (ELECTR1 highlighted in green), one output channel (shown in orange), and one thermistor (highlighted in brown). *Id.*, 2:12-19, 2:26-35, 2:59-65, 3:12-28, 4:45-55, 5:15-20, 5:56-68, 7:30-38, 7:39-60, 8:48-60, 9:1-10, 10:49-65, 11:25-30, 15:11-31, 18:1-13.



208. Stern's Figure 15 teaches a bipolar configuration having bipolar electrode pairs (electrodes 220 and 222), and one output channel.

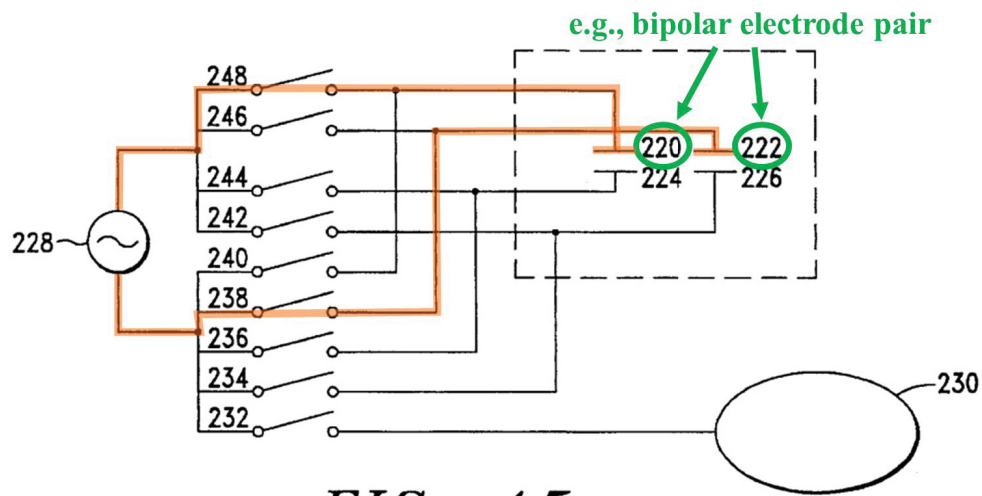


FIG. – 15

As I have annotated above, switches 248 and 238 are closed to make bipolar pairs 220 and 222. However, the circuit has multiple switches, and therefore provides the numerous subsystems having different bipolar pairs and output channels. This would be accomplished by closing different combinations of switches, as Stern teaches.

209. Stern also teaches that the monopolar embodiment of Figure 5 can be combined with the bipolar configuration of Figure 15. While describing Figure 5’s “unipolar power delivery,” Stern teaches that “improved control can be achieved...if a bipolar operation is utilized.” *Id.*, 12:8-24. When describing Figure 5, Stern explains that heating depends on the current’s return path. In Figure 5, a monopolar system, the return path is dictated by the placement of the return patch. Stern

explains that “improved control can be achieved...if a bipolar operation is utilized” (e.g., Figure 15) where the current flows between “selected pairs of the electrodes.” *Id.*, 11:20-27; 12:8-24. A person of ordinary skill in the art reading Stern would have therefore understood that circuitry shown in Figure 5 of Stern could be modified in view of the circuitry shown in Figure 15 to include bipolar pairs from Figure 15, having respective output channels, and would have understood from Stern the benefit of doing so. Such a modification would require nothing more than adding switches and wires from Figure 15 to selectively connect the electrodes in pairs with a generator so they can be controlled in a bipolar mode. Indeed, Stern teaches that each thermistor and electrode can have its own power lead and that such circuitry is “well known.” *Id.*, 11:20-27.

210. A person of ordinary skill in the art would have found it obvious to modify Edwards-’535 in view of Stern’s teaching of the circuitry required to energize bipolar RF electrodes, output channels, and sensors into multiple subsystems for the same reasons I discussed for Elements 1[d]-1[f]. Likewise, a person of ordinary skill in the art would have reasonably expected success in doing so for the same reasons. For example, because the combination involves applying a known technique (connecting a pair of bipolar electrodes with an output channel and a sensor in Stern’s subsystems) to a known device (a device like Edwards-’535’s

energy delivery device) that is ready for improvement (Edwards-'535 omission of details regarding independent energy delivery), to yield predictable results (independent feedback and control systems for each bipolar pair as Stern teaches). In fact, configuring the circuitry of an RF ablation device to implement multiple subsystems was known well 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. I note that the '318 patent does not provide any detail beyond what someone skilled in the art would have known.

211. For these reasons, it is my opinion that claim 13 is obvious in view of Edwards-'535 and Stern.

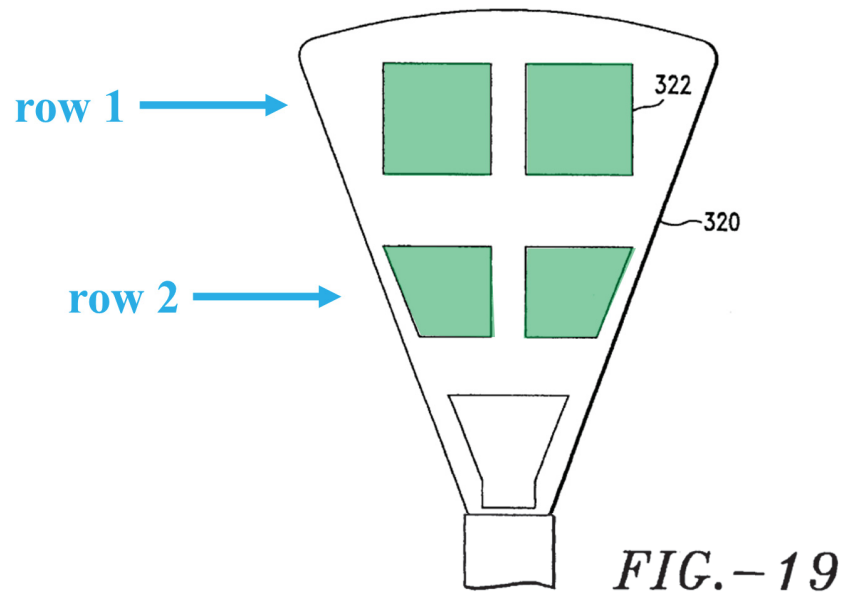
8. **Claim 15: The device of claim 1, wherein the multiple pairs of bipolar radiofrequency electrodes comprise two rows of electrodes.**

212. Claim 15 depends from claim 1. Therefore, I incorporate by reference my discussion of claim 1.

213. Edwards-'535 and Stern teach the additional limitation of claim 15.

214. Edwards-'535 in combination with Stern disclose that the multiple pairs of bipolar RF electrodes *comprise two rows of electrodes*. Stern teaches that “a

plurality of electrodes 322 are formed on the surface of the bladder 320.” Ex.1033-Stern, 14:26-38. As I have shown and annotated in Figure 19 below, Stern’s electrodes 322 in green are arranged in *two rows* indicated by light blue arrows:



215. Stern’s Figure 4A similarly depicts an array of electrodes arranged in two rows and that the electrodes can be operated in bipolar pairs. *Id.*, 2:36-40, 13:1-44, FIG.4A.

216. Moreover, as I discussed above for Elements 1[d] and 1[e], such an electrode arrangement would have been obvious to incorporate in Edwards-’535. Likewise, a person of ordinary skill in the art would have reasonably expected success in doing so for the same reasons. There are only a small number of ways to configure an array of bipolar electrodes, especially when the array contains bipolar

pairs, *id.*, 2:26-40. The term “array” itself would suggest that an arrangement of bipolar electrodes in rows and columns is appropriate and may even be necessary. A person of ordinary skill in the art would have considered ordered arrangements of electrodes (such as two or more rows of active and return electrodes, respectively, or alternating active and return electrodes) to be appropriate arrangements. Choosing among such finite choices amounts to a mere rearrangement of electrodes in rows and/or columns that were obvious and well within a person of ordinary skill in the art’s ability. For the same reason, a person of ordinary skill in the art would have had a reasonable expectation of success in implementing electrodes in two or more rows, as Stern teaches.

217. For these reasons, it is my opinion that claim 15 is obvious in view of Edwards-’535 and Stern.

9. **Claim 16: The device of claim 1, wherein each of the multiple sensors is coupled with a respective one of the multiple radiofrequency output channels.**

218. Claim 16 depends from claim 1. Therefore, I incorporate by reference my discussion of claim 1.

219. Edwards-’535 in combination with Stern teach the additional limitation of claim 16.

220. Edwards-'535 and Stern disclose multiple sensors, for example impedance sensors and/or thermocouples as Edwards-'535 teaches, or thermocouples as Stern teaches (i.e., *each of the multiple sensors*). These sensors are coupled with output channels as Stern teaches (i.e., *coupled with a respective one of the multiple radiofrequency output channels*).

221. For example, Stern's Figure 5, which I annotated below, shows that thermistors (THERM1 highlighted in brown) is coupled with an output channel (shown in orange).

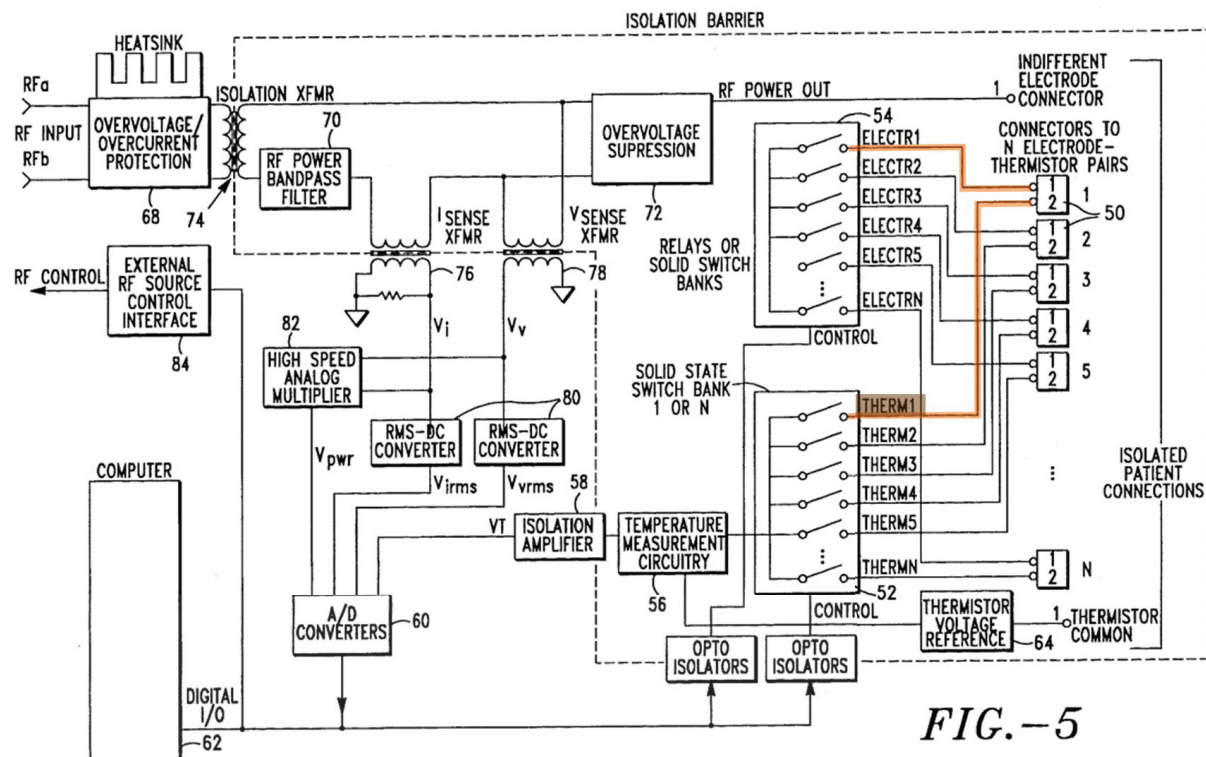


FIG. -5

222. Additionally, Stern's Figure 15, which I reproduced and annotated below, shows electrodes in green that are connected to output channels in orange. Stern further teaches that "a temperature sensor [can be] mounted on at least one of the electrodes." Ex.1033-Stern, 4:56-68. A person of ordinary skill in the art would have understood that these temperature sensors would also be connected with the output channels, just as the electrodes are.

