

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. IPR2024-00277

U.S. Patent No. 11,241,271

**DECLARATION OF DR. GREGORY T.
MARTIN REGARDING CLAIMS 1, 4, 8-10 OF
U.S. PATENT NO. 11,241,271**

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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. 11,241,271 (the “’271 patent”). I understand that Petitioners are challenging claims 1-4, 6-12, and 16 of the ’271 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 Cytac 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 Oponix, 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. 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.

7. 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."

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 '271 patent and have had no contact with the named inventors of the '271 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 either explicitly or

inherently in a single prior art reference. I have also been informed that, to be an inherent disclosure, the prior art reference must necessarily disclose the limitation, and the fact that the reference might possibly practice or possibly contain a claimed limitation is insufficient to establish that the reference inherently teaches the limitation.

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. When a product is available, design incentives and other market forces can prompt variations of it, either in the same field or a different one. 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 '271 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. In addition, I had a conversation with Dr. John DelGaudio on January 10, 2024 regarding his opinions for the '271 patent.

V. LEVEL OF ORDINARY SKILL IN THE ART

24. It is my understanding that when considering the claims of the '271 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. The '271 patent was filed on July 17, 2019 and claims priority to a series of patent applications, starting with provisional application 61/496,930 filed on June 14, 2011. *See* Ex.1001-USP271, Cover. Therefore, I understand the claimed priority date is June 14, 2011. I do not offer any opinion as to whether the '271 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 July 17, 2019.

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

27. Based on these factors as well as my experience and expertise, a person of ordinary skill in the art at 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 '271 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 '271 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 '271 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 '271 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 (“By 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 bladder...”); 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”).

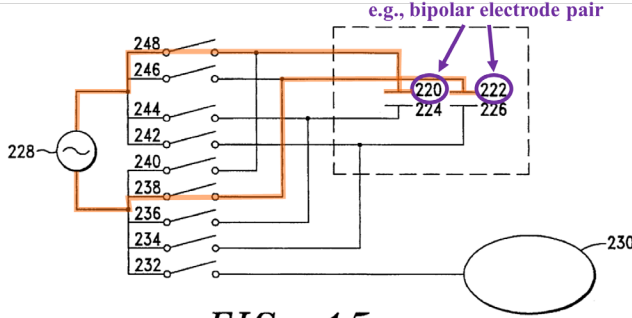
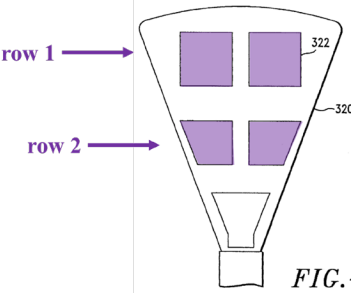
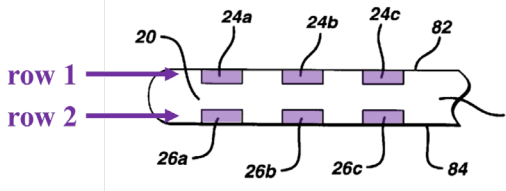
31. By the early 2000s, many devices incorporated RF ablation technology and different components needed to deliver RF energy. Most had similar features, like handles and shafts that were flexible and steerable. Ex.1011-Baker, 5:27-47; Ex.1021-Makower, [0186].

32. Electrically, these devices were capable of either bipolar or monopolar configurations, or both. Ex.1011-Baker, 5:47-58; Ex.1012-Goble, 6:33-68; 11:23-49. 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. Some of these electrodes could penetrate target tissue, for example, if they were needle electrodes (sometimes referred to as “penetrating electrodes”), Ex.1016-

Edwards-'886, 26:54-28:8, or the electrodes could be surface electrodes and only contact the surface of tissue without puncturing it (sometimes referred to as "non-penetrating electrodes"), Ex.1010-Edwards-'535, 4:55-60; Ex.1011-Baker, 5:47-58. Such devices could target tissue underneath the surface without ablating the surface tissue, for example by penetrating the tissue to a desired depth (as is the case for needle electrodes) or by cooling the surface of the tissue, thereby allowing only the subsurface tissue to heat (*see, e.g.*, Ex.1010-Edwards-'535, 4:60-65). Cooling systems could also be used in general to avoid overheating tissue. Ex.1016-Edwards-'886, 28:60-31:14.

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.

34. There were several ways to arrange such bipolar electrodes. One common way to arrange such electrodes was in two or more rows:

Ex.1033-Stern, FIGs. 15, 19 (showing pair 220-222)¹	Ex.1012-Goble, FIG. 4 (showing pairs 24a, 26a; 24b, 26b; 24c, 26c)²
 FIG. -15  FIG. -19	FIG. 4 

35. Aligning multiple pairs of electrodes along the surface of an energy delivery device ensures that, if the targeted tissue is a large surface, then the entirety of the target tissue will be ablated.

¹ See also Ex.1033-Stern, 2:36-40, 3:29-40, 12:7-13:55.

² See also Ex.1012-Goble, 8:46-57.

36. Likewise, the ways in which RF energy could be delivered to tissue and modify that tissue's properties were well studied and understood by 2011. One common way of delivering RF energy was to contact RF electrodes directly with target tissue and apply RF current to the tissue to introduce heat, which thereby destroys the tissue. Ex.1010-Edwards-'535, 5:27-32 (“[E]xpandable member 132 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.”), 8:12-14 (“the energy delivery device may be positioned on a surface 147 of the expandable member,” which would then be used to apply energy through contact with tissue rather than through any intermediary heating device), 8:26-39 (describing function of similar surface-mounted electrodes); Ex.1017-Chen, 240 (describing placing a probe on the tissue surface to apply energy); Ex.1033-Stern, 3:12-15 (“electrode...for effecting electrical contact with tissue of said body organ.”), 3:29-37 (“According to the invention there is provided an apparatus for selectively applying RF energy to a body organ. The apparatus comprises an electrode means for effecting electrical contact with tissue of said body organ....”). Another known way to deliver RF energy to tissue was to use RF electrodes to heat an intermediary liquid, which would either transfer heat to the tissue through conduction or produce ionization radiation that

enters and destroys adjacent tissue. Ex.1038-Thapliyal, 26:12-40 (heating liquid with RF energy, which in turn heats tissue through conduction), 4:38-58 (producing ionization in liquid that destroys adjacent tissue); Ex.1040-Kong, 215 (describing a plasma “ion vapor layer” that is used to destroy nerve tissue). By 2011 these technologies were well known and developed. Indeed, some devices could be configured for multiple modes of operation. *See, e.g.*, Ex.1038-Thapliyal, 26:12-44.

37. Many devices included systems that would help the clinician monitor the treatment, like visualization capabilities and guidance, Ex.1010-Edwards-’535, 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. Monopolar and Bipolar RF Electrode Configurations

38. 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 (-).

39. 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).

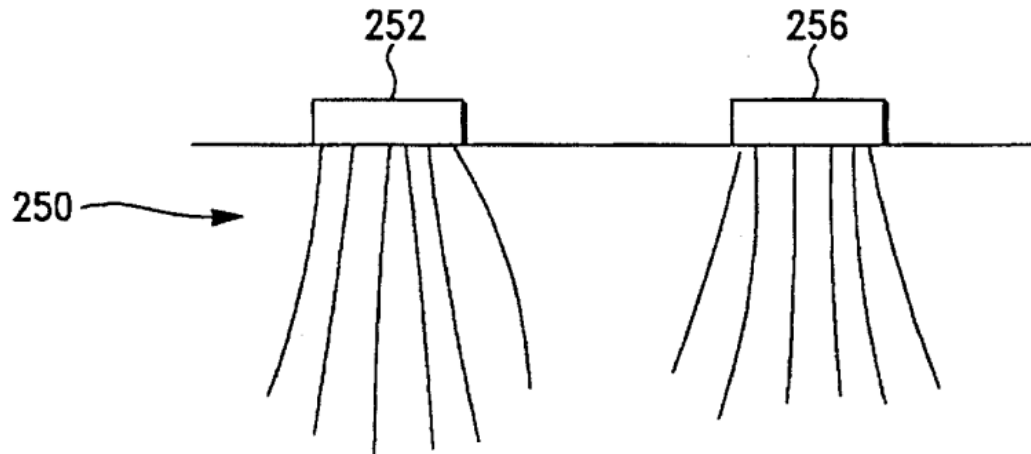


FIG. - 16

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

signals his or her brain. Ex.1024-Hovda, 5:4-18. By the early 2000s, it was well known that this can be safer than a monopolar arrangement, where current flows more broadly through a patient's body to a more distant return electrode. Such uncontrolled and dispersed current could interfere with the electrical signals (e.g., brain signals) in a patient's head.

