

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEURENT MEDICAL INC. & NEURENT MEDICAL LTD.

Petitioners,

v.

AERIN MEDICAL, INC.

Patent Owner.

Case No. IPR2024-00282

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

**DECLARATION OF DR. GREGORY T. MARTIN
REGARDING CLAIMS 1-4 AND 7-9 OF
U.S. PATENT NO. 11,766,286**

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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. 11,766,286 (the “’286 patent”). I understand that Petitioners are challenging claims 1-4 and 7-9 of the ’286 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 '286 patent and have had no contact with the named inventors of the '286 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 '286 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 '286 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.B (Relevant Prosecution History), the '286 patent was filed on May 21, 2021, and claims priority to a series of patent applications, starting with provisional application 61/496,930 filed on June 14, 2011. *See* Ex.1001-USP286, Cover. Therefore, I understand the claimed priority date is June 14, 2011. I do not offer any opinion as to whether the '286 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 21, 2021.

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 all 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 '286 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 '286 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 '286 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 '286 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.1010-Edwards-’535, 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.1017-Chen, 240; Ex.1033-Stern, 3:12-15, 3:29-37. Other systems used RF energy to heat liquid, where the heated liquid then transferred heat to the tissue or produced ionization, which destroyed the tissue. Ex. 1038-Thapliyal, 26:12-40, 4:38-58; Ex.1040-Kong, 215. Some devices were capable of doing both. *See, e.g.*, Ex.1038-Thapliyal, 26:12-44.

36. As an example, RF energy was applied to the nasal cavity to ablate nasal tissue well before the '286 patent. A clinical review paper authored by Coste

reports that at least ten years before the '286 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, and nasal obstruction secondary to non-allergic or allergic rhinitis (Ex.1031-Hytönen, Abstract), or to shrink enlarged tissue or remove a blockage (Ex.1010-Edwards-'535, Abstract; Ex.1023-Coste, 894; Ex.1031-Hytönen, Abstract). RF ablation had also been used to improve nasal airflow. Ex.1010-Edwards-'535, 4:53-67.

37. By the 2000s, there were several RF devices commercially used within the nose. Ex.1021-Makower, ¶¶ [0020]-[0021], [0038]-[0040]; *see also* Ex.1042-Bäck, Abstract, 1808; Ex.1044-Lee, Abstract, 108-109.

38. Also before 2011, RF ablation was being used to treat rhinitis. One way this was done was by targeting the nerves in the nasal cavity. Ex.1040-Kong, 215; Ex.1017-Chen; Ex.1055-Fang; Ex.1056-Liang; Ex.1029-Arora. *See generally* Ex.1031-Hytönen, (surveying effectiveness of RF ablation for various indications, including rhinitis and nasal obstruction).

C. Monopolar and Bipolar RF Electrode Configurations

39. 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 (-).

40. 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).

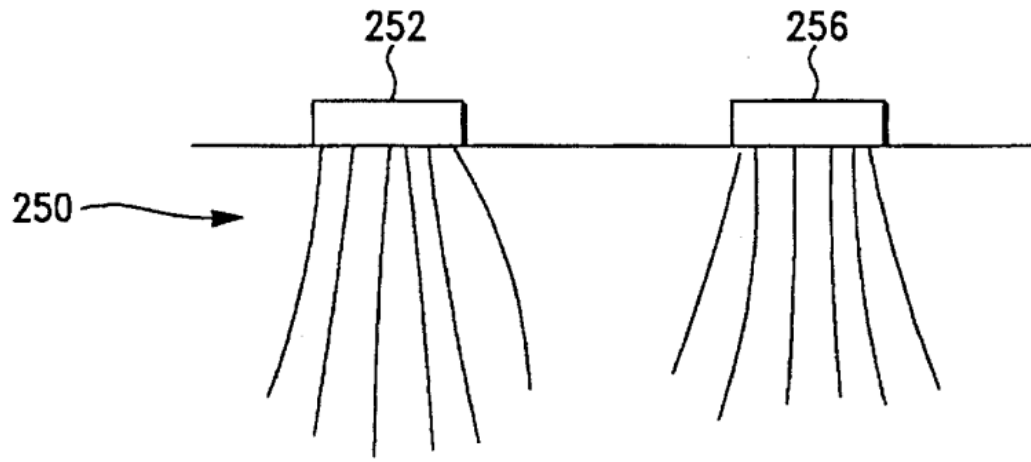


FIG. - 16

41. 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.

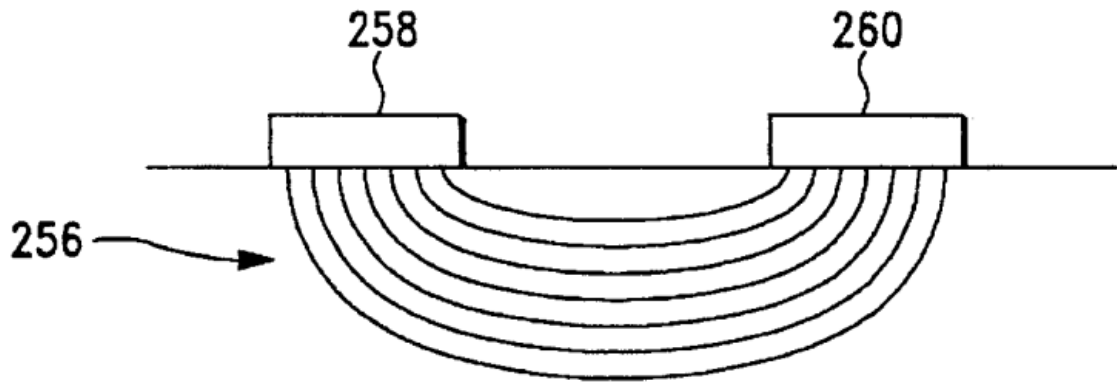


FIG.-17

42. 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 in 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.

43. 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).

44. 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 '286 PATENT

A. Overview of the Patent

45. The '286 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-USP286, 1:33-39, and more specifically by “reshaping, remodeling, strengthening, or changing the properties of the tissues of the nose.” *Id.*, 11:27-30. The specification describes various forms of energy, but the claims are directed to a device that delivers RF energy. *See, e.g., id.*, 6:53-55, Clm.1.

46. 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.*, 9:56-58. 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.*, 27:56-64.

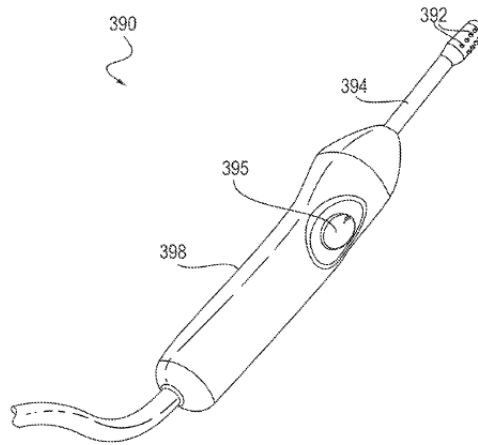
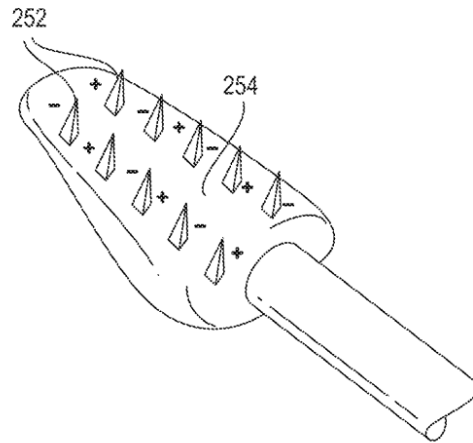


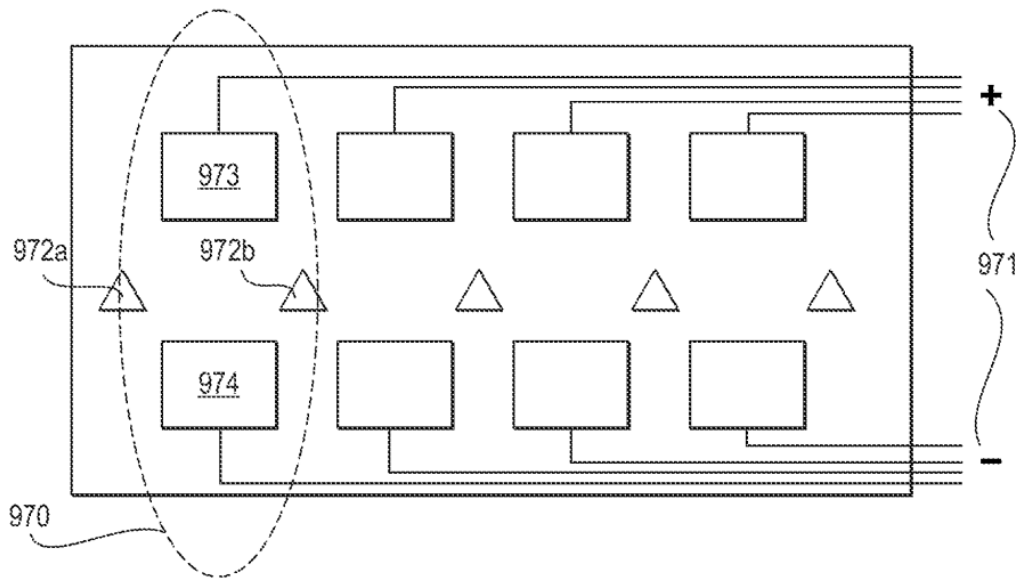
FIG. 18

47. The challenged claims in the '286 patent require a device having electrodes that are configured in a particular way. The electrodes must be 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 one impedance sensor.

48. The '286 patent includes Figure 8F, copied below, which depicts: “electrodes comprising one, two, or many pairs of bipolar needles 252...located on a treatment element.” *Id.*, 24:32-34.



49. 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,” and “controlled RF channels 971.” *Id.*, 49:47-53, FIG.40, Fig.41 (copied below).



50. Claim 1's preamble in the '286 patent recites treatment of rhinitis. My review of the '286 patent did not uncover any specific details regarding how RF energy could have been applied to treat rhinitis. For example, there was no disclosure of specific locations where RF energy could be applied, how long RF energy should be applied, or which electrode arrangements might be successful in treating rhinitis. The '286 patent discloses that its methods and devices "improve nasal airflow" "[w]hatever the cause," and do not specifically focus on treating rhinitis. Ex.1001-USP286, 4:4-16. Allergic rhinitis and non-allergic rhinitis are two of at least six possible causes of poor nasal airflow listed in the '286 patent, the other causes being deviated septum, turbinate hyperplasia, nasal tip ptosis, and nasal polyposis. *Id.*

B. An Overview of the Prosecution History for the '286 Patent

51. The Patent Owner filed the application that issued as the '286 patent on May 21, 2021. Ex.1003-USP286FH, 30, 34-35. 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-USP286, Cover. I have assumed that priority date is correct for my analysis in this Declaration and have not analyzed whether the '286 patent is entitled to that priority date under the law.

52. When the application was filed, Patent Owner filed a preliminary amendment to replace the originally filed claims 1-13 with new claims 14-23. Ex.1003-USP286FH, 214.

53. The examiner rejected claims 14-23 as being unpatentable over claims 1-17 of USP 11,033,318—the parent patent application— on the basis of non-statutory double patenting. *Id.*, 219-22.

54. I understand and have been informed that there may be circumstances where the examination of a parent application provides additional information about the examiner’s reasons for allowing the challenged claims. During prosecution of the parent patent application, the Patent Examiner issued a non-final office action rejecting certain claims over the Makower reference that I rely on in this Declaration. Ex.1063-USP318FH, 506-513. Patent Owner filed a response which included an amendment to the claims to require “pairs” of bipolar radiofrequency electrodes, “multiple radiofrequency output channels connected with the multiple pairs of bipolar radiofrequency electrodes,” and “impedance sensors,”—the same claim limitations that appear in the challenged claims—to distinguish Makower. Ex.1063-USP318FH, 571-88. The examiner then issued a notice of allowance, which did not offer an explanation for the Examiner’s reasons for allowance. *Id.*, 590-613. But as I discuss below, none of these added features were new or non-obvious.

VIII. CLAIM CONSTRUCTION

55. 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.

56. 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.

57. 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.

58. I have been informed and understand that Petitioners are arguing that the second part of claim 1's preamble, the underlined portion of "*A device for delivering energy to a nasal airway to treat rhinitis, the device comprising...*" is not limiting.

59. In my review of the challenged claims, the part of the preamble reciting "*to treat rhinitis*" is not a limitation because it does not recite a structure that is essential, and is unnecessary to give the claim life, meaning, and vitality. The body of the challenged claims recites a structurally complete apparatus that would not change whether the device is improving nasal airflow, like the preamble in the parent '318 application, or whether the device is treating rhinitis, like in the '286 patent. The challenged claims here are very similar to the claims of the parent '318 patent that were found patentable based on the claimed structure. Ex.1063-USP318FH, 571-88, 590-613.

60. For all other claim elements besides the preamble, I will give the claim terms their plain and ordinary meaning, including as understood in the field of the '286 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 '286 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

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

- **Ground I:** Claims 1-3 and 7-9 are rendered obvious by the combination of Edwards-'535 and Stern under 35 U.S.C. §103.
- **Ground II:** Claim 8 is rendered obvious by the combination of Edwards-'535, Stern, and Edwards-'886 under 35 U.S.C. §103.
- **Ground III:** Claims 1-4, 7-9 are rendered obvious by the combination of the combination of Makower, and Stern, and Edwards-'535 under 35 U.S.C. §103.
- **Ground IV:** Claim 8 is rendered obvious by the combination of Makower in view of Stern, and Edwards-'886 under 35 U.S.C. §103.
- **Ground V:** Claims 1-3 and 7-9 are rendered obvious by the combination of Edwards-'535 in view of Stern and Liang.
- **Ground VI:** Claim 8 is rendered obvious by the combination of Edwards-'535 in view of Stern, Liang, and Edwards-'886.
- **Ground VII:** Claims 1-4 and 7-9 are rendered obvious by the combination of Makower in view of Stern, Edwards-'535, and Liang.
- **Ground VIII:** Claim 8 is rendered obvious by the combination of Makower in view of Stern, Edwards-'535, Liang, and Edwards-'886.

62. These grounds demonstrate in detail that claims 1-4 and 7-9 are unpatentable as being obvious in view of the prior art. A copy of the Challenged Claims are attached as Appendix C.

63. Before discussing the specific grounds, I provide below a brief overview of the prior art references asserted in the grounds:

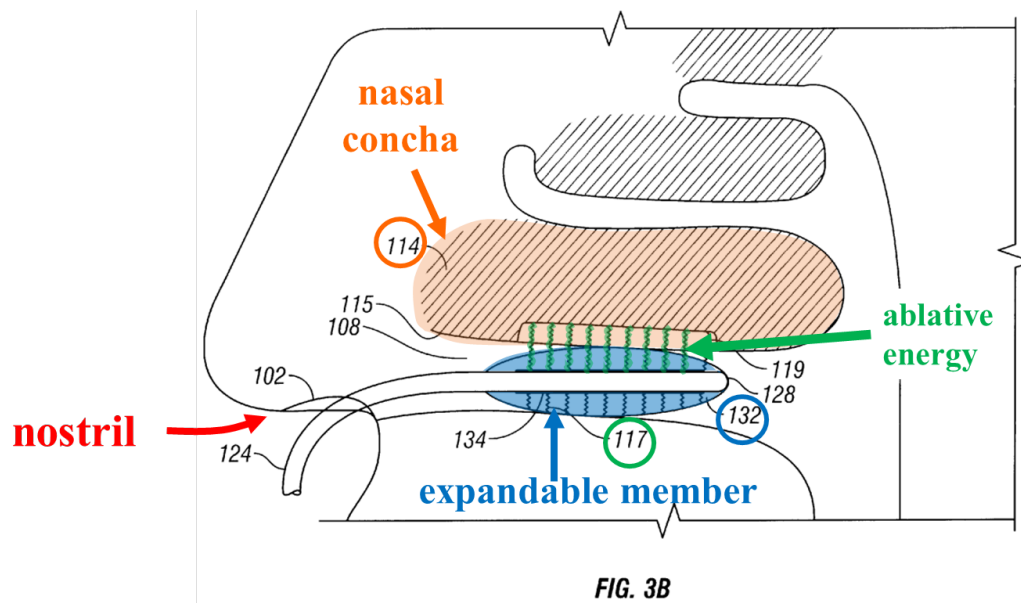
1. Edwards-'535

64. U.S. Patent No. 6,517,535, entitled “Apparatus for Ablating Turbinates,” issued on February 11, 2003 to Edwards-'535 (“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.

65. 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

¹ Claim 1 of the '286 patent claims a “device for delivering energy to a nasal airway to treat rhinitis...” Ex.1001-USP286, Clm.1.

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.



Id., FIG.3B.²

66. 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, 6:66-24, FIGs.3A-4C.

² All annotations added unless otherwise stated.

67. 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.”). Edwards-'535 describes how these sensors could measure different parameters, including impedance and tissue temperature. *Id.*, 9:14-23, 9:46-56.

2. Stern

68. 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.

69. 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.

70. 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.