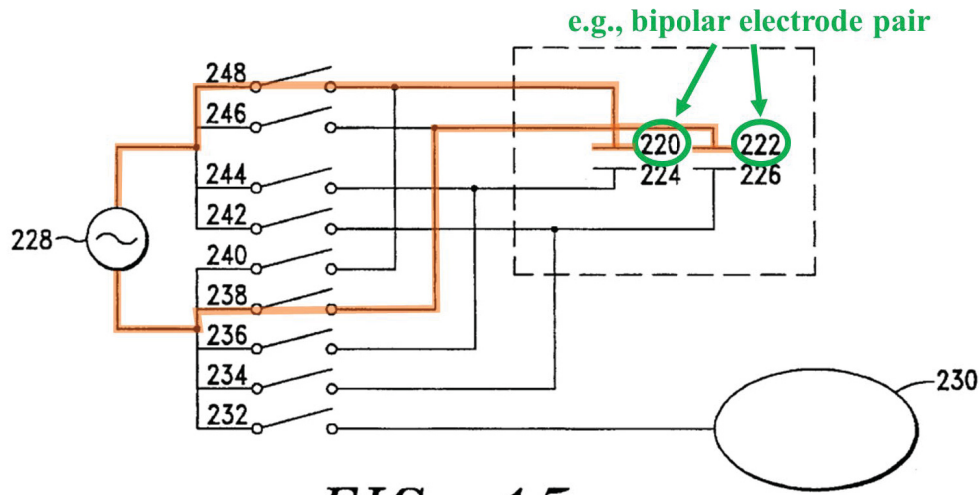


FIG.-15

223. A person of ordinary skill in the art would have found it obvious and predictable to organize the electrodes, sensors, and output channels in the manner Stern describes, in the apparatus 124 of Edwards-'535, for the reasons I stated above for Elements 1[d]-1[f] and claim 13. Likewise, a person of ordinary skill in the art would have reasonably expected success in doing so for the same reasons.

224. For these reasons, it is my opinion that claim 16 is obvious in view of Edwards-'535 and Stern.

10. **Claim 17: The device of claim 1, wherein the multiple pairs of bipolar radiofrequency electrodes are connected to one another and to the multiple radiofrequency output channels in a multiplexed configuration.**

225. Claim 17 depends from claim 1. Therefore, I incorporate by reference my discussion of claim 1.

226. Edwards-'535 and Stern teach the additional limitation of claim 17.

227. The '318 patent describes a “multiplexed configuration” as “allowing pairing of any of the positive electrodes to any of the negative electrodes to form a complete circuit.” Ex.1001-USP318, 10:47-50; *see also id.*, 49:19-32, 49:46-60. Edwards-'535 in view of Stern teaches one or more of bipolar electrode pair 220 and 222 (e.g., *multiple pairs of bipolar radiofrequency electrodes*) connected to channels in Figure 15 (*connected to one another and to the multiple radiofrequency output channels*) in a switching arrangement (i.e., *in a multiplexed configuration*). *See* Ex.1033-Stern, 12:46-13:2.

228. Figures 8 and 9 in Edwards-'535 show impedance measurements connected to multiplexer 188 based on the current path to electrodes. *See* Ex.1010-Edwards-'535, FIGs.8-9. Edwards-'535 teaches that “[a] multiplexer can be

included to measure current, voltage and temperature, at numerous sensors, and energy can be delivered to the energy delivery device 189 in monopolar or bipolar fashion.” *Id.*, 8:15-35, 10:28-32. Since the “numerous sensors” can include the electrodes, *id.*, FIGs.8-9, 10:26-11:7, a person of ordinary skill in the art would understand Edwards-’535’s device to be in a *multiplexed configuration* because the multiplexer 206 is connected to the output channels from power circuits 200.

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

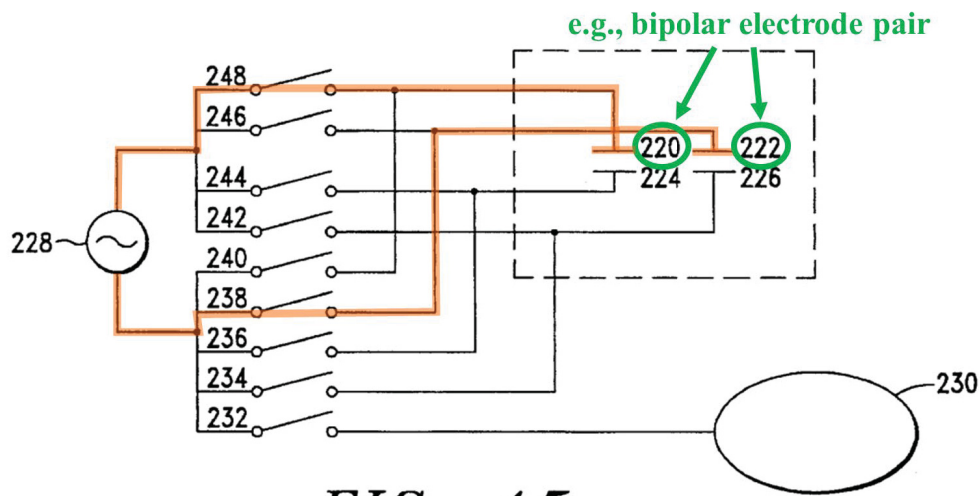


FIG.-15

Accordingly, Stern's teaches that bipolar electrodes can be selectively controlled in connected pairs through output channels in a multiplexed configuration.

230. A person of ordinary skill in the art would have found it to be obvious and predictable to arrange electrodes and output channels in the manner Stern teaches in Edwards-'535's device for the same reasons discussed I above for Elements 1[d], 1[e], and 1[f]. Multiplexed configurations are ubiquitous in energy based medical devices and are commonly used to control the delivery of energy. Ex.1011-Baker, 6:40-54, 9:14-23, 11:6-12:43; Ex.1012-Goble, 2:20-23, 8:65-9:16; Ex.1067-Edwards-'730, 1:23-29, 5:53-68, 6:1-13.

231. Further, a person of ordinary skill in the art would have had a reasonable expectation of success in doing so and would have been motivated to

include the circuitry and multiplexed configuration of Stern for the same reasons discussed I above for Elements 1[d], 1[e], and 1[f].

232. For these reasons, it is my opinion that claim 17 is obvious in view of Edwards-'535 and Stern.

B. GROUND II: Claim 6 In View of the Combination of Edwards-'535, Stern, and Patel

233. As I discussed above Ground I, Edwards-'535 in view of Stern render obvious *inter alia* claims 1 and 4. Dependent claim 6 is also obvious in view of Edwards-'535 and Stern in further view of Patel.

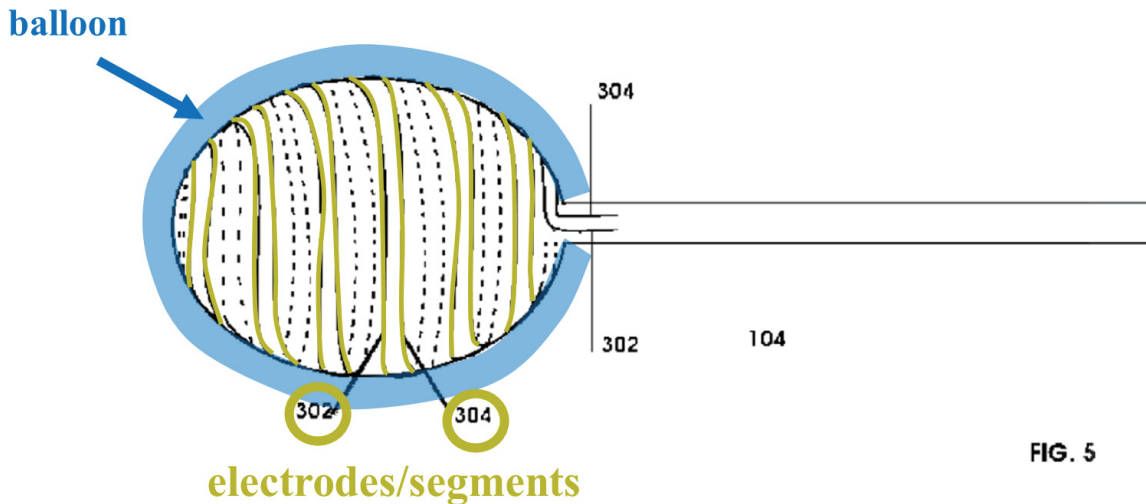
1. Claim 6: The device of claim 4, wherein the multiple segments comprise a shape-memory alloy material configured to expand to a desired size and shape.

234. Claim 6 depends from claim 4. Therefore, I incorporate by reference my discussion of Claims 1 and 4 in the context of Ground I.

235. Edwards-'535 and Stern in further view of Patel render obvious the additional limitation of Claim 6.

236. The combination of Edwards-'535, Stern and Patel renders obvious that a plurality of surface segments 42 (e.g., in Stern) as discussed above for claim 4 (i.e., *multiple segments*) may comprise nitinol (i.e., a *shape-memory alloy material*) that allows folding or furling during insertion and unfolds or unfurls after insertion (i.e., *configured to expand to a desired size and shape*).

237. Patel teaches a bipolar probe for treating tissue using RF energy. Ex.1034-Patel, [0036]. As shown in Patel's Figure 5, which I have annotated below, Patel's probe includes "a balloon...covered with circumferential, parallel and spirally disposed bipolar electrodes 302 and 304." *Id.*, [0090], FIG.5. The balloon is inserted into the body in a collapsed state, then inflated with liquid after insertion to expand the balloon, and the balloon's surface is then pressed against tissue. *Id.*, [0038]. The bipolar electrodes on the surface of the balloon subsequently deliver RF energy to ablate the targeted tissue. *Id.*



Id., FIG.5. Patel teaches that "[t]he electrodes 302 and 304 on the balloon are made of thin flexible metallic strips to allow folding or furling of the balloon during insertion. Suitable metals for the electrodes on the balloon include nitinol..." *Id.*, [0090]. A person of ordinary skill in the art would have known that nitinol, a nickel

titanium alloy, is a commonly used shape memory alloy. *See also* Ex.1030-Kunis, 14:22-65, 18:55-65, 20:1-10, 20:65-21:1; 26:1-15; Ex.1061-Szold, 1493–96.

238. Similar to Edwards-'535 and Stern, Patel is related to treating tissue in a body cavity and does so by application of RF energy to the tissue using an expandable device. Ex.1034-Patel, Abstract, [0002], [0036]-[0038], [0090], FIG.5. Patel therefore is in the same field as the '318 patent and reasonably pertinent to solving the problems addressed in the '318 patent (treating human tissue) using the same type of solution (expandable devices for applying energy to the tissue).

239. A person of ordinary skill in the art would have been motivated to construct the electrodes on Edwards-'535's expandable member 132 (as modified by Stern) using nitinol as taught by Patel due to its thermal conductivity and biocompatibility. There are a finite number of conductive materials to make electrodes from, especially materials that are suitable for use inside the body. When determining what material to make electrodes from, it would have been obvious for a person of ordinary skill in the art to choose nitinol because it is flexible while still being highly conductive and because nitinol is already used in surgical devices, so a person of ordinary skill in the art would have had reasonable expectation of success in doing so. *See also* Ex.1030-Kunis, 14:22-65, 18:55-65, 20:1-10, 20:65-21:1;

26:1-15; Ex.1061-Szold, 1493-96. A person of ordinary skill in the art would have understood that nitinol has very good thermal conductivity and would be particularly suitable for ablation devices to conduct heat used for treatment, as it is used in many devices. Further, nitinol has been safely used for decades in medical devices due to its biocompatibility. And because nitinol is a shape-memory alloy, a person of ordinary skill in the art would have understood that electrodes made of nitinol would be especially advantageous in conjunction with Edwards-'535's expandable member, which is inserted into the body in a collapsed state, expanded to deliver treatment, and re-collapsed for removal, because nitinol is flexible, provides easy shape change, and conforms to irregularly shaped tissue. *See also* Ex.1030-Kunis, 14:22-65, 18:55-65, 20:1-10, 20:65-21:1; 26:1-15; Ex.1034-Patel, [0090]; Ex.1061-Szold, 1493-96.

240. For these reasons, it is my opinion that claim 6 is obvious in view of Edwards-'535, Stern, and Patel.

C. GROUND III: Claims 9 and 10 In View of the Combination of Edwards-'535, Stern, and Edwards-'886

241. As I discussed above, Edwards-'535 in view of Stern render obvious *inter alia* claims 1, 9 and 10. Dependent claims 9 and 10 are additionally obvious in view of Edwards-'535 and Stern in further view of Edwards-'886.

1. **Claim 9:**

- a. **Element 9[a]: The device of claim 1, further comprising: a radiofrequency generator configured to receive sensed signals from the multiple sensors and deliver radiofrequency energy separately to each of the multiple radiofrequency output channels in the form of a 460 KHz sinusoid wave; and**

242. Claim 9 depends from claim 1. Therefore, I incorporate by reference my discussion of Claim 1. I also incorporate by reference my discussion of Claim 9 in the context of Ground I.