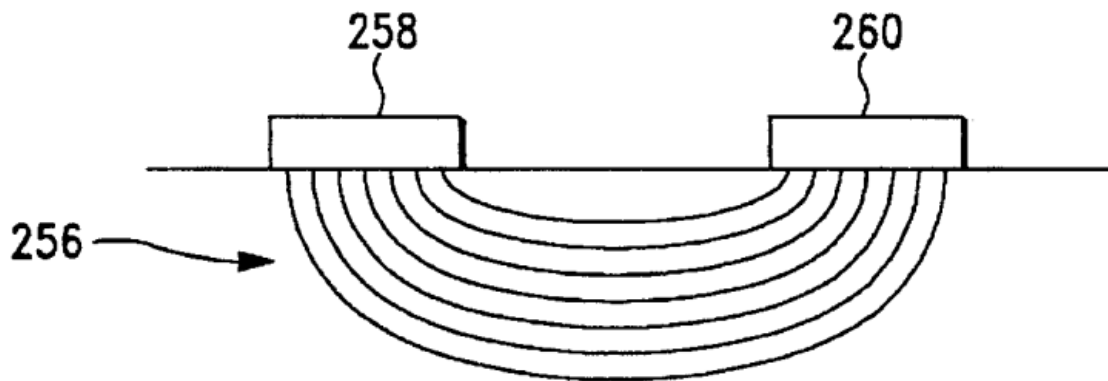


FIG.-17

41. Bipolar RF ablation configurations 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)

42. 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 FIG. 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.*

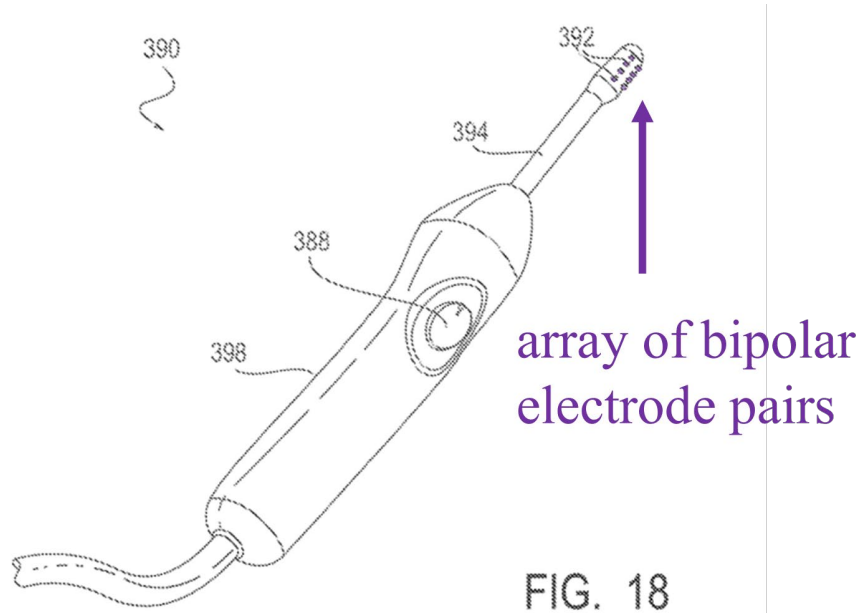
VII. OVERVIEW OF THE '271 PATENT

43. The '271 patent discloses various devices for treating the nasal airway. Ex.1001-USP271, Abstract. In particular, disclosed embodiments of the '271 patent

are directed to “improv[ing] breathing by decreasing airflow resistance or perceived airflow resistance in the nasal airways.” *Id.*, 4:38-42.

44. The '271 patent states that energy can be delivered to nasal tissue, sometimes in combination with mechanical force, to improve airflow. *Id.*, 13:38-62. I understand Dr. DelGaudio will discuss the clinical results and treatments disclosed in the '271 patent, including its disclosure regarding reducing mucous production in his Declaration. However, the devices disclosed in the '271 patent all consist of standard and known components, and the patent does not identify any additional structure specifically designed to produce this result.

45. For example, the challenged claims require that the claimed treatment device comprise two rows of bipolar electrode pairs. *Id.*, Clm.1. Such an arrangement of “pairs of bipolar electrodes 392” is shown in Figure 8F. *Id.*, 26:63-67.



Ex.1001-USP271, FIG.18. As I explained in Section IX.A, it was already well known by 2011 to use two rows of bipolar RF electrode pairs.

VIII. CLAIM CONSTRUCTION

46. 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.

47. 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.

48. 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.

49. For the purposes of this Declaration, I will give the claim terms their plain and ordinary meaning, including as understood in the field of the '271 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 '271 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

50. I understand that Petitioners argue that the challenged claims are invalid based on the following grounds:

- **Ground I:** Claims 1-3, 6-12, 16 are rendered obvious by the combination of Edwards-'535, Kong, and Stern under 35 U.S.C. §103.
- **Ground II:** Claim 4 is rendered obvious by the combination of Edwards-'535, Kong, Stern, and Edwards-'886 under 35 U.S.C. §103.
- **Ground III:** Claims 1-3, 6-12, 16 are rendered obvious by the combination of Edwards-'535, Liang, and Stern under 35 U.S.C. §103.
- **Ground IV:** Claim 4 is rendered obvious by the combination of Edwards-'535, Liang, Stern, and Edwards-'886 under 35 U.S.C. §103.

51. A copy of the Challenged Claims are attached as Appendix C.

52. I have been asked to offer opinions regarding the following limitations as they relate to the above-referenced grounds:

- **Limitation 1[a]:** ...wherein the treatment element comprises two rows of bipolar electrode pairs
- **Claim 4:** The method of claim 1, wherein the radiofrequency energy is applied in the form of a 460 kHz sinusoid wave.
- **Claim 8:** The method of claim 1, wherein the radiofrequency energy is produced by a radiofrequency energy source configured to run between 1 Watt and 100 Watts.
- **Claim 9:** The method of claim 1, wherein applying the radiofrequency energy comprises heating the target tissue to a temperature between 50 degrees Celsius to 70 degrees Celsius.
- **Claim 10:** The method of claim 1, wherein the amount of time the radiofrequency energy is applied to the target tissue is between fifteen seconds and one minute.

53. The technical features and structures described in these limitations were well-known and routinely applied in medical devices in a manner suitable for treating tissue in a nasal cavity. These structures and features were routinely used and combined with other features of known devices to yield predictable results..