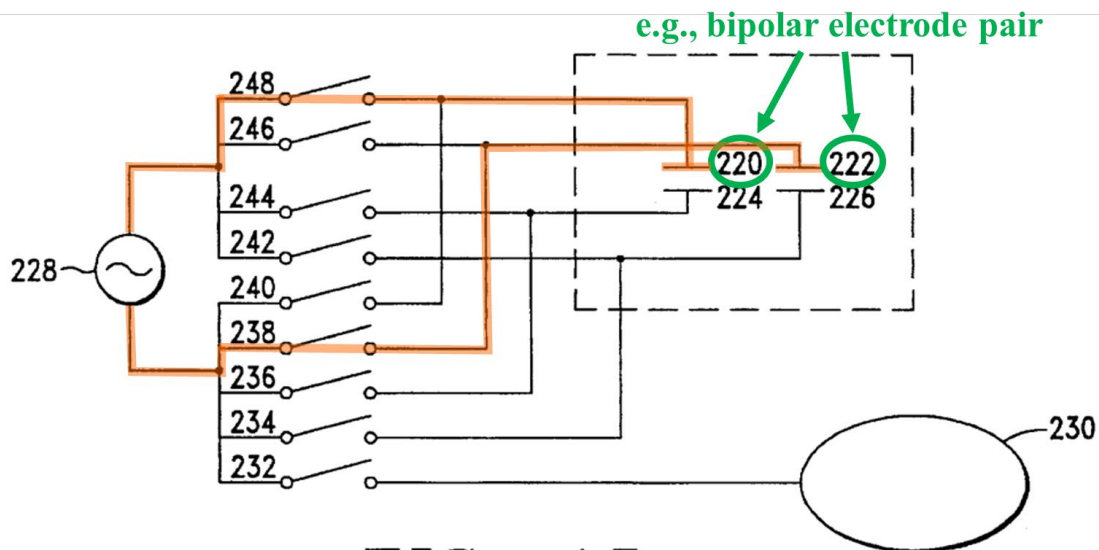
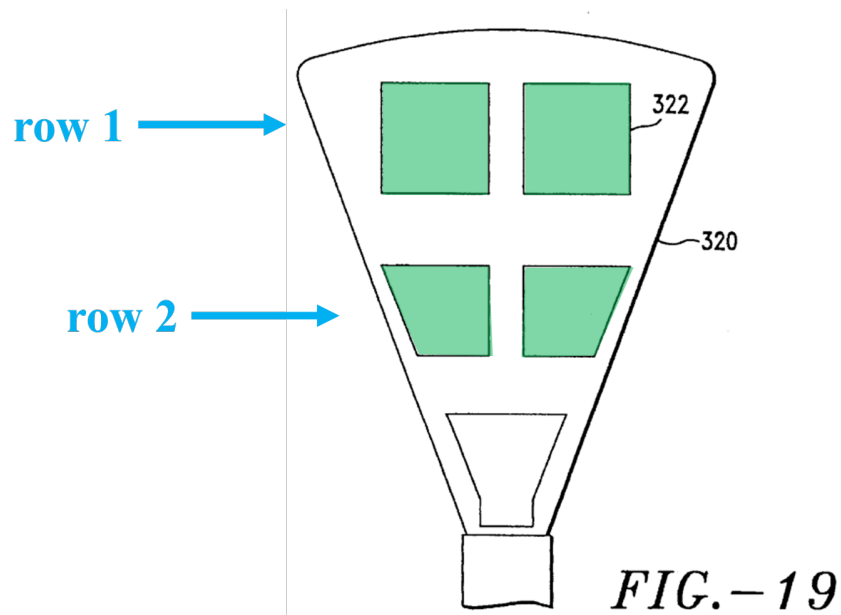


FIG. – 15

71. 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.

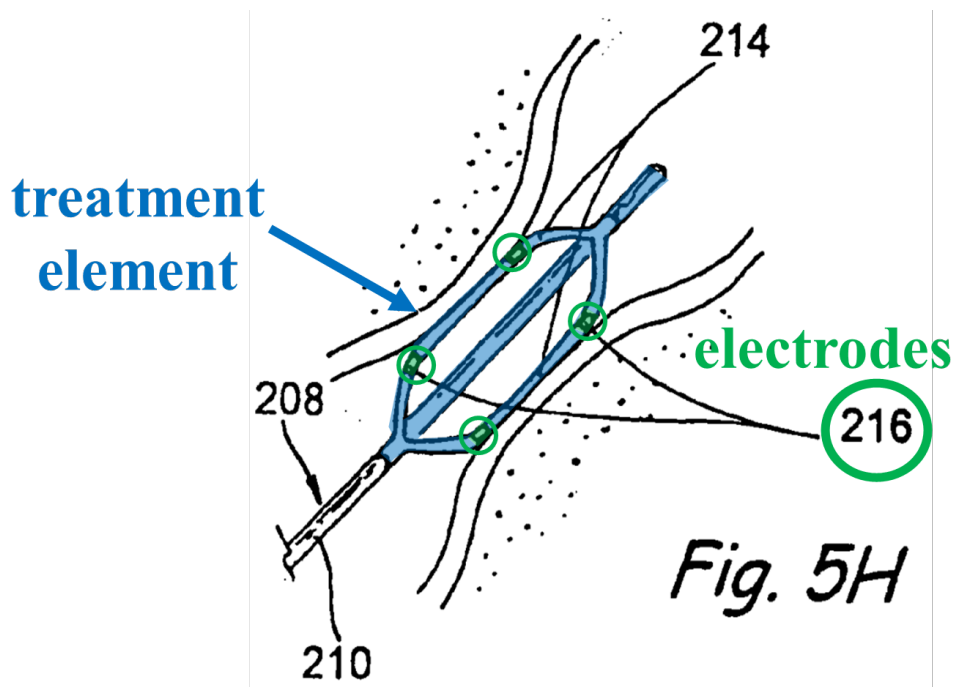


Ex.1033-Stern, FIGs.15, 19.

3. Makower

72. 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.

73. 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. Liang

74. The article titled “Radiofrequency treatment of ethmoidal nerve with allergic rhinitis under nasal endoscopy,” was published in August 1999 in the *Journal of Clinical Otorhinolaryngology*.

75. Liang discloses the results of a clinical study demonstrating that applying RF energy to the nasal airway was a promising technique for treating allergic rhinitis. Ex.1056-Liang, Abstract, 243. Liang explains that RF energy delivery may generate high tissue temperatures and cause thermal coagulation to treat disease. Ex.1056-Liang, 341. Liang also discloses that such RF energy applied to the nose “can cause varying degrees of damage to the deep ethmoidal nerve,”

which may decrease a patient's runny nose symptoms and improve other rhinitis symptoms. Ex.1056-Liang, 342.

76. Liang discusses using a device referred to as the SHP-I, which is described in more detail in a Chinese Utility Model Patent (Ex.1059). The SHP-I has a "main unit" that "includes the power supply, radiofrequency signal generator, power amplifier circuit, timing device, power adjustment circuit, and other electrical components." Ex.1059-Liang-'227, 1. The SHP-I also has an application device that "consists of a metal treatment probe, a gun barrel, a switch, a gun handlebar, and a metal wire" to the main unit. *Id.* To apply RF energy, "[t]he treatment head of the probe comes into contact with the patient's tissues to produce an internal thermal effect at a temperature up to 60°C - 80°C, which causes protein tissues to heat coagulate, dehydrate, shrink, harden, form blood clots, and gradually subside or disappear, leading to necrosis and detachment, achieving the purpose of treatment." *Id.* A drawing representative of the SHP-I is shown below from Figure 1 of the Utility Model:

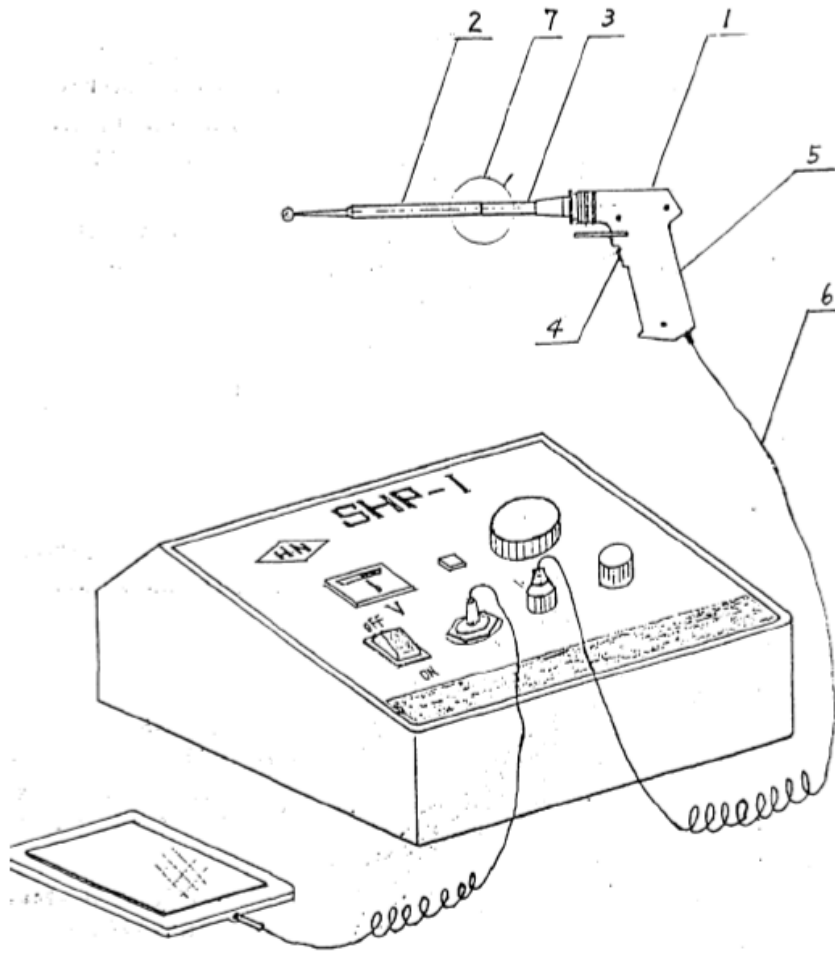


Figure 1

5. Edwards-'886

77. 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.

78. Edwards-’886 teaches “an energy generator, to supply energy to an electrode structure to heat a tissue region.” *Id.*, Abstract. 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 1-3 and 7-9 In View of the Combination of Edwards-’535 and Stern

79. As detailed below, the combination of Edwards-’535 and Stern teaches each limitation of claims 1-3 and 7-9.

1. Claim 1

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

80. Should the parts of the preamble besides “to treat rhinitis” be found to be limiting (which I understand is a legal determination), Edwards-’535 discloses the preamble. If the preamble recites an intended use, the Edwards-’535 device modified by Stern would have been capable of being used to treat rhinitis for the reasons that such use would have been obvious to a person of ordinary skill in the art as I explain below.

81. 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*).³

82. 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.*, 1:21-25, 1:60-2:6, 3:18-36, FIGs.3A-4C. The nasal concha “form at least a portion of the[] nasal passageways,” and are therefore part of the nasal airway. *Id.*, 1:60-2:6.

83. 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 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;

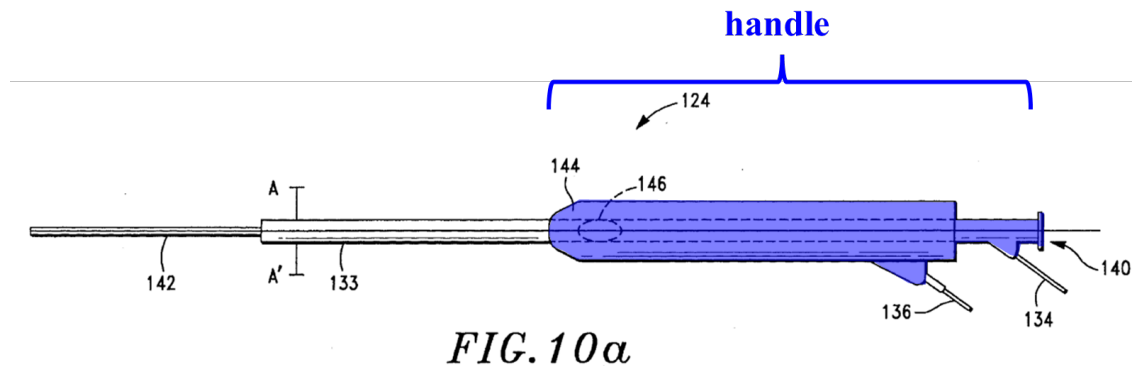
84. Edwards-'535 or Edwards-'535 in view of Stern renders obvious Element 1[a].

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

85. 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 a device like 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. Ex.1010-Edwards-'535, 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.4, 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, 10:32034, FIG.2; Ex.1013-Baker-'980, 11:7-12:6, 13:5-
15, FIG.1.

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



87. 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 below 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

88. 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.

89. 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.4, 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;

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

91. 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*).

92. Here, I focus in particular on the Edwards-'535 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).

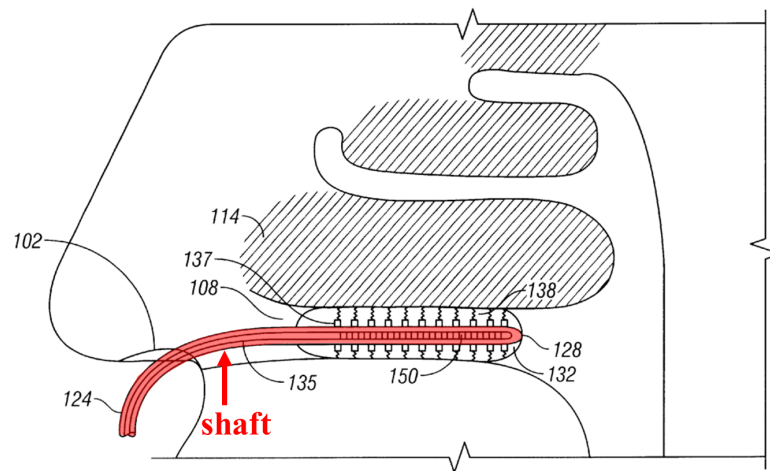
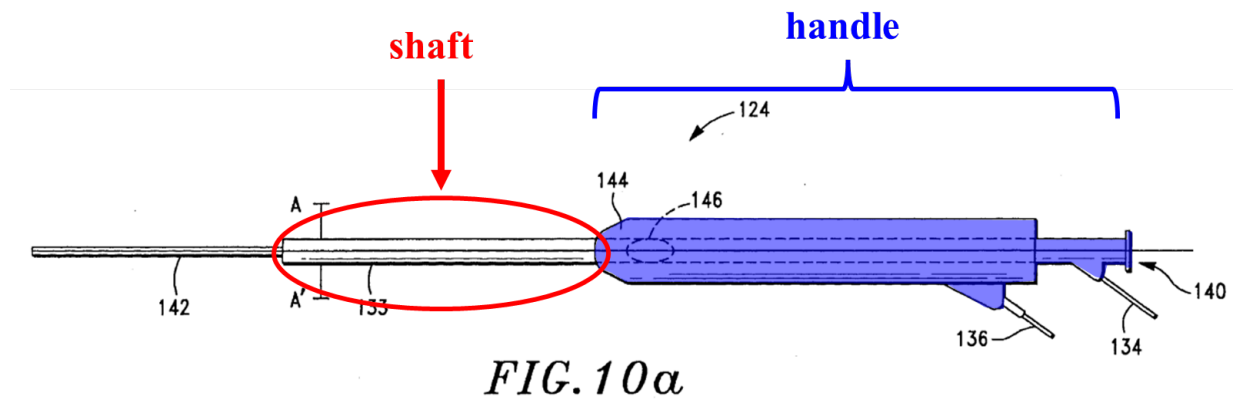


FIG. 3C

93. 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 obvious as a further implementation of Stern’s teachings in Edwards-’535, because, for example, Stern teaches an element (*a shaft*) connected to the distal end (*extending from one end*) of the applicator device 124 (*of the handle*).