243. As I explained regarding claim 9 in Ground I, Edwards-'535 in view of Stern discloses this limitation.

244. Edwards-'886 likewise teaches applying a *460 KHz sinusoid wave* across multiple channels. For example, Edwards-'886 teaches “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 to apply energy from electrodes. Ex.1016-Edwards-'886, FIGs.77, 2, 39:35-55, 39:56-40:3 (describing usage of sensor signals). Edwards-'886 further teaches that “four independent radio frequency channels” can be “configured to operate eight electrodes...in...a bipolar mode.” *Id.*, 36:66-37:10. “Each channel is capable of supplying up to 15 watts of radio frequency energy with a sinusoidal waveform at 460 kHz.” *Id.*

245. Similar to Edwards-535 and Stern, Edwards-'886 is related to treating tissue in a body cavity and does so by application of 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. Edwards-'886 is therefore in the same field as the '318 patent and reasonably pertinent to solving the problems addressed in the '318 patent (treating human tissue) using the same type of solution (expandable devices for applying energy to the tissue)

246. Additionally, although Edwards-'535 in view of Stern renders obvious a frequency range inclusive of 460 kHz, like I explained in Ground I claim 8, it also would have been obvious in view of Edwards-'886 to apply RF energy having a sinusoidal waveform at a frequency of 460 kHz as taught by Edwards-'886. Because Edwards-'535 and Edwards-'886 share a common inventor and are both related to similar devices used for similar purposes. A person of ordinary skill in the art would have found it obvious apply RF energy with the device of Edwards-'535 in view of Stern, with a sinusoidal waveform at 460 kHz as Edwards-'886 teaches. As discussed above, Stern teaches applying a frequency of “at least 250 kHz and less than 100 MHz.” Ex.1033-Stern, 2:18-20; 3:15-20, Clm.1. Edwards-'886 teaches using bipolar RF for the same purpose as Edwards-'535 and Stern—tissue ablation. Moreover, Edwards-'535 and Edwards-'886 have a common, eponymous inventor

and relate to similar devices used for similar purposes. For example, both insert expandable devices that use bipolar RF surface electrodes into a body cavity to ablate tissue. *Compare* Ex.1010-Edwards-'535, Abstract, 5:18-34, 8:19-33, 10:25-31, 10:52-61, FIGs.3A-3B, *with* Ex.1016-Edwards-'886, 13:13-14:3, 36:66-37:7, FIGs.3-4, 9-19. Accordingly, a person of ordinary skill in the art would have been motivated to combine teachings from the same author to ablate using Edwards-'886's specified frequency parameters and would have had a reasonable expectation of success in doing so. That is because most RF ablation generators sold prior to 2011 operated at a frequency of 460 kHz, with suitable and predictable results, making this frequency selection an appropriate and an almost necessary choice given industry availability. Ex.1052-Sackenheim, 90 (explaining that one of three companies that manufactured RF ablation generators in the United States used a 460 kHz generator); Ex.1053-Bronzino, 63-4, Tbl.63.3 (teaching that a typical bipolar mode frequency range is between 300 kHz and 1050 kHz); Ex.1054-Koyyalagunta, 4 (explaining that modern RF ablation probes use frequencies of 100-500 kHz); Ex.1051-Haemmerich, 53 (noting that RF ablation devices operate in the 450-500 kHz frequency range). Furthermore, Edwards-'535 and Edwards-'886 each teach ablating mucosal tissue. *See, e.g.,* Ex.1010-Edwards-'535, Abstract (discussing the turbinates, which are in the nasal cavity and are lined with mucosal

tissue); Ex.1016-Edwards-'886, 10:58-67 (treating “mucosal surface of the esophagus 10”). A person of ordinary skill in the art would have understood that mucosal tissue, regardless of its location in the body, would have similar moisture content, and would therefore have similar electrical properties for purposes of ablation. Thus, Edwards-'886's teaching of ablating mucosal tissue in the kHz range is equally applicable to Edwards-'535's device. Edwards-'535's teaching that RF energy is “preferably” in the MHz range, would not have deterred a person of ordinary skill in the art from applying energy at other frequencies. For example, it would have been obvious for a person of ordinary skill in the art to apply RF energy in Edwards-'535's device at 460 kHz as Stern teaches, because that frequency was also known by a person of ordinary skill in the art to deliver RF energy to adequately ablate tissue. *See* Ex.1033-Stern, 2:18-20; 3:15-20, Clm.1. Indeed, most RF ablation devices for various body tissues operate at a frequency of about 460 kHz. *See, e.g.,* Ex.1016-Edwards-'886, 36:66-37:2; *see also* Ex.1050-Hong, S181 (explaining that “generators manufactured in the United States are capable of...delivering high frequency (460-500 kHz) alternating current via RF electrodes”); *id.*, S179 (“Radiofrequency waves as applied in medicine cause thermal ablation of a defined volume of tissue.”); Ex.1052-Sackenheim, 90 (explaining that one of three companies that manufactured RF ablation generators in

the United States used a 460 kHz generator); Ex.1053-Bronzino, 63-4 (teaching that a typical bipolar mode frequency range for an electrosurgical device is between 300 kHz and 1050 kHz); Ex.1054-Koyyalagunta, 4 (explaining that modern RF ablation probes use frequencies of 100-500 kHz); Ex.1051-Haemmerich, 53 (noting that RF ablation devices for different tissues, including cancer tissue, cardiac tissue, and uterine tissue, operate in the 450-500 kHz frequency range). A person of ordinary skill in the art would have been well aware of this range and would have understood that the MHz range in Edwards-'535 may contain a typographical error that should have referred to the more commonly used kHz range. Whether or not this statement is a typographical error, the inclusion of this range does not change my opinions in this Declaration, including because Edwards-'535 teaches, consistent with my experience, that a person of ordinary skill in the art could—and it would have been obvious to—adjust a radiofrequency generator to a desired range for RF ablation as a matter well within their skill (e.g., to a kHz range that is more typical for ablation than a MHz range). *See* Ex.1010-Edwards-'535, 11:46-12:4.

b. Element 9[b]: a cable coupled to the handle for plugging the handle into the radiofrequency generator.

247. Claim 9 depends from claim 1. Therefore, I incorporate by reference my discussion of Claim 1. I also incorporate by reference my discussion of Claim 9 in the context of Ground I, which is equally applicable and sufficient for this Ground.

248. For these reasons, it is my opinion that claim 9 is obvious in view of Edwards-'535, Stern, and Edwards-'886.

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

249. Claim 10 depends from claim 9. Therefore, I incorporate by reference my discussion of claim 9. I also incorporate by reference my discussion of Claim 10 in the context of Ground I.

250. As I explained in claim 10 in Ground I, Edwards-'535 teaches this limitation. Edwards-'886 likewise teaches that the generator 38 (i.e., *radiofrequency generator*) is configured to run with “four independent radio frequency channels. Each channel is capable of supplying ***up to 15 watts*** of radio frequency energy” (i.e., *configured to run at a power of between 5 and 75 watts*). Ex.1016-Edwards-'886, 36:66-37:10.

251. For these reasons, it is my opinion that claim 10 is obvious in view of Edwards-'535, Stern, and Edwards-'886. For the same reasons I explained for Claim

9 above, a person of ordinary skill in the art would have been motivated to use Edwards-'886's parameters for ablation in Edwards-'535's device as modified by Stern, and would have reasonably expected success in doing so.

D. GROUND IV: Claims 1, 4-6, 12, 13, 15-17 In View of the Combination of Makower and Stern

252. As detailed below, the combination of Makower and Stern teach each limitation of Claims 1, 4-6, 12, 13, 15-17.

253. In the examination of the '318 patent before the United States Patent and Trademark Office, the examiner initially rejected issued claim 1 over Makower, as described in Section VII.B (Relevant Prosecution History) but found that Makower did not teach certain limitations that the Patent Owner had added to the claims via amendment, including (1) pairs of bipolar radiofrequency electrodes, (2) multiple radiofrequency output channels connected with the multiple pairs of bipolar radiofrequency electrodes, or (3) multiple sensors on the tissue treatment surface. Ex.1003-USP318FH, 572-88. Stern teaches these features.

1. Claim 1

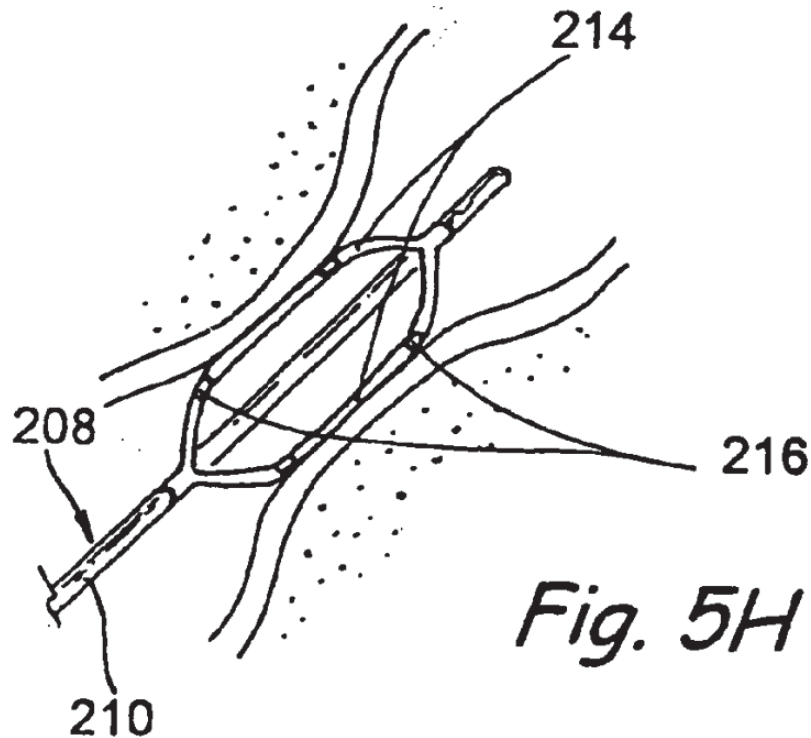
a. Element 1[pre]: A device for delivering energy to a nasal airway to improve nasal airflow, the device comprising:

254. I have been informed and understand that, in general, there are circumstances where the preamble of a claim does not limit the scope of the claim,

and there are circumstances where the preamble does limit the scope of the claim. Should the preamble be found to be limiting (which I understand is a legal determination), Makower teaches Element 1[pre].

255. For example, Makower discloses electrosurgical device 208 (*a device*) that delivers laser, RF, thermal or other energy (*for delivering energy*) to a nasal cavity (*to a nasal airway*) “for treating sinusitis and other ear, nose & throat disorders” (*to improve nasal airflow*). Ex.1021-Makower, [0001], [0131].

256. Makower’s electrosurgical device 208 includes electrodes 216 that deliver RF energy. *Id.*, [0187]. Makower’s device delivers RF energy to a nasal airway because it “is advanced into a passageway such as a nostril, nasal cavity.” *Id.*, [0043], [0161], [0187]. Makower’s electrosurgical device 208 is shown below in Figure 5H.



257. Makower discloses treatment of “sinusitis,” *id.*, [0001], one symptom of which is “difficulty breathing through one or both nostrils,” *id.*, [0007]-[0014]. Accordingly, a person of ordinary skill in the art would have understood electrosurgical device 208 to be a device for delivering energy to a nasal airway to improve nasal airflow.

b. Element 1[a]: a handle;

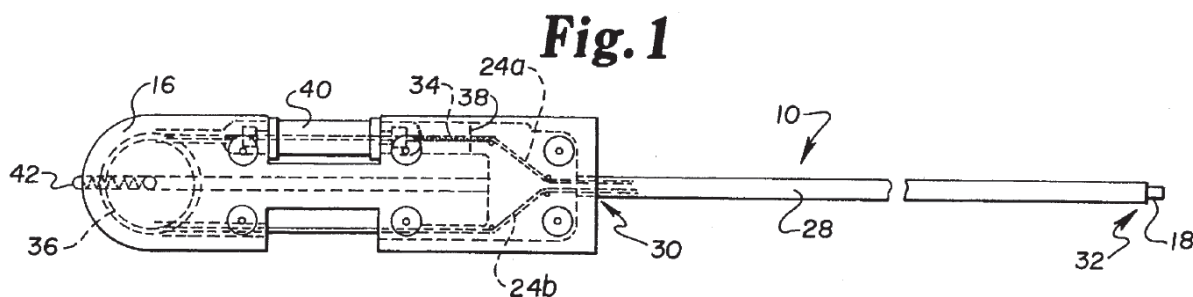
258. As I explained above with reference to Ground I, Element 1[a], a person of ordinary skill in the art would have understood RF ablation devices to include handles to help control and position the device. If there were no handle, it would be difficult to introduce the device through a patient’s nostril and position the device

once inside the nostril. Makower or the combination of Makower and Stern renders a handle obvious.