54. Before discussing the specific grounds, I provide below a brief overview of the references I discuss in my Declaration:

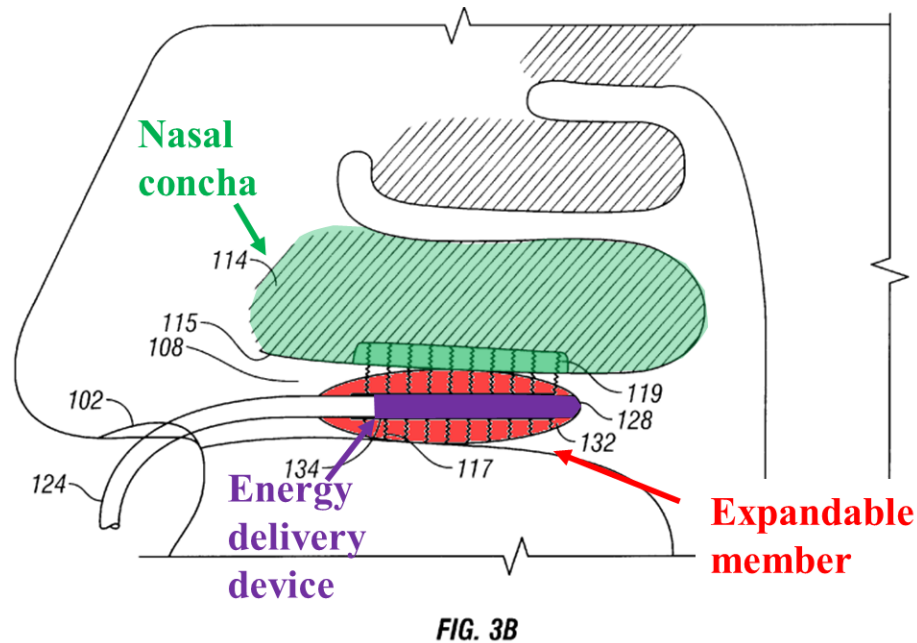
1. Edwards-'535

55. 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.

56. 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. Edwards-'535's RF device includes an expandable member 132 through which ablative energy was delivered to nasal concha 114, as annotated below in Edwards-'535 Figure 3C. “[T]o expand the expandable member 132,” fluid such as an electrolytic medium (e.g., saline) is delivered through a lumen

135 “within the distal portion of the apparatus into the expandable member 132.”

Id., 5:52-67.



Id., FIG.3B.³

57. 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 Ex.1010-Edwards-'535, 4:53-67, 5:18-26, 6:10-51, 6:66-24, FIGs.3A-4C.

³ All annotations added unless otherwise stated.

58. Edwards-'535 teaches the use of an energy delivery member 134, which can include “a plurality of energy delivery devices where energy is independently deliverable to each energy delivery device” that are “positioned on a surface 147 of the expandable member.” *Id.*, 8:12-17. To improve energy delivery, Edwards-'535 discloses using different sensors as part of a control system used to monitor and control the ablative energy. *See, e.g.*, Ex.1010-Edwards-'535, 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.”).

2. Stern

59. 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.

60. 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.

61. 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.

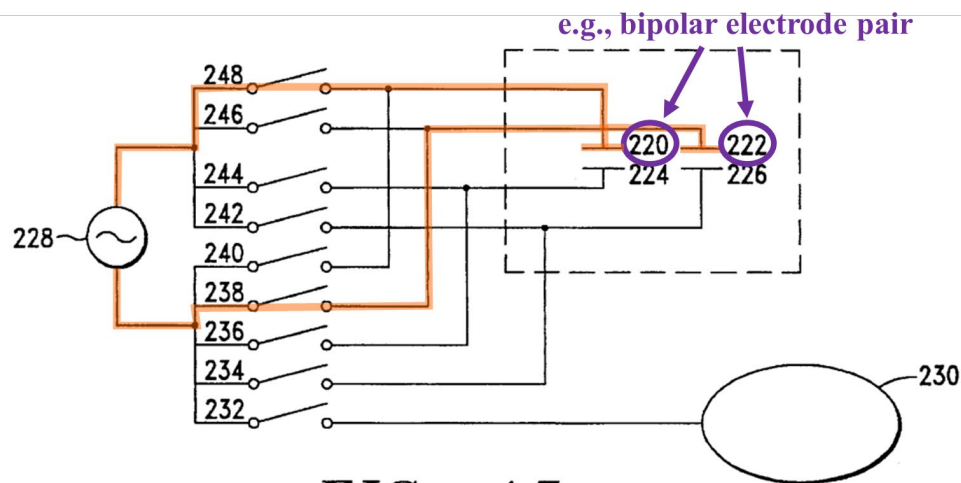
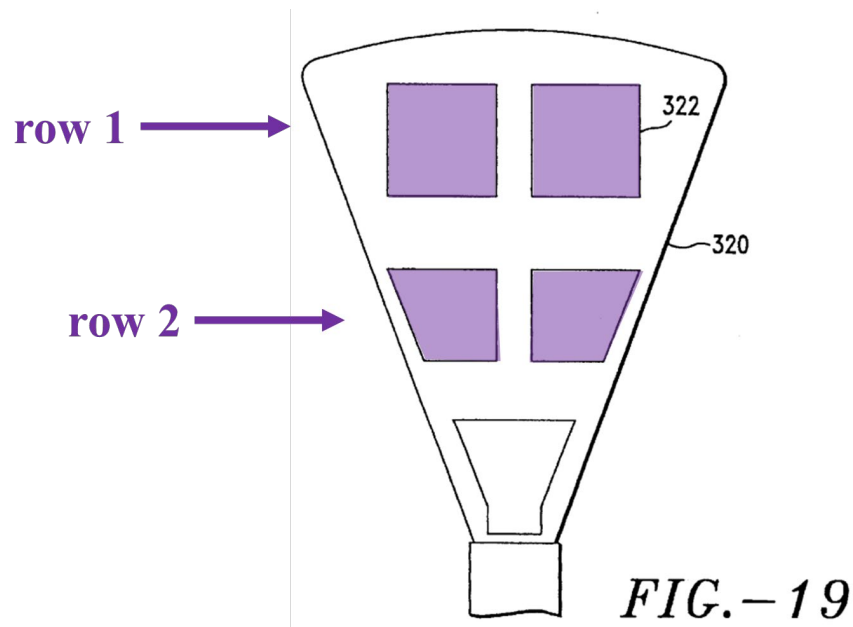


FIG.-15

62. Stern discloses various arrangements for the disclosed bipolar pairs of electrodes, including arranging the 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. Edwards-'886

63. 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.

64. Edwards-'886 teaches "an energy generator, to supply energy to an electrode structure to heat a tissue region." Ex.1016-Edwards-'886, 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. Grounds I and II: Claim 1, Limitation 1[a], and Claims 8-10 in View of the Combination of Edwards-'535 and Stern

65. As detailed below, the combination of Edwards-'535 and Stern teaches at least the limitations of the Challenged Claims I identify below.

1. Limitation 1[a]: ... wherein the treatment element comprises two rows of bipolar electrode pairs

66. Edwards-'535 in view of Stern teaches *wherein the treatment element comprises two rows of bipolar electrode pairs* (e.g., plurality of bipolar energy delivery devices).

67. Edwards-'535 teaches "an apparatus 124 having a distal portion 128 with an expandable member 132 and an energy delivery device 134" that is used to treat a nasal concha 114. Edwards-'535 explains that the energy delivery device 134 can include "a plurality of energy delivery devices," and that each of these energy delivery devices can independently deliver energy. Ex.1010-Edwards-'535, 8:12-

32 (“The energy delivery device may be a single energy delivery device or may include a plurality of energy delivery devices where energy is independently deliverable to each energy delivery device. ... As noted above, energy may be delivered to all of the energy delivery devices or may be independently delivered to each energy delivery device.”), FIGs.3A-3B, 3D, 4A, 6. Edwards-’535 further teaches that the electrodes or energy delivery devices may deliver RF energy in a bipolar mode. *Id.*, 8:17-32, 8:50-54, 10:30-32, 10:52-61. According to Edwards-’535, these energy delivery devices (such as ring electrodes 156) “may be disposed in parallel with their axes aligned with a long axis 160 of the catheter body 126.” *Id.*, 8:19-33, FIG.6. That is, the electrodes are placed in a row along an axis of a catheter.

68. Edwards-’535 discloses different locations to implement the electrodes or energy delivery devices, including those with electrodes located on the surface of the expandable member 132, which I will refer to as “surface electrodes,” Ex.1010-Edwards-’535, 4:53-67, 5:18-35, 8:8-17, Clm.1, FIGs.3A-3C, and other configurations with the electrodes located inside the expandable member, which I will refer to as “internal electrodes,” *id.*, 8:8-25, FIGs. 5-6.