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



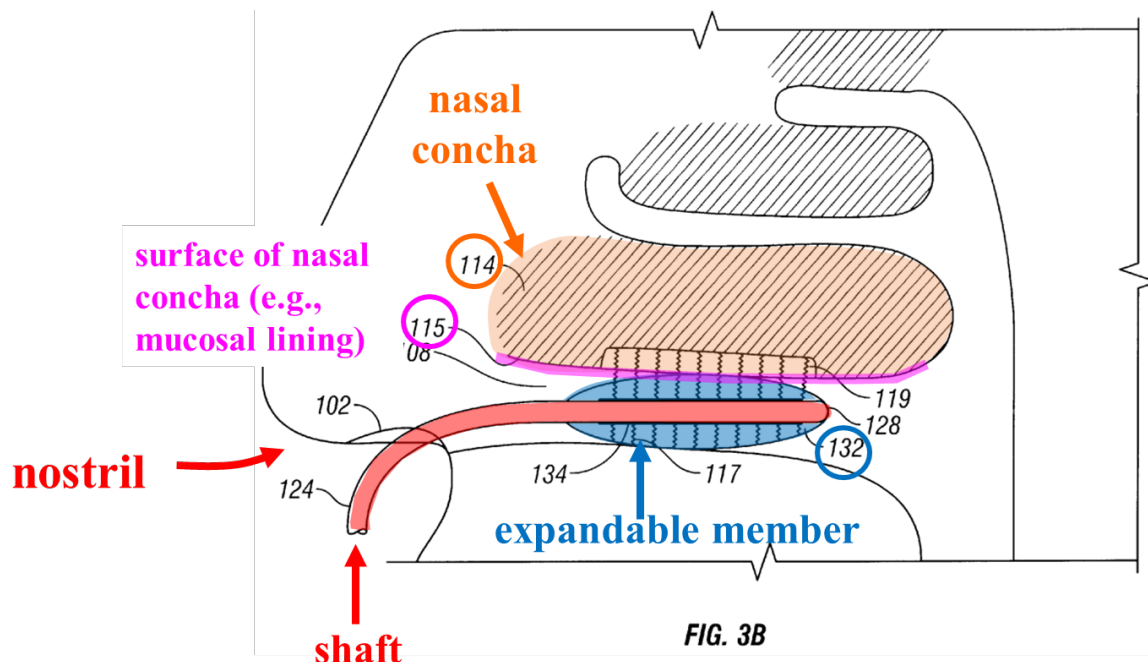
95. Accordingly, once Stern's teaching of a handle is implemented, a person of ordinary skill in the art would have understood Edwards-'535's description of the catheter to be a shaft extending between the handle and the device's distal end, just as Stern discloses. Ex.1010-Edwards-'535, 5:20-26, 5:52-61. 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.4, 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, to contact nasal mucosa lining the nasal airway;**

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

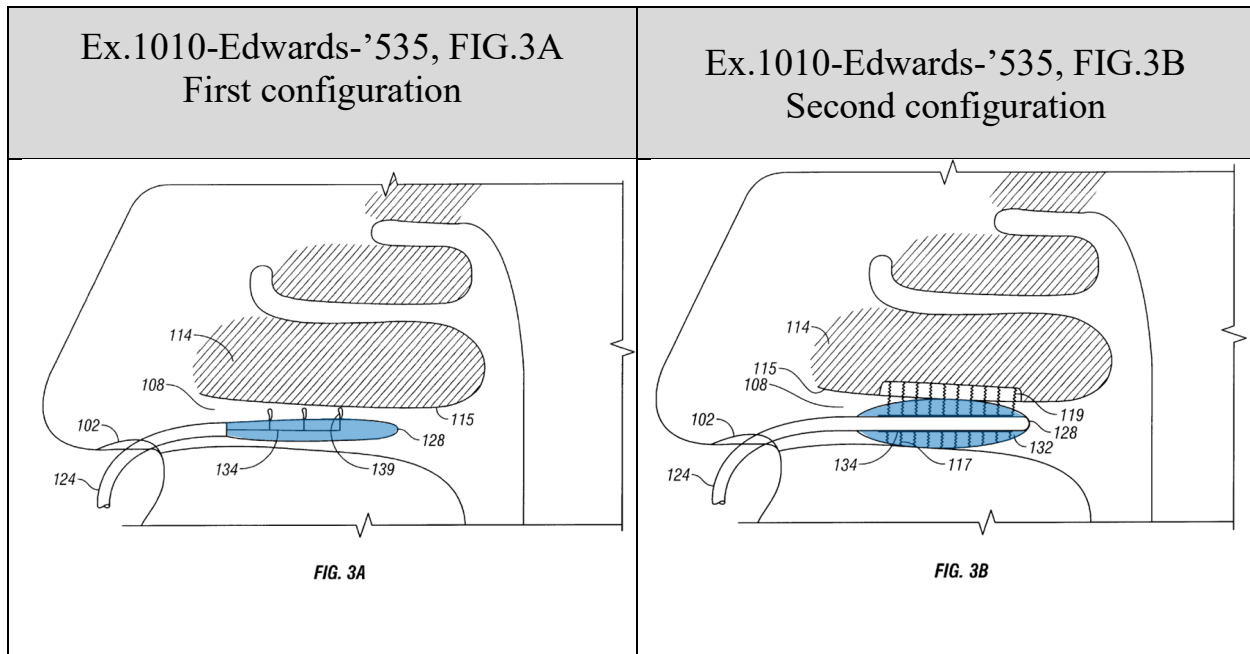
97. Figure 3C from Edwards-'535 is shown below.



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

99. 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.

100. 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.



101. 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.

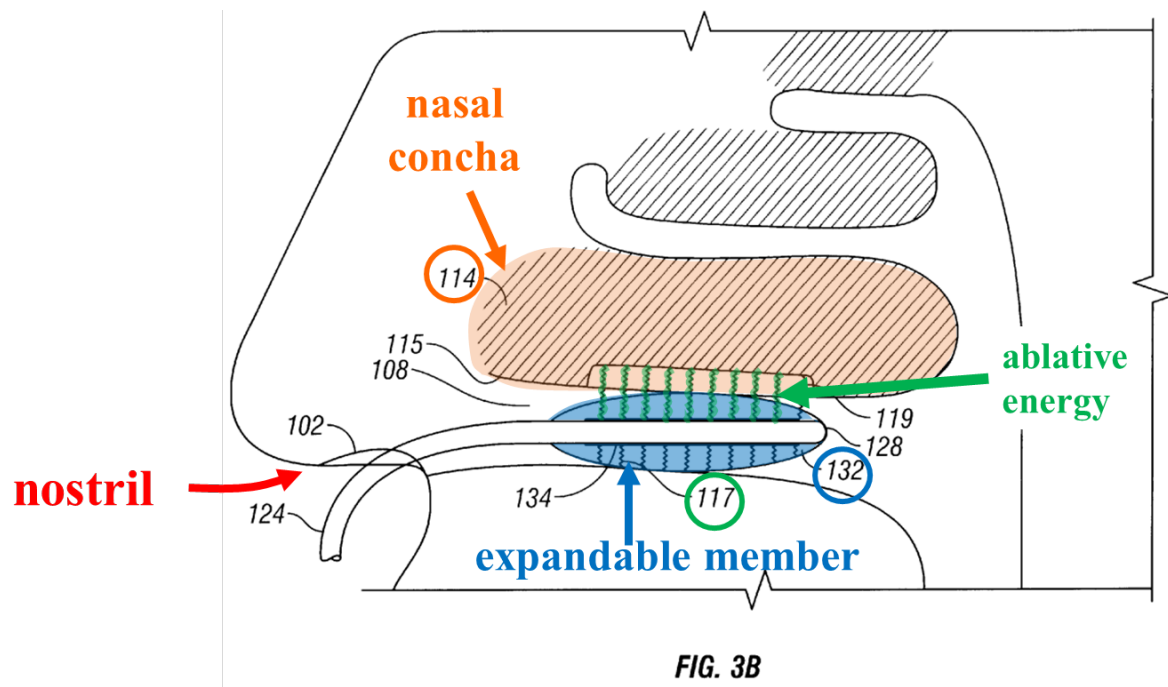
102. The “energy delivery device [134] may be positioned on a surface 147 of the expandable member.” *Id.*, 8:12-16, FIG.6, 8:17-32. “[T]he expandable member 132 is brought into contact with the surface 115 of the nasal concha 114 to be treated.” *Id.* RF energy is then applied to treat the nasal concha 114. Ex.1010-Edwards-’535, 8:50-54. The surface of the nasal concha is lined with a mucus membrane. *See generally* Ex.1023-Coste, 894; Ex.1031-Hytönen, 1258 (“Radiofrequency ablation (RFA) is a relatively new method for the reduction of submucosal tissue. RFA causes fibrosis of the underlying stroma leaving the surface epithelium intact. RF energy creates an elliptical submucosal lesion in soft tissues.”). Therefore, by the expendable member 132 and energy delivery device 134 coming into contact with the nasal concha 114, Edwards-’535 teaches that its treatment element is configured to *contact nasal mucosa lining the nasal airway*.

e. Element 1[d]: multiple pairs of bipolar radiofrequency electrodes disposed on the treatment element;

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

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

105. Edwards-'535 teaches a device where there are "a plurality of energy delivery devices...positioned on the surface of the expandable member [132]." Ex.1010-Edwards-'535, 8:17-32; *see also id.* 5:27-37, 7:33-40, FIG.3. I have shown this below in Figure 3B.



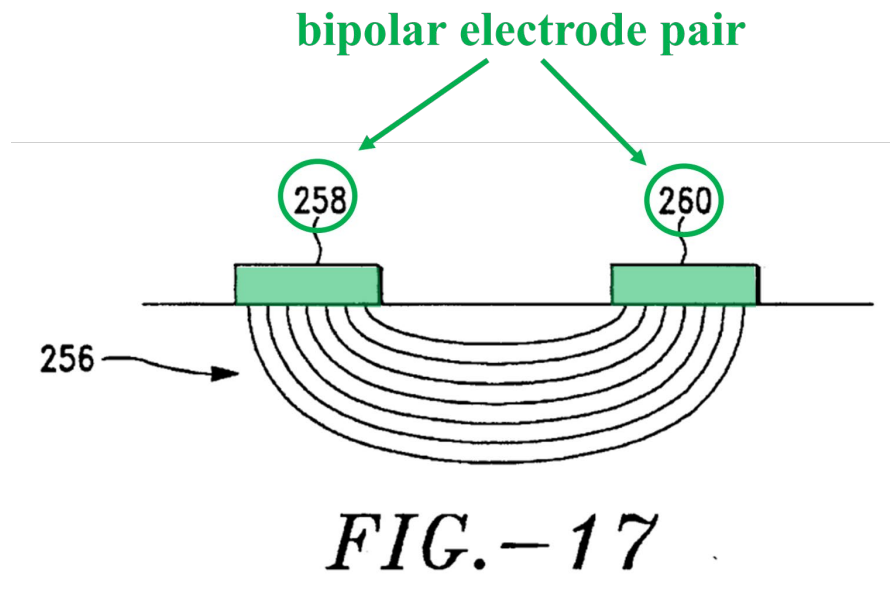
106. Edwards-'535 also describes that in one embodiment, "ring electrodes 156" are "disposed on the surface of the expandable member 132." Ex.1010-Edwards-'535, 8:19-33. A person of ordinary skill in the art would have also been aware of other configurations for a surface energy delivery device. *See, 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. Ex.1010-Edwards-'535, 8:17-32, 8:50-54, 10:30-32, 10:52-61.

107. 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. Ex.1010-Edwards-'535, 10:52-61.

108. 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.

109. Stern discloses “a system of selective delivery of...bipolar RF energy to chosen pairs ... of separate [bipolar] electrodes.” *Id.*, 2:36-40, 3:29-40, 12:7-13:55, Clm.4, FIGs.13, 15, 17, 18. I show an example of a bipolar electrode pair below:

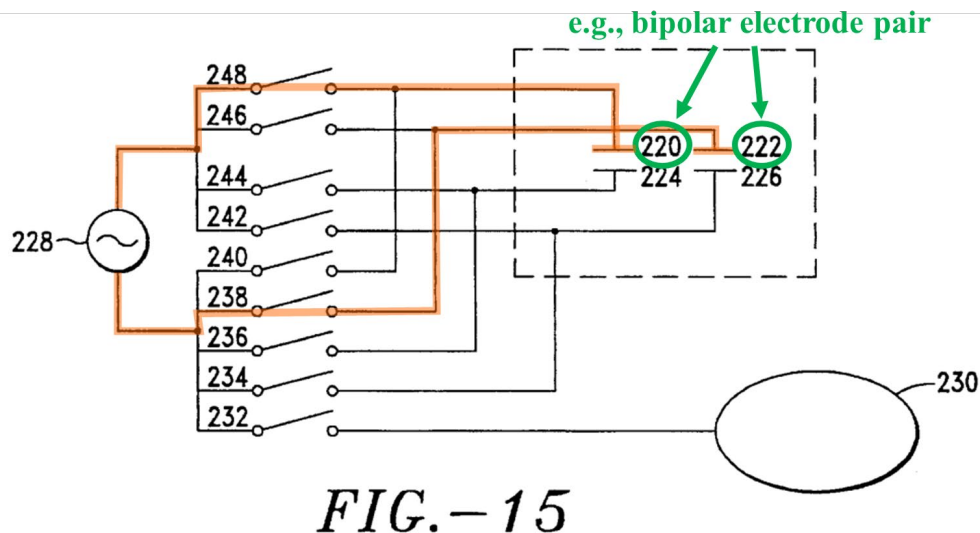


Stern's Figure 17, above, also shows the field lines for the current that travels between the bipolar electrodes. *Id.* 13:13-14. As shown above, current travels from one electrode to another. *Id.*

110. Stern teaches that its RF ablation device may have an expandable member, like Edwards-'535's device, and that 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." *Id.*, 2:36-40

111. 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 switch or 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.



Id., FIG.15.

i. Motivation to Combine and Reasonable Expectation of Success

112. 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. 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 '286 patent and reasonably pertinent to solving the problems addressed in the '286 patent (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. A person of skill in the art would have also been motivated to make such a combination for the reasons below.

113. 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. Also, 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 a heterogeneous surface.

114. 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.

115. 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 also take up less space than multiple generators, and would have been simpler and cheaper than multiple complex voltage sources.

116. 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, 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. *Id.*, 12:38-13:2, FIG.15.

117. 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 discloses.

118. 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”), 12:26-37 (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).

119. 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 or 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. 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.

120. 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.

121. 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.

122. 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.

123. Stern's 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.

124. 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.

125. 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.

126. 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.

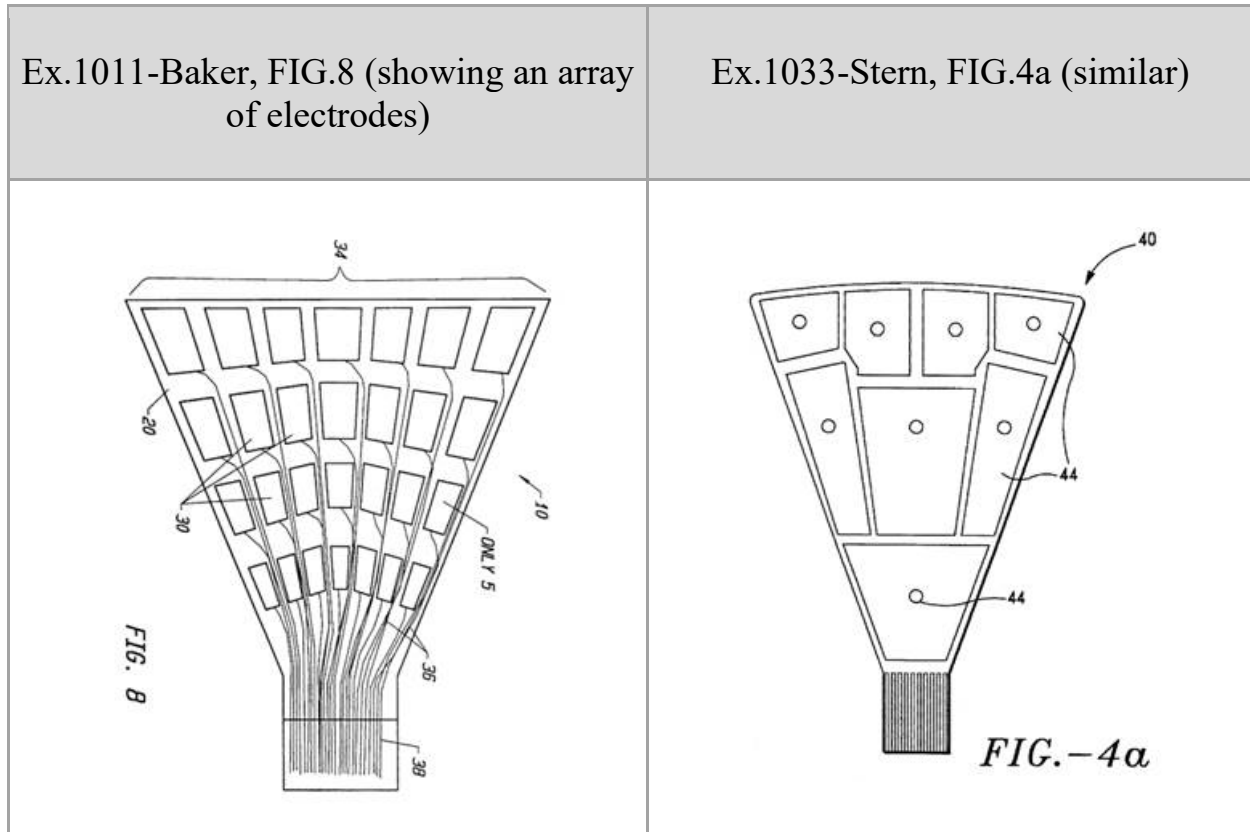
127. Moreover, in the combination, Stern's known techniques would have been used to improve Edwards-'535's similar device in the same way. For example, Edwards-'535 describes an expandable device that has bipolar surface RF electrodes for delivering RF energy to a body cavity, Ex.1010-Edwards-'535, Abstract, 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.

128. 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.*, 8:25-33. 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.

129. 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, 5:67, 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.

130. Baker and Stern both depict very similar devices:



131. 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.

132. 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.

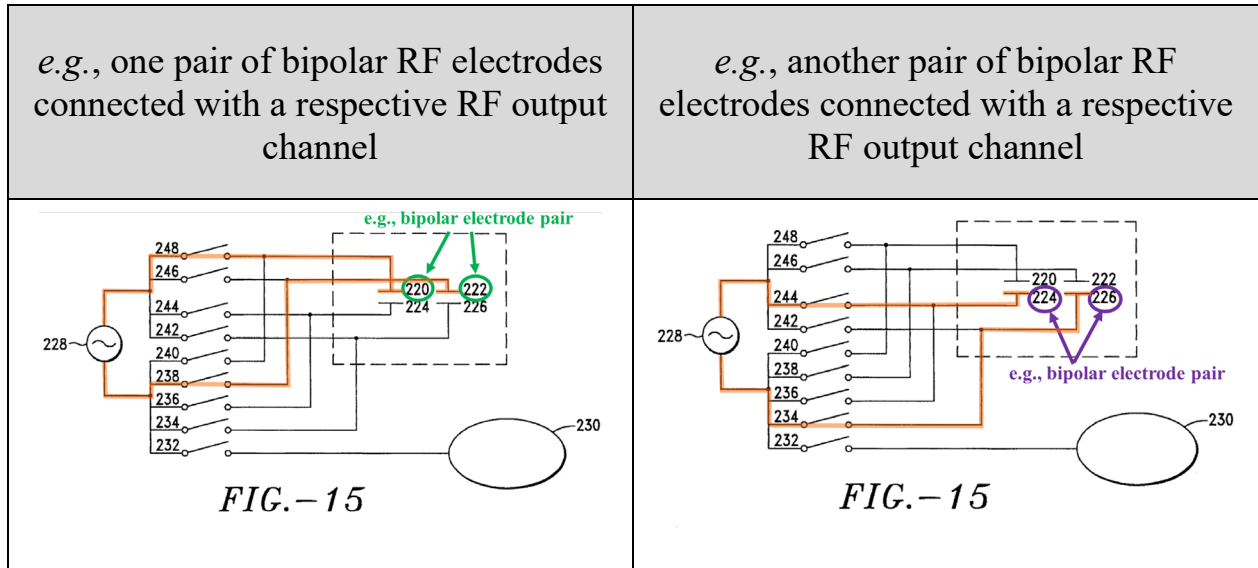
133. Accordingly, applying Stern’s teachings to Edwards-’535 would have been a matter of routine implementation within the skill of a person of ordinary skill

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**

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

135. 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.