259. Makower does not specify that a handle is attached to electrosurgical device 208, but Makower teaches that device 208 may be steerable. Indeed, “[s]teerable catheters and scopes are well known in the art.” Ex.1021-Makower, [0195]. For example, numerous references disclose handles that control movement of steerable catheters. *See, e.g.*, Ex.1045-Savage, 4:49-5:20 (describing handle 16 having a threaded rod and pulley mechanism used to “control[] the movement of steerable catheter 10”); Ex.1030-Kunis, 8:1-15 (describing a “precision controlled” “steering mechanism” inside the handle used to steer the “distal end of the catheter...into the...pulmonary veins”). And numerous references disclose handles for energy delivery devices generally. *See, e.g.*, Ex.1024-Hovda, 33:3-26 (describing a handle “that is easily molded into a suitable shape for handling by the surgeon”); Ex.1022-Odom, [0040] (describing a movable handle used to control jaw members of a RF forceps device); Ex.1067-Edwards-’730, 4:16-41 (describing a handle with various actuators that “provide physician control of [the] ablation apparatus”); Ex.1011-Baker, 5:28-46 (same); Ex.1012-Goble, 4:1-6 (explaining that the device “has a handle [] by which a user may grasp the device”); Ex.1013-Baker-’980, 11:7-12:6 (describing a handle that “has a size and configuration that

facilitates holding in one or both hands and may include ridges, indentations, curved contours, and the like, to enhance the ergonomic feel and secure handling of the device,” as well as an “activation mechanism” “for activating one or more device functions.”). A person having ordinary skill in the art would understand that to steer a catheter, some sort of *handle* would be incorporated in the device.

260. I understand that Makower cites and incorporates several references. Some of these references teach handles as mechanisms for how to control steerable devices, including United States Patent No. 5,507,725 (“Savage”). The handle shown in Savage is one example of how a handle can be used to effectuate the functionality of a RF ablation device. Ex.1045-Savage, 4:49-60, FIGs.1, 2A. Savage’s handle, for example, has a pulley mechanism that controls the movement of a catheter through the body of the RF ablation device. *Id.* Handle 16 is shown schematically below in Figure 1 and Savage describes handle 16 as controlling the movement of steerable catheter 10, shown below. *Id.*, 4:49-60.



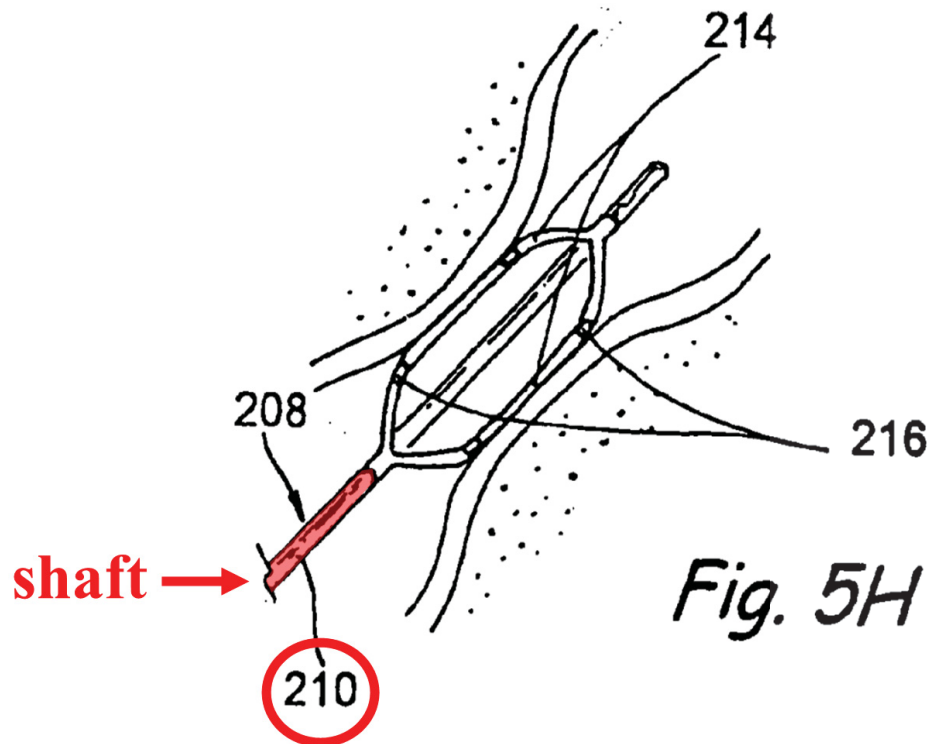
261. It would have been obvious to a person of ordinary skill in the art to include a handle in a device like Makower's in view of Stern, for the same reasons I explained that it would have been obvious to include a handle in a device like Edwards-'535's in view of Stern in Section IX.A.1.b., for example, to control and deploy the ablation device. Ex.1021-Makower, [0138], [0161].

262. As I explained in Ground I, Element 1[a], Stern teaches a handle (application device 124) that allows a physician or clinician to control the device and deploy bladder 142, an expandable member. Stern teaches that handle can have a retraction knob 144 and a thumb detent 146. These knobs and indents further allow a physician to deploy bladder 142 by retracting the catheter sheath. The handle can also allow a physician to collapse the bladder when the treatment is finished by advancing the catheter sheath over the bladder. Ex.1033-Stern, 10:11-29, 10:37-49, 13:56-65, 14:5-8, 18:13-28, FIGs.10a, 11a, 12. Including this functionality in Makower's device would have been helpful to expand device 208 once it is positioned inside the nose and collapse the device after treatment.

c. Element 1[b]: a shaft extending from one end of the handle;

263. Makower teaches shaft 210 (*a shaft*) *extending from one end of the handle.*

264. I have reproduced Figure 5H below, which shows a shaft (shaft 210 in red) extending from electrosurgical device 208.



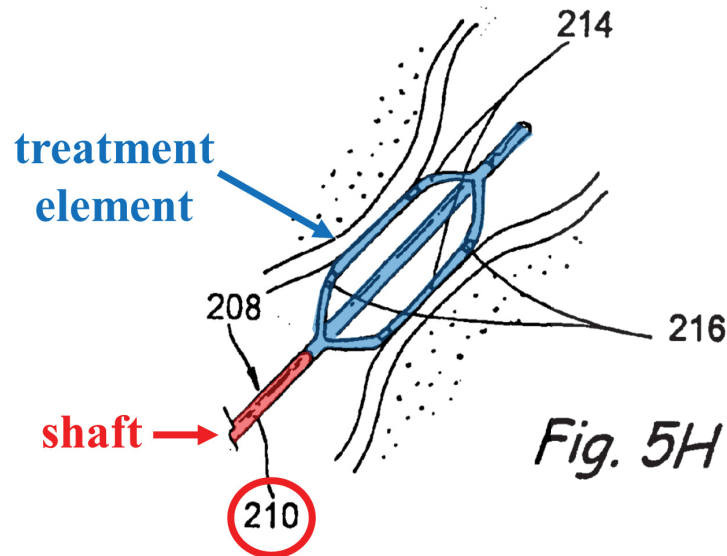
265. As I explained above with reference to Element 1[a], Makower does not specify a handle, or that a handle is attached to shaft 210. But this would have been obvious for the same reasons I explained in Ground I Element 1[a] and in Ground IV Element 1[a].

266. Additionally, a device that has a shaft extending from one end of the handle in Makower would have been obvious in view of Stern for the same reasons I explained in Elements 1[a] and 1[b] in Ground I and Ground IV—for example, to control the ablation device. Ex.1021-Makower, Abstract, [0153], [0159], [0187].

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

267. Makower teaches an electrosurgical device 208 having a portion used to treat tissue shown in blue in Figure 5H (*treatment element*) that is placed at the distal end of shaft 210 shown in red in Figure 5H (*coupled with a distal end of the shaft*). “Device 208 is advanced into...a nostril” (*sized to be inserted into a nostril*), and the strut members 214 on the device are collapsible and expandable (*configured to change from a first configuration to a second configuration*). The electrodes 216 on the surface of strut members 214 are brought into contact with tissue (*wherein the treatment element comprises a tissue treatment surface*).

268. I have again reproduced Figure 5H below, now showing the treatment element in blue.



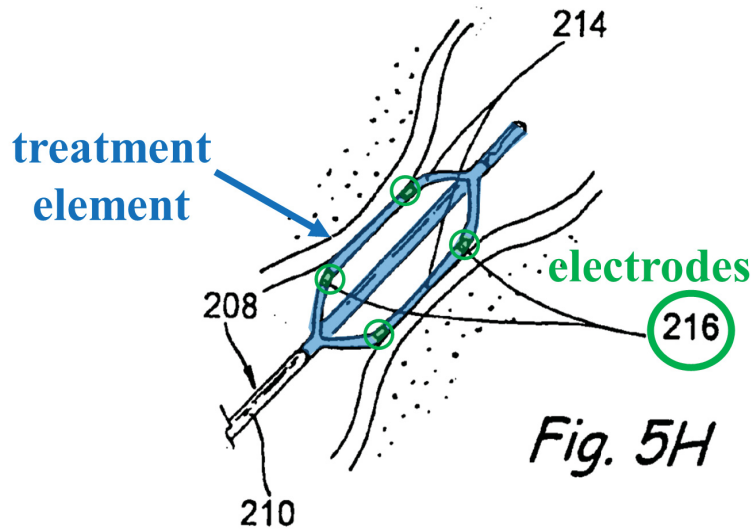
269. Makower teaches that electro-surgical device 208 has “arched strut members 214” and “[e]lectrodes 216 are located on the strut members 214.” Ex.1021-Makower, [0187], [0164], FIG.5H. “[T]he strut members 214 may be collapsible and expandable. In operation, the device 208 is advanced into a [nasal] passageway.... Thereafter, current is applied to the electrodes 216 causing tissue adjacent to the struts 214 to be cauterized or heated.” *Id.* Therefore, Makower teaches this Element.

- e. **Element 1[d]: an array of multiple pairs of bipolar radiofrequency electrodes disposed along the treatment surface of the treatment element;**

270. Makower teaches electrodes 216 shown in green in Figure 5H (*an array of multiple...bipolar radiofrequency electrodes*) that are placed on the surface of the strut members 214 (*disposed along the treatment surface of the treatment element*).

See Ex.1021-Makower, [0187] (noting that “electrodes 216 may be bipolar”),
FIG.5H.

271. Figure 5H is reproduced below.



272. As I explained in Ground I Element 1[d], using bipolar RF electrode pairs in RF devices was ubiquitous. Pairs of bipolar electrodes have many advantages, as I explained, for example to ensure that RF energy is applied only to intended tissue and not to nontargeted tissue. Energizing RF electrodes in bipolar pairs is also beneficial to control heating and temperature on a local scale. Indeed, operating electrodes on the smallest scale possible—with electrode pairs—was well known by 2011 because of the many benefits of such a configuration, as I explained in Ground I Element 1[d].