69. In both the surface electrode and internal electrode embodiments, Edwards-’535 leaves the specific implementation of how bipolar electrodes should

be configured and wired to a person of ordinary skill in the art, as it was well within the person of ordinary skill in the art's knowledge and skill to configure and wire bipolar electrodes. *See id.*, 10:52-61.

70. Stern teaches that the electrodes on the surface of an expandable RF ablation device can be arranged in two rows of 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”), 3:29-40, 12:7-13:55, Clm.4, FIGs.13, 15, 17, 18, Title. Stern's electrodes are configured for “selective delivery of either monopolar RF energy to a single electrode or bipolar RF energy to chosen *pairs* of an array of separate electrodes which are used to bring the endometrial temperature to a desired level.” *Id.*, 2:36-40, 13:1-44. I show an example of a bipolar electrode pair below, from Stern Figure 17:

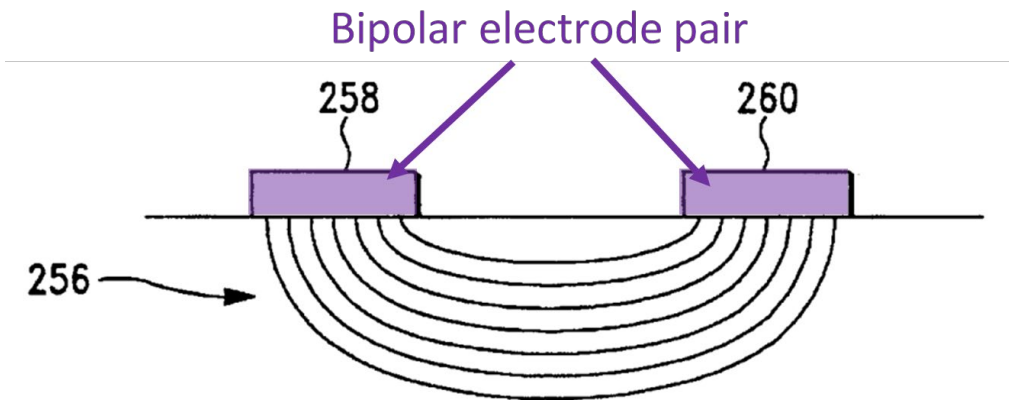


FIG.-17

Id., FIG.17. Like Edwards-'535, Stern places the array of RF electrodes on the surface of its expandable member. *Id.*, 2:26-35. 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.*

71. Stern's Figure 15, which I have reproduced below, shows the circuitry that controls the bipolar RF energy includes four electrodes 220, 222, 224 and 226 and switches 232-248 that determine which bipolar electrodes are active or return electrodes depending on which switch or switches are open and which are closed. *See 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. One such example would involve the scenario where

“switch 248 and switch 238 are closed” which would result in “bipolar operation between the electrodes 220 and 222.” *Id.*, 12:65-13:2.

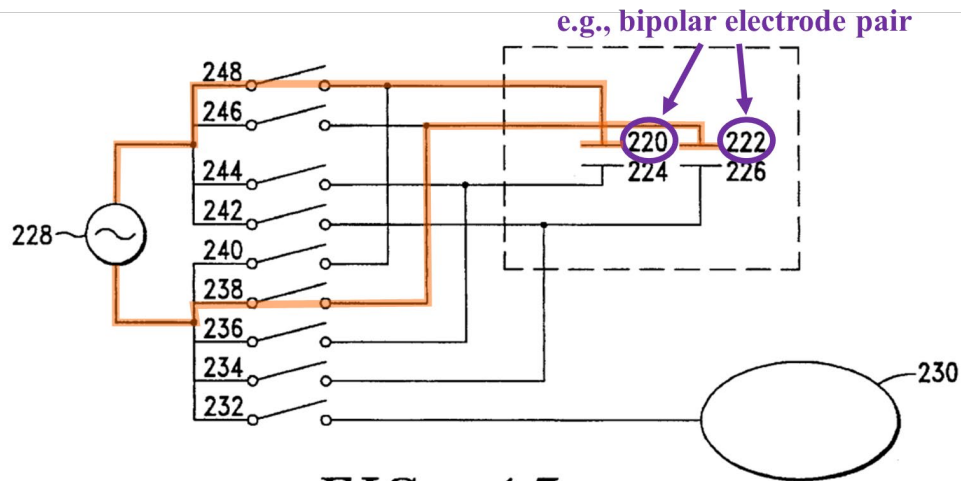


FIG. – 15

Id., FIG.15.

72. After discussing how to control pairs of electrodes with reference to the four bipolar electrodes of Figure 15, Stern teaches how to manufacture the “device of the invention,” including by offering details on the physical electrode structure and arrangement on the surface of a bladder. *Id.*, 13:39-14:7. These examples of physical arrangements are complementary to the control structure in Figure 15, as they all relate to the “device of the invention.” *Id.*

73. Stern describes various such embodiments with reference to the figures, including Figure 19, which shows two pairs of electrodes (i.e., four bipolar electrodes, just as in Figure 15) physically arranged in two rows. I show these two

rows in Figure 19 below, and with example rows annotated for the two corresponding two pairs of electrodes in the circuit diagram Figure 15:

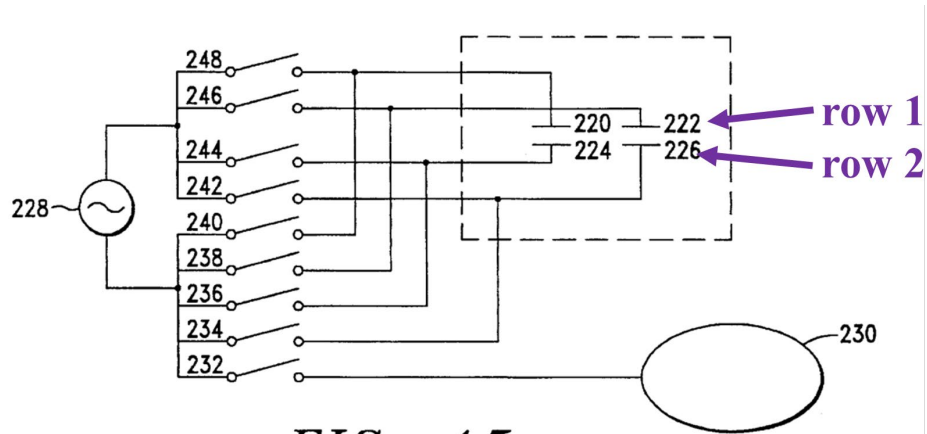
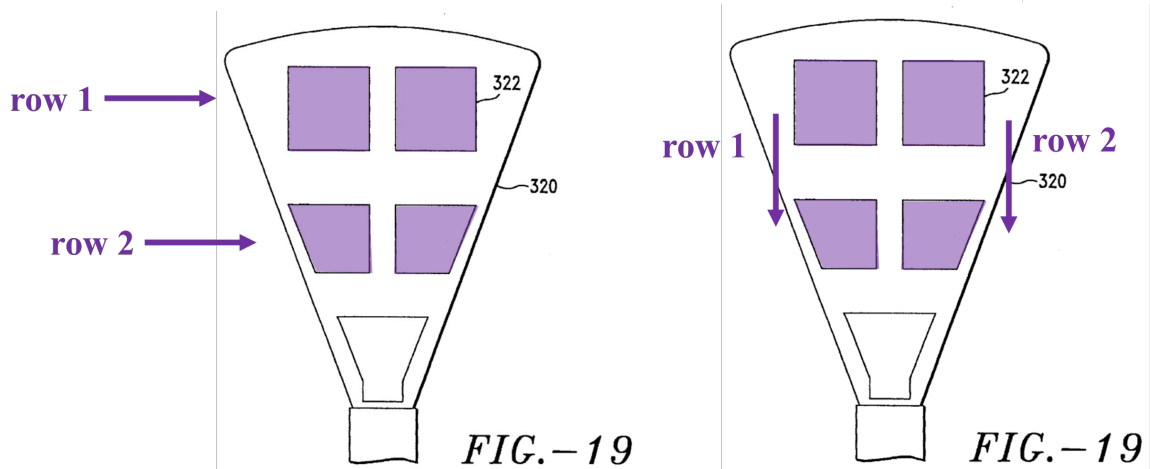


FIG.-15



Id., FIGs.15, 19, 14:26-28 (“At least one electrode is formed on the bladder 320. In the embodiment illustrated in FIG. 19, a plurality of electrodes 322 are formed on the surface of the bladder 320.”).