136. 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.

137. 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.

138. 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 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

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 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.

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

139. 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 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.

140. 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 heterogeneous surface.

141. 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.

142. 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 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.

143. 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.

144. 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 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 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).

145. 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.

146. 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.

147. 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.

148. 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.

149. 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.

150. 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 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 multiple pairs of bipolar electrodes.

151. 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.

152. 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 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.

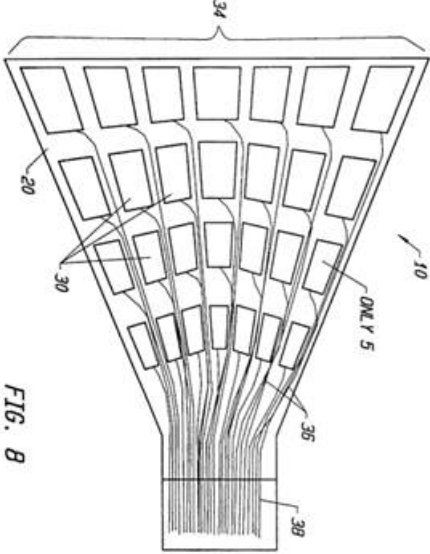
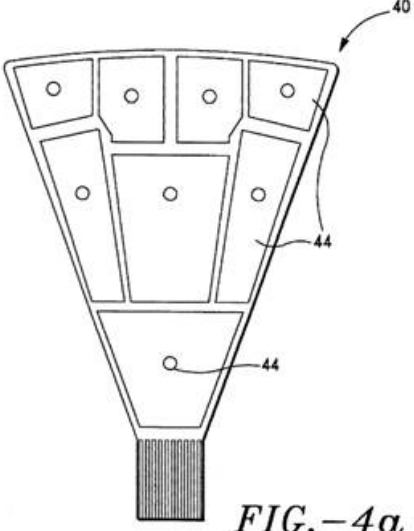
153. Moreover, in the combination, Stern's known techniques would have been used to improve Edwards-'535's similar device in the same way. For example, Edwards-'535 describes an expandable device that has bipolar surface RF electrodes for delivering RF energy to a body cavity, Ex.1010-Edwards-'535, Abstract, 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.

154. 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.

155. 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.

156. Baker and Stern both depict very similar devices:

Ex.1011-Baker, FIG.8 (showing an array of electrodes)	Ex.1033-Stern, FIG.4a (similar)
	

157. 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.

158. 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]: at least one impedance sensor configured to measure impedance in the multiple pairs of bipolar radiofrequency electrodes.

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

160. Edwards-'535 discloses impedance sensors, impedance calculation device 194, and/or monitor 210 (i.e., *at least one impedance sensor*) that make measurements based on the current and voltage delivered to the multiple bipolar electrodes, configured in pairs as taught by Stern (i.e., *configured to measure impedance in the multiple pairs of bipolar radiofrequency electrodes*).

161. For example, Edwards-'535 teaches that multiple sensors may be used to “detect a variety of operating parameters including...the impedance generated.” Ex.1010-Edwards-'535, 9:14-23. The sensors that Edwards-'535 teaches include sense impedance based on the current and voltage delivered to the electrodes. *Id.*, 20:4-8, Fig. 8. Edwards-'535 does not condition its measurements of impedance on monopolar embodiments (*id.*, 9:14-23, 10:4-11, 10:62-11:45) such that Edwards-'535's disclosure of impedance sensing was equally applicable when using electrodes in one or more bipolar pairs as taught by Stern.

162. 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, 55 (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).

163. 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.”

Ex.1010-Edwards-’535, 10:4-11.

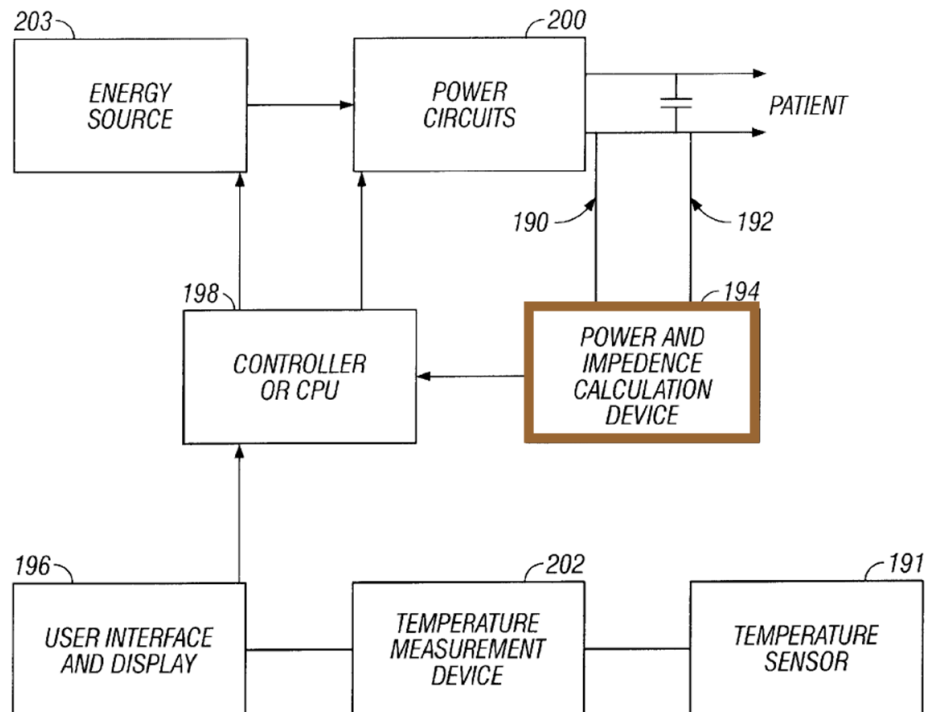


FIG. 8

Id., FIG.8.

164. Edwards-’535 teaches that its system can use an impedance feedback loop “so that the output energy of the energy source is adjusted in relation to the [impedance] sensed by the sensor.” *Id.*, 9:45-55. Edwards-’535 further explains that

“[a] monitor 210 ascertains tissue impedance,” and if the sensed impedance exceeds a particular value, energy delivery is halted, otherwise energy is delivered. Ex.1010-Edwards-535, 11:23-44.

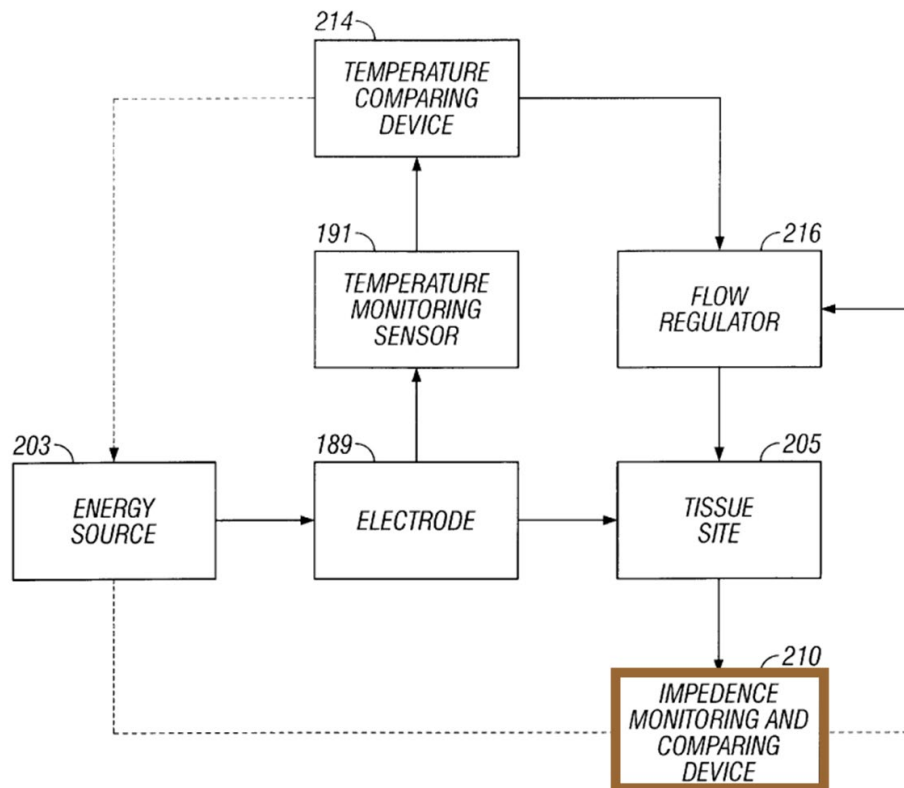


FIG. 10

Ex.1010-Edwards-535, FIG.10; *see also id.* 10:4-11, 11:1-44 (describing the impedance feedback loop system).

165. 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].

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

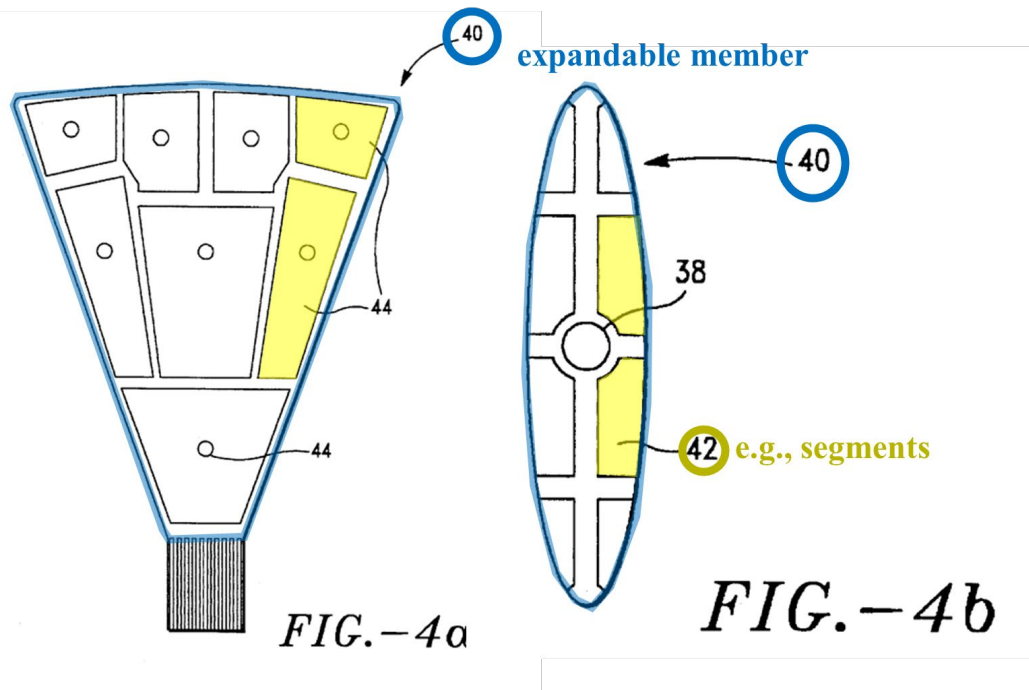
166. Claim 2 depends from claim 1. Therefore, I incorporate by reference my discussion of claim 1.

167. Edwards-'535 in view of Stern teaches the additional requirement of claim 2.

168. 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*).

169. 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.

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



171. 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.

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

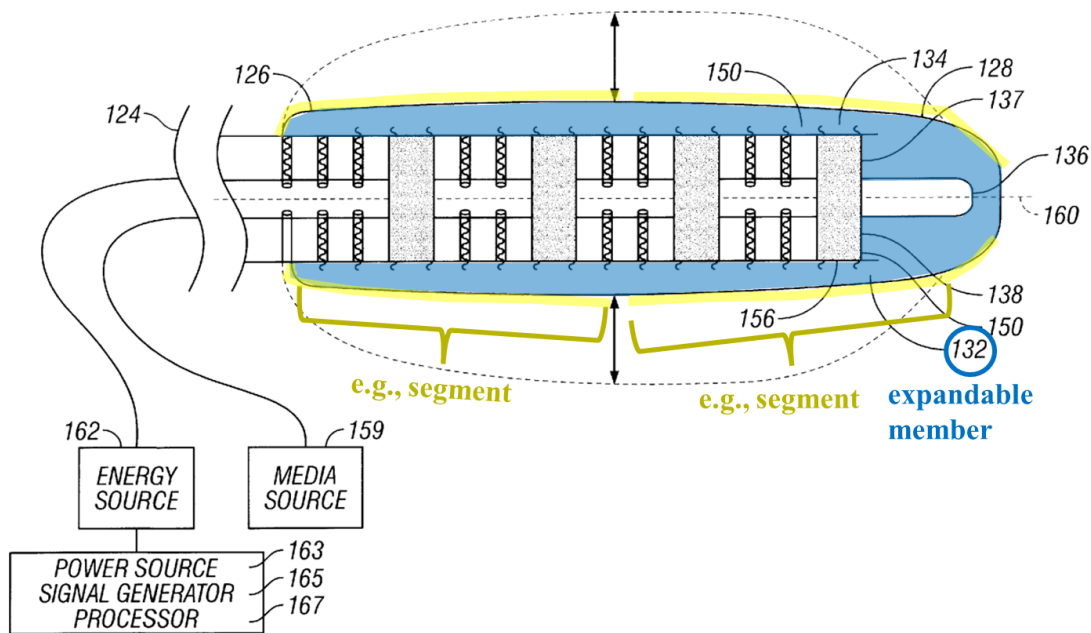


FIG. 6

173. 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]. 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 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.

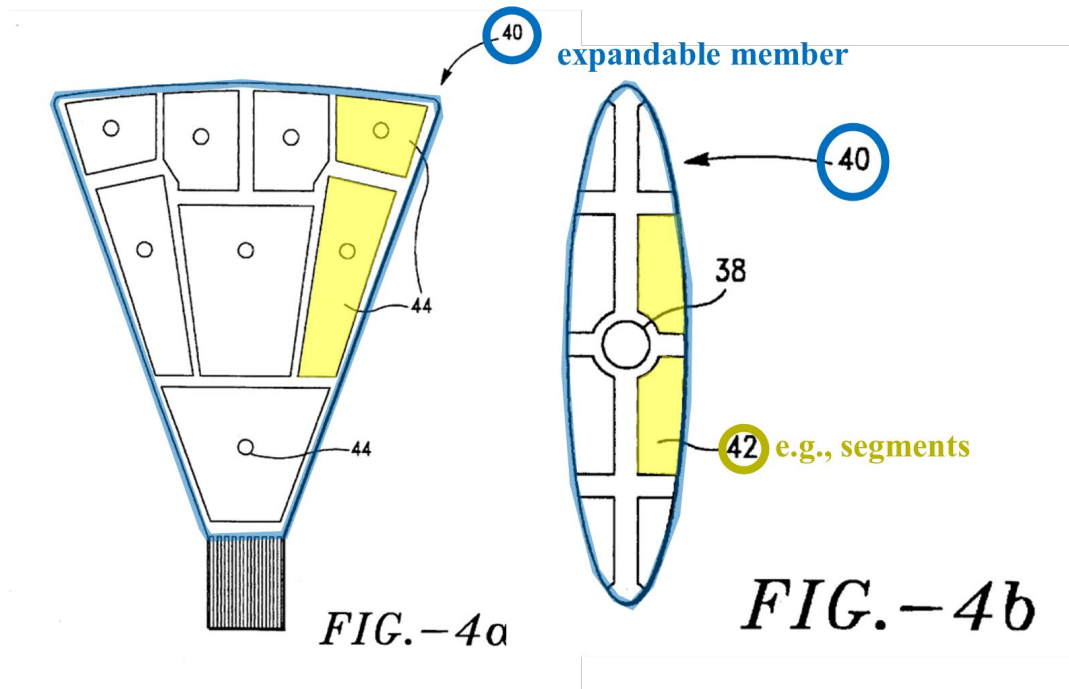
3. **Claim 3: The device of claim 2, wherein at least one electrode of the multiple pairs of bipolar radiofrequency electrodes is coupled with each of the multiple segments.**

174. Claim 3 depends from claim 2. Therefore, I incorporate by reference my discussion of claim 2.

175. Edwards-'535 in view of Stern teaches the additional limitation of claim 3. 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 electrode of the multiple pairs of bipolar radiofrequency electrodes*) is coupled with plurality of surface segments 42 in Stern (*coupled with each of the multiple segments*).

176. 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 2, Stern's Figures 4A and 4B show a plurality of surface segments on the expandable member. Ex.1033-Stern, 8:53-59.



177. As I explained with respect to claim 2, 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.

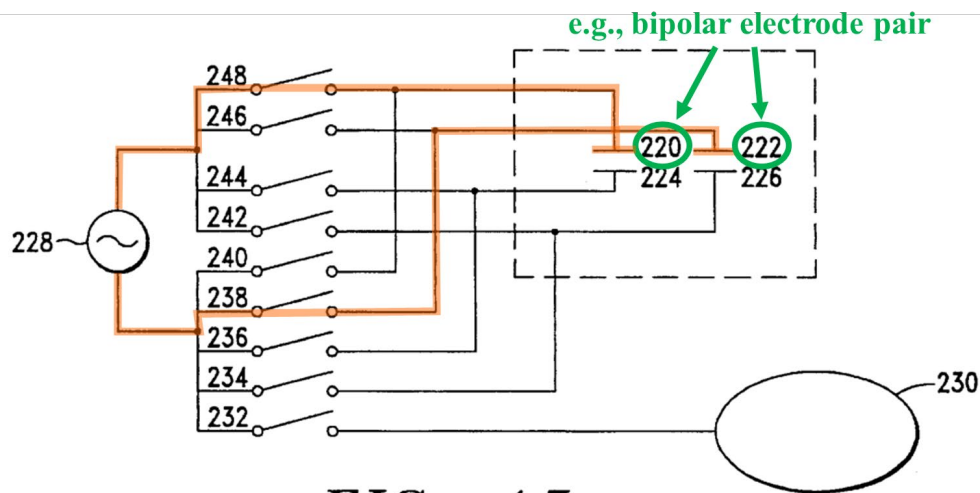


FIG. - 15

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

179. As I explained above for claims 1 and 2, 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 3, which would be implemented in the same way I discussed in claims 1 and 2.