273. As I explained with reference to Element 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.

274. Figure 17 of Stern is reproduced below.

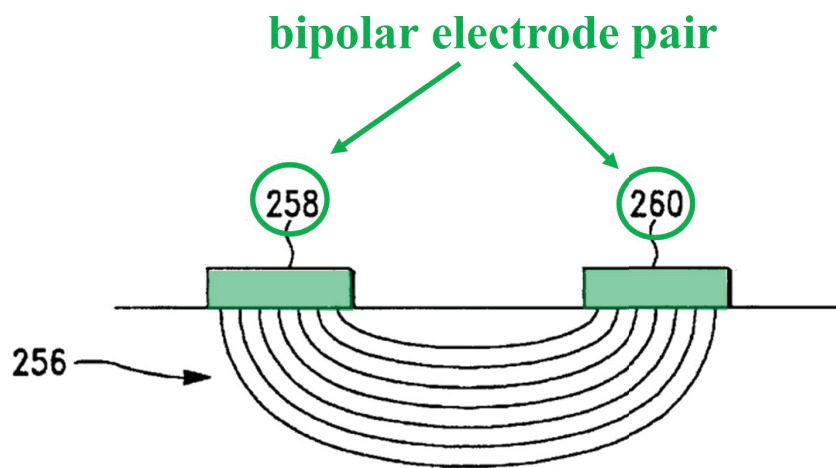


FIG.-17

275. Stern's Figure 15 is also reproduced below.

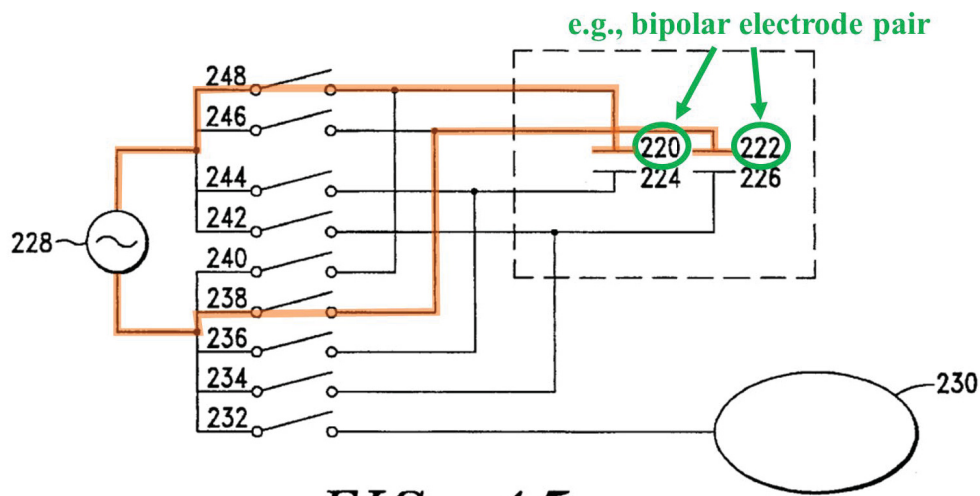


FIG.-15

276. Figure 15 shows the circuitry that Stern uses to operate the bipolar electrodes in pairs. *See id.*, FIG.15. For 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.

a. Motivation to Combine and Reasonable Expectation of Success

277. I note that Makower, like Stern and Edwards-’535 I discussed above, confronts the problem of treating tissue in the body and solves that problem by applying RF energy. Makower, [0001], [0043], [0132], [0164], [0187]. Makower is therefore in the same technical field as the ’318 patent and reasonably pertinent to solving the problems addressed in the ’318 patent (treating human tissue in a body cavity) using the same type of solution (expandable devices for applying energy to

the tissue via 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).

278. Bipolar RF ablation devices with multiple surface electrodes were well-known to those skilled in the art at the time. Ex.1010-Edwards-'535, 4:55-60; Ex.1011-Baker, 5:47-58.

279. Makower teaches that “[r]adiofrequency energy is...delivered to heat...submucosal tissue” using electrodes. Ex.1021-Makower, [0040]. Makower explains that the “electrodes 216 may be bipolar, monopolar or facilitated by any other suitable form of energy...” *Id.*, [0187]. However, Makower omits details on how to implement such energy delivery and therefore leaves such details up to a person of ordinary skill in the art.

280. As I explained in Section III.C, I have been informed by Petitioners’ counsel and understand that for a claim to be obvious, a person of ordinary skill in the art must have had a reason or motivated to combine or modify the relevant teachings in the prior art to obtain the claimed invention, and one of ordinary skill in the art must have had a reasonable expectation of success in doing so. It is my opinion that a person having ordinary skill in the art would already know how to implement such energy delivery or would look to other sources for that information, especially where Makower leaves the specific implementation of pairing and wiring

bipolar electrodes up to the discretion and skill of a person having ordinary skill in the art. *See id.*, [0043]-[0046], [0187] (noting that current is delivered to electrodes but failing to teach the circuitry and software required to maintain the desired delivery of energy), [0191], [0232]. Stern teaches a number of details regarding how to design an RF ablation device with surface electrodes, like the device in Makower, such that the electrodes are bipolar. A person of ordinary skill in the art would have used Stern's configuration in Makower because doing so would have involved using Stern's known bipolar pairing technique to fill in the missing details of Makower, which would have been desirable for increased safety and precision in the nose, as described in further detail below.

281. A person of ordinary skill in the art would have been motivated to improve Makower's device to include Stern's teachings of multiple pairs of bipolar electrodes because of the advantages and benefits Stern discloses, as I explained in Ground 1 with reference to Element 1[d].

282. For example, Stern exemplifies the benefits of its technique for pairing bipolar RF surface electrodes (described above and in Element 1[d] in Ground I) and wiring them to allow for independent delivery of RF energy to each bipolar pair (described above and in Element 1[e] in Ground I). These benefits include, for example, the ability to control electrical field lines, the ability to control the heating

of targeted tissue, and the ability to ensure that tissue is heated evenly, including tissue with uneven morphology. Ex.1033-Stern, 12:25-37, 13:21-29, FIGs.15, 18.

283. A person having ordinary skill in the art would have recognized these benefits in Stern as I described in Ground I Element 1[d] and would have been motivated by them to modify Makower in view of Stern. 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.

284. Moreover, a person of ordinary skill in the art would have been motivated to combine Makower and Stern because the combination would have simply applied Stern's known bipolar pairing technique to Makower's known device that was ready for improvement (because Makower is silent as to how to pair and wire the electrodes) to yield predictable results.

285. Both Makower and Stern describe similar techniques regarding how to deliver bipolar RF ablation energy through expandable devices to tissue of different body cavities, such that their combination would have yielded predictable and straightforward results. Ex.1021-Makower, [0040], [0043]; Ex.1033-Stern, 1:16-43; 7:38-8:38. For example, both describe ablation devices with at least four surface electrodes. *Compare* Ex.1021-Makower, FIG.5H, [0187], *with* Ex.1033-Stern, FIGs.15, 19, 12:38-13:55. And both disclose expandable devices that are introduced

into passageways of the body for the purpose of ablating tissue. *Compare* Ex.1021-Makower, FIG.5H, [0126], [0179], [0187], *with* Ex.1033-Stern, FIG.2, 2:19-24, 7:39-8:16, Abstract. Furthermore, as I have explained herein, Makower omits detail regarding how to deliver bipolar RF energy, and Stern offers many benefits of independently delivering bipolar RF energy to the different bipolar electrode pairs to adequately heat and ablate tissue. Ex.1021-Makower, [0040], [0161], [0167], [0185]-[0188]; Ex.1033-Stern, 10:48-65.

286. As discussed above in Ground 1 Elements1[d], 1[e], and 1[f], a person having ordinary skill in the art would have had a reasonable expectation of success in implementing Stern's teaching of bipolar RF electrode pairs and individual output channels in a device like Makower's given that, as explained above, Makower is silent as to the circuitry required and therefore recognizes it was within a person of ordinary skill in the art's skill to design a system to deliver RF energy to various electrodes.

287. Additionally, the known techniques of Stern could have been used to improve Makower's similar device in the same way. Makower's device is similar to Stern's because it is also an expandable device with surface RF electrodes that deliver RF energy. Ex.1021-Makower, [0187]. Stern teaches a way to pair surface bipolar RF electrodes and wire such electrodes for independent energy delivery.

Ex.1033-Stern, 2:49-53, 12:25-27, 13:21-39. Thus, Stern's teachings would have been applied to Makower in the same way those teachings are used in Stern itself.

288. The application of Stern's teachings to Makower would have been well within the skill of a person of ordinary skill in the art and would have yielded predictable results as it would have simply required routine implementation. Namely, implementing bipolar electrode pairs and selectively energizing them as Stern teaches into Makower's similar device with a reasonable expectation of success.

- f. 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**

289. Makower in view of Stern teaches energy output in Stern's Figure 15 (*multiple radiofrequency output channels*) connected with the multiple pairs of Makower's electrodes 216, controlled in pairs as Stern teaches (*bipolar radiofrequency electrodes*), and as shown in Figure 15 in Stern, *each pair of the multiple pairs of bipolar radiofrequency electrodes is connected with a respective one of the multiple radiofrequency output channels.*

290. The '318 patent states that “[i]n some embodiments of treatment devices comprising an array or multiple pairs of electrodes, each pair of electrodes (bipolar) or each electrode (monopolar) may have a separate, controlled electrical channel to allow for different regions of the treatment element to be activated separately.” Ex.1001-USP318, 24:45-49.

291. As discussed above in Ground I Element 1[e], Stern discloses 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.

i. Motivation to Combine and Reasonable Expectation of Success

292. As I explained above for Element 1[d], Makower does not provide instructions to a person of ordinary skill in the art as to how to pair and wire bipolar electrodes to deliver RF energy. Therefore, such a person would have been motivated to look to Stern, which discloses how accomplish that pairing and wiring of bipolar electrodes in order to deliver energy to certain electrode pairs.

293. As I explained in Section III.C, I have been informed by Petitioners’ counsel and understand that for a claim to be obvious, a person of ordinary skill in the art must have had a reason or motivated to combine or modify the relevant teachings in the prior art to obtain the claimed invention, and one of ordinary skill

in the art must have had a reasonable expectation of success in doing so. It is my opinion that to selectively energize any pair of electrodes, it would have been an obvious and routine implementation to wire each electrode pair to a respective output channel, as Stern teaches. And doing so would allow a person of ordinary skill in the art to obtain the benefits of bipolar pairs discussed in Ground I for Element 1[d]—for example, because it provides for local and even temperature control when ablating tissue. The combination of Makower and Stern would have involved merely applying a known technique (the pairing technique and wiring for bipolar electrodes taught by Stern), to a known device (Makower’s expandable bipolar RF ablation device) that was ready for improvement (which a person of skill in the art would recognize from Makower’s omission as to how to pair and wire the bipolar electrodes) to yield predictable results.

294. Furthermore, a person having ordinary skill in the art would already know how to implement such individual output channels or would look to other sources for that information, especially where Makower leaves the specific implementation of pairing and wiring bipolar electrodes up to the discretion and skill of a person having ordinary skill in the art. *See* Ex.1021-Makower, [0043]-[0046], [0187] (noting that current is delivered to electrodes but failing to teach the circuitry and software required to maintain the desired delivery of energy), [0191], [0232].

Stern teaches a number of details regarding how to design an RF ablation device with surface electrodes, like the device in Makower, such that the electrodes are bipolar. A person of ordinary skill in the art would have used Stern's configuration in Makower because doing so would have involved using Stern's known bipolar pairing technique to fill in the missing details of Makower, which would have been desirable for increased safety and precision in the nose, as described in further detail below.

295. A person of ordinary skill in the art would have been motivated to improve Makower's device to include Stern's teachings of individual output channels because of the advantages and benefits Stern discloses, as I explained in Ground 1 with reference to Element 1[e].

296. For example, Stern exemplifies the benefits of its technique for pairing bipolar RF surface electrodes (described above and in Element 1[d] in Ground I) and wiring them to allow for independent delivery of RF energy to each bipolar pair (described above and in Element 1[e] in Ground I). These benefits include, for example, the ability to control electrical field lines, the ability to control the heating of targeted tissue, and the ability to ensure that tissue is heated evenly, including tissue with uneven morphology. Ex.1033-Stern, 12:25-37, 13:21-29, FIGs.15, 18.

297. A person having ordinary skill in the art would have recognized these benefits in Stern as I described in Ground I Element 1[e] and would have been motivated by them to modify Makower in view of Stern's teachings. Doing so would have simply involved using known circuitry as taught by Stern to implement the missing details of Makower in the way that Stern teaches.

298. Moreover, a person of ordinary skill in the art would have been motivated to combine Makower and Stern because the combination would have simply applied Stern's known output channels to Makower's known device that was ready for improvement (because Makower is silent as to how to pair and wire the electrodes) to yield predictable results.

299. Both Makower and Stern describe similar techniques regarding how to deliver bipolar RF ablation energy through expandable devices to tissue of different body cavities, such that their combination would have yielded predictable results. Ex.1021-Makower, [0040], [0043]; Ex.1033-Stern, 1:16-43; 7:38-8:38. For example, both describe ablation devices with at least four surface electrodes. *Compare* Ex.1021-Makower, FIG.5H, [0187], *with* Ex.1033-Stern, FIGs.15, 19, 12:38-13:55. And both disclose expandable devices that are introduced into passageways of the body for the purpose of ablating tissue. *Compare* Ex.1021-Makower, FIG.5H, [0126], [0179], [0187], *with* Ex.1033-Stern, FIG.2, 2:19-24,

7:39-8:16, Abstract. Furthermore, as I have explained herein, Makower omits detail regarding how to deliver RF energy, and Stern offers many benefits of independently delivering bipolar RF energy to the different bipolar electrode pairs over separate output channels to adequately heat and ablate tissue. Ex.1021-Makower, [0040], [0161], [0167], [0185]-[0188]; Ex.1033-Stern, 10:48-65.