74. As I show above, Stern discloses two rows regardless of which two electrodes in Figures 15 or 19 are paired. That is, two rows can be seen either in a horizontal configuration (left image of Figure 19) or vertical configuration (right

image of Figure 19). Those rows are apparent regardless of which electrodes are paired, as well. For example, even where electrodes are paired diagonally, there are still two physical rows in Figure 19.

i. Motivation to Combine Edwards-'535 and Stern and Reasonable Expectation of Success

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

Stern teaches that its bipolar electrode configuration provides a number of benefits, including providing even heating and precise energy delivery control that are particularly beneficial when trying to ablate an entire uneven (e.g., heterogeneous) surface.

76. Edwards-'535 exemplifies that using RF ablation devices with multiple bipolar surface electrodes in body cavities was well-known. 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, leaving it to the skill of a person of ordinary skill in the art. *See id.*, 10:52-61. A person of 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,” Ex.1010-Edwards-'535, 8:18-25, because Stern provides very detailed schematics and information about how to design a device that can accomplish this goal.

77. In view of Edwards-'535's silence on how to specifically configure its bipolar electrodes or independent energy delivery, a person of 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 (as Stern teaches), 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, more practical, and more reliable than one with numerous power sources. For example, using a single voltage source reduces the number of cables required to connect the voltage source to the treatment device, which minimizes the potential for cable and connection issues. Switches or relays also take up less space than multiple generators, and would have been simpler and cheaper than multiple complex voltage sources.

78. 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 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. *Id.*, 12:38-13:2, FIG.15. Stern also provides specific details regarding how to manufacture and arrange electrodes on the surface of an expandable bladder, an example of which is shown in Figure 19. *Id.*, 14:8-60, FIG. 19.

79. Further, a person of ordinary skill in the art would have also been motivated to improve Edwards-'535's device by including Stern's two rows of bipolar pairs of electrodes based on the advantages and benefits of Stern's design, as Stern teaches.

80. Stern teaches a number of advantages and benefits resulting from pairing bipolar electrodes . *First*, bipolar electrode pairs allow a user to precisely control the electrical current delivered to tissue, which in turn provides for control

of the area being heated. 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 precise control allows a user to selectively ablate a small portion of tissue while leaving other important tissue structures intact. 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).

81. *Second*, 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.

82. *Third*, 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.B 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.

83. *Fourth*, these benefits compound in a way that enables ablation over broader areas, as opposed to single, discrete portions. For example, Stern explains that its teachings allow for ablation of an “entire surface” of tissue. *Id.* 2:6-19, 6:44-62, 10:49-65.

84. A person of ordinary skill in the art would have relied on those advantages as teachings, suggestions, and motivations to modify Edwards-’535 in view of Stern to include those advantages in Edwards-’535’s device. 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.

85. Stern's bipolar pairing technique would have also improved Edwards-'535's similar device in a similar way as it improved or led to advantages for 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.

86. The Edwards-'535 and Stern references teach 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.

87. 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 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.

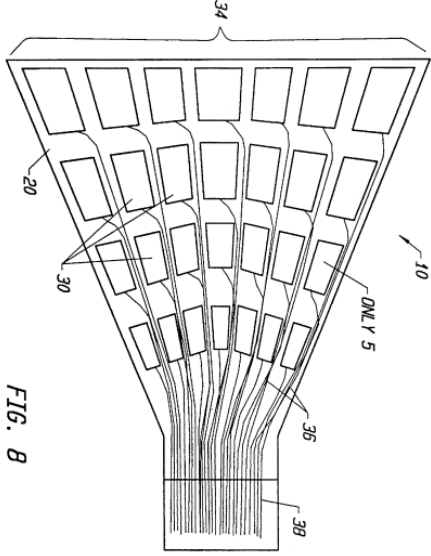
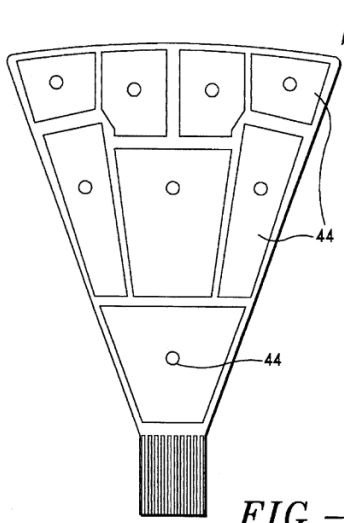
88. Moreover, in the combination, Stern's known techniques would have been used to improve Edwards-'535's similar device in the same way. For example, Edwards-'535 describes an expandable device that has bipolar surface RF electrodes for delivering RF energy to a body cavity, Ex.1010-Edwards-'535, Abstract,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

89. 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, "An 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.

90. Like Stern, Baker 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 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. Baker even teaches individually controlling electrodes, like Stern and Edwards-’535. Ex.1011-Baker, 9:13-45.

91. As I show below, Baker and Stern both depict devices with similar shapes and electrode layouts:

Ex.1011-Baker, FIG. 8	Ex.1033-Stern, FIG. 4a
 FIG. 8	 FIG.-4a

In light of Edwards-’535’s direction to incorporate teachings from Baker, a person of skill in the art would have also expected to be able to incorporate implementation details from the similar Stern device.

92. 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. 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.

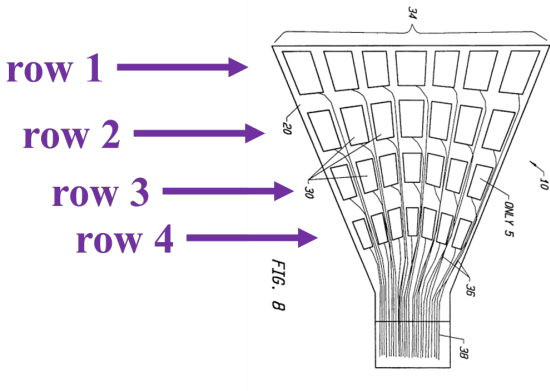
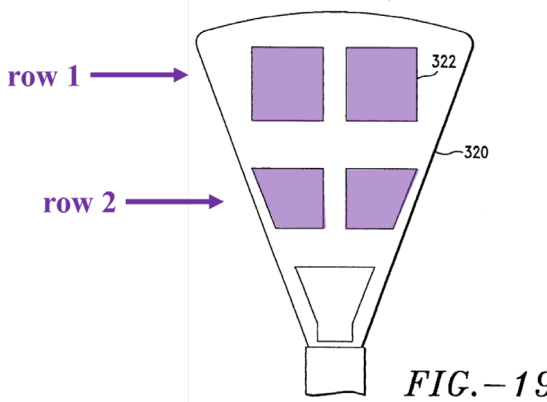
Ex.1033-Stern, 18:27-40.

93. 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.

94. A person of skill in the art also would have been motivated to configure Edwards-'535's bipolar electrodes in **two rows** as Stern teaches.