4. Claim 7:

- a. Element 7[a]: The device of claim 1, further comprising: a radiofrequency generator configured to receive sensed signals from the at least one impedance**

sensor and deliver radiofrequency energy separately to each of the multiple radiofrequency output channels; and

180. Claim 7 depends from claim 1. Therefore, I incorporate by reference my discussion of Claim 1.

181. The combination of Edwards-'535 and Stern teach Element 7[a].

182. 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 (*configured to receive sensed signals from the at least one impedance sensor*) 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*).

183. As I discussed above for Element 1[f], Edwards-'535 teaches an impedance feedback control system where “the output energy of the energy source is adjusted in relation to the property sensed by the sensor.” Ex.1010-Edwards-'535, 9:45-56. In particular, Edwards-'535 explains that a controller 198 receives the impedance value determined by the impedance calculation device, and then generates a “control signal” which is “used by energy circuits 200 to adjust the

energy output in an appropriate amount in order to maintain the desired energy delivered at each energy delivery device 189.” Ex.1010-Edwards-535, 10:3-18. The use of impedance in a feedback loop such as that taught by Edwards-’535 would have been beneficial because it indicates when reduced current is flowing to the tissue and energy delivery can be reduced or halted.

184. Therefore, Edwards-’535 teaches *a radiofrequency generator (i.e., signal generator) that receives sensed signals from the at least one impedance sensor and delivers radiofrequency energy.*

185. 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, although, Stern’s feedback control loop uses temperature control, where “RF electrodes are separately, independently, and sequentially energized with thermistor temperature feedback to bring the [tissue] temperature up to a desired level.” Ex.1033-Stern, 10:48-52. 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 I discussed in Elements 1[d], 1[e], and 1[f].

186. Edwards-'535 also explains that both temperature and impedance can be used together in one feedback system, as illustrated in Figure 10 below:

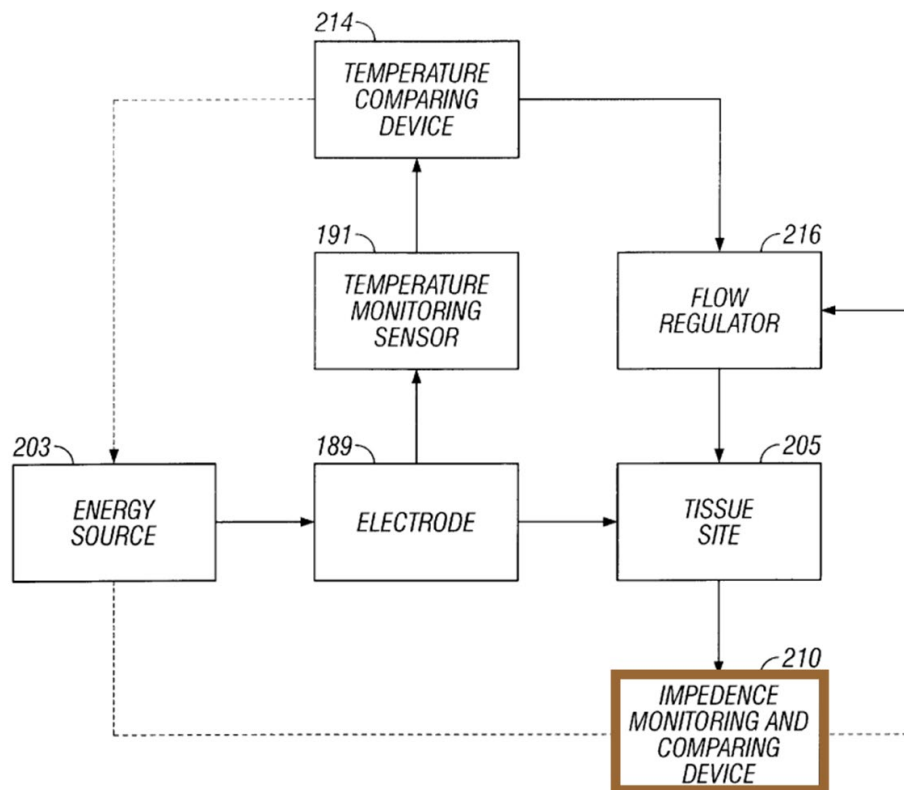


FIG. 10

Ex.1010-Edwards-535, FIG.10.

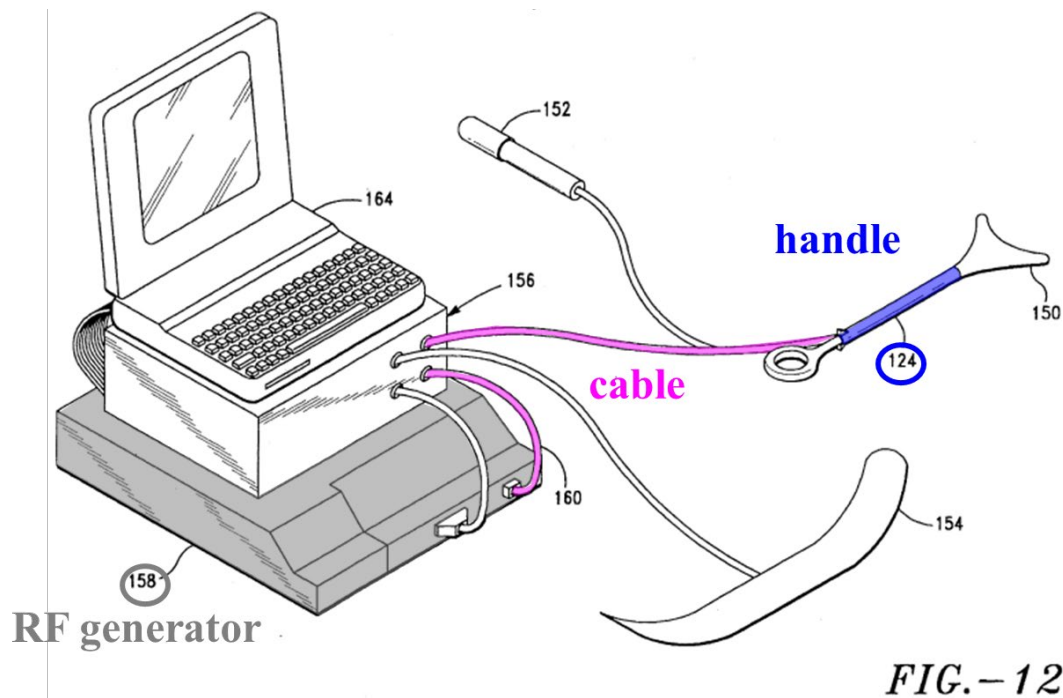
187. For this reason and the reasons I explained in Elements[d]-[e], a person of ordinary skill in the art would have been motivated to combine these aspects of Edwards-'535 and Stern, and would have had a reasonable expectation of success when doing so.

b. Element 7[b]: a cable coupled to the handle for plugging the handle into the radiofrequency generator.

188. Edwards-'535 in view of Stern teaches Element 7[b].

189. 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*).

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



191. 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 7[a].

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

192. Claim 8 depends from claim 7. Therefore, I incorporate by reference my discussion of claim 7.

193. Edwards-'535 in view of Stern teaches the additional limitation of claim 7.

194. Edwards-'535 in view of Stern teaches that signal generator 165 of Edwards-'535 and/or RF generator 158 of Stern (*radiofrequency generator*) “selectively provid[e] current to said electrode means at a frequency greater than 250 kHz” (Ex.1033-Stern, 2:18-20) (*is configured to deliver the radiofrequency energy in a form of a 460kHz sinusoid wave*) and 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.

195. First, Stern teaches applying RF energy in a range of frequencies including a *460 kHz wave* across multiple channels. For example, Stern discloses that “[t]he RF current has a frequency of at least 250 kHz and less than 100 MHz,” which includes the claimed *460 kHz*. Ex.1033-Stern, 2:18-20; 3:15-20, Clm.1. This is because 100 MHz is equal to 100000 kHz.

196. 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* Ex.1033-Stern,

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 Edwards-’535 inventor that teaches a generator that supplies RF energy “with a sinusoidal waveform at 460kHz.” Ex.1016-Edwards-’886, 36:66-37:3; *see also* Ex.1050-Hong, S181 (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, 3 (explaining that one of three companies that manufactured RF ablation generators in the United States used a 460 kHz generator); Ex.1053-Bronzino (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, at 1 (noting that RF ablation devices operate in the 450-500 kHz frequency range).

197. 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 the Edwards-’535 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 the 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. 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 energy 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 delivering 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.

198. Stern discloses using bipolar RF energy for the same purposes as Edwards-'535—to ablate tissue. Because Edwards-'535 and Stern both relate to

similar devices (inflatable energy delivery devices) 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 moisture content, and would therefore behave similarly when ablated at a frequency in the kHz range.

199. 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.

200. The '286 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-USP286, 34:35-39. Thus, selecting an appropriate frequency for ablation would have simply involved routine optimization from a range of frequencies Stern already discloses.

201. Second, 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 ’286 patent nor the cited prior art provide such reason.

202. 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 460kHz); Ex.1010-Edwards-'535, 8:54-60 (explaining that signal generator 165 can produce sine waves and other waveforms).

203. Edwards-'535 teaches that “RF energy delivered to the nasal concha is preferably sufficient to deliver between about 5 and about 30 watts of RF energy to at least a portion of the nasal concha being treated.” Ex.1010-Edwards-'535, 5:48-51. I have been instructed that, under the law, Edwards-'535 and Stern teach this additional limitation because Edwards-'535 discloses a range (5 to 30 watts) within the claimed range (5 to 75 watts) and Stern discloses a range (greater than 250 kHz and less than 100MHz) which includes the claimed value (460 kHz).

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

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

205. Edwards-'535 and Stern teach the additional requirement of claim 9.

206. 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*) and the output channels shown in orange in Figure 15 in Stern (*multiple radiofrequency output channels*) are organized into multiple subsystems, and wherein each of the multiple subsystems comprises one of the multiple pairs of bipolar radiofrequency electrodes and one of the multiple radiofrequency output channels.

207. Stern discloses *multiple subsystems* as I show below in Stern's Figure 15. Stern's Figure 15 illustrates a bipolar configuration having bipolar electrode pairs (electrodes 220 and 222), and one output channel.

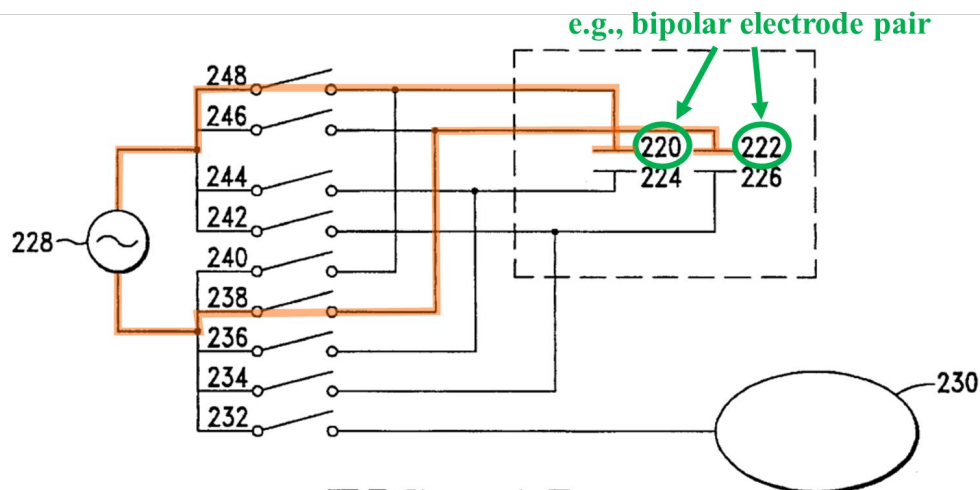


FIG.-15

208. 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. 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, which includes subsystems, where each subsystem has a bipolar electrode pair and an output channel for the reasons I discussed above for Elements 1[d] and 1[e]. Such a combination would have involved involves nothing more than applying a known technique (Stern's subsystems connecting a pair of bipolar electrodes with an output channel) to a known device (Edwards-'535's energy delivery device) ready for improvement (Edwards-'535's omission of details regarding independent energy delivery) to yield predictable results (independent feedback and control systems for each bipolar pair). 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 ’286 patent does not provide any detail beyond what someone skilled in the art would have known.

B. GROUND II: Claim 8 In View of the Combination of Edwards-’535, Stern, and Edwards-’886

210. As I discussed above regarding Ground I, Edwards-’535 in view of Stern render obvious claims 1-4 and 7-9. Dependent claim 8 is obvious in view of Edwards-’535 and Stern in further view Edwards-’886.

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

211. Claim 8 depends from claim 7. Therefore, I incorporate by reference my discussion of Claim 7. I also incorporate by reference my discussion of Claim 8 in the context of Ground I.

212. Edwards-’535 and Stern renders obvious the additional limitation of Claim 8.

213. Edwards-’886 also discloses delivery of a *460 KHz sinusoid wave and to run at a power of between 5 and 75 watts* across multiple channels. For example, Edwards-’886 discloses a “controller 52 [that] commands the generator 38 to apply bursts of low level radio frequency energy through each electrode selected for

operation” to “derive[] a local impedance value for each electrode” (*i.e.*, sensor signal) and then apply energy from electrodes. Ex.1016-Edwards-’886, 39:35-55, 39:56-40:3 (describing usage of sensor signals), FIGs.2, 73, 77. Edwards-’886 further explains that “four independent radio frequency channels” can be “configured to operate eight electrodes...in...a bipolar mode.” *Id.*, 36:66-37:10. “Each channel is capable of supplying up to 15 watts of radio frequency energy with a sinusoidal waveform at 460 kHz.” *Id.*, 36:66-37:10.

214. 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 ’286 patent and reasonably pertinent to solving the problems addressed in the ’286 patent (treating human tissue) using the same type of solution (expandable devices for applying energy to the tissue). 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 had motivation to ablate tissue using Edwards-'886's parameters and would have reasonably expected to be successful in doing so. 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. In fact, most RF ablation generators sold before 2011 operated at 460 kHz and at a power of between 5 and 75 watts. This made this frequency and power selection an almost necessary choice. *See* 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).

215. 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 and thermal 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.

216. 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 460kHz 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.

217. Therefore, a person of ordinary skill in the art would have been motivated using Edwards-'886's parameters for ablation with Edwards-'535's device and would have reasonably expected success when doing so.

C. GROUND III: Claims 1-4 and 7-9 In View of the Combination of Makower, Stern, and Edwards-'535

218. As detailed below, the combination of Makower and Stern and Edwards-'535 teach each limitation of Claims 1-4 and 7-9.

1. Claim 1

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

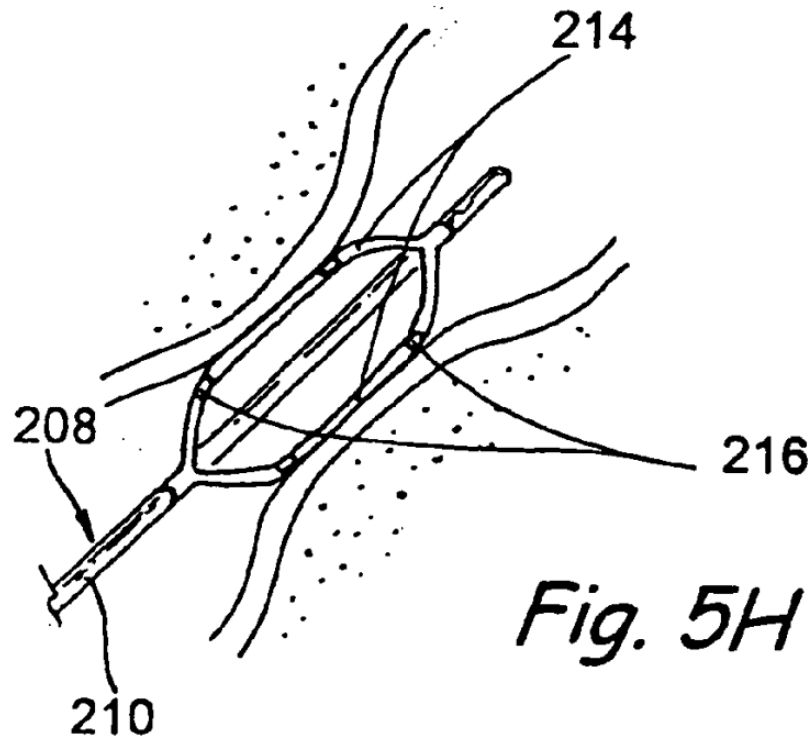
219. I have been informed and understand that, in general, there are circumstances where the preamble of a claim does not limit the scope of the claim, and there are circumstances where the preamble does limit the scope of the claim. Should the preamble be found to be limiting (which I understand is a legal determination), Makower teaches Element 1[pre].

220. If the parts of the preamble other than “*to treat rhinitis*” are limiting, Makower discloses the preamble. 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*). Ex.1021-Makower, [0001], [0131].

221. 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].