300. As discussed above in Ground 1 Elements 1[d], 1[e], and 1[f], a person having ordinary skill in the art would have had a reasonable expectation of success in implementing Stern's individual output channels to bipolar electrode pairs in Makower's modified device given that, as explained above, Makower is silent as to the circuitry required and therefore recognizes it was within a person of ordinary skill in the art's skill to design a system to deliver RF energy to various electrodes.

301. Additionally, the known techniques of Stern could have been used to improve Makower's similar device in the same way. Makower's device is similar to Stern's because it is also an expandable device with surface RF electrodes that deliver RF energy. Ex.1021-Makower, [0187]. Stern teaches a way to pair surface bipolar RF electrodes and wire such electrodes for independent energy delivery. Ex.1033-Stern, 2:49-53, 12:25-27, 13:21-39. Thus, Stern's teachings would have been applied to Makower in the same way those teachings are used in Stern itself.

302. The application of Stern's teachings to Makower would have well within the skill of a person of ordinary skill in the art and would have yielded predictable results as it would have simply required routine implementation. Namely, implementing bipolar electrode pairs and selectively energizing them as Stern teaches into Makower's similar device with a reasonable expectation of success.

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

303. Makower discloses multiple sensing elements (*multiple sensors*) that are attached to strut members 214 (*on the tissue treatment surface*), the sensors include thermocouples (*wherein the multiple sensors are selected from the claimed group—e.g., thermocouples*).

304. For example, Makower teaches that “sensing elements may...be attached to the catheter and/or strut members to monitor...temperature.” Ex.1021-Makower, [0187]. Temperature sensors come in many different forms. For example, thermocouples were a well-known type of temperature sensor. *See, e.g.,* Ex.1052-Sackenheim, 90 (thermosensors); Ex.1051-Haemmerich, 5 (thermal sensors); Ex.1034-Patel, [0015] (thermal sensor); Ex.1030-Kunis, 7:1-52

(temperature sensors); Ex.1024-Hovda, 10:13-21 (temperature sensors); Ex.1067-Edwards-'730, 6:13-20, 7:17-20 (temperature sensors); Ex.1033-Stern, 7:50-60 (thermistors and thermocouples).

305. A person having ordinary skill in the art would have been motivated to implement the sensors of Makower using common, readily available thermocouples because thermocouples are a type of temperature sensor and were widely used.

306. Further, Makower teaches that “any of the devices described...may be further modified to include...sensor[s],” such as an “RF sensor,” or “thermal sensor.” Using sensors in this way was ubiquitous at the time. For example, Makower and Stern both teach the use of temperature sensors. Ex.1021-Makower, [0192]; Ex.1033-Stern, 15:11-31. Stern also teaches using a feedback system where the system measures tissue temperature and controls RF energy “to bring the [tissue] temperature up to a desired level.” Ex.1033-Stern, 10:48-52. Edwards-'535 also 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. Edwards-'535 also discloses an impedance calculation device 194 that utilizes current and voltage inputs to calculate impedance. *Id.*, 10:4-11, FIG.8. Edwards-'535 also discloses a monitor 210 that determines tissue impedance and

adjusts energy delivery based on an impedance feedback loop. *Id.*, 11:23-44, FIG.

10.

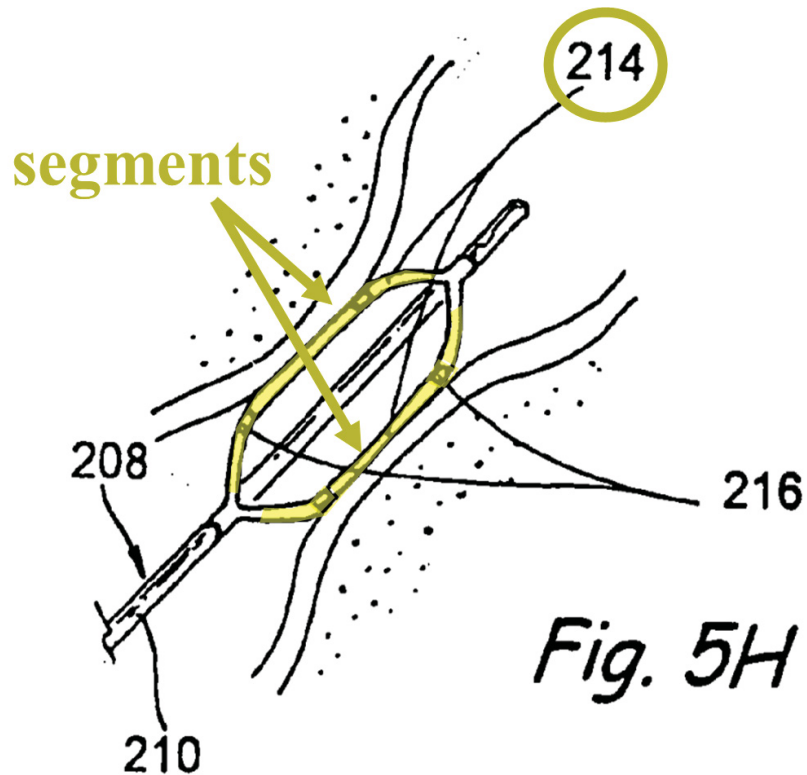
2. **Claim 4: The device of claim 1, wherein the treatment element comprises multiple segments that are expandable from the first configuration to the second configuration.**

307. Claim 4 depends from claim 1. Therefore, I incorporate by reference my discussion of Claim 1 in Ground IV.

308. Makower teaches that electrosurgical device 208 (*the treatment element*) has multiple strut members 214 (*comprises multiple segments*) that are collapsible and expandable (*expandable from the first configuration to the second configuration*). Ex.1021-Makower, [0187], FIG.5H.

309. Makower teaches that electrosurgical device 208 has “arched strut members 214” and “[e]lectrodes 216 are located on the strut members 214.” “[T]he strut members 214 may be collapsible and expandable.” *Id.*

310. I have reproduced Figure 5H below, showing multiple segments in dark yellow.



311. As I explained in Ground 1, Element [c], these segments are expandable and collapsible.

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

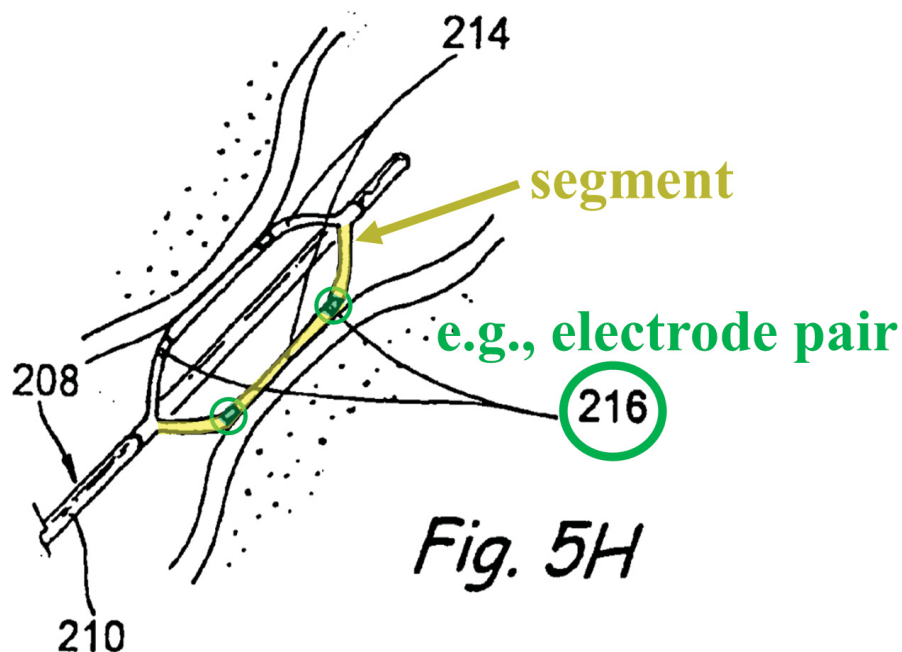
312. Claim 5 depends from claim 4. Therefore, I incorporate by reference my discussion of claim 4.

313. Makower and Stern teach that the electrodes 216 in Makower controlled as pairs as Stern teaches (*at least one pair of multiple pairs of bipolar radiofrequency electrodes*) is coupled with strut members 214 (*each of the multiple*

segments). Ex.1021-Makower, FIG.5H, [0187], [0194]; Ex.1033-Stern, 8:53-59, 5:48-51, FIGs.4a, 4b.

314. As I explained in this Ground for Elements 1[d], [e], and 1[f], it would have been obvious to control bipolar RF electrodes, as Makower teaches, in pairs, as Stern teaches. A person of ordinary skill in the art also would have been motivated to pair two adjacent electrodes 216 on each strut 214 to provide localized delivery of energy and control of tissue temperature in that region.

315. Figure 5H of Makower is reproduced below and annotated to show a bipolar electrode pair (in green) that is coupled to a segment of the electrosurgical device 208 (in dark yellow).



Ex.1021-Makower, FIG.5H, [0187], [0194].

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

316. Claim 6 depends from claim 4. Therefore, I incorporate by reference my discussion of claim 4. I also incorporate by reference my discussion of claim 4 in the context of Ground I.

317. Makower discloses that the strut members 214 (*multiple segments*) can be made of nitinol (*comprise a shape-memory alloy material*) and that the strut members 214 are collapsible and expandable (*configured to expand to a desired size and shape*).

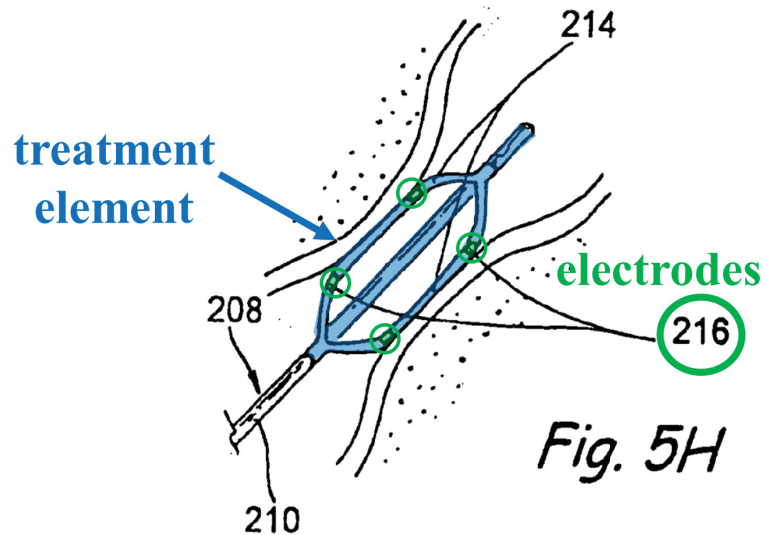
318. As I explained above for claim 4, Makower discloses that “strut members 214 may be collapsible and expandable.” Ex.1021-Makower, [0187]. Makower further teaches that “any...elongate flexible devices of this invention may include design elements that impact performance features.” *Id.*, [0194]. This 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). As I explained with respect to Claim 4 in Grounds I and II, it was well-known to use nitinol inside the body because of the several advantages that it provides.

319. A person of ordinary skill in the art would have understood Makower to suggest that strut members 214 could be made out of nitinol, a shape memory alloy, to facilitate collapse and expansion, because the strut members 214 deflect when expanded.

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

320. Claim 12 depends from claim 1. Therefore, I incorporate by reference my discussion of claim 1.

321. Makower teaches that electrodes 216 (*the radiofrequency electrodes*) contact the surface of tissue (*comprise non-penetrating electrodes*). For example, I have reproduced Figure 5H below, which shows that the electrodes (in green) that are located on the surface of the treatment element (in blue) and do not penetrate the tissue. Ex.1021-Makower, [0187].



322. As I explained in Ground I, claim 12, a person having ordinary skill in the art would understand electrodes that do not pierce tissue to be non-penetrating. Additionally, as described in Ground I claim 12, Stern also teaches non-penetrating electrodes.