Although Edwards-'535 discloses some electrode configurations, such as those in Figure 6, Edwards-'535 does not disclose any particular arrangement of electrodes for bipolar operation on the surface of the expandable member. Instead, Edwards-'535 directs a person of skill in the art to Baker for how to dispose electrodes on the surface of an expandable device. Ex.1010-Edwards-'535, 8:26-33. As I show below, Baker, like Stern, discloses multiple rows of electrodes that are individually controllable:⁴

⁴ Ex.1033-Stern, (“At least one electrode is formed on the bladder 320. In the embodiment illustrated in FIG. 19, a plurality of electrodes 322 are formed on the surface of the bladder 320.”); Ex.1011-Baker, 9:13-30 (“As shown in FIG. 8 a flexible circuit 34 is made of individual electrodes 28 in zones 30 and positioned within conforming member 20. FIG. 9 shows individual electrodes 28, with thermocouples, that can be used and multiplexed in either of monopolar or bipolar schemes. Referring again to FIG. 8, electrodes 28 and zones 30 are capable of multiplexing so that only certain electrodes 28 deliver RF and thermal energy at a particular time period. Zones 30 provide individual ablative coverage, and delivery, for the entire conductive surface 24....”).

Ex.1011-Baker, FIG. 8 (showing rows of electrodes)	Ex.1033-Stern, FIG. 19 (same)
	

95. The import of arranging electrodes in different surface configurations would have been readily apparent to a person of skill in the art. For example, arranging electrodes in rows, as opposed to some other arrangement such as placing electrodes at random, would have allowed for simplified spatial resolution of the applied energy. Pairs of bipolar electrodes are especially effective at directing energy to discrete locations due to the nature of how energy travels between the paired electrodes, as I discussed in Section VI.B. Thus, one simple way to direct energy to specific locations for treatment would have been to place pairs of electrodes in rows at along the device at the locations being treated. As further evidence that two rows of electrodes would have been obvious, Edwards-'535 discloses one row of ring electrodes in Figure 6 that run along the device axis; adding

another row of electrodes would have been as simple as duplicating electrodes in a different spatial arrangement.

96. A person of skill in the art would have reasonably expected success when implementing *two rows of bipolar radiofrequency electrodes* Edwards-'535's expandable member 132. As I mentioned above, Edwards-'535 recognizes that selectively and independently delivering energy to individual electrodes is beneficial. Ex.1010-Edwards-'535, 6:10-51, 7:38-50, 8:17-32. By Edwards-'535 giving a person of skill in the art discretion on how to implement and configure individually activated electrodes, Edwards-'535 also demonstrates that other aspects of electrode arrangement and control would have been within the level of ordinary skill. *Id.*, 6:10-51, 7:38-50.

97. Implementing Edwards-'535's expandable member 132 with Stern's two rows of bipolar electrode pairs on the surface would have involved combining known prior art elements (Edwards-'535's apparatus 124 with Stern's electrodes and control scheme) with known methods (e.g., Stern's and Edwards-'535's selective control techniques) to yield predictable results (fine-tuned energy delivery and control). It would have also involved substituting Edwards-'535's surface-mounted energy delivery device 134 for another Stern's rows of paired bipolar electrodes and control scheme, which would have predictably facilitated finer control of energy

delivery and temperature control for Edwards-'535's device. Using Stern's individual bipolar electrode control and arrangement would have also improved the similar Edwards-'535 RF ablation device in a similar way, namely by providing finer granularity for control of energy, and therefore more precise temperature control/maintenance. Edwards-'535's RF ablation device was ready for such improvement, since Edwards-'535 left electrode arrangement/control details to the discretion of a person of skill in the art.

2. **Claim 8: The method of claim 1, wherein the radiofrequency energy is produced by a radiofrequency energy source configured to run between 1 Watt and 100 Watts.**

98. Claim 8 depends from claim 1. Therefore, I incorporate by reference my discussion of limitation 1[a] in Section IX.A.1.

99. Edwards-'535 discloses the additional requirements of claim 8.

100. As I explained above for claim 6, Edwards-'535 discloses using an energy source to generate the RF energy used in Edwards-'535's apparatus to ablate

tissue.⁵ Edwards-'535 also discloses that the generator produces “pulses of RF energy” that “provide between about 5 and about 30 watts of RF energy to at least a portion of the turbinate,” which falls within the range of *between 1 Watt and 100 Watts*. Ex.1010-Edwards-'535, 9:1-11, *see also id.*, 5:48-51 (“The 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.”), 10:52-58.

3. **Claim 9: The method of claim 1, wherein applying the radiofrequency energy comprises heating the target tissue to a temperature between 50 degrees Celsius to 70 degrees Celsius.**

101. Claim 9 depends from claim 1. Therefore, I incorporate by reference my discussion of limitation 1[a] in Section IX.A.1.

102. Edwards-'535 in view of Stern renders obvious the additional requirements of claim 9.

⁵ Edwards-'535 discloses energy sources 162 and 203, each of which supplies energy to the disclosed apparatus. Ex.1010-Edwards-'535, 8:37-9:13 (energy source 162), 11:20-45 (energy source 203).

103. Edwards-'535 discloses that the purpose of applying RF energy is for “*heating* at least a portion of the nasal concha being treated to a temperature above about 40° C.” Ex.1010-Edwards-'535, 5:35-44. However, Edwards-'535 did not expressly tell a person of skill in the art how much above 40° C to heat the target tissue.

104. Stern discloses that tissue destruction—the purpose of ablation in both Stern and Edwards—can be “optimally accomplished by a temperature between by heating tissue between 55° C. to 65° C.” Ex.1033, 2:63-7:6. Between 55° C to 65° C falls within the range of *between 50 degrees Celsius to 70 degrees Celsius*, which I understand is sufficient to anticipate a range.

105. Faced with the open-ended question posed by Edwards-'535 of how much above 40° C to heat tissue, person of skill in the art would have found it obvious to heat the tissue to a temperature of between 55°C to 65°C. The range of 55°C to 65°C is certainly above 40°C, and therefore satisfies Edwards-'535's criteria. Moreover, Stern discloses—as was also well-known at the time—that heating tissue to a temperature between 55°C to 65°C is sufficient to destroy the tissue, which is precisely what Edwards-'535 requires to reduce the size of the turbinates. *See also* Ex.1053-Bronzino, 64-4-64-5. (“Sufficient continued energy absorption and release can result in local temperature increases which, as energy

input increases, result in protein denaturation (41 to 65°C)...”); Ex.1059, 1 (explaining SHP-I device includes a “treatment head of the probe” that “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”).

106. A person of skill in the art would have understood that ablating tissue is temperature and time dependent. Ablation at lower temperatures requires longer exposure to destroy the tissue, whereas higher temperature ablation can destroy tissue much quicker. This is not only a known principle in medical device engineering, but also in the real world: the severity of a burn in a kitchen-related accident, for example when touching something hot, depends both on the temperature of the item you touch and how long you touch it for. Touching a red-hot electric heating element, even for an instant, can cause a significant burn, whereas a splash from boiling water for the same amount of time may only cause minor irritation. However, if one places their hand in a boiling pot of water for more time, severe burns would certainly occur.

107. Edwards-’535 recognizes this by noting that the tissue would be heated above 40°C. Above that temperature (and closer to 50°C), heat begins to impact the

targeted cells' ability to divide such that the tissue will eventually die out. However, this type of ablation requires extensive application times.

108. Ablation becomes more efficient at roughly 50-60°C, where thermocoagulation of blood begins. The coagulated blood inhibits delivery of oxygen to the nearby cells, which eventually die. Thermocoagulation happens more quickly as temperatures increase. *See, e.g.*, Ex.1051-Haemmerich, 54 (“As a rough guideline, it takes a few minutes to kill cells at 50°C, but only seconds at temperatures above 60°C.”); Ex.1050-Hong, S180 (“Mammalian tissue is very sensitive to temperature changes. At 55°C, for example, tissue death results within 2 seconds”).

109. As the tissue temperature approaches 70°C, more proteins in the tissue begin to denature. Ablation above 70°C is not advisable, as tissue can begin to adhere to the electrode, which can cause damage when the electrode is removed. *See, e.g.*, Ex.1051-Haemmerich, 55 (“At very high RF energy densities (typically close to the electrode), carbonized tissue can form, which is often referred to as “tissue charring,” an irreversible process that limits further RF energy deposition.”).