222. If the whole preamble is limiting, Makower teaches that its device is capable of *treating rhinitis*. Makower discloses treatment of “sinusitis,” *id.*, [0001], one symptom of which is “difficulty breathing through one or both nostrils,” *id.*, [0007]-[0014]. Makower further teaches that its device, a “working device,” may be used “for treating sinusitis and other ear, nose & throat disorders,” which a person of ordinary skill in the art would understand to have included rhinitis. Ex.1021-Makower, [0001], [0131], [0164]. In fact, Makower mentions that some working devices may deliver “substances that are used to treat rhinitis, nasal polyps, nasal inflammation, and other disorders of the ear, nose and throat...” Ex.1021-Makower, [0161], [0164], [0169]-[0176]. Further, Makower teaches that its device may treat “nasal polyps, which may result from chronic allergic rhinitis.” *Id.* [0006], [0176].

223. Below is a figure from Makower depicting such a working device:



Ex.1021-Makower, Fig. 5H.

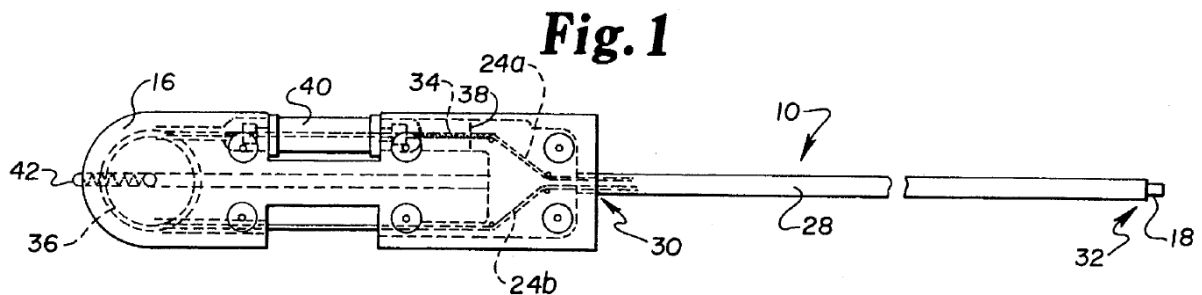
b. Element 1[a]: a handle;

224. 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.

225. 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], [0187]. 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.

226. 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.



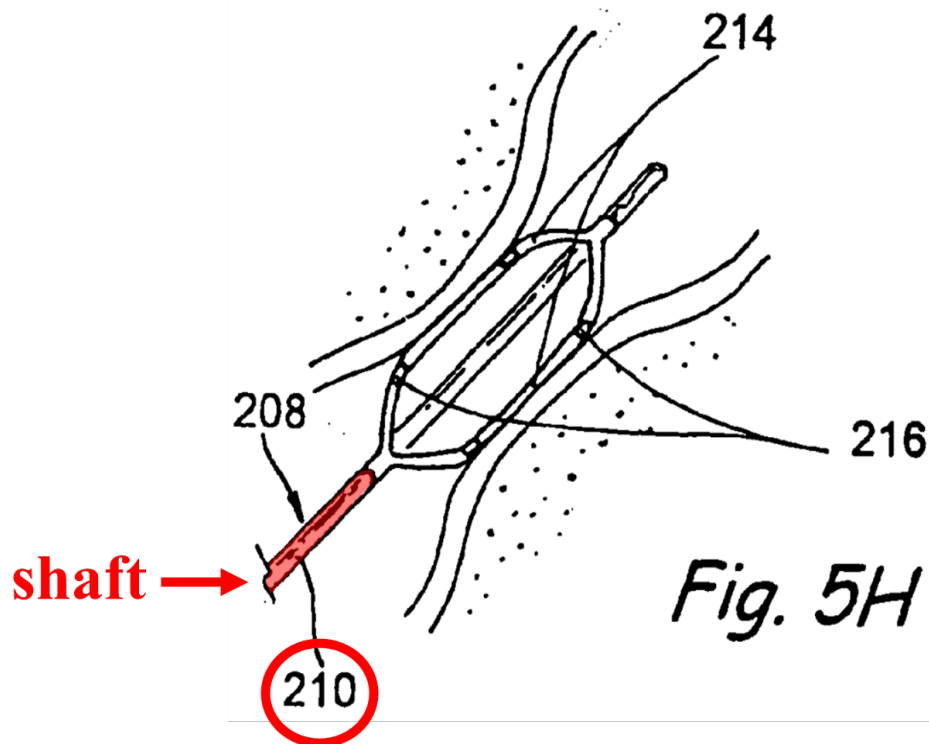
227. It would have been also obvious to a person of ordinary skill in the art to include a handle in a device like Makower’s in view of Stern, for the same reasons I explained that it would have been obvious to include a handle in a device like Edwards-’535’s in view of Stern in Ground I Element 1[a], for example, to control and deploy the ablation device. Ex.1021-Makower, [0137], [0153].

228. 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 a device like Makower's 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;

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

230. I have reproduced Figure 5H below, which shows a shaft (shaft 210 in red) extending from electrosurgical device 208. Ex.1021-Makower, [0187], [0164], FIG.5H.



231. 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].

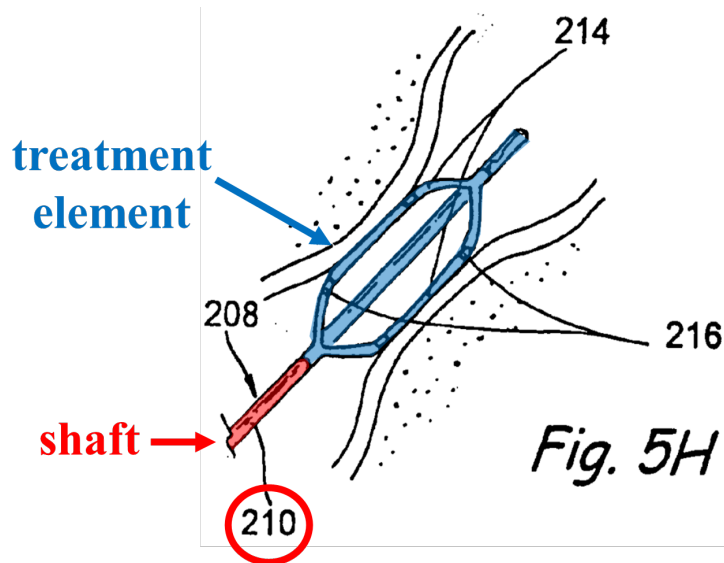
232. Additionally, a device that has a shaft extending from one end of the handle in Makower would have been obvious in view of Stern for the same reasons I explained in Elements 1[a] and 1[b] in Ground I and Ground IV—for example, to control the ablation device. Ex.1021-Makower, Abstract, [0153], [0159],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

233. 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 may be placed in contact with mucosal tissue in the nose such as the nasal turbinates (*to contact nasal mucosa lining the nasal airway*).

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



235. 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* Ex.1021-Makower, [0187], [0164], FIG.5H.

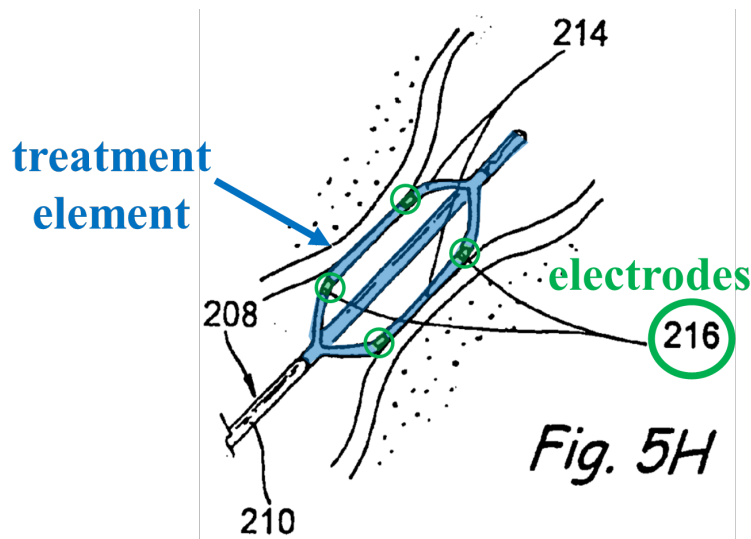
236. Makower further teaches that its device can be used in a variety of places in the nose where it would come into contact with mucosal tissue. *Id.* [0043]. For example, Makower describes using its device to contact the nasal turbinates, which are covered with mucosal tissue. *Id.* [0004], [0018],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

237. Therefore, Makower teaches this Element.

e. Element 1[d]: multiple pairs of bipolar radiofrequency electrodes disposed on the treatment element;

238. Makower teaches electrodes 216 shown in green in Figure 5H (*multiple...bipolar radiofrequency electrodes*) that are placed on the surface of the strut members 214 (*disposed on the treatment element*). See Ex.1021-Makower, [0187] (noting that “electrodes 216 may be bipolar”), [0164], FIG.5H.

239. Figure 5H is reproduced below.

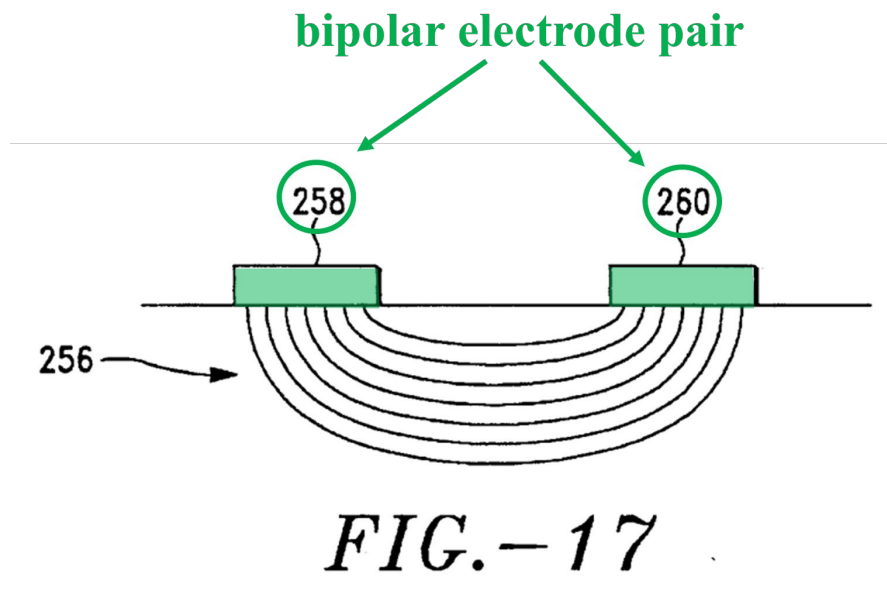


240. As I explained in Ground I Element 1[d], using bipolar RF electrode pairs in RF devices was ubiquitous. Pairs of bipolar electrodes have many advantages, as I explained, for example to ensure that RF energy is applied only to intended tissue and not to nontargeted tissue. Energizing RF electrodes 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] .

241. 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.

242. Figure 17 of Stern is reproduced below.



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

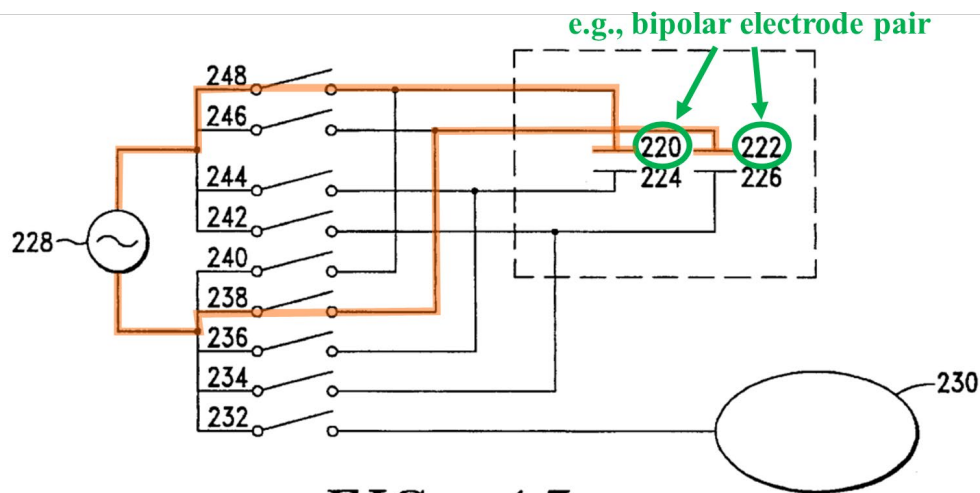


FIG. - 15

244. 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.

i. Motivation to Combine and Reasonable Expectation of Success

245. First, 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 ’286 patent and reasonably pertinent to solving the problems addressed in the ’286 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.

246. Second, 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 combine Makower and Stern and would have reasonably expected to be successful in doing so. 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.

247. Makower teaches that “[r]adiofrequency energy is...delivered to heat...submucosal tissue” using electrodes. Ex.1021-Makower, [0040] [0032], [0187], [0191], [0207]. 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.

248. 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.

249. 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].

250. 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 Grounds I and V). 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.

251. 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.

252. 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.

253. 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, 10:48-65. 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. As I have explained herein, Makower omits detail regarding how to deliver bipolar RF energy, and Stern offers many benefits of independently delivering RF energy to the bipolar electrode pairs to adequately heat and ablate tissue. Ex.1021-Makower, [0040], [0161], [0167], [0185]-[0188]; Ex.1033-Stern, 10:48-65.

254. 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.

- 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

255. 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*.

256. 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

257. 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 bipolar RF energy. Therefore, such a person would have been motivated to look to Stern, which discloses how accomplish that pairing and wiring in of bipolar electrodes in order to deliver energy to certain electrode pairs.

258. 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 Grounds I and III 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.

259. 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.

260. 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].

261. 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 Grounds I and III). 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.

262. 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.

263. 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.

264. 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 bipolar 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.

265. As discussed above in Ground III 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 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 bipolar RF energy to various electrodes.

266. 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 bipolar 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.

267. 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.

g. Element 1[f]: at least one impedance sensor configured to measure impedance in the multiple pairs of bipolar radiofrequency electrodes.

268. Makower in view of Stern and Edwards-'535 discloses multiple sensing elements, such as impedance sensors, impedance calculation device 194, and/or monitor 210 in Edwards-'535 (*at least one impedance sensor*) that make impedance measurements based on the current and voltage delivered to the multiple bipolar electrodes in Makower, configured in pairs as taught by Stern (configured to measure impedance in the multiple pairs of bipolar RF electrodes).

269. 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. However, Makower and Stern do not expressly disclose sensing impedance. Edwards-’535 teaches the use of impedance sensors and explains that *both* temperature and impedance can be used as helpful metrics in a feedback system to monitor the status of RF treatment. Ex.1010-Edwards-’535, 10:3-18, 10:48-52, 11:24:45.

270. As I described in Ground I, Element 1[f], which I incorporate herein, Edwards-’535 discloses impedance sensors. Ex.1010-Edwards-535, 9:14-23. 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.

271. As I explained with respect to Element 1[d] in this Ground, it would have been obvious to combine the teachings of Makower and Stern. It would have further been obvious to supplement Makower and Stern’s teachings with

Edwards-'535's teachings of impedance sensors because of the numerous advantages of measuring impedance in an RF ablation system, for example, for establishing initial contact with tissue and for determining whether the target tissue has been desiccated, or dried out, as a result of the heating. Ex.1011-Baker, 3:5-10, 6:25-30, 8:58-63, 9:47-56, 11:34-12:55, FIGs.2-3, 10; Ex.1051-Haemmerich, 55-57; Ex.1052-Stockenheim, 90-91.

272. As I explained regarding Ground I, Element 1[f], impedance is the ratio of voltage divided by current. Edwards-'535 describes the use of impedance measurements in a feedback loop, so that when the impedance is greater than a certain value, the delivery of RF energy can be reduced or halted. Ex.1010-Edwards-535, 11:24:45. When the impedance is above a certain threshold value, this means very little current is flowing to the tissue. Accordingly, the tissue has already been heated up sufficiently and dried out, such that there is no need to apply additional energy. If the impedance is an acceptable value, RF energy may continue to be applied. *Id.* Therefore, Edwards-'535 provides a teaching, suggestion, or motivation to use impedance sensors—to measure the progress of RF treatment—that would have led a person of ordinary skill in the art to combine Edwards-'535's teaching of impedance sensors with the combination of Makower and Stern.

273. Beyond the reasons disclosed in Edwards-'535, impedance can be a proxy for other information about what is occurring in the body. For example, a person of ordinary skill in the art would have known to use impedance monitoring to ensure that the device has made sufficient contact with the tissue before beginning ablation, to monitor how much tissue has been ablated, and to evaluate when to halt treatment. *See, e.g.,* Ex.1011-Baker, 11:50-68 (“Impedance measurement can be achieved by supplying a small amount of non-therapeutic RF energy. Voltage and current are then measured to confirm electrical contact.”).

274. Further, a person of ordinary skill in the art would have been motivated to use impedance sensing and temperature sensing because each measurement provides different information about the treated tissue. Using *both* impedance and temperature in RF ablation feedback systems is desirable to take advantages of their unique benefits—for example, if tissue temperature is less than the target temperature, the clinician may still desire to shut off the device if impedance is greater than a predetermined threshold and vice versa.

275. A person of ordinary skill in the art would have reasonably expected to be successful in implementing the combination. The combination would have been a straightforward application of a known technique (impedance feedback control) to a known device (Makower’s device incorporating Stern’s teaching of the circuitry

required to operate bipolar pairs) which was ready for improvement (Makower and Stern do not expressly disclose impedance monitoring) in the same way (using a sensed property—i.e., impedance or temperature—to vary RF energy delivery). Even if a person of ordinary skill in the art chose to use *either* temperature or impedance feedback, using impedance feedback amounts to simple substitution of a known element (temperature sensors for feedback control) for another (impedance sensors for feedback control) to obtain predictable results (adjusting RF energy delivery based on a tissue property—i.e., impedance or temperature). For the reasons I described above, each option offers unique benefits. Further, a person of ordinary skill in the art would have found that use of impedance sensing and feedback as taught by Edwards-'535 an obvious technique to try given that there were only a finite number of identified, predictable solutions (i.e., monitoring impedance or monitoring temperature) with a reasonable expectation of success.