6. **Claim 13: The device of claim 1, wherein the multiple pairs of bipolar radiofrequency electrodes, the multiple radiofrequency output channels and the multiple sensors are organized into multiple subsystems, and wherein each of the multiple subsystems comprises one of the multiple pairs of bipolar radiofrequency electrodes, one of the multiple radiofrequency output channels and one of the multiple sensors.**

323. Claim 12 depends from claim 1. Therefore, I incorporate by reference my discussion of claim 1.

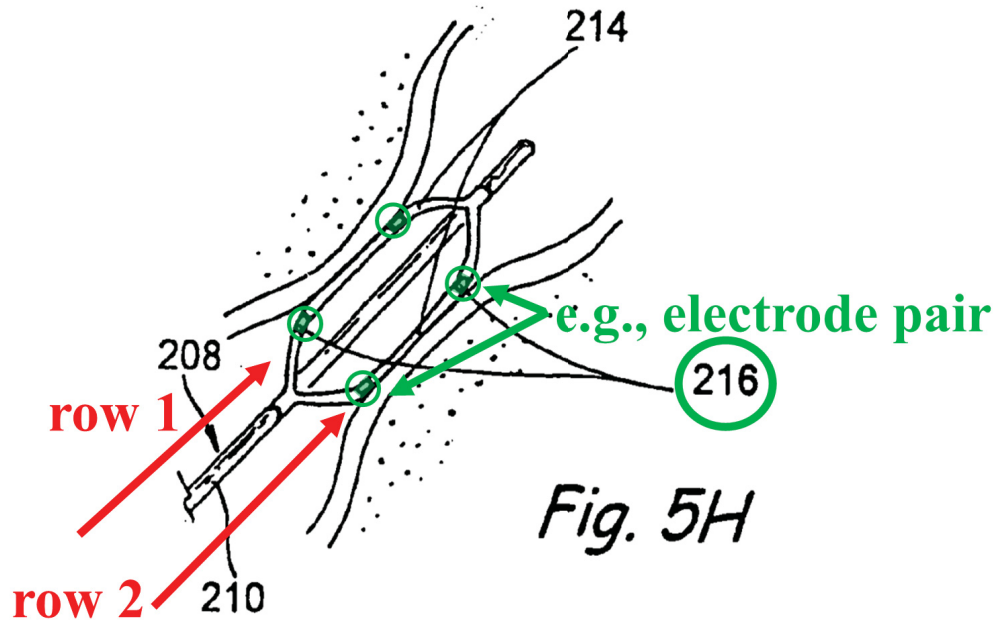
324. As I explained in Ground I, claim 13, Stern teaches this limitation. And as I discussed in Elements 1[d] and 1[e], a person of ordinary skill in the art would

have found it obvious to incorporate Stern's teaching of a paired-electrode control architecture, including the electrical connections between the electrodes, channels, and sensors, into Makower's device. Likewise, a person of ordinary skill in the art would have reasonably expected success in doing so for the same reasons.

7. **Claim 15: The device of claim 1, wherein the multiple pairs of bipolar radiofrequency electrodes comprise two rows of electrodes.**

325. Claim 15 depends from claim 1. Therefore, I incorporate by reference my discussion of claim 1.

326. As shown in Figure 5H, reproduced below, Makower teaches that the electrodes 216 in green (*multiple...radiofrequency electrodes*) are arranged in two rows shown with red arrows (*comprise two rows of electrodes*). Ex.1021-Makower, [0187].



327. As I explained in Element 1[d] and claim 5, a person of ordinary skill in the art would have been motivated to incorporate Stern's teachings of using pairs of bipolar electrodes on the struts 214.

8. **Claim 16: The device of claim 1, wherein each of the multiple sensors is coupled with a respective one of the multiple radiofrequency output channels.**

328. Claim 16 depends from claim 1. Therefore, I incorporate by reference my discussion of claim 1.

329. As I discussed in Ground I Element 1[f], Stern teaches this limitation. And as I explained in Elements 1[d] and 1[e], a person having ordinary skill in the art would have found it obvious to incorporate Stern's teaching of the paired electrode control architecture, *i.e.*, the electrical connections between the electrodes,

channels, and sensors, into a device like Makower's. Likewise, a person of ordinary skill in the art would have reasonably expected success in doing so for the same reasons.

9. **Claim 17: The device of claim 1, wherein the multiple pairs of bipolar radiofrequency electrodes are connected to one another and to the multiple radiofrequency output channels in a multiplexed configuration.**

330. Claim 17 depends from claim 1. Therefore, I incorporate by reference my discussion of claim 1.

331. As I discussed in Ground I, claim 17, Stern teaches this limitation. And as I explained in Elements 1[d] and 1[e], a person having ordinary skill in the art would have found it obvious to incorporate Stern's teaching of the paired electrode control architecture, *i.e.*, the electrical connections between the electrodes, channels, and sensors, into a device like Makower's. Likewise, a person of ordinary skill in the art would have reasonably expected success in doing so for the same reasons.

E. GROUND V: Claims 9 and 10 In View of the Combination of Makower, Stern, and Edwards-'886

332. As I discussed above Ground IV, Makower in view of Stern render obvious *inter alia* claim 1. Dependents claim 9 and 10 are also obvious in view of Makower and Stern in further view of Edwards-'886.

1. Claim 9

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

333. Claim 9 depends from claim 1. Therefore, I incorporate by reference my discussion of claim 1.

334. The combination of Makower with Stern and Edwards-'886 renders obvious Stern's teaching of a RF generator 158 (*a radiofrequency generator*) connected to Makower's disclosure of thermocouples (*configured to receive sensed signals from the multiple sensors*) that supplies energy to electrodes via Stern's teaching of multiple RF output channels (*deliver radiofrequency energy separately to each of the multiple radiofrequency output channels*) using Edwards-'886's instruction to use a sinusoidal waveform at 460 kHz (*in the form of a 460 KHz sinusoid wave*).

335. As I explained above for claim 1, Makower in view of Stern renders obvious that Makower's teaching of strut members 214 would include thermocouples, which would have been obvious to connect to multiple RF output channels for control, as Stern teaches. Like the circuitry discussed for claim 1,

Makower also omits certain implementation details regarding how the energy used to control the electrodes is generated.

336. Stern fills in these details. For example, Stern discloses an RF generator that is used to supply energy to electrodes. Ex.1033-Stern, Abstract, 8:66-9:24 (describing voltage supplied to electrodes), 10:36-48 (describing generator), 12:46-13:2 (describing voltage source), Clm.1, FIGs.5, 12, 15 (showing voltage source). That generator is operated based on a “feedback arrangement” in which thermistors—which, similar to the thermocouples of Makower, produce a signal indicative of temperature of the tissue to be ablated—provide signals to the control circuitry that are used to operate the electrodes. *Id.*, Abstract (describing feedback), 2:25-64 (describing temperature feedback), 8:66-9:24 (describing voltage supplied to electrodes), 10:36-48 (describing generator), 10:49-65 (describing temperature feedback), 12:46-13:2 (describing voltage source), Clm.1, FIGs.5, 12, 15 (showing voltage source). Stern further teaches that the electrodes are supplied with “an RF current [that] has a frequency of at least 250 kHz and less than 100 MHz.” *Id.*, 2:6-18 (describing frequency), 3:12-28 (describing frequency).

337. This “feedback arrangement” facilitates the benefits discussed for Elements 1[d]-1[f]. For example, as I explained above for claim 1, temperature feedback allows Stern’s device to selectively control the amount of energy delivered

to a particular region, such that each region can be evenly heated. Thus, a person of ordinary skill in the art would have found it obvious to supply bipolar electrodes, as taught by Makower, with RF energy using an RF generator, and further to provide the output of temperature sensing elements (i.e., thermocouples) as taught by Makower, as feedback for controlling energy delivery to the target tissue over Stern's multiple output channels for the reasons I identified above for Elements 1[e]-1[f]. Likewise, a person of ordinary skill in the art would have reasonably expected success in doing so for the same reasons.

338. As I discussed above for claim 9 in Ground III, Edwards-'886 discloses applying a *460 KHz sinusoid wave* across multiple channels. This frequency falls within Stern's disclosure of 250 kHz to 100 MHz for RF energy delivery. As I discussed for claim 9 in Grounds I and III, one of the most common forms of RF energy delivery for tissue ablation is a 460 kHz sine wave. Thus, it would have been obvious to use a generator like the one taught by Stern (which is reportedly capable of generating energy in a range of 250 kHz to 100 MHz) to generate a 460 kHz to supply to electrodes, as taught by Makower, for the reasons I discussed for claim 9 in Grounds I and III above.

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

339. As I explained above for limitation 9[b] in Ground I, Stern discloses *a cable coupled to the handle for plugging the handle into the radiofrequency generator*. Thus, it would have been obvious to incorporate *a cable coupled to the handle for plugging the handle into the radiofrequency generator* for the reasons I explained above for limitation 9[b] in Ground I and limitation 9[a] in Ground V.

340. For these reasons, it is my opinion that claim 9 is obvious in view of Edwards-'535, Stern, and Edwards-'886.

2. Claim 10

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

341. Claim 10 depends from claim 9. Therefore, I incorporate by reference my discussion of claim 9.

342. As I explained in claim 10 in Ground I, Edwards-'535 teaches this limitation. Edwards-'886 likewise teaches that the generator 38 (i.e., *radiofrequency generator*) is configured to run with “four independent radio frequency channels. Each channel is capable of supplying up to 15 watts of radio frequency energy” (i.e., *configured to run at a power of between 5 and 75 watts*). Ex.1016-Edwards-'886, 36:66-37:10. It would have been obvious to operate a generator like that disclosed

by Stern to deliver power of up to 15 watts to Makower's teaching of electrodes for the reasons I discussed above for claim 9 in Ground V and claim 10 in Ground III.

343. For these reasons, it is my opinion that claim 10 is obvious in view of Makower, Stern, and Edwards-'886.

X. AVAILABILITY FOR CROSS-EXAMINATION

344. In signing this declaration, I recognize that the declaration will be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I also recognize that I may be subject to cross examination in the case and that cross examination will take place within the United States. If cross examination is required of me, I will appear for cross examination within the United States during the time allotted for cross examination.

XI. RIGHT TO SUPPLEMENT

345. I reserve the right to supplement my opinions in the future to respond to any arguments that Patentee raises and to take into account new information as it becomes available to me.

XII. JURAT

346. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: January 15, 2024



Gregory T. Martin, Ph.D.

APPENDIX A

Gregory T. Martin, Ph.D.

2 Shipway Place, Boston, MA 02129 USA, +1-617-429-3911, greg.martin@tremontconsult.com

Summary:

Dr. Martin is an executive, entrepreneur, engineer and scientist with 25 years of experience developing products, commercializing medical technologies and building successful businesses in start-ups and publicly-traded corporations. He has a track record of success in executive management, team building, change/crisis management, business development, strategic partnerships, product launch, marketing, operations, program management, product development, R&D, clinical research, and regulatory affairs.

Professional Experience:**Tremont Consulting, LLC**

Boston, MA

Principal

2012-2013, 2018-present

Provide consulting services on a variety of topics to the medical device and diagnostics industry including strategy, fund raising, opportunity analysis, due diligence, regulatory strategy, program/portfolio management, product development, technology development, R&D, grant writing and expert witness testimony (patent & product liability). Clients include startups, corporations, law firms and investment firms.

- Recent engagements include surgical robotics, infectious disease diagnostics & therapies (including SARS-CoV-2 and sepsis), endoscopy, neurodegenerative disease, neuro-oncology, neurovascular devices, laparoscopic surgery, tissue ablation, ICU monitoring, transdermal drug delivery, & women's health.
- Can act as a stand-in CTO/COO, team mentor and Entrepreneur in Residence.

Boston University, Department of Biomedical Engineering

Boston, MA

Senior Lecturer (part time)

2019-2020

- Course Director and Instructor for BE695: Advanced Biomedical Design & Development (graduate)

Opsonix, Inc.

Wakefield, MA

Vice President of Research and Development

2017- 2018

Developed a device-biologic combination product and companion diagnostic to remove pathogens and endotoxins from blood via an extracorporeal circuit to treat sepsis. Opsonix was spun out of the Harvard Wyss Institute with \$9 million investment from Baxter Ventures and Hansjörg Wyss.

Responsibilities

- Led the product development, design verification and preclinical studies
- Provided periodic technical updates to the BOD
- Identified and engaged clinical sites

Accomplishments

- Implemented a cloud-based design control and PLM system in compliance with FDA QSR
- Directly interfaced with the FDA via 4 presubmission meetings & associated interactions
- Obtained FDA IDE approval for a first in human clinical study with 15 patients, January 2018

Boston University, Department of Biomedical Engineering

Boston, MA

Senior Lecturer and Director of the Coulter Translational Research Program

2013 – 2017

Led a Coulter Foundation program to translate medical device & diagnostics to commercialization.

Responsibilities

- Solicited & evaluated grants, selected awardees, mentored investigators, & managed progress
- Instructor for BE467: Product Design & Innovation in Biomedical Engineering (undergraduate)
- Instructor for BE695: Advanced Biomedical Design and Development (graduate)
- Instructor for Health Care Entrepreneurship for BU medical students at the School of Business

Accomplishments

- Deployed approximately \$1 million each year to provide gap funding for technology translation
- Facilitated the formation of 3 startup companies with the Office of Technology Development
- Created and delivered a seminar series on medical device commercialization to the faculty
- Taught medical device product development to over 300 students in total

Hologic, Inc. (NASDAQ: HOLX)

Marlborough, MA

Vice President of Research and Development

2007- 2011

A leading women's health company with specialization in laboratory diagnostics, digital mammography, bone densitometry and minimally invasive surgical devices with annual revenue of over \$1.7 billion. Responsible for R&D in the Surgical Products Division for all released and new products. The released products account for approximately \$300 million in annual revenue.