110. The tissue to be ablated is also a factor to consider. Where, for example, there are important structures adjacent to the target tissue that the operator does not want to ablate, it can be more desirable to target lower temperatures to allow the

operator or device more time to respond to undesirable heating of adjacent tissue and to allow the adjacent tissue more time to equilibrate with the environment as the ablated tissue degrades slowly. Furthermore, where, like in Edwards-'535, cooling is used to prevent the surface from overheating while ablating underlying tissue, it can be more desirable to target lower temperatures with longer application times so as to prevent the surface tissue from quickly heating up.

111. A person would have been well aware of these basic and ubiquitous principles. In light of these principles, a person of skill in the art would have been well equipped to test ablation at various temperatures above 40° C for various amounts of time in order to produce the desired tissue effect—namely destruction of tissue underlying the surface. Selecting a temperature above 50°C but below 70°C would take advantage of the beneficial effects of thermocoagulation without adhering tissue to the electrodes.

112. In my review of the '271 patent, I have not found anything supposedly critical about heating tissue to *between 50 degrees Celsius to 70 degrees Celsius*. Instead, the patent describes this range as just one “example” from a set of even broader ranges, including of 30-90, or even 40-80 degrees Celsius. Ex.1001-USP271, 43:19-30. As with any ablation apparatus, selecting an appropriate temperature to heat tissue to would have involved the typical optimization routinely

performed by persons of skill in the art. It would have been a matter of routine testing and design optimization to locate tissue samples represented of the tissue to be ablated, heat those samples to different temperatures, and determine which temperature above 40 Celsius is sufficient to destroy the target tissue.

4. **Claim 10: The method of claim 1, wherein the amount of time the radiofrequency energy is applied to the target tissue is between fifteen seconds and one minute.**

113. Claim 10 depends from claim 1. Therefore, I incorporate by reference my discussion of limitation 1[a] in Section IX.A.1.

114. Edwards-'535 renders obvious the additional requirements of claim 10.

115. Edwards-'535 discloses that the apparatus is configured to heat tissue to a “desired temperature for a selected period of time without impeding out.” Ex.1010-Edwards-'535, 9:65-10:3. However, Edwards-'535 left the choice of selecting a particular time to the engineering discretion of a person of skill in the art. In doing so, Edwards-'535 recognized that the duration of energy application is a well-known result-effective parameter that can be varied to obtain a particular desired result, such as heating tissue to a temperature sufficient to cause damage. *Id.* (discussing, without specifying, a “selected period of time”). This is consistent with my experience as an engineer designing ablation devices—selecting a treatment time

would have been well within the set of routine engineering tasks I or other skilled artisans would have performed.

116. Many disclosures relating to RF ablation from the relevant time period demonstrate the knowledge generally available to a person of skill in the art would have led a person of skill in the art to select an energy delivery duration in the range of 3 seconds to 10 minutes. *See, e.g.*, Ex.1058-Wong, [0053] (it takes 3-30 seconds of bipolar RF energy application to denature protein, which is representative of the time to denature protein in human tissue); Ex.1033-Stern, 6:63-7:6 (heating tissue with RF energy application between 10 seconds to 10 minutes); Ex.1016-Edwards-'886, FIG.79 (the temperature of tissue heated using RF ablation increases during the first 15 seconds to 1 minute before stabilizing). Energy applications in the *fifteen second to one minute* range were not only disclosed in numerous prior art references (e.g., Stern discloses 10 seconds to 10 minutes and Wong discloses 3-30 seconds), but also would have been obvious based on the general knowledge in the prior art and in light of the routine engineering and design choices engaged in by those in the field. This is again consistent with my experience designing ablation devices during the relevant time period.

117. A person of skill in the art would have understood that ablating tissue is temperature and time dependent, as I discussed for claim 9 above. In light of this

ubiquitous principle, a person of skill in the art would have been well equipped to test ablation at various temperatures above 40° C for various amounts of time in order to produce the desired tissue effect—namely destruction of tissue underlying the surface.

118. A person of skill in the art would have further recognized that the amount of time required to sufficiently ablate tissue would depend on the amount of energy applied to the tissue over a given area. For example, lower energy applications or those that dissipate more energy over an entire surface area would take longer to heat the tissue to a desired temperature, whereas higher energy applications or those that provide more concentrated application of energy would take less time to heat to a desired temperature. These tradeoffs would have been well known to a person of skill in the art, and selecting a time for energy application for a particular part of the body would have been a routine matter of experimentation and optimization.

119. I have reviewed the '271 patent's disclosure, which does not identify anything critical to the 15 seconds to 1 minute range. The patent even suggests a duration of energy application that is three times as long as the largest claimed duration. Ex.1001-USP271, 20:63-21:4, 43:31-48.

B. Grounds II and IV: Claim 4 In View of the Combination of Edwards-'535, Stern and Edwards-'886

1. Claim 4: The method of claim 1, wherein the radiofrequency energy is applied in the form of a 460 kHz sinusoid wave.

120. Claim 4 depends from claim 1. Therefore, I incorporate by reference my discussion of limitation 1[a] in Section IX.A.1.

121. Edwards-'535 in view of Stern and Edwards-'886 renders obvious the additional requirements of claim 4.

122. As I explained above for limitation 1[a], Edwards-'535 in view of Stern renders obvious two rows of bipolar RF electrodes. Such electrodes are used to apply RF energy. *See, e.g.*, Ex.1010-Edwards-'535, 4:53-67 (“Ablation of a nasal concha is accomplished according to the present invention by the introduction of ablative energy into a section of nasal concha tissue. ...”), 5:27-35 (“... Ablative energy 117 is then delivered through the apparatus and the energy delivery device 134 to the nasal concha 114. Sufficient energy 117 is delivered through the surface 115 of the nasal concha 114 to ablate at least a portion 119 of the nasal concha 114.”), 6:9-7:17 (“In one embodiment of the method, the surface of the nasal concha to be ablated is cooled during the delivery of energy to ablate the nasal concha. ...”), 11:23-44 (“Ablative energy is delivered to energy delivery device 189 by energy source 203, and applied to tissue.”), FIGs.4A-4C

123. Stern teaches applying RF energy in a range of frequencies including a *460 kHz wave* across multiple channels. For instance, Stern teaches the “RF current has a frequency of at least 250 kHz and less than 100 MHz,” which includes the claimed 460 kHz. Ex.1033-Stern, 2:18-20, 3:15-20, Clm.1.

124. 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 '271 patent nor the cited prior art provide such reason.

125. 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).

126. Furthermore, Edwards-'886 expressly teaches applying energy in the form of a 460 kHz sine wave: “the integrated generator 38 has four independent radio frequency channels. Each channel is capable of supplying up to 15 watts of radio frequency energy with a sinusoidal waveform at 460 kHz. ...” Ex.1016-Edwards-'886, 36:66-37:7. Edwards-'886 further explains that “controller 52 [that] commands the generator 38 to apply bursts of low level radio frequency energy through each electrode selected for operation” to “derive[] a local impedance value

for each electrode” (*i.e.*, sensor signal) and then to apply energy from electrodes. Ex.1016-Edwards-’886, FIGs.77, 2, 39:35-55, 39:56-40:3 (usage of sensor signals). In Edwards-’886’s system, “four independent radio frequency channels” can be “configured to operate eight electrodes...in...a bipolar mode.” *Id.*, 36:66-37:10.