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

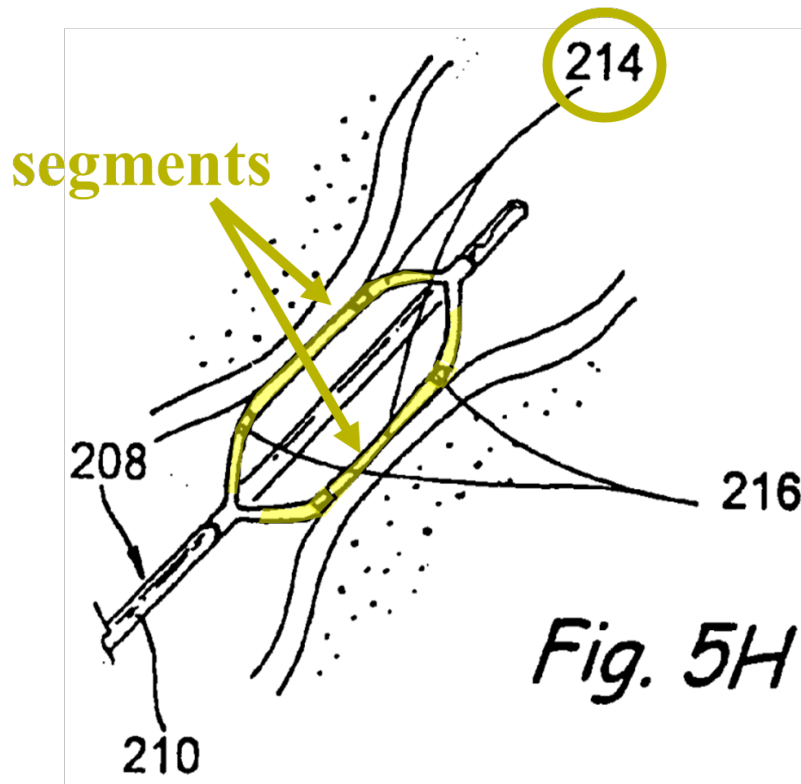
276. Claim 2 depends from claim 1. Therefore, I incorporate by reference my discussion of Claim 1 in Ground III.

277. 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.

278. 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.*

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



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

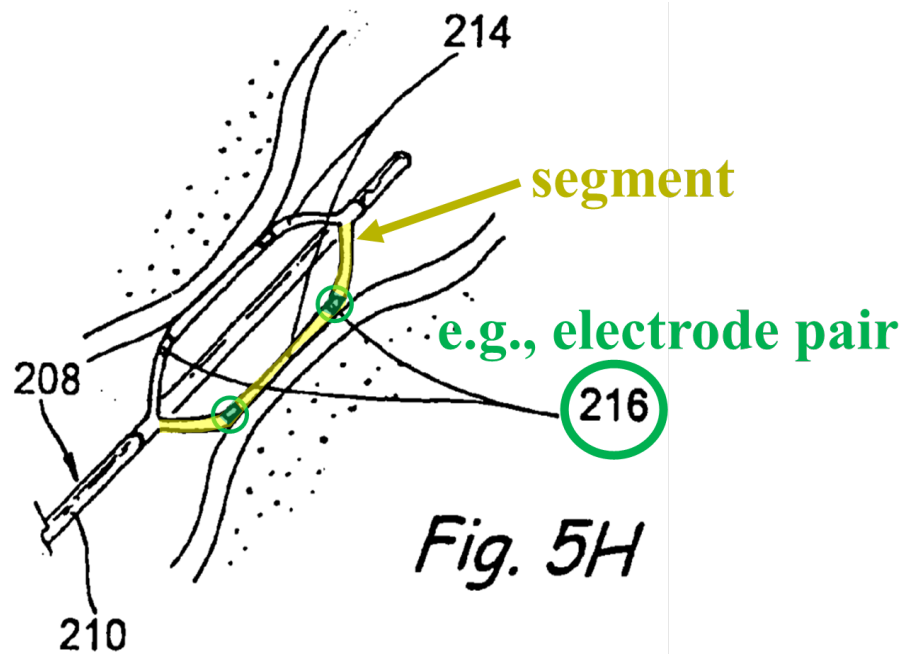
3. **Claim 3: The device of claim 2, wherein at least one electrode of the multiple pairs of bipolar radiofrequency electrodes is coupled with each of the multiple segments.**

281. Claim 3 depends from claim 2. Therefore, I incorporate by reference my discussion of claim 3 in Ground III.

282. Makower and Stern teach that the electrodes 216 in Makower controlled as pairs as Stern teaches (*at least one electrode 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.

283. As I explained in this Ground for Elements 1[d], [e], and 1[f], it would have been obvious to control Makower's bipolar RF electrodes 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.

284. 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).



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

285. Claim 4 depends from claim 2. Therefore, I incorporate by reference my discussion of claim 2 in Ground III. I also incorporate by reference my discussion of claim 2 in the context of Ground I.

286. Makower discloses that the strut members 214 (*multiple segments*), which a person of ordinary skill in the art would have understood are mechanically shaped (*are pre-shaped*), 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*).

287. As I explained above for claim 2, 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).

288. A person of ordinary skill in the art would have understood Makower to teach or suggest that strut members 214 are mechanically shaped, i.e., *pre-shaped*, and could be made out of nitinol, a shape memory alloy, to facilitate collapse and expansion, because the strut members 214 deflect when expanded. Ex.1061-Szold, 1493. A person of ordinary skill in the art would understand that strut-like ablation devices made of nitinol, like the one depicted in Makower Figure 5H, are typically pre-shaped to ensure they deploy in the proper configuration in the body. Ex. 1030-Kunis, FIG.3, 12:10-18 (“Distal carrier arm segments 44 and proximal arm segments 42 are constructed of a flexible material, such as Nitinol, and can be resiliently biased in a straight or umbrella tip configuration.”).

5. **Claim 7:**

- a. **Element 7[a]: The device of claim 1, further comprising: a radiofrequency generator configured to receive sensed signals from the at least one impedance sensor and deliver radiofrequency energy separately to each of the multiple radiofrequency output channels; and**

289. Claim 7 depends from claim 1. Therefore, I incorporate by reference my discussion of Claim 1 in Ground III.

290. The combination of Makower, Stern, and Edwards-'535 teaches Element 7[a].

291. The combination of Makower, Stern, and Edwards-'535 discloses 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 (*configured to receive sensed signals from the at least one impedance sensor*) to selectively control energy delivery to the electrodes in Makower, as implemented by the multiple RF output channels Stern teaches (*deliver radiofrequency energy separately to each of the multiple radiofrequency output channels*).

292. Each of Edwards-'535, Stern, and Makower disclose *a radiofrequency generator* (e.g., signal generator 165 in Edwards-'535, RF generator 158 in Stern,

RF generator in Makower) that serves as RF input power. Ex.1010-Edwards-535, 10:3-1; Ex.1033-Stern, 10:44-50; Ex.1021-Makower, [0040].

293. As I discussed above for Elements 1[d]-[f] in Ground I, Edwards-'535 teaches an impedance feedback control system wherein “the output energy of the energy source is adjusted in relation to the property sensed by the sensor.” Ex.1010-Edwards-'535, 9:45-56. Particularly, Edwards-'535 teaches that a controller 198 receives the impedance value determined by the impedance calculation device, and then generates a “control signal” which is “used by energy circuits 200 to adjust the energy output in an appropriate amount in order to maintain the desired energy delivered at each energy delivery device 189.” Ex.1010-Edwards-535, 10:3-18. The use of impedance in a feedback loop such as that taught by Edwards-'535 would have been beneficial because it indicates when reduced current is flowing to the tissue and energy delivery can be reduced or halted.

294. Therefore, Edwards-'535 teaches *a radiofrequency generator (i.e., signal generator) that receives sensed signals from the at least one impedance sensor and delivers radiofrequency energy.*

295. As I discussed above for Elements 1[d]-[f] in Ground III, Makower in combination with Stern teaches the delivery of *radiofrequency energy separately to each of the multiple radiofrequency output channels.* Makower does not provide

details regarding to how implement the energy delivery 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 as I described in Ground I Elements 1[d]-1[e] and Ground III Element 1[f], a person of ordinary skill in the art would have been motivated to use Edwards-'535's impedance control system in combination with Makower's device using the circuitry taught by Stern, especially because Stern's feedback control loop uses temperature control and Edwards-'535's impedance control is compatible with a temperature control feedback system.

296. Edwards-'535 also explains that both temperature and impedance can be used together in one feedback system, as illustrated in Figure 10 below:

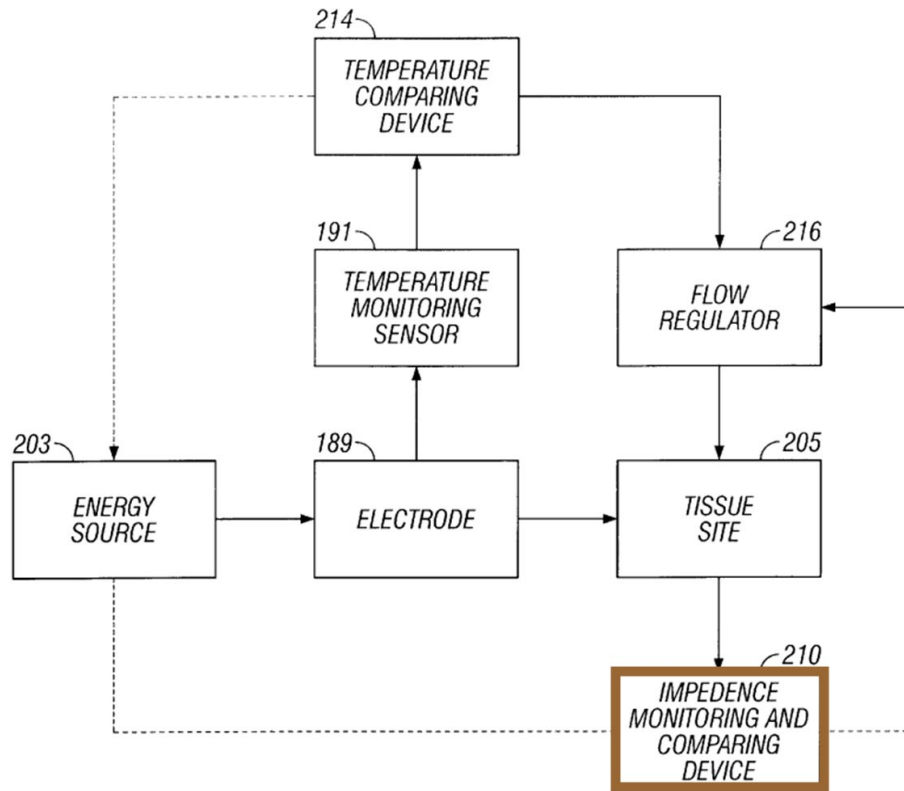


FIG. 10

Ex.1010-Edwards-535, FIG.10.

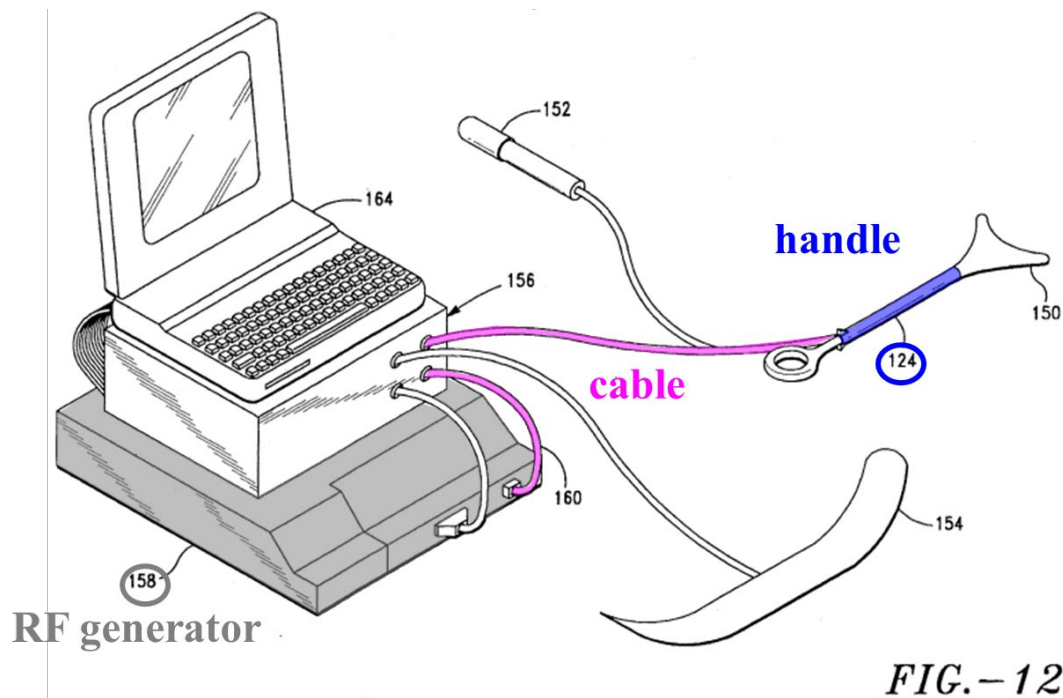
297. For this reason and the reasons in Element 1[d]-[F] in Grounds I and III, a person of ordinary skill in the art would have been motivated to combine these aspects of Makower, Stern, and Edwards-'535 with a reasonable expectation of success in doing so.

b. Element 7[b]: a cable coupled to the handle for plugging the handle into the radiofrequency generator.

298. Makower in view of Stern and Edwards-'535 teaches Element 7[b].

299. Makower in view of Stern and Edwards-'535 discloses interference cables 160 in Stern (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*).

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



301. 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 7[a].

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

302. Claim 8 depends from claim 7. Therefore, I incorporate by reference my discussion of Claim 7 in Ground III.

303. As I explained in Ground I, claim 8, Edwards-'535 in view of Stern teaches or renders obvious this limitation. Makower in view of Edwards-'535 and Stern also renders obvious this limitation.

304. Makower discloses using RF energy and a power source to ablate tissue in the nose, Ex.1021-Makower, [0156], [0182], Clm.81. However, Makower does not provide implementation details on the particular frequency, waveform, and wattage. It would have been obvious to a person of ordinary skill in the art to modify the combination in Ground III, claim 7 to include a RF generator configured to deliver RF energy in a form of a 460 kHz sinusoid wave and to run at a power of between 5 and 75 watts for the same reasons I discussed for claim 8 in Ground I.

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

**radiofrequency electrodes and one of the multiple
radiofrequency output channels.**

305. Claim 9 depends from claim 1. Therefore, I incorporate by reference my discussion of claim 1 in Ground III.

306. As I explained in Ground I, claim 9, Stern teaches this limitation. And as I discussed in Elements 1[d] and 1[e] in Ground III, 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 a device like Makower's.

D. GROUND IV: Claim 8 In View of the Combination of Makower, Stern, Edwards-'535, and Edwards-'886

307. As I discussed above, Makower in view of Stern and Edwards-'535 render obvious claims 1-4 and 7-9. Dependent claim 8 is additionally obvious in view of Makower, Stern, Edwards-'535, and Edwards-'886.

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

308. Claim 8 depends from claim 7. Therefore, I incorporate by reference my discussion of Claim 7 in Ground III. I also incorporate by reference my discussion of Claim 8 in the context of Ground I and II.

309. As I discussed in Ground III, which I incorporate by reference, Claim 8 is obvious over Makower, Stern, and Edwards-'535. It would have also been obvious to modify the combination in Ground III, claim 8 to include a RF generator configured to deliver RF energy in a form of a 460 kHz sinusoid wave and to run at a power of between 5 and 75 watts for the same reasons discussed in Ground II, claim 8.

310. For example, Edwards-'886 discloses delivery of a *460 KHz sinusoid wave and to run at a power of between 5 and 75 watts* across multiple channels. For example, Edwards-'886 discloses a “controller 52 [that] commands the generator 38 to apply bursts of low level radio frequency energy through each electrode selected for operation” to “derive[] a local impedance value for each electrode” (*i.e.*, sensor signal) and then apply energy from electrodes. Ex.1016-Edwards-'886, 39:35-55, 39:56-40:3 (describing usage of sensor signals), FIGs.2, 73. Edwards-'886 further explains that “four independent radio frequency channels” can be “configured to operate eight electrodes...in...a bipolar mode.” *Id.*, 36:66-37:10. “Each channel is capable of supplying up to 15 watts of radio frequency energy with a sinusoidal waveform at 460 kHz.” *Id.*, 36:66-37:10.

311. 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 '286 patent and reasonably pertinent to solving the problems addressed in the '286 patent (treating human tissue) using the same type of solution (expandable devices for applying energy to the tissue). Additionally, although Edwards-'535 in view of Stern renders obvious a frequency range inclusive of 460 kHz, 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 had motivation to ablate tissue using Edwards-'886's parameters and would have reasonably expected to be successful in doing so. In fact, most RF ablation generators sold before 2011 operated at 460 kHz and at a power of between 5 and 75 watts. This made this frequency and power selection 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 at power between 1 and 70 watts); 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); Ex.1034-Patel, [0087] (noting that “radiofrequency electrosu[r]gical generators are generally used to provide a wattage of typically 15-40 watts”).