Accomplishments

- Led the release of the next generation products (capital equipment with software and invasive surgical devices) which increased divisional revenue and significantly improved product quality
- Conceived, initiated and led numerous R&D and new product development projects
- Expanded the research and product development pipeline to include organic innovation
- Partnered with development/start-up companies to expand technology and product portfolio
- Key member of senior management team that grew annual divisional revenue to \$300 million
- Key member of the deal team for the \$352 million acquisition of Interlace Medical, Inc.
- Led technical due diligence for numerous potential acquisition candidates.
- Created a program management function to manage product portfolio and development
- Integrated the R&D functions from acquisition sites into the Marlborough facility

Responsibilities

- Managed approximately 45 direct and indirect reports within the R&D department
- Directly/indirectly guided over 100 people in matrix functions that supported R&D programs
- Managed relationship with off-shore high volume manufacturing facility
- Provided mentoring and oversight for manufacturing engineering and process development
- Key member of senior management team that formulated divisional strategy and set goals
- Formulated and implemented R&D and product development strategy
- Set division and departmental goals and priorities related to R&D
- Provided periodic updates to the Board of Directors
- Ensured the department achieved annual goals and budget targets
- Directly interfaced with FDA to support applications/amendments for PMA Class 3 devices
- Reported to the division general manager

Cytec Corporation (NASDAQ: CYTC)

Marlborough, MA

Vice President of Research and Development

2007

A leader in women's health with annual revenue of \$700 million. Responsible for R&D in the medical device (Cytec Surgical Products) division for all released and new products. CSP marketed world-class products to treat menorrhagia (NovaSure®), breast cancer with radiotherapy (MammoSite®), and brain cancer with radiotherapy (GliaSite®). Cytec merged with Hologic in October 2007.

Accomplishments

- Created and lead the divisional R&D department at corporate headquarters
- Led the transition of the R&D department from California to Massachusetts
- Built an outstanding medical device R&D department, hired entire department staff
- Created an entrepreneurial environment to enhance innovation
- Led technical due diligence for acquisitions, venture investments & development agreements
- Key member of the deal team for the \$215 million acquisition of Aadiana
- Led the integration of R&D facilities, resources and programs obtained via acquisition
- Created close cross functional collaboration with Marketing, Sales, and Operations

Responsibilities

- Managed R&D at 3 national sites
- Created and managed product pipeline/portfolio
- Formulated research and product development plans, and budgets
- Set division and departmental goals and priorities related to R&D
- Responsible for ensuring that R&D achieved annual goals and budget targets
- Managed development agreements with partner start-up companies
- Reported to the division president

Hemedex, Inc.

Cambridge, MA

Co-founder, Chief Technology Officer and Corporate Director

2000-2007

A medical device start-up that developed and commercialized a device to monitor cerebral blood flow at the bedside in neurosurgery patients with traumatic brain injury, cerebro-vascular disease and stroke. Responsible for R&D, Engineering, Manufacturing, Regulatory/QA and Clinical Studies.

Accomplishments

- Co-founded this medical device startup company, ran day-to-day operations
- Wrote business plan and gave investor presentations
- Personally responsible for raising \$2.3 million in angel investment
- Key member of the deal team which raised a total of \$12.2 million
- Created a partnership with a Korean life sciences company (Hanmi) for distribution in Asia
- Engaged, negotiated & signed an exclusive distribution agreement with J&J (Codman Division)
- Co-inventor of core enabling algorithm technologies
- Led the product development for the company's flagship patient blood flow monitor that included a minimally invasive catheter and a monitor with its associated software
- Implemented ISO 9000/13485 and oversaw the transition to ISO 13485:2003
- Recruited and collaborated with Key Opinion Leaders
- Marketed products at national surgery conferences and sold devices into key accounts
- Trained surgeons, nurses and ICU staff on the use of the device for target indications

Responsibilities

- Member of the Board of Directors (5 members total: 3 investors, 2 management)
- Hired entire technical staff, consultants and VP level personnel
- Hired key vendors, engineering firms, contract manufacturers and service providers
- Conceived, planned, and executed technology, research and product development projects
- Supervised entire technical staff (mechanical, electrical, software engineers and technicians)
- Ensured product development complied with applicable FDA and international standards
- Responsible for 510(k) FDA submissions and CE Mark applications

Thermal Technologies, Inc.

Cambridge, MA

Vice President of Research and Development and Corporate Director

1998-2000

A medical device incubator/contract research company that developed technologies for the measurement of tissue blood flow, cardiac output, tissue oxygen concentration, radiotherapy dosage and tumor temperature for use in hyperthermia therapy. Responsible for the conception, funding, and execution of original research programs.

- As Principal Investigator awarded \$3.6 million in grants from US National Institutes of Health
- Licensed core technologies from M.I.T.
- Led the development of experimental preclinical and clinical devices
- Managed an interdisciplinary team of mechanical, electrical, biomedical & software engineers
- Identified and investigated potential clinical applications for the company's technologies
- Developed international collaborations with clinicians and researchers
- Trained clinical collaborators & set up clinical research sites
- Managed contract research projects with industry, academic and government clients

Harvard-M.I.T. Division of Health Sciences and Technology at M.I.T.

Cambridge, MA

Research Staff Scientist (non-tenure track)

1996-1998

In collaboration with the Dana-Farber Cancer Institute, led a team of engineers to develop computer-based tools to aid in the treatment of tumors using hyperthermia (heat) induced by high power ultrasound. Also, wrote grants, made conference presentations, supervised graduate thesis students.

M.I.T. Biomedical Engineering Center

Cambridge, MA

Post-Doctoral Researcher

1995-1996

Researched novel technology to apply electroporation to transdermal drug delivery.

Other Activities:

MIT Enterprise Forum of Cambridge Cambridge, MA
 Vice Chair, Board of Directors 2015-present

Fractyl Laboratories, Inc. Waltham, MA
Founding member of the Business and Scientific Advisory Board 2011-2014
 Advised this VC-backed medical device start-up company on the design and testing of its duodenal ablation device to treat Type II Diabetes

Maternova Providence, RI
Advisory Board Member 2011-present
 Advise this NGO on medical devices for maternal/neonate health in developing countries.

Mass Challenge Boston, MA
Volunteer Mentor 2010, 2013
 Mentor to start-up companies in the life sciences sector, including 2013 winner Hemova Medical.

M.I.T. Venture Mentors Cambridge, MA
Volunteer Mentor 2006-2009
 Advised and mentored faculty, alumni and students on the commercialization of medical devices

US National Institutes of Health Bethesda, MD
Study Section Member, Brain Disorders and Clinical Neurosciences (BDCN-10) 1999-2005
 Reviewer for bioengineering grants submitted by companies, hospitals, and universities.

Seacoast Technologies, Inc. Portsmouth, NH
Scientific Advisory Board Member and Consultant 2001-2005
 A VC funded start-up company that developed devices for neuro-protection after stroke using local, profound tissue cooling.

CryoCath Technologies, Inc. (Toronto Stock Exchange: CYT) Montreal, Quebec Canada
Scientific Advisory Board Member and Consultant 1996-1998
 Advised the CEO and Board of Directors on the scientific direction of the device development.
 CryoCath was acquired by Medtronic in September 2008 for \$380 million.

World Health Organization Geneva, Switzerland
Consultant and Principal Investigator 1990-1993

Education:

Massachusetts Institute of Technology Cambridge, MA
Doctor of Philosophy Mechanical Engineering June 1995
Master of Science Mechanical Engineering June 1991
Bachelor of Science Mechanical Engineering June 1988

Executive Education:

University of Chicago, Booth School of Business, Chicago, IL
 High Performance Leadership, Negotiation, and Strategic Business Leadership March 2010

Publications and Patents:

- More than 20 peer-reviewed scientific, engineering, and clinical publications
- 17 invited presentations.
- 9 issued US patents
- <https://scholar.google.com/citations?hl=en&user=sTxPvIAAAAAJ>

APPENDIX B

Appendix B: Materials Considered

Exhibit No.	Description
1001	U.S. Patent No. 11,033,318 (“’318 patent”)
1003	File History of U.S. Patent No. 11,033,318
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”)
1015	U.S. Patent No. 6,033,397 (“Laufer”)
1016	U.S. Patent No. 6,273,886 (“Edwards-’886”)
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”)
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”)
1033	U.S. Patent No. 5,562,720 (“Stern”)
1034	U.S. Patent Application No. 2007/0287994 (“Patel”)

Martin Declaration: Appendix B (Materials Considered)

Exhibit No.	Description
1035	M. Philipppson, Principles of Electrical Resistance of Living Tissue, BULL. CL. SCI. ACAD. R. BELG. ser. 5, vol. 7 (1921) (English Translation) (“Philipppson”)
1045	U.S. Patent No. 5,507,725 (“Savage”)
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”)
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APPENDIX C

Appendix C (Challenged Claims)

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

Claim No.	Challenged Claim Language	Grounds for Finding Claim Invalid
1[pre]	A device for delivering energy to a nasal airway to improve nasal airflow, the device comprising:	<u>Ground I</u> <u>Ground IV</u>
1[a]	a handle;	
1[b]	a shaft extending from one end of the handle;	
1[c]	a treatment element coupled with a distal end of the shaft, sized to be inserted into a nostril, and configured to change from a first configuration to a second configuration, wherein the treatment element comprises a tissue treatment surface;	
1[d]	an array of multiple pairs of bipolar radiofrequency electrodes disposed along the treatment surface of the treatment element;	
1[e]	multiple radiofrequency output channels connected with the multiple pairs of bipolar radiofrequency electrodes, wherein each pair of the multiple pairs of bipolar	

Martin Declaration: Appendix C (Challenged Claims)

Claim No.	Challenged Claim Language	Grounds for Finding Claim Invalid
	radiofrequency electrodes is connected with a respective one of the multiple radiofrequency output channels; and	
1[f]	multiple sensors on the tissue treatment surface, wherein the multiple sensors are selected from the group consisting of impedance sensors, electrodes and thermocouples.	
4	The device of claim 1, wherein the treatment element comprises multiple segments that are expandable from the first configuration to the second configuration.	<u>Ground I</u> <u>Ground IV</u>
5	The device of claim 4, wherein at least one pair of the multiple pairs of bipolar radiofrequency electrodes is coupled with each of the multiple segments.	<u>Ground I</u> <u>Ground IV</u>
6	The device of claim 4, wherein the multiple segments comprise a shape-memory alloy material configured to expand to a desired size and shape.	<u>Ground II</u> <u>Ground IV</u>
9[a]	The device of claim 1, further comprising: a radiofrequency generator configured to receive sensed signals from the multiple sensors and deliver radiofrequency energy separately to each of the multiple radiofrequency output channels in the form of a 460 KHz sinusoid wave; and	<u>Ground I</u> <u>Ground III</u> <u>Ground V</u>
9[b]	a cable coupled to the handle for plugging the handle into the radiofrequency generator.	

Martin Declaration: Appendix C (Challenged Claims)

Claim No.	Challenged Claim Language	Grounds for Finding Claim Invalid
10	The device of claim 9, wherein the radiofrequency generator is configured to run at a power of between 5 and 75 watts.	<u>Ground I</u> <u>Ground III</u> <u>Ground V</u>
12	The device of claim 1, wherein the radiofrequency electrodes comprise non-penetrating electrodes.	<u>Ground I</u> <u>Ground IV</u>
13	The device of claim 1, wherein the multiple pairs of bipolar radiofrequency electrodes, the multiple radiofrequency output channels and the multiple sensors are organized into multiple subsystems, and wherein each of the multiple subsystems comprises one of the multiple pairs of bipolar radiofrequency electrodes, one of the multiple radiofrequency output channels and one of the multiple sensors.	<u>Ground I</u> <u>Ground IV</u>
15	The device of claim 1, wherein the multiple pairs of bipolar radiofrequency electrodes comprise two rows of electrodes.	<u>Ground I</u> <u>Ground IV</u>
16	The device of claim 1, wherein each of the multiple sensors is coupled with a respective one of the multiple radiofrequency output channels.	<u>Ground I</u> <u>Ground IV</u>
17	The device of claim 1, wherein the multiple pairs of bipolar radiofrequency electrodes are connected to one another and to the multiple radiofrequency output channels in a multiplexed configuration.	<u>Ground I</u> <u>Ground IV</u>