127. A person of ordinary skill in the art would have found it obvious apply RF energy with the device of Edwards-’535 in view of Stern, with a sinusoidal waveform at 460 kHz as Edwards-’886 teaches. As discussed above, Stern teaches applying a frequency of “at least 250 kHz and less than 100 MHz,” which includes the claimed 460 kHz frequency. Ex.1033-Stern, 2:18-20; 3:15-20, Clm.1. Edwards-’886 teaches using bipolar RF for the same purpose as Edwards-’535 and Stern—tissue ablation using expandable devices. *See, e.g.*, Ex.1010-Edwards-’535, Abstract; Ex. 1033-Stern, Abstract; Ex.1016-Edwards-’886, 15:13-33. Moreover, Edwards-’535 and Edwards-’886 have a common, eponymous inventor and relate to similar devices used for similar purposes (just as Edwards-’535 and Stern). For example, both insert expandable devices that use bipolar RF surface electrodes into a body cavity to ablate tissue. *Compare* Ex.1010-Edwards-’535, Abstract, 5:18-34, 8:19-33, 10:25-31, 10:52-61, FIGs.3A-3B, *with* Ex.1016-Edwards-’886, 13:13-14:3, 36:66-37:7, FIGs.3-4, 9-19. Accordingly, a person of ordinary skill in the art would have been motivated to combine teachings from the same author to ablate using

Edwards-'886's specified frequency parameters and would have had a reasonable expectation of success in doing so. That is because, as I explain below, most RF ablation generators sold prior to 2011 operated at a frequency of 460 kHz, with suitable and predictable results, making this frequency selection an appropriate and an almost necessary choice given industry availability.

128. Edwards-'535's teaching that RF energy is "preferably" in the MHz range, would not have deterred a person of ordinary skill in the art from applying energy at other frequencies. For example, it would have been obvious for a person of ordinary skill in the art to apply RF energy in Edwards-'535's device at 460 kHz as Stern teaches, because that frequency was also known by a person of ordinary skill in the art to deliver RF energy to adequately ablate tissue. *See* Ex.1033-Stern, 2:18-20; 3:15-20, Clm.1. Indeed, most RF ablation devices for various body tissues operate at a frequency of about 460 kHz. *See, e.g.*, Ex.1016-Edwards-'886, 36:66-37:2; *see also* Ex.1050-Hong, S181 (explaining that "generators manufactured in the United States are capable of...delivering high frequency (460-500 kHz) alternating current via RF electrodes"); *id.*, S179 ("Radiofrequency waves as applied in medicine cause thermal ablation of a defined volume of tissue."); Ex.1052-Sackenheim, 90 (explaining that one of three companies that manufactured RF ablation generators in the United States used a 460 kHz generator); Ex.1053-

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

129. A person of ordinary skill in the art also would have been motivated to use a frequency of 460 kHz because this frequency adequately balances RF energy delivery with acceptable energy loss in the circuit. The higher the frequency, the lower the impedance. Impedance is a measure of how RF energy travels through

tissue, so the lower the impedance the easier it is for RF energy to travel through the tissue. Ex.1035-Philippson, 3, FIG.2. The relationship between frequency and impedance is logarithmic, so the benefits of reducing impedance become marginal as the frequency approaches the MHz range. *Id.* Likewise, as the frequency approaches MHz levels, it becomes more difficult for the energy to travel from the generator to the electrodes, and then to the tissue. This is analogous to cables acting like antennas at high frequencies, dissipating energy from the generator before it reaches the delivery device. Due to skin effects, high frequency currents travel closer to the cable surface, using less space and therefore creating more resistance. A person of ordinary skill in the art would have understood that a frequency in the kHz range would be the most desirable to ensure reduced impedance while avoiding the pitfalls associated with the delivery of RF energy at high frequencies. Further, choosing a number in the kHz range would have been a matter of routine experimentation and optimization for a person of ordinary skill in the art, and Stern and Edwards-'886 (among many other references) suggested such a range.

130. As discussed above, Edwards-'886 and Stern teaches using bipolar RF energy for the same purposes as Edwards—tissue ablation. Because all three references relate to similar 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 Edwards-'886's and 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. 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.

131. The '271 patent does not state there is anything critical about ablation at 460 kHz in particular—it is just one example from the entire RF range. Ex.1001-USP271, 33:53-57. Thus, selecting an appropriate frequency for ablation would have involved mere routine optimization from a range Stern already discloses at the particular value Edwards-'886 discloses.

X. AVAILABILITY FOR CROSS-EXAMINATION

132. 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.

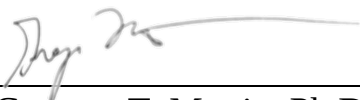
XI. RIGHT TO SUPPLEMENT

133. 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

134. 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 14, 2024



Gregory T. Martin, Ph.D.

APPENDIX A

Martin Declaration: Appendix A (Resume)

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

Principal

Boston, MA
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

Senior Lecturer (part time)

Boston, MA
2019-2020

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

Opsonix, Inc.

Vice President of Research and Development

Wakefield, MA
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

Senior Lecturer and Director of the Coulter Translational Research Program

Boston, MA
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.11,241,271 (“’271 patent”)
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”)
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”)
1031	Hytönen et al., Radiofrequency Thermal Ablation for Patients with Nasal Symptoms: A Systematic Review of Effectiveness and Complications, 266 EUR. ARCH. OTORHINOLARYNGOL. (2009) (“Hytonen”)
1033	U.S. Patent No. 5,562,720 (“Stern”)
1035	M. Philippon, Principles of Electrical Resistance of Living Tissue, BULL. CL. SCI. ACAD. R. BELG. ser. 5, vol. 7 (1921) (English Translation) (“Philippon”)

Martin Declaration: Appendix B (Materials Considered)

Exhibit No.	Description
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”)
1050	Hong, Radiofrequency Ablation: Mechanism of Action and Devices, J. VASC. INTERV. RADIOL. 21 (2010) (“Hong”)
1051	Haemmerich, Biophysics of Radiofrequency Ablation, CRITICAL REVIEWS IN BIOMEDICAL ENGINEERING, 38(1) (2010) (“Haemmerich”)
1052	Sackenheim, Radio Frequency Ablation the Key to Cancer Treatment, J. DIAGNOSTIC MEDICAL SONOGRAPHY Vol.19, No. 2 (2003) (“Sackenheim”)
1053	Bronzino, Medical Devices and Systems, Chapter 63, THE BIOMEDICAL ENGINEERING HANDBOOK 3E (2006) (“Bronzino”)
1054	Koyyalagunta et al., Radiofrequency and Cryoablation for Cancer Pain, TECHNIQUES IN REGIONAL ANESTHESIA & PAIN MANAGEMENT Vol.14 (2010) (“Koyyalagunta”)
1058	U.S. Patent App. No. 2002/0016588 (“Wong”)
1059	Chinese Patent No. 2225227 (“Liang ’227”)
1062	Sedra et al., MICROELECTRONIC CIRCUITS (3d Ed. 1991) (Excerpts) (“Sedra”)

APPENDIX C

Appendix C (Challenged Claims Addressed in This Declaration)

Ground	35 U.S.C. Section	Claims	References
I	103	1-3, 6-12, 16	Edwards-'535 + Kong + Stern
II	103	4	Edwards-'535 + Kong + Stern + Edwards '886
III	103	1-3, 6-12, 16	Edwards-'535 + Liang + Stern
IV	103	4	Edwards-'535 + Liang + Stern + Edwards '886

Claim No.	Challenged Claim Language	Prior Art Addressed in My Declaration
1[a]	... wherein the treatment element comprises two rows of bipolar electrode pairs;	<u>Edwards '535 + Stern</u>
4	The method of claim 1, wherein the radiofrequency energy is applied in the form of a 460 kHz sinusoid wave.	<u>Edwards '535 + Stern</u> <u>+ Edwards '886</u>
8	The method of claim 1, wherein the radiofrequency energy is produced by a radiofrequency energy source configured to run between 1 Watt and 100 Watts.	<u>Edwards '535 + Stern</u>
9	The method of claim 1, wherein applying the radiofrequency energy comprises heating the target tissue to a temperature between 50 degrees Celsius to 70 degrees Celsius.	<u>Edwards '535 + Stern</u>
10	The method of claim 1, wherein the amount of time the radiofrequency energy is applied	<u>Edwards '535 + Stern</u>

Martin Declaration: Appendix C (Challenged Claims)

Claim No.	Challenged Claim Language	Prior Art Addressed in My Declaration
	to the target tissue is between fifteen seconds and one minute.	