E. Ground V: Claims 1-3 and 7-9 In View of the Combination of Edwards-’535, Stern, and Liang

312. As detailed below, the combination of Edwards-’535, Stern, and Liang teaches each limitation of claims 1-3 and 7-9.

1. Claim 1

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

313. Should the parts of the preamble besides “to treat rhinitis” be found to be limiting (which I understand is a legal determination), Edwards-’535 discloses the preamble. As I explained above in Ground I, 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*). If the preamble recites an intended use, the Edwards-’535 device modified by Stern would have been capable of being used to treat rhinitis for the reasons that such use would have been obvious to a person of ordinary skill in the art as I explained in Ground I. If the whole preamble is limiting, Edwards-’535 in view of Stern and Liang disclose an apparatus

124 of Edwards-'535 (*a device*) that delivers ablative energy (*for delivering energy*) to a nasal concha 114 in Edwards-'535 (*to a nasal airway*), which Liang teaches has been successfully used to treat rhinitis (*to treat rhinitis*).

314. As I explained in Ground I Element 1[pre] and Element 1[a], Edwards-'535 teaches a method of using RF energy to ablate the turbinates, including the middle turbinate. Edwards-'535 further teaches ablation of an inner portion of tissue on any one of the turbinates, including a middle turbinate. Ex.1010-Edwards-'535, 1:60-2:29, 4:19-52, 4:53-67, 6:66-7:4, 6:39-42, 7:5-17, 11:23-44. Liang teaches techniques for using RF energy to treat nasal airway conditions, including ablation and damaging the “deep ethmoidal nerve” in the middle turbinate. Ex.1056-Liang, 341-42. Similar to Edwards-'535 and Stern, Liang confronts the problem of treating tissue in a body cavity and solves that problem by applying RF energy to the tissue. Ex.1056-Liang, 341-42. Liang is therefore in the same field as the '286 patent and reasonably pertinent to solving the problems addressed in the '286 patent (treating human tissue) using the same type of solution (expandable devices for applying energy to the tissue). Additionally, a person of ordinary skill in the art would have been motivated to combine these teachings by using a device like that taught in Edwards-'535 as modified by Stern in a technique like that taught in Liang—to reduce production of mucus by application of RF energy to the

ethmoidal nerve within the middle turbinate, Ex.1056-Liang, 341-42. A person of ordinary skill in the art would have reasonably expected to be successful in doing so.

315. First, Liang discloses the use of an RF ablation device to treat the “middle turbinate,” which Liang also refers to as the “nasal ridge,” to *treat rhinitis*. Ex.1056-Liang, 341; *see also id.* Abstract, 342. Liang discloses the benefits of using RF energy to treat the same location as Edwards-’535 (middle turbinate) but acknowledges particular drawbacks with Liang’s device. Regarding benefits, Liang teaches an “effective rate of 95.5%” in treating allergic rhinitis, including by “reducing its sensitivity to adverse external physical and chemical stimuli, reducing the secretion of vasoactive peptides, inhibiting sneezing reflex, reducing runny nose, and improving nasal ventilation.” Ex.1056-Liang, 341-42. The clinical results from treatment using Liang’s method showed that out of 88 patients, 83% “showed marked effectiveness.” Ex.1056-Liang, 341. However, Liang also teaches that its technique caused “bloody secretions due to nasal reactions” after treatment and that some patients “developed nasal adhesion” (where two surfaces damaged during the procedure heal together). Ex.1056-Liang, 341, 342. Liang was therefore ready for improvement with a device that was less harmful to the surface tissue, and therefore would be less likely to result in adhesion.

316. Second, Edwards-'535 teaches how to address problems presented by Liang's device. Edwards-'535's device, which supplies cooling to the contacted tissue, is less damaging to the surface mucosa. For example, Edwards-'535 discloses that its method may "remove an internal section of a nasal concha without damaging the surface of the nasal concha." Ex.1010-Edwards-'535, 4:53-67. Additionally, unlike Liang's technique, Edwards-'535's "procedure can be performed bloodlessly..., thereby significantly reducing the risk of infection." Ex.1010-Edwards-535, 4:53-67, 6:10-22. These teachings would have motivated a person of ordinary skill in the art to use a device like that taught in Edwards-'535, as modified by Stern, (which does not damage surrounding tissue) for the same purpose as Liang's RF device.

317. Third, as I explained above, Edwards-'535 and Liang describe similar techniques such that their combination would have yielded predictable results. Both Edwards-'535's and Liang's device teach delivery of RF energy to tissue within the middle turbinate, which destroys tissue. *See, e.g.*, Ex.1010-Edwards-'535, 5:30-34, 6:66-7:17, 6:9-65, 4:53-5:15, FIGs. 3A-4C; Ex.1056-Liang, 341-342. Therefore, using Edwards-'535's device as augmented by Stern's teachings is simply improving Liang's technique in the same manner as the device is used in Edwards-'535.

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

319. Fourth, a person of ordinary skill in the art would have reasonably expected to be successful in using a device like Edwards-'535's apparatus 124 for Liang's method to treat rhinitis because, as I explained above, Edwards-'535 expressly discloses that its methods can be used to ablate the same tissue ablated in Liang, and that both Edwards-'535's and Liang's methods result in destruction of turbinate tissue. Therefore, combining Edwards-'535's and Liang's teachings would have been a matter of routine implementation that was well within the skill of a person of ordinary skill in the art and would have yielded predictable results—e.g., Edwards-'535's apparatus 124 being utilized to deliver RF energy to treat allergic rhinitis as taught by Liang—with a reasonable expectation of success. Liang's reported 95.5% effectiveness rate from using a standard RF energy, Ex.1056-Liang,

341, would have further led a person of ordinary skill in the art to expect success using other RF energy devices like that disclosed by Edwards-'535.

320. Therefore, a person of ordinary skill in the art would have been motivated to combine the teachings of Edwards-'535, Stern, and Liang.

b. Elements 1[a] and 1[b].

321. As I discussed in Ground I, Edwards-'535 in view of Stern render these elements obvious.

c. 1[c]: a treatment element coupled with a distal end of the shaft, sized to be inserted into a nostril, and configured to change from a first configuration to a second configuration to contact nasal mucosa lining the nasal airway;

322. As I discussed in Ground I, Edwards-'535 in view of Stern teaches this limitation. Liang also notes that the RF device contacts the “bilateral nasal ridge and the corresponding nasal septum mucosa” and that the treatment should result in “white spots of local mucosa.” Ex.1056-Liang, 341. Because nasal septum mucosa is nasal mucosa lining the nasal airway, Liang discloses that the device is configured *to contact nasal mucosa lining the nasal airway*. Further, contacting the bilateral nasal ridge, which Liang refers to as the turbinate, also means that the device is configured to *contact nasal mucosa lining the nasal airway*.

d. Elements 1[d]-1[f].

323. As I discussed in Ground I, Edwards-'535 in view of Stern teach these elements.

2. Claims 2, 3, and 7-9

324. As I discussed in Ground I, Edwards-'535 in view of Stern teach these claims or render them obvious.

F. Ground VI: Claim 8 In View of the Combination of Edwards-'535, Stern, Liang, and Edwards-'886

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

325. As I explained in Ground V, Claim 8 is obvious over Edwards-'535, Stern, and Liang. It also would have been obvious to modify the combination in Ground V, Claim 8 to include a RF generator configured to deliver RF energy in a form of a 460 kHz sinusoid wave and to run at a power of between 5 and 75 watts for the same reasons I explained in Ground II.

G. Ground VII: Claims 1-4 and 7-9 In View of the Combination of Makower, Stern, Edwards-'535, and Liang

326. As detailed below, the combination of Edwards-'535, Stern, and Liang teaches each limitation of claims 1-3 and 7-9.

1. **Claim 1**

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

327. If the parts of the preamble other than “*to treat rhinitis*” are limiting, Makower discloses the preamble. For example, as I explained above in Ground III, 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*). If the whole preamble is limiting, Makower in view of Liang disclose an apparatus 124 of Edwards-’535 (*a device*) that delivers ablative energy (*for delivering energy*) to a nasal concha 114 in Edwards-’535 (*to a nasal airway*), which Liang teaches has been successfully used to treat rhinitis (*to treat rhinitis*).

328. As I explained in Ground III Element 1[pre] and Element 1[a], Makower teaches ablating tissue, and particularly tissue in the nose such as the turbinates. Ex.1021-Makower, [0004], [0018], [0020]-[0021], [0030]-[0031], [0039]-[0041], [0130], [0132], [0140], [0179] (describing meatus), [0182], [0186], [0188], Abstract. One example of Makower’s target tissue is submucosal tissue within the nasal turbinates. *Id.*, [0039]-[0041]. Liang teaches techniques for using RF energy to treat nasal airway conditions, including ablation and damaging the “deep ethmoidal nerve” in the middle turbinate. Ex.1056-Liang, 341-42.

329. A person of ordinary skill in the art would have been motivated to combine these teachings by using a device like that taught in Makower in a technique like that taught in Liang—to reduce production of mucus by application of RF energy to the ethmoidal nerve within the middle turbinate, Ex.1056-Liang, 341-42. A person of ordinary skill in the art would have reasonably expected to be successful in doing so for at least the reasons I explained in Ground V. For instance, Liang and Makower use similar RF devices for treatment in the nose. *See, e.g.*, Ex.1056-Liang, 341; Ex.1059-Liang-'271, 1-2 (describing SHP-I device in Liang with electrodes, energy source for use in nasal treatments). As I explained in Ground V, Liang teaches that applying RF energy to the middle turbinate to treat rhinitis would produce a number of benefits, all of which would be equally applicable to the device of Makower (as modified by Stern and Edwards-'535).

330. A person of ordinary skill in the art would have reasonably expected to be successful in using a device like Makower's for Liang's method to treat rhinitis for the reasons I addressed in Ground V. As one example, both Makower and Liang treat the same tissue (middle turbinate). Therefore, combining Makower's and Liang's teachings would have been a matter of routine implementation that was well within the skill of a person of ordinary skill in the art and would have yielded

predictable results—e.g., Makower’s device being utilized to deliver RF energy to treat allergic rhinitis as taught by Liang—with a reasonable expectation of success.

331. Therefore, a person of ordinary skill in the art would have been motivated to combine the teachings of Makower and Liang.

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

332. As I discussed in Ground III, Makower or Makower in view of Stern render these elements obvious.

c. 1[c]: a treatment element coupled with a distal end of the shaft, sized to be inserted into a nostril, and configured to change from a first configuration to a second configuration to contact nasal mucosa lining the nasal airway;

333. As I discussed in Ground III, Makower teaches this limitation. As I explained in Ground V, Liang also notes that the RF device is configured *to contact nasal mucosa lining the nasal airway*.

d. Element 1[f].

334. As I discussed in Ground III, Makower in view of Stern and Edwards-’535 teach this limitation.

2. Claims 2-4 and 7-9

335. As I discussed in Ground III, Makower in view of Stern and Edwards-’535 teach these claims or render them obvious.

H. Ground VIII: Claim 8 In View of the Combination of Makower, Stern, Edwards-'535, Liang, and Edwards-'886

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

336. As I explained in Ground VII, Claim 8 is obvious over Makower, Stern, Edwards-'535, and Liang. It also would have been obvious to modify the combination in Ground VII, Claim 8 to include a RF generator configured to deliver RF energy in a form of a 460 kHz sinusoid wave and to run at a power of between 5 and 75 watts for the same reasons I explained in Ground IV.

X. AVAILABILITY FOR CROSS-EXAMINATION

337. 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

338. 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

339. 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. 11,766,286 (“’286 patent”)
1003	File History of U.S. Patent No. 11,766,286
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”)
1017	Chen et al., Radiofrequency Treatment of Nasal Posterior-Under Nerve, Ethmoidal Nerve and Infratubinal for Perennial Allergic Rhinitis Under Nasal Endoscope, CHINA J. ENDOSCOPY 11:3 (2005) (English translation) (“Chen”)
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”)
1029	Arora et al., Cryodestruction of Vidian Nerve Branches, INDIA J. OTOLARYNGOLOGY 32:3 (1980) (“Arora”)
1030	U.S. Patent No. 8,979,841 (“Kunis”)

Martin Declaration: Appendix B (Materials Considered)

Exhibit No.	Description
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”)
1035	M. Philippon, Principles of Electrical Resistance of Living Tissue, BULL. CL. SCI. ACAD. R. BELG. ser. 5, vol. 7 (1921) (English Translation) (“Philippon”)
1038	U.S. Patent No. 6,109,268 (“Thapliyal”)
1040	Kong et al., Clinical Observation on Radiofrequency Ablation Treatment in Perennial Allergic Rhinitis, J. CLIN OTORHINOLARYNGOL (China) Vol.19, No.5 (2005) (English translation) (“Kong”)
1042	Bäck et al., Submucosal Bipolar Radiofrequency Thermal Ablation of Inferior Turbinates: A Long-Term Follow-up with Subjective and Objective Assessment, LARYNGOSCOPE 112 (2002) (“Bäck”)
1044	Lee et al., Surgical Management of Turbinate Hypertrophy in the Office: Three Mucosal Sparing Techniques, OPERATIVE TECHNIQUES IN OTTOLARYNGOLOGY--HEAD AND NECK SURGERY 12:2 (2001) (“Lee”)
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”)
1052	Sackenheim, Radio Frequency Ablation the Key to Cancer Treatment, J. DIAGNOSTIC MEDICAL SONOGRAPHY Vol.19, No. 2 (2003) (“Sackenheim”)

Martin Declaration: Appendix B (Materials Considered)

Exhibit No.	Description
1053	Bronzino, Medical Devices and Systems, Chapter 63, THE BIOMEDICAL ENGINEERING HANDBOOK 3E (2006) (“Bronzino”)
1054	Koyyalagunta et al., Radiofrequency and Cryoablation for Cancer Pain, TECHNIQUES IN REGIONAL ANESTHESIA & PAIN MANAGEMENT Vol.14 (2010) (“Koyyalagunta”)
1055	Fang et al., Nasal Endoscopy Combined with Multiple Radiofrequency for Perennial Allergic Rhinitis, J. FIRST MIL MED UNIV 25:7 (2005) (“Fang”)
1056	Liang et al., Radiofrequency Treatment of Ethmoidal Nerve with Allergic Rhinitis Under Nasal Endoscopy, 13:8 J. CLIN OTORHINOLARYNGOL. (China) 341 (August 1999) (English Translation) (“Liang”)
1061	Szold, Nitinol: Shape-Memory and Super-Elastic Materials in Surgery, 20 SURGICAL ENDOSCOPY & OTHER INTERVENTIONAL TECHNIQUES (2006) (“Szold”)
1062	Sedra et al., MICROELECTRONIC CIRCUITS (3d Ed. 1991) (Excerpts)(“Sedra”)
1063	File History of U.S. Patent No. 11,033,318
1067	U.S. Patent No. 5,505,730 (“Edwards-’730”)

APPENDIX C

Appendix C (Challenged Claims)

Ground	35 U.S.C. Section	Claims	References
I	103	1-3, 7-9	Edwards-'535 + Stern
II	103	8	Edwards-'535 + Stern + Edwards-'886
III	103	1-4, 7-9	Makower + Stern + Edwards-'535
IV	103	8	Makower + Stern + Edwards-'535 + Edwards-'886
V	103	1, 2, 3, 7-9	Edwards-'535 + Stern + Liang
VI	103	8	Edwards-'535 + Stern + Liang + Edwards-'886
VII	103	1-4, 7-9	Makower + Stern + Edwards-'535 + Liang
VIII	103	8	Makower + Stern + Edwards-'535 + Liang + Edwards-'886

Claim No.	Challenged Claim Language	Grounds for Finding Claim Invalid
1[pre]	A device for delivering energy to a nasal airway to treat rhinitis, the device comprising:	<u>Ground I</u> <u>Ground III</u> <u>Ground V</u> <u>Ground VII</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, to contact nasal mucosa lining the nasal airway;	

Martin Declaration: Appendix C (Challenged Claims)

Claim No.	Challenged Claim Language	Grounds for Finding Claim Invalid
1[d]	multiple pairs of bipolar radiofrequency electrodes disposed on the treatment element;	
1[e]	multiple radiofrequency output channels connected with the multiple pairs of bipolar radiofrequency electrodes, wherein each pair of the multiple pairs of bipolar radiofrequency electrodes is connected with a respective one of the multiple radiofrequency output channels; and	
1[f]	at least one impedance sensor configured to measure impedance in the multiple pairs of bipolar radiofrequency electrodes.	
2	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 III</u> <u>Ground V</u> <u>Ground VII</u>
3	The device of claim 2, wherein at least one electrode of the multiple pairs of bipolar radiofrequency electrodes is coupled with each of the multiple segments.	<u>Ground I</u> <u>Ground III</u> <u>Ground V</u> <u>Ground VII</u>
4	The device of claim 2, wherein the multiple segments are pre-shaped and comprise a shape-memory alloy material configured to expand to a desired size and shape.	<u>Ground III</u> <u>Ground VII</u>
7[a]	The device of claim 1, further comprising: a radiofrequency generator configured to	<u>Ground I</u>

Martin Declaration: Appendix C (Challenged Claims)

Claim No.	Challenged Claim Language	Grounds for Finding Claim Invalid
	receive sensed signals from the at least one impedance sensor and deliver radiofrequency energy separately to each of the multiple radiofrequency output channels; and	<u>Ground III</u> <u>Ground V</u>
7[b]	a cable coupled to the handle for plugging the handle into the radiofrequency generator.	<u>Ground VII</u>
8	The device of claim 7, wherein the radiofrequency generator is configured to deliver the radiofrequency energy in a form of a 460 kHz sinusoid wave and to run at a power of between 5 and 75 watts.	<u>Ground I</u> <u>Ground II</u> <u>Ground III</u> <u>Ground IV</u> <u>Ground V</u> <u>Ground VI</u> <u>Ground VII</u> <u>Ground VIII</u>
9	The device of claim 1, wherein the multiple pairs of bipolar radiofrequency electrodes and the multiple radiofrequency output channels are organized into multiple subsystems, and wherein each of the multiple subsystems comprises one of the multiple pairs of bipolar radiofrequency electrodes and one of the multiple radiofrequency output channels.	<u>Ground I</u> <u>Ground III</u> <u>Ground V</u> <u>Ground VII</